Proposed Re-evaluation Decision

Santé

Canada

PRVD2022-04

Corn gluten meal and Its **Associated End-use Products**

Consultation Document

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Proposed re-evaluation decision

Under the authority of the *Pest Control Product Act*, all registered pesticides must be reevaluated by Health Canada's Pest Management Regulatory Agency (PMRA) to ensure that they continue to meet current health and environmental safety standards and continue to have value. The re-evaluation considers data and information from pesticide manufacturers, published scientific reports, and other regulatory agencies. Health Canada applies internationally accepted risk assessment methods as well as current risk management approaches and policies to all reevaluations.

Corn gluten meal is registered as a herbicide on turf grass, residential lawns, municipal and commercial properties, golf courses, sports fields, parks and sod farms for pre-emergent inhibition of seed germination of dandelion, crabgrass (smooth and large) and white clover. It is also registered for flower, vegetable and fruit gardens for pre-emergent inhibition of seed germination of weeds. They are registered as commercial and domestic class products (formulated as a solid or granular). Currently registered technical grade active ingredient and end use products containing corn gluten meal are listed in Appendix I.

This document presents the proposed regulatory decision for the re-evaluation of corn gluten meal products, including the proposed risk mitigation measures.

When the label directions are followed, potential risks to human health (occupational, dietary, residential and bystander) and the environment (aquatic and terrestrial organisms) are considered to be acceptable. Corn gluten meal and its end-use products are also shown to have value in providing a pest management solution. Currently, most labels indicate personal protective equipment (PPE) for the purpose of good hygiene practices. To mitigate potential allergic reactions, PPE for commercial products is proposed as a requirement. Furthermore, to meet the current labelling standards and for consistency, PPE is recommended for good hygiene practice for all domestic products, and, to meet current labelling standards, precautionary statement, and environmental statements (disposal and storage) are proposed to be updated. In addition, based on the review of information from incident reports, a precautionary statement to prevent pets from consuming the applied product is proposed. See Appendix II.

Under the authority of the *Pest Control Products Act*, and based on the evaluation of currently available scientific information, products containing corn gluten meal (listed in Appendix I) are proposed for continued registration in Canada, with the proposed label amendments (Appendix II). Registered pesticide product labels include specific directions for use. Directions include risk mitigation measures to protect human health and the environment that must be followed by law.

All products containing corn gluten meal registered in Canada are subject to this proposed reevaluation decision. This document is subject to a public consultation¹, during which written comments and additional information may be submitted to PMRA Publications. The final reevaluation decision will be published taking into consideration the comments and information received.

Next steps

The public, including the registrants and stakeholders, are encouraged to submit comments and additional information during the 90-day public consultation period upon publication of this proposed re-evaluation decision.

All comments received during the 90-day public consultation period will be taken into consideration in preparation of the re-evaluation decision document,² which could result in revised risk mitigation measures. The re-evaluation decision document will include the final re-evaluation decision, the reasons for it and a summary of comments received on the proposed re-evaluation decision with Health Canada's responses.

Additional scientific information

Additional scientific data are not required at this time.

Other information

The relevant confidential test data on which the proposed decision is based (see References section of this document) are available for public inspection, upon application, in Health Canada's Reading Room. For more information, please contact Health Canada's Pest Management Information Service.

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[&]quot;Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

² "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Science evaluation

1.0 Human health assessment

Based on the available information, corn gluten meal is expected to be of low toxicity via the oral, dermal and inhalation routes, minimally irritating to the skin, mildly irritating to the eyes, and is expected to be a potential dermal sensitizer. There was no evidence to indicate that corn gluten meal is carcinogenic, genotoxic, neurotoxic, or a developmental or reproductive toxicant. No toxicological reference values have been established for corn gluten meal. For more details on the toxicology assessment, refer to PRD2013-17 (Canada, 2013).

Corn gluten meal is considered a feed grade material in Canada, regulated by the Canadian Food Inspection Agency (CFIA). Based on the CFIA guidelines for the mycotoxins, it is required that the mycotoxin levels present in the products do not exceed the tolerance levels established by the CFIA for feeds. The most common adverse effect reported in humans for corn and corn byproducts in the published literature is allergy. To protect people who are sensitive to corn, all commercial and domestic product labels instruct users not to apply the product if a member of the household is sensitive or allergic to corn.

