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PEST CONTROL PRODUCTS ACT

Regulations Amending the Pest Control Products Regulations

P.C. 2010-706 June 3, 2010

Her Excellency the Governor General in Council, on the recommendation of the Minister of Health, pursuant to subsections 67(1) and (3) of the *Pest Control Products Act* (see footnote a), hereby makes the annexed *Regulations Amending the Pest Control Products Regulations*.

REGULATIONS AMENDING THE PEST CONTROL PRODUCTS REGULATIONS

AMENDMENTS

1. Subsection 16(4) of the *Pest Control Products Regulations* (see footnote 1) is replaced by the following:

Information required with renewal applications

(4) An application to renew the registration of a pest control product must be accompanied by all of the following:

(*a*) the information required by subsection 6(1);

(*b*) the statement required by subsection 6(3);

(*c*) the information required by section 8;

(*d*) if the Minister requests them, an electronic copy of the approved label and two hard copies of the marketplace label; and

(*e*) in the case of a registration that was issued in the circumstances described in sections 17.7 to 17.94, a valid letter of access, as defined in section 17.1.

2. The Regulations are amended by adding the following after section 17:

PROTECTION OF TEST DATA

INTERPRETATION

Definitions

17.1 The following definitions apply in sections 17.2 to 17.94.

"agreement"
« *entente* »

"agreement" means an agreement described in subsection 66(1) of the Act.

"compensable data"
« *données soumises à des droits d'utilisation* »

"compensable data" means test data other than the following:

(*a*) test data that was submitted to support the registration of a new active ingredient and the pest control products associated with that ingredient, including any test data that was part of the additional information reported under section 12 of the Act in relation to that ingredient and those products;

(*b*) test data that is included in a scientific study that has been published; and

(*c*) test data that is generated by a scientific study that is fully funded by a government or one of its institutions.

"crop group"
« *groupe de cultures* »

"crop group" means a group of crops in which the residues at harvest are similar, based on similarities in appearance, harvestable commodity, edible portions and growth habits.

"letter of access"
« *lettre d'accès* »

"letter of access" means a document that is signed by a registrant in which the registrant authorizes a named person to use or rely on identified test data.

"letter of confirmation of source" « *lettre de confirmation de source* »

"letter of confirmation of source" means a document that is signed by a registrant in which the registrant confirms that they have agreed to provide an identified registered pest control product to a named person.

"minor use"
« *usage limité* »

"minor use", in respect of a pest control product, means a use the demand for which originates with a grower or a group of growers and which product is intended to be used on a particular pest in connection with a particular host organism, in all of the following circumstances:

(*a*) the use is for an agricultural purpose;

(*b*) a federal or provincial agricultural authority supports the use; and

(*c*) the use is supported by crop residue data or dislodgeable foliar data.

"representative crop"
« *culture répresentative* »

"representative crop" means a crop in a crop group from which extrapolations of residue levels and maximum residue limits may be made to one or more crops in the group.

"test data"
« *données d'essai* »

"test data" means test data that is included in the information used by the Minister in any of the following circumstances:

(*a*) to support an application to register a pest control product or to amend a registration under section 7 or 12 of the Act;

(*b*) in response to a notice delivered to the registrant under subsection 16(3), 18(1) or 19(1) of the Act; or

(*c*) in support of a registration before June 28, 2006.

APPLICATION

Equivalent active ingredients

17.2 Sections 17.1 and 17.3 to 17.94 apply only to applications to register a pest control product whose active ingredient has been determined by the Minister under subsection 7(2) of the Act to be equivalent to the active ingredient of a registered pest control product.

Re-evaluations and special reviews

17.3 Sections 17.1, 17.2 and 17.4 to 17.94 apply, with any necessary modifications, to a registrant who wishes to use or rely on test data of another registrant for the purpose of subsection 16(5) or 18(3) of the Act.

Non-application — product copies

17.4 When an applicant wishes to use or rely on test data of a registrant in order to register a pest control product that is equivalent to the registrant's product, using a pest control product provided by that registrant, sections 17.5 to 17.94 do not apply if

(*a*) the registrant provides the Minister with a letter of confirmation of source; and

(*b*) the only pest control product used in the manufacture of the applicant's product is the one provided by that registrant.

