

PROCEDURES FOR THE IDENTIFICATION AND RESOLUTION OF NAFTA PESTICIDE TRADE IRRITANTS

I. Introduction

Historically, CUSTA, and now NAFTA, committees have worked to identify and resolve pesticide trade irritants. What constituted a trade irritant, however, had never been formally defined. As a result, the work of the CUSTA/NAFTA committees was fairly narrowly focussed on MRLs/tolerances that did not exist in the importing country. The trade irritant issues which have surfaced in recent years have prompted the Food Residues Subcommittee of the NAFTA Technical Working Group on Pesticides (NAFTA TWG) to establish a formal approach to the process of identifying, prioritizing, and resolving existing trade irritants. To develop this procedure, a Trade Irritant Process Team was established to allow industry and other government agencies the opportunity to provide their views to the Food Residues Subcommittee. This Team is made up of representative stakeholders from industry, user groups and government as indicated in Appendix D, and includes the Subcommittee Co-chairs.

The Trade Irritant Process Team identified 5 categories of trade irritants and made recommendations for resolving each one. While the Food Residues Subcommittee will play a lead role in the resolution of Category A trade irritants, they will have no direct involvement in the resolution of Category B, Category C and Category D trade irritants.

A trade irritant may also result when an existing MRL/tolerance is revoked in a NAFTA member country. In those cases in which the MRL/tolerance are revoked due to dietary risk concerns, the trade irritant cannot be resolved until the underlying issues that caused the revocation are resolved.

The 5 categories of trade irritant are defined as follows:

Category A -- a discrepancy arising when an MRL/tolerance has been established in the exporting country, but it is lower or does not exist in the importing country, and the commodity has been documented to be out of compliance in the importing country;

Category B -- a discrepancy arising when an MRL/tolerance has been established in the exporting country, but it is lower or does not

exist in the importing country, and there have been no compliance violations;

Category C -- a pesticide-commodity combination is registered in one country but not a second country, while the commodity growers in the second country want to treat their commodity with that pesticide;

Category D -- a discrepancy resulting from a non-registered use in the exporting country,

Category E -- a registered use with a time-limited tolerance in the exporting country.

II. Current Trade Irritants

CATEGORY A

An MRL/tolerance discrepancy resulting from a registered use in the exporting country and a compliance violation.

1. Criteria

- a. An MRL/tolerance has been established in an exporting NAFTA country and the MRL/tolerance is lower or does not exist in the importing NAFTA country,

AND

- b. Commodities have been documented to be out of compliance in the importing country.

2. Actions needed for resolution of Category A trade irritants

The following action is needed in order to resolve a trade irritant of this type:

- An MRL/tolerance must be established in the importing country that is at least as high as the MRL/tolerance in the exporting country.

3. Identification of Category A trade irritants

Category A trade irritants can be identified by all interested parties, including growers, importers, exporters, and government agencies. For each trade irritant that is identified, the following should be submitted:

- the chemical name of the pesticide;
- the name of the commodity;
- the name address and telephone number of the person submitting the proposed trade irritant. An e-mail address should be provided, if available;

- the name of the pesticide manufacturer, and the name address and telephone number of a contact person for the pesticide manufacturer. An e-mail address should be provided, if available;
- the exporting country
- the importing country
- level of support of the manufacturer, and of any other data submitters if applicable. One of the following statements should be included in your submission:
 - a) *The manufacturer/submitter has made a commitment to submit all of the required data;*
 - b) *The manufacturer/submitter has not made a commitment to submit all of the required data.*

If the submitter is not the manufacturer, one of the following statements must be included in your submission:

- a) *The manufacturer supports action to establish/revise the MRL/tolerance and/or registration for the pesticide-commodity combination;*
- b) *The manufacturer objects to the establishment/revision of the MRL/tolerance and/or registration for the pesticide-commodity combination.*

If data are to be submitted by a group other than the manufacturer, this should be specifically stated, and the name of the data submitter, and the name and e-mail, phone number, or address of a contact for the data submitter should be included. If sufficient information is not provided concerning the level of support by the manufacturer, and other data submitter if applicable, the trade irritant will be assigned zero points for this criterion.

- any available information explaining how the pesticide-commodity combination fulfils any applicable criteria listed in Appendix B
- any additional information about this trade irritant that you would like the pesticide regulatory agency of the importing country to consider when prioritizing trade irritants.

Time frame for identification of candidates

The work on Category A trade irritants will be reviewed annually. Candidates should be submitted to one of the co-chairs of the Food Residues Subcommittee by March 31 in order that they might be scheduled for consideration within the next year. If no candidates are proposed by March 31 of any year, no work on Category A trade irritants will be undertaken during that year.