The products containing corn gluten meal are formulated as granular or solid formulations, applied by a spreader. Occupational workers or homeowners could be exposed to corn gluten meal when handling/applying the end use product or entering the treated site. Bystander exposure is also expected from application. However, potential occupational, residential and bystander risk is considered acceptable. To minimise potential allergic reactions, the following is proposed:

- Commercial products: PPE on commercial product labels are currently indicated for good hygiene practices. However, as part of this re-evaluation, PPE is proposed as a requirement (baseline PPE, such as a long-sleeved shirt, long pants, shoes and socks, and chemical-resistant gloves, protective eyewear (googles or faceshield) and a NIOSH-approved N95 (minimum) filtering facepiece respirator (dust mask) are required).
- Domestic products: Currently, only certain labels included PPE for good hygiene practice. For consistency and to meet current labelling standard, all domestic product labels are proposed to be updated to include a long-sleeved shirt, long pants, socks, closed footwear, waterproof gloves, and a dust mask when handling and applying the product as part of good hygiene practice.
- Allergy warning statement: the registered technical grade active ingredient (Reg. No. 28808) contains sulphur dioxide. A label statement indicating that the product contains the allergen sulphites is required for this technical grade active ingredient and any end use products that are formulated with the technical grade active ingredient as indicated in Canada Gazette, Part II, Vol. 142, No. 13, SI/2008-67 (2008-06-25).

Corn gluten meal is applied on top of soil (pre-emergence of weeds) and potential exposure to food, and drinking water is considered negligible. The potential dietary risk is considered to be acceptable.

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential, and other non-occupational sources, and from all known or plausible exposure routes (oral, dermal, and inhalation).

When corn gluten meal is used according to proposed label directions, aggregate exposure risk is considered acceptable. This includes all anticipated dietary (food and drinking water) exposures and all other non-occupational exposures (dermal and inhalation) for which there is reliable information.

The *Pest Control Products Act* requires that Health Canada considers the cumulative exposure to pesticides with a common mechanism of toxicity. For the current re-evaluation, the PMRA did not identify information indicating that corn gluten meal shares a common mechanism of toxicity with other pest control products. Therefore, there is no requirement for a cumulative assessment at this time.

2.0 Environmental assessment

Based on the use pattern and the fact that corn gluten meal is expected to break down rapidly when applied to soil, exposure to non-target terrestrial and aquatic organisms is expected to be minimal. Corn gluten meal is also used as a feed for animals, birds and fish and in the commercial fishing industry as commercial fish food, and, risks to terrestrial and aquatic organisms are considered to be acceptable (Canada, 2003 and Canada, 2013). Corn gluten meal does not meet all Track 1 criteria, and is not considered a Track 1 substance as per the Toxic Substances Management Policy. To meet the current labelling standards, information on the labels related to environmental statements (disposal and storage) for all products are proposed to be updated.

3.0 Value assessment

Corn gluten meal is a non-conventional herbicide as it is a by-product of corn processing that has historically been used as an animal feed. The corn gluten meal prevents normal development of plant roots by releasing organic dipeptides into soil and inhibiting root formation of germinating seeds. It does not prevent seed germination or affect root systems of established plants but rather causes seedlings with less than normal root systems to succumb to dehydration when exposed to drought stress. Corn gluten meal has values as a reduced risk alternative herbicide.

4.0 **Incident report**

As of 1 August 2021, a total of 131 incidents, including 13 for human and 81 for domestic animal, were reported in Canada.

The human incidents were minor or moderate in nature related to the exposure to corn gluten meal. Individuals were exposed during application, entering the treatment area, or working in the vicinity of stored products. Symptoms in the incident reports include minor respiratory, skin, and eye irritation (such as irritated throat and nose, itchy eyes and skin, and rash), as well as a few gastrointestinal effects were reported. As indicated in section 1.0, additional mitigation measures are proposed for human health (related to precautionary statements, PPE requirement for commercial products, recommendation of PPE for domestic products, Appendix II). No further mitigation measures are proposed based on the human incident reports.

Almost all domestic animal incidents were considered to be at least possibly related to ingestion of corn gluten meal, with mostly minor effects observed. Gastrointestinal effects such as vomiting or diarrhea were reported in almost all incidents. Lethargy, eye and skin irritation, and thirst were also reported. Corn gluten meal looks like dry dog food and is feed grade, and makes it palatable to dogs. Only three currently registered corn gluten meal product labels contain a statement to prevent postapplication exposure of pets to the product. Therefore, to inform users and to improve consistency on corn gluten meal product labels, a precautionary statement to keep pets away from the treatment area are proposed to be added for all products.

As of 1 August 2021, thirty-seven environment incident were reported in Canada. All incidents were minor in nature and occurred in Canada. Three environment incidents involved the death of small mammals and a bird, but there was no witnessed exposure to the product. Thirty-four environment incidents involved minor lawn injury after application. In all lawn incidents, details surrounding the application and the onset of symptoms were generally not provided. The date that the incident occurred was also not provided, so it is unclear whether they adhered to the use directions found on all product labels that instruct the user to apply in the early spring or late summer/fall, after heat stress risk. Given these use instructions, no concerns were identified in the environmental incidents received for corn gluten meal. No additional risk mitigation measures are proposed.

