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 CHARLOTTE IRELAND
(Affirmed December 7, 2021)

I, Charlotte Ireland, of the City of Toronto, in the Province of Ontario, AFFIRM AS FOLLOWS:

1. I am a paralegal at Ecojustice Canada in the City of Toronto. I have been employed by Ecojustice Canada since 2014.

2. In the course of my employment I have accessed the documents that are attached as exhibits to this affidavit, all of which are publicly available online. I therefore have personal knowledge of the source and authenticity of the documents that are affirmed in this affidavit.

A. JMPR Summary Report

3. I accessed the website of the World Health Organization ("WHO") and downloaded the 2019 Summary Report of the Joint FAO/WHO Meeting on Pesticide Residue ("JMPR"), available at https://www.who.int/foodsafety/areas_work/chemical-risks/Sep_2019_JMPR_Summary_Report.pdf. Excerpts of the JMPR Summary Report is attached as **Exhibit "A"** to this affidavit.

B. WTO Specific Trade Concern

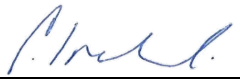
4. I accessed the website of the World Trade Organization and downloaded a Word copy of Specific Trade Concern #474, "Modification of EU MRLs for plant protection products: Chlorpyrifos and Chlorpyrifos-methyl", dated February 10, 2021, available at http://spsims.wto.org/en/SpecificTradeConcerns/View/476. Specific Trade Concern #474 is attached to this affidavit as **Exhibit "B"**.

5. I make this affidavit in support of the within judicial review applications and for no improper or other purpose.

AFFIRMED REMOTELY by Charlotte Ireland stated as being located in the City of Toronto, in the Province of Ontario, before me in the City of Brampton, in the Province of Ontario on December 7, 2021, in accordance with O. Reg 431/20, Administering Oath or Declaration Remotely.

Commissioner for Taking Affidavits
(or as may be)

Laura Bowman, LSO # 53645K



CHARLOTTE IRELAND

This is **Exhibit "A"** referred to in the affidavit of **Charlotte Ireland** affirmed remotely before me in accordance with O. Reg 431/20, Administering Oath or Declaration Remotely this 7th day of December, 2021.

Commissioner for Taking Affidavits
(or as may be)

Food and Agriculture Organization of the United Nations

World Health Organization

JOINT FAO/WHO MEETING ON PESTICIDE RESIDUES

Geneva, 17-26 September 2019

SUMMARY REPORT

**ACCEPTABLE DAILY INTAKES, ACUTE REFERENCE DOSES,
ACUTE AND LONG-TERM DIETARY EXPOSURES,
RECOMMENDED MAXIMUM RESIDUE LEVELS, SUPERVISED TRIALS MEDIAN RESIDUE VALUES
AND OTHER VALUES RECORDED
BY THE 2019 MEETING**

Issued October 2019

The following extracts of the results of the 2019 Joint FAO/WHO Meeting on Pesticide Residues (JMPR) are provided to make them accessible to interested parties at an early date.

The Meeting evaluated 28 pesticides and in addition, a number of pesticides used on spices were considered. The Meeting estimated maximum residue levels, which it recommended for use as maximum residue limits (MRLs) by the CCPR. It also estimated supervised trials median residue (STMR) and highest residue (HR) levels as a basis for estimation of the dietary exposure to residues of the pesticides reviewed. The allocations and estimates are shown in the Table 1.

Pesticides for which the estimated dietary exposures might, on the basis of the available information, exceed their acceptable daily intakes (ADIs) are marked with footnotes, which are also applied to specific commodities when the available information indicated that the acute reference dose (ARfD) of a pesticide might be exceeded when the commodity was consumed.

The table includes the Codex reference numbers of the compounds and the Codex classification numbers (CCNs) of the commodities, to facilitate reference to the Codex maximum limits for pesticide residues (Codex Alimentarius, Vol. 2B) and other documents and working documents of the Codex Alimentarius Commission. Compounds and commodities are both listed in alphabetical order.

Apart from the abbreviations indicated above, the following qualifications are used in Table 1.

* (following name of pesticide)	New compound
** (following name of pesticide)	Compound reviewed within CCPR periodic review programme
(*) (following a recommended maximum residue level)	At or about the limit of quantification
ar	The median or highest residue is reported at the moisture content of the feed commodity "as received"
dw	The value is reported in the dry weight of the feed commodity
HR-P	Highest residue in a processed commodity, in mg/kg, calculated by multiplying the HR in the raw commodity by the processing factor
Po	The recommendation accommodates post-harvest treatment of the commodity.
PoP (following recommendation for processed foods) (classes D and E in the Codex classification)	The recommendation accommodates post-harvest treatment of the primary food commodity.

