2008

Status Report
of the Commissioner of the Environment and Sustainable Development to the House of Commons

MARCH

Chemicals Management

Chapter 2
Pesticide Safety and Accessibility

Office of the Auditor General of Canada

The March 2008 Status Report of the Commissioner of the Environment and Sustainable Development comprises The Commissioner's Perspective—2008, Main Points—Chapters 1 to 14, Appendices, and 14 chapters. The main table of contents for the Report is found at the end of this publication.

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Chapter

2

Pesticide Safety and Accessibility

All of the audit work in this chapter was conducted in accordance with the standards for assurance engagements set by The Canadian Institute of Chartered Accountants. While the Office adopts these standards as the minimum requirement for our audits, we also draw upon the standards and practices of other disciplines.

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Main Points

What we examined

Health Canada's Pest Management Regulatory Agency is the federal agency responsible for regulating pesticides in Canada. The Agency's primary objective is to prevent unacceptable risks to people and the environment from the use of pesticides. It does this by evaluating proposed new pesticides and registering the acceptable ones for use in Canada, re-evaluating older pesticides against current health and environmental standards, and setting the maximum levels of residues of active ingredients allowable on foods. The Canadian Food Inspection Agency also plays a role by testing whether the residues of active ingredients used in pesticides are within allowable limits in fresh fruits and vegetables that are imported or intended for export or inter-provincial trade.

This audit examined the progress made by the federal government in selected aspects of managing the safety and accessibility of pesticides since our 2003 audit. We looked at the Pest Management Regulatory Agency's application of its own procedures for evaluating and registering new pesticides, the application of its own procedures for re-evaluating older registered pesticides, and the time it takes to get new, possibly safer pesticides on the market for use.

We also looked at the progress made by the Canadian Food Inspection Agency in increasing the scope of its program that tests for residues of active ingredients in fresh fruits and vegetables.

Why it's important

Many pesticides are designed to be toxic to pests. They play an important role in maintaining Canada's food supply by protecting food crops. Canadians also use pesticides to control weeds on lawns, insects in gardens and homes, and parasites on pets. There are approximately 5,000 pesticides currently registered for use in Canada. When used improperly, pesticides can have serious consequences for human health and the environment, which can range from respiratory tract problems to cancer or the death of fish or birds.

What we found

- Since our 2003 audit, the federal government has made satisfactory progress in selected aspects of managing the safety and accessibility of pesticides. We concluded that based on our sample of newly registered pesticides, the Pest Management Regulatory Agency has applied its procedures for evaluating new pesticides consistently, completely, and with adequate documentation. It ensures that companies applying to register a new pesticide submit all the information needed, at the required standard of quality, to assess the risks associated with the pesticide. It has shortened the time it takes to evaluate new pesticides while still following all the steps in its evaluation process. The Agency has taken action to give Canadian growers access to new, more effective, and possibly safer pesticides—particularly minor-use pesticides (those used in small quantities or on crops where few pest control options exist), which manufacturers tend not to register in Canada because of low potential sales volumes.
- The Pest Management Regulatory Agency is consistently applying its procedures to re-evaluate older pesticides that were registered before new standards were put in place in 1995. Although it has completed a number of re-evaluations since our last audit, many more await completion and the Agency's target continues to change. In addition, the Agency never developed a detailed action plan to help meet its timelines.
- The Canadian Food Inspection Agency has increased the number of active ingredients it analyzes in its program that tests for residues in fresh fruits and vegetables. The Agency now has more information on the active ingredients that are not included in its residue testing program. It is in the early stages of assessing which of these active ingredients are priorities for attention, based on their toxicity and the potential for human exposure to them.

Introduction

Active ingredient—the ingredient of a pesticide that actually controls the targeted pest. The active ingredient is combined with other ingredients to make a pesticide or end use product.

Formulant—ingredient of a pesticide that serves a purpose other than the actual control of the targeted pest. For example, an ingredient's purpose can be to give solubility to an end use product. Formulants can include sugar, propane, or citric acid.

End use product —a product, organism, or substance that is used to control, destroy, attract, or repel a pest, or to lessen or prevent its harmful or troublesome effects. It has been manufactured, packaged, and labelled in a form that is usable by the consumer. For brevity, we have referred to such products as pesticides in this chapter.

2.1 Pesticides are used in the production of many foods Canadians eat. They are also used in paint to stop mildew; and they are used to control weeds on lawns, insects and rodents in gardens and homes, and parasites on pets. Many farmers consider pesticides essential tools to preventing the damage to crops caused by pests such as weeds, insects, or disease. Pesticides are made up of two components: the **active ingredient** and the **formulant**. Combined, these ingredients form an **end use product** known as a pesticide. There are approximately 5,000 pesticides currently registered for use in Canada.

2.2 Because most pesticides are designed to be toxic to pests, they can also present potentially serious threats to health or the environment if they are misused. For example, Chlorpyrifos is a pesticide used to control pests on foods such as wheat and on non-foods such as forests. Symptoms of overexposure to Chlorpyrifos can include muscle weakness, dizziness, and sweating.

2.3 Some pesticides have been linked to causing cancer, reproductive disorders, and respiratory tract problems in humans, or the deaths of fish or birds. Because of the risks, these products are regulated by municipal, provincial, territorial, and federal governments. Health Canada's Pest Management Regulatory Agency determines which pesticides can be used in Canada and under what conditions. The Agency's mandate is to protect human health and the environment from unacceptable risks associated with exposure to or use of the pesticide. It does this by administering and applying the *Pest Control Products Act*. The Canadian Food Inspection Agency also plays a role by testing for active ingredients in fresh fruits and vegetables that are imported, intended for export, or traded between provinces, in order to verify that the active ingredient residues do not exceed the limits set by the Pest Management Regulatory Agency.

To protect human health, a sign indicates that people should keep off a freshly sprayed lawn.

2.4 Only pesticides that are registered for use under the *Pest Control Products Act* can be imported, sold, or used in Canada. Provinces and territories may further regulate the sale, storage, transportation, and disposal of pesticides, issue permits for them, and monitor their use. They may also set further conditions on the use of pesticides or allow municipalities to do so. For example, the province of Quebec restricted the use of some pesticides to decrease the potentially harmful effects on children and the environment.

