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Canada Gazette, Part I, Volume 158, Number 51: Regulations Amending the Pest Control Products Fees and Charges Regulations (Annual Charge)

Please be advised that the consultation period for this proposed regulation is now closed. Submitted comments will be posted once they have been reviewed. If you have concerns, please contact us using our <u>Contact the Canada Gazette Directorate</u> page.

December 21, 2024

Statutory authority *Pest Control Products Act*

Sponsoring department Department of Health

REGULATORY IMPACT ANALYSIS STATEMENT

(This statement is not part of the Regulations.)

General Comment

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Executive summary

Issues: The *Pest Control Products Act* (PCPA) provides a legislative framework enabling Health Canada, on behalf of the Minister of Health, to regulate pest control products (also known as pesticides) in order to protect human health and the environment from the risks associated with pesticides. As part of its regulatory responsibilities, Health Canada undertakes a range of postmarket pesticide activities, including periodic re-evaluations of pest control products, special reviews of pest control products, and compliance and enforcement. When the current fee regulations came into effect in 2017, Health Canada increased the annual charge payable by registrants (mainly pesticide companies) for product registration by 30%. This reflected some of the increase in inflation over the twenty years since the implementation of the previous fee regulations.

The proportion of post-market regulatory costs that are recovered is low compared to the regulatory costs assumed by Health Canada and the commercial benefits that registrants gain from post-market regulatory activities.

Description: The proposed amendments would increase the annual charge and replace the current sales-based approach for determining the annual charge payable with a tiered approach, based on the number of pest control product registrations held by each registrant. A lower annual charge would apply for, among other things, registrations held by small businesses; registrations that are semiochemicals, microbial agents, or non-conventional pest control products; and registrations for certain specialized niche products. Registrations held by the departments or agencies of federal and provincial governments, or municipalities, would not be subject to the annual charge.

Rationale: The proposed amendments to the annual charge would contribute to establishing a more appropriate sharing of costs between public and private contributions for the post-market oversight of pest control products, while continuing to prevent unacceptable risks to human health and the environment.

Issues

Health Canada undertook an analysis of its current post-market fees for pest control products and found that

- they do not reflect the current regulatory costs for post-market regulatory activities, meaning taxpayers are assuming an increasing economic burden. For example, compliance and enforcement costs are currently being funded entirely from public funds; and
- they are not aligned with fees charged by other international regulatory bodies.

Due to the statutory requirement to initiate re-evaluations on a 15-year cycle, Health Canada faces growing pressures in its pesticide re-evaluation workload as the number and complexity of re-evaluations initiated annually continue to exceed Health Canada's capacity to conduct and complete these post-market reviews.

The low proportion of post-market regulatory costs that Health Canada recovers has affected its ability to identify and address pesticide-related risks by making timely post-market re-evaluation decisions.

With regard to fee mitigations, the amount currently payable per pest control product is based on sales revenue reported by the registrant. While this was intended to support small businesses and access to "niche" products, the minimum annual charge is currently applied to the majority (60%) of pest control product registrations, 20% of which are owned by the top five registrants by estimated gross revenue in Canada. This charge reduction does not appear to be meeting its intended purpose. It also contrasts with more targeted mitigation approaches applied by international regulatory bodies and other Health Canada regulatory programs, such as mitigation for small businesses.

Having the annual charge based on registrant-reported sales revenue also poses compliance challenges. In 2023 and early 2024, Health Canada conducted an audit on 276 registrants to validate the sales information they provided. The results of this audit showed that 30% of audited registrants either showed gaps in their supporting sales information, or opted to pay the full annual charge in lieu of going through the audit. This led to the recovery of \$1.2M in annual charge adjustments. The number of discrepancies identified in the above audit further reinforces that the reduced annual charge based on self-reported sales is not meeting its intended purpose.

Background

The Minister of Health's mandate under the PCPA is to prevent unacceptable risks to health and the environment associated with the use of pest control products. To meet this objective, the PCPA requires the Minister of Health to conduct pre-market assessments of pest control products to determine if the health and environmental risks and the value of a pest control product are acceptable. If so, a pest control product is registered. Once a pest control product has been registered, it becomes subject to a system of post-market risk management controls. This includes

- periodic re-evaluations (meaning, a registered pesticide is re-evaluated to determine whether the risks and value of the product continue to be acceptable according to current standards);
- special reviews (in response to international regulatory activity or where the Minister has reasonable grounds to believe that the health or environmental risks or value of the product is unacceptable);
- compliance and enforcement activities to promote and verify compliance, and prevent noncompliance, with the PCPA; namely, to ensure that only registered products are manufactured, imported, distributed and used in Canada according to regulatory requirements, and that they are used according to approved label directions; and

 reporting of health and environmental incidents, pursuant to the <u>Pest Control Products Incident</u> <u>Reporting Regulations</u>.

By charging fees to registrants, Health Canada ensures that the burden of funding pesticide regulatory activities is shared between taxpayers and registrants of pest control products.

The fee regulations for pest control products that came into force in 1997 ¹ consisted of two main elements:

- application fees, which are primarily set based on the type of product (for example, a new active ingredient or a product containing an already registered active ingredient), as well as the type of scientific information that must be reviewed as part of an application (for example, information pertaining to toxicology, metabolism, or environmental fate); and
- an annual charge, which is applied to each pest control product registration.

The most current regulations pertaining to fees, the <u>Pest Control Products Fees and Charges</u> <u>Regulations</u> (SOR/2017-9, hereafter referred to as PCPFCR), came into force in 2017. The annual charge applied to each registration is set to the lowest between

- \$4,317.93, for a product with gross sales revenue during the preceding fiscal year greater than \$107,948.25; and
- 4% of the actual gross sales revenue for a product during the registrant's preceding fiscal year, but not less than \$119.93, for revenue lower than \$107,948.25 (the \$119.93 floor equates to an annual gross sales revenue below \$2,998.25).

These values are derived by taking the values set out in subsection 9(1) of the PCPFCR, modified by the annual adjustment established by section 17 of the *Service Fees Act*. $\frac{2}{2}$

Under the Treasury Board of Canada Secretariat (TBS) <u>Directive on Charging and Special Financial</u> <u>Authorities</u>, departments are required to periodically review the activities for which fees are charged. To that end, Health Canada conducted a review of its pest control product annual charge in 2023, which led to this proposal.

Objective

The proposed amendments would

- improve predictability and consistency of the annual charge regime, for both registrants and Health Canada;
- increase the sustainability of the pest control product regulatory process, particularly for postmarket activities;

- strengthen oversight of pest control products to better protect people in Canada from risks to their health and safety, and to better protect the environment, as a result of higher cost recovery from registrants;
- provide incentives for small businesses; for federal and provincial governments; and for holders
 of semiochemical, microbial, non-conventional, and certain niche product registrants, to
 maintain their registrations;
- provide incentives for registrants submitting applications for active ingredients that have not previously been registered; and
- achieve greater alignment with the charges set out by key comparable international pesticide regulators.

Description

To address the issues and meet the objectives identified above, the proposed amendments would replace the current sales-based system for determining annual charges with a tiered charge, based on the number of pest control product registrations held by the registrant. More specifically:

- the registrant's first 2 registrations (i.e. registrations 1–2) would be subject to an annual charge of \$6,130 (per registration);
- the registrant's next 23 registrations (i.e. registrations 3–25) would be subject to an annual charge of \$4,598 (per registration);
- the registrant's next 50 registrations (i.e. registrations 26–75) would be subject to an annual charge of \$5,211 (per registration); and
- any of the registrant's subsequent registrations (i.e. registration 76 or above) would be subject to an annual charge of \$5,517 (per registration).

