Hon. Minister Jean-Yves Duclos
Pest Management Regulatory Agency
Health Canada
House of Commons
Ottawa, Ontario,
Canada
K1A 0A6

Dec. 12, 2022

RE: Notice of Objection to PMRA's Final Decision RVD2021-05 (Imidacloprid and its associated end-use products) open submission 2021-3441

In response to the release of the **PMRA Re-evaluation Decision - RVD2021-05 for Imidacloprid published on May 19, 2021,** I am filing a **revised Notice of Objection** to include all references cited as requested.

Please find attached my Notice of Objection and the scientific justification for reconsidering the Final Re-evaluation Decision for Imidacloprid, including the reference list, and enclosed is a document containing PDFs of all the published papers used in this NOI.

Kind regards

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I have reviewed the final re-evaluation decision for Imidacloprid RVD2021-05 and am filing a Notice of Objection (submission 2021-24441) based on the following 14 scientific considerations:

Unacceptable Risk to Aquatic Invertebrates

1) **The PMRA placed an undue emphasis on mesocosm studies and ignored a body of evidence (and standard SSD approaches) from lab toxicity studies conducted on a wide range of aquatic insect species to derive water quality effect levels.**

The original proposed PMRA (2016) decision used toxicity data and a multi-species sensitivity distribution (SSD) approach to determine the adverse effect levels for aquatic invertebrates. This is standard practice and in line with what regulators in the EU and Netherlands have done (EFSA 2014, Smit et al 2015), the Canadian Council for Ministers on the Environment (CCME 2007), and independent scientists (Mineau and Palmer 2013, Morrissey et al. 2015, and Wang et al. 2022). However, in the most recent re-evaluation and final decision, the PMRA have deviated from their own standard approach to prioritize 27 available mesocosm studies – ultimately with emphasis on a NOEC for 1 species (*Cloeon dipterum)* claiming these tier 2 studies have more real-world relevance. The revised PMRA final decision on imidacloprid using a mesocosm approach alone ultimately caused the chronic endpoint to increase more than 10 fold from 0.011 (0.0005 –0.077) ug/L derived from SSDs to 0.16 ug/L using the 28-d TWA NOEC for *Cloeon dipterum* abundance. PMRA's chosen acute effects endpoint (0.54 ug/L) and the chosen chronic effects endpoint (0.16 ug/L) fall well short of acute to chronic ratios (ACRs) observed for imidacloprid (e.g. ratios averaged 90.9 fold (range 47-108) (Wang et al. 2022). This is a clear indication that PMRA`s chosen chronic endpoint is not sufficiently protective.

There are essentially 3 methods for deriving water quality effect levels: 1) applying a safety or Assessment Factor (AF) to the lowest sensitive endpoint (AF-approach), statistical extrapolation using Species Sensitivity Distributions (SSD-approach), or micro or mesocosm studies (model ecosystem approach) (Smit et al. 2015). While I accept that mesocosm studies are higher tier studies that provide valuable information to consider and validate effects on communities under field relevant situations, mesocosms are semi-field systems and the data and thus interpretation are known to be highly variable and lack statistical power (Montforts and DeJong 2007). This is often due to varying exposure regimes and environmental conditions that can strongly affect organism sensitivity (Cavallaro et al. 2018, Posthuma et al. 2001), toxicity can either exceed or fall below effect levels reported in the lab (Maloney et al. 2018a), and sensitive species may be underrepresented or not present at all in the simplified system, and thus mesocosms alone are not recommended for derivation of water quality guidelines. Therefore, while SSDs are preferred, an appropriate application of AF of 2-10 is needed when using mesocosms (Posthuma-Doodeman 2008). Indeed, in the 2016 decision, the PMRA identified the challenges of using the mesocosm approach stating "deficiencies such as (1) an inadequate number of exposure concentrations; (2) short study duration; (3) application regimes that are not representative of most exposure scenarios; and, (4) a low abundance of sensitive invertebrate species prevented reliable statistical evaluation" (PMRA, 2016). The mesocosm data should be interpreted with caution, particularly if it deviates from the conclusions from the more standard SSD approach and without application of any safety or assessment factor.

This selection of a mesocosm only approach (instead of the SSD) in setting the benchmark LOC endpoint directly contradicts the CCME and Environment Canada's own guidelines (Spry and Branch 2015) for standard best practice in setting thresholds in water quality guidelines. It also counters the recommended methods and effect levels derived by other jurisdictions using the

European Water Framework Directive (Posthuma-Doodeman 2008, Smit et al. 2015, Morrissey et al. 2015). If the PMRA wishes to deviate from standard practice to incorporate more environmentally relevant and ecologically realistic endpoints from the field, the use of probabilistic methods and safety or assessment factors are still scientifically preferred rather than defaulting to a NOEC or LOEC for a single species and study. Indeed, Van den Brink 2006 notes that due to a lack of statistical power, mesocosm effect levels should be calculated at the community level and not at the population level. The purpose of mesocosms is often to refine the HC_5 from an SSD or determine the weight of assessment factors to be considered in light of multiple community level structural and functional effects observed. The wealth of aquatic invertebrate lab acute and chronic toxicity data available strongly warrants using the SSD approach over a mesocosm endpoint measure for a single species. Given the PMRAs (2021) decision to deviate from standard practice and their own approach used in 2016 to now use an effect level >10x higher than the 2016 assessment, the acceptability criteria for mesocosm studies suggests greater scrutiny is needed and the rationale for deviation from the SSD approach has not been defined nor transparently communicated.

2) **There is evidence the PMRA exerted prejudice in the selection of inappropriate water monitoring data largely produced by industry and disregarded or removed independent peer reviewed water monitoring data.**

There appears to have been selective prejudice for water monitoring data particularly in Prairie Canada. The PMRA have preferentially retained unpublished industry studies that indicated water concentrations were below regulatory effect thresholds – notably from the most agro-intensive prairie region. These registrant-produced studies were taken after the preliminary 2016 decision to phase out the neonicotinoids and were sampled during dry years or from repeated sampling of clean wetlands to inflate the sample sizes and artificially lower the average concentrations (eg. Canola Growers Assoc 2019 – PMRA doc 3169611). There was also a removal of data in the most recent assessment including the largest publicly available wetland monitoring dataset in Canada from several published and shared datasets by Dr. C Morrissey's lab (Main et al. 2014, 2015 and 2016 - PMRA doc 2612760, 2612761, 2612762). The only dataset from Dr. Morrissey's team that was used (partially) was an unpublished dataset (Morrissey et al 2016, PMRA doc 2712896).