What we found in 2003

2.5 We audited the issue of the Pest Management Regulatory Agency's re-evaluation of older pesticides in 1988, 1999, 2002, and 2003. In 1988 and 1999, we noted that older pesticides needed to be re-evaluated. In 2002, we indicated that the Agency was conducting re-evaluations of older pesticides but that progress was slow. In our 2003 audit, Chapter 1, Managing the Safety and Accessibility of Pesticides, we examined how the Agency was managing selected aspects of pesticide use in Canada. We found that the Pest Management Regulatory Agency

- had a sound, evolving framework for evaluating pesticides, but was not applying it consistently;
- was approving some pesticides based on inadequate information;
- was estimating risks of pesticide use based on some assumptions that were unrealistic or not tested;
- was not meeting the timelines it set for how quickly it evaluated new, possibly safer pesticides; and
- was still slow in re-evaluating older pesticides.

We also found that while the Canadian Food Inspection Agency was testing fresh fruits and vegetables for almost 270 active ingredients, it had identified more than 190 other active ingredients for which practical methods were not available for testing to determine whether the residues exceeded the limits set by the Pest Management Regulatory Agency.

Events since 2003

2.6 The new *Pest Control Products Act* came into force on 28 June 2006. The objective of the Act is to better protect Canadians and the environment from the risks of pesticide use. The new Act also requires that all pesticides be re-evaluated every 15 years against the most current health and environmental standards for use.

Focus of the audit

2.7 This status report assesses the Pest Management Regulatory Agency's progress in response to select findings and recommendations from our 2003 report. Issues were selected based on their current relevance and significance. We did not audit the Agency's progress in improving its compliance activities or in managing human resource issues. Nor did we audit other government departments' contributions

to developing water quality guidelines. The objective of this audit was to determine whether the Agency is making satisfactory progress in

- systematically and consistently applying its evaluation and re-evaluation policies and procedures;
- providing timely access to new, possibly safer pesticides; and
- meeting its target for re-evaluating older pesticides.

We also examined whether the Canadian Food Inspection Agency has made satisfactory progress in improving the number of active ingredients tested in fresh fruits and vegetables as part of its National Chemical Residue Monitoring Program. We examined the scope of testing that is taking place as part of the Program; we did not audit the Program's planning, sample collection activities, or public reporting.

2.8 More details on the audit objectives, scope, approach, and criteria are in **About the Audit** at the end of this chapter.

Observations

Evaluating new pesticides

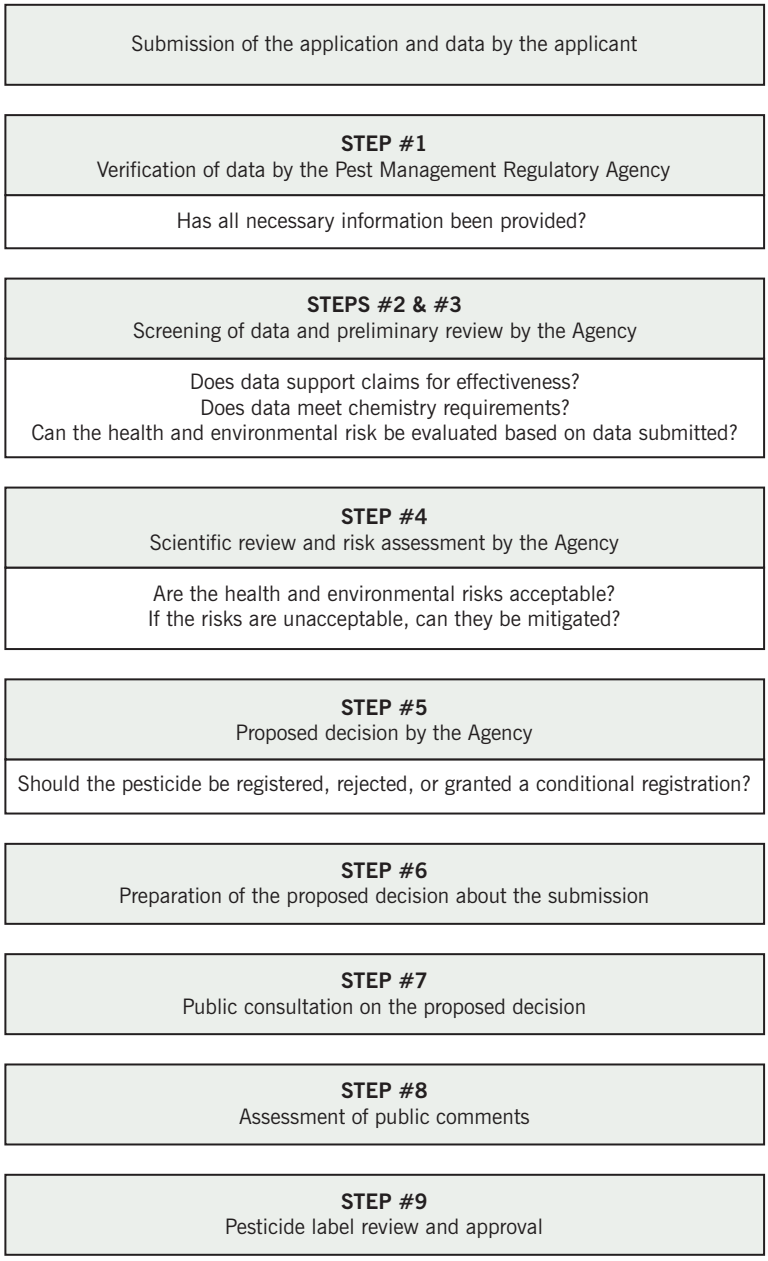
Risk to human health or the environment—In determining whether a pesticide poses a risk to human health, the Agency examines such things as the capacity of the pesticide to cause cancer. For the environment, the Agency examines such things as what happens to fish if the pesticide gets into a water body.

2.9 Any pesticide sold in Canada must first be approved by the Pest Management Regulatory Agency. Any company wishing to manufacture or sell a pesticide in Canada must submit detailed information and scientific data to the Agency for evaluation of the active ingredient and end use product. The Agency determines whether the pesticide poses any **risks to human health or the environment** and whether it is effective for its intended use. If after the evaluation, the Agency determines that there are no unacceptable risks from using the pesticide, it will grant the pesticide registration for use in Canada.