To mitigate the effect of the increase to the annual charge, and to replace the fee reductions being removed, the proposed amendments would provide a reduced annual charge for the following situations:

- eligible small businesses would have a reduced annual charge of \$2,000 per registration, with small business being defined as any person, including its affiliates, that has fewer than 100 employees and less than \$5 million in annual gross revenues;
- the proposed regulations would also include provisions for determining what constitutes "affiliation," including for subsidiaries, individuals, corporations and other entities. In addition, if it may reasonably be considered that one of the main reasons two or more corporations are

separate is so that one of them can be considered a small business, then the implicated corporations are deemed to be affiliated with each other;

- pest control products that are, or contain as their only active ingredient, semiochemicals, microbial agents, or non-conventional active ingredients would have a reduced annual charge of \$1,000 per registration, regardless of the size of business holding the registration;
 - semiochemicals are defined in the *Pest Control Products Regulations* (PCPR) as "a messagebearing chemical that is produced by a plant or an animal, or a synthetic analogue of such a chemical, that evokes a behavioural response in individuals of the same or another species".
 - microbial agents are defined in the PCPR as "a pest control product whose active ingredient is a micro-organism. It includes any metabolites and toxins produced by the microorganism."
 - a pest control product would be required to meet certain criteria, set out in the PCPFCR, for it to be considered "non-conventional" for the purposes of the annual charge. In general, the product would be considered "non-conventional" if
 - it is, or contains as its only active ingredient
 - a food or an extract derived from food,
 - a plant extract or oil,
 - a chemical or substance that is widely available to the public for uses other than as a pest control product, or
 - other material; and
 - the Minister has determined, at the time of registration under section 8 of the PCPA or confirmation or amendment of the registration under section 21 of the PCPA, that it meets the following conditions:
 - it does not have chronic toxicity, genotoxicity, carcinogenicity, neurotoxicity or immunotoxicity,
 - it does not cause reproductive or developmental effects,
 - it does not metabolize into compounds of toxicological concern, and
 - it is neither anticipated to, nor does it, bioaccumulate.

These conditions are consistent with criteria set out in Health Canada's guidance document, "Guidance for the Registration of Non-Conventional Pest Control Products."

pest control products that are considered specialized or "niche" products, regardless of the size
of business holding the registration, would also have a reduced charge of \$1,000 per

registration. A pest control product would be considered niche if

- it has the product class designation "commercial" or "restricted";
- the registrant attests that the annual charge that would otherwise be payable on the pest control product's registration would be greater than 10% of the annual gross revenues of the pest control product in question during their preceding fiscal year; and
- either
 - the purpose of the product is for use only on agricultural crops that are cultivated in a total area of 1 000 000 hectares or less in Canada per crop; or
 - the intended effects of the product support the management of a public health threat by the Government of Canada or the government of a province or a municipality, the management of an invasive species, or the management of an existing or potential threat to a species at risk; and the registrant provides confirmation from the Government of Canada or the government of a province or a municipality that the use of the product is necessary to support that purpose.
- registrations for new active ingredients, including technical-grade active ingredients ³ (TGAIs), that have not previously been registered, as well as any end-use products that are derived from the TGAI and accompanied the TGAI's application for registration, would not be subject to the annual charge for the first three years after initial registration, provided the product's registration is intended for end use in Canada; and
- registrations held by the departments or agencies of federal and provincial governments, or municipalities, would not be subject to the annual charge. However, this exemption will not apply to Crown or municipal corporations that operate on a for-profit basis, meaning that they would be subject to the annual charge.

For registrants who notify the Minister that they intend to discontinue their registration any time before the proposed amendments come into force, the PCPFCR in its current form would apply for the remainder of the product's registration. The current annual charge would apply to products during any registrant-initiated phase out after the coming into force of the amended regulations. If a registrant notifies after the amendments come into force, the final two years of such a product's registration following receipt of a registrant's intent to discontinue a pest control product would be subject to a reduced annual charge of \$1,000.

The proposal would allow Health Canada to request additional information from a registrant that would help confirm eligibility for the reductions available for small businesses or niche products. Registrants would be required to respond within 60 days of Health Canada making the request. If Health Canada determines that such information does not confirm eligibility, or if it is not provided within 60 days, then the annual charge would revert to the default \$6,130 (and be subject to the tiered reductions noted above) or the annual charge payable by small businesses, as the case may be, with interest from the date payment is due.

Review of the PCPFCR has also revealed a grammatical error in the French version: the noun « écomone » ("semiochemical") is presented as a masculine noun (« un écomone ») but it is a feminine noun (« une écomone »). To correct this error, the proposed amendments would modify the French version so that « écomone » be presented using the feminine.

Regulatory development

Consultation

Health Canada undertook consultations to inform the proposed amendments to the PCPFCR. On January 17, 2024, Health Canada published a consultation discussion paper entitled "Consultation on a proposal to update fees for pest control products." The consultation period lasted 74 days.

In the consultation discussion paper, Health Canada proposed a default annual charge of a flat \$6,130 per registration, without the tiered reduction for subsequent registrations. The proposal also did not include

- the three-year annual charge exemption for new TGAIs and associated end use products;
- the exemption for registrations held by the departments or agencies of federal and provincial governments, or municipalities; or
- the provisions pertaining to registrant-initiated cancellation before the coming into force and registrant-initiated phase out after the coming into force of the proposed amendments.

In parallel with the discussion paper, a cost-benefit questionnaire was circulated to registrants and industry associations. The answers to the questionnaire informed analysis of

- the distribution of small and large businesses among pest control product registrants, based on gross revenue from all sources and number of employees (including affiliates);
- the distribution (e.g. by size, by geographic location) of registrants who would pay more annual fees than what they currently pay;
- the distribution of products that are subject to reduced fees by product type (e.g. biopesticides);
- the anticipated type and number of registered products withdrawn due to increased annual fees based on the costing survey; and
- the anticipated percentage of cost pass-through from registrants to consumers.

Targeted stakeholder consultations to inform the proposed amendments took place between October 2023 and March 2024. Key components of the proposed amendments were discussed, including Health Canada's cost recovery guiding principles, the process used to set fees, and the proposed new annual charge and mitigation measures.

Health Canada received written comments from 45 stakeholders on the proposed amendments, and 55 responses to the cost-benefit questionnaire. In general, feedback received during the consultation period and during targeted consultations pertained to the topics set out below.

Fee amounts

Stakeholders asserted that the proposed increase to the annual charge would create a financial disincentive for registrants to maintain pest control product registrations. The resulting reduced access to pest control products could negatively affect the competitiveness of Canadian growers. Moreover, smaller registrants claimed that they would not have the capacity to absorb the increased charge.

Health Canada response

Health Canada recognizes that the proposed amendments would lead to some registrants paying a significantly higher annual charge than they did previously. In order to address these concerns, Health Canada has revised the proposal to incorporate a tiered structure to the annual charge, where the amount payable per registration generally increases as the number of registrations increase for a given registrant. Furthermore, to encourage innovation, Health Canada has revised the proposal to exempt from the annual charge, for the first three years after initial registration, active ingredients, including TGAIs, and associated end use products that have not previously been registered. Finally, other fee mitigation measures, such as the reduced annual charge for small businesses or for semiochemical, microbial agent, non-conventional, or niche pest control products, would provide relief to registrants.

Instituting a cap on the annual charge

Stakeholders noted that the U.S. system is designed so that there is a maximum total annual charge (a "cap") that is payable by each registrant and inquired as to whether a similar approach was considered.

