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This affidavit contains confidential information.

**There is only confidential information located in
Exhibit "D" CTR document #408 [attachment].**

AFFIDAVIT OF DR. ELAINE MACDONALD
Affirmed January 19, 2022

Court File No. T-956-21

FEDERAL COURT

BETWEEN:

SAFE FOOD MATTERS INC.
and PREVENT CANCER NOW

Applicants

and

ATTORNEY GENERAL OF CANADA
and MINISTER OF HEALTH

Respondents

Court File No. T-1412-21

FEDERAL COURT

BETWEEN:

SAFE FOOD MATTERS INC.
and PREVENT CANCER NOW

Applicants

and

ATTORNEY GENERAL OF CANADA
and MINISTER OF HEALTH

Respondents

AFFIDAVIT OF DR. ELAINE MACDONALD
(Affirmed January 19, 2022)

I, Dr. Elaine MacDonald, of the City of Toronto, in the Province of Ontario, AFFIRM AS
FOLLOWS:

A. Introduction

1. I am employed as a Program Director and Senior Scientist at Ecojustice Canada. Before this, I was a senior scientist at Ecojustice Canada. Ecojustice Canada is registered with the Law Society of Ontario as a Civil Society Organization providing legal services to the public and represents the applicants in this judicial review. In the course of my employment, I frequently investigate and research matters related to toxic chemicals, pesticides and environmental health to assist counsel. I have personal knowledge of the facts stated in this affidavit, except where those facts are stated to be based upon information and belief, in which case I believe them to be true.
2. The purpose of this affidavit is to set out the regulatory history of chlorpyrifos based on publicly available information and to describe the key documents contained in the Certified Tribunal Record (“**CTR**”) served in Court File T-956-21. As part of my work for Ecojustice I monitor consultation processes and regulatory decisions and policies of the Pest Management Regulatory Agency (“**PMRA**”). The PMRA maintains a public registry and a number of public databases for this purpose which I use. I discuss aspects of the regulatory process used by the PMRA, and provide broader regulatory context for the CTR documents and the conclusions and processes used by regulators. In doing so I describe the contents of regulatory documents to assist the court in identifying relevant information.
3. Unless otherwise stated, I have downloaded Canadian re-evaluation and registration documents and policies from the website of the PMRA or otherwise obtained them through electronic request forms on the PMRA website or correspondence with the PMRA. Some referenced policies were downloaded from other locations on Health Canada’s website.
4. Unless otherwise stated I have obtained U.S. risk assessment documentation from the U.S. Environmental Protection Agency (“**EPA**”) website and associated online public registries in the U.S. such as the federal register or regulations websites. I have obtained European information from the website of the European Food Safety Authority.

5. For each of the above sets of documents from the PMRA, EPA and European Food Safety Authority I reference the exhibits in the affidavit of Elizabeth Gabel, affirmed November 17, 2021 (“**Gabel Affidavit**”). I have independently verified and downloaded the referenced exhibits to the Gabel Affidavit from the respective websites of these organizations.
6. As the record in this matter contains a large number of acronyms, I have created, with the assistance of counsel, a glossary of these acronyms to assist the court based on my understanding of their meaning gleaned from my experience with PMRA regulatory processes, reviewing the record and other documents. This glossary is attached as **Exhibit “A”**.
7. The PMRA’s re-evaluation history of chlorpyrifos spans over two decades. My affidavit summarizes the key events relevant to this application. However, for the benefit of the court, and with assistance of counsel, I have created a summary of the chronology and key events in the re-evaluation history of chlorpyrifos. This chronology is attached as **Exhibit “B”**.
8. Additionally, over the course of the PMRA’s re-evaluation of chlorpyrifos, the PMRA made multiple requests for data to the registrants of pest control products containing chlorpyrifos. Again for the benefit of court and with the assistance of counsel, I have prepared a chart summarizing the data requests for drinking water, greenhouse uses and mosquito uses. This chart is attached as **Exhibit “C”**.
9. I have reviewed certain portions of the CTR for Court File T-956-21 which are described below. The respondents first served the CTR on August 17, 2021, and a revised CTR was served on September 20, 2021. A further revised public version of the CTR was served on November 15th. This affidavit summarizes certain documents contained in the November 15th CTR. Excerpts from the November 15th CTR are attached to this affidavit as **Exhibit “D”**.

B. About chlorpyrifos

10. Chlorpyrifos is an organophosphate pesticide, first registered in Canada in 1969 for agricultural use on various food crops (**Gabel Affidavit, Exhibit A6, PACR2003-03,**

p.3). It shares a common mechanism of toxicity with other organophosphate pesticides. Organophosphates were originally developed as a toxic nerve agent in World War II (see **Exhibit F** to this affidavit below, p.16).

11. According to PMRA documents, Chlorpyrifos specifically inhibits acetylcholinesterase (“AChE”), an enzyme necessary for the proper functioning of the nervous system. Chlorpyrifos may also affect brain development by altering a number of cellular processes and these effects may be independent of its effects on acetylcholinesterase (**Gabel Affidavit, Exhibit A6**, PACR2003-03, p.4).
12. Chlorpyrifos is applied directly to growing crops (food and feedstuffs) which may result in human exposure to chlorpyrifos in food. Currently, chlorpyrifos is used on a wide variety of crops including canola, flax, lentil, corn, strawberry, celery, cucumber, green peppers, pak choi, broccoli, brussels sprouts, cabbage, cauliflower, garlic, potatoes, barley, wheat, oats onions, carrots, and other crops. It can be applied through foliar, soil or aerial applications depending on the crop. The details for the allowable uses are set out in the labels for pest control products containing chlorpyrifos, which are summarized in **Exhibit L** to this affidavit.
13. According to publicly available regulatory documents, humans may also be exposed to chlorpyrifos through aerial and ground-based fogger adult mosquitocide applications and golf course turf applications (**Gabel Affidavit, Exhibit A6**, p.9). In occupational settings, exposure may occur while handling the pesticide prior to application, as well as during application. There is also a potential for post-application exposure for workers re-entering treated fields (**Gabel Affidavit, Exhibit C11**, p.17). Such exposures may occur through oral, inhalation, or dermal routes (**Gabel Affidavit, Exhibit C8** p.69085).
14. Public regulatory documents also describe how organophosphate pesticides degrade into various metabolites and transformation products in the environment. These are referred to in the record as transformation products (TPs). These include TCP (3,5,6-trichloropyridinol or 3,5,6-trichloro pyridine-2-phenol), DES (O-ethyl O-(3,5,6-trichloro-2-pyridinol) phosphorothioate) and chlorpyrifos oxon. Chlorpyrifos oxon is described as a more toxic AChE inhibitor than chlorpyrifos (**Gabel Affidavit, Exhibit C8**, pp.69082, 69087, 69096).

C. Registration history of chlorpyrifos

a. Harmonization with US reviews

15. Chlorpyrifos has been used in Canada since 1969. The PMRA began the re-evaluation of chlorpyrifos under a predecessor to the modern *Pest Control Products Act* (“PCPA”) in 1999 (**Gabel Affidavit, Exhibit A1**). A re-evaluation is what is referred to as a “post-market” review, meaning that it verifies that an already registered pesticide continues to pose acceptable risk. The 1999 re-evaluation of chlorpyrifos was ongoing until the time of the 2021 decisions that are the subject of the applications for judicial review.
16. The PMRA has long harmonized its reviews and Maximum Residue Limit decisions with those of the EPA. The PMRA stated it was working with the EPA to “harmonize” the regulation of pesticides, noting that the “starting point” for Canadian re-evaluations would be the reviews conducted by the EPA. (**Gabel Affidavit, Exhibit A1**, p.2). After reviewing the EPA’s assessments, the PMRA intentionally followed the actions taken by the EPA (**Gabel Affidavit, Exhibit A2**).
17. The PMRA assigned the early stages of the re-evaluation of chlorpyrifos to what it called “Program 3” (**Gabel Affidavit, Exhibit A6**, p.1). Program 3 involved reassessment of pest control products with common mechanisms of toxicity, such as organophosphates (**Gabel Affidavit, Exhibit B4**, pp.6-7). This program included products scheduled for food residue reassessment by the EPA under the U.S. *Food Quality Protection Act*. (**Gabel Affidavit, Exhibit B4**, p.6).
18. The U.S. *Food Quality Protection Act* requires that a food residue limit or “tolerance” (referred to in Canada as a maximum residue limit) can only be established if the administrator under that legislation determines that there is “reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue...” An excerpt from this legislation is attached to my affidavit as **Exhibit “E”**.
19. Early PMRA regulatory actions which used or relied on the EPA’s reviews or regulatory decisions included:

- a) In 2000, the PMRA entered into voluntary agreements for cancellation of various chlorpyrifos products and uses after the EPA negotiated similar agreements (**Gabel Affidavit, Exhibit A3**).
 - b) The PMRA also determined that based on EPA evidence at the time, there was no “imminent” threat to public health. (**Gabel Affidavit, Exhibit A3**).
 - c) Also in 2000, the PMRA implemented registration changes for chlorpyrifos products restricting their uses and lowering maximum residue limits (or “MRLs”) in a manner it described as “similar” or “identical” to those used by the EPA (**Gabel Affidavit, Exhibit A3, p.1**)
 - d) In 2001, the PMRA commented publicly on the EPA’s forthcoming cumulative assessment of organophosphate pesticides stating it intended to “use the revised EPA assessment to the greatest extent possible with consideration, where appropriate, of differences in Canadian use patterns.” (**Gabel Affidavit, Exhibits A4 and A5**).
20. The PMRA utilized the information in EPA reviews to inform areas of hazard or risk that should be further investigated with respect to Canadian use patterns (**Gabel Affidavit Exhibit A1, p.2. and Exhibit B4, p.2**), and in later phases of the re-evaluation to require data from registrants in support of the re-evaluation (**CTR Doc 198, attachment p.2**). The PMRA and the EPA also strive to “align the timing of key science work for certain pesticides” and to “communicate regularly with respect to ongoing re-evaluations.” (**Gabel Affidavit, Exhibit B6, DIR2016-04, p.11**).
21. The PMRA also has a policy of examining international reviews and any other new information in the course of its re-evaluations. The PMRA stated in its 2016 re-evaluation policy that “if during the re-evaluation review phase new scientific findings are established, the PMRA will apply these to pre-market and post-market decisions”. Registrants also had obligations pursuant to PMRA policy to submit new studies “if the study demonstrates any new hazard or any risk that may be greater than the risk determined at the time of registration...” (**Gabel Affidavit, Exhibit B6, DIR2016-04, p.17**).

b. PMRA process for reviewing pesticide health risks

22. The PMRA publishes a variety of public documents that explain how it conducts human health risks assessments for pest control products. These explain that the PMRA first defines potential hazards and then identifies the degree and likelihood of the risk associated with a defined exposure. Toxic effects that have a dose threshold are subject to acute and chronic reference values. The starting point for calculation of the reference value is the no observed adverse effect level (“**NOAEL**”). Then the PMRA may apply various uncertainty factors to account for uncertainty in using animal studies, variability within the human population, and protection of pregnant women, infants and children. The PMRA typically considers estimated exposures below the reference value to be acceptable for the purposes of the *Pest Control Products Act* (*Pest Control Products Act*, ss.7(7)(b)(ii), 11(2)(a)(iii), 19(2)(b)(ii); **Gabel Affidavit, Exhibit B13**, pp.2-7).
23. Dietary risk assessments compare estimated human exposures to a dietary reference value (**Gabel Affidavit, Exhibit B10**, pp.7-9). Dietary risk assessments are intended to be based on the maximum potential exposure through all sources in the diet, including drinking water. This exposure is then compared with the reference dose (**Gabel Affidavit, Exhibit B12**, p.4). For dietary risk, the PMRA is also required to conduct what are called “aggregate” risks assessments of pesticide residues in food, drinking water and residues from non-occupational sources (**Gabel Affidavit, Exhibit B11**, p.4, *Pest Control Products Act* ss. 7(7)(b)(i), 11(2)(a)(i), 19(2)(b)(i)). Chronic dietary risk averages out consumption over a lifetime and is compared with the acceptable daily intake (“**ADI**”). When the expected intake is less than the ADI, the intake is not considered to be of concern. (**Gabel Affidavit, Exhibit A6**, p.7). In a dietary exposure assessment the PMRA determines how much of a pesticide residue may be ingested with the daily diet, including residues in milk and meat for all uses registered in Canada and in imported produce. Acute dietary risk is calculated using a statistical analysis of consumption and residue levels that might be eaten in a day to estimate a value representing the high end of this distribution - potential daily intake (“**PDI**”). This is compared with the acute reference dose (“**ARfD**”) which is the daily dose at which no adverse health effects are expected. When the expected dietary intake from residues is

less than the acute reference dose, the expected intake from diet is not considered to be of acute concern (**Gabel Affidavit, Exhibit A6**, p.7).

24. The PMRA recognizes that certain subpopulations such as women of child-bearing age, pregnant and nursing women, infants and children require “special consideration”. This is because of biological differences that cause children to absorb, metabolize, and excrete chemicals differently than adults do, resulting in differing levels of susceptibility to chemical hazards. Further, children may be exposed to residues through different means than adults because of behavioral and dietary differences. The PMRA may apply additional uncertainty factors to address this (**Gabel Affidavit, Exhibit B12**, pp.2 and 4).
25. The *Pest Control Products Act* also requires cumulative risk assessments of exposure to other pest control products with common mechanisms of toxicity (**Gabel Affidavit, Exhibit B12**, p.6; *Pest Control Products Act*, ss.7(7)(b)(i), 11(2)(a)(ii), 19(2)(b)(i)). However, the PMRA does not do cumulative risk assessments, as will be discussed below.
 - c. *The PMRA has long been concerned about neurodevelopmental toxicity and drinking water for chlorpyrifos*
26. In 2003 the PMRA released a re-evaluation update, referenced in the record as PACR2003-03. The PMRA concluded there was evidence to demonstrate that chlorpyrifos could cause adverse health impacts, and specifically inhibits AChE, an enzyme necessary for the proper functioning of the nervous system. The PMRA also stated that “a number of publications suggest that chlorpyrifos may have the potential to affect brain development by altering a number of cellular processes and that these effects may be independent of its effects on acetylcholinesterase.” (**Gabel Affidavit, Exhibit A6**, PACR2003-03, p.4).
27. The PMRA determined at the time there were no dietary health concerns for any populations in Canada, while also noting however that “there are significant data gaps in the field residue data” (**Gabel Affidavit, Exhibit A6**, p.9). The PMRA also stated that it did not have sufficient reliable monitoring data to quantify risk from drinking water, which is normally part of an aggregate dietary risk assessment (**Gabel Affidavit, Exhibit A6**, p.9). The 2003 re-evaluation update proposed various mitigation measures for

identified issues with chlorpyrifos uses including, the addition of an expanded and (or) standardized toxicological label information, discontinuing a variety of crop uses, reductions in number of applications per season, restricting aerial application and lowering certain maximum residue limits. At the time of the 2003 re-evaluation update these measures were merely proposed, and were not implemented.

28. The 2003 re-evaluation update contained an assessment of dietary risk based on an assessment completed in October 2000 (**CTR Doc 375**). This assessment did not include drinking water (**CTR Doc 375**, pp.4-5). As noted above, the 2003 dietary intake assessment did not include exposure via drinking water due to insufficient monitoring data to quantify the risk from drinking water (**Gabel Affidavit, Exhibit A6**).
29. The dietary risk assessment conducted in the 2003 re-evaluation concluded that the potential daily intake accounted for 71% of the acute reference dose for children 1-6 years and 74% of the acute reference dose in females 13-50 years (**Gabel Affidavit Exhibit A6**, p.8). As the acute dietary risk estimated using incomplete information, excluding drinking water at that time, it was below the acute reference dose and was considered acceptable. The conclusion of the 2003 re-evaluation update was that the “use of chlorpyrifos and associated [end use products] does not entail an unacceptable risk of harm to human health or the environment ...**provided that the proposed mitigation measures described in this document are implemented**” (my emphasis) (**Gabel Affidavit, Exhibit A6**, p.29).
30. The PMRA updated the re-evaluation in 2007. Many of the proposed mitigation measures in the 2003 re-evaluation update were abandoned by the PMRA in 2007 and never implemented. For many years, the PMRA completed no updates to reflect the broader use patterns permitted in 2007 or later, nor was drinking water data and modelling added to calculate all aggregate sources of exposure. (**Gabel Affidavit, Exhibit A7**, REV2007-01, p.3; **CTR Docs 025**, and **026** attached draft Briefing Note).
31. In the 2007 re-evaluation update the PMRA stated that neurological risks found in animal studies were “likely to correlate with that of postnatal development in humans. Thus, there remain considerable uncertainties in the extent of potential sensitivity and its relevance to the human child.” In light of this the PMRA applied an additional

uncertainty factor (**Gabel Affidavit, Exhibit A7**, appendix I, p.9). Supplemental drinking water and other data were requested, and the re-evaluation update notes that “model estimates for areas where cole crops are grown indicate that acute drinking water concentrations may be of concern” (**Gabel Affidavit, Exhibit A7**, appendix I, p.19).

d. Events after the 2007 re-evaluation update

32. Although the PMRA publicly committed to finalizing the chlorpyrifos re-evaluation in 2008, this did not occur (**Gabel Affidavit, Exhibit A7**, pp.1 and 17). Between 2007 and 2019 there were no public updates for the PMRA’s re-evaluation of chlorpyrifos.
33. In February 2008, the PMRA put the re-evaluation of chlorpyrifos on hold “pending data requirements and policy issues” (**CTR Doc 383**). The decision to put the re-evaluation on-hold was never announced to the public. The PMRA determined that the “next round” of the re-evaluation would be “based on data call-in and cooperation with the EPA” (**CTR Doc 383**). There does not appear to be an associated Briefing Note in the CTR. A summary of data requirements for drinking water, greenhouse uses and mosquito uses is included in my affidavit as **Exhibit C**.
34. During this period, environmental and labour organizations in the US petitioned the EPA to revoke all food residue or “tolerance” levels for chlorpyrifos and to cancel the registration of all products containing chlorpyrifos. In Canada these food residue limits are referred to as maximum residue limits. The petition related to the neurodevelopmental impacts of chlorpyrifos (**Gabel Affidavit, Exhibit C8**, p.69082). Ultimately the petitioners engaged in several rounds of administrative litigation at the United States Court of Appeals for the Ninth Circuit (the “**9th Circuit Court**”). Attached as **Exhibit “F”** to my affidavit is the 9th Circuit Court decision in *League of United Latin American Citizens v. Regan* (No. 19-71979) which summarizes the procedures that occurred.
35. The EPA released several risk assessments in response to these petitions. The focus of these risk assessments was on neurodevelopmental effects in humans that might occur below the reference doses established using AChE inhibition. These effects arose from other unknown causes and mechanisms. These effects were then investigated because if harms could occur below the established reference doses based on AChE, then the

reference doses used to calculate acceptable uses and dietary risk would not necessarily be human health protective for neurodevelopmental effects.

36. In 2008 the EPA began to look at epidemiological data to determine whether there were adverse neurodevelopmental outcomes demonstrated. The EPA and its peer review advisory panels concluded that “maternal chlorpyrifos exposure would likely be associated with adverse neurodevelopmental outcomes.” (**Gabel Affidavit, Exhibit C3**, 2008 SAP minutes, p.13; **Exhibit C4**, 2008 Discussion Paper, pp.4-5).
37. The EPA described this as a shift in focus from the reference doses (or points of departure) used in the 2000 chlorpyrifos risk assessment to address “more recent data on neurodevelopmental effects associated with early exposure to chlorpyrifos” (**Gabel Affidavit, Exhibit C4**, p.51). The peer review panel expressed uncertainty about whether the older AChE based reference doses were protective for effects on the developing brain, noting that “this conclusion is highly uncertain given the lack of information” (**Gabel Affidavit, Exhibit C3**, pp.51, 52 and 56).
38. The PMRA was aware that the EPA was trying to identify new toxicological endpoints to address neurodevelopmental toxicity. For example, a September 2008 Briefing Note between Health Evaluation Directorate Staff describes the results of the 2008 EPA peer review or “Science Advisory Panel” (SAP) (**CTR Doc 440**). The Briefing Note explains that a PMRA epidemiologist will be working on a white paper with the EPA concerning the use of epidemiological data for risk assessment.
39. In February 2009, the PMRA received information on new epidemiological data from epidemiologist Scott Weichenthal (**CTR Docs 223, 227, 228**). A paper authored by Dr. Weichenthal discusses some of the results of the epidemiology used by the EPA and the SAP (**CTR Doc 223**). The PMRA received a presentation that appears to be from Dr. Weichenthal comparing acceptable levels for chlorpyrifos in the US and Canada, showing that the EPA’s no observed adverse effect level and acceptable dietary intake levels were lower than the lowest observed adverse effect level or LOAEL used in Canada, and that uncertainty factors applied by the EPA were higher than those used by the PMRA in Canada (**CTR Doc 228**). The presentation slides note that women exposed through both diet and work may have exposures greater than the estimated no observed

effect level in the epidemiological studies. The use and significance of these effect levels in risk assessment is described in the **Gabel Affidavit, Exhibit B11**, pp.3-6 and **Gabel Affidavit, Exhibit B13**, pp.2-18. These documents explain that the no observed effect levels and lowest observed effect levels are established before the application of uncertainty factors.

40. These documents conclude that the “main message” is that current values used by the PMRA “appear to be protective” but also notes that occupational exposures of pregnant women remain a concern (**CTR Doc 228**). The paper indicates that “findings suggest that low-level prenatal exposure to chlorpyrifos may have an adverse effect on fetal growth and cognitive development” and that “exposures of pregnant women outside the home are the primary concern” (**CTR Doc 223**). Dr. Weichenthal goes on to state that the blood level of chlorpyrifos expected at current dietary intake and exposure levels in Canada equals the no observed effect level for decreased birthweight. It is not clear from the record what actions the PMRA took, if any, in 2009 to review its approach to this epidemiological information.
41. A May 2011 email chain that appears to be discussing the epidemiological evidence utilized by the EPA describes three independent studies on neurodevelopment and organophosphates that “appear to be well-conducted and corroborate each other and the findings are significant in the biological sense” (**CTR Doc 014**). PMRA staff also noted that “someone could request a special review based on this latest information” and further note that this should be flagged to upper management for special review potential (**CTR Doc 014**).
42. A special review may be requested by any member of the public under section 17(4) of the PCPA. Under section 17(1), even without a request from a member of the public, the Minister “shall initiate a special review of the registration of a pest control product if the minister has reasonable grounds to believe that the health and environmental risks of the product are, or its value is, unacceptable.”
43. Accordingly, this May 2011 email chain could be suggesting that the EPA risk assessments might raise reasonable grounds to doubt the acceptability of chlorpyrifos risks under the Canadian PCPA. The PMRA did not update the public with this

information, nor did the Minister initiate a special review. Although I did not review every document and associated attachment in the CTR, I was unable to locate associated Directors General or Science Management Committee briefings, agendas or minutes in the CTR considering this information by reviewing the index to the CTR.

44. In 2012 the EPA's Science Advisory Panel's minutes drew new conclusions questioning whether the use of levels protective for AChE also protected for neurodevelopmental toxicity, stating that "[t]he Panel notes that multiple lines of evidence suggest chlorpyrifos can affect neurodevelopment at levels **lower than** those associated with AChE inhibition." (p.19, emphasis added). The 2012 SAP Minutes source this concern to the epidemiological studies (pp.50-51) animal studies (pp.51-52) and "several *in vitro* mechanistic studies" (pp.52-53). After reviewing these three types of evidence the 2012 SAP Minutes conclude that: "the use of AChE inhibition data **may not be the most appropriate** for dose-response modeling and derivation of a point of departure for assessment of the neurodevelopmental risks of chlorpyrifos" (p.53, emphasis added) (**Gabel Affidavit, Exhibit C7**, 2012 SAP Minutes, pp.50-53).
45. In 2014 the EPA released a revised human health risk assessment for chlorpyrifos. This assessment concluded that the epidemiological evidence consistently identified adverse neurodevelopmental outcomes in children after chlorpyrifos exposure, including evidence of "delays in mental development in infants (24-36 months), attention problems and pervasive developmental disorder in early childhood, and intelligence decrements in school age children" (**Gabel Affidavit, Exhibit C11**, 2014 EPA Human Health Risk Assessment, p.42). The 2014 EPA risk assessment also noted the uncertainty around effects on the developing brain meant that "it is impossible at this time to rule out even a single day of high exposure to chlorpyrifos having a potential adverse neurodevelopmental effect in humans" (**Gabel Affidavit, Exhibit C11**, p.50).
46. In 2016 the EPA further confirmed these findings in another human health risk assessment, concluding there was "sufficient evidence that there are neurodevelopmental effects occurring at chlorpyrifos exposure levels below that required for AChE inhibition" (**Gabel Affidavit, Exhibit C12**, 2016 EPA Human Health Risk Assessment, p.13).

47. Later in 2016 the EPA released a conclusion that it had completed further analysis and risk assessments including of dietary exposure to drinking water. It noted that residues of chlorpyrifos on most individual food crops exceeded the reasonable certainty of no harm standard under US legislation, and that the “majority of estimated drinking water exposures from currently registered uses, including water exposures from non-food uses, continue to exceed safe levels even taking into account more refined drinking water exposures.” This finding was associated with a further proposal to revoke all food tolerances for chlorpyrifos (**Gabel Affidavit, Exhibit C13**, EPA November 2016 Proposed Rules, p.81050). Food tolerances are the equivalent of maximum residue limits in Canada.

e. The PMRA decides not to update its toxicology endpoints to align with the EPA review

48. The PMRA was aware of these changes to the EPA’s approach to chlorpyrifos. In March 2015 PMRA staff were presented with the EPA’s findings on toxicology endpoints/reference doses and drinking water (**CTR Doc 229**). In May 2015 a comprehensive draft briefing note was prepared for the Director General’s planning meeting at the PMRA which describes the various updates to the EPA’s risk assessments in some detail and recommends that the PMRA update the toxicology endpoints in light of the EPA’s risk assessments (**CTR Doc 026**, attachment). As discussed below at paras 61-68 this briefing note would be heavily edited by senior managers to remove these recommendations (**CTR Docs 027, 029 and 031** (attachments) and final Briefing Note **CTR Doc 386**).

49. It was ultimately decided at the Director General level that the reference values (also referred to in the record as toxicology endpoints) for chlorpyrifos that the PMRA was using would not be updated (**CTR Doc 388**). Similar Briefing Notes were prepared in 2016 (**CTR Docs 443 and 449**).

50. The PMRA continued to use the 2000 toxicology endpoints to evaluate registration amendments and new registrations for chlorpyrifos products until at least 2018 (**CTR Docs 388 and 026**, attached draft Briefing Note, pp.3-5, see also reliance on toxicology endpoints from PACR2003-03 referenced in various specific registration occupational

exposure evaluations in **CTR Docs 259**, p.2, **293**, p.3, **298**, p.4, **307**, pp.10-11, **308**, p.4, **325**, p.7, **329**, p.7, **333**, p.5 and **346**, p.6).

f. The PMRA uses the 2014 EPA Human Health Risk Assessment to evaluate drinking water risks

51. The 2003 re-evaluation update and the supporting October 2000 dietary risk assessment for chlorpyrifos did not include consideration of drinking water exposure, noting “[t]he PMRA does not have sufficient reliable monitoring data to quantify the risk from drinking water” (**Gabel Affidavit, Exhibit A6**, p.9). The modern PCPA came into force on June 28, 2006. Attached as **Exhibit “G”** to my affidavit is an information note describing the 2006 changes to the PCPA. The aggregate exposure to chlorpyrifos in the diet of the public from all sources was not known pursuant to sections 7, 11 and 19 of the modern PCPA because the risk assessment in the 2003 PMRA re-evaluation did not include this information and it was not updated.
52. Drinking water data deficiencies were identified in 2000, 2003 and 2007 by the PMRA in its public re-evaluation updates. These are summarized in the chart included as **Exhibit C** to my affidavit. They are also listed in the attachment to the draft May 2015 Briefing Note (**CTR Doc 026**, attachment, pp.8-9).
53. In the PMRA’s 2003 Science Policy Notice (**Gabel Affidavit, Exhibit B15**), the PMRA provided guidance on how it conducts drinking water assessments and uses estimated environmental concentrations (“**EECs**”) to calculate drinking water levels of comparison (“**DWLOCs**”), on pp.8-9, emphasis added:

If a pesticide has any potential to contaminate water resources based on use patterns, the PMRA uses water exposure models to estimate the concentration of the pesticide that could run off into surface water or leach into shallow groundwater. The concentration estimates generated from the models are considered to be upper bounds on pesticide concentrations in drinking water obtained from surface and groundwater sources. The PMRA then calculates a drinking water level of comparison (DWLOC), which is the **highest concentration of a pesticide in drinking water that would be acceptable** (i.e., produce total exposure equal to the reference dose), considering the estimated exposure to that pesticide from other sources (i.e., food and residential uses).

54. The 2003 PMRA re-evaluation update also describes the drinking water levels of comparison as relevant to a finding of the likelihood of adverse health effects:

Canadian drinking water levels of comparison (DWLOCs) were derived from the overall allowable risk from residues permitted in the diet after considering the contribution by food. The DWLOC is the maximum concentration in drinking water that, when considered together with dietary exposure, does not exceed a level of concern based on the respective reference dose. (**Gabel Affidavit, Exhibit A6**, p.9).

55. Emails between PMRA staff in May 2006 state that: “the existing PMRA publications on chlorpyrifos do not address potential drinking water exposure” and that the modelling numbers from December 2003 resulted in the finding that “acute estimate does not meet target”, going on to say “I presume that this aspect of the health assessment should be discussed in the 2008 environmental assessment” (**CTR Doc 003**).
56. The reference to “acute estimate does not meet target” suggests that there was further drinking water modelling done after the release of the 2003 re-evaluation update that showed risks of concern. Similar comments are included in **CTR Doc 063**. However, based on a review of the CTR index it does not appear that this information is included in the CTR. I am advised by counsel and believe it to be true that this modelling was requested by the applicants, and counsel for the respondents sent a letter on September 17, 2021 indicating that they considered this information outside the scope of the CTR. This letter is included as **Exhibit “H”**.¹
57. It appears that the PMRA did receive some drinking water data from the United States prior to the 2007 re-evaluation update. The 2007 re-evaluation update requested further drinking water data (**Gabel Affidavit, Exhibit A7**, pp.5-6, 18-19). Emails from PMRA staff indicate that the US data was found to be “insufficient”, that further drinking water data was still required, and that the registrants did not submit Canadian surface water data (**CTR Docs 003 and 004**).
58. In 2015, the PMRA began reviewing the drinking water issue in relation to the ongoing EPA process in more detail. In March 2015, the EPA gave a presentation on chlorpyrifos

¹ This letter uses the old CTR document numbers which are available in the CTR index in the column “Orig Tab”.

to the PMRA. The PowerPoint slides from this presentation are contained in **CTR Doc 229**. In a summary of the aggregate risk, the slides note that several estimated drinking water concentrations exceeded levels of concern for chlorpyrifos oxon, a transformation product of concern in drinking water in the United States. The EPA (and later European Regulators) identified chlorpyrifos oxon as more toxic than chlorpyrifos. Chlorpyrifos oxon was not assessed as a residue of concern in drinking water in the 2000-2003 PMRA re-evaluation of chlorpyrifos (**CTR Doc 034**, attachment, see also **CTR Doc 139**, p.2).

59. The PMRA used the EPA documents to identify drinking water issues of concern. For example, in September 2015 PMRA staff observed that the estimated drinking water concentrations exceeded the drinking water levels of comparison, resulting in a “potential risk of concern” for infants in the 2014 EPA Human Health Risk Assessment (**CTR Doc 038**, p.2). In this discussion they noted the EPA identified the conversion of 100% of chlorpyrifos into the metabolite chlorpyrifos oxon through chlorination. The PMRA referenced a study noting that chlorpyrifos oxon as 1000 times more toxic than chlorpyrifos (**CTR Doc 038**, p.3 and 1st attachment).
60. However, the PMRA’s draft October 2000 dietary risk assessment (**CTR Doc 375**) was not updated. It therefore did not reflect subsequent changes to use patterns or include aggregate food and drinking water risks (**CTR Doc 026**, p.3). The October 2000 dietary risk assessment used in the 2003 re-evaluation update (PACR2003-03) would continue to be relied on by PMRA staff for the review of dietary risks for new or amended registrations of chlorpyrifos (see for example, **CTR Doc 307**, pp.10-11, and **CTR Doc 333**, pp.4-5).
61. On May 12, 2015, an email was sent between PMRA staff with an attached draft Briefing Note on the EPA’s new approach to reference doses (**CTR Doc 026**). This draft Briefing Note was prepared for the Director General Planning meeting to take place at the end of May 2015.
62. The draft Briefing Note states that for the PMRA “[t]he last comprehensive toxicology assessment was conducted in 2000”, and the “last comprehensive dietary (food only) risk assessment was conducted in 2000, and risks of concern were not identified. Exposure from drinking water has never been included in the PMRA’s dietary assessment for this

active [ingredient]. The use pattern has been changed since 2000 and several MRL's have been revised/added in both Canada and the US" (**CTR Doc 026**, attachment, p.3).

63. The document confirms that "An aggregate (food + drinking water + residential) risk assessment has not been conducted for this active." It also notes that for occupational risk the last comprehensive occupational risk assessment was conducted in 2003, there was new data available and that a greenhouse worker assessment was not conducted. This document further states that "[t]he 2000 PMRA risk assessment may be out of date, against current practices", and that "the interim mitigation measures (2007) did not reflect all mitigation measures identified in the 2000 risk assessment. Therefore it is highly recommended that PMRA revise and complete the human health risk assessment for chlorpyrifos" (**CTR Doc 026**, attachment, pp.3-4).
64. The draft Briefing Note goes on to make several recommendations detailed in a chart. Option 4 was to assess the new toxicological endpoints from the EPA and if acceptable conduct a new comprehensive risk assessment for both residential and occupational exposures using EPA toxicological endpoints and newly available exposure data and current practices. It also included a recommendation to conduct a drinking water risk assessment, update the existing food dietary risk assessment, and complete an aggregate assessment of dietary risk, and follow up on the outstanding data requirements for monitoring data, greenhouse and mosquito data and field trials for residue limits (**CTR Doc 026**, attachment, pp.4-8).
65. The draft Briefing Note also includes a comparison of reference values used by the PMRA and the EPA, and the included table identifies that several reference values (including one for infants, children, youth and women 13-49 years for drinking water residue of concern chlorpyrifos oxon) had not yet been established by the PMRA (**CTR Doc 026**, attachment, pp.12-14).
66. As demonstrated through the attached word documents and associated emails in **CTR Docs 026, 027, 028, 029** and **031** (attachments) this draft Briefing Note would subsequently be heavily edited by senior managers and possibly others at the PMRA. It was modified to remove the detailed options or recommend any actions by the PMRA. The subsequent version of the Briefing Note changes the conclusions and states that

“[t]he PMRA’s current reference values are generally more conservative than those most recently proposed by the EPA” and that “[w]hile EPA’s current assessment may have scientific merit, it would be premature to consider alignment at this stage.” (**CTR Doc 028**, attachment).

67. The senior-manager-approved Briefing Note is attached to an email on May 15, 2015 (**CTR Doc 029**), while Health Evaluation Directorate of the PMRA input for the Briefing Note was sent on May 19, 2015 (**CTR Doc 031**). The versions of the Briefing Note from May 14, 15, and 19 delete the portions of the chart showing that the PMRA did not have reference values for chlorpyrifos oxon associated with water exposure (**CTR Docs 028, 029 and 031**). The final Briefing Note, agendas and minutes for this May 26, 2015 Directors General meeting are contained at **CTR Docs 386, 387, and 388**.
68. The final decision from the associated Directors General meeting was that the PMRA would complete the chlorpyrifos re-evaluation without updating the 2000 toxicology endpoints (i.e. reference doses). The final phase would focus on conducting assessments for mosquito adulticide, greenhouse uses and a refined environmental risk assessment (**CTR Doc 388**).
69. After the May 2015 Directors General meeting, the lack of any Canadian reference doses for chlorpyrifos oxon remained a concern for PMRA staff. In a September 2015 email chain between Shairoz Ramji, the Section Head of the Exposure Re-Evaluation Section 2 of the Health Evaluation Directorate, and Jian Wei He, a Dietary Evaluation Officer in that section, the two discuss the 2014 EPA Human Health Risk Assessment and other EPA documents from 2008 (**CTR Doc 038**). Shairoz Ramji concludes that the “bottom line” was that the PMRA needs toxicological endpoints for chlorpyrifos oxon, especially for drinking water. The email from Jian Wei He notes that the drinking water level of comparison for oxon was exceeded for infants in the 2014 EPA Human Health Risk Assessment.
70. In November of 2015 the EPA proposed to revoke all tolerances (food residue limits) for chlorpyrifos (**Gabel Affidavit, Exhibit C8**). The EPA explained that “The agency is proposing to revoke all of these tolerances because EPA cannot, at this time, determine that aggregate exposure to residues of chlorpyrifos, including all anticipated dietary

exposures and all other nonoccupational exposures for which there is reliable information, are safe.” The EPA defines “safe” to mean “reasonable certainty that no harm will result from aggregate exposure to the pesticide...” (**Gabel Affidavit, Exhibit C8**, p.69081).

71. On November 2, 2015, an email from Shairoz Ramji states that Margherita Conti, the Director General of the Value Assessment and Re-Evaluation Directorate of the PMRA, had a call with the EPA and other PMRA staff. The email circulates the proposed EPA decision to revoke food tolerances and states that the PMRA “directors” planned another meeting to discuss the path forward for chlorpyrifos (**CTR Doc 041**).
72. The decision in the minutes for the January 2016 Directors General meeting (**CTR Doc 390**) confirms that the focus would be on completing the environmental risk assessment and that the Environmental Assessment Directorate of the PMRA would provide estimated environmental concentrations to the Health Evaluation Directorate for comparison to the 2003 drinking water levels of comparison. Whether or not toxicology endpoints would be updated to account for chlorpyrifos oxon is not mentioned in the minutes. Similarly, updates to the human health risk assessment to address the previously identified mosquito fogging and greenhouse uses is not mentioned.
73. The PMRA concluded by 2016 that chlorpyrifos was converted to the oxon metabolite by chlorination and therefore it could be assumed that 100% of chlorpyrifos was converted to oxon in drinking water (**CTR Doc 446**, May 2016, **CTR Doc 451**, April 2017, **CTR Doc 095**, September 2019).
74. On November 3, 2016, the EPA released a new human health risk assessment (**Gabel Affidavit, Exhibit C12**). The EPA concluded that there was “evidence of delays in mental development in infants (24-36 months), attention problems and autism spectrum disorder in early childhood, and intelligence decrements in school age children who were exposed to [organophosphates] during gestation” (p.12) and again confirmed that there were neurodevelopmental effects occurring below exposure levels that were required from adverse effects for AChE inhibition (p.13).

75. A related 2016 EPA document on the proposed revocation of food residue tolerances explains that the EPA had completed further analysis and risk assessments including of exposure to drinking water. Their analysis indicated that there were a variety of issues identified for dietary risk such as “expected residues of chlorpyrifos on most individual food crops exceed the ‘reasonable certainty of no harm’ safety standard under the Federal Food, Drug and Cosmetic Act” and that “the majority of estimated drinking water exposures from currently registered uses, including water exposures from non-food uses, continue to exceed safe levels” such that the “risk from aggregate exposure does not meet the... safety standard” (**Gabel Affidavit, Exhibit C13**).

D. PMRA begins to conduct a drinking water assessment

76. At some point in 2016, it seems that the PMRA may have requested more water monitoring data for chlorpyrifos from registrants (**CTR Doc 085**, attachment, p.5). However, based on my review of the CTR index, the call for more data and any responses is not included in the CTR. The applicants on this judicial review application requested further CTR documents on this issue and these were rejected as outside the scope of the application. Attached to my affidavit as **Exhibit H** is a letter from the respondents dated September 17, 2021 detailing this position.²
77. In May 2016 the PMRA discussed the approach it would take to updating the drinking water assessment for dietary risk. A May 2016 Briefing Note to the Directors General Work Planning Meeting stated that the estimated environmental concentrations (Level 1) required to conduct the drinking water assessment were provided to the Health Evaluation Directorate (HED) some time before May 2016, and that they exceeded the drinking water levels of comparison for “certain populations” (**CTR Doc 391**). It also stated that refined (Level 2) EECs would be provided by the end of September 2016. Once this was done HED would compare to the 2003 drinking water level of comparison. It notes that the PMRA’s toxicology endpoints date to 2003, several years before the EPA identified chlorpyrifos oxon as “more toxic” than chlorpyrifos in the 2014 EPA Human Health Risk Assessment and that “this metabolite has not been addressed by the PMRA

² This letter uses the old CTR document numbers which can be found in the CTR index under the column “Orig Tab”.

to date.” Accordingly, the drinking water assessments from 2016 showed DWLOCs were exceeded without considering the more toxic metabolite, chlorpyrifos oxon. (**CTR Doc 391**, see also **CTR Doc 390**).

78. In November 2016 another Briefing Note confirmed that “[t]he current EEC for chlorpyrifos alone already exceeded the 2003 DWLOCs for certain populations,” which was to be addressed in the April and June 2017 meetings (**CTR Doc 394**, see also **CTR Docs 396, 448, and 449**). A related memo states that “further refinement will require additional data” (**CTR Doc 448**, p.2).
79. In April 2017, the PMRA’s Health Evaluation Directorate had received the preliminary drinking water values (this appears to relate to the Level 2 EECs) and that based on those values “the risk assessment does not look good” (**CTR Doc 045**, last email in chain). The Level 1 EECs exceeded the 2003 drinking water levels of comparison and the refined Level 2 EECs still exceeded the 2003 drinking water levels of comparison for “certain populations” (**CTR Doc 050**, attached Draft Briefing Note, p.1). The documents do not state if these populations were pregnant women and infants identified in EPA documents or not. PMRA staff noted that in the EECs, “chlorpyrifos” can be defined as “chlorpyrifos + chlorpyrifos oxon” and that the PMRA treated chlorpyrifos and chlorpyrifos oxon as equally toxic (**CTR Doc 045**).
80. A set of May 2017 emails between PMRA staff confirm that the Level 2 EECs for chlorpyrifos and another transformation product called TCP exceeded the 2003 acute drinking water levels of comparison for all populations and chronic for certain populations. It confirms that it would not be possible to provide information on combined residues of concern. The refined Level 2 EECs for chlorpyrifos alone still exceeded the drinking water levels of comparison for “certain populations.” (**CTR Doc 045**, see also later **CTR Doc 066**).
81. Human health issues requiring further consideration are listed in a Briefing Note prepared for the Directors General work planning meeting from July 2017. This document confirms a need for additional data on mosquito uses and greenhouse ornamentals. It presents removing these uses as an option. For mosquito larvicide, the Briefing Note questions whether the estimated environmental concentrations used to compare with the

- drinking water levels of comparison included mosquito larvicide uses (**CTR Doc 400**, p.2).
82. The July 2017 Briefing Note states that the revised estimated environmental concentration for chlorpyrifos alone exceeded the 2003 DWLOCs for acute risk for certain populations. This included the revised EEC derived from water monitoring data (**CTR Doc 400**, p.1). Chlorpyrifos oxon was not included, the DWLOC was “already exceeded when considering chlorpyrifos alone.” The document also highlights that there was still insufficient data on another transformation product, DES. (**CTR Doc 400**, p. 2).
83. In a scientific monograph dated May 12, 2017, the PMRA noted that there was an insufficient amount of data for chlorpyrifos oxon to represent the Canadian environment, and therefore a value from monitoring could not be given (**CTR Doc 454**). While the PMRA stated oxon was not expected to be significantly found in the environment from the limited data available, any chlorpyrifos present in drinking water was expected to be converted entirely to chlorpyrifos oxon, and the PMRA concluded that the chronic and acute dietary risk assessments should assume all chlorpyrifos was converted to oxon in drinking water (**CTR Doc 454**). The PMRA did not have information on the levels of oxon in drinking water.
84. Around this time, the PMRA also became aware that levels of exposure to chlorpyrifos were higher than those used in the 2003 re-evaluation updates, which noted that detectible residues of chlorpyrifos were found on only 0.3% of domestic samples and 1.9% of imported samples of food, with some samples having residues higher than the MRLs (**Gabel Affidavit, Exhibit A6**, p.9). Email correspondence between PMRA staff from August 2017 details then-newly released Canadian Health Measures Survey biomonitoring data finding chlorpyrifos in 99% of samples (**CTR Doc 220**, attachment, p.2) and the geometric mean concentration was slightly higher than reported in US biomonitoring studies. In-addition, PMRA staff noted that Canadian Food Inspection Agency monitoring data (2013-2017) showed residues of chlorpyrifos in various commodities that were “significantly higher than those used in the 2000 [dietary exposure assessment]” (**CTR Doc 467**, p.2, see also original CFIA data discussed in PACR2003-

03, **Gabel Affidavit, Exhibit A6**, p.9). As discussed below this raised questions about whether residues on food alone were safe, even without considering drinking water.

85. The PMRA did not publicly release any updates to the re-evaluation to explain these findings to the public nor did it explain to the public what steps might be taken. However, in the fall of 2017 the PMRA did update the technical grade active ingredient registrants on the drinking water findings as well as outstanding human health data requirements for mosquito uses and greenhouse ornamentals (**CTR Doc 085**, attachment, p.5, **CTR Docs 402, 455 and 235**).

E. The PMRA revisits the drinking water risk assessment based on reduced use patterns.

86. In 2018 the PMRA was preparing the interim decision for the environmental risk assessment as part of the chlorpyrifos re-evaluation. As a result of that assessment, it was anticipated that various uses would be discontinued, although this ultimately would not occur until December 2020 and would be done on a three-year phase-out. The PMRA decided to re-assess drinking water levels of comparison based on the anticipated exposures from the remaining uses that would be permitted once the environmental risk phase out was complete (later scheduled for December 2023). In the record this is referenced as the “reduced” or “revised” use pattern.
87. In August 2018 a 1-pager on the status of the chlorpyrifos re-evaluation was prepared by PMRA staff (**CTR Doc 070**, attachment). In the 1-pager it is noted that even with the reduced use patterns, the estimated environmental concentrations exceeded drinking water levels of comparison for chlorpyrifos:

“[N]ew estimated environmental concentrations (EECs) in drinking water have been determined based on the reduced use pattern required to address the environmental risk noted above. **Although these EECs still exceed the drinking water levels of concern identified in the health risk assessment from Phase 2**, exposure from drinking water is expected to be greatly reduced with the revised use pattern. An updated health risk assessment, including exposure from drinking water, will be conducted in the next round of re-evaluation for chlorpyrifos.” (my emphasis, **CTR Doc 070**, attachment, p.1, see also **CTR Doc 063, CTR Doc 404**).

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88. Between November and December 2018, PMRA staff would be asked to engage in a “qualitative” assessment that would “assume” that the reduced use pattern did not result in significant exposures to drinking water (**CTR Docs 078, 400** p.2, **081, 082, 083, 085, 408** and attachment p.5, **198**, attachment p.4)) These documents also discuss that the underlying science memo had to be edited to match these conclusions.
89. The present-day use pattern is not the revised or reduced use pattern mentioned in these PRMA documents. Until December 2023 the uses of chlorpyrifos used to conclude that the Level 1 and Level 2 estimated environmental concentrations exceeded drinking water levels of concern will not change. The reduced/revised use pattern in the environmental risk assessment and the label amendments proposed in that environmental risk assessment have been superseded by the PMRA’s decision to terminate all uses at the end of December 2023.

F. Mosquito adulticide and greenhouse ornamental uses were proposed for cancellation

90. The PMRA requested data from registrants in 2003 and 2007 related to the human health aspects of greenhouse and mosquito adulticide uses; a summary of the repeated data calls related to these uses is included in my table at **Exhibit C**. This data was required to be submitted by 2009 (**CTR Doc 003**). Summaries of the data call ins, and the lack of submission of data are also included in **CTR Doc 012**, p.2, and the July 2017 Briefing note in **CTR Doc 400**, pp.2-3.
91. The December 2018 Briefing Note mentioned above recommended that greenhouse and mosquito adulticide uses be cancelled due to a lack of human health data that as outstanding since at least 2007 (**CTR Doc 404**, p.5). The SMC decision agreed with the briefing note “pending modifications.” (**CTR Doc 406**). The recommendation to cancel greenhouse ornamental and adult mosquito control uses was maintained in the revision and the Briefing Note was approved by the SMC (**CTR Doc 408**, attachment, p.6).
92. However, ultimately, instead of cancelling the mosquito adulticide and greenhouse ornamental uses, a new data call-in would be issued in 2019. The rationale appears to be that all technical grade active ingredient registrants might not be aware of the data requirements as discussed in emails and draft and final Briefing notes (**CTR Doc 103**,

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email and first attachment, pp.5-7, **CTR Doc 409** pp.4-6). A copy of the 2019 data call-in is included in the **Gabel Affidavit, Exhibit A12**. Data was required by August 4, 2019.

93. Data that was submitted in response to the 2019 data call-in would ultimately be rejected by the PMRA, however the uses would be allowed to continue indefinitely in the December 2020 environmental risk assessment decision (**CTR Docs 103, 142, and 145, Gabel Affidavit, Exhibit A10, RVD2020-14, pp.2-3**).

G. PMRA's 2019 and 2020 environmental risk assessment publications did not disclose the PMRA's findings on drinking water

94. Previous Directors General work planning decisions had planned to include mosquito, greenhouse and aggregate (food + water + residential) health assessments in the final phase of the re-evaluation (**CTR Doc 388**). Following the late 2018 science management committee decisions on the environmental risk assessment, the PMRA began to prepare the public-facing environmental re-evaluation document for public consultation purposes, referenced in PMRA documents as the Proposed Re-Evaluation Decision ("**PRVD**") which was ultimately released in 2019. This document ultimately did not include any specific information on the health re-evaluation.
95. A January 2019 email chain PMRA staff discussed that there would be a drinking water section in the PVRD (**CTR Doc 086**). One PMRA staff member stated that "[t]he message I think we want to convey with this PRVD is that with the proposed reduced use pattern (resulting from environmental risk) the remaining uses are not expected to pose a risk of concern for drinking water."
96. In response, Mei Qi, (the Re-evaluation coordinator for chlorpyrifos) noted the language used in a prior science management committee briefing note and stated that "[t]he PRVD needs to capture that drinking water does not pass with the current use pattern, so the stakeholders can comment properly with information that potentially could be used in referencing this particular risk" (**CTR Doc 086** also see referenced November 29, 2018 Science Management Committee briefing note **CTR Doc 408**, attachment). Mei Qi also noted that "the registrant" had already been told of the "risk of concern" for drinking water with the current use pattern and said "[r]emoving this [from] the PRVD may give them an impression that drinking water is OK with the current use pattern."

97. In response, Shairoz Ramji, the section head at the Health Evaluation Directorate, made changes that are attached to the email chain to address Mei Qi's request. Shairoz Ramji wanted to alert various PMRA senior managers about the change to the acceptability statement for drinking water made by Mei Qi and says that there would be later drafts and "you can change or remove it at that time if you want." (**CTR Doc 086**). The attached draft public re-evaluation document included the following language on drinking water:

Regarding the health risk assessment from drinking water exposure, chlorpyrifos concentrations from the most recent water monitoring data, which would reflect the currently registered uses of chlorpyrifos, indicate potential unacceptable risk for some population groups. (**CTR Doc 086**, attachment, pp.2 and 30)

97. The above statement on potential unacceptable risk for drinking water remained throughout revisions to the draft PRVD, including in a version dated January 15, 2019, in which Mei Qi questioned in a comment bubble why no drinking water results were shown or described in the PRVD (**CTR Doc 089**, attachment, pp.27-28). The following day Shairoz Ramji wrote to Mei Qi noting that the drinking water section will be considerably shortened because the Health Evaluation Directorate "did not do a risk assessment, and the focus of the document is the environmental assessment" (**CTR Doc 090**).

98. The revised PRVD no longer included a section on the Health Risk Assessment, and PMRA staff removed any mention of the drinking water assessment (**CTR Doc 103**, second attachment, p.25). While this section is still listed in the Table of Contents, it has been entirely deleted (this deletion can also be seen by choosing to view "Track Changes" on Microsoft Word, see **CTR Doc 103**, second attachment, pp.27-28).

99. On May 31, 2019, the PMRA released the final Proposed Environmental Re-evaluation Decision for public comment (**Gabel Affidavit, Exhibit A9**). The entire human health risk assessment section that had been included in earlier drafts of the PVRD (see **CTR Docs 086** and **089**), including all discussion of drinking water results, was now removed and replaced with a brief statement on the status of human health (**Gabel Affidavit, Exhibit A9**, p.3). In this statement the PMRA indicated that Health Canada "will be"

requesting relevant information to update the human health risk assessment including the drinking water assessment.

H. PMRA's 2020 environmental risk re-evaluation decision

100. Based on environmental risk, in May 2019 the PMRA proposed cancellation of all uses of chlorpyrifos, except for five uses including adult mosquito control and greenhouse ornamentals, which would be subject to label changes.
101. In December 2020, the PMRA issued the final environmental risk re-evaluation decision. This decision cancelled all outdoor uses of chlorpyrifos except for the previously identified uses, including larval and adult mosquito and greenhouse uses and elm bark beetle and mountain pine beetle control. These uses would require label amendments. The cancellation decision was phased in over a three-year period. By the time of this decision the technical grade active ingredient registrant had already discontinued all greenhouse ornamental uses (**Gabel Affidavit, Exhibit A10**, RVD2020-14, pp.3 and 43).
102. The PMRA indicated in that decision that the human health risk assessment was ongoing:

In [PRVD2019-05], Health Canada also informed the public that new studies related to human health assessment have been generated, which, as indicated by various international jurisdictions, may inform the re-evaluation of chlorpyrifos. Based on the relevant new information, Health Canada will be updating the human health assessment, and it will be presented in a future publication.

In response to calls to cancel chlorpyrifos as part of the public consultation the PMRA stated that it was “aware of the new scientific information cited in the recent international reviews” (**Gabel Affidavit, Exhibit A10**, p.31).
103. The PMRA did not disclose that it had already estimated drinking water concentrations and found that the current use pattern, which would continue for three more years, was potentially unacceptable from a human health perspective because it exceeded drinking water levels of comparison. The PMRA also did not disclose that the current human health data it had on greenhouse and adult mosquito uses, which would also continue were insufficient. As discussed below, the PMRA also did not disclose that it considered and rejected a special review on human health.

I. European Decisions on Chlorpyrifos

104. In April 2019, as part of the standard regulatory renewal of approval processes for these substances, experts from European Food Safety Authority (“EFSA”) and Member States convened to discuss the human health assessment of chlorpyrifos and chlorpyrifos-methyl. Experts concluded that concerns related to human health existed, in particular in relation to possible genotoxicity and developmental neurotoxicity. A European Commission document downloaded from its website explaining and summarizing this is attached as **Exhibit “I”**.
105. In August 2019, EFSA published statements in the EFSA journal, from an approval (dated July 2019) for both substances, confirming that concerns for human health have been identified and that safe levels of exposure could not be determined based on the available data. EFSA concluded that the approval criteria for human health laid down in the EU legislation are not met (**Gabel Affidavit, Exhibit D1**).
106. EFSA’s conclusion was reviewed by the European Commission’s Standing Committee on Plants, Animals, Food and Feed in December 2019, and the committee considered and approved a draft implementing regulation that decided not to renew chlorpyrifos (see **Exhibit I** above). The final regulation was adopted by the European Commission on January 10, 2020 (**Gabel Affidavit, Exhibit D3**).
107. The final regulation summarizes the events leading to the non-renewal including the July/August EFSA conclusions noting:
- Based on the information available, it cannot be excluded that chlorpyrifos has a genotoxic potential, since positive results were found in a number of *in vitro* and *in vivo* studies. Consequently, it is not possible to establish health-based reference values for chlorpyrifos and to conduct the relevant consumer and non-dietary risk assessments. Furthermore, developmental neurotoxicity (DNT) effects were observed in the available study on developmental neurotoxicity in rats and epidemiological evidence exists showing an association between exposure to chlorpyrifos and/or chlorpyrifos-methyl during development and adverse neurodevelopmental outcomes in children. (**Gabel Affidavit, Exhibit D3, p.7**)
108. The final regulation notes that:

[I]t has not been established, with respect to one or more representative uses of at least one plant protection product that the approval criteria provided for in Article

4 of Regulation (EC) No 1107/2009 are satisfied. The environmental risk assessment, although not finalised, cannot alter this conclusion since the approval criteria related to the effects on human health are not satisfied and should therefore not delay further the decision-making on the renewal of the approval of the active substance. It is therefore appropriate not to renew the approval of the active substance chlorpyrifos in accordance with Article 20(1)(b) of that Regulation. (**Gabel Affidavit, Exhibit D3**, p.7)

J. PMRA decides not to launch a special review based on EU ban in 2020-2021

109. The PMRA was aware of the EFSA assessment, and PMRA staff noted that the EFSA conclusions on chlorpyrifos-methyl were the same as chlorpyrifos (**CTR Docs 112, 118, 119**). The PMRA staff began to discuss whether the EFSA decision might trigger a requirement for a special review under s. 17(2) of the *Pest Control Products Act*. (**CTR Docs 130, 131, and 132**)
110. The PMRA conducted a preliminary analysis of the need for a special review in early 2020 (**CTR Doc 352**). The purpose of the analysis was to determine the aspects of concern identified by the EU in their 2020 decision, determine if initiation of a special review was required, and to determine the approach for addressing aspects of concern if a special review is not initiated.
111. The PMRA summarized many of the human health concerns relied on by the EU in their decision, including the genotoxic potential of chlorpyrifos (in vitro and in vivo positive findings of chromosome aberration, and in vivo DNA damage which may trigger infant leukaemia), developmental neurotoxicity of chlorpyrifos (adverse effects seen at the lowest dose tested in rats, and epidemiological evidence showing an association between exposure during development and adverse neurodevelopmental outcomes in children), and reproductive toxicity of chlorpyrifos (**CTR Doc 352**, pp.4-5). Genotoxic potential, developmental neurotoxicity, and reproductive toxicity were therefore all listed as “human health aspects of concern” identified by the PMRA (**CTR Doc 352**, p.5).
112. The PMRA then noted that the human health risk assessment for chlorpyrifos was still ongoing at the time, and made the following recommendation (**CTR Doc 352**, p.6):

Therefore, it is recommended that the scope of the human health risk assessment for the re-evaluation of products containing chlorpyrifos include the human health aspects of concern identified in the 2020 Commission decision.

113. It appears from the record that a senior management decision was made to not initiate a special review sometime in May of 2020 (**CTR Doc 131**). The Science Management Committee appears to have met about this issue on June 4, 2020, but based on a review of the CTR index, no briefing notes are in the CTR (see **CTR Docs 417**, and **425**). In October 2020, a Briefing Note to the Science Management Committee presented the conclusions of the chlorpyrifos re-evaluation since 2003 (**CTR Doc 425**). The PMRA noted in the Briefing Note that based on international reviews, “new studies on human health are now available”, which the PMRA was identifying to determine the significance on the future health risk assessment. The Briefing Note also noted that aspects of concern identified in the EU decision, including potential genotoxicity and potential developmental neurotoxicity, would be included as part of the human health re-evaluation of chlorpyrifos. (**CTR Doc 425**, p.3). Although the decision not to initiate a special review appears to have been made by October 2020, it was not included in the December 2020 re-evaluation decision discussion on human health, despite stakeholders’ requests for bans on the basis of human health described in that consultation (**Gabel Affidavit, Exhibit A10**, p.31).
114. The PMRA’s decision under s. 17 of the PCPA not to initiate a special review was documented on February 10, 2021, many months later (**CTR Doc 354**). This decision was included in the detailed public registry under the submission number for the re-evaluation of chlorpyrifos on an unknown date. However it was not posted for public consultation or as a public-facing decision on the announcement or “decisions and updates” portion of the PMRA website, nor was it announced through the RSS feed. These are the locations where other special review decisions have been posted for the many years (<https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/decisions-updates.html>) and is where I would expect to see a new decision on special reviews. Unless a member of the public already knew that the decision was being considered or made, or that something new had happened related to the re-evaluation, there would be no reason to check the re-evaluation submission number in the public registry database to find this document. I was not aware that the decision was made on a special review until reviewing the CTR,

despite making frequent use of the PMRA registry, decisions and updates page and RSS feed.

K. The published phase-out and cancellation decision for all chlorpyrifos products and associated data call (2021)

115. On February 10, 2021 the PMRA issued a human health data call-in for the active ingredient chlorpyrifos. This data call-in is described in the affidavit of Margaret Sears at paras 36-38. Some of the data on toxicology requested was many decades old (**CTR Doc 210**, attachment). The PMRA required the data to be submitted in 30 calendar days (**Gabel Affidavit, Exhibit A13**). This data included data requests dealing with the need to update toxicology endpoints, as originally proposed by PMRA experts back in May 2015 (see para 48 above and **CTR Doc 026**, attachment, pp.4-5).
116. This 2021 Data Call-In was issued in relation to the only two remaining active registrants Adama Agricultural Solutions Canada Ltd. (**Adama**) and Sharda Cropchem Limited (**Sharda**). The registrants did not provide the data and on April 8, 2021, the PMRA notified the registrants that their registrations would be cancelled with a three-year phase-out (**CTR Docs 506, 507, and 508**). The data call in list was generated by looking at studies from other international regulators in California, the, US EPA, European Food Safety Authority and Australia (**CTR Doc 198**, attachment, p.2).
117. The data were not submitted and in early April the PMRA sent letters to Adama and Sharda indicating that the registrations would be cancelled (**CTR Docs 507 and 508**).
118. PMRA staff then prepared a draft re-evaluation note for public view. An email chain from April 24, 2021 includes extensive discussion between PMRA staff on the content of this re-evaluation note (**CTR Doc 212**). Margherita Conti, the Director General of the Value Assessment and Re-evaluation Management Directorate, initially added language to the re-evaluation note to “cover the imminent risk issue”, stating:

Based on existing information, there are no imminent or serious health risks of concern and thus, a shortened phase-out is not considered necessary. (**CTR Doc 211**, attachment)
119. There is no associated documentation from PMRA science staff in the CTR documenting whether they had completed an analysis of imminent or serious risks. For example, there

is no corresponding monograph or science memo. This reference to serious or imminent risk likely references the language in the PMRA's DIR2018-01: "Policy on Cancellations and Amendments Following Re-evaluation and Special Review" (**Gabel Affidavit, Exhibit B3**). DIR2018-01 sets out possible cancellation timelines under the PCPA, some of which are a three-year phase-out similar to the one used for the chlorpyrifos cancellation: one year of sale by registrant, followed by one year of sale by retailer, followed by one year of use. However according to DIR2018-01, this timeline is only appropriate where "risks of concern are not considered imminent or serious" (**Gabel Affidavit, Exhibit B3**, DIR 2018-01, at p. 4).

120. However, Margherita Conti qualified her proposed addition of imminent risk language stating that with respect to imminent risk "maybe I should stay silent on this and let the NoO take care of that part" (**CTR Doc 212**). It seems likely that "NoO" refers to the February 2021 notices of objection of the applicants and others, which were submitted a few weeks before and included some human health aspects (affidavit of Mary Lou McDonald affirmed November 3, 2021 ("**McDonald Affidavit**"), **Exhibit D**, pp.20-22). Ms. Conti then sought feedback from the Director General and Chief Registrar Frederic Bissonette and Lindsay Hanson with the PMRA's office of policy and strategic advice, as well as a name that is redacted for solicitor-client privilege (**CTR Doc 211**). The draft re-evaluation note also contains a summary of past actions on human health for the proposed Re-evaluation update, which would later be removed (**CTR Doc 211**, attachment).
121. A subsequent email chain contains a reply from Mei Qi, the re-evaluation coordinator for chlorpyrifos. She states "[r]egarding the text that you suggested on the imminent risk, I think its better not to include it in this RevNote as we haven't done the additional work related to human health", and goes on to state "perhaps NoO can consider to include it on questions related to the health aspect." Conti then replies, agreeing with this. (**CTR Doc 212**). A few weeks later the PMRA asked the applicants to withdraw the notice of objection (**McDonald Affidavit, Exhibit G**).
122. Nothing in the CTR I have found suggests that the PMRA did an analysis of the risks of concern it identified (for example in **CTR Doc 352**, or drinking water risks of concern/unacceptable risk identified in **CTR Doc 86**) to determine if they were imminent

or serious, or confirming whether the risks were acceptable in respect of the full use pattern that would continue for the three-year phase-out prior to the cancellation decision. For example, I have not located a health evaluation monograph or memorandum in the CTR from Toxicology or HED staff concluding this. There is also no document approved by the relevant PMRA science staff stating that the risks of the current uses of chlorpyrifos are acceptable for the three-year phase-out period. As noted above, this comment on serious or imminent risk was not included in the final public-facing document either.

123. In other re-evaluations I have been involved in, such as the 2019 re-evaluation of neonicotinoids, a conclusion and explanation regarding serious and imminent risk and acceptable risk was included in the public-facing re-evaluation document when a multi-year phase-out was used. Attached as **Exhibit “J1”** and **Exhibit “J2”** are summaries of previous decisions of this nature from the PMRA’s website for the active ingredients thiamethoxam and clothianidin, respectively.
124. An April 29, 2021 Briefing Note to the Science Management Committee is attached to **CTR Doc 213**. The Briefing Note discusses the cancellation and phase out in the context of the human health re-evaluation. In this version of the Briefing Note there is no explanation for the three-year phase-out (**CTR Doc 213**, attachment p.2).
125. The Science Management Committee agreed to the publication of the proposed RevNote on April 29, 2021, with the direction that the Directors General were to provide comments on the RevNote by close of business that day (**CTR Doc 431**).
126. On or about May 3, 2021 the PMRA became aware of the 9th Circuit Court decision requiring the EPA to revoke or amend chlorpyrifos tolerances and criticizing the EPA for years of delays. (**CTR Doc 214**). As stated above this court decision is included in my affidavit as **Exhibit F**.
127. A few days later, on May 6, 2021, a new Briefing Note was prepared for the Science Management Committee regarding the closure of the re-evaluation for chlorpyrifos. (**CTR Doc 215**, attachment, also see **CTR Doc 433**). This Briefing note states that in reference to the February 2021 data call-in notices, the data was not submitted and that

“[c]onsequently, the PMRA cancelled all their chlorpyrifos products on April 8, 2021 and the same 3-year cancellation timeline as noted above was applied.” The Briefing Note explains that this timeline “will avoid potential confusion for the users”, and further states that as a result of the cancellation and lack of data “PMRA will not proceed with the planned update to the human health assessment” (**CTR Doc 215**, attachment pp.2-3).

128. This explanation that the timeline for phase-out would be aligned with the phase-out period in the 2020 environmental risk assessment in order to avoid potential confusion for users is the only explanation for the three-year phase-out provided. Notably, the PMRA documents do not state that the PMRA was concerned about disposal, enforcement, alternatives, value or economic issues. The briefing notes such as **CTR Doc 433** do not discuss any specific acceptable risk issues for human health for the phase-out period, and they also do not include or suggest any other rationale for delayed implementation. The PMRA does not cite its cancellation policy or the standard used in that policy in the Briefing Note or associated documents to explain the three year phase-out.
129. The final decision to cancel all uses of chlorpyrifos on a three-year timeline was approved by the Science Management Committee on May 6, 2021, three days after the 9th Circuit Court decision was released in the US requiring the EPA to revoke tolerances of chlorpyrifos.
130. On May 13, 2021, the PMRA released “REV2021-02: Re-evaluation Note: Update on the Re-evaluation of Chlorpyrifos.” This was the only public information released about the PMRA’s human health risk evaluations and the only public explanation for the human health related cancellations or phase-out decisions. Ultimately the PMRA provided no explanation for the three-year phase out in the public Re-evaluation note, and relied only on the absence of data to justify the human health cancellation, under s.20(1)(a) of the PCPA (**Gabel Affidavit, Exhibit A11**). The language proposed by PMRA directors on serious or imminent risk noted above was not included. There was no public comment by the PMRA on the acceptable risk to human health of the use of chlorpyrifos for three more years.

131. Under REV2021-02 the PMRA stated that it “has cancelled” all remaining chlorpyrifos uses and products, and ordered the existing stocks of all chlorpyrifos products to be phased out with the following timelines:
- i. Last date of sale by registrant: 10 December 2021;
 - ii. Last date of sale by retailers: 10 December 2022; and
 - iii. Last date of use for all chlorpyrifos uses/products: 10 December 2023.
132. The PMRA further stated in REV2021-02 that the PMRA’s “intended work to update the human health assessment is no longer needed as all pest control products containing chlorpyrifos are being cancelled due to failure to satisfy requested data requirements” (**Gabel Affidavit, Exhibit A11**).
133. The PMRA was awaiting the completion of the individual organophosphates before initiating a cumulative assessment of the potential effects of combinations of organophosphates having common mechanisms of action. I was involved in correspondence with the PMRA about the refusal to complete cumulative risk assessments until all organophosphate post-market reviews were complete on individual active ingredients, including chlorpyrifos. This correspondence is attached as **Exhibit “K”**. It is not clear how the PMRA will complete the cumulative risk assessment with other organophosphates if it does not complete the human health risk assessment for chlorpyrifos.

L. Status of registrations 2020-2021

134. As of June 2021, the PMRA public registry indicated live registrations continued for the 24 products until various expiry dates. On the face of the public registry, it is not clear if the registrations were actually “cancelled” or discontinued or when this occurred as they were still listed as active registrations. The majority of the active registrations expire at the end of 2023. I prepared a summary of the information found on the public registry including the label uses that are permitted based on my review of the registry and labels, this is attached to my affidavit as **Exhibit “L”**.

135. It appears that some discontinuations are associated with the 2019 human health data call. For example, NewAgco and Agrogill registrations were cancelled involuntarily on a three-year phase-out in late 2020 with PMRA correspondence referencing a failure to respond to the 2019 human health data call-in (**CTR Docs 176, 177, 190, 503, 504**).
136. Correspondence in the CTR indicates that Corteva/Dow sought to voluntarily cancel all greenhouse uses in late 2020 rather than submit data related to human health (**CTR Docs 499**). Further Corteva/Dow registrations were discontinued in early 2021, including potentially on timelines shorter than three years (**CTR Doc 187**) although based on a review of the CTR index other associated documents are not included in the CTR.
137. The Adama and Sharda registrations were cancelled after the February 10, 2021 data call in (**CTR Docs 200**, attachment, **201**, attachment, **202**, attachment, **203**, attachment, **204**, **205, 206, 207** and **208, 505, 506, 507**, and **508**).
138. None of the correspondence from registrants listed in the index to the CTR include requests for a 3-year phase out timeline, or any other phase-out timeline. Even though registrations were discontinued in relation to the 2019 or 2021 data calls for human health information, the PMRA provided all registrants with a three-year phase-out without explanation (**CTR Docs 176, 177, 190, 507, 508**).
139. At some point in the fall of 2021 the PMRA updated the registry to mark the remaining chlorpyrifos product statuses as “phase-out” instead of “registered”. They are not listed as being cancelled. The re-evaluation/special review is listed as “pending” as are two notices of objection. I am advised by counsel and believe it to be true that counsel for the respondents in this judicial review advised the applicants that the PMRA “recently” updated the registry on November 1, 2021.

M. Maximum residue limits

a. How the PMRA sets Maximum Residue Limits

140. As noted above maximum residue limits are the legal residue limits permitted on food. In the United States these are called “tolerances.” The PMRA has described MRLs as “an essential part of ensuring that the dietary intake of pesticide residues does not lead to unacceptable exposure and risks to human health.” An excerpt from a PMRA science

policy note explaining this is attached as **Exhibit “M”** (SPN 2001-01, p.18). Further details about dietary risk assessment processes followed by the PMRA uses are included above at paragraphs 22-25 of this affidavit.

141. MRLs are the highest residues at the farm gate that could possibly be found on food resulting from the maximum use according to the label. This is determined based on crop field trial data, the percentage of a crop that is treated and commercial and consumer practices. The MRL is the legal limit of pesticide residue that is allowed to remain in or on a treated food commodity. The PMRA claims to consider “all available data” in establishing MRLs (**Gabel Affidavit, Exhibit B11**, pp. 7, 36, **Exhibit A7**, Appendix I, pp.14-15).
142. When setting MRLs, the PMRA determines the quantity of residues that are likely to remain in or on the food when the pesticide is used according to label directions and that such residues will not be a concern to human health. This quantity is then legally established as a maximum residue limit. A copy of a recent MRL decision for chlorpyrifos explaining this process is attached to this affidavit as **Exhibit “N”**.
143. When setting MRLs, the PMRA policy also states that the PMRA takes into consideration the risks from aggregate exposures, meaning that the PMRA considers drinking water and non-occupational sources of exposure (for example residential exposure) (**Gabel Affidavit, Exhibit B11**, p.7). MRLs are established on imported commodities when the commodities are not grown in Canada or when a pesticide is not registered for a given crop in Canada, based on supervised field trials conducted at the maximum label rates (**Gabel Affidavit, Exhibit A7**, Appendix I, p.15).
144. The history of the MRLs for chlorpyrifos is described in an email chain in **CTR Doc 197**. It describes how the 2003 and 2007 re-evaluation updates proposed to revoke a 0.1 ppm general MRL and replace it with specific ones and that further data was requested so that the PMRA could develop specific MRLs. After this, 33 MRLs were established for imports and some domestic crops through PMRA decisions in 2011, 2012 and 2014.

b. MRL decision

145. In early February of 2021, PMRA staff explained that an “updated dietary risk assessment will be conducted in this phase of the re-evaluation... to assess potential dietary exposure and risks for commodities with currently established MRLs, and thus, to confirm the continued acceptability of these MRLs (for imported food commodities)” (CTR Doc 197, p.2). PMRA staff also noted that at the end of a re-evaluation or other post-market review (such as a special review) under the PCPA “MRL changes are typically required to address dietary risks of concern” (CTR Doc 188).
146. A draft memo from February 2021 from the toxicology and exposure re-evaluation sections of the PMRA identified that dietary “food only” exposure and risk assessment for imported food commodities were among the human health issues to be considered in the next phase of the chlorpyrifos re-evaluation. It notes that:

Although all food uses of chlorpyrifos are to be cancelled, the dietary exposure assessment for chlorpyrifos needs to be updated to consider exposure of chlorpyrifos from imported treated foods, the most recent residue monitoring data from CFIA and USDA PDP, metabolites of chlorpyrifos, and any possible revisions of the dietary toxicology reference values. (CTR Doc 198, attachment, pp.3-4).

147. However, as the human health re-evaluation was terminated due to lack of data from the registrants, the PMRA made a decision on MRLs for chlorpyrifos. On April 19, 2021, at an MRL Trackers’ Meeting the issue of whether to maintain MRLs was discussed (CTR Doc 469). A Briefing Note for this meeting sets out the background and requirements for this decision (CTR Docs 467 and 469, attachment):

Briefly, the current status is that all Canadian chlorpyrifos products will be cancelled with an expiration date of December 10, 2023. The PMRA had a Section 19 data call-in for toxicology and exposure data, and registrants were not able to provide the required data. As a result, registrants either chose to discontinue their products or PMRA issued cancellations for registrants who failed to satisfy the data call-in requirements.

