



Agriculture and  
Agri-Food Canada

Food Production  
and Inspection Branch

Plant Industry Directorate

Agriculture et  
Agro-alimentaire Canada

Direction générale,  
Production et inspection des aliments

Direction de l'industrie des produits végétaux

**Dir93-17**

## Regulatory Directive

### **Assessment of the Economic Benefits of Pesticides**

This Regulatory Directive is intended to provide registrants of pesticides and other interested groups with a guideline for assessing economic benefits for pesticide products involving a new active ingredient or major new uses of an active ingredient. This document has been structured to cater to pesticides used in agriculture, forestry and possibly other applications. Several types of pesticides will not, however, be covered - particularly those used as antimicrobials.

This Regulatory Directive replaces Memorandum to Registrants R-90-05, dated October 10, 1990, and provides further details on Section 8.4 of Appendix I of Regulatory Directive Dir93-03.

*(publié aussi en français)*

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**Canada**

The need for an economic benefits guideline has been expressed in various quarters. Accordingly, Policy Branch and the Plant Industry Directorate of Agriculture and Agri-Food Canada have worked in conjunction with a committee of the Crop Protection Institute of Canada to develop this guideline.

This document does not attempt to address benefits other than economic ones. For example, the special benefits of products that adapt well to Integrated Pest Management programs, or products which may have certain safety features that are desirable are beyond the scope of this guideline. With some adjustments, however, this document may provide the basis for benefit assessments for pesticides under reevaluation.

## **Reason for Benefits Assessments**

Difficult situations arise when the scientific data base supporting the registration is less than ideal. Similar conditions occur when the risks presented by the use of the chemical appear to be significant for users, consumers and non-target organisms. In certain instances, risks may be so great that benefits of any kind may not overcome them. In other situations, risks appear to be manageable. In these cases, it is useful to have documentation of the benefits, risks and the risk management procedures available

Formal documentation of the benefits is an important part of the regulatory decision making process. It is necessary to be aware of the benefits of the registration, the ensuing or continued use of a pesticide, as well as the negative impact of a decision not to register, to cancel or suspend the use of a given pesticide.

## **Information Submission**

Information submitted in support of the Economic Benefits Assessment must include the actual field test data or published reports from which the summary is derived. Details and proposed content for the Economic Benefits Assessment package are outlined in Appendix 1.

This package provides further details on Section 8.4, Economic benefits, of Regulatory Directive Dir93-03. The information should be submitted according to the format in Appendix II (Part 8.4 Pesticide Benefits).

It is important to identify the limitations of the data and information contained in the submission. Where there are limitations on key variables, sensitivity analysis should be undertaken and included in the submission. One must document both the assumptions used and the limitations of the analysis when lack of analytical resources or data preclude a more rigorous study.

## **Confidentiality of Data**

It is suggested that any information provided in the Summary Report (Part 8.4.2) could be made accessible to the public by Agriculture and Agri-Food Canada without first requesting written agreement of the registrant/applicant. The information submitted as a part of the regular data package (8.4.3-8.4.7) will be maintained confidential in so far as it is governed by the provisions of the *Access to Information Act*.

For example, if the registrant does not wish to reveal the possible retail price of the pesticide, this information may be reported in Part 8.4.5 of the submission, while the Summary Report (8.4.2) may refer to the price by stating that the pesticide in question will be competitively priced with an alternative chemical.

Please direct any inquiries regarding this Regulatory Directive to:

The Information Service  
Pest Management Regulatory Agency  
Health Canada  
2250 Riverside Drive  
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## Appendix I

### 8.4 Economic Benefits

#### 8.4.1 Summaries

#### 8.4.2 Summary Report

This section is a summary report which will highlight the advantages of the pesticide. It will also indicate the general economic benefits that might be expected to result from the continued or new registration of the product.

#### 8.4.3 Profile of Pesticide (insert name) and Market Sector

The general intent of this section is to provide background information. This will put the data contained in subsequent sections into context.

##### 8.4.3.1 Description of Proposed Uses and Any Current Uses

Outline what the pesticide is, discuss which crop(s) or for what purpose it is to be used, which pest(s) it is designed to control, and in which region of the country or location it would be used. If it is currently registered for other uses, indicate which ones. If it is to be used as part of a pest control program such as Integrated Pest Management, Intensive Forest Management, or Intensive Cereal Management, provide general information on the program and how the product will fit in.

##### 8.4.3.2 Description of Market Sector

For each proposed crop use, provide current information on the area and value of crop produced on a regional and aggregate basis. Indicate the level and value of imports and exports of the crop in question. Provide an indication of the significance of the crop to Canada. If the proposed use is other than for crops, provide information on the value of this area of activity to the Canadian economy.

#### 8.4.4 Evaluation of Pesticide Product (insert name)

The purpose of this section is to provide available scientific information about the product, as well as information concerning alternative control methods.

#### 8.4.4.1 Crop Losses Due to Pests: Quality and Quantity

Include quantitative data or estimates by scientific experts of crop losses (yield), quality losses (grades) or any other losses caused by the pest. An indication of losses from high, medium and low levels of infestation could be provided. Provide an indication of the significance of infestation and whether the occurrence is periodic or epidemic.

