Registration Decision RD2026-10

Spidoxamat, Velancor, Plenexos Smart, Plenexos Care

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Under the authority of the *Pest Control Products Act*, pesticides must be assessed before they are sold or used in Canada in order to determine that they do not pose unacceptable risks to humans or the environment and have value when used according to the label instructions. The pre-market assessment considers available data and information[1] from pesticide registrants, published scientific reports, other governments, and international regulatory agencies, as well as written comments directly related to the proposed decision, such as comments directed to the science evaluation, if received during public consultations. Health Canada applies internationally accepted current risk assessment methods as well as risk management approaches and policies. More details, on the legislative requirements, risk assessment and risk management approach, are provided under the section of Evaluation approach of this document.

Registration Decision Statement[2] for Spidoxamat, Velancor, Plenexos Smart, Plenexos Care

Health Canada's Pest Management Regulatory Agency (PMRA), pursuant to subsection 8(1) of the *Pest Control Products Act*, is granting registration for the sale and use of Spidoxamat Technical Insecticide, Velancor, and Plenexos Care, containing the technical grade active ingredient spidoxamat, and Plenexos Smart, containing the technical grade active ingredients spidoxamat and flupyradifurone, to control labelled pests on pome fruits, stone fruits, small fruits vine climbing (except fuzzy kiwifruit) and tree nuts (except almonds).

The Proposed Registration Decision PRD2025-15*, Spidoxamat, Velancor, Plenexos Smart, Plenexos Care*, containing the detailed evaluation of the information submitted in support of this registration, underwent a 30-day consultation period ending on 18 December 2025. The evaluation found that, under the approved conditions of use, the health and environmental risks and the value of the pest control products are acceptable. Health Canada received written comments relating to the health and environmental assessments during the public consultation period conducted in accordance with section 28 of the *Pest Control Products Act*. In addition, the PMRA is addressing an error found in PRD2025-15. However, some of the comments were not directly related to the proposed decision in PRD2025-15, *Spidoxamat, Velancor, Plenexos Smart, Plenexos Care*.

Comments and responses

Health Canada received comments from the registrant, and the responses are provided below.

1. Comment related to the acute inhalation toxicity classification of the end-use product Plenexos Smart

The registrant stated that the guideline acute inhalation toxicity study conducted with Plenexos Smart assessed the highest feasible dose of the test material, and it is therefore non-toxic by inhalation. Specifically, the comment cites OECD Guidance Document 39,[3] noting that "when a

1 Information Note – *Determining Study Acceptability for use in Pesticide Risk Assessments*
2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.
3 OECD (2018), Guidance Document on Inhalation Toxicity Studies - Second edition, OECD Series on Testing and Assessment, No. 39, OECD Publishing, Paris, https://doi.org/10.1787/fba59116-en.

limit test is used for a virtually non-toxic substance – and less than 50% lethality occurs at the limit or maximum attainable concentration – no further testing is needed".

The comment specifies that 1.41 mg/L was the maximum attainable dose of the test material in the study and there was a lack of mortality, therefore the true LC_{50} must exceed 2.0 mg/L and Plenexos Smart should be classified as being of low acute toxicity via the inhalation route.[4]

Health Canada response:

Based on results of the acute inhalation study submitted to support the registration of Plenexos Smart, the end-use product was classified as being of slight acute toxicity via the inhalation route based on the LC_{50} of > 1.41 mg/L in male and female rats. In the study, the only concentration tested was 1.41 mg/L, so it was unclear whether the true LC_{50} exceeds 2.0 mg/L, which would classify the product as being of low acute toxicity via the inhalation route per Health Canada's acute hazard classification system for pesticides. In the absence of data to confirm a higher value, the classification was conservatively assigned to slight acute toxicity via inhalation (LC_{50} > 0.5 and ≤ 2.0) in accordance with Health Canada's acute hazard labelling guidelines for pesticides.[4]

Given the confirmation that the test material assessed in the acute inhalation study was the highest achievable concentration and the lack of mortalities at this concentration of 1.41 mg/L, the acute hazard classification of Plenexos Smart had been updated to indicate that it is of low acute inhalation toxicity. Accordingly, the hazard statement "POISON" will not be required on the label.

2. Comment related to exposure from drinking water, application rates

The registrant stated that the inter-application interval should be 14 days based on the rate used, rather than 10 as given in PRD2025-15.