Health Canada response

Health Canada explored this option and determined that a cap was not feasible. The proposed amendments are designed to improve the predictability and sustainability of the regulatory system for pest control products, while promoting innovation and minimizing impacts on small businesses and holders of semiochemical, microbial, non-conventional, or certain niche registrations. Instituting a cap would run counter to the intention of the proposal, because a cap would negatively affect the

sustainability of the regulatory system and would only benefit the largest businesses operating in the Canadian pesticide market. The tiered annual charge noted above would provide relief to registrants that hold several registrations.

Definition of "small business"

Stakeholders expressed appreciation that the proposal would add a reduced annual charge for small businesses, but some noted that the proposed small business definition would be more restrictive than that applied by the United States. As a result, those stakeholders recommend using a definition more in line with the United States, so that more registrants could qualify for reduced fees. Some small business stakeholders expressed concerns with inconsistencies in the definition used among Health Canada programs, which could lead to confusion and the potential for differential treatment.

Health Canada response

Under the proposal, eligible small businesses would pay significantly less per registration than in the United States. The proposed definition was modelled after the definition in the <u>TBS Policy on Limiting</u>. <u>Regulatory Burden on Business</u>, and established taking into account other Health Canada regulatory programs. This definition was arrived at through careful consideration of the policy intent behind the mitigation measure, which is meant to ensure that eligible small businesses benefit from this provision; coupled with the definitions in use by other programs and the lessons learned following their implementation. The United States provide reduced fees based on two small business definitions: "small business", which requires the business to have 500 or fewer employees, have less than \$60 million in annual gross revenue from pesticide sales; and "qualified small business", which requires the business than \$10 million in total annual gross revenues, and hold not more than five registrations.

The U.S. Environmental Protection Agency (EPA) provides relief to small businesses in the form of a reduced maintenance fee on a registrant's 22nd registration (\$2,625 instead of \$4,875), and a waiver on the entire maintenance fee for a registrant's 23rd through 50th registration. Qualified small businesses only receive a 25% discount applied to their first registration.

Internal data indicates that a large majority of expected small businesses hold fewer than 10 pest control product registrations, making the EPA's system of reduced maintenance fees for small businesses redundant for most small business registrants.

Taken on the whole, the proposed amendments would be more favourable towards small businesses than the U.S. approach, as a result of providing a reduced annual charge across most registrants' portfolios (compared to only the 22nd through 50th registrations for U.S. small businesses), and for all registrations (compared to U.S. qualified small businesses).

Scope of eligibility for reduced annual charges lacks clarity and should be expanded

Stakeholders requested that the eligibility criteria be clarified regarding what products would be subject to a reduced annual charge, to avoid "case-by-case" justifications. Other stakeholders noted that registrants had valid reasons for a pest control product to not be marketed in Canada; for example, some registrations relate to pest control products that have variable demand from year to year, or are not anticipated being marketed for several years. Those stakeholders indicated that such registrations should not have to pay an increased annual charge in light of those reasons.

Health Canada response

Eligibility requirements will be clarified, both in the regulations and in interpretive guidance, to increase predictability and minimize administrative burden. Health Canada treats all registrations as equal. Products not marketed in Canada nonetheless require significant scientific resources during the regulatory life cycle, including special reviews and re-evaluations. It is appropriate that the annual charge represent a fair share of regulatory costs, regardless of the business decisions made by registrants on whether to market a product. Registrants may be able to benefit from the reduced annual charge for niche pest control products, or the exemption from the annual charge, for the first three years after initial registration, for TGAIs and associated end use products that have not previously been registered.

Timing and implementation considerations

Stakeholders requested that Health Canada not update the annual charge until the costs of other Health Canada initiatives could be determined. For example, Health Canada's plan to implement <u>modernized business processes</u>, such as the new continuous oversight and proportional effort models, may require additional changes to fees.

Stakeholders also noted the need for a fair and orderly process for registrants to cancel registrations, in advance of the regulations coming into force, should those registrants opt to remove their product from the market rather than pay the higher annual charge.

Health Canada response

The decision to review the annual charge was based on the TBS requirement that departments periodically review their fee regimes and was made independently from the decision to implement modernized business practices. As a result, the amendments being proposed are directly related to addressing the review's findings, namely that the pest control product fee regime was not reflective of the current post-market regulatory costs and did not align with fees charged by other international regulatory bodies. Any changes required as a result of implementing modernized business practices will be treated separately.

Consistent with the current approach and timelines, registrants that decide to cancel their registration any time before the coming into force of the amended regulations would only need to pay the current annual charge (meaning, the annual charge that would be required under the previous version of the PCPFCR). The current annual charge would apply to products during any registrant-initiated phase out after the coming into force of the amended regulations; however, the final two years of such a product's registration would be subject to a reduced annual charge of \$1,000.

Modern treaty obligations and Indigenous engagement and consultation

As required by the Cabinet Directive on the Federal Approach to Modern Treaty Implementation, an assessment of modern treaty implications was conducted on the proposal. The assessment did not identify any modern treaty implications or obligations.

Instrument choice

Regulatory amendments are required to address the identified issues, as the PCPFCR already contain provisions regarding the annual charge. Therefore, amendments to the PCPFCR are required to update the annual charge and implement the proposed reductions above. Changes to the annual charge should therefore be done in regulation in order to clearly link to this provision, as well as other provisions in the PCPA applicable to fees and charges. Taken on the whole, amendments to the PCPFCR are the most suitable instrument for making changes to the annual charge.

Regulatory analysis

Benefits and costs

The overall approach used to estimate the incremental costs and benefits of the proposed amendments to the PCPFCR, as well as the conclusions of the cost-benefit analysis (CBA), are described below. For the purposes of the analysis, it is assumed that the proposed amendments would be registered in period 1 (2026) and impacts would also commence in period 1 (2026). Estimations are projected over 10 periods of 12 months. All values are estimated in 2024 constant dollars discounted using a 7% discount rate.

On January 17, 2024, Health Canada published a consultation discussion paper entitled "Consultation on a proposal to update fees for pest control products." In parallel with the discussion paper, a costbenefit questionnaire was circulated to registrants and industry associations. Health Canada received 55 responses to the cost-benefit questionnaire.

The full CBA report is available upon request. Please contact <u>pmra.regulatory.affairs-</u> affaires.reglementaires.arla@hc-sc.gc.ca.

Baseline scenario

The baseline scenario represents what would happen over time in the absence of the proposed amendments. Under this scenario, pest control product registrants would continue to pay annual charges as currently specified in the PCPFCR.

Under the current PCPFCR, the annual charge payable is based on the gross sales revenue of each pest control product (regardless of the type of product and the size of the business). As required per sections 17 and 18 of the *Service Fees Act*, the minimum and maximum fees are adjusted each April to reflect the previous year's All-Items consumer price index (please see details <u>here</u>). For fiscal year 2021–2022, the gross annual charge revenue was approximately \$8.5M, and registrants paid \$104 for products with zero/very low sales, with annual charges increasing based on a sliding scale of 4% of gross sales revenue up to a maximum of \$3,745.27.

Health Canada is developing a web portal for fee payers to declare whether they are small businesses. Health Canada plans to implement the web portal prior to the coming into force date of this proposal. Because the web portal would proceed whether this proposal goes ahead or not, the development and implementation costs of the portal are considered as baseline costs.

Based on the *Service Fees Act* and the following assumptions, the annual charge is estimated to be \$10.38M in period 1.

- The average annual net growth rate of pest control product registrations was approximately 1% between 2016 and 2021. It is assumed that the annual growth rate of registrations would remain at 1% (for each type of pest control product) for periods 1–10.
- As the CBA is done in 2024 constant dollars, no adjustments are made for inflation.

Regulatory scenario

The proposal would replace the current annual charge (payable based on sales of each pest control product) with a tiered fee structure based on the number of pest control product registrations per registrant.