Based on Table 2 of the Final Decision RVD2021-05, below is the breakdown of how many wetland sites were included or excluded from the assessment. Note that more sites were excluded than were included effectively reducing the sample size by over half. In addition, with the exception of 18 sites, the majority used in the assessment were from wetlands not in fields known to be treated with imidacloprid which essentially prohibits interpretation of the utility of those datasets used. The removal of published and unpublished datasets (2012-2016) provided to PMRA for their original assessment in 2016 covered a cross section of wetlands of all size classes and crop types to provide a representative sample of the contamination frequency across landscape.

Table 1: Summary of studies of wetlands in the prairies that were included in the 2021 final re-evaluation and excluded based on information provided in RVD2021-05.

Studies included in PMRA assessment	**N wetlands**	**Studies excluded in PMRA assessment**	**N wetlands**
Morrissey 2016 Unpublished	46	Morrissey 2016 Unpublished	69
Bayer (Imidacloprid)	18	Main et al 2014	138
Bayer (clothianidin)	48	Main et al 2015	144
Syngenta (thiamethoxam)	114 (56+58)	Main et al 2016	16
Ducks Unlimited 2017-2018	60		
Canadian Canola Growers	17		
TOTAL # WETLAND SITES INCLUDED	**303**	**TOTAL # WETLAND SITES EXCLUDED**	**367**

I note that the PMRA removed 18 studies previously used in the earlier 2016 assessment including peer reviewed published studies. Importantly, they removed only datasets for the prairies that were not collected by the registrants or under the Environmental Monitoring Working Group spearheaded by industry. These data included Main et al. 2014, 2015 and 2016 which sampled 298 wetland sites and analyzed 683 samples. This is in addition to removing 69 sites from the above 2014 sample data set. The reasons cited for excluding all published peer reviewed studies were described in Appendix X (page 251) of the final 2021 decision:

> **"Reason for exclusion:** Wetlands were sampled once in the spring, summer and fall of 2012 and in the spring of 2013. The wetland classes ranged from temporary ponds to permanent ponds. *Site locations were not provided*. Crop in the fields where the wetlands were sampled were provided; however, site locations were not identified. The sites consist, at least in part, of sites *not relevant* to aquatic risk assessments. Without information on site location, an assessment of the relevance of the detections to an aquatic risk assessment cannot be made."

This major omission of data in the final decision appears to be a direct result the PMRA citing "location data not provided". Upon investigation, this arbitrary decision to remove data where confidential GPS locations of private lands were not included, is in direct response to report commissioned by the registrant, Bayer Crop Science (PMRA doc 2870577 and 2870578). Bayer undertook an investigation to revisit sites that Main and Morrissey sampled in 2014 three years later and during the driest month of August. Bayer's 27-page proprietary report (PMRA doc 2870577) commissioned after the 2016 PMRA decision was initiated to invalidate the Morrissey 2016 dataset containing results of the 115 wetland water samples conducted across the Prairie region in 2014 [Unpublished monitoring data on neonicotinoids in wetlands sampled in the summer of 2014 along breeding bird survey routes across Saskatchewan (PMRA doc 2712896)]. Bayer Crop Science was given the unpublished dataset collected by Dr. Morrissey through the PMRA, without consent or notice (Ducks Unlimited pers. comm.).

The original Morrissey 2016 wetland water survey of 115 sites was conducted to complement bird counts and aquatic macroinvertebrate sampling at wetland sites along established "Breeding Bird Survey" routes that are conducted annually on roadsides. Wetlands were selected within 100m access of the road at random locations along these routes. In most, but not all cases, the GPS points provided were of the actual edge of the water body, but in some instances, they were approximated from the road. The Bayer review of the dataset was done without consultation by Dr. Morrissey and proceeded to arbitrarily detail which of our wetland sampling sites were "relevant" and which were "irrelevant" for aquatic invertebrate monitoring based on Bayer's subjective criteria. These criteria identified 4 categories of wetland samples as follows:

1. Flowing watercourse (total n= 13, Bayer Relevant = 1)
2. Low area/edge of road (total n=49, Bayer Relevant = 1)
3. Shallow wetland in agricultural field (total n=6, Bayer Relevant = 0)
4. Wetlands (total n=47, Bayer Relevant = 43)

In several cases, Bayer staff subsequently used a series of photographs and Google aerial imagery taken of the sites 3 years later and/or from site visits done in late summer for their determination of "relevancy" which in some cases the site had dried or was now cropped into as is typical in dry periods in the Prairie Pothole Region (eg. DRI4 site was photographed in Aug 2017 but the original data were collected in June 2014). Of great importance was their position that all the high sites with high levels of contamination (>1000 ng/L) should all be deemed "irrelevant". (eg. DRI-DW had clothianidin concentration of 2059 ng/L and DEN-3 had clothianidin concentration of 1806.1 ng/L (imidacloprid conc of 168.1ng/L) - both were deemed irrelevant and removed). Since the justification for removing sites or deeming them irrelevant was based on Bayer personnel viewing and classifying these wetlands in August 2017 (3 years after they were sampled and during the end of the summer when many would have been dry), this is completely inappropriate as prairie wetlands are known to dry or change class during and across seasons. Ironically, Bayer conducted a study themselves in 2017 and found that 1/6 of their SK wetlands were dry by the end of the season, citing "extremely dry weather" (Doc 2921987). The argument that seasonal wetlands or those that dry later in the season are *irrelevant* for aquatic invertebrates is completely unsubstantiated. These wetlands are known to thaw first in spring and are the most ecologically productive early in the season and are critically important to breeding waterfowl, shorebirds and other consumers such as aerial insectivores.

Bayer went further to suggest that all the published data from the Morrissey lab should not be included because "location data was not provided" and thus concluded that the utility of those published datasets and the sites sampled were "irrelevant". I note that PMRA used the same language in their Final 2021 Decision where they removed or excluded the 69 samples from the 2014 unpublished water monitoring dataset by the Morrissey lab citing "Only results from a subset of the sites from this data set (46 out of 115 sites) were considered *relevant* for an aquatic risk assessment and are included here" (Footnote 9, Table 5, page 264). This effectively reduced the detection frequency by two thirds (from 41 to 14). This reduced the max total clothianidin concentration from 2059 ng/L to 389 ng/L. Similarly, the maximum imidacloprid concentration was also reduced from 351 ng/L to 198 ng/L.

