Post-Market Newsletter

In this issue:

- Neonicotinoids
- ➤ Label changes now in effect for several chemicals
- Product cancellations
- ➤ Upcoming post-market consultations and decisions in 2021
- Earlier access to test data for post-market consultations
- ➤ Improvements to the reevaluation program

Welcome!

We've heard from a number of stakeholders that they would like to receive updates on Health Canada's post-market activities. So here it is... A newsletter!

The newsletter will be issued periodically and report on the implementation of post-market decisions, ongoing consultations and projects that impact the post-market program.

Check out the latest work plan!

On June 22, 2021, the latest work plan for post-market reviews was published.

The work plan let's you know when to expect new re-evaluations to start and when consultation and decision documents will be published.



Neonicotinoids

Health Canada has launched a new website on the <u>neonicotinoid insecticides</u>. There have been a number of activities related to the review of these products in recent years, so an infographic titled <u>Neonicotinoids in Canada</u> has been created to outline what's been done to date. Earlier in 2021, the following assessments were completed (including some of the risk mitigation measures that are required):

Imidacloprid Thiamethoxam Clothianidin The special review decision for The re-evaluation decision for The special review decision for imidacloprid required a reduction thiamethoxam introduced clothianidin resulted in in application rates, removal of application rate reductions for application rate reductions for certain application methods, many crops and cancellation of many crops and cancellation of cancellation for several crops, soil drench on potato and foliar in-furrow application on potato and new label precautions. In application on lowbush and seed treatment for field blueberries. As of 31 March 2023. addition, measures to prevent sown leafy vegetables and release from greenhouses is now users must follow the updated bunching onion. As of 31 March required. As of 19 May 2023, label. 2023, users must follow the users must follow the updated updated label. labels.

Label changes in effect for several chemicals

Active Ingredient	Label Changes ¹
N-Octyl bicycloheptene dicarboximide (MGK-264)	 Limits to product concentrations, application rates and amounts handled per day Space spray restrictions Must comply with label directions in PRO2018-04 Label changes in effect as of August 2021 See cancellation table below
<u>Triforine</u>	 PHI of 60 days for cherries, peaches, plums and prunes Updated PPE, REIs, PHIs and spray drift statements Updated spray buffer zones and environmental hazard statements Label changes in effect as of August 2021
<u>Permethrin</u>	 Cancellation of electric mistblower and total release fumigating fogger applications Limited mushroom house application timing Reduced application rate for residential yards Increased PPE and REIs and updated plant-back intervals Additional statements for products used in residential areas Reduced number of applications on tomato Environmental hazard statements for pollinators, beneficial insects, birds and aquatic organisms Updated spray buffer zones and run-off precautions (eg. vegetative filter strip) Label changes in effect as of August 2021
Iron (present as ferrous sulfate monohydrate or ferrous sulfate heptahydrate)	 Updates to the REI and drift statements Environmental precaution statements Label changes in effect as of September 2021
Clodinafop- propargyl	 Closed mix/load when handling >15 kg per day Updated PPE, PHIs, plant-back interval and buffer zones Runoff reduction precautions Label changes in effect as of January 2022
<u>Folpet</u>	 Cancellation of azalea stem soak Updated PPE, REIs, buffer zones and plantback intervals Acceptable greenhouse uses clarified Restrictions for number of applicationts for cut flowers and tomatoes not grown for processing Field sprayer, airblast and runoff mitigation Aerial application prohibited Wettable powder products: Cancellation of apples, crab apples and cranberries and application restrictions Label changes in effect as of January 2022

Follow the links for more information!

Find your current labels Here

PMRA's Smart Phone Label App



¹ The label changes presented are provided as a brief summary for your information and may not cover all required changes. Consult the current product label for specific restrictions, precautions and directions for use.

More label changes in effect!

Active Ingredient	Label Changes ¹
<u>Uniconazole-P</u>	Cancellation of greenhouse cut flowers
	Prohibition of handheld mist blowers/airblast and handheld foggers
	Updated PPE
	Label changes in effect as of February 2022
Streptomyces strain K61	Greenhouse use only
	Updated PPE and REI statements
	Label changes in effect as of February 2022
<u>Dimethomorph</u>	Mist and fog application prohibition
	Updated REIs, buffer zones and spray drift statements
	Aquatic organism, runoff and groundwater precautions
	Label changes in effect as of February 2022
<u>Acephate</u>	Cancellation of potato use
	Cancellation of soluble powder products
	 Prohibition of handheld mist blowers and handheld foggers
	 Prohibition of foliar application to residential trees and ornamentals
	Reduced rates and number of applications and increased application
	intervals
	Label changes in effect as of April 2022



Cancellation notification! This is the Last Year of Use!