Health Canada response:

There were two proposed use patterns as part of these submissions: a higher rate with a 14-day interval and a lower rate with a 10-day interval. The PMRA considered a more conservative use pattern for modelling (in other words, the higher rate and the shorter application interval). Although the modelled application interval is more conservative than what was proposed, risks were still found to be acceptable. The PMRA, therefore, will retain the current modelled use pattern.

[4] PMRA (2013). Guidance for Waiving or Bridging of Mammalian Acute Toxicity Tests for Pesticides.

3. Comment related to residues modelled and fate inputs (Table 3.5.1 Major fate inputs for the modelling, from PRD2025-15)

The registrant commented that as suggested in the aerobic aquatic metabolism study report PMRA No. 3395690, the slow degradation observed in the 1WS Humsterbach system was attributed to partially anaerobic conditions in sediment during sampling (Eh = -211 mV, Table 1) and during experiment (Eh ranged from -283 mV to -25 mV, Table 5), significantly more negative than the 2WS Schwarzenbach system (Eh ranged from -76 mv to 141 mV, Table 6). Therefore, the degradation in 1WS Humsterbach system did not represent the degradation under aerobic conditions.

Health Canada response:

According to OECD 308, the guidance with which the aerobic aquatic metabolism study (PMRA No. 3395690) was conducted, the sediment for the aerobic study has "typical average redox potentials (Eh) in the anaerobic zone of the sediment range from -80 to -190 mV". The data for the 1WS system (Table 5) results in an average Eh of about -114 mV, which is within the cited range for sediment. This cited range was exceeded in only two sampled replicates (in other words, Eh < -190 mV; -216 mV for 1WS (sample 9) on day 21 and -283 mV for 1WS (sample 14) on day 60; Table 5). These minor deviations were not considered to have a large effect on the study results. Therefore, according to PMRA guidance, as half-lives were available from two systems, the longer half-life of these two systems (in other words, 1WS) was chosen for the drinking water modelling.

4. Comment related to exposure from drinking water, residues modelled and fate inputs Table 3.5.1

The registrant calculated an aerobic aquatic degradation half-life of 744.6 days for spidoxamat total residues in water (parent + BCSAH92431). This value is the maximum half-life of the two aerobic water/sediment systems, which were derived from PestDF modelling with output shown in Figure B-15 and B-16 in Chen (2022, PMRA No. 3395677). The output was further adjusted from 20°C (lab) to 25°C (for modelling) using a Q_{10} of 2. The registrant recommends that the PMRA use 744.6 days as the water half-life in drinking water modelling, or at least mention this value in the "Note" column of Table 3.5.1. References: Chen, J. (2022), Drinking Water Exposure Assessment of Spidoxamat Based on Proposed Uses in Canada, PMRA No. 3395677, M-814657-01-1.

Health Canada response:

While the single first-order (SFO) calculated by Chen (2022; PMRA No. 3395677) in Figure B-15 and the PMRA are identical (1503 days), the values generated for the indeterminate order rate equation (IORE) model differ considerably. As none of the models produced a good fit to the degradation curve, the longest reported representative half-life was chosen (IORE). This approach is in line with current PMRA guidance. Furthermore, as the value from Chen (2022) was included as part of this comment, the addition of a note to Table 3.5.1 would not add value to the published document.

Ecoscenario modelling was not required to further characterize the environmental risk to aquatic organisms as there was no risk observed at the screening level. Modelling EECs were thus only used in the human health dietary risk assessment, where groundwater modelling EECs were higher than those for surface water. Model input parameters for groundwater do not include aquatic aerobic biotransformation. Accordingly, any changes to the aquatic biotransformation half-life would not result in any difference to the modelling EECs, and consequently, no differences in the outcome of the risk assessment.

5. Following publication of the PRD2025-15, *Spidoxamat, Velancor, Plenexos Smart, Plenexos Care*, the PMRA identified an error in Table 11, The required personal protective equipment based on the acute toxicity profile of the 3 end-use product formulations and exposure to spidoxamat. A higher level of respiratory protection than is required was incorrectly identified in Footnote 1. The corrected wording of Footnote 1 is as follows:

> The respirator MUST be a NIOSH-approved N95 (minimum) filtering facepiece respirator (dust mask) that is properly fit tested.

Other information

The relevant confidential test data on which the decision is based (as referenced in PRD2025-15, *Spidoxamat, Velancor, Plenexos Smart, Plenexos Care*) are available for public inspection, upon application, in the PMRA's Reading Room. For more information, please contact the Pest Management Information Service.

