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Agri-Food Canada

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Production et inspection des aliments

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Canada
Pro93-01

Regulatory Proposal

Guidelines for Registration of Antisapstain Products

The purpose of this document is to request comments from registrants, advisors, provincial pesticide regulatory officials (Canadian Association of Pesticide Control Officials), stakeholders and other interested groups on proposed new data requirements for antisapstain products. Data requirements and rationales have been prepared by federal advisors and Agriculture Canada officials; the proposals and rationales are enclosed as Appendices I, II, III, and IV.

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Plant Industry Directorate
Agriculture and Agri-Food Canada
Ottawa, Ontario
K1A 0C5
(613) 993-4544

Facsimile: (613) 998-1312
Telex: 053-3282
Envoy 100: Pesticide
Information Service: 1-800-267-6315

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1.0 Products

Products covered under the proposed guidelines would include technical active ingredients and end-use products for use in lumber sapstain control. These industrial pesticides are applied to freshly sawn wood to prevent lumber degradation and waste caused by the growth of mould stain and decay fungi during storage and transit. Because this use pattern is considered unique for chemical pesticides, registration of these products has traditionally been determined on a case by case basis. Recently, federal scientific advisors have requested studies which have not previously been considered essential for registration of sapstain control products.

2.0 Background

In 1987 and 1989, Agriculture Canada and federal advisors produced Discussion Documents on antisapstain products. The response to the Discussion Documents from a variety of stakeholders led to the following regulatory decisions being implemented.

In 1990, Agriculture Canada granted temporary registrations for the antisapstain chemicals, didecyl dimethyl ammonium chloride (DDAC), 3-iodo-2-propynyl butylcarbamate (IPBC) and Azaconazole 200EC.

Agriculture Canada responded to the Majority Stakeholder's Report of the British Columbia Multi-stakeholder Forum by establishing a regulatory position which provides for:

- a) re-evaluation of the older active ingredients used for sapstain control (Borax, TCMTB and Copper-8-quinolinolate);
- b) annual review of the temporary registrations;
- c) annual monitoring of schedules for additional studies for technical active ingredients; and
- d) cooperative development of appropriate exposure data for sapstain control products.

Federal advisors have been asked to review registrant data commitments and further define studies that are desirable to facilitate ongoing reviews and re-evaluations requested in the Majority Stakeholders Report of the British Columbia Multi-Stakeholder Forum.

In some instances, this has resulted in identifying studies which are already included in the existing Pesticides Directorate Trade Memorandum, T-1-245, "Guidelines For Developing A Toxicology Data Base" (1984), and Trade Memorandum, T-1-255, "Guidelines for Determining Environmental Chemistry and Fate of Pesticides" (1987).

Some unique studies have also been identified which are associated with this use pattern. Rationales for requiring these studies are given in Appendix I. The proposed studies are outlined in Appendix II and Appendix III for technical active ingredients and end-use products, respectively.

The B.C. Regional Office of Environment Canada has requested that lumber leaching studies be included to facilitate development of effluent standards for antisapstain products. This information is included as Appendix IV.

Health and Welfare Canada has chosen not to deviate from the current Guidelines for Developing Toxicology as outlined in Trade Memorandum T-1-245. Stakeholders should be aware that recently, requests have been directed to some formulators to produce short-term toxicity studies when two or more active ingredients are formulated in a product. These studies are part of T-1-245 Guidelines for Developing Toxicology.

Another important development related to safety information involves new initiatives for developing an appropriate protocol for conducting operator exposure studies. This protocol will facilitate the conduct of exposure studies as a required component of the data package for sapstain control products.

Appendix V outlines the type of data that Agriculture Canada traditionally requested for end-use antisapstain products. The proposed data requirements in Appendices II, III and IV represent substantial change, particularly for end-use (formulated) products. One possible regulatory approach for implementing these proposals has been included for comment.

3.0 Regulatory Proposal

It is proposed that the new data described in Appendices II, III and IV be incorporated into the Data Guidelines for antisapstain products with the following Regulatory considerations.

4.0 Regulatory Considerations

4.1 Registered Products

Data bases on currently registered products including a number of temporary registrations, used for sapstain control, would require upgrading to comply with the proposed guidelines.

Agriculture Canada would continue to allow applicants and registrants to provide scientifically sound rationales for the exemption, substitution, or extrapolation of information. Rationales would be required as part of an application for registration or as part of the process of re-evaluation.