According to PMRA’s current policy and practices “*PA-2 Publication Process for Revoking and/or Amending Maximum Residue Limits*” (attached), in general if dietary risks were shown to be acceptable in the re-evaluation assessment, no actions are taken on established MRLs. However, if dietary risks were not shown to be acceptable, MRL actions such as revocation or establishment of risk-based

MRLs are to be taken for the purposes of risk mitigation. As per policy, all MRL actions need to be supported by the scientific assessment and documented for publication accordingly.

148. The Briefing Note further notes that “The 2000 dietary risk assessment is dated and does not reflect the current science and residue information for chlorpyrifos. It cannot be relied upon solely in making any re-evaluation decisions related to MRLs. Nor would it be sufficient to support PMRA's position to maintain MRLs as per the above policy” (**CTR Doc 467** and attached proposed policy).
149. Three options were proposed through the Briefing Note:
- (1) Maintain the current MRLs as per PMRA policy and based on the most recently published dietary risk assessment in PACR2003-01.
 - (2) Revoke all current MRLs, and set at limit of quantification levels to be health protective, based on the fact that sufficient information has not been provided to demonstrate risk acceptability. This is similar to the approach that EU has taken.
 - (3) Update the dietary risk assessment, and then take MRL actions based on outcomes of the dietary exposure assessment. (**CTR Doc 467**)
150. Pros and cons were listed for each option. The cons for Option #1, maintaining current MRLs, were that “[t]he current dietary risk to Canadians is unknown and could be underestimated if relying on the 2000 DEA”, “[t]he future dietary risk to Canadians from imports only is unknown”, and “[i]f questioned, PMRA would not be able to scientifically justify maintaining current MRLs based on the outdated dietary risk assessment” (**CTR Doc 467**).
151. Cons for Option #2, revoking the current MRLs to be health protective, included that there would not be a “complete up-to-date dietary risk assessment in which risks were not shown to be acceptable”, and therefore that it would be difficult to justify the decision without this risk assessment. Documentation may therefore be considered “incomplete” for World Trade Organization purposes or stakeholder inquiries. A further con for Option

#2 was that there may be a potential trade issue. One part of this is redacted for solicitor-client privilege (**CTR Doc 467**).

152. The Briefing Note also summarized issues that had changed since the last dietary risk assessment in 2000, giving rise to questions about whether the PMRA had sufficient information about acceptable risk: (**CTR Doc 467**, p.2)

The 2000 dietary risk assessment is dated and does not reflect the current science and residue information for chlorpyrifos. It cannot be relied upon solely in making any re-evaluation decisions related to MRLs. Nor would it be sufficient to support PMRA's position to maintain MRLs as per the above policy.

The 2000 dietary risk assessment is dated based on the following considerations:

Changes to the residue definition. In the 2000, the dietary assessment was conducted for the parent alone. Subsequent information at PMRA and in foreign reviews indicate that the metabolite 3,5,6-trichloro-2-pyridinol (TCP) may need to be considered or added to the residue assessments.

Higher potential residues. The most recent CFIA monitoring data (2013-2017) showed residues of chlorpyrifos in various commodities were significantly higher than those used in the 2000 DEA. This suggests that higher dietary exposure is possible, especially acute exposure. ...

Higher percent crop treated. New percent crop treated (PCT) information is available for crops grown in the US. Increased PCTs were observed for certain crops, e.g. the maximum PCT of grapes was 7% in the 2000 DEA, whereas it was 40% in the 2020 USEPA review.

Use expansions and new MRLs for several crop groups. The 2000 DEA was not updated to include these new commodities, since it was expected that these commodities would not significantly change the risk conclusions based on qualitative considerations. However, the overall impact of the number of use expansions over time has not been considered. Newer consumption data is available. New version of DEEM.

153. The Briefing note added that “As per policy, all MRL actions need to be supported by the scientific assessment and documented for publication accordingly.”
154. The decision made at the April 19, 2021 MRL Trackers’ Meeting was Option #1, to maintain current MRLs for chlorpyrifos (**CTR Doc 469**). It is noted in the record for this decision that “[t]he cancellation of uses came from required data not being submitted by

registrants during a Section 19 data-call in, not from the results of the re-evaluation *per se*. Uses will be cancelled by Dec 2023.”

155. In the decision document the PMRA also explained that it would “rely on the most current international reference doses” and that “[w]e would not mention the hazard assessment” (emphasis added). This document also explains that the PMRA would look at monitoring data during the cumulative risk assessment (presumably of organophosphates) or a new special review (**CTR Doc 469**).
156. As with many other Briefing Notes in the CTR, the Briefing Note for the MRL trackers meeting was discussed in draft. The MRL trackers meeting Briefing Note was prepared by Jian Wei He and Shairoz Ramji and suggested edits were provided by Trevor Satchwill. By way of an April 16, 2021 email, Trevor Satchwill questioned whether the PMRA could make changes to MRLs based on not having sufficient information to demonstrate acceptability (**CTR Doc 209**).
157. On the same day as the SMC considered the PMRA’s decision to phase-out chlorpyrifos, a May 6, 2021 Briefing Note was provided to the Science Management Committee on the file closure for the re-evaluation of chlorpyrifos (**CTR Doc 433**). Included in the Briefing Note is a section on MRLs and next steps following the 2021 cancellation and phase-out decision:

Potential dietary risks from chlorpyrifos have been considered based on recent use expansions ... Health Canada will be monitoring the regulatory status of chlorpyrifos in other countries, as well as the degree of potential exposure in imported foods. Future MRL actions will be considered in the context of potential exposure and risk.

158. Accordingly, although it was originally identified as an issue to be addressed in the re-evaluation, the PMRA neither completed nor updated its re-evaluation of dietary risks to support the MRLs. In an email dated May 14, 2021, Jian Wei He of the PMRA responded to an information request from a representative of the Ontario Fruit and Vegetable Growers’ Association about the status of MRLs post-cancellation (**CTR Doc 216**). Jian Wei responded as follows:

As noted, no new human health assessment is now being conducted and thus, the established maximum residue limits (MRLs) are currently not scheduled to be

revoked. This decision takes into account similar actions that have occurred in other jurisdictions, such as the European Union, along with the cancellation of all uses in Canada, which, collectively, will result in the reduced use of this product on food commodities. In turn, dietary exposure and risk are expected to decrease. Having said that, Health Canada will continue to monitor the regulatory status of chlorpyrifos in other countries. This information will be used to re-assess whether future MRL actions are required, but again, within the context of potential dietary exposure and risk.

159. None of the above documents find acceptable risk of the MRLs on domestic products during the three year period to December 2023 during which time current use patterns for chlorpyrifos would continue, including on domestic food, nor do they identify the acceptability of aggregate risks from food and drinking water for the use patterns that would continue until December 2023.

N. Cancellations without prolonged phase-outs are not unprecedented for chlorpyrifos in Canada and elsewhere

160. In the 2000 re-evaluation the PMRA discontinued uses on schools and playgrounds as well as on tomatoes and household “domestic class” products available for retail sale. This phase-out was to be completed within a year. (**Gabel Affidavit, Exhibit A3**, p.1) in that instance timelines for implementation were said to be “identical” to those used by the EPA.
161. On August 30, 2021, in response to the April 2021 9th Circuit Court order in *League of Latin American Citizens* (attached above as **Exhibit F**), the EPA published a final rule which revoked all tolerances for chlorpyrifos, a decision which takes effect six months from the date of publication in the Federal Register. The final rule is attached to the **Gabel Affidavit** as **Exhibit C14**. This document explains that the EPA was unable to conclude that the risk from aggregate exposure from the use of chlorpyrifos meets the reasonable certainty of no harm standard of US legislation. My understanding is that by revoking tolerances, chlorpyrifos can no longer be used on food, however some non-food uses of chlorpyrifos may still be permitted in the US.
162. The document explains that aggregate exposures (i.e., exposures from food, drinking water, and residential exposures), which stem from currently registered uses, exceed safe levels according to the EPA. The EPA stated that it could not determine that there is a

reasonable certainty that no harm will result from aggregate exposure to residues. The final rule became effective October 29, 2021, meaning all chlorpyrifos tolerances (the equivalent of Canadian MRLs) will expire on February 28, 2022. The stated reason for the six-month delay was trade related (**Gabel Affidavit, Exhibit C14**, p.48315).

163. The European Commission took less than one calendar year to require all member states to withdraw authorizations for chlorpyrifos. As described above, the EFSA gave an interim opinion in July of 2019 that was confirmed later that year, and a regulation was implemented by January 2020. The regulation requires all European Union member states to revoke authorizations by February 16, 2020, a three-month grace period was allowed to be granted by Member States until April 16, 2020. These grace periods are contained within the implementing regulation (**Gabel Affidavit, Exhibit D3**). The regulation itself notes that since the health criteria were not met, the completion of an environmental risk assessment should not delay implementation. The regulation notes that the three months was granted to give member states time to implement, and it noted that the decision was being taken ahead of the product's actual expiry date and "should apply as soon as possible" (**Gabel Affidavit, Exhibit D3**, p.7, subclauses 13, 15, 16 and 17).
164. Delayed implementation of restrictions on use of chlorpyrifos in Canada can have a potential impact on user behavior. On September 2, 2021, the Western Producer published an article entitled "Growers stockpile Lorsban ahead of ban". In the article, author Robert Arnason states that a number of prairie farmers are stocking up on Lorsban, a chlorpyrifos-containing pesticide, in preparation for the 2023 ban. According to the author these farmers are currently stocking up on chlorpyrifos in order to "have sufficient supplies for the 2022 and 2023 growing seasons." This article is attached as **Exhibit "O"**.

O. Use and possession of expired or cancelled pesticides are addressed through clear disposal procedures and enforced through largely voluntary measures.

165. Pesticides in Canada are disposed of in accordance with provincial requirements. The need to adhere to provincial requirements for disposal is specified on the label for each of the 24 products in issue in this application, see for example the label for Pyrate 480 EC at

Exhibit “P” at page 4 of which states that “[f]or information on disposal of unused, unwanted product, contact the manufacturer or the provincial regulatory agency.” At the provincial level, if the pesticide cannot be used, it can be taken back by the supplier or removed by a licenced waste hauler who can take hazardous wastes. Some municipalities also accept unused pesticides as hazardous waste. Provincial governments each have information on their websites identifying how to dispose of pesticides. Many provinces have a free collection program. These processes are described on provincial websites that I have accessed, copies of which are attached as **Exhibit “Q”**.

166. The PMRA also has a history of non-aggressive enforcement of use and possession after cancellation. The PMRA releases pesticide compliance and enforcement annual reports. In the last published compliance annual report, the PMRA conducted only 169 on-farm inspections out of approximately 200,000 farms. The enforcement actions taken at the user level were exclusively sending letters or verbal education. No farmers were prosecuted. Similarly, a very limited number of inspections (134) were done of retailers, resulting in only verbal education and letters. The PMRA conducts outreach work to educate retailers and users about the outcomes of their re-evaluation decisions. The 2017-2018 annual report shows that enforcement orders and penalties are extremely rare and that prosecution is rarely, if ever used by the PMRA. The most recent available compliance report from the PMRA is attached to my affidavit as **Exhibit “R”**.

P. Remedies under the PCPA

167. Under section 35 of the PCPA a person may file a notice of objection to a decision that was subject to public consultation. As the PMRA did not consult the public about the special review decision, the decision to phase-out chlorpyrifos for lack of human health data, or the decision to maintain MRLs a notice of objection was not available for these decisions.
168. The PMRA limits its reviews of notices of objection to scientific issues and will not deal with the legality of registration decisions. It is PMRA policy that “[o]bjections that concern matters of regulatory practice, claim allegations of bias and/or concern an issue on which the PMRA has available recent independent expert opinion would not normally be referred to a panel.” This policy is attached to my affidavit as **Exhibit “S”**. I was

involved in a notice of objection where the PMRA refused to consider regulatory issues. This response is attached at **Exhibit “T”** to my affidavit. The response to this request took approximately three years. There is no legislated time for the PMRA to respond to such notices.

169. In my experience it is also often not practical to file a notice of objection because of lack of access to confidential test data through the PMRA’s reading room request process makes it extremely difficult to know what information the PMRA may have overlooked. Requests to access the data may not be granted until after the 60-day notice of objection period in the Act. The result of a successful objection is that a review panel is appointed to engage in a peer review of the PMRA’s decision-making. To my knowledge the PMRA has never appointed a review panel. In this instance there is no proposed or final health re-evaluation for such a panel to review. As noted in the **Affidavit of Mary Lou McDonald, Exhibit G**, the PMRA requested that the existing notice of objection of the applicants (to the decision on the environmental risk assessment) be withdrawn due to the cancellations.
170. I make this affidavit for the application for judicial review and for no improper or other purpose.

AFFIRMED REMOTELY by Dr. Elaine MacDonald stated as being located at the City of Toronto, in the Province of Ontario, before me at the City of Toronto, in the Province of Ontario on January 19, 2022, in accordance with O. Reg 431/20, Administering Oath or Declaration Remotely.



Commissioner for Taking Affidavits
(or as may be)

Charlotte Ireland, LSO # P10772



DR. ELAINE MACDONALD

This is **Exhibit “A”** referred to in the affidavit of
Dr. Elaine MacDonald affirmed remotely before
me in accordance with O. Reg 431/20,
Administering Oath or Declaration Remotely this
19th day of January 2022.



Commissioner for Taking Affidavits
(or as may be)

Glossary

Acronym	Meaning
AChE	Acetylcholinesterase, an enzyme necessary for the proper functioning of the nervous system. Chlorpyrifos (along with other organophosphates) is an AChE inhibitor.
ADI	Acceptable Dietary Intake/Allowable Daily Intake
AEL	Acceptable Exposure Level
ARD/ARfD	Acute Reference Dose
BN	Briefing Note
CCCEH	Columbia study, one of three epidemiological studies of chlorpyrifos conducted in the U.S. known as the "Human Cohort Studies."
CES	Chemistry Evaluation Section
CFIA	Canadian Food Inspection Agency
CHAMACOS	A specific epidemiological study on farm labourers for diet/occupational exposure/risk, one of the Human Cohort Studies.
CODEX	Codex is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.
DACO	PMRA data numbering code
DAF	Dermal Absorption Factor
DCI	Data Call-In
DEA	Dietary Exposure Assessment
DES	DES (O-ethyl O-(3,5,6-trichloro-2-pyridinol) phosphorothioate) a metabolite of concern of chlorpyrifos.
DFR	Dislodgeable Foliar Residue
DG	Directors General Of PMRA
DNT	Developmental Neurotoxicity
DRA	Dietary Risk Assessment
DUB	PMRA abbreviation for chlorpyrifos
DWLOC	Drinking Water Levels of Comparison
EAD	Environmental Assessment Directorate of PMRA
ED	Effective Dose
EDO	Executive Director's Office of PMRA
EDWC	Estimated Drinking Water Concentrations
EEC	Estimated Environmental Concentrations
EP/EUP	End-Use Product
EPA	Environmental Protection Agency
e-PRS	Electronic Pesticide Regulatory System of the PMRA, where documents may be uploaded by registrants.
ERS	Exposure Re-evaluation Section of PMRA
FDR	Food and Drug Regulations
GAP	Good Agricultural Practice
HCB	Hexachlorobenzene
HC5	Hazardous Concentration/Dose to 5% of the species
HED	Health Evaluation Directorate of PMRA
JPMR	Joint Committee on Pesticide Residues

LOAEC	Lowest Observed Adverse Effect Concentration
LOAEL	Lowest Observed Adverse Effect Level
LOC	Level of Concern
LOEC	Lowest Observed Effect Concentration
LOD	Limit of Detection
LOQ	Limit of Quantification
MOE	Margins of Exposure
MRL	Maximum Residue Limit
MS	Most Sensitive
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observable Adverse Effect Level
NOEC	No Observed Effect Concentration
NoO	Notice Of Objection
OP	Organophosphate
PACR	Proposed Acceptability for Continuing Registration (PMRA)
PAD	Population Adjusted Dose
PBPK/PD	Physiologically based pharmacokinetic and pharmacodynamic (PBPK/PD) model, has been used to describe physiological changes in typical individuals as they grow from birth to adulthood.
PCPA	<i>Pest Control Products Act</i>
PDI	Potential Daily Intake
PMRA	Pest Management Regulatory Agency
PRVD	Proposed Re-Evaluation Decision of PMRA
PWC	Pesticides in Water Calculator Model
RAC	Raw Agricultural Commodity
RD	Registration Directorate
REC	Re-Evaluation Coordinator
RED	Reregistration Evaluation Decision of US EPA
REMD	Re-Evaluation Management Directorate
REV	Re-Evaluation Note
RfD	Reference Dose (aka acceptable exposure)
ROC	Residue of Concern
RPF	Relative Potency Factor
RQ	Risk Quotient
SAP	EPA Scientific Advisory Panel
SH	Section Head of PMRA
SOC	Science Operations Committee of PMRA
SMC	Science Management Committee of PMRA
STL	Science Team Lead of PMRA
SSD	Species Sensitivity Distributions
TCP	Metabolite of chlorpyrifos (3,5,6-trichloropyridinol or 3,5,6-trichloro pyridine-2-phenol)
TGAI	Technical Grade Active Ingredient
Tolerance	See maximum residue limit. Tolerances are the equivalent food residue limit used in the United States.
TOX-1	Toxicology Evaluation Section (within the Health Evaluation Directorate) of the PMRA.

TP	Transformation Products
TSMP	Toxic Substances Management Policy (under <i>Canadian Environmental Protection Act</i>)
UF	Uncertainty Factor
URMULE	User Requested Minor Use Label Expansion
VRD	Value assessment and Re-Evaluation Management Directorate
VUI	Verified Use Information – Chlorpyrifos (PMRA Report, 2016)

This is **Exhibit “B”** referred to in the affidavit of
Dr. Elaine MacDonald affirmed remotely before
me in accordance with O. Reg 431/20,
Administering Oath or Declaration Remotely this
19th day of January 2022.



Commissioner for Taking Affidavits
(or as may be)

CONFIDENTIAL INFORMATION:

Subject to Protective Agreement in Court File nos. T-956-21, T-1412-21 and/or T-121-22

Chronology of Key Events

Date	Issue	Document
1999	Re-evaluation of chlorpyrifos products commenced under former <i>Pest Control Products Act</i> .	Gabel Affidavit, Exhibit A1
October 2000	Draft Dietary Risk Assessment monograph prepared by PMRA, does not include consideration of drinking water.	CTR Docs 375, 376
March 18, 2003	PMRA relies on draft Dietary Risk Assessment from October 2000 in preparing the 2003 re-evaluation update (PACR2003-03), proposes mitigation measures, identifies neurotoxic effects, concludes that PMRA does not have sufficient data to quantify risk from drinking water.	Gabel Affidavit, Exhibit A6 (PACR2003-03) CTR Doc 378
October 20, 2006	PMRA identifies requirements for greenhouse, drinking water and mosquito data. Greenhouse data required within 24 months, other data not immediately required.	CTR Doc 003
June 28, 2006	The new PCPA comes into force, adding new requirements to include aggregate and cumulative risks in sections 7, 11 and 19.	<i>Pest Control Products Act</i> , SC 2002, c 28, < https://canlii.ca/t/52lpp >, s.90, Information note, bringing into force the new PCPA: https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/cps-spc/alt_formats/pdf/pubs/pest/fact-fiche/new-PCPA-Information-nouvelle-LPA-eng.pdf
January 5, 2007	PRMA re-evaluation update withdrawing many proposed mitigation measures from PACR2003-03, identifies drinking water as issue of concern, identifies missing drinking water, greenhouse and mosquito data, and proposes final re-evaluation decision in 2008.	Gabel Affidavit, Exhibit A7 (REV2007-01)
September 2007	Environmental and Labour organizations in United States launch petition to EPA to revoke tolerances and cancel all registrations of chlorpyrifos.	MacDonald Affidavit, Exhibit F, p.19
February 7, 2008	PMRA decides to put re-evaluation on hold "pending data requirements and policy issues" decides that next round will complete risk assessment based on data call in and in cooperation with EPA.	CTR Doc 383

CONFIDENTIAL INFORMATION:

Subject to Protective Agreement in Court File nos. T-956-21, T-1412-21 and/or T-121-22

Date	Issue	Document
May 2015	PMRA reviews EPA's 2014 risk assessment and concludes that there are potential issues with chlorpyrifos oxon and drinking water it has not addressed. PMRA decides not to update its toxicological endpoints in line with EPA assessments.	CTR Docs 026, 032, 229, 386
January 2016	Directors General of PMRA decide not to act on EPA decision to revoke food tolerances or update health risk assessment. PMRA decides to analyze drinking water levels of comparison.	CTR Docs 041, 390
May 2016	PMRA concludes that drinking water levels of comparison are exceeded for certain populations based on estimated "Level 1" environmental concentrations.	CTR Docs 390, 391
November 2016	Findings in May 2016 Briefing note reviewed again through subsequent PMRA briefings.	CTR Docs 396, 448, 449
April to July 2017	Level 2 estimated environmental concentrations still exceed drinking water levels of comparison for certain populations, some transformation products not included (TCP, DES) PMRA confirms need for additional data on greenhouse and mosquito uses.	CTR Docs 045, 050 (attachment), 066, 137, 400, 454
August 2017	PMRA staff become aware that public exposures to chlorpyrifos were higher than in 2003 evaluations.	Gabel Affidavit A6, p.9 CTR Docs 220, 467
October 2017	PMRA updates technical grade active ingredient registrants on drinking water, mosquito and greenhouse issues, Dow Agrisciences confirms would not object to cancellation of all greenhouse and adult mosquito uses.	CTR Docs 85 (attachment p. 6), 402, 235
2018	In 2018 a qualitative risk assessment for drinking water was conducted based on future proposed reduced use pattern. EAD assumed that exposure will be limited, and the reduced use pattern not expected to significantly contribute to chlorpyrifos and TCP in drinking water, thus acceptable once revised use pattern implemented.	CTR Docs 070 (attachment), 078, 081, 082, 085 (attachment), 086 (attachment, p.30), 102 (and attachment, 137, 198 (attachment pp.4 and 18)), 404, 466
December 2018	SMC relies on qualitative risk assessment to determine that levels in drinking water will be acceptable once revised use	CTR Doc 408 and attachment

CONFIDENTIAL INFORMATION:**Subject to Protective Agreement in Court File nos. T-956-21, T-1412-21 and/or T-121-22**

Date	Issue	Document
	pattern from environmental risk assessment is implemented.	
January 2019	Drinking water section removed from re-evaluation public consultation document including removal of a statement that drinking water risk was not acceptable under current use pattern.	CTR Docs 086 (and attachment pp.2 and 30), 089 (attachment p.28), 090, 103 (and 1 st attachment, pp.5-6 and p.25)
June 4, 2019	2019 human health data call in.	Gabel Affidavit Exhibit A12
January 10, 2020	EFSA bans all uses of chlorpyrifos effective in April 2020.	Gabel Affidavit, Exhibit D3
November 2019 to October 8, 2020	PMRA becomes aware of EFSA/EU ban of chlorpyrifos, conducts preliminary analysis of need for special review, decides not to launch special review.	CTR Docs 112, 118, 119, 130, 131, 132, 352, 354, 425
September 2020	PMRA staff debate whether to include drinking water data in human health data call in.	CTR Docs 138, 139, 150 (attachment), 198 (attachment)
February 4, 2021	PMRA staff document 2018 qualitative assessment of drinking water under reduced use pattern.	CTR Doc 466
February 8, 2021	Applicants submit notice of objection to environmental risk assessment, citing human health concerns.	McDonald Affidavit, Exhibit E
February 10, 2021	PMRA issues human health data call in.	Gabel Affidavit, Exhibit A13
February 10, 2021	PMRA documents October 2021 decision not to launch special review based on EU ban.	CTR Doc 354
April 8, 2021	Adama and Sharda registrations cancelled based on Feb 10, 2021 data call in.	CTR Docs 507 and 508
April 19, 2021	MRL trackers meeting where it is decided to leave the MRLs in place based on the "outdated" October 2000/PACR2003-01 risk assessment.	CTR Doc 467, 469
April 29, 2021	9 th Circuit Court orders EPA to revoke all tolerances for Chlorpyrifos.	MacDonald Affidavit, Exhibit F
May 6, 2021	SMC considers PMRA decision to cancel/phase out chlorpyrifos, Briefing Note submitted on file closure.	CTR Doc 433
May 13, 2021	PMRA publishes final decision cancelling all uses on a three year phase-out.	McDonald Affidavit, Exhibit G

This is **Exhibit “C”** referred to in the affidavit of
Dr. Elaine MacDonald affirmed remotely before
me in accordance with O. Reg 431/20,
Administering Oath or Declaration Remotely
this 19th day of January 2022.



Commissioner for Taking Affidavits
(or as may be)

Chart of Data Call-In Requests

1. MRLs

Document	Location in Record	Data Gap identified	Data requested
REV2001-05	Gabel Affidavit Exhibit A4	Stakeholders are also encouraged to identify any Canadian specific use information and water monitoring, or other data that could be used to refine the Canadian assessment.	
PACR2003-03	Gabel Affidavit Exhibit A6	In the case of chlorpyrifos, sufficient data have been provided to support MRLs for some domestic and imported commodities, but not others ... For all other commodities, additional data are needed to support the establishment of MRLs. Table 2 indicates commodities registered for treatment in Canada that are lacking adequate supporting MRL data. During this consultation period, the PMRA is requesting that registrants, or other stakeholders, identify those crops that they intend to support. If adequate data are not provided, the PMRA may be unable to recommend new MRLs for some commodities, and sale of those commodities with chlorpyrifos residues above the limit of quantification will not be allowed in Canada. During the re-evaluation of chlorpyrifos, deficiencies in the data were determined. To address some aspects of the health assessment and to complete refined environmental assessments for the remaining uses, the following data are required. Failure to adequately address these requirements will be interpreted as a lack of support for the product by registrants or other stakeholders.”	(a) As indicated in 9.1.3, “Proposed regulatory actions relating to dietary risk”, residue data are required to determine appropriate MRLs for use in Canada on a number of crops. The registrant has indicated that there might be sufficient data in their files for the following crops: canola, celery, Chinese radish, cucumber, onions (bulb), radish, grain. Parties with additional supporting data for these crops, or that are willing to provide MRL support for flax, rutabagas, strawberry and wheat should contact the PMRA during this consultation period. (b) As also indicated in 9.1.3, residue data are needed to determine appropriate import MRLs for any commodity not included in Appendix IV.
REV2007-01	Gabel Affidavit Exhibit A7	The technical registrant requests that the PMRA review the submitted crop residue data to ensure that any new MRL that is established take full advantage of USEPA reviews. This will allow both agencies to set the same tolerances/MRLs and avoid trade-related issues. It also expects the	No specific data requirement.

		<p>PMRA to consult the JMPR reviews for chlorpyrifos and consider the CODEX MRLs when establishing MRLs for Canada, as well as take into account the outcome from the consultation on the <i>NAFTA Guidance Document on Data Requirements for Tolerances on Imported Commodities in the United States and Canada</i>.</p> <p>PMRA Response All available data will be considered in establishing MRLs. Where a registrant petitions the PMRA for an import MRL by submitting appropriate data, import MRLs will be established based on the supporting data, taking into consideration the established tolerances and MRLs of foreign jurisdictions to minimize the impact on trade.</p>	
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2. Drinking Water

Document	Location in Record	Data Gap identified	Data requested
REV2001-05	Gabel Affidavit Exhibit A4	Stakeholders are also encouraged to identify any Canadian specific use information and water monitoring, or other data that could be used to refine the Canadian assessment. The PMRA may contact selected stakeholders to obtain further data in these areas. Registrants are also encouraged to advise the PMRA during this comment period if they no longer support any registered uses, in particular, residential uses.	
PACR2003-03	Gabel Affidavit Exhibit A6	During the re-evaluation of chlorpyrifos, a number of deficiencies in the data were determined. To address some aspects of the health assessment and to complete refined environmental assessments for the remaining uses, the following data are required. Failure to adequately address these requirements will be interpreted as a lack of support for the product by registrants or other stakeholders.	<p>10.3 Data requirements relating to aggregate risk (b) The registrant must provide confirmatory drinking water monitoring data. These data have also been requested by the U.S. EPA.</p>
REV2007-01	Gabel Affidavit Exhibit A7	The PMRA had requested monitoring of drinking water be conducted. A registrant provided American data on surface water monitoring as well as commented that these data are	<p>2.6.1 Data Associated With the Active Ingredient ...Drinking Water</p>

		<p>representative of Canadian conditions and should be used by the PMRA.</p> <p>PMRA Response In response to the PMRA request, a registrant submitted a study conducted in the United States that reported concentrations for several pesticides, including chlorpyrifos, for finished water.</p> <p>This study was determined to be of limited value for our assessment as the concentrations were measured in finished water rather than raw water. However, other information submitted by the registrant indicated Canadian data were available for surface water. In addition, at the time of the initial assessment of chlorpyrifos, a standardized approach for determining potential drinking water concentrations was in development, but not yet available for inclusion in the risk assessment. In the intervening time, the approach was finalized. This new approach allows consideration of both a modelling approach and the use of monitoring data.</p> <p>The results of water modelling for surface and ground water as well as an analysis of available monitoring data have now been completed and have been considered in the final decision. Estimated levels of drinking water residues present over prolonged periods of time (i.e., leading to chronic exposure) are not a health concern for chlorpyrifos. Acute drinking water levels of comparison fall between the lower and upper bound estimates defined by available monitoring data and model estimates, respectively. Model estimates for areas where cole crops are grown indicate that acute drinking water concentrations may be of concern. There is uncertainty in the monitoring data used as the lower bound of drinking water concentrations: samples may not have been collected from areas where chlorpyrifos is used and they may not have been collected at a time likely to capture the maximum concentration of chlorpyrifos. Therefore, further drinking water monitoring data are required, especially from areas where wheat or cole crops are grown, with concomitant</p>	<p>Supplemental drinking water monitoring data are required, especially from areas where wheat or cole crops are grown, with concomitant chlorpyrifos use information from the areas surrounding sample collection.</p>
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		chlorpyrifos use information from the areas surrounding sample collection.	
November 29, 2018 Draft Re-evaluation Briefing Note	CTR Doc 85, Attachment p.5	PMRA required further drinking water monitoring data to ensure residue levels are below the Drinking water levels of concern. Water monitoring data from federal departments as well as provinces have been collected in the recent years. In 2016, PMRA called-in water monitoring data for chlorpyrifos from registrants.	

3. Mosquito Fogging

Document	Location in Record	Data Gap identified	Data requested
REV2001-05	Gabel Affidavit Exhibit A4	Stakeholders are also encouraged to identify any Canadian specific use information and water monitoring, or other data that could be used to refine the Canadian assessment. The PMRA may contact selected stakeholders to obtain further data in these areas. Registrants are also encouraged to advise the PMRA during this comment period if they no longer support any registered uses, in particular, residential uses.	Canadian specific use information Canadian water monitoring
PACR2003-03	Gabel Affidavit Exhibit A6	During the re-evaluation of chlorpyrifos, a number of deficiencies in the data were determined. To address some aspects of the health assessment and to complete refined environmental assessments for the remaining uses, the following data are required. Failure to adequately address these requirements will be interpreted as a lack of support for the product by registrants or other stakeholders.	10.3 Data requirements relating to aggregate risk (a) Mosquito fogging: although fogging for mosquito control is not currently reported to be a practice in any province, should it become necessary due to public health concerns, confirmatory chemical specific air monitoring data following ground based mosquitocide application to quantify inhalation post-application exposure is required. As this is also a data requirement in the U.S., data may become available as a result of uses in the U.S. and should be submitted to the PMRA.

REV2007-01	Gabel Affidavit Exhibit A7		<p>2.6.2 Data Associated With Specific Uses of Chlorpyrifos</p> <p>Mosquito Fogging Use</p> <p>Fogging with chlorpyrifos for mosquito control is not currently reported to be a practice in any province. Should it become necessary due to public health concerns, confirmatory chemical-specific air monitoring data following ground-based mosquito adulticide application are required to quantify inhalation postapplication exposure. This is also a data requirement in the United States to support these uses, and these data must also be submitted to the PMRA once they become available.</p>
Data Call In: June 4, 2019	Gabel Affidavit Exhibit A12		<p>5.9 Deposited and/or Transferable Turf Residue data, including dissipation for mosquito adulticide uses</p> <p>5.10 Outdoor air monitoring data including dissipation for mosquito adulticide use. Items listed above are required within 60 calendar days.</p>
September 10, 2019	CTR Doc 462	Preliminary screen of seven studies on indoor structural, greenhouse and mosquito data submitted in response to 2019 DCI data requirements partially met for greenhouse ornamentals and mosquito adulticide.	Registrant is encouraged to address the deficiencies noted above or submit information on alternative methods to address human exposure for greenhouse ornamentals and mosquito fogging.
Data Call In: February 10, 2021	Gabel Affidavit Exhibit A13		Various data were requested under occupational exposure for Data Codes 5.9 and 5.10 for occupational risk (Deposited and/or Transferable Turf Residue data and Outdoor Monitoring Data for mosquito adulticide use, see Gabel Affidavit A12).

4. Greenhouse uses

Document	Location in Record	Data Gap Discussion (if any)	Data requested
PACR2003-03	Gabel Affidavit Exhibit A6	During the re-evaluation of chlorpyrifos, a number of deficiencies in the data were determined. To address some aspects of the health assessment and to complete refined environmental assessments for the remaining uses, the following data are required. Failure to adequately address these requirements will be interpreted as a lack of support for the product by registrants or other stakeholders.	10.2 Data requirements relating to occupational risk Greenhouse ornamentals: field crop DFR data was not considered a suitable surrogate for greenhouse ornamentals. Appropriate chemical specific DFR data needs to be developed.
November 2006 Letters to Registrant	CTR Docs 479-481	Registrants should note that the additional data in Attachment II may be required by the PMRA in the future.	The registrant of technical grade chlorpyrifos is required to submit the following within 24 months of this letter: Greenhouse Ornamentals Field crop dislodgeable foliar residue (DFR) data are not a suitable surrogate for greenhouse ornamentals. To confirm the acceptability of continued registration of chlorpyrifos for use on greenhouse ornamentals, appropriate chemical-specific DFR data or a suitable science-based rationale is required.
REV2007-01	Gabel Affidavit Exhibit A7		Greenhouse Ornamentals Field crop dislodgeable foliar residue (DFR) data are not a suitable surrogate for greenhouse ornamentals. To confirm the acceptability of continued registration of chlorpyrifos for use on greenhouse ornamentals, appropriate chemical-specific DFR data or a suitable science-based rationale is required.
Data Call In, June 4, 2019	Gabel Affidavit Exhibit A12		5.9 Dislodgeable Foliar Residue data including dissipation for greenhouse ornamentals 5.10 Indoor air monitoring data including dissipation for greenhouse uses

			Items listed above are required within 60 calendar days.
September 10, 2019 Memorandum from HED Evaluation Officer to Re- evaluation Coordinator,	CTR Doc 462	Preliminary screen of seven studies on indoor structural, greenhouse and mosquito data submitted in response to 2019 DCI data requirements partially met for greenhouse ornamentals and mosquito adulticide.	Registrant is encouraged to address the deficiencies noted above or submit information on alternative methods to address human exposure for greenhouse ornamentals and mosquito fogging.
Data Call In February 10, 2021	Gabel Affidavit Exhibit A13	Data call in	Various information under Data Codes 5.9 and 5.10 under occupational risk (Dislodgeable Foliar Residue data and Indoor air monitoring data including dissipation for greenhouse ornamentals, see Gabel Affidavit A12)

This is **Exhibit “D”** referred to in the affidavit of
Dr. Elaine MacDonald affirmed remotely before
me in accordance with O. Reg 431/20,
Administering Oath or Declaration Remotely
this 19th day of January 2022.



Commissioner for Taking Affidavits
(or as may be)

PLEASE SEE **EXHIBIT “D”** FOLDER
CONTAINING NOVEMBER 15 CTR EXCERPTS

This is **Exhibit “E”** referred to in the affidavit of
Dr. Elaine MacDonald affirmed remotely before
me in accordance with O. Reg 431/20,
Administering Oath or Declaration Remotely
this 19th day of January 2022.



Commissioner for Taking Affidavits
(or as may be)

Public Law 104–170
104th Congress

An Act

To amend the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug, and Cosmetic Act, and for other purposes.

Aug. 3, 1996
[H.R. 1627]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the “Food Quality Protection Act of 1996”.

Food Quality
Protection Act of
1996.
7 USC 136 note.

TITLE I—SUSPENSION-APPLICATORS

SEC. 101. REFERENCE.

Whenever in this title an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Insecticide, Fungicide, and Rodenticide Act.

Subtitle A—Suspension

SEC. 102. SUSPENSION.

(a) SECTION 6(c)(1).—The second sentence of section 6(c)(1) (7 U.S.C. 136d(c)(1)) is amended to read: “Except as provided in paragraph (3), no order of suspension may be issued under this subsection unless the Administrator has issued, or at the same time issues, a notice of intention to cancel the registration or change the classification of the pesticide under subsection (b).”.

(b) SECTION 6(c)(3).—Section 6(c)(3) (7 U.S.C. 136d(c)(3)) is amended—

(1) by inserting after the first sentence the following new sentence: “The Administrator may issue an emergency order under this paragraph before issuing a notice of intention to cancel the registration or change the classification of the pesticide under subsection (b) and the Administrator shall proceed to issue the notice under subsection (b) within 90 days of issuing an emergency order. If the Administrator does not issue a notice under subsection (b) within 90 days of issuing an emergency order, the emergency order shall expire.”; and

(2) by striking “In that case” and inserting “In the case of an emergency order”.

analysis of costs, burdens placed on agricultural producers and other pesticide users, and effectiveness in tracking risk reduction by those options.

(b) The Secretary shall submit this report to Congress not later than 1 year following the date of enactment of this section.

TITLE IV—AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

Food Quality
Protection Act of
1996.

SEC 401. SHORT TITLE AND REFERENCE.

(a) SHORT TITLE.—This title may be cited as the “Food Quality Protection Act of 1996”. 21 USC 301 note.

(b) REFERENCE.—Whenever in this title an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act.

SEC. 402. DEFINITIONS.

(a) SECTION 201(q).—Section 201(q) (21 U.S.C. 321(q)) is amended to read as follows:

“(q)(1) The term ‘pesticide chemical’ means any substance that is a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act, including all active and inert ingredients of such pesticide.

“(2) The term ‘pesticide chemical residue’ means a residue in or on raw agricultural commodity or processed food of—

“(A) a pesticide chemical; or

“(B) any other added substance that is present on or in the commodity or food primarily as a result of the metabolism or other degradation of a pesticide chemical.

“(3) Notwithstanding paragraphs (1) and (2), the Administrator may by regulation except a substance from the definition of ‘pesticide chemical’ or ‘pesticide chemical residue’ if—

“(A) its occurrence as a residue on or in a raw agricultural commodity or processed food is attributable primarily to natural causes or to human activities not involving the use of any substances for a pesticidal purpose in the production, storage, processing, or transportation of any raw agricultural commodity or processed food; and

“(B) the Administrator, after consultation with the Secretary, determines that the substance more appropriately should be regulated under one or more provisions of this Act other than sections 402(a)(2)(B) and 408.”.

(b) SECTION 201(s).—Paragraphs (1) and (2) of section 201(s) (21 U.S.C. 321(s)) are amended to read as follows:

“(1) a pesticide chemical residue in or on a raw agricultural commodity or processed food; or

“(2) a pesticide chemical; or”.

(c) SECTION 201.—Section 201 (21 U.S.C. 321) is amended by adding at the end the following:

“(gg) The term ‘processed food’ means any food other than a raw agricultural commodity and includes any raw agricultural

commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling.

“(hh) The term ‘Administrator’ means the Administrator of the United States Environmental Protection Agency.”.

SEC. 403. PROHIBITED ACTS.

Section 301(j) (21 U.S.C. 331(j)) is amended in the first sentence by inserting before the period the following: “; or the violating of section 408(i)(2) or any regulation issued under that section.”.

SEC. 404. ADULTERATED FOOD.

Section 402(a) (21 U.S.C. 342(a)) is amended by striking “(2)(A) if it bears” and all that follows through “(3) if it consists” and inserting the following: “(2)(A) if it bears or contains any added poisonous or added deleterious substance (other than a substance that is a pesticide chemical residue in or on a raw agricultural commodity or processed food, a food additive, a color additive, or a new animal drug) that is unsafe within the meaning of section 406; or (B) if it bears or contains a pesticide chemical residue that is unsafe within the meaning of section 408(a); or (C) if it is or if it bears or contains (i) any food additive that is unsafe within the meaning of section 409; or (ii) a new animal drug (or conversion product thereof) that is unsafe within the meaning of section 512; or (3) if it consists”.

SEC. 405. TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES.

Section 408 (21 U.S.C. 346a) is amended to read as follows:

“TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES

“SEC. 408. (a) REQUIREMENT FOR TOLERANCE OR EXEMPTION.—

“(1) GENERAL RULE.—Except as provided in paragraph (2) or (3), any pesticide chemical residue in or on a food shall be deemed unsafe for the purpose of section 402(a)(2)(B) unless—

“(A) a tolerance for such pesticide chemical residue in or on such food is in effect under this section and the quantity of the residue is within the limits of the tolerance; or

“(B) an exemption from the requirement of a tolerance is in effect under this section for the pesticide chemical residue.

For the purposes of this section, the term ‘food’, when used as a noun without modification, shall mean a raw agricultural commodity or processed food.

“(2) PROCESSED FOOD.—Notwithstanding paragraph (1)—

“(A) if a tolerance is in effect under this section for a pesticide chemical residue in or on a raw agricultural commodity, a pesticide chemical residue that is present in or on a processed food because the food is made from that raw agricultural commodity shall not be considered unsafe within the meaning of section 402(a)(2)(B) despite the lack of a tolerance for the pesticide chemical residue in or on the processed food if the pesticide chemical has been used in or on the raw agricultural commodity in conformity with a tolerance under this section, such residue in or on the raw agricultural commodity has been removed

to the extent possible in good manufacturing practice, and the concentration of the pesticide chemical residue in the processed food is not greater than the tolerance prescribed for the pesticide chemical residue in the raw agricultural commodity; or

“(B) if an exemption for the requirement for a tolerance is in effect under this section for a pesticide chemical residue in or on a raw agricultural commodity, a pesticide chemical residue that is present in or on a processed food because the food is made from that raw agricultural commodity shall not be considered unsafe within the meaning of section 402(a)(2)(B).

“(3) RESIDUES OF DEGRADATION PRODUCTS.—If a pesticide chemical residue is present in or on a food because it is a metabolite or other degradation product of a precursor substance that itself is a pesticide chemical or pesticide chemical residue, such a residue shall not be considered to be unsafe within the meaning of section 402(a)(2)(B) despite the lack of a tolerance or exemption from the need for a tolerance for such residue in or on such food if—

“(A) the Administrator has not determined that the degradation product is likely to pose any potential health risk from dietary exposure that is of a different type than, or of a greater significance than, any risk posed by dietary exposure to the precursor substance;

“(B) either—

“(i) a tolerance is in effect under this section for residues of the precursor substance in or on the food, and the combined level of residues of the degradation product and the precursor substance in or on the food is at or below the stoichiometrically equivalent level that would be permitted by the tolerance if the residue consisted only of the precursor substance rather than the degradation product; or

“(ii) an exemption from the need for a tolerance is in effect under this section for residues of the precursor substance in or on the food; and

“(C) the tolerance or exemption for residues of the precursor substance does not state that it applies only to particular named substances and does not state that it does not apply to residues of the degradation product.

“(4) EFFECT OF TOLERANCE OR EXEMPTION.—While a tolerance or exemption from the requirement for a tolerance is in effect under this section for a pesticide chemical residue with respect to any food, the food shall not by reason of bearing or containing any amount of such a residue be considered to be adulterated within the meaning of section 402(a)(1).

“(b) AUTHORITY AND STANDARD FOR TOLERANCE.—

“(1) AUTHORITY.—The Administrator may issue regulations establishing, modifying, or revoking a tolerance for a pesticide chemical residue in or on a food—

“(A) in response to a petition filed under subsection (d); or

“(B) on the Administrator’s own initiative under subsection (e).

As used in this section, the term ‘modify’ shall not mean expanding the tolerance to cover additional foods.

“(2) STANDARD.—

“(A) GENERAL RULE.—

“(i) STANDARD.—The Administrator may establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe. The Administrator shall modify or revoke a tolerance if the Administrator determines it is not safe.

“(ii) DETERMINATION OF SAFETY.—As used in this section, the term ‘safe’, with respect to a tolerance for a pesticide chemical residue, means that the Administrator has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.

“(iii) RULE OF CONSTRUCTION.—With respect to a tolerance, a pesticide chemical residue meeting the standard under clause (i) is not an eligible pesticide chemical residue for purposes of subparagraph (B).

“(B) TOLERANCES FOR ELIGIBLE PESTICIDE CHEMICAL RESIDUES.—

“(i) DEFINITION.—As used in this subparagraph, the term ‘eligible pesticide chemical residue’ means a pesticide chemical residue as to which—

“(I) the Administrator is not able to identify a level of exposure to the residue at which the residue will not cause or contribute to a known or anticipated harm to human health (referred to in this section as a ‘nonthreshold effect’);

“(II) the lifetime risk of experiencing the non-threshold effect is appropriately assessed by quantitative risk assessment; and

“(III) with regard to any known or anticipated harm to human health for which the Administrator is able to identify a level at which the residue will not cause such harm (referred to in this section as a ‘threshold effect’), the Administrator determines that the level of aggregate exposure is safe.

“(ii) DETERMINATION OF TOLERANCE.—Notwithstanding subparagraph (A)(i), a tolerance for an eligible pesticide chemical residue may be left in effect or modified under this subparagraph if—

“(I) at least one of the conditions described in clause (iii) is met; and

“(II) both of the conditions described in clause (iv) are met.

“(iii) CONDITIONS REGARDING USE.—For purposes of clause (ii), the conditions described in this clause with respect to a tolerance for an eligible pesticide chemical residue are the following:

“(I) Use of the pesticide chemical that produces the residue protects consumers from adverse effects on health that would pose a greater risk than the dietary risk from the residue.

“(II) Use of the pesticide chemical that produces the residue is necessary to avoid a significant

disruption in domestic production of an adequate, wholesome, and economical food supply.

“(iv) CONDITIONS REGARDING RISK.—For purposes of clause (ii), the conditions described in this clause with respect to a tolerance for an eligible pesticide chemical residue are the following:

“(I) The yearly risk associated with the non-threshold effect from aggregate exposure to the residue does not exceed 10 times the yearly risk that would be allowed under subparagraph (A) for such effect.

“(II) The tolerance is limited so as to ensure that the risk over a lifetime associated with the nonthreshold effect from aggregate exposure to the residue is not greater than twice the lifetime risk that would be allowed under subparagraph (A) for such effect.

“(v) REVIEW.—Five years after the date on which the Administrator makes a determination to leave in effect or modify a tolerance under this subparagraph, and thereafter as the Administrator deems appropriate, the Administrator shall determine, after notice and opportunity for comment, whether it has been demonstrated to the Administrator that a condition described in clause (iii)(I) or clause (iii)(II) continues to exist with respect to the tolerance and that the yearly and lifetime risks from aggregate exposure to such residue continue to comply with the limits specified in clause (iv). If the Administrator determines by such date that such demonstration has not been made, the Administrator shall, not later than 180 days after the date of such determination, issue a regulation under subsection (e)(1) to modify or revoke the tolerance.

Regulations.

“(vi) INFANTS AND CHILDREN.—Any tolerance under this subparagraph shall meet the requirements of subparagraph (C).

“(C) EXPOSURE OF INFANTS AND CHILDREN.—In establishing, modifying, leaving in effect, or revoking a tolerance or exemption for a pesticide chemical residue, the Administrator—

“(i) shall assess the risk of the pesticide chemical residue based on—

“(I) available information about consumption patterns among infants and children that are likely to result in disproportionately high consumption of foods containing or bearing such residue among infants and children in comparison to the general population;

“(II) available information concerning the special susceptibility of infants and children to the pesticide chemical residues, including neurological differences between infants and children and adults, and effects of in utero exposure to pesticide chemicals; and

“(III) available information concerning the cumulative effects on infants and children of such

residues and other substances that have a common mechanism of toxicity; and

“(ii) shall—

“(I) ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue; and

Publication.

“(II) publish a specific determination regarding the safety of the pesticide chemical residue for infants and children.

Surveys.

The Secretary of Health and Human Services and the Secretary of Agriculture, in consultation with the Administrator, shall conduct surveys to document dietary exposure to pesticides among infants and children. In the case of threshold effects, for purposes of clause (ii)(I) an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. Notwithstanding such requirement for an additional margin of safety, the Administrator may use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for infants and children.

“(D) FACTORS.—In establishing, modifying, leaving in effect, or revoking a tolerance or exemption for a pesticide chemical residue, the Administrator shall consider, among other relevant factors—

“(i) the validity, completeness, and reliability of the available data from studies of the pesticide chemical and pesticide chemical residue;

“(ii) the nature of any toxic effect shown to be caused by the pesticide chemical or pesticide chemical residue in such studies;

“(iii) available information concerning the relationship of the results of such studies to human risk;

“(iv) available information concerning the dietary consumption patterns of consumers (and major identifiable subgroups of consumers);

“(v) available information concerning the cumulative effects of such residues and other substances that have a common mechanism of toxicity;

“(vi) available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances, including dietary exposure under the tolerance and all other tolerances in effect for the pesticide chemical residue, and exposure from other non-occupational sources;

“(vii) available information concerning the variability of the sensitivities of major identifiable subgroups of consumers;

“(viii) such information as the Administrator may require on whether the pesticide chemical may have an effect in humans that is similar to an effect pro-

duced by a naturally occurring estrogen or other endocrine effects; and

“(ix) safety factors which in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives are generally recognized as appropriate for the use of animal experimentation data.

“(E) DATA AND INFORMATION REGARDING ANTICIPATED AND ACTUAL RESIDUE LEVELS.—

“(i) AUTHORITY.—In establishing, modifying, leaving in effect, or revoking a tolerance for a pesticide chemical residue, the Administrator may consider available data and information on the anticipated residue levels of the pesticide chemical in or on food and the actual residue levels of the pesticide chemical that have been measured in food, including residue data collected by the Food and Drug Administration.

“(ii) REQUIREMENT.—If the Administrator relies on anticipated or actual residue levels in establishing, modifying, or leaving in effect a tolerance, the Administrator shall pursuant to subsection (f)(1) require that data be provided five years after the date on which the tolerance is established, modified, or left in effect, and thereafter as the Administrator deems appropriate, demonstrating that such residue levels are not above the levels so relied on. If such data are not so provided, or if the data do not demonstrate that the residue levels are not above the levels so relied on, the Administrator shall, not later than 180 days after the date on which the data were required to be provided, issue a regulation under subsection (e)(1), or an order under subsection (f)(2), as appropriate, to modify or revoke the tolerance.

Regulations.

“(F) PERCENT OF FOOD ACTUALLY TREATED.—In establishing, modifying, leaving in effect, or revoking a tolerance for a pesticide chemical residue, the Administrator may, when assessing chronic dietary risk, consider available data and information on the percent of food actually treated with the pesticide chemical (including aggregate pesticide use data collected by the Department of Agriculture) only if the Administrator—

“(i) finds that the data are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide chemical residue;

“(ii) finds that the exposure estimate does not understate exposure for any significant subpopulation group;

“(iii) finds that, if data are available on pesticide use and consumption of food in a particular area, the population in such area is not dietarily exposed to residues above those estimated by the Administrator; and

“(iv) provides for the periodic reevaluation of the estimate of anticipated dietary exposure.

“(3) DETECTION METHODS.—

“(A) GENERAL RULE.—A tolerance for a pesticide chemical residue in or on a food shall not be established or

modified by the Administrator unless the Administrator determines, after consultation with the Secretary, that there is a practical method for detecting and measuring the levels of the pesticide chemical residue in or on the food.

“(B) DETECTION LIMIT.—A tolerance for a pesticide chemical residue in or on a food shall not be established at or modified to a level lower than the limit of detection of the method for detecting and measuring the pesticide chemical residue specified by the Administrator under subparagraph (A).

“(4) INTERNATIONAL STANDARDS.—In establishing a tolerance for a pesticide chemical residue in or on a food, the Administrator shall determine whether a maximum residue level for the pesticide chemical has been established by the Codex Alimentarius Commission. If a Codex maximum residue level has been established for the pesticide chemical and the Administrator does not propose to adopt the Codex level, the Administrator shall publish for public comment a notice explaining the reasons for departing from the Codex level.

“(c) AUTHORITY AND STANDARD FOR EXEMPTIONS.—

“(1) AUTHORITY.—The Administrator may issue a regulation establishing, modifying, or revoking an exemption from the requirement for a tolerance for a pesticide chemical residue in or on food—

“(A) in response to a petition filed under subsection (d); or

“(B) on the Administrator’s initiative under subsection (e).

“(2) STANDARD.—

“(A) GENERAL RULE.—

“(i) STANDARD.—The Administrator may establish or leave in effect an exemption from the requirement for a tolerance for a pesticide chemical residue in or on food only if the Administrator determines that the exemption is safe. The Administrator shall modify or revoke an exemption if the Administrator determines it is not safe.

“(ii) DETERMINATION OF SAFETY.—The term ‘safe’, with respect to an exemption for a pesticide chemical residue, means that the Administrator has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.

“(B) FACTORS.—In making a determination under this paragraph, the Administrator shall take into account, among other relevant considerations, the considerations set forth in subparagraphs (C) and (D) of subsection (b)(2).

“(3) LIMITATION.—An exemption from the requirement for a tolerance for a pesticide chemical residue in or on food shall not be established or modified by the Administrator unless the Administrator determines, after consultation with the Secretary—

Publication.

“(A) that there is a practical method for detecting and measuring the levels of such pesticide chemical residue in or on food; or

“(B) that there is no need for such a method, and states the reasons for such determination in issuing the regulation establishing or modifying the exemption.

“(d) PETITION FOR TOLERANCE OR EXEMPTION.—

“(1) PETITIONS AND PETITIONERS.—Any person may file with the Administrator a petition proposing the issuance of a regulation—

“(A) establishing, modifying, or revoking a tolerance for a pesticide chemical residue in or on a food; or

“(B) establishing, modifying, or revoking an exemption from the requirement of a tolerance for such a residue.

“(2) PETITION CONTENTS.—

“(A) ESTABLISHMENT.—A petition under paragraph (1) to establish a tolerance or exemption for a pesticide chemical residue shall be supported by such data and information as are specified in regulations issued by the Administrator, including—

Regulations.

“(i)(I) an informative summary of the petition and of the data, information, and arguments submitted or cited in support of the petition; and

“(II) a statement that the petitioner agrees that such summary or any information it contains may be published as a part of the notice of filing of the petition to be published under this subsection and as part of a proposed or final regulation issued under this section;

“(ii) the name, chemical identity, and composition of the pesticide chemical residue and of the pesticide chemical that produces the residue;

“(iii) data showing the recommended amount, frequency, method, and time of application of that pesticide chemical;

“(iv) full reports of tests and investigations made with respect to the safety of the pesticide chemical, including full information as to the methods and controls used in conducting those tests and investigations;

“(v) full reports of tests and investigations made with respect to the nature and amount of the pesticide chemical residue that is likely to remain in or on the food, including a description of the analytical methods used;

“(vi) a practical method for detecting and measuring the levels of the pesticide chemical residue in or on the food, or for exemptions, a statement why such a method is not needed;

“(vii) a proposed tolerance for the pesticide chemical residue, if a tolerance is proposed;

“(viii) if the petition relates to a tolerance for a processed food, reports of investigations conducted using the processing method(s) used to produce that food;

“(ix) such information as the Administrator may require to make the determination under subsection (b)(2)(C);

“(x) such information as the Administrator may require on whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects;

“(xi) information regarding exposure to the pesticide chemical residue due to any tolerance or exemption already granted for such residue;

“(xii) practical methods for removing any amount of the residue that would exceed any proposed tolerance; and

“(xiii) such other data and information as the Administrator requires by regulation to support the petition.

If information or data required by this subparagraph is available to the Administrator, the person submitting the petition may cite the availability of the information or data in lieu of submitting it. The Administrator may require a petition to be accompanied by samples of the pesticide chemical with respect to which the petition is filed.

“(B) MODIFICATION OR REVOCATION.—The Administrator may by regulation establish the requirements for information and data to support a petition to modify or revoke a tolerance or to modify or revoke an exemption from the requirement for a tolerance.

Publication.

“(3) NOTICE.—A notice of the filing of a petition that the Administrator determines has met the requirements of paragraph (2) shall be published by the Administrator within 30 days after such determination. The notice shall announce the availability of a description of the analytical methods available to the Administrator for the detection and measurement of the pesticide chemical residue with respect to which the petition is filed or shall set forth the petitioner’s statement of why such a method is not needed. The notice shall include the summary required by paragraph (2)(A)(i)(I).

Regulations.

“(4) ACTIONS BY THE ADMINISTRATOR.—

“(A) IN GENERAL.—The Administrator shall, after giving due consideration to a petition filed under paragraph (1) and any other information available to the Administrator—

“(i) issue a final regulation (which may vary from that sought by the petition) establishing, modifying, or revoking a tolerance for the pesticide chemical residue or an exemption of the pesticide chemical residue from the requirement of a tolerance (which final regulation shall be issued without further notice and without further period for public comment);

“(ii) issue a proposed regulation under subsection (e), and thereafter issue a final regulation under such subsection; or

“(iii) issue an order denying the petition.

“(B) PRIORITIES.—The Administrator shall give priority to petitions for the establishment or modification of a tolerance or exemption for a pesticide chemical residue that appears to pose a significantly lower risk to human health

from dietary exposure than pesticide chemical residues that have tolerances in effect for the same or similar uses.

“(C) EXPEDITED REVIEW OF CERTAIN PETITIONS.—

“(i) DATE CERTAIN FOR REVIEW.—If a person files a complete petition with the Administrator proposing the issuance of a regulation establishing a tolerance or exemption for a pesticide chemical residue that presents a lower risk to human health than a pesticide chemical residue for which a tolerance has been left in effect or modified under subsection (b)(2)(B), the Administrator shall complete action on such petition under this paragraph within 1 year.

“(ii) REQUIRED DETERMINATIONS.—If the Administrator issues a final regulation establishing a tolerance or exemption for a safer pesticide chemical residue under clause (i), the Administrator shall, not later than 180 days after the date on which the regulation is issued, determine whether a condition described in subclause (I) or (II) of subsection (b)(2)(B)(iii) continues to exist with respect to a tolerance that has been left in effect or modified under subsection (b)(2)(B). If such condition does not continue to exist, the Administrator shall, not later than 180 days after the date on which the determination under the preceding sentence is made, issue a regulation under subsection (e)(1) to modify or revoke the tolerance.

Regulations.

“(e) ACTION ON ADMINISTRATOR’S OWN INITIATIVE.—

“(1) GENERAL RULE.—The Administrator may issue a regulation—

“(A) establishing, modifying, suspending under subsection (1)(3), or revoking a tolerance for a pesticide chemical or a pesticide chemical residue;

“(B) establishing, modifying, suspending under subsection (1)(3), or revoking an exemption of a pesticide chemical residue from the requirement of a tolerance; or

“(C) establishing general procedures and requirements to implement this section.

“(2) NOTICE.—Before issuing a final regulation under paragraph (1), the Administrator shall issue a notice of proposed rulemaking and provide a period of not less than 60 days for public comment on the proposed regulation, except that a shorter period for comment may be provided if the Administrator for good cause finds that it would be in the public interest to do so and states the reasons for the finding in the notice of proposed rulemaking.

“(f) SPECIAL DATA REQUIREMENTS.—

“(1) REQUIRING SUBMISSION OF ADDITIONAL DATA.—If the Administrator determines that additional data or information are reasonably required to support the continuation of a tolerance or exemption that is in effect under this section for a pesticide chemical residue on a food, the Administrator shall—

“(A) issue a notice requiring the person holding the pesticide registrations associated with such tolerance or exemption to submit the data or information under section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act;

Notice.

Rules.

Federal Register,
publication.

“(B) issue a rule requiring that testing be conducted on a substance or mixture under section 4 of the Toxic Substances Control Act; or

“(C) publish in the Federal Register, after first providing notice and an opportunity for comment of not less than 60 days’ duration, an order—

“(i) requiring the submission to the Administrator by one or more interested persons of a notice identifying the person or persons who will submit the required data and information;

“(ii) describing the type of data and information required to be submitted to the Administrator and stating why the data and information could not be obtained under the authority of section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act or section 4 of the Toxic Substances Control Act;

“(iii) describing the reports of the Administrator required to be prepared during and after the collection of the data and information;

“(iv) requiring the submission to the Administrator of the data, information, and reports referred to in clauses (ii) and (iii); and

“(v) establishing dates by which the submissions described in clauses (i) and (iv) must be made.

The Administrator may under subparagraph (C) revise any such order to correct an error. The Administrator may under this paragraph require data or information pertaining to whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects.

“(2) NONCOMPLIANCE.—If a submission required by a notice issued in accordance with paragraph (1)(A), a rule issued under paragraph (1)(B), or an order issued under paragraph (1)(C) is not made by the time specified in such notice, rule, or order, the Administrator may by order published in the Federal Register modify or revoke the tolerance or exemption in question. In any review of such an order under subsection (g)(2), the only material issue shall be whether a submission required under paragraph (1) was not made by the time specified.

“(g) EFFECTIVE DATE, OBJECTIONS, HEARINGS, AND ADMINISTRATIVE REVIEW.—

“(1) EFFECTIVE DATE.—A regulation or order issued under subsection (d)(4), (e)(1), or (f)(2) shall take effect upon publication unless the regulation or order specifies otherwise. The Administrator may stay the effectiveness of the regulation or order if, after issuance of such regulation or order, objections are filed with respect to such regulation or order pursuant to paragraph (2).

“(2) FURTHER PROCEEDINGS.—

“(A) OBJECTIONS.—Within 60 days after a regulation or order is issued under subsection (d)(4), (e)(1)(A), (e)(1)(B), (f)(2), (n)(3), or (n)(5)(C), any person may file objections thereto with the Administrator, specifying with particularity the provisions of the regulation or order deemed objectionable and stating reasonable grounds therefor. If the regulation or order was issued in response to a petition under subsection (d)(1), a copy of each objection filed by

a person other than the petitioner shall be served by the Administrator on the petitioner.

“(B) HEARING.—An objection may include a request for a public evidentiary hearing upon the objection. The Administrator shall, upon the initiative of the Administrator or upon the request of an interested person and after due notice, hold a public evidentiary hearing if and to the extent the Administrator determines that such a public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the objections. The presiding officer in such a hearing may authorize a party to obtain discovery from other persons and may upon a showing of good cause made by a party issue a subpoena to compel testimony or production of documents from any person. The presiding officer shall be governed by the Federal Rules of Civil Procedure in making any order for the protection of the witness or the content of documents produced and shall order the payment of reasonable fees and expenses as a condition to requiring testimony of the witness. On contest, such a subpoena may be enforced by a Federal district court.

“(C) FINAL DECISION.—As soon as practicable after receiving the arguments of the parties, the Administrator shall issue an order stating the action taken upon each such objection and setting forth any revision to the regulation or prior order that the Administrator has found to be warranted. If a hearing was held under subparagraph (B), such order and any revision to the regulation or prior order shall, with respect to questions of fact at issue in the hearing, be based only on substantial evidence of record at such hearing, and shall set forth in detail the findings of facts and the conclusions of law or policy upon which the order or regulation is based.

Orders.

“(h) JUDICIAL REVIEW.—

“(1) PETITION.—In a case of actual controversy as to the validity of any regulation issued under subsection (e)(1)(C), or any order issued under subsection (f)(1)(C) or (g)(2)(C), or any regulation that is the subject of such an order, any person who will be adversely affected by such order or regulation may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein that person resides or has its principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within 60 days after publication of such order or regulation, a petition praying that the order or regulation be set aside in whole or in part.

“(2) RECORD AND JURISDICTION.—A copy of the petition under paragraph (1) shall be forthwith transmitted by the clerk of the court to the Administrator, or any officer designated by the Administrator for that purpose, and thereupon the Administrator shall file in the court the record of the proceedings on which the Administrator based the order or regulation, as provided in section 2112 of title 28, United States Code. Upon the filing of such a petition, the court shall have exclusive jurisdiction to affirm or set aside the order or regulation complained of in whole or in part. As to orders issued following a public evidentiary hearing, the findings of the Administrator with respect to questions of fact shall be sustained only if

supported by substantial evidence when considered on the record as a whole.

“(3) ADDITIONAL EVIDENCE.—If a party applies to the court for leave to adduce additional evidence and shows to the satisfaction of the court that the additional evidence is material and that there were reasonable grounds for the failure to adduce the evidence in the proceeding before the Administrator, the court may order that the additional evidence (and evidence in rebuttal thereof) shall be taken before the Administrator in the manner and upon the terms and conditions the court deems proper. The Administrator may modify prior findings as to the facts by reason of the additional evidence so taken and may modify the order or regulation accordingly. The Administrator shall file with the court any such modified finding, order, or regulation.

“(4) FINAL JUDGMENT; SUPREME COURT REVIEW.—The judgment of the court affirming or setting aside, in whole or in part, any regulation or any order and any regulation which is the subject of such an order shall be final, subject to review by the Supreme Court of the United States as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of a regulation or order.

“(5) APPLICATION.—Any issue as to which review is or was obtainable under this subsection shall not be the subject of judicial review under any other provision of law.

“(i) CONFIDENTIALITY AND USE OF DATA.—

“(1) GENERAL RULE.—Data and information that are or have been submitted to the Administrator under this section or section 409 in support of a tolerance or an exemption from a tolerance shall be entitled to confidential treatment for reasons of business confidentiality and to exclusive use and data compensation to the same extent provided by sections 3 and 10 of the Federal Insecticide, Fungicide, and Rodenticide Act.

“(2) EXCEPTIONS.—

“(A) IN GENERAL.—Data and information that are entitled to confidential treatment under paragraph (1) may be disclosed, under such security requirements as the Administrator may provide by regulation, to—

“(i) employees of the United States authorized by the Administrator to examine such data and information in the carrying out of their official duties under this Act or other Federal statutes intended to protect the public health; or

“(ii) contractors with the United States authorized by the Administrator to examine such data and information in the carrying out of contracts under this Act or such statutes.

“(B) CONGRESS.—This subsection does not authorize the withholding of data or information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee.

“(3) SUMMARIES.—Notwithstanding any provision of this subsection or other law, the Administrator may publish the

informative summary required by subsection (d)(2)(A)(i) and may, in issuing a proposed or final regulation or order under this section, publish an informative summary of the data relating to the regulation or order.

“(j) STATUS OF PREVIOUSLY ISSUED REGULATIONS.—

“(1) REGULATIONS UNDER SECTION 406.—Regulations affecting pesticide chemical residues in or on raw agricultural commodities promulgated, in accordance with section 701(e), under the authority of section 406(a) upon the basis of public hearings instituted before January 1, 1953, shall be deemed to be regulations issued under this section and shall be subject to modification or revocation under subsections (d) and (e), and shall be subject to review under subsection (q).

“(2) REGULATIONS UNDER SECTION 409.—Regulations that established tolerances for substances that are pesticide chemical residues in or on processed food, or that otherwise stated the conditions under which such pesticide chemicals could be safely used, and that were issued under section 409 on or before the date of the enactment of this paragraph, shall be deemed to be regulations issued under this section and shall be subject to modification or revocation under subsection (d) or (e), and shall be subject to review under subsection (q).

“(3) REGULATIONS UNDER SECTION 408.—Regulations that established tolerances or exemptions under this section that were issued on or before the date of the enactment of this paragraph shall remain in effect unless modified or revoked under subsection (d) or (e), and shall be subject to review under subsection (q).

“(k) TRANSITIONAL PROVISION.—If, on the day before the date of the enactment of this subsection, a substance that is a pesticide chemical was, with respect to a particular pesticidal use of the substance and any resulting pesticide chemical residue in or on a particular food—

“(1) regarded by the Administrator or the Secretary as generally recognized as safe for use within the meaning of the provisions of subsection (a) or section 201(s) as then in effect; or

“(2) regarded by the Secretary as a substance described by section 201(s)(4);

such a pesticide chemical residue shall be regarded as exempt from the requirement for a tolerance, as of the date of enactment of this subsection. The Administrator shall by regulation indicate which substances are described by this subsection. Any exemption under this subsection may be modified or revoked as if it had been issued under subsection (c).

Regulations.

“(l) HARMONIZATION WITH ACTION UNDER OTHER LAWS.—

“(1) COORDINATION WITH FIFRA.—To the extent practicable and consistent with the review deadlines in subsection (q), in issuing a final rule under this subsection that suspends or revokes a tolerance or exemption for a pesticide chemical residue in or on food, the Administrator shall coordinate such action with any related necessary action under the Federal Insecticide, Fungicide, and Rodenticide Act.

“(2) REVOCATION OF TOLERANCE OR EXEMPTION FOLLOWING CANCELLATION OF ASSOCIATED REGISTRATIONS.—If the Administrator, acting under the Federal Insecticide, Fungicide, and Rodenticide Act, cancels the registration of each pesticide that

contains a particular pesticide chemical and that is labeled for use on a particular food, or requires that the registration of each such pesticide be modified to prohibit its use in connection with the production, storage, or transportation of such food, due in whole or in part to dietary risks to humans posed by residues of that pesticide chemical on that food, the Administrator shall revoke any tolerance or exemption that allows the presence of the pesticide chemical, or any pesticide chemical residue that results from its use, in or on that food. Subsection (e) shall apply to actions taken under this paragraph. A revocation under this paragraph shall become effective not later than 180 days after—

Effective date.

“(A) the date by which each such cancellation of a registration has become effective; or

“(B) the date on which the use of the canceled pesticide becomes unlawful under the terms of the cancellation, whichever is later.

“(3) SUSPENSION OF TOLERANCE OR EXEMPTION FOLLOWING SUSPENSION OF ASSOCIATED REGISTRATIONS.—

Applicability.
Effective date.

“(A) SUSPENSION.—If the Administrator, acting under the Federal Insecticide, Fungicide, and Rodenticide Act, suspends the use of each registered pesticide that contains a particular pesticide chemical and that is labeled for use on a particular food, due in whole or in part to dietary risks to humans posed by residues of that pesticide chemical on that food, the Administrator shall suspend any tolerance or exemption that allows the presence of the pesticide chemical, or any pesticide chemical residue that results from its use, in or on that food. Subsection (e) shall apply to actions taken under this paragraph. A suspension under this paragraph shall become effective not later than 60 days after the date by which each such suspension of use has become effective.

“(B) EFFECT OF SUSPENSION.—The suspension of a tolerance or exemption under subparagraph (A) shall be effective as long as the use of each associated registration of a pesticide is suspended under the Federal Insecticide, Fungicide, and Rodenticide Act. While a suspension of a tolerance or exemption is effective the tolerance or exemption shall not be considered to be in effect. If the suspension of use of the pesticide under that Act is terminated, leaving the registration of the pesticide for such use in effect under that Act, the Administrator shall rescind any associated suspension of tolerance or exemption.

“(4) TOLERANCES FOR UNAVOIDABLE RESIDUES.—In connection with action taken under paragraph (2) or (3), or with respect to pesticides whose registrations were suspended or canceled prior to the date of the enactment of this paragraph under the Federal Insecticide, Fungicide, and Rodenticide Act, if the Administrator determines that a residue of the canceled or suspended pesticide chemical will unavoidably persist in the environment and thereby be present in or on a food, the Administrator may establish a tolerance for the pesticide chemical residue. In establishing such a tolerance, the Administrator shall take into account both the factors set forth in subsection (b)(2) and the unavoidability of the residue. Subsection (e) shall apply to the establishment of such tolerance. The Adminis-

Applicability.
Review.

trator shall review any such tolerance periodically and modify it as necessary so that it allows no greater level of the pesticide chemical residue than is unavoidable.

“(5) PESTICIDE RESIDUES RESULTING FROM LAWFUL APPLICATION OF PESTICIDE.—Notwithstanding any other provision of this Act, if a tolerance or exemption for a pesticide chemical residue in or on a food has been revoked, suspended, or modified under this section, an article of that food shall not be deemed unsafe solely because of the presence of such pesticide chemical residue in or on such food if it is shown to the satisfaction of the Secretary that—

“(A) the residue is present as the result of an application or use of a pesticide at a time and in a manner that was lawful under the Federal Insecticide, Fungicide, and Rodenticide Act; and

“(B) the residue does not exceed a level that was authorized at the time of that application or use to be present on the food under a tolerance, exemption, food additive regulation, or other sanction then in effect under this Act;

unless, in the case of any tolerance or exemption revoked, suspended, or modified under this subsection or subsection (d) or (e), the Administrator has issued a determination that consumption of the legally treated food during the period of its likely availability in commerce will pose an unreasonable dietary risk.

“(6) TOLERANCE FOR USE OF PESTICIDES UNDER AN EMERGENCY EXEMPTION.—If the Administrator grants an exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136p) for a pesticide chemical, the Administrator shall establish a tolerance or exemption from the requirement for a tolerance for the pesticide chemical residue. Such a tolerance or exemption from a tolerance shall have an expiration date. The Administrator may establish such a tolerance or exemption without providing notice or a period for comment on the tolerance or exemption. The Administrator shall promulgate regulations within 365 days after the date of the enactment of this paragraph governing the establishment of tolerances and exemptions under this paragraph. Such regulations shall be consistent with the safety standard under subsections (b)(2) and (c)(2) and with section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act.

Regulations.

“(m) FEES.—

“(1) AMOUNT.—The Administrator shall by regulation require the payment of such fees as will in the aggregate, in the judgment of the Administrator, be sufficient over a reasonable term to provide, equip, and maintain an adequate service for the performance of the Administrator’s functions under this section. Under the regulations, the performance of the Administrator’s services or other functions under this section, including—

Regulations.

“(A) the acceptance for filing of a petition submitted under subsection (d);

“(B) establishing, modifying, leaving in effect, or revoking a tolerance or establishing, modifying, leaving in effect, or revoking an exemption from the requirement for a tolerance under this section;

“(C) the acceptance for filing of objections under subsection (g); or

“(D) the certification and filing in court of a transcript of the proceedings and the record under subsection (h); may be conditioned upon the payment of such fees. The regulations may further provide for waiver or refund of fees in whole or in part when in the judgment of the Administrator such a waiver or refund is equitable and not contrary to the purposes of this subsection.

“(2) DEPOSIT.—All fees collected under paragraph (1) shall be deposited in the Reregistration and Expedited Processing Fund created by section 4(k) of the Federal Insecticide, Fungicide, and Rodenticide Act. Such fees shall be available to the Administrator, without fiscal year limitation, for the performance of the Administrator’s services or functions as specified in paragraph (1).

