PEST MANAGEMENT REGULATORY AGENCY

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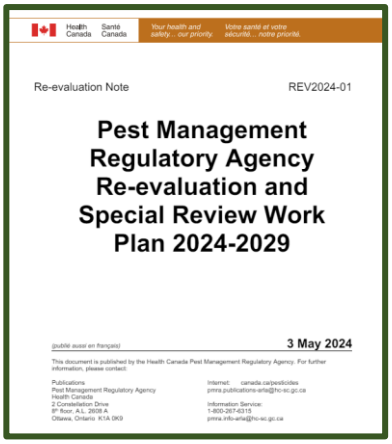
Newsletter

Here is the latest news from Health Canada's Pest Management Regulatory Agency (PMRA).

The newsletter is issued periodically and reports on the implementation of post-market decisions, important Agency initiatives and projects, upcoming consultations and information to help registrants and stakeholders navigate PMRA business processes.

In this issue:

Check out the latest post-market review work plan!



Re-evaluation Note REV2024-01

Pest Management Regulatory Agency Re-evaluation and Special Review Work Plan 2024-2029

3 May 2024

On May 3, 2024, the latest work plan for post-market reviews was published. The work plan (REV2024-01) lets you know when new re-evaluations are expected to start and when consultation and decision documents are planned to be published.

Senior management updates at PMRA

Recently, PMRA's senior management structure was modified. Manon Bombardier is now the Assistant Deputy Minister at PMRA working closely with Frédéric Bissonnette, who has taken on the new role of Senior Director General of Regulatory Science and Operations, and Lindsay Noad, who has taken on the role of Senior Director General, Horizontal Policy and Integration.

Jason Flint is now acting Chief Registrar (Director General of Registration Directorate) at PMRA.

In the Health Evaluation Directorate, Director General Connie Moase has retired following a long and distinguished career at PMRA. As of May 13, 2024, Minoli Silva has taken over Director General duties while a long-term replacement is selected.

In the Environmental Assessment Directorate, Director General Janine Murray has retired after many dedicated years throughout the public service. Acting Director General duties will be assumed by Heather Simmons until a permanent replacement is chosen.

We know that stakeholders will join us in wishing Connie and Janine all the best in their well-deserved retirements!

Health Canada Santé Canada

Transformation updates

Although the initial funding period for the development of Transformation initiatives at PMRA has passed, the projects and new policies that have been adopted are now being implemented and the work is moving forward. Follow the links for the latest information on various projects under Transformation at the PMRA, including Continuous Oversight, Water Monitoring and the Targeted Review of the Pest Control Products Act.

On April 16, the Government of Canada's 2024 budget included $39 million to Health Canada and Agriculture and Agri-food Canada (AAFC) over the next two years, to strengthen the pesticide regulatory system, and continue to monitor and promote sustainable pesticide use in Canada.

IT modernization update

PMRA is in the process of modernizing its information technology (IT) systems. Accomplishments last year included the first release of a web-based eIndex Builder, new HTML forms and tools, and stakeholder engagement associated with a new pesticide use information intake form and structured label. This year, we plan to update the secure web portal with new functionalities designed to more seamlessly manage and share data and documents. Finally, we will continue to develop the structured label by taking advantage of user experience through a proof-of-concept exercise.

PMRA is aware of many issues and limitations with the first release of the new web-based eIndex Builder. Many of the issues will be resolved with the next update later in the summer, and we expect the release of the new portal will address the remaining limitations users are experiencing. PMRA will continue to accept PRZ files that were made using the old desktop version in the meantime. However, be aware that the old version may not contain DACOs for some new forms.

The vision is to transform the PMRA systems, moving from a legacy document-based process to a future with an end-to-end data centric business model, where all regulatory processes are managed within an interconnected system. This will enable registrants to file and manage their applications via an external facing portal, facilitate a more efficient data-driven scientific review process and allows PMRA to more effectively release the data that supports our reviews, thus improving transparency.

For more information about the changes and release dates, please refer to the new IT Modernisation webpage or contact us at pmra.it.modernisation.ti.arla@hc-sc.gc.ca.

Residual solvents

The PMRA has established limits for certain residual solvents of concern in technical grade active ingredients (TGAIs) to minimize their levels in the manufacture of pest control products (DACO 2.13.4), in order to protect the health of Canadians and the environment.