The proposal would also introduce annual charge reduction measures linked to specific and/or existing policy goals:

- Registrants who are small businesses would be charged \$2,000 per pest control product;
- PCPs that are, or contain as their only active ingredient, semiochemical, microbial, or nonconventional active ingredients would be charged \$1,000 per pest control product;
- PCPs that are identified as niche products would be charged \$1,000 per pest control product;
- New active ingredients and associated end use products would have the annual charge waived for three periods after registration date;

 Registrations held by the departments or agencies of federal and provincial governments, or municipalities, would not be subject to the annual charge. However, this exemption will not apply to Crown corporations that operate on a for-profit basis.

Under the proposed regulations, the annual charge revenue would increase from \$10.38M to \$21.87M in period 1. The analysis to estimate the regulatory scenario revenue assumes the number of registrations would increase at a rate of 1% per year for periods 1–10. (Table 1)

Annual charge revenue	Total	Period 1	Period 2	Period 3	Period 4	Period 5	Period 6	Period 7	Period 8	Period 9	Period 10
(in million dollars)		Based on 1% annual growth rate of registration									
Baseline scenario	\$108.65	\$10.38	\$10.49	\$10.59	\$11.70	\$10.81	\$10.91	\$11.02	\$11.13	\$11.25	\$11.36
Regulatory scenario	\$228.80	\$21.87	\$22.09	\$22.31	\$22.53	\$22.76	\$22.98	\$23.21	\$23.45	\$23.68	\$23.92
Projected increase of annual charge revenues	\$120.16	\$11.48	\$11.60	\$11.72	\$11.83	\$11.95	\$12.07	\$12.19	\$12.31	\$12.44	\$12.56

Benefits

The total benefits are estimated to be \$90.20 million (present value [PV]) over 10 years or \$12.84 million (annualized).

Benefits to Government

The total direct benefits to the Government are estimated to be \$89.80 million (PV) over 10 periods or \$12.79 million (annualized). The benefits are increased fee revenue to the government.

Currently, the annual charge revenue covers only 17% of the costs associated with the post-market review of pest control products (i.e. re-evaluations and special reviews). With the implementation of this proposal, the increased annual fee revenue is anticipated to increase the cost recovery ratio to up to 42% of post-market costs. This increased cost recovery would in turn strengthen the sustainability of the post-market program by enhancing Health Canada's ability to conduct and complete post-market review activities in a timely manner and thus ensure that the health and safety of people in Canada are well protected.

The proposed amendments would also improve the fairness of the regulatory system, by shifting costs towards direct beneficiaries and by better reflecting the actual costs for delivering post-market programs.

Benefits to industry

The total benefits to the industry are estimated to be \$395,253 (PV) over 10 periods or \$56,275 (annualized). The benefits are from cost savings for registrants due to the removal of the requirement to report sales value per product annually.

Under the current PCPFCR, the annual charge payable is based on the gross sales revenue of each pest control product. The registrants incur time/labour costs to discover and report the gross sales revenue to help determine the actual fee for each product. The proposed amendments would save these costs.

Additionally, the proposed mitigation measures would provide incentives for small businesses; for federal departments and provincial ministries; and for holders of semiochemical, microbial, non-conventional, and certain niche product registrants, to maintain their registrations in Canada. In addition, the proposal would also support innovation in pest control products by providing incentives (i.e. annual fee exemptions) for registrants submitting applications for active ingredients that have not previously been registered.

Benefits to the environment

The proposed amendments would provide a financial incentive for products that are used for the management of invasive species or situations involving a species at risk. Registrants may be more willing to submit or maintain registrations for such products, which in turn may lead to indirect positive environmental impacts.

Costs

The total costs are estimated to be \$91.54 million (PV) over 10 periods or \$13.03 million (annualized).

Costs to registrants

The total costs to registrants are estimated to be \$90.09 million (PV) over 10 periods or \$12.83 million (annualized). The costs include the direct costs to registrants due to an increase in annual charges, one-time costs to familiarize themselves with the requirements of the proposed regulatory changes, and costs to apply for products to be eligible for reduced annual charges.

Increase in annual charges

The direct costs to registrants due to an increase in annual charges are estimated to be \$89.80 million (PV) over 10 periods or \$12.79 million (annualized).

Under the proposed regulations, 684 registrants would pay the annual charge in period 1. The annual charge revenue would increase from \$10.38M to \$21.87 in Period 1. It is assumed that the number of registrations would grow at a rate of 1% per year across all types of products for periods 1–10.

The amount of annual charges payable by registrants based on this proposal is higher than the current PCPFCR. Although the estimated total incremental costs to the industry are estimated to be \$12.83 million (annualized), the impacts on registrants relative to the economic scale of the pesticide industry are expected to be low. The pesticide industry is well established and generated approximately \$4.4 billion (2020 estimates) in gross revenue in Canada. Assuming no growth in PCP sales revenue it is estimated that the incremental costs due to the proposed annual fees to the industry would account for less than 1% (0.26%) of gross revenues of pest control products in period 1.

Costs to apply for a mitigation/reduction in annual charges

The costs to registrants to provide attestation for the application of niche products are estimated to be \$159,226 (PV) over 10 periods or \$22,670 (annualized).

For niche pest control products whose purpose is only agricultural crop production, PMRA would establish an ongoing process to help identify which products are eligible for a reduced annual charge (i.e. \$1,000 per product). Based on the most recent publicly available Statistics Canada data, the pest control products used in crops cultivated in an area of 1 million hectares or less per crop would be considered to be niche products. There would be no additional costs to registrants.

However, for niche products used in other segments (e.g. supporting the management of a public health threat, invasive species, or an existing or potential threat to a species at risk), PMRA would require that registrants attest that the products meet the mitigation criteria of niche products mentioned above. In these cases, there could be costs to registrants to provide such information in the attestation process. It is estimated that there would be about 10 niche products that need to provide an attestation for each of the periods 1–10. For each of the 10 products, the registrant would spend 37.5 hours completing the attestation.

Costs to become familiar with the amendment

There would be one-time costs for registrants to become familiar with the proposed amendments and new guidance materials. It would take about 4 hours for each of the 684 registrants to complete the task. The costs are estimated to be \$126,142 (PV) over 10 periods or \$17,960 (annualized).

Indirect pass-through of costs from registrants

The pest control product market is highly competitive, where a substantial number of suppliers (namely, the approximately 700 registrants) provide approximately 7 500 products (2021 figures) to end users. While certain products fulfil unique roles, it can reasonably be assumed that there are lower-priced substitutes available for most higher-priced pest control products.

Moreover, the elasticity of demand for pest control products is estimated to be inelastic, with a value of -0.28 (Reference: Böcker, T. and R. Finger [2017], *A Meta-Analysis on the Elasticity of Demand for Pesticides, Journal of Agricultural Economics*). This means that a 1% increase in the price of a pest control product is associated with a 0.28% decrease in the quantity demanded for that product. In other words, a moderate price increase will not cause a significant decrease in demand.

Registrants estimated in their responses to the cost-benefit questionnaire that, on average, 66% of the annual charge increase would be passed through the supply chain to pest control product users (agricultural sector = 40%, domestic sector = 78%, other sectors = 71%). According to PMRA administrative data, pest control products used in the agricultural sector accounted for about 30% of the pest control products that paid annual charges in 2021/22. The total incremental costs for agricultural-use pest control products are estimated at \$3.44 million (PV) in the first period. The estimated 40% cost pass-through ratio for agricultural sector PCPs would result in registrants passing about \$1.38 million (PV) incremental costs to agricultural product users (i.e. growers).