2.10 In our 2003 audit, we reported that Agency evaluators occasionally skipped steps during their evaluation of pesticides—contrary to the Agency's own evaluation process (Exhibit 2.1). We also noted that some required data was not received from applicants or did not meet acceptable quality standards, and that assumptions for how pesticides were being used were not tested. We recommended that the Agency ensure data used for risk assessments is complete and reliable, assumptions are realistic and tested, and that evaluators follow the Agency's own evaluation policies and procedures systematically. The Agency agreed to reassess its procedures to ensure data is complete and reliable and that deviations from the norm are approved and documented. For this status report, we conducted an in-depth file review of a sample of new pesticides registered for use in Canada in

the 2005–06 fiscal year. We expected the Agency to have followed its own evaluation procedures and reviewed all required scientific studies meeting quality standards.

Exhibit 2.1 **Pesticides are evaluated using a nine-step process**



Source: Adapted from the Pest Management Regulatory Agency

The Agency is systematically applying its procedures for evaluating new pesticides

2.11 Evaluation steps were carried out. In the sample of newly registered pesticides we reviewed for this audit, the Agency completed all the steps in its evaluation process. This enabled it to determine whether there were any unacceptable risks to human health or the environment from the use of the pesticide. When the Agency did not follow its evaluation process—for example, when deciding to shorten the review period—this deviation was reviewed and approved by senior management.

2.12 Studies used for risk assessments are checked for quality and reliability. The Agency requires applicants to provide a complete package of information on the pesticide that they want to register. The Agency's policy states that all scientific information submitted for review must be from a laboratory whose methods for testing are certified. This is intended to ensure the quality and validity of the data used to assess the human health and environmental risks of the pesticide.

2.13 In our 2003 audit, we reported that there were several examples where data submitted by applicants did not meet such standards. In the files we examined for newly registered pesticides during this follow-up audit, we noted that the Agency reviewed the complete data package. In some cases, we found that the Agency accepted and used data with no indication of whether it was from laboratories whose methods were certified. However, Agency scientists assessed and validated the quality of the data and documented their assessment in a data evaluation report. This report was then reviewed by other scientists, and the decision to accept the data for use during the risk assessment was approved by senior management (Exhibit 2.2).

2.14 The Agency is making progress on testing assumptions of how pesticides are used. When the Agency evaluates a pesticide it may make assumptions (such as how the pesticide is applied) to ensure that there are no unacceptable risks to human health or the environment. Testing these assumptions is important to help the Agency ensure that its assessments will protect human health and the environment from the pesticide's potential risks. Once assumptions have been validated, this information is used during the evaluation and re-evaluation of other pesticides.

Nozzles spraying pesticides on a golf course.

2.15 In our 2003 audit, we reported that Agency evaluators did not test the assumptions they used to mitigate the risks of the pesticide. We also found that the Agency assumed users followed label instructions when applying pesticides, even though some studies demonstrated this was not the case. This could, for example, result in

unsafe levels of pesticide application and cause health problems such as respiratory illness or skin irritation. We expected that since 2003, the Agency would have put in place mechanisms to verify that its assumptions are realistic and tested. We examined whether it has integrated the results of the assumption testing into its pesticide evaluations or re-evaluations.

2.16 We found that since 2003, the Agency has been working with other parts of Health Canada, Agriculture and Agri-Food Canada, the Canadian Food Inspection Agency, Environment Canada, Fisheries and Oceans Canada, and Natural Resources Canada to verify assumptions that can provide more realistic estimates for risk assessments. In June 2007, the Agency identified 10 priority areas that require research, including assumption testing. In the 2007–08 fiscal year, these departments plan to conduct 15 research projects, which will address some of the Agency's needs. For example, one research project will assess the effect of pesticides on wild Atlantic and Pacific salmon. As part of its compliance activities, the Agency is also testing its assumptions on the extent to which users comply with pesticide labels and directions as part of its inspection programs. This is an improvement from 2003 when limited research was being conducted to test assumptions.

2.17 The Agency is starting to integrate the results of its assumption testing into the evaluation of new pesticides and the re-evaluation of older pesticides. For example, the Agency verified its assumption about the percentage of crops treated with pesticides through data collected in farm surveys and polls. The results contributed to refining the Agency's health risk assessments, which estimates human dietary exposure to pesticides. The Agency now has a better understanding of the amount of pesticides applied to various crops and therefore how much pesticide residues humans are exposed to in their diet (Exhibit 2.2).

2.18 Industry will be required to provide pesticide sales information to the Agency. The Pest Management Regulatory Agency originally committed to having a database in place by 2001 to track annual sales of pesticides. This additional information would be used to help assess the risks of pesticides to human health and the environment. Such a database would also provide valuable information for testing assumptions about pesticide use by tracking sales. In addition, it would help the Agency better target its research, monitoring, and compliance activities. In 2003, we noted that Canada was the only Organisation for Economic Co-operation and Development country that had no such database in place. In 2006, we found that a database was put in place; however, it contained no data. In this audit, we found that regulations that came into force in October 2006 will require registrants to supply data by 1 June 2008.

Exhibit 2.2 Progress in addressing our recommendation on the strengthening of its evaluation process is satisfactory

Recommendation	Progress
To ensure that pesticides meet today's environmental and health standards, the Agency should continue to strengthen its pesticides evaluations. In particular, it should ensure that data are complete and reliable, ensure that assumptions are realistic and tested, and follow its own evaluation policies and procedures more systematically. (2003 Report of the Commissioner of the Environment and Sustainable Development, Chapter 1, paragraph 1.50)	Satisfactory

Satisfactory—Progress is satisfactory, given the significance and complexity of the issue, and the time that has elapsed since the recommendation was made.

Unsatisfactory—Progress is unsatisfactory, given the significance and complexity of the issue, and the time that has elapsed since the recommendation was made.

Not all temporary registrations of pesticides have been addressed

2.19 Under the 2006 *Pest Control Products Act*, pesticides are granted a "conditional registration" that is now valid for three years, instead of the previous "temporary registration" for a one-year period. If registrants do not submit all required data during this time, the Minister of Health may extend the expiry date to allow the applicant to provide the data or cancel the registration.