Based on the information presented, the JMPR concluded that given the extremely conservative estimates produced when assuming all commodities have residues present at the MRL, a LoP of less than 100% does not necessarily indicate that approved uses will lead to an exceedance of the ARfD in practice. The JMPR suggests that a more realistic assessment of the LoP could be made by assuming residues at the MRL for a single commodity and residues from monitoring data for other commodities in the assessment.

The Meeting agreed that a probabilistic approach to acute dietary exposure assessments should be considered in the future when adequate data and appropriate tools are available.

2.5 Need for a guidance on toxicological interpretation due to the shift from maximum tolerated dose (MTD)-based to kinetically-derived maximum dose (KMD)-based evaluation of pesticide residues

In guideline studies of the toxicity of pesticides, the chemicals are evaluated using a dose-selection protocol that includes a maximum tolerated dose (MTD), designed to maximize the detection of any toxicity in experimental animals by the treatment. The introduction of concurrent in-life toxicokinetics into repeat-dose studies has revealed that in a number of such studies absorption is highly non-linear, and that in some cases there is no additional systemic exposure above a certain dose. Not only does this complicate interpretation of dose-response relationships, but it also results in the unnecessary use of animals, as no useful information is obtained from those dose groups above the point of saturation.

But non-linear toxicokinetics may be manifest not only in saturation of absorption but also in saturation of distribution, metabolism and/or elimination of the parent and/or its metabolites. This confounds toxicological interpretation of the studies.

Most pesticides are toxic at high doses when people are directly exposed to pesticides (Factsheet, WHO 2018[1]), however people are not exposed to pesticides at saturated blood levels through residues in the diet. Thus, consideration of internal exposure to pesticides and/or their metabolites is key to effective dietary risk assessment of pesticide residues with extrapolation to humans.

A top dose for use in animal toxicity testing based on evidence of dose non-proportionality has been termed the kinetically-derived maximum dose (KMD). If sufficient data are available for KMD-based evaluation, it is considered appropriate that the toxicological evaluation of pesticide residues shifts from MTD-based to KMD-based, both from the perspective of dietary risk assessment of pesticide residues with extrapolation to humans and from the viewpoint of scientific progress. In particular, the KMD-based toxicological interpretations are likely to contribute to evaluation on the carcinogenicity observed at high doses and on the results of teratogenicity studies conducted by oral gavage.

However, in order to increase the consistency and transparency of such toxicity assessments, guidance on KMD-based toxicity interpretation is needed.

It is recommended that the Joint Secretariat convene a group of experts to prepare guidance on the KMD-based evaluation of pesticide residues.

2.6 Comments on chlorpyrifos

The Meeting is aware of new information from the European Food Safety Authority (EFSA) statement on the available outcomes of the human health assessment in the context of the peer review of chlorpyrifos.

The EFSA stated that an in vivo Comet assay, proposed in order to clarify the positive findings observed in an in vitro chromosome aberration test and in two studies on unscheduled DNA synthesis, was not provided.

[1] WHO Fact Sheet 2018. Pesticide Residues in Food. https://www.who.int/news-room/fact-sheets/detail/pesticide-residues-in-food

According to EFSA's opinion, chlorpyrifos can produce DNA damage through topoisomerase II inhibition, which might be involved as a molecular initiating event for infant leukaemia that has also been associated with pesticide exposure in some epidemiological studies.

EFSA also stated that a Comet assay study might not be sufficient to rule out this concern, supporting the need for additional data to address the concerns regarding chromosome aberration and DNA damage caused by oxidative stress or through topoisomerase II inhibition.

An additional concern highlighted by EFSA was neurodevelopmental toxicity, based on the effects (decrease in cerebellum height corrected by brain weight) observed in rats and also supported by the available epidemiological evidence related to developmental neurological outcomes in children.

Given the 20-year gap since chlorpyrifos was last reviewed by the JMPR and the magnitude of potential concerns identified by the EU, the Meeting strongly recommends chlorpyrifos be prioritized for periodic re-evaluation. It was noted that aspects of epidemiology should be included.

2.7 Possible need for amendments to the Environmental Health Criteria (EHC) 240 guidance on appropriate use of toxicological historical control data (HCD)

The Meeting noted a certain degree of recurring inconsistencies in the use of HCD. Although there is guidance in EHC 240 on the role of historical control data in the overall evaluation of toxicological data some points might need amendment. The Joint Secretariat was asked to set up an electronic working group that will identify and, if necessary, propose amendments to relevant paragraphs in EHC 240.