“(n) NATIONAL UNIFORMITY OF TOLERANCES.—

“(1) QUALIFYING PESTICIDE CHEMICAL RESIDUE.—For purposes of this subsection, the term ‘qualifying pesticide chemical residue’ means a pesticide chemical residue resulting from the use, in production, processing, or storage of a food, of a pesticide chemical that is an active ingredient and that—

“(A) was first approved for such use in a registration of a pesticide issued under section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act on or after April 25, 1985, on the basis of data determined by the Administrator to meet all applicable requirements for data prescribed by regulations in effect under that Act on April 25, 1985; or

“(B) was approved for such use in a reregistration eligibility determination issued under section 4(g) of that Act on or after the date of enactment of this subsection.

“(2) QUALIFYING FEDERAL DETERMINATION.—For purposes of this subsection, the term ‘qualifying Federal determination’ means a tolerance or exemption from the requirement for a tolerance for a qualifying pesticide chemical residue that—

“(A) is issued under this section after the date of the enactment of this subsection and determined by the Administrator to meet the standard under subsection (b)(2)(A) (in the case of a tolerance) or (c)(2) (in the case of an exemption); or

“(B)(i) pursuant to subsection (j) is remaining in effect or is deemed to have been issued under this section, or is regarded under subsection (k) as exempt from the requirement for a tolerance; and

“(ii) is determined by the Administrator to meet the standard under subsection (b)(2)(A) (in the case of a tolerance) or (c)(2) (in the case of an exemption).

“(3) LIMITATION.—The Administrator may make the determination described in paragraph (2)(B)(ii) only by issuing a rule in accordance with the procedure set forth in subsection (d) or (e) and only if the Administrator issues a proposed rule and allows a period of not less than 30 days for comment on the proposed rule. Any such rule shall be reviewable in accordance with subsections (g) and (h).

“(4) STATE AUTHORITY.—Except as provided in paragraphs (5), (6), and (8) no State or political subdivision may establish

or enforce any regulatory limit on a qualifying pesticide chemical residue in or on any food if a qualifying Federal determination applies to the presence of such pesticide chemical residue in or on such food, unless such State regulatory limit is identical to such qualifying Federal determination. A State or political subdivision shall be deemed to establish or enforce a regulatory limit on a pesticide chemical residue in or on a food if it purports to prohibit or penalize the production, processing, shipping, or other handling of a food because it contains a pesticide residue (in excess of a prescribed limit).

“(5) PETITION PROCEDURE.—

“(A) IN GENERAL.—Any State may petition the Administrator for authorization to establish in such State a regulatory limit on a qualifying pesticide chemical residue in or on any food that is not identical to the qualifying Federal determination applicable to such qualifying pesticide chemical residue.

“(B) PETITION REQUIREMENTS.—Any petition under subparagraph (A) shall—

“(i) satisfy any requirements prescribed, by rule, by the Administrator; and

“(ii) be supported by scientific data about the pesticide chemical residue that is the subject of the petition or about chemically related pesticide chemical residues, data on the consumption within such State of food bearing the pesticide chemical residue, and data on exposure of humans within such State to the pesticide chemical residue.

“(C) AUTHORIZATION.—The Administrator may, by order, grant the authorization described in subparagraph (A) if the Administrator determines that the proposed State regulatory limit—

“(i) is justified by compelling local conditions; and

“(ii) would not cause any food to be a violation of Federal law.

“(D) TREATMENT.—In lieu of any action authorized under subparagraph (C), the Administrator may treat a petition under this paragraph as a petition under subsection (d) to modify or revoke a tolerance or an exemption. If the Administrator determines to treat a petition under this paragraph as a petition under subsection (d), the Administrator shall thereafter act on the petition pursuant to subsection (d).

“(E) REVIEW.—Any order of the Administrator granting or denying the authorization described in subparagraph (A) shall be subject to review in the manner described in subsections (g) and (h).

“(6) URGENT PETITION PROCEDURE.—Any State petition to the Administrator pursuant to paragraph (5) that demonstrates that consumption of a food containing such pesticide residue level during the period of the food’s likely availability in the State will pose a significant public health threat from acute exposure shall be considered an urgent petition. If an order by the Administrator to grant or deny the requested authorization in an urgent petition is not made within 30 days of receipt of the petition, the petitioning State may establish and enforce a temporary regulatory limit on a qualifying pesticide chemical

residue in or on the food. The temporary regulatory limit shall be validated or terminated by the Administrator's final order on the petition.

“(7) RESIDUES FROM LAWFUL APPLICATION.—No State or political subdivision may enforce any regulatory limit on the level of a pesticide chemical residue that may appear in or on any food if, at the time of the application of the pesticide that resulted in such residue, the sale of such food with such residue level was lawful under this section and under the law of such State, unless the State demonstrates that consumption of the food containing such pesticide residue level during the period of the food's likely availability in the State will pose an unreasonable dietary risk to the health of persons within such State.

“(8) SAVINGS.—Nothing in this Act preempts the authority of any State or political subdivision to require that a food containing a pesticide chemical residue bear or be the subject of a warning or other statement relating to the presence of the pesticide chemical residue in or on such food.

“(o) CONSUMER RIGHT TO KNOW.—Not later than 2 years after the date of the enactment of the Food Quality Protection Act of 1996, and annually thereafter, the Administrator shall, in consultation with the Secretary of Agriculture and the Secretary of Health and Human Services, publish in a format understandable to a lay person, and distribute to large retail grocers for public display (in a manner determined by the grocer), the following information, at a minimum:

“(1) A discussion of the risks and benefits of pesticide chemical residues in or on food purchased by consumers.

“(2) A listing of actions taken under subparagraph (B) of subsection (b)(2) that may result in pesticide chemical residues in or on food that present a yearly or lifetime risk above the risk allowed under subparagraph (A) of such subsection, and the food on which the pesticide chemicals producing the residues are used.

“(3) Recommendations to consumers for reducing dietary exposure to pesticide chemical residues in a manner consistent with maintaining a healthy diet, including a list of food that may reasonably substitute for food listed under paragraph (2). Nothing in this subsection shall prevent retail grocers from providing additional information.

“(p) ESTROGENIC SUBSTANCES SCREENING PROGRAM.—

“(1) DEVELOPMENT.—Not later than 2 years after the date of enactment of this section, the Administrator shall in consultation with the Secretary of Health and Human Services develop a screening program, using appropriate validated test systems and other scientifically relevant information, to determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect as the Administrator may designate.

“(2) IMPLEMENTATION.—Not later than 3 years after the date of enactment of this section, after obtaining public comment and review of the screening program described in paragraph (1) by the scientific advisory panel established under section 25(d) of the Federal Insecticide, Fungicide, and Rodenticide Act or the science advisory board established by

Publication.
Public
information.

section 8 of the Environmental Research, Development, and Demonstration Act of 1978 (42 U.S.C. 4365), the Administrator shall implement the program.

“(3) SUBSTANCES.—In carrying out the screening program described in paragraph (1), the Administrator—

“(A) shall provide for the testing of all pesticide chemicals; and

“(B) may provide for the testing of any other substance that may have an effect that is cumulative to an effect of a pesticide chemical if the Administrator determines that a substantial population may be exposed to such substance.

“(4) EXEMPTION.—Notwithstanding paragraph (3), the Administrator may, by order, exempt from the requirements of this section a biologic substance or other substance if the Administrator determines that the substance is anticipated not to produce any effect in humans similar to an effect produced by a naturally occurring estrogen.

“(5) COLLECTION OF INFORMATION.—

“(A) IN GENERAL.—The Administrator shall issue an order to a registrant of a substance for which testing is required under this subsection, or to a person who manufactures or imports a substance for which testing is required under this subsection, to conduct testing in accordance with the screening program described in paragraph (1), and submit information obtained from the testing to the Administrator, within a reasonable time period that the Administrator determines is sufficient for the generation of the information. Orders.

“(B) PROCEDURES.—To the extent practicable the Administrator shall minimize duplicative testing of the same substance for the same endocrine effect, develop, as appropriate, procedures for fair and equitable sharing of test costs, and develop, as necessary, procedures for handling of confidential business information.

“(C) FAILURE OF REGISTRANTS TO SUBMIT INFORMATION.—

“(i) SUSPENSION.—If a registrant of a substance referred to in paragraph (3)(A) fails to comply with an order under subparagraph (A) of this paragraph, the Administrator shall issue a notice of intent to suspend the sale or distribution of the substance by the registrant. Any suspension proposed under this paragraph shall become final at the end of the 30-day period beginning on the date that the registrant receives the notice of intent to suspend, unless during that period a person adversely affected by the notice requests a hearing or the Administrator determines that the registrant has complied fully with this paragraph. Notice.

“(ii) HEARING.—If a person requests a hearing under clause (i), the hearing shall be conducted in accordance with section 554 of title 5, United States Code. The only matter for resolution at the hearing shall be whether the registrant has failed to comply with an order under subparagraph (A) of this paragraph. A decision by the Administrator after comple-

tion of a hearing shall be considered to be a final agency action.

“(iii) TERMINATION OF SUSPENSIONS.—The Administrator shall terminate a suspension under this subparagraph issued with respect to a registrant if the Administrator determines that the registrant has complied fully with this paragraph.

“(D) NONCOMPLIANCE BY OTHER PERSONS.—Any person (other than a registrant) who fails to comply with an order under subparagraph (A) shall be liable for the same penalties and sanctions as are provided under section 16 of the Toxic Substances Control Act (15 U.S.C. 2601 and following) in the case of a violation referred to in that section. Such penalties and sanctions shall be assessed and imposed in the same manner as provided in such section 16.

“(6) AGENCY ACTION.—In the case of any substance that is found, as a result of testing and evaluation under this section, to have an endocrine effect on humans, the Administrator shall, as appropriate, take action under such statutory authority as is available to the Administrator, including consideration under other sections of this Act, as is necessary to ensure the protection of public health.

“(7) REPORT TO CONGRESS.—Not later than 4 years after the date of enactment of this section, the Administrator shall prepare and submit to Congress a report containing—

“(A) the findings of the Administrator resulting from the screening program described in paragraph (1);

“(B) recommendations for further testing needed to evaluate the impact on human health of the substances tested under the screening program; and

“(C) recommendations for any further actions (including any action described in paragraph (6)) that the Administrator determines are appropriate based on the findings.

“(q) SCHEDULE FOR REVIEW.—

“(1) IN GENERAL.—The Administrator shall review tolerances and exemptions for pesticide chemical residues in effect on the day before the date of the enactment of the Food Quality Protection Act of 1996, as expeditiously as practicable, assuring that—

“(A) 33 percent of such tolerances and exemptions are reviewed within 3 years of the date of enactment of such Act;

“(B) 66 percent of such tolerances and exemptions are reviewed within 6 years of the date of enactment of such Act; and

“(C) 100 percent of such tolerances and exemptions are reviewed within 10 years of the date of enactment of such Act.

Regulations.

In conducting a review of a tolerance or exemption, the Administrator shall determine whether the tolerance or exemption meets the requirements of subsections (b)(2) or (c)(2) and shall, by the deadline for the review of the tolerance or exemption, issue a regulation under subsection (d)(4) or (e)(1) to modify or revoke the tolerance or exemption if the tolerance or exemption does not meet such requirements.

“(2) PRIORITIES.—In determining priorities for reviewing tolerances and exemptions under paragraph (1), the Administrator shall give priority to the review of the tolerances or exemptions that appear to pose the greatest risk to public health.

“(3) PUBLICATION OF SCHEDULE.—Not later than 12 months after the date of the enactment of the Food Quality Protection Act of 1996, the Administrator shall publish a schedule for review of tolerances and exemptions established prior to the date of the enactment of the Food Quality Protection Act of 1996. The determination of priorities for the review of tolerances and exemptions pursuant to this subsection is not a rulemaking and shall not be subject to judicial review, except that failure to take final action pursuant to the schedule established by this paragraph shall be subject to judicial review.

“(r) TEMPORARY TOLERANCE OR EXEMPTION.—The Administrator may, upon the request of any person who has obtained an experimental permit for a pesticide chemical under the Federal Insecticide, Fungicide, and Rodenticide Act or upon the Administrator’s own initiative, establish a temporary tolerance or exemption for the pesticide chemical residue for the uses covered by the permit. Subsections (b)(2), (c)(2), (d), and (e) shall apply to actions taken under this subsection.

“(s) SAVINGS CLAUSE.—Nothing in this section shall be construed to amend or modify the provisions of the Toxic Substances Control Act or the Federal Insecticide, Fungicide, and Rodenticide Act.”.

SEC. 406. AUTHORIZATION FOR INCREASED MONITORING.

For the fiscal years 1997 through 1999, there is authorized to be appropriated in the aggregate an additional \$12,000,000 for increased monitoring by the Secretary of Health and Human Services of pesticide residues in imported and domestic food.

SEC. 407. ALTERNATIVE ENFORCEMENT.

Section 303(g) (21 U.S.C. 333(f)) is amended—

(1) by redesignating paragraphs (2), (3), and (4) as paragraphs (3), (4), and (5), respectively;

(2) by inserting after paragraph (1) the following:

“(2)(A) Any person who introduces into interstate commerce or delivers for introduction into interstate commerce an article of food that is adulterated within the meaning of section 402(a)(2)(B) shall be subject to a civil money penalty of not more than \$50,000 in the case of an individual and \$250,000 in the case of any other person for such introduction or delivery, not to exceed \$500,000 for all such violations adjudicated in a single proceeding.

“(B) This paragraph shall not apply to any person who grew the article of food that is adulterated. If the Secretary assesses a civil penalty against any person under this paragraph, the Secretary may not use the criminal authorities under this section to sanction such person for the introduction or delivery for introduction into interstate commerce of the article of food that is adulterated. If the Secretary assesses a civil penalty against any person under this paragraph, the Secretary may not use the seizure authorities of section 304 or the injunction authorities of section 302 with respect to the article of food that is adulterated.

“(C) In a hearing to assess a civil penalty under this paragraph, the presiding officer shall have the same authority with regard

This is **Exhibit “F”** referred to in the affidavit of
Dr. Elaine MacDonald affirmed remotely before
me in accordance with O. Reg 431/20,
Administering Oath or Declaration Remotely
this 19th day of January 2022.



Commissioner for Taking Affidavits
(or as may be)

FOR PUBLICATION

**UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT**

LEAGUE OF UNITED LATIN
AMERICAN CITIZENS; PESTICIDE
ACTION NETWORK NORTH AMERICA;
NATURAL RESOURCES DEFENSE
COUNCIL; CALIFORNIA RURAL
LEGAL ASSISTANCE FOUNDATION;
FARMWORKERS ASSOCIATION OF
FLORIDA; FARMWORKER JUSTICE;
LABOR COUNCIL FOR LATIN
AMERICAN ADVANCEMENT;
LEARNING DISABILITIES
ASSOCIATION OF AMERICA;
NATIONAL HISPANIC MEDICAL
ASSOCIATION; PINEROS Y
CAMPESINOS UNIDOS DEL NOROESTE;
UNITED FARM WORKERS;
GREENLATINOS,

Petitioners,

v.

MICHAEL S. REGAN, Administrator,
United States Environmental
Protection Agency; U.S.
ENVIRONMENTAL PROTECTION
AGENCY,

Respondents.

No. 19-71979

EPA No.
EPA-HQ-OPP-
2007-1005

STATE OF NEW YORK; STATE OF
CALIFORNIA; STATE OF
WASHINGTON; STATE OF
MARYLAND; STATE OF VERMONT;
COMMONWEALTH OF
MASSACHUSETTS,

Petitioners,

DISTRICT OF COLUMBIA; STATE OF
HAWAII; STATE OF OREGON,

Intervenors,

v.

MICHAEL S. REGAN, Administrator,
United States Environmental
Protection Agency; U.S.
ENVIRONMENTAL PROTECTION
AGENCY,

Respondents.

No. 19-71982

EPA No.
EPA-HQ-OPP-
2007-1005

OPINION

On Petition for Review of an Order of the
Environmental Protection Agency

Argued and Submitted July 28, 2020
San Francisco, California

Filed April 29, 2021

Before: Jay S. Bybee and Jacqueline H. Nguyen, Circuit Judges, and Jed S. Rakoff,* District Judge.

Opinion by Judge Rakoff;
Dissent by Judge Bybee

SUMMARY**

Environmental Protection Agency

The panel granted petitions for review, vacated the Environmental Protection Agency (“EPA”)’s 2017 Order and 2019 Order, and remanded with instructions to the EPA in cases challenging the EPA’s regulation of the pesticide chlorpyrifos.

The EPA has recognized that when pregnant mothers are exposed to chlorpyrifos residue, this likely harms infants *in utero*. This proceeding began in 2007, when two environmental non-profit organizations filed a petition asking the EPA to prohibit foods that contain residue of the insecticide chlorpyrifos. The EPA declined to take final action on the 2007 Petition for more than a decade. This Court issued multiple writs of mandamus requiring the EPA to move forward. In 2017, the EPA denied the 2007 Petition, and in 2019 denied all objections to that decision.

* The Honorable Jed S. Rakoff, United States District Judge for the Southern District of New York, sitting by designation.

** This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

The panel held that the EPA had abdicated its statutory duty under the Federal Food, Drug and Cosmetic Act (“FFDCA”). The panel held that the EPA spent more than a decade assembling a record of chlorpyrifos’s ill effects and repeatedly determined, based on that record, that it could not conclude, to the statutorily required standard of reasonable certainty, that the present tolerances caused no harm. Rather than ban the pesticide or reduce the tolerances to levels that the EPA could find were reasonably certain to cause no harm, the EPA sought to evade through delay tactics its plain statutory duty. Because the FFDCA permitted no further delays, the panel ordered the EPA within 60 days after issuance of the mandate either to modify chlorpyrifos’s tolerances and concomitantly publish a finding that the modified tolerances are safe, including for infants and children – or to revoke all chlorpyrifos tolerances. The panel also ordered the EPA to correspondingly modify or cancel related Federal Insecticide, Fungicide and Rodenticide Act (“FIFRA”) regulations for food use in a timely fashion consistent with the requirements of 21 U.S.C. § 346a(a)(1).

Specifically, the panel first considered whether the EPA lawfully denied the 2007 Petition. The panel rejected the EPA’s argument that it could leave in effect tolerances, without a new safety finding, when the EPA concluded the petition contained insufficient evidence for the EPA to undertake proceedings to revoke or modify tolerances. The panel held, first, once the EPA became aware, through a petition or otherwise, of genuine questions about the safety of an existing tolerance, the EPA had its own continuing duty under the FFDCA to determine whether a tolerance that was once thought to be safe still is. Here, the EPA’s own studies and pronouncements still in effect showed that it regarded chlorpyrifos as harmful at levels below the existing tolerances. Second, the 2007 Petition, under the EPA’s own

regulations, contained more than sufficient evidence to undertake a safety review, and the EPA recognized as much. The panel held that when the EPA publishes a petition seeking revocation of a tolerance and later takes final action denying that petition, the EPA leaves that tolerance in effect. The EPA can only do so if it finds the tolerance to be safe for the general population and for infants and children. The EPA failed to make such findings, directly contrary to the FFDCA.

The panel held that even if the FFDCA did not require a safety finding here, the EPA's denial of the 2007 Petition was arbitrary and capricious. The panel rejected the EPA's four objections to the data.

The panel held that its remand with specific instructions did not raise due process concerns. On this record, immediate issuance of a final regulation was the only reasonable action, and the panel ordered the EPA to do so. The panel clarified that this was not an open-ended remand, or a remand for further factfinding.

Dissenting, Judge Bybee wrote that the majority opinion erred by misreading the FFDCA, and misallocating the risk of nonpersuasion; overruling the EPA's judgment on the validity and weight to be given technical evidence within the EPA's expertise; and, by its decision to give the EPA 60 days to issue a final decision, likely predetermining EPA's option.

COUNSEL

Patti A. Goldman (argued), Marisa C. Ordonia, and Kristen L. Boyles, Earthjustice, Seattle, Washington, for Petitioners League of United Latin American Citizens, Pesticide Action Network North America, Natural Resources Defense Council, California Rural Legal Assistance Foundation, Farmworkers Association of Florida, Farmworker Justice, Labor Council for Latin American Advancement, Learning Disabilities Association of America, National Hispanic Medical Association, Pineros y Campesinos Unidos del Noroeste, United Farm Workers, and GreenLatinos.

Frederick A. Brodie (argued), Assistant Solicitor General Of Counsel; Andrea Oser, Deputy Solicitor General; Barbara D. Underwood, Solicitor General; Letitia James, Attorney General; Office of the Attorney General, Albany, New York; Xavier Becerra, Attorney General; Christie Vosburg, Supervising Deputy Attorney General; Reed Sato, Deputy Attorney General; Office of the Attorney General, Sacramento, California; Robert W. Ferguson, Attorney General; William R. Sherman, Counsel for Environmental Protection; Attorney General's Office, Seattle, Washington; Brian E. Frosh, Attorney General; Steven M. Sullivan, Solicitor General; Joshua M. Segal, Special Assistant Attorney General; Office of the Attorney General, Baltimore, Maryland; Thomas J. Donovan Jr., Attorney General; Nichols F. Persampieri, Assistant Attorney General; Office of the Attorney General, Montpelier, Vermont; Clare E. Connors, Attorney General; Wade H. Hargrove III, Deputy Attorney General; Department of the Attorney General, Honolulu, Hawaii; Ellen F. Rosenblum, Attorney General; Benjamin Gutman, Solicitor General; Office of the Attorney General, Salem, Oregon; Maura Healey, Attorney General; I. Andrew Goldberg, Assistant

Attorney General; Environmental Protection Division, Office of the Attorney General, Boston, Massachusetts; Karl A. Racine, Attorney General; Loren L. Alikhan Solicitor General; Caroline S. Van Zile, Principal Deputy Solicitor General; Brian R. Caldwell, Assistant Attorney General, Public Integrity Unit; Office of the Attorney General, Washington, D.C.; for Petitioners States of New York, California, Washington, Maryland, Vermont, Hawaii, Oregon, the Commonwealth of Massachusetts, and the District of Columbia.

Mark L. Walters (argued) and Jessica O'Donnell, Environmental Defense Section, United States Department of Justice, Washington, D.C.; Angela Huskey, Office of General Counsel, United States Environmental Protection Agency, Washington, D.C.; for Respondents.

Shaun A. Goho, Emmett Environmental Law & Policy Clinic, Harvard Law School, Cambridge, Massachusetts, for Amici Curiae American Academy of Pediatrics, Alliance of Nurses for Healthy Environments, American Public Health Association, Migrant Clinicians Network, Physicians for Social Responsibility, and Union of Concerned Scientists.

Edward Lloyd, Jacob Elkin, Claire MacLachlan, and Basil Oswald, Columbia Environmental Clinic, Morningside Heights Legal Services, New York, New York, for Amicus Curiae Congressman Henry Waxman.

Kathryn E. Szmuszkovicz and Andrew C. Stilton, Beveridge & Diamond P.C., Washington, D.C.; Rachel Lattimore, Senior Vice President & General Counsel; Ashley Boles, Counsel; CropLife America, Washington, D.C.; for Amicus Curiae CropLife America.

David Y. Chung, Kirsten L. Nathanson, and Elizabeth B. Dawson, Crowell & Moring LLP, Washington, D.C., for Amici Curiae Agribusiness Council of Indiana, Agricultural Retailers Association, American Farm Bureau Federation, AmericanHort, American Seed Trade Association, American Soybean Association, American Sugarbeet Growers Association, Beet Sugar Development Foundation, California Alfalfa and Forage Association, California Citrus Mutual, California Cotton Ginners and Growers Association, California Seed Association, California Specialty Crops Council, California Walnut Commission, Florida Fruit and Vegetable Association, National Agricultural Aviation Association, National Association of Wheat Growers, National Corn Growers Association, National Cotton Council, National Onion Association, National Sorghum Producers, North Dakota Grain Growers Association, Oregonians for Food and Shelter, Washington Friends of Farms & Forests, Western Agricultural Processors Association, Western Growers, and Western Plant Health Association.

OPINION

RAKOFF, District Judge:

This dispute concerning the documented health risks posed by a widely used pesticide, chlorpyrifos, has been before this Court more than a half-dozen times. The Environmental Protection Agency (“EPA” or the “Agency”) has recognized that when pregnant mothers are exposed to chlorpyrifos residue, this likely harms infants *in utero*. Nevertheless, in derogation of the statutory mandate to ban pesticides that have not been proven safe, the EPA has failed to act, requesting extension after extension. The Agency’s present position is effectively more of the same.

The proceeding began in 2007, when two environmental non-profit organizations – Pesticide Action Network North America (“PANNA”) and the Natural Resources Defense Council, Inc. (“NRDC”) – filed a petition (the “2007 Petition”) asking the EPA to prohibit foods that contain any residue of the insecticide chlorpyrifos. Then, and now, the EPA has permitted distribution of food containing chlorpyrifos residue as long as the residue is less than a limit known as a “tolerance,” which varies depending on the food. The 2007 Petition argued that, even at levels beneath these tolerances, chlorpyrifos poses neurodevelopmental risks, especially to infants and children.

The Federal Food, Drug and Cosmetic Act (“FFDCA”) provides that the EPA’s “Administrator may establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe. The Administrator shall modify or revoke

a tolerance if the Administrator determines it is not safe.”¹ The statute also requires that the EPA “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue” and “publish a specific determination regarding the safety of the pesticide chemical residue for infants and children.”²

Since 2007, the evidence of harm has continued to build, primarily through two kinds of studies: experimental studies on live mice and rats and epidemiological studies tracking humans who were exposed to chlorpyrifos *in utero*. Between 2007 and 2016, the EPA published several Human Health Risk Assessments regarding chlorpyrifos and convened its Scientific Advisory Panel (“SAP”) several times. Those assessments and SAP reviews increasingly recognized the persuasiveness of the studies showing chlorpyrifos’s risks. Nevertheless, the EPA declined to take final action on the 2007 Petition for more than a decade. Eventually, PANNA, NRDC, and others sought judicial relief, and this Court issued multiple writs of mandamus requiring the EPA to move forward. But, *festina lente*, the EPA continued to delay ruling on the 2007 Petition. This, moreover, was despite the fact that in November 2015, the EPA published a Notice of Proposed Rulemaking that proposed to revoke all chlorpyrifos tolerances because the EPA could not find them to be safe. Similarly, in 2016, the EPA issued a Revised Human Health Risk Assessment

¹ 21 U.S.C. § 346a(b)(2)(A)(i).

² *Id.* § 346a(b)(2)(C)(i)–(ii).

finding that the present tolerances are “not sufficiently health protective.”³

In 2017, the EPA, pursuant to a court-set deadline, finally ruled on the 2007 Petition. But in the very face of its own prior acknowledgements of the health risks posed by chlorpyrifos, the EPA denied the 2007 Petition, and in 2019 denied all objections to that decision. In reality, however, this was just one more attempt at delay, because the EPA did not conclude that the tolerances were safe, but simply denied the Petition on the ground that the EPA would forgo further consideration of the question of safety until chlorpyrifos underwent a registration re-review under a separate statute, which could be as late as 2022. As explained below, this delay tactic was a total abdication of the EPA’s statutory duty under the FFDCA.

In short, the EPA has spent more than a decade assembling a record of chlorpyrifos’s ill effects and has repeatedly determined, based on that record, that it cannot conclude, to the statutorily required standard of reasonable certainty, that the present tolerances are causing no harm. Yet, rather than ban the pesticide or reduce the tolerances to levels that the EPA *can* find are reasonably certain to cause no harm, the EPA has sought to evade, through one delaying tactic after another, its plain statutory duties. The FFDCA permits no further delay. Accordingly, for the reasons that follow, the Court grants the petitions for review and orders the EPA within 60 days after the issuance of the mandate either to modify chlorpyrifos tolerances *and* concomitantly publish a finding that the modified tolerances are safe,

³ Chlorpyrifos; Tolerance Revocations; Notice of Data Availability and Request for Comment, 81 Fed. Reg. 81,049, 81,050 (Nov. 17, 2016) (hereinafter “2016 Notice of Data Availability”).

including for infants and children – or to revoke all chlorpyrifos tolerances. The Court also orders the EPA to correspondingly modify or cancel related FIFRA registrations for food use in a timely fashion consistent with the requirements of 21 U.S.C. § 346a(a)(1).

BACKGROUND

I. The EPA’s Duty to Regulate Pesticides

Congress requires the EPA to regulate the use of pesticides on food pursuant to the FFDCFA. Congress also requires the EPA to regulate the use of pesticides more generally under the Federal Insecticide, Fungicide and Rodenticide Act (“FIFRA”). This case principally concerns the FFDCFA.

The FFDCFA begins with a general rule that food containing pesticide residue is unsafe and prohibited.⁴ Congress empowered the EPA to make exceptions to that rule by promulgating “tolerances” for a pesticide – *i.e.*, threshold levels of pesticide residue that the EPA is reasonably certain will cause no harm.⁵ If the EPA promulgates a tolerance for a pesticide, then food may contain residue of that pesticide in an amount not exceeding the applicable tolerance.⁶

The EPA’s discretion to set such tolerances is circumscribed, however, by an uncompromisable limitation:

⁴ *Id.* §§ 331, 342(a)(2)(B), 346a(a)(1). The FFDCFA applies only to food and other products in interstate commerce. *See* 21 U.S.C. § 331.

⁵ *Id.* § 346a(b)(1), (b)(2)(A).

⁶ *Id.* § 346a(a)(4).

the pesticide must be determined to be safe for human beings. The EPA “may establish or leave in effect a tolerance for a pesticide chemical residue in or on a food *only* if the Administrator determines that the tolerance is safe.”⁷ Furthermore, following enactment of the Food Quality Protection Act of 1996 (“FQPA”), it is now clear that the EPA must look beyond food to consider all of the ways someone might be exposed to a pesticide, “including all anticipated dietary exposures and all other exposures for which there is reliable information.”⁸ The EPA can determine that a tolerance is safe only if “there is a *reasonable certainty* that no harm will result from *aggregate* exposure to the pesticide chemical residue.”⁹

In addition to requiring this general safety finding, the FFDCa also conditions the EPA’s authority to set or leave in effect a tolerance on its determination that the tolerance is safe for infants and children. “In establishing, modifying, leaving in effect, or revoking a tolerance . . . , the Administrator . . . shall . . . ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue,” and shall “publish a specific determination regarding the safety of the pesticide chemical residue for infants and children.”¹⁰ If a tolerance is not safe – in other words, if the EPA cannot determine that there is a reasonable certainty of no harm across all sources of exposure for infants, children, and adults – then the EPA no longer has discretion. Rather, the

⁷ *Id.* § 346a(b)(2)(A)(i) (emphasis added).

⁸ *Id.* § 346a(b)(2)(A)(ii).

⁹ *Id.* (emphases added).

¹⁰ *Id.* § 346a(b)(2)(C)(ii).

law commands that the EPA “shall modify or revoke [the] tolerance.”¹¹

The FFDCA authorizes “[a]ny person [to] file . . . a petition proposing the issuance of a regulation establishing, modifying, or revoking a tolerance.”¹² The EPA, by regulation, may dictate what a petition seeking revocation of a tolerance must contain.¹³ Pursuant to that authority, the EPA requires that a petition state “reasonable grounds for the action sought,” including “an assertion of facts.”¹⁴ If the EPA determines that a petition has met the threshold requirements, then it must publish the petition within 30 days.¹⁵ “[A]fter giving due consideration to a petition . . . and any other information available to the Administrator,” the EPA “shall” do one of three things: “issue a final regulation (which may vary from that sought by the petition) establishing, modifying, or revoking a tolerance . . . (which final regulation shall be issued without further notice and without further period for public comment),” “issue a proposed regulation . . . and thereafter issue a final regulation,” or “issue an order denying the petition.”¹⁶ If the EPA denies a petition, “any person may file objections

¹¹ *Id.* § 346a(b)(2)(A)(i).

¹² *Id.* § 346a(d)(1).

¹³ *Id.* § 346a(d)(2)(B).

¹⁴ 40 C.F.R. § 180.32(b).

¹⁵ 21 U.S.C. § 346a(d)(3).

¹⁶ *Id.* § 346a(d)(4)(A).

thereto with the Administrator.”¹⁷ The Administrator “shall issue an order stating the action taken upon each . . . objection” “[a]s soon as practicable.”¹⁸ Those affected may seek “judicial review . . . in the United States Court of Appeals.”¹⁹

Separately, the EPA also regulates pesticides pursuant to FIFRA. Under FIFRA, pesticides must be registered by the EPA before they can be distributed or sold.²⁰ To register a pesticide, the EPA must determine, among other things, that it does not have “unreasonable adverse effects on the environment.”²¹ FIFRA defines “unreasonable adverse effects” to include “a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with” the standards of the FFDCA.²² In other words, FIFRA incorporates the FFDCA safety standard for food uses, among other considerations. FIFRA requires the EPA to reevaluate pesticides as part of a registration review every fifteen years.²³

¹⁷ *Id.* § 346a(g)(2)(A).

¹⁸ *Id.* § 346a(g)(2)(C).

¹⁹ *Id.* § 346a(h)(1).

²⁰ *See* 7 U.S.C. § 136a(a).

²¹ *Id.* § 136a(c)(5)(C)–(D).

²² *Id.* § 136(bb).

²³ *See id.* §§ 136a(c)(1)(F)(iii), (g)(1)(A), 136a-1(a).

II. This Administrative Proceeding and Related Litigation

This administrative proceeding began with the filing of the 2007 Petition, which sought revocation of all tolerances and registrations for chlorpyrifos. Chlorpyrifos is an organophosphate pesticide. Organophosphates were first developed as toxic nerve agents for potential use in chemical warfare during World War II, and chlorpyrifos was initially registered as a pesticide in the United States in 1965. Since then, farmers have used chlorpyrifos to protect dozens of types of crops. As of 2017, “[b]y pounds of active ingredient, it [was] the most widely used conventional insecticide in the country.”²⁴ Nevertheless, in 2019, California (and the European Union) announced they would ban the sale of chlorpyrifos.²⁵

Chlorpyrifos disrupts the functioning of acetylcholinesterase (“AChE”), a crucial enzyme that breaks down the neurotransmitter acetylcholine.²⁶ In setting

²⁴ Chlorpyrifos; Order Denying PANNA and NRDC’s Petition to Revoke Tolerances, 82 Fed. Reg. 16,581, 16,584 (Apr. 5, 2017) (hereinafter “2017 Order”).

²⁵ Press Release, Cal. Env’t Prot. Agency & Cal. Dep’t of Pesticide Regul., *Agreement Reached to End Sale of Chlorpyrifos in California by February 2020* (Oct. 9, 2019), <https://www.cdpr.ca.gov/docs/pressrels/2019/100919.htm>; Stephen Gardner, *EU to Ban Chlorpyrifos Pesticide Starting in February*, Bloomberg L. News (Dec. 6, 2019, 6:43 AM), <https://news.bloomberglaw.com/environment-and-energy/eu-to-ban-chlorpyrifos-pesticide-starting-in-february>.

²⁶ See EPA, Office of Prevention, Pesticides, and Toxic Substances, EPA 738-R-01-007, Interim Reregistration Eligibility Determination for Chlorpyrifos 2 (Feb. 2002) (“Chlorpyrifos can cause [AChE] inhibition in humans; that is, it can overstimulate the nervous system causing

chlorpyrifos tolerances, the EPA must determine the greatest exposure amount that poses no risk of harm, which is known as a “point of departure.” Since enactment of the FQPA, the EPA has tied the chlorpyrifos point of departure directly to acute AChE inhibition, finding that exposure to chlorpyrifos residue on food would be unsafe if aggregate exposure across all sources caused more than 10% acute AChE inhibition.

However, for decades, the EPA has itself expressed concerns that chlorpyrifos might also be causing harm through a different mechanism: neurotoxic effects that are especially harmful to infants and children.²⁷ The 2007 Petition was partly based on these concerns. Yet, despite the EPA’s expressed concerns, the EPA repeatedly failed to act on the 2007 Petition until this Court compelled it to do so. The following is a chronological summary both of the EPA’s assessment of chlorpyrifos’s safety and of this dispute.

A. 2000–2006: The EPA Finds Certain Chlorpyrifos Tolerances Safe, Despite Concerns

Between 2000 and 2006, even before the Petition was filed, the EPA began taking steps to reduce exposure to chlorpyrifos as part of its reevaluation of chlorpyrifos’s safety, as required by the FQPA. The FQPA imposed the requirements, still included in the FFDCa today, that the

nausea, dizziness, confusion, and at very high exposures (e.g., accidents or major spills), respiratory paralysis and death.”).

²⁷ This different mechanism of harm might still relate to AChE inhibition; the EPA has considered the possibility that *chronic* AChE inhibition at levels of less than 10% might cause permanent damage. Herein, unless stated otherwise, AChE inhibition means *acute* AChE inhibition of 10% or more.

EPA (1) consider proof of safety as an absolute prerequisite to establishing or leaving in effect a tolerance, without balancing it against other factors; (2) assess a pesticide's cumulative exposure from multiple sources (*e.g.*, drinking water as well as food); and (3) specifically assess the pesticide's potential risks to children. The FQPA also required the EPA to reassess the safety of all then-authorized pesticides using this new standard.

During this period, the EPA began to express concerns that chlorpyrifos might be causing harms through a mechanism other than AChE inhibition. For example, in a 2000 Human Health Risk Assessment, the EPA recognized that studies had preliminarily shown that AChE inhibition might not be the only mechanism of harm.²⁸

The EPA also began acting on its concerns about chlorpyrifos safety, in collaboration with the pesticide industry. In 2000, the EPA and the chlorpyrifos technical registrants entered into an agreement regarding chlorpyrifos that eliminated or phased out its use for virtually all residential and termiticide purposes, and on tomatoes and, during the growing season, grapes and apples.²⁹ In 2002, the

²⁸ EPA, Office of Pesticide Programs, Human Health Risk Assessment-Chlorpyrifos 4 (June 8, 2000), https://archive.epa.gov/scipoly/sap/meetings/web/pdf/hed_ra.pdf (discussing live animal studies and explaining that “new data in the literature also gave rise to uncertainties such as the suggestion that the inhibition of [AChE] may not be essential for adverse effects on brain development”).

²⁹ Letter to Aaron Colangelo, NRDC, & Margaret Reeves, PANNA, from Steven Bradbury, EPA, re: Chlorpyrifos Petition Dated September 12, 2007 (hereinafter “2007 Petition”), at 6 (July 16, 2012).

EPA announced certain risk mitigation measures, especially for people exposed to chlorpyrifos through their work.³⁰

Subject to these changes, however, the EPA determined in February 2002, based upon the evidence then available, that “[d]ietary exposures from eating food crops treated with chlorpyrifos are below the level of concern for the entire U.S. population, including infants and children,” and that “[d]rinking water risk estimates . . . are generally not of concern.”³¹ The EPA reiterated its safety finding in July 2006, stating that chlorpyrifos tolerances “meet the safety standard under Section 408(b)(2) of the FFDCA.”³²

B. 2007: PANNA and NRDC File a Petition to Revoke Tolerances, Citing Mounting Evidence of Harm

In September 2007, PANNA and NRDC filed an administrative petition with the EPA seeking revocation of all chlorpyrifos tolerances under the FFDCA and the cancellation of all of chlorpyrifos’s FIFRA registrations. The 2007 Petition asserted that scientific evidence now available showed that the current chlorpyrifos tolerances were not safe, especially for infants and children; indeed, they argued, “no safe level of early-life exposure to

³⁰ Interim Reregistration Eligibility Decision for Chlorpyrifos, *supra* note 26.

³¹ *Id.* at 2.

³² EPA, Office of Prevention, Pesticides and Toxic Substances, Memo to Jim Jones from Debra Edwards, Finalization of Interim Reregistration Eligibility Decisions and Interim Tolerance Reassessment and Risk Management Decisions for the Organophosphate Pesticides, and Completion of the Tolerance Reassessment and Reregistration Eligibility Process for the Organophosphate Pesticides 2 (July 31, 2006).

chlorpyrifos can be supported.”³³ They cited “[m]any studies published since 2001 [that] report that fetal exposure to chlorpyrifos is more damaging than adult exposure.”³⁴

The 2007 Petition relied in part upon certain experiments performed on live mice and rats. They were exposed *in utero* to levels of chlorpyrifos below those previously known to cause AChE inhibition. The scientists found marked declines in thinking and movement, indicative of neurological effects. The declines were sex-linked, harming males more than females.

The 2007 Petition also relied upon an epidemiological study, known as the “Columbia Study.” Researchers worked with a cohort of pregnant women and their children, collecting data on the mothers’ organophosphate exposure (including chlorpyrifos) during pregnancy, and then following the development of the children for many years. Some of the participating children were born before the EPA and the registrants agreed to end residential use of chlorpyrifos, and others were born after. Over time, the researchers found a correlation between prenatal chlorpyrifos exposure and several negative outcomes:

- at age three, lower performance in motor and mental development tests and higher incidences of attention-deficit hyperactivity disorder and autism spectrum disorder;

³³ Marc S. Wu et al., NRDC, & Susan E. Kegley, PANNA, Petition to Revoke All Tolerances and Registrations for the Pesticide Chlorpyrifos 5 (Sept. 12, 2007).

³⁴ *Id.* at 6.

- at age seven, changes in brain morphology and lower IQ scores; and
- at age eleven, a greater likelihood of mild or moderate tremors.

Like the live animal experiments, the Columbia Study found that *in utero* exposures were harmful even beneath the levels thought to cause notable AChE inhibition and that harms were sex-linked, disproportionately affecting boys.

Two other groups of researchers also conducted epidemiological studies similar to the Columbia Study (the “Mount Sinai Study” and the “CHAMACOS Study”; collectively with the Columbia Study, the “Human Cohort Studies”). The Mount Sinai and CHAMACOS Studies looked at exposure to organophosphate pesticides and, like the Columbia Study, found a correlation between prenatal organophosphate exposure and cognitive impairments in early childhood.³⁵

C. 2008–2011: The EPA Preliminarily Links Chlorpyrifos to Neurotoxic Harms in Infants and Children

Within a year of the 2007 Petition, the EPA, in August 2008, published a Science Issue Paper, which reviewed existing scientific studies and “preliminarily concluded that chlorpyrifos likely played a role” in the low birth rate and delays in infant mental development observed in the Human

³⁵ Although the Mount Sinai Study and the CHAMACOS Study were not cited in the 2007 Petition, they later became part of the administrative record.

Cohort Studies.³⁶ The EPA recognized that some of these studies found these effects despite lesser AChE inhibition, suggesting there was a different mechanism of harm.³⁷ However, the paper also noted that it was “not a full and complete risk assessment/characterization,” and that the EPA “ha[d] not developed any final conclusions regarding updates to the chlorpyrifos hazard assessment.”³⁸

In September 2008, the EPA convened a committee of experts known as a Scientific Advisory Panel (“SAP”) to peer-review its findings. The 2008 SAP considered “the results of the three [Human Cohort Studies] (with an emphasis on the Columbia [S]tudy) . . . along with the findings from experimental studies in animals,” and concluded that “maternal chlorpyrifos exposure would likely be associated with adverse neurodevelopmental outcomes in humans.”³⁹ The SAP “agreed with [the EPA’s] conclusion that chlorpyrifos likely played a role in the birth and neurodevelopmental outcomes noted in the three [Human Cohort Studies].”⁴⁰

³⁶ Health Effects Division, Office of Pesticide Programs, EPA, Science Issue Paper: Chlorpyrifos Hazard and Dose Response Characterization 52 (Aug. 21, 2008).

³⁷ *Id.* at 40–41 & fig.5.

³⁸ *Id.* at 7.

³⁹ SAP Minutes No. 2008-04, A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding: The Agency’s Evaluation of the Toxicity Profile of Chlorpyrifos 13 (Sept. 16–18, 2008) (hereinafter “2008 SAP Minutes”).

⁴⁰ *Id.* at 37.

However, the SAP also posited that the effects might not be entirely attributable to chlorpyrifos; rather, they might also reflect exposure to other AChE-inhibiting insecticides. A majority of SAP members agreed that the adverse outcomes of the Columbia Study were concerning, especially “in light of evidence demonstrating that low levels of exposure to toxicants once thought to have adverse neurodevelopmental effects only at high levels (i.e. lead, mercury, and PCBs) are now known to produce significant effects at lower levels.”⁴¹ Nevertheless, the 2008 SAP found that the Human Cohort Studies had “utility for risk characterization, but not as the principal basis for establishing the point of departure.”⁴²

About three years later, in 2011, the EPA published a Preliminary Human Health Risk Assessment. The EPA discussed the three Human Cohort Studies and noted the 2008 SAP’s conclusion that those studies, “in concert with the animal studies[,] indicate that ‘maternal chlorpyrifos exposure would likely be associated with adverse

⁴¹ *Id.* at 43–44.

⁴² 2007 Petition, *supra* note 29, at 6–7. The Dissent notes that the 2008 SAP expressed “concerns that the Columbia Study—the most robust of the three—did not provide sufficient data to be the sole factor for risk assessment or modifying tolerances and produced uncertainty through its measurement method.” Dissent, *infra*, at 91. In fact, although the 2008 SAP recognized that “there were limitations . . . that precluded [the Human Cohort Studies] from being used to directly derive the [point of departure] or the uncertainty factor,” it also concluded that the Columbia Study “could be used to determine bounding values for the levels of chlorpyrifos that might cause a measurable effect.” 2008 SAP Minutes, *supra* note 39, at 46. Thus, even as early as 2008, the SAP recognized the utility of the Columbia Study for risk assessment.

neurodevelopmental outcomes in humans.”⁴³ While the Preliminary Human Health Risk Assessment asserted that the EPA could not yet identify the mechanism of action for neurotoxic harm, nevertheless, it viewed the Human Cohort Studies favorably, describing the Columbia Study as a “natural experiment” since some participants were pregnant before the EPA banned residential use of chlorpyrifos and some were pregnant after the ban.⁴⁴ The EPA “intend[ed] to carefully consider the strengths and limitations of the epidemiology studies along with the available empirical data in a full weight of evidence analysis in the final [Human Health Risk Assessment].”⁴⁵ Thus, while the EPA continued to use 10% AChE inhibition to set a point of departure, it explained that “ongoing analyses will ensure that [the points of departure] in [its] preliminary assessment are [also] human health protective for neurodevelopmental toxicity that may arise from pre- or postnatal exposure.”⁴⁶

⁴³ Memo from Danette Drew et al. to Tom Myers re: Chlorpyrifos: Preliminary Human Health Risk Assessment for Registration Review, EPA, at 28 (June 30, 2011).

⁴⁴ *Id.* at 31.

⁴⁵ *Id.* at 34.

⁴⁶ *Id.* at 42.

D. 2012–2015: The EPA Expresses Increasing Certainty That Chlorpyrifos Causes Neurotoxic Effects in Infants and Children

In April 2012, having received no response from the EPA on the pertinent arguments raised in the 2007 Petition,⁴⁷ PANNA and NRDC petitioned this Court for a writ of mandamus.

Meanwhile, also in April 2012, the EPA convened another SAP. The 2012 SAP opined with more certainty than the 2008 SAP that multiple “lines of evidence suggest that chlorpyrifos can affect neurodevelopment at levels lower than those associated with AChE inhibition, and that the use of AChE inhibition data may not be the most appropriate for . . . [assessing] the neurodevelopmental risks of chlorpyrifos.”⁴⁸ The 2012 SAP paid particular attention to the Human Cohort Studies and identified “nine strengths” of them, including, among others, the longitudinal design, the use of biomarkers of exposure (rather than only self-reported exposure), and “the relative consistency of findings in different populations while using similar standardized exposure and outcome measures.”⁴⁹ The 2012 SAP also identified some shortcomings of the Human Cohort Studies, such as a relatively small sample size and uncertainty

⁴⁷ The 2007 Petition raised several other claims, some of which the EPA addressed at earlier points in time, but here petitioners only press the claims related to neurotoxic effects.

⁴⁸ SAP Minutes No. 2012-04, A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding Chlorpyrifos Health Effects 53 (Apr. 10–12, 2012) (hereinafter “2012 SAP Minutes”).

⁴⁹ *Id.* at 18.

regarding whether harms could be attributed to chlorpyrifos alone. Overall, though, it found that “[t]he strengths of the three studies support the Panel’s conclusion.”⁵⁰

Specifically, the 2012 SAP, based on its review of all the evidence available at the time, “concur[red] with the 2008 SAP and the Agency in concluding that chlorpyrifos likely plays a role in impacting the neurodevelopmental outcomes examined in the three cohort studies.”⁵¹ It noted that the Human Cohort Studies showed potentially serious harms to infants and children, including “abnormal reflexes in the newborn, pervasive development disorder at 24 or 36 months, mental development at 7–9 years, and attention and behavior problems at 3 and 5 years of age.”⁵²

Despite all this, the EPA, following issuance of the 2012 SAP report, still did not take final action on the 2007 Petition; but it represented in the mandamus proceedings that it had “a concrete timeline for final agency action that would resolve the 2007 Petition by February 2014.”⁵³ In light of that representation, this Court, in July 2013, denied PANNA and NRDC’s petition for a writ of mandamus.

February 2014 came and went, but the EPA did not take final action on the 2007 Petition. PANNA and NRDC

⁵⁰ *Id.*

⁵¹ *Id.*

⁵² *Id.* at 17.

⁵³ *PANNA v. EPA (In re PANNA)*, 532 F. App’x 649, 651 (9th Cir. 2013).

returned to this Court in September 2014 with a second petition for a writ of mandamus.

Shortly thereafter, in December 2014, the EPA published a Revised Human Health Risk Assessment. It expressed greater certainty both that chlorpyrifos was causing the neurotoxic harms seen in the cohort studies and that it was doing so through a mechanism other than AChE inhibition.⁵⁴

Because the EPA concluded that chlorpyrifos could cause harm even if exposure was below the AChE inhibition-related point of departure, the EPA proposed a new method for calculating a point of departure. But with all this, the EPA still did not act on the 2007 Petition.

In August 2015, this Court therefore granted the second mandamus petition.⁵⁵ The EPA had offered an “ambiguous plan to possibly issue a proposed rule nearly nine years after receiving the administrative petition,” and the Court found this to be “too little, too late.”⁵⁶ The Court found the EPA’s delay “egregious” and ordered the EPA “to issue a full and

⁵⁴ Memo from Danette Drew et al. to Tom Myers et al. re: Chlorpyrifos: Revised Human Health Risk Assessment for Registration Review, EPA (Dec. 29, 2014) (hereinafter “2014 Revised Human Health Risk Assessment”), at 43 (“[C]hlorpyrifos likely played a role in the neurodevelopmental outcomes observed in these epidemiology studies.”); *id.* at 46 (“[The] EPA believes it is unlikely mothers enrolled in the [Human Cohort Studies] experienced [red blood cell] AChE inhibition”); *see also id.* (“Given the differences across laboratory animal and epidemiology studies, the qualitative similarity in research findings is striking.”).

⁵⁵ *PANNA v. EPA (In re PANNA)*, 798 F.3d 809, 811 (9th Cir. 2015).

⁵⁶ *Id.*

final response to the petition no later than October 31, 2015.”⁵⁷

E. 2015–2016: The EPA Finds That Chlorpyrifos Tolerances Are Unsafe

Once again, this Court’s deadline came and went, and the EPA still did not take final action on the 2007 Petition. But in November 2015, the EPA published in the Federal Register a Notice of Proposed Rulemaking “proposing to revoke all tolerances for residues of the insecticide chlorpyrifos.”⁵⁸ It wrote: “The agency is proposing to revoke all of these tolerances because [the] EPA cannot, at this time, determine that aggregate exposure to residues of chlorpyrifos, including all anticipated dietary exposures and all other non-occupational exposures for which there is reliable information, are safe.”⁵⁹ Specifically, the EPA found that “contributions to dietary exposures to chlorpyrifos from food and residential exposures are safe,” but “when those exposures are combined with estimated exposures from drinking water, as required by the FFDCA, . . . safe levels of chlorpyrifos in the diet may be exceeded for people whose drinking water is derived from certain vulnerable watersheds throughout the United States.”⁶⁰

⁵⁷ *Id.*

⁵⁸ Chlorpyrifos; Tolerance Revocations, 80 Fed. Reg. 69,080, 69,081 (Nov. 6, 2015) (hereinafter “2015 Notice of Proposed Rulemaking”).

⁵⁹ *Id.*

⁶⁰ *Id.*

The EPA adhered to the findings of the 2014 Revised Human Health Risk Assessment. It relied upon “a considerable and still-growing body of literature on the effects of chlorpyrifos on the developing brain of laboratory animals (rats and mice) indicating that gestational and/or postnatal exposure may cause persistent behavioral effects into adulthood.”⁶¹ It also relied upon the three Human Cohort Studies:

[The] EPA has considered the strengths and limitations of these studies, and believes that random or systematic errors in the design, conduct or analysis of these studies were unlikely to fully explain observed positive associations between *in utero* [organophosphate] exposure and adverse neurodevelopmental effects observed at birth and through childhood (age 7 years). [The] EPA believes these are strong studies which support a conclusion that [organophosphates] likely played a role in these outcomes.⁶²

The EPA acknowledged “significant uncertainties . . . about the actual exposure levels experienced by mothers and infant participants in the three children’s health cohorts,” but found that the measured exposures “are likely low enough that they were unlikely to have resulted in AChE inhibition.”⁶³

⁶¹ *Id.* at 69,090.

⁶² *Id.* at 69,091.

⁶³ *Id.* at 69,093.

Since, however, the proposed rule did not constitute a final response to the 2007 Petition, this Court, in December 2015, ordered the EPA “to take final action by December 30, 2016 on its proposed revocation rule and its final response to . . . [the] 2007 [P]etition.”⁶⁴ In other words, this Court, despite the EPA’s repeated disregard of this Court’s orders, most leniently gave the EPA yet another year to rule on the 2007 Petition.

In April 2016, the EPA convened another SAP, which peer-reviewed the 2014 Revised Human Health Risk Assessment. The 2016 SAP “agree[d] that both epidemiology and toxicology studies suggest there is evidence for adverse health outcomes associated with chlorpyrifos exposures below levels that result in 10% red blood cell [AChE] inhibition.”⁶⁵

However, the 2016 SAP disagreed with the EPA’s method for calculating a new point of departure. Specifically, “with the exception of one Panel member, the Panel stated that using [umbilical] cord blood chlorpyrifos concentrations for derivation of the [point of departure] could not be justified by any sound scientific evaluation.”⁶⁶ “Many Panel members” also objected to the specific threshold of harm that the EPA used to replace 10% AChE inhibition – a 2% decline in working memory – saying that

⁶⁴ *PANNA v. EPA (In re PANNA)*, 808 F.3d 402 (9th Cir. 2015).

⁶⁵ SAP Minutes No. 2016-01, A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding: Chlorpyrifos: Analysis of Biomonitoring Data 18 (Apr. 19–21, 2016) (hereinafter “2016 SAP Minutes”).

⁶⁶ *Id.* at 26.

such a change in working memory was “of questionable biological significance.”⁶⁷

On the other hand, the 2016 SAP explained that, in general, it “support[ed] the use of measured maternal chlorpyrifos blood concentrations as a surrogate for fetal exposure”⁶⁸ And the SAP offered some guidance on how to proceed. “Multiple panel members noted that [physiologically based pharmacokinetic (“PBPK”)] modeling is a valuable tool,”⁶⁹ and the SAP recommended that the EPA “consider determination and characterization of time-weighted average blood concentrations for different exposure scenarios,”⁷⁰ rather than measurements based upon umbilical cord blood concentrations at a single point in time.

The EPA returned to this Court in June 2016, claiming that it once again could not meet the much-extended deadline for final action on the 2007 Petition. In August 2016, the Court denied the EPA’s request for an additional six months.⁷¹ The Court did, however, grant the EPA a three-month extension, to March 31, 2017. The Court acknowledged that “evidence may be imperfect . . . [,] the feasibility inquiry is formidable, and . . . premature rulemaking is undesirable,” but the Court found that “at this stage, a claim of premature rulemaking has come and

⁶⁷ *Id.* at 27.

⁶⁸ *Id.* at 18.

⁶⁹ *Id.*

⁷⁰ *Id.* at 70.

⁷¹ *NRDC v. EPA (In re PANNA)*, 840 F.3d 1014, 1015 (9th Cir. 2016).

gone.”⁷² The Court warned that this was “the final extension” and that the Court would “not grant any further extensions.”⁷³

In November 2016, the EPA revised its Human Health Risk Assessment again. The 2016 Revised Human Health Risk Assessment remains the EPA’s most recent comprehensive assessment of the risks of chlorpyrifos. In the assessment, the EPA “continue[d] to conclude that the [Human Cohort Studies] provide the most robust available epidemiological evidence.”⁷⁴ The EPA “acknowledge[d] the lack of [an] established” mechanism of action that would explain the neurotoxic effects and also recognized “the inability to make strong causal linkages, and the unknown window(s) of susceptibility.”⁷⁵ The EPA concluded, nevertheless, that “[t]hese uncertainties do not undermine or reduce the confidence in the findings of the epidemiology studies. The epidemiology studies . . . represent different investigators, locations, points in time, exposure assessment procedures, and outcome measurements.”⁷⁶ “In summary,” the EPA concluded that “the [Columbia Study], with supporting results from the other [two Human Cohort Studies] and the seven additional epidemiological studies

⁷² *Id.* (quoting *Public Citizen Health Rsch. Grp. v. Chao*, 314 F.3d 143, 154–55 (3d Cir. 2002)).

⁷³ *Id.*

⁷⁴ Memo from Wade Britton to Dana Friedman re: Chlorpyrifos: Revised Human Health Risk Assessment for Registration Review, EPA (Nov. 3, 2016) (hereinafter “2016 Revised Human Health Risk Assessment”), at 12.

⁷⁵ *Id.*

⁷⁶ *Id.*

reviewed in 2015, provides sufficient evidence that there are neurodevelopmental effects occurring at chlorpyrifos exposure levels below that required for AChE inhibition.”⁷⁷ Based on this finding, the EPA continued to conclude that it was necessary to adopt an approach “protective of both the AChE inhibition and any adverse effects that could occur at lower doses.”⁷⁸

The EPA acknowledged that “the 2016 SAP did not support using the [Columbia Study] cord blood” to derive a new point of departure.⁷⁹ Responsive to those comments, the EPA adopted a different approach.⁸⁰ It accepted the 2016 SAP’s statement that the “EPA should use estimated peak blood concentrations or [time-weighted average] blood concentrations within the prenatal period” rather than umbilical cord blood concentrations at the time of delivery.⁸¹ Also, consistent with the 2016 SAP’s comments, the EPA

⁷⁷ *Id.* at 13.

⁷⁸ *Id.*

⁷⁹ *Id.*

⁸⁰ *Id.* at 4 (“Given that the window(s) of susceptibility are currently not known for the observed neurodevelopmental effects, and the uncertainties associated with quantitatively interpreting the [Columbia Study] cord blood data, the SAP recommended that the agency use a time weighted average . . . blood concentration of chlorpyrifos for the [Columbia] [S]tudy cohort as the [point of departure] for risk assessment. [The] EPA has chosen to follow that advice in this assessment.”).

⁸¹ *Id.* at 14.

estimated blood concentrations using a PBPK model devised by a chlorpyrifos registrant.⁸²

When the EPA compared the resulting safety thresholds against typical pesticide exposure scenarios, it determined that chlorpyrifos tolerances were not safe – even considering food alone, without aggregating other exposure sources, like drinking water.⁸³ For example, the EPA found that expected food exposure for children 1–2 years of age was 14,000% of the threshold level of risk concern.⁸⁴

The EPA announced the findings of the 2016 Revised Human Health Risk Assessment through a Notice of Data Availability published in the Federal Register,⁸⁵ and it reopened the comment period on its 2015 Notice of Proposed Rulemaking. In the Notice of Data Availability, the EPA reiterated that the present tolerances are “not

⁸² *Id.*

⁸³ *Id.* at 24.

⁸⁴ *Id.* at 6.

⁸⁵ 2016 Notice of Data Availability, *supra* note 3, 81 Fed. Reg. at 81,050 (“After careful consideration of public comments and the SAP’s recommendations, [the] EPA has concluded the most appropriate path for reconciling the SAP’s concerns is to follow through on the SAP’s recommendation to use a time weighted average approach. The agency agrees with the 2016 FIFRA SAP (and previous SAPs) that there is a potential for neurodevelopmental effects associated with chlorpyrifos exposure to occur at levels below 10% RBC AChE inhibition, and that [the] EPA’s existing point of departure (which is based on 10% AChE inhibition), is therefore not sufficiently health protective.”).

sufficiently health protective.”⁸⁶ The Agency explained that its

revised analyses do not result in a change to the EPA’s proposal to revoke all tolerances but it does modify the methods and risk assessment used to support that finding in accordance with the advice of the SAP. The revised analysis indicates that expected residues of chlorpyrifos on most individual food crops exceed the ‘reasonable certainty of no harm’ safety standard under the [FFDCA].

The EPA adhered to its proposal to revoke chlorpyrifos tolerances, rather than modify them, explaining that the “EPA has not identified a set of currently registered uses that meets the FFDCA safety standard because it is likely only a limited number of food uses alone, and in combination with predicted drinking water exposures, would meet the standard.”⁸⁷ The EPA has never retracted the findings in its 2016 Revised Human Health Risk Assessment.⁸⁸

⁸⁶ *Id.*

⁸⁷ *Id.*

⁸⁸ Today, the EPA’s website continues to warn about chlorpyrifos, citing the 2016 Revised Human Health Risk Assessment:

What does [the] EPA’s revised human health risk assessment show?

This assessment shows dietary and drinking water risks for the current uses of chlorpyrifos. Based on

F. 2017–Present: The EPA Denies the 2007 Petition

Faced with this Court’s statement that it would brook no further delays in the EPA’s ruling on the 2007 Petition, the EPA finally in April 2017 ruled on the 2007 Petition. Notwithstanding the findings in its own 2016 Revised Human Health Risk Assessment, however, the EPA’s order denying the 2007 Petition (the “2017 Order”) stated that, “despite several years of study, the science addressing neurodevelopmental effects remains unresolved.”⁸⁹ Therefore, the EPA concluded that “further evaluation of the science during the remaining time for completion of [FIFRA] registration review is warranted to achieve greater certainty as to whether the potential exists for adverse neurodevelopmental effects to occur from current human exposures to chlorpyrifos.”⁹⁰

current labeled uses, the revised analysis indicates that expected residues of chlorpyrifos on food crops exceed the safety standard under the [FFDCA]. In addition, the majority of estimated drinking water exposure from currently registered uses, including water exposure from non-food uses, continues to exceed safe levels

EPA, Revised Human Health Risk Assessment on Chlorpyrifos, *available at* <https://www.epa.gov/ingredients-used-pesticide-products/revised-human-health-risk-assessment-chlorpyrifos> (last accessed Apr. 17, 2021).

⁸⁹ 2017 Order, *supra* note 24, 82 Fed. Reg. at 16,583.

⁹⁰ *Id.*

The EPA further explained that it was denying the 2007 Petition only because this Court had ordered it to make a decision, but that

[the] EPA has . . . concluded that it will not complete the human health portion of the registration review or any associated tolerance revocation of chlorpyrifos without first attempting to come to a clearer scientific resolution Because the [Ninth] Circuit’s August 12, 2016 order has made clear, however, that further extensions to the March 31, 2017 deadline for responding to the Petition would not be granted, [the] EPA is today also denying all remaining petition claims.

PANNA, NRDC, and others objected to the EPA’s denial of the 2007 Petition, both by filing objections with the EPA and by seeking relief from this Court. The Court denied mandamus relief on the ground that the EPA had “now complied with our orders” to issue a decision, and “substantive objections must first be made through the administrative process.”⁹¹

But even though the statute required the EPA to rule on petitioners’ objections “[a]s soon as practicable after receiving the arguments of the parties,” 21 U.S.C. § 346a(g)(2)(C), and even though these objections were simply reiterations of the positions petitioners had consistently taken since 2007, the EPA had still not responded to petitioners’ objections *14 months later*, when

⁹¹ *PANNA v. EPA (In re PANNA)*, 863 F.3d 1131, 1132 (9th Cir. 2017).

the Court heard oral argument on petitioners’ petition for review of the 2017 Order.

The EPA objected to this Court’s consideration of the merits of the decision on the ground that, until the EPA ruled on petitioners’ administrative objections, this Court lacked jurisdiction. A panel of this Court concluded that “the EPA is engaging in yet more delay tactics to avoid our reaching the merits of . . . whether chlorpyrifos must be banned from use on food products because the EPA has not determined that there is a ‘reasonable certainty’ that no harm will result from its use, even under the established tolerances.”⁹² The panel held that, under these circumstances, the Court had jurisdiction and that, on the merits, “the EPA bears a continuing obligation to revoke tolerances that it can no longer find with a ‘reasonable certainty’ are safe,” and because the Agency could not make such a finding, the tolerance must be revoked.⁹³ The panel vacated the 2017 Order and remanded to the EPA with instructions to revoke all chlorpyrifos tolerances within 60 days after issuance of the mandate.⁹⁴

Subsequently, however, a majority of nonrecused active judges voted to rehear the case en banc. The en banc Court did not address the jurisdictional question, but instead issued a writ of mandamus requiring the EPA to rule on the objections to the 2017 Order within 90 days.⁹⁵ In July 2019,

⁹² *LULAC v. Wheeler*, 899 F.3d 814, 827 (9th Cir. 2018), *vacated on reh’g en banc*, 914 F.3d 1189 (9th Cir. 2019).

⁹³ *Id.* at 829.

⁹⁴ *Id.*

⁹⁵ *LULAC v. Wheeler*, 922 F.3d 443, 445 (9th Cir. 2019) (en banc).

the EPA issued a final order (the “2019 Order”) denying petitioners’ objections and thereby completing the administrative denial of the 2007 Petition. The 2019 Order again relied upon the need for greater scientific certainty, but went further and held that “the objections and the underlying Petition are not supported by valid, complete, and reliable evidence sufficient to meet the Petitioners’ burden under the FFDCA, as set forth in [the] EPA’s implementing regulations.”⁹⁶

With the Court’s jurisdiction now clear, petitioners petitioned for review of the 2017 and 2019 Orders. Several states moved to intervene. The en banc Court granted the motion to intervene, consolidated the cases, and returned the matter to this panel as a “comeback case.”⁹⁷

STANDARD OF REVIEW

The Administrative Procedure Act (“APA”) authorizes the Court to “hold unlawful and set aside agency action, findings, and conclusions” if they are “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law,”⁹⁸ and to “compel agency action unlawfully withheld or unreasonably delayed.”⁹⁹ Agency action is arbitrary and capricious where the agency has “offered an explanation for

⁹⁶ Chlorpyrifos; Final Order Denying Objections to March 2017 Petition Denial Order, 84 Fed. Reg. 35,555, 35,557 (July 24, 2019) (hereinafter “2019 Order”).

⁹⁷ *LULAC v. Wheeler*, 940 F.3d 1126, 1126–27 (9th Cir. 2019) (en banc); see 9th Cir. Gen. Order 3.6(b).

⁹⁸ 5 U.S.C. § 706(2)(A).

⁹⁹ *Id.* § 706(1).

its decision that runs counter to the evidence before the agency.”¹⁰⁰

ANALYSIS

I. Merits

The Court first considers whether the EPA lawfully denied the 2007 Petition. Petitioners argue that the EPA’s 2017 and 2019 Orders were *ultra vires* under the FFDCA and arbitrary and capricious under the APA.

A. Whether the EPA Left in Effect a Tolerance Without Determining That It Is Safe

As noted above, the FFDCA provides that the EPA “may establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe. The Administrator shall modify or revoke a tolerance if the Administrator determines it is not safe.”¹⁰¹ The statute also specifically requires that the EPA “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue” and “publish a specific determination regarding the safety of the pesticide chemical residue for infants and children.”¹⁰²

Courts “normally interpret[] a statute in accord with the ordinary public meaning of its terms at the time of its

¹⁰⁰ *Motor Vehicle Mfrs. Ass’n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

¹⁰¹ 21 U.S.C. § 346a(b)(2)(A)(i).

¹⁰² *Id.* § 346a(b)(2)(C)(ii)(I)–(II).

enactment.”¹⁰³ Furthermore, the FFDCA must be “given a liberal construction consistent with the Act’s overriding purpose to protect the public health.”¹⁰⁴

The EPA admits that the 2017 and 2019 Orders left in effect tolerances without determining that they are safe, claiming that it could delay this determination for several more years until it had resolved safety-related issues in the 15-year FIFRA registration review. Since, as discussed below, the EPA’s duty to engage in a periodic FIFRA registration review is separate from its continuous obligation to ensure safety under the FFDCA, this concession is effectively dispositive in favor of petitioners.

FIFRA aside, the EPA argues that it may leave in effect tolerances, without a new safety finding, “when [the] EPA concludes the petition contains insufficient evidence for [the] EPA to undertake proceedings to revoke or modify tolerances.” This argument fails for two reasons. First, once the EPA has become aware, through a petition or otherwise, of genuine questions about the safety of an existing tolerance, the EPA has its own continuing duty under the FFDCA to determine whether a tolerance that was once thought to be safe still is, and here the EPA’s own studies and pronouncements still in effect show that it regards chlorpyrifos as harmful at levels below the existing tolerances. Second, in any case, the 2007 Petition, under the EPA’s own regulations, contained more than sufficient evidence to undertake a safety review, and the EPA recognized as much, began such a review, and only now,

¹⁰³ *Bostock v. Clayton County*, 140 S. Ct. 1731, 1738 (2020).

¹⁰⁴ *United States v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 798 (1969).

13 years later, claims for the first time that the 2007 Petition was somehow inadequate.

1. The EPA's Duty to Ensure Human Safety

The FFDCA imposes a continuous duty upon the EPA by permitting it to “leave in effect” a tolerance “only” if it finds it is safe. To “leave” something in effect means “to cause or allow [it] to be or remain in a specified condition.”¹⁰⁵ Denying the 2007 Petition caused the chlorpyrifos tolerances to remain in place; as the EPA itself wrote in its brief, it “le[ft] the existing tolerances in place pending . . . registration review.” But in so doing, the EPA did not “determine[] that the tolerance is safe.”¹⁰⁶ Rather, the EPA's own pronouncements show that it has already concluded that it can no longer be reasonably certain that chlorpyrifos is safe at current tolerances.

It should be noted in this respect that, because of the FQPA, assurance of safety for human health is the primary issue the EPA must consider. Before 1996, when Congress unanimously passed the FQPA, the EPA interpreted the FFDCA to permit the balancing of safety against other considerations, such as economic factors. Congress was

¹⁰⁵ Merriam Webster, “Leave,” *available at* <https://www.merriam-webster.com/dictionary/leave> (last accessed Apr. 17, 2021). The Dissent quibbles with our use of the dictionary, arguing that the phrase “leave in effect” is unambiguous. But then the Dissent ascribes to that term a meaning of the Dissent's own creation: that the EPA leaves in effect a tolerance only when it conducts FIFRA registration review. The statute imposes no such limitation on the phrase.

¹⁰⁶ 21 U.S.C. § 346a(b)(2)(A)(i).

aware of this,¹⁰⁷ and the FQPA largely abrogated that approach.¹⁰⁸ Congress made the explicit decision to prioritize safety over all else. This makes the FFDCA a remedial statute, which, as noted, must be “given a liberal construction consistent with the Act’s overriding purpose to protect the public health.”¹⁰⁹ Reading the EPA’s duty narrowly would undermine the statute’s health-protective purpose.

The EPA argues that one of Congress’s purposes was to provide the EPA with regulatory discretion. The EPA points to the fifteen-year registration review cycle under FIFRA¹¹⁰ as evidence that “Congress recognized that [reregistration] would be a complex and potentially burdensome proceeding”; thus, by contrast, Congress must have intended “a different” – and less burdensome – obligation “[w]hen [the] EPA responds to a petition to revoke pesticide tolerances” under the FFDCA. This contention is unpersuasive because of the differences between FIFRA and

¹⁰⁷ H.R. Rep. No. 104-669, pt. 2, at 40 (1996) (noting that under the prior procedure for setting tolerances, the EPA was authorized to consider “factors including the necessity for production of an adequate, wholesome, and economical food supply”).

¹⁰⁸ Notwithstanding the safety standard, in certain circumstances the EPA may leave a tolerance in effect if “[u]se of the pesticide chemical . . . is necessary to avoid a significant disruption in domestic production of an adequate, wholesome, and economical food supply.” 21 U.S.C. § 346a(b)(2)(B)(iii)(II). However, this is permitted only where the risk of harm from a “nonthreshold effect,” such as cancer, is not significantly greater than would be allowed for threshold effects. *See id.* § 346a(b)(2)(B)(iv). Nonthreshold effects are not at issue here.

¹⁰⁹ *Bacto-Unidisk*, 394 U.S. at 798.

¹¹⁰ *See* 7 U.S.C. § 136a(g)(1)(A)(iii)–(iv).

the FFDCA. The statutes impose different duties that require different assessments. Under FIFRA, the EPA has a discretionary power to cancel registrations for a variety of reasons.¹¹¹ Specifically, FIFRA requires the EPA to balance several factors in determining whether a pesticide should be registered. For example, although FIFRA review includes an assessment of safety under the FFDCA,¹¹² it also requires a more general assessment of a pesticide’s “economic, social, and environmental costs and benefits,”¹¹³ including “the impact of [any proposed] action . . . on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy.”¹¹⁴ Given these differences, Congress’s decision to give the EPA discretion to set FIFRA priorities does not translate to the FFDCA. The EPA’s obligations under the FFDCA are linked to a single issue, safety, but they are mandatory.¹¹⁵ The whole point of the FQPA would be destroyed if the EPA could exercise unfettered discretion to defer safety considerations until it

¹¹¹ 7 U.S.C. § 136d(b).

¹¹² See *id.* § 136(bb). The Dissent accuses us of “repeatedly miss[ing] this point,” Dissent, *infra*, at 83 n.6, but the fact that FIFRA reregistration review includes, as one component, an assessment of safety under the FFDCA does not gainsay the many *other* factors FIFRA review also encompasses. FIFRA’s wider scope justifies that statute’s periodic rereview timeline and the greater agency discretion that approach entails. By contrast, the FFDCA’s singular focus on safety corresponds with the EPA’s continuous duty to leave in effect a tolerance only if it finds that the tolerance is safe.

¹¹³ 7 U.S.C. § 136(bb).

¹¹⁴ *Id.* § 136d(b).

¹¹⁵ See 21 U.S.C. § 346a(b)(2)(A)(i) (“The Administrator *shall* modify or revoke [an unsafe tolerance].” (emphasis added)).

was prepared to engage in the full multi-factor balancing assessment required for FIFRA registration.