According to Statistics Canada data, in 2021, about 151 805 farms reported that their total net operating income was \$20.75 billion and about 64 000 farms reported pesticide expenses. Using these figures as references, the potential cost pass through from pesticide suppliers to Canadian farmers would reduce the net operating income per farm by between \$21 (PV) per farm who reported pesticide expenses (=\$1.38M/64 000) and \$9 (PV) per farm for all reporting farms (=\$1.38M/151 805). Since pesticide expenses account for about 4% of total farm operating expenses, the impact of the cost pass-through on farm operating costs would therefore be negligible.

Notwithstanding the anticipated impacts, the actual cost pass-through from registrants to users may be much lower than that indicated by the survey results. For example, the 2015 cost recovery survey that was used to inform the 2017 regulations indicated that registrants would pass 50% of the increases to fees to users. However, Statistics Canada's farm input price index shows that the pesticide price index remained stable from 2017 to 2019 and grew in much lower rates than the allitem farm input price index did from 2020 to 2023. This would indicate that the anticipated passthrough did not materialize. If industry were to pass costs through to end users, the demand for pest control products is not anticipated to fall.

In light of the considerations noted above, the estimated incremental costs to industry would be fully attributed to registrants. Should registrants choose to pass a portion of the increased annual charge to users, a portion of the incremental costs estimated would be shifted to that group, without a

change to the total cost amount.

Costs to government

The total costs to the Government are estimated to be \$1.45 million (PV) over 10 periods or \$206,068 (annualized).

The implementation and ongoing costs to the Government include

- One-time costs of processing cancellation and expiration of PCPs due to an anticipated increase in product cancellations due to the proposal. Additional resources would be needed to track and process the discontinued products;
- One-time costs of auditing the information provided by registrants pertaining to whether or not the registrant is a small business;
- One-time costs of developing an approved list of niche products and establishing SOPs;
- One-time costs of updating guidance documents to reflect amendments to the PCPFCR;
- One-time costs of managing inquiries from stakeholders on the new fee structure for periods 1– 3;
- One-time costs of additional compliance and enforcement activities;
- Ongoing costs of implementation and maintenance of IT updates for semiochemical, microbial, and non-conventional products; and
- Ongoing costs of processing whether the registered product is eligible for fee mitigations based on uses, reviewing/validating niche conventional products (e.g. reviewing attestation).

As noted in the "Baseline scenario" section above, Health Canada plans to use a web portal for small business declarations, with the portal being implemented prior to the coming into force date of this proposal. Should the portal not be implemented by the time of coming into force, Health Canada would also incur one-time costs to develop an interim reporting method. It is assumed that the interim method would be used for a maximum of 12 months before the portal becomes operational. This would result in total costs to the Government being estimated at \$1.52 million (PV), rather than the \$1.45 million stated above.

Cost-benefit statement

The total monetized costs of the proposal include the direct costs to registrants due to an increase in annual charges, one-time costs to familiarize themselves with the requirements of the proposed regulatory changes, and costs to apply for products to be eligible for reduced annual charges. Government costs include upfront and ongoing implementation costs. The total cost is estimated at \$91.54 million (PV) or \$13.03 million (annualized).

The total direct benefits are estimated to be \$90.20 million (PV) over 10 periods or \$12.84 million (annualized). The benefits include cost savings for registrants due to removal of reporting sales revenue per product and the increase in fee revenue to the Government.

The result is a net monetized cost of \$1.34 million PV over 10 periods or \$190,423 (annualized).

Number of periods: 10 (2026 to 2035)

Price year: 2024

Present-value base year: Period 1

Discount rate: 7%

Monetized benefits

Impacted stakeholder	Description of benefit	Period 1	Period 5	Period 10	Total PV	Annualized value
Government	Increase in fee revenue	\$11.48M	\$11.95M	\$12.56M	\$89.80M	\$12.79M
Industry	Removal of reporting PCP sales revenue	\$0.05M	\$0.05M	\$0.06M	\$0.40M	\$0.05M
All stakeholders	Total benefits	\$11.54M	\$12.00M	\$12.62M	\$90.20M	\$12.84M

Monetized costs

Impacted stakeholder	Description of cost	Period 1	Period 5	Period 10	Total PV	Annualized value
Industry	Increase in annual fees	\$11.48M	\$11.95M	\$12.56M	\$89.80M	\$12.79M
	Attestation costs for niche products	\$0.02M	\$0.02M	\$0.02M	\$0.16M	\$0.02M
	One time cost of familiarizing with the proposed amendments to the PCPFCR and new guidance materials	\$0.13M	\$0	\$0	\$0.13M	\$0.02M
Government	One-time implementation costs	\$0.69M	\$0	\$0	\$0.73M	\$0.1M
	Ongoing costs	\$0.31M	\$0.06M	\$0.06M	\$0.72M	\$0.1M
All stakeholders	Total costs	\$12.63M	\$12.03M	\$12.64M	\$91.54M	\$13.03M

Summary of monetized benefits and costs

Impact	Period 1	Period 5	Period 10	Total PV	Annualized value
Total costs	\$12.63M	\$12.03M	\$12.64M	\$91.54M	\$13.03M
Total benefits	\$11.53M	\$12.00M	\$12.62M	\$90.20M	\$12.84M
Net impact (costs)	\$1.10M	\$0.03M	\$0.02M	\$1.34M	\$0.19M

Quantified (non-monetized) and qualitative impacts

Positive impacts

- strengthening and improving the sustainability and efficiency of the post-market program;
- increasing fairness by shifting costs to direct beneficiaries and aligning charges more closely with true costs;
- providing incentives for products that may have potential indirect positive environmental impacts; and
- supporting innovation by encouraging the registration of new active ingredients.

Negative impacts

- It is acknowledged that registrants may pass increased annual charge costs to pest control
 product users by means of increasing product prices (i.e. cost pass through). However, due to
 the competitive nature of the pest control product market in Canada, inelastic demand for pest
 control products, and fee increases representing a small proportion of the pest control market, it
 is not expected that annual charge increases will significantly impact prices; and
- Based on stakeholder feedback, there is a risk that registrants may discontinue product registrations due to fee increases. While the overall withdrawal rate is estimated at 28%, a majority of the products that could be withdrawn are zero or very low sale products and therefore would not have an impact on supply. Even for those zero or very low sale products, some would be retained in the market for various reasons, such as protecting the registrant's initial registration investment, providing bridging data to support the registration of similar pesticides, and representing a valuable asset to external stakeholders. To note, withdrawal of products has been accounted for in the model to forecast increased fees on industry.

Small business lens

Small business lens summary

Based on Health Canada internal data, it was estimated that 448 registrants (65%) met the small business definition in the <u>Policy on Limiting Regulatory Burden on Business</u>. These small registrants held 41% of total product registrations, including 54% of all semiochemical, microbial, and non-conventional pest control products, and 36% of all niche products. The proposal would provide mitigation measures specific to small businesses who have less than \$5M in gross revenues and fewer than 100 employees. The incremental impact on all 448 small registrants (defined by the aforementioned policy) due to the increase of annual charges is estimated to be \$30.54 million PV over the ten 12-month periods following period 1 (annualized \$4.35 million, or \$9,705.34 per registrant per year).