2.8 Use of monitoring data for the estimation of maximum residue levels

The JMPR estimates maximum residue levels primarily based on supervised residue trial data conducted according to good agricultural practice GAP. They are recommended to the Codex Alimentarius Commission as MRLs. However, monitoring data were used as a basis of estimating extraneous maximum residue levels.

For a number of years, the CCPR had considered possibilities of setting MRLs for commodities of importance to developing countries. The Thirty-sixth Session of CCPR in 2004 agreed that MRLs for spices should be set on the basis of monitoring data because of the diverse production practices with spices and as GAP information was not available for spices. Noting that there had already been Codex MRLs for a number of pesticides in/on sweet/chili peppers and tea, the CCPR also agreed that chili peppers, tea and herbs fell outside of the definition of “spices” for the purposes of setting MRLs on the basis of monitoring data (irrespective of the Codex Classification). For these commodities, GAP and corresponding supervised trial data should be used for the estimation of maximum residue levels. The Thirty-sixth CCPR also requested JMPR to review existing MRLs on peppers with the view of setting MRLs for dried chili peppers using processing/dehydration factors as appropriate. (ALINORM 04/27/24, paras. 235-247)

The 2002 JMPR elaborated guidelines for selective surveys to provide residue data for estimating maximum residue levels in spices (JMPR Report 2002, Section 2.7). The 2004 JMPR, in response to the request of the Thirty-sixth CCPR above, developed principles and methodology for evaluating monitoring data on spices and estimated a number of maximum residue levels for spices based on monitoring data (JMPR Report 2004, Section 2.6 and 4.27). The principles and methodologies were refined by the 2015 JMPR (JMPR Report 2015, Section 5.30)(FAO Manual, 3rd Ed., 2016; Sections 3.9, 5.11, and 11.1).

The current Meeting received monitoring data on a number of spice commodities including dried chili peppers (HS 0444 in the Spice Group) and fresh curry, leaves (HH 0729, in the Herb Group).

The Meeting stressed that it prefers supervised trials conducted according to GAP as the basis of estimating maximum residue levels and confirmed its previous decisions to use monitoring data only for estimation of extraneous residue levels and of maximum residue levels for spices. It further

This is **Exhibit "B"** referred to in the affidavit of **Charlotte Ireland** affirmed remotely before me in accordance with O. Reg 431/20, Administering Oath or Declaration Remotely this 7th day of December, 2021.

Commissioner for Taking Affidavits
(or as may be)

STC number: 474

Modification of EU MRLs for plant protection products: Chlorpyrifos and Chlorpyrifos-methyl

Maintained by:	European Union
Raised by:	Colombia; Ecuador
Supported by:	Dominican Republic; Egypt; Guatemala; Honduras; Indonesia; Paraguay; Peru
First date raised:	June 2020 G/SPS/R/99 paras. 3.37-3.58. See STC 448.
Dates subsequently raised:	
Number of times subsequently raised:	0
Relevant document(s):	G/SPS/N/EU/360 G/SPS/GEN/1761 G/SPS/GEN/1807
Products covered:	
Primary subject keyword:	Food safety
Subject keywords:	Technical Barriers to Trade (TBT); Food safety; Human health; Pesticides; Maximum residue limits (MRLs); International Standards / Harmonization
Status:	Not reported
Solution:	
Date reported as resolved:	

Extracts from SPS Committee Meeting summary reports

In June 2020, Colombia thanked Ecuador for co-sponsoring this specific trade concern, and to the Dominican Republic, Egypt, Paraguay, Guatemala, Peru, Chile and Indonesia for supporting it. Colombia noted that the support was evidence that this and other STCs related to changes in MRLs were not a bilateral or regional concern, but that they affected countries of different regions and products. Colombia referred Members to document G/SPS/GEN/1761.

Ecuador introduced document G/SPS/GEN/1807 and submitted the following statement: Ecuador shares this concern regarding the ban on the use of more plant protection tools that are key to pest eradication and food quality. Such measures can seriously hamper the entry of many agricultural products into the market of our main trading partner.