Active Ingredient	What's Cancelled
<u>Ziram</u>	All agricultural products will be phased out as of December, 2021
<u>Thiram</u>	 All foliar uses Sweet potato sprout root dip Seed treatment of grasses, dry bulb onion, alfalfa grown for forage and importation of these treated seeds into Canada Commercial seed treatment of wheat, barley, oats, canola, mustard, rapeseed, rye, triticale and corn On-farm liquid hopperbox/seed drill treatment for all crops Revocation of all MRLs of thiram including those established for imports Phase-out period ending December, 2021
<u>Ferbam</u>	All agricultural products being phased out as of December, 2021
N-Octyl bicycloheptene dicarboximide (MGK-264)	 Domestic-class products: cancellation of dust products, pressurized products for use as a metered-release space spray and products with concentrations greater than 0.4% Commercial-class products with concentrations greater than 3.35% Phase-out period ending August, 2022
<u>Permethrin</u>	 Raid Fumigator Fumigating Fogger Phase-out period ending August, 2022

Upcoming post-market consultations and decisions

Consultation on proposed decision	Final decision
Chlorothalonil Special Review Ancymidol Dried Blood Flucarbazone Octadec-9-enoic acid Trinexapac-ethyl Kaolin P-menthane-3,8-diol Abemectin Atrazine Special Review Potassium Dimethyldithiocarbamate Sodium Dimethyldithiocarbamate Corn Gluten Meal Predacide cluster: Sodium Monofluoroacetate and Strychnine S-metolachlor and R-enantiomer 1-Methylcyclopropene 1- or 3-Monomethylol-5,5-dimethylhydantoin 1,3-Bis(hydroxymethyl) -5,5-dimethylhydantoin	Naled Special Review Cyromazine Iprodione Special Review Cymoxanil Paint Cluster: Sodium omadine, Chlorothalonil, Dazomet, Folpet, Ziram and Diodofon Special Review Clothianidin, Thiamethoxam and Imidacloprid Squash Bee Special Review Pentachlorophenol Special Review

Re-evaluation Note <u>REV2021-03</u>, Pest Management Regulatory Agency Re-evaluation and Special Review Work Plan 2021-2026

NB: Some publications have been delayed due to the pause during the federal election.

Earlier access to test data for post-market consultations

In 2019, PMRA undertook a consultation on a proposal to expand access to confidential test data (CTD) to the proposed decision stage of post-market reviews. On May 31, 2021, PMRA published a summary of comments received on the 2019 consultation: Consultation Summary: Consultation on Inspecting Confidential Test Data for Post-market Reviews in the Reading Room, Discussion Document DIS2019-01.

Following consideration of the comments received from stakeholders, the PMRA will be moving ahead with the proposal to expand access to CTD and providing the public, upon request, with the opportunity to inspect this data at the proposed decision stage for post-market reviews.

As of January 1, 2022, Canadians can access CTD once the proposed post-market decision documents are published for public consultation.

Information on how to request CTD can be found online:

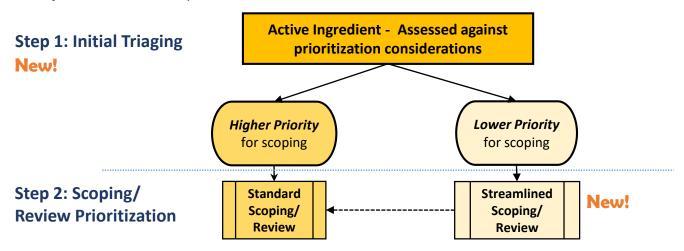
https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/public/protecting-your-health-environment/public-registry.html#ictd.

Improvements to the re-evaluation program

Risk-based approach to prioritization

PMRA has implemented a risk-based approach to prioritize re-evaluations (refer to the work plan for more information). This allows PMRA to concentrate effort and resources where its needed, higher priority re-evaluations, while taking a stream-lined approach to lower priority re-evaluations to ensure that all re-evaluations are completed in a timely manner.

Considerations in determining re-evaluation workflow include but aren't limited to: nature and outcome of existing health and environmental concerns, information from incident reports and other jurisdictions, the use pattern and scale of use.



Improvements to the re-evaluation program

Requirement for study abstracts for the list of available studies (New in 2021-2022)

As part of the re-evaluation process, PMRA requires registrants to submit lists of available studies (titles only) at the initiation phase, related to their active ingredient². This information helps determine what data may need to be called-in for review. However, it has been challenging for PMRA based on study titles alone, to make a determination of the relevance of a particular study. In order to address this concern, for new re-evaluations initiated after <u>April 1, 2021, registrants are now required to submit the study abstract or "executive summary"</u> of each study title as per PMRA or US EPA evaluation templates when they submit their list of available studies.

Specifically for higher priority re-evaluations as outlined in the annual work plan (REV2021-03), registrants are being requested to extract the executive summaries (or abstracts) from individual studies and submit them to PMRA. This will allow PMRA to identify relevant studies for the re-evaluation in a more timely manner and will assist in the overall efficiency of the post-market program.

As an interim measure, PMRA has extended the timelines for submission of the data list and executive summaries (abstracts) from the current 30 days to 90 days for the 2021-22 re-evaluation initiations. Registrants are also given guidance related to the executive summaries with the initiation letter.

The executive summary sections of the PMRA <u>Evaluation Templates</u> is to be provided with each study title.

² As described in DIR2016-04, Management of Pesticides Re-evaluation Policy