Number of small businesses impacted: 448

Number of periods: 10 (2026 to 2035)

Price year: 2024

Present-value base year: period 1

Discount rate: 7%

Benefits

Administrative or compliance	Description of benefit	Present value	Annualized value
Administrative	Removal of the self-reported PCP sales revenue	\$0.35M	\$0.05M
Total	Total benefits	\$0.35M	\$0.05M

Costs

Administrative or compliance	Description of cost	Present value	Annualized value
Administrative	Increased annual charge	\$30.02M	\$4.27M
Compliance	Familiarize with the process (e.g. guidance documents) of the proposed amendments on PCPFCR	\$0.86M	\$0.12M
Total	Total costs	\$30.88M	\$4.40M

Net impacts

Amount	Present value	Annualized value	

Total net impact (costs)	\$30.54M	\$4.35M
Average net impact on each impacted small business	\$68,166.26	\$9,705.34

As noted above, the definition of "small business" used in the proposal differs from that used in the Policy on Limiting Regulatory Burden on Business. Experience with applying that definition in other Health Canada programs revealed that a significant number of companies qualified as a small business because of a low employee count, but reported very high annual gross revenue. This led to concerns that the existing definition did not reflect the underlying policy intent of fee mitigation for a business that can be reasonably regarded as "small"; such concerns were equally relevant to pest control products. This led to the proposed small business definition that required businesses to satisfy both low employee and low revenue criteria in order to qualify for fee mitigation as a small business.

One-for-one rule

The "one-for-one" rule applies since there is an incremental decrease in administrative burden on business.

As per the *Red Tape Reduction Regulations*, the assessment of administrative impacts was conducted for a period of 10 years commencing from registration. All values listed in this section are presented in 2012 dollars, discounted to 2012 at a rate of 7%. The proposal is considered burden OUT under the rule and would result in an annualized administrative net cost savings of \$9,997.

The total annualized cost savings from reduced administrative burden is estimated to be \$17,025. The amendments related to the removal of the requirement to self-report PCP sales revenues represent an annualized total cost savings of \$17,025. Up to 684 businesses would save two hours to complete the task once per year. The average wage (including overhead) of the responsible individual is estimated to be \$32.09.

The total annualized cost of the incremental administrative burden is estimated to be \$7,028. The amendments related to preparing an attestation for niche unconventional products represent an annualized total cost of \$7,028. It is assumed that each of the 10 attestations would require one professional staff in natural and applied science to spend 37.5 hours to complete the task once per year. It is also assumed that the cost of preparing attestation would be a one-time cost and the number of new attestations would increase by 1% in each period. The average wage of the responsible individual is estimated to be \$47.10.

Regulatory cooperation and alignment

The proposed amendments are not related to any work plan or commitment under a formal regulatory cooperation forum. No international standards exist pertaining to pesticide fees or annual charges.

Health Canada performed an environmental scan to explore whether the proposed amendments would align with the approaches taken by other jurisdictions. There is wide variation internationally in how post-market review fees are structured and the types of activities that they support. Registrants generally view North America as a common pesticide market, and pesticide users in Canada expect to be able to access a range of pest control products comparable to what is available in the United States. As a result, analysis focused on whether it was feasible to increase or maintain alignment with the United States' system where possible.

Europe, Australia, and the United Kingdom

European Union (EU) member states, Australia and the United Kingdom (UK) charge application fees to support their post-market review activities (also known as registration renewal and reconsideration), with the amount payable linked to the complexity of review. Australia, the United Kingdom and several European countries also charge levies based on pesticide sales to support pesticide regulatory activities. This contrasts with Canada, where registrants pay an annual charge for each pest control product to support post-market review activities rather than application fees.

United States

Pesticide fees and charges in the United States represent the principal benchmark for Health Canada pest control product fees and charges, as registrants often view Canada and the United States as a single market. Historically, the EPA recovers approximately 30% of its pesticide-related costs from fees. Similar to Health Canada, the EPA applies an annual charge, known as a maintenance fee, for each pest control product. Similar to Health Canada, the EPA does not apply service standards and remissions to post-market regulatory activities and has performance targets for conducting re-evaluation activities. Key points of comparison between the values of Health Canada's pesticide annual charge and the EPA's corresponding maintenance fees can be found in the following table:

Annual charge typeCurrent HC annual charge (per registration)EPA maintenance fee (per registration) *Proposed HC annual charge (per registration)	Annual charge type	5 1	EPA maintenance fee (per registration) [*]	5 1
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Regular charge	\$119.93–\$4,317.93 **	\$6,338 No fee for registrations #37–50 No fee for registrations beyond #72	 \$6,130 for registrations #1–2 \$4,598 for registrations #3–25 \$5,211 for registrations #26–75 \$5,517 for registrations beyond #75
Small business ***	\$119.93–\$4,317.93 **	\$6,338 No fee for registrations #23–50 No fee for registrations beyond #67	\$2,000
Qualified small business ***	\$119.93–\$4,317.93 **	\$4,753 for registration #1 \$6,338 for registrations #2–5 No further registrations permitted beyond #5	\$2,000
Microbial, semiochemical, non-conventional product	\$119.93–\$4,317.93 **	N/A	\$1,000
Niche product	\$119.93-\$4,317.93 **	\$0–\$6,338 <u>****</u>	\$1,000

- Presented in Canadian dollars (US\$1 = CAN\$1.3)
- Annual charge per pest control product based on 4% of sales, from a minimum of \$119.93 to a maximum of \$4,317.93
- Small business: 500 or fewer employees; average global gross revenue from pesticide sales under \$60M. Qualified small business: 500 or fewer employees; average global gross revenue from all sources under \$10M.
- Comparable registrations in the United States may have their maintenance fees waived or reduced, depending on the type of product (e.g. fee waived for products used on a crop with less than 300 000 cultivated acres; pesticides used in public health programs with limited economic returns).

As set out in the table, Health Canada's proposed annual charge is generally lower than the EPA's comparable maintenance fees. In particular

- Under the proposed tiered structure, the annual charge amount payable would be lower than in the United States, except for a small number of large registrants with many registrations, given EPA's maintenance fee cap. Health Canada does not intend to institute a cap on the annual charge;
- The proposed \$2,000 annual charge for small business (meaning a person [both individuals and organizations], including affiliates, that has under 100 employees and under \$5 million in annual gross revenue from all sources) would be lower than the corresponding EPA maintenance fees for small business (meaning either under 500 employees and under \$78 million in annual revenue from pesticide sales, or under 500 employees and under \$13 million in annual revenue from all sources for qualified small businesses); and the proposed eligibility criteria better reflect the small business context in Canada than the EPA definition does;
- The proposed reduced annual charge of \$1,000 for products that are semiochemicals, microbial agents, or non-conventional pest control products is lower than the EPA's comparable maintenance fee, as the EPA does not provide a reduced maintenance fee for such products; and
- The proposed reduced annual charge of \$1,000 for niche products is similar to, but may in some circumstances be higher than, the EPA's comparable maintenance fees for products used on lowacreage crops and for public health with limited sales potential and high impact to users. The EPA has the authority to waive or reduce the maintenance fees for such products.

Taken on the whole, these proposed amendments would increase alignment with the U.S. fee regime. No trade impacts have been identified or are anticipated due to any inconsistencies between the proposed amendments and the approaches used in other areas.

Effects on the environment

In accordance with the *Cabinet Directive on Strategic Environmental and Economic Assessment*, a strategic environmental assessment was performed. Indirect important positive environmental impacts were noted. For example, the proposed amendments would provide a financial incentive for products that are used for the management of invasive species or situations involving a species at risk. Registrants may be more willing to submit or maintain registrations for such products, which in turn may lead to positive indirect environmental impacts.

The proposal is also expected to contribute positively to Goals 12 and 15 of the <u>Federal Sustainable</u> <u>Development Strategy</u>. In particular:

- Goal 12 aims, among other things, to reduce waste, in part through continued pesticide review. The increased cost recovery being anticipated by the proposed amendments would contribute to meeting this goal; and
- Goal 15 aims to protect and recover species and conserve Canadian biodiversity. The reduced annual charge that would be made available for niche pest control product registrations that are (among other things) for the management of an invasive species, or for the management of a situation involving a threat to a species at risk, could make registrants more willing to submit or retain registrations for such products as a result, which could contribute to positive biodiversity effects.

