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Registration Decision

RD2026-18

# Deltamethrin, Ultratec 5SC MUP and Raid Bug Defense

*(publié aussi en français)*

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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<sup>1</sup> 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 Evaluation Approach section of this document.

## **Registration Decision Statement<sup>2</sup> for Deltamethrin**

Health Canada, pursuant to subsection 8(1) of the *Pest Control Products Act*, is granting registration for the sale and use of Deltamethrin Technical Insecticide, Ultratec 5SC MUP and Raid Bug Defense containing the active ingredient deltamethrin to control ants, cockroaches, house flies, stable flies and spiders on and around the home (outdoors only).

This decision is consistent with the Proposed Registration Decision PRD2026-12, *Deltamethrin, Ultratec 5SC MUP and Raid Bug Defense*, containing the detailed evaluation of the information submitted in support of this registration, which underwent a 30-day consultation period ending on 16 August 2026. The evaluation found that, under the approved conditions of use, the health and environmental risks and the value of the pest control product(s) are acceptable. Health Canada received written comments relating to the health, environmental and value assessments during the public consultation period conducted in accordance with section 28 of the *Pest Control Products Act*. However, some of the comments were not directly related to the proposed decision in PRD2026-12, Deltamethrin, Ultratec 5SC MUP and Raid Bug Defense.

In addition, a comment from a homeowner was received in support of deltamethrin.

## **Comments and responses**

**Health Canada received comments from the applicant and a non-governmental organization on the health, environmental and value assessments.**

### **1. Comment related to the toxicokinetic and toxicodynamic contributors to age-related sensitivity in the rat**

The applicant stated that immature rats (at least through 21 days of age) are more sensitive to deltamethrin than adult rats due to their limited metabolic capacity leading to increased brain concentrations, suggesting that the observed sensitivity was due to toxicokinetics (TK) differences and not due to toxicodynamic (TD) sensitivity (that is, not due to an innate difference in neural tissue sensitivity). Specifically, the applicant cites acute oral LD<sub>50</sub> values of 5, 11, and 81 mg/kg bw in 11-, 21-, and 72-day old male rats, respectively, as well as comparable brain concentrations that were observed at different lethal doses in 21- and 72-day old rats. It is also noted by the applicant that at an acute oral dose of 4 mg/kg bw deltamethrin, both 21- and 72-

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<sup>1</sup> Information Note – *Determining Study Acceptability for use in Pesticide Risk Assessments*.

<sup>2</sup> “Decision statement” as required by subsection 28(5) of the *Pest Control Products Act*.

day old rats experience 50% decreases in acoustic startle response, indicating that sensitivity of young rats may only be applicable to high doses.

### **Health Canada response**

The potential for the observed neurotoxic responses in the young following exposure to deltamethrin to be due to either TK or TD differences when compared to adult animals was taken into consideration in the review that was summarized in PRD2026-12. However, the available toxicology database did not demonstrate a clear lack of TD sensitivity. Of note is a study in the published literature (Williams et al., 2019, PMRA No. 3686295) in which tremors occurred in pups on post-natal day (PND) 15 at comparable and threefold lower brain levels of deltamethrin than adult rats (PND 90), without the presence of other signs of neurotoxicity. There were also more severe tremors in pups at up to fourfold lower brain levels (before brain  $C_{max}$  occurred) compared to adults with mild tremor (at brain  $C_{max}$ ) and mortality in pups occurred at up to 2.3-fold lower brain levels than adults without mortality.

Another study in the published literature (Symington et al., 2023, PMRA No. 3686298) indicated that there may also be differences in adult and juvenile rat voltage gate sodium channels (VGSC) in the brain, specifically juvenile VGSC appeared to have greater sensitivity to modification of VGSC kinetics at all tested levels of deltamethrin.

Other evidence of potential TD-based juvenile sensitivity to deltamethrin includes a rat oral toxicokinetic study (Kim et al., 2008, PMRA No. 2007549; Kim et al., 2010, PMRA No. 2007551) in which salivation and tremors were observed in PND 21 but not PND 40 or PND 90 rats at comparable peak brain levels of deltamethrin. The severity of salivation also appeared to be higher in PND 40 rats at lower peak brain levels of deltamethrin than in PND 90 rats. Additionally, this published study may have been underestimating TD sensitivity to neurotoxicity and mortality due to the use of non-fasted PND 10 pups, but fasted animals in other age groups. Furthermore, the lack of brain concentration measurements in juveniles with neurotoxic signs starting 1-hour post-dosing (that is, before brain  $C_{max}$ ) could also have contributed to this underestimation of juvenile sensitivity.