2.20 During the evaluation of a pesticide, the Agency may conclude that, even if the applicant has submitted all the data required for the Agency's health or environmental risk assessments, additional data may be required to confirm the results of its risk assessment. For example, the Agency may have uncertainties when extrapolating data from small scale field trials to actual pesticide use. The Agency therefore applies a "worst case scenario" assumption so that applicable safety measures can be put in place if needed. To have the safety measures removed, the applicant is required to provide data proving the worst case scenario does not apply. If the worst case scenario does apply, safety measures are kept in place to protect human health or the environment. In these cases, the Agency may approve a "conditional registration" to allow the temporary use of a new pesticide.

Registrant—a company or individual that holds the certificate of registration granted from the Pest Management Regulatory Agency to produce, sell, and/or use a pesticide in Canada.

2.21 During the time that a pesticide is "conditional," the **registrant** is expected to complete and submit any additional studies required to confirm the Agency's assessment of risk. Permission to use the pesticide is temporary; full registration is granted once these additional studies have been submitted and the Agency has reviewed and accepted them.

2.22 In our 2003 audit, we found that the Agency was relying heavily on temporary registrations and that some of the additional data requirements for these registrations were necessary to assess the health or environmental risks of the pesticide. For this status report, we examined the number of temporary registrations. We also expected that any pesticides that had received a conditional registration were not missing any data required to conduct the Agency's risk assessments.

2.23 We found that of all the new pesticides registered in the 2006–07 fiscal year, 13 percent were conditional. Of those that we examined, the additional data requested for full registration was not needed to conduct the human health or environmental risk assessments. We found only one pesticide granted a conditional registration that was missing a study required to evaluate its effect on the environment. Without this study, the Agency made a conservative assumption (that is, applied a worst case scenario) of how the pesticide would react in water and determined that there were no unacceptable risks. The assumption will be confirmed when the registrant submits the outstanding study.

2.24 We also found nine pesticides that have been "temporary" for between 10 and 20 years, and one for as long as 21 years—this cannot be considered temporary. The Agency indicated that, subsequent to the initial registration of these pesticides, it identified new conditions of registration and/or requested more data. More work needs to be done to address the number and length of some of these pesticides' conditional registrations. The Agency has indicated that it will monitor and use its authority under the new *Pest Control Products Act* to limit the length of conditional registrations (Exhibit 2.3).

Exhibit 2.3 Progress in addressing our finding on the heavy use of temporary registrations is unsatisfactory

Finding	Progress
A heavy use of temporary registrations was made by the Agency. For some of these temporary registrations, the missing information should have been included in the original application and was critical to the Agency's assessment of the health or environmental risk of use. (2003 Report of the Commissioner of the Environment and Sustainable Development, Chapter 1, see paragraph 1.37)	Unsatisfactory

Satisfactory—Progress is satisfactory, given the significance and complexity of the issue, and the time that has elapsed since the finding was made.

Unsatisfactory—Progress is unsatisfactory, given the significance and complexity of the issue, and the time that has elapsed since the finding was made.

Providing access to new pesticides

The Agency has programs in place to improve access to new pesticides

2.25 In 2003, we noted that farmers were demanding quicker access to new, more effective, and possibly safer pesticide products, as well as access to the same pesticides available for use by competitors in the United States. The gap in available pesticides was the result of the small Canadian market, Canadian regulatory requirements, and pesticide re-evaluation decisions that have restricted or removed pesticides from the Canadian market. As safe and effective alternative products are not always immediately available, evaluation delays can have serious consequences for farmers.

2.26 Since our last audit, the Pest Management Regulatory Agency has embarked on a number of initiatives, on its own and in partnership with other federal departments and other countries that are members of the Organisation for Economic Co-operation and Development, to improve access to pesticides in Canada. For example, the Agency has classified pesticides that are known to be less toxic as "lower risk," thus requiring less data for the risk assessment and accelerating the evaluation process (Exhibit 2.4). The Agency has increased **joint reviews** with other countries—6 were completed in 2003–04, 16 in 2006–07, and as of 1 June 2007, there were 16 under way. Joint reviews are possible since these other countries share similar standards for evaluating new pesticides.

Joint review—the evaluation of a pesticide application is shared between two or more countries.

Exhibit 2.4 Example of enabling access to a lower-risk pesticide—The mountain pine beetle epidemic

An epidemic of the mountain pine beetle in British Columbia has caused widespread destruction of the lodgepole pine trees on which the beetle feeds. The beetle is the size of a grain of rice and carries a fungus that kills the tree by clogging its pores. Verbenone, a lower-risk pesticide that received a temporary registration in 2006, sends a signal to beetles that the tree is infested and deters them from infecting it. Due to the high costs of applying this pesticide, it is used only in urban areas, campsites, and golf courses.

Source: www.bcforestinformation.com

The Agency reclassified Verbenone as lower-risk compared with conventional pesticides, noting that it is less toxic, occurs naturally, is effective at very low application rates, and dissipates rapidly in the environment. When evaluating lower-risk products, the Agency makes a decision more quickly because less data is needed to conduct the health and environmental risk assessment. The Agency stated that a flexible regulatory approach that promotes timely access to new lower-risk pesticides is important in instances such as the mountain pine beetle epidemic.

2.27 In 2003, we found that joint reviews had not resulted in the efficiency gains for pesticide evaluations, as the Agency had anticipated. In this audit however, we noted that the Agency is achieving efficiency gains in the amount of time it takes to evaluate a pesticide using joint reviews. Other benefits of joint reviews include

- registering new products simultaneously in both Canada and the United States, thus slowing the growth of the gap between pesticides available in the United States but not in Canada;
- making it easier to trade agricultural products between countries; and
- making scientific decisions regarding the use of a pesticide supported by more scientists involved in assessing and discussing the risks associated with its use.

New initiatives are increasing the availability of minor-use pesticides

2.28 Some pesticides are required by users in such small quantities that the anticipated sales volume is not considered sufficient for a manufacturer to register the pesticide in Canada. These minor-use pesticides can be particularly important for situations where few pest control options exist. In 2003, we noted that growers felt they were not getting access to needed minor-use pesticides. For this status report, we examined whether the availability of registered minor-use pesticides had improved since 2003.