4. Prioritization of Category A trade irritants

The Trade Irritant Process Team has developed a point value rating system, as outlined in Appendix B, which is to be applied when prioritizing Category A trade irritants. Countries have agreed to set aside resources each year to resolve Category A trade irritants through the Food Residues Subcommittee. The member pesticide regulatory agencies will make an effort to schedule work on as many of these trade irritants as resources permit. Category A trade irritants will be prioritized by importing countries in cooperation with their counterparts on the Food Residues Subcommittee. Priority setting is necessary in order that where there are insufficient resources to handle resolution of all trade irritants, those assigned highest priority will be addressed first.

For some proposed trade irritants, it may be apparent that resolution is not possible without prior resolution of certain issues. Issues which might preclude the acceptance of a proposed trade irritant include, but are not limited to:

- an incomplete toxicology data base
- an unacceptable dietary exposure assessment for the existing uses of the pesticide.

In such cases, the Subcommittee will issue a letter to the group or individual that proposed the trade irritant which provides details of the issues that need to be resolved.

5. Procedures for the resolution of a Category A trade irritant

Once the trade irritants have been identified, the following procedures are followed:

- The exporting country sends to the importing countries the review supporting the establishment of the MRL/tolerance, and a list of the raw data evaluated. If the MRL/tolerance in the exporting country was established based on data and/or evaluations from another country, the exporting country will obtain the evaluations and list of raw data evaluated from the other country, and then send these to the importing country.

- The importing countries then contact the company representative in the exporting country to request the data used to support the original evaluation. At their discretion, the importing country may also request any other supporting data developed since the original evaluation. In addition, the importing country may, when appropriate, use data for similar uses from studies that were conducted in the importing country or other countries.
- The importing country then examines the proposal to determine whether it is acceptable for assessment. Some issues which might preclude the acceptance of a proposed trade irritant might be:
 - ▶ an incomplete toxicology data base
 - ▶ an unacceptable dietary exposure assessment for the existing uses of the pesticide.
- If accepted, the importing country then evaluates the proposed MRL/tolerance and moves to establish the required MRL/tolerance.
- The importing country establishing the MRL/tolerance should utilize the reviews of the other member country to the greatest extent possible in making the regulatory decision. It is recognized, however, that, in certain areas where unique data requirements exist, e.g. residue trial data requirements, crop rotation data requirements, etc., additional data and subsequent review will be required.
- The NAFTA member countries' regulators will then work together to establish, to the extent possible, MRLs/tolerances that are harmonized and cover the appropriate use patterns .

Once the proposal is either rejected, or the MRL/tolerance is established, the trade irritant issue is considered to be resolved. The decision will be reported through established proceedings in each country, and in the NAFTA progress and status reports.

CATEGORY B

An MRL/tolerance discrepancy resulting from a registered use in the exporting country (no compliance violation).

1. Criteria

- a. An MRL/tolerance has been established in an exporting country and the MRL/tolerance is lower or does not exist in the importing country.

2. Actions needed for resolution of Category B trade irritants

The following action is needed in order to resolved a trade irritant of this type:

- An MRL/tolerance must be established in the importing country that is at least as high as the MRL/tolerance in the exporting country.

3. Identification of Category B trade irritants

Category B trade irritants can be identified by all interested parties, which may include growers, importers, exporters, and government agencies.

4. Procedures for the resolution of Category B trade irritants

There will not be any direct involvement of the Food Residues Subcommittee in the resolution of Category B trade irritants. Trade irritants of this type can be resolved using the following procedures:

- An application to establish an MRL/tolerance should be submitted to the importing country by the representative company/user group. The application to establish an MRL/tolerance should include notification that an MRL/tolerance and/or registration for the pesticide-commodity use exists in the exporting country. Details of the MRL/tolerance should be provided with the application.
- At the time of submission of the application, the company should request that the evaluations from the country in which the pesticide is registered be forwarded to the country wishing to register the pesticide-commodity combination.

- The company/user group should then work with the exporting country to provide sufficient data to establish the MRL/tolerance.
- The importing country establishing the MRL/tolerance should utilize the reviews of the other member country to the greatest extent possible in making the regulatory decision. It is recognized, however, that in certain areas where unique data requirements exist additional data and subsequent review will be required.
- The NAFTA member countries' regulators will then work together to establish, to the extent possible, MRLs/tolerances that are harmonized and cover the registered use patterns.

CATEGORY C

A registration discrepancy

1. Criteria

- a. One NAFTA member country has a use registered for a commodity with an MRL/tolerance established¹

AND

- b. A second NAFTA member country does not have the same use registered², and the commodity growers in that country want to treat their commodity with the pesticide

2. Actions needed for the resolution of Category C trade irritants

The following action is needed in order to resolve a trade irritant of this type:

- The use for the commodity must be registered in the second NAFTA member country. In addition, an MRL/tolerance must be established in the second NAFTA member country if one is not already in place.

3. Identification of Category C trade irritants

Growers and company representatives are responsible for identifying this type of trade irritant.

4. Procedures for the resolution of Category C trade irritants

The normal route for the resolution of this situation is for the company to submit an application for the registration of the pesticide-commodity combination in the second country. This can be done at any time. There will not be any direct involvement of the Food Residues Subcommittee in the resolution of Category C trade