Guatemala provided the following statement: We thank Colombia, Costa Rica, Ecuador and Paraguay for including this item on the Committee's agenda. The European Food Safety Authority (EFSA) has reduced the maximum residue levels (MRLs) for chlorpyrifos, which is applied manually in Guatemala to control pests in banana production, by placing ties on each banana and plantain bunch and using protective sleeves for the fruit, instead of using the spray method. The banana sector has repeatedly said that, domestically, there are no alternatives proven to be effective as chlorpyrifos available for immediate use. In the Latin American banana sector, tests are being carried out using other substances, including an EFSA approved molecule called pyriproxifen that

might be similarly effective to chlorpyrifos. However, it is still being trialled and farmers are looking for lower risk alternatives. Although farmers have considered using pyriproxifen, obtaining and introducing it in the country at this crucial time has been hampered by quarantine measures in several countries due to COVID-19, and by domestic requirements for registration, including field tests, which obviously cannot be conducted at this time. In addition to the challenges to obtaining substitutes for the above-mentioned agricultural chemical, the global health emergency caused by COVID-19 is having a serious impact on domestic farmers, due to the isolation of technical and field staff, interruptions in supply processes and shortages in production inputs. This may lead to an increase in pests and diseases that will have an adverse effect on banana and plantain production. If this is compounded by the current transition periods for the use of chlorpyrifos, they will pose an additional challenge to existing difficulties caused by the coronavirus, which would fall on producers and exporters, putting at even greater risk their ability to maintain levels of production, comply with delivery programmes as per contracts, guarantee the supply of fruit in the various markets and ensure employment in the sector. It should be noted that, in such a health situation and with no immediate alternative to replace chlorpyrifos, farmers will see 10 to 15% of their fruit go to waste due to the damage done to the banana skins by the increase in sucking/eating insects, lowering the commercial value of the bananas. In addition to the loss of produce and the immobility of staff due to the health emergency, the cost of production will increase and productivity will decrease, making banana production riskier due to direct economic losses and even creating a negative social effect. In light of the above, Guatemala has sent communications to the European Union asking it to postpone the application of this measure and to provide scientific evidence of the damage to European consumers' health caused by eating bananas and other agricultural products from third countries. We reiterate the request made and previously discussed in document in G/SPS/GEN/1778.

Indonesia provided the following statement: Indonesia would like to thank Colombia for placing this important issue into the STC agenda. While we are still examining the potential impact of the European Union's proposed MRLs, Indonesia supports this STC and registers its interest to following this STC's discussions. We fully noted the statements delivered by Colombia and other proponents to this STC on its potential implication to specific agricultural products sourced mainly from developing and LDC Members; and lack of scientific evidence in determining new MRLs. In this regard, Indonesia wishes to urge the European Union in preparing the level of MRLs, to carry it out in accordance with the SPS Agreement and international standards, as necessary, and that these MRLs do not create any unnecessary barriers to trade.

Paraguay provided the following statement: My delegation shares the trade concern submitted by the delegations of Colombia and Ecuador and thanks these delegations for including it on today's agenda. As well as reiterating our systemic concern regarding the EU's approach to establishing the MRLs in question, we would like to highlight the importance of these substances for Paraguay. While chlorpyrifos is important for our agriculture, as a substance commonly used in the rotation system practised by our farmers to prevent the resistance of pests in corn, sesame, soya bean and wheat crops, it is also vital for human health because it is used as a base substance for mosquito repellents, in a country where a dengue fever epidemic strikes every year in summer, affecting hundreds of thousands of people. In 2020 alone, the Ministry of Public Health and Social Welfare reported more than 137,000 dengue notifications and 135 deaths between January and March, just in the Republic of Paraguay. To put this in perspective, across the world approximately the same number of cases of COVID-19 were reported in the same period. The figures for Paraguay reflect the number of cases of dengue even with the availability of repellent products and fumigation to eliminate breeding sites; imagine how the numbers would look if these products were not available. Climatic conditions in Paraguay require the use of particular products and, following the EU's decision to suspend the use of this substance in its territory, one of the main companies producing it has announced that it will discontinue its production, not because it deems the substance to be dangerous, but because it is no longer commercially viable. This is the peril faced by the small countries using such compounds; we do not have the capacity to produce or develop alternatives. As for alternatives to control dengue, we have to raise our concern about cypermethrin and citronella oil, also key substances, being included on the list of the upcoming EFSA review of substances and which in all likelihood will be removed. We once again urge the European Union to base its measures on conclusive scientific evidence and to take into consideration the unintended consequences and implications that its policies will have for third countries, which have different climatic conditions from those of European countries and therefore have to deal with other pests and diseases affecting not only agriculture but also people's health.

Peru provided the following statement: Peru wishes to point out that the standard applied by the EU for chlorpyrifos will have an impact on Peruvian exports. Specifically, Peru wishes to state that, when making this type of modification, Article 5.3 of the WTO SPS Agreement should be taken into consideration, to determine the potential damage that this regulation would cause, and Article 5.4, concerning the objective of minimizing negative trade effects.

