Health Canada's Pest Management Regulatory Agency's Response to the Intersol Group Ltd. Report

Recommendations: Administering the Data Protection Program for Pesticides in Canada

(publié aussi en français)

30 December 2016

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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Introduction

Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has the mandate to protect human health, safety and the environment by preventing unacceptable risks from the use of pest control products.

The data protection provisions of the *Pest Control Products Regulations* intend to strike a balance between encouraging the registration of new innovative products and generic pesticides by outlining the conditions that an applicant needs to follow to rely on an existing registrant's data to support their application. Data generated by pesticide registrants to support registrations in Canada receive exclusive or compensable protection status for a period of time to encourage innovation. Registrants of products under exclusive protection status can voluntarily allow applicants (generic registrants) to rely on their data. After the exclusive period, the data can be relied upon by others (generic registrants) to support the registration of competing "generic" products, thereby potentially lowering the price for pesticide users. During the compensable protection status period data can be relied upon providing compensation is paid.

PMRA requested advice from a neutral third party consultant on whether its pesticide data protection system was achieving the right balance, thereby optimizing its impact on the competitiveness of the Canadian agricultural sector. On November 20, 2014, the final report from the Intersol Group Ltd. was received and sent to stakeholders. PMRA discussed the recommendations within the report with stakeholders on December 2, 2014. Further submissions from stakeholders were received regarding the final report recommendations from December 2014 to February 2015.

The consultant's final report indicated that most stakeholder representatives from among grower groups, innovative companies and generics companies supported the overall approach and design of the data protection program, and saw no need for a fundamental re-design. At the same time, many stakeholders noted that the current design and delivery of a number of key process elements was limiting the timeliness and predictability of the data protection program, and inhibiting the rate at which companies were seeking to register generic products.

The consultant made a number of recommendations in its report to address these issues. This document sets out Health Canada's response to those recommendations taking into account stakeholder's views.

Recommendation 3.1: Preparation of Compensable Data Lists

3.1.1: Timelines for Producing Compensable Data Lists

1. **Establish a more realistic time standard for the preparation of compensable data lists taking into account current actual times required to prepare and finalize compensable data lists, and estimated impacts of planned process improvements and learning effects as the PMRA, registrants and applicants become more familiar with the process. The resulting time standard should incorporate an element of "stretch" so that efficiency improvements continue to be developed and implemented.**

2. **Finalise and publish its proposed revisions to the time standard for preparing compensable data lists (and proposed changes to the preparation process) for stakeholder comment as soon as possible and, ideally, no later than the end of February 2015.**

PMRA supports the recommendations that a more realistic time standard for the preparation of compensable data lists be established and finalized. As such, PMRA has established a 365 day performance standard for generating the compensable data list as well as performance standards for various steps in the list-generating process, to make the process more transparent and predictable.

This standard was implemented in December 2014, following consultations with stakeholders, for applications received after that date.

3. **Provide applicants with regular updates – monthly or every two months – as to which step in the compensable data list preparation process their applications have reached.**

PMRA supports the recommendation in principle and agrees that applicants should be provided timely information on which step in the compensable data list preparation process their applications have reached. As such, PMRA will continue to provide applicants updates, upon request.

4. **Report on a twice-yearly basis on the extent to which applications are processed within the target time standards. This reporting should provide the number of applications for which compensable data lists were issued during the six month period, the median or average times, and the minimum and maximum times required to produce compensable data lists, with the performance of the PMRA and registrants shown separately. Trend data should also be included in this reporting.**

PMRA supports in principle the recommendation to make available on a regular basis, information relating to compensable data lists that includes reporting on the extent to which applications are processed within the target time standard. This reporting will be done through PMRA's existing reporting mechanisms, such as in the Annual Report and through the Economic Management Advisory Council (EMAC).

3.1.2: Scope of Information on Studies on Compensable Data Lists

1. **Expand the amount of information provided on compensable data lists, focusing on the provision of summary descriptive information on the purpose, scope and method(s) of studies listed on compensable data lists, in addition to the data currently provided and proposed for inclusion by PMRA in March 2014.**

2. **Investigate the extent to which the provision of this information may be accommodated while remaining within the scope of requirements to preserve the confidentiality of registrants' test data, and provide appropriate guidance to applicants and registrants.**

PMRA supports the recommendation to expand the amount of information on the final data compensation list and implemented this change in December 2014, after consultations with stakeholders. The final data compensation list now includes the report title, report number, report date, purpose of the report, PMRA identification number and commencement of protection period.

However, having investigated the matter as per the second recommendation, PMRA does not support requiring the provision of summary descriptive information concerning scope and methods of studies (i.e., abstracts), as this would require PMRA to divert resources from activities related to its core mandate of protecting Canadian's health and environment to conduct in-depth reviews of each study to ensure that no confidential business information was included in the summary. Applicants and registrants seeking additional information on specific studies are instead encouraged to consult other public documents made available by PMRA (e.g., evaluation reports and consultation documents), which may contain further details they might find useful.

3.1.3: Earlier Applicant Access to Compensable Data Lists

1. **Provide applicants with a copy of the preliminary compensable data list at the same time it is made available to registrants, making it clear that the list is provided to aid applicant planning only.**

2. **Provide applicants with the same opportunity, and time period, to appeal the inclusion of any study on the preliminary compensable data list as is provided to registrants. Applicant and registrant reviews of preliminary compensable data lists should be conducted in parallel. Appeals of the content of preliminary compensable data lists by applicants should be restricted to confirming if the listed studies are eligible for compensable protection, that is, satisfy the conditions for compensability contained in the PCPR (S 17.1, S 17.7). PMRA would continue to determine the content of the final compensable data list, taking into account the comments and evidence provided by registrants and/or applicants during the appeal period.**

PMRA supports the recommendation to provide applicants with a copy of the preliminary compensable data list at the same time it is made available to registrants. PMRA implemented this new process in December 2014, after consultations with stakeholders.