4.2 End-Use Products

New end-use products would be considered for temporary registration provided:

- a) Active ingredients are currently registered for sapstain control in Canada;
- b) Application rates for the active ingredients are in line with established efficacy requirements;
- c) The formulated product is applied by improved technology or equivalent technology, currently used for existing registered products;
- d) A commitment is made by the applicant to produce appropriate exposure data using the maximum use rate for the end-use formulation. The data would be required to be submitted within the first year of a temporary registration. This window would accommodate exposure protocol requirements;
- e) Commitment is made by the applicant to perform and submit additional studies or exemption rationales arising from the proposed new data requirements;
- f) The product is supported by data described in Appendix V; and
- g) No new information is available that would indicate unacceptable adverse effects or risk.

5.0 Data Protection

Data ownership would be recognized within the current policy on Product Specific Registration and Proprietary Rights to Data. Point values for new studies in the proposed guidelines would be assigned based on input received during the public comment period for this document.

6.0 Regulatory Rationale

The Proposal would utilize the existing regulatory mandate under the *Pest Control Products Act and Regulations* as outlined in Section 17 of the *Regulations*. (Temporary Registration for Pest Control Products.)

The Regulations state:

The Minister may, upon such terms and conditions, if any, as he may specify, register a control product for a period not exceeding one year where the applicant agrees to endeavour to produce additional scientific or technical information in relation to the control product.

The Proposal:

- a) provides a regulatory control mechanism through the use of temporary registration, which responds to new use experience, annual reviews, or ongoing re-evaluations. This regulatory practice has, after public consultation, been adapted for specific end-use products such as NP-1;
- b) provides a practical mechanism for improving the knowledge base for pest control products and represents an equitable regulatory process;
- c) does not expand the use pattern for any of the active ingredients which are currently registered and used at industrial mill sites in Canada;
- d) will provide for a more cost competitive market and/or improved products;
- e) recognizes the need for a regulatory mechanism to generate operator exposure data on antisapstain products in Canada; and
- f) recognizes that data guidelines are evolutionary in nature and opportunities for new scientific investigation will arise in the future.

7.0 Comment Period

Comments on the proposed operational change should be submitted no later than 90 days from the date of this Regulatory Proposal. Please forward your comments to Mr. Clifford Ralph, Agriculture Canada, Plant Industry Directorate, Ottawa, Ontario, K1A 0C5.

Appendix I

Rationale for Data Proposal - Antisapstain Products

Environment Canada should receive a copy of all proposed environmental data listed.

The following comments address the rationale for requesting specific data.

Technical Product - Environmental Chemistry and Fate

For environmental chemistry and fate data, requirements are the same as those described for all pesticides in Agriculture Canada's Trade Memorandum T-1-255, "Environmental Chemistry and Fate Guidelines for Registration of Pesticides in Canada." Special studies done with the technical product include: 1) photo-transformation on wood; and 2) analytical methods. In addition, incineration studies are required as part of the disposal/decontamination information submission.

Generally, phototransformation studies are used to identify transformation products and establish dissipation rates, thereby permitting the assessment of the significance of phototransformation for the dissipation of a product in the environment. Much of the rationale for requiring phototransformation studies is outlined on pages 14 to 18 of the Environmental Chemistry and Fate Guidelines. Among the items in the Guidelines, it is noted that:

- i) identification of major phototransformation products must be done with radiolabelled pesticide;
- ii) the rates of transformation of the pesticide can be determined using any suitable analytical technique; the rates of transformation of major transformation products may need to be determined, as decided on a case-by-case basis.

For antisapstain products, we are considering asking for data on phototransformation in water and on soil only, with a caveat that studies on wood may be required on a case-by-case basis, depending on product chemistry and the transformation products and rates identified in the water and soil phototransformation studies. However, it may be fairer and more expedient to simply request the wood studies, while recognizing that the applicant may request a waiver on sound scientific grounds.

Analytical methods for residue detection and quantification have generally been included as part of studies submitted in Part 2, Part 6, and Part 7. The methods should be submitted as one package as part of Part 6. These are listed under "Special studies" in the accompanying list.

Incineration is a common method of disposal for treated wood waste. These wastes may include cut ends, as well as residues resulting from the planing of treated lumber. Treated wood waste may also be generated during further machining or use, and these wastes may be burned in kilns or furnaces or in the open. Incineration studies should be done at two temperatures to identify transformation products when burning at low and high temperatures.

