

Comments Received on the Proposed Pest Control Products Sales Reporting Regulations and the PMRA's Analysis

The proposed Pest Control Products Sales Reporting Regulations were published in the *Canada Gazette*, Part I, on 27 March 2004 for a 75-day comment period. Comments were received from 13 organizations, most of them representing registrants and two other non-government organizations. Comments were summarized under a number of headings to group them into similar themes.

All comments and recommendations will be taken into consideration as will the costs to government and industry and benefits to Canadians to achieve the most cost-effective balance while satisfying the intent of the proposed regulations.

1. Difficulty in Providing Sales of End-Use Product, by Province, When Products Are Sold Through Regional or National Distributors

The PMRA received numerous comments on this topic, and issues were raised about placing the burden of reporting distributor sales on the registrant. Some suggested that sales information should be obtained directly from distributors or at the retail level, as a provincial requirement, or limiting the required reporting under the *Pest Control Products Act* to registrant sales. The use of estimates for provincial breakdown was generally supported as a means of tracking regional trends and suggestions were made that methodologies for collection and analysis of estimated sales data be developed to ensure consistency and comparability.

Comments and suggestions will be taken into consideration when reviewing the PMRA's position on the scope and use of estimated data.

2. Providing Sales by Province of Products Sold as Fertilizer-Pesticides, Treated Feed or Treated Seed

Comments were expressed about the difficulty of tracking products once they have been sold to manufacturers of other products such as combination products. It was indicated that without these data, a significant amount of pesticide usage would be misread. Suggestions were made to only require the reporting of registrant sales and to allow the use of estimates for further breakdowns (e.g., by province).

Consideration will be given to the suggestions provided regarding the level of reporting and the use of estimates. If the suggested approaches provide usable, representative sales figures and satisfy the intent of the regulation, changes to the proposed regulations will be made.

3. Providing Sales by Province of Technical Grade Active Ingredients and Manufacturing Concentrates

Some respondents felt that collecting information on active ingredients and manufacturing concentrates, in addition to end-use products, would lead to double counting, while others felt this approach would provide more complete information on pesticides sold annually.

Consideration will be given to altering the reporting requirements for technical grade active ingredients and manufacturing concentrates, while ensuring they will be captured somewhere along the sales process.

4. Minor Use Products and Formulants/Microcontaminants of Toxicological Significance

Some respondents suggested that sales data on minor use products, formulants and microcontaminants of toxicological significance be submitted and tracked separately.

The requirement to submit sales data would apply to all registered products, including minor use products.

5. Public Disclosure of Sales by Active Ingredient

Several respondents were concerned that the disclosure of sales data by active ingredient or of technical grade active ingredients would enable determination of a registrant's sales. They suggested that the PMRA discuss report templates and groupings before implementation and provide registrants with an opportunity to review reports prior to public release.

The Regulatory Impact Analysis Statement for the *Canada Gazette*, Part II, and subsequent guidance documents will provide greater detail on this issue and the mechanism for placing information in the Register to better inform stakeholders. Consideration will be given to altering the reporting requirements for technical grade active ingredients and manufacturing concentrates, while ensuring they will be captured somewhere along the sales process. Groupings could be re-examined and consideration will be given to stakeholder involvement prior to implementation of parameters, groupings and report templates.

6. Disclosure of Confidential Sales Information in Confidence to Other Regulators

There was some concern about the protection of confidential information that might be disclosed to other regulators.

The new *Pest Control Products Act* specifies to whom and under what circumstances confidential information may be disclosed in confidence, such as to respond to a situation that endangers human health or safety or the environment or to make a medical diagnosis. Before

confidential information is disclosed to provincial regulators or regulators in other countries, there must be an agreement in place, and the Minister must be satisfied that the other party can provide protection from unfair commercial use or disclosure of the information. The new *Pest Control Products Act* prohibits the disclosure of confidential information obtained in this way and use of the information for any purpose other than the purpose for which it was obtained. Any person who contravenes these prohibitions is subject to regulatory action.

7. Time Period for Reports

Some respondents suggested that the regulation allows registrants to report for a period based on their fiscal year rather than by calendar year. On the other hand, fiscal year variability among registrants would make tracking of trends very difficult.

8. Emergency Situations

There were suggestions that the time line for reporting in emergency situations is too long and should be amended to require the provision of available data within 7 days.

The 15-day timeline for reporting emergency situations was based on the proposed reporting requirement of serious adverse effects, which seemed to be sufficient. Comments and suggestions will be taken into consideration when reviewing the PMRA's position on the scope and use of estimated data.

9. Retention of Records

As suggested by a respondent, electronic records would be permitted.

10. Auditing of Reports

A respondent suggested that all reports be subject to audit, including interim (emergency) reports. On the other hand, the auditing of interim reports may not be cost-effective given that the attestation of accuracy will still be required for them.

11. Use of Sales Data as a Surrogate for Use Data and/or to Represent Exposure

Several respondents noted the inadequacies of sales data as a proxy for use data in risk assessments. The pesticide use reporting systems in the United States were described as credible and accurate. Some suggested that the regulation be amended to require collection and reporting of pesticide use, while others endorse the collection of sales data as a necessary first step in estimating pesticide use. Some respondents said that no other Canadian industries or other Organisation of Economic Co-operation and Development (OECD) countries require such detailed reporting from registrants and disclosure of information.

Consideration will be given to the required level of reporting. However, internationally, the importance of sales data reporting has been recognized by the OECD's Working Group on Pesticides. Member countries agree that data on pesticide use are fundamental to target and track risk-reduction programs and to develop pesticide risk indicators, but recognize that the collection of use data is expensive. Most OECD countries collect sales data as a reasonable surrogate for use information. In addition, the Food and Agriculture Organization of the United Nations in its International Code of Conduct on the Distribution and Use of Pesticides—developed through the joint effort of government experts, non-governmental organizations, the pesticide industry and other United Nations organizations—requires the pesticide industry to provide their national governments with clear and concise data on sales and quantity of pesticides.