Re-evaluation of Imidacloprid

Pest Management Regulatory Agency

Overview

- Objective of webinar: Provide a general summary of the Pest Management Regulatory Agency's risk assessment for imidacloprid.

- Outline
  - Pest control product regulation in Canada
  - Re-evaluations of imidacloprid - status
  - Registered uses of imidacloprid
  - Risk assessment and management framework
  - Human health risk assessment
  - Environmental risk assessment
    - Data sources
    - Terrestrial risk assessment
    - Aquatic risk assessment

Pest Control Products Act (PCPA)

- Health Canada's Pest Management Regulatory Agency (PMRA) is responsible for the regulation of pest control products in Canada under the authority of the *Pest Control Products Act* (PCPA).

- The primary objective is to prevent unacceptable risks to people and the environment from the use of pest control products.

- All registered pesticides must be re-evaluated by the PMRA on a cyclical basis to make sure they continue to meet modern health and environment safety standards and continue to have value.

Re-evaluations of Imidacloprid - Status

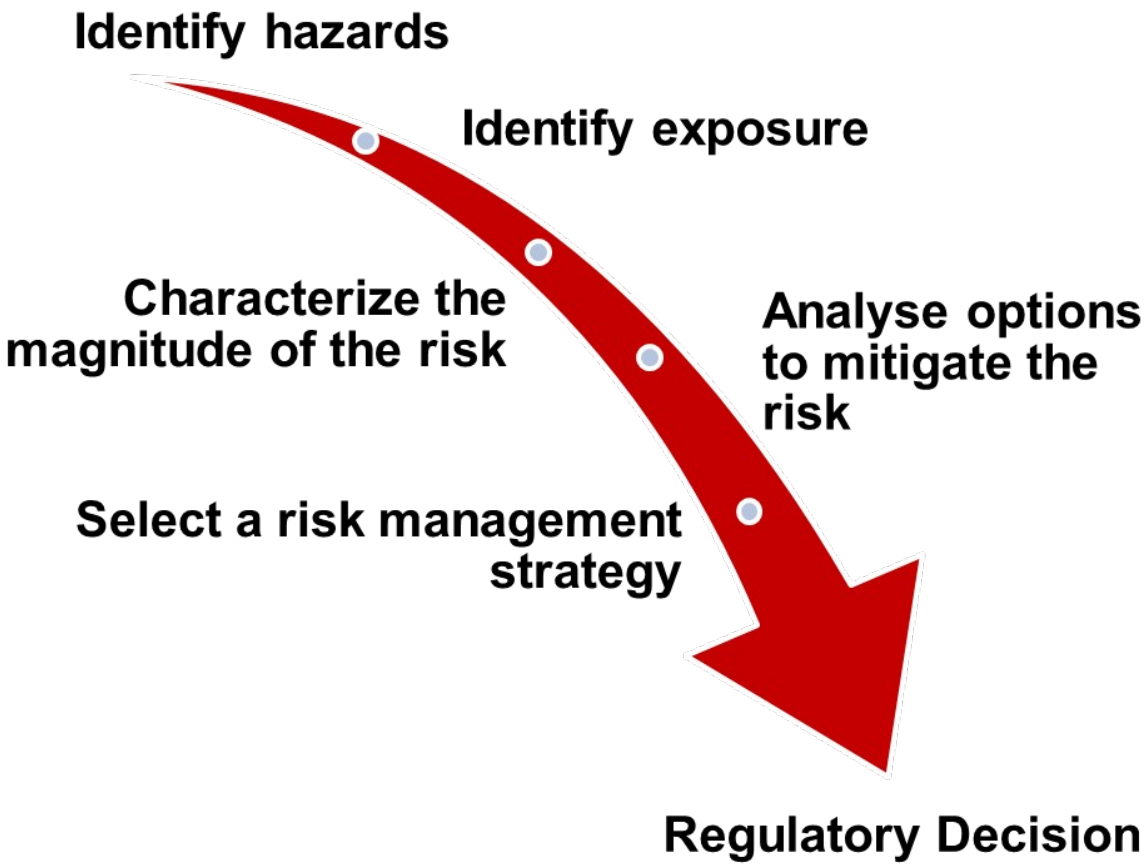
- The PMRA has now completed its cyclical re-evaluation of imidacloprid and has published its risk assessment and proposed re-evaluation decision for public comment.
  - Comment period closes February 21, 2017.