Program (PMRA#)	Province	Type of waterbody	Limit of detection or reporting limit (µg/L)	Year	Number of sites	Number (percentage) of sites with detections	Maximum concentration (µg/L)	Number (percentage) of sites with detections exceeding the chronic effects metric[2]	Number (percentage) of sites with detections exceeding the acute effects metric[3]
Syngenta Canada (PMRA# 2947434, 3070838)	Saskatchewan	Wetlands in fields planted with thiamethoxam-treated seeds	0.0006	2018	56	1 (2%)	0.0057	0 (0%)	0 (0%)
	Manitoba, Saskatchewan, Alberta	Wetlands in fields planted with thiamethoxam-treated seeds	0.0006	2019	58	2 (3%)	0.0092	0 (0%)	0 (0%)
Morrissey, 2016 (unpublished; PMRA# 2712896)	Saskatchewan	Wetlands	0.0012	2014	46[9]	14 (30%)	0.198	7 (15%)	0 (0%)
Canadian Canola Growers Association (PMRA# 3169611)	Saskatchewan, Alberta	Wetlands	0.0032	2019	17	3 (18%)	0.0262	0 (0%)	0 (0%)
Ministry of Agriculture and Forestry (PMRA# 2842307, 2842433, 3167974)	Alberta	Rivers	0.0032	2017	28	3 (11%)	0.0632	0 (0%)	0 (0%)
				2018	23	2 (9%)	0.0447	0 (0%)	0 (0%)
		Streams	0.0032	2017	29	3 (10%)	0.0546	0 (0%)	0 (0%)
				2018	26	6 (23%)	0.0368	0 (0%)	0 (0%)
		Wetlands	0.0032	2018	18	3 (17%)	0.122	0 (0%)	0 (0%)
		Reservoirs	0.0032	2018	8	0 (0%)	0.0016	0 (0%)	0 (0%)
		Irrigation canals[10]	0.0032	2017	50	2 (4%)	0.0702	0 (0%)	0 (0%)
				2018	21	6 (29%)	0.0366	0 (0%)	0 (0%)
		Tile drains[10]	0.0032	2017	3	0 (0%)	0.0016	0 (0%)	0 (0%)
				2018	6	0 (0%)	0.0016	0 (0%)	0 (0%)
Environment and Climate Change Canada (PMRA# 2707947, 2889992)	British Columbia	Rivers, creeks, sloughs	0.00128	2014	5	3 (60%)	0.0125	0 (0%)	0 (0%)
				2015	7	3 (43%)	0.0332	0 (0%)	0 (0%)
				2016	6	6 (100%)	0.0459	0 (0%)	0 (0%)
Ministry of Agriculture (PMRA# 2842180, 3168173)	British Columbia	Rivers, streams	0.005	2017	15[11]	6 (40%)	0.74	1 (7%)	1 (7%)
				2018	15[11]	5 (33%)	0.574	2 (13%)	2 (13%)

Figure1: Excerpt of Table 5 of RVD2021-05

This further influenced the PMRA to remove the published data used in the previous assessment from Main et al. (2014, 2015 and 2016). PMRA excluded these studies "because an assessment of the detections and of the *relevance* of each of the wetlands sampled to Health Canada's aquatic invertebrate risk assessment could not be made." (PMRA Response to webinar). Therefore, this confirms that the industry's use of an unsubstantiated report had a major influence on the PMRA decision to remove data that were important to represent risk to wetlands and conditions found in the Canadian Prairies and replace this high quality data with the registrant's own preferred collection of biased water samples from selected wetlands.

It is worth noting that PMRAs own guidance document on "Determining Study Acceptability for use in Pesticide Risk Assessments – 28 Aug 2019 (Health Canada 2019)" states in Table 1 the criteria defined as "unacceptable": 1) Major study design flaws 2) For guideline studies, does not comply with the specified test guideline and does not provide any reliable or useful information or 3) Study provides no valid endpoints and no information that may be useful or informative for the risk assessment. There are no criteria to suggest that raw monitoring data must contain GPS site identifiers, which is highly unconventional as it would violate confidentiality to the landowners. Regardless, if PMRA had wanted this information for their internal use, they could have requested it from Dr. Morrissey.

3) **Aquatic invertebrate risks for multiple crops and uses with exceedance of Levels of Concern (LOC; RQ > 1) in surface waters based on both modelling and monitoring data were frequently ignored or inadequately addressed.**

The PMRA conducted extensive regional and crop-specific modelling as part of the tier 1 aquatic risk assessment to determine exposure. These data are important to generate toxicity-to-exposure ratios (TERs) or Risk Quotients (RQs) which according to the EU directive 91/414/EEC (EC 1991), typical standards for restricting registration are when TER values exceed 100, 10, or 5, depending on the nature of the effect parameters (e.g., 100 on median values for acute mortality and 5 on chronic no-effect concentrations). Notwithstanding the above comments on the setting of imidacloprid's acute and chronic effect thresholds too high using non-standard and non-protective methods (see point 1), there was still significant exceedance for foliar, seed treatment and soil applications across many regions of Canada. Exceedances of the LOC by 5-40x were apparent for seed treatments for canola, soybeans, and soil applications for brassica, potatoes, and other root vegetable crops and virtually all foliar applications. Even where the modelling and monitoring data agreed, the PMRA failed to accurately characterize the risk. For example, seed treatment uses of corn and soybean resulted in chronic RQs for freshwater invertebrates significantly above the LOC (e.g Soybean RQs of 3.4 to 9.4 across the country). Similarly, the highest concentrations measured in waterbodies where most of the corn and soybeans are grown in Canada (mainly Eastern Canada) were also consistent with the modelling results. I found it remarkable that the PMRA only focussed on the most egregious exceedances for some vegetable crops with foliar applications and ignore the other uses that the modelling and often monitoring clearly showed were high risk to aquatic invertebrates. Given the fact that any RQ>1 means the exposure is higher than the toxicity threshold, this should be a clear indication of potential risk warranting mitigation.

In disregarding the risks observed from the modelling, the PMRA validated their decision by focussing on the biased water monitoring data. It should be noted that even when sites are selected without bias, water monitoring is known to seriously underestimate exposure exceedances. For example, Xing (2013) showed that, even when taken weekly, grab water samples typically underestimate average concentrations of pesticide residues by 50% and maximum concentrations by 1 to 3 orders of magnitude. EPA showed a reasonable correspondence between their water modeling efforts and field samples. Using water monitoring information (considered by the PMRA to be higher tier and therefore better information) may not lead to the most unbiased evaluation. Therefore, monitoring data should be interpreted cautiously and considered an underestimate of actual exposures.

The use of new water monitoring data collected largely after the initial 2016 decision by the industry-led Pan Canadian Environmental Water Monitoring Group, which in the absence of more balanced and published studies, greatly undermines the confidence in the assessment. For wetlands, the PMRA stated "4671 (99%) of the samples and 599 (93%) of the site-years constitute new data not previously considered in the proposed re-evaluation decision for imidacloprid." According to RVD2021-05 Appendix X, Table 3 and 4, for wetlands, these were exclusively collected by Bayer and Syngenta and in most cases (except 18 wetland sites, p.44), sampling was done from wetlands in fields that were not treated with imidacloprid so these data completely lack relevance to the imidacloprid assessment. In addition, the Prairie region was also heavily resampled- almost exclusively by industry - to collect 4717 surface water samples from 488 different sites. This level of resampling of the same locations is highly suspect. It means on average, each waterbody was sampled 9.6x but in many instances, the same location was sampled up to 19 and 22x (Appendix X Table 2). The repeated resampling of clean sites will inappropriately bias the results in favour of non-detects.