Our dissenting colleague reaches a different conclusion regarding the EPA's obligations, or lack thereof, when confronted with a petition for revocation of tolerances. The Dissent focuses upon two sentences in the FFDCA:

The Administrator may establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe. The Administrator shall modify or revoke a tolerance if the Administrator determines it is not safe.¹¹⁶

We think that these two simple sentences are – with their emphasis on the word “only” – remarkably straightforward. As here explained, they mean that the EPA can lawfully deny the 2007 Petition and thereby “leave in effect” a tolerance “*only* if the Administrator determines that the tolerance is safe.” The Dissent’s more strained reading of these sentences is to the effect that there are three possible scenarios, one in which the EPA “determines that a tolerance is safe,” one in which the EPA “determines it is not safe,” and one in which the EPA is unwilling or unable to make a safety determination at this time. In this latter, middle world, the Dissent continues, the statute is silent as to the EPA’s obligations, leaving the EPA with the discretion to leave in

¹¹⁶ *Id.* The EPA and the Dissent also contend that our reading renders the second sentence superfluous, but it does not. The second sentence limits the EPA’s discretion by explaining that when it finds that a tolerance is not safe, it may not, for example, convene a SAP or wait 15 years pending further research; its only options are to revoke or modify the tolerance.

effect a tolerance based on its *prior* safety finding (here, the 2006 safety finding).

One problem (among others) with the Dissent's imaginative reading is that other statutory provisions are not silent. The FFDCA imposes an overarching obligation that the EPA protect human safety, and particularly the safety of infants and children:

In establishing, modifying, leaving in effect, or revoking a tolerance or exemption for a pesticide chemical residue, the Administrator shall assess the risk of the pesticide chemical residue . . . and shall ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue.¹¹⁷

Congress has excluded the middle, not this Court. The EPA can only lawfully take agency action to establish or leave in effect a tolerance (*e.g.*, denying the 2007 Petition) if the EPA finds that the tolerance is safe.

2. The Burdens of Production and Persuasion

The EPA claims that the issue of safety as it bears on an existing tolerance need not be addressed unless a petitioner meets a threshold burden to come forward with evidence that the existing tolerance is unsafe. In this regard, the EPA points to the fact that the FFDCA gives the EPA the authority to “establish the requirements for information and

¹¹⁷ 21 U.S.C. § 346a(b)(2)(C) (punctuation and section lettering omitted).

data to support a petition to modify or revoke a tolerance.”¹¹⁸ In a regulation promulgated pursuant to that authority, the EPA requires such a petition to “furnish reasonable grounds for the action sought.”¹¹⁹ Reasonable grounds “include . . . an assertion of facts (supported by data if available) showing . . . that new data are available as to toxicity of the chemical, or that experience with the application of the tolerance . . . may justify its modification or revocation.”¹²⁰

We do not doubt that the EPA has gatekeeping authority to reject a wholly frivolous petition – *i.e.*, a petition that fails even to “furnish reasonable grounds for the action sought” – without publishing a notice of its filing if the petition is deficient on its face, and in such circumstances we can assume the EPA need not address the concerns raised by the petition. But the record here unequivocally shows both that the 2007 Petition met all relevant requirements and that, in fact, it caused the EPA to re-evaluate the safety of the chlorpyrifos tolerances, thus triggering the EPA’s duty to ensure a reasonable certainty of no harm.

The FFDCA requires the EPA to determine whether a petition satisfies the threshold requirements *prior* to publishing a notice of the filing of the petition.¹²¹ Here, the EPA published a notice of the filing of the 2007 Petition in

¹¹⁸ 21 U.S.C. § 346a(d)(2)(B).

¹¹⁹ 40 C.F.R. § 180.32(b).

¹²⁰ *Id.*

¹²¹ See 21 U.S.C. § 346a(d)(3) (“A notice of the filing of a petition that the Administrator determines has met the [data and information] requirements . . . shall be published by the Administrator within 30 days after such determination.” (emphasis added)).

October 2007,¹²² thereby finding that it met the data and information requirements in the FFDCa and the EPA's regulations promulgated thereunder. The EPA cannot now be heard, more than a dozen years later, to claim that the petition did not, in fact, meet those threshold requirements.

Independently, even if the EPA had raised this issue thirteen years ago when the 2007 Petition was filed, the EPA offers no specific way in which the petition failed to comply with the EPA's technical requirements and no plausible argument for why the 2007 Petition does not contain "reasonable grounds" for revocation. The EPA points to the continued scientific uncertainty regarding how chlorpyrifos harms infants and children and the fact that the 2007 Petition did not attach complete underlying data for the studies that it cited. But the regulation does not say that the petition must *prove* that revocation is required; it requires only that the petition state "reasonable grounds" for revocation. And the grounds listed in the 2007 Petition meet any definition of "reasonable"; indeed, the EPA has implicitly acknowledged as much by reacting to the 2007 Petition with years of deliberation, hundreds of pages of analysis, several convenings of the SAP, and a Notice of Proposed Rulemaking and further Notice of Data Availability proposing to grant the requested relief, all substantially based on grounds cited in the 2007 Petition.

The Dissent contends that a petitioner who seeks revocation of a pesticide tolerance bears not only a burden of production, *i.e.*, to provide "reasonable grounds" for revocation, but also a burden of persuasion, *i.e.*, to offer valid, complete, and reliable data that affirmatively demonstrate that the tolerances are unsafe. However, as

¹²² 72 Fed. Reg. 58,845 (Oct. 17, 2007).

previously explained, the Dissent’s reading is inconsistent with the FQPA’s health protective purpose and the FFDCA’s overarching command that the EPA, whenever leaving in effect a tolerance, “assess the risk of the pesticide chemical residue . . . and . . . ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure”¹²³ The Dissent’s reading is also inconsistent with the EPA’s regulations, which only impose a burden of production on the petitioner.¹²⁴ Indeed, in its brief the EPA relies upon the burden-setting regulation that would apply if the EPA conducted an evidentiary hearing on the 2007 Petition. Although there was no evidentiary hearing here, the regulation is illustrative. Ordinarily, “[t]he party whose request for an evidentiary hearing was granted has the burden of going forward in the hearing with evidence as to the issues relevant to that request for a hearing.”¹²⁵ However, when section 408 of the FFDCA is at issue, the section pertaining to “safety,” then “[t]he party or parties who contend that a regulation satisfies the criteria of section 408 of the FFDCA has the burden of persuasion in the hearing on that issue, whether the proceeding concerns the establishment, modification, or revocation of a tolerance or exemption from the requirement for a tolerance.”¹²⁶ Put simply, on the question of safety, while the burden of production is on the petitioners, the burden of persuasion always rests on the party claiming that a tolerance is safe. For these reasons, the Court concludes that when the EPA

¹²³ 21 U.S.C. § 346a(b)(2)(C).

¹²⁴ 40 C.F.R. § 180.32(b).

¹²⁵ 40 C.F.R. § 179.91(a).

¹²⁶ *Id.* § 179.91(b).

publishes a petition seeking revocation of a tolerance and later takes final action denying that petition, the EPA leaves that tolerance in effect. The EPA can only do so if it finds the tolerance to be safe for the general population and for infants and children.¹²⁷ Here, the EPA did not make such findings, so it acted directly contrary to the FFDCFA.

B. Whether Denying the 2007 Petition Was Arbitrary and Capricious

Separately, in light of the present record and the EPA's assessment of that record, petitioners argue that, even if the FFDCFA does not require a safety finding here (which we find it does), the EPA's denial of the 2007 Petition was arbitrary and capricious. The Court agrees.

An agency has a baseline obligation to “articulate a satisfactory explanation for its action including a ‘rational connection between the facts found and the choice made.’”¹²⁸ The EPA has not done so because none of the reasons proffered in the 2017 and 2019 Orders provides “a satisfactory explanation for” denying the 2007 Petition.

The EPA has not retracted the 2016 Revised Human Health Risk Assessment indicating that chlorpyrifos is not safe at current tolerances and has not issued a new Human

¹²⁷ This is not to say, of course, that the EPA must perform a new Human Health Risk Assessment in response to every petition. The EPA might consider the issues raised by the petition alongside all the other evidence considered in its most recent safety determination and conclude that it need not conduct further review before reaffirming its prior findings.

¹²⁸ *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43 (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962)).

Health Risk Assessment or SAP report since 2016. Rather, the 2017 Order denied the 2007 Petition on purely discretionary grounds, relying upon the EPA’s purported authority to demand more study through at least 2022. After 13 years of delay, a desire for yet more delay does not rationally support denial of a petition that the EPA’s own prior studies indicate raises a genuine issue of ongoing harm to infants and children.

The EPA asserted in the 2017 Order that it “may lawfully re-prioritize the registration review schedule developed by earlier [presidential] administrations.”¹²⁹ In other words, more delay. Furthermore, while the EPA recognized that the 2007 Petition was filed under the FFDCA and raised arguments concerning human safety, the EPA found in its 2017 Order that it had to be permitted to synchronize its review of the petition with FIFRA registration review. To find otherwise “would effectively give petitioners under the FFDCA the authority to re-order scheduling decisions regarding the FIFRA registration review process that Congress has vested in the Administrator.”¹³⁰

But the FIFRA registration review, as already noted, is a different animal, in that it permits a balancing of multiple factors, whereas a FFDCA review is limited to the sole issue of safety but allows no balancing as far as that factor is concerned. Chlorpyrifos’s wide use and the significance of this issue to the Administration are not valid legal considerations, as the EPA recognized in its 2017 Order.¹³¹

¹²⁹ 2017 Order, *supra* note 24, 82 Fed. Reg. at 16,590.

¹³⁰ *Id.*

¹³¹ *Id.*

As already noted, the FQPA amended the FFDCA to explicitly prohibit the EPA from balancing safety against other considerations, including economic or policy concerns, in most instances. Thus, the EPA's citation to these admittedly extralegal factors in its denial of the 2007 Petition is telling. It strongly suggests that the EPA's about-face in 2017 was motivated by factors unrelated to human safety, contrary to the FFDCA's commands.

The reference in the denial to the FIFRA 15-year period of review is, instead, nothing but a red herring, as the 2007 Petition does not concern FIFRA registration review. It concerns a petition under the FFDCA that contends that chlorpyrifos is unsafe. The EPA's position would largely strip FFDCA petitions of meaning, converting them into comments for the EPA to consider whenever it gets around to the next FIFRA registration review. The EPA offers no statutory support for this – because there is none. When, as here, a petitioner files a detailed petition identifying new evidence providing reasonable grounds to believe that exposure at less than a pesticide's current tolerances may be unsafe, the EPA has a duty to “giv[e] due consideration to [the] petition . . . and any other information available”¹³² and to act on that petition with reasonable dispatch to protect human health – not fifteen years later. For these reasons, consistent with what this Court has said for years, the EPA's desire for delay is not a satisfactory explanation for denying the 2007 Petition.

The 2019 Order (unlike the 2017 Order) relied upon a second ground for denial of the 2007 Petition. The EPA found that PANNA and the NRDC bore an initial burden of production that, according to the EPA, they did not meet.

¹³² 21 U.S.C. § 346a(d)(4)(A).

The EPA pointed out that the FFDCA requires it to consider “the validity, completeness, and reliability of the available data”¹³³ and authorizes it to promulgate regulations stating what a petition must contain.¹³⁴ As noted above, under this authority, the EPA promulgated a regulation requiring a petition to include “reasonable grounds” for revocation, which include an “assertion of facts (supported by data if available).”¹³⁵ Given this initial burden of production, the “EPA conclude[d] that the information . . . presented by Petitioners is not sufficiently valid, complete, and reliable to support abandoning the use of AChE inhibition as the critical effect for regulatory purposes under the FFDCA section 408.”¹³⁶ Thus, the EPA concluded that the FFDCA safety issue was not before it.

For reasons already stated, this finding is unreasonable and inconsistent with the petition itself. The 2007 Petition claimed in detail that chlorpyrifos posed a risk of neurotoxic harm, especially to infants and children, and it invoked the live animal studies and the Columbia Study as evidence. The EPA acknowledges that it “has, since [2006], consistently concluded that the available data support a conclusion of increased sensitivity of the young to the neurotoxic effects of chlorpyrifos and for the susceptibility of the developing brain to chlorpyrifos.”¹³⁷ Therefore, under any reasonable construction, the 2007 Petition met the low

¹³³ 21 U.S.C. § 346a(b)(2)(D)(i).

¹³⁴ *Id.* § 346a(d)(2)(B).

¹³⁵ 40 C.F.R. § 180.32.

¹³⁶ 2019 Order, *supra* note 96, 84 Fed. Reg. at 35,563.

¹³⁷ *Id.*

bar of stating “reasonable grounds” for revocation with an “assertion of facts” in support. Also, as noted above, the time for finding that the petition did not meet the burden of production was in 2007, *before* the EPA published the petition in the Federal Register.

Because the Court rejects both of the EPA’s justifications for refusing to make a safety finding, the Court concludes that the EPA’s denial of the 2007 Petition was arbitrary and capricious.¹³⁸

Although not necessary for this determination, the Court, for completeness, also considers the EPA’s four objections to the data.

First, the EPA objects, in general, that “the science on this question is not resolved and would benefit from additional inquiry.”¹³⁹ It will always be possible to conduct additional studies or to reach a greater degree of certainty, but a generalized concern that the science is not resolved is not a rationale sufficient to support denying a revocation petition. The FFDCA requires that the EPA make a safety determination based on whatever “information” is

¹³⁸ The Dissent takes great umbrage at this conclusion, reminding us that “[w]hen an agency makes determinations ‘within its area of special expertise, at the frontiers of science . . . a reviewing court must generally be at its most deferential.’” Dissent, *infra*, at 109 (alteration in original) (quoting *Balt. Gas & Elec. Co. v. NRDC*, 462 U.S. 87, 103 (1983)). If the 2019 Order had found that existing chlorpyrifos tolerances were safe, then such deference would be appropriate. But no such finding was made. It is the Order’s utter *failure* to make a required safety determination that this Court finds was arbitrary and capricious. This has nothing to do with deference or non-deference to expertise and everything to do with simple compliance with the law.

¹³⁹ *Id.* at 35,560.

“available.”¹⁴⁰ And, as this Court has said before, a statutory mandate to rely on “available” scientific data “does not mean ‘the best scientific data possible.’”¹⁴¹

Second, the EPA argues that it does not know *how* chlorpyrifos’s neurotoxic effects harm infants and children. But that is not the question before the EPA. The question is *whether* chlorpyrifos causes such harms. Even if the mechanism is unknown, if a tolerance is unsafe, then the EPA must revoke it.¹⁴²

Third, the EPA argues that the studies of rats and mice applied a “dosing regimen . . . that differs from internationally accepted protocols.”¹⁴³ The EPA says:

[T]he in vivo laboratory animal studies generally use fewer days of dosing that are aimed at specific periods of rodent fetal or early post-natal development compared to internationally adopted guideline studies which are intended to cover both pre- and post-gestational periods. The degree to which these shorter dosing periods coincide

¹⁴⁰ 21 U.S.C. § 346a(d)(4)(A).

¹⁴¹ *San Luis & Delta-Mendota Water Auth. v. Jewell*, 747 F.3d 581, 602 (9th Cir. 2014) (quoting *Building Indus. Ass’n v. Norton*, 247 F.3d 1241, 1246 (D.C. Cir. 2001)).

¹⁴² *Cf. Am. Trucking Ass’ns, Inc. v. EPA*, 175 F.3d 1027, 1055 (D.C. Cir. 1999) (finding the EPA was not required to prove “how particles actually interact with cells and organs to cause sickness and death”), *aff’d in part and rev’d in part on other grounds sub nom. Whitman v. Am. Trucking Ass’n’s*, 531 U.S. 457 (2001).

¹⁴³ 2019 Order, *supra* note 96, 84 Fed. Reg. at 35,563.

with comparable windows of susceptibility in human brain development is unclear.¹⁴⁴

This argument, apparently raised for the first time in the 2019 Order, is stated in cursory fashion. The EPA does not identify these “internationally accepted protocols” or explain why the EPA did not find deviations from these protocols to be troubling in the 2015 Notice of Proposed Rulemaking, the 2016 Notice of Data Availability, the 2016 Revised Human Health Risk Assessment, or the many other publications by the EPA that relied upon the animal studies. In any event, however, even if the Court were convinced, for the sake of argument, that divergence from these internationally accepted dosing protocols might somewhat diminish the value of these studies, it would not change the result, for reasons described below.

Fourth and finally, the EPA objects that it has been unable to get the raw data, as well as information concerning how residential pesticides were applied, from the Columbia Study. (Columbia, for its part, has expressed reasonable concerns about the subjects’ privacy, especially given that the study covered a small geographic radius. Nevertheless, Columbia suggested to the EPA that it could make at least

¹⁴⁴ *Id.* The EPA also explains that “except for some studies conducted recently, most of the in vivo laboratory studies use doses that are higher than doses that cause 10% [red blood cell] AChE inhibition. These studies are therefore are [sic] not useful quantitatively to evaluate whether [the] EPA’s current regulatory standard is or is not sufficient to preclude the potential for neurodevelopmental effects.” *Id.* This objection is, of course, valid as far as it goes: studies that apply pesticide at doses above the current tolerance are less helpful in showing whether the tolerance is safe. But the EPA concedes that “some studies” use lower doses. The EPA offers no justification for refusing to consider these studies.

some of the datasets available for viewing in a secure data center.¹⁴⁵) The EPA has changed its position over time regarding the value of this data. It initially requested the data, but after meeting with the Columbia researchers in 2014, the EPA abandoned its request for this data.¹⁴⁶ Later, when the EPA sought to develop a point of departure based upon the umbilical cord blood measurements in the Columbia Study, it sought the data again. However, the 2016 SAP took issue with an approach based upon those cord blood measurements, so, as explained above, the EPA moved to a time-weighted average approach based upon a registrant's PBPK model. As a result, the EPA once again determined that it did not need the Columbia data, explaining that its new approach "does not directly rely on quantitative measures of chlorpyrifos in cord blood obtained from [Columbia], and thus, the lack of access to the raw data from [Columbia] is less of an uncertainty."¹⁴⁷ The EPA has now reversed position yet again, reiterating its desire for the data.

¹⁴⁵ See Chlorpyrifos Epidemiology Study Data De-identification Discussion (July 31, 2018).

¹⁴⁶ 2014 Revised Human Health Risk Assessment, *supra* note 54, at 391 ("As a result of this meeting and additional discussions with [Columbia] staff, [the] EPA concluded that access to the raw data would either not provide answers to [the] EPA's questions or that the information [the] EPA sought could be obtained without analyzing the raw data. Indeed, based on discussions in that meeting as well as further work conducted by agency staff, [the] EPA has gained additional information to better clarify and characterize the major issue areas identified as uncertainties. For these reasons, [the] EPA decided that it would not further pursue its request for the analytic data file from the [Columbia] researchers.") (emphasis added).

¹⁴⁷ 2016 Revised Human Health Risk Assessment, *supra* note 74, at 14.

The EPA's flip-flopping suggests the weakness of this objection. Nevertheless, even if the Court were to assume for the sake of argument that the underlying data, and information concerning the method of residential pesticide application, would be of some use and that the EPA's inability to access it might diminish the value of the Columbia Study, it would not change the result in this case.

This is because, while the EPA might reasonably conclude that divergences from international protocols and lack of access to raw data might affect the weight the EPA accords to these studies, they are nowhere near enough to show that the studies are entirely unreliable. The FFDCRA requires the EPA to consider the "information" that is "available"¹⁴⁸ and to make a safety determination based on that information. In this case, live animal studies showing sex-linked, neurotoxic harms from *in utero* chlorpyrifos exposure are available – even if such studies are supposedly not perfectly aligned with (unspecified) international standards. And peer-reviewed cohort studies showing harms to infants' neurological development following their mothers' exposure to chlorpyrifos are available – even if the underlying data is not. The EPA speculates that it might find an error if the unspecified international standards were applied to the animal studies or if the data from the Human Cohort Studies were available. But that is all it is: speculation. Such speculation "runs counter to the evidence before the agency,"¹⁴⁹ so it cannot form the basis for denying the 2007 Petition.

¹⁴⁸ 21 U.S.C. § 346a(d)(4)(A).

¹⁴⁹ See *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43.

II. Remedy

The Court concludes that the EPA lacked power to deny the 2007 Petition without making the safety findings required by the FFDCA and that the EPA's decision was arbitrary and capricious. Therefore, the Court must, at least, "set aside the order or regulation complained of"¹⁵⁰ and remand to the EPA. Petitioners argue that the Court should also order the EPA to revoke the current chlorpyrifos tolerances and registrations by a date certain. Under the APA, the Court has the power to "compel agency action unlawfully withheld or unreasonably delayed."¹⁵¹ The Court returns once more to the two sentences of the FFDCA that are key to assessing whether the Court should order the relief petitioners request:

The Administrator may establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe. The Administrator shall modify or revoke a tolerance if the Administrator determines it is not safe.¹⁵²

The second sentence is more than a mere gloss on the first because the command inherent in the second sentence

¹⁵⁰ 21 U.S.C. § 346a(h)(2).

¹⁵¹ 5 U.S.C. § 706(1).

¹⁵² 21 U.S.C. § 346a(b)(2)(A)(i).

is important.¹⁵³ To be sure, the “only if” clause in the first sentence, standing alone, limits what the EPA may do when it determines that a tolerance is unsafe: it may not leave it in effect. But what are the EPA’s options? May it order additional study? Convene another SAP? Wait for fifteen years to see if further evidence appears? No. The second sentence makes clear that, once the EPA has determined that a tolerance is not safe, it has no discretion to temporize pending additional research; it must modify or revoke the tolerance. For these reasons, if the EPA has determined that the present chlorpyrifos tolerances are not safe – or if that is the only conclusion the EPA could reasonably draw on this record – then the EPA has unlawfully withheld the relief that petitioners request.

On the present record, the only reasonable conclusion the EPA could draw is that the present tolerances are not safe within the meaning of the FFDCA. The EPA can find a tolerance safe only if there is “a reasonable certainty” of “no harm,”¹⁵⁴ and for nearly a decade, the EPA and its SAPs have concluded that there is *not* a reasonable certainty of no harm:

- **2012 SAP:** “[E]vidence suggest[s] that chlorpyrifos can affect neurodevelopment at levels lower than those associated with AChE inhibition, and that the use of AChE inhibition data may not be the most appropriate for dose-response modeling and

¹⁵³ For this reason, the EPA and the Dissent are also incorrect to contend that petitioners’ reading of the statute contains surplusage. *See* Dissent, *infra*, at 80.

¹⁵⁴ 21 U.S.C. § 346a(b)(2)(A)(ii).

derivation of a point of departure for assessment of the neurodevelopmental risks of chlorpyrifos.”¹⁵⁵

- **2014 Revised Human Health Risk Assessment:** “[C]hlorpyrifos likely played a role in the neurodevelopmental outcomes observed in these epidemiology studies.”¹⁵⁶ Moreover, “it is unlikely mothers enrolled in the [Human Cohort Studies] experienced [red blood cell] AChE inhibition.”¹⁵⁷
- **2015 Notice of Proposed Rulemaking:** “[The] EPA cannot, at this time, determine that aggregate exposure to residues of chlorpyrifos, including all anticipated dietary exposures and all other non-occupational exposures for which there is reliable information, are safe.”¹⁵⁸
- **2016 SAP:** “[B]oth epidemiology and toxicology studies suggest there is evidence for adverse health outcomes associated with chlorpyrifos exposures

¹⁵⁵ 2012 SAP Minutes, *supra* note 48, at 53.

¹⁵⁶ SAP Minutes No. 2008-04, A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding: The Agency’s Evaluation of the Toxicity Profile of Chlorpyrifos 43 (Sept. 16–18, 2008).

¹⁵⁷ *Id.* at 46.

¹⁵⁸ 2015 Notice of Proposed Rulemaking, *supra*. note 58, 80 Fed. Reg. at 69,081.

below levels that result in 10% red blood cell [AChE] inhibition.”¹⁵⁹

- **2016 Revised Human Health Risk Assessment:** The Columbia Study, “with supporting results from the other [Human Cohort Studies] and the seven additional epidemiological studies reviewed in 2015, provides sufficient evidence that there are neurodevelopmental effects occurring at chlorpyrifos exposure levels below that required for AChE inhibition.”¹⁶⁰
- **2016 Notice of Data Availability:** “[E]xpected residues of chlorpyrifos on most individual food crops exceed the ‘reasonable certainty of no harm’ safety standard under the [FFDCA] [The] EPA has not identified a set of currently registered uses that meets the FFDCA safety standard”¹⁶¹

Even in its brief here, the EPA, though it purports to withhold judgment on chlorpyrifos’s safety, admits that it cannot conclude there is a reasonable certainty of no harm. Rather, the EPA represents that there are “*uncertainties* concerning the impact of chlorpyrifos on children” (emphasis added).

The EPA has not determined, and on this record reasonably could not determine to a “reasonable certainty”

¹⁵⁹ 2016 SAP Minutes, *supra* note 65, at 18.

¹⁶⁰ 2016 Revised Human Health Risk Assessment, *supra* note 74, at 13.

¹⁶¹ *Id.*

that aggregate chlorpyrifos exposures under the current tolerances pose no risk of harm. Therefore, by statutory definition, the present tolerances are not safe. Accordingly, the EPA's obligation is clear: it must modify or revoke chlorpyrifos tolerances and modify or cancel chlorpyrifos registrations.

The EPA cites cases counseling that upon reversal of agency action, an open-ended remand is the correct approach, “[g]enerally speaking”¹⁶² and “except in rare circumstances.”¹⁶³ But this is not a typical case. On the present record the EPA has limited legal discretion: its only options are to modify or revoke the tolerances. Nor would it be reasonable to remand for further factfinding after thirteen years of interminable delay. Indeed, further delay would make a mockery, not just of this Court's prior rulings and determinations, but of the rule of law itself. This is precisely the sort of “rare circumstance” where yet another open-ended remand would only frustrate the purpose of the FFDCA.

Finally, the EPA argues that “any order by this Court unilaterally ordering [the] EPA to revoke the existing tolerances for chlorpyrifos or cancel the existing registrations would raise serious due process concerns” for registrants and “violate Congress's procedures.” Here, however, the Court is not unilaterally ordering the EPA to revoke existing tolerances; as explained below, it may instead modify such tolerances if it can make the requisite safety findings.

¹⁶² *INS v. Orlando Ventura*, 537 U.S. 12, 16 (2002).

¹⁶³ *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985).

In any event, remanding with specific instructions does not raise due process concerns. In responding to a petition, the FFDCA explicitly authorizes the EPA to “issue a final regulation modifying or revoking a tolerance . . . (*which final regulation shall be issued without further notice and without further period for public comment*).”¹⁶⁴ On this record, immediate issuance of a final regulation is the only reasonable action, and the Court orders the EPA to do so.

Such a final regulation could take one of two forms: either it could revoke all chlorpyrifos tolerances or it could modify chlorpyrifos tolerances *and* conclude that under the new tolerances there is a “reasonable certainty that no harm will result” due to “aggregate exposure to the pesticide chemical residue” that would result from such modified tolerances, including “to infants and children.”¹⁶⁵ To be clear, the EPA may only choose to modify chlorpyrifos tolerances, rather than to revoke them, if at the same time it publishes such a safety determination.¹⁶⁶ On this record, it

¹⁶⁴ 21 U.S.C. § 346a(d)(4)(A)(i) (emphasis added) (comma omitted).

¹⁶⁵ *Id.* § 346a(b)(2)(A)(ii), (b)(2)(C)(ii)(I).

¹⁶⁶ The Dissent opines that the Court “may have effectively foreclosed other options Congress made available,” Dissent, *infra*, at 112 n.11, such as the exceptional steps the EPA may take when “the residue protects consumers from adverse effects on health that would pose a greater risk than the dietary risk” or when the tolerance “is necessary to avoid a significant disruption in domestic production of an adequate, wholesome, and economical food supply.” 21 U.S.C. § 346a(b)(2)(B)(iii). These provisions offer alternatives to the FFDCA’s general safety requirement for certain “eligible pesticide chemical residues,” but only for adults. While subparagraph (b)(2)(B) provides an exception to “subparagraph [(b)(2)(A)(i)],” the general safety rule, it expressly requires compliance with subsection (b)(2)(C), which

may well be that the EPA cannot make such a determination. In 2016, the EPA explained that it “ha[d] not identified a set of currently registered uses that meets the FFDCSA safety standard,”¹⁶⁷ a finding consistent with more than a decade of EPA issue papers, revised human health risk assessments, and SAP proceedings.

Nevertheless, during the pendency of this proceeding, in December 2020, the EPA issued a Proposed Interim Registration Review Decision proposing to modify certain chlorpyrifos tolerances. The EPA also convened another SAP in 2020. If, based upon the EPA’s further research the EPA can now conclude to a reasonable certainty that modified tolerances or registrations would be safe, then it may modify chlorpyrifos registrations rather than cancelling them.¹⁶⁸

mandates that the EPA assure a reasonable certainty of no harm to children specifically. *Id.* § 346a(b)(2)(B)(vi). Thus, these provisions are irrelevant because regardless of whether chlorpyrifos is an “eligible” pesticide for purposes of § 346a(b)(2)(B) – a question not briefed by the parties and raised sua sponte by the Dissent – the EPA may only leave in effect chlorpyrifos tolerances that are safe for children.

¹⁶⁷ 2016 Notice of Data Availability, *supra* note 3, 81 Fed. Reg. at 81,050.

¹⁶⁸ Whichever path the EPA chooses to take, the FFDCSA also provides that within 60 days after the EPA publishes a final response to the 2007 Petition, either modifying chlorpyrifos tolerances and publishing a safety finding or revoking chlorpyrifos tolerances, anyone may object to the EPA’s final order, 21 U.S.C. § 346a(g)(2)(A), and the EPA must then “issue an order stating the action taken” on those objections, *id.* § 346a(g)(2)(C). It is hard to imagine that registrants will have much to add, given the many opportunities they have already received to comment on the 2015 Notice of Proposed Rulemaking and the 2016 Notice of Data Availability, as well as to participate as *amici*

To be clear, however, this is not an open-ended remand or a remand for further factfinding. The EPA must act based upon the evidence and must immediately revoke or modify chlorpyrifos tolerances.

For these reasons, the Court remands this matter to the EPA with instructions to publish a legally sufficient final response to the 2007 Petition within 60 days of the issuance of the mandate. That response must be a final regulation that either revokes all chlorpyrifos tolerances or modifies chlorpyrifos tolerances *and* makes the requisite safety findings based on aggregate exposure, including with respect to infants and children.

While the Dissent effectively views this as a “tight deadline[,]”¹⁶⁹ it agrees that the “EPA dithered far too long.”¹⁷⁰ The EPA has had nearly 14 years to publish a legally sufficient response to the 2007 Petition. During that time, the EPA’s egregious delay exposed a generation of American children to unsafe levels of chlorpyrifos. By remanding back to the EPA one last time, rather than compelling the immediate revocation of all chlorpyrifos tolerances, the Court is itself being more than tolerant. But the EPA’s time is now up.

curiae before this Court. But, in any event, registrants’ 60-day period to object will follow the EPA’s *final* revocation of chlorpyrifos tolerances (or modification with concomitant safety findings). If registrants ask the EPA to promulgate new chlorpyrifos tolerances or revert to higher tolerances, they must provide proof of safety, and the EPA can approve registrants’ request only if the EPA concludes that there is a reasonable certainty of no harm, including for infants and children.

¹⁶⁹ Dissent, *infra*, at 115.

¹⁷⁰ Dissent, *infra*, at 67.

CONCLUSION

We **GRANT** the petitions for review. The 2017 Order and the 2019 Order are vacated, and the matter is remanded to the EPA, with instructions to (1) grant the 2007 Petition; (2) issue a final regulation within 60 days following issuance of the mandate that either (a) revokes all chlorpyrifos tolerances or (b) modifies chlorpyrifos tolerances and simultaneously certifies that, with the tolerances so modified, the EPA “has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information,”¹⁷¹ including for “infants and children”;¹⁷² and (3) modify or cancel related FIFRA registrations for food use in a timely fashion consistent with the requirements of 21 U.S.C. § 346a(a)(1).

VACATED AND REMANDED, WITH INSTRUCTIONS.

BYBEE, Circuit Judge, dissenting:

This is a consequential proceeding. EPA has before it a petition to revoke the tolerances for chlorpyrifos, one of the most important pesticides in the United States. This is a very complicated statute and I agree with the majority that EPA dithered far too long before ruling on the petition. Beyond that, I disagree with the majority opinion and judgment. In

¹⁷¹ 21 U.S.C. § 346a(b)(2)(A)(ii).

¹⁷² *Id.* § 346a(b)(2)(C)(ii)(I).

my view it has misread EPA's obligations to review pesticide chemical residue tolerances EPA has previously found to be "safe" under the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. § 346a(b)(2)(A)(i). Further, the majority has substituted its own judgment for EPA's decision and then concluded that, because there is a difference of opinion, EPA's decision must be arbitrary and capricious. *See* 5 U.S.C. § 706(2)(A). Difference is not caprice. Finally, among the options Congress entrusted to EPA when an existing tolerance is determined to be unsafe, the majority effectively mandates the option that EPA will enforce.

As to the first point, I part with the majority over EPA's duty with respect to the petition. According to the majority, EPA must find that chlorpyrifos is safe for human use, and EPA did not do so here. *Maj. Op.* at 41–46. EPA did find chlorpyrifos safe. That was the result of the proceedings in 2006, made final shortly before the present petition was filed. The question EPA had to answer in this proceeding is whether new scientific evidence is sufficient to require EPA to "modify or revoke" its prior determination. Under the FFDCA, EPA must do so "if the Administrator determines it is *not safe*." 21 U.S.C. § 346a(b)(2)(A)(i) (emphasis added). Because EPA found that chlorpyrifos was safe when it concluded its prior rulemaking in 2006, EPA properly determined here that there was insufficient evidence to conclude that chlorpyrifos is "not safe" and thus it was not required to "modify or revoke" those tolerances. EPA does not start from scratch when it is reviewing a petition to revoke or modify, but may rely on its prior finding. The majority would require, contrary to the FFDCA, that EPA start all over again. I take this point up in Part I.

As to the second point, the majority cherry-picks EPA's careful and honest questions about the safety of chlorpyrifos in light of various studies produced in the petition. Admittedly, it feels like EPA had this question under review for far too long—through three administrations—but the majority then assumes EPA's tentative conclusions are proven and concludes that it was arbitrary and capricious for EPA to determine otherwise. However, EPA never concluded that the studies presented to it were scientifically established. At every step of its overly cautious proceedings, EPA referred these studies to its Scientific Advisory Panel (SAP), which ultimately advised EPA that it could not verify the studies' conclusions. When EPA requested the underlying data, the studies' authors declined to produce it. Left without means of authenticating the studies, EPA concluded there was insufficient verifiable evidence to conclude that chlorpyrifos was "not safe" and to require EPA to modify or revoke its prior approval. The petition failed for lack of scientifically verifiable evidence. EPA explained all of this in detail, explained why it needed additional time to conduct the appropriate inquiries, and advised how it would proceed through the reregistration required by the statute. There is nothing arbitrary and capricious about that. I address this problem in Part II.

Not only do we decide that EPA's decision was arbitrary and capricious, but we have effectively decided the appropriate remedy. By ordering EPA either to revoke all tolerances or modify the tolerances with the requisite safety findings within 60 days, our order virtually guarantees the EPA will revoke chlorpyrifos tolerances. This is a vast overreach, a clear abuse of our discretion, as I discuss in Part III.

We can be unhappy with EPA’s dilatory proceedings, but the remedy for that is a writ of mandamus, which we issued in *League of United Latin American Citizens v. Wheeler (LULAC III)*, 922 F.3d 443 (9th Cir. 2019) (en banc). Now that EPA has complied fully with our directions, we don’t get to set aside EPA’s decision “simply because [we are] unhappy with the result reached.” *Vt. Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 558 (1978). Nor do we get to “second-guess[] the [agency’s] weighing of risks and benefits.” *Dep’t of Com. v. New York*, 139 S. Ct. 2551, 2571 (2019). “[A] reviewing court must remember that” when an agency is acting “within its area of special expertise, at the frontiers of science,” we “must generally be at [our] most deferential.” *Balt. Gas & Elec. Co. v. NRDC*, 462 U.S. 87, 103 (1983). I respectfully dissent.

I

For starters, I fundamentally disagree with the majority over its construction of the FFDCA. The majority reads § 346a(b)(2)(A)(i), which is the critical section of the FFDCA for setting standards for pesticide use, as creating a binary choice for EPA: either a tolerance is “safe” or it is “not safe.” The majority concludes that because EPA did not conclude that the chlorpyrifos tolerances were “safe” when it denied the petition, EPA must have concluded that they were “not safe” and the petition should have been granted. *See* Maj. Op. at 41 (EPA “left in effect tolerances without determining that they are safe . . .”). With respect, the majority has misread the statute and its logic. I will start with some background on the statutes, then turn to how the majority has misread the statute, and conclude by addressing two additional arguments the majority makes.

A

Let's start with some background. EPA regulates pesticides pursuant to two statutes: the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. § 346a, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136a–136y. The provisions relevant here were adopted as amendments to those Acts in the Food Quality Protection Act of 1996 (FQPA), Pub. L. No. 104-170, 110 Stat. 1489 (Aug. 3, 1996). *See Nw. Coal. for Alts. to Pesticides v. EPA*, 544 F.3d 1043, 1046 (9th Cir. 2008). The FFDCA authorizes EPA to regulate pesticides used on food that pose safety risks to humans and to establish pesticide tolerance levels “necessary for the protection of public health.” 21 U.S.C. § 346. FIFRA authorizes EPA to “limit the distribution, sale, or use” of pesticides “[t]o the extent necessary to prevent unreasonable adverse effects on the environment” and issue registrations for distribution or sale of pesticides. 7 U.S.C. § 136a(a).

The FFDCA begins with a presumption that all “pesticide chemical residue in or on a food . . . [is] unsafe.” 21 U.S.C. § 346a(a)(1)(A). If the EPA Administrator determines that a pesticide is “safe,” the Administrator may establish a regulatory “tolerance.”¹ A pesticide may be deemed “safe” if EPA has found “that there is a reasonable

¹ EPA may also exempt a pesticide from the FFDCA, where either (1) use of the pesticide protects consumers from greater adverse health effects than the dietary risk of the pesticide or (2) the pesticide is necessary to avoid significant disruption in the food supply chain, so long as aggregate risk is not too high. 21 U.S.C. § 346a(b)(2)(B)(ii)–(iv).

Although some of the statutes I will cite here refer to exemptions, EPA did not consider exemption of chlorpyrifos in this proceeding.

certainty that no harm will result from aggregate exposure to the pesticide.” *Id.* § 346a(b)(2)(A)(i), (ii). The FFDCA has a separate requirement protecting infants and children. EPA must separately assess the risk of the pesticide based on available information concerning consumption patterns, special susceptibility, and cumulative effects unique to infants and children. *Id.* § 346a(b)(2)(C)(i). Based on this assessment, EPA must “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure” and “publish a specific determination regarding safety” of the pesticide for infants and children. *Id.* § 346a(b)(2)(C)(ii). In making these determinations, EPA “shall consider . . . the validity, completeness, and reliability of the available data” and “available information concerning the relationship of the results of such studies to human risk.” *Id.* § 346a(b)(2)(D)(i), (iii).

In addition to establishing safe tolerance levels for pesticides under the FFDCA, EPA regulates pesticides under FIFRA by issuing registrations required for distribution or sale. 7 U.S.C. § 136a(a). EPA may register a pesticide where, in addition to other requirements, “it will perform its intended function without unreasonable adverse effects on the environment” and “when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.” *Id.* § 136a(c)(5)(C), (D). “Unreasonable adverse effects on the environment” are unreasonable risks to man or the environment, including “human dietary risk . . . inconsistent with the standard under section 346a of Title 21.” *Id.* § 136(bb). Thus, FIFRA incorporates the FFDCA safety determination into its registration assessment.

At the time the FQPA was passed in 1996, there were a number of existing tolerances in effect. The use of

chlorpyrifos, for example, has been federally authorized since 1965. *See Chlorpyrifos; Final Order Denying Objections to March 2017 Petition Denial Order*, 84 Fed. Reg. 35,555, 35,558 (July 24, 2019) (*Final Order*). The FFDCA, as amended by the FQPA, provided that “[r]egulations that establish tolerances” issued on or before August 3, 1996, “shall remain in effect unless modified or revoked.” 21 U.S.C. § 346a(j)(3). The Act also instructed EPA to “review tolerances and exemptions for pesticide chemical residues in effect on [August 2, 1996],” and to determine whether to leave in effect, “modify or revoke” those tolerances in accordance with the new standards. *Id.* § 346a(q)(1).² The FFDCA provided that EPA “shall . . . modify or revoke the tolerance or exemption if the tolerance or exemption does not meet such requirements.” *Id.* The FFDCA further provided that at any time EPA could, on its own initiative, issue regulations “establishing, modifying, . . . or revoking a tolerance for a pesticide . . .” *Id.* § 346a(e)(1)(A). Once a pesticide has been approved and registered, FIFRA requires EPA to reevaluate the registration within 15 years, in this case no later than October 2022. 7 U.S.C. § 136a(g)(1)(A)(iii), (iv). During FIFRA reregistration, EPA must decide whether to leave a tolerance in effect or revoke or modify it. *Id.* § 136a(g)(1)(A).

The general standards for establishing, leaving in effect, modifying, or revoking tolerances are found in § 346a(b)(2)(A)(i):

² The FQPA required EPA to review tolerances in existence in 1996 according to a priority schedule. 21 U.S.C. § 346a(q)(1), (2). EPA placed chlorpyrifos in its first priority group and completed its review in 2006. *Final Order*, 84 Fed. Reg. at 35,558.

The Administrator may establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe. The Administrator shall modify or revoke a tolerance if the Administrator determines it is not safe.

These sentences are awkwardly written. For readability we can transpose them as follows:

Only if the Administrator determines that a tolerance for a pesticide chemical residue in or on a food is safe may the Administrator establish or leave in effect the tolerance.³ If the Administrator determines a tolerance is not safe, the Administrator shall modify or revoke the tolerance.

These standards are consistent with the presumption against the use of pesticides in food. *If* EPA determines a pesticide is safe, *then* EPA *may* establish a new tolerance or leave in place a tolerance previously established. However, *if* EPA determines a tolerance is not safe, *then* EPA *shall* modify or revoke the tolerance. Establishing or leaving a tolerance in place is not mandatory, even if EPA determines that a pesticide is safe; but if EPA determines a tolerance is not safe, it must modify or revoke the tolerance.

³ This sentence could also be written as “If the Administrator establishes or leaves in effect a tolerance, then he has determined that the tolerance is safe.”

When acting on its own initiative or in response to a petition,⁴ the FFDCA requires EPA to consider “the validity, completeness, and reliability of the available data from studies of the pesticide” as well as other available information concerning risks and effects. § 346a(b)(2)(D). The statute also authorizes EPA to adopt regulations governing “requirements for information and data to support a petition to modify or revoke a tolerance.” § 346a(d)(1), (d)(2)(B). EPA has issued regulations establishing these requirements and mandating supporting data and studies. 40 C.F.R. § 180.32(b). A petition must be supported by “reasonable grounds for the action sought,” including “an assertion of facts (supported by data if available)” that “may justify [the tolerance’s] modification or revocation.” *Id.* § 180.32(b). The regulations also specify the form and content required for a petition. *Id.* § 180.7(b). Under its regulations, EPA may deny a petition when it finds that a petition is not supported by “reasonable grounds” for revocation. *Id.* § 180.32(b).

B

Now to the majority’s errors. The majority reads § 346a(b)(2)(A)(i) as creating a binary choice, an “either/or” scenario: either a tolerance is “safe” or it is “not safe.” For the majority, there is no middle ground. *See Maj. Op.* at 13, (“If a tolerance is not safe—in other words, if the EPA cannot determine that there is a reasonable certainty of no harm across all sources of exposure for infants, children, and adults—then the EPA no longer has discretion.”), 62–63

⁴ The FFDCA provides a mechanism for interested persons to petition EPA to “propos[e] the issuance of a regulation establishing, modifying, or revoking a tolerance for a pesticide chemical residue in or on a food.” *Id.* § 346a(d)(1)(A).

(“EPA has not determined . . . that aggregate chlorpyrifos exposures under the current tolerances pose no risk of harm. Therefore, by statutory definition, the present tolerances are not safe.”). The majority’s logic is irrefutable because the statement is, of course, a tautology. But as a tautology it is not helpful, because it doesn’t tell us anything about the actual state of affairs. As Ludwig Wittgenstein once commented, “I know nothing about the weather when I know that it rains or does not rain.”⁵ The problem with the majority’s reasoning is, in a phrase, the fallacy of the excluded middle. See *Wall v. Mich. Rental*, 852 F.3d 492, 496 (6th Cir. 2017) (“[A] statement of two contradictory facts [is] a statement of nothing at all under a venerable principle of logic—the law of the excluded middle.”); *Miller v. Henman*, 804 F.2d 421, 426 (7th Cir. 1986) (rejecting the “Law of the Excluded Middle” in favor of “a third alternative”). It is true that § 346a(b)(2)(A)(i) uses the terms “safe” and “not safe.” But the context for the terms is different. The terms are opposites, but they do not exhaust the possible outcomes.

We should be familiar with the problem of the excluded middle from other areas of law and life. For example, “guilty” and “not guilty,” as logical opposites, describe the universe, so long as we don’t care about factual innocence. But if we do, we have to consider a third alternative. Thus, we have examples where courts have gone beyond the binary thinking of guilty/not guilty to declare persons “factually innocent.” See *Humphries v. Cnty. of L.A.*, 554 F.3d 1170, 1181–82 & nn. 6, 8 (9th Cir. 2009) (discussing the legality and effect of findings of “factually innocent” by a California criminal court and “not true” by a California juvenile court

⁵ Ludwig Wittgenstein, *Tractatus Logico-Philosophicus*, quoted in Joseph G. Brennan, *A Handbook of Logic* 160 (2d ed. 1961).

in a child abuse case), *rev'd in part on other grounds*, *Cnty. of L.A. v. Humphries*, 562 U.S. 29 (2010). Other countries offer juries the option of a third verdict. See Samuel L. Bray, Comment, *Not Proven: Introducing a Third Verdict*, 72 U. Chi. L. Rev. 1299, 1299–1300 (2005) (“Not proven and not guilty are both acquittals, indistinguishable in legal consequence but different in connotation. Not guilty is for a defendant the jury thinks is innocent; not proven, for a case with insufficient evidence of guilt”; citing Scottish law as an example). In football, a ruling may be overturned only if there is indisputable evidence that it was wrong. But what if the ruling is not indisputably wrong? Do we care if it was correct, or just “not wrong”? Turns out that we do. The presumption will lie with the official who made the call. If the ruling cannot be overturned, “the ruling on the field stands.” But if the ruling on the field is correct, then “the ruling on the field is confirmed.” See *NCAA Football Rules Book* R. 12, § 6, art. 1.d (2019) (distinguishing three options: “the ruling on the field is confirmed,” “the ruling on the field stands,” and reversing a ruling). There is no practical difference in the immediate effect on the game between “the ruling on the field stands” and “the ruling on the field is confirmed,” but there are collateral consequences for officials and for the lively debates among the fans that inevitably follow in close games.

The majority’s premise that a pesticide is either “safe” or “not safe” ignores an important alternative—namely, that there is insufficient information to reach either of those conclusions. That is why Congress instructed EPA to consider “the validity, completeness, and reliability of the available data”—it understood that the evidence might be inconclusive. 21 U.S.C. § 346a(b)(2)(D)(i). That is also why § 346a(b)(2)(A)(i) allocates a burden of persuasion. I hesitate to use the term “burden of proof” because it suggests

that EPA and petitioners are adverse to each other; they are not. EPA is responsible for regulating pesticide use and, as a court, we assume that it has developed an expertise. We also assume that EPA will be an honest broker in assessing the safety of a pesticide; after all, agency employees have to eat the same food we do. So instead of “burden of proof,” I am going to use the term “risk of nonpersuasion.”

Here is how the risk of nonpersuasion figures into the FFDCA. When EPA receives a petition, it has a duty of inquiry, but it is a different duty depending on whether the decision on the table is whether to *establish or leave in effect* a tolerance (the first sentence of § 346a(b)(2)(A)(i)) or to *modify or revoke* a tolerance (the second sentence in that subsection). EPA (or a petitioner) has the initial burden to show that a proposed tolerance can be safely established. If the proposal does not satisfy that standard, EPA cannot adopt the proposed tolerance. EPA has the same burden when it considers an existing tolerance for reregistration. Recall that when the FQPA was adopted in 1996, that Act tightened the standards for pesticides. Because EPA had approved pesticides in use, the FQPA required EPA to review and reregister all existing tolerances to determine whether to “leave in effect” those tolerances. 21 U.S.C. §§ 346a(j)(3), (q)(1). Additionally, the FQPA, amending FIFRA, mandated that following that reregistration, EPA must review existing tolerances no less frequently than every 15 years. 7 U.S.C. § 136a(a), (g)(1)(A)(iv). In these reregistration proceedings, EPA must conclude that the existing tolerance is “safe” before it can “leave [it] in effect.” 21 U.S.C. § 346a(b)(2)(A)(i). What happens if the evidence is inconclusive? Since there is a presumption that all pesticides are “unsafe,” *id.* § 346a(a)(1), the risk of nonpersuasion means that EPA must either approve the tolerance or exempt it under other provisions of the FFDCA,

see id. § 346a(a)(1)(A), (B). As I transposed § 346a(b)(2)(A)(i) for readability, “only if the Administrator determines that the tolerance is safe may [the Administrator] establish or leave in effect a tolerance.”

By contrast, when a petitioner requests modification or revocation of an existing tolerance, the risk of nonpersuasion cuts in the opposite direction. EPA has previously found the tolerance to be “safe.” If EPA subsequently determines that the pesticide is “not safe,” then it must modify or revoke the tolerance. What happens if the evidence is inconclusive? The risk of nonpersuasion means that EPA may, but does not have to, modify or revoke the tolerance. Section 346a(b)(2)(A)(i) is clear (as I have revised it for readability): “If the Administrator determines a tolerance is not safe, the Administrator shall modify or revoke the tolerance.” Accordingly, when a petitioner files an appropriate petition claiming that a tolerance is not safe, EPA assumes a duty of inquiry, but not a duty of declaring anew that the tolerance is “safe.” Here is the crucial distinction: *determining that a tolerance is “not safe”* is not the same as *not determining that a tolerance is “safe.”* The majority’s either/or approach has excluded the middle. As the First Circuit explained, albeit in a different context:

Confronted by such conflict a reasonable person investigates matters further; he receives assurances or clarification before relying. A reasonable person does not gamble with the law of the excluded middle, he suspends judgment until further evidence is obtained. Explicit conflict engenders doubt, and to rely on a statement the veracity of which one should doubt is unreasonable. The law does not supply epistemological

insurance. Nor does it countenance reliance on one of a pair of contradictories simply because it facilitates the achievement of one's goal.

Trifiro v. Nw. York Life Ins. Co., 845 F.2d 30, 33–34 (1st Cir. 1988).

The majority's either/or treatment of § 346a(b)(2)(A)(i) has two important consequences. First, it effectively reads the second sentence of that subsection out of the statute because, in the majority's understanding, EPA always has the burden to show that a tolerance is "safe," which means that it is, by definition, not "not safe." Or, to put it another way, in the majority's view, if at any time EPA does not affirmatively declare that a tolerance is "safe," the tolerance is, again by definition, "not safe." Under the majority's reading, the second sentence of § 346a(b)(2)(A)(i) doesn't do any work because in order to determine that a tolerance is "not safe" EPA must decide that it is not "safe." In other words, for the majority, in every case EPA has a duty of reregistration. The reason the majority has committed this error of logic is that it fails to appreciate the different context for the two sentences in § 346(b)(2)(A)(i). In the first sentence, the presumption runs against the tolerance because EPA is required to establish or reregister ("leave in effect") the tolerance. In the second sentence, *EPA has already determined that the tolerance is "safe,"* so the question is whether there is enough evidence to show that it is "not safe." When EPA denies a petition for insufficient evidence, it may rely on its prior determination that the tolerance is "safe." The two sentences operate in different contexts.

Second, the majority's reading means that petitioners can seize control of the statutory schedule for reviewing existing

tolerances. Under the FQPA, EPA had to review all existing tolerances, such as chlorpyrifos, under the new standard. And it had to do so “as expeditiously as practicable,” but no later than 2006. 21 U.S.C. § 346a(q)(1). This EPA did in 2006, leaving in effect the chlorpyrifos tolerance. Under the FIFRA and the FFDCA, EPA would have to reevaluate chlorpyrifos for reregistration no later than October 2022. See 7 U.S.C. § 136a(g)(1)(A)(iv); *Final Order*, 84 Fed. Reg. at 35,558. In the interim, any interested person may petition EPA to modify or revoke the tolerance. Under the majority’s reading of the FFDCA, to respond to the petition, EPA must either reregister chlorpyrifos as “safe” or modify or revoke the tolerance—but in either case the petition has altered the statutory review process for chlorpyrifos. Since petitioners can file petitions at will, EPA has lost control over its docket, and the statutory schedule has been derailed. As EPA put it, if

EPA were required to truncate its ongoing registration review process to make a new FFDCA safety finding every time it received a petition to modify or revoke tolerances, petitioners would effectively have the authority to re-order the Administrator’s scheduling of registration review decisions under FIFRA and dictate the extent of inquiry EPA may put to a matter before reaching a resolution.

Final Order, 84 Fed. Reg. at 35,565.

C

Despite the (relative) clarity of these provisions, the majority makes two arguments to get around this reading of § 346a(b)(2)(A)(i). First, the majority holds that any time

EPA considers a petition to modify or revoke an existing tolerance (which is governed by the second sentence of § 346a(b)(2)(A)(i)), it is “leave[ing] in effect” the tolerance (which is governed by the first sentence). *Maj. Op.* at 41–42. It concludes that EPA has “a continuous duty” under the FFDCA “to ‘leave in effect’ a tolerance ‘only’ if it finds it is safe.” *Id.* at 42. Second, the majority claims that once EPA accepted the petition, because it was not “wholly frivolous,” EPA had an independent duty to determine whether chlorpyrifos is “safe” and cannot now claim that the petition was “somehow inadequate.” *Id.* at 42, 47. Neither point withstands scrutiny.

The majority’s focus on EPA “leaving in effect” the chlorpyrifos tolerance misconceives the proceedings. Under the FFDCA, any petitioner had the right to petition EPA to “establish[], modify[] or revok[e]” a tolerance. 21 U.S.C. § 346a(d)(1)(A). “Leave in effect” is not mentioned as an option in the petition subsection, and for good reason: “leave in effect” has a particular context and meaning in the FFDCA. As I have explained, prior to the adoption of the FQPA in 1996, which established the current statutory standards in the FFDCA, there were tolerances in place for pesticides such as chlorpyrifos. The FQPA imposed a duty and a schedule on EPA to review all existing tolerances and to decide whether to “leave in effect” those tolerances. 21 U.S.C. § 346a(q)(1). *See also id.* § 346a(l)(3)(B) (explaining if EPA suspends a tolerance it “shall not be considered to be in effect,” but if the suspension is terminated, “leaving the registration of the pesticide for such use in effect,” EPA must rescind the suspension). Because the prior tolerances were not established under the same standards demanded by the FFDCA, as amended by the FQPA, EPA had to determine afresh that the preexisting tolerances were “safe.” With respect to that review, EPA

could “leave in effect a tolerance . . . only if the Administrator determines that the tolerance is safe.” *Id.* § 346a(b)(2)(A)(i). Under FIFRA, EPA must also re-certify its tolerances no less than every 15 years and decide whether to leave a tolerance in effect or modify or revoke it. 7 U.S.C. § 136a(g)(1)(A).⁶ The majority has conflated EPA’s responsibility with respect to the preexisting tolerances with its responsibility when it reviews a petition.

The majority reaches its conclusion because it reads § 346a(b)(2)(A)(i) in isolation from the rest of the statute. That leads the majority to consider a dictionary definition of the phrase. *Maj. Op.* at 42. Dictionaries can be useful for understanding terms. Here, recurring to a dictionary is neither necessary nor useful, because the term “leave in effect” is not ambiguous when it is read in context with the remainder of the statute. *See Carson Harbor Vill., Ltd. v. Unocal Corp.*, 270 F.3d 863, 878 (9th Cir. 2001) (en banc)

⁶ Contrary to the majority’s statements, FIFRA incorporates the FFDCA’s standards. *See* 7 U.S.C. § 136(bb) (referring to “the standard under Section 346a of Title 21”). As part of its reregistration requirements for licensing, FIFRA requires EPA to review its FFDCA standards no less than every 15 years. *See Final Order*, 84 Fed. Reg. at 35,557 (“In the FQPA, Congress integrated action under the two statutes by requiring that the safety standard under the FFDCA be used as a criterion in FIFRA registration actions for pesticide uses that result in residues in or on food.”). Because FIFRA requires periodic recertification under FFDCA, the FFDCA standard governs chlorpyrifos’s use, independent of anything required for licensing under FIFRA. The majority repeatedly misses this point. *See Maj. Op.* at 43–44 (“[EPA’s claim that reregistration is required by FIFRA] is unpersuasive because of the differences between FIFRA and the FFDCA. The statutes impose different duties that require different assessments.”), 51 (“FIFRA registration review . . . is a different animal, in that it permits a balancing of multiple factors, whereas a FFDCA review is limited to the sole issue of safety . . .”).

(“Where the language is plain and admits of no more than one meaning the duty of interpretation does not arise, and the rules which are to aid doubtful meanings need no discussion.” (quoting *Caminetti v. United States*, 242 U.S. 470, 485 (1917)); see also *Hughes Aircraft Co. v. Jacobson*, 525 U.S. 432, 438 (1999) (“[W]here the statutory language provides a clear answer, [the inquiry] ends there . . .”); *Robinson v. Shell Oil Co.*, 519 U.S. 337, 340 (1997) (“Our inquiry must cease if the statutory language is unambiguous and the statutory scheme is coherent and consistent.” (internal quotation marks and citations omitted)); *United States v. Williams*, 659 F.3d 1223, 1225 (9th Cir. 2011) (“If the plain meaning of the statute is unambiguous, that meaning is controlling . . .”). When the statute offers a definition of a term, the statutory definition—even if it is a functional usage—governs. *Carson Harbor Vill.*, 270 F.3d at 878 (“When a statute includes an explicit definition, however, we must follow that definition, even if it varies from that term’s ordinary meaning.” (quoting *Stenberg v. Carhart*, 530 U.S. 914, 942 (2000) (alteration omitted)); see also *United States v. Havelock*, 664 F.3d 1284, 1289 (9th Cir. 2012) (en banc) (“Statutory construction must begin with the language employed by Congress and the assumption that the ordinary meaning of that language accurately expresses the legislative purpose. That assumption, however, does not apply where Congress provides a statutory definition.” (internal citations and quotation marks omitted)). The FFDCA, as amended by the FQPA, is quite clear that “leave in effect” refers to a particular kind of proceeding mandated by Congress.

That brings us to the majority’s second point. The majority attempts to shift the risk of nonpersuasion through a contorted reading of EPA’s regulations regarding the filing of a petition. According to the majority, EPA has a

“gatekeeping authority to reject a wholly frivolous petition.” Maj. Op. at 47. But if EPA accepts a petition, it “trigger[s] the EPA’s duty to ensure a reasonable certainty of no harm” by re-evaluating chlorpyrifos and, if it decides to “leave in effect” the tolerance, it must certify chlorpyrifos as “safe.” *Id.* According to the majority, accepting a petition flips the risk of nonpersuasion. But EPA’s regulations say nothing of the kind.

In an exercise of its “gatekeeping authority,” EPA has adopted “Procedure for modifying and revoking tolerances or exemptions from tolerances.” 40 C.F.R. § 180.32. That regulation provides in relevant part:

Any person may file with the Administrator a petition proposing the issuance of a regulation modifying or revoking a tolerance or exemption from a tolerance for a pesticide chemical residue. The petition shall furnish reasonable grounds for the action sought. Reasonable grounds shall include . . . an assertion of facts (supported by data if available) showing that new uses for the pesticide chemical have been developed or old uses abandoned, that new data are available as to toxicity of the chemical, or that experience with the application of the tolerance or exemption from tolerance may justify its modification or revocation.

Id. § 180.32(b). There is not a word in the regulation that would affect the risk of nonpersuasion. The regulation requires little to be a qualifying petition: “reasonable grounds,” including “an assertion of facts” which shall be “supported by data *if available.*” *Id.* (emphasis added). That

is the most modest of rules. EPA will generously accept such petitions and consider them. Accepting a petition—which in the majority’s phrase means that they are not “wholly frivolous”⁷—is the lowest of bars. This is as it should be. We want interested persons—“any person”—to be able to go to EPA and suggest that it take a second look at a tolerance for a pesticide going on our food. But the majority takes EPA’s decision to accept the petition as nullifying EPA’s prior decision to approve the tolerance; effectively, EPA must start all over again. That’s not how administrative law usually works. Under the FFDCA, EPA must modify or revoke the tolerance if it is “not safe.” The majority would require EPA to prove that the tolerance is “safe.”

Although EPA’s *Final Order* was overdue, there was nothing improper in its form. EPA denied the petition and instead relied upon its 2006 safety determination for chlorpyrifos tolerances because it found that the data and studies supporting the petition were “not sufficiently valid, complete, and reliable” to support revocation. *Final Order*, 84 Fed. Reg. at 35,562–63. In other words, the data supporting the petition was not sufficient to support a determination that chlorpyrifos tolerances are “not safe.” 21 U.S.C. § 346a(b)(2)(A)(i).

The FFDCA does not require EPA to make a new safety determination in response to a petition supported solely by studies that EPA has already considered and found insufficient for revocation while conducting its FIFRA review. Here, EPA considered the petition’s cited studies at multiple instances during its own review and found that they

⁷ So far as I can tell, the phrase “wholly frivolous” belongs to the majority.

were not reliable enough to support revocation without more information. See *Final Order*, 84 Fed. Reg. at 35,563. The agency's determination that the petition did not present sufficiently valid, complete, or reliable information to support revocation is thus supported by the record. See § 346a(b)(2)(D). Because the 2007 petition did not present reasonable grounds for modification or revocation, EPA was entitled to rely upon its 2006 safety finding while it engaged in its FIFRA review of chlorpyrifos tolerances. The tolerance had already been deemed "safe," and the petition did not raise sufficient grounds to overcome that presumption.

Under a correct reading of the statute, and proper allocation of the risk of nonpersuasion, we should be reviewing EPA's determination that the petition, and the evidence it mustered, was insufficient to determine that the chlorpyrifos tolerance is "not safe." That is not the inquiry the majority conducts, so in Part II I will review the proceedings before EPA, as punctuated by our orders, and its *Final Order*, which is the only decision we have authority to review. 5 U.S.C. § 704.

II

EPA's denial of the 2007 petition was not arbitrary or capricious. The denial of the petition did not conflict with any final agency findings or conclusions and, to the contrary, was supported by the extensive record of EPA's concerns with the petition's supporting studies over the course of nearly a decade. The only final agency action in effect for chlorpyrifos tolerances is the 2006 safety determination, and EPA's denial of the petition comports with this determination.

I will begin with a brief review of EPA's 2006–17 proceedings, with some emphasis on the questions and qualifications EPA raised at each step of those proceedings. I will then turn to the *Final Order* and our review under the APA.

A

In 2006, pursuant to the FFDCA, EPA completed a tolerance reassessment of chlorpyrifos and found that chlorpyrifos was eligible for reregistration and met the standard of 21 U.S.C. § 346a(b)(2). EPA, Office of Prevention, Pesticides and Toxic Substances, *Memo to Jim Jones from Debra Edwards, Finalization of Interim Reregistration Eligibility Decisions and Interim Tolerance Reassessment and Risk Management Decisions for the Organophosphate Pesticides, and Completion of the Tolerance Reassessment and Reregistration Eligibility Process for the Organophosphate Pesticides* (July 31, 2006) (2006 Reregistration Decision); see also *Final Order*, 84 Fed. Reg. at 35,558. In doing so, EPA found that chlorpyrifos tolerances were safe and left them in effect.

1. The Petition is filed; EPA conducts various studies for reregistration

In September 2007, the Pesticide Action Network North America (PANNA) and the National Resources Defense Council (NRDC) filed a petition with EPA to revoke all tolerances for chlorpyrifos based on new studies purporting to show that current chlorpyrifos tolerances were not safe. See *Petition to Revoke All Tolerances and Cancel All Registrations for the Pesticide Chlorpyrifos; Notice of Availability*, 72 Fed. Reg. 58,845 (Oct, 17, 2007); see also *Final Order*, 84 Fed. Reg. at 35,556. Petitioners raised ten claims alleging numerous errors in the 2006 Reregistration

Decision, including claims that EPA ignored or misinterpreted data.⁸ EPA was able to resolve seven of the ten claims relatively quickly. In July 2012 and July 2014, EPA issued interim responses indicating its intent to deny all but the three claims at issue here (grounds 7–9 in the petition), and it informed Petitioners of its intent to finalize all interim conclusions (grounds 1–6, and 10) when it resolved the remaining three claims, a decision to which Petitioners did not object. *Final Order*, 84 Fed. Reg. at 35,556; see also *In re Pesticide Action Network North America (PANNA I)*, 532 F. App'x 649 (9th Cir. 2013) (denying petition for mandamus). The three claims not addressed by EPA in those responses were interrelated and concerned the potential for chlorpyrifos exposure at current tolerance levels to cause neurodevelopmental effects in children. *Final Order*, 84 Fed. Reg. at 35,556. However, EPA did not give these claims short shrift. Instead, early in its review, in 2009, the agency found the issues raised important enough questions that they should be addressed as part of an accelerated reregistration review of chlorpyrifos. *Id.* at 35,556 (noting that these claims “raised novel, highly complex scientific issues” that should be addressed in EPA’s

⁸ Petitioners alleged that EPA: (1) “ignored genetic evidence of vulnerable populations”; (2) “needlessly delayed a decision regarding endocrine disrupting effects”; (3) “ignored data regarding cancer risks”; (4) “misrepresented risks and failed to apply FQPA 10X safety factor” in its 2006 cumulative risk assessment; (5) “over-relied on registrant data”; (6) “failed to properly address the exporting hazard in foreign countries from chlorpyrifos”; (7) “failed to quantitatively incorporate data demonstrating long-lasting effects from early life exposure to chlorpyrifos in children”; (8) “disregarded data demonstrating that there is no evidence of a safe level of exposure during pre-birth and early life stages”; (9) “failed to cite or quantitatively incorporate studies and clinical reports suggesting potential adverse effects below 10% cholinesterase inhibition”; and (10) “failed to incorporate inhalation routes of exposure.” *Final Order*, 84 Fed. Reg. at 35,556.

expedited reregistration review). Despite its 2022 statutory deadline, EPA announced that it planned to prioritize review of chlorpyrifos and complete reevaluation by 2015, years ahead of schedule. *Id.* at 35,558. However, this review proved to be complex, particularly with regard to the potential human health risks and neurodevelopmental effects of chlorpyrifos tolerances. *Id.*

In the interim, EPA convened scientific panels to evaluate the evidence and published reports. In 2008, as part of its reregistration review, EPA published a Science Issue Paper addressing chlorpyrifos hazards. EPA, Office of Pesticide Programs, *Science Issue Paper: Chlorpyrifos Hazard and Dose Response Characterization* (Aug. 21, 2008). The paper summarized “data relevant to infants, children, and pregnant women,” interpreted this data, and suggested alternatives for updating the mechanism used to assess chlorpyrifos tolerance safety. *Id.* at 7. The paper “preliminarily concluded that chlorpyrifos likely played a role in” adverse health effects in children. *Id.* at 52. However, the paper specifically noted that there had not been “a full and complete risk assessment/characterization” of the human health risks of chlorpyrifos and that “the [EPA] has not developed any final conclusions regarding updates to the chlorpyrifos hazard assessment.” *Id.* at 7.

Later that year, EPA convened a Science Advisory Panel (SAP or the Panel), a federal advisory committee “established under the provisions of FIFRA” that “serves as the [EPA’s] primary scientific peer review mechanism” for pesticide matters, to peer review the paper. EPA, *SAP Minutes No. 2008-04: A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding: The Agency’s Evaluation of the Toxicity Profile of Chlorpyrifos 2* (Sept. 16–18, 2008). The SAP also

considered several new studies concerning the risk of chlorpyrifos to pregnant women and children. The SAP's evaluation noted that "Panel members were concerned that a high degree of uncertainty is evident in the available data" *Id.* at 10. First, the Panel expressed concerns about several laboratory studies involving live rodents and the meaning of phrases used and experimental methods employed, and concluded that this data was "insufficient." *Id.* at 11–12. The Panel also considered three epidemiology studies, referred to as the Mt. Sinai, CHAMACOS, and Columbia University studies. The Columbia Study, which assessed chlorpyrifos risk to pregnant women, infants, and children, commanded particular attention. *Id.* at 12. The Panel found defects in all three of the studies, including concerns that the Columbia Study—the most robust of the three—did not provide sufficient data to be the sole factor for risk assessment or modifying tolerances and produced uncertainty through its measurement method. *Id.* at 12–13, 32–35, 43–44. Although the SAP found that the studies "raise concerns," the SAP also agreed that the studies were inconclusive. *Id.* at 13–14. The SAP concluded that "chlorpyrifos could have contributed to the birth and neurodevelopmental outcomes" indicated in the studies, but "that due to their limitations, the epidemiological data currently available are useful primarily for hazard identification." *Id.* at 13.

In 2011, EPA published a Preliminary Human Health Risk Assessment (*PHHRA*) for chlorpyrifos as part of its forthcoming FIFRA review. EPA, Office of Chemical Safety & Pollution Prevention, *Chlorpyrifos: Preliminary Human Health Risk Assessment for Registration Review* 1–2 (June 30, 2011). This assessment again considered the laboratory and epidemiology studies evaluated by the 2008 SAP and similarly noted their limitations. *Id.* at 29–34. The

PHHRA also considered developments since the 2008 SAP, including new data and follow-up analysis on the Columbia Study that had been recommended by the Panel. *Id.* at 34. EPA came to no definitive conclusion in the *PHHRA*, instead stating that analyses were ongoing and the final assessment would

be based on a full scientific weight of evidence approach that considers the best available science and integrates all key lines of evidence, from empirical animal toxicology to observational human epidemiology studies, in an integrated framework analysis and will transparently address and clearly characterize the strength of the evidence and areas of remaining uncertainty and variability.

Id. at 42.

In April 2012, EPA again convened the SAP to consider the health effects of chlorpyrifos. EPA, *SAP Minutes 2012-04: A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding Chlorpyrifos Health Effects* (April 10–12, 2012). The SAP recognized “a growing body of literature with laboratory animals (rats and mice) indicating that gestational and/or early postnatal exposure to chlorpyrifos may cause persistent effects into adulthood” and epidemiology studies “that have reported associations with birth outcomes, childhood neurobehavioral and neurodevelopment outcomes.” *Id.* at 10. In addition to nine new laboratory studies, the 2012 SAP reviewed the same laboratory studies evaluated by the 2008 SAP, again noting the laboratory studies’ limitations and “recommend[ing] these experimental outcomes be

regarded as exploratory, and hypothesis-generating, as opposed to being evidence of toxicity.” *Id.* at 15. However, the Panel found that, despite concerns about the studies, “the collective weight of evidence from these studies demonstrate that it is probable that there are significant long-term adverse effects from chlorpyrifos exposure.” *Id.* at 16. The 2012 SAP likewise considered the same epidemiology studies analyzed by the 2008 SAP, recognizing their strengths and limitations. *Id.* at 17–18, 48–50. The Panel noted that the epidemiological studies indicated “that chlorpyrifos likely plays a role in impacting the neurodevelopmental outcomes examined in the three cohort studies” but proposed further study because “the data generated from these studies alone are not adequate enough” to make a definitive risk assessment. *Id.* at 18–19. The SAP advised EPA to “explore additional ways of using these studies” and conduct additional research. *Id.* at 19–20.

In December 2014, EPA published a Revised Human Health Risk Assessment (*2014 RHHRA*) for chlorpyrifos. EPA, Office of Chemical Safety & Pollution Prevention, *Chlorpyrifos: Revised Human Health Risk Assessment for Registration Review* (Dec. 29, 2014). This revised assessment incorporated comments on the preliminary assessment and included assessment of new data. *Id.* at 5. The *2014 RHHRA* found that data, including the laboratory and epidemiology studies, “indicate that chlorpyrifos likely played a role in the neurodevelopmental outcomes reported by the epidemiologic study (Columbia University) investigators” but that “uncertainties . . . preclude definitive causal inference.” *Id.* at 6. Yet again, EPA noted that the studies reflected both strengths and “notable limitations.” *Id.* at 43. In this assessment, EPA also revised its approach to calculating chlorpyrifos “points of departure,” or the

ceiling for safe exposure to a pesticide based on these studies. *Id.* at 40, 62–70, 131.

In January 2015, EPA announced the availability of the 2014 RHHRA and sought public comments on “the Agency’s risk assessment methodologies and assumptions . . . [and] suggestions for mitigating any risks identified in the [2014 RHHRA].” *Chlorpyrifos Registration Review; Revised Human Health Risk Assessment; Notice of Availability*, 80 Fed. Reg. 1,909, 1,910 (Jan. 14, 2015). Additionally, in March 2015, EPA advised counsel for the petitioners by letter that it intended to deny the three unresolved claims in the 2007 Petition—the claims at issue in this appeal. EPA, Office of Chemical Safety & Pollution Prevention, *Re: Chlorpyrifos Petition Dated September 12, 2007; March 2015 Provisional Response* (Mar. 26, 2015). EPA incorporated its prior partial petition responses from 2012 and 2014, which denied seven of the ten claims raised in the petition. *Id.* With respect to the three remaining claims, which were those related to infants and children and based on the Columbia, Mount Sinai, and CHAMACOS studies, EPA advised counsel that “EPA does not believe the claims raised in your petition establish a basis to revoke all chlorpyrifos tolerances and cancel all chlorpyrifos registrations.” *Id.* at 3. The letter noted that EPA had “risk concerns” with exposure to chlorpyrifos in drinking water, but it was seeking comment on its 2014 RHHRA and would “take appropriate action under the FFDCA and/or FIFRA to ensure that exposures to chlorpyrifos are consistent with the requirements of those statutes.” *Id.* at 3–4.

2. We issue mandamus; EPA proposes to revoke the tolerances

Six months later, in August 2015, we issued a writ of mandamus ordering EPA “to issue either a proposed or final

revocation rule or a full and final response to the administrative petition.” *In re Pesticide Action Network North America (PANNA II)*, 798 F.3d 809, 815 (9th Cir. 2015). In response, EPA issued a proposed rule to revoke all chlorpyrifos tolerances because “EPA cannot, at this time, determine that aggregate exposure to residues of chlorpyrifos, including all anticipated dietary exposures and all other non-occupational exposures for which there is reliable information, are safe.” *Chlorpyrifos; Tolerance Revocations*, 80 Fed. Reg. 69,080, 69,080–81 (Nov. 6, 2015) (*2015 Proposed Rule*). EPA advised that it was issuing the proposed rulemaking because of our mandamus order and that the proposal was “in advance of [EPA] completing its refined drinking water assessment.” *Id.* at 69,083. EPA explained that it “believe[d] that acute dietary risk from food only does not present a significant risk” and that “EPA would therefore not be proposing the revocation of chlorpyrifos if dietary exposures were confined to food.” *Id.* at 69,096–97. The basis for the proposed revocation was instead new data indicating that “for some portions of the country, food exposures, when aggregated with residential exposures and potentially more significant drinking water exposures, do present a significant risk concern and support revocation of all chlorpyrifos tolerances.” *Id.* at 69,097. At the same time, EPA stated that it had “insufficient time to address comments received on the [2014] RHHRA,” and it would “update this action . . . as EPA completes additional work.” *Id.* at 69,083. EPA also cautioned that its analysis was incomplete and that it might yet modify the proposed rule based on the completed analysis and comments. *Id.* We then ordered EPA to take final action on the proposed rule and on PANNA and NRDC’s petition no later than December 30, 2016. *In re Pesticide Action Network North America (PANNA III)*, 808 F.3d 402, 403 (9th Cir. 2015).