EXCLUSIVE USE

Exclusive use period

17.5 (1) The registrant of a new active ingredient has the exclusive use of the following test data for 10 years after the date of registration:

(*a*) test data that was provided in support of the initial application to register the active ingredient;

(*b*) test data that was provided in support of a concurrent application to register a pest control product that contains that active ingredient; and

(*c*) test data that was included in any additional information that was reported to the Minister under section 12 of the Act in relation to those applications.

Exclusive use — compounds and substances

(2) The registrant of a new pest control product described in paragraph 2(*b*) has the exclusive use of the test data submitted in support of the initial application to register it, for 10 years after the date of registration, if the product has never been an ingredient in a registered pest control product.

Extension — minor uses

(3) The Minister must extend the exclusive use period in all of the following circumstances:

(*a*) the registrant

(i) includes minor uses in an application to register a pest control product referred to in paragraph (1)(*b*), or

(ii) on or after August 1, 2007 but in any case within seven years after the date of registration of a pest control product referred to in paragraph (1)(*b*), either makes an application to amend that registration to add minor uses or makes an application, that includes minor uses, to register a new pest control product that contains the same active ingredient;

(*b*) the registrant requests an extension of the period, within eight years after the date of registration; and

(*c*) the Minister determines that the proposed minor uses are minor uses, as defined in section 17.1, and approves their addition to the registration.

Calculation of extension

(4) The following rules apply when calculating an extension:

(*a*) the exclusive use period is extended at the rate of one year for each three minor uses that are added to the registration, to a maximum total period of 15 years; and

(*b*) the maximum number of minor uses in respect of a crop group is the number of representative crops in the crop group.

When minor use withdrawn or removed

(5) A one-year extension is cancelled if the registrant withdraws a minor use from their registration, or the Minister amends the registration and removes a minor use, such that the remaining number of minor uses is insufficient to support the extension.

Letter of access

17.6 During the exclusive use period, an applicant may use or rely on test data of a registrant in an application to register a pest control product or amend a registration if the registrant provides the applicant with a letter of access.

AGREEMENTS

Conditions — use or reliance

17.7 (1) Subject to subsection 17.94(2), an applicant may use or rely on compensable data of a registrant if they pay compensation to the registrant in accordance with an agreement for the relevant period described in subsection (2) and provide the Minister with a copy of a letter of access.

Compensable period

(2) Compensation is payable in respect of the following compensable data that is submitted to or considered by the Minister for the first time, for the following periods:

(*a*) in the case of test data that supports an application to register a pest control product whose active ingredient is already registered, for 12 years after the date of the application;

(*b*) in the case of test data that supports an application to amend a registration, for 12 years after the date of the application;

(*c*) in the case of test data submitted in response to a notice delivered to the registrant under subsection 16(3), 18(1) or 19(1) of the Act, for 12 years after the date on which the Minister receives the data; and

(*d*) subject to subsection (3), in the case of foreign test data considered by the Minister in the course of a re-evaluation or special review, for 12 years after the date on which the Minister initiates the re-evaluation or special review.

Condition — foreign test data

(3) Foreign test data is compensable only if the registrant is able to provide the Minister with the foreign test data on request.

Minister to identify compensable data

17.8 (1) For the purpose of subsection 7(2) of the Act, the Minister must provide the applicant with a list of the compensable data that they may use or rely on and in respect of which they will need to enter into an agreement with the registrant.

Request to enter agreement

(2) On receipt of the list of compensable data, the applicant may send a copy of an agreement to the registrant to enter into with respect to such of that data that they wish to use or rely on, by certified or registered mail or any other method of delivery that provides proof of delivery.

NEGOTIATION AND ARBITRATION

Agreement entered into

17.9 (1) On delivery of the proposed agreement, the applicant and the registrant must enter into the agreement and begin to negotiate the compensation payable in respect of the data that the applicant wishes to use or rely on.

Negotiation period

(2) The parties must reach a negotiated settlement with respect to the compensation payable within 120 days after delivery of the agreement.