- Risks to bees and other pollinators were not a part of this cyclical re-evaluation, as they are part of an ongoing pollinator risk assessment (see Re-evaluation Note REV2016-05, *Re-evaluation of Imidacloprid – Preliminary Pollinator Assessment* for more details).
  - Proposed re-evaluation decision for pollinator risk assessment targeted for publication by December 2017.

Registered Uses of Imidacloprid

- Imidacloprid is a neonicotinoid insecticide used by commercial applicators and growers to manage insects on a large number of agricultural crops:
  - Cereals and grains
  - Legumes, pulses (such as beans, chickpeas, lentils and peas)
  - Oilseeds
  - Horticultural crops, specialty crops
- Other uses include:
  - Trees and Ornamentals
  - Turf
  - Indoor and outdoor structural sites
  - Cats and dogs
- It can be applied as a foliar spray, soil application, seed treatment or tree injection as well as in insect bait stations and spot-on applicators to cats and dogs.

Risk Assessment and Management



Risk Characterization – Tiered Approach

- Screening Level Risk Assessment
  - Goal to identify:
    - Pesticides that do not pose a concern
    - Group(s) of organisms that would not be at risk
    - Pesticides that have a potential for concern, and risk needs further characterization
  - Based on conservative scenarios, simple methods

- Higher Tiered Risk Assessment
  - Goal: further characterize the risk using more realistic scenarios
  - Risks from spray drift and runoff are assessed separately
  - Runoff is assessed based on water modelling
  - Monitoring data are considered, when available

Human Health Risk Assessment

- No human health risks of concern were identified for any of the following exposure scenarios:
  - Diet (food and water);
  - Applying the pesticide at home, or coming into contact with the pesticide after it has been applied; or
  - Applying the pesticide to agricultural crops or seeds, or coming into contact with the pesticide after it has been applied.

Data Sources for Environmental Assessment

- Registrant submitted data (> 100 studies)
- Open literature (> 200 studies)
- Unpublished data (> 20 datasets, e.g., mainly water monitoring data)
- Foreign reviews
  - California Department of Pesticide Regulation 2006: Environmental Fate of Imidacloprid
  - U.S. EPA 2008: EFED Problem Formulation for the Imidacloprid Environmental Fate and Ecological Risk Assessment
  - EFSA Scientific Report 2008: Conclusion on the peer review of imidacloprid
  - USDA 2005: Imidacloprid – Humean Health and Ecological Risk Assessment – Final Report
  - EFSA 2014: Peer review on imidacloprid (Art. 21)
  - Worldwide Integrated Assessment on the Impact of Systemic Pesticides on Biodiversity and Ecosystems: WIA reports 2014

Environmental Fate of Imidacloprid

- Persistence
  - Imidacloprid can persist in terrestrial and aquatic systems.
    - Terrestrial DT_{50}: 157 to 973 days in laboratory studies and 22 to 426 days in field studies
    - Aquatic total system DT_{50}: 30 to 159 days under aerobic conditions and about 27 days under anaerobic conditions
  - Accumulation in soil over time has been observed until a plateau is reached after about 3 years of use.
  - In aquatic systems, imidacloprid can transform rapidly in sunlight; however, this would be limited to clear shallow water bodies.
- Mobility
  - Highly soluble in water
  - Medium to high potential for mobility in soil
  - Frequent detection in surface water and groundwater based on monitoring data
- Bioaccumulation
  - Not likely to accumulate in the tissues of organisms (e.g., fish)

Terrestrial Risk Assessment

- Soil dwelling organisms
  - Imidacloprid use is not expected to pose a risk to earthworms.
  - Limited field data indicate risk to other soil dwelling organisms.

- Beneficial arthropods
  - Foliar uses of imidacloprid are expected to pose a risk to beneficial arthropods (on field and adjacent to treated fields from spray drift).
  - Limited field data indicate that other non-foliar uses (granular and seed treatments) may also pose a risk.