The study used for the point of departure for Health Canada's human health risk assessment (Sheets et al., 1994, PMRA No. 1857302) also suggests juvenile sensitivity to mortality, as PND 21 weanlings had higher mortality and lower deltamethrin brain concentration levels than PND 72 counterparts.

Therefore, given the toxicology data currently available, Health Canada cannot conclude that juvenile sensitivity in rats is due exclusively to age-related TK differences.

## **2. Comment related to the fetal, infant and child sensitivity**

The applicant stated that while rats are generally appropriate to characterize effects of pyrethroids on the human nervous system due to comparable functionality and distribution of VGSC, there are differences in the enzymes involved in pyrethroid degradation. While rats develop the key enzymes for deltamethrin metabolism over several weeks (as observed by increased sensitivity of 11- and 21-day old rats compared to adult rats), the applicant noted that human infants have comparable deltamethrin metabolism capacity to adults as early as 6 months of age because of carboxylesterase (CES) enzymes in liver tissue. Therefore, the applicant

asserted that the 10-fold PCPA factor is not required as this ontogeny of CES enzymes should be considered.

Similarly, another comment stated that due to a lack of increased fetal mortality and lack of increased fetal sensitivity compared to maternal animals, the guideline developmental toxicity, developmental neurotoxicity, and two-generation reproductive studies indicate a lack of fetal sensitivity to deltamethrin. According to the applicant, this is expected to be due to low maternal exposure, maternal animals effectively clearing deltamethrin from the blood, and/or limited transfer through the placenta to the fetus. The applicant stated that human fetuses are also likely to develop the ability to metabolize deltamethrin during gestation, and there are no known reports of adverse health events in fetal or newborn humans associated with deltamethrin exposure. Finally, the applicant noted that rats are appropriate models to predict TD sensitivity in humans and toxicity studies in rats also do not demonstrate evidence of fetal toxicity.

### **Health Canada response**

Health Canada acknowledges that different enzyme configurations are involved in human and rat metabolism of deltamethrin. As summarized in the literature (Pitzer et al., 2022, PMRA No. 3516195) there remain outstanding concerns for additional vulnerability of human children to the neurotoxic effects of deltamethrin beyond the age of 6 months due to immature blood-brain barriers, lower body fat availability to sequester compounds, greater free fractions in circulation due to lower plasma protein binding, lower rates of metabolism, more vulnerable neurodevelopmental processes (including proliferation, migration, synaptogenesis, gliogenesis, apoptosis, myelination, and activity-dependent connectivity) compared to adult brains (Pitzer et al., 2021, PMRA No. 3905942). This vulnerability begins during organogenesis and extends through the fetal period to birth, through childhood, adolescence, and into early adulthood in humans as the brain develops. Collectively, these factors indicate that pre-natal and post-natal brain development are susceptible life stages. Further, some evidence summarized in the literature (Pitzer et al., 2021, PMRA No. 3905942) indicates that carboxylesterase enzyme expression is higher in adults than in children or fetuses, and there is also evidence of microsome activity being higher in adults than children or fetuses.

Regarding fetal sensitivity and exposure, there is evidence in the literature (Huang et al., 2025, PMRA No. 3826229) that maternal exposure to deltamethrin leads to alternations in neural structures in fetuses following exposure as low as 1 mg/kg bw, and presents as behavioural effects at higher dose levels. Similarly, in another study (Hao et al., 2024, PMRA No. 3826231) dams dosed with deltamethrin resulted in offspring with altered dendritic branching at maternal doses of 1 mg/kg bw and numerous neurotoxic effects at 4 mg/kg bw.

Therefore, while the exact avenue for juvenile sensitivity may differ between rats and humans, concern for juvenile sensitivity in the developing human cannot be entirely dismissed based on the ontogeny of CES enzymes, or maternally-mediate exposure.