Extension

(3) If the parties fail to reach a negotiated settlement within the 120-day period, they may continue negotiating if they both agree to do so.

When no negotiated settlement — notice of arbitration

17.91 (1) If the parties fail to conclude a negotiated settlement in accordance with section 17.9, the applicant may, by notice in writing delivered to the registrant, submit the determination of the compensation payable to binding arbitration in accordance with the agreement.

Parties' offers in writing

(2) The notice must include the last offers of the parties, if they were presented in writing at the end of the negotiation.

Method of delivery

(3) The notice must be delivered by certified or registered mail or any other method of delivery that provides proof of delivery.

Arbitral award

(4) An arbitral award must be made within 120 days after delivery of the notice, unless the parties agree to an extension.

When no offer in writing

17.92 If the registrant does not put their last offer in writing at the end of the negotiation, the applicant may make the request referred to in subsection 17.93(1) without having to meet the conditions set out in section 17.93.

Conditions on early registration

17.93 (1) If a negotiation ends without a negotiated settlement, the applicant may, once a notice referred to in section 17.91 has been delivered, use or rely on the compensable data and request that the Minister register their product in the absence of a letter of access, if the following conditions are met:

(*a*) the applicant enters into an escrow agreement with a third party;

(*b*) the third party is a person who is entitled under the laws of a province to receive and hold money on behalf of another person;

(*c*) pursuant to the escrow agreement, the applicant deposits with the third party an amount of money equal to the registrant's last offer referred to in subsection 17.91(2); and

(*d*) the escrow agreement contains all of the following terms:

(i) the third party holds the money until it is payable in accordance with the escrow agreement,

(ii) on receipt of a copy of the registration certificate, the third party pays the registrant an amount equal to the applicant's last offer referred to in subsection 17.91(2),

(iii) on receipt of a copy of the negotiated settlement or arbitral award, the third party pays the registrant the amount determined in that settlement or award, less the amount paid under subparagraph (ii), and

(iv) the third party pays any remaining balance to the applicant.

Copy and proof to Minister

(2) The applicant must send the Minister both a copy of the escrow agreement and proof that the applicant has deposited the money with the third party in accordance with paragraph (1)(*c*).

Letter of access

17.94 (1) On the determination of the compensation payable, whether by negotiated settlement or arbitral award, the registrant must provide the applicant with a letter of access in accordance with the settlement or award.

Failure to provide letter of access

(2) If the registrant fails to provide the letter of access, the applicant may use or rely on the compensable data without having to comply further with the negotiated settlement or arbitral award.

TRANSITIONAL

3. (1) These Regulations apply to an application to register a pest control product or to amend a registration made on or after August 1, 2007 and before the day on which these Regulations come into force, if the applicant wishes to use or rely on compensable data of a registrant and the Minister has requested in writing that the parties negotiate the amount of compensation payable for that use or reliance.

(2) Despite subsection (1), if the Minister's request is made more than 60 days before the coming into force of these Regulations and the applicant sends a copy of an agreement to the registrant under subsection 17.8(2) of the *Pest Control Products Regulations*, as enacted by section 2, the 120-day period specified in subsection 17.9(2) of those Regulations, as enacted by section 2, is reduced to 60 days from the day after the agreement is sent.

4. Despite paragraph 17.5(3)(*b*) of the *Pest Control Products Regulations*, as enacted by section 2, the Minister must extend the exclusive use period established in accordance with section 17.5 of those Regulations, as enacted by section 2, if all of the following conditions are met:

(*a*) there remain at least six months before the exclusive use period expires;

(*b*) minor uses are added to the registration on or after August 1, 2007 but before the day on which these Regulations come into force; and

(*c*) the registrant requests an extension of the exclusive use period within 30 days after the day on which these Regulations are published in the *Canada Gazette* , Part II.

COMING INTO FORCE

5. These Regulations come into force on the day on which they are registered.

REGULATORY IMPACT ANALYSIS STATEMENT

(*This statement is not part of the Regulations.*)

Executive summary

Issue: A number of multi-stakeholder-led initiatives have recommended modernizing Canada's pesticide data protection system to encourage innovation and timely grower access to competitively priced generic pesticides. There is also a need to provide incentives to industry to register their pesticides for use on minor crops such as fruits and vegetables.