Gender-based analysis plus

No impacts based on gender and other identity factors (such as sex, race, language, religion, national and ethnic origin, Indigenous origin or identity, age, sexual orientation, socio-economic conditions, education, geography, culture and disability) have been identified for this proposal.

Rationale

The proposed amendments would contribute to establishing a more appropriate sharing of costs between public and private contributions for the post-market oversight of pest control products. A more appropriate sharing of costs would, in turn, strengthen regulatory oversight of pest control products and increase the sustainability of post-market activities, while shifting the costs of such activities away from taxpayers. This will benefit consumers, people in Canada, and pest control product users, while continuing to prevent unacceptable risks to human health and the environment. While registrants will pay a higher annual charge under the proposed amendments, pest control product applicants and registrants would also benefit from increased predictability regarding the annual charge that they must pay over time, as the annual charge would no longer be based on sales information that changes every year.

Implementation, compliance and enforcement, and service standards

Implementation

The proposed regulations would come into force on the day they are registered or on April 1, 2026, whichever is later.

All current and future product registrations, including submissions under review, will be subject to the new charges following the coming into force. Registrants that decide to cancel their registration any time before the coming into force of the amended regulations would only need to pay the current annual charge (meaning, the annual charge that would be required under the previous version of the PCPFCR) in respect of any remaining period of the product's registration. Internal electronic systems that Health Canada uses to record information on pest control product registrations and registrants will require updates to properly identify which products are eligible for reduced annual charges, as well as which registrants are eligible for the small business reduction. All system updates are expected to be completed before the coming into force of the proposed regulations.

The existing invoicing process for the annual charge would continue to apply, with an information package being sent to registrants every year in advance of being invoiced. Small businesses that wish to have their annual charge reduced would be required to provide an attestation of their status (i.e. employee total and annual gross revenue, including affiliates) using an online portal. Registrants who wish to have their annual charge reduced for being a niche product would be required to provide substantiating information as set out in the proposed regulations. Health Canada would notify registrants of the need to provide attestations in advance of invoices being generated.

The proposed regulations will result in changes to related policies and interpretive guidance. Consistent with Health Canada's obligations under the PCPA, consultation on those changes to policies and guidance will take place as required. Any such changes would be finalized at the time of final publication of the proposal and would be communicated to stakeholders through regular communications tools, such as updates on HCs website or through the information package sent to registrants as noted above.

Compliance and enforcement

Any unpaid fees or charges by registrants would be collected according to standard practice. Furthermore, in accordance with subsection 23(1) of the PCPA and as noted previously, Health Canada can cancel or amend a registrant's registrations, or refuse to consider applications from a registrant entirely, if they fail to pay a fee or charge as required under the Regulations. The department will also take appropriate enforcement action for the distribution of products without proper registration.

Existing outreach channels, such as PMRA's registrant and stakeholder newsletters and annual charge webinars, would be used to inform registrants of changes to the annual charge process and promote compliance.

Service standards

The TBS <u>Directive on Charging and Special Financial Authorities</u> states that senior departmental managers are responsible for establishing service standards. With respect to the annual charge, Health Canada's service standard is to issue an invoice by April 30 of the current fiscal year, or within 30 days of submitting a completed annual charge form if after April 30.

Health Canada reports annual charge performance against service standards as part of its <u>fees</u> <u>reports</u>.

Contact

Please direct all questions and inquiries to Jordan Hancey Policy and Operations Directorate Pest Management Regulatory Agency 2 Constellation Drive Ottawa, Ontario K1A 0K9 Email: <u>pmra.regulatory.affairs-affaires.reglementaires.arla@hc-sc.gc.ca</u>

PROPOSED REGULATORY TEXT

Notice is given that the Governor in Council proposes to make the annexed *Regulations Amending the Pest Control Products Fees and Charges Regulations (Annual Charge)* under section 67 ^a of the *Pest Control Products Act* ^b.

Interested persons may make representations concerning the proposed Regulations within 60 days after the date of publication of this notice. They are strongly encouraged to use the online commenting feature that is available on the *Canada Gazette* website but if they use email, mail or any other means, the representations should cite the *Canada Gazette*, Part I, and the date of publication of this notice, and be sent to Jordan Hancey, Director, Policy and Regulatory Affairs Division, Policy and Operations Directorate, Pest Management Regulatory Agency, Department of Health, Address Locator: 2608A, 2 Constellation Drive, Ottawa, Ontario K1A 0K9 (email: <u>pmra.regulatory.affairs-affaires.reglementaires.arla@hc-sc.gc.ca</u>).

Ottawa, December 13, 2024

Wendy Nixon Assistant Clerk of the Privy Council

Regulations Amending the Pest Control Products Fees and Charges Regulations (Annual Charge)

Amendments

1 Subsection 2(3) of the French version of the *Pest Control Products Fees and Charges Regulations* $\frac{4}{2}$ is replaced by the following:

Agents microbiens ou écomones — annexe 2

(3) Les droits d'examen par le ministre d'une demande à l'égard d'un produit antiparasitaire qui est un agent microbien ou une écomone correspondent aux droits figurant dans la colonne 2 de l'annexe 2 en regard du type de demande figurant dans la colonne 1.

2 Part 2 of the Regulations is replaced by the following:

PART 2 Interpretation

Definitions

9 (1) The following definitions apply in this Part.

entity

means an organization as defined in section 2 of the Criminal Code. (entité)

small business

means a person in respect of which the following criteria apply:

(a) the total of the number of employees of the person and of the persons with which the person is affiliated is fewer than 100; and

(b) the total of the annual gross revenue of the person and of the persons with which the person is affiliated is less than \$5 million. (*petite entreprise*)

Affiliation

(2) For the purposes of this Part,

(a) one entity is affiliated with another entity if one of them is the subsidiary of the other or both are subsidiaries of the same entity or each of them is controlled by the same entity or individual;

(b) if two entities are affiliated with the same entity at the same time, they are deemed to be affiliated with each other; and

(c) an individual is affiliated with an entity if the individual controls the entity.

Subsidiary

(3) For the purposes of this Part, an entity is a subsidiary of another entity if it is controlled by that other entity.

Control

(4) For the purposes of this Part,

(a) a corporation is controlled by an entity or an individual if

(i) securities of the corporation to which are attached more than 50% of the votes that may be cast to elect directors of the corporation are held, directly or indirectly, whether through one or more subsidiaries or otherwise, other than by way of security only, by or for the benefit of that entity or individual, and

(ii) the votes attached to those securities are sufficient, if exercised, to elect a majority of the directors of the corporation; and

(b) an entity other than a corporation is controlled by an entity or individual if the entity or individual, directly or indirectly, whether through one or more subsidiaries or otherwise, holds an interest in the entity that is not a corporation that entitles them to receive more than 50% of the profits of that entity or more than 50% of its assets on dissolution.

Deemed affiliation

(5) For the purposes of this Part, if it may reasonably be considered that one of the main reasons for the separate existence of two or more corporations is so that one of them meets the applicable conditions for a reduction of an annual charge fixed under this Part for which only small businesses are eligible, the two or more corporations are deemed to be affiliated with each other.

Non-Application

Non-application

9.01 This Part does not apply to departments or agencies of the Government of Canada or of the government of a province or to municipalities, including Crown or municipal corporations that operate otherwise than for profit.