Technical Product - Environmental Toxicology

Pending further discussions of the draft Non-target Plant Guidelines, only an algal test is requested for plant testing.

End-Use Formulated Product - Environmental Chemistry

For environmental chemistry and fate data, requirements are the same as those described for all pesticides in Agriculture Canada's Trade Memorandum T-1-255, Environmental Chemistry and Fate Guidelines for Registration of Pesticides in Canada.

Number of sites, location, and rates for field dissipation studies will be decided on a case-by-case basis.

Field aquatic studies may be waived if laboratory data have shown that the product is not persistent in aquatic systems.

Special studies include leaching from lumber. A standard protocol for leaching from lumber has recently been developed by Peter Krahn, DOE EP - Pacific and Yukon region. Available from Environment Canada, 224 West Esplanade, North Vancouver, B.C., V7M 3H7.

End-Use Formulated Product - Environmental Toxicology

As with all pesticide types, environmental toxicology data should generally be submitted for every end-use formulation. Requests for waivers must be based on sound scientific arguments. In the case where an end-use formulation contains a mixture of two or more active ingredients, a full package must be submitted for end-use formulation.

Appendix II

Environmental Data Requirements for Registration of Technical Active Ingredients of Antisapstain Products

Part 1: **Label**

- Label

Part 2: **Product Chemistry**

- Specific gravity
- Dissociation constant (pK_a)
- Product Specification Form

Part 6: **Environmental Chemistry and Fate**

Physicochemical properties:

- Vapour pressure
- Water solubility
- Hydrolysis
 - in water
- Phototransformation
 - in water
 - on soil
- Octanol/water partitioning coefficient (K_{ow})

Mobility:

- Adsorption/desorption in soils
- Leaching in soil

Biotransformation (laboratory):

- Aerobic transformation
 - in soil
 - in water or sediment/water
- Anaerobic transformation
 - in sediment/water

Special studies:

- Phototransformation
 - on wood
- Analytical methodology
 - detection and quantification of residues
 - in soil
 - in water
 - in sediment

- in biota (including fish tissue)
- detection limit, in water, must be lower than the NOEL for the most sensitive non-target aquatic species tested.

Storage, disposal and decontamination:

- Incineration/thermal decomposition

Part 7: **Environmental Toxicology**

Acute toxicity

Fish:

- 96-hour flow-through exposure testing of fingerlings of rainbow trout (*Oncorhynchus mykiss*); determination of an LC₅₀;
- 96-hour flow-through exposure testing of fingerlings of coho salmon (*Oncorhynchus kisutch*), chinook salmon (*Oncorhynchus tshawytscha*) or Atlantic salmon (*Salmo salar*), to be followed by a 48-hour flow-through salinity challenge test; determination of an LC₅₀ plus additional mortality observations and serological determinations as required in the salinity challenge test.

Aquatic invertebrates:

- 48-hour static or flow-through exposure testing of the freshwater daphnid (*Daphnia magna*); determination of an LC₅₀;
- 48-hour static or flow-through exposure testing of a representative estuarine or marine crustacean such as the mysid shrimp (*Mysidopsis bahia*) or the grass shrimp (*Palaemonetes pugio*); determination of an LC₅₀.

One of:

- 48-hour exposure testing (flow-through) of an estuarine or marine mollusc - embryo larvae study; determination of an LC₅₀;

or

- 96-hour exposure testing (flow-through) of an estuarine or marine mollusc - shell deposition study; determination of an LC₅₀.

Plants:

- Growth inhibition testing of one algal species; determination of an LC₅₀.

Birds:

- Acute oral toxicity testing of mallard duck or bobwhite quail; determination of a single-dose LD₅₀;
- Dietary toxicity testing of mallard duck or bobwhite quail; determination of a 5-day feeding LC₅₀.

Chronic toxicity to aquatic organisms

To be performed on the most sensitive species as determined in the acute studies.

One of:

- Flow-through exposure testing of early life stages (egg to fry) of coho, chinook or Atlantic salmon

or

- Flow-through life-cycle testing of daphnid or mysid shrimp

or

- Flow-through exposure testing of a representative estuarine or marine mollusc.

Bioconcentration

- Flow-through bioconcentration/depuration testing of fingerlings of rainbow trout, coho, chinook or Atlantic salmon; determination of a bioconcentration factor (BCF) and a depuration time (time required for residues in tissue to return to non-detectable levels).