- Plants
  - Imidacloprid use is not expected to pose a risk to terrestrial plants.

Terrestrial Risk Assessment – Birds and Mammals

- Foliar spray
  - Imidacloprid may pose an acute and reproductive risk to small birds feeding on insects at the highest foliar use rates.

- Seed treatments
  - Ingestion of treated seed may pose an acute and reproductive risk to birds and small mammals.
  - For most treated seeds, the number of seeds needing to be consumed to elicit intoxication may be extremely small (<1 seed to up to 5 seeds).
  - There is uncertainty whether or not certain treated seeds would be an attractive food source for birds and mammals.

Terrestrial Risk Assessment – Birds and Mammals

- Commercial granular formulations for turf
  - Exposure to imidacloprid from ingestion of granules may pose a risk to birds.
  - Because granular imidacloprid products are watered in after application, the potential exposure period for which birds would have an opportunity to ingest a harmful amount of granules is expected to be of short duration.
  - Current labels for commercial granular products require irrigation or rainfall within 24 hours of application of granules.

Aquatic Risk Assessment

- Use of imidacloprid is not expected to pose a risk to:
  - Aquatic plants
  - Freshwater or marine fish
  - Amphibians
  - Algae

- Acute and chronic risks were identified for aquatic invertebrates.

Aquatic Invertebrates – Laboratory Data

- Sufficient toxicity data were available to determine HC_5 values for freshwater (acute and chronic) and marine/estuarine invertebrates (acute only).

	Most sensitive species	Least sensitive species	HC_5
Freshwater			
Acute	0.65 µg/L (96h LC_{50}, mayfly, *E. longinamus*)	88 µg/L (48h LC_{50}, *D. magna*)	0.36 µg/L (32 species)
Chronic	0.12 µg/L (28d EC_{50} immobility, mayfly, *C. dipterum*)	20 µg/L (21d NOEC mortality, *D. magna*)	0.041 µg/L (10 species)
Marine/estuarine			
Acute	10 µg/L (24h LC_{50}, blue crab, *C. sapidus*)	>145 µg/L (96h LC_{50}, Eastern oyster, *C. virginica*)	1.37 µg/L (6 species)
Chronic	0.33 µg/L (28d NOEC reduced growth, mysid, *M. bahia*)		Insufficient data

Aquatic Field Data

- Mesocosm studies
  - Can allow determination of effects at community level and recovery time.
  - 22 available studies, conducted under a variety of conditions simulating lotic and lentic environments.

- Collective findings
  - Decreased species diversity and abundance of the invertebrate community
  - Mayfly species are particularly sensitive
  - In studies of sufficient duration, communities recovery shown within 6-8 weeks after the last application.

Aquatic Field Data

- Collective interpretation of mesocosm data – difficult and problematic

- Deficiencies
  - Inadequate number of exposure concentrations (e.g., 1 or 2)
  - Population/community level effects were not measured
  - Application regime not representative of a most conservative exposure scenario
  - Inadequate study duration to measure recovery
  - Low abundance of sensitive species prevented statistical evaluation of a NOEC and recovery (e.g., mayfly species)

  Mesocosm data confirm laboratory data. However, based on deficiencies and the absence of a suitable community endpoint (NOEC), mesocosm data were not directly useful for risk assessment

- Similar conclusions were drawn by EFSA(2014) regarding mesocosms (deficiencies, etc.)