2.29 We found that since our audit in 2003, the Agency has made it a priority to help improve access to new minor-use pesticides. We found that it better understands the priorities for registration of 137 pesticides currently available to growers in the United States that are not available to growers in Canada. If made available, most would be considered minor-use pesticides. The fact that US growers have more access to potentially lower-risk and more effective pesticides than Canadian growers puts Canadians at a competitive disadvantage. The Agency has received approval for $14 million, starting in the 2007–08 fiscal year, to evaluate priority pesticides and increase the availability of minor-use pesticides over the next four years.

2.30 In addition, we noted in 2003 that a new government program allocated $54.5 million over six years to Agriculture and Agri-Food Canada to conduct research on minor-use pesticides. At that time, Agriculture and Agri-Food Canada began holding an annual conference with growers with the goal of identifying priority minor-use pesticides needed for crops across Canada. Once this list is compiled each year, Agriculture and Agri-Food Canada conducts the necessary research for

the Pest Management Regulatory Agency to assess the human health and environmental risks of the pesticide. This research can include trials to test whether the pesticide actually kills, deters, or repels the pest.

2.31 Between 2003 and April 2007, Agriculture and Agri-Food Canada reported that it had started 385 research projects and submitted 79 completed projects to the Pest Management Regulatory Agency. Of those submitted, 40 minor-use pesticides have been registered by the Pest Management Regulatory Agency. Agriculture and Agri-Food Canada has stated that it takes approximately three years to complete the research and submit the data to the Pest Management Regulatory Agency. The Pest Management Regulatory Agency then takes almost one year to evaluate and possibly register the pesticide for use (Exhibit 2.5).

2.32 While the program was slow to get going, grower groups have indicated to us that they are generally satisfied with the program and that it is starting to achieve results; however, they would like to see faster approval of pesticides currently available only to US growers. Agriculture and Agri-Food Canada has informed us that it is conducting consultations and developing a general policy document that will determine future directions for agricultural policy and programs, including minor use work.

Exhibit 2.5 Registration of pesticides can be extended if no alternatives exist

The Pest Management Regulatory Agency re-evaluated the insecticide Terbufos in 2003 and decided that all uses should be phased-out because of unacceptable risks to wildlife. Based on discussions with stakeholders and in accordance with the *Pest Control Products Act*, the Agency accepted continued registration for use on one crop until December 2006 because there was no alternative available to growers. Based on the limited use of Terbufos for this one crop, the Agency determined that the environmental risks were not a concern. The Agency indicated it would revisit the December 2006 timeline and has since extended its use until 2009.

Terbufos was used on canola to control the flea beetle and cabbage maggot.

Source: Pest Management Regulatory Agency

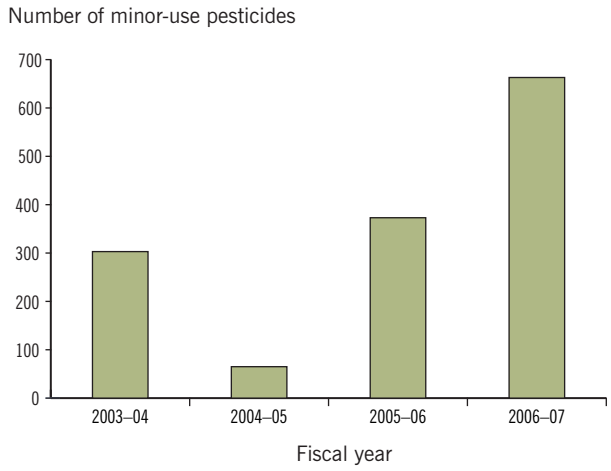
According to the Act, the Agency may delay implementation of the date by which the unacceptable pesticide must be removed from the market. Agriculture and Agri-Food Canada began research on an alternative to Terbufos in 2007. Since it takes the department an average of three years to conduct trials and the Agency approximately one year to evaluate a new minor-use pesticide, an alternative is not likely to be available on the market until 2011, unless a company submits a new pesticide to the Agency for evaluation.

2.33 With the combined efforts of the above-noted programs (paragraphs 2.28–2.32), the Pest Management Regulatory Agency registered 663 minor-use pesticides in the 2006–07 fiscal year (Exhibit 2.6). Taking into account these recent efforts, the Agency has made satisfactory progress since 2003 to improve access to pesticides (Exhibit 2.7).

The time it takes to evaluate new and minor-use pesticides has improved

2.34 The Pest Management Regulatory Agency set timelines for itself to complete each step in its evaluation process (Exhibit 2.1). These timelines can range from 400 to almost 1,000 days, depending on the type of pesticide and its intended use. In 2003, we reported that the Agency was not consistently meeting the timelines it set for evaluating applications to register new or minor-use pesticides in Canada.

Exhibit 2.6 Between 2003 and 2007, the registration of minor-use pesticides has increased



Source: Pest Management Regulatory Agency

Exhibit 2.7 Progress in addressing our finding that growers were not provided timely access to needed pesticides is satisfactory

Finding	Progress
Growers were not being provided with adequate access to minor-use pesticides. (2003 Report of the Commissioner of the Environment and Sustainable Development, Chapter 1, see paragraph 1.73)	Satisfactory

Satisfactory—Progress is satisfactory, given the significance and complexity of the issue, and the time that has elapsed since the finding was made.

Unsatisfactory—Progress is unsatisfactory, given the significance and complexity of the issue, and the time that has elapsed since the finding was made.

2.35 In this audit, we examined all 40 new pesticide applications registered in the 2006–07 fiscal year, from the time their evaluation began until the pesticide label was approved. Based on parliamentary and public consultation, the Agency publicly reports on the time it takes to evaluate a new pesticide for four steps of the evaluation process—the preliminary review, the scientific review and risk assessment, the decision on the registration, and the preparation of documents for public consultation (Exhibit 2.1). When we assessed the time it takes the Agency to complete all nine steps of the evaluation process, we found that the Agency met its timelines 68 percent of the time compared with 62 percent in 2002–03. As well, when it exceeded the timelines, it did so by an average of 17 days, compared with 153 days in 2002–03. The timelines were exceeded at the last step where applicants were required to make corrections to their pesticide labels, which negatively impacted the Agency's performance.