### 3. Comment related to the mode of action and reversibility of effect

The applicant stated that the neurotoxic effects associated with pyrethroid insecticides occur at the time of peak brain concentrations, and are reversible given the mode of action for type II pyrethroids (that is, due to action potential blockade). As per the applicant, the acute neurotoxic effects observed at the point of departure (POD) of 1 mg/kg bw are therefore rapidly-reversible, making this POD with a 100-fold uncertainty factor for inter- and intra-species variability conservative and not necessitating retention of the full 10-fold PCPA factor.

#### Health Canada response

Health Canada acknowledges that signs of neurotoxicity associated with deltamethrin, namely in adult rats, are sometimes reversible. However, as per the adverse outcome pathway (AOP) mapping the key events covered by the developmental neurotoxicity in vivo battery (DNT IVB) for deltamethrin developed by the European Food Safety Authority (EFSA) (PMRA No. 3681074), downstream effects and subsequent adverse outcomes from deltamethrin binding to VGSC during development are not necessarily reversible. The AOP also notes that exact critical developmental windows are currently unknown, as are the quantitative relationships between the key event relationships and the adverse outcomes. The findings of the AOP are supported by in vivo evidence from developmental exposure to pyrethroids, specifically deltamethrin, that indicates potential irreversible effects on behaviour and neurochemistry that may be delayed until adulthood, or persist from juvenile exposure into adulthood (Jimenez et al., 2022, PMRA No. 3826210, Curtis et al., 2023, PMRA No. 3826211 and Curtis et al., 2024, PMRA No. 3826212), including at dose levels comparable to the current point of departure of 1 mg/kg bw (Pitzer et al., 2019, PMRA No. 3470523; Eriksson et al., PMRA No. 2007557).

With respect to the magnitude of the PCPA factor, there are seven key considerations that contribute to the weight of evidence for determining the level of concern for prenatal and postnatal toxicity (see Table 1 of SPN2008-01, *Science Policy Note on The Application of Uncertainty Factors and the Pest Control Products Act Factor in the Human Health Risk Assessment of Pesticides*).

One of these key considerations is seriousness of the endpoint. As per the SPN2008-01, a serious endpoint is one that causes congenital malformation, results in persistent or significant disability or incapacity, is life-threatening or results in death. If the critical endpoint is based on a serious toxicological effect, a high degree of concern would be identified. The temporal nature of the effect (for example, time of onset, persistence, recovery) will influence the determination of the degree of concern, with irreversible findings eliciting greater concern.

In general, endpoints indicative of developmental neurotoxicity are considered serious in the context of determining the degree of concern for prenatal and postnatal toxicity and the appropriate magnitude of the PCPA factor. As indicated above, several studies with deltamethrin have shown irreversible effects on the developing nervous system. Additionally, the endpoint driving the point of departure in the Sheets et al., 1994 study is a decrease in acoustic startle response (ASR) amplitude, which is an evolutionarily conserved protective response. A robust, treatment-related change in ASR is therefore an impairment in an evolutionarily conserved protective neurological function. When observed following developmental exposure, the alteration may also indicate that the development or maturation of the sensory, central neural

and/or motor systems have been interfered with. This impairment could reasonably be considered a significant functional incapacity, which is a criterion for seriousness highlighted in SPN2008-01, even if its precise manifestation in humans cannot be predicted. Therefore, the ASR effects observed across the toxicological database, especially after developmental exposure, indicate relative seriousness.

Furthermore, a high degree of concern for pre- and postnatal toxicity is also indicated based on the other six considerations outlined in SPN2008-01, including sensitivity or susceptibility of the young, dose response, toxicokinetics, mode of action, confidence in the data, and human information, as elucidated further below.

Regarding sensitivity or susceptibility of the young, a high degree of concern is considered when there is qualitative or quantitative sensitivity. In the case of deltamethrin, there is evidence in the database of quantitative sensitivity of juvenile rats, as described in PRD2026-12 and in the response to Comment 1. A relatively steep dose response is also seen in studies in the database, increasing the level of concern. In the Williams et al., 2019 publication, tremors are observed at 1 mg/kg bw, and mortality is observed at 2 mg/kg bw. Additionally, there is no NOAEL in the Sheets et al., 1994 study from which the POD is derived. In another guideline study (See PRVD2015-07, PMRA No. 1549379) at a dose level of 7 mg/kg bw there was one instance of mortality, but 14 instances at 11 mg/kg bw, further suggesting a steep dose response in the manifestation of deltamethrin toxicity.