Heavy metals

The PMRA has established limits of quantitation (LOQs) for the methods used to measure heavy metals considered to be of concern in TGAIs to minimize their levels in the manufacture of pest control products (DACO 2.13.4), in order to protect the health of Canadians and the environment.

Chemistry requirements for Food Chemicals Codex (FCC) grade TGAIs

The PMRA has developed attestation forms to streamline reviews of food-derived technical and end-use products in order to introduce efficiencies to the review process.

6302 - Attestation form for mycotoxin levels in Technical Grade Active Ingredient (TGAI) or Integrated System Product (ISP)
6303 - Attestation form for chemistry requirements for Food Grade Edible (FGE) Technical Grade Active Ingredient (TGAI) or Integrated System Product (ISP)
6304 - Attestation form for chemistry requirements for End-use Product (EP) or Manufacturing Concentrate (MA) containing Food Grade Edible (FGE) active ingredient(s)

In addition, applicants are required to submit levels of residual solvents of concern used in the manufacturing or extraction process of Food-Grade (Food Chemicals Codex - FCC) TGAI (technical grade active ingredient) products when they are not included in the FCC monographs. The analysis must be conducted using an appropriate validated method, such as High-Performance Liquid Chromatography (HPLC) or Gas Chromatography (GC). The levels of solvents of concern in TGAIs must be shown not to exceed the established limits.

The analysis of solvents of concern is not required for Food-Grade Edible (FGE) TGAI products.

Information note regarding dsRNA-based pesticides

The PMRA has published an Information note regarding dsRNA-based pesticides - Canada.ca to communicate the current regulatory status of double-stranded ribonucleic acid (dsRNA)-based pesticides, and the current approach to their regulation under the *Pest Control Products Act*.

New minor use registrations for spotted lanternfly

Spotted lanternfly (SLF), *Lycorma delicatula*, is an invasive sap-feeding planthopper with the potential to harm agriculture and forestry in Ontario and is a quarantine pest in Canada. If you see a suspected spotted lanternfly, Report your Sightings to the Canadian Food Inspection Agency. Follow this link and see this infographic for more information on SLF.

PMRA has been involved in engagement and advisory activities involving SLF through working groups with other government departments and grower groups for a number of years. In 2023, PMRA approved an emergency registration for one year for the active ingredient flupyradifurone on ornamental crops. Also in 2023, two minor use registrations were approved: the active ingredient fenpropathrin for use on several horticulture crop groups and the active ingredient potassium salts of fatty acids for use on certain horticultural and ornamental crops. This year, two additional minor use registrations will be completed for flupyradifurone for use against SLF, one for a variety of horticultural crop groups and one on outdoor ornamentals.

Products registered and to be registered for spotted lanternfly

Product	Active ingredient	Use site[1]
Danitol Insecticide Reg. No. 33817	Fenpropathrin	Pome fruits (Crop Group 11-09), Stone fruits (Crop Group 12-09)
Kopa Insecticidal Soap Reg. No. 31433	Potassium salts of fatty acids	Fruit trees Grapes Ornamental and shade trees Outdoor flowering, foliage, and bedding plants
Sivanto Prime Insecticide Reg. No. 31452	Flupyradifurone	Pome fruits (Crop Group 11-09), Stone fruits (Crop Group 12-09), Small fruits vine climbing, except fuzzy kiwifruit (Crop Subgroup 13-07F)
Altus Insecticide Reg. No. 33176	Flupyradifurone	Outdoor nursery and landscape ornamentals

[1] See product labels for complete directions for use, precautions and restrictions.

Genetic pest control - report by the Council of Canadian Academies

On November 8th, 2023, the Council of Canadian Academies published the report Framing Challenges and Opportunities for Canada. This report highlights the findings of the expert panel on regulating gene-edited organisms for pest control (or “genetic pest control”). The report concluded that while gene-editing may be a useful tool for pest control in Canada, further research and development is needed to explore the potential risks involved.

Modernizing the aerial spray deposition model

As of June 1, 2024, the PMRA will be updating versions of the spray deposition model used to determine regulatory aerial spray buffer zones (BZs) from AGDISP version 8.21 to 8.29. The PMRA has evaluated several updated versions of AGDISP and considers version 8.29 to be the most suitable for regulatory use. AGDISP version 8.29 will be used to determine the aerial BZs on all new active ingredients, upcoming re-evaluations, and the addition of new aerial applications to registered actives currently permitted for ground application only. All aerial BZs for other currently registered pesticides will continue to be determined with AGDISP version 8.21 until the active undergoes re-evaluation.