2.36 When evaluating minor-use pesticides, we found that the Agency took an average time of about six months in 2003–04 and in 2006–07. In this audit, we noted that the Agency met its timelines 67 percent of the time. When it exceeded its timelines, it did so by an average of 24 days, compared with an average of 107 days in 2003–04. By reducing the length of time it exceeds its timelines, the Agency is providing more timely access to minor-use pesticides (Exhibit 2.8).

Exhibit 2.8 Progress in addressing our finding that the Agency was not meeting its performance timelines is satisfactory

Finding	Progress
The Agency was not meeting its performance timelines for how quickly it evaluates new and minor-use pesticides for registration in Canada. (2003 Report of the Commissioner of the Environment and Sustainable Development, Chapter 1, see paragraphs 1.67, 1.68, and 1.74)	Satisfactory

Satisfactory—Progress is satisfactory, given the significance and complexity of the issue, and the time that has elapsed since the finding was made.

Unsatisfactory—Progress is unsatisfactory, given the significance and complexity of the issue, and the time that has elapsed since the finding was made.

Re-evaluating older pesticides

2.37 The Pest Management Regulatory Agency committed in 2001 to re-evaluate 405 active ingredients in pesticides that were registered in Canada before new standards for use were established in 1995. These standards require the Agency to consider, among other issues, impacts to bystanders, reproductive impacts on later generations, and the greater susceptibility of children to the pesticides. In 2005, the number

of active ingredients to be re-evaluated decreased to 401 as four are disinfectants that are no longer regulated under the *Pest Control Products Act*; they are now addressed by the *Food and Drugs Act*.

2.38 This is the fifth time that we have audited the issue of re-evaluation of older pesticides. Our past audits noted serious deficiencies in the Agency's progress to re-evaluate older pesticides. In 2003, we recommended that the Agency speed up its re-evaluations and develop guidelines to determine how quickly a pesticide with unacceptable risk should be taken off the market. The Agency agreed with our recommendations and recognized that it needed to accelerate the re-evaluation of older pesticides. For this status report, we expected that the Agency would have

- made significant progress in completing the re-evaluation of older pesticides;
- put in place an action plan containing detailed time and cost estimates to ensure it will meet its target to complete the re-evaluations by the 2008–09 fiscal year;
- demonstrated that all pertinent risks to health and the environment have been assessed during re-evaluations; and
- developed guidelines for determining how quickly pesticides with unacceptable risks should be removed from the market.

While the Agency has made progress, important components of the re-evaluation process are not in place

2.39 **The Agency has increased the number of active ingredients re-evaluated.** As of March 2007, the Agency had fully completed the re-evaluation of 90 active ingredients. An additional 58 active ingredients have a published regulatory proposal and their re-evaluations are in the process of being completed. Another 76 active ingredients did not need a full re-evaluation because they were withdrawn by the registrant. This is an improvement from 2003 when only 6 had been fully re-evaluated. One of the challenges to re-evaluating older pesticides is the length of time it takes to review new data. Re-evaluations of active ingredients using assessments from the United States to speed up the decision take an average of almost two years, while re-evaluations of some of the more widely used active ingredients such as 2,4-D have taken more than four years. The Agency stated that it has delayed the re-evaluation of less complex active ingredients until the end of the process, and that these reviews should be simpler and faster. However, the Agency still has to fully

complete 235 active ingredient re-evaluations in two years when it took six years to fully complete 166 (Exhibit 2.9).

2.40 An example of how lengthy this process can be is the re-evaluations of seven of the most commonly used active ingredients in lawn care pesticides (diazinon, carbaryl, malathion, 2,4-D, mecoprop, dicamba, and MCPA). In 2000, the Minister of Health announced an initiative to re-evaluate the lawn and turf uses of these seven active ingredients. The re-evaluations were to have originally been completed in 2001 (Exhibit 2.10). This target has not been met; at the time of our audit, only three re-evaluations had been fully completed. The Agency has published proposed decisions for three others, which it plans to finalize once the re-evaluation of all remaining uses is completed. The review of carbaryl is ongoing. The Agency stated that delays in re-evaluating these active ingredients occurred because the risk assessments were complex and involved many registrants, and it took longer to go through the large amounts of data than was originally anticipated.

Exhibit 2.9 The Agency has increased the number of re-evaluations of active ingredients completed since 2003

	Fully re-evaluated active ingredients	Re-evaluation decisions in the process of being completed	Withdrawn active ingredients
2003 Audit	6	23	44
2008 Audit	90	58	76

Source: Pest Management Regulatory Agency

Exhibit 2.10 The re-evaluation of 2,4-D took longer than anticipated

The active ingredient 2,4-D was first registered for use in Canada in 1946. It is the most commonly used active ingredient in pesticides to control and suppress weeds and to help produce food in Canada. In almost 20 years, the Agency stated that it has received over 300 applications to register different products containing 2,4-D. It has re-evaluated the active ingredient numerous times and has requested changes through the years, including new manufacturing processes, label improvements to increase safety, and the addition of new uses. The latest re-evaluation of lawn and turf uses of 2,4-D began in 2000, and a proposed decision was published in 2006. However, the final decision was supposed to be fully completed in 2001. Agency officials now expect to fully complete the re-evaluation of 2,4-D in 2008.

The Agency found that the risks to human health and the environment associated with the use of 2,4-D were acceptable and the active ingredient could continue to be used with certain mitigation measures. We noted that the Agency's re-evaluation of 2,4-D included the review of hundreds of scientific and academic studies, international decisions on the chemical, and scientific review panels.

2.41 The target date for completing the re-evaluation of older pesticides continues to change. Since the re-evaluation program was established, the Agency has twice received additional funds to re-evaluate older pesticides, and has extended the target date for completing the re-evaluation three times; first to 2006, then 2008–09, and now 2009–10. The Agency received its latest additional funding as part of the Chemical Management Plan initiative (see Chapter 1, Substances Assessed Under the *Canadian Environmental Protection Act, 1999*) to complete the re-evaluation of the remaining older pesticides by the 2009–10 fiscal year.