The degree of concern for prenatal or postnatal toxicity is also elevated in situations where there is a higher internal dose of a toxic chemical in the young compared to adults, and when there is evidence for significant placental or lactational transfer. The toxicokinetic studies in the deltamethrin database indicate higher internal dose levels in younger animals compared to adults receiving the same external dose. There is also evidence for lactational transfer based on the detection of deltamethrin in the brain of young rats (PND 10, 14, and 16) following exposure during lactation.

With respect to the mode of action, deltamethrin exerts its effects in part by actions on VGSC that are common amongst mammals, and thus relevant to humans. There is evidence based on the results of several studies that this mode of action leads to adverse consequences in the young, including the evidence in the database for persistent and delayed neurotoxic effects.

Confidence in the data depends on the quality of the database, limitations with key studies, and whether the critical POD is poorly defined. The overall toxicology database for deltamethrin is of good quality in that there are several studies designed to examine pre- and postnatal toxicity. However, there are some gaps with respect to exposure of the young during certain periods of development that were not assessed. There are also certain limitations associated with the study used for the POD used in the human health risk assessment (Sheets et al., 1994, PMRA No. 1857302). Finally, a NOAEL was not defined in the key study and the critical POD was a LOAEL, although the observed change at the LOAEL was expected to be close to a threshold response.

With respect to human information, there is ample evidence that paresthesia, which is relevant to the neurotoxic mode of action of deltamethrin, is reported following dermal exposure. While epidemiology studies have shown associations between biomarkers of potential deltamethrin exposure and adverse neurological outcomes, these studies come with limitations in that a causal relationship cannot be determined.

Overall, the above considerations point to a high degree of concern for pre- and postnatal toxicity, thus warranting the retention of the full 10-fold PCPA factor.

#### **4. Comment related to the introduction of a domestic-class use for deltamethrin**

The commenter stated that PRD2026-12 introduces, for the first time in Canada, a domestic-class use of deltamethrin and therefore fundamentally changes the risk profile of the active in Canada. The commenter noted that previous Canadian decisions identified the absence of domestic-class uses and argued that the proposed registration creates a new residential handler exposure pathway involving homeowners mixing, loading, handling, and applying the product. The commenter further stated that the risk assessment relies on standard American consumer-product exposure algorithms and does not adequately explain why a risk-management position that excluded homeowner use for several decades is no longer warranted.

#### **Health Canada response**

Health Canada has considered the comment that the proposed registration of Raid Bug Defense represents a new domestic-class use of deltamethrin in Canada and that this new use pattern required additional consideration beyond the residential risk assessment presented in PRD2026-12.

Health Canada notes that the historical absence of a domestic-class deltamethrin registration in Canada should not be interpreted as a previous determination that homeowner use was unacceptable. Under the *Pest Control Products Act*, Health Canada assesses the specific uses that are proposed by applicants for registration. Previous registration and re-evaluation decisions reflected the uses that had been requested and supported by applicants at those times. The absence of a domestic-class use from the previously published decision documents since the first registration does not mean that a domestic class use had been proposed for registration and denied. The current application includes a proposed domestic-class end-use product and, consequently, residential handler, postapplication, bystander, and aggregate exposure assessments were conducted for this use pattern as part of the risk assessment. The assessments included algorithms and relevant inputs, which have been validated internationally and are based on an extensive database of studies (refer to Comment 6).

The environmental risks of the product were also assessed. The environmental risk assessment considered the available environmental fate and effects data from previous assessments of deltamethrin along with the proposed domestic use pattern as localized spot and crack and crevice treatments on and around residential structures. The fact that previous decisions did not include the registration of domestic-class products therefore reflects the scope of the uses under consideration in those earlier assessments rather than a standing regulatory position that domestic uses of deltamethrin could not be supported.