There was also significant bias in the registrant's study wetland selection. For example, in PMRA Doc 2921987, 2921988, 2921989, 2921990, 2818734, 2818735, Bayer conducted their own water monitoring in the years following the initial 2016 decision for banning the neonicotinoids. This involved selection of 6 study wetlands that were monitored for 2 years (2017 and 2018). After initially selecting wetlands that were clean (all ND in 2017), in 2018, 1 wetland was excluded (dry) and 4/5 sites had detectable imidacloprid concentrations and 5/5 had detectable clothianidin, 3/5 had detectable thiamethoxam. The PMRA weighted these data equally in their assessment for the Imidacloprid re-evaluation even though the study design was biased to sample from sites that had no previous contamination and were in fields using clothianidin or thiamethoxam crop treatments (not imidacloprid). These same 6 wetlands were then repeatedly sampled and the authors averaged these results which grossly inflates non-detects or low detects. Ultimately due to the selective bias of industry favourable water quality data and sites, the PMRA deemed wetlands in the prairie region to have concentrations sufficiently below Levels of Concern. This is a dramatic reversal of the earlier decision and was caused by PMRA 1) lowering the chronic effect level, 2) selective removal of reputable monitoring data, and 3) inclusion and oversampling of biased registrant collected monitoring data.

4) **The PMRA only selectively recommended mitigation measures for specific crops but without scientific support of their efficacy to remove unacceptable risks to aquatic invertebrates under existing real world use patterns.**

There is an increasing trend within the PMRA to preferentially use mitigation instead of cancellation of pest control products even where risks have been clearly identified. It is remarkable to propose a phase out of all neonicotinoids in 2016 due to risks being "unacceptable" and a complete reversal of that decision in 2021 in favour of mitigation only with select minor use cancellations. The mitigation strategies in the aquatic risk assessment included 1) rate and application reductions, 2) spray buffer zones near waterbodies, 3) regulation on greenhouse releases,4) label warning changes and 5) select cancellations of minor use crops.

The use of mitigation, while seemingly desirable, lacks credible scientific evidence of efficacy to reduce or remove the identified unacceptable risks. Under real world use patterns, there is no evidence the industry will self regulate to impart riparian buffer zones or lower application rates voluntarily on farmlands. In the prairie region, cropping occurs right up to the margin of wetlands often directly into the wetland basin. While the use of vegetative buffer zones holds promise (Wade 2021), there is absolutely no guidance on the size, structure or composition of plant buffers that would be required to reduce movement of imidacloprid into surface waters to meet the regulatory threshold for reducing concentrations to below effect thresholds in any region of Canada. There is no enforcement of mitigation measures by the PMRA or any other government body in Canada. There also is no current national pesticide use or water monitoring in place to track trends or regulate any mitigation measure proposed. Therefore, the approach to mitigate instead of ban pesticides posing unacceptable risk lacks rigour in protecting Canada's aquatic and terrestrial ecosystems under the Canadian Environmental Protection Act (CEPA 1999).

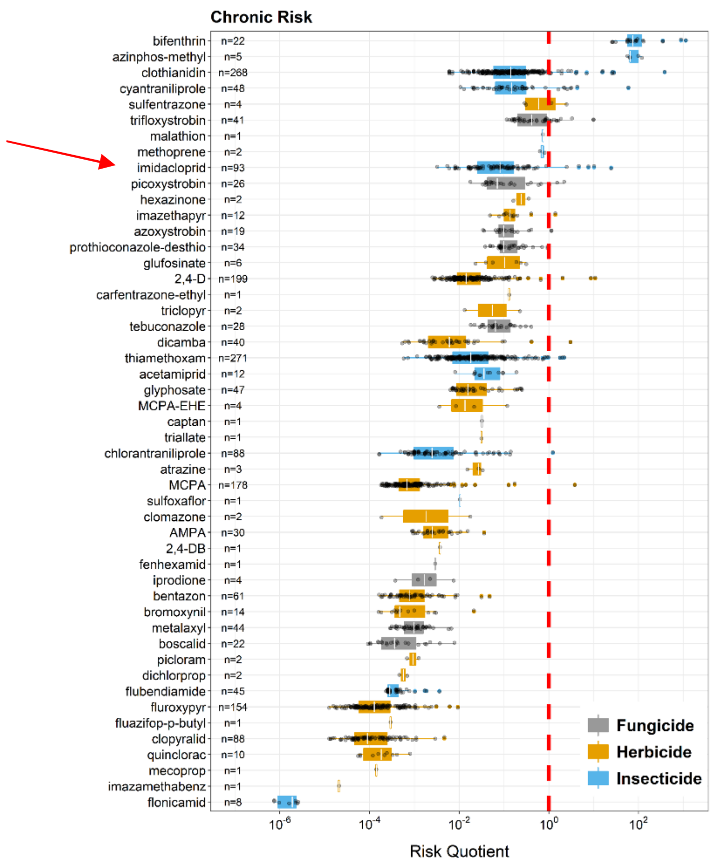
5) **Evaluation of imidacloprid alone and without consideration of known co-occurrence, cumulative action, and mixture toxicity dangerously ignores the actual exposure profiles and toxicity risk to aquatic invertebrates.**

The re-evaluation of the neonicotinoids in separate reviews – one for imidacloprid and another for clothianidin and thiamethoxam fails to adequately consider the known effects from cumulative exposures. Indeed, the PMRA used the same water monitoring datasets for the different re-evaluations showing these compounds commonly co-occur in the same water bodies as mixtures. Neonicotinoid mixtures have been tested against *Chironomus dilutus* in acute and chronic studies (Maloney et al. 2017, 2018b) indicating that effects are at least additive (and sometimes slightly synergistic) when acutely or chronically exposed causing reduced insect emergence. We also know that they are more toxic than predicted in the field than in the lab (Maloney et al. 2018a). Concentration averaging that was used in the re-evaluation ignores the published evidence that neonicotinoids behave as cumulative toxicants (Sanchez-Bayo and Tennekes 2020) and that repeated exposures can induce long term or delayed effects. For example, Stoughton et al. (2008) showed that a short term pulse of imidacloprid followed by an observation period in clean water had the same effect level as a 28 d exposure for one of the two species tested. So it is completely archaic to ignore the established mechanistic understanding of these compounds. The risk of cumulative toxicity over time and the additive toxicity from combined exposures is ignored by evaluating RQs for each neonicotinoid compound separately and as a discrete exposure event when indeed they are used on a vast array of field crops, frequently occur in common waterbodies from repeated applications and run off events, co-occur as mixtures in a wide range of surface waters, and would clearly exceed thresholds if combined under assumed time-weighted additivity (eg. as TEQs). The result is that the PMRA determination of neonicotinoid exceedances of LOCs are likely grossly underestimated.