2.42 When the Agency committed to re-evaluating older pesticides to speed up its own process, it decided to rely heavily on assessments already completed in the United States. The Agency says that its re-evaluation target changed because the US target changed.

2.43 The Agency has no detailed action plan to guide its re-evaluations. The Agency has produced general guidance on the classes of active ingredients under re-evaluation of highest concern. However, it decided not to develop a priority list ranking the 401 older pesticides according to their level of risk. Therefore, it was not possible to assess whether older pesticides were being addressed in order of priority according to their level of risk. In addition, there is no detailed action plan with timelines to address these active ingredients given the resources available or a contingency plan in the event the United States falters on its progress. While some elements of an action plan do exist, such as annual work plans, they lack information such as detailed time and cost estimates to ensure it will meet its target to complete the re-evaluations on time.

2.44 The Agency is systematically following its re-evaluation procedure. In 2003, we found that the risk assessment process used to re-evaluate older active ingredients against current health and environmental standards is similar to that followed for new pesticides before they are sold or used in Canada. For this audit, we expected that the Agency is systematically and consistently applying its re-evaluation procedure. When the Agency uses assessments completed in the United States for its own re-evaluation decisions, it relies on the Environmental Protection Agency to ensure that data used in its risk assessment meets quality standards.

2.45 During our file review of 20 re-evaluation decisions made between 2003 and 2006, we found that the Agency consistently followed its procedures. This enabled it to determine whether there were any unacceptable risks to human health and the environment

from continued use of the active ingredient. When risks were unacceptable, the Agency required changes to labels to mitigate these risks, or required phase-out of pesticides containing the active ingredient.

2.46 The Agency's progress in addressing our 2003 recommendation and finding is unsatisfactory since

- it still has 235 active ingredients to fully re-evaluate in a two-year period when it took six years to complete 166,
- it never developed a detailed action plan with timelines to guide its progress, and
- its target for completion has changed three times. (Exhibit 2.11)

Exhibit 2.11 Progress in addressing our finding and recommendation that the Agency is not using basic tools and should speed up re-evaluations is unsatisfactory

Finding and Recommendation	Progress
Finding. The Agency is not using basic management tools to guide its re-evaluations, including a plan containing detailed time and cost estimates by which to gauge the Agency's level of effort and progress, or a priority listing of pesticides to be re-evaluated. The Agency is also working with incomplete information during the re-evaluation of older pesticides. (2003 Report of the Commissioner of the Environment and Sustainable Development, Chapter 1, see paragraphs 1.58 and 1.61)	Unsatisfactory
Recommendation. To reduce the risks of older pesticides, the Agency should speed up its re-evaluations. It should demonstrate how it will meet its re-evaluation deadlines. (2003 Report of the Commissioner of the Environment and Sustainable Development, Chapter 1, see paragraph 1.62)	Unsatisfactory

Satisfactory—Progress is satisfactory, given the significance and complexity of the issue, and the time that has elapsed since the finding or recommendation were made.

Unsatisfactory—Progress is unsatisfactory, given the significance and complexity of the issue, and the time that has elapsed since the finding or recommendation were made.

The Agency has developed guidelines for removing older unacceptable pesticides from the market

2.47 In 2003, we recommended that the Agency develop and implement guidelines for determining how quickly pesticides with unacceptable risks should be removed from the market after re-evaluation. The Agency agreed and committed to developing these guidelines by March 2004.

2.48 During the course of our audit, the Agency finalized its guidelines for determining how quickly a pesticide that does not meet

current health or environmental standards for use should be taken off the Canadian market. These were put in place in March 2006. Given that these guidelines are recent, we were unable to verify the Agency's implementation of them; however, we consider progress to date satisfactory (Exhibit 2.12).

Exhibit 2.12 Progress made in addressing our recommendation that the Agency develop guidelines for removing pesticides with unacceptable risks from the market is satisfactory

Recommendation	Progress
To better manage the risks associated with older pesticides, the Agency should develop and implement guidelines for determining how quickly pesticides with unacceptable risks should be removed from the market. (2003 Report of the Commissioner of the Environment and Sustainable Development, Chapter 1, see paragraph 1.63)	Satisfactory

Satisfactory—Progress is satisfactory, given the significance and complexity of the issue, and the time that has elapsed since the recommendation was made.

Unsatisfactory—Progress is unsatisfactory, given the significance and complexity of the issue, and the time that has elapsed since the recommendation was made.

Testing for pesticides in fresh fruits and vegetables

More active ingredients are being monitored

2.49 Canada's Food Guide recommends that Canadians eat between 4 and 10 servings of fruits and vegetables on a daily basis, depending on one's age. When trying to fulfill these basic nutritional requirements, Canadians need assurance that the food they eat is safe. By developing economical test methods, the Canadian Food Inspection Agency can verify whether the residues of active ingredients used in pesticides are present in fresh fruits and vegetables, and if they are present, whether they are within acceptable limits.

The Canadian Food Inspection Agency tests fresh fruits and vegetables for residues of active ingredients.

2.50 As part of its National Chemical Residue Monitoring Program, the Canadian Food Inspection Agency uses a risk-based approach to test fresh fruits and vegetables, as well as other commodities such as meat, eggs, and dairy products, for the presence of chemicals, such as active ingredients used in pesticides, veterinary drugs, and environmental pollutants. With respect to fresh fruits and vegetables, the Program focuses on the federally registered sector, that is, fresh produce that is imported or intended for export or inter-provincial trade.

2.51 In 2003, we noted that the Canadian Food Inspection Agency tested fresh fruits and vegetables for residues of 269 different active ingredients. For this status report, we expected the Agency to have expanded the scope of its residue testing program.

2.52 We found that the Canadian Food Inspection Agency is now testing for over 300 residues. This includes some of the 190 active ingredients identified in 2003 for which practical testing methods were not available. The Agency is also developing a new test method that could potentially cover more than 140 additional residues.