One of:

- Flow-through bioconcentration/depuration testing of a representative estuarine or marine crustacean such as the mysid shrimp or the grass shrimp

or

- Flow-through bioconcentration/depuration testing of a representative marine bivalve such as the common edible clam (*Mercenaria mercenaria*), the blue mussel (*Mytilus edulis*) or the oyster (*Crassostrea gigas*); determination of a bioconcentration factor (BCF) and a depuration time (time required for residues in tissue to return to non-detectable levels).

Notes on Technical Active Ingredient

1. Additional data from laboratory studies may be requested depending on the outcome of the initial review of the submitted data.
2. Environmental fate and environmental toxicology of major transformation products may need to be addressed.
3. Test concentrations must be confirmed analytically and expressed as units of active ingredient.
4. Tests must be conducted with the analytical grade of the active ingredient for radioisotopic studies and the technical or analytical grade of the active ingredient for other environmental chemistry and fate studies. Tests must be conducted with the technical grade of the active ingredient for environmental toxicology studies. Certain toxicology studies, however, will be conducted with end-use products. Such studies should be included in the data package on the end-use products. However, they may also

be included in the data package for the technical active ingredient if they are applicable to a number of end-use formulations.

5. If more than one active ingredient constitutes a technical product, then the technical grade of each active ingredient must be tested separately. In addition, a partial or full environmental fate and/or environmental toxicology data package may be required for the technical product (as a single product), depending on the outcome of the initial review of each of the active ingredients.

Appendix III

Environmental Data Requirements for Registration of End-Use Antisapstain Products

Part 1: **Label**

- Label
 - rates of application
 - method of application
 - timing of application
 - frequency of application
 - use limitations

Part 2: **Product Chemistry**

- Product Specification Form

Part 6: **Environmental Chemistry and Fate**

Field studies

- Field dissipation and accumulation
 - terrestrial
 - aquatic (water/sediment/biota)

Special studies

- Leaching (wash-off) from wood; determination of stormwater concentration, expressed as units of active ingredient.

Part 7: **Environmental Toxicology**

Acute toxicity:

- 96-hour static or flow-through exposure testing of the most sensitive species (fish or invertebrate) as determined in toxicity testing of the technical active ingredient; determination of an LC₅₀.

Notes on End-Use Product

1. Additional data from laboratory studies and/or field studies may be requested depending on the outcome of the initial review of the submitted data.
2. Environmental fate and environmental toxicology of major transformation products may need to be addressed.
3. An end-use formulation which consists of more than one active ingredient will require testing as a single product.

4. A full environmental toxicology data package, equivalent to that required for the technical active ingredient, may be required if more than one active ingredient constitutes an end-use formulation or if formulation composition may lead to differences in toxicity from the technical active ingredient(s).
5. Test concentrations must be confirmed analytically and expressed as units of active ingredient.
6. If major changes in use-pattern, formulation or label rate are made following completion of the initial review, the changes must be submitted for review and the need for additional data determined on a case-by-case basis.

Appendix IV

Environment Canada B.C. Region Proposal

Executive Summary

Research conducted by various government and private laboratories showed that antisapstain chemicals will leach from treated lumber. Various studies have been done to simulate this leaching in laboratory scale tests. Non-standard test conditions such as variations in lumber package sizes, intensity and duration of artificial rainfall and sampling frequency have made it difficult to relate the results between tests and to conditions which would normally be experienced by operating antisapstain facilities.

Recent leaching studies conducted at various mills by Environment Canada have indicated that leachate dripping from treated lumber is diluted an average of 15 times by rainfall before it discharges from the storage yard. Numerous variables at individual mill sites caused a range of dilutions from 6 to 24 times. These observations led to the development of a standard leaching test which can be conducted using natural or artificial rain. The standard leaching test can be used to predict the concentrations of the antisapstain chemicals in the runoff at operating facilities. Environment Canada has recommended to Agriculture Canada that the test procedure be included in the registration requirements for new antisapstain formulations.

Appendix V

Data Traditionally Requested for End-Use (Formulated) Products

- A. Application Form
- B. Product Specifications, chemistry information, MSDS on Inerts
- C. Draft Labels
- D. Letter confirming a registered source of active ingredient for the product
- E. Acute toxicity, data on the formulation
- F. Acute fish toxicity data on the formulation
- G. Efficacy data
- H. Fees