Any person may file a notice of objection,[5] which must be based on scientific grounds, regarding this registration decision on *spidoxamat, Velancor, Plenexos Smart, Plenexos* Care within 60 days from the date of publication of this Registration Decision through the Public Engagement Portal (Public Engagement Portal forms – Notice of Objection). The request for reconsideration must include the Notice of Objection form, the scientific explanation of the objection and the supporting scientific evidence in possession of the requestor that wouldn't already be in the PMRA's possession or cite specific PMRA documentation they wish to rely on as supporting evidence (for example, scientific reports) in the form of electronic copies of cited references. Each of the references provided or cited must be clearly associated with the objection it supports. Failure to provide a complete package may result in the Notice of Objection being considered ineligible for further consideration by the PMRA.

For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and pest management portion of the Canada.ca website or contact the Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act.*

Evaluation approach

Legislative framework

The Minister of Health's primary objective under the *Pest Control Products Act* subsection 4(1) is to prevent unacceptable risks to individuals and the environment from the use of pest control products.

As noted in the preamble of the Act, it is in the national interest that the attainment of the objectives of the federal regulatory system continue to be pursued through a scientifically-based national registration system that addresses risks to human health, the environment and value both before and after registration and applies to the regulation of pest control products throughout Canada; and that pest control products with acceptable risk and value be registered for use only if it is shown that their use would be efficacious and if there is acceptable risk to human health and the environment, taking into account the conditions of registration.

For the purposes of the Act, the health or environmental risks of a pest control product are acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from exposure to or use of the product, taking into account its conditions of registration as per subsection 2(2) of the *Pest Control Products Act*.

Risk for the human health and environment, and value are defined under the Act subsection 2(1) as follows:

> **Health risk**, in respect of a pest control product, means the possibility of harm to human health resulting from exposure to or use of the product, taking into account its conditions or proposed conditions of registration.
>
> **Environmental risk**, in respect of a pest control product, means the possibility of harm to the environment, including its biological diversity, resulting from exposure to or use of the product, taking into account its conditions or proposed conditions of registration.
>
> **Value**, in respect of a pest control product, means the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact.

When evaluating the health and environmental risks of a pesticide and determining whether those risks are acceptable, subsection 19(2) of the *Pest Control Products Act* requires Health Canada to apply a scientifically-based approach. The science-based approach to assessing pesticides considers both the toxicity and the level of exposure of a pesticide in order to fully characterize risk.

Pre-market assessments are based on a required set of scientific data that must be provided by the applicants for pesticide registrations. Additional information from published scientific reports, other government departments and international regulatory agencies are also considered.[6]

Risk and value assessment framework

Health Canada uses a comprehensive body of modern scientific methods and evidence to determine the nature as well as the magnitude of potential risks posed by pesticides. This approach allows for the protection of human health and the environment through the application of appropriate and effective risk management strategies, consistent with the purpose described in the preambular text set out above.

Health Canada's approach to risk and value assessment is outlined in A Framework for Risk Assessment and Risk Management of Pest Control Products.[7] A high-level overview is provided below.

i) Assessing potential health risks

With respect to the evaluation and management of potential health risks, Health Canada's risk assessments follow a structured, predictable process that is consistent with international approaches and the Health Canada Decision-Making Framework for Identifying, Assessing, and Managing Health Risks.[8]

The evaluation of potential health risks begins with a consideration of the toxicological profile of a pesticide to establish reference doses at which no adverse effect is expected and against which the expected exposure is assessed. This includes, where appropriate, the use of uncertainty (protection) factors to provide additional protection that accounts for the variation in sensitivity among members of human population and the uncertainty in extrapolating animal test data to humans. Under certain conditions, the *Pest Control Products Act* requires the use of another factor to provide additional protection to pregnant women, infants, and children. Other uncertainty factors, such as a database deficiency factor, are considered in specific cases. More details related to the application of the uncertainty factors are provided in SPN2008-01.[9]

Assessments estimate potential health risks to defined populations[10] under specific exposure conditions. They are conducted in the context of the proposed or registered conditions of use, such as the use of a pesticide on a particular field crop using specified application rates, methods and equipment. Potential exposure scenarios consider exposures during and after application of the pesticide in occupational or residential settings, food and drinking water exposure, or exposure when interacting with treated pets.

