Re-evaluation Note REV2018-09

Re-evaluation Project Plan for Flufenacet

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Background

In Canada, flufenacet is under re-evaluation by Health Canada's Pest Management Regulatory Agency (PMRA). The PMRA re-evaluates registered pesticides to determine whether the use of these products continues to be acceptable in terms of value, human health and the environment according to current standards.

Flufenacet is a herbicide registered for use in Eastern Canada only. It is registered for use on field corn and soybeans for control or suppression of annual grass and broadleaf weeds.

Under the authority of section 16 of the *Pest Control Products Act*, the registrant of flufenacet was notified of the initiation of the re-evaluation of flufenacet. Following this, the registrant of flufenacet technical grade active ingredient in Canada indicated support of all uses included on the labels of end-use products in Canada.

The re-evaluation project plan below outlines the timeline, the anticipated areas of focus for the risk assessments, and the data requirements for the re-evaluation of flufenacet.

Re-evaluation Project Plan

Anticipated Re-evaluation Timeline

The re-evaluation of flufenacet is defined as a Category 1 as described in Regulatory Directive DIR2016-04, *Management of Pesticides Re-evaluation Policy*. However, because this re-evaluation was initiated prior to the publication of DIR2016-04, the proposed re-evaluation decision for flufenacet is anticipated to be published for consultation by December 2019. The re-evaluation timeline may be updated if, during the risk assessment, the PMRA identifies additional areas of focus that should be considered.

Human Health Risk Assessment

New assessments will be conducted for toxicology and dietary exposure. Existing assessments with minor updates are considered to be adequate to support the re-evaluation of flufenacet for the other aspects of human health assessment.

Environmental Risk Assessment

New assessments will be conducted for environmental fate, water modelling and environmental exposure.

Value

The value of flufenacet will be considered. The viability of alternatives will be examined for certain uses if risks of concern requiring mitigation are identified.

Data Requirements

The PMRA has identified the need for the technical registrant to provide data for flufenacet related to toxicology and environmental fate and exposure. Relevant data/studies have been requested and received from the technical registrant. A summary of the data call-in is found in the PMRA's Public Registry, found online at https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/public/protecting-your-health-environment/public-registry.html. For a list of data categories that have been required, see Appendix I. In addition, information regarding the registered use pattern has been requested and received from the registrant, to inform the risk assessments.

Additional Information

The PMRA documents can be found in the Pesticides and Pest Management section of Canada.ca at https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management.html. The PMRA documents are also available through the Pest Management Information Service:

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Appendix I Data Required Under Subsection 19(1) of the *Pest Control Products Act* for the Re-evaluation of Flufenacet

I. Toxicology Data

4.3.7	Short-term Inhalation (21/28-day)
4.5.1	Multigeneration Reproduction (rodent)
4.5.14	Developmental Neurotoxicity
4.5.15	Immunotoxicity
4.8	Other Studies/Data/Reports
12.5.4	Foreign Reviews of Toxicology

II. Environmental Chemistry and Fate Data

8.2.2.1	Analytical Methodology (parent compound and transformation products)- Soil
8.2.2.3	Analytical Methodology (parent compound and transformation products)- Sediment
8.2.2.4	Analytical Methodology (parent compound and transformation products)- Biota
8.2.3.2	Laboratory Studies of Transformation- Hydrolysis
8.2.3.3.1	Phototransformation- Soil
8.2.3.4.2	Biotransformation in Soil- Aerobic Soil 20°-30°C
8.2.3.5.4	Biotransformation in Aquatic Systems- Aerobic Water/Sediment 20°-30°C
8.2.3.5.6	Biotransformation in Aquatic Systems- Anaerobic Sediment/Water 20°-30°C

III. Ecotoxicology Data

9.2.4.1	Bees/Pollinators- Acute Contact
9.2.4.2	Bees/Pollinators- Acute Oral
9.2.4.3	Bees/Pollinators- Hive Study (including Brood)
9.2.4.4	Bees/Pollinators- Bee Adult Chronic Toxicity
9.3.2	Non-Target Freshwater Invertebrates- *Daphnia* sp. Acute
9.4.2	Non-Target Marine Invertebrates- Acute (Crustacean)
9.4.5	Non-Target Marine Invertebrates- Chronic (Mollusk or Crustacean)
9.5.2.1	Acute Studies- Cold Water Fish (Rainbow Trout)
9.5.2.2	Acute Studies- Warm Water Fish (Bluegill Sunfish)
9.5.2.4	Acute Studies- Marine/Estuarine Fish
9.5.3.2	Sublethal and Chronic Studies- Fish, Life Cycle Toxicity Test
9.6.2.3	Wild Birds Acute Studies- Oral (LD50) Other Species
9.8.2	Non-Target Plants- Fresh Water Algae
9.8.4	Non-Target Plants- Terrestrial Vascular Plants
9.8.5	Non-Target Plants- Aquatic Vascular Plants