In March 2016, EPA published a new Chlorpyrifos Issue Paper and solicited comment from the SAP regarding changing points of departure based solely on neurodevelopmental effects measured by the Columbia Study. EPA, Office of Pesticide Programs, *Chlorpyrifos Issue Paper: Evaluation of Biomonitoring Data from Epidemiology Studies 9* (Mar. 11, 2016) (2016 Issue Paper). At the time EPA had proposed to revoke chlorpyrifos tolerances, “EPA had not completed a refined drinking water assessment or additional analysis of the hazard from chlorpyrifos that was suggested by several commenters.” EPA, Office of Chemical Safety & Pollution Prevention, *Chlorpyrifos: Revised Human Health Risk Assessment for Registration Review 3* (Nov. 3, 2016) (2016 RHHRA). After engaging in additional research, EPA—in this Issue Paper—proposed using different “toxicological points of departure” based on data from the Columbia Study, and sought the advice of the 2016 SAP on this new approach. 2016 Issue Paper at 9.

In April 2016, the SAP convened to review the Issue Paper. EPA, *SAP Minutes No. 2016-01: A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding: Chlorpyrifos: Analysis of Biomonitoring Data* (April 19–21, 2016) (2016 SAP Minutes). The SAP expressed significant disagreement with the substance of the paper, including a lack of confidence that the Columbia Study “c[ould] accurately be used” in determining new points of departure. *Id.* at 18. The panel “thought the quality of the [Columbia Study] data is hard to assess when raw analytical data have not been made available, and the study has not been reproduced.” *Id.* The SAP noted that review of the raw data from the Columbia Study could resolve some uncertainty regarding the study’s conclusions. *Id.* at 20.

By mid-2016, claiming “extraordinary circumstances,” EPA requested a six month extension on our order of final action. *In re Pesticide Action Network North America (PANNA IV)*, 840 F.3d 1014, 1015 (9th Cir. 2016). EPA advised us that it had “issued its proposed rule before completing two studies that may bear on the Agency’s final rule.” *Id.* at 1015. We characterized EPA’s request as “another variation on a theme ‘of partial reports, missed deadlines, and vague promises of future action.’” *Id.* (quoting *PANNA II*, 798 F.3d at 811). We denied EPA’s request and ordered final action by March 31, 2017. *Id.*

In November 2016, EPA released yet another Revised Human Health Risk Assessment, responding to the 2016 SAP’s concerns. EPA, Office of Chemical Safety & Pollution Prevention, *Chlorpyrifos: Revised Human Health Risk Assessment for Registration Review* (Nov. 3, 2016) (*2016 RHHRA*). EPA recounted that in 2013 it had sought the raw data used in the Columbia Study, and although the researchers would not agree to provide EPA with the data, EPA “gained valuable insight into the conduct of the study.” *Id.* at 9–10. EPA concluded that the SAP had rejected both the approach in the *2015 Proposed Rule* and the new method based on the Columbia Study. *Id.* at 3. EPA agreed with the SAP that, despite uncertainties in the studies, there was “sufficient evidence that there are neurodevelopmental effects occurring at chlorpyrifos exposure levels” below the tolerances. *Id.* at 13. As a result, EPA proposed following the 2016 SAP’s recommendation to use a hybrid point of departure, rather than relying solely on the data from the Columbia Study. *Id.* at 13–14.

Within two weeks of issuing the *2016 RHHRA*, EPA reopened the comment period on the *2015 Proposed Rule. Chlorpyrifos; Tolerance Revocations; Notice of Data*

Availability and Request for Comment, 81 Fed. Reg. 81,049 (Nov. 17, 2016) (*2016 Request for Comments*). EPA noted that it was not proposing “a change to the EPA’s proposal to revoke all tolerances but it does modify the methods and risk assessment used to support that finding in accordance with the advice of the SAP.” *Id.* at 81,050; *see also id.* (“[T]he agency’s analysis provided in this notice continues to indicate that the risk from the potential aggregate exposure does not meet the FFDCA safety standard.”). At the same time, EPA expressed frustration with the process, and advised that “the timing of EPA’s issuance of the proposal was dictated” by our order in *PANNA II*. *Id.* EPA was clear that the basis for its proposed revocation depended on studies that were incomplete. It observed that EPA had completed a water assessment, but “[b]ecause of the court decision . . . EPA was not able to complete a more refined drinking water assessment for chlorpyrifos in advance of the proposed rule” and that with additional time it conducted the assessment to provide “a more tailored approach to risk mitigation.” *Id.* at 81,051. EPA admitted that

In the proposal, EPA proposed revoking all tolerances largely because the agency could not make a safety finding based on drinking water exposure in highly-vulnerable watersheds. EPA reasoned if it could better identify where such vulnerable areas might be, it could be possible for registrants to amend product labeling in ways that might make unnecessary some number of the proposed tolerance revocations.

Id. Importantly, EPA warned that its proposed course of conduct was not fixed:

Since EPA is still in the process of deliberating the provisions of a final rule, EPA cannot definitively state whether this information will provide support for any provision of the final rule, or that the agency has determined that it is appropriate to rely on this information in developing the final rule.

Id.

3. EPA denies the petition; we issue mandamus

In April 2017, EPA reversed course, issuing a final response to the 2007 petition, which denied it in full. *Chlorpyrifos; Order Denying PANNA and NRDC's Petition to Revoke Tolerances*, 82 Fed. Reg. 16,581 (April 5, 2017) (*2017 Denial*). The order stated:

Following a review of comments on both the November 2015 proposal and the November 2016 notice of data availability, EPA has concluded that, despite several years of study, the science addressing neurodevelopmental effects remains unresolved and that further evaluation of the science during the remaining time for completion of registration review is warranted to achieve greater certainty as to whether the potential exists for adverse neurodevelopmental effects to occur from current human exposures to chlorpyrifos. EPA has therefore concluded that it will not complete the human health portion of the registration review or any associated tolerance revocation of chlorpyrifos without

first attempting to come to a clearer scientific resolution on those issues.

Id. at 16,583. EPA thus denied the petition without resolving all scientific uncertainty concerning the tolerances “[b]ecause the 9th Circuit’s August 12, 2016 order has made clear, however, that further extensions to the March 31, 2017 deadline for responding to the Petition would not be granted.” *Id.* (referring to *PANNA IV*, 840 F.3d at 1015). EPA explained that the comments received in response to the *2015 Proposed Rule* “suggest that there continue to be considerable areas of uncertainty with regard to what the epidemiology data show and deep disagreement over how those data should be considered in EPA’s risk assessment.” *Id.* at 16,590. It then explained why it was denying the petition, rather than continuing its prior course:

As the 9th Circuit has made clear . . . EPA must provide a final response to the Petition by March 31, 2017, regardless of whether the science remains unsettled and irrespective of whatever options may exist for a more complete resolution of these issues

Although past EPA administrations had chosen to attempt to complete [FIFRA] review several years in advance of the statutory deadline (and respond to the Petition on the same time frame), it has turned out that it is not possible to fully address these issues early in the registration review period Accordingly, EPA is denying these Petition claims and intends to complete a full and appropriate review of the neurodevelopmental data before either

finalizing the [2015] proposed rule . . . or taking an alternative regulatory path.

Id. EPA concluded that “given the importance of this matter and the fact that critical questions remain regarding the significance of the data addressing neurodevelopmental effects, EPA believes there is good reason to extend the registration review of chlorpyrifos and therefore to deny the Petition.” *Id.*

Various organizations petitioned our court for review of EPA’s order. On review of EPA’s *2017 Denial*, the panel ordered EPA to revoke the chlorpyrifos tolerances. *League of United Latin American Citizens v. Wheeler (LULAC I)*, 899 F.3d 814, 829 (9th Cir. 2018). Judge Fernandez dissented on the grounds that the *2017 Denial* was not a final action. *Id.* at 830–32 (Fernandez, J., dissenting). We granted en banc review, vacated the panel opinion, and ordered EPA to issue a final order. *League of United Latin American Citizens v. Wheeler (LULAC II)*, 922 F.3d 443, 445 (9th Cir. 2019) (en banc). EPA issued its *Final Order* in July 2019, and we referred the petition back to the three-judge panel. *League of United Latin American Citizens v. Wheeler (LULAC III)*, 940 F.3d 1126, 1127 (9th Cir. 2019).

B

EPA’s *Final Order* responded to the two objections raised in *LULAC I*: (1) that the “EPA has unlawfully left chlorpyrifos tolerances in place without making the safety finding required by the FFDCA”; and (2) that EPA must revoke the tolerances because it “has previously found that chlorpyrifos tolerances are unsafe and has not disavowed those findings.” *Final Order*, 84 Fed. Reg. at 35,561.

1. Failure to find that chlorpyrifos is “safe”

EPA first addressed Petitioners’ argument that EPA was required to make a new safety finding to deny the petition. EPA found that it was not required to make a new safety determination in response to every revocation petition, the FFDCA did not require revocation in the absence of a new safety determination for each petition, and *even if* a new safety determination was required, both the FFDCA and EPA implementing regulations “require petitioners seeking withdrawal of a tolerance to support this request with valid, complete and reliable data that set forth why the tolerances are unsafe.” *Id.* at 35,562.

The agency found that petitioners had not met their burden of presenting evidence that the tolerances must be revoked because “the information yet presented by Petitioners is not sufficiently valid, complete, and reliable.” *Id.* at 35,562–63. EPA had already considered, during its 2006 review, the laboratory and epidemiological studies cited by Petitioners and had “consistently concluded” these studies did not warrant revocation based on “an evaluation across multiples lines of evidence.” *Id.* at 35,563. EPA determined these studies were deficient because they lacked a “mechanistic understanding for effects on the developing brain,” which precluded EPA from having a “valid or reliable way[] to bridge the scientific interpretation” of the studies with chlorpyrifos; the dosing regimen of the in vivo studies presented problems for “quantitative interpretation and extrapolation of the results” because they did not align with “internationally accepted protocols”; and EPA had been unable to obtain the raw data underlying the epidemiological studies, despite numerous efforts, to allow for verification of validity and reliability as well as replication. *Id.* EPA candidly acknowledged that its conclusion was “at odds”

with its 2016 *RHHRA* but ultimately asserted that it had “undertaken considerable efforts to assess the available chlorpyrifos data.” *Id.* at 35,564; *see also id.* (“EPA acknowledges this conclusion differs from the position supported in the 2016 revised human health risk assessment.”). The agency concluded that “the shortcomings of the data identified raise issues of validity, completeness and reliability under the FFDCA that direct against using the data for risk assessment at this time.” *Id.*

EPA explained that a majority of the 2016 SAP had concluded that use of the scientific studies under review for developing points of departure “could not be justified by any sound scientific evaluation.” *Id.* at 33,564. The SAP “expressed significant reservations” about using the studies as the sole source of revised points of departure and “noted the incompleteness of the information,” including the “reproducibility” of the data. *Id.* EPA concluded that “[b]ased on the uncertainties identified by the 2016 SAP,” the data were “not complete.” *Id.* EPA further laid out its requests to obtain the raw data underlying the studies and “visit[] [to] Columbia University in an attempt to better understand their study results and what raw data exist.” *Id.* at 33,565. Although the university initially had pledged to share its data, it failed to produce it, citing “privacy concerns.” *Id.* As a result, “EPA cannot validate or confirm the data analysis performed, the degree to which the statistical methods employed were appropriate, or the extent to which (reasonable or minor) changes in assumptions may have changed any final results or conclusions.” *Id.* As a consequence, EPA concluded petitioners had “failed to meet their initial burden of providing sufficiently valid, complete, and reliable evidence that neurodevelopmental effects may be occurring at levels below EPA’s current regulatory standard.” *Id.*

EPA further concluded that denying the 2007 petition was appropriate because the claims in the petition would be subject to FIFRA registration review, which is a “more up-to-date, thorough and methodical” review. *Id.* EPA reiterated its commitment to complete FIFRA and FFDCA review of chlorpyrifos tolerances in advance of the October 2022 deadline, anticipating some updates “by summer of 2020.” *Id.* at 35,566.

2. EPA’s prior finding that chlorpyrifos is “not safe”

EPA also addressed petitioners’ objection that the agency had already found chlorpyrifos to be unsafe in its 2015 proposed tolerance revocation. *Id.* at 35,566. EPA, however, was quite clear that “EPA has not made any findings that chlorpyrifos tolerances are not safe.” *Id.* EPA pointed out that its last final action regarding the safety of chlorpyrifos tolerances—and the only regulatory finding in effect—was its 2006 reregistration and safety determination. *Id.* The *2015 Proposed Rule* was not a final agency action, and “EPA made clear it was issuing the proposal because of” the Ninth Circuit’s order, “without having resolved many of the issues critical to EPA’s FFDCA determination and without having fully considered comments previously submitted to the Agency.” *Id.* It was up to EPA to “choose to finalize, modify or withdraw the proposal based on the comments received.” *Id.* Accordingly, its prior proposed findings were “not binding pronouncements.” *Id.*

C

EPA’s decision to deny the petition in its entirety in response to our writ of mandamus is entirely reasonable. We ordered EPA to grant or deny the petitions; EPA did as we ordered. It has explained why it did so and explained how it will proceed with the chlorpyrifos reregistration, in which it

will have to decide whether it is “safe.” There is nothing arbitrary or capricious in EPA’s decision.

Although petitioners can argue that the denial of the petition conflicts with EPA’s prior proposal, the *2015 Proposed Rule* is just that—a *proposed* rule. *2015 Proposed Rule*, 80 Fed. Reg. at 69,083 (“EPA may update this [proposed rule] with new or modified analyses as EPA completes additional work after this proposal.”). “Agencies are entitled to change their minds.” *Defenders of Wildlife v. Zinke*, 856 F.3d 1248, 1262 (9th Cir. 2017) (citation omitted); *see also Nat’l Ass’n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 658–59 (2007) (“[T]he only ‘inconsistency’ respondents can point to is the fact that the agencies changed their minds—something that, as long as the proper procedures were followed, they were fully entitled to do.”). “The federal courts ordinarily are empowered to review only an agency’s *final* action, *see* 5 U.S.C. § 704, and the fact that a preliminary determination . . . is later overruled . . . does not render the decisionmaking process arbitrary and capricious.” *Nat’l Ass’n of Home Builders*, 551 U.S. at 659. Agencies that change their mind are not “subjected to more searching review.” *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 514 (2009). What is important is that the agency “display awareness that it is changing position” and has explained itself. *Id.* at 515. EPA did not act arbitrarily and capriciously merely because it reversed course from its *2015 Proposed Rule*—a reversal that EPA explained.

Nor was the *2016 RHHRA* a final agency action. Human Health Risk Assessments are part of FIFRA reregistration review but are not in themselves safety determinations. *2016 RHHRA* at 3. It is the final Reregistration Eligibility Decision—which in this case was issued in 2006—that

serves as the final EPA action for determining safety pursuant to the FFDCA. *2006 Reregistration Decision* at 1–2. Although the *2016 RHHRA* stated that the studies cited by the petition provided “sufficient evidence that there are neurodevelopmental effects occurring at chlorpyrifos exposure levels below” current tolerances, this conclusion is tentative until the agency adopts it as part of a final order or rule. *2016 RHHRA* at 13. The *2016 RHHRA* remains part of a broader review process that will culminate in another Registration Eligibility Decision no later than 2022. In the meantime, however, relying on its Scientific Advisory Panel, EPA has explained why that study is flawed. The methodology used in the *2015 Proposed Rule* was rejected by the SAP, and the *2016 RHHRA* attempted to address the SAP’s concerns by using a different approach. *Id.* at 3–4.

As it is entitled to do, EPA has sufficiently explained its rationale for reversing course from the *2015 Proposed Rule* and *2016 RHHRA* and denying the petition. EPA was required to “examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made.” *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Ins. Co.*, 463 U.S. 29, 43 (1983) (quotations marks and citation omitted). EPA did articulate an explanation for its departure from the *2015 Proposed Rule* and the *2016 RHHRA* in its *2017 Denial* and *Final Order*. In its *2017 Denial* of the petition, EPA explained that responses from the 2016 SAP and comments received in response to the *2015 Proposed Rule* raised “considerable areas of uncertainty” regarding the studies. *2017 Denial*, 82 Fed. Reg. at 16,590. Based on this uncertainty, EPA concluded that it should instead “explore approaches raised by the SAP and commenters on the proposed rule, and possibly seek additional authoritative peer review of EPA’s risk

assessment prior to finalizing any regulatory action in the course of registration review.” *Id.*

EPA again explained the rationale for its departure from the 2016 RHHRA in its *Final Order*. EPA explicitly recognized its denial of the petition was “at odds with” the 2016 RHHRA, but it explained that it had “undertaken considerable efforts to assess the available chlorpyrifos data,” summarizing its longstanding concerns about the studies relied on by petitioners. *Final Order*, 84 Fed. Reg. at 35,564. EPA discussed its decision to convene the SAP in 2016 to specifically consider the EPA’s proposal to use information derived from the Columbia Study to develop a point of departure—a meeting EPA noted “was unique in focus compared to the previous meetings”—and the SAP’s rejection of using that data alone as the basis for the new point of departure. *Id.* EPA explained that the 2016 SAP’s feedback on the proposal based on the Columbia Study data was “consistent with concerns raised in public comments EPA received on the use of the epidemiology data throughout the course of registration review.” *Id.* EPA further noted that, although the 2008 and 2012 SAPs recognized strengths in the Columbia Study, neither recommended changing points of departure based on the study, and the 2016 SAP expressed even more reservation about using the study in this way. *Id.* Thus, despite preliminary assessments that recognized potential in the Columbia Study data, EPA ultimately concluded that “the shortcomings of the data identified raise issues of validity, completeness and reliability under the FFDCA that direct against using the data for risk assessment at this time.” *Id.* EPA also noted that this was not its final conclusion regarding the validity of the studies and that it “intends to continue its exploration of the uncertainty” with regards to the studies’ conclusions. *Id.* Because these studies—which

met the threshold requirements for consideration on the merits—were not sufficiently valid, complete, and reliable to support revocation, EPA decided not to modify or revoke the chlorpyrifos tolerances.

Nothing in EPA’s explanations is arbitrary or capricious. It is clear that the agency has struggled with the scientific studies before it. But nothing in either the procedure or the substance of EPA’s actions—aside from playing Hamlet—suggests that the agency has been irresponsible. To the contrary, at every step of the way, EPA has conscientiously examined the evidence. In 2015, it told petitioners it would deny the petition outright. This was not surprising because EPA had long advised the petitioners and other interested persons of the flaws in the studies. It changed course later that year when it was forced to make a decision in response to our writ of mandamus. EPA then proposed revoking the chlorpyrifos tolerances based on a novel measure of the effect on infants and children—only to have the SAP disapprove of the measure in 2016 and recommend further study. EPA requested further comments on the science—and an extension of time to make a decision. When we told EPA that there would be no further extensions, EPA called for additional comments and repeated that the studies were inconclusive, but EPA continued to believe it had no choice but to revoke the tolerances. But even as it called for last comments, EPA advised that it was “still in the process of deliberating the provisions of a final rule.” *2016 Request for Comments*, 81 Fed. Reg. at 81,051.

So how do we assess this convoluted history? It is certainly true that the agency had some stops and starts along the way, but that is evidence of deliberate decisionmaking, not dereliction of duty. We, of all institutions, should respect that there will be give-and-take in complicated matters of

consequence. The FFDCA does not demand unanimity within EPA, any more than it requires unanimity from this court before we may issue a judgment in this case.

In my view, the majority has intervened in ongoing debates within EPA over what the evidence proves and how it should be weighed. It is not our place to second-guess EPA's scientific assessment of laboratory and epidemiological studies supporting the petition. "Deference to an agency's technical expertise and experience is particularly warranted with respect to questions involving . . . scientific matters." *United States v. Alpine Land & Reservoir Co.*, 887 F.2d 207, 213 (9th Cir. 1989). When an agency makes determinations "within its area of special expertise, at the frontiers of science . . . a reviewing court must generally be at its most deferential." *Balt. Gas & Elec. Co. v. NRDC*, 462 U.S. 87, 103 (1983). The majority improperly makes its own assessment of the reliability of the studies and whether EPA's concerns are sufficient to determine that chlorpyrifos tolerances are "not safe." Maj. Op. 54–58, 60–63. But EPA's assessment of the scientific strength of the studies supporting the petition is precisely the type of analysis that should be given deference. FFDCA safety determinations are within EPA's area of expertise. We should not second-guess EPA's scientific conclusions with regards to the value of these studies. EPA's denial of the 2007 petition was neither arbitrary nor capricious.

* * *

The FFDCA does not require EPA to engage in a full-blown FFDCA safety evaluation in response to every petition filed with the agency. Instead, where a petition presents reasonable grounds for revocation, EPA must consider whether the petition puts forth data that supports a determination that a pesticide tolerance is not safe. Where

the data supporting a petition are not sufficiently valid, reliable, or complete, EPA may deny the petition and rest on its operative safety determination. Here, EPA complied with its statutory obligation: the agency considered the petition on the merits and determined that the data supporting the petition was insufficient to support revocation. Based on this determination, EPA denied the petition and relied on its 2006 finding that chlorpyrifos tolerances are safe. EPA explained the deficiencies in the underlying petition's supporting studies and its rationale for departing from its prior preliminary determinations. EPA did all that the FFDCA required.

III

Even if I thought the majority had read the statute correctly and had a clear-eyed view of the validity and weight to be given to the scientific evidence, the remedy ordered by the majority is an abuse of our discretion. Assuming that petitioners have demonstrated that chlorpyrifos is “not safe,” the FFDCA gives EPA the discretion to decide whether to modify or to revoke the tolerance. *See* 21 U.S.C. § 346a(b)(2)(A)(i); Maj. Op. at 60 (“[O]nce the EPA has determined that a tolerance is not safe, . . . it must modify or revoke the tolerance.”). Concluding that on this record “the present tolerances are not safe,” Maj. Op. at 63, the majority orders EPA to “modify or revoke chlorpyrifos tolerances and modify or cancel chlorpyrifos registrations,”⁹ Maj. Op. at 63, and gives EPA 60 days to do

⁹ In ordering the modification or cancellation of FIFRA registrations, Maj. Op. at 67, the majority has exceeded the scope of what a petition under the FFDCA allows: modification or cancellation of chlorpyrifos *tolerances* under the FFDCA. *See* 21 U.S.C. § 346a(d)(1)(A) (allowing petitions “proposing the issuance of a

so, Maj. Op. at 67. It is more than a little ironic that this court will have taken over a year since the filing of the last brief to decide this case, but we will expect EPA to make an informed decision in the next 60 days.

The 60 days the majority gives EPA is not a number drawn from the statutes, but one made up by the majority, and it may well foreordain the option EPA must choose. In my view, the stakes in this case are too high for the majority to take upon itself to decide what the United States will do with respect to chlorpyrifos. “By pounds of active ingredient, [chlorpyrifos] is the most widely used conventional insecticide in the country” and for some crops it is “currently the only cost-effective choice for control of certain insect pests.” *Final Order*, 84 Fed. Reg. at 35,558.¹⁰ That, of course, is not an argument for finding chlorpyrifos safe, as EPA recognized, but it should sharpen our focus on what we are doing. *See 2017 Denial*, 82 Fed. Reg. at 16,590 (“Although not a legal consideration, it is important to recognize that for many decades chlorpyrifos has been and remains one of the most widely used pesticides in the United States, making any decision to retain or remove this pesticide from the market an extremely significant policy choice.”). That is why EPA should be considering the options Congress

regulation establishing, modifying or revoking a *tolerance*” under that statute (emphasis added)). Although modification or revocation of a tolerance under the FFDCA will necessarily impact registrations under FIFRA, the FFDCA does not afford this court authority to order modification or cancellation under FIFRA.

¹⁰ Chlorpyrifos tolerances are classified by crop (*e.g.*, alfalfa, almonds, apples, corn, cotton, grapes, oranges, pears, soybeans, walnuts, and wheat) and usage (*e.g.*, cockroach and fire ant control, mosquito abatement, utility pole treatments) and are region specific. The complexity of the tolerances is difficult to overstate.

made available, not us. And we have not given anything but the most fleeting consideration to the options.¹¹

It is far from clear that EPA will be able to do anything in the next 60 days other than revoke the tolerances. Yet, between argument and the issuing of this decision, EPA advised us that it has issued an interim decision to reregister chlorpyrifos, with modifications. *Pesticide Registration Review; Proposed Interim Decision for Chlorpyrifos; Notice of Availability*, 85 Fed. Reg. 78,849 (Dec. 7, 2020) (2020 *Proposed Interim Decision*) (inviting comments on EPA, *Chlorpyrifos: Proposed Interim Registration Review Decision* (Dec. 3, 2020) (2020 *Proposed Interim Registration*)). In the 2020 *Proposed Interim Registration*, EPA explained that it was proceeding with suggested modifications, but that it still faced “numerous novel scientific issues, notably the potential for neurodevelopment effects on the young.” 2020 *Proposed Interim Registration Decision* at 10. Candidly, EPA stated:

Despite several years of study, the science addressing neurodevelopmental effects remains unresolved. . . . Notwithstanding,

¹¹ The majority may have effectively foreclosed other options Congress made available to EPA. Under the FFDCA, if a petitioner can show that it not safe, EPA must modify or revoke the tolerance; or, in its periodic statutory review, if EPA cannot determine chlorpyrifos is safe, it cannot leave the tolerance in place. But if EPA arrives at that point, there is yet an additional option: EPA has the power to leave in effect or modify a tolerance if it concludes that certain consequences will follow—if “the residue protects consumers from adverse effects on health that would pose a greater risk than the dietary risk” or if the tolerance “is necessary to avoid a significant disruption in domestic production of an adequate, wholesome, and economical food supply.” 21 U.S.C. § 346a(b)(2)(B)(iii). These contingencies would still require EPA to certify that the tolerances modified or left in effect satisfy the “no harm” to infants and children criteria in 21 U.S.C. § 346a(b)(2)(C).

EPA recognizes that the science is evolving on this topic, and that there may be new information available prior to the completion of registration review that may impact the agency's conclusions about these effects.

Id. It further advised that it had convened a SAP in September 2020 “to assess new approval methodologies that might used to evaluate developmental neurotoxicity in EPA’s assessment of risks to human health.” *Id.*; *see also id.* at 40, 63. The SAP’s report was issued a week later in December 2020. EPA, *FIFRA Scientific Advisory Panel Meeting Minutes and Final Report No. 2020-02: Peer Review of the Use of New Approach Methodologies (NAMs) to Derive Extrapolation Factors and Evaluate Developmental Neurotoxicity for Human Health Risk Assessment* (Sept. 15–18, 2020) (report released Dec. 15, 2020). For the reasons I have explained, in this latest proceeding, the risk of nonpersuasion runs against the existing tolerances. That means that EPA will have to decide the issues reserved in its interim proceedings—and, specifically, the question of safe tolerances for children and youth—and it must do so by 2022, the deadline set by Congress.

What effect the majority’s order will have on EPA’s latest proceeding is unclear, but the majority’s order presents it with two unsatisfactory choices: either issue modified tolerances outside the procedure required by the FFDCA, FIFRA, and APA, or revoke the tolerances. Given the *2020 Proposed Interim Registration Decision*, maybe EPA will be comfortable issuing modified tolerances, but in order to do so it will have to accelerate its schedule, and that may mean skipping some steps. *See 2020 Proposed Interim Registration Decision* at 4, 8–9 (explaining that EPA is

awaiting revised biological opinions from the National Marine Fisheries Service and the U.S. Fish & Wildlife Service). Alternatively, EPA may be forced to revoke tolerances that it has tentatively concluded it will reregister or reregister with modifications. Perhaps EPA will again approve registration of chlorpyrifos at some future date once it completes full FIFRA and FFDCa review, but our precipitous order will have imposed tremendous costs on various sectors of the economy without waiting for the system to work.

Finally, I have to comment on the artificial schedule that our court has imposed on EPA, not only in this case, but time and again in these proceedings. EPA took the 2007 petition to revoke chlorpyrifos very seriously. Unlike reregistration under FIFRA, there is no statutory deadline for dealing with a petition, although in principle twelve years seems like more than enough time. The extraordinary delay, however, makes more sense in context: EPA initially believed that it could accelerate the FIFRA reregistration due in 2022 and address both the petition and the reregistration at the same time and well before that date. In the meantime, the petitioners asked us to intervene and order EPA to rule on its petition. EPA repeatedly advised us that it could not meet those demands if it was to complete the reregistration process properly. We insisted. Eventually, but reluctantly, EPA proposed to revoke the tolerances—even as it stated that it was doing so without complete information. *See, e.g., 2016 Request for Comments*, 81 Fed. Reg. at 81,050; *2015 Proposed Rule*, 80 Fed. Reg. at 69,080. After further proceedings, EPA concluded that it was better to deny the petitions outright because the petitioners had failed to show that the tolerances were not safe, and then complete the FIFRA reregistration process, where it would have a full record. EPA's decision is consistent with the FFDCa, as

amended by the FQPA. Although in hindsight the process took much longer than EPA anticipated, that was a reasonable decision on EPA's part at the time.

When we intervene in scientific inquiries with impatience and impose artificial deadlines, we bear some responsibility for the confusion that results. In *San Luis & Delta-Mendota Water Authority v. Jewell*, 747 F.3d 581 (9th Cir. 2014), the district court ordered the U.S. Fish & Wildlife Service to produce a complex, 400-page biological opinion in less than a year. The resulting biological opinion was

a jumble of disjointed facts and analyses. It appears to be the result of exactly what we would imagine happens when an agency is ordered to produce an important opinion on an extremely complicated and technical subject matter covering multiple federal and state agencies and affecting millions of acres of land and tens of millions of people.

Id. at 605; *see also id.* at 605 n.15 (noting that “the FWS had less time to produce its opinion than either the district court or we will have had to review it”). We “wonder[ed] whether anyone was ultimately well-served by the imposition of tight deadlines in a matter of such consequence.” *Id.* at 606. When we interject ourselves into technical proceedings, our “[d]eadlines become a substantive constraint on what an agency can reasonably do. . . . Such scientific tasks may not be as well suited to deadlines as producing written copy; the final product will necessarily reflect the time allotted to the agency.” *Id.* We can only hope that “[f]uture analyses [will] be given the time and attention that these serious issues deserve.” *Id.*

In any event, our order is an abuse of any discretion the APA confers on us. We have the power to “compel agency action . . . unreasonably delayed,” 5 U.S.C. § 706(1), but we do not have the power to choose among the options available to EPA. Our deadline may effectively make the choice for EPA.

IV

There are manifest errors in the majority opinion. It has misread the FFDCA and misallocated the risk of nonpersuasion. It has overruled EPA’s judgment on the validity and weight to be given technical evidence within EPA’s expertise. And by its decision to give EPA 60 days to issue a final decision in this case, the majority has likely predetermined EPA’s option. I respectfully, but firmly, dissent.

This is **Exhibit “G”** referred to in the affidavit of
Dr. Elaine MacDonald affirmed remotely before
me in accordance with O. Reg 431/20,
Administering Oath or Declaration Remotely
this 19th day of January 2022.



Commissioner for Taking Affidavits
(or as may be)



Health
Canada

Santé
Canada

*Your health and
safety... our priority.*

*Votre santé et votre
sécurité... notre priorité.*

Information Note: The New *Pest Control Products Act*

Canada 



June 28, 2006

The new *Pest Control Products Act* (PCPA) came into force on June 28, 2006, replacing the current PCPA, which is now over 35-years old. Health Canada's Pest Management Regulatory Agency (PMRA) administers the PCPA.

The new Act improves the pesticide regulatory system by increasing transparency and strengthening health and environmental protection and post-registration control of pesticides. A number of provisions in the new Act formalize existing policies and practices of the PMRA.

Pesticides will continue to require approval before they can be imported into, manufactured, sold or used in Canada. Before approving a pesticide, the PMRA carefully reviews all of the available data to determine if the pesticide is acceptable for use, and then sets the standards and conditions under which it can be used.

The new Act provides for strong protection of human health and the environment. In 1998, as a matter of policy, the PMRA established policies that required additional protection for children and pregnant women and took into account pesticide exposure from all sources, including food and water. The new Act formalizes these policies into law. The new Act also supports pesticide risk reduction, for example, by ensuring that only pesticides that make a useful contribution to pest management are registered and by expediting the registration of lower-risk products. These activities are key in protecting human health and the environment.

Under the new Act, the PMRA will be able to further increase its efforts to support sustainable pest management practices. The new Act supports Canadian growers in gaining quicker access to newer, safer pesticides so they can be competitive in international markets. As well, the new Act provides greater flexibility in the area of minor-use registration and improves access to lower-risk products.

Transparency Provisions in the New Act

The PMRA welcomes the transparency provisions of the new Act. With these provisions in place, after a pesticide is registered, the PMRA is able to share with the public the same information and data it reviewed to approve the pesticide for registration. To accomplish this, the PMRA has developed:

- a public registry available on the PMRA website that will allow access to: detailed evaluation reports on approved pesticides; PMRA consultation statements and decision statements; conditions of registration of registered pesticides; information on research permits, Own-Use Import permits, international harmonization activities; and regulations, policies, guidelines and codes of practice; and,
- a reading room where the public can inspect the confidential test data on which the pesticide evaluations are based.



As a matter of policy, the PMRA has been consulting with the public before making final decisions on pesticide re-evaluations and registrations. The new Act formalizes into law these practices to support continued public participation in decision-making through consultation documents, requests for reconsideration and special reviews.

Stronger Post-registration Control of Pesticides

In 1998, again as a matter of policy, the PMRA began re-evaluating all pest control products that were registered prior to 1995 to ensure that their acceptability for continued use is examined using current scientific approaches. The new Act now provides, under law, that all pest control products be re-evaluated on a 15-year cycle. This provision provides the PMRA, on behalf of the Minister of Health, with the authority to remove a pesticide from the market if the data required to re-evaluate it are not supplied. Furthermore, the new Act increases the powers of inspection to ensure compliance with the new Act and allows the PMRA to impose higher penalties, up to \$1 million for the most serious offences.

The new PCPA requires that incidents of potential adverse effects relating to pesticides be reported by the registrant of the pest control product. The new PCPA also requires that sales data be reported. These new, mandatory requirements ensure that pesticide use is monitored and that incidents relating to pesticide use are reported to Health Canada, and will lead to increased protection of Canadians' health and their environment.

The new Act is supported by modernized Pest Control Products Regulations. New regulations to support the reporting provisions of the Act and outline the details of how incidents of adverse effects and sales data will be reported have been previously proposed in the Canada Gazette, Part I, and will be finalized in the near future.

History of the New Act

The new PCPA received Royal Assent in December 2002. It has taken considerable time and effort to bring the new Act into force. Health Canada has now developed the infrastructure needed to implement the transparency provisions of the new Act, established the list of formulants and contaminants of health or environmental concern and revised the Pest Control Products Regulations to support the new Act. The health of Canadians and their environment was not compromised by the delay as key provisions to strengthen health and environmental protection in the new PCPA had already been implemented through policy by Health Canada in the late 1990s. The new PCPA meets the Government of Canada's Smart Regulation initiative principle of greater openness and transparency in the Canadian regulatory system

This is **Exhibit “H”** referred to in the affidavit of
Dr. Elaine MacDonald affirmed remotely before
me in accordance with O. Reg 431/20,
Administering Oath or Declaration Remotely
this 19th day of January 2022.



Commissioner for Taking Affidavits
(or as may be)



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Via Email

Our File Number: LEX-500016917

September 17, 2021

Laura Bowman and Daniel Cheater
Ecojustice
1910 – 777 Bay Street, PO Box 106
Toronto, ON M5G 2C8
Fax: 416-363-2746
Tel: 416-368-7533 ext 522

Dear Ms. Bowman and Mr. Cheater:

Re: Safe Food Matters et al v AGC et al (T-956-21)

I write further to your letters of August 27 and September 1, 2021 and your email of September 15, 2021, to address the items the Applicants have identified with the Certified Tribunal Record (CTR) in the above matter. We have been able to locate the majority of the documents noted in your correspondence, which will be produced in a Confidential Amended CTR that we hope to transmit early next week, followed by a Public CTR shortly thereafter. For ease of reference, I have included a chart below addressing each document identified in your correspondence, along with the AGC's position. I have also addressed the other issues you have raised.

1) CTR Concerns Identified by Applicants and the AGC's Response

Original CTR Doc #	Applicants' Concern	AGC Response
Missing Attachment(s)		
31		Located and to be included as attachment in amended CTR
66		Located and to be included as attachment in amended CTR
67		Located and to be included as attachment in amended CTR
71		Located and to be included as attachment in amended CTR

72		Located and to be included as attachment in amended CTR
80		The attachment could not be located. The original email was deleted as transient.
96		Located and to be included as attachment in amended CTR
192		Located and to be included as two attachments in amended CTR
373		Produced at document 424
376		Produced at document 375
379		Produced at document 430
385		Produced at document 384
404		Produced as attachment to document 126
450		Located and to be included as attachment in amended CTR
452		Located and to be included as attachment in amended CTR
Dead Links		
22		Located and included as attachment
85	EAD memo and PMRA water assessment document	Outside of scope of CTR, information gathered as part of environmental assessment
102		Produced at documents 472; 474; 471
157		Document produced at attachment to Doc 165
Documents referencing other documents		
12	References a March 2011 Briefing Notice for SMC/SOC not included, nor are associated agendas or meeting minutes	Email references 2008 SMC decision, which is produced at document 367
14	References a May 2011 meeting of senior management and not agendas, meeting minutes or briefing notes in CTR	Health Canada has not located any records in relation to this meeting
86	2016 DCI identified and not produced	Outside scope of CTR, this DCI was for the environmental assessment
131	Missing document "chlorpyrifos: Third revised human health risk assessment for registration review" dated September 21, 2020	To be provided as attachment in amended CTR
291	October 2000 food assessment not included	Outside scope of CTR, not considered by PMRA in making decision
311	October 2002 food assessment not included	Outside scope of CTR, not considered by PMRA in making decision

432	PMRA Doc 2639299 (May 2016) regarding oxon and chlorination not included	Produced at document 427
471	Corr to PMRA Pinzon, D to Conti M, July 30 th , 2019	Outside scope of CTR as it relates to environmental assessment
Documents suggesting other documents exist		
3	December 2003 modelling not included	Outside scope of CTR, not considered by PMRA in making decision
63	Document suggests further drinking water modelling before 2006 but after PACR2003 not included in CTR	Outside scope of CTR, not considered by PMRA in making decision
69	2016 DCI for drinking water not included	Outside the scope of CTR. The DCI for drinking water formed part of the Re-evaluation Decision for the Environment, which final decision was published in December 2020 and is not part of this challenge.
70	Incomplete email thread	Health Canada was unable to locate further documents
107	Email references excel spreadsheet that is not included	Transient document is not in Health Canada's records. Two versions of the spreadsheet that Health Canada was able to located to be included in amended CTR
108	Email references excel spreadsheet that is not included	As above
124	Email references preparation of September 2020 SMC meeting and briefing memo is not included	Produced at document 337
195	Final changes to re-evaluation update appear to be missing	The draft REVNote is produced at document 194, the final note is produced as attachment to document 412
196	Refers to consideration of dietary risks by PMRA	Documents related to the dietary risk assessment discussed at the meeting were produced in the Review Memos section of the CTR
198	May 2021 SMC meeting has briefing note but no associated minutes	Produced at document 418
212	Associated meeting minutes not provided	No minutes were located
214	Associated meeting minutes not provided	No minutes were located
367	There are no associated briefing notes or agendas for Feb 7, 2008 SMC meeting	No agenda was found; briefing note is located at document 363
384	No earlier drafts of the July 2017 briefing note or any associated emails in the CTR	Produced as attachments to documents 42 and 43

391	Final briefing note is not attached	To be included in amended CTR
436	Associated agenda and minutes for Sept 2017 conference call with registrants	This meeting took place on October 6. No minutes were located, all documents in Health Canada's records related to this meeting are produced at documents 213-218
450	States NOO will be discussed at April 15, 2021 SMC meeting but agendas/minutes/briefings are not included	Outside scope of CTR. The referenced NOOs are in relation to the final decision on the environmental re-evaluation with is beyond the scope of this application.

2) Section 37 documents

As I noted in my letter dated August 24, 2021, Health Canada sought consent to disclose certain relevant information from the two regulators who shared information with Health Canada on a confidential basis. I can now advise that APVM has consented to the disclosure of its documents with minimal redactions to remove the only names or email addresses of certain officials in compliance with APVM's obligations under its privacy legislation. Accordingly, the redactions at documents 56, 58 and 59 will be removed in the Amended CTR and additional documents involving communications with APVM will be included. The EPA has also consented to the disclosure of relevant documents without any redaction, and those documents will also be included in the Amended CTR.

3) Scope of CTR Search

In making the decision to cancel the remaining uses of chlorpyrifos following registrants' decisions to discontinue their products (12223, 25823, 14879, 19656, 20320, 20407, 29650, 21997, 27479, 33113, 23705) or following registrants' failure to comply with the data call-in notice (23621, 23704, 32694, 32768), PMRA had regard to the 2007 proposed re-evaluation decision and subsequent health related information obtained by PMRA. Accordingly, in creating the CTR, PMRA searched for documents that post-dated the 2007 decision that informed their decision concerning the application of the phase out period for the cancellation or discontinuance of any uses that remained following the environmental assessment.

4) Documents that are not confidential

As noted above, we will provide a public version of the record as soon as practicable once issues with the scope of the CTR have been resolved. I can confirm that Health Canada has reviewed the CTR that was produced on August 19, 2021 and we are working to review and apply their proposed redactions. Health Canada will also need to review the additional documents that will be produced so that we can prepare a complete public record.

In the meantime, I can advise that Health Canada has confirmed that following documents transmitted on August 19, 2021 do not contain confidential information and do not need to be treated as confidential pursuant to the parties Confidentiality Agreement: 3-6, 9-18, 20-33, 35-37, 39-46, 48-50, 52-59, 61-68, 71-83, 85, 88, 90, 93, 95-101, 103, 105-108, 111, 113, 115-125, 127-131, 133, 142-146, 148-154, 157, 161, 163-164, 167, 169, 175, 179, 182, 192, 194-195, 197, 201, 204, 206-208, 210-217, 219, 221-225, 257, 266- 267, 269, 274, 298-301, 307-311, 317-319, 326, 329-330, 334-338, 340-341, 343, 345-348, 351-353, 357, 359-360, 363, 365-367, 370-379, 381-386, 388-391, 393-407, 409-411, 413-414, 417, 419-421, 423-425, 427-430, 432-442, 445-449, 454-460, 471-474, 476, and 482-488. These documents numbers refer to the numbers in the CTR transmitted on August 19, 2017. The Amended CTR includes additional documents which will impact document numbering. It also removes some duplicates that were missed in our prior review. However, we will ensure the index to the Amended CTR includes the original document number for the parties' reference.

Sincerely,



Andrea Bourke
Senior Counsel
Litigation, Extradition and Advisory Division

This is **Exhibit "I"** referred to in the affidavit of
Dr. Elaine MacDonald affirmed remotely before
me in accordance with O. Reg 431/20,
Administering Oath or Declaration Remotely
this 19th day of January 2022.



Commissioner for Taking Affidavits
(or as may be)



Food Safety

Food Safety

Chlorpyrifos & Chlorpyrifos-methyl

What are chlorpyrifos and chlorpyrifos-methyl?

Chlorpyrifos (sometimes referred to as chlorpyrifos-ethyl) and chlorpyrifos-methyl are insecticides used to control insect pests on a range of crops. Chlorpyrifos-methyl is also used to treat stored cereal grain and empty warehouses.

What is the current status of chlorpyrifos and chlorpyrifos-methyl in the EU?

On 6 December 2019, at the meeting of the [Standing Committee on Plants, Animals, Food and Feed](#) EN (PAFF Committee) the Member States voted on two draft Implementing Regulations proposing **to not renew the approvals of chlorpyrifos and chlorpyrifos-methyl**.

For both substances, a qualified majority was reached.

The European Commission formally adopted the Regulations on 10 January 2020, meaning that Member States must, within one month, withdraw all authorisations for plant protection products containing the active substances.

A short period of grace for final storage, disposal and use (maximum 3 months) may be granted by the Member States. After that, such plant protection products can no longer be placed on the market or used in the EU.

Why did the Commission propose not to renew the approvals?

In April 2019, as part of the standard regulatory renewal of approval processes for these substances, experts from EFSA and Member States convened to discuss the human health assessment of chlorpyrifos and chlorpyrifos-methyl. **Experts concluded that concerns related to human health exist, in particular in relation to possible genotoxicity and developmental neurotoxicity.**

In the light of these concerns and given the delays with the environmental risk assessment, the Commission mandated EFSA to provide statements on the main findings on human health for chlorpyrifos and chlorpyrifos-methyl.

On **2 August 2019**, [EFSA published statements for both substances](#) EN | ●●●, confirming that concerns for human health have been identified and that safe levels of exposure cannot be determined based on the available data. EFSA concluded that the approval criteria for human health laid down in the EU legislation are not met.

A second expert discussion on chlorpyrifos-methyl took place in early September 2019. **On 26 November 2019**, [EFSA published its updated statement on chlorpyrifos-methyl](#) EN | ●●●, which confirmed the earlier findings.

The Commission has and will continue to remove active substances from the market for which it cannot be demonstrated that the approval criteria enshrined in the legislation are satisfied.

What about the maximum residue levels (MRLs) in food?

On 18 February 2020, Member States endorsed a proposal by the Commission to lower the Maximum Residue Levels (MRLs) of chlorpyrifos and chlorpyrifos-methyl in food and feed to the **lowest level that can be measured by analytical laboratories**.

In view of issues identified by EFSA, the endorsed Regulation includes a shorter than normal period of deferral for the application of the lower MRLs (3 months instead of the usual period of 6 months from the date of entry into force of the Regulation). Moreover, no further transitional period will be granted for products already on the market on the date of application.

The new lowered MRLs will become applicable **around October 2020** and will apply both to food produced in the EU and also to imports.

This is **Exhibit “J1”** referred to in the affidavit of **Dr. Elaine MacDonald** affirmed remotely before me in accordance with O. Reg 431/20, Administering Oath or Declaration Remotely this 19th day of January 2022.



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> [Reports and Publications – Consumer Product Safety](#)

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Re-evaluation Decision RVD2019-04, Thiamethoxam and Its Associated End-use Products: Pollinator Re-evaluation

Pest Management Regulatory Agency

11 April 2019

ISSN: 1925-0886 (PDF version)

Catalogue number: H113-9/2019-4E-PDF (PDF version)

To obtain a full copy of [Re-evaluation Decision RVD2019-04, Thiamethoxam and Its Associated End-use Products: Pollinator Re-evaluation](#) please contact our publications office.

Should you require further information please contact the [Pest Management Information Service](#).

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Re-evaluation Decision

Under the authority of the Pest Control Products Act, Health Canada's Pest Management Regulatory Agency (PMRA) conducted a re-evaluation of all agricultural and ornamental uses for thiamethoxam and its associated end-use products, specifically to assess the risk to pollinators, such as honey bees, bumble bees, and solitary bees. This re-evaluation assessed the potential risk to pollinators in light of international updates to the pollinator risk assessment framework. Extensive information obtained from published literature, as well as data received from registrants, was considered. Health Canada applied internationally accepted risk assessment methods as well as current risk management approaches and policies. In addition to the pollinator risk assessment, the value of the active ingredient to the various use sectors was assessed.

Products containing thiamethoxam are sold as sprays to be applied to plants and to bare soil. Thiamethoxam is also used as a coating on crop seeds to prevent insects from eating the seeds when they are planted in the ground and to protect the plants grown from treated seeds. Some uses result in thiamethoxam being taken up by the plants from the soil or through their leaves, where it then moves into parts of the flower where nectar and pollen are produced. Because bees use nectar and pollen as their primary sources of food, bees may be exposed to thiamethoxam (and its breakdown products) when they visit certain flowers to collect pollen and nectar. Bees may also be accidentally sprayed or collect water containing thiamethoxam. Currently registered products containing thiamethoxam that are subject to this re-evaluation are listed in Appendix I.

This document (RVD2019-04, Thiamethoxam and Its Associated End-use Products: Pollinator Re-evaluation) presents the final regulatory decision ¹ for the pollinator re-evaluation of thiamethoxam, including the required risk mitigation measures to protect bees. Most products containing thiamethoxam are subject to this regulatory decision. The proposed regulatory decision published in PRVD2017-24, Thiamethoxam and Its Associated End-use Products: Pollinator Re-evaluation, ² has undergone a 90-day consultation that ended on 19 March 2018.

Health Canada received comments mostly relating to the value and pollinator risk assessments. These comments are summarized in Appendix II of RVD2019-04, Thiamethoxam and Its Associated End-use Products: Pollinator Re-evaluation, along with the responses by Health Canada. The comments did not result in a change to the risk assessments. Therefore, this decision is consistent with the proposed re-evaluation decision stated in PRVD2017-24. All of the data that were used as the basis for the

proposed re-evaluation decision are published in PRVD2017-24. Further data used in the final re-evaluation decision, including data received during the consultation period, are listed in Appendix IV of RVD2019-04.

Outcome of Science Evaluation

The risk assessment, conducted according to the Guidance for Assessing Pesticide Risks to Bees,³ determined that there are varying degrees of effects on bees. Some current uses of thiamethoxam are not expected to affect bees. For some uses, mitigation measures (in other words, changes to the conditions of registration) are required to minimize potential exposure to bees. Mitigation measures include changes to the use pattern and label improvements. When thiamethoxam is used in accordance with these new risk reduction measures, the reduced environmental exposure is considered adequate and risks are acceptable. Label statements informing users of the potential for toxicity to pollinators are required on product labels. For other uses, risks to pollinators were not found to be acceptable; therefore, these uses are cancelled.

Regulatory Decision for Thiamethoxam

Health Canada has completed the pollinator re-evaluation of thiamethoxam. Under the authority of the Pest Control Products Act, Health Canada has determined that, with required amendments, continued registration of products containing thiamethoxam is acceptable; however, certain uses of thiamethoxam are cancelled to address potential risks of concern to pollinators. An evaluation of available scientific information found that some uses of thiamethoxam products meet current standards for protection of pollinators when used according to the conditions of registration, which include required amendments to label directions. Label amendments, as summarized below and listed in Appendix III of RVD2019-04, are required for all end-use products. No additional data are requested.

Risk Mitigation Measures to Protect Pollinators

Registered pesticide product labels include specific directions for use. Directions include risk mitigation measures to protect human health and the environment and must be followed by law. As a result of this re-evaluation of thiamethoxam, further risk mitigation measures for product labels are required.

Certain crops are highly attractive to bees when their flowers are in bloom. Since large numbers of bees are attracted to these crops when they are in bloom and based on an assessment of the risks to bees, the application of pesticides containing thiamethoxam can lead to effects that may have an impact on the survival of bee colonies or solitary bee species.

In order to protect pollinators, **Health Canada is cancelling the following uses of thiamethoxam:**

- Foliar and soil application to ornamental crops that will result in pollinator exposure (in other words, are planted outdoors and are attractive to pollinators)
- Soil application to berry crops, cucurbit crops and fruiting vegetables, and
- Foliar application to orchard trees.

Due to the attractiveness of some crops to bees and based on an assessment of the risks to bees, application of pesticides containing thiamethoxam before and during crop flowering can lead to effects that may have an impact on the survival of bee colonies or solitary bee species.

In order to protect pollinators, **Health Canada is changing the timing of application for the following uses of thiamethoxam**

The following crops cannot be sprayed before or during bloom:

- Foliar application to legume and outdoor fruiting vegetables, and
- Foliar application to berry crops (with renovation required for woody berries).

The following crops cannot be sprayed during bloom:

- Foliar application to sweet potato and potato

To minimize bee exposure to dust during planting of treated seed, **additional label statements are required for the following use:**

- Seed treatment of cereal and legume crops.

The additional risk mitigation measures described above will be implemented over a 24-month period. The risks identified are not considered imminent because they are not expected to cause irreversible harm over this period. Potential effects include sublethal effects on colonies or solitary bees, but affected pollinator populations are expected to recover following implementation of the additional restrictions which will reduce exposure. Moreover, recovery is expected because risks to pollinators are geographically

limited to areas where these products are applied and areas adjacent to application sites. The presence of unaffected solitary bees, bumble bees, and honey bees in areas where products are not being used will further facilitate recovery since unaffected bees in the environment can move back into areas where effects may have occurred. Overall, risk to pollinators is acceptable over the time period required to implement the mitigation measures.

As a result of this decision, growers will be required to change their pest management practices. Pesticides have extensive and precise instructions and often require specialized application and safety equipment and training. This transition period will allow for an orderly and safe implementation of these new restrictions, and should reduce the risk of product misuse or the improper disposal of products as users switch to alternatives, where required. This approach is consistent with Health Canada's current policy and practice with respect to phase out of uses as a result of a re-evaluation (Regulatory Directive DIR2018-01, Policy on Cancellations and Amendments Following Re-evaluation and Special Review) and with the practice of other international regulators.

A small subset of uses were found to lack alternatives for the management of certain serious pests (the invasive brown marmorated stink bug and certain weevils) on a very few crops present in limited geographical areas of Canada. As a result, the implementation of the re-evaluation decision for these uses will be delayed for an additional year to allow growers to find pest management solutions. During this period, the overall exposure to pollinators will be significantly reduced through both removal of uses to control other pests on these crops and other crops that pose a risk to bees, as well as through implementation of additional restrictions in application timing which will further reduce pollinator exposure. The risks to pollinators are therefore considered acceptable for an additional year for this small subset of uses.

Next Steps

To comply with this decision, taking into account Regulatory Directive DIR2018-01, Policy on Cancellations and Amendments Following Re-evaluation and Special Review, the required mitigation measures must be implemented on all product labels sold by registrants no later than 24 months after the publication date of this decision document. Appendix I lists the products containing thiamethoxam that are registered under the authority of the Pest Control Products Act.

Other Information

Any person may file a notice of objection ⁴ regarding this decision on thiamethoxam within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the [Pesticides](#) section of the Canada.ca website ([Request a Reconsideration of Decision](#)) or contact the PMRA's [Pest Management Information Service](#).

Appendix I Registered Thiamethoxam Products in Canada Subject to This Re-evaluation

Table 1 Registered Thiamethoxam Products in Canada Subject to This Re-evaluation as of 2 October 2018, excluding discontinued products and products with a submission to discontinue

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
26665	Technical	Syngenta Canada Inc.	Thiamethoxam Technical	Dust or powder (solid)	99.1%
26637	Commercial	Syngenta Canada Inc.	Helix Liquid Seed Treatment	Suspension	Thiamethoxam 10.3%; metalaxyl-M and S isomer 0.39%; fludioxonil 0.13%; difenoconazole 1.24%
27045			Cruiser 5FS Seed Treatment		Thiamethoxam 47.6%

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
27986			Cruiser 350FS Seed Treatment Insecticide		Thiamethoxam 29.9%
28407			Actara 240SC Insecticide		Thiamethoxam 240 g/L
28408			Actara 25WG Insecticide	Wettable granules	Thiamethoxam 25.0%
28821			Cruiser Maxx Beans Seed Treatment	Suspension	Thiamethoxam 22.6%; metalaxyl-M and S isomer 1.70%; fludioxonil 1.12%
29127			Cruiser Maxx Cereals Commercial Seed Treatment		Thiamethoxam 2.8%; metalaxyl-M and S isomer 0.56%; difenoconazole 3.36%
29192			Cruiser Maxx Cereals Seed Treatment		Thiamethoxam 2.8%; metalaxyl-M and S isomer 0.56%; difenoconazole 3.36%

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
30388			A18046A Seed Treatment		Thiamethoxam 261 g/L; metalaxyl-M and S isomer 19.7 g/L; fludioxonil 12.9 g/L; azoxystrobin 10.4g/L
30404			Endigo Insecticide		Thiamethoxam 141 g/L; lambda-cyhalothrin 106 g/L
30436			Cruiser Maxx Vibrance Cereals Seed Treatment		Thiamethoxam 30.7 g/L; sedaxane 8.0 g/L; metalaxyl-M and S isomer 9.5 g/L; difenoconazole 36.9 g/L
30723			Flagship Insecticide	Wettable granules	Thiamethoxam 25%
30900			Minecto Duo 40WG	Wettable granules	Thiamethoxam 20%; cyantraniliprole 20%
30901			Mainspring X Insecticide		Thiamethoxam 20%; cyantraniliprole 20%

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
31024			Cruiser Maxx Potato Extreme	Suspension	Thiamethoxam 250 g/L; fludioxonil 62.5 g/L; difenoconazole 123 g/L
31453			Cruiser Vibrance Quattro		Thiamethoxam 61.5 g/L Difenoconazole 36.9 g/L Metalaxyl-M and S-Isomer 9.2 g/L Sedaxane 15.4 g/L Fludioxonil 7.7 g/L
31454			Helix Vibrance		Thiamethoxam 269 g/L Difenoconazole 16 g/L Metalaxyl-M and S-Isomer 5 g/L Sedaxane 3.4 g/L Fludioxonil 1.7 g/L

- 1 "Decision statement" as required by subsection 28(5) of the Pest Control Products Act.
- 2 "Consultation statement" as required by subsection 28(2) of the Pest Control Products Act.

- 3 United States Environmental Protection Agency (USEPA), Health Canada, California Department of Pesticide Regulation. USEPA Pollinator Risk Assessment Guidance webpage, <https://www.epa.gov/pollinator-protection/pollinator-risk-assessment-guidance>, accessed March 2019.
 - 4 As per subsection 35(1) of the Pest Control Products Act.
-

Date modified:

2020-02-10

This is **Exhibit “J2”** referred to in the affidavit of **Dr. Elaine MacDonald** affirmed remotely before me in accordance with O. Reg 431/20, Administering Oath or Declaration Remotely this 19th day of January 2022.



Commissioner for Taking Affidavits
(or as may be)



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of Canada

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du Canada

[Canada.ca](#) > [Health](#) > [Product safety](#) > [Consumer products and cosmetics](#)

> [Reports and Publications – Consumer Product Safety](#).

> [Pesticides and pest management reports and publications](#) > [Decisions and Updates](#)

Re-evaluation Decision RVD2019-05, Clothianidin and Its Associated End-use Products: Pollinator Re-evaluation

Pest Management Regulatory Agency

11 April 2019

ISSN: 1925-0886 (PDF version)

Catalogue number: H113-9/2019-5E-PDF (PDF version)

To obtain a full copy of [Re-evaluation Decision RVD2019-05, Clothianidin and Its Associated End-use Products: Pollinator Re-evaluation](#) please contact our publications office.

Should you require further information please contact the [Pest Management Information Service](#).

Summary

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Re-evaluation Decision

Under the authority of the Pest Control Products Act, Health Canada's Pest Management Regulatory Agency (PMRA) conducted a re-evaluation of all agricultural and turf uses for clothianidin and its associated end-use products, specifically to assess the risk to pollinators, such as honey bees, bumble bees, and solitary bees. This re-evaluation assessed the potential risk to pollinators in light of international updates to the pollinator risk assessment framework. Extensive information obtained from published literature, as well as data received from registrants, was considered. Health Canada applied internationally accepted risk assessment methods as well as current risk management approaches and policies. In addition to the pollinator risk assessment, the value of the active ingredient to the various use sectors was assessed.

Products containing clothianidin are sold as sprays to be applied to plants and to bare soil. Clothianidin is also used as a coating on crop seeds to prevent insects from eating the seeds when they are planted in the ground and to protect the plants grown from treated seeds. Some uses result in clothianidin being taken up by the plants from the soil or through their leaves, where it then moves into parts of the flower where nectar and pollen are produced. Because bees use nectar and pollen as their primary sources of food, bees may be exposed to clothianidin (and its breakdown products) when they visit certain flowers to collect pollen and nectar. Bees may also be accidentally sprayed or collect water containing clothianidin. Currently registered products containing clothianidin that are subject to this re-evaluation are listed in Appendix I.

This document (RVD2019-05, Clothianidin and Its Associated End-use Products: Pollinator Re-evaluation) presents the final regulatory decision ¹ for the pollinator re-evaluation of clothianidin, including the required risk mitigation measures to protect bees. Most products containing clothianidin are subject to this regulatory decision. The proposed regulatory decision published in PRVD2017-23, Clothianidin and Its Associated End-use Products: Pollinator Re-evaluation, ² has undergone a 90-day consultation that ended on 19 March 2018.

Health Canada received comments mostly relating to the value and pollinator risk assessments. These comments are summarized in Appendix II of RVD2019-05, Clothianidin and Its Associated End-use Products: Pollinator Re-evaluation, along with the responses by Health Canada. The comments did not result in a change to the risk assessments. Therefore, this decision is consistent with the proposed re-evaluation decision stated in PRVD2017-23. All of the data that were used as the basis for the proposed re-evaluation

decision are published in PRVD2017-23. Further data used in the final re-evaluation decision, including data received during the consultation period, are listed in Appendix IV of RVD2019-05.

Outcome of Science Evaluation

The risk assessment, conducted according to the Guidance for Assessing Pesticide Risks to Bees,³ determined that there are varying degrees of effects on bees. Some current uses of clothianidin are not expected to affect bees. For some uses, mitigation measures (in other words, changes to the conditions of registration) are required to minimize exposure to bees. Mitigation measures include changes to the use pattern and label improvements. When clothianidin is used in accordance with these new risk reduction measures, the reduced environmental exposure is considered adequate and risks are acceptable. Label statements informing users of the potential for toxicity to pollinators are required on product labels. For other uses, risks to pollinators were not found to be acceptable; therefore, these uses are cancelled.

Regulatory Decision for Clothianidin

Health Canada has completed the pollinator re-evaluation of clothianidin. Under the authority of the Pest Control Products Act, Health Canada has determined that, with required amendments, continued registration of products containing clothianidin is acceptable; however, certain uses of clothianidin are cancelled to address potential risks of concern to pollinators. An evaluation of available scientific information found that some uses of clothianidin products meet current standards for protection of pollinators when used according to the conditions of registration, which include required amendments to label directions. Label amendments, as summarized below and listed in Appendix III of RVD2019-05, are required for all end-use products. No additional data are requested.

Risk Mitigation Measures to Protect Pollinators

Registered pesticide product labels include specific direction for use. Directions include risk mitigation measures to protect human health and the environment and must be followed by law. As a result of this re-evaluation of clothianidin, further risk mitigation measures for product labels are required.

Certain crops are highly attractive to bees when their flowers are in bloom. Since large numbers of bees are attracted to these crops when they are in bloom and based on an assessment of the risks to bees, the application of pesticides containing clothianidin can lead to effects that may have an impact on the survival of bee colonies or solitary bee species.

In order to protect pollinators, **Health Canada is cancelling the following uses of clothianidin:**

- Foliar application to orchard trees and strawberries, and
- Foliar application to municipal, industrial and residential turf sites.

In order to protect pollinators, **Health Canada is changing the conditions of use of clothianidin:**

- Reduce maximum number of foliar applications to cucurbit vegetables to one per season.

To minimize bee exposure to dust during planting of treated seed, **additional label statements are required for the following use:**

- Seed treatment of cereal crops.

The additional risk mitigation measures described above will be implemented over a 24-month period. The risks identified are not considered imminent because they are not expected to cause irreversible harm over this period. Potential effects include sublethal effects on colonies or solitary bees, but affected pollinator populations are expected to recover following implementation of the additional restrictions which will reduce exposure. Moreover, recovery is expected because risks to pollinators are geographically limited to areas where these products are applied and areas adjacent to application sites. The presence of unaffected solitary bees, bumble bees, and honey bees in areas where products are not being used will further facilitate recovery since unaffected bees in the environment can move back into areas where effects may have occurred. Overall, risk to pollinators is acceptable over the time period required to implement the mitigation measures.

As a result of this decision, growers will be required to change their pest management practices. Pesticides have extensive and precise instructions and often require specialized application and safety equipment and training. This transition period will allow for an orderly and safe implementation of these new restrictions, and should reduce the risk of

product misuse or the improper disposal of products as users switch to alternatives, where required. This approach is consistent with Health Canada's current policy and practice with respect to phase out of uses as a result of a re-evaluation ([Regulatory Directive DIR2018-01, Policy on Cancellations and Amendments Following Re-evaluation and Special Review](#)) and with the practice of other international regulators.

A small subset of uses were found to lack alternatives for the management of a serious pest (the invasive brown marmorated stink bug) on a very few crops present in limited geographical areas of Canada. As a result, the implementation of the re-evaluation decision for these uses will be delayed for an additional year to allow growers to find pest management solutions. During this period, the overall exposure to pollinators will be significantly reduced through both removal of uses to control other pests on these crops and other crops that pose a risk to bees, as well as through implementation of additional restrictions in application timing which will further reduce pollinator exposure. The risks to pollinators are therefore considered acceptable for an additional year for this small subset of uses.

Next Steps

To comply with this decision, taking into account [Regulatory Directive DIR2018-01, Policy on Cancellations and Amendments Following Re-evaluation and Special Review](#), the required mitigation measures must be implemented on all product labels sold by registrants no later than 24 months after the publication date of this decision document. Appendix I lists the products containing clothianidin that are registered under the authority of the Pest Control Products Act.

Other Information

Any person may file a notice of objection ⁴ regarding this decision on clothianidin within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the [Pesticides](#) section of the Canada.ca website ([Request a Reconsideration of Decision](#)) or contact the PMRA's [Pest Management Information Service](#).

Appendix I Registered Clothianidin Products in Canada Subject to This Re-evaluation

Table 1 Registered Clothianidin Products in Canada Subject to This Re-evaluation as of 2 October 2018, excluding discontinued products and products with a submission to discontinue

Registration number	Marketing Class	Registrant	Product name	Formulation type	Guarantee
27445	Technical Grade Active Ingredient	Sumitomo Chemical Company Inc.	Clothianidin Technical Insecticide	Solid	<ul style="list-style-type: none"> • Clothianidin 97.5%
27449	Commercial	Bayer CropScience Inc.	Titan Insecticide	Suspension	<ul style="list-style-type: none"> • Clothianidin 600 g/L
27453		Bayer CropScience Inc.	Poncho 600 FS Seed Treatment Insecticide	Suspension	<ul style="list-style-type: none"> • Clothianidin 600 g/L
27564		Bayer CropScience Inc.	Prosper FL Flowable Insecticide And Fungicide Seed Treatment	Suspension	<ul style="list-style-type: none"> • Clothianidin 120 g/L; • carbathiin 56 g/L; • thiram 120 g/L; • metalaxyl 4g/L
28975		Valent Canada Inc.	Nipsit Inside 600 Insecticide	Suspension	<ul style="list-style-type: none"> • Clothianidin 600g/L

Registration number	Marketing Class	Registrant	Product name	Formulation type	Guarantee
29158		Bayer CropScience Inc.	Prosper T 200 Flowable Insecticide And Fungicide Seed Treatment	Suspension	<ul style="list-style-type: none"> • Clothianidin 142.8g/L; • carbathiin 50g/L; • trifloxystrobin 7.14g/L; • metalaxyl 5.36g/L
29159		Bayer CropScience Inc.	Prosper FX Flowable Insecticide And Fungicide Seed Treatment	Suspension	<ul style="list-style-type: none"> • Clothianidin 285.7 g/L; • carbathiin 50 g/L; • trifloxystrobin 7.14g/L; • metalaxyl 5.36 g/L
29382		Valent Canada Inc.	Clutch 50 WDG Insecticide	Water dispersible granules	<ul style="list-style-type: none"> • Clothianidin 50%
29383		Valent Canada Inc.	Arena 50 WDG Insecticide	Water dispersible granules	<ul style="list-style-type: none"> • Clothianidin 50%
29384		Valent Canada Inc.	Clothianidin Insecticide	Water dispersible granules	<ul style="list-style-type: none"> • Clothianidin 50%
30362		Bayer CropScience Inc.	Emesto Quantum	Suspension	<ul style="list-style-type: none"> • Clothianidin 207g/L; penflufen 66.5 g/L

Registration number	Marketing Class	Registrant	Product name	Formulation type	Guarantee
30363		Bayer CropScience Inc.	Prosper Evergol	Suspension	<ul style="list-style-type: none"> • Clothianidin 290 g/L; • rifloxystrobin 7.15g/L; • penflufen 10.7g/L; • metalaxyl 7.15g/L
30972		Bayer CropScience Inc.	Sepresto 75 WS	Wettable powder	<ul style="list-style-type: none"> • Clothianidin 56.25%; • imidacloprid 18.75%
31355		Valent Canada Inc.	Nipsit Suite Canola Seed Protectant	Suspension	<ul style="list-style-type: none"> • Clothianidin 279 g/L; • metalaxyl 5.23 g/L; • metconazole 1.04 g/L
31357		Valent Canada Inc.	Nipsit Suite Cereals Of Seed Protectant	Suspension	<ul style="list-style-type: none"> • Clothianidin 30.7 g/L; • metalaxyl 9.24 g/L; • metconazole 4.62 g/L

1 "Decision statement" as required by subsection 28(5) of the Pest Control Products Act.

2 "Consultation statement" as required by subsection 28(2) of the Pest Control Products Act.

- 3 United States Environmental Protection Agency (USEPA), Health Canada, California Department of Pesticide Regulation. USEPA Pollinator Risk Assessment Guidance webpage, <https://www.epa.gov/pollinator-protection/pollinator-risk-assessment-guidance>, accessed March 2019.
 - 4 As per subsection 35(1) of the Pest Control Products Act.
-

Date modified:

2020-03-04

This is **Exhibit “K”** referred to in the affidavit of
Dr. Elaine MacDonald affirmed remotely before
me in accordance with O. Reg 431/20,
Administering Oath or Declaration Remotely
this 19th day of January 2022.



Commissioner for Taking Affidavits
(or as may be)



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File No.:386

March 5, 2018

Pest Management Regulatory Agency Publications Section
Pest Management Regulatory Agency (PMRA)
Health Canada
2720 Riverside Drive
Ottawa, Ontario K1A 0K9

Sent by E-mail: PMRA.publications@hc-sc.gc.ca

Dear Sir/Madam:

Re: Re-evaluation Note REV2018-01, Special review of Dichlorvos and its associated end-use products: Proposed decision for consultation (ISSN: 1925-0649 / Catalogue number: H113-5/2018-1E-PDF)

I am counsel for the Canadian Association of Physicians for the Environment, the David Suzuki Foundation, Environmental Defence and Équiterre, and submit these comments on their behalf.

Health Canada's Pest Management Regulatory Agency (PMRA) initiated a special review of pest control products containing Dichlorvos, based on 2007 and 2012 European Union regulatory decisions. The European Commission (EC) found in 2007 that the information on dichlorvos is insufficient with regard to uncertainties of the genotoxic and carcinogenic properties for workers and bystanders exposure. In 2012 the EC decision found that the "scenarios evaluated in the human health risk assessment as well as in the environmental risk assessment showed a potential and unacceptable risk".¹ I am writing on behalf of the above clients with respect to the narrow issue of whether the special review of dichlorvos and related special reviews and re-evaluations of other organophosphates comply with subsection 19(2)(b)(i) of the *Pest Control Products Act*.²

In the consultation document for the Dichlorvos special review page 13 indicates that the PMRA is required to consider the cumulative effects of pest control products that have a common mechanism of toxicity, including organophosphates.³ However, the consultation document indicates that the PMRA will only undertake such a cumulative assessment "upon the completion

¹ 2012/254/EU

² *Pest Control Products Act*, SC 2002, c 28

³ ISSN: 1925-0649 / Catalogue number: H113-5/2018-1E-PDF

of the re-evaluation of the individual chemicals in the organophosphate group with all relevant chemicals and scenarios of the common mechanism group.”

Similar statements are found in other special reviews and re-evaluations for organophosphate products, listed in Schedule A to this letter. In 2016 the PMRA released its approach to the cumulative effects of pesticides. This document identifies organophosphates as a group of pesticides having a common toxic effect that occurs by the same mechanism. This document stated that completing individual assessments for pesticides within the same group/class is “the first step in the cumulative assessment process.” However it is clear that this is in-fact not a step in the cumulative effects process for organophosphates since no cumulative effects analysis is included in the individual organophosphate special reviews and re-evaluations. This document also states that the PMRA expects to have a finalized methodology in place to complete cumulative effects analysis by this year (2018).⁴

Subsection 19(2)(b)(i) of the *Pest Control Products Act* requires that the PMRA consider “cumulative effects of the pest control product and other pest control products that have a common mechanism of toxicity” during an evaluation that is done in the course of a re-evaluation or special review. As such any decision to defer the consideration/evaluation of cumulative effects of organophosphates until all such reviews are completed is contrary to the express requirements of the Act.

Not only is the procedure of deferring cumulative effects analysis until after the completion of re-evaluations and special reviews unlawful, but it raises some very serious concerns about whether the health of Canadians is being adequately protected. The re-evaluation of chlorpyrifos has been ongoing for over a decade and is not expected to be completed until March 2020. It is unclear on what timeline the PMRA will complete all of the organophosphate special reviews and re-evaluations and commence its cumulative effects analysis. It is also unclear why, over a decade after the *Pest Control Products Act* was brought into force the PMRA has not developed a methodology to complete a cumulative effects analysis of organophosphates.

The PMRA’s approach to cumulative effects references best practices from other jurisdictions including the US-EPA. The US-EPA completed a preliminary cumulative effects analysis for organophosphates, including dichlorvos in 2002, the same year that the *Pest Control Products Act* requirement to conduct cumulative effects analysis during the course of re-evaluations and special reviews was enacted. The 2002 cumulative effects review by the US-EPA was completed in-addition to the US-EPA assessment of individual organophosphates. The US-EPA cumulative effects assessment of organophosphates was updated in 2006.⁵ The 2006 update states that the same methodology was used as in the 2002 review and that the US-EPA “has developed a highly refined and complex cumulative risk assessment for organophosphates that

⁴ Health Canada “Pest Management Regulatory Agency's Approach to Assessing Cumulative Effects of Pesticides.” online: <<https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/public/protecting-your-health-environment/response-commissioner-environment-sustainable-development-2015-audit/regulatory-agency-approach-assessing-cumulative-effects.html?=&wbdisable=true>>

⁵ Organophosphorus Cumulative Risk Assessment (2006 Update) online: <<https://www.regulations.gov/document?D=EPA-HQ-OPP-2006-0618-0002>>

represents the state of the science regarding existing hazard and exposure data, and the models and approaches used.”