Comparison of Endpoint Values

Source	Reference value or endpoint (µg/L)	Justification
PMRA	Acute: 0.36	HC_5 - LC_{50}/EC_{50} values for 32 invertebrate species
	Chronic: 0.041	HC_5 - EC_{50} values for 10 invertebrate species
CCME (2007)	0.23	Interim water quality guideline for the protection of freshwater life - 28d LOEC of 2.25 µg/L for *C. riparius* multiplied by a safety factor of 0.1.
EFSA (2014)	Acute: 0.49	HC_5 - EC_{50} for 15 insect species
	Chronic: 0.027	HC_5 - EC_{10} data for 3 insect species
EFSA (2008)	0.2	NOEC = 0.6 µg/L from a 21day German microcosm study. An assessment factor of 1 -3 applied based on expert deliberations.
EPA (2014)	1.05	Aquatic life benchmark - methodology uncertain
RIVM (2008) Netherlands	0.067	Maximum permissible concentration (MPC) for long term exposure derived from the lowest NOEC value for chronic toxicity studies. Assessment factor of 10 applied.
RIVM (2014) Netherlands	0.0083	Updated MPC for long term exposure derived from chronic studies using SSD approach and HC_5 applied to $NOEC/LC_{10}/EC_{10}$ values with an assessment factor of 3 applied.
Mineau and Palmer (2013)	0.0086	The higher of two empirically-determined acute chronic ratios applied to the most sensitive of 8 aquatic species
	0.029	HC_5 from SSD generated using NOECs from studies of 7 single species and 1 species assemblage.

Risk to Freshwater Invertebrates

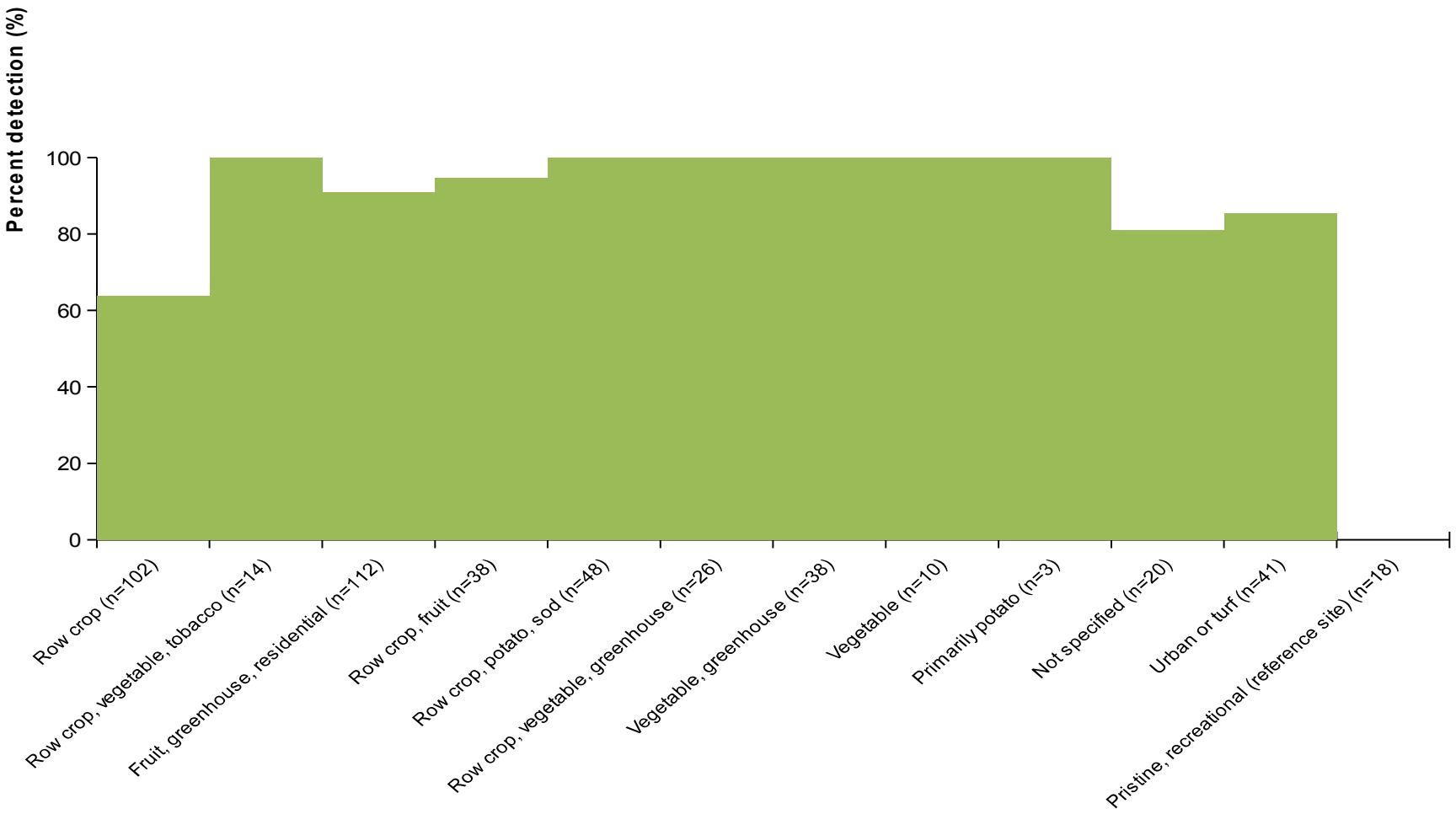
Exposure	Endpoint (µg/L)	Exposure Concentration (µg/L)		Risk Quotient	Risk of Concern
Acute	HC_5 = 0.36	Screening level	73.4	203	Yes
		Foliar spray drift	0.34 - 30	0.9 - 83	Yes
		Runoff modelling	1.8 - 52	5.0 - 144	Yes
		Surface water monitoring	11.9	33	Yes
Chronic	HC_5 = 0.041	Screening level	73.4	1790	Yes
		Foliar spray drift	0.34 - 30	8.3 - 732	Yes
		Runoff modelling	0.87 - 24.9	21 - 607	Yes
		Surface water monitoring	1.26	31	Yes