Accordingly, Health Canada concludes that the proposed registration does not represent an unassessed change in the risk profile of deltamethrin. Rather, the new residential use pattern was rigorously evaluated through residential, aggregate, bystander, and environmental risk assessments using current risk-assessment methodologies and updated hazard characterization. Based on the available scientific information, Health Canada determined that the risks associated with the proposed domestic-class use of Raid Bug Defense are acceptable when used according to the proposed label directions.

#### **5. Comment related to the consideration of the literature and PAN European withdrawal petition with regards to the toxicology point of departure**

The commenter made several arguments to support their claim that evidence in the literature does not support the current POD selected by Health Canada for use in human health risk assessment. In particular, the commenter noted that the critical POD used for human health risk assessment (the LOAEL of 1 mg/kg bw from the Sheets et al., study; PMRA No. 1857302) has not changed since the previous assessment in 2015 (PRVD2015-07), and that Health Canada identified several limitations with this study. They further noted that the updated assessment in PRD2026-12 restores the full 10-fold PCPA factor where it had previously been reduced to threefold in PRVD2015-07 based on new evidence in the scientific literature confirming greater sensitivity of the young to deltamethrin's neurotoxic effects. While the commenter agreed with the retention of the full 10-fold PCPA factor, the commenter noted that the same literature evidence reported neurotoxic effects in the young at dose levels at or below the existing point of departure of 1 mg/kg bw. The commenter objected to the fact that the accumulation of these studies was not deemed sufficient to revisit the point of departure itself. The commenter also objected to the studies being classified as limited based on the absence of historical control data and noted that other limitations (such as graphical representation of data, unclear methods, among others) should be addressed by contacting the study authors or resolved by the registrant. The commenter also cited published literature studies that had not been included in the review summarized in PRD2026-12, as well as a formal request by the Pesticide Action Network Europe (PAN Europe) that deltamethrin be banned in the European Union based on the assertion that no safe dose for developmental neurotoxicity has been demonstrated.

#### **Health Canada response**

The commenter is correct that the LOAEL of 1 mg/kg bw/day based on reduced acoustic startle response in weanling (PND 21) rats from the Sheets et al. 1994 (PMRA No. 1857302) study, continues to be the critical POD for assessing risks to human health from exposure to deltamethrin for most exposure scenarios. The major revision to the human health assessment with the recent expansion of use is the retention of the full 10-fold PCPA factor when relying on this POD for risk assessment. This decision to retain the full 10-fold PCPA factor was informed by the limitations in the Sheets et al., 1994 study as well as qualitative evidence in the scientific literature strengthening the concern for effects on the developing nervous system. Although some of these literature studies identified potential developmental neurotoxic effects at dose levels below the POD of 1 mg/kg bw, those studies were limited in their ability to be used quantitatively in the assessment, and the retention of the full 10-fold PCPA factor would therefore afford additional protection for the disproportionately affected sub-population of children and neonates.

While the lack of historical control data was one noted limitation of these studies, this omission was considered minor and it was the weight of the collection of limitations that rendered these studies unqualified to provide a point of departure for risk assessment. It should be noted that both Health Canada and the registrant contacted the authors of the most critical studies in the literature and obtained what information they could to address the noted limitations. Despite this, sufficient limitations remained to preclude the studies from being utilized for the POD.

The published literature studies that the commenter cited that had not been included in the review summarized in PRD2026-12 were considered by Health Canada but not included in the hazard characterization as the focus was placed on those studies that were critical to determining a point of departure for human health risk assessment. The cited studies were epidemiology studies in which associations between urinary pyrethroid metabolite concentrations and impaired neurological indices in children were noted. Epidemiology studies are typically designed to look for associations, rather than causes. The most useful and relevant epidemiological studies are those that properly characterize exposure in terms of how the product is used. Animal studies that were highlighted by the commenter as being cited in PAN Europe's letter to the European Commission and not summarized in PRD2026-12 were also considered by Health Canada but were not deemed critical to the assessment as the doses tested in those studies exceeded the critical POD and thus the established toxicology reference values would afford protection against any reported effects in those studies, and as such were not included in PRD2026-12.