The re-evaluations and special reviews of organophosphates undertaken by the PMRA all commenced after the completion of the initial US-EPA cumulative effects assessment for organophosphates in 2002 and accordingly after the US-EPA cumulative effects methodology for organophosphates was developed. Other individual PMRA reviews of organophosphates commenced after the 2006 US-EPA update. It is therefore unclear on a practical level why the PMRA did not employ or refine the US-EPA methodology to comply with subsection 19(2)(b)(i) of the *Pest Control Products Act* and complete the cumulative effects analysis during the course of re-evaluations and special reviews of organophosphates.

To be clear, it is our clients’ position that the finalization of any of the outstanding re-evaluations or special reviews of organophosphates, including dichlorvos without completing a cumulative effects analysis would be unlawful.

Please advise me of the following:

1. When does the PMRA intend to complete the remaining organophosphate re-evaluations and special reviews?
2. Is the PMRA’s cumulative effects methodology for organophosphates completed and will it consult the public on that methodology?
3. When will the PMRA initiate and complete a cumulative effects assessment of the health risks of organophosphates?

I look forward to your response.

Regards,



Laura Bowman
Barrister & Solicitor

Encl. Schedule A

cc: Muhannad Malas, Lisa Gue, Karen Ross, Kim Perrotta

Schedule A

acephate

bensulide

chlorpyrifos

coumaphos

diazinon

dichlorvos

dimethoate

fenitrothion

malathion

methidathion

naled

phorate

phosmet

propetamphos

tetrachlorvinphos

trichlorfon

This is **Exhibit “L”** referred to in the affidavit of
Dr. Elaine MacDonald affirmed remotely before
me in accordance with O. Reg 431/20,
Administering Oath or Declaration Remotely
this 19th day of January 2022.



Commissioner for Taking Affidavits
(or as may be)

	Registration number	Product name - English	Registrant name	Label uses permitted	Use Site Category	Marketing type	Registration Status	Current / Historical	Last sale by registrant	Last sale by retail	Expiry date	Date first registered	Active ingredients - English	Discontinuation application no.	discontinuation application date received	Application No	application date received	application date completed	application, category, outcome
1	12223	DURSBAN 2.5 INSECTICIDE	CORTEVA AGRISCIENCE CANADA COMPANY*	Control for larvae of mosquito. Standing water - temporary pools, ground and aircraft application, flooded area treatment.	2-AQUATIC NON-FOOD SITES	RESTRICTED	Full Registration	Current	9/30/2017	9/30/2018	9/30/2021	7/1/1973	CHLORPYRIFOS	2017-5055	9/21/2017	2014-2875	7/31/2014	2014-08-18	D - renewal, registered
2	14879	LORSBAN 4E INSECTICIDE	CORTEVA AGRISCIENCE CANADA COMPANY*	Agricultural Chemical. Soil, Foliar and Arial Application. Canola, Flax, Lentil, Corn (Filed and Sweet), Strawberry, Celery, Cucumber, Green (pepper), Pak Choi, Broccoli, Brussels Sprout, Cabbage, Cauliflower, Chinese Cabbage, Garlic, Rutabaga, Potato, Sunflower, Sugarbeet, Barley, Wheat, Oats, Onion (bulb and picking), Tobacco, Carrot, Filbert, Asian Radish, Radish, Chinese broccoli, green onion, lodgepole pine, ornamentals commercial production greenhouse nurseries, turf (sod farms only)	4-FOREST AND WOODLOTS, 6-GREENHOUSE NON-FOOD CROPS, 7-INDUSTRIAL OIL SEED & FIBRE CROPS, 27-ORNAMENTALS OUTDOOR, 13-TERRESTRIAL FEED CROPS, 14-TERRESTRIAL FOOD CROPS, 30-TURF	COMMERCIAL + RESTRICTED USES	Full Registration	Current	12/9/2021	12/9/2022	12/9/2023	7/1/1979	CHLORPYRIFOS	2021-0239	1/21/2021	2016-5085	8/17/2016	2016-12-07	D-renewal, registered
3	16458	LORSBAN* 15G INSECTICIDE	CORTEVA AGRISCIENCE CANADA COMPANY*	To control certain pests in onions, field, seed and sweet corn, broccoli, Brussels sprouts, cabbage, cauliflower and rutabagas. Ground application.	13-TERRESTRIAL FEED CROPS, 14-TERRESTRIAL FOOD CROPS	COMMERCIAL	Full Registration	Current	12/9/2021	12/9/2022	12/9/2023	3/12/1980	CHLORPYRIFOS	2021-0240	1/21/2021	2020-5917 (product listed as confidential but application is listed under this product in new database)	44182	2021-02-16	Discontinued, withdrawn
4	19656	DURSBAN FM INSECTICIDAL CHEMICAL	CORTEVA AGRISCIENCE CANADA COMPANY*	Manufacturing use only	4-FOREST AND WOODLOTS, 6-GREENHOUSE NON-FOOD CROPS, 7-INDUSTRIAL OIL SEED & FIBRE CROPS, 27-ORNAMENTALS OUTDOOR, 20-STRUCTURAL, 13-TERRESTRIAL FEED CROPS, 14-TERRESTRIAL FOOD CROPS, 30-TURF	TECHNICAL ACTIVE	Full Registration	Current	12/9/2021	12/9/2022	12/9/2023	2/23/1987	CHLORPYRIFOS	2021-0233	1/21/2021	2019-5056	9/10/2019	2019-11-29	D-renewal, registered
5	20320	DURSBAN HF INSECTICIDAL CONCENTRATE	CORTEVA AGRISCIENCE CANADA COMPANY*	Manufacturing use only	2-AQUATIC NON-FOOD SITES, 4-FOREST AND WOODLOTS, 6-GREENHOUSE NON-FOOD CROPS, 16-INDUSTRIAL & DOMESTIC VEGETATION CONTROL, 27-ORNAMENTALS OUTDOOR, 20-STRUCTURAL, 30-TURF	MANUFACTURING CONCENTRATE	Full Registration	Current	12/9/2021	12/9/2022	12/9/2023	3/2/1988	CHLORPYRIFOS	2021-0234	1/21/2021	2019-5058	9/10/2019	2019-11-29	D-renewal, registered
6	20407	DURSBAN W INSECTICIDAL CONCENTRATE	CORTEVA AGRISCIENCE CANADA COMPANY*	Manufacturing use only	blank	MANUFACTURING CONCENTRATE	Full Registration	Current	12/9/2021	12/9/2022	12/9/2023	4/18/1988	CHLORPYRIFOS	2021-0235	1/21/2021	2019-5059	9/10/2019	2019-11-29	D-renewal, registered
7	20944	LORSBAN 50W INSECTICIDE	CORTEVA AGRISCIENCE CANADA COMPANY*	Airblast, ground, hand applicator. Use Lorsban 50W Insecticide for the control of subterranean cutworms in green peppers, cucumbers, potatoes, Chinese cabbage, cabbage, broccoli, Brussels sprouts, cauliflower, rutabagas, onions (excluding bunching onions), celery, carrots, field and sweet corn, root maggots in tobacco and cabbage, strawberry cutworm (crown borer) in strawberries, potato flea beetle and tarnished plant bug in potatoes.	13-TERRESTRIAL FEED CROPS, 14-TERRESTRIAL FOOD CROPS	COMMERCIAL + RESTRICTED USES	Full Registration	Current	12/9/2021	12/9/2022	12/9/2023	4/18/1989	CHLORPYRIFOS	2021-0238	1/21/2021	2020-5916 (product listed as confidential)	44182	2021-02-16	D- discontinued withdrawn
8	21997	DURSBAN WATER SOLUBLE INSECTICIDE	CORTEVA AGRISCIENCE CANADA COMPANY*	Ground or handheld application. Turf; ornamentals (commercial) greenhouse, nurseries, industrial sites; around buildings (non residential);native elm bark with authorization from provincial authorities.	6-GREENHOUSE NON-FOOD CROPS, 27-ORNAMENTALS OUTDOOR, 20-STRUCTURAL, 30-TURF	COMMERCIAL	Full Registration	Current	12/9/2021	12/9/2022	12/9/2023	1/21/1992	CHLORPYRIFOS	2021-0236	1/21/2021	2019-5060	9/10/2019	2019-11-29	D-renewal, registered
9	23621	PYRINEX TECHNICAL CHLORPYRIFOS INSECTICIDE	ADAMA AGRICULTURAL SOLUTIONS CANADA LTD.	For use in manufacturing, formulating or repackaging. To be used only in the manufacture of an insecticide which is registered under the Pest Control Products Act	6-GREENHOUSE NON-FOOD CROPS, 27-ORNAMENTALS OUTDOOR, 20-STRUCTURAL, 30-TURF	TECHNICAL ACTIVE	Full Registration	Current	12/10/2021	12/10/2022	12/10/2023	5/19/1994	CHLORPYRIFOS	2021-1513	4/12/2021	2021-0973 (product listed as confidential)	44256	2021-04-21	C-amendment, withdrawn
10	23704	PYRATE 480 EC INSECTICIDE	ADAMA AGRICULTURAL SOLUTIONS CANADA LTD.	Non-food use. Restricted Uses to Control: Adult and Larval Mosquitoes, Mountain Pine Beetle in Forestry Situations. To Be Applied Only Under The Direct Supervision of Commercial Applicators Responsible For Pest Control Programs.	2-AQUATIC NON-FOOD SITES, 4-FOREST AND WOODLOTS, 6-GREENHOUSE NON-FOOD CROPS, 16-INDUSTRIAL & DOMESTIC VEGETATION CONTROL, 27-ORNAMENTALS OUTDOOR, 20-STRUCTURAL, 30-TURF	COMMERCIAL + RESTRICTED USES	Full Registration	Current	12/10/2021	12/10/2022	12/10/2023	5/1/1995	CHLORPYRIFOS	2021-1514	4/12/2021	2021-0959 (product listed as confidential)	44259	2021-04-21	C - amendment, withdrawn
11	23705	PYRINEX 480EC FOR FOOD CROPS	ADAMA AGRICULTURAL SOLUTIONS CANADA LTD.	Agricultural - canola, flax, lentils, corn (filed and sweet), strawberry, Asian Radish, Radish, celery, cucumber, green pepper, Pak Choi, Broccoli, Brussels sprouts, Cabbage, Cauliflower, Chinese Cabbage, Chinese Broccoli, Garlic, Rutabaga, Carrot, Potato, Sunflower, Sugarbeet, Barley, Wheat, oats, onion, Tobacco, Filbert, Forest: Lodgepole Pine - mountain pine beetle, (some permit aerial spray some don't). Field spraying.	4-FOREST AND WOODLOTS, 7-INDUSTRIAL OIL SEED & FIBRE CROPS, 13-TERRESTRIAL FEED CROPS, 14-TERRESTRIAL FOOD CROPS	COMMERCIAL	Full Registration	Current	2021-12-10	12/10/2022	12/10/2023	3/27/1995	CHLORPYRIFOS	2021-0947	3/4/2021	2016-6485	9/26/2016	2016-12-28	D-renewal, registered

	Registration number	Product name - English	Registrant name	Label uses permitted	Use Site Category	Marketing type	Registration Status	Current / Historical	Last sale by registrant	Last sale by retail	Expiry date	Date first registered	Active ingredients - English	Discontinuation application no.	discontinuation application date received	Application No	application date received	application date completed	application, category, outcome
12	24648	PYRIFOS 15G INSECTICIDE	LOVELAND PRODUCTS CANADA INC.*	Ground application only (do not apply by aircraft). Corn (sweet and field), onions, broccoli, brussels sprouts, cabbage, cauliflower, and rutabagas, potato,	7-INDUSTRIAL OIL SEED & FIBRE CROPS, 13-TERRESTRIAL FEED CROPS, 14-TERRESTRIAL FOOD CROPS	COMMERCIAL	Full Registration	Current	12/10/2021	12/10/2022	12/10/2023	11/6/1996	CHLORPYRIFOS	2020-5919	12/17/2020	2019-4567	8/7/2019	2019-11-15	D-renewal, registered
13	25823	CHLORPYRIFOS TECHNICAL	FMC OF CANADA LIMITED	To be used only in the manufacture of an insecticide which is registered under the Pest Control Products Act.	25-HUMAN HABITAT AND RECREATIONAL AREAS, 7-INDUSTRIAL OIL SEED & FIBRE CROPS, 20-STRUCTURAL, 13-TERRESTRIAL FEED CROPS, 14-TERRESTRIAL FOOD CROPS	TECHNICAL ACTIVE	Full Registration	Current	12/31/2018	12/31/2019	12/31/2022	6/23/1999	CHLORPYRIFOS	2018-1010	3/13/2018	2017-5436	9/5/2017	2017-12-28	D-renewal, registered
14	25831	NUFOS 4E INSECTICIDE	FMC OF CANADA LIMITED	Soil, Foliar and aerial uses. Barley, Wheat Oats, cucumber no air, celery no air, green pepper no air, Chinese broccoli no air, (Broccoli, Brussels sprouts, Cabbage, Cauliflower, Chinese cabbage, Pak Choi - no air), Garlic no air, potato no air, rutabaga no air, corn (sweet and field seed treatment only) no air, radish no air, Asian radish no air, carrot no air, bulb onion no air, canola, flax, lentils, strawberries no air), sugarbeets no air, sunflower, filbert no air, tobacco no air.	7-INDUSTRIAL OIL SEED & FIBRE CROPS, 13-TERRESTRIAL FEED CROPS, 14-TERRESTRIAL FOOD CROPS	COMMERCIAL	Full Registration	Current	12/10/2021	12/10/2022	12/10/2023	8/20/1999	CHLORPYRIFOS	2020-5918	12/17/2020	2019-5802	43745	2020-06-23	C-amendment, registered
15	27479	CITADEL 480EC INSECTICIDE	INTERPROVINCIAL COOPERATIVE LIMITED	Aerial or ground Field Crops canola, cereals (barley, wheat, oats). Ground only - Corn (sweet and field). Ground or aerial flax, lentil. Ground only - potato, sugar beet. Ground or air - Sunflower. Ground only - carrot. Ground only - Celery, cucumber peppers. Ground only - cabbage, cauliflower, broccoli, brussel sprout, pak choi, Chinese cabbage, garlic, onion, strawberry, rutabaga, Asian radish, radish, Chinese broccoli, filbert. Restricted - mountain pine beetle must be authorized.	4-FOREST AND WOODLOTS, 7-INDUSTRIAL OIL SEED & FIBRE CROPS, 13-TERRESTRIAL FEED CROPS, 14-TERRESTRIAL FOOD CROPS	COMMERCIAL	Full Registration	Current	12/10/2020	12/10/2021	12/10/2022	9/17/2003	CHLORPYRIFOS	2020-5846	12/11/2020	2018-3529	8/1/2018	2018-10-10	D-renewal, registered
16	29650	LORSBAN NT INSECTICIDE	CORTEVA AGRISCIENCE CANADA COMPANY*	Ground or aerial - Cereals (Barley, Wheat, Oats), Canola. Ground only soil or seedling corn field and sweet. Ground or air - flax, lentil. Ground or air (for one pest)- sunflower. Ground- carrot, celery, cucumber, green pepper, garlic, onion, pak choi, broccoli, brussels sprout, cabbage, cauliflower, Chinese cabbage, potato, rutabaga, strawberry, sugarbeet, tobacco.	4-FOREST AND WOODLOTS, 6-GREENHOUSE NON-FOOD CROPS, 7-INDUSTRIAL OIL SEED & FIBRE CROPS, 27-ORNAMENTALS OUTDOOR, 13-TERRESTRIAL FEED CROPS, 14-TERRESTRIAL FOOD CROPS, 30-TURF	COMMERCIAL+RESTRICTED USES	Full Registration	Current	12/9/2021	12/9/2022	12/9/2023	7/13/2010	CHLORPYRIFOS	2021-0237	1/21/2021	2019-3472 (product listed as confidential)	43663	2020-04-29	C-amendment, withdrawn
17	29984	WARHAWK 480 EC INSECTICIDE	LOVELAND PRODUCTS, INC.*	Airblast applications peaches and nectarines. Ground or air - canola. Ground - filbert. Ground or air - Flax, lentil. Seed treatment - corn (field or sweet). Ground only - strawberry, celery, cucumber, pepper (green), pak choi, broccoli, brussels sprout, cabbage, cauliflower, Chinese cabbage, garlic, rutabaga, carrot, potato. Ground or air (for one pest) sunflower. Ground - sugarbeet. Ground or air - barley, wheat, oats. Ground - onion, tobacco, Asian radish, radish, Chinese broccoli.	7-INDUSTRIAL OIL SEED & FIBRE CROPS, 13-TERRESTRIAL FEED CROPS, 14-TERRESTRIAL FOOD CROPS	COMMERCIAL	Full Registration	Current	12/10/2021	12/10/2022	12/10/2023	3/2/2011	CHLORPYRIFOS	2020-5920	12/17/2020	2016-5617	9/15/2016	2017-01-17	D-renewal, registered
18	30985	MPOWER KRYPTON	NEWAGCO INC.*	Ground or aerial - Barley, Wheat, Oats. Ground only - Cucumber, Celery, Green pepper, Chinese broccoli, Broccoli, Brussels sprouts, Cabbage, Cauliflower, Chinese cabbage, Pak Choi, garlic, potato, rutabaga, corn sweet and field), radish, Asian radish, carrot, bulb onion. Ground or air - canola, flax, lentils. Ground only strawberries, sugarbeet. Ground or air (one pest) sunflower. Ground only - filbert, tobacco.	7-INDUSTRIAL OIL SEED & FIBRE CROPS, 13-TERRESTRIAL FEED CROPS, 14-TERRESTRIAL FOOD CROPS	COMMERCIAL	Full Registration	Current	12/10/2021	12/10/2022	12/10/2023	6/21/2013	CHLORPYRIFOS	2020-5907	12/17/2020	2019-4604	8/14/2019	2019-11-19	D-renewal, registered
19	31417	CHLORPYRIFOS AGROGILL TECHNICAL GRADE ACTIVE INGREDIENT	AGROGILL CHEMICALS PTY LTD*	For manufacturing, formulating or repackaging	blank	TECHNICAL ACTIVE	Full Registration	Current	12/10/2021	12/10/2022	12/10/2023	8/15/2014	CHLORPYRIFOS	2020-5910	12/17/2020	2019-4134	7/22/2019	2019-10-25	D-renewal, registered
20	32694	SHARDA CHLORPYRIFOS TECHNICAL INSECTICIDE	SHARDA CROP-CHEM LIMITED	manufacturing, formulating or repackaging.	4-FOREST AND WOODLOTS, 6-GREENHOUSE NON-FOOD CROPS, 7-INDUSTRIAL OIL SEED & FIBRE CROPS, 27-ORNAMENTALS OUTDOOR, 13-TERRESTRIAL FEED CROPS, 14-TERRESTRIAL FOOD CROPS, 30-TURF	TECHNICAL ACTIVE	Full Registration	Current	12/10/2021	12/10/2022	12/10/2023	8/9/2017	CHLORPYRIFOS	2021-1502	4/12/2021	2021-0476 (product listed as confidential)	44229	2021-04-21	C - Amendment, withdrawn

	Registration number	Product name - English	Registrant name	Label uses permitted	Use Site Category	Marketing type	Registration Status	Current / Historical	Last sale by registrant	Last sale by retail	Expiry date	Date first registered	Active ingredients - English	Discontinuation application no.	discontinuation application date received	Application No	application date received	application date completed	application, category, outcome
21	32768	SHARPHOS INSECTICIDE	SHARDA CROPCHEM LIMITED	Ground or air - canola. Ground only - filbert, Ground or air - flax, lentil. Ground seed treatment only - corn (field, sweet) Ground - Strawberry, celery, cucumber, pepper green), pak choi, broccoli, brussels sprout, cabbage, cauliflower, Chinese cabbage, garlic, rutabaga, carrot, potato. Ground or air (one pest) sunflower. Ground only - sugar beet. ground or air barley, wheat, oats. Ground - onions, tobacco, Asian radish, radish, chinses broccoli. Restricted forestry lodgepole pine ground only western Canada as authorized.	4-FOREST AND WOODLOTS, 6-GREENHOUSE NON-FOOD CROPS, 7-INDUSTRIAL OIL SEED & FIBRE CROPS, 27-ORNAMENTALS OUTDOOR, 13-TERRESTRIAL FEED CROPS, 14-TERRESTRIAL FOOD CROPS, 30-TURF	COMMERCIAL + RESTRICTED USES	Full Registration	Current	12/10/2021	12/10/2022	12/10/2023	8/9/2017	CHLORPYRIFOS	2021-1511	4/12/2021	2021-0571 (product name listed as confidential)	44236	2021-04-21	C- amendment, withdrawn
22	33113	PYRINEX 450 LV EC	ADAMA AGRICULTURAL SOLUTIONS CANADA LTD.	Agricultural - canola, flax, lentils, corn, strawberry, Asian Radish, Radish, celery, cucumber, green pepper, Pak Choi, Broccoli, Brussels sprouts, Cabbage, Cauliflower, Chinese Cabbage, Chinese Broccoli, Garlic, Rutabaga, Carrot, Potato, Sunflower, Sugarbeet, Barley, Wheat, oats, onion, Tobacco, Filbert, Forest: Lodgepole Pine - mountain pine beetle, (some permit aerial spray some don't)	4-FOREST AND WOODLOTS, 7-INDUSTRIAL OIL SEED & FIBRE CROPS, 13-TERRESTRIAL FEED CROPS, 14-TERRESTRIAL FOOD CROPS	COMMERCIAL	Full Registration	Current	12/10/2021	12/10/2022	12/10/2023	6/28/2018	CHLORPYRIFOS	2021-0946	3/4/2021	2017-2005	4/19/2017	2018-06-28	B-new, registered
23	33295	NEWAGCO CHLORPYRIFOS TECHNICAL	NEWAGCO INC	For use in manufacturing, formulating or repackaging	4-FOREST AND WOODLOTS, 6-GREENHOUSE NON-FOOD CROPS, 7-INDUSTRIAL OIL SEED & FIBRE CROPS, 27-ORNAMENTALS OUTDOOR, 13-TERRESTRIAL FEED CROPS, 14-TERRESTRIAL FOOD CROPS, 30-TURF	TECHNICAL ACTIVE	Full Registration	Current	12/10/2021	12/10/2022	12/10/2023	12/10/2018	CHLORPYRIFOS	2020-5909	12/17/2020	2018-6269	11/19/2018	2018-12-10	L-new, registered
24	33356	MPOWER CHLORPYRIFOS INSECTICIDE	NEWAGCO INC	Ground or air - canola, flax, lentil. Ground only - corn (field or sweet), strawberry, celery, cucumber, pepper green), pak choi, broccoli, brussels sprout, cabbage, cauliflower, Chinese cabbage, garlic, rutabaga, potato. Ground or air (one pest) sunflower. Ground only - sugarbeet. Ground or air - barley, wheat, oats. Ground only - onion, tobacco, filbertasian radish, radish, Chinese broccoli. Forest : Lodgepole pine western Canada only restricted. Spray - ornamentals (commercial production only) - greenhouses and nurseries only. Spray - Turf sod farms.	4-FOREST AND WOODLOTS, 6-GREENHOUSE NON-FOOD CROPS, 7-INDUSTRIAL OIL SEED & FIBRE CROPS, 27-ORNAMENTALS OUTDOOR, 13-TERRESTRIAL FEED CROPS, 14-TERRESTRIAL FOOD CROPS, 30-TURF	COMMERCIAL	Full Registration	Current	12/10/2021	12/10/2022	12/10/2023	2/20/2019	CHLORPYRIFOS	2020-5908	12/17/2020	2019-0419	1/21/2019	2019-02-20	L-new, registered

This is **Exhibit “M”** referred to in the affidavit of **Dr. Elaine MacDonald** affirmed remotely before me in accordance with O. Reg 431/20, Administering Oath or Declaration Remotely this 19th day of January 2022.



Commissioner for Taking Affidavits
(or as may be)



Science Policy Notice

SPN2000-01

Technical Paper

A Decision Framework for Risk Assessment and Risk Management in the Pest Management Regulatory Agency

(publié aussi en français)

December 22, 2000

This document is published by the Submission Management and Information Division,
Pest Management Regulatory Agency. For further information, please contact:

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1.0 Introduction

Pesticides are designed to “control, prevent, destroy, mitigate, attract or repel” pests. Because of the properties and characteristics that make them effective for their intended purposes, they also may pose risks to people and the environment.

In developing a decision framework that is based on the assessment and management of risk, one must identify the types of risks to be controlled; the nature of the sources from which those risks may arise; the types of activities that may cause them to arise; the means available for assessing the magnitude of the risks; the means available to mitigate and minimize the risks; appropriate means to involve stakeholders in the decision-making process; and appropriate means to enable and facilitate interaction and cooperation with other jurisdictions and regulatory bodies.

This document describes framework that guides the Pest Management Regulatory Agency (PMRA) in the assessment and management of risk and in its regulatory decision making. A cornerstone of the framework is its strong reliance on a comprehensive body of scientific evidence and scientific methods to determine the nature and magnitude of the risks posed by pesticides. This allows application of appropriate and effective risk management strategies for the protection of both human health and the environment. The PMRA’s risk-based approach to the regulation of pesticides reflects approaches of pesticide regulatory agencies in other countries. It is also consistent with approaches for regulation of other chemicals in Health Canada. The framework provides for a systematic application of science to support the PMRA’s regulatory decisions. It enhances predictability and transparency of the process that protects the health of Canadians and their environment. By considering all relevant criteria in a comprehensive fashion, it also ensures completeness in risk management decision making.

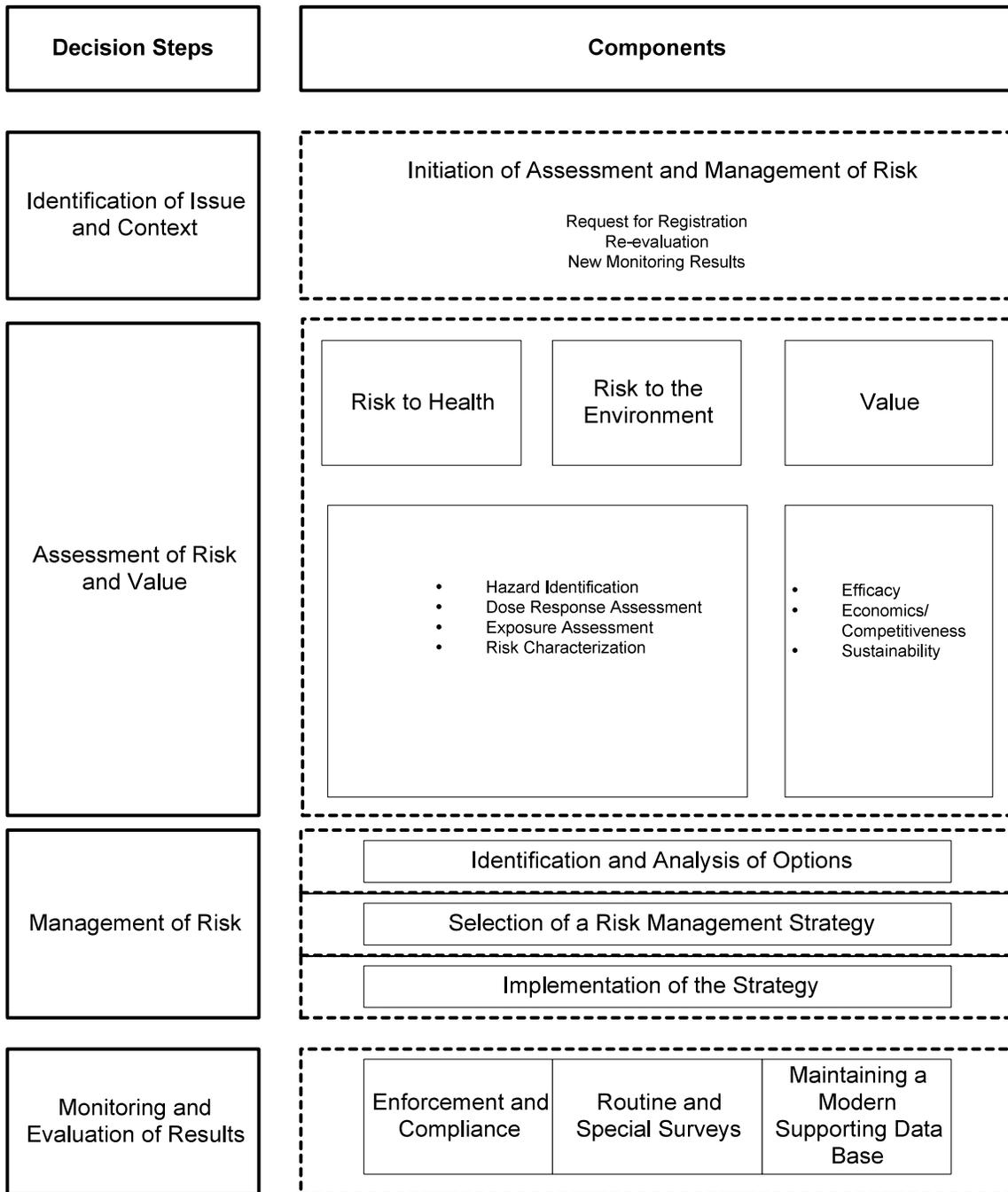
2.0 Overview of the framework

The decision framework is divided into a number of identifiable decision steps and components, as outlined in Figure 1.

Although the framework is presented as a series of sequential steps leading from a starting point, such as a request to register a new pesticide, to a defined end point, such as the decision to register, the underlying process is highly iterative and interactive. This is particularly evident in the development of risk management options. If there is a concern that the use of a product as proposed by the applicant may be associated with an unacceptable level of risk, PMRA will consider restrictions on use or other regulatory options to reduce the risk to acceptable levels. The process usually results in a number of possible management options. Each of these options must be elaborated on in sufficient detail to allow quantitative re-examination of the initially calculated risk. Typically, this requires several iterations of the assessment of risk and recalculation of risk under the different options considered.

The majority of registration decisions within the PMRA concern chemical pesticides. Accordingly, this framework is based to a large extent on the processes and approaches used to arrive at decisions about a new chemical pesticide or one under re-evaluation. With modifications specific to the situation, however, the framework also applies to registration decisions for microbial and pheromone pesticides.

Figure 1 Decision framework of the Pest Management Regulatory Agency



3.0 Identification of the Issue and its Context

All pesticides must be registered before they can be sold or used in Canada. Therefore, the most common trigger for initiating the decision-making process is a request for registration of a new pesticide or for amendments to an existing registration. The identification of the need for a re-evaluation will also trigger the decision-making process.

The *Pest Control Products Act*¹ (PCP Act) and Regulations is the primary federal legislation for the regulation of pesticides in Canada and governs their importation, manufacture, sale and use. This legislation entrenches the authority for risk assessment and risk management based decisions, whereby the risks and value of a product must be considered acceptable by the Minister for it to enter and remain on the market in Canada. The legislation also includes provisions to facilitate enforcement of compliance with the PCP Act and Regulations. It should also be noted that provincial pesticide legislation plays an important role in the overall process of pesticide regulation in Canada.

The PCP Act provides the authority for decision making on the basis of risk assessment and risk management : it requires a risk based, proactive approach for new products which are subject to premarket approval, and it requires a continued regulatory vigilance to ensure that registered products remain acceptable.

Part of the regulatory context is consideration of the compatibility of pesticide registrations with federal policies, such as the Toxic Substances Management Policy (TSMP), and international agreements on Persistent Organic Pollutants (POPs), and the Montreal Protocol on ozone depleting substances. Substances identified as Track 1 under the federal TSMP, ozone depleting substances, such as methyl bromide identified in the Montreal Protocol, and POPs are considered unacceptable for registration as new pesticide active ingredients, and would not enter the decision-making process except in highly unusual and very restricted cases, such as emergencies² and critical need situations.³ Their presence in existing pesticide products as active ingredients, formulants or contaminants could lead to a reassessment of their registration status and regulatory action consistent with pertinent federal policies and international commitments. It is also important to ensure that the use of a pesticide will not contravene other federal statutes before that use is approved under the PCP Act.

¹ Where a pesticide is used on food products, i.e., on food crops or directly on food products, the PMRA evaluates and establishes appropriate maximum residue limits (MRLs). Maximum residue limits are set for each pesticide used on food in Canada or present on food imported into Canada. The MRLs are established as a regulation under the *Food and Drugs Act* (FDA).

² See Regulatory Directive DIR94-05, *Registration of Pesticides for Emergency Use*, March 30, 1994.

³ See Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, March 12, 1999.

As in other Organisation for Economic Co-operation Development (OECD) countries, detailed risk and value assessment and risk management methodology or policies are not included in statute or regulation, but rather in directives and guidelines, so that they can be adapted quickly as scientific knowledge and public policy evolve.

4.0 Assessment of Risk and Value

Assessments of health risk, environmental risk and value are central to PMRA's decision-making process. They provide a solid factual and contextual basis for making sound registration decisions that protect human health and the environment from unacceptable risks from pesticides. Each of these three components must be acceptable before a pesticide is considered acceptable for registration. This means that products that do not work are considered to not have value and therefore would not be registered even if the health and environmental risks were acceptable. The converse is also true that if the product was very efficacious and useful to an important commodity, it would not be registered if there were unacceptable health and environmental risks.

4.1 The risk component (human health and environment)

There is broad international consensus amongst regulatory agencies that the acceptability of a pesticide should be predicated on the nature and degree of risk it poses. The PMRA employs a risk-based approach for assessment of pesticides that necessarily involves consideration of the toxicity and the level of exposure to fully characterize risk. The extensive premarket assessment of pesticides allows the PMRA to identify potential hazards and risks to health and the environment prior to making the registration decision.

The risk assessments carried out by the PMRA follow a structured predictable process that is consistent with international approaches. Assessments are based on a prescribed set of scientific data provided by registrants. These assessments provide best estimates of risk to defined populations exposed under defined exposure conditions. They are conducted in the context of well defined use scenarios, such as the use of a new pesticide on a particular field crop using specified application rates, methods and equipment. Potentially exposed populations and environments are also defined and considered in the risk assessment. The data required from registrants in support of a pesticide are tailored to provide the necessary information for the different proposed uses. The PMRA has specified extensive and detailed data requirements for over 30 different use scenarios.⁴

Only products with a database that includes all of the required studies are allowed to progress within the evaluation process and reach the decision stage. These data are generated in accordance with validated study protocols and must follow Good

⁴ See Regulatory Proposal PRO98-02, *Organizing and Formatting a Complete Submission for Pest Control Products*, February 5, 1998.

Laboratory Practices.⁵ Risk assessments can, and often do, use additional scientific data from other sources, particularly in the re-evaluation of older pesticides.

It is the nature of predictive toxicology and risk assessment that scientific uncertainties may arise even when the database is complete. For example, interpretation of the applicability of toxic effects in animals to humans, or extrapolation from small scale laboratory and field trials to actual pesticide use situations are both potential sources of uncertainty. These uncertainties are dealt with at each appropriate step in the framework. Where scientific uncertainties cannot be fully resolved through additional data, the PMRA applies “worst case” assumptions and uses increased safety factors in its risk assessment.

Re-evaluation entails assessing the risks associated with the use of currently approved pesticides and the acceptability of these risks in the light of current standards. The same steps as described for the premarket assessment are used within the process of re-evaluation and decision making. In addition, the re-evaluation program allows for placing pesticides with particular identified concerns under a “special review.” Threats of serious or irreversible damage to health or the environment are triggers for special reviews and regulatory action. These actions could include severe restrictions of use, phase-out or cancellation of a pesticide.

4.2 The value component

Value is the third component assessed for determination of the acceptability of a pesticide. The primary consideration is whether the product is efficacious, i.e., ‘does it do what it is claimed to do’. The assessment is based on results from field studies. These are conducted under typical use conditions and they must demonstrate that the pesticide provides effective control or suppression of a pest that is threatening animal and human life or health, or an agricultural and industrial commodity, process or product.

As will be discussed in Section 5.0 and 6.0 of this document, the assessment of value has an additional function. It allows for the development and evaluation of risk management options by providing information on the inherent cost of risk mitigation and impacts on economic benefits and competitiveness. It also can bring into the decision-making process, information for considering impacts on trade, such as the potential impediment to movement of commodities that may arise from differences between major trading partners with respect to the regulatory status of pesticides and allowable pesticide residue limits.

It must be emphasized that health and environmental risks must be acceptable before a product is considered eligible for registration regardless of the value of the product.

⁵ See Regulatory Directive DIR98-01, *Good Laboratory Practice*, July 27, 1998.

4.3 Assessment of Risks to Human Health

The purpose of conducting an assessment of risks to human health is to define the nature of the risk (hazard) and to provide a measure of the likelihood and the magnitude of the risk associated with a defined exposure. The assessment follows a four-step process:⁶ (1) hazard identification, (2) dose–response assessment, (3) exposure assessment and (4) risk characterization.

The main source of information for identifying hazards (toxic end points or adverse health or environmental effects) and for determining the relationship between dose and response are animal toxicity studies. These are considered to be well understood predictors of toxicity in humans. The PMRA relies heavily on toxicological data to establish reference doses for acute (ARD) and chronic (ADI) effects and to derive estimates of potential cancer risks.

With few exceptions, i.e., carcinogenic and mutagenic effects, most toxic effects occur only when a dose threshold has been exceeded. These differences must be taken into account and as a result the PMRA is using two different approaches for assessing the acceptability of risks from pesticides to human health: a margin of safety approach for “threshold” effects and a quantitative risk assessment for non-threshold effects, such as cancer.

For toxic end points that have a threshold, the PMRA establishes a reference dose, taking into account both the acute and the chronic nature of the toxic effects. The lowest level of exposure in test animals that causes no adverse effects, the no observed adverse effect level (NOAEL), is the starting point for calculating the reference dose. The NOAEL is selected for a toxic end point observed in animals that is relevant to humans, and it is usually from a study in which animal exposure is representative of the route, frequency and duration of human exposure.

Furthermore, the establishment of reference doses must take into account uncertainties arising from the extrapolation of effects observed in animals to potential effects in humans. It also considers that some humans in the population are more sensitive to potential effects than others. Therefore, the reference dose incorporates two safety factors: a 10-fold factor to account for extrapolation from animals to humans (i.e., interspecies) and an additional 10-fold factor to account for the variation within the human population (i.e., intraspecies). In this way, the calculated reference dose for humans is a minimum of 100-fold lower than the dose that caused no adverse effects in animal studies.

⁶ This internationally accepted process was first introduced by the United States (U.S.) National Research Council in 1983 in the so-called “Red Book” on *Risk Assessment in the Federal Government: Managing the Process*.

In addition to these two 10-fold safety factors, additional safety factors are applied to the reference dose to address severity of toxicology end point, sensitive sub-populations and any concerns or uncertainties about the precision of toxicity and exposure estimates. Increased sensitivity of the young and exposure of infants and children, as well as pregnant women, to a pesticide are considered during the risk assessment process, with the goal of providing additional protection where warranted, consistent with the practice established by the U.S. *Food Quality Protection Act* of 1996. Where reliable scientific data are available, a case specific determination as to the size of the additional factor is used. This approach is consistent with that of the U.S. Environmental Protection Agency (EPA).

The determination of whether the exposure is acceptable is made by comparing the estimated human exposure to the reference dose. Exposures that fall below the reference dose are considered to provide sufficient margins of safety and are unlikely to be associated with unacceptable risk to health.

The assessment of a chemical's potential to cause cancer requires a different kind of assessment and expression of risk. Cancer risk assessment for pesticides is based on evidence from cancer studies in at least two species, usually the rat and the mouse, together with evidence from in vitro and in vivo genotoxicity studies. The cancer studies are evaluated on the basis of the number and type of lesions elicited in test animals. They are typically carried out at dose levels that are much higher than expected human exposures. These studies are in many cases complemented with studies that shed light on the mechanism by which the pesticide causes the carcinogenic effect. The outcome of the animal studies together with mechanistic considerations are used in a weight-of-evidence approach to decide if a pesticide is likely to pose a cancer risk to humans. This type of approach is used by the International Agency for Research on Cancer in identifying agents that may pose a cancer risk to humans.

The quantitative assessment of cancer risk requires the use of sophisticated statistical models to estimate potential cancer risks at the lower levels of exposure seen in humans. A model used widely for regulatory purposes is the linearized multistage (LMS) model.⁷ This model results in an expression of a unit cancer risk, Q_1^* , that allows for the calculation of the likelihood or probability of cancer (lifetime cancer risk) for an average daily lifetime exposure. For example, a 1×10^{-6} cancer risk means that an individual has a one in a million chance of developing a cancer from an average daily lifetime exposure to a particular pesticide.

The acceptability of cancer risk is a risk management decision that cannot rely exclusively on a numerical standard, but needs to take into consideration all the factors that influence the risk. Given historical actions of regulatory agencies such as the EPA,

⁷ The LMS model is based on the assumption that the dose–response curve is linear at low doses with no threshold. The LMS model is generally considered more appropriate for genotoxic than for nongenotoxic carcinogens.

it is recognized that areas of regulatory concern for lifetime cancer risk are in the neighbourhood of 10^{-4} to 10^{-6} . A lifetime cancer risk that is below 1×10^{-6} (one in a million) usually does not indicate an unacceptable risk for the general population when exposure occurs through pesticide residues in or on food, and to otherwise unintentionally exposed persons. In some instances, cancer risks in the range of 1×10^{-5} to 1×10^{-6} (one in one-hundred thousand to one in a million) have been tolerated for industrial workers exposed occupationally to carcinogenic chemicals. These risk ranges are used by the PMRA as a guide in reaching decisions about the acceptability of lifetime cancer risk.

Both types of risk assessment, the margin of safety approach and the quantitative cancer risk assessment, provide estimates of risk arising from defined exposures. Usually the estimate reflects a “typical” exposure and use situation taking into consideration whether exposure is occasional or frequent and of short or long (life-time) duration. The estimate is kept conservative by generally overestimating exposure and risk and by using many “worst case” assumptions, such as assuming that 100 percent of the crop would be treated at the maximum application rate, or that 100 percent of the pesticide deposited on the skin would penetrate through the skin.

The PMRA currently aggregates exposure for a single pesticide active ingredient by combining exposures from all food residues and drinking water. The Agency will also take into account exposure from residential activities. It should be noted that the aggregation of exposure is a concept only recently introduced by regulatory agencies.

There are only a few chemical groups that are toxicologically well enough understood to allow estimation of cumulative risk (the combined risk from several pesticides) on the basis of a common mechanism of toxicity. The development of a standardized approach and appropriate methods to conduct cumulative risk and aggregate exposure assessments for pesticides with a common toxic mechanism are still under development.⁸ The EPA is awaiting the outcome of their Scientific Advisory Panel before being able to implement this approach.

4.4 Assessment of Environmental Risk

The assessment of environmental risk requires the integration of information on environmental exposure and effects. Although the environmental risk assessment is in principle similar to human health risk assessment, it poses a very different challenge. It requires identification of the potential toxic effects to a vast number of organisms in the environment, and is focussed on potential effects on individuals, but can also include potential effects on species, ecosystems and the food chain. It is necessary to consider not only local effects at the site where the pesticide is being used, but also the potential of the pesticide to move and to be transported to other sensitive environmental compartments

⁸ Approaches to cumulative and aggregate exposure assessments are discussed by the U.S. National Research Council in their 1993 report on *Pesticides in the Diets of Infants and Children*.

such as groundwater or lakes and rivers, or via atmospheric transport and deposition into remote environments.

Since it is not possible to study all potentially affected organisms and ecological systems, it is important to specify at the outset of a risk assessment the parts or levels of the environment intended to be protected. The PMRA includes in its consideration the maintenance of biological diversity, ecosystem health, achievement of sustainable development and the protection of particular species of animals or plants. The characterization of environmental risk identifies which, if any, organisms or ecosystems (environmental compartments) are at risk, and also identifies any uncertainties in estimating risk. Based on this information, risk management strategies can be explored to see if any are available that might sufficiently mitigate the risk. It provides the basis for deciding if risk management strategies are necessary to ensure that there are no unacceptable environmental risks and provides a focus for protection of a particular environmental compartment.

Environmental risk assessment is thus based on effects on indicator organisms and expected environmental exposures for defined environmental compartments. A key component of the assessment is consideration of the persistence of a pesticide in the various environmental compartments and its potential for accumulation up the food chain.

Laboratory and field studies, including acute and chronic toxicity tests in a range of standard test organisms from different taxonomic groups, are used to characterize the toxic response and to determine the dose–effect relationship of the pesticide and its major transformation (degradation) products. These are used as predictors for effects on ecosystems. The adverse effects considered are lethal and sub-lethal effects, including mortality, organ toxicity and reduced growth. The median lethal dose or the median lethal concentration (LD_{50} or LC_{50}) and the median effective dose or the median effective concentration (ED_{50} or EC_{50}) are determined as well as the concentration at which there is no observed adverse effect, the No Observed Effect Concentration (NOEC).

Potential effects in non-target biota are assessed and characterized by using a series of internationally recognized indicator species. Terrestrial species used represent the following major taxonomic groups: birds, mammals, terrestrial invertebrate species including insects and terrestrial plants. Potential effects in aquatic biota can be characterized in both freshwater and, when necessary, marine species that include fish and aquatic invertebrates, as well as algal species and aquatic vascular plants, both submergent and emergent. To estimate environmental exposure to pesticides, it is essential to know how, when and under what conditions a pesticide is being used and to predict from its behaviour and fate in the environment the extent of exposure (concentrations in soil, surface and ground water) at the use site and in other environmental compartments.

For a pre-market assessment, the estimation of exposure is based to a significant degree on modelling of Expected Environmental Concentrations (EECs). The modelling requires a detailed understanding of the physico-chemical properties and information on transformation rates. These rates give an indication of the transformation potential in the various environmental compartments, sometimes under a range of different conditions. This is necessary to predict fate and transport of a pesticide in soil, water and air, as well as the potential for uptake by plants or animals and the transfer from organism to organism through the food web to higher trophic levels. The reliability of the models can be enhanced with results from field trials under conditions that reflect the Canadian environment.

A standard method for expressing environmental risks quantitatively is the ratio of the highest concentration without any adverse effect in a relevant and sensitive species to the expected environmental concentration in a relevant environmental compartment (NOEC/EEC). The larger the ratio, the larger the margin of safety, and the more limited the environmental impact is expected to be. When the ratio of NOEC to EEC approaches 1 or falls below 1, it identifies that environmental effects are likely to occur. This allows PMRA to decide when additional risk management options need to be implemented to ensure that environmental concentrations do not approach or exceed effect concentrations.

The PMRA is following closely recent advances in methods for environmental risk assessments on the basis of probabilistic exposure assessments and will consider incorporation of these new methods in future adjustments of its approach to environmental risk assessments.

4.5 Assessment of Value

The determination of value is an important element of the pre-market evaluation of pest control products. Value assessments, as conducted by the PMRA, consist of three components: an assessment of efficacy, of economic benefits and competitiveness, and of a pesticide's contribution to sustainability.

The PMRA carries out a value assessment for all new pesticides corresponding to a new active ingredient or new formulation, or amendments to existing products proposing new uses, such as addition of new pests, new hosts or new application methods. The extent and focus of the value assessment is case specific. It may include a review of all the components of efficacy, of economics and competitiveness and of sustainability, or a review of efficacy only for an amendment to add a new pest to a registered pesticide.

The assessment of pesticide efficacy involves an evaluation of the pesticide's performance under field conditions. Pesticides that do not achieve an effective level of control or suppression of a pest are not candidates for registration, even if they do not pose risks to human health or the environment.

Where the efficacy of a pesticide is acceptable, the assessment serves to establish appropriate label claims or directions and the lowest application rate (or rate range) that is required to provide effective and consistent pest control, without unacceptable damage or injury to the host or crop and subsequent hosts or crops, under normal use conditions. In some cases, the objective is to attain the lowest overall amount of pesticide required to control the pest during a use season, rather than the lowest single application rate.

The efficacy of a pesticide is related to the concentration or amount of the pesticide that is used and the method and timing of use. These factors can also have a significant impact on the risks that are associated with the use. The required amount, method and timing of use for successfully dealing with a pest can lead to unacceptable risks, and thus preclude registration. There is also the possibility of modifying these factors while still maintaining an acceptable level of efficacy, thus providing a significant opportunity for developing risk management options.

Several aspects of product performance may be considered under the general category of efficacy assessment. These include the effectiveness of the pesticide in controlling the target pest, the tolerance of the host or crop to the pesticide applied and the tolerance of succeeding host(s) or crop(s) to the pesticide applied.

Some or all of these components may be considered during the review of a submission, dependent upon the type of pesticide involved and the proposed use. Data for an efficacy assessment are derived from field or laboratory trials. Field trials are carried out at different geographical locations and can extend over more than one use season to allow determination of the pesticide performance over a variety of conditions.

In most cases, proof of efficacy establishes the nature of the expected benefits, so that the PMRA would not normally engage in an in-depth or extensive evaluation of benefits. Assessment of economic benefits and competitiveness may be undertaken in particular cases where aggressive risk management options must be developed. A high economic value of the commodity to be protected usually allows consideration of a wider range of mitigation options than lower value commodities. In the case of high economic value, users may accept higher cost measures and thus more aggressive mitigation measures can be imposed. Otherwise, the product will not be registered.

The PMRA assesses the compatibility of a pesticide with sustainable agricultural or industrial practices and production systems. In particular, the assessment identifies existing alternative methods of control for the target pests, the fit of the pesticide with established integrated pest management (IPM) programs and the role of the pesticide in resistance management strategies.

The PMRA also considers the potential impact on resistance development and the role a pesticide plays in the management of pesticide resistance. The introduction of a pesticide with an existing mode of action may accelerate the development of resistance, while a pesticide with a new, unique mode of action may provide the opportunity to delay the development of resistance, thus increasing its value.

The assessment of the value of a pesticide during re-evaluation has a particular purpose. During re-evaluation, value is examined under current conditions and in light of alternative pest control methods (both chemical and nonchemical) that may have been developed since the pesticide was first registered. The efficacy component of the value assessment is not repeated during re-evaluation because product performance has been established through its history of use. With the development and implementation of IPM programs, however, the use of a pesticide may now be targeted to specific application times during the season, or the rate required for efficacy may be reduced owing to an IPM approach. In such cases, studies of pesticide efficacy from published sources may be incorporated in the reviews.

4.6 Outcome of the risk and value assessments

As discussed above, the outcome of the risk and value assessments can have various results which set the path for different regulatory decisions.

When the risks to health and the environment are acceptable and the pesticide has value, i.e., the pesticide can be used safely and effectively without any modifications to its proposed or existing uses, the registration of the new pesticide must be granted. In the context of a re-evaluation, the re-registration of an existing pesticide will be maintained.

When a pesticide has value but the risks to health or the environment are unacceptable, PMRA will identify and develop risk management options to reduce the identified risk(s) in such a manner and to such an extent that the pesticide can be used without unacceptable risks to health and the environment. These mitigation options will reduce exposure and could include protective clothing for applicators, buffer zones to protect environment, reduction of application rates, and lengthening preharvest intervals. The extent of these mitigation measures cannot reduce the efficacy beyond acceptable levels. If that is the case, the product is not registerable.

When the risks to the environment or health, *or* the pesticide's value are unacceptable, and the risks cannot be mitigated through modifications of the conditions of use, then the registration of a new pesticide will be denied and, in the context of a re-evaluation, the registration of an existing pesticide will be discontinued or its uses will be phased out.

When the use of the pesticide is incompatible with federal policies and international agreements, such as the TSMP, the Montreal Protocol on ozone depleting substances and international agreements on POPs, or the use of a pesticide would contravene other federal acts, a new pesticide can be refused and the registration of an existing pesticide can be discontinued or its uses may be phased out.

5.0 Identification and Analysis of Risk Management Options

The outcomes of the assessments of risks to health and the environment, and the assessment of value, are the basis for the next step: identification and analysis of risk management options. The goal is to identify a range of options that have the potential to reduce the extent of human and environmental exposures, and to analyse these options to determine if they can achieve acceptable risk standards for human health and the environment. The identification and analysis must be focussed and must be responsive to the nature and extent of risk, its source, the affected human population and the environmental populations and compartments that were identified in the risk assessment steps. It is essential that the scientists who assessed the potential risks and risk managers participate in the identification and analysis of management options.

As mentioned previously, the identification and analysis of risk management options is a dynamic process, requiring recalculation of risk under various risk mitigation scenarios. In many cases, the choice is not between individual risk management options, but the choice of a combination of options. There may be competing risks within the range of possible risk mitigation options: what may be a reasonable strategy to reduce risk to applicators/farmers may increase risks to the environment leaving the product unregistrable. Thus, development of options must provide a clear basis to ensure that all risk elements are considered and are acceptable.

The range of risk management options is constrained by legal and practical considerations. The risk management options must be consistent with the requirements of the PCP Act and must be legally enforceable. The development of risk management options, therefore, relies on mitigative measures that can be prescribed in the conditions of use, as prescribed on the legally binding label.

The risk management options available under these legal constraints can include denial of registration or imposition of conditions and restrictions with respect to: classification of use (domestic, commercial or restricted class), provincial permit requirement, professional qualification of applicator, specification of application technique and equipment, personal protective equipment, use conditions (use quantities, application rates, timing and frequency of application, pre-harvest intervals, re-entry intervals), crops, use scenario, buffer zones and other mitigative measures to protect sensitive environments and particularly vulnerable plant and animal species, and safe storage and disposal. Options can also consider changes to the pesticide product, such as changes to the formulation, or the physical and chemical make-up of the pesticide product.

The practicality of risk management options is guided by a thorough understanding of the use situation, use practices, application technology, extent of use, and geographical location. This level of detailed understanding is necessary to focus the development of options on those that are appropriate and can realistically be achieved.

The value assessment plays a significant role in defining some of the limits of management options because application rates, frequency, technology and practices influence the effective use of a pesticide. The efficacy assessment provides the basis for determining these practical limits.

The value assessment also provides an estimate of the cost to the user of implementing a particular option. Since no management option is without cost, excessive or disproportionate costs can influence the benefit to the user. It provides a measure for gauging the cost tolerance of the user and thus focuses the development of management options on realistic options. If the cost of reducing the risk to an acceptable level outweighs the benefit of the pesticide, it would not be registered.

There is a growing recognition that, in addition to these regulatory approaches to risk mitigation, there are a number of ways to further strengthen the label statements to influence the pesticide users in their practices and choice of dealing with pests. These additional management options have become increasingly important, particularly within the context of modern agriculture. They can significantly enhance regulatory measures and compliance. The PMRA is working with a variety of stakeholders, including user groups, to develop IPM programs to help reduce reliance on pesticides as a sole means of pest management.

6.0 Selection of a Strategy

The selection of a risk management strategy, including the selection of one or a combination of management options developed and elaborated in the previous step, involves a great deal of scientific expertise. Expertise has been built up in the PMRA over many years and on numerous practical examples. The selection of a strategy is to a significant degree based on data indicating that the anticipated risks to health and the environment are acceptable and that the pesticide is effective. It also includes experience in deciding if the selected strategy is practicable from both a use pattern and a compliance and enforcement perspective.

Part of the strategy selection process involves the recalculation of the margins of exposure or level of risk remaining under various possible management strategies. This recalculated level of risk provides a measure of how well a management option fulfills criteria of acceptable risk. Options that do not ensure that risks are within acceptable limits are not further pursued.

The choice of options can be further narrowed by considering their inherent cost and their impact on economic benefits and competitiveness. A high economic value of a commodity allows consideration of higher cost management options. Options for which the cost exceeds the economic value are not likely to be accepted by users and the pesticide would not be registered if there would be an expectation of low user compliance.

The consideration of practicality and expected compliance with management options is much more difficult to quantify. In-depth knowledge of user groups, their level of “sophistication” in pesticide use, their past record on compliance and an understanding of countervailing pressures are essential for this task.

The selection of management options, therefore, is case specific and is a search for the optimal combination of choices that achieve an acceptable level of risk while maintaining an acceptable value of the product.

7.0 Implementation of the Strategy

The selected risk management strategy forms an essential part of the regulatory decision. It is implemented as part of the registration or de-registration decision.

In the case of acceptable risks to health and the environment and value, the PMRA registers the pesticide and specifies the registration conditions on the legally binding label. Any use in contravention of the label is illegal under the PCP Act.

There are few pesticides that do not require safety precautions to achieve an acceptable level of risk. In fact, most pesticides require very specific measures to achieve an acceptable level of risk. In each case, the selected strategy provides the basis for specific registration conditions and restrictions. They are specified on the label and include domestic, commercial, restricted category, permit requirement, use conditions and restrictions, measures to protect users and the environment, re-entry and pre-harvest intervals, and buffer zones.

For pesticides used on food crops, MRLs are established and promulgated in regulations under the FDA. MRLs are an essential part of ensuring that the dietary intake of pesticide residues does not lead to unacceptable exposure and risks to human health.

All registered pesticides are thus restricted in that they can be used only for the specified purposes under specified use conditions.

8.0 Monitoring and Evaluation of Results

Decisions to register pesticides reflect the state of knowledge and regulatory practices at the time the decision is taken. Post-registration monitoring plays an essential role to ensure the continued safety and value of a registered pesticide.

There are three essential elements to post-registration monitoring: (1) the enforcement of compliance with the PCP Act and the FDA;⁹ (2) the conduct of routine inspections and special monitoring (e.g., for environmental levels and effects¹⁰), food residue surveys and health surveys;¹¹ and (3) the maintenance of a modern database on the potential effects on human health and the environment including periodic up-dating of approaches to risk assessment and risk management.

The stronger the need for measures to manage the risks associated with pesticides, the stronger the need to monitor compliance with these measures. Inspection programs of the PMRA respond to this need. Additional support mechanisms for ensuring compliance are certification and training of users, Best Management Practices for pesticide user sectors and IPM programs. These support mechanisms are largely provincial responsibilities. They are encouraged and supported, and in some cases led, by the PMRA through the close interaction among all partners of the Federal/Provincial/Territorial Committee on Pesticide Management and Pesticides (F/P/T Committee).

Compliance with the PCP Act is mandatory. The PMRA enforces compliance through the National Pesticide Compliance Program, which is designed to promote and verify compliance with the PCP Act through inspections and investigations. This is achieved through a full range of compliance techniques and measures. PMRA inspectors encourage voluntary reporting of suspected infractions, inspect for compliance and respond to noncompliance situations. All suspected infractions are examined and action is taken, as provided by the PCP Act. This includes education, warning and criminal prosecution. The results of these activities are used by the PMRA in the risk assessment, particularly in special reviews and during re-evaluation.

The Canadian Food Inspection Agency (CFIA) enforces compliance with the MRLs for pesticide residue in food established by the PMRA and promulgated in regulations under the FDA.

Monitoring, particularly environmental presence and effects monitoring, is carried out by provincial and territorial agencies, other federal government departments and the registrants themselves. The monitoring can include a wide range of pesticides, can be regional, can apply to a part of the environment (e.g., groundwater), can be use specific (e.g., corn herbicides), or can be narrowly focussed on a single pesticide.

⁹ The enforcement of MRLs of pesticides in or on food is the responsibility of the Canadian Food Inspection Agency (CFIA).

¹⁰ Environment Canada and provinces/territories.

¹¹ Health Canada.

Post registration developments in scientific knowledge and in experience may indicate that the initially required studies and information on which the registration decision was based should be improved, and that additional information should be obtained and assessed to determine whether a registration can continue to be supported.

The following situations may indicate the need for a re-assessment: (1) new scientific knowledge of toxicological end points of concern, often combined with new investigative methods; (2) adverse effects reporting, incidence reporting, results from epidemiological studies, environmental monitoring and surveys; (3) age of supporting database (over time, data requirements have expanded, quality and scientific rigour have increased and a wider range of risks must be considered).

In recognition of these factors, particularly consideration of the age of the database for a large number of older pesticides, the PMRA has presented a Regulatory Proposal¹² for a comprehensive re-evaluation program for pesticides registered prior to 1995. Under this program, the assessment and management of risks of pesticides will follow the same steps that are outlined in this document.

Once a pesticide has been registered, there is a need to track its actual use. The National Pesticide Sales Database, which is currently being established by the PMRA, is a first step in collecting comprehensive pesticides sales data on a regular basis. The sales data will be useful for estimating pesticide use and will provide important information for the re-evaluation of pesticides and risk reduction activities.

9.0 Involvement of Interested and Affected Parties

The registration decisions of the PMRA affect users and registrants, and those exposed to pesticides and pesticide residues. They are also of interest to a large number of other parties, including the Canadian public in general, other federal departments and provincial agencies and departments with health and environmental protection mandates, and various organizations representing the interests of pesticide users, consumers and environmental and health advocacy groups.

The framework of decision making allows the PMRA to interact with these affected and interested parties in a manner that is commensurate to their degree of being affected by and interest in regulatory decisions.

¹² See Regulatory Proposal PRO99-01, *A New Approach to Re-evaluation*, December 3, 1999.

9.1 Interaction with registrants

The PMRA has published a Regulatory Proposal¹³ for a Management of Submission Policy (MOSP) that sets out prescribed processes and procedures for both the PMRA and registrants of pesticides. Interaction and consultation with registrants occur frequently within this process: during the pre-submission phase, the screening for completeness of the submitted data, and the review of deficiencies in the initial stages of review. The PMRA further provides an opportunity for registrants to comment on the mitigation measures that the PMRA intends to impose as a condition of registration. This provides registrants an opportunity to decide if they are willing to accept the conditions or forego registration and marketing of their product.

9.2 Informing and consulting with the public and other interested parties

To document the basis for individual registration and re-registration decisions, and to consult and inform other interested parties and the public about the decision, the PMRA publishes a number of documents. Major decisions, such as the registration of a new pesticide and major new uses for an existing pesticide, are documented in a Regulatory Note (REG) or in a Proposed Regulatory Decision Document (PRDD) followed by a Regulatory Decision Document (RDD). Re-evaluation decisions are published in a Proposed Acceptability for Re-registration Document (PAR) followed by a Re-registration Decision Document (RRD).

Under the current provisions of the PCP Act, the PMRA must request permission from registrants before publishing PRDDs, PARs and other documents, e.g., REGs, that contain product specific information and (proposed) decisions. When requesting permission to publish a PRDD, the only changes that PMRA will entertain from registrants are corrections of factual errors that might have occurred.

It should be noted that PMRA also solicits public comment on new policies and programs through a mailing to PMRA's stakeholders and the posting on the internet of Regulatory Proposals. A comment period of 45 or 60 days allows for public input to be received. Responses are then reviewed and, where appropriate, changes are made to reflect public input and concerns.

9.3 Advisory bodies

The Pest Management Advisory Council (PMAC), established in November 1998, provides a forum for stakeholders to provide advice on policies and issues relating to the federal pest management regulatory system. The Council's membership includes environmental, health, labour and consumer groups, academics and pesticide manufacturers and users.

¹³

PRO96-01, June 7, 1996

The Economic Management Advisory Committee (EMAC) was established in April 1997 to advise the Executive Director of the PMRA on specific ways to improve efficiency and cost effectiveness without compromising health or environmental protection while maintaining industry competitiveness. Members of the EMAC include pesticide industry representatives, grower groups and officials from the PMRA.

The Federal/Provincial/Territorial Committee (F/P/T Committee), established in October 1997, brings together federal and provincial/territorial pesticide officials together to exchange information and expertise. The F/P/T Committee provides advice and direction to governments on programs, policies and issues relating to pesticides and actively pursues solutions to shared issues of concern through the activities of its working groups.

Other government departments. Memoranda of Understanding provide a mechanism for the Executive Director of the PMRA to consult on policy issues with Assistant Deputy Ministers from other federal government departments, such as Agriculture and Agri-Foods Canada, Natural Resources Canada, Environment Canada, and relevant branches of Health Canada.

10.0 Summary

In its decision making, the PMRA uses a well defined decision framework. The framework describes a multi-step process through which pesticide registration decisions are developed, implemented and monitored. They consist of (1) identification of the issue and its context, (2) assessment of risks and value, management of risk on the basis of (3) identification and analysis of risk management options, (4) selection of a risk management strategy and (5) implementation of the chosen strategy. The final step (6) is the monitoring and evaluation of results. Involvement of interested and affected parties (7) is integral to the overall process.

The PMRA decision making is designed to protect human health and the environment and only allow pesticides that provide value to users and the Canadian society to be registered. Decisions are made on the basis of a comprehensive body of scientific evidence and scientific methods to determine the nature and magnitude of the risks posed by pesticides and by applying appropriate and effective risk management strategies.

List of abbreviations

ADI	allowable daily intake
ARfD	acute reference dose
CFIA	Canadian Food Inspection Agency
EC ₅₀	median effect concentration
ED ₅₀	median effect dose
EEC	expected environmental concentration
EMAC	Economic Management Advisory Committee
F/P/T	Federal/Provincial/Territorial
FDA	<i>Food and Drugs Act</i>
IPM	integrated pest management
LC ₅₀	median lethal concentration
LD ₅₀	median lethal dose
LMS	linearized multistage
MRL	maximum residue limit
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
OECD	Organisation for Economic Co-operation Development
PAR	Proposed Acceptability for Re-registration Document
PCP Act	<i>Pest Control Products Act</i>
PMAC	Pest Management Advisory Council
PMRA	Pest Management Regulatory Agency
POP	persistent organic pollutants
PRDD	Proposed Regulatory Decision Document
RDD	Regulatory Decision Document
REG	Regulatory Note
RRD	Re-registration Decision Document
TSMP	Toxic Substances Management Policy
U.S. EPA	United States Environmental Protection Agency

This is **Exhibit “N”** referred to in the affidavit of
Dr. Elaine MacDonald affirmed remotely before
me in accordance with O. Reg 431/20,
Administering Oath or Declaration Remotely
this 19th day of January 2022.



Commissioner for Taking Affidavits
(or as may be)



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Proposed Maximum Residue Limit

PMRL2012-37

Chlorpyrifos

(publié aussi en français)

17 July 2012

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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Canada 

ISSN: 1925-0835 (print)
1925-0843 (online)

Catalogue number: H113-24/2012-37E (print version)
H113-24/2012-37E-PDF (PDF version)

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Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has concluded that the addition of a new use on green onions to the product label of Lorsban 4E Insecticide, containing technical grade chlorpyrifos, is acceptable. The specific use approved in Canada is detailed on the label of Lorsban 4E Insecticide, *Pest Control Products Act* Registration Number 14879.

The evaluation of this chlorpyrifos application indicated that the end-use product has merit and value and the human health and environmental risks associated with the new use are acceptable. Details regarding the registration can be found in the corresponding Evaluation Report available in the Pesticides and Pest Management section of Health Canada's website, under Public Registry, Pesticide Product Information Database.¹

Before registering a pesticide for food use in Canada, the PMRA must determine the quantity of residues that are likely to remain in or on the food when the pesticide is used according to label directions and that such residues will not be a concern to human health. This quantity is then legally established as a maximum residue limit (MRL). An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

Consultation on the proposed MRL for chlorpyrifos is being conducted via this document (see Next Steps, the last section of this document).

To comply with Canada's international trade obligations, consultation on the proposed MRL is also being conducted internationally by notifying the World Trade Organization, as coordinated by the Standards Council of Canada.

The proposed MRL in Canada in or on food, to be added to the MRLs already established for chlorpyrifos, is as follows.

Table 1 Proposed Maximum Residue Limit for Chlorpyrifos

Common Name	Residue Definition	MRL (ppm)	Food Commodity
Chlorpyrifos	<i>O,O</i> -diethyl- <i>O</i> -(3,5,6- trichloro-2-pyridyl) phosphorothioate, including the metabolite 3,5,6-trichloro-2-pyridinol	0.5	Green onion subgroup (Crop Subgroup 3-07B)

ppm = parts per million

¹ The relevant report can be accessed by selecting Programs and Special Actions/Minor Use/Historical and requesting the Evaluation Report listed under Application Number 2011-0720.

MRLs are proposed for each commodity included in the green onion subgroup in accordance with the Residue Chemistry Crop Groups webpage in the Pesticides and Pest Management section of Health Canada's website.

A complete list of pesticide MRLs established in Canada, as of the date indicated, can be found on the Maximum Residue Limits for Pesticides webpage in the Pesticides and Pest Management section of Health Canada's website.

International Situation and Trade Implications

The proposed green onion subgroup MRL for chlorpyrifos in Canada does not have a corresponding American tolerance or Codex MRL². Tolerances established in the United States are listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. Codex MRLs are listed on the Codex Alimentarius Pesticide Residues in Food webpage, by pesticide or commodity.

Next Steps

The PMRA invites the public to submit written comments on the proposed MRLs for chlorpyrifos up to 75 days from the date of publication of this document. Please forward your comments to Publications (see the contact information on the cover page of this document). The PMRA will consider all comments received before making a final decision on the proposed MRLs for chlorpyrifos and posting a corresponding Established Maximum Residue Limit document in the Pesticides and Pest Management section of Health Canada's website.

² The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

This is **Exhibit “O”** referred to in the affidavit of
Dr. Elaine MacDonald affirmed remotely before
me in accordance with O. Reg 431/20,
Administering Oath or Declaration Remotely
this 19th day of January 2022.



Commissioner for Taking Affidavits
(or as may be)

Growers stockpile Lorsban ahead of ban

By **Robert Arnason**

Published: September 2, 2021

News

Reading Time: 3 minutes



Growers are buying chlorpyrifos (Lorsban) while they can because in December 2022 retailers must stop selling the insecticide in Canada. Health Canada announced a phase-out of the chemical in December 2020. P SEP | File photo

A number of prairie farmers are stocking up on chlorpyrifos in preparation for a 2023 ban of the insecticide.

The growers are buying chlorpyrifos (Lorsban) while they can because in December 2022 retailers must stop selling the insecticide in Canada. Health Canada announced a phase-out of the chemical in December 2020.

“(Farmers) have been reaching out to us, they (want) to pre-book the generic version of chlorpyrifos,” said Deepak Chaunkaria, sales agronomist with Johnston’s Grain — a grain brokerage and crop inputs supplier in Calgary.

“Guys are assessing their demand for the next couple of crop years. After that, they can’t use it.”

Chlorpyrifos has been around for more than 50 years and is still effective on a wide range of crop pests, including grasshoppers, cutworms, wheat midge and others, Chaunkaria said.

Hundreds of farmers possibly used it this summer to control a plague of grasshoppers on the Prairies.

“This year (there) was a huge grasshopper outbreak in southern Saskatchewan — south of Regina all the way to the southwestern part of the province,” Chaunkaria said.

Parts of Alberta also had grasshopper infestations.

Chlorpyrifos may be effective, but it is also controversial. For years, environmental groups have called for its ban, saying it’s a threat to human health, birds, mammals and beneficial insects.

Health Canada’s Pest Management Regulatory Agency announced its ban in 2020. A couple of weeks ago, in August, the United States Environmental Protection Agency revoked all “tolerances” for the chemical, which effectively prohibits its use.

“Today EPA is taking an overdue step to protect public health. Ending the use of chlorpyrifos on food will help to ensure children, farmworkers, and all people are protected from the potentially dangerous consequences of this pesticide,” said EPA administrator Michael S. Regan.

The EPA added that chlorpyrifos has been found to inhibit an enzyme, which leads to neurotoxicity, and has also been associated with potential neurological effects in children.

In its decision on chlorpyrifos, Health Canada’s Pest Management Regulatory Agency said the insecticide is an environmental hazard because it creates unacceptable risks for spiders, birds and mammals.

The American Farm Bureau Federation, one of the largest producer groups in the U.S., said the EPA decision was not based on science and “takes away an important tool to manage insects and pests.”

The president of the Michigan Farm Bureau, Carl Bednarski, had harsher comments about the EPA’s ban.

“The safety of this chemistry stands on over 50 years of experienced use, health and safety of workers and applicators, and over 4,000 studies that prove scientifically, the safety of this product to human health, and environmental impact,” he told Michigan Farm News. “The decision by the EPA robs Michigan’s growers of their due process and rights.”

In Canada, some growers are frustrated that Health Canada is banning chlorpyrifos, but farm groups have been relatively quiet about the issue.

In August 2019, Alberta Wheat, Alberta Barley, Alberta Pulse Growers and Alberta Canola sent a letter to Health Canada, reminding the PMRA why chlorpyrifos is an important tool for growers.

“In wheat and barley Lorsban is the only option for controlling both eggs and adults in wheat midge as any alternatives only control adult populations.... In canola, Lorsban is used when necessary to control outbreaks of bertha army worms, cutworms, diamond back moth larvae, grasshoppers, alfalfa looper and lygus bugs. In pulse crops chlorpyrifos is a consistent and effective pesticide for the control of grasshoppers in lentil crops.”

Farmers have other options for controlling grasshoppers and other pests, said John Gavloski, an entomologist with Manitoba Agriculture.

But removing chlorpyrifos from the market is a problem for wheat growers because it takes away one of only two insecticides registered for killing wheat midge.

“If you take chlorpyrifos off the market, that leaves you with just dimethoate.... That does create a shortfall (of options),” Gavloski said.

Wheat growers could opt for varieties with resistance to wheat midge, which offer some protection from the pest.

“I have a feeling there will be much more uptake of the midge-tolerant wheat varieties, once the chemical control options get thinner,” Gavloski said.

When chlorpyrifos is removed from the market at the end of 2023, insect control could become more costly for some growers.

A generic version of Lorsban likely costs around \$6 to \$8 per acre, Chaunkaria said.

He estimated the cost of replacement insecticides at \$15 to \$25 per acre.

That explains why western Canadian farmers are stocking up on chlorpyrifos, so they have sufficient supplies for the 2022 and 2023 growing seasons.

“This year, we have ordered containers and containers of this product, to satisfy the demand (from) our growers,” Chaunkaria said.

“Guys (farmers) have a real interest in this product and want to secure it.”

This is **Exhibit “P”** referred to in the affidavit of
Dr. Elaine MacDonald affirmed remotely before
me in accordance with O. Reg 431/20,
Administering Oath or Declaration Remotely
this 19th day of January 2022.



Commissioner for Taking Affidavits
(or as may be)

Permanent label

PYRATE 480EC

GROUP	1B	INSECTICIDE
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(Contains Chlorpyrifos) Insecticide For Non-Food Uses

This product is not to be used in and around homes or other residential areas such as parks, school grounds, playing fields. It is not for use by homeowners or other uncertified users.

Restricted Uses to Control: Adult and Larval Mosquitoes, Mountain Pine Beetle in Forestry Situations. To Be Applied Only Under The Direct Supervision of Commercial Applicators Responsible For Pest Control Programs.

Do Not Formulate This Product Into Other End-Use Products.

COMMERCIAL

READ THE LABEL AND ATTACHED BROCHURE BEFORE USING



DANGER

POISON

KEEP OUT OF REACH OF CHILDREN

GUARANTEE: Chlorpyrifos 480 g/L
Warning, contains the allergen, soy

REGISTRATION NO. 23704 PEST CONTROL PRODUCTS ACT

NET CONTENTS: 10 L

Adama Agricultural Solutions Canada Ltd.
302 - 179 McDermot Avenue.
Winnipeg, MB
R3B 0S1

PRECAUTIONS

KEEP OUT OF REACH OF CHILDREN, MAY BE FATAL IF SWALLOWED, MAY CAUSE SKIN IRRITATION

DANGER EYE IRRITANT

Do not get in eyes, on skin or on clothing. Avoid breathing vapour or spray mist. Handle only with adequate ventilation. Wear protective clothing, impervious gloves and chemical worker's goggles when handling. Wash thoroughly with soap and water after handling and before eating or smoking. Immediately remove contaminated clothing and wash before reuse. Destroy contaminated leather articles, including shoes. Do not apply this product in such a manner as to directly or through drift expose workers or other persons.