Risk to Marine Invertebrates

Exposure	Endpoint (µg/L)	Exposure concentration (µg/L)		Risk Quotient	Risk of Concern
Acute	HC_5 = 1.4	Screening level	73.4	54	Yes
		Foliar spray drift	0.34 - 30	0.2 - 22	Yes
		Runoff modelling	1.8 - 52	1.3 - 38	Yes
		Surface water monitoring	Data are not robust enough to use in a risk assessment		
Chronic	28d NOEC = 0.33	Screening	73.4	222	Yes
		Foliar spray drift	0.34 - 30	1.0 - 91	Yes
		Runoff modelling	0.87 - 24.9	2.6 - 75	Yes
		Surface water monitoring	Data are not robust enough to use in a risk assessment		

Sampling Locations from Robust Canadian Datasets – Quebec, Ontario and Saskatchewan

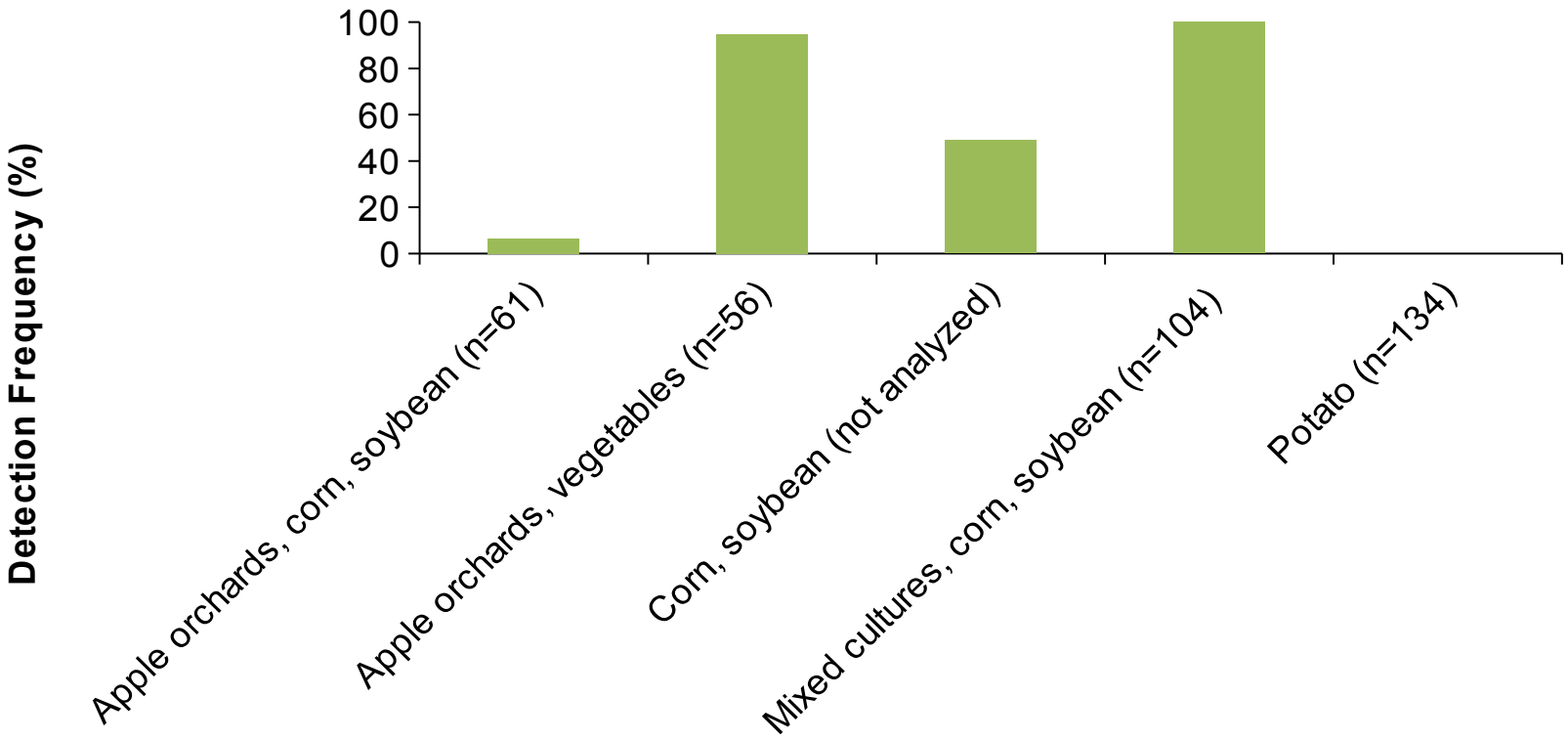
Ontario – Imidacloprid Detection Frequency



Comparison of Imidacloprid Monitoring Data from Southwestern Ontario with Aquatic Toxicity Endpoints

	Overall	Fruit, greenhouse, residential	row crop, or row crop, fruit	Row crop, potato, sod	Row crop, vegetable, greenhouse	Row crop, vegetable, tobacco	Vegetable	Vegetable, greenhouse
N samples	391	112	140	48	26	14	10	38
Maximum (µg/L)	10.4	0.486	0.076	0.028	4.03	0.005	0.097	10.4