Annual Charge

Payable annually

9.02 A registrant must pay each year, in respect of each pest control product that is registered in their name on April 1 of the year, an annual charge of

(a) \$6,130 for each of the first two registrations;

- (b) \$4,598 for each of the third to twenty-fifth registrations;
- (c) \$5,211 for each of the twenty-sixth to seventy-fifth registrations; and
- (d) \$5,517 for each additional registration beyond the seventy-fifth registration.

Reduction — small businesses

9.03 (1) Despite section 9.02 and subject to subsection (2), if the registrant is a small business, the annual charge payable in respect of each pest control product that is registered in their name on April 1 of the year is \$2,000.

Information — small businesses

(2) For the purposes of subsection (1), the registrant must provide the following to the Minister, in the manner specified by the Minister:

(a) in the case where the registrant has completed their first fiscal year,

(i) an attestation that the registrant was a small business in their preceding completed fiscal year, and

(ii) the following information:

(A) a list of the persons with which the registrant was affiliated in the registrant's preceding completed fiscal year,

(B) the start and end dates of the registrant's fiscal year and of the fiscal year of the persons with which the registrant was affiliated in the registrant's preceding completed fiscal year,

(C) the number of employees of the registrant in their preceding completed fiscal year and of the persons with which the registrant was affiliated in those persons' preceding completed fiscal year, and

(D) the gross revenue of the registrant in their preceding completed fiscal year and of the persons with which the registrant was affiliated in those persons' preceding completed fiscal year; and

(b) in the case where the registrant has not completed their first fiscal year,

(i) an attestation that the registrant anticipates being a small business in their first fiscal year, and

(ii) the following information:

(A) a list of the persons with which the registrant is affiliated in the registrant's first fiscal year,

(B) the start and end dates of the registrant's fiscal year and of the fiscal year of the persons with which the registrant is affiliated in the registrant's first fiscal year,

(C) the number of employees of the registrant in their first fiscal year and of the persons with which the registrant is affiliated in those persons' preceding completed fiscal year, and

(**D**) the projected gross revenue of the registrant in their first fiscal year and the gross revenue of the persons with which the registrant is affiliated in those persons' preceding completed fiscal year.

Reduction — active ingredients

9.04 Despite sections 9.02 and 9.03, if the registered pest control product is, or contains as its only active ingredient, one or more of the following ingredients, the annual charge payable in respect of that product is \$1,000:

- (a) a semiochemical;
- (b) a microbial agent;

(c) a food or an extract derived from food, a plant extract or oil, a chemical or substance that is widely available to the public for uses other than as a pest control product or other material that the Minister has determined, at the time of registration under section 8 of the *Pest Control Products Act* or confirmation or amendment of the registration under section 21 of that Act, meets the following conditions:

(i) it does not have chronic toxicity, genotoxicity, carcinogenicity, neurotoxicity or immunotoxicity,

(ii) it does not cause reproductive or developmental effects,

(iii) it does not metabolize into compounds of toxicological concern, and

(iv) it is neither anticipated to nor does it bioaccumulate.

Reduction — specialized pest control products

9.05 (1) Despite sections 9.02 and 9.03 and subject to subsection (2), if the registered pest control product has a product class designation of "COMMERCIAL" or "RESTRICTED", as required by the *Pest Control Products Regulations*, and meets one of the following conditions, the annual charge payable in respect of that product is \$1,000:

(a) the purpose of the product is for use only on agricultural crops that are cultivated in a total area in Canada of 1 000 000 ha or less per crop;

(b) the intended effects of the product support

(i) the management of a public health threat by the Government of Canada or the government of a province or by a municipality,

(ii) the management of an invasive species, or

(iii) the management of an existing or potential threat to a *species at risk*, as defined in subsection 2(1) of the *Species at Risk Act*.

Information — specialized pest control products

(2) For the purposes of subsection (1), the registrant must provide the following to the Minister, in the manner specified by the Minister:

(a) an attestation that the annual charge that would otherwise be payable is greater than 10% of the annual gross revenues of the product during their preceding fiscal year; and

(b) in respect of paragraph (1)(b), confirmation from the Government of Canada or the government of a province or from a municipality that the use of the product is necessary to support one of the purposes set out in that paragraph.

Reduction — discontinuation

9.06 Despite sections 9.02 and 9.03, if, under section 22 of the *Pest Control Products Act*, a registrant notifies the Minister that they intend to discontinue the sale of a pest control product and the Minister determines an effective date of the cancellation of the registration, the annual charge payable for each of the last two years of the registration of that product, following receipt of the notification, is \$1,000.

Annual charge exemption

9.07 A registrant is exempt from paying an annual charge during the first three years after a pest control product is registered if the product is, or contains, a new active ingredient that has not previously been registered in Canada and the product's registration is intended for end-use in Canada.

Timing of payment

9.08 The annual charge is payable

(a) in full, on receipt of a notice from the Minister requiring payment; or

(b) in four equal quarterly payments, the first of which is payable on receipt of a notice from the Minister requiring payment.

Information

Information on request

9.09 If the Minister determines that additional information is necessary to demonstrate that the registrant is eligible to pay the annual charge set out in section 9.03 or 9.05, the Minister may request that the registrant provide, within 60 days after the day on which the request is made, additional information, including the following:

(a) records of the registrant's annual gross revenue prepared in accordance with generally accepted accounting principles and certified by the individual responsible for the registrant's financial affairs; and

(b) records of the registrant's annual gross revenue that have been audited by a qualified independent auditor.

Information not submitted or insufficient

9.1 The annual charge that is payable by the registrant is the amount set out in section 9.02 or 9.03, as the case may be, if

(a) the registrant has not provided the additional information requested under section 9.09 within the period specified in that section; or

(b) the registrant has provided the additional information requested under section 9.09 within the period specified in that section, but the Minister determines, after the period ends, that the information provided is not sufficient.

3 The heading of Schedule 1 to the French version of the Regulations is replaced by the following:

Droits relatifs aux demandes visant l'homologation ou la modification de l'homologation d'un produit antiparasitaire, sauf celui qui est un agent microbien ou une écomone

4 The heading of Schedule 2 to the French version of the Regulations is replaced by the following:

Droits relatifs aux demandes à l'égard d'un produit antiparasitaire qui est un agent microbien ou une écomone

Transitional Provision

Notification before coming into force

5 If, before the day on which these Regulations come into force, the Minister received a notification under subsection 22(1) of the *Pest Control Products Act* that a registrant intends to discontinue the sale of a pest control product for all of the uses for which it is registered,

Part 2 of the *Pest Control Products Fees and Charges Regulations*, as it read immediately before that day, continues to apply in respect of any remaining period of the product's registration beyond that day.

Coming into Force

6 These Regulations come into force on April 1, 2026, but if they are registered after that day, they come into force on the day on which they are registered.

Terms of use and Privacy notice

Footnotes

- <u>a</u> S.C. 2020, c. 1, s. 206
- <u>b</u> S.C. 2002, c. 28
- 1 Regulations Prescribing the Fees to be Paid for a Pest Control Product Application Examination Service Provided by or on behalf of Her Majesty in Right of Canada, for a Right or Privilege to Manufacture or Sell a Pest Control Product in Canada and for Establishing a Maximum Residue Limit in Relation to a Pest Control Product (SOR/97-173, <u>https://laws.justice.gc.ca/eng/regulations/SOR-97-173/</u>)
- <u>2</u> S.C. 2017, c. 20, s. 451, <u>https://laws.justice.gc.ca/eng/acts/S-8.4/</u>
- A technical grade active ingredient (TGAI) is a type of pest control product that is used only in the manufacture of other pest control products. TGAI registrations generally only contain the active ingredient, and impurities that are by-products of the manufacturing process.
- <u>4</u> SOR/2017-9