The revised process also provides applicants and registrants with a 45 day period to review the data identified as being compensable in the assessment and provide PMRA written comments on that data with respect to seeking: confirmation that the data was used in the review; and clarification on the uses that the data supports. PMRA will continue to ensure that compensable data meets the eligibility requirements set out in the *Pest Control Products Regulations*, including sections 17.1 and 17.7.

Recommendation 3.2: Establishing the Compensable Status of Foreign Test Data

1. **Finalize and issue its guidance regarding reliance on proprietary data when making re-evaluation and special review decisions as a matter of priority in order to provide clear guidance to applicants and registrants.**

2. **Establish, as part of this guidance, the starting date for compensability of foreign test data as being the time a re-evaluation or special review is initiated, subject to the data meeting current scientific standards and being relevant to the Canadian usage context.**

3. **Implement, as part of this guidance, the proposed requirement for registrants to submit copies of foreign test data at the time they submit their initial data compensation list (assuming the March 2014 proposal that registrants prepare the initial list is implemented).**

PMRA supports the recommendation to finalize guidance regarding reliance on proprietary data when making re-evaluation and special review decisions; this would be done following planned amendments to the *Pest Control Products Regulations* aimed at clarifying the process for data protection during re-evaluations and special reviews.

Under the *Pest Control Products Regulations*, the starting date for compensability of foreign test data used in a re-evaluation or special review is already established as the date on which PMRA initiates that re-evaluation or special review; for greater clarity this will also be reflected in guidance. PMRA will also clarify what foreign test data is compensable for generic applications. PMRA supports the recommendation that registrants submit the foreign test data with their initial data compensation list. PMRA implemented this change in December 2014, after consultation with stakeholders.

Recommendation 3.3: Conduct of the Arbitration Process

3.3.1: Effectiveness of the Final Offer Selection Arbitration Method

1. **PMRA should not change the method of arbitration – from Final Offer Selection to bounded conventional arbitration – at this time. Instead, it should wait until there is an established level of experience with the use of the Final Offer Selection method and then assess if any changes are warranted.**

PMRA supports the recommendation to maintain the Final Offer Selection method of arbitration at this time. This has been supported by most stakeholders.

As recommended, PMRA will wait until there is an established level of experience with the use of the Final Offer Selection method before considering amendments to this process.

3.3.2: Binding Nature of Arbitral Awards

1. **The PMRA should modify the requirements of the data protection program to clarify that the payment of arbitral awards is conditional upon applicants opting to pursue registration.**

2. **Provide arbitral tribunals with the power to determine the allocation of arbitration and the parties' costs between the registrant and applicant in the event that the applicant subsequently chooses to discontinue their application.**

3. **Require applicants to notify the arbitral tribunal and registrant no later than 30 days from the date an arbitral award is rendered if they intend to seek registration of their product and pay the arbitral award. In the event that the applicant provides no indication of its registration intentions or indicates they will not be registering their product, the applicant will be subject to the arbitral tribunal's decision regarding the allocation of costs under point two, above.**

PMRA supports these recommendations and is examining options for implementing them, including amending the arbitration provisions as proposed in the Agreement for Data Protection under Section 66 of the *Pest Control Products Act* (currently called the Ministerial Agreement for Data Protection under the *Pest Control Products Act*).

Although stakeholders (generic and innovator registrants) have divergent views on this recommendation, PMRA considers that this proposed approach balances appropriately the needs of both generic and innovator registrants.

PMRA aims to consult on a proposed approach to implementing these recommendations in fiscal year 2016-17.

Recommendation 3.4: Time Limits for Applicant Decision-making

1. **The PMRA should establish a time limit of 30 days for an applicant to notify the PMRA and the registrant if they are going to continue or withdraw their applications following:**
    - **the issuance of a compensable data list, and**
    - **the completion or cessation of negotiations.**

PMRA acknowledges the recommendation. Under the revised application process implemented in December 2014, after consultation with stakeholders, these proposed notifications are no longer applicable. This is because the Phase I activities are concluded after the PMRA has finalized the equivalency assessment and established the list of compensable data. The applicant may proceed with the new phase of the application process once a letter of access is provided to the PMRA or the data is no longer under compensable protection status. Therefore, no further action is required.

Recommendation 3.5: Monitoring and Review of Performance

1. **Report annually on trends in the numbers of new innovative products registered, the numbers of minor use registrations for innovative products that qualify for extensions of data exclusivity, and generic product registrations. This reporting would be in addition to the reporting on the range of times taken to prepare CD Lists included in recommendation 3.1.1, above.**

2. **Commission a further independent impact study within three to four years to assess the effectiveness and efficiency of the data protection program once the various elements have been fully implemented and the extent to which the expected outcomes are being achieved is more evident.**

PMRA supports in principle the recommendation to report on the number of new innovative products registered, the number of minor use registrations for innovative products that qualify for extensions of data exclusivity and the number of generic product registrations. The PMRA reported on these statistics to EMAC in June 2015, and again in May and October 2016. As well, they were included in the Pest Management Regulatory Agency's 2014-2015 and 2015-2016 annual reports, and will continue to be reported using such existing mechanisms.

The PMRA acknowledges the recommendation to commission a further independent impact study and will consider this once an appropriate level of experience has been gained with the current and proposed changes to the process.