Average (µg/L)	0.217	0.051	0.006	0.004	0.913	0.003	0.027	1.419
	Acute endpoint HC_5 = 0.36 µg/L							
N detects (% of samples) exceeding endpoint	44 (11%)	3 (3%)	0 (0%)	0 (0%)	15 (58%)	0 (0%)	0 (0%)	26 (68%)
RQ using maximum	28.9	1.4	0.2	0.08	11.2	0.01	0.3	28.9
	Chronic endpoint HC_5= 0.041µg/L							
N detects (% of samples) exceeding chronic endpoint	111 (28%)	41 (37%)	4 (3%)	0 (0%)	26 (100%)	0 (0%)	2 (20%)	38 (100%)
RQ using average	5.3	1.3	0.2	0.1	22.3	0.06	0.7	34.6

Quebec – Imidacloprid Detection Frequency



Comparison of Imidacloprid Monitoring Data from Quebec with Aquatic Toxicity Endpoints

	Overall	Corn, soybean	Potato and mixed vegetable/potato
N samples	306	165	141
Maximum (µg/L)	7.77	0.11	7.77
Average (µg/L)	0.054	0.004	0.112
	Acute endpoint HC_5= 0.36 µg/L		
N detects (% of samples) exceeding the acute endpoint	2 (<1%)	0 (0%)	2 (1%)
RQ using maximum	21.6	0.3	21.6
	Chronic endpoint HC_5= 0.041 µg/L		
N detects (% of samples) exceeding the chronic endpoint	66 (22%)	2 (1%)	64 (45%)
RQ using average concentration	1.3	0.1	2.7