2.53 The Canadian Food Inspection Agency has more information on which active ingredients are not covered by its residue testing program. This includes newly registered active ingredients in Canada, as well as those that may be used in other countries. The Canadian Food Inspection Agency is in the early stages of reviewing these active ingredients to identify priorities for developing residue testing methods. The priorities are based on their toxicity and their potential for human exposure to them. The Canadian Food Inspection Agency has indicated that it will share and discuss the results of its review with the Pest Management Regulatory Agency. It now needs to develop a work plan with timelines for completing this review (Exhibit 2.13).

Exhibit 2.13 Progress in addressing our finding regarding the scope of the Canadian Food Inspection Agency's testing program is satisfactory

Finding	Progress
More than 190 active ingredients used in pesticides were not included in the Canadian Food Inspection Agency's methods for the testing of active ingredient residues in fresh fruits and vegetables. (2003 Report of the Commissioner of the Environment and Sustainable Development, Chapter 1, see paragraph 1.91)	Satisfactory

Satisfactory—Progress is satisfactory, given the significance and complexity of the issue, and the time that has elapsed since the finding was made.

Unsatisfactory—Progress is unsatisfactory, given the significance and complexity of the issue, and the time that has elapsed since the finding was made.

Conclusion

2.54 The government's progress in selected aspects of managing the safety and accessibility of pesticides since our last audit in 2003 is satisfactory.

2.55 We found that the Pest Management Regulatory Agency is following all of the steps in its evaluation process for new pesticide products. It is also testing its assumptions, ensuring adequate information is submitted by applicants for review, and checking the quality of data used for its risk assessments. The Agency has also initiated a number of programs to improve growers' access to new,

possibly safer pesticides. It has also developed programs that assign priority to making minor-use pesticides (those used in small quantities or on crops where few pest control options exist) available in Canada. However, pesticides registered as conditional are not being addressed—nine of these pesticides have been registered for 10 years or more. This can no longer be considered temporary.

2.56 To manage the risks associated with other pesticides, the Pest Management Regulatory Agency is consistently applying its procedures to re-evaluate the 401 active ingredients that were registered before the implementation of new standards in 1995. The number of active ingredients re-evaluated to date has increased since 2003, but many more await completion. Since the initiative began, the Agency has changed its target date for completion three times, and has never developed a detailed action plan to meet its timelines.

2.57 The Canadian Food Inspection Agency has increased the number of active ingredients included in its residue testing activities from 269 to over 300. It also has a better understanding of the active ingredients that are not included in its residue testing program. The Canadian Food Inspection Agency is in the early stages of assessing these active ingredients to identify priorities for developing residue testing methods; a work plan with timelines for completing this risk assessment process is needed.

About the Audit

Objectives

Our overall audit objective was to determine whether the Pest Management Regulatory Agency and the Canadian Food Inspection Agency have made satisfactory progress implementing key recommendations and addressing select findings from our 2003 Report on Managing the Safety and Accessibility of Pesticides. Our audit work included four sub-objectives, to which we applied specific criteria derived from our 2003 audit. Three of these sub-objectives were to determine whether the Pest Management Regulatory Agency has made satisfactory progress in

- ensuring pesticides meet today's health and environmental standards,
- improving timely access to pesticides, and
- managing the risks associated with older pesticides.

The last sub-objective was to determine whether the Canadian Food Inspection Agency has made satisfactory progress in improving its residue testing program for pesticides in fresh fruits and vegetables.

Scope and approach

This follow-up audit examined selected issues from the 2003 audit, Chapter 1, Managing the Safety and Accessibility of Pesticides. Issues were selected from the previous audit based on their current level of relevance and significance. These issues included the evaluation of new pesticides, timely access to new pesticides, the re-evaluation of older pesticides, and testing methods for residues of active ingredients on fresh fruits and vegetables. We did not audit the Agency's progress in improving its compliance activities or in managing human resource issues. Nor did we audit other government departments' contributions to developing water quality guidelines for pesticides.

We interviewed over 40 people from outside the federal government and inside the departments and agencies involved in pesticide management. These included senior managers and other scientific staff from the Pest Management Regulatory Agency, and other stakeholders. Stakeholders provided input on access to needed pesticides. Departmental officials provided information that contributed to understanding the Agency's policies and procedures, as well as any changes since our 2003 audit.

As a basis for auditing the process used for the evaluation of new pesticides, we selected a representative sample of 20 pesticides from a population of 57 pesticides evaluated and registered by the Pest Management Regulatory Agency in the 2005–06 fiscal year. Sample size was based on a desired confidence interval of 10 percent, and a desired confidence level of 90 percent. Evaluation and registration procedures were assessed through an examination of working documents, files, and electronic data from the pesticide sample. To assess re-evaluation procedures, pesticides were divided into two risk groups based on use (low and high) for sampling purposes. As a result of this sampling, all 6 pesticides from the high use group were examined because they represented those most widely used in Canada. In addition, a sample of 14 pesticides was selected from a population of 87 lower use pesticides. For the sample of low use files, sample size was based on a desired confidence interval of 10 percent, and a desired confidence level of 70 percent. A lower confidence level was chosen because the files were lower risk based on use.

We interviewed senior managers from the Canadian Food Inspection Agency and reviewed documentation relevant to their National Chemical Residue Monitoring Program. We examined the scope of testing that is taking place as part of the Program; we did not audit the Program's planning, sample collection activities, or public reporting.

Criteria

The criteria for this audit were derived from recommendations and findings in our 2003 report on Managing the Safety and Accessibility of Pesticides.

For this follow-up audit, we expected the Pest Management Regulatory Agency to

- be systematically and consistently applying its evaluation and re-evaluation procedures;
- have put in place mechanisms to ensure that data used for evaluation and re-evaluation are complete and meet quality standards;
- have put in place mechanisms to ensure that assumptions are realistic and tested;
- be consistently meeting its performance timelines for pesticide registration;
- be providing Canadian growers with access to minor-use pesticides;
- be increasing the efficiency of the registration process through joint reviews with the United States Environmental Protection Agency;
- be on track to meet its target to re-evaluate older pesticides; and
- have developed and implemented guidelines to determine how quickly pesticides with unacceptable risks should be removed from the market.

We also expected the Canadian Food Inspection Agency to have improved its program testing for residues of active ingredients in fresh fruits and vegetables by increasing the number of active ingredients it tests for.

Audit work completed

Audit work for this chapter was substantially completed on 30 June 2007.

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