## **6. Comment related to the postapplication exposure to adults and children**

In PRD2026-12, postapplication exposure for both adults and children and aggregate exposure for children were not quantified. The commenter considered that the Health Canada assessment was based on assumptions about behaviour around treated surfaces rather than on data specific to this new use pattern. As such, the commenter requested that quantitative postapplication dermal and incidental oral exposure assessments for both adults and children, specific to the proposed use pattern (perimeter and spot treatments to home exteriors and ant hills) be conducted, rather than relying on a categorical exemption developed for a different regulatory context (USEPA turf/lawn use).

### **Health Canada response**

Health Canada has considered the comment regarding the use of residential exposure assessment assumptions originating from the United States Environmental Protection Agency (USEPA), including the exposure scenarios used in the assessment.

Health Canada acknowledges that elements of the residential exposure assessment, including certain scenario assumptions, were derived from established exposure assessment methodologies described in the 2012 USEPA Residential SOPs. Health Canada adopted the SOPs as it is based on an extensive database of studies monitoring human behaviour in relationship to their environment. This database includes task force data, studies available in the public literature and the USEPA Exposure Factors Handbook (2011). Health Canada has evaluated these methodologies and determined that the resulting exposure scenarios are applicable for characterizing potential residential pesticide exposures in the Canadian context. Consequently, these exposure assessment approaches continue to be used where they are considered scientifically appropriate and protective of human health.

In addition, the commenter did not submit new exposure data, which demonstrated any quantifiable contact by adults and children to treated surfaces specific to the use pattern under registration. As no new data were submitted, Health Canada did not conduct a quantitative postapplication risk assessment.

## **7. Comment related to the environmental mitigation requirements**

The commenter states that PRD2026-12 does not explain why only general toxicity and contamination-avoidance statements are proposed when additional mitigation has previously been required for other deltamethrin products. The commenter cites RVD2018-27 and PRVD2015-07, noting that measures such as avoiding application when heavy rain is forecast, runoff-reduction practices, vegetative-strip guidance, and restrictions related to drift and runoff were previously required because of the high aquatic toxicity of deltamethrin, particularly to aquatic invertebrates.

The commenter also references the USEPA Interim Registration Review Decision for Deltamethrin (2020), which imposed use-specific mitigation measures for residential and urban outdoor structural/perimeter applications, including restrictions related to foundation perimeter treatments, applications to impervious surfaces, application before rainfall, and contamination of drains.

The commenter notes that Raid Bug Defense is intended for outdoor residential use, including applications to foundation perimeters and other spot-treatment locations around homes, and argues that this use pattern is comparable to those for which Health Canada and the USEPA previously required runoff- and rain-related mitigation. The commenter therefore requests that Health Canada either provide the use-specific data and rationale supporting the conclusion that additional rain-forecast and runoff-avoidance label statements are unnecessary for this product or add such statements consistent with RVD2018-27 (Appendix III, Section VI).

## **Health Canada response**

Although the commenter states that Raid Bug Defense can be applied to foundation perimeters, this product is intended for spot treatment and crack and crevice treatment only, and not for perimeter treatment. The label defines spot application as being localized to a surface area not more than 0.2 m<sup>2</sup> and spots are not to be adjoining. Crack and crevice treatment is an application directly into narrow openings on the surface of the structure and does not include the treatment of exposed surfaces. Environmental exposure, including exposure from drift and runoff, is expected to be minimal for these uses.

As indicated by the commenter, the environmental risk mitigation measures proposed for Raid Bug Defense include standard hazard statements informing users that the product is toxic to bees, beneficial insects, and aquatic organisms, as well as statements to prevent contamination of irrigation, drinking water supplies and aquatic habitats. These statements are generally consistent with those included on the labels of other registered products used exclusively for structural applications (in other words, Annihilator PolyZone, Reg. No. 33526; PRD2019-07; RD2019-15). However, as Annihilator PolyZone is a commercial-class product and its uses include broadcast application to the exterior surfaces of buildings, not all statements on this product's label were considered appropriate for the Raid Bug Defense label.

The re-evaluation of deltamethrin (PRVD2015-07, RVD2018-27) assessed uses on food and feed crops, and non-crop areas, which have much higher potential for environmental exposure to aquatic habitats than the spot and crack and crevice treatments considered in PRD2026-12. Although the re-evaluation of deltamethrin is referred to as the source of the environmental fate and ecotoxicity data considered in the assessment of Raid Bug Defense, the proposed spot and crack and crevice treatments would result in minimal environmental exposure and, therefore, do not require the same statements for mitigation of runoff exposures as products that can be applied over more substantial areas.