In addition to updating the model version, several of the model inputs will also be updated to reflect current use scenarios, including:

- **Aircraft** - To reflect the current most popular aircraft in Canada, the default aircraft will be changed to the Air-Tractor AT502B (fixed-wing) and the Bell 206 B Jet Ranger III (rotary-wing).
- **Wind speed** – To better align with labelled wind speeds, the default modelled wind speed will be changed from 4.47 m/s (10 mph) to 4.44 m/s (16 km/h).
- **Surface roughness** – To represent a larger majority of field crops grown in Canada, surface roughness for crops will be changed from 0.1 (~ 3 m crop) to 0.01 (~ 0.3 m crop). Surface roughness is related to the surface texture and affects the wind profile that determines the downwind transport of released material.
- **Swath offset** – To align with current pilot practice, the swath offset will be changed from ‘0’ (aircraft body situated on field perimeter) to ‘½’ (wing tip situated on field perimeter).

Overall, these changes will allow the PMRA to more precisely determine the aerial spray BZs needed to protect aquatic and terrestrial habitats while also considering aerial application equipment and methods that are more representative of current Canadian use scenarios.

2024 Annual charge overview

- All registrants are required to pay an annual charge for **each active product registered** in their name.
- This charge remains payable as long as the product is registered, irrespective of whether the product is actively being sold or not.
- The annual charge is required until the **expiration date** of the product.
- The 2024 Annual Charge Forms were sent to all registrants in February.
- Registrants are required to complete sales information in these annual charge forms.
- This is separate from the requirement to report sales volumes to the Sales Reporting Program (pmrasales-ventesarla@hc-sc.gc.ca).

Annual Charge Sales Audit:

- Registrants who apply for fee reductions based on low/no sales may be subject to an audit.
- These registrants may be required to have a qualified independent auditor or chartered accountant review and certify their sales records.

2024 Annual Charge Invoices:

- The 2024 annual charge invoices will be sent to registrants via email in April 2024.
- Registrants have the option of paying the invoices **in one payment or in quarterly payments.**

New Online Payment Option:

- Credit card payments can be made using the new Common Online Payment System at Payment - Health Canada.
- Acceptable card types include:
    - Visa and Visa Debit
    - MasterCard and Debit MasterCard
    - American Express
- To use this service, you **must have a valid customer number or group account number**.
- Please see the Requirements section on how to locate or obtain these numbers

PMRA Fee review proposal

On January 31, 2024, Health Canada launched consultations on a proposal to update post-market fees for pest control products. In response to stakeholder requests, the Department extended the original 60-day consultation period by two weeks. The consultation period closed on April 14, 2024.

By updating the annual charge, Health Canada seeks to improve the sustainability of Health Canada's pesticide program, better reflect Health Canada's current regulatory costs for pesticides, and better align with fee regimes of other foreign regulators.

Health Canada anticipates publishing proposed regulatory amendments to the Pest Control Products Fees and Charges Regulations in the Canada Gazette Part 1 in Fall 2024 with regulatory amendments targeting final publication in 2025. The implementation of the revised annual charge would follow thereafter.

Regulations Amending the Pest Control Products Regulations – Canada Gazette, Part I

The PCPA and its regulations provide the legislative framework for the regulation of pest control products federally. Recently, proposed amendments to the *Pest Control Product Regulations* (PCPR) were published in the Canada Gazette Part I, which aim to support the strategic objectives of the PMRA's transformation initiative by improving transparency and access to information and data, and further strengthening environmental protection. The proposed amendments are classified under four items:

- Facilitate access to confidential test data
- Proposed requirements for MRL applications
- Proposed amendment on cumulative effects on the environment
- Proposed amendment on species at risk

The consultation period for these amendments is 70 days, ending on August 24, 2024. The proposed amendments related to MRLs, cumulative effects on the environment and species at risk would come into force on the day on which they are published in the Canada Gazette, Part II. To provide applicants and registrants with time to adjust to the CTD amendments, the proposed amendments related to CTD would come into force 180 days after the day on which they are published in the Canada Gazette, Part II.

