Proposed Special Review Decision PSRD2020-05

Special Review for Linuron and its associated end-use products

Consultation Document

(publié aussi en français)

5 November 2020

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6607 D
Ottawa, Ontario K1A 0K9

Internet: canada.ca/pesticides
hc.pmra.publications-arla.sc@canada.ca
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
hc.pmra.info-arla.sc@canada.ca

Canada

ISSN: 2561-6366 (online)

Catalogue number: H113-30/2020-5E (print)
H113-30/2020-5E-PDF (PDF version)

Table of Contents

1.0 Introduction

Pursuant to subsection 17(2) of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) initiated a special review of linuron (Canada, 2013). This special review was based on the decision taken by Norway in 2007 to prohibit the use of linuron due to human health and environmental concerns (Rotterdam Convention, 2007).

In 2017, the European Union (EU) prohibited all uses of linuron as plant protection products due to human health and environmental concerns (European Commission, 2017). The aspects of concern identified in the 2017 EU decision are also considered as part of this special review.

Pursuant to subsection 18(4) of the *Pest Control Products Act*, Health Canada has evaluated the aspects of concern that prompted the special review of pest control products containing linuron. The aspects of concern for this special review are relevant to human health and the environment.

2.0 Uses of linuron in Canada

Linuron is an herbicide registered for commercial use in Canada. All currently registered pest control products are considered in this special review (Appendix I).

Re-evaluation of linuron was completed in 2020, and continued registration is granted for uses on carrots, parsnip, potato, asparagus, and shelterbelts with additional risk mitigation measures (Canada, 2012; Canada, 2020). The following uses of linuron are cancelled following re-evaluation (Canada, 2020) since health and environmental risks were not shown to be acceptable:

- Tree fruit (apple, peach, pear, plum/prune, cherry), corn (field and sweet), wheat, barley, oats, soybean, celery, Saskatoon berries, chokecherries, dill, coriander, caraway, sweet white lupins, and pre-emergent combined with postharvest application to asparagus.

3.0 Aspects of the pest control product that prompted the special review

Based on the review of the Norwegian and EU decisions, Health Canada identified the aspects of concern that prompted the special review of linuron as:

Human health

- Potential reproductive and developmental effects;
- Potential carcinogenicity;
- Potential for hematologic effects;
- Potential for endocrine disruption;
- Potential for risk from occupational exposure;
- Potential for risk from residential exposure.

Environment

- Persistence and accumulation;
- Potential for groundwater leaching and surface water runoff;
- Potential risk to aquatic and terrestrial organisms;
- Potential from endocrine disruption.

4.0 Evaluation of the aspects of concern that prompted the special review

Following the initiation of the special review of linuron, Health Canada requested information from provinces and other relevant federal departments and agencies in accordance with subsection 18(2) of the *Pest Control Products Act*. In response, water monitoring data were received and were considered.

In order to evaluate the aspects of concern, Health Canada has considered all currently available relevant scientific information, which includes the available information from Norway and the European Union, incident reports, and existing reviews of linuron (Canada, 2012; Canada, 2020).

While the special review of linuron was underway, Health Canada completed its re-evaluation in 2020. As part of this re-evaluation, Health Canada conducted a comprehensive assessment of human health and environmental risks of linuron, including the aspects of concern identified in the special review (Canada, 2020). As a result of this review, several uses were cancelled and additional risk mitigation measures were implemented to address the potential risk to human health and the environment.

As the 2020 re-evaluation review included the assessment of the aspects of concern identified under the special review and there was no additional information identified that are related to the aspects of concern, the special review is based on the 2020 comprehensive human health and environmental review.

Aspects of concern related to human health

Evaluation of available scientific information related to the aspects of concern indicated that the 2020 assessment of linuron (Canada 2012; Canada, 2020) addresses the following aspects of concern related to human health:

- Potential reproductive and developmental effects;
- Potential carcinogenicity;
- Potential for hematologic effects;
- Potential for endocrine disruption;
- Potential for risk from occupational exposure;
- Potential for risk from residential exposure.