The Dominican Republic provided the following statement: The Dominican Republic wishes to express its support for this agenda item. We reiterate our concern that the EU continues to reduce its maximum residue levels (MRLs) to the minimum detection level and to reduce MRLs for active substances that remain approved under the Codex Alimentarius, without conducting the requisite scientific risk assessments, as stipulated in the SPS Agreement. As explained in the communication in document G/SPS/GEN/1761, chlorpyrifos is an essential compound for protecting crops against pests and diseases, which is used to maintain the quality and safety of products before their entry into the European market. Measures of this kind have a direct impact on our exports, not to mention a social and economic impact on the region. We therefore ask that any measure applied by the European Union be prepared in accordance with the WTO SPS Agreement, based on scientific principles and risk assessment criteria.

The European Union provided the following response: The European Union has carefully studied all the information available and confirms that there is sufficient evidence to conclude that both substances pose serious concerns for human health. The available regulatory studies and scientific literature, including epidemiological data, provide evidence of developmental neurotoxicity, leading to adverse neurological outcomes in children. In addition, a genotoxic potential cannot be excluded for the two substances, in particular concerning the ability of the substances to damage DNA. It is therefore not possible to set safe levels of exposure for human health, which in turn makes it impossible to carry out a risk assessment for consumers. The identified issues are based on a consideration of all the available information and concerns identified from that information, not due to missing data. The European Union legislation prescribes that it is the responsibility of the industry to demonstrate that substances and products they contain do not have any harmful effects on human and animal health or unacceptable effects on the environment. The Regulations concerning the non-renewal of approval received a favourable opinion at the Standing Committee on Plants, Animals, Food and Feed, on 6 December 2019, after being duly notified under the WTO TBT procedure. The Regulations were adopted and published on 10 January 2020. The Regulations required EU member States to withdraw authorisations for plant protection products containing chlorpyrifos and chlorpyrifos-methyl by 16 February 2020 and allowed member States to grant a short period of grace until 16 April 2020 for placing on the market, storage, disposal and use of plant protection products. On 18 February 2020, member States endorsed a Commission proposal to lower the Maximum MRLs of chlorpyrifos and chlorpyrifos-methyl in food and feed to the Level of Quantification, which was duly notified under the WTO SPS Agreement. 3.53. Notwithstanding the serious health concerns identified by EFSA, the Regulation includes a deferral period for the application of the lower MRLs - 3 months from the date of entry into force of the Regulation. Therefore, it does not lead to immediate trade disruptions as the new MRLs will not become applicable before November 2020. It is important to note that given the concerns identified by EFSA, it is not possible to determine MRLs based on a risk assessment and therefore all MRLs must be lowered to the limit of determination. For the same reason, no additional transitional measures can be provided for products that will have been produced in the European Union or imported into the European Union before the Regulation becomes applicable. Some WTO Members consider that the European Union is moving away from Codex procedures and its international norms and that the JMPR has rejected the European Union argumentations. The European Union has been supporting the work of the Codex Alimentarius Commission since its inception and strongly believes in the role the organisation plays in the protection of consumers' health and to facilitate trade. The European Union is the highest contributor to the Codex Trust Fund 2 and has also spearheaded an initiative supported by many other Codex members to ensure sustainable funding for Codex scientific advice. In addition, EU law stipulates that MRLs set at the international level by the Codex Alimentarius Commission should be considered when Community MRLs are being set, taking into account corresponding good agricultural practice. When deciding on the setting, modification, or deletion of an MRL, the European Commission is therefore bound to take into account existing Codex MRLs (CXLs) - and this is what the European Union does. However, at times the European Union scientific bodies and experts consider that existing or proposed CXLs are not sufficient to protect EU consumers and recommend different MRLs. Chlorpyrifos was originally evaluated by JMPR in 1972. It was evaluated for toxicology in 1982 by JMPR and for residues in 1995, and it was reviewed for toxicology in 1999 and for residues in 2000, 2004 and 2006. There

is a 20-year gap since chlorpyrifos was last reviewed by JMPR, as it is also indicated in the General Considerations (point 2.6) of the 2019 Report of the Extra Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food (JMPR) and the Environment and the WHO Core Assessment Group on Pesticide Residues. The European Union has submitted recently a concern form to the Codex Secretariat and the JMPR to raise awareness on its latest findings. The European Union considers that a re-evaluation for toxicology and residues of chlorpyrifos, and all the JMPR CXLs, is necessary and this task should be prioritised in the JMPR calendar. The European Union hopes that the replies conveyed address the concerns of delegates.