Description: These Regulations are designed to provide a legally enforceable and fair process of pesticide data protection. They are intended to benefit pesticide users, particularly in the agricultural sector, by encouraging the registration of new, innovative and minor uses and facilitating the timely and predictable entry of competitively priced generic pesticides via a clear negotiation and arbitration process. More specifically, these Regulations provide 10 years of exclusive-use protection for data used to support the Canadian registration of a new pesticide that contains a new active ingredient. And, by adding minor uses of significance to the original registration, the exclusive use period can be extended by up to five years (i.e. to a maximum of 15 years). This minor use incentive provision is designed to encourage pesticide companies to register pesticides for use on minor use crops in return for extended data protection for these pesticides. Further, data that supports registrations and amendments to registrations, but that does not qualify for exclusive use protection, receive a 12-year compensatory protection status. During the compensatory period, an applicant can use or rely on the innovator's data provided the applicant complies with the regulatory requirement to compensate the registrant. The companies will be expected to determine the amount of data compensation owed through time-limited negotiation (and, if necessary, time-limited binding arbitration) without Health Canada being involved in determining the value of the data.

Cost-benefit statement: The Canadian agriculture and agri-food system provides one in eight jobs and employs nearly 2.1 million people. The time-limited data compensation process under the Regulations will enable growers in this sector to gain benefits from the entry of generic pesticides (including potential price savings) sooner than under the previous data protection policy. Assuming there will be price declines following the entry of generic pesticides, the incremental benefits to growers from more timely access to generic pesticides could range from $11 million to $26 million over 10 years. This will depend on the number of future generic pesticides and on the take-up by innovators in registering minor uses on their pesticides in order to extend data protection on their pesticides. This take-up on extending data protection could represent a "cost" to certain growers, since it would delay generic companies from relying on an innovator's data to introduce a generic pesticide (thereby delaying the entry of competitor generic pesticides and potential price savings by up to five years). It is anticipated, however, that the potential benefits to growers from this incentive provision will outweigh the potential costs to growers given the number and scope of current unmet minor use needs in Canada.

Business and consumer impacts: Administrative costs and consumer impacts are expected to be minimal.

Domestic and international coordination and cooperation: These Regulations are consistent with international requirements, such as those of the North American Free Trade Agreement (NAFTA) and the World Trade Organization's Trade-Related Aspects of Intellectual Property Rights (TRIPS). They are similar to approaches in

other countries, notably that taken by the United States Environmental Protection Agency (U.S. EPA).

Performance measurement and evaluation plan: The effectiveness of these Regulations will be evaluated as part of the broader pesticide regulatory program evaluation on a regular basis.

Issue

The goals of sustainable pest management are to meet society's needs for human health protection, food and fibre production and resource utilization, and to conserve or enhance natural resources and the quality of the environment for future generations, in an economically viable manner. Pesticides play a significant role in diverse areas of the economy and other aspects of quality of life throughout Canada, particularly as tools to practice integrated pest management (IPM). Without access to a variety of pesticides, the agricultural sector is at a disadvantage relative to competitors in other countries.

Before pesticides are marketed, Health Canada evaluates scientific data submitted by pesticide companies in support of a registration to ensure that the pesticides are of acceptable health and environmental risk, and of value to Canada, in accordance with the *Pest Control Products Act* (PCPA). Under certain circumstances, a generic pesticide company can rely on an innovator company's scientific data when applying for registration. Thus, Health Canada's approval process needs to be as timely as possible and provide for fair innovator data protection so as to encourage the registration of a variety of pesticides for growers.

A number of multi-stakeholder-led initiatives (e.g. the Own-Use Import [OUI] Task Force) have recommended modernizing Canada's pesticide data protection system to encourage innovation and timely grower access to competitively priced generic pesticides. Innovator and generic pesticide companies have indicated a need for aligning the data protection rules with those of the U.S. EPA, and by making them more predictable, timely, and fair. There is also a need to provide incentives to pesticide companies to register their pesticides for minor use crops such as fruits and vegetables due to the minimal financial incentives for pesticide companies to register pesticides for these uses.