6) **The PMRA have disregarded the wider available evidence and conclusions of reputable scientists and other international regulatory agencies that have consistently found that, where imidacloprid is used, contamination of the aquatic and terrestrial environment are frequently long term and at concentrations often exceeding toxicity thresholds and causing measurable impacts to ecosystems.**

The PMRA re-evaluation for aquatic ecosystems showed little evidence of inclusion of the vast number of published peer reviewed studies on imidacloprid's slow dissipation rates, high motility, and high environmental persistence leading to widespread chronic contamination of surface waters Morrissey et al. 2015. There is a wealth of science showing that lakes, wetlands, rivers and streams around the world experience frequent detections and/or high concentrations even at sites distanced from agricultural activity that suggests their ubiquity in the environment (eg. Jeschke et al. 2011; Goulson 2013; Simon-Delso et al. 2015; Schaafsma et al. 2015, Morrissey et al. 2015, Sheets et al. 2016; Buszewski et al. 2019), Hladik et al. 2014, Hladik and Kolpin 2016; Hladik et al. 2017, Hladik et al. 2018, Struger et al. 2017, Kuechle et al. 2019, Berens et al. 2021). This extensive body of water quality research has been the basis to which other jurisdictions and regulatory bodies such as the EU and UK have concluded that risks to aquatic invertebrates are "unacceptable". In Canada, even where we have published studies showing these risks exist under real world conditions (e.g. Main et al. 2014, 2015, Schaafsma et al. 2015, Struger et al. 2017, Cavallaro et al. 2019), the PMRA have relied almost exclusively on volumes of biased industry and provincial government supplied data produced by the industry led Environmental Working Group's (EWG) Pan Canadian Water Monitoring Group submitted after the 2016 decision.

Remarkably, these EWG data showing lower than average concentrations detected (except at select greenhouses) appears to contradict the dozens of reputable published studies that exist from within Canada and around the world. In fact, our team collected extensive wetland monitoring during the same period 2017-2019 in Prairie Canada. In contrast to the data submitted by the EWG, we found high prevalence of imidacloprid (n=93 detects) as well as clothianidin (n=268 detects) in over 300 wetlands sampled over 3 years - 2017, 2018, 2019 with approximately 20% of samples exceeding chronic risk quotients for aquatic invertebrates (Fig 2).



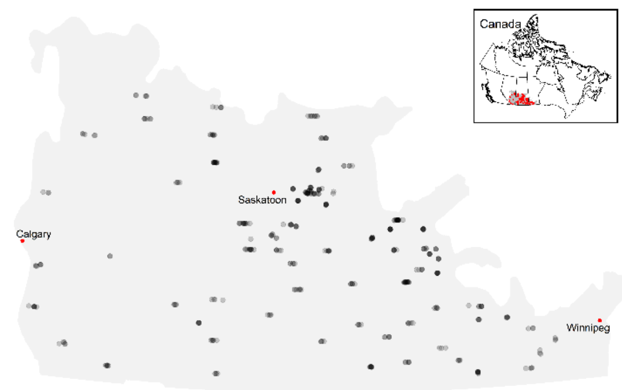


Figure 2: Wetland water monitoring data (2017, 2018, 2019) from >300 sites collected across the 3 prairie provinces showing pesticide detections (n) and exceedances of chronic risk to aquatic invertebrates. Each water sample was analysed for >220 pesticides. Each wetland was sampled once in spring (pre-seeding) and summer (post seeding). Source: Malaj and Morrissey (in prep).

The PMRA has defended the EWG monitoring studies as being more reliable than peer reviewed published data but without sufficient justification. This preference for one data source is not consistent of a “weight of evidence approach”. I further caution that more recent imidacloprid concentrations detected in surface water may appear lower on average across sites but this does not reflect changes in the exposure profile or risk to aquatic invertebrates within a site. These data simply reflect changes in the market share of the compound relative to the other neonicotinoids (clothianidin and thiamethoxam) that are now in more widespread use. In fact, the industry conducted studies typically found clothianidin and thiamethoxam in their study wetlands which was attributed to the lack of use of imidacloprid in the area (PMRA Doc 2921987, 3050879, 3050882). The PMRA has largely ignored the broad scientific consensus, based on a true weight of evidence approach, that shows imidacloprid and the other nitroguanidine compounds have unacceptable risks to aquatic ecosystems – EFSA, IUCN, RIVS, European Academies Science Advisory Council, USEPA.

Unacceptable Risks to Avian and Mammalian Wildlife

7) **The PMRA has demonstrated clear bias and undue influence by industry including an over reliance on registrant-provided avian toxicity reports and reviews, including laboratory aversion and repellency studies that are unpublished, inadequately conducted, or of limited ecotoxicological relevance.**

The PMRA showed a clear lack of scientific rigour and industry influence throughout its assessment of imidacloprid. After reviewing dozens of industry conducted studies supplied through a reading room request, it is clear that the registrant has been aware of the toxicity concerns to birds for decades. Technical reports by Bayer Crop Science indicated acute toxicity to Bobwhite quail (PMRA doc 1155842, 1155843, 1155846), Japanese quail (PMRA doc 1157924, 1157925), mallard ducks (PMRA doc 1155847, 1155848, 1182374), House sparrows (PMRA doc 1157921), Pigeons (PMRA doc 1157922), and Canaries (PMRA doc 1157923). Symptoms of intoxication include ataxia, hyperactivity, immobility, incoordination, loss of appetite, weight loss, and diarrhea at doses at or below 25mg/kg. Grey partridges are particularly sensitive with LD50 of 7mg/kg and even in 1990 (more than 30 years ago), the registrant report characterized the risk of death from ingestion of just 10g of seed which represents 25-33% of the daily food consumption stating the "*theoretical risk of poisoning is very high*." (PMRA doc 2523508). This was followed up by a field study in 1997 (PMRA doc 1191041) where the researchers observed birds on winter cereal fields with the Imidacloprid product Gaucho™ applied and concluded there was "no risk to Grey partridges or game birds" despite observing many birds foraging on the fields. It was not clear *how* they drew that conclusion.

It is also not clear how the PMRA missed the well characterized toxicity data to birds at the time of initial registration. The risks to birds and mammals was identified in the PMRA Re-evaluation in 2016. What is clear from the Final 2021 Re-evaluation is that the PMRA subsequently relied on industry analyses to 'pick and choose' what information it considered in its final assessment in order to make "refinements" to the risk assessment. For example, as described in its final 2021 decision document (RVD2021-05), the PMRA relied on a 'registrant-commissioned report' to invalidate three acute toxicity studies on the grounds that the methods did not report study designs or conditions. An examination of at least two of these studies (obtained from the US EPA and a PMRA reading room request) revealed that key methods such as dosing technique, adjuvant, dose groups, observation times, symptoms, etc were fully described. The argument that the studies were also flawed on the grounds that there were 5 birds per dose groups or less is similarly unsound and not in line with current methodology which strives to reduce animal testing where higher animal numbers are not warranted statistically when effects are clear. An examination of the Bayer Crop Science avian toxicity data show clear dose response relationships needed for unambiguous determination of an LD50. What makes this argument even more specious is that two of the three studies in question were conducted by the registrant, Bayer Crop Science. Clearly, if more details other than those provided had been needed (which is doubtful) the information could have been obtained from the sponsor of the review that excluded those very studies.