Canada Gazette, part II publication: A new modern regulatory framework for biocides

Health Canada has introduced a new single framework, *Biocides Regulations*, under the Food and Drugs Act (FDA) for the regulation of biocides. Biocides are products that sanitize or disinfect hard or soft non-living and non-liquid surfaces to prevent disease.

The framework will harmonize regulatory requirements for biocides and see the transfer of certain surface sanitizers regulated under the Pest Control Products Act (PCPA), disinfectants that are currently regulated under the Food and Drug Regulations (FDR), and all surface sanitizers for use in food premises that fall under the purview of the FDA, to the Biocides Regulations.

Approximately 65 pest control products will be affected by these new regulations, while many others product will remain subject to the PCPA, including:

- Algaecides, slimicides, material preservatives and products for odour control;
- Sanitizers and disinfectants that meet the definition of a drug, but that are for use in air or water. This includes pool and spa disinfectants, and air treatments;
- Material preservatives and antimicrobial treated articles. This includes antimicrobial or bacteriostatic coatings; and
- Uses against plant pathogens. This includes greenhouse and agriculture antimicrobial agents.

The Biocides Regulations come into force May 31, 2025 (i.e., one year after the regulations were registered). Additional information pertaining to these new regulations can be found at this website.

Planned post-market publications for FY 2024-2025 from REV2024-01

APR 2024	MAY 2024	JUN 2024
	Sodium chloride RVD	Agrobacterium *radiobacter* strain K84 and K1026 RVD Octenol RVD
JUL 2024	**AUG 2024**	**SEP 2024**
	Fosetyl aluminum SRD Flufenacet RVD Silicon dioxide cluster RVD	3-Methyl-2-Cyclohexen-1-one PRVD Tebuconazole RVD
OCT 2024	**NOV 2024**	**DEC 2024**
Carbon dioxide cluster PRVD Iodocarb (3-iodo-2-propynyl butyl carbamate) PSRD Cumulative health risk assessment: Organophosphates (project plan)	Pydiflumetofen PSRD	*Streptomyces lydicus* strain WYEC108 PRVD
JAN 2025	**FEB 2025**	**MAR 2025**
Cellulose PRVD Dicamba PSRD Fatty Acid cluster PRVD	Famoxadone PRVD Potassium bicarbonate PRVD	Chlorothalonil SRD German Cockroach Extract PRVD Nonylphenoxypolyethoxyethanol PRVD Sulphur PRVD

PRVD = Proposed Re-evaluation Decision document, PSRD = Proposed Special Review Decision document, RVD = Re-evaluation Decision document, SRD = Special Review Decision document

Planned re-evaluations initiations for FY 2024-2025 from REV2024-01

APR 2024	MAY 2024	JUN 2024
Beauveria bassiana Strain HF23 Ethofumesate 2-Phenylphenol and Salts cluster *Clonostachys rosea* strain J1446 Imazapyr Oxirane Derivatives – 50% minimum Pyrazon Industrial uses of Sodium Chlorite and Sodium Chlorite cluster	2,4-D cluster *Bacillus thuringiensis* cluster Bromoxynil Chlorantraniliprole Dodine MCPA cluster Sulfentrazone Tetrakis Hydroxymethyl Phosphonium Sulphate	Pendimethalin Spirotetramat
JUL 2024	**AUG 2024**	**SEP 2024**
1,2-Benzisothiazolin-3-one Streptomycin	Chlorthal (present as Dimethyl Ester) Dicamba cluster Mandipropamid Mineral Oil Propylene Glycol	Cloransulam-Methyl Phosphonic Acid cluster
OCT 2024	**NOV 2024**	**DEC 2024**
Triazole cumulative risk assessment	Cyprosulfamide Metaldehyde Ozone Thiencarbazone-Methyl	
JAN 2025	**FEB 2025**	**MAR 2025**
Glutaraldehyde Maleic Hydrazide Picloram cluster	*Metarhizium brunneum* strain F52 Naphthalene Acetic Acid	Alkyl Dimethyl Benzyl Ammonium Chloride Cluster (ADBAC) Didecyl Dimethyl Ammonium Chloride Cluster (DDAC) *Coniothyrium minitans* Strain CON/M/91-08 Flumioxazin

Consult the 5-year workplan (REV2024-01) for a list of upcoming re-evaluation initiations for FY 2025/2026

Information on ongoing special reviews

The following table presents a summary of the currently open special reviews at PMRA. Please note that the information in this table is subject to change as information is reviewed.