With respect to the risk mitigation measures described in the USEPA Interim Registration Review Decision for Deltamethrin, the restrictions on treatable perimeter distance from building foundations and prohibitions on application to impervious surfaces except as spot or crack and crevice treatment are not applicable to the uses of Raid Bug Defense as it is used for spot and crack and crevice treatments only and not for perimeter or broadcast applications. Although U.S. labels for similar deltamethrin products contain rain-related statements, current Canadian standards do not require these statements for domestic products that are solely used as spot or crack and crevice treatments.

After considering the comments provided by the commenter, no further updates to the environmental label statements are required.

## **8. Comment related to the cumulative assessment**

The commenter stated that the cumulative health risk assessment in PRD2026-12 is not adequate to address the cumulative effects for the new use of deltamethrin to support the registration of Raid Bug Defense. As such, the commenter requested Health Canada to either complete the pyrethroid cumulative health risk assessment before finalizing this registration or publish a use-specific scoping determination, explaining why this particular use does not warrant cumulative assessment prior to registration.

### **Health Canada response**

Health Canada has considered the comment and confirmed that a use-specific scoping determination was considered. The product Raid Bug Defense is to be applied to control certain insects on and around the home (outdoors). Based on this analysis, it was determined that non-occupational exposure from this major new use of deltamethrin is minimal. Therefore, the use of Raid Bug Defense does not warrant a cumulative risk assessment prior to its registration.

As noted in PRD2026-12, there is exposure of deltamethrin to residential applicators during spot and crack and crevice application of the ready-to-use product. A quantitative risk assessment was conducted for this exposure scenario, which resulted in calculated MOEs of at least 350000 (target MOE of 1000; 0.29% of the risk cup). Postapplication residential exposure is expected to be minimal based on limited human activity in treated areas. In addition, exposure from food or drinking water from the use of the product is not expected. As such, the non-occupational exposure attributable to the use of Raid Bug Defense minimally contributes to the cumulative exposure of pyrethroids, and a cumulative health risk assessment for the new use of deltamethrin is not required.

## **9. Comment related to the date of literature review conducted**

The commenter stated that there is an inconsistency regarding the date the literature search was conducted, with one instance in PRD2026-12 listing March 2025, while another instance states November 2025. Specifically, clarification was requested on when the literature search was conducted and whether studies published after March 2025 and before the closure of the consultation period will be considered.

### **Health Canada response**

An initial literature search was conducted by Health Canada in March 2025, and footnote 6 on page 10 of PRD2026-12 reflects that. Before finalization of the review and documentation later in 2025, another literature search was conducted in November 2025 to ensure any studies published between the initial search in March and November 2025 were captured. Health Canada considers all comments raised during the consultation period. New published scientific literature concerning deltamethrin will continue to be monitored as part of Health Canada's continuous oversight approach for monitoring scientific information sources.

## **10. Comment related to the value assessment**

Subsection 2(1) of the *Pest Control Products Act* defines "value" to include not only efficacy, but the product's health, safety, and environmental benefits and its social and economic impact, considered together with its conditions of registration. PRD2026-12's value assessment addresses efficacy alone, that Raid Bug Defense kills the target pests, without weighing that benefit against the incremental health and environmental cost of introducing, for the first time, an unrestricted consumer application pathway for this active ingredient (Comment 4), into a market that already offers effective alternatives using registered active ingredients with an established domestic-use history. The commenter requested Health Canada supplement the value assessment to address the incremental risk-benefit analysis required by subsection 2(1) of the *Pest Control Products Act*.

### **Health Canada response**

Subsection 2(1) of the *Pest Control Products Act* does not require a risk-benefit analysis. The subsection refers only to health, safety, and environmental benefits, not costs or risks. Examples of health or environmental benefits of a pest control product would include such things as a pesticide's ability to control pests that are disease vectors or invasive species, respectively. Social and economic impacts of a product such as Raid Bug Defense would include the provision of an additional choice to the consumer and an additional product on the market which could influence competitive pricing.