This example is given, not because these specific data points are necessarily critical to the results of the evaluation (PMRA did attach a safety factor of 10 to the lowest acute toxicity study 'left standing' in order to account for interspecies differences given that several of the acute toxicity studies were rejected) but to show that the PMRA is unduly influenced by industry pointing out which data they should favour and which they should discard which affected their ability to use an SSD approach and thus defaulting to a more primitive and perhaps less convincing effect level for birds. It was also clear that when the data appeared to be in industry's favour – such as a study where residues quickly dissipated from treated seed because of heavy rains, the PMRA cites the data as evidence of reduced risk even though … "*The rate of application of imidacloprid to the seeds, the location and number of fields, and the environmental conditions of this study were not reported*." (RVD2021-05; p.18)

Much of the PMRA refinements to the avian risk assessment appear to be derived directly from a registrant supplied report produced in Dec 2016 (PMRA doc 2744282), where Bayer Crop Science introduced a range of unsubstantiated studies citing evidence that the risks to birds is lower than predicted. For example, the report concluded there was no risk to seed eating species due to "dehusking, learned avoidance, seed burial, degradation of the pesticide, low acute mortality, and chemical repellency". Curiously, these factors were included almost verbatim in the PMRA final re-evaluation (RVD2021-05, section 3.5.2). Since all the original study references were redacted from their reference list, there is absolutely no way to confirm their source or validity of the reported studies.

8) **The PMRA has not adequately considered relevant information beyond lethal endpoints from published peer reviewed studies including sub lethal effects, indirect effects, reports of frequent exposures, and field observations of treated seed consumption in their assessment.**

Recent studies have pointed out that a major factor of bird population declines is the use of neonicotinoid insecticides and other pesticides, either because of indirect effects on habitat and food supply (Hallmann et al. 2014; Goulson, 2014) or because of direct toxic effects on the health of birds (Mineau and Whiteside, 2013). Imidacloprid has proven to not only have lethal effects, but also numerous deleterious sub-lethal effects on secondary sexual traits, physiology, immune response and reproduction in partridges at levels equivalent to <20% of treated seed in diet (Lopez-Antia et al., 2013, 2015). The probability of lethality in birds increases when the ratio between the LD_{50} and the estimated field exposure dose is low (EFSA, 2009). Compounds with higher LD_{50} or lower risk of exposure can still produce a range of sub-lethal effects such as loss of body condition, immunosuppression, neurological impairments, or endocrine disruption (Fry, 1995). In white tailed deer, exposure to imidacloprid caused significant sublethal effects on body weight, organ weight, activity behaviour, and water consumption (Berheim et al 2019). All these effects may ultimately affect survival, migration, or reproduction, with impacts on population stability.

A proprietary Bayer 2016 report (PMRA doc 2744282) was particularly revealing in presenting a synthesis (not original data) of industry findings from 33 feeding trials spanning many years which involved captive bird studies where imidacloprid or clothianidin treated and untreated seed was presented to various species of granivorous birds. In 20 of 33 (60%) trials, they report loss of body mass and many birds showed signs of "post intestinal distress" and signs of intoxication. This is consistent with studies conducted by Eng et al. 2017 and 2019 that showed severe and rapid weight loss in white crowned sparrows given 1.2 or 3.9 mg/kg imidacloprid. Eng et al. 2019 reported a 70% reduction in food consumption, 5.9% reduction in mass, 9% reduction in fat within just 6 hours post dosing. This suggests that sublethal effects to birds have been known by the registrant for several decades and this information was never considered by the PMRA during the registration or re-evaluation process.

A Bayer 2016 report placed significant emphasis on the concept of aversion and learned avoidance but did not present the actual studies for PMRA (or I) to critically evaluate these. This makes any conclusions about the aversion and learned avoidance highly suspect. For example, in summarizing several clothianidin feeding studies with Japanese quails (Barfknecht 1998 in PMRA doc 2744282) the authors suggest that birds showed "*Signs of intoxication weight loss and pathological findings" but then went on to state "Aversion to treated seed was noted. On observation of feeding behaviour only untreated was noted as consumed*". I question the validity of these statements. How can a bird that shows signs of intoxication and weight loss not be consuming (ie avoiding) the treated seed?

9) **The PMRA relied on poorly justified or incorrect assumptions in their determination that wildlife exposure to treated seeds is limited due to "spill cleanup, seed burial at planting, seed emergence and dissipation of imidacloprid and dehusking". These assumptions place wildlife at undue risk of exposure**.

Despite clear indication of risk to wildlife from treated seeds, the PMRA used poor or incorrect assumptions about the following in order to negate the findings of the screening level assessment.

Spill clean up and seed burial: The PMRA relies on a series of incorrect assumptions and puts the onus of bird protection on the farmers. By stating that: "*Growers are obliged to ensure that seed spills are cleaned up in accordance with the label.*" (RVD2021-05; p. 17) they believe they can ignore the high risks identified. To think that farmers will come down from their tractor cab to manually cover seed every time the planting equipment leaves seed on the surface is ridiculously naïve and shows a complete disregard for standard agricultural practice. This is despite the fact that researchers have already identified seed spills occur frequently in the agricultural landscape (Roy et al. 2019). The number of seeds needed to reach toxicity thresholds all represent <10% of diet, most are <1-2%. Many granivorous birds are known to scrape the soil and dig in search of seed. Therefore, the entire premise by which high toxicological risks were rejected by the PMRA show a disregard for biological reality and an undue influence of industry.

PMRA also relied on an industry review (PMRA# 2744282) to conclude that treated seed, even on the soil surface, will be avoided or consumption rates will be modified by birds searching although they also acknowledged that treated seed are frequently taken. The bait station data confirms bird consumption of multiple crops with seed treatment uses places them at undue risk even with just a few treated seeds. The PMRA relied on assumptions that birds needed to forage over a larger area to reach toxic thresholds which effectively reduced the calculated exposure by 97-99%. This assumption completely ignores the reality of how treated seed is found and consumed by animals foraging in the natural environment. Food stress, predation and competition in the wild will affect feeding rate and increase the likelihood of poisoning (Pascual et al. 1999). The assumption also fails to acknowledge that lethality can happen before sublethal toxicity affecting foraging rate sets in (Bennett 1989). Frequent small and large spills, unburied, or broadcast seeds are extremely common and would act as an attractant (particularly for flocking species) whereby individuals can rapidly ingest many seeds without the search time required to delay the onset of gastrointestinal toxicity. In fact, feeding efficiency and handling time in granivorous birds is known to be affected more by bill size, seed mass and availability of preferred seed (Marone et al. 2022), rather than search area. This suggests there may be large differences in exposures among bird species that were not captured by the PMRA risk assessment.