The toxicological reference values selected for the 2020 human health risk assessment are considered protective of the identified health effects (Canada, 2020).

To determine if risk to Canadians from exposure to linuron was acceptable, Health Canada conducted scientifically-based risk assessments relative to the aspects of concern (Canada, 2012; Canada 2020), including assessments of occupational, residential and dietary (food and drinking water) risks. The assessment indicated that the potential risks to human health associated with the use of linuron and associated end-use products are considered acceptable when these products are used according to the risk mitigation measures and revised label directions as outlined in Re-evaluation Decision RVD2020-10, *Linuron and its associated end-use products*, (Canada, 2020). The risk mitigation measures required included the cancellation of several uses, and additional personal protective equipment for workers. As the required mitigation measures necessary to address the aspects of concern related to human health are already included in RVD2020-10, they are not listed in this proposed decision. However, a summary of the required label amendments for the special review are included in Appendix II. No additional risk reduction measures are proposed as part of the special review.

Environment

Evaluation of available scientific information related to the aspects of concern indicated that the 2020 assessment of linuron (Canada 2012; Canada 2020) addresses the following aspects of concern related to the environment:

- Persistence and accumulation;
- Potential for groundwater leaching and surface water runoff;
- Potential risk to aquatic and terrestrial organisms;
- Potential for endocrine disruption.

To determine if risks to the environment from exposure to linuron were acceptable, Health Canada conducted scientifically-based risk assessments relative to the aspects of concern (Canada 2012; Canada 2020), including assessments of potential risk to terrestrial and aquatic organisms. Potential for groundwater leaching and runoff was considered as part of the drinking water assessment. The environmental assessment conducted in support of the 2020 re-evaluation determined that potential risks to the environment associated with the use of linuron and associated end-use products are acceptable when these products are used according to revised label directions and mitigation measures, which include a reduced use pattern, reduced application rates and updated buffer zones (Canada, 2020). For details on the required mitigation measures, refer to the Linuron Re-evaluation decision (RVD2020-10; Canada, 2020). As the required risk mitigation measures necessary to address the aspects of concern related to the environment are already included in RVD2020-10, they are not listed in this proposed decision. However, a summary of the required label amendments for the special review are included in Appendix II. No additional risk reduction measures are proposed as part of the special review.

5.0 Incident reports

Incident reports involving linuron were considered for the 2020 re-evaluation decision (Canada, 2012; Canada, 2020). Since publication of the re-evaluation decision, no additional incidents involving linuron were submitted to Health Canada. For additional information related to linuron incident reports refer to Proposed Re-evaluation Decision PRVD2012-02, *Linuron* and RVD2020-10.

6.0 Proposed special review decision for linuron

Evaluation of available scientific information related to the aspects of concern indicated that the potential risk to human health and the environment resulting from exposure to linuron are considered acceptable when the risk mitigation measures described in RVD2020-10 (Canada, 2020) are implemented. Therefore, no further mitigation measures are proposed as a result of this special review.

On this basis, Health Canada, pursuant to subsection 21(1) of *the Pest Control Product Act*, is proposing continued registration of linuron products for sale and use in Canada. The mitigation measures stated in RVD2020-10 (Canada, 2020) are adequate, and additional mitigation measures are not proposed as a result of this special review.

This proposed special review decision is a consultation document.[1] Health Canada will accept written comments on this proposal up to 45 days from the date of publication of this document. All comments are to be directed to Publications (contact information on the cover page of this document).

7.0 Next steps

Before making a final decision on the special review of linuron, Health Canada will consider all comments received from the public in response to this consultation document. A science-based approach will be applied in making a final decision on linuron. Health Canada will then publish a special review decision document, which will include the decision, the reasons for it, a summary of the comments received on the proposed decision, and Health Canada's response to these comments.