As described in the PMRA Guidance Document, *A Framework for Risk Assessment and Risk Management of Pest Control Products*, health risk, environmental risk, and value each must be acceptable before a pesticide can be registered. The primary consideration in the value assessment process is whether the product is efficacious. In most cases, proof of performance establishes the value of the pesticide, so that Health Canada would not normally engage in an in-depth or extensive evaluation of benefits. 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.

For further information on Health Canada's approach to the value assessment of pesticides, please refer to published Guidance Documents such as *Value Assessment of Pest Control Products* and *Value Guidelines for New Plant Protection Products and Label Amendments*, available on Health Canada's website.

## **Other information**

### **Inspection of confidential test data**

The relevant confidential test data on which the decision is based (as referenced in PRD2026-12, *Deltamethrin, Ultratec 5SC MUP and Raid Bug Defense*) are available for public inspection, upon application, in the Pesticides Regulatory Directorate's Reading Room. For more information, please contact the Pesticides Information Service.

### **Notice of objection**

Any person may file a notice of objection,<sup>3</sup> which must be based on scientific grounds, regarding this registration decision on deltamethrin, *Ultratec 5SC MUP and Raid Bug Defense* 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 Health Canada's possession or cite specific Health Canada 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 Health Canada. 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 Pesticides Information Service.

### **Proportional effort**

Active ingredients registered in Canada are categorized based on criteria in Health Canada's Policy on Proportional Effort. The categorization is used to inform Health Canada's allocation of resources related to pesticide reviews in alignment with the required level of regulatory effort. Deltamethrin is categorized as higher proportional effort based on the health and environmental criteria. Information on the risk assessment conclusions that resulted in the categorization is included in the proposed regulatory decision PRD2026-12. The proportional effort categorization will be used to inform the scope and level of effort needed for future reviews.

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<sup>3</sup> As per subsection 35(1) of the *Pest Control Products Act*.

## **Continuous oversight**

Health Canada's policy on continuous oversight of pesticides and the associated information note describe the process by which Health Canada monitors published scientific literature for active ingredients registered in Canada, and the criteria used to determine which active ingredients will be monitored when a final regulatory decision is made. The criteria in the information note have been met, therefore, scientific literature and regulatory information will be monitored as part of continuous oversight for this active ingredient.

## 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.<sup>4</sup>

### **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*.<sup>5</sup> 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.<sup>6</sup>

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.<sup>7</sup>

Assessments estimate potential health risks to defined populations<sup>8</sup> 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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<sup>4</sup> Information Note – *Determining Study Acceptability for use in Pesticide Risk Assessments*.

<sup>5</sup> PMRA Guidance Document, *A Framework for Risk Assessment and Risk Management of Pest Control Products*.

<sup>6</sup> Health Canada Decision-Making Framework for Identifying, Assessing, and Managing Health Risks – August 1, 2000.

<sup>7</sup> Science Policy Note: *The Application of Uncertainty Factors and the Pest Control Products Act Factor in the Human Health Risk Assessment of Pesticides*.

<sup>8</sup> 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, as well as 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 takes 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**

|                  |                                               |
|------------------|-----------------------------------------------|
| AOP              | adverse outcome pathway                       |
| bw               | body weight                                   |
| C <sub>max</sub> | maximum concentration                         |
| CES              | carboxylesterases                             |
| DNT IVB          | developmental neurotoxicity in vivo battery   |
| EFSA             | European Food Safety Authority                |
| kg               | kilogram                                      |
| LD <sub>50</sub> | lethal dose 50%                               |
| LOAEL            | lowest observed adverse effect level          |
| mg               | milligram                                     |
| MOE              | margin of exposure                            |
| MUP              | manufacturing use product                     |
| NOAEL            | no observed adverse effect level              |
| PCPA             | <i>Pest Control Products Act</i>              |
| POD              | point of departure                            |
| PMRA             | Pest Management Regulatory Agency             |
| PND              | postnatal day                                 |
| TD               | toxicodynamic                                 |
| TK               | toxicokinetics                                |
| USEPA            | United States Environmental Protection Agency |
| VGSC             | voltage gate sodium channels                  |

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