Seed treatment dissipation: The assumption that "*dissipation of the active ingredient from treated seed would result in negligible risk to wildlife*" (RVD2021-05; p. 17) is both naïve to the ecology of birds and wildlife and clearly not in keeping with the mode of action and behaviour of this systemic pesticide. The reliance on dissipation of the chemical washed off the seed ignores the reality that spring seeding in Canada does not simultaneously occur across the landscape and usually happens when its dry enough to seed. There are freshly seeded fields available for wildlife consumption over a period of about 2 months with adjacent fields being seeded at unpredictable intervals and that birds and mammals can forage over large areas in multiple fields at different times. Across a bird's migration- there is seeding occurring over approx 4 months representing the entire window of bird migration which is known to be a sensitive period to put on fat as fuel and when they are highly vulnerable to sublethal effects on body mass (Eng et al. 2017, 2019). After acknowledging that lethal endpoints could be reached in the ingestion of as little as one tenth of a seed in some species, a risk scenario where residues are still 50% of initial levels 5 days after seeding and in the absence of rain (RVD2021-05; p. 18) does not return a conclusion of "*negligible risk*".

The subsequent discussion in RVD2021-05 makes it clear that information on dissipation rates from seeds to seedlings was available to the PMRA. There was therefore no credible reason not to investigate this exposure scenario fully. By ignoring this potential route of exposure, the PMRA fails in its assessment of the risk to many species including notable species at risk – such as whooping cranes known to take germinating seedlings, as they migrate through the mid-continent farmland or declining agricultural species such as Horned Larks.

Dehusking: While some authors have found that dehusking by small mammals (eg. wood mice) can reduce pesticide exposure by up to 66-98% (eg. barley or sunflower seeds) (Bruhl et al. 2011), many species of birds and mammals do not dehusk seeds and some crop seeds, including those that present the greatest risk to wildlife based on availability and application rates, are not readily dehusked (eg. corn, canola). The PMRA acknowledged this in the RVD2021-05 stating "…birds do not always dehusk seed (Prosser and Hart, 2005; PMRA# 2574060)." This has been demonstrated in studies. Avery et al. 1997 found that mourning doves swallowed the seed whole. House finches, red-winged blackbirds, and boat-tailed grackles discarded the seed hulls, however, but only removed 15–40% of the initial chemical treatment. Therefore, the generic assumption that dehusking will be sufficiently protective is unrealistic and overly optimistic.

10) **The PMRA has disregarded the clear evidence that the Level of Concern for many small birds and mammals is exceeded across all major crops from consumption of treated seeds even where the lethal and sublethal dose would be reached even with tiny fraction of the diet from seed consumption. Instead, they accepted and heavily weighted their decision using a highly questionable series of "learned avoidance" studies submitted by the registrant to justify that lethal doses would not be reached.**

The assessment of seed treatment risks to birds and mammals indicated "potential risks of concern to birds and mammals were identified for all seed treatment uses. The highest RQs of each use ranged from 25 (cereal) to 11468 (lettuce), for small birds acutely exposed via diet. For mammals the highest RQs of each use ranged from 2.3 (cereal) to 1075(lettuce), for small individuals exposed chronically (p15, RVD2021-05)."

Much of the PMRAs 2021 final decision weighed heavily on industry claims that learned avoidance and aversion to imidacloprid on seeds will offer sufficient protection to birds and other wildlife. Studies with captive red winged blackbirds (Avery et al. 1993) or red legged partridges (Lopez-Antia et al. 2014) offered a choice of treated or untreated seed has shown that when providing either one on two choice tests, birds generally will consume more untreated seeds. This response, however, appears to consistently be caused by a learned aversion only AFTER poisoning and is caused to a large extent by toxicity associated post ingestional distress. There is absolutely no evidence in the wild of birds being capable of avoiding consumption of imidacloprid treated seeds through a learned response or through aversion to the taste, smell, or appearance of treated seeds. Therefore, the assumption of "learned aversion" is based solely on sublethal poisoning and presumed recovery of captive individuals.

For a bird to learn to avoid the treated seed, they would a) have to encounter and consume a sublethal dose that produced an adverse reaction, b) associate the negative physiological response (ie post ingestional distress) with some feature of the seed (colour, position, association with place) and then c) retain this information over a period of days to weeks. This series of events is highly unlikely in the wild as there would be numerous random seed piles or exposed seeds, birds would not be able to detect visual cues when the scenario changes, and a prior intoxication event would likely affect the brain's memory and learning centres. In captive experiments, Lopez-Antia et al. 2014 found that partridges were averse to imidacloprid seeds only when there was a choice of treated and untreated seed - a situation that would never be present in the wild. They also found that when the number and diversity of food sources increased, their exposure also increased and ultimately, despite some aversion, birds still consumed enough treated seeds to be poisoned (toxic effects including death were observed).

Field conditions clearly would carry higher risk for birds than captivity, both from a risk of mortality from starvation, predation or cold exposure after a poisoning event as well as higher likelihood of increased feeding rates affecting the dose. This is evidenced by Berny et al. (1999) who found high levels of imidacloprid in crops and gizzards in intoxicated partridges and pigeons found in the field compared to others testing partridges under captive conditions (Lopez-Antia et al. 2014). There are numerous reports of birds foraging on freshly seeded fields treated with neonicotinoids, finding large amounts of treated seed in the crop, gizzard or intestine, and trail camera footage at simulated bait stations which indicates the assumption of learned avoidance or aversion under field settings is likely false and clearly not protective (Roy and Coy 2020).

11) **The PMRA has improperly relied on a lack of field incident and mortality reports in Canada as a measure to support the decision without considering the high likelihood that such events would be underreported and a known paucity of systematic mortality monitoring data of neonicotinoid treated fields.**

In addition to the incorrect statements of assumptions above, the PMRA also suggested that since field incidents and reporting of mortalities were rare, this is evidence that imidacloprid related incidents and mortalities were of low risk to wildlife. I am not aware of any published mortality search studies that have been conducted on imidacloprid or other neonicotinoid treated fields to justify this conclusion that mortality risk is negligible based on lack of incidents. There have been documented cases of wild bird mortalities due to exposure to imidacloprid (Berny et al. 1999, Mineau and Palmer 2013). There is also a growing body of literature showing that wild birds and mammals are routinely exposed with high frequency of detection of the neonicotinoids in tissues (eg. see Millot et al. 2017; Lopez-Antia et al. 2016; Ertl et al. 2018, Hao et al. 2018).