PRECAUTIONS FOR MIXERS/LOADERS

For EC formulations packaged in containers more than 10 L

Mixers/loaders must use a closed mechanical transfer loading system. Mixers/loaders must wear:

- coveralls over a long-sleeved shirt and long pants;
- chemical-resistant gloves;
- an air purifying respirator with an -R or -P series filter; and
- socks and shoes.

For EC formulations packaged in containers holding 10 L or less

Mixers/loaders must wear:

- coveralls over a long-sleeved shirt and long pants;
- chemical-resistant gloves;
- a chemical-resistant apron;
- chemical-resistant footwear plus socks; and
- an air purifying respirator equipped with an -R or -P series filter.

PRECAUTIONS FOR APPLICATORS

Do not apply as a paintbrush treatment for indoor uses.

Do not apply with high-pressure wand equipment.

Applicators using ground application equipment with a closed cab must wear:

- a long-sleeved shirt and long pants;
- chemical-resistant gloves when leaving cab for clean-up and repair (gloves must be removed and left outside when re-entering the cab); and
- socks and shoes.

Applicators using ground application equipment with an open cab must wear:

- coveralls over a long-sleeved shirt and long pants;
- chemical-resistant gloves; and
- socks and shoes.

Applicators using handheld equipment must wear:

- a long-sleeved shirt and long pants;
- chemical-resistant coveralls and head protection (if spray is upwardly directed);
- chemical-resistant footwear and socks;
- chemical-resistant gloves; and
- an air purifying respirator with an -R or -P series filter.

If this pest control product is to be used on a commodity that may be exported to the U.S. and you require information on acceptable residue levels in the U.S., visit CropLife Canada's web site at www.croplife.ca.

ENVIRONMENTAL PRECAUTIONS

HAZARDS

This pesticide is extremely toxic to fish and aquatic organisms. Fish and crustaceans may be killed at application rates recommended on this label. Do not apply where these are important resources. Drift and runoff from treated areas may be hazardous to aquatic organisms in adjacent aquatic sites. Do not apply where runoff is likely to occur.

Do not apply where weather conditions favour drift from areas treated. This product contains a petroleum distillate that is moderately to highly toxic to aquatic organisms. Avoid contamination of aquatic systems during application. Do not contaminate these systems through direct application, disposal of waste or cleaning equipment. Spilled material should be soaked up with absorbent material and disposed of in an approved manner.

TOXIC to birds. TOXIC to wild mammals. TOXIC to bees exposed to direct treatment, drift, or residues on blooming plants. Do not use on flowering crops or weeds. TOXIC to certain beneficial insects. Minimize spray drift to reduce harmful effects on beneficial insects in habitats next to the application site such as hedgerows and woodland. Avoid spraying tree crown before mid-morning. Do not apply when birds are nesting in trees to be treated.

DO NOT apply this product or allow it to drift to flowering crops or weeds if bees are visiting the treatment area. Applicators should inform local beekeepers prior to application if hives are in adjacent fields. Minimize spray drift to reduce harmful effects on bees in habitats close to the application site.

To reduce runoff from treated areas into aquatic habitats, consider the characteristics and conditions of the site before treatment. Site characteristics and conditions that may lead to runoff include, but are not limited to, heavy rainfall, moderate to steep slope, bare soil, poorly draining soil (e.g., soils that are compacted or fine textured such as clay). Avoid application of this product when heavy rain is forecast. Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip (buffer zone) between the treated area and the edge of the water body.

FIRST AID

IF SWALLOWED, call a poison control centre or doctor immediately for treatment advice. Do not induce vomiting unless told to do so by a poison control centre or doctor. Do not give **any** liquid to the person. Do not give anything by mouth to an unconscious person.

IF ON SKIN OR CLOTHING, take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control centre or doctor for treatment advice.

IF INHALED, move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control centre or doctor for further treatment advice.

IF IN EYES, hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control centre or doctor for treatment advice.

Take the container label or product name and Pest Control Product Registration Number with you when seeking medical attention.

TOXICOLOGICAL INFORMATION

Chlorpyrifos is an organophosphate that is a cholinesterase inhibitor. Typical symptoms of overexposure to cholinesterase inhibitors include headache, nausea, dizziness, sweating, salivation, runny nose and eyes. This may progress to muscle twitching, weakness, tremors, incoordination, vomiting, abdominal cramps and diarrhea in more serious poisonings. A life threatening poisoning is signified by loss of consciousness, incontinence, convulsions and respiratory depression with a secondary cardiovascular component. Treat symptomatically. If exposed, plasma and red blood cell cholinesterase tests may indicate degree of exposure (baseline data are useful). Atropine, only by injection, is the preferable antidote. Oximes, such as pralidoxime chloride, may be therapeutic if used early; however, use only in conjunction with atropine. In cases of severe acute poisoning, use antidotes immediately after establishing an open airway and respiration. With oral exposure, the decision of whether to induce vomiting or not should be made by an attending physician.

NOTE: Product contains a petroleum distillate solvent.

PHYSICAL AND CHEMICAL HAZARDS

COMBUSTIBLE – Do not store or use near heat or open flame.

STORAGE

Do not contaminate water, food or feed by storage or disposal of wastes. Avoid storage at high temperatures. Protect from moisture. Avoid contamination with water, acids or alkalis. Do not store near heat or open flame. Keep container closed.

DISPOSAL

Do not reuse this container for any purpose. This is a recyclable container, and is to be disposed of at a container collection site. Contact your local distributor/dealer or municipality for the location of the nearest collection site. Before taking the container to the collection site:

1. Triple-or pressure-rinse the empty container. Add the rinsings to the spray mixture in the tank.
2. Make the empty, rinsed container unsuitable for further use.

If there is no container collection site in your area, dispose of the container in accordance with provincial requirements.

For information on disposal of unused, unwanted product, contact the manufacturer or the provincial regulatory agency. Contact the manufacturer and the provincial regulatory agency in case of a spill, and for clean-up of spills.

NOTICE TO USER: This pest control product is to be used only in accordance with the directions on the label. It is an offence under the *Pest Control Products Act* to use this product in a way that is inconsistent with the directions on the label. The user assumes the risk to persons or property that arises from any such use of this product.

Booklet

PYRATE 480 EC

GROUP	1B	INSECTICIDE
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(Contains Chlorpyrifos) Insecticide For Non-Food Uses

This product is not to be used in and around homes or other residential areas such as parks, school grounds, playing fields. It is not for use by homeowners or other uncertified users.

Restricted Uses to Control: Adult and Larval Mosquitoes, Mountain Pine Beetle in Forestry Situations. To Be Applied Only Under The Direct Supervision of Commercial Applicators Responsible For Pest Control Programs.

Do Not Formulate This Product Into Other End-Use Products.

COMMERCIAL

READ THE LABEL AND ATTACHED BROCHURE BEFORE USING



DANGER

POISON

KEEP OUT OF REACH OF CHILDREN

GUARANTEE: Chlorpyrifos 480 g/L
Warning, contains the allergen, soy

REGISTRATION NO. 23704 PEST CONTROL PRODUCTS ACT

NET CONTENTS: 10 L

Adama Agricultural Solutions Canada Ltd.
302 - 179 McDermot Avenue.
Winnipeg, MB
R3B 0S1

PRECAUTIONS

**KEEP OUT OF REACH OF CHILDREN; MAY BE FATAL IF SWALLOWED; MAY CAUSE SKIN IRRITATION
DANGER EYE IRRITANT**

Do not get in eyes, on skin or on clothing. Avoid breathing vapour or spray mist. Handle only with adequate ventilation. Wear protective clothing, impervious gloves and chemical worker's goggles when handling. Wash thoroughly with soap and water after handling and before eating or smoking. Immediately remove contaminated clothing and wash before reuse. Destroy contaminated leather articles, including shoes. Do not apply this product in such a manner as to directly or through drift expose workers or other persons.

PRECAUTIONS FOR MIXERS/LOADERS

For EC formulations packaged in containers more than 10 L

Mixers/loaders must use a closed mechanical transfer loading system. Mixers/loaders must wear:

- coveralls over a long-sleeved shirt and long pants;
- chemical-resistant gloves;
- an air purifying respirator with an -R or -P series filter; and
- socks and shoes.

For EC formulations packaged in containers holding 10 L or less

Mixers/loaders must wear:

- coveralls over a long-sleeved shirt and long pants;
- chemical-resistant gloves;
- a chemical-resistant apron;
- chemical-resistant footwear plus socks; and
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PRECAUTIONS FOR APPLICATORS

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- socks and shoes.

Applicators using ground application equipment with an open cab must wear:

- coveralls over a long-sleeved shirt and long pants;
- chemical-resistant gloves; and
- socks and shoes.

Applicators using handheld equipment must wear:

- a long-sleeved shirt and long pants;
- chemical-resistant coveralls and head protection (if spray is upwardly directed);
- chemical-resistant footwear and socks;
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If this pest control product is to be used on a commodity that may be exported to the U.S. and you require information on acceptable residue levels in the U.S., visit CropLife Canada's web site at www.croplife.ca.

ENVIRONMENTAL PRECAUTIONS

HAZARDS

This pesticide is extremely toxic to fish and aquatic organisms. Fish and crustaceans may be killed at application rates recommended on this label. Do not apply where these are important resources. Drift and runoff from treated areas may be hazardous to aquatic organisms in adjacent aquatic sites. Do not apply where runoff is likely to occur. Do not apply where weather conditions favour drift from areas treated. This product contains a petroleum distillate that is moderately to highly toxic to aquatic organisms. Avoid contamination of aquatic systems during application. Do not contaminate these systems through direct application, disposal of waste or cleaning equipment. Spilled material should be soaked up with absorbent material and disposed of in an approved manner.

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IF INHALED, move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control centre or doctor for further treatment advice.

IF IN EYES, hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control centre or doctor for treatment advice.

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Chlorpyrifos is an organophosphate that is a cholinesterase inhibitor. Typical symptoms of overexposure to cholinesterase inhibitors include headache, nausea, dizziness, sweating, salivation, runny nose and eyes. This may progress to muscle twitching, weakness, tremors, incoordination, vomiting, abdominal cramps and diarrhea in more serious poisonings. A life threatening poisoning is signified by loss of consciousness, incontinence, convulsions and respiratory depression with a secondary cardiovascular component. Treat symptomatically. If exposed, plasma and red blood cell cholinesterase tests may indicate degree of exposure (baseline data are useful). Atropine, only by injection, is the preferable antidote. Oximes, such as pralidoxime chloride, may be therapeutic if used early;

however, use only in conjunction with atropine. In cases of severe acute poisoning, use antidotes immediately after establishing an open airway and respiration. With oral exposure, the decision of whether to induce vomiting or not should be made by an attending physician.

NOTE: Product contains a petroleum distillate solvent.

PHYSICAL AND CHEMICAL HAZARDS

COMBUSTIBLE – Do not store or use near heat or open flame.

STORAGE

Do not contaminate water, food or feed by storage or disposal of wastes. Avoid storage at high temperatures. Protect from moisture. Avoid contamination with water, acids or alkalis. Do not store near heat or open flame. Keep container closed.

DISPOSAL

Do not reuse this container for any purpose. This is a recyclable container, and is to be disposed of at a container collection site. Contact your local distributor/dealer or municipality for the location of the nearest collection site. Before taking the container to the collection site:

1. Triple-or pressure-rinse the empty container. Add the rinsings to the spray mixture in the tank.
2. Make the empty, rinsed container unsuitable for further use.

If there is no container collection site in your area, dispose of the container in accordance with provincial requirements.

For information on disposal of unused, unwanted product, contact the manufacturer or the provincial regulatory agency. Contact the manufacturer and the provincial regulatory agency in case of a spill, and for clean-up of spills.

NOTICE TO USER: This pest control product is to be used only in accordance with the directions on the label. It is an offence under the *Pest Control Products Act* to use this product in a way that is inconsistent with the directions on the label. The user assumes the risk to persons or property that arises from any such use of this product.

DIRECTIONS FOR USE

Do not formulate this product into other end-use products. DO NOT APPLY BY AIR.

GENERAL INFORMATION

PYRATE 480 EC is an insecticide for use to control pests of turf on golf courses, road medians and industrial sites.

PYRATE 480 EC Insecticide is an emulsifiable concentrate insecticide for use as a spray to control various pests injurious to turf. PYRATE 480 EC Insecticide is compatible with insecticides, miticides, and fungicides commonly recommended except for alkaline materials such as Bordeaux mixture and lime. It is recommended that a small amount of mixture be prepared to check for compatibility before mixing a large volume of spray.

RESISTANCE-MANAGEMENT RECOMMENDATIONS

For resistance management, please note that PYRATE 480 EC Insecticide contains a Group 1B insecticide. Any insect population may contain individuals naturally resistant to PYRATE 480 EC Insecticide and other Group 1B insecticides. The resistant individuals may dominate the insect population if this group of insecticides are used repeatedly in the same fields. Other resistance mechanisms that are not linked to site of action but are specific for individual chemicals, such as enhanced metabolism, may also exist. Appropriate resistance-management strategies should be followed.

To delay insecticide resistance:

- Where possible, rotate the use of PYRATE 480 EC Insecticide or other Group 1B insecticides with different groups that control the same pests in a field.
- Use tank mixtures with insecticides from a different group when such use is permitted.
- Insecticide use should be based on an IPM program that includes scouting, record keeping, and considers cultural, biological and other chemical control practices.
- Monitor treated pest populations for resistance development.
- Contact your local extension specialist or certified crop advisors for any additional pesticide resistance-management and/or IPM recommendations for the specific site and pest problems in your area.
- For further information or to report suspected resistance contact Adama Agricultural Solutions Canada Ltd. at 855-264-6262

Pests of Turf on Golf Courses, highway medians and industrial sites and sod farms

Control the pests in the following table by application of PYRATE 480 EC Insecticide at the recommended rates while following directions given below. Dilute PYRATE 480 EC Insecticide in sufficient water and apply using a coarse, low pressure spray to obtain complete and uniform coverage of the infested area.

Pest	Amount of Product per 100 m²	Specific Directions
Ants, Chinch bugs, Cutworm	22.5 mL*	Spray when pests first appear, repeat when needed. Maximum number of applications is 2 per season.
Crane fly larvae (leatherjackets)	20-25 mL	Apply as a drenching spray in water in late fall after the flight of adult crane flies has ceased for the year.
Sod webworms	22.5 mL	For sod webworms delay watering or mowing the treated area for 12 to 24 hours after treatment.
Turfgrass (Hyperodea) Weevil (Annual and Bluegrass weevil)	22.5 mL	Spray suspected problem areas in mid-April and again in mid-May, or as recommended by your local Agricultural Representative.
*22.5 mL/100 m ² = 112.5 mL/500 m ² = 225 mL/1000 m ² or 2.25 L/ha (10,000 m ²)		

Pests of Ornamentals (commercial production only) – greenhouses, nurseries, industrial sites

Treat flowers, shrubs, vines, shade and flowering trees and evergreens found to be infested with the pests listed in the following table. Dilute PYRATE 480 EC Insecticide with water as per directions given in the table and use spray equipment which would provide complete and uniform coverage. Apply as a wetting spray to upper and lower leaf surfaces and infested branches and trunk areas. Do not overspray to the point of excessive run-off. Treat when pests appear and at 7 to 10 day intervals as needed.

NOTE: Do not use on azaleas, camellias, coleus, geraniums, oxalis, poinsettias, rose bushes or variegated ivy because of possible phytotoxic injury to these plants.

PRECAUTIONS FOR POST-APPLICATION WORKERS

Use on Greenhouse Ornamentals

Do not permit workers conducting crop contact activities to re-enter greenhouse for two days when conducting crop contact activities.

Pest	Amount of Product Per 1000 L	Specific Host Plants
Spittlebugs	88-150 mL	Various ornamental plants
Mealybugs	200 mL	Various ornamental plants
Aphids	375 mL	Beech, birch, elm, hickory, linden, maple, oak, pine, flowering cherry, flowering plum, spruce, tulip tree, viburnum, willow, spirea, nasturtium
Clover mite, European red mite, Honey locust mite, Red oak mite, Spruce spider mite, Two-spotted spider mite	375-500 mL	Arborvitae, juniper
Borers such as Ash and Lilac borers	500 mL	Locust, birch, mountain ash, willow, lilac
Eastern and Forest Tent Caterpillars	500 mL	Ash, birch
European Pine Sawfly Red-Headed Pine Sawfly	500 mL	Conifers, mountain ash
Grasshoppers	500 mL	Various ornamental plants
Thrips	500 mL	Various ornamental plants
Whiteflies	500 mL	Various ornamental plants
Leafhoppers such as Potato and Six spotted leafhoppers	1 L	Various ornamental plants
Scale insects such as Lecanium, cottony maple, San Jose, oystershell	2 L	Various ornamental plants

500 mL is equivalent to 240 g of chlorpyrifos per 1000 L

1 L is equivalent to 480 g of chlorpyrifos per 1000 L

2 L is equivalent to 960 g of chlorpyrifos per 1000 L

Native Elm Bark Beetle

RESTRICTED USE: To be used only under a provincial Dutch Elm disease program. Consult provincial regulatory officials for required authorization.

Prevention of Overwintering: To prevent the adult beetle from overwintering in uninfected trees and to reduce beetle populations in disease free areas, apply a 0.48% (480 g ai/100 L) mixture of chlorpyrifos in water to the bottom 0.5 m of the tree trunk. Wet the trunk thoroughly but do not allow the spray to run-off. Care should be taken to apply the spray right to the base of the root flare. Applications can be made with either a back pack mist blower or a hydraulic pressure sprayer from spring through early fall.

1. Make only one application per season.
2. Bystanders should be advised to keep away from treated areas until residues are dry.
3. Do not apply next to water bodies. Highly toxic to fish and other aquatic organisms.

Amount of Final Spray Solution	Amount of PYRATE 480 EC Insecticide
5 L	50 mL
10 L	100 mL
100 L	1 L
1000 L	10 L

For best results, PYRATE 480 EC Insecticide should be used in a total integrated Dutch Elm disease control program, which includes both chemical treatments and necessary sanitation techniques.

INDUSTRIAL PESTS INDOORS

General Information

Use PYRATE 480 EC Insecticide to control the pests indicated in the areas listed below by application as a 0.24% or 0.48% chlorpyrifos spray. Use the low rate to control light infestations and the high rate to quickly reduce heavy infestations. Dilute PYRATE 480 EC Insecticide with water according to the following table. Repeat the treatment as needed. **KEEP OFF TREATED AREAS UNTIL SPRAY HAS DRIED.**

SPRAY DILUTION CHART

Litres of Spray Mixture Desired Water-Based Spray	mL of PYRATE 480 EC Insecticide to Use 0.24% Spray	mL of PYRATE 480 EC Insecticide to Use 0.48% Spray
1	5	10
2	10	20
4	20	40
8	40	80
25	125	250

Crack and Crevice treatment in ships holds, railroad boxcars, industrial plants, manufacturing plants, warehouses, meat packing plants and food processing plants only. Use only during close down periods.

For spot treatment in industrial plants, manufacturing plants, warehouses, meat packing plants and food processing plants.

Use as a spot treatment to control cockroaches, ants, crickets, firebrats, silverfish and spiders, by application as a coarse, low pressure (150 kPa or less) spray to localized areas where the above pests have been seen or are suspected of hiding or entering. Apply only enough spray to thoroughly cover the surfaces treated using special care to avoid unnecessary runoff. Do not introduce the spray into the air or allow the spray to contact food-contacting surfaces. Areas treated may include dark corners of rooms and closets, along and behind baseboards, beneath and behind stoves, refrigeration units and equipment, floor drains, and around plumbing and other utility installations.

For ants apply to ant trails and wherever these pests may find entrance. Spot treatment may encompass crack and crevice treatment by applying small amounts of material directly into openings leading to voids and hollow spaces in walls, equipment legs and bases or at points between different elements of construction or between equipment and floors. The use of chlorine based cleaning materials will significantly reduce the residual effect of PYRATE 480 EC Insecticide.

Remove all food, packaging materials and utensils before spraying. After spraying wash all surfaces that may contact food and rinse thoroughly with potable water before re-use for food processing. Do not use in food preparation or serving areas, e.g. restaurants.

Repeat treatment as needed but not more often than once every 14 days in food processing plants and meat packing plants.

NOTE: A period of 4 to 7 days is normally required for maximum effect on cockroaches.

Keep off treated areas until product is dry.

Attention (Pests Indoors): **Do not** apply water-base sprays of this product in conduits, motor housing, junction and switch boxes or other electrical equipment because of possible shock hazard.

RESTRICTED USE - MOSQUITO CONTROL (Ground application only)

NATURE OF THE RESTRICTION: This product is to be used only in the manner authorized. Contact local pesticide regulatory authorities for appropriate permits which may be required.

RESTRICTED USE: Mosquitoes: PYRATE 480 EC Insecticide mixes readily with water or oil such as kerosene or No. 2 diesel fuel oil. PYRATE 480 EC Insecticide should be thoroughly mixed with the amount of water or oil required to give uniform coverage and applied to non-crop areas with suitable equipment such as hand or power sprayers, mist applicators, or by aerial application. Use at rates provided on the following table.

LARVAL CONTROL (MOSQUITOES) - EC FORMULATION		
SITE (STANDING WATER)	APPLICATION	RATE
Temporary Pools (e.g. shallow, grassy depression, flooded woodlands, industrial parks, roadway ditches, railway marshalling yards, small temporary sloughs)	RESTRICTED USE	13-53 g ai/ha
NOT TO BE USED IN PERMANENT WATER BODIES SUCH AS: LAKES, DUGOUTS OR FISH PONDS	<p>GROUND: Apply uniformly to standing water. Spot applications may be made to catch basins, culverts, and similar areas where mosquitoes may breed. Application should be made when larvae are first noticed. Spray equipment must be properly calibrated to deliver the required amount of insecticide. Application equipment giving medium to coarse spray droplets should be used for mosquito larval control. The high rate (53 g ai/ha) should be used only if algal content or aquatic vegetation does not allow thorough penetration of spray solution or if multiple generations or asynchronous hatching of mosquitoes is expected. Use the lower rate (13 g ai/ha) if aquatic vegetation is not dense and thorough penetration of spray solution is expected.</p> <ol style="list-style-type: none"> 1. DO NOT REPEAT MORE OFTEN THAN ONCE EVERY TWO WEEKS. 2. THIS PESTICIDE IS VERY HIGHLY TOXIC TO FISH AND OTHER AQUATIC ORGANISMS SUCH AS AQUATIC INSECTS AND CRUSTACEANS. DO NOT APPLY TO PERMANENT WATER BODIES AS THESE MAY CONTAIN FISH AND OTHER AQUATIC ORGANISMS. 3. APPLY ONLY IN ACCORDANCE WITH FEDERAL, PROVINCIAL AND LOCAL LAWS AND REGULATIONS GOVERNING CHEMICAL TREATMENT OF BODIES OF WATER FOR CONTROL OF MOSQUITOES. 4. DO NOT APPLY IN AREAS THERE MAY BE POTENTIAL EXPOSURE TO BYSTANDERS. 5. THIS PRODUCT SHOULD BE APPLIED AT AN APPROPRIATE DISTANCE FROM RESIDENCES, 	

LARVAL CONTROL (MOSQUITOES) - EC FORMULATION		
SITE (STANDING WATER)	APPLICATION	RATE
	<p>HOSPITALS, SCHOOLS, PARKS, PLAYFIELDS, AND PLAY- GROUNDS. THIS DISTANCE SHOULD BE ESTABLISHED BY THE MUNICIPALITY/PROVINCE.</p> <p>Consult provincial pesticide regulatory officials for required authorization.</p>	

ADULT CONTROL (MOSQUITOES) - EC FORMULATION		
SITE (STANDING WATER)	APPLICATION	RATE
OUTDOOR AREA	<p>RESTRICTED USE: GROUND: Mix with the proper amount of water or oil required to give uniform coverage and applied to non-crop areas with suitable equipment such as hand or power sprayers or mist applicators. Apply to wet grassy or wooded areas when adults first become a nuisance. Equipment giving fine sprays, mists or aerosol droplets will give best results. Retreat as required. Use the higher rate where vegetation is dense. Where vegetation is too dense to permit adequate penetration, the spray swath should be reduced to 50 m. Use 26 g/ha for light to medium vegetative cover. 53 g/ha for medium to heavy vegetative cover.</p> <p>– ONLY TO BE USED AFTER CONSULTATION WITH FEDERAL/PROVINCIAL/TERRITORIAL REGULATORY AUTHORITIES TO ADDRESS PUBLIC HEALTH CONCERNS.</p> <p>Consult provincial pesticide regulatory officials for required authorization.</p>	26-53 g in kerosene, No. 2 diesel or water per hectare

SPECIFIC APPLICATION EQUIPMENT: For mistblowers, calculate application rates as in this example: For mistblowers calibrated to deliver 350 L per hour covering a spray swath of 100 m at a vehicle speed of 9 km per hour, use 5 to 10 L of PYRATE 480 EC Insecticide in 350 L of water. Use the higher rate where vegetation is dense. Where vegetation is too dense to permit adequate penetration, the spray swath should be reduced to 50 m. (See Table for rate of application.)

AMOUNT TO USE PER HECTARE		
Condition of Area To Be Treated	PYRATE 480 EC Insecticide (mL)	Chlorpyrifos (g)
Larval Control None to medium vegetative cover or Low organic matter	28 - 55	13 - 26
Medium to heavy vegetative cover or High organic matter	55 - 110*	26 - 53*
Adult Control	55	26
Light to medium vegetative cover Medium to heavy vegetative cover	110*	53*

*The higher dosage of PYRATE 480 EC Insecticide should be used only where vegetative cover is dense or where larval aquatic areas are high in organic matter. The use of this rate under conditions of little or no vegetative cover of water organic content is harmful to fish or crustaceans and should be used only where kill of these species can be tolerated.

RESTRICTED USE – FORESTRY

NOTICE TO USER: This pest control product is to be used only in accordance with the directions on the label. It is an offence under the *Pest Control Products Act* to use this product in a way that is inconsistent with the directions on the label. The user assumes the risk to persons or property that arises from any such use of this product.

NATURE OF THE RESTRICTION: This product is to be used only in the manner authorized. Contact local pesticide regulatory authorities for appropriate permits which may be required.

Mountain Pine Beetle: For ground use only to control small infestations of mountain pine beetle in lodgepole pine forest stands. Monitor stand in the period mid-June to mid-July to determine the trees which are infested. Apply treatment to infested trees within a few weeks of the expected beetle emergence, usually early July, in order to kill the adult beetles. Avoid spraying when conditions favour drift from spray area.

Use 1 L of PYRATE 480 EC Insecticide in 24 L of water (42 L in 1000 L of water) to make a spray containing 2% active ingredient by weight. Apply at a rate of 1 L spray/m² of bark prior to adult beetle emergence. Treat boles from ground level up to a height of at least 3 meters or until a bole diameter of 12.5 cm is reached.

This label transcript service is offered by the Pest Management Regulatory Agency to provide efficient searching for label information. This service and this information do not replace the official hard-copy label. The PMRA does not provide any guarantee or assurance that the information obtained through this service is accurate, current or correct, and is therefore not liable for any loss resulting, directly or indirectly, from reliance upon this service.

This is **Exhibit “Q1”** referred to in the affidavit of **Dr. Elaine MacDonald** affirmed remotely before me in accordance with O. Reg 431/20, Administering Oath or Declaration Remotely this 19th day of January 2022.



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Surplus Pesticides Disposal

Be sure to safely dispose of pesticides that you do not need or cannot use. Options for proper disposal include:

- Contact the supplier. It is sometimes possible to return unused pesticide if it is still in its original, unopened container.
- Hire a licensed waste hauler who is licensed under Part V of the *Environmental Protection Act* to carry hazardous wastes.
- Cleanfarms operates a free Obsolete Pesticide and Animal Health Product Collection Program throughout the province every 3 years. To locate the closest collection point and date, visit the [Cleanfarms](#), contact Cleanfarms at 416-622-4460 (toll-free at 877-622- 4460) or info@cleanfarms.ca or contact your local dealer for program details.
- Contact your municipality to see if any hazardous waste collection days are scheduled and verify whether quantities of agricultural pesticides will be accepted.

This is **Exhibit “Q2”** referred to in the affidavit of **Dr. Elaine MacDonald** affirmed remotely before me in accordance with O. Reg 431/20, Administering Oath or Declaration Remotely this 19th day of January 2022.



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Pesticides need to be handled, used, and disposed of appropriately, in order to minimize risk to human health and the environment. If you have unwanted pesticide products and/or containers and are considering disposal options, the first thing you should do is **read the label. The label may describe disposal procedures. These must be followed.**

How can I dispose of unwanted Domestic or household pesticides?

“Domestic” class pesticides have the word “Domestic” displayed on the main information panel of their labels. They include, for example, some brands of Roundup, Killex, and Sevin that can be purchased at local garden stores.

1. If your pesticide **container is not opened**:

- You may be able to return unopened Domestic pesticide containers to the manufacturer or the vendor from which it was purchased. Call them beforehand to inquire.

2. If you wish to **dispose of household pesticides**:

- First read the label. The label may describe disposal procedures. These must be followed.
- If the label does not provide details or you need more information, contact the Recycling Hotline of British Columbia.
- If you have unlabelled or poorly-labelled containers that you know or suspect may contain a pesticide, you should take a precautionary approach to handling and disposing of these products. To discuss the disposal of these products contact the Recycling Hotline of British Columbia.
- If the container is leaky or in poor condition, place the entire container into another larger container to prevent any leaks from escaping while you store or transport the pesticide.

Recycling Hotline of British Columbia (RCBC): <https://www.rcbc.ca/services/recycling-hotline>

BC Toll-Free: 1-800-667-4321

Lower Mainland: 604-RECYCLE (604-732-9253)

Email: hotline@rcbc.ca

What about empty pesticide containers?

Domestic or **household** pesticide containers may be disposed of in the household garbage. Do not put them into “blue boxes” for recycling. It is always best to rinse empty containers before disposing of them. Use the rinse water when mixing a new batch of pesticide or pour it onto the ground in the area where you applied the pesticide; do not pour it down the drain.

How can I dispose of unwanted Commercial or Restricted pesticides?

“Commercial” class pesticides will have the word “Commercial” (or, “Agricultural”, “Horticultural”, or “Industrial”) displayed on the main information panel of their labels. “Restricted” class pesticides will have the word “Restricted” displayed on the main panel of their labels. In general, these are concentrated pesticides that require dilution before they are used. Examples include agricultural insecticides like diazinon and endosulfan, forestry herbicides like glyphosate and horticultural fungicides like Captan.

There currently are no permanent locations in B.C. where commercial pesticides can be taken for disposal. The following options are available:

1. You may be able to return your unused pesticides, in their original containers to the vendor or supplier from which they were purchased. Call them beforehand to inquire about this option.
2. You may use the pesticide according to label directions. For example, apply it to a crop specified on the label.
3. If you are a licensed pesticide user, you may give your unused pesticides to another licensed pesticide user. Please ensure that you are giving it to someone who will be using it for the purposes described on the product label.
4. Contact your municipality or regional district and ask them if they operate a hazardous waste roundup or a similar program, and ask what sort of pesticides they accept. Commercial class pesticides may or may not be acceptable, depending on the program, so be prepared to tell them the type and quantity of product you have.
5. You may obtain the services of a company that specializes in hazardous waste disposal. These companies will assist you to determine if you have a hazardous material and will arrange pick up and disposal of your unwanted pesticides for a fee. You will need to provide the company with the pesticide name, number and size of containers, and approximate volume of liquid pesticides or weight of solid pesticides.

Helpful hazardous waste information:

<https://www2.gov.bc.ca/gov/content/environment/waste-management/hazardous-waste>

<https://bceia.com/hazwaste/>

6. Keep your pesticides properly stored, and wait for a B.C. Pesticide Return event.

CleanFarms collects and safely disposes of obsolete or otherwise unwanted agricultural pesticides through their obsolete pesticide collection program. For more information on this program and pesticide collection schedule in your area visit the CleanFarms site.

CleanFarms: www.cleanfarms.ca

7. Under B.C. law, commercial pesticides must be stored in a structure that is locked, vented, and has a sign saying “WARNING – CHEMICAL STORAGE”. If your pesticides are in leaky containers, consider storing these containers inside larger, secure containers, such as 20 L plastic pails or 200 L plastic drums. Keep liquids and solids separate, and properly labelled.

What about empty pesticide containers?

Commercial pesticide containers must be appropriately rinsed, and may be taken to a container collection site for recycling. For instructions on how to properly rinse containers, and a list of empty container recycling sites in B.C. visit the CleanFarms website (above) or contact your local government.

This is **Exhibit “Q3”** referred to in the affidavit of **Dr. Elaine MacDonald** affirmed remotely before me in accordance with O. Reg 431/20, Administering Oath or Declaration Remotely this 19th day of January 2022.



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Disposal of Pesticide Waste

FACTS AT YOUR FINGERTIPS

March 2008

To ensure the environment is protected, pesticides and pesticide waste must be disposed in an appropriate manner.

Pesticide containers

Albertans can take empty and rinsed non-returnable plastic and metal pesticide containers to approved pesticide container collection sites across the province. These sites are listed in the *Guide to Crop Protection with Chemicals* published by Alberta Agriculture and Rural Development and on Alberta Environment's website. Information regarding the operation of container collection sites is available through municipal offices (contact the Agricultural Fieldman). Empty pesticide containers are collected through an pesticide industry stewardship program, processed and recycled or used for heat (energy) recovery.

There are approximately 100 permanent pesticide container collection sites located throughout the province to collect empty and rinsed non-returnable plastic and metal pesticide containers. The sites are not to be used for the disposal of pesticide concentrate or other refuse. Empty bags that contained granular pesticides contaminated cardboard packaging or plastic liners should be disposed at a Class II landfill. Clean cardboard boxes and container booklets should be recycled.

Leftover pesticide tank solutions and rinsate

Excess pesticide solution and tank rinsate can be disposed of by using the solution as mix water in spraying operations or it can be re-sprayed over a treatment area provided that label application rates are not exceeded and that use is in accordance with label.

Treated seed

The Disposal of Treated Seed fact sheet provides information about disposing of seed or grain that has been treated or mixed with a pesticide. The Waste Management Guidelines for Commercial Seed Protectant Services fact sheet has information about minimizing and managing wastes for businesses that apply commercial seed protectants. These documents are available from Alberta Environment regional offices or at www.environment.alberta.ca.

Unwanted/unusable pesticide concentrates

The most economical method for disposing of pesticide concentrates is to use the concentrate according to label directions. If the pesticide has no further use, another qualified user may be found.

Pesticides must be stored properly according to provincial regulations and industry standards. Label directions usually indicate if a pesticide's effectiveness or formulation degrades from freezing or heating.

In some instances, it may be necessary to dispose of a pesticide that is no longer effective, suitable or registered for use.

Hazardous waste classification

Most commercial pesticide concentrates intended for disposal will be classified as hazardous waste according to the following provincial hazardous waste criteria:

- Poisonous or Toxic Substances (Class 6)
 - with an oral LD₅₀ of 5,000 mg/kg
 - with a dermal LD₅₀ of 1,000 mg/kg;
- Flammable Substances (Class 3) having a flash point at a temperature less than 61°C;
- Toxic Leachate (Class 9). Leachate concentration in excess of values listed in the table included at the end of this factsheet.

The following exemptions apply:

- Pesticide waste amounts less than five litres or five kilograms generated in any month (hazardous waste in excess of five litres or five kilograms cannot be sub-divided into several months to qualify for this exemption);
- Pesticide wastes where products carry a federal DOMESTIC label classification.

Disposal of Pesticide Waste

FACTS AT YOUR FINGERTIPS

Materials containing pesticides

Waste materials (e.g., sawdust, kitty litter) containing pesticides resulting from pesticide spills are considered hazardous waste if the leachate extracted from the material (using standardized tests) contains pesticide residues that exceed specified limits. Hazardous waste leachate testing must be done by qualified environmental laboratories.

If materials are heavily contaminated with pesticide residues, or the pesticide residues are highly leachable and disposal amounts are relatively small, it may be more economical to skip the leachate testing and manage the materials as hazardous waste.

The five kilogram hazardous waste exemption for wastes generated in any one month applies to pesticide waste materials as well as pesticide concentrates.

Pesticide residues in soil (in excess of label application rates) can result when equipment fails or vehicle accidents. The preferred method of managing pesticide residues in soil is to encourage the in-situ decomposition of residues through cultivation and fertilization. If in-situ remediation is not feasible due to the type of pesticide, residue concentration, land area or environmental concerns, the soil will have to be excavated and disposed as hazardous waste.

Accidents involving pesticide release into the environment must be reported to Alberta Environment (1-800-222-6514) to ensure proper clean-up and remediation.

Waste treatment and disposal

Hazardous waste treatment facilities require an approval from Alberta Environment. Anyone accepting or transporting hazardous waste must have a Personal Identification Number (PIN) as a Hazardous Waste Carrier. Anyone generating hazardous waste (except farmers through crop production) in excess of the five litre or five kilogram exemption must obtain a PIN as a hazardous waste generator prior to removing waste. These authorizations are issued by Alberta Environment.

Copies of the *Environmental Protection and Enhancement Act* and its regulations are available from the Queen's Printer at www.qp.gov.ab.ca.

Questions about pesticide regulations may be directed to an Alberta Environment office:

Grande Prairie 780-538-5351
Room 1701, Provincial Building
10320 - 99 Street
Grande Prairie, Alberta T8V 6J4

Edmonton 780-427-7614
Twin Atria Building
#111 4999-98 Avenue
Edmonton, Alberta T5K 2J6

Spruce Grove 780-960-8600
250 Diamond Avenue
Spruce Grove, Alberta T7X 4C7

Red Deer 403-340-7052
3rd Floor, Provincial Building
4920 - 51 Street
Red Deer, Alberta T4N 6K8

Calgary 403-297-7602
2nd Floor, Deerfoot Square
2938 - 11 Street NE
Calgary, Alberta T2E 7L7

Lethbridge 403-381-5511
2nd Floor, Provincial Building
200 - 5 Avenue South
Lethbridge, Alberta T1J 4C7

To be connected toll-free, dial 310-0000.

This is **Exhibit “Q4”** referred to in the affidavit
of **Dr. Elaine MacDonald** affirmed remotely
before me in accordance with O. Reg 431/20,
Administering Oath or Declaration Remotely
this 19th day of January 2022.



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What to Do with Unwanted Pesticides and Obsolete Livestock Medications

What to Do with Unwanted Pesticides and Obsolete Livestock Medications

Crop Production News 2020



Crop Production News provides Saskatchewan farmers with the information they need to produce their crops economically and sustainably. It is sent out via email every two weeks during the growing season. If you're interested in receiving the newsletter, please fill out our

> [subscription form](#).

Contact Us

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∨ More

[View all contacts in the directory](#)

By Richard Wilkins, Provincial Specialist – Pesticide Regulatory, Regina

August 2020

With the majority of farm chemical application done and harvest around the corner, producers may find themselves with a left over supply of unwanted or obsolete farm chemicals. Similarly, livestock producers may also have some expired livestock medicine, which is no longer usable. The question then becomes how can these products be safely disposed of in an environmentally sound manner? Cleanfarms has a solution.

Cleanfarms is an industry sponsored, not-for-profit, stewardship organization that delivers recycling and disposal solutions to help producers and their communities safely manage farm waste. Cleanfarms' mandate is to support agriculture to be both responsible and sustainable in all operations, particularly recycling. Its ultimate vision is to achieve zero waste from our farming practices.

In 2020, Cleanfarms will be running its long-standing Unwanted Pesticides and Livestock/Equine Medications collection program. Cleanfarms runs this collection program in Saskatchewan and other provinces every three years on a rotating basis.

The targeted regions this year includes Southern Saskatchewan. The dates for Southern Saskatchewan are October 26 to 30, 2020. Northern Saskatchewan will have collection events in 2021. For more information on the type of material that can be disposed of through these collection events, the dates and location of the collection, please visit the [fall 2020 collection page](#). The materials collected will be transported by a licensed waste hauler to a high temperature incinerator facility for safe disposal. The program is offered to producers at no cost.

Since the inception of the program, between 2007 and 2019, approximately 670,000 kilograms of unwanted farm chemicals have been collected from Saskatchewan producers. The last time the program was offered in Saskatchewan, approximately 185,000 kilograms of material was collected. For all of Canada, 3,242 tonnes of expired, unwanted and obsolete pesticides and livestock/equine medications have been safely removed from the environment.



A producer dropping off old and unwanted farm chemicals at a collection depot.

The Ministry of Agriculture strongly encourages producers to participate in this program and safely dispose of expired, unwanted and obsolete pesticides and livestock medications.

For additional information on this or other Cleanfarms recycling initiatives pesticide containers, used grain bags, empty seed, pesticide and fertilizer bags, bailer twine and more, please visit the [Cleanfarms website](#).

We need your feedback to improve saskatchewan.ca. [Help us improve](#)

This is **Exhibit “Q5”** referred to in the affidavit of **Dr. Elaine MacDonald** affirmed remotely before me in accordance with O. Reg 431/20, Administering Oath or Declaration Remotely this 19th day of January 2022.



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Information Bulletin - Supplementary Pesticide Disposal & Empty Container Guidelines



THE INFORMATION PRESENTED BELOW IS TO PROVIDE INFORMATION ON THE PROPER DISPOSAL OF PESTICIDES AND PESTICIDE CONTAINERS IN THE PROVINCE OF MANITOBA.

DOMESTIC PESTICIDE WASTE & CONTAINER MANAGEMENT

Containers with unused pesticides, and/or empty containers in Manitoba can be recycled through the Household Hazardous Waste (HHW) Disposal program in the City of Winnipeg.

Location: Miller Environmental Corporation
1803 Hekla Avenue
Phone: (204) 925-9615

Open from 9 a.m. - 4 p.m. on the first and last Saturday of each month from April to September.
Open from 9 a.m. - 4 p.m. on the first Saturday of each month from October to March.

In addition, Green Manitoba offers an appointment system to book a drop-off time for Wednesdays and Thursdays. For telephone bookings, call Miller Environmental at 925-9600.

In rural areas, the **HHW spring collection events** will take place from 10:00am-2:00pm, contact Green Manitoba.

For more information:
City of Winnipeg HHW Program
<http://www.winnipeg.ca/>
Phone: 311

Green Manitoba
<http://www.greenmanitoba.ca/>
Phone: (204) 945-3268
Toll Free (in Manitoba): 1-866-460-3118

COMMERCIAL/RESTRICTED PESTICIDES

Empty triple rinsed containers in Manitoba can be taken to municipal pesticide container collection sites or returned to certified Agrichemical Warehousing Standards Association (AWSA) sites.

For more information:
Contact Your Local Municipality
Or; Pesticide Dealer (AWSA certified)

Unused, obsolete or unregistered pesticides should be disposed of by a licensed hazardous waste handling facility.

CropLife Canada in partnership with the Government of Manitoba has jointly sponsored the CleanFarms program in Manitoba (2008 being most recent). The CleanFarms program allows producers to dispose of any unwanted or obsolete pesticide products free of charge.

For more information:
CropLife Canada
www.croplife.ca

OVERSIZED PESTICIDE CONTAINERS

Pesticide containers which are oversized (over 23 litres) that are not accepted at the local municipal collection sites can be returned to where the product was purchased that has Agrichemical Warehousing Standards Association certification (AWSA).

****REMEMBER WHEN RETURNING EMPTY CONTAINERS...**

Empty, triple rinse, remove lids and label booklets!

This is **Exhibit “Q6”** referred to in the affidavit of **Dr. Elaine MacDonald** affirmed remotely before me in accordance with O. Reg 431/20, Administering Oath or Declaration Remotely this 19th day of January 2022.



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Pesticides

- About pesticides
- Ministerial actions
- Reviews, guides and reports
- Quebec Strategy 2015-2018
- Ministerial authorization
- Pesticide Management Code
- Pesticide waste
- Legal and regulatory framework
- Permits and certificates
- SAGÉ pesticides
- Sectors
- Public registers

Pesticide waste management in Quebec

Pesticide waste is waste consisting, in whole or in part, of pesticides as well as materials contaminated by pesticides. This definition includes rinse water (from rinsing empty containers and sprayers), concentrates that have expired or withdrawn from the market, empty containers, leftover spray, spill residue and contaminated soil.

There are two types of waste; domestic waste generated by the personal use of class 4 and 5 pesticides, and commercial waste generated by the use of class 1, 2 and 3 pesticides. All of this waste can, on certain occasions, become hazardous materials in under the [Regulation respecting hazardous materials](#) .

Household waste (empty containers and tightly wrapped small spill containment materials) can be disposed of through household waste if they are not hazardous materials. Expired domestic products are collected through domestic hazardous waste collections organized by the municipalities. Agricultural, commercial and industrial waste must be disposed of in accordance with the following obligations and advice.

- [Empty containers](#)
- [Leftover porridge](#)
- [Rinsing water](#)
- [Surplus concentrates and expired products](#)
- [Spill residues and contaminated soils](#)
- [Important phone numbers](#)
- [Pesticides classified as hazardous materials](#)

Empty containers

All empty containers should be carefully drained and rinsed using the triple rinse or pressure rinse technique. The rinsed containers are then rendered unusable by crushing or puncturing them (except those taken back by the manufacturer) to ensure that they will not be used for other purposes. Empty containers, kept in a safe place until final disposal, must not be burned or buried under any circumstances.

[AgriRÉCUP](#) organizes an annual empty agricultural container recovery program. Empty, clean (three times rinsed) containers with their caps and labels removed are accepted at participating retailer recovery sites.

Several companies offer high volume returnable and reusable containers. The containers are filled and sealed at the factory; after use, the non-rinsed containers are returned to the companies' depot. The use of water soluble bags or containers can also limit the proliferation of empty containers in the environment.



Leftover porridge

In order to avoid excess spray mixture, it is important to assess as accurately as possible the quantities of spray mixture to be spread according to the area to be treated and the recommended dose. The excess spray can be saved for later application or used on an area that has not yet been treated but requires the same treatment. These residues should not be dumped on vacant land or unused land so as not to unnecessarily damage any other ecosystem. Likewise, they must not be thrown into the sanitary or storm sewer, or into equipment which is discharged therein. Easy-drain tanks are recommended to reduce excess spray amounts.

Rinsing water

The rinsing water produced by cleaning containers (empty containers, sprayers, etc.) produces a large quantity of liquids containing low concentrations of pesticides. These rinsings must be spread over the area already treated when this operation does not affect the effectiveness of the treatment. If this type of disposal is not suitable, it is preferable to spray the rinsing water in an area with low risk, far from rivers, lakes and wells (50 meters). The rinsing water must not be discharged into the storm or sanitary sewer or in any equipment which empties therein.

Pesticide injection systems installed on sprayers, which allow the concentrated pesticide and water to be mixed immediately before passing through the nozzles, are recommended. Water soluble bags that limit rinsing water and returnable containers are also recommended.

Surplus concentrates and expired products

Surplus concentrates and expired products contain concentrated active ingredients. These products are generally toxic and should be stored in a safe place.

Intact containers of unused product may be kept for later use or returned to suppliers, if accepted by suppliers. In addition, every three years, [AgriRÉCUP](#) implements a program for the safe collection and disposal of approved, obsolete or unusable agricultural pesticides.

As a last resort, unusable pesticides (expired or out of use), which are not household products, must be disposed of properly. As they often have the [properties of a hazardous material](#) according to the Regulation respecting hazardous materials, they must be recycled or disposed of by holders of Ministry authorizations. Their addresses are accessible to the [regional offices of the Ministry](#). To dispose of these pesticides, either burn them (organic ingredients) in hazardous waste incinerators or stabilize them (inorganic ingredients). In the event that the products must be stored for a certain period of time before their elimination, the storage standards of the Regulation respecting hazardous materials only apply when the products are recognized as being hazardous materials and the quantity of concentrated pesticides is greater than 100 kilograms.



Spill residues and contaminated soils

Dans le cas d'un déversement, il est nécessaire de prévenir [Urgence-Environnement Québec](#). En attendant, il est primordial de confiner les liquides en construisant un remblai autour de l'endroit contaminé, avec des absorbants. Dans tous les cas, même s'il s'agit d'un déversement mineur, les absorbants utilisés pour ramasser les résidus (sable, bran de scie, vermiculite, etc.) sont considérés comme des déchets de pesticides. Ainsi, ils doivent, tout comme les matières contaminées par des pesticides, ayant les propriétés d'une matière dangereuse, être gérés comme des matières dangereuses, à moins que des analyses démontrent que les résidus sont contaminés en deçà des normes permises par le règlement.

Lors d'un déversement sur le sol (autre qu'un déversement d'envergure qui fera l'objet d'une décontamination du sol), la terre contaminée et excavée est, elle aussi, considérée comme déchet de pesticides. Tous les récipients contenant de la terre ou des matériaux absorbants imprégnés de pesticides doivent être scellés, marqués et entreposés dans un lieu sûr jusqu'à leur élimination par une entreprise spécialisée détentrice du permis du Ministère. Il ne faut jamais utiliser d'eau pour diluer les pesticides répandus.

Dans le cas d'une contamination des sols résultant de l'entreposage déficient de pesticides, d'un incendie d'entrepôt de pesticides, ou d'un déversement accidentel important ou lors de la détection d'une contamination majeure, une réhabilitation des terrains est prévue. Selon la [Politique de protection des sols et de réhabilitation des terrains contaminés](#), le propriétaire du terrain doit inscrire au Bureau de publicité des droits la présence et la nature de la contamination du sol. Les terrains qui constituent un risque significatif pour la santé humaine, la faune et la flore, doivent faire l'objet, selon le cas, de mesures de décontamination, de confinement ou des mesures restrictives d'utilisation. Les sols et les sédiments excavés doivent être gérés de sorte qu'ils ne constituent pas une nouvelle source de contamination pour l'environnement. Ainsi, l'excavation, le transport et le traitement des sols doivent se faire de façon à empêcher ou à minimiser la dilution et le transfert de contaminants dans un autre milieu.



Numéros de téléphone importants

[Urgence-Environnement](#)

[Canutec](#)

Urgence 613 996-6666
Information 613 992-4624

Centre antipoison du Québec

Québec 418 656-8090
Ailleurs 1 800 463-5060

[AgriRÉCUP](#)

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Pesticides

[À propos des pesticides](#)

[Actions ministérielles](#)

[Bilans, guides et rapports](#)

[Stratégie québécoise 2015-2018](#)

[Autorisation ministérielle](#)

[Code de gestion des pesticides](#)

[Déchets de pesticides](#)

[Encadrement légal et réglementaire](#)

[Permis et certificats](#)

[SAGÉ pesticides](#)

[Secteurs d'activités](#)

[Registres publics](#)

Gestion des déchets de pesticides au Québec

Les déchets de pesticides sont des déchets constitués, en tout ou en partie, de pesticides ainsi que de matériaux contaminés par des pesticides. Cette définition inclut les eaux de rinçage (provenant du rinçage des contenants vides et des pulvérisateurs), les produits concentrés périmés ou retirés du marché, les contenants vides, les restants de bouillie, les résidus de déversement et les sols contaminés.

Il existe deux types de déchets ; les déchets domestiques générés par l'utilisation personnelle de pesticides de classes 4 et 5, et les déchets commerciaux générés par l'utilisation de pesticides de classes 1, 2 et 3. Tous ces déchets peuvent, dans certaines occasions, devenir des matières dangereuses en vertu du [Règlement sur les matières dangereuses](#).

Les déchets domestiques (contenants vides et matériaux de confinement de petits déversements bien enveloppés) peuvent être éliminés via les ordures ménagères s'ils ne constituent pas des matières dangereuses. Les produits périmés domestiques sont récupérés via les collectes de déchets dangereux domestiques organisées par les municipalités. Les déchets agricoles, commerciaux et industriels doivent être éliminés selon les obligations et les conseils qui suivent.

- [Contenants vides](#)
- [Restants de bouillies](#)
- [Eaux de rinçage](#)
- [Les surplus de concentrés et les produits périmés](#)
- [Résidus de déversement et sols contaminés](#)
- [Numéros de téléphone importants](#)
- [Pesticides classés comme matières dangereuses](#)

Contenants vides

Tous les contenants vides doivent être égouttés et rincés, avec soin, selon la technique du triple rinçage ou du rinçage sous pression. Les contenants rincés sont ensuite rendus inutilisables en les écrasant ou en les perforant (sauf ceux repris par le fabricant) afin de s'assurer qu'ils ne seront pas utilisés à d'autres fins. Les contenants vides, conservés en lieu sûr jusqu'à leur élimination finale, ne doivent en aucun cas être brûlés ou enterrés.

[AgriRÉCUP](#) organise annuellement un programme de récupération de contenants vides agricoles. Les contenants vides, propres (rincés trois fois) et débarrassés de leur bouchon et de leur étiquette sont acceptés dans les sites de récupération des détaillants participants.

Plusieurs compagnies offrent des contenants de fort volume consignés et réutilisables. Les contenants sont remplis et scellés à l'usine ; après leur utilisation, les contenants non rincés sont retournés au dépôt des compagnies. L'utilisation de sacs ou de contenants hydrosolubles peut également limiter la prolifération des contenants vides dans l'environnement.



Restants de bouillies

Afin d'éviter les surplus de bouillie, il est important d'évaluer le plus exactement possible les quantités de bouillie à épandre selon l'étendue à traiter et la dose recommandée. L'excédent de bouillie peut être conservé pour une application ultérieure ou utilisé sur une zone n'ayant pas encore été traitée mais nécessitant le même traitement. Ces résidus ne devraient pas être déversés sur des terrains vagues ou des terres inutilisées afin de ne pas endommager inutilement tout autre écosystème. De même, ils ne doivent pas être jetés dans l'égout sanitaire ou pluvial, ou encore dans un équipement qui s'y déverse. Les réservoirs à vidange facilitée sont recommandés pour réduire les quantités de bouillie excédentaires.

Eaux de rinçage

Les eaux de rinçage produites par le nettoyage des récipients (contenants vides, pulvérisateurs, etc.) occasionnent une quantité importante de liquides contenant de faibles concentrations de pesticides. Ces rinçures doivent être épandues sur la superficie déjà traitée lorsque cette opération ne nuit pas à l'efficacité du traitement. Si ce type d'élimination ne convient pas, il est préférable de pulvériser les eaux de rinçage dans une zone peu à risque, loin des cours d'eau, des lacs et des puits (50 mètres). Les eaux de rinçage ne doivent pas être rejetées dans l'égout pluvial ou sanitaire ou encore dans un équipement qui s'y déverse.

Les systèmes d'injection de pesticides installés sur les pulvérisateurs, qui permettent de mélanger le pesticide concentré et l'eau immédiatement avant le passage dans les buses, sont recommandés. Les sacs hydrosolubles qui limitent les eaux de rinçage et les contenants consignés sont également recommandés.

Les surplus de concentrés et les produits périmés

Les surplus de concentrés et les produits périmés contiennent des ingrédients actifs concentrés. Ces produits sont généralement toxiques et doivent être entreposés en lieu sûr.

Les contenants intacts de produits inutilisés peuvent être gardés pour une utilisation ultérieure ou être retournés aux fournisseurs, si ces derniers les acceptent. De plus, tous les trois ans, [AgriRECUP](#) met en œuvre un programme de collecte et d'élimination sécuritaire des pesticides agricoles homologués, périmés ou non utilisables.

En dernier recours, les pesticides inutilisables (périmés ou hors d'usage), qui ne sont pas des produits domestiques, doivent être éliminés correctement. Comme ils ont souvent les [propriétés d'une matière dangereuse](#) selon le Règlement sur les matières dangereuses, ils doivent être recyclés ou éliminés par des détenteurs d'autorisations du Ministère. Leurs adresses sont accessibles aux [bureaux régionaux du Ministère](#). Pour éliminer ces pesticides, il convient soit de les brûler (ingrédients organiques) dans des incinérateurs à déchets dangereux, soit de les stabiliser (ingrédients inorganiques). Dans le cas où les produits doivent être entreposés durant un certain temps avant leur élimination, les normes d'entreposage du Règlement sur les matières dangereuses s'appliquent seulement lorsque les produits sont reconnus comme étant des matières dangereuses et que la quantité de pesticides concentrés est supérieure à 100 kilogrammes.



Résidus de déversement et sols contaminés

Dans le cas d'un déversement, il est nécessaire de prévenir [Urgence-Environnement Québec](#). En attendant, il est primordial de confiner les liquides en construisant un remblai autour de l'endroit contaminé, avec des absorbants. Dans tous les cas, même s'il s'agit d'un déversement mineur, les absorbants utilisés pour ramasser les résidus (sable, bran de scie, vermiculite, etc.) sont considérés comme des déchets de pesticides. Ainsi, ils doivent, tout comme les matières contaminées par des pesticides, ayant les propriétés d'une matière dangereuse, être gérés comme des matières dangereuses, à moins que des analyses démontrent que les résidus sont contaminés en deçà des normes permises par le règlement.

Lors d'un déversement sur le sol (autre qu'un déversement d'envergure qui fera l'objet d'une décontamination du sol), la terre contaminée et excavée est, elle aussi, considérée comme déchet de pesticides. Tous les récipients contenant de la terre ou des matériaux absorbants imprégnés de pesticides doivent être scellés, marqués et entreposés dans un lieu sûr jusqu'à leur élimination par une entreprise spécialisée détentrice du permis du Ministère. Il ne faut jamais utiliser d'eau pour diluer les pesticides répandus.

Dans le cas d'une contamination des sols résultant de l'entreposage déficient de pesticides, d'un incendie d'entrepôt de pesticides, ou d'un déversement accidentel important ou lors de la détection d'une contamination majeure, une réhabilitation des terrains est prévue. Selon la [Politique de protection des sols et de réhabilitation des terrains contaminés](#), le propriétaire du terrain doit inscrire au Bureau de publicité des droits la présence et la nature de la contamination du sol. Les terrains qui constituent un risque significatif pour la santé humaine, la faune et la flore, doivent faire l'objet, selon le cas, de mesures de décontamination, de confinement ou des mesures restrictives d'utilisation. Les sols et les sédiments excavés doivent être gérés de sorte qu'ils ne constituent pas une nouvelle source de contamination pour l'environnement. Ainsi, l'excavation, le transport et le traitement des sols doivent se faire de façon à empêcher ou à minimiser la dilution et le transfert de contaminants dans un autre milieu.



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This is **Exhibit “R”** referred to in the affidavit of
Dr. Elaine MacDonald affirmed remotely before
me in accordance with O. Reg 431/20,
Administering Oath or Declaration Remotely
this 19th day of January 2022.



Commissioner for Taking Affidavits
(or as may be)

Health Canada's Pest Management Regulatory Agency / Regulatory Operations and Regions Branch Compliance and Enforcement Report

2017-2018

NATIONAL PESTICIDE COMPLIANCE PROGRAM

ANNUAL REPORT

2017 – 2018

YOUR HEALTH AND SAFETY... OUR PRIORITY.



Également offert en français sous le titre :

Rapport annuel 2017-2018 du Programme national de surveillance de la conformité des pesticides

This publication is also available on the Internet at Canada.ca/pesticides

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The Pest Management Regulatory Agency publications team was responsible for the translation, formatting and publication of this document.

For additional copies, please contact:

Publications

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2720 Riverside Drive

Ottawa ON K1A 0K9

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Facsimile: 1-613-736-3758

ISSN: 2371-0713 (PDF version)

Catalogue Number: H111-5E-PDF (PDF version)

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This document does not constitute part of the Pest Control Products Act (Act) or its associated Regulations and in the event of any inconsistency or conflict between that Act or Regulations and this document, the Act or the Regulations take precedence. This document is not intended to provide legal advice regarding the interpretation of the Act or Regulations. If a regulated party has questions about their legal obligations or responsibilities under the Act or Regulations, they should seek the advice of legal counsel.

Mission and Vision

OUR MISSION

The mission of Health Canada's National Pesticide Compliance Program is to help protect the health and environment of Canadians by promoting, monitoring and enforcing compliance with the *Pest Control Products Act* and its Regulations.

OUR VISION

The vision is to strive for excellence in pesticide compliance and enforcement.

Executive Summary

This report outlines the results of compliance and enforcement activities conducted by Health Canada's National Pesticide Compliance Program (NPCP) in the 2017-2018 fiscal year. The NPCP is responsible for promoting, monitoring and enforcing compliance with the *Pest Control Products Act* and its Regulations. The program is administered jointly by Health Canada's Pest Management Regulatory Agency (PMRA) and the Regulatory Operations and Regions Branch (RORB). The PMRA sets the strategic direction, program priorities and policies, and determines how those priorities are implemented nationally. The RORB is responsible for the delivery of compliance and enforcement activities and for maintaining valuable relationships with provincial and territorial partners and stakeholders.

The scope of the NPCP covers the full range of parties regulated by the *Pest Control Products Act*, including pesticide registrants, manufacturers, importers, retailers, and users. To align activities with these regulated parties and better capture the work we do, the NPCP adopted a new framework beginning in 2017-2018. The NPCP is now divided into seven sectors: Registrants, Importation, Marketplace, Users, Re-Evaluation, Surveillance, and Inquiries and Complaints. NPCP highlights are noted below, with details of activities conducted in each sector provided in later chapters.

To account for regional variation, the NPCP includes both national and regional activities. The diversity of NPCP programs allows the Pesticide Compliance Program to assess a sample of users from a variety of subsectors and provides the PMRA with information about compliance issues or potential trends.

Compliance activities are prioritised based on risk. In some instances, when non-compliance is known or suspected, a targeted approach may be used, which may result in higher rates of non-compliance. In other situations, random inspections are preferred. Compliance rates presented in this report reflect the regulated parties inspected and are not representative of the industry as a whole. The results presented in this report include summary findings of all compliance observations, which include all levels of risk. These findings are used in planning compliance priorities for subsequent years.

2017-2018 KEY STATISTICS

- 253 Compliance Outreach activities were conducted to promote compliance with the *Pest Control Products Act*. These activities included presentations, meetings, exhibit booths at trade shows, and other activities such as providing publications for mail-outs and contributing to association newsletters.
- 933 inspections were conducted.
- 428 samples were analyzed by the PMRA's laboratory.

- The rate of compliance varied by subsector, ranging from 11% to 100%.
- The most common violation types noted for all inspections were sale (34%), possession (25%), and importation (21%). This includes violations noted during planned activities (1288) and compliance verifications (242). 796 enforcement responses were issued to non-compliant parties. Enforcement responses included verbal education (75), written education (359), enforcement letters (341), and Compliance Orders (21).
- In addition, 30 Notices of Violation (NOVs) with penalty and 2 Notices of Violation (NOVs) with warning were issued under the *Agriculture and Agri-Food Administrative Monetary Penalties (AMPs) Act*.

Chapter 1- Overview of NPCP

The NPCP is responsible for promoting, monitoring and enforcing compliance with the *Pest Control Products Act* and its Regulations. The program is administered jointly by Health Canada's PMRA and the Regulatory Operations and Regions Branch (RORB). The PMRA sets the strategic direction, program priorities and policies, and determines how those priorities are implemented nationally. The RORB is responsible for the delivery of compliance and enforcement activities and for maintaining valuable relationships with regional partners and stakeholders.

The NPCP is coordinated from Ottawa and is delivered by regional inspectors located in Burnaby, Kelowna, Edmonton, Calgary, Lethbridge, Regina, Saskatoon, Winnipeg, London, Guelph, Toronto, Montreal, Quebec City, Ottawa, Moncton, Charlottetown, and Kentville. In Newfoundland and Labrador, the NPCP is implemented by the provincial inspectors located in St. John's, Corner Brook, and Gander. The NPCP is supported by the PMRA's ISO 17025 accredited laboratory located in Ottawa.



Figure 1. Map of Pesticide Compliance Program Regional Offices and Headquarters (Ottawa)

The scope of the NPCP covers the full range of parties regulated under the *Pest Control Products Act*, including: pesticide registrants, manufacturers, importers, retailers, and users. To align activities with these regulated parties and better capture the work we do, the NPCP adopted a new framework starting in 2017-2018. The NPCP is now divided into seven sectors: Registrants, Importation, Marketplace, Users, Re-Evaluation, Surveillance, and Inquiries and Complaints. Details on activities conducted in each of these sectors can be found in Chapter 3.

The following sections outline the program's priority setting and implementation approach.

IDENTIFYING COMPLIANCE ISSUES

The PMRA and the RORB identify compliance issues through:

- Ongoing NPCP activities including responding to complaints;
- Voluntary reporting of suspected infractions; and/or
- Information reported from other government agencies.

When a situation of non-compliance has been identified, a compliance risk analysis is performed to determine an appropriate response.

Given the broad scope of the regulated community, factors that affect compliance can vary. Factors which may influence compliance rates across Canada include commodities produced, provincial and municipal requirements, and availability of grower networks and associations. The diversity of NPCP programs allows the Pesticide Compliance Program to assess a cross section of sectors and provides Health Canada with information about compliance issues or potential trends both nationally and regionally. In addition to any enforcement action taken in response to non-compliance, identified trends are considered during planning for future compliance activities.

SETTING NPCP PRIORITIES

Annual compliance promotion and inspection priorities are determined after consultation with the PMRA science directorates, the RORB staff and provincial and territorial partners. Results from previous inspection programs, stakeholder concerns and changes in product registration status or use patterns are also considered. NPCP activities cover specific subsectors periodically in order to remain aware of challenges faced by stakeholders, changes in compliance levels, and to maintain a presence in the regulated community.

Every fall, all relevant information is assessed on a risk basis, from which priorities are selected for activities for the upcoming fiscal year. Both national and regional priorities are selected at this time. These risk-based work plans include activities in each of the three pillars of Health Canada's compliance and enforcement framework. Figure 2 represents the activities which fall

under each pillar of compliance and enforcement.

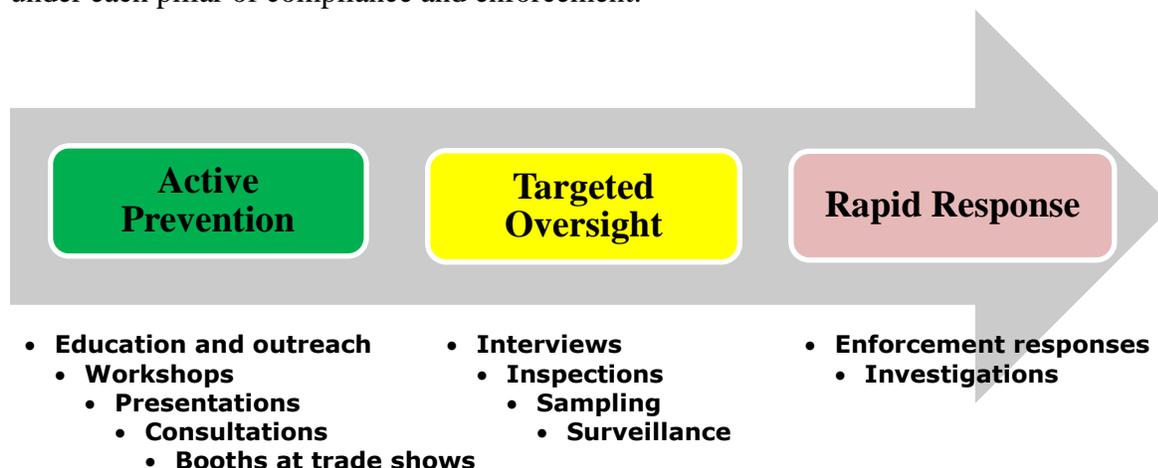


Figure 1. PMRA Compliance and Enforcement Framework

IMPLEMENTING THE NPCP

The following is a description of current measures used in the delivery of compliance promotion, inspection, and enforcement activities under the Pest Control Products Act and its Regulations.

Active Prevention: Encouraging and Promoting Compliance

There are a number of activities conducted to encourage and promote compliance. These activities support the collection, distribution and exchange of information and include the following:

- Compliance education and outreach;
- Working agreements, partnerships and consultations with other regulators of pesticides; and
- Sector consultations with the regulated community.

Targeted Oversight: Inspecting for Compliance

In general, inspections are conducted to review and examine the compliance status of a pest control product or any place or operation where pest control products are manufactured, held, stored, marketed, sold, distributed, transported, used or disposed. Different types of inspections conducted by the Pesticide Compliance Program include:

- Inspections conducted to verify compliance as part of planned NPCP activities;
- Surveillance inspections to confirm return to compliance; and
- Compliance Verification inspections in response to complaints or incidents.

During an inspection, the inspector assesses the activities conducted by the regulated party and records any deviations from the regulatory requirements in accordance with the *Pest Control Products Act* and Regulations. When required, samples are taken and submitted to the PMRA's ISO 17025 accredited laboratory in Ottawa for chemical analysis.

In some instances, when non-compliance is known or suspected, a targeted approach may be used, which may result in higher rates of non-compliance. In other situations, a randomly selected inspection is preferred. Compliance rates reflect the regulated parties inspected and are not representative of the industry as a whole. Findings are used in planning compliance priorities for subsequent years.

Rapid Response: Managing the Risk Resulting From Situations of Non-Compliance

A compliance risk management approach is taken when there is a known or suspected non-compliance that would result in an unacceptable risk. All violations are assessed to determine if there is knowledge, intent, and/or lack of ability to comply with regulatory requirements. The following factors are also considered:

- The history of compliance, including corrective action already taken;
- The degree of actual or potential risk to human health or the environment as a result of non-compliance; and
- The level of response necessary to achieve and maintain compliance by the violator and others in the regulated community.

Since the majority of the regulated community will generally comply when they understand the requirements, violations are often addressed through education. Education is typically used when the resulting infraction has limited health or environmental impact, the offender clearly does not understand or know of their obligations, or in some circumstances, it is not clear that they were responsible. Other enforcement options could include: enforcement letters, Compliance Orders, Notices of Violation (NOVs) with warning or monetary penalty, prosecution, suspension or cancelation of registration, recall, seizure and detention or forfeiture, and denial of product entry into Canada.

Chapter 2- Compliance Overview

Compliance activities were prioritised based on risk. In some instances, when non-compliance is known or suspected, a targeted approach was used, which may result in higher rates of non-compliance. In other situations, random inspections were preferred. Compliance rates presented reflect the regulated parties inspected and are not representative of the industry as a whole. The results presented include summary findings of all compliance observations, which include all levels of risk. These findings are used in planning compliance priorities for subsequent years. A summary of compliance findings is presented in Table 1 below.

TABLE 1. COMPLIANCE RATES BY SUBSECTOR

Sector	Subsector	Scope	Number and Type of Activities Conducted ¹	Compliance Rate (%)
Registrant	Registrants	National	36 inspections	33% ²
	Research	National	19 inspections	89% ²
	Emergency Registration	National	5 inspections	60%
Importation	Commercial Importation	National	126 inspections	25%
	Border Work	National	413 Admissibility Decisions	45%
Marketplace	Agricultural Retailers	National	134 inspections	62%
	Hydroponic Marketplace	National	100 inspections	11%
User	On-Farm	National	169 inspections	60%
	Pest Control Operators	National	145 inspections	35%
	Antisapstain	Regional	13 inspections	100%
	Malathion	Regional	12 inspections	75%
Re-Evaluation	Phosphine	National	8 inspections	38%
	Paraquat	National	78 inspections	33%
	Phorate	Regional	13 inspections	92%
	Soil Fumigants	Regional	8 inspections	88%
Surveillance		National	56 inspections	63%
Inquiries and Complaints		National	185 enforcement responses	n/a

¹ Only inspection activities where a compliance rate was calculated are included above. For example, Active Prevention activities, or border blitz events conducted under the Border Work subsector are not included.

² See Chapter 3.1 Registrant Sector for a description of the Compliance Rating System used for the Registrant and Research Authorization & Notification subsectors in 2017-2018.

Activities in the registrant, commercial importation, border work, hydroponic and pest control operator subsectors continue to be a high priority for the NPCP in 2018-2019.

SAMPLES ANALYZED

In support of the program, 428 samples of soil, plant tissues, animal tissues, liquids, and surface wipes were analyzed by the PMRA's laboratory to verify compliance with the *Pest Control Products Act*. Among these samples, 144 were collected during compliance verification inspections to determine compliance with the *Pest Control Products Act*.

TYPE OF VIOLATION

The overall breakdown of violations of the *Pest Control Products Act* detected in 2017-2018 is shown in Figure 3. This includes violations noted during planned activities including requests for admissibility decisions from the Canada Border Services Agency (CBSA) (1288) and compliance verifications (242). The most common violation types are sale (34%), possession (25%), and importation (21%) for all violations.

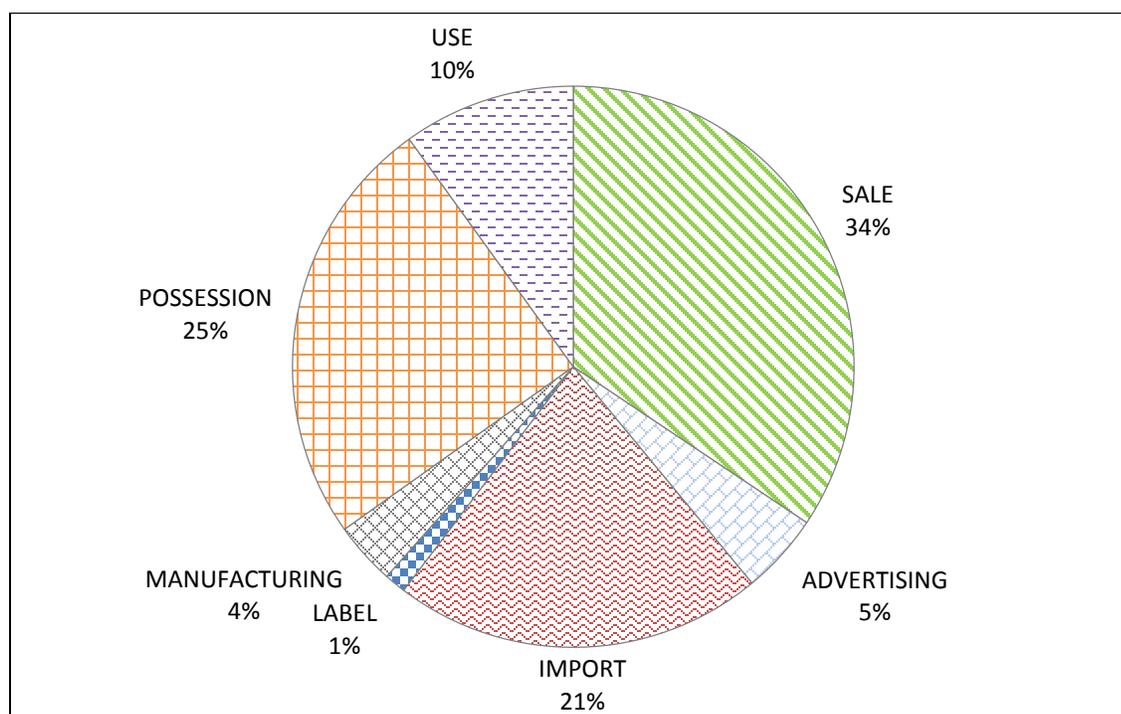


Figure 2. Violation by type, all violations 2017-2018

RETURN TO COMPLIANCE

Of the regulated parties targeted for surveillance inspections in 2017-2018 due to previous non-compliance with the Act or Regulations, 63% (35 out of 56) were found to have returned to compliance at the time of inspection.