Comparison of Imidacloprid Monitoring Data from Saskatchewan with Aquatic Toxicity Endpoints

	Overall	Spring 2012	Summer 2012	Fall 2012	Spring 2013	Summer 2013	Spring 2014
N samples	683	138	134	80	90	166	75
Maximum (µg/L)	0.256	0.03	0.256	0.001	0.005	0.196	0.001
Average (µg/L)	The sampling regime did not allow for a longer term exposure concentration within a waterbody.						
	Acute endpoint HC_5= 0.36 µg/L						
N detects (% of samples) exceeding the acute endpoint	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
RQ using maximum	0.7	0.08	0.7	0.002	0.01	0.5	0.005
	Chronic endpoint HC_5= 0.041 µg/L						
N detects (% of samples) exceeding the chronic endpoint	13 (2%)	4 (3%)	13 (10%)	0 (0%)	0 (0%)	9 (5%)	0 (0%)
RQ using the single highest detection	6.3	0.7	6.3	0.01	0.1	4.8	0.01

Risk to Aquatic Invertebrates – Monitoring Data

- Based on recent Canadian water monitoring data
  - Imidacloprid levels in certain areas of intensive agriculture pose risks of concern to aquatic invertebrates (acute and chronic).
  - Higher concentration and more frequent exceedances associated with:
    - Greenhouse and vegetable areas in Ontario
    - Potato uses and mixed vegetable areas in Quebec
- Risks cannot be readily attributed to a specific use
  - Regions monitored represent multiple crops and application methods

Risk to Aquatic Invertebrates – Monitoring Data

- Other considerations
  - Row crops (mainly corn and soybeans) in Ontario and Quebec
    - No exceedances of acute and few exceedances of chronic endpoints
    - Imidacloprid is not typically used on corn and soybeans.
  - Oilseed and cereals crops in Saskatchewan
    - No exceedances of acute and few exceedances of chronic endpoints
    - Use of neonicotinoids in the prairies is primarily as a seed treatment.
    - Seeds for many prairie crops including canola tend to be treated with insecticides other than imidacloprid.

Monitoring Data Uncertainties and Challenges

- Areas of Canada where monitoring data are lacking
  - Detection patterns are expected to be similar to what has been found in areas with similar uses.
- Challenges in interpreting the available information
  - Land uses differ between data sets.
  - Land use information is often not available.
  - Multiple uses within some watersheds
- Non-detections difficult to interpret
  - Non-transport of the chemical from the site of application
  - Lack of use of the chemical in the area studied
  - Lack of sensitivity of the analytical method
- Monitoring data likely provide an underestimate of actual exposure

Risk Mitigation for Aquatic Invertebrates

- Current labelling requirements include:
  - Precautionary statements on all labels to reduce runoff into adjacent waterbodies
  - Prohibition of releases of imidacloprid from greenhouses into surface waters

- Despite current labelling requirements, imidacloprid levels posing a risk to aquatic invertebrates have been detected in Canadian waterbodies located in areas of intensive agriculture (including greenhouses).

Risk Mitigation for Aquatic Invertebrates

- Effective risk mitigation through a use-reduction strategy would be difficult to achieve:
  - Difficult to identify specific uses causing elevated levels in water because much of the monitoring data come from mixed-use areas of agriculture.
  - Cannot accurately predict how much use reduction would be necessary to achieve acceptable levels.
  - Extensive and comprehensive water monitoring information would be required to confirm that risk reduction targets are being achieved.
  - Cannot estimate how long a reduction in environmental levels would take.
  - Future intensification of use may lead to additional risks of concern.

Next Steps

- The PMRA invites the public to submit written comments on the proposed re-evaluation decision.
  - http://www.hc-sc.gc.ca/cps-spc/pest/part/consultations/_prvd2016-20/index-eng.php
- The consultation period is open for comment from 23 November 2016 to 21 February 2017.
- Written comments can be sent to PMRA.Publications@hc-sc.gc.ca or

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Questions