In August 2007, the *Protection of Proprietary Interests in Pesticide Data in Canada* (PPIP policy) was implemented in part to address the above issues. The policy removed Health Canada from facilitating the determination of the amount of data compensation owed between companies (as under the previous policy), but some aspects of the policy can not be enforced without regulations (e.g. pursuing arbitration).

Objectives

These Regulations will encourage the registration of new innovative pesticides, including registration for use on minor crops, and facilitate timely entry of competitively priced generic pesticides. This will ultimately benefit pesticide users, particularly the agricultural sector.

Description

These Regulations define the rules on how the scientific data used to support a pesticide registration is protected from reliance by another applicant or registrant. These regulations give 10 years of exclusive use protection to data supporting a new registration that contains an active ingredient never before registered in Canada. The exclusive use period begins at the time of registration. If minor uses of significance and with supporting data are added to this new registration, the exclusive use period can be extended to a maximum of 15 years. These additional five years of protection are applied at the rate of one additional year for three minor uses.

Subsequently submitted data that does not support the registration of a new active ingredient to Canada and is used to amend or maintain a registration, or register a new product, are given a 12-year compensatory protection status. The compensable protection status begins at the time of application.

Once either the exclusive use or compensable period for protected data has lapsed, the data becomes generic and can be used or relied upon without consent and without payment of compensation.

These Regulations permit the reliance on a registrant's compensable data by generic companies (or applicants). If they wish to determine the compensation payable in accordance with the Regulations, the innovator (or data owner, or registrant) and the generic company will be required to enter into an agreement, as prescribed by the Minister under section 66 of the PCPA, and to begin to negotiate a settlement. The negotiation period will be limited to 120 days, unless the parties agree to extend the period. If the negotiations fail to produce agreement, the generic company can initiate binding, final-offer arbitration. If arbitration is pursued, the arbitrator will have to issue an award within 120 days of the commencement of the arbitration period unless the parties agree to extend the timeframe.

Once the amount of compensation payable is determined through a negotiated settlement or arbitral award, the innovator is required to provide a letter of access to the data, in accordance with the terms of the settlement or award. The letter of access provides the basis on which the generic pesticide is registered. If the innovator fails to provide a letter of access when the applicant has complied with the terms of the settlement or award, the applicant can obtain the registration and be relieved of the obligation to comply with any outstanding compensation payable. If the settlement or award provides for a schedule of compensation payments, the generic pesticide is granted a one-year registration, and the validity of this registration is determined at renewal. The registration can occur earlier if the generic company enters into an escrow agreement and deposits with a third party funds sufficient to meet the innovator's last offer made at the end of the negotiation period.

The PCPA provides for the Minister to conduct a re-evaluation or special review of registered pesticides. At the outset of a re-evaluation or special review, the Minister identifies the data on hand and determines if a data call-in is necessary. The Minister initiates a re-evaluation or a special review by delivering a written notice to registrants with the reasons for initiating the re-evaluation or special review, and if necessary, requiring registrants to provide data; foreign test data is only requested as required. The Minister can use data on-hand at the outset of the re-evaluation or special review; on-hand data (including foreign test data) only has to be compensated if later relied upon to

register a new product or amend a registration. All data that registrants provide in response to a call-in is compensable if used by the Minister. Compensation for the data provided in response to a call-in is determined after the re-evaluation or special review is completed. Registrants who did not provide the data called-in and wish to continue their registration can sign a Ministerial agreement under section 66 of the Act for determining the compensation to be paid, with the data owner; the registration is continued if the Ministerial agreement is signed and the registration is confirmed if a letter of access is provided.

These Regulations are modelled on the U.S. EPA system and are consistent with NAFTA and TRIPS, which require protection from unfair commercial use.

Regulatory and non-regulatory options considered

In developing these Regulations, two instrument options were considered: continue to rely on a voluntary policy (i.e. PPIP policy), or rely on regulations. The option of proceeding with regulations was selected, since it provides for a legally binding process for compensation. Therefore, it is enforceable, while providing more predictability than a policy.