For more information on how special reviews are conducted, see the following guidance document, Approach to Special Reviews of Pesticides.

Although special reviews are usually targeted on one or a few aspects of concern, all registrants of the active in question are recommended to monitor the reviews for changes that may affect areas outside of the aspect of concern

Active Ingredient	Application number	PCPA refer-ence[1]	Aspect(s) of concern	Assessments conducted
Atrazine (plus related active triazines)	2017-1079	17(1)	• Potential changes to toxicology endpoint(s) used for previous human health and environmental risk assessments. • The impact of those potential changes to human health from atrazine in drinking water. • The impact of those potential changes to the environment from atrazine in surface water.	Human Health • Toxicology • Occupational/Residential exposure • Dietary exposure Environment • Environmental fate • Environmental toxicology and exposure
Methyl Bromide	2018-1207	17(2)	• Potential occupational and bystander risks .	Human Health • Occupational exposure
Chlorothalonil	2018-1645	17(1)	• Potential changes to environmental fate and ecotoxicological endpoints. • Exposure to metabolites R417888, R419492, R471811, SYN507900, M3, M11, M2, M7 and M10 from groundwater. • Potential genotoxicity of chlorothalonil metabolites. • Potential carcinogenicity of chlorothalonil (related to dietary exposure). • Potential risk to amphibians and fish.	Human Health • Dietary exposure Environment • Environmental fate • Environmental toxicology and exposure
Fosetyl-aluminum	2022-1396	17(1)	• Potential environmental risk to amphibians.	Environment • Amphibian toxicology and exposure
Glufosinate-ammonium	2018-5173	17(2)	• Potential reproductive toxicity . • Potential occupational health risk. • Potential bystander risk.	Human Health • Toxicology • Occupational/Residential exposure
Dicamba	2019-6324	17(1)	• Risk to non-target terrestrial plants from the use dicamba products (OTT and non-OTT) when air temperatures exceed 25°C during the application season.	Environment • Terrestrial plant exposure

Information on ongoing special reviews (cont)

Active Ingredient	Application number	PCPA refer-ence[1]	Aspect(s) of concern	Assessments conducted
Desmedipham	2022-1082	17(2)	• Potential risk from dietary exposure to desmedipham and its metabolites aniline (free and/or conjugated) and 4-aminophenol.	Human Health • Toxicology • Dietary exposure Environment • Environmental fate • Drinking water modelling
MCPA cluster	2022-0889 2022-0890 2022-0891 2022-0892	17(1)	• Potential inhalation occupational and residential risk from the use of MCPA based on the current conditions of use.	Human Health • Toxicology • Occupational/Residential exposure
Chlorpro-pham	2022-1493	17(2)	• Dietary (food only) risk from exposure to chlorpropham and 3-chloroaniline residues.	Human Health • Toxicology • Dietary exposure
Propicon-azole	2022-3213	17(1)	• Potential exposure to propiconazole's transformation products (NOA436613, SYN547889, and CGA91305) in groundwater; • Potential reproductive risk to fish.	Human Health • Toxicology • Dietary exposure Environment • Environmental fate • Fish reproduction and toxicology • Drinking water modelling
3-Iodo-2-propynyl butyl carbamate	2022-6248	17(1)	• Potential occupational dermal risk to workers exposed to iodocarb-treated metalworking fluids.	Human Health • Occupational exposure
Ethofumesate	2022-6293	17(1)	• Potential risk from exposure to ethofumesate and transformation products NC 8493, NC 9607, and NC 20645 in drinking water; • Potential risk to terrestrial and aquatic plants.	Human Health • Toxicology • Dietary exposure Environment • Environmental fate • Plant (terrestrial and aquatic) toxicology and exposure • Drinking water modelling
Pydiflumet-ofen	2023-1713	17(1)	• Potential risk related to occupational inhalation exposure.	Human Health • Occupational exposure

Information on ongoing special reviews (cont)

Active Ingredient	Application number	PCPA refer-ence[1]	Aspect(s) of concern	Assessments conducted
Hydantoins	2024-0779	17(1)	• Potential occupational inhalation risk for workers handling halohydantoin products formulated as granules; • Potential residential postapplication cancer risk from incidental oral exposure to bromate in outdoor swimming pools treated with bromine-based halohydantoins and in swimming pools, spas and hot tubs in combination with electrolysis, ozonation or UV devices.	Human Health • Occupational/Residential exposure
Novaluron	2024-1092	17(1)	• Potential dietary risks (food and water) from exposure to novaluron.	Human Health • Toxicology • Dietary exposure
Thiacloprid	2022-1773	17(2)	• Potential exposure to thiacloprid's transformation products M30, M34, and M46 in groundwater.	• TBD