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6 Information Note – *Determining Study Acceptability for use in Pesticide Risk Assessments*

7 PMRA Guidance Document, *A Framework for Risk Assessment and Risk Management of Pest Control Products*

8 *Health Canada Decision-Making Framework for Identifying, Assessing, and Managing Health Risks* - August 1, 2000

9 Science Policy Note: *The Application of Uncertainty Factors and the Pest Control Products Act Factor in the Human Health Risk Assessment of Pesticides*

10 Consideration of Sex and Gender in Pesticide Risk Assessment

Also considered are the anticipated durations (short-, intermediate- or long-term) and routes of exposure (oral, inhalation, or skin contact). In addition, an assessment of health risks must consider available information on aggregate exposure and cumulative effects.

ii) Assessing risks to the environment

With respect to the evaluation of environmental risks, Health Canada's environmental risk assessments follow a structured, tiered approach to determine the likelihood that exposure to a pesticide can cause adverse effects on individual organisms, populations, or ecological systems. This involves screening assessments starting with simple methods, conservative exposure scenarios and sensitive toxicity effects metrics, then moving on, where required, to more refined assessments that can include exposure modelling, monitoring data, results from field or mesocosm studies, and probabilistic risk assessment methods.

The environmental assessment considers both the exposure (environmental fate, chemistry, and behaviour, along with the application rates and methods) and hazard (toxic effects on organisms) of a pesticide. The exposure assessment examines the movement of the pesticide in soil, water, sediments and air, as well as the potential for uptake by plants or animals and transfer through the food web. The possibility for the pesticide to move into sensitive environmental compartments such as groundwater or lakes and rivers, as well as the potential for atmospheric transport, is also examined. The hazard assessment examines effects on a large number of internationally recognized indicator species of plants and animals (terrestrial organisms include invertebrates such as bees, beneficial arthropods, and earthworms, birds, mammals, plants; aquatic organisms include invertebrates, amphibians, fish, plants and algae), and includes considering effects on biodiversity and the food chain. Acute and chronic effects endpoints are derived from laboratory and field studies that characterize the toxic response and the dose–effect relationship of the pesticide.

The characterization of environmental risk requires the integration of information on environmental exposure and effects to identify which, if any, organisms or environmental compartments may be at risk, as well as any uncertainties in characterizing the risk.

iii) Value assessment

Value assessments consist of two components: an assessment of the performance of a pest control product and its benefits.

Assessing pesticide performance involves an evaluation of the pesticide’s efficacy in controlling the target pest and the potential for the pesticide to damage host crops or use sites. Where the efficacy of a pesticide is acceptable, the assessment serves to establish appropriate label claims and directions and an application rate (or rate range) that is effective without being excessive, and with no unacceptable damage to the use site or host organism/crop (and subsequent hosts or crops) under normal use conditions.

In many cases, proof of performance alone is sufficient to establish the value of the pesticide, so that an in-depth or extensive evaluation of benefits may not be required. However, a more thorough assessment of benefits may be undertaken in particular cases where performance alone does not sufficiently demonstrate value, or while developing risk management options.

Risk management

The outcomes of the assessments of risks to human health and the environment, and the assessment of value, form the basis for identifying risk management strategies. These include appropriate risk mitigation measures and are a key part of decision-making on whether health and environmental risks are acceptable. The development of risk management strategies take place within the context of the pesticide's conditions of registration. Conditions can relate to, among other things, the specific use (for example, application rates, timing and frequency of application, and method of application), personal protective equipment, pre-harvest intervals, restricted-entry intervals, buffer zones, spray drift and runoff mitigation measures, handling, manufacture, storage or distribution of a pesticide. If feasible conditions of use that have acceptable risk and value cannot be identified, the pesticide use will not be eligible for registration.

The selected risk management strategy is then implemented as part of the registration decision. The pesticide registration conditions include legally-binding use directions on the label. Any use in contravention of the label or other specified conditions is illegal under the *Pest Control Products Act*.

Following a decision, continuous oversight activities such as post-market assessments, monitoring and surveillance, including incident reporting, all play an essential role to help ensure the continued acceptability of risks and value of registered pesticides.

List of abbreviations

%	percent
>	greater than
≤	lesser than or equal to
EEC	estimated environmental concentration
Eh	redox potential
L	litre
LC_{50}	lethal concentration 50%
mV	millivolts
mg	milligram(s)
OECD	Organisation for Economic Co-operation and Development
PMRA	Pest Management Regulatory Agency
PRD	Proposed Registration Decision
Q_{10}	Temperature coefficient
1WS	water/sediment system no 1, Humsterbach
2WS	water/sediment system no 2, Schwarzenbachtalsperre

References

PMRA Document Number	Reference
3395690	2018, [Phenyl-UL-14C]BCS-AA10147: Aerobic degradation and metabolism in two water/sediment systems, DACO 8.2.3.5.4
3395677	2022, Drinking water exposure assessment of spidoxamat based on proposed uses in Canada, DACO: 8.6