ENFORCEMENT RESPONSES & ENFORCEMENT ACTIONS TAKEN

In 2017-2018, inspections resulted in a total of 796 enforcement responses issued to non-compliant parties: 611 from planned inspections including requests for admissibility decisions from the CBSA and 185 as a result of complaints. Enforcement responses included verbal education (75), written education (359), enforcement letters (341), and Compliance Orders (21). In addition, 2 Notices of Violation (NOVs) with warning and 30 Notices of Violation (NOVs) with penalty were issued under the *Agriculture and Agri-Food Administrative Monetary Penalties (AMPs) Act*.

In response to non-compliant products detected in 2017-2018, 1549 enforcement actions were taken. These enforcement actions included: requests to cease activity or remove product (588), requests to dispose of product (478), denials of entry at the border (209) requests to return or recall product (116), order to cease activity or remove product (43), collection of investigative samples (41), and other actions (74).

CHAPTER 3- NPCP SECTORS

This chapter details the 2017-2018 results for each of the seven NPCP sectors: Registrants, Importation, Marketplace, Users, Re-Evaluation, Surveillance, and Inquiries and Complaints. For a summary of all results, refer to Chapter 2, Compliance Overview.

3.1 REGISTRANT

Registrants play a key role in product availability and stewardship with respect to product distribution and use. Preventing and correcting compliance issues prior to reaching the production or distribution chain may reduce the number of issues occurring in the marketplace. Inspections of registrants are conducted annually. In 2017-2018, the national focus was registrants, research authorization and notification, and emergency registrations.

Starting in 2016-2017 as part of Health Canada's transparency initiative, [results for each of the registrant inspections](#) were posted on Health Canada's website and made available to the public. To aid in the classification and interpretation of compliance results posted online, the following [compliance rating criteria were used](#):

- A regulated party will be classified as compliant if at the time of the inspection, the regulated party has demonstrated the activities inspected are in compliance with the *Pest Control Products Act* and Regulations. Requirements have been met and desired behaviours were observed.
- A regulated party will be classified as compliant with observations if at the time of the inspection, the regulated party has demonstrated some deviations (called observations) from the requirements of the *Pest Control Products Act* or Regulations of a technical

nature and for which the potential or the probability for causing any harm (i.e., to human health or safety, or to the environment or the integrity of the regulatory system) is low. The observations do not require immediate corrective actions.

- A regulated party will be classified as non-compliant if at the time of the inspection, observations have been documented where the potential or the probability for causing any harm (i.e., to human health or safety, or to the environment or to the integrity of the regulatory system) is moderate or if these observations indicate a situation causing harm or where the potential for causing any harm (i.e., to human health or safety, to the environment or to the integrity of the regulatory system) is significant. The observations in these cases require immediate corrections in a specific timeline.

REGISTRANT (NATIONAL)

In 2017-2018, an information package was sent to all registrants to provide them with the following information:

- Information outlining the mandate of Health Canada's role in pesticide compliance and enforcement;
- An overview of the Registrant Inspection Program;
- A checklist to help prepare for an inspection; and
- Information on Health Canada's transparency initiative.

A total of 36 inspections were conducted of registrants selected using a risk-based approach. Registrants may be prioritized for inspection if: the registrant has not been inspected in the past few years; the registrant has poor compliance history; the registrant did not submit sales reporting and/or incident reporting information; the inspector has reasonable ground to suspect any other potential non-compliance. Overall, 8 registrants were determined to be compliant at the time of inspection (22%) and another 4 registrants (11%) were determined compliant with observations. The remaining 24 registrants were determined non-compliant (67%) at the time of inspection. The most common violations noted were related to labelling (17), sales reporting (12), and advertising (11).

For all instances of non-compliance detected, enforcement responses were issued to the registrant including verbal education (2), written education (4), and enforcement letters (21). Note that some registrants received more than one enforcement response depending on the nature of the non-compliance. The registrant inspection program continues to be a priority for 2018-2019.

RESEARCH AUTHORIZATION AND NOTIFICATION (NATIONAL)

The PMRA may authorize the use of an unregistered pest control product for research purposes. Depending on the nature of the proposal, a research authorization or research notification certificate is granted to an applicant to conduct research under certain conditions. Health Canada inspects for compliance with the requirements for research, specifically with the conditions set out in the research certificate and on the experimental label.

In addition to verifying that the conditions of the research are being followed, this inspection program also provides the benefit of engagement with the research community; increased knowledge of new and emerging pest management technologies; and increased awareness of pesticide import and/or broker activity for research products.

Research establishments to be inspected were selected based on risk. Considerations included the use of a new active ingredient; conditions and restrictions placed on the research permit (such as where crops must be destroyed after the research is completed, buffer zones, or application in sensitive environments); or compliance history. Nationally 19 research sites were inspected across Canada; 16 were found fully compliant (84%) and one was determined to be compliant with observations (5%) at the time of inspection. The instances of non-compliance identified related to the application of pesticides at the wrong rate, which is contrary to the experimental label directions. The violations noted involved a single registrant. An enforcement letter was issued to the registrant outlining the violations related to the Research Notifications.

The continuously changing nature of research, with applicants, co-operators, trial sites and pesticide products necessitates maintaining a regulatory presence to encourage compliance within this subsector. Inspections for the 2018-2019 fiscal year will be conducted using a risk based approach.

EMERGENCY REGISTRATION (NATIONAL)

Under the provisions of Section 18 of the Pest Control Products Regulations, the Minister may register a pest control product, for a period not exceeding one year, for the emergency control of seriously detrimental infestations.

An emergency is generally deemed to exist when both of the following criteria are met:

1. An unexpected and unmanageable pest outbreak or pest situation occurs that can cause significant health, environmental or economic problems; and
2. Registered pesticides and cultural control methods or practices are insufficient to address the pest outbreak.

For pest control products registered under Emergency Registration, the label directions may differ from those indicated on the labels approved through the normal registration process. In addition, the Emergency Registration labels may change over time, increasing the potential for misuse when users rely on their past experience for pesticide applications.

In 2017-2018, five inspections were conducted to verify adherence to the conditions of the Emergency Registrations granted for various products and 60% of users inspected (3 of 5) were determined to be compliant. For the two instances of non-compliance, Emergency Registration products were distributed with US labels instead of Canadian emergency registration labels. Emergency Registration inspections are continuing in 2018-2019 on an as-needed basis.

SECTOR SUMMARY: Preventing and correcting compliance issues prior to reaching the production or distribution chain may reduce the number of instances of non-compliance occurring in the marketplace. 60 inspections of registrants, research permit recipients, and emergency registration users were conducted.

3.2- IMPORTATION

The vast majority of pest control products used in Canada are foreign-made and imported. Products are imported via several streams, including commercial, postal service, courier, and traveller (on-person). This also includes unregistered pest control products which have not been evaluated or approved for use by the PMRA. The importation of pest control products that do not meet the requirements set out by the *Pest Control Products Act* and Regulations may pose a potential risk to human and environmental health and safety.

Continued presence in the import sector via monitoring, outreach, and where appropriate, enforcement, supports activities in the other NPCP sectors by preventing the entry of unregistered products into the Canadian marketplace. In 2017-2018, the national focus was commercial importation, outreach to customs brokers, international vendors, and responding to requests for admissibility decisions from the CBSA.

COMMERCIAL IMPORTATION (NATIONAL)

Health Canada's Pesticide Compliance Program uses import data from the CBSA to identify trends in pesticide imports and to gather information about potentially non-compliant importations. An inspection program targeted at importers was delivered in 2017-2018 to verify the compliance of pesticide importations and to educate importers of the requirements under the *Pest Control Products Act*.

Importations were targeted for inspection based on a number of factors including compliance history and products known to be non-compliant. Of the 126 targeted inspections conducted of suspected non-compliant importations, 25% of these inspections (32 of 126) were found to be compliant with the *Pest Control Products Act*. Importers included retailers, growers, commercial applicators, and consumers. Many of the non-compliant importations were American-registered products available online. Enforcement responses issued to non-compliant importers included verbal education (4), written education (35), enforcement letters (39), compliance orders (9), and Notices of Violation with penalty (3).

CUSTOMS BROKERS OUTREACH (NATIONAL)

Customs brokers act as professional agents for importers or exporters by preparing and submitting all documents for clearing goods through customs. Customs brokers operating in Canada range from small, local operations to large multi-national firms.

A compliance promotion activity to inform customs brokers of the requirements for importation under the *Pest Control Products Act* and Regulations has been ongoing since 2016-2017. As customs brokers play a crucial role as facilitators between Canadian importers and the CBSA, the objective of this activity was to promote awareness of the *Pest Control Products Act* and its requirements to prevent the future importation of unregistered pest control products, reducing the risk to health, the environment and regulatory integrity. In 2017-2018, inspectors communicated regulatory requirements with 12 customs brokerage firms across the country. Continued compliance promotion with associations representing customs brokers is continuing in 2018-2019.

BORDER WORK (NATIONAL)

Health Canada continued to work with the CBSA and other federal agencies at border points nationwide to identify, examine, and intercept non-compliant shipments at the border. Of 424 requests from the CBSA for admissibility decisions, 413 were determined to be subject to the *Pest Control Products Act*. 229 (55%) resulted in denials of entry of the pesticide products into Canada. The vast majority of products that were refused entry were products purchased online by Canadian consumers. Health Canada's pesticide program also participated in two inspection blitzes at border points and 17 training opportunities with CBSA Border Services Officers to provide information about the importation requirements for pest control products.

INTERNATIONAL VENDORS (NATIONAL)

Since 2015-2016, the NPCP has identified vendors located internationally that export unregistered pest control products into Canada. In 2017-2018, enforcement letters were sent to 11 international vendors of suspected non-compliant pest control products informing them of Canadian regulatory requirements and the consequences of non-compliance. The Pesticide Compliance Program is continuing to monitor importations from these vendors and may take additional enforcement actions in the future.

SECTOR SUMMARY: *The importation of pest control products that do not meet the requirements set out by the Pest Control Products Act and Regulations may pose a potential risk to human health and the environment. In 2017-2018, 29 Compliance Outreach activities were conducted with customs brokers and CBSA Border Services Officers (BSOs). 552 Targeted Oversight activities were conducted including: inspections of commercial importers of pesticide products, enforcement actions against international vendors, admissibility decisions at the border and participation in border blitzes.*

3.3- MARKETPLACE

Health Canada verifies that only pest control products compliant with the *Pest Control Products Act* are offered for sale to Canadians. There are thousands of retailers across Canada and in the online marketplace accessible to Canadians. Active prevention, targeted oversight and surveillance activities are used to promote, monitor and enforce industry compliance with the *Pest Control Products Act* and its Regulations as they pertain to pesticides used by consumers.

Target subsectors are determined using a risk-based approach where patterns of non-compliance are suspected or regulatory changes have occurred. In 2017-2018, the national focus was agricultural retailers, essential-oil based personal insect repellants, and hydroponic and indoor garden marketplace.

AGRICULTURAL RETAILERS (NATIONAL)

Periodic inspections of agricultural retailers are conducted to ensure that only products compliant with the *Pest Control Products Act* are sold in Canada. Inspectors verified product registration status as well as changes to labelling or other risk mitigation measures, such as those required as a part of the recent re-evaluation decisions for paraquat, diquat and diazinon.

Nationally, 134 inspections were conducted and 62% of retailers were found to be compliant at the time of inspection. Of the 14,008 individual pest control products inspected nationally, 13,845 were compliant (99%). The majority of violations related to distribution of expired product (37) and of products that were never registered (12). Deficiencies in labelling (4) and packaging (1) were also noted. Lack of knowledge of product registration status and frequency of obsolete product disposal were noted to be key factors in this subsector.

For the three recently re-evaluated products that were included in this inspection program, all paraquat and diquat products complied with labelling changes, while three retailers were found to be distributing expired diazinon products.

As a result of the inspection findings, enforcement responses included verbal education (1), education letters (20), and enforcement letters (28).

ESSENTIAL-OIL BASED PERSONAL INSECT REPELLANTS (NATIONAL)

Consumers have continued to demonstrate a demand for personal insect repellent products that are made with naturally derived ingredients, such as essential oils. Many consumers and retailers are unaware that these natural products require registration and may pose human health risks. Methyl eugenol is a carcinogenic compound present in some essential oils. A PMRA assessment concluded that the methyl eugenol content in products used as personal insect repellents must be below 0.0002%. Since these products are widely available in the marketplace, including online,

the Pesticide Compliance Program conducted a sampling program of essential oil insect repellents known to be unregistered to quantify the levels of methyl eugenol.

Of the 22 samples of unregistered products collected, methyl eugenol levels exceeded 0.0002% in seven of the samples. Enforcement letters were sent to the manufacturers of the products sampled and one Compliance Order was issued. Communication material was posted on the [Health Canada website](#), and via social media to advise Canadians to purchase only registered personal insect repellents to mitigate the potential risks associated with unregistered pest control products.

HYDROPONIC AND INDOOR GARDEN MARKETPLACE (NATIONAL)

Hydroponic and horticultural retailers supply users with products for growing plants indoors or in greenhouses in a variety of growing mediums. In some areas, it is a relatively new and rapidly expanding industry. Products marketed to hydroponic, indoor garden, and cannabis growers may not identify the presence of pesticide ingredients and may lack adequate use instructions or safety precautions.

In 2017-2018, 100 retailers of hydroponic products were inspected and 10 samples were taken. Overall, 11 (11%) retailers were found to be compliant at the time of the inspection. However, it is important to note that of 1404 products inspected across the country in 2017-2018, 988 (70%) were found to be compliant. The majority of the violations related to distribution or manufacturing of unregistered pest control products. Knowledge of the *Pest Control Products Act* and regulatory obligations was low within the retailers inspected. Enforcement responses included verbal education (2), written education (48), enforcement letters (34), and Compliance Orders (4). Inspections are continuing in 2018-2019 at the retailer level with an added focus on manufacturer and distributor follow-up to prevent these products from entering the Canadian marketplace.

SECTOR SUMMARY: *Health Canada verifies that only pest control products compliant with the Pest Control Products Act are offered for sale to Canadians. 234 inspections were conducted of agricultural retailers and hydroponic retailers and 10 samples were collected. An additional 22 samples of essential oil personal insect repellents were collected and analyzed for methyl eugenol content.*

3.4- USER

Health Canada strives to prevent unacceptable risks to people and the environment from the use of pesticides. Pesticides are used by a variety of users including agricultural growers of food and non-food crops as well as commercial and industrial users. These sub-sectors are large, diverse, encompass many different commodities and require the use of various types of pesticides.

Due to the large volume and diversity of pesticide users, compliance verification of this sector is completed annually. In order to focus efforts effectively and in a manner relevant to the nature of the risk, specific sub-sectors for compliance monitoring are selected using a risk-based approach.

In 2017-2018, national and regional focuses were on-farm, outreach, pest control operators, animal poisoning, antisapstain, and malathion users.

ON-FARM (NATIONAL)

According to the 2011 Census of Agriculture, Canada has approximately 200 000 farms employing 41,660 farmers. Traditionally, agricultural inspections as part of the NPCP inspect a small percentage of this population through risk targeted, sector specific activities. While regional differences exist, there are common requirements for farmers who use pesticides; including following label directions, which indicate necessary personal protective equipment (PPE) and use practices, and reporting pesticide incidents.

In 2017-2018 specific commodities were targeted using a risk-based approach for compliance verification of on-farm pesticide use across Canada. The commodities targeted for inspection in 2017-2018 were strawberries, cherries, poultry producers, market gardeners, ginseng, cranberries, and aquaculture. This monitoring of various communities provided valuable information on compliance with regulatory requirements. This approach also allowed for efficient outreach to various groups of agricultural users. Non-compliant behaviour identified will inform planning for future activities within the agricultural sector.

In 2017-2018, 169 growers were inspected across Canada. Overall, 101 were determined to be compliant at the time of inspection (60%). During inspections, 114 samples were collected and 93% were found to be compliant. Of the violations reported, 54 were related to storage of expired or never registered pesticide products, and for 24 of those growers (35% of the non-compliant growers), storage was the only violation noted at the time of inspection. Other violations included use contrary to label directions (32) such as incorrect crop, pest, rate, site, application method, failure to respect Restricted Entry Interval (REI), etc. This included 8 samples where active ingredients not registered on the sampled commodity were detected. Eleven violations were due to inadequate use of PPE. Other violations noted included use of an expired (4) or never registered (1) product.

Enforcement responses issued for instances of non-compliance included verbal education (2), education letters (34), and enforcement letters (56). This inspection program is continuing in 2018-2019 targeting the following commodities: hops, aquaculture, corn, leafy vegetables, and poultry producers.

OUTREACH (NATIONAL)

Conducting outreach to the user community to communicate and raise awareness of the regulatory requirements under the *Pest Control Products Act* is a core activity of the Pesticide Compliance Program. The primary objective of the Act is to mitigate risks to people and the environment from the use of pesticides. Engaged and informed Canadians and stakeholders will have the confidence that the science supporting the registration of pesticides is sound and will understand that pesticides can be used safely. The outreach subsector optimizes local

opportunities to engage the agriculture and non-agriculture pesticide sectors across the country. Compliance outreach activities specific to another NPCP subsector are reported within that subsector's activities. The outreach subsector is divided into two user groups:

- The agriculture stakeholder group includes, but is not limited to: growers, seasonal workers, grower associations, extension specialists, consultants, custom applicators, and third party auditors.
- The non-agricultural stakeholder group includes, but is not limited to: vegetation management specialists, aerial applicators, gardeners, arborists, industrial users, university and college students, homeowners and the general public.

A total of 163 outreach activities were conducted, including presentations (59), meetings (66) and exhibit booths at trade shows (36), and other activities such as providing publications for mail-outs and contributing to association newsletters (2). Communication materials such as posters, fact sheets, pest notes, Power Point presentations, and engagement activities were developed and distributed and included topics such as chemical resistant gloves, personal protective equipment (PPE), Incident Reporting, Restricted Entry Intervals (REI) and Pre-Harvest Intervals (PHI). Where applicable, information was provided in several languages. The outreach subsector continues to be a core activity within the NPCP and is continuing in 2018-2019.

PEST CONTROL OPERATORS (NATIONAL)

Pest Control Operators (PCOs) are commercial applicators who provide structural and landscaping extermination services for a wide range of clients in residential, commercial, and institutional settings. These applicators apply pest control products to control a vast array of indoor and outdoor pests. Concerns regarding the potential use of pesticides by PCOs which are not permitted for use in residential areas led to an increased number of inspections targeting PCOs holding landscape licenses/certificates as well as an expansion of the sampling component nationally.

Compliance promotion activities focused on Health Canada's regulatory role, new risk mitigation measures following the re-evaluation of specific pest control products, and the safe use of PPE. In 2017-2018, 17 compliance promotion activities including booths, presentations, and meetings were conducted to promote compliance with the *Pest Control Products Act*. In addition, fact sheets promoting the changes from the re-evaluations of boric acid and propoxur were created and distributed to the industry.

In 2017-2018, 145 PCOs (both landscape and/or structural) were inspected across the country to verify compliance with pest control product labels. Key elements verified during the inspections included:

- Safe use of products, e.g., use of proper PPE, proper handling of products and precautionary notifications;

- Product use according to label specifications, e.g., pest controlled, use site and rate; and
- Use of Canadian registered products.

Overall, 51 out of 145 PCOs inspected (35%) were compliant at the time of inspection. During inspections, 123 application equipment samples (wipe and spray tank formulation) were collected, and 102 (83%) were found to be compliant. The use of pest control products contrary to label directions continues to be the primary violation reported, particularly related to incorrect use sites or locations (39), pests not included on the label (30), bait stations not properly labelled (19), and lack of appropriate PPE (17). Possession of unregistered (never registered or expired) products was also noted in 29 instances.

Enforcement responses issued for instances of non-compliance included verbal education (2), education letters (18), enforcement letters (65). Additional enforcement actions may be considered to address non-compliance in this subsector. This inspection program remains a high priority for the 2018-2019 NPCP activities.

ANIMAL POISONING (REGIONAL)

In the prairie region, off-target animal poisoning involving the use of pest control products, such as rodenticides and notably strychnine, continue to be reported either through the Incident Reporting process or directly to inspectors. The active prevention activities in this subsector were designed to establish relationships with local animal protection groups and provide information about pest control products and Incident Reporting so they will be better positioned to address situations of animal poisonings involving pest control products.

Prairie region inspectors held a total of 18 meetings with various municipal and provincial animal protection groups. General information about the regulation of pesticides in Canada, the importance of using pesticides according to the label, and reporting incidents to Health Canada were distributed.

ANTISAPSTAIN (REGIONAL)

Antisapstain products are used to control blue stain, mold and decay in freshly cut lumber and are regulated as pest control products under the *Pest Control Products Act*. Due to the gaps in worker protection identified during inspections in British Columbia in 2016-2017, the inspection program continued in 2017-2018. Thirteen saw mills were inspected in the British Columbia region to verify that registered antisapstain products were used according to label directions. Inspectors also used this opportunity to raise awareness of recent Re-evaluation Decisions and upcoming label changes that will impact the industry. While some PPE concerns were noted by inspectors, no violations of the *Pest Control Products Act* were noted and all of the saw mills were fully compliant with requirements of the *Pest Control Products Act* at the time of inspection.

MALATHION (REGIONAL)

In Canada, malathion is a registered insecticide mainly used to control insects in agriculture, but it can also be used in and around the home. In some municipalities, it is applied either aerially or by spray equipped trucks. Manitoba has historically used Ultra Low Volume (ULV) malathion products to control mosquitoes for nuisance and public health reasons (West Nile Virus, Equine Encephalitis, etc.).

The malathion re-evaluation decision (RVD2012-10, [Malathion](#)) imposed additional risk mitigation measures for human health and the environment. Isomalathion, a toxic metabolite of malathion, can naturally form when malathion products are stored at elevated temperatures or for extended periods of time. After storage for more than a year, levels of isomalathion could become a concern, even when containers are stored correctly. Therefore, a one year storage restriction was implemented for all malathion pest control products. In 2016, Health Canada [advised Canadians](#) to stop using pesticides that contain malathion when products are older than one year, as there can be chemical changes in the product over time.

For 2017-2018 compliance promotion and inspection activities were implemented in Manitoba to educate distributors and users, including rural municipalities, of changes in ULV malathion pest control products and uses. In total, five active prevention activities including booths (2), presentations (2) and meetings (1) were conducted to provide information about the storage requirements. To verify proper use and storage of the products, 12 inspections were conducted and 75% (9 out of 12) were found to be compliant. Not all municipalities were aware of the changes implemented for malathion products, and the non-compliance noted related to use (1) and possession (1) of expired products and use of a pest control product contrary to label directions (1). To address the non-compliance, two education letters and one enforcement letter were issued.

SECTOR SUMMARY: *Pesticides are used by a variety of users including agricultural growers of food and non-food crops as well as commercial and industrial users. 203 Compliance Outreach activities were conducted with a broad variety of agricultural and non-agricultural users of pesticides. 339 inspections were conducted of agricultural users, pest control operators, antisapstain users, malathion users, and agencies involved in the reporting of animal poisoning events. 237 samples were collected. The majority of the violations related to storage or possession of unregistered (expired or never registered) products and use of registered products contrary to the label directions.*

3.5- RE-EVALUATION

The *Pest Control Products Act* mandates re-evaluation of all active ingredients every fifteen years. Following re-evaluation, Health Canada may:

- Retain the registration with no changes;
- Amend the label directions to improve safety of health and/or the environment;

- Modify maximum residue limits;
- Place conditions on use; or
- Eliminate or phase-out uses, formulations or the registration.

Re-evaluation decisions may create challenges at the retail and user level due to the number and type of changes in registrations and uses. Compliance activities are conducted annually to verify that re-evaluation decisions are adequately implemented and maintained. In 2017-2018, the national and regional focuses were paraquat, phosphine, phorate, and soil fumigants.

Paraquat (National)

The PMRA completed the special review of paraquat in 2015 (REV2015-14, [Special Review Decision: Paraquat](#)) and concluded that continuing registration for this active ingredient and associated end-uses was acceptable, provided that new and revised risk mitigation measures and a stewardship/ outreach program for applicators and vendors were implemented. In 2016-2017, the NPCP inspected the marketplace to determine completion of the registrant's stewardship plan which focused on alerting retailers and users to the label changes.

In 2017-2018, on-farm inspections were conducted to determine user awareness and compliance with the changes to product use which focused heavily on personal protective equipment for various mixing/loading and application scenarios. Of 78 inspections conducted, 33% were determined to be compliant at the time of inspection (26). The violations noted related to inadequate PPE (45), possession of expired product (23), and use contrary to label directions (17), including use site, application method, and lack of licensing or certification. While many growers had at least one instance where inadequate PPE was noted for a given scenario, in many cases only a single piece of PPE was missing. The label had changed in 2016, adding additional PPE which may account for the number of PPE violations. In all cases where the growers applied product to the wrong use site, it was used for personal weed control, not on a commercial crop. Storage violations may be due to growers waiting to take advantage of the Clean Farms Obsolete Product Disposal program to dispose of unwanted agricultural products without cost which is available every three years.

Enforcement responses included written education (23), and enforcement letters (13). The single remaining end-use paraquat product, at the current concentration and in the current packaging, will expire 31 December 2018.

Phosphine (National)

The re-evaluation of aluminum phosphide, magnesium phosphide and phosphine gas was completed in 2015 and is detailed in RVD2015-03, [Aluminum/Magnesium Phosphide and Phosphine Gas](#). At this time, the PMRA required the implementation of additional risk mitigation measures for all fumigated sites to further limit potential exposure to workers and bystanders. Label changes to buffer zones around fumigations are ongoing. An active prevention

program was planned to help ensure users are aware of the label changes found on various phosphine labels.

A total of 20 active prevention activities were conducted, including presentations (10), meetings (7) and exhibit booths at trade shows (2), and an outreach email to various stakeholders including various agricultural, industrial, and commercial users of phosphine products. During the course of these active prevention activities, eight interviews with growers were conducted and 38% were determined to be compliant. Conversations with the growers indicated that awareness of label requirements for on-farm grain treatment was limited, especially with respect to PPE and placarding requirements. The five non-compliant growers were issued enforcement letters. It is recommended that inspections of users of phosphine products continue once all label changes are implemented.

Phorate (Regional)

For the 2016-2017 growing season, new mitigation measures including the use of the SmartBox pesticide application system and pinch valve were added to phorate product labels which decreases applicator and environmental exposure significantly. Inspections in 2016-2017 found instances where the grower did not have the SmartBox equipment or it was not installed as per the label and manufacturer's instructions. Inspections in 2017-2018 verified that phorate products were used according to label directions and that the SmartBox technology was correctly installed on the planter. 13 inspections of users were conducted and 12 (92%) were found to be compliant. There was one instance of expired phorate product being used by a grower and one instance of a distributor distributing the expired product. As a result, both parties were issued written education and four NOVs were issued to the distributor. Inspections of retail and smaller growers not previously inspected are planned for 2018-2019.

Soil Fumigants (Regional)

The re-evaluation of soil fumigants required registrants to make amendments to their product labels to further limit human exposure during applications, as well as to further protect bystanders and the environment. Label amendments included increased PPE, buffer zones, re-entry restrictions and requirement for applicators to complete a Fumigation Management Plan (FMP) for all applications. Inspections in this subsector have been conducted in British Columbia and Manitoba since 2015-2016 due to ongoing non-compliance with label requirements. In these regions, soil fumigations are largely conducted by growers rather than custom applicators and there was a general lack of understanding of the label requirements.

In 2017-2018, eight inspections were conducted and 88% of applicators (7 out of 8) were found to be compliant at the time of inspection. This is a significant increase from 2016-2017 where 17% of applicators inspected were found to be compliant. Inspectors provided education and support to the applicator before the fumigation takes place and as the paperwork is drafted. Growers were able to submit draft documentation, providing the opportunity for errors and omissions in FMPs to be corrected. Vendors also provided the growers with information on the documentation required for the use of these products and connected interested growers with

inspectors for information early in the fumigation process. This support has resulted in increased compliance rates in this sector.

One instance of non-compliance was noted for use contrary to label directions. An enforcement letter was issued to the applicator.

SECTOR SUMMARY: *Compliance activities are conducted annually to verify that re-evaluation decisions are adequately implemented and maintained. 21 Compliance Outreach activities were conducted with users of phosphine and soil fumigants. 107 inspections were conducted of users and retailers of phosphine, paraquat, phorate, and soil fumigants. The majority of violations related to inadequate or lack of PPE and storage or possession of unregistered (expired or never registered) pest control products.*

3.6- SURVEILLANCE

The surveillance inspection program verified whether there was a return to compliance by previously inspected regulated parties.

Regulated parties and individuals were targeted in 56 surveillance inspections based on previous non-compliance and the likelihood to re-offend. In addition to inspections, seven samples were collected and analyzed to verify compliance. 63% of these inspections (35 out of 56) were found to have returned to compliance.

Of the 21 inspections where non-compliance was noted, 17 were non-compliant with respect to the original violation, while four had corrected the original violation but were found to have additional violations at the time of the inspection. The majority of the violations were related to the distribution of unregistered products (13), misleading advertising (3), use contrary to label directions (3), distribution of unregistered pest control products (2).

Enforcement responses issued to date to address the non-compliance noted were verbal education (3), written education (5) enforcement letters (7), Compliance Orders (3), and Notices of Violation (1). Inspections within the Surveillance sector are continuing in 2018-2019 to address ongoing non-compliance with a focus on higher risks for repeat violations, and possible health and safety and regulatory impacts of continued non-compliance.

3.7- INQUIRIES & COMPLAINTS

The Pesticide Compliance Program dedicates significant effort to unplanned compliance activities. The Inquiries and Complaints sector is responsible for triaging incoming inquiries, referrals and complaints received from a variety of sources: the public, media, stakeholders (e.g. importers, registrants, distributors/retailers, users), other Health Canada branches and Government departments, and provincial, territorial, and international partners.

Inquiries, referrals, and complaints are assessed in the context of requirements and conditions in the *Pest Control Products Act* and its Regulations, and the responses may involve compliance

promotion, inspection, sample collection, and /or enforcement action, as needed. The compliance risk of each case determines the appropriate response to be taken.

In 2017-2018, 185 enforcement responses were issued as a result of suspected non-compliance and complaints received from the public and regulated parties. The majority of violations noted were related to distribution of unregistered (expired or never registered) products and advertising. As a result, enforcement responses issued included verbal education (30), written education (48), enforcement letters (95), Compliance Orders (12). In addition, 8 Notices of Violation were issued in 2017-2018 related to complaints.

Chapter 4- Laboratory Activities

The PMRA Laboratory's core objective is to conduct timely pesticide sample analyses in support of compliance verification and the enforcement of the *Pest Control Products Act*. The laboratory supports planned NPCP inspection activities as well as surveillance and compliance verification activities, collaborates on international pesticide laboratory proficiency testing, and maintains ISO17025 accreditation of its laboratory facilities.

In 2017-2018, the PMRA's laboratory analyzed 428 samples: 284 in support of NPCP activities and 144 compliance verification samples in response to complaints. During the fiscal year, the laboratory improved its methods for diatomaceous earth, methyl eugenol, and glyphosate analysis and became the first lab in Canada with an ISO17025 accredited method for quantitative analysis of pesticides in cannabis samples.

Chapter 5- National & International Partnerships

NATIONAL COLLABORATION

Health Canada's Pesticide Compliance Program works collaboratively with federal, provincial, territorial and municipal partners on a number of priority issues. This includes conducting joint inspections, delivering compliance promotion activities, participating on intergovernmental working groups, contributing to provincial certification/licensing activities, and communicating on topics such as responsible pest control and emerging issues such as invasive species. Relationships with various industry associations allow for the dissemination of important regulatory information. A few examples from 2017-2018:

- Cannabis for Medical Purposes collaboration
- Compliance Promotion

Cannabis for Medical Purposes Collaboration

In 2017-2018, the Pesticide Compliance Program continued to partner with Health Canada's Cannabis Legalization and Regulation Branch to provide pesticide-related training, inspection, and laboratory support to the cannabis for medical purposes inspection program. As a result of this collaboration, the Pesticide Compliance Program developed additional training materials and laboratory analysis methodologies related to cannabis.

Compliance Promotion

The Pesticide Compliance Program continues to provide regulatory information and updates on a variety of pesticide related topics such as personal protective equipment (PPE), to the public, seasonal workers, applicator and grower associations, and provincial and territorial partners. Information was provided both as print material such as articles in newsletters, factsheets and handouts, and during presentations at meetings and conferences. For example, the Ontario Pesticide Compliance Program delivered presentations to several academic institutions to promote a greater understanding of the *Pest Control Products Act* and use of PPE to students in agricultural and pesticide related programs.

As another example, Health Canada's Quebec Pesticide Compliance Program collaborated with the Union des Producteurs Agricoles, the Commission of Standards, Fairness, Occupational Health and Safety, the Ministry of Agriculture, Food, Fisheries and Agri-Food du Québec, and the National Institute of Public Health of Québec to prepare and deliver a two-day training for more than two hundred stakeholders, on the various aspects of pesticide risk reduction for farm workers.

In addition, Health Canada's Prairie Pesticide Compliance Program collaborated with Manitoba Hydro and Manitoba Sustainable Development to finalize zebra mussel preparedness planning to protect power generation in Manitoba.

International Collaboration

With world commerce growing larger, more complex, and even more interconnected, surveillance is increasingly essential to protect the health of Canadians. The NPCP engages with a wide variety of organizations, including other government agencies and international organizations, to leverage information. Through effective engagement with selected partners, the NPCP expands its reach to protect health and the environment with finite resources.

During 2017-2018, the NPCP continued to strengthen working relationships with other government agencies including the United States Environmental Protection Agency (USEPA). For example, Health Canada's British Columbia Pesticide Compliance Program worked collaboratively with the USEPA, Washington State Department of Agriculture and Oregon State Department of Agriculture with respect to the manufacture and sale of unregistered pest control products in the hydroponic industry.

During 2017-2018, the NPCP continued to strengthen working relationships with its international regulatory partners through the Organization of Economic Cooperation and Development (OECD) Network of Illegal Trade of Pesticides (ONIP). The access to the OECD Rapid Alert System facilitated quick sharing of information when illegal or unsafe shipment of pest control products was identified by one of its member countries. In 2018, Health Canada participated in the organization of the first Workshop on Compliance and Enforcement of Pesticide Regulation in West Africa to inform and raise awareness on the control of illegal pesticides at the border, and which was attended by 17 countries from West and Central Africa.

Summary

By collaborating with our international partners and working with other federal and provincial/territorial ministries, Health Canada has rapid access to compliance information for promoting and verifying compliance with the *Pest Control Products Act* and educating individuals, local officials and grower groups on regulatory requirements.

Chapter 6- Forward Planning

Several priorities were identified by the NPCP for the 2018-2019 fiscal year:

- Delivering the 2018-2019 NPCP commitments in the following sectors: registrant, import, marketplace, re-evaluation, and users; as well as continuing the delivery of surveillance inspections targeting regulated parties who were previously non-compliant, and continuing to respond to complaints and inquiries received from Canadians;
- Delivering on-going compliance outreach activities to encourage and promote compliance, for example by providing information and educational outreach materials;
- Continuing to deliver the Regulatory Transparency and Openness commitments, including web posting of the 2017-2018 Compliance and Enforcement report, and the registrant inspection information;
- Continuing the assessment of technology and tools to conduct inspections and gain efficiencies in reporting of compliance activities;
- Improving information sharing with regulatory partners, and strengthening compliance and enforcement relationships with other governments and organizations, including the OECD ONIP, the CBSA, and other government departments; and
- Establishing a new three year (2019–2022) NPCP planning cycle that will continue to include an environmental scan to identify areas of high risk.

Glossary

Active Prevention: Promotion of appropriate import, manufacture, distribution, sale, and use of pest control products. See also the definition of compliance promotion.

Administrative Monetary Penalties (AMPs): *The Agriculture and Agri-Food Administrative Monetary Penalties Act* provides a system of penalties and warnings for violations of several federal Acts including the *Pest Control Products Act*. The *Agriculture and Agri-Food Administrative Monetary Penalties Act* allows Canadian pesticide regulatory officials to impose penalties without having to pursue formal prosecution.

Candidate: The person or business reported or suspected of being in contravention of the *Pest Control Products Act* or its associated Regulations.

Compliance: The full implementation of legal requirements. It is the state of conformity of a regulated party (including a corporation, institution, individual or other legal entity) or a pest control product with the *Pest Control Products Act* and its associated Regulations.

Compliance Monitoring: Collecting and analysing information on compliance status of a pest control product or a facility (place or operation where pest control products are manufactured, held, stored, marketed, sold, distributed, transported, used or disposed or where records relating to such activities are maintained) or of an industry or use sector. Compliance monitoring involves interviews, inspections and sampling.

Compliance Orders: A tool to inform the regulated party of a violation of the *Pest Control Products Act* and its associated Regulations which requires timely action to prevent risk to health and safety.

Compliance Promotion: Action taken to assist regulated enterprises, individuals and other legal entities to comply with the *Pest Control Products Act* and its associated Regulations. These actions include educational activities and the provision of information on legislation and policies.

Compliance Verification: Inspections that are conducted outside of a planned inspection program in response to specific violations, suspected violations, or complaints.

Contravention: The act of coming into conflict with a provision of legislation. Under the *Pest Control Products Act* and its associated Regulations, a contravention can lead to either a violation or an offence.

Co-operator: Any individual, corporation or institution not engaged in pesticide research who has agreed to use or allows the use of a pesticide for research purposes on a site owned or operated by that individual, corporation or institution.

Detention: The act of holding a pest control product in the custody of the PMRA, which nullifies the rights of the owner over this product, until the provisions of the *Pest Control Products Act* and its associated Regulations are complied with.

Education Letters: Primarily provides an individual or company with information about their regulatory obligations.

Emergency Registration: Registration of a pest control product, for a period not exceeding one year, for the emergency control of seriously detrimental pest infestations.

Enforcement Letters: In addition to informing stakeholders of their regulatory obligations, enforcement letters require that action be taken to restore compliance.

Enforcement Actions: Specific actions that are requested or ordered by Health Canada's Pesticide Compliance Program in response to non-compliance in order to bring the candidate into compliance with the *Pest Control Products Act*. Examples include requests to remove product from sale or dispose of non-compliant products.

Enforcement Responses: Actions that may be taken by Health Canada's Pesticide Compliance Program to induce, encourage or compel compliance by the regulated party with the *Pest Control Products Act* and its Regulations or to cause a contravention to cease, to prevent future contravention or to impose sanctions for non-compliance. Enforcement responses include education letters, enforcement letters, compliance orders, Administrative Monetary Penalties, and Prosecution. Enforcement responses include specific enforcement actions that must be taken to return to compliance.

Forfeiture: The loss or surrendering of an item to the Crown as part of the enforcement response to a contravention, where an item has been seized and detained and subsequently forfeited using either section 55 of the *Pest Control Products Act* or section 22 of the *Agriculture and Agri-Food Administrative Monetary Penalties Act*.

Guarantee Limits: The active ingredient(s) levels in the pest control product must be in compliance with its declared guarantee statement and product specifications.

Inspection: The review and examination of the compliance status of a pest control product or any place or operation where pest control products are manufactured, held, stored, marketed, sold, distributed, transported, used or disposed, or where records relating to such activities are maintained.

Interview: A compliance monitoring activity that is part of the National Pesticide Compliance Program and involves a questionnaire. Health Canada's pesticide program officer gathers information to determine risk of non-compliance. The consideration of this risk determines the nature, type and frequency of oversight in a given situation.

Investigation: Actions taken to gather evidence to support a case referral for potential judicial determination regarding specific violations of the *Pest Control Products Act* and its associated Regulations. This includes taking statements and activities carried out under the *Criminal Code*, i.e., executing search warrants.

Phase-out: The gradual elimination of registered product uses, product formulations, or product registrations, through the PMRA's Re-evaluation Program.

Pre-Harvest Interval (PHI): The time between the last application of the pesticide and harvest.

Rapid Response: Enforcement responses to non-compliance, which can vary depending on a number of factors, such as the harm or potential harm caused by the infraction, compliance history, whether the regulated party acted with indifference or premeditation, the likelihood that the problem will reoccur, and the probable and likely outcome of each enforcement action.

Registrant: A person in whose name a pest control product is registered.

Restricted-Entry Interval (REI): A restricted-entry time after the application of a pest control product.

Seizure: The act of taking possession of a product under the authority of the *Pest Control Products Act* without the person's consent for the purposes of placing the product under detention. Seizure deprives the owner of the item from freely doing anything with the item, but unlike forfeiture, he/she retains ownership of the item.

Surveillance: Follow-up inspections conducted to verify a candidate's return to compliance with the *Pest Control Products Act* and Regulations.

Targeted Oversight: Early detection of health, safety and environmental concerns at the appropriate stage of a pest control product's life cycle. This is achieved by undertaking a variety of activities including inspections, sampling and surveillance to identify risks.

Violation: A contravention of the Act or the Regulations that may be proceeded with in accordance with the *Agriculture and Agri-Food Administrative Monetary Penalties Act* see subsection 2(2) of the *Pest Control Products Act*.

Abbreviations

AMPs Act	<i>Agriculture and Agri-Food Administrative Monetary Penalties Act</i>
CBSA	Canada Border Services Agency
FMP	Fumigation Management Plan
GROU	Grower Requested Own Use
ISO	International Organization for Standardization
NOV	Notice of Violation
NPCP	National Pesticide Compliance Program
OECD	Organization of Economic Cooperation and Development
ONIP	OECD's Network for Fighting Illegal Trade of Pesticides
PCO	Pest Control Operator
PHI	Pre-Harvest Interval
PMRA	Pest Management Regulatory Agency
PPE	Personal Protective Equipment
REI	Restricted-Entry Interval
RORB	Regulatory Operations and Regions Branch
ULV	Ultra Low Volume

This is **Exhibit “S”** referred to in the affidavit of
Dr. Elaine MacDonald affirmed remotely before
me in accordance with O. Reg 431/20,
Administering Oath or Declaration Remotely
this 19th day of January 2022.



Commissioner for Taking Affidavits
(or as may be)



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Your health and safety... our priority.

Votre santé et votre sécurité... notre priorité.

Discussion Document

DIS2007-01

Reconsideration of Decisions Under the New *Pest Control Products Act*

(publié aussi en français)

1 October 2007

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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A.L. 6605C
Ottawa, Ontario
K1A 0K9

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Canada 

ISBN: 978-0-662-46894-3 (978-0-662-46895-0)
Catalogue number: H113-19/2007-1E (H113-19/2007-1E-PDF)

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Foreword

This draft guidance document is intended to provide stakeholders and the Health Canada Pest Management Regulatory Agency (PMRA) with information and guidance regarding the reconsideration-of-decision process (reconsideration process) as specified in the *Pest Control Products Act* and the proposed Review Panel Regulations. Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. This document is intended to be used in conjunction with the *Pest Control Products Act* and the proposed Review Panel Regulations. The document is not to be considered a substitute for the Act and/or the proposed Review Panel Regulations, nor should it be used as a stand-alone document.

The PMRA is soliciting comments from interested parties on this draft guidance document. The PMRA will accept written comments up to 45 days from the date of publication of this draft guidance document. Please forward all comments to Publications (contact information on the cover page of this document).

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1.0 The Reconsideration-of-Decision Process

The new [Pest Control Products Act](#) came into force on 28 June 2006. A number of provisions under the Act provide for increased transparency and public participation.

As per the new legislation, any person who provides a scientific basis may file a notice of objection (notice) requesting the reconsideration of a major registration decision within 60 days after the decision is made public. Major registration decisions are decisions granting or denying an application to register a new active ingredient for use in Canada; granting or denying an application to effect a major amendment to a registration; or confirming, amending or cancelling a registration of a pest control product (pesticide) on completion of a re-evaluation or special review. Conditional registrations, granted under the new Pest Control Products Regulations, are not subject to the reconsideration of decision provisions under the *Pest Control Products Act* unless they are converted into a full registration or renewed. When a registrant applies to convert a conditional registration to full registration or to renew a conditional registration, a consultation must take place on the proposed decision and the reconsideration process applies.

Any person who believes there is a scientific basis for requesting a reconsideration of decision may file a notice of objection. Notices will be reviewed and recommendations will be forwarded to PMRA senior management to determine if there is need to obtain the advice of a panel of experts in relation to the objection. PMRA officials are duly qualified to act on behalf of the Minister of Health in accordance with the *Interpretation Act*. A review panel (panel) will be established depending:

- on whether the information in the notice raises scientific-founded doubt as to the validity of the evaluations, on which the decision was based, of the health and environmental risks and the value of the pesticide; and
- on whether the advice of the expert scientists would assist in addressing the subject matter of the objection.

This document is intended to provide information and guidance regarding the reconsideration process specified in the *Pest Control Products Act* and the proposed Review Panel Regulations published in the [Canada Gazette](#), Part I. It describes the various steps in the reconsideration process. A process map is provided in Appendix I.

2.0 Filing a Notice of Objection

A notice requesting a reconsideration of decision must include standard information such as the name of the person who is filing the objection (objector), the substantive issue(s) to which the objection relates (i.e. the health risks, environmental risks and/or value of the active ingredient and/or product) and the scientific basis for the objection. The objector is responsible for ensuring that the notice is complete and accurate. A sample form for filing an objection is attached in Appendix II.

Prior to filing any notice, the objector can apply to consult the confidential test data supporting the registration decision. If the product is registered, this confidential test data will be available for public inspection in the Reading Room. The PMRA places a higher priority on applications to inspect data associated with a recent regulatory decision for which the 60-day reconsideration period is still open. As the time frame to submit a notice is established by legislation, applications to inspect the confidential test data in question should be received well in advance of the closing date of the reconsideration period for processing if the intention is to consider submitting a notice. Further details for accessing the [confidential test data](#) are provided on the PMRA's website.

Where an objector refers to information such as scientific reports or confidential test data to provide evidence for the notice, the objector should include this information as part of the scientific basis of the objection. The objector should also explain how the information in the notice raises scientifically founded doubt as to the validity of the evaluations on which the decision was based. Where the scientific information provided is new information (e.g. a new epidemiology study), the information will be reviewed to determine its admissibility in the reconsideration process. The information provided may instead be subjected to other kinds of review (e.g. special review) rather than a review panel examination. It is important to note that the reconsideration process is not an opportunity to add to the content of the original submission (e.g. the addition of a new use) or to circumvent established processes for amending registrations.

Individuals submitting an objection must also provide some personal information prescribed by the proposed Review Panel Regulations and defined in the *Privacy Act* (e.g. name, address). This personal information may be made public as authorized by the *Pest Control Products Act* and its Regulations for the purpose of the reconsideration process.

2.1 Reviewing a Notice of Objection

All notices will be reviewed once the 60-day filing period has ended. The objector is responsible for ensuring the information provided to the PMRA is complete; normally, there will be no additional opportunity to file additional objections or amend a submitted objection.

2.1.1 Recommendations to Establish a Panel

The PMRA will take all reasonable measures to ensure impartiality when determining if a panel should be established. The notice, including the scientific rationale, will be reviewed by a team of PMRA evaluators who were not involved in the original registration decision. This team will provide recommendations on the validity and the scientific plausibility of the issue(s) raised in the notice. These recommendations will be considered by PMRA senior management, who will determine if a panel should be established.

2.1.2 Criteria for Establishing a Review Panel

The decision whether to establish a panel must be made on the merits of the case presented by the objector who filed the notice. In general, the following criteria will be considered in determining whether to establish a panel:

- whether the information in the notice raises doubt as to the interpretation of the scientific information, on which the decision was based;
- whether the information in the notice raises any disagreements as to the applied methodology of the scientific information, on which the decision was based;
- whether the information in the notice raises concern(s) as to the relative weights given to data impacting on the risk assessment of the scientific information, on which the decision was based;
- whether the information in the notice raises concern(s) regarding the conclusion reached during the decision making process;
- whether the advice of one or more expert scientists would be useful and appropriate in responding to the issue(s) identified in the notice; and
- whether the Minister has not already received such above noted advice.

Objections that concern matters of regulatory practice, claim allegations of bias and/or concern an issue on which the PMRA has available recent independent expert opinion would not normally be referred to a panel. Providing knowingly false or misleading information to a review panel is an offence under the *Pest Control Products Act* and may be subject to prosecution.

2.2 Notice to Establish a Review Panel

When it is determined that the objection has merit and advice of scientific expert(s) would be useful and appropriate in responding to the issue(s) identified in the notice, a panel will be established. The objector who filed the notice and the affected registrant(s) or applicant(s) will be advised. A notice on the establishment of a panel will be placed in the Public Registry on the PMRA's website.

Where issue(s) raised in the notice have or may have merit, but can be resolved quickly and efficiently without the need for advice of scientific expert(s), the objector will be informed and no panel will be established.

If the objection raises sufficient concern that the registration may pose unacceptable risks, the registration decision may be suspended until a final decision is made on completion of the review and all matters are resolved. In such a situation, a suspension will continue until the PMRA makes a final decision on completion of the review or until the panel is dissolved.

Where a request to reconsider a registration decision is refused, the reasons for refusal will be communicated in writing, without delay, to the objector who filed the notice. The reasons for refusal will be placed in the Public Registry on the PMRA's website.

2.3 Terms of Reference for Review Panels

The PMRA will determine the terms of reference (ToR) that will establish the panel's mandate and provide guidance to persons interested in making representations by identifying the specific issues(s) that the panel will consider. The ToR will require that the panel focus on the review of science and the review be limited to issue(s) that can be properly dealt with by persons with scientific expertise without relying on persons trained in law. The ToR will also suggest target timelines for the panel procedures and may require a detailed workplan on how the milestones will be achieved and regular status updates for tracking purposes. The ToR will be made available in the Public Registry on the PMRA's website. Any requests for revision to the ToR must be submitted to the PMRA for consideration.

2.4 Establishing Review Panels

Without undue delay, the PMRA will contact potential panel members who have expertise relevant to the ToR and examine their credentials (e.g. professional credentials, educational background). Panel members will be required to possess scientific knowledge and be capable of evaluating and assessing objectively the representations made to the panel by interested parties who participate in the review. The PMRA will select as many experts as are needed to evaluate and assess the representations. All panel members will also be required to meet conflict of interest and security clearance requirements. Any person who was involved with decisions related to the registration decision will not be eligible to become a panel member. Each panel member will be paid travel and living expenses in accordance with applicable Treasury Board of Canada directives.

2.4.1 Removal of Panel Members

Panel members that are unable to perform their duties can be removed. Members can also be removed if a conflict of interest arises or if a member requests to be removed from the panel for other reasons. Another qualified person shall be selected to replace a member unless the review can be properly completed by the remaining members.

2.5 Review Panel Proceedings

The panel is responsible for determining the acceptability of the request(s) to make a representation and the admissibility of evidence based on whether they are relevant to the ToR. In all cases, the panel will advise the person(s) who made the request(s) of its decision and the reasons for accepting or refusing the request(s), or portions thereof.

If it will not impair anyone's ability to participate effectively in a hearing, the chairperson may allow teleconferencing or videoconferencing equipment to be used to make representations. A panel may also conduct any or all of the review using documentary submissions only.

All participants, other than panel members, are responsible for the costs of participating in the hearings.

2.5.1 Admissibility of Evidence

The panel may receive and accept any evidence or information it considers relevant to its mandate, regardless of its admissibility in a court of law. The conduct of the review will not be hampered by judicial rules of evidence or procedure. The panel has the authority to determine what information is relevant to the ToR, the level of credibility of the information and what weight to give to it. In addition, the panel may request and receive information and advice from persons who have not made an application to participate in the hearings.

2.5.2 Consideration of Confidential Information

Panel members and participants in a hearing will have access to confidential information that is in the Register. They are required to take all reasonable precautions to avoid any prohibited disclosures of the information. The review panel hearings will be closed to the public when confidential information is being discussed to prevent public disclosure. Participants making representations are responsible for notifying the panel in advance if they wish to discuss confidential information at the hearing. The panel will note items of the hearing agenda that are restricted to panel members and participants only.

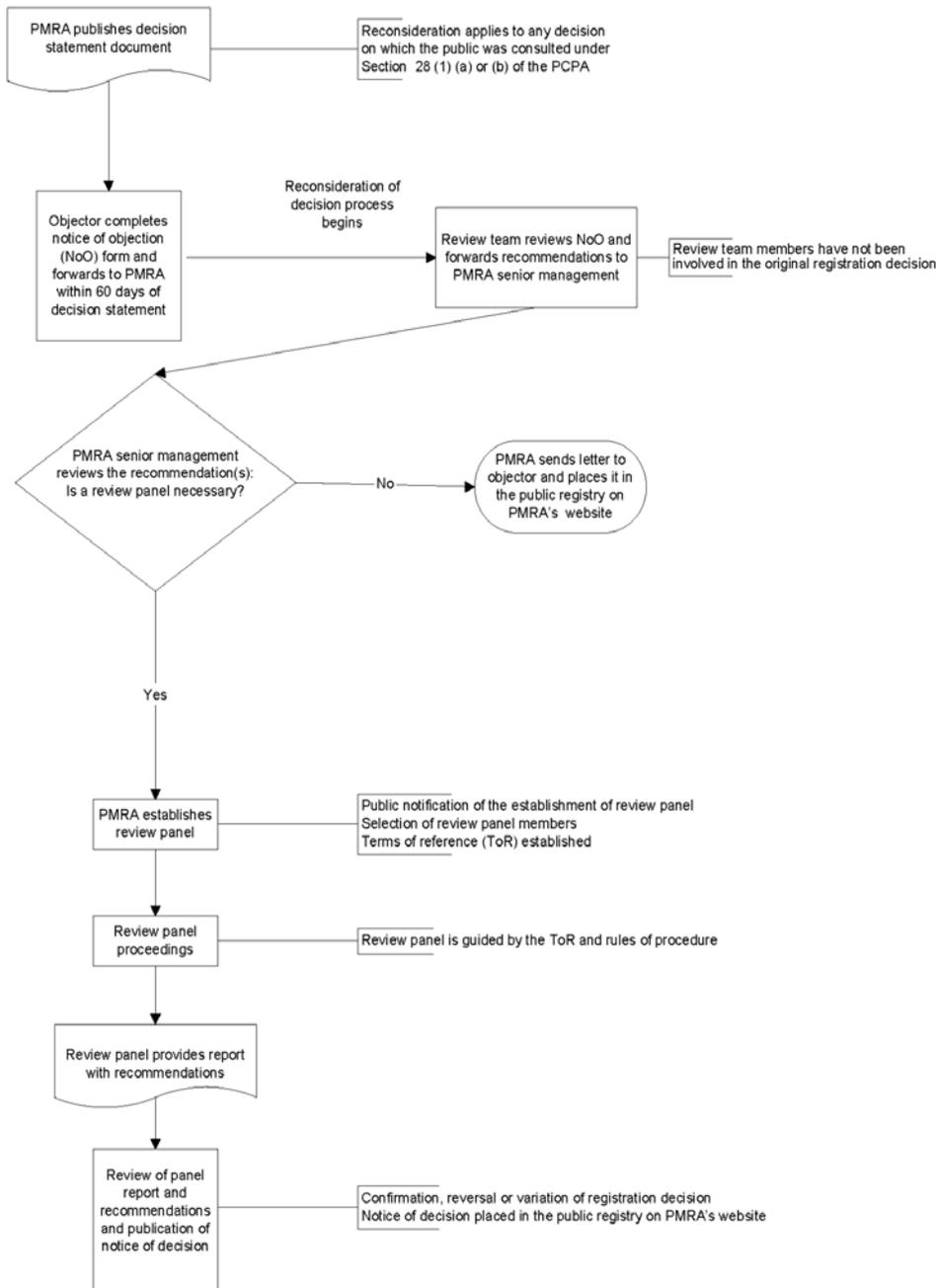
To access confidential information that is not in the Register, participants must submit a request to the panel in the form of a sworn affidavit or statutory declaration. Requests must contain an undertaking not to disclose the information or data to any other person and not to use it for any purpose other than for participation in the hearing. Only the hearing participants who have satisfied the access request requirements will be permitted to be present at such hearings.

3.0 Review Panel Report and the PMRA's Final Decision

At the conclusion of its review, the panel will provide a report to the PMRA without undue delay. The report will contain its findings, analysis and recommendation(s). It will summarize the evidence and the arguments and provide an assessment, indicating where the panel agrees and disagrees with the presentations. If the panel is unable to reach unanimity on a recommendation, the panel's report will document the differences of position of the panel members. Recommendations provided by the panel to the Minister are not binding. The panel's report will be placed in the Public Registry on the PMRA's website.

Once the panel report is submitted, the PMRA may request clarification from the panel members with respect to specific recommendations. The PMRA's confirmation, reversal or variation of the registration decision (e.g. an amendment to a label), along with the reasons and summary of the information considered, will be made available in the Public Registry on the PMRA's website. No further opportunity for formal consultation on the confirmation, reversal or variation of the PMRA's decision will follow the reconsideration of a decision. In taking the final decision, the same scientific standards will be applied as during the registration process.

Appendix I Reconsideration-of-Decision Process Map



Appendix II Notice of Objection Form

 Health Canada Pest Management Regulatory Agency		Santé Canada Agence de réglementation de la lutte antiparasitaire		Date Received - Date de réception :	
Notice of Objection to a Registration Decision under Subsection 35(1) of the Pest Control Products Act		Avis d'opposition à une décision d'homologation en vertu du paragraphe 35(1) de la Loi sur les produits antiparasitaires			
1. Objector information - Information sur l'opposant					
Name - Nom / Corporation - société / Organization - organisation					
Postal Address - Adresse postale					
City/Town - Ville	Province/State - Province/État	Country - Pays	Postal Code/ZIP - Code postal/Zip		
Phone - Téléphone	Fax - Télécopieur	E-mail - Adresse électronique			
2. Product information - Information sur le produit					
Name of active ingredient to which the decision relates: Nom de la matière active à laquelle la décision se rapporte :					
Name of end-use product to which the decision relates: Nom de la préparation commerciale à laquelle la décision se rapporte :					
3. Registration decision to which the objection relates - Décision d'homologation pour laquelle vous déposez un avis d'opposition					
Decisions on application - Décision concernant la demande <input type="checkbox"/> Granting registration - Homologation accordée <input type="checkbox"/> Denying registration - Homologation rejetée <input type="checkbox"/> Granting an amendment of a registration - Modification à l'homologation accordée <input type="checkbox"/> Denying an amendment of a registration - Modification à l'homologation rejetée					
Decisions on re-evaluation or special review - Décision concernant la réévaluation ou l'examen spécial <input type="checkbox"/> Confirming registration - Homologation confirmée <input type="checkbox"/> Cancelling registration - Homologation annulée <input type="checkbox"/> Amending registration - Modification à une homologation					
4. Date the decision statement was made public: Date de la publication de l'énoncé de décision :					
5. Area of scientific evaluation to which the objection relates - Volet de l'évaluation scientifique touché par l'avis d'opposition <input type="checkbox"/> Health risk assessment (toxicology, food residue, occupational exposure) - Évaluation des risques pour la santé (toxicologie, résidus dans les aliments, exposition professionnelle) <input type="checkbox"/> Environmental risk assessment (environmental fate, environmental toxicology) - Évaluation des risques pour l'environnement (devenir dans l'environnement, écotoxicologie) <input type="checkbox"/> Value and efficacy assessments (crop tolerance, value) - Évaluation de la valeur et de l'efficacité (tolérance des cultures, valeur)					
6. Scientific basis for the objection Fondement scientifique de l'opposition		Attachment included: Pièce jointe incluse :		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Oui <input type="checkbox"/> Non	
7. Signature of objector or representative - Signature de l'opposant ou de son représentant			Printed Name - Nom en lettres moulées		
<p>Objectors who submit confidential information (i.e., confidential business information, confidential test data) are responsible for identifying this information which is part of their submission.</p> <p>Information required to process the notice of objection may include some personal information as defined in the <i>Privacy Act</i>. In accordance with that Act, such personal information may be made public as authorized by the <i>Pest Control Products Act</i> and its regulations. Under the <i>Privacy Act</i>, individuals have the right to look at their personal information. For more information on how PMRA manages personal information, contact the PMRA Information Services at 1-800-267-6315 within Canada and 1-613-736-3799 outside of Canada or via e-mail at pmra_info@hc-sc.gc.ca.</p> <p>Les opposants qui soumettent des renseignements confidentiels (c.-à-d. des renseignements commerciaux confidentiels, des données d'essai confidentielles) sont responsables de les désigner comme tels dans leur envoi.</p> <p>L'information requise pour traiter cet avis d'opposition peut comprendre certains renseignements personnels tels que définis dans la <i>Loi sur la protection des renseignements personnels</i>. Conformément à cette Loi, ces renseignements peuvent être rendus publics, ce qui est permis par la <i>Loi sur les produits antiparasitaires</i> et son Règlement. En vertu de la <i>Loi sur la protection des renseignements personnels</i>, tous les individus ont le droit de consulter leurs renseignements personnels. On peut obtenir des précisions sur la gestion des renseignements personnels auprès de l'Agence de réglementation de la lutte antiparasitaire (ARLA) en communiquant avec le Service de renseignements au 1-800-267-6315 au Canada, ou au 1-613-736-3799 de l'extérieur du Canada, ou par courrier électronique à pmra_info@hc-sc.gc.ca.</p>					

Guidance for Completing the Application to File a Notice of Objection

Type or print clearly
Leave shaded areas blank

- 1. Objector information:**
The person identified on the form will be the one to file the notice of objection. If you are not the objector and are filing a notice of objection as a representative of a corporation or an organization, please identify yourself, state the corporation or organization you represent and provide the corporation or organization information.
- 2. Product information:**
Identify the active ingredient or the end-use product to which the decision relates.
- 3. Registration decision to which the objection relates:**
Indicate the registration decision to which the objection relates. Specify whether the objection relates to the granting or denying of a registration of a new active ingredient or end-use product or a registration amendment. If the objection relates to a decision made following a re-evaluation or special review, specify whether it relates to the confirmation or cancellation or amendment of a registration. Notices of objection are only applicable to decisions published in a decision statement.
- 4. Decision statement date:**
Indicate the date printed on the cover page of the decision statement document. A notice of objection must be filed with all required information within 60 days from the date of publication of the decision statement.
- 5. Area of scientific evaluation to which the objection relates:**
Identify the science area(s) to which the objection relates. For objections related to human health risk, specify toxicology, food residue, or occupational exposure. For environmental risks, specify environmental fate or environmental toxicology and for efficacy, specify crop tolerance or value.
- 6. Scientific basis for the objection:**
This section must include evidence and an explanation on how the evidence raises scientifically founded doubt as to the validity of the evaluations on which the decision was based.

Anyone wishing to inspect confidential test data for a registered product to which an objection relates should refer to the PMRA website on inspecting confidential test data, www.pmlra-arla.gc.ca/english/pubreg/testdata-e.html.

With any attachment submitted, please indicate on each page your name and the active ingredient, or the end-use product to which the notice of objection relates and ensure that each page is numbered.
- 7. Signature of objector or representative:**
The signature must match the name of the objector or representative identified in the objector's information section.

Note: A notice of objection may contain more than one basis of objection. Only one notice of objection per objector per decision statement will be accepted for consideration. A notice of objection that is incomplete may be returned to the objector and not considered further.

Submit the notice of objection form to:

Health Canada Pest Management Regulatory Agency
Address Locator: 6606E
2720 Riverside Drive
Ottawa, Ontario K1A 0K9

Objectors who submit confidential information (i.e., confidential business information, confidential test data) are responsible for identifying this information which is part of their submission.

Information required to process the notice of objection may include some personal information as defined in the *Privacy Act*. In accordance with that Act, such personal information may be made public as authorized by the *Pest Control Products Act* and its regulations. Under the *Privacy Act*, individuals have the right to look at their personal information. For more information on how PMRA manages personal information, contact the PMRA Information Services at 1-800-267-6315 within Canada and 1-613-736-3799 outside of Canada or via e-mail at pmra_info@hc-sc.gc.ca.

 Health Canada
Santé Canada
PMRA/ARLA 7004 (2007/07)

Guide pour remplir le Dépôt d'un avis d'opposition

Taper ou écrire clairement en lettres moulées
Ne pas remplir les zones ombragées

- 1. Information sur l'opposant :**
La personne identifiée sur le formulaire sera celle qui déposera l'avis d'opposition. Si vous n'êtes pas l'opposant et remplissez l'avis d'opposition à titre de représentant d'une société ou d'une organisation, veuillez inscrire votre nom, identifier la société ou l'organisation que vous représentez et fournir les renseignements pertinents.
- 2. Information sur le produit :**
Identifier la matière active ou la préparation commerciale à laquelle se rapporte la décision d'homologation.
- 3. Décision d'homologation pour laquelle vous déposez un avis d'opposition :**
Indiquer la décision d'homologation pour laquelle vous déposez un avis d'opposition. Préciser si l'opposition vise l'acceptation ou le refus d'homologation d'une nouvelle matière active ou d'une préparation commerciale ou d'une modification à une homologation. Si l'opposition est liée à une décision prise à la suite d'une réévaluation ou d'un examen spécial, préciser si elle vise la confirmation, l'annulation ou la modification d'une homologation. Les avis d'opposition sont seulement applicables aux décisions publiées dans un énoncé de décision.
- 4. Date de la publication de l'énoncé de décision :**
Indiquer la date imprimée sur la page couverture de l'énoncé de décision. Un avis d'opposition doit être rempli avec tous les renseignements requis au plus tard 60 jours suivant la date de la publication de l'énoncé de décision.
- 5. Volet de l'évaluation scientifique touché par l'avis d'opposition :**
Identifier le volet scientifique pour lequel l'opposition a été déposée. Dans le cas des oppositions touchant les risques pour la santé humaine, préciser s'il s'agit des données toxicologiques, de celles sur les résidus alimentaires ou de celles sur l'exposition professionnelle. Dans le cas des oppositions touchant les risques pour l'environnement, préciser s'il s'agit des données sur le devenir dans l'environnement ou sur les effets écotoxicologiques. Dans le cas des oppositions touchant l'efficacité, préciser s'il s'agit des données concernant la tolérance des cultures ou la valeur.
- 6. Fondement scientifique de l'opposition :**
Cette section doit comprendre des éléments de preuve et une explication sur la façon dont ces éléments mettent en doute la validité scientifique des évaluations qui ont servi de fondement à la décision.

Toute personne désireuse de consulter des données d'essai confidentielles concernant un produit antiparasitaire au sujet duquel un avis d'opposition a été déposé devrait se reporter à la section du site Web de l'ARLA relative à la consultation de ce type de renseignements : www.pmlra-arla.gc.ca/francais/pubreg/testdata-f.html.

Veuillez indiquer sur chaque page de toute pièce jointe soumise votre nom et celui de la matière active ou de la préparation commerciale pour laquelle l'avis d'opposition a été déposé et assurez-vous que toutes les pages soumises sont numérotées.
- 7. Signature de l'opposant ou de son représentant :**
La signature doit correspondre au nom de l'opposant ou de son représentant tel qu'identifié dans la section de l'information sur l'opposant.

Note : Un avis d'opposition peut contenir plus d'une raison pour s'opposer. On n'acceptera d'examiner qu'un seul avis d'opposition par opposant, et ce, par énoncé de décision. Un avis d'opposition incomplet peut être retourné à l'opposant et ne sera donc pas considéré.

Veuillez soumettre le formulaire d'avis d'opposition à :

Agence de réglementation de la lutte antiparasitaire de Santé Canada
Indice d'adresse : 6606E
2720, promenade Riverside
Ottawa (Ontario) K1A 0K9

Les opposants qui soumettent des renseignements confidentiels (c.-à-d. des renseignements commerciaux confidentiels, des données d'essai confidentielles) sont responsables de les désigner comme tels dans leur envoi.

L'information requise pour traiter cet avis d'opposition peut comprendre certains renseignements personnels tels que définis dans la *Loi sur la protection des renseignements personnels*. Conformément à cette Loi, ces renseignements peuvent être rendus publics, ce qui est permis par la *Loi sur les produits antiparasitaires* et son Règlement. En vertu de la *Loi sur la protection des renseignements personnels*, tous les individus ont le droit de consulter leurs renseignements personnels. On peut obtenir des précisions sur la gestion des renseignements personnels auprès de l'Agence de réglementation de la lutte antiparasitaire (ARLA) en communiquant avec le Service de renseignements au 1-800-267-6315 au Canada, ou au 1-613-736-3799 de l'extérieur du Canada, ou par courrier électronique à pmra_info@hc-sc.gc.ca.

 Canada

This is **Exhibit “T”** referred to in the affidavit of
Dr. Elaine MacDonald affirmed remotely before
me in accordance with O. Reg 431/20,
Administering Oath or Declaration Remotely
this 19th day of January 2022.



Commissioner for Taking Affidavits
(or as may be)

Charlotte Ireland

From: Clément-Mathieu, Guillaume (HC/SC) <guillaume.clement-mathieu@canada.ca>
Sent: July-07-16 1:33 PM
To: Charles Hatt; Randy Christensen; castrillij@sympatico.ca
Cc: jb@sierraclub.ca; joe@wildernesscommitee.org; info@equiterre.org; mkerry@davidsuzuki.org
Subject: Decision Letter on Notice of Objection to Registration Decision RD2013-14 / Lettre de décision portant sur l'avis d'opposition à la décision d'homologation RD2013-14
Attachments: COD - NoO Decision Letter to CELA and Ecojustice sent on 5 July 2016.pdf; COD - NoO Decision Letter to CELA and Ecojustice sent on 5 July 2016 FR.pdf

Dear Messrs. Hatt and Castrilli,

The purpose of this email is to inform you that a decision letter has been sent to you regarding the notice of objection to the renewal of the conditional registrations for foliar and in-furrow uses of clothianidin. Please find enclosed e-copy of this letter.

Ce courriel vise à vous informer qu'une lettre de décision vous a été envoyée. Celle-ci porte sur l'avis d'opposition à la décision de renouveler les conditions d'homologation relatives aux utilisations foliaires et dans les sillons de la clothianidine. Veuillez trouver ci-joint une copie électronique de cette lettre.

Best regards,
Cordialement,

Guillaume Clément-Mathieu

Re-evaluation Coordinator, Pest Management Regulatory Agency
Health Canada and Public Health Agency of Canada | Government of Canada
guillaume.clement-mathieu@canada.ca | Tel: 613-736-3735

Coordonnateur de la réévaluation, Agence de réglementation de la lutte antiparasitaire
Santé Canada et Agence de la santé publique du Canada | Gouvernement du Canada
guillaume.clement-mathieu@canada.ca | Tél: 613-736-3735



Health
Canada

Santé
Canada

Pest
Management
Regulatory
Agency

Agence de
réglementation
de la lutte
antiparasitaire

Sent via courier

Reference Numbers 2013-5037/5038/5039/5040

July 5, 2016

Charles Hatt
Counsel
Ecojustice
1910-777 Bay Street
PO Box 106
Toronto ON M4W 3X8

Joseph F. Castrilli
Counsel
Canadian Environmental Law Association
130 Spadina Avenue, Suite 301
Toronto ON M5V 2L4

Dear Messrs. Hatt and Castrilli:

**Re: Notice of Objection to Registration Decision RD2013-14,
*Clutch 50 WDG, Arena 50 WDG and Clothianidin Insecticides***

Your Notice of Objection, filed under subsection 35(1) of the *Pest Control Products Act*, regarding the renewal of the conditional registrations for foliar and in-furrow uses of clothianidin (i.e., Clutch 50 WDG, Arena 50 WDG and Clothianidin Insecticides), has now been reviewed and assessed in accordance with the Act and Regulations.

The Notice of Objection, including the scientific rationale and related information, was assessed by a team of scientists who were not involved in the original registration decision. This team provided recommendations as to the requirement for a review panel based on the validity and the scientific plausibility of the issues raised in the Notice. A review panel can be established depending:

- on whether the information in the notice raises scientifically-founded doubt as to the validity of the evaluations, on which the decision was based, of the health and environmental risks and the value of the pesticide; and
- on whether the advice of the expert scientists would assist in addressing the subject matter of the objection.

As noted in Discussion Document DIS2007-01, *Reconsiderations of Decisions under the New Pest Control Products Act*, objections that concern regulatory practice are not normally referred to a review panel.

The following information was received and reviewed in support of your Notice of Objection:

- the scientific basis for the objection, including references to numerous scientific studies, PMRA publications, and the Act and Regulations;
- a review prepared for the objectors by Dr. Mark Chernaik, Biochemist; and
- a review prepared for the objectors by Dr. Ralph V. Cartar, Bee Ecologist.

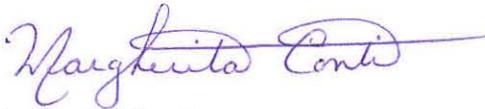
PMRA concluded that under the approved conditions of use, Clutch 50 WDG, Arena 50 WDG and Clothianidin Insecticides did not present an unacceptable risk to human health or the environment. No grounds for denying an extension were identified, and consequently, the conditional registration was renewed.

Since the initial conditional registration, studies submitted by clothianidin registrants have not indicated any areas of risk concern that would trigger additional regulatory action. In particular, a hive study was submitted and subsequently reviewed by PMRA in 2011. While this study did not fully meet all of the PMRA's data quality criteria, it was an informative study that did not indicate any significant adverse effects on the exposed hives. In this context, the initial conditions of registration pertaining to the environmental fate and long-term effects of clothianidin were maintained in the renewal.

As part of the evaluation of the Notice of Objection, PMRA reviewed the 32 studies referenced in your letter and deemed that a number of the 32 studies were not relevant for the following reasons: some of the studies pertained to neonicotinoid pesticides other than clothianidin or thiamethoxam (which transforms to clothianidin), and some of the articles were not related to foliar application of clothianidin, including studies on effects from treated seeds. PMRA also determined that a number of other studies did not require further in-depth review as they either have already been considered by PMRA in the registration decision or they were review articles that presented information that has already been considered by PMRA, and none of this information raised concerns about the product's acceptability, taking into account conditions of registration. The five remaining studies were further assessed by PMRA and it was determined that three of the studies examined effects that could not be used in a quantitative risk assessment as they did not clearly demonstrate ecologically-relevant endpoints; one study did not provide any additional or relevant information that would raise scientific doubt; and one study fed clothianidin to bees at concentrations that would not occur in the environment when used according to the label directions.

Therefore, after examining the totality of the information provided in the Notice of Objection, it has been determined that the information would not have affected the risk assessment on which the decision to renew the conditional registration was based; the information does not raise scientifically-founded doubt as to the validity of the PMRA evaluation on foliar and in-furrow uses of clothianidin; nor would the advice of external expert scientists assist in addressing the subject matter of the Objection. As a consequence, a review panel will not be established to reconsider the decision regarding the renewal of the conditional registration for foliar and in-furrow uses of clothianidin.

Yours truly,



Margherita Conti

Director General

Value Assessment and Re-evaluation Management Directorate

Pest Management Regulatory Agency