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

Appendix I Registered products containing linuron as of 7 August 2020

Registration number	Marketing class	Registrant	Product Name	Formulation type	Guarantee
19696	Technical	TESSENDERLO KERLEY, INC.	LINURON FLAKE TECHNICAL	Wettable Granules	96.9%
27852	Technical	TESSENDERLO KERLEY, INC.	LINUREX TECHNICAL	Dust or Powder	96.8%
16279	Commercial	TESSENDERLO KERLEY, INC.	LOROX L HERBICIDE	Suspension	480 g/L
16363	Commercial	ADAMA AGRICULTURAL SOLUTIONS CANADA LTD.	AFOLAN F HERBICIDE	Suspension	450 g /L

Appendix II Summary of risk mitigation measures related to the aspects of concern

Uses not supported by manufacturers for re-evaluation and will be removed from all product labels:

- Field corn (post-emergence);
- Aerial and handheld applications.

Cancelled uses to be removed from all product labels:

- Tree fruit (apple, peach, pear, plum/prune, cherry), corn (field and sweet), wheat, barley, oats, soybean, celery, Saskatoon berries, chokecherries, dill, coriander, caraway, sweet white lupins, and pre-emergent combined with postharvest application to asparagus.
- Airblast and right-of way application equipment.

Human health

Risk mitigation:

To protect human health from exposure, the following risk-reduction measures are required for uses with continued registration (carrots, parsnip, potato, asparagus and shelterbelts):

- Revised maximum application rates
  - Limit pre-emergent and postemergent applications to carrots to a maximum annual application rate of 1.68 kg a.i./ha
  - Limit pre-emergent and postemergent applications to parsnips to a maximum annual rate of 1.50 kg a.i./ha
  - Limit pre-emergent application to potatoes to a maximum annual rate of 1.78 kg a.i/ha
  - Limit pre-emergent or postemergent application to asparagus to a maximum annual application rate of 1.63 kg a.i./ha
  - Limit dormant stage application to shelterbelts to a maximum annual application rate of 2.16 kg a.i./ha
- To protect consumers, increase the plant back interval restriction from 4 months to 12 months for carrots, potato, and parsnip.
- To protect mixers/loaders and applicators: increased personal protective equipment (PPE), addition of engineering controls (closed mixing loading and closed cab application), and restrictions on some types of application equipment.
- To protect postapplication workers: increased restricted-entry intervals (REIs) for all activities.
- To protect bystanders from spray drift: require a statement to promote best management practices to minimize human exposure from spray drift or spray residues resulting from drift.

Environment

Label improvements to meet current standards:

- Updated discharge of effluent statements;
- Updated storage statements.

Risk mitigation:

To protect the environment, the following risk-reduction measures are required for uses with continued registration (carrots, parsnip, potato, asparagus and shelterbelts):

- Standard label statements are required to minimize potential risks resulting from runoff;
- Standard hazard statements to inform users of the potential toxic effects to sensitive biota;
- Aerial application is prohibited;
- Buffer zones are required to mitigate risks from spray drift.

References

Information Considered in the Special Review not Supplied by Registrant

Published

PMRA Document Number	Reference
2211137	Canada, 2012. Proposed Re-evaluation Decision PRVD2012-02. Linuron. Pest Management Regulatory Agency. 27 July 2012. 207 pages.
2405939	Canada, 2013. Pest Management Regulatory Agency Regulatory Note REV2013-06, Special Review Initiation of 23 Active Ingredients. 5 pages.
3122789	European Commission, 2017. COMMISSION IMPLEMENTING REGULATION (EU) 2017/244 of 10 February 2017 concerning the non-renewal of approval of the active substance linuron, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. European Commission. 10 February 2017. http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1490350984535&uri=CELEX:32017R0244
3122793	Rotterdam Convention, 2007. PIC Circular XXVI – December 2007.
	Canada, 2020. Re-evaluation Decision: Linuron and its associated end-use products. RVD2020-10