Appendix I Registered corn gluten meal in Canada as of 1 February 2022 (excluding discontinued products or products with a submission for discontinuation)

Table 1 Registered corn gluten meal in Canada as of 1 February 2022 (excluding discontinued products or products with a submission for discontinuation)

Registration number	Marketing class	Registrant	Product name	Formulation type	Guarantee
28808	Technical grade active ingredient	Ingredion Canada Corporation	Corn Gluten Meal Technical	Granular	100%
27865	Commercial	The Environmental Factor Inc.	Turfmaize Pro Corn Gluten Herbicide Pre- Emergent Weed Seed Germination	Granular	98%
29304	Commercial	AG Global Canada GP Inc.	Amaizeingly Green Corn Gluten Meal Herbicide	Solid	99.975%
29640	Commercial	Ingredion Canada Corporation	Prairie Gold Corn Gluten Meal C	Granular	99.7%
27491	Domestic	The Environmental Factor Inc.	Turfmaize Corn Gluten Herbicide Pre- Emergent Weed Seed Germination Inhibitor	Granular	98%
28647	Domestic	AG Global Canada GP Inc.	Amaizeingly Green Corn Gluten Meal Herbicide	Granular	99.975%
29060	Domestic	Scotts Canada Ltd.	Scotts Turf Builder Weed Prevent Corn Gluten Meal	Solid	99.975%
29639	Domestic	Ingredion Canada Corporation	Prairie Gold Corn Gluten Meal D	Granular	99.7%
30981	Domestic	Premier Tech Inc.	Plant-Prod Ultimate Garden Weed Preventer With Corn Gluten Meal	Granular	100%
31835	Domestic	Scotts Canada Ltd.	Vigoro Weed Prevent Corn Gluten Meal	Solid	99.975%
31961	Domestic	AG Global Canada GP Inc	Amaizeingly Green Corn Gluten Meal Herbicide Ddg	Granular	84.975%
32210	Domestic	Evergreen BioInnovations Ltd.	Crab Arrest	Granular	84.975%
32529	Domestic	Scotts Canada Ltd.	Scotts Turf Builder Weed Prevent	Solid	84.975%

Appendix II Label updates for products containing corn gluten meal

The label amendments presented below do not include all label requirements for the registered end-use product. Information on labels of currently registered products should not be removed unless it contradicts the label statements provided below.

- 1. Technical grade active ingredient products:
 - 1.1 Replace the term "guarantee" with "active ingredient".
 - 1.2 On the front panel of Reg. No. 28808, add the following statement
 - "Warning, contains the allergen sulfites"
 - 1.3 The following statement must be included in a section entitled **DISPOSAL**

"Canadian manufacturers should dispose of unwanted active ingredients and containers in accordance with municipal and provincial regulations. For additional details and clean up of spills, contact the manufacturer and the provincial regulatory agency."

- 2. Commercial class products:
 - 2.1 Replace the term "guarantee" with "active ingredient".
 - 2.2 On the front panel, all end use products formulated with Reg. No. 28808, add the following statement
 - "Warning, contains the allergen sulfites"
 - 2.3 The following statement must be included in a section entitled **PRECAUTIONS**

Wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes, protective eyewear (googles or faceshield), and a NIOSH-approved N95 (minimum) filtering facepiece respirator (dust mask) when handling, mixing/loading or applying the product, and during all clean-up/repair activities.

The following statement must be included in a section entitled **PRECAUTIONS**

"Keep pets away from treated area until the applied product is no longer visible."

2.4 The following statement must be included in a section entitled **STORAGE**

"Store this product away from food or feed"

- 3. Domestic class products:
 - 3.1 Replace the term "guarantee" with "active ingredient".
 - 3.2 On the front panel, all end use products formulated with Reg. No. 28808, add the following statement
 - "Warning, contains the allergen sulfites"
 - 3.3 The following statement must be included in a section entitled **PRECAUTIONS**
 - "For good hygiene practice, wear a long-sleeved shirt, long pants, closed footwear, waterproof gloves, and a dust mask when handling and applying the product.
 - 3.4 The following statement must be included in a section entitled **PRECAUTIONS**
 - "Keep pets away from treated area until the applied product is no longer visible."
 - 3.5 Add the following statement to a section entitled **DISPOSAL**
 - "DO NOT reuse empty container. Dispose the empty container with household garbage."
 - "Unused or partially used products should be disposed at provincially or municipally designated hazardous waste disposal sites."
 - 3.6 The following statement must be included in a section entitled **STORAGE**
 - "Store this product away from food or feed"

Reference list

PMRA#	Reference	
651090	Canada, 2003, Regulatory Note, REG2003-09, Corn Gluten Meal	
2314018	Canada, 2013, Proposed Regulatory Decision, PRDD2013-17, Corn	
	Gluten Meal	