#### 8.4.4.2 Efficacy Trials and Yield/Quality Effects

Provide a summary of results of efficacy trials conducted (including research permit data and commercial scale data). Indicate how well the product controls the pest(s) in question, and the impact on yield and quality of the treated crop. Data may be reported in tabular form, including mean and variance values. The efficacy trial data must still be submitted as it has been in the past. It may be submitted as an annex to this subsection.

#### 8.4.4.3 Pest Control Alternatives and Relative Efficacy/Yield Effects

This section should provide comparative efficacy data on the pesticide product and available pest control alternatives. The available test data (including yield effects), with the various treatments may be summarized in tabular form. Mean values and tests for statistical significance of difference should be provided. Indicate any other relevant information such as developing pesticide resistance.

#### 8.4.4.4 Other Pesticide Features

Other relevant features of the pesticide may be indicated in this section. Such features may include any impact on crop sequences, safety to the crop and adjacent crops and non target flora. The length of crop growing period and whether this pesticide is associated with new agricultural technology may also be included.

#### 8.4.5 Economic Impact on Crop Producers

This section will provide an economic assessment of the benefits of the pesticide at the crop producer level.

##### 8.4.5.1 Comparative Cost of Pesticide (insert name) and Alternatives

Treatment cost of alternatives may be presented on a per unit basis (e.g., area), using suggested retail prices and recommended application rates. If the treatment cost of the product is not available an estimate range may be

provided. Take into account multiple treatments needed to achieve the same level of control and differences in equipment required.

#### 8.4.5.2 Projected Usage

For new product use indicate who would use the pesticide and under what circumstances. Provide an estimate (indicate a range) of the expected use; that is, possible area of crop to be treated or quantity of material that may be treated. This estimate should relate to the level of pest problem and actual usage as indicated above for pesticides under reevaluation.

#### 8.4.5.3 Economic Impact

Indicate the economic impact resulting from the use of the pesticide, for an average crop producer. This may include value of improved yield and changes in production costs. An economic comparison with alternative control products may be presented.

### 8.4.6 Aggregate Economic Impacts

It is not expected that the information provided in this section will be complete or detailed. With a new pesticide or new use, any assessment of total economic impacts is speculative. Nevertheless, it may be possible to make some estimates and an opportunity to do so is provided in this section. It is not anticipated that information will be provided for each subsection.

#### 8.4.6.1 Aggregate Impact on Supply Sectors

Indicate the possible benefits of the pesticide for the use sector in question. This may include an estimate of aggregate increase in quantity and value of production. A range of values rather than a point estimate may be more appropriate here. Judge the significance of the pesticide to producers/users in the short and long term.

#### 8.4.6.2 Impact on Consumers

Report any relevant, potential impact on consumers. This may include any price impacts, improved availability of domestic production, or enhanced crop quality.

#### 8.4.6.3 Impact on Crop Protection Industry and Marketing System

Indicate what, if any, impact there may be on the crop protection industry in Canada. Indicate if the product may cause changes in transportation or crop storage practices.

#### 8.4.6.4 Regional Impacts

Report any potential, regional impacts, such as improved crop production, or the improvement of the competitive conditions of one region over another (for example, where the pest problem is regional in nature, estimate the importance of the pesticide to single-industry towns and communities).

#### 8.4.6.5 Macroeconomic Impacts

Where relevant, indicate the probable magnitude of import or domestic manufacturing industries dependent upon the crops at risk (e.g., the likely impact on associated manufacturing production levels, employment, balance of trade, etc.)

#### 8.4.7 Bibliography of Public Sources

Cite reference documents and other sources consulted in the preparation of the document

## Appendix II

### Part 8.4 Economic Benefits

- 8.4.1 Summaries
- 8.4.2 Summary Report
- 8.4.3 Profile of Pesticide and Market Sector
  - 8.4.3.1 Description of Proposed Uses and Any Current Uses of Pesticide
  - 8.4.3.2 Description of Market Sector (area and value of crops produced, dependent manufacturing sector, export/import situation)
- 8.4.4 Evaluation of Pesticide
  - 8.4.4.1 Crop Losses Due to Pest: Quality and Quantity
  - 8.4.4.2 Efficacy Trials and Yield/Quality Effects
  - 8.4.4.3 Pest Control Alternatives and Relative Efficacy/Yield Effects
  - 8.4.4.4 Other Pesticide Features (e.g., phytotoxicity, effect on crop sequences, crop varieties, a new technology, etc.)
- 8.4.5 Economic Impact on Crop Producers
  - 8.4.5.1 Comparative Cost of Pesticide and Alternatives
  - 8.4.5.2 Projected Usage
  - 8.4.5.3 Economic Impact (change in operating costs, production/yield and revenues)
- 8.4.6 Aggregate Economic Impacts
  - 8.4.6.1 Aggregate Impact on Supply Sectors
  - 8.4.6.2 Impact on Consumer
  - 8.4.6.3 Impact on Crop Protection Industry and Marketing System
  - 8.4.6.4 Regional Impacts
  - 8.4.6.5 Macroeconomic Impacts (resource-dependent manufacturing sector, inflation, trade, employment, etc.)
- 8.4.7 Bibliography of Public Sources