[1] 17(1) The Minister shall initiate a special review of the registration of a pest control product if the Minister has reasonable grounds to believe that the health or environmental risks of the product are, or its value is, unacceptable.
17(2) When a member country of the Organisation for Economic Co-operation and Development prohibits all uses of an active ingredient for health or environmental reasons, the Minister shall initiate a special review.

Pesticide product changes: amendments and cancellations

Note: 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**.

Product amendments and cancellations

Naled

- Cancelled uses from product labels - Label changes in effect as of January 12, 2024
  - Beans (dry or field), lima beans, peas (processing), alfalfa, clover, vetch, potato, sugar beets
  - Rangeland, field areas, and pastures (aerial application for grasshopper treatment)
  - All greenhouse uses (roses and ornamentals grown for cut flowers, tomatoes, cucumbers, eggplants, peppers)
  - All structural uses including indoor uses (in and around dairy barns, livestock barns, pig pens, poultry houses, cider mills, and wineries), and
  - Woodland
- Label amendments for accepted uses - Label changes in effect as of January 12, 2024
  - Prohibition of use of ultra-low volume sprayer and handheld mistblower/fogger
  - Prohibition of aerial application for tomato
  - Closed mixing and loading and closed cab tractors for certain uses
  - Increased PPE for mixers, loaders or applicators
  - Limits on the amount of naled handled per day
  - Updated buffer zones
  - Environmental precautions statements regarding toxicity, runoff, not to be used for aquatic pests, minimum spray volume of 10 L and removal of No. 2 fuel oil as a diluent for aerial application

Kresoxim-methyl

- Label amendments for accepted uses - Label changes in effect as of January 31, 2024
  - Increased PPE for handheld airblast/mistblower
  - Reduced number of applications and seasonal max rates
  - New precautionary environmental statements
  - Prohibit use to control aquatic pests

Triticonazole

- Label amendments for accepted uses - Label changes in effect as of February 25, 2024
  - Updated or increased PPE
  - Updated REI and tank mix statements for turf
  - Reduced max label rate for turf
  - Closed cab tractor for planting treated seed
  - Environmental precautionary statements for foliar and seed treatment uses
  - Updated buffer zones

Pesticide product changes: amendments and cancellations (cont)

Product Changes

Florasulam

- Label amendments for accepted uses - Label changes in effect as of April 7, 2024
  - Updated PPE, REI and drift reduction statements
  - Updated environmental precaution statements
  - Label statement on the potential toxic effects to non-target terrestrial and aquatic vascular plants
  - Updated spray buffer zones.
  - Precaution statements warning of the potential for leaching and groundwater contamination.

Isoxaflutole

- Label amendments for accepted uses - Label changes in effect as of April 7, 2024
  - Updated REI and drift reduction statements
  - Label statement on the potential toxic effects to aquatic organisms and terrestrial plants
  - Updated spray buffer zones.
  - Precaution statements warning of the potential for leaching and runoff.

Difenoconazole

- Label amendments for accepted uses - Label changes in effect as of April 7, 2024
  - Corn, canola, rapeseed, mustard seed treatment
    - Closed transfer systems for commercial treatment
  - Cereal seed treatment
    - Chemical-resistant coveralls for cleaners for commercial treatment
    - Closed cab planters
    - Coveralls when loading seed for planting
  - Precautionary statements to inform users of the potential hazard to beneficial arthropods, non-target terrestrial plants and aquatic organisms.
  - Updated spray buffer zones
  - Statement to inform users of the potential hazard to birds and small wild mammals where spilled or exposed treated seed must be incorporated into the soil or removed.

Trinexapac-ethyl

- Label amendments for accepted uses - Label changes in effect as of August 18, 2024
  - Closed mixing/loading and closed cab tractor when handling more than 70 kg active ingredient per day
  - Updated REIs, PPE and drift statements
  - Prohibition of use in residential areas other than golf courses
  - Updated buffer zone

Find your current product labels: Pesticide Label Search