Despite Health Canada's PMRA having a field incident monitoring system in place, the paucity of incident reports does not suggest that mortality or incidents are rare. Researchers have indicated that reporting of wildlife mortality from pesticide poisoning across multiple jurisdictions is underused and a lack of mortality reports are unreliable in determining risk of adverse effects from pesticides (de Shoo et al. 1999). I would suggest that the PMRA discloses how many incident reports for wildlife have been reported in the same time period for any pesticide? I suspect the number is incredibly low which is not suggestive of no risk, rather it's more probably due to a lack public awareness and education of reporting mechanisms and a lack of scouting effort to detect bird mortality on agricultural lands. We already know that small birds that die in the field are almost never found, even when systematic searches are undertaken. This is due to scavenger and predator populations, animal behavior, carcass morphology, habitat type, search intensity and searcher ability (Vyas 1999, Mineau 2005). Bird carcasses are also usually only encountered by the public in areas frequented by human activity, such as golf courses or work sites, rather than remote farm fields. Reporting of a mortality event to the appropriate authorities may initiate an investigation and I would hazard that few farmers would be inclined to actually do this, for risk of penalty. Therefore, the lack of incidents reported in Canada should not be used as evidence of acceptable risk.

12) **Even where unacceptable risks have been identified, the PMRA only recommended select mitigation measures (eg. rate reduction, label changes for seed burial), but without scientific support of their utility to protect wildlife (including SARA-listed species) under normal operational use patterns and without consideration of species ecology.**

PMRA recommended risk mitigation measures for seed treatments for birds and mammals by 1) rate reduction for corn and 2) hazard labelling to prohibit broadcast seeding and encourage seed spill clean up and burial. These mitigation measures have no scientific validity and are impractical under real world conditions to be protective of wild birds or mammals, including species at risk.

For example, the PMRA recommended a 50% reduction in rate on corn. However, I question how this would be protective for birds if a small 20g songbird only needs 1/10th of a seed to reach the LD50 under the current application rates then under the revised application rate, they would need to consume 2/10th of a seed to reach LD50. The PMRA states "Several treated seed crops have enough imidacloprid on just a few seeds or less to reach the LD50; these include: some legumes including soybean, corn (sweet and field), broccoli, cabbage and lettuce" (RVD2021-05 p.16). This is despite the fact that many species are known to consume dozens or hundreds of seeds/day which the PMRA states. In both the proposed (PRVD2016-20) and final decisions (RVD2021-05) it was demonstrated that "birds can take enough untreated seed from bait stations in a single visit to reach the screening-level effects metrics." The fact that these serious risks are acknowledged by the PMRA, and yet only minor mitigation measures were recommended clearly lacks justification.

The use of hazard labelling to encourage seed burial and to stop broadcast seeding also is not likely protective. Broadcast seeding is still promoted and used by producers including tips available by Canola Council of Canada on this practice https://www.canolacouncil.org/canola-watch/2017/05/17/broadcast-seeding-canola-tips/. Farmland birds are at risk of exposure to imidacloprid-treated seeds because sown seeds (not withstanding spills) are often not properly buried in the field. The USEPA estimated that about 1-2% of the drilled seeds remain accessible for granivorous vertebrates. In addition, spillages are routine during sowing activities (especially at field corners) and are attractive for foraging birds and mammals thereby increasing the risk of exposure and toxicity to the insecticide (Roy et al. 2019). Therefore, ingestion rates of treated seeds are highly likely to reach toxic thresholds over a short period, particularly where seed piles and spills are present - a regular occurrence in farming. I know of no farmers that would get off their seeder during spring to go and bury seeds that may have spilled or jammed in a typical 160 acre prairie field. This is a completely unrealistic recommendation and is wholly unprotective for wildlife, including at risk species. The PMRA acknowledges this concern in their own statement that "seed spills are not an uncommon occurrence" (RVD2021-05 p.15) but later and then contradicts it with the conclusion that exposure is limited due to "spill cleanup {and} seed burial at planting" (RVD2021-05 p.23).

Lack of Agronomic and Economic Benefits

13) **Despite evidence showing there is limited or no economic or agronomic value for use of neonicotinoids on specific crops, particularly imidacloprid which has largely been replaced by other systemic insecticides, the PMRA has failed to incorporate a cost-benefit approach in their risk evaluation and final determination.**

All of the ecotoxicological impacts of imidacloprid and other neonicotinoids must be weighed against agronomic benefits in most crops. The USEPA initially released a report in 2014 (USEPA 2014) that showed the economic cost benefit analysis for soybeans concluding that seed treatments offered no real economic benefit to farmers, with the exception of the southern U.S. where pest populations are more intense. Seed and agrichemical companies have strongly objected to these conclusions and, AgroInformatics (Mitchell and Conley 2017) commissioned their own study, which analyzed published information, industry field trials and insecticide screening tests and asked farmers to self-report the monetary value of seed treatments to them. Not surprisingly, they concluded that farmers reported neonicotinoids were valuable on *all* crops.

Over the next few years, independent expert entomologists have conducted systematic literature reviews and controlled studies and have conclusively warned that widespread, prophylactic seed treatment use provides negligible benefits for increasing corn and soybean yields but poses significant risk to beneficial insects - see Krupke et al 2017 and Krupke and Tooker 2020 and Mourtzinis et al. 2019. The PMRA appears to have failed to assess the true cost-benefit of these products in their weight of evidence evaluation of imidacloprid.

Failure to Protect the Environment

14) **The Precautionary Principle, while not specified in the Pest Control Products Act, should be invoked given the overwhelming evidence of risk to aquatic ecosystems and wildlife, which under Canadian law, are protected under the Canadian Environmental Protection Act, Species at Risk Act, and Migratory Birds Act.**

Canadians expect Health Canada's PMRA to respect the principles under the Canada Environmental Protection Act (CEPA 1999) which aims to maintain a high level of protection for environmental health, base decisions upon available scientific and technical data, apply preventive action at source, and follow the "polluter pays" and the precautionary principle. The Precautionary Principle is defined within CEPA as "where there are threats of serious or irreversible damage, lack of full scientific certainty will not postpone cost-effective measures to prevent environmental degradation". Although the Pest Control Products Act does not contain these specific clauses, actions by Health Canada's PMRA under the PCPA should not contradict from established principles and environmental laws as agricultural lands are part of our natural environment and wildlife require protection from damaging pesticides. There are clear indications that imidacloprid causes irreversible harm - a widely used pesticide that has high environmental persistence, water solubility and toxicity, would under CEPA fall under Schedule 1 for virtual elimination. Therefore, it is a failure of government to allow chemicals that have limited agronomic and economic benefit to be used when they clearly show unacceptable risks to Canada's biodiversity and water quality.

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