Two design options were considered for the Regulations in relation to the timing of generic registrations: (*a*) only allow registering after a letter of access is received, and (*b*) allow registering before a letter of access is received, if the generic company enters into an escrow agreement and deposits with a third party funds sufficient to meet the innovator's last offer made at the end of the negotiation period.

Stakeholders were divided on the above-mentioned design options. Innovators argued option (*b*) was not necessary, as it provided the generic company less than four months for an early registration, and it would take time and resources for the two parties to negotiate the terms of the escrow agreement. Innovators indicated that the "timing of registration" issue could be mitigated by generic companies applying earlier in the process. Generic companies largely supported option (*b*), which could minimize delays in generic registration after the end of the exclusive use period. Some generic companies proposed that the amount to be put in trust be less than the amount of the registrant's last offer, so as to prevent unreasonable demands by innovators.

In response to stakeholders, option (*b*) was selected, since it provides flexibility and balance by guaranteeing payment while facilitating the timely market entry of competitively priced generic pesticides. The generic companies enter into an escrow agreement with the third party by themselves, if they wish to use that option.

Benefits and costs

The full cost-benefit analysis of the Regulations is available on request.

Canadian growers will be the main beneficiaries of these Regulations. The Canadian agriculture and agri-food system provides one in eight jobs and employs nearly 2.1 million people. Pesticides are important to Canadian agriculture as a valuable input in maximizing crop yield and quality, and as a driver of farm operating costs (4.7% of net

farm operating expenses in 2007, according to Agriculture and Agri-Food Canada [AAFC]).

Grower access to generic pesticides

It is generally accepted within the grower community and pesticide industry that the introduction of generic pesticides can lead to additional competition, result in reduced prices and generate savings to growers on their pesticide inputs, although views vary on the potential magnitude of such impacts. Literature and data analysis on the effects of generic pesticides on pesticide prices are limited.

The more timely data compensation process envisioned under these Regulations means that growers would gain access to and accrue benefits from the market entry of generic pesticides approximately one year sooner than under the previous policy.

To estimate the potential magnitude of the benefit of growers "saving sooner" under the Regulations, a two-step analysis was conducted based on assumptions regarding the impact of generic competition, the number of generic pesticides entering the market and several other factors.

In the first step, generic submissions currently in the queue were examined to identify, where possible, the innovator pesticides with which generic companies are likely to compete. Proprietary data was used to determine recent grower expenditures on these innovator pesticides. The estimated grower savings on pesticide expenditures were calculated based on an assumed price decline that was linked to whether generic versions of these pesticides are already available, and if so, the number of competing generic pesticides. Use of a pesticide was assumed to be constant in response to a price decline (inelastic demand). (see footnote 2)

In the second step, impacts in future years were estimated based on an assumed number of generic submissions per year (10), on the assumed expenditures associated with each pesticide ($7.5 million) and on the assumed price decline on generic entry (15%). These assumptions were premised on an expectation of sustained interest by generic companies in introducing competitor pesticides to the Canadian market, the presumption being that generic companies will pursue pesticides associated with high grower expenditures (i.e. above $20 million in annual sales) as well as those with much lower expenditures for which they can have some competitive advantage. Limited price declines were also anticipated, considering that many future generic pesticides would enter a market in which other generic versions are already available (and thus serve to decrease the extent of price declines).

Based on this analysis, the estimated benefit to growers of accruing savings one year sooner as a result of a more timely entry of generic pesticides would be $11 million over 10 years: $6 million from generic pesticides with submissions now in the queue, and $5 million from generic pesticides assumed to be introduced in future years. Estimates from this simplified analysis are sensitive to changes in assumptions, but even significant changes to underlying assumptions (e.g. doubling of the number of generic submissions per year and a doubling of the expenditures for each pesticide) still generate an overall benefit of approximately $27 million over 10 years. Nevertheless, as discussed below, benefits to growers from a more timely process could be offset by the

impact of delays in generic entry as a result of extended data protection under the minor use incentive.

Grower access to pesticides for use on minor crops

To the extent that pesticide companies register minor uses in the future, growers of minor use crops will gain access to an increased number of pesticides addressing significant unmet pest control needs.

While minor uses are recognized by growers as essential to cost-effective pest control, pesticide companies often have minimal commercial incentive to register pesticides on these crops. That is, the costs that a registrant will incur to develop data to support a minor use registration (e.g. residue and efficacy data) may be too high given the projected revenues from registration.

"Minor use" needs manifest themselves in different ways:

- The absence of registered pesticides for important crop-pest use combinations may result in diminished crop yield and quality. A subset of this issue is the limited number of registered biopesticides that can be used on organic-certified crops. Lack of access to pesticides that are available in other countries can place Canadian growers at a competitive disadvantage.
- If there is an insufficient range of available pesticides, reliance on a single pesticide could elevate the risk of target pests becoming resistant.
- Practical disadvantages of existing pesticides (e.g. long worker re-entry intervals) can preclude growers from monitoring crops for other pest control problems, and large environmental buffer zones can reduce the acreage on which a crop can be grown.
- Existing pesticides could have characteristics that hinder adoption of IPM practices aimed at reducing overall pesticide use.

The potential benefit to growers from the minor use incentive provision depends on the expected number of additional minor uses that will be registered and the assumed benefit per use. Both are difficult to predict. A similar incentive provision exists under the U.S. EPA pesticide data protection system; however, take-up in the past has been minimal, although companies have recently begun to show interest in using the mechanism. A review of the agricultural economics literature and discussions with minor use experts suggests that quantifying benefits of minor use pesticides is challenged by lack of data as well as by the different types of benefits that could arise (as above).

This presents a further challenge for analyzing the overall impact of the Regulations to growers. While take-up of the minor use incentive provision by pesticide companies will lead to benefits to growers of minor use crops, the extended data protection granted to companies in return for registering eligible minor uses could mean delays in grower access to generic pesticides. That is, the benefits of growers "saving sooner" as a result of a more timely data compensation process would not arise where an innovator's data receives extended data protection, because generic companies would be precluded from relying on this data for up to an additional five years.

A key question arising from the minor use incentive provision is the likelihood of whether the benefits accrued by minor use crop growers from access to additional minor use pesticides would exceed the costs to other growers (for example growers of major grain and oilseed crops who purchase pesticides in large volumes) of delayed access to generic pesticides. The cost-benefit analysis included an analysis of hypothetical thresholds that an average minor use would need to meet to exceed costs to growers from delayed generic entry. The thresholds depend on assumptions regarding pesticide expenditures, the price decline on entry of generic pesticides and the number of years of extended data protection.

Based on the number and scope of current minor use needs in Canada, it is reasonable to anticipate that benefits to minor use crop growers from additional minor use registrations will be above potential costs to other growers from extended data protection. Grower groups, provincial agricultural experts and AAFC have compiled a national listing of approximately 3 600 minor use needs, reflecting the broad range of challenges now facing growers of minor use crops. Needs are particularly acute for tree fruit and berry growers, where Health Canada re-evaluation decisions to phase out a number of insecticides would, in the absence of alternative pesticides being registered, leave growers of these high value crops without effective control of several significant pests.

Administrative costs and consumer impacts

Administrative costs and consumer impacts are expected to be minimal. It is unlikely that consumers will experience a decline in food prices as a result of the Regulations, since growers do not control food prices and intermediate parties are involved in marketing the food. Growers may also reallocate any savings from lower pesticide prices to other costs (e.g. loans, fuel and fertilizer).

Overall, the Regulations are expected to be resource neutral for Health Canada.

Strategic environmental assessment

It was determined through a strategic environmental assessment that these Regulations could result in minor positive environmental impacts by facilitating access to lower risk replacements that are introduced as a result of re-evaluation or special review where pesticides and uses are phased out and improved technology follows.

Rationale

The Regulations endeavour to strike a fair balance between the competing views of innovator and generic companies and strive to provide an equitable process for determining compensation and meet the objectives stated above (see “Objectives”). They will also support ongoing work done by AAFC and provincial governments on minor use expansion.

Consultation

Pesticide data protection has been under a voluntary policy since the 1980s. Over the years, several informal and formal consultations have taken place to improve the

previous and current policies. A number of multi-stakeholder initiatives (e.g. the OUI Task Force) have recommended modernizing Canada's pesticide data protection system to encourage innovation and timely grower access to competitively priced generic pesticides. In 2006, the current policy was consulted on and finalized and published in 2007 (see DIR2007-03 at www.hc-sc.gc.ca/cps-spc/pubs/pest/ _pol-guide/dir2007-03), with the intent to make regulations to have a policy that is enforceable.

The Regulations were pre-published in the *Canada Gazette*, Part I, on November 14, 2009 (see www.gazette.gc.ca/rp-pr/p1/ 2009/2009-11-14/pdf/g1-14346.pdf), followed by a 75-day comment period. Comments were received from 19 respondents, comprising a balance of growers, and innovator and generic companies. A face-to-face consultation also took place with interested stakeholders on February 16, 2010, to discuss the comments received and proposed responses. The comments are summarized as follows:

Respondents requested that the phrase "generated by a government," as it relates to the definition of compensable data in the English version of the proposed Regulations, be clarified in order to demonstrate data ownership. In response to this request, the phrase has been changed to "generated by a scientific study that is fully funded by a government."

One representative of innovator companies requested that the applicant be required to pay the registrant an amount equal to the applicant's last offer (the minimum) immediately on early registration, for a greater guarantee of payment. In response, paragraph 17.93(1)(*d*) of the Regulations provides for the applicant to pay the minimum amount payable as requested since it would be fairer for innovators to receive compensation for that amount at the same time as the generic companies can enter the market with their products.

Respondents indicated that, unless changed or parties negotiate voluntarily, the proposed transitional section 3(1) would not provide for a shortened negotiation period (i.e. less than 120 days) as intended. In response, transitional sections 3(1) and 3(2) provide for a 60-day negotiation period, calculated as of the day after an agreement is sent, if the equivalency and list of compensable data are established, and if the Minister has requested the parties to negotiate more than 60 days before the Regulations came into force. Otherwise, the negotiation period will be 120 days. Parties can agree to extend a negotiation period at any time. This is consistent with the original intent of the proposed Regulations.

Respondents also requested editorial changes, clarification of the cost-benefit analysis, and clarification of aspects related to implementation (e.g. regarding the list of compensable data, last offers, performance standards, and the provision of marketplace and electronic labels at renewal). In response, editorial or clarification changes were made as needed, a guidance document will be developed to clarify the process issues raised, and subsection 16(4) codifies the current practice about renewal.

More details on the comments received were presented at a stakeholder meeting held on February 16, 2010. Substantive policy changes were not made since they would require extensive consultation and further analysis or a change to the Act, and delay gazetting. The aforementioned approach was generally supported at the February 16, 2010,

meeting where participants expressed that the proposed Regulations strike a fair balance in addressing the various concerns. There was support for making these Regulations as soon as possible.

Implementation, enforcement and service standards

The Regulations do not alter existing compliance mechanisms under the provisions of the PCPA and the *Pest Control Products Regulations*. The Regulations also contain incentives for compliance by both the generic and innovator companies; i.e. the Regulations allow the Minister of Health to grant a registration or reject a submission if either party fails to comply. Health Canada will process submissions to register pesticides or amend registrations consistent with the principles of its Management of Submissions Policy, and in accordance with the Regulations.

Performance measurement and evaluation

The effectiveness of these Regulations will be evaluated as part of the broader pesticide regulatory program evaluation on a regular basis. The evaluation will examine whether more innovative pesticides, minor uses and generic pesticides were introduced in Canada after the Regulations were enacted, and whether the prescribed time-limited compensation process was effective.

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Footnote a
S.C. 2002, c. 28

Footnote 1
SOR/2006-124

Footnote 2
The rationale for this assumption is that pesticide use is determined primarily by the presence and level of pest pressure. Irrespective of a decline in pesticide price, use of a pesticide by growers when it is not needed would represent a waste of limited grower resources, could potentially damage a crop and could possibly elevate the risk of pest resistance.