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Registration Decision

RD2026-14

# Etofenprox, RF2129 EC and RF2220 Premium Aerosol II-M Premise Spray

*(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 section of Evaluation approach of this document.

## **Registration Decision Statement<sup>2</sup> for Etofenprox, RF2129 EC and RF2220 Premium Aerosol II-M Premise Spray**

Health Canada, pursuant to subsection 8(1) of the *Pest Control Products Act*, is granting registration for the sale and use of Etofenprox Technical, RF2129 EC and RF2220 Premium Aerosol II-M Premise Spray, containing the technical grade active ingredient etofenprox, to control arthropod pests in and on various structures, including buildings, modes of transportation, kennels, and pet bedding, by broadcast, spot, crack and crevice, perimeter, void, and furniture treatments.

The Proposed Registration Decision PRD2026-04, *Etofenprox, RF2129 EC and RF2220 Premium Aerosol II-M Premise Spray*, containing the detailed evaluation of the information submitted in support of this registration, underwent a 30-day consultation period ending on 11 April 2026. 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*. Health Canada also received comments that were not directly related to the proposed decision in PRD2026-04, *Etofenprox, RF2129 EC and RF2220 Premium Aerosol II-M Premise Spray*.

### **Comments and responses**

Health Canada received comments from members of the public on the health and environmental assessments of etofenprox, RF2129 EC and RF2220 Premium Aerosol II-M Premise Spray.

#### **(1) Comment related to etofenprox causing effects on the thyroid**

One commenter highlighted that etofenprox affected the thyroid.

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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*.

### **Health Canada response:**

Health Canada agrees that there are effects in the thyroid in the mammalian toxicology database that was reviewed for etofenprox. Etofenprox caused thyroid tumours in rats, as well as an increase in the number of microfollicles, changes in thyroid hormones, and organ weight after repeated dosing. After long-term dietary dosing in rats, cystic follicles of the thyroid were additionally noted. The risk assessment for etofenprox protects against thyroid effects by ensuring that the level of exposure to humans is well below the lowest dose level at which these effects occurred in animal tests.

### **(2) Comment related to etofenprox causing endocrine disruption and intergenerational effects**

One commenter mentioned that there are emerging peer-reviewed studies that point to pyrethroids having endocrine-disrupting properties, and suggested there could be potential intergenerational impacts on children.

### **Health Canada response:**

Etofenprox is classified as a pyrethroid-like ether compound. Any emerging studies related to etofenprox and endocrine disruption were not provided by the commenter. With regards to the endocrine-disrupting potential of etofenprox, Health Canada has reviewed the required animal studies that evaluate downstream consequences of any potential effects on the endocrine system. The database contains a 2-generation reproductive toxicity study in rats; three special studies assessing developmental and reproductive toxicity in rats covering pre-mating, gestational, and lactational exposure to etofenprox; a prenatal developmental toxicity study in rats; two prenatal developmental toxicity studies in rabbits; and a developmental neurotoxicity study in rats. Together, these studies assess any adverse effects during preconception through gestation, lactation, and postnatal growth and development. Developmental effects in the young, including effects on the nervous system, malformations and variations in offspring, as well as reproductive effects on parental animals including fertility, reproductive performance, and reproductive tissues, have all been accounted for in the hazard assessment. The risk assessment for etofenprox protects against any potential effects on the endocrine system by ensuring that the level of exposure to humans is well below the lowest dose level at which effects occurred in the above-noted animal tests.

### **(3) Comment related to the cumulative effects to people and pets**

One commenter noted that the assessment of cumulative health effects is inadequate for etofenprox.

### **Health Canada response:**

As indicated in PRD2026-04, *Etofenprox, RF2129 EC and RF2220 Premium Aerosol II-M Premise Spray*, the pyrethroid cumulative human health risk assessment is currently in the initial planning phase and will consist of a complex standalone quantitative assessment. As part of that assessment, an evaluation will be undertaken to determine whether etofenprox shares a common mechanism of mammalian toxicity with other pyrethroids, and if so, a cumulative assessment for etofenprox and relevant pyrethroids will be conducted.

**(4) Comment related to the effects on people and pets**

One commenter indicated that there are potential deleterious effects of etofenprox on people and pets.

**Health Canada response:**

The risk assessment protects against potential effects by ensuring that the level of exposure is well below the lowest dose level at which these effects occurred in animal tests. In addition, statements are present on the RF2129 EC and RF2220 Premium Aerosol II-M Premise Spray labels, according to PMRA Guidance Document, Structural Pest Control Products: Label Updates, which provide restrictions on application and re-entry after application in order to limit exposure to people and pets. Label statements instruct the applicator to not apply when people or pets are present and to not allow people or pets to enter treated areas until sprays have dried. Users are encouraged to ventilate indoor treated areas, which minimizes applicator and postapplication inhalation exposure, and to not allow spray to drip or drift onto non-target surfaces, which reduces postapplication dermal exposure.

**(5) Comment related to the risks to non-target species (wildlife and pollinators) including cumulative effects to aquatic life and pollinator populations**

One commenter stated that the use of etofenprox in the environment cannot protect the wildlife, that are non-target species, let alone the pollinators and that cumulative effects to aquatic life and pollinator populations are wholly inadequate.

**Health Canada's response:**

As presented in PRD2026-04, *Etofenprox, RF2129 EC and RF2220 Premium Aerosol II-M Premise Spray*, etofenprox has limited outdoor use and Health Canada determined that environmental releases are expected to be minimal. The risks to non-target terrestrial (including pollinators) and aquatic organisms are not expected from the use of etofenprox when used according to label directions.

**(6) Comment related to spray drift and spray buffer zones**

One commenter stated that there are certain unpreventable spray drift damages to aquatic life and suggests a 100m buffer zone to provide protections to people and not allowing use on waterfront properties to protect watersheds. In addition, the commenter suggested that there should be a requirement for informed consent for anyone inside the 100m buffer zone.

**Health Canada's response:**

As presented in PRD2026-04, *Etofenprox, RF2129 EC and RF2220 Premium Aerosol II-M Premise Spray*, etofenprox is applied directly to the target pests using a low-pressure sprayer, void injector, or as an aerosol spray. Health Canada determined that the risk to non-target aquatic organisms from spray drift is expected to be negligible and that no spray buffer zones are required to protect the environment.

In addition, label statements are present, based on the PMRA Guidance Document, Structural Pest Control Products: Label Updates, which restrict application to when people or pets are not present and to not allow spray to drip or drift onto non-target surfaces. As such, Health Canada has determined that human exposure to spray drift will be negligible.

## **Other information**

### **Inspection of Confidential Test Data**

The relevant confidential test data on which the decision is based (as referenced in PRD2026-04, *Etofenprox, RF2129 EC and RF2220 Premium Aerosol II-M Premise Spray*) 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 Etofenprox, RF2129 EC and RF2220 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 would not 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 (PE). 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. Etofenprox is categorized as lower PE based on the health criteria and environmental criteria. Information on the risk assessment conclusions that resulted in the categorization is included in the proposed regulatory decision, PRD2026-04, *Etofenprox, RF2129 EC and RF2220 Premium Aerosol II-M Premise Spray*. The PE categorization will be used to inform the scope and level of effort needed for future reviews.

### **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

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

been met, therefore, scientific literature and regulatory information will be monitored as part of continuous oversight for this active ingredient. Information found through continuous oversight will allow Health Canada to keep pace with evolving science, and to identify emerging risks and take timely regulatory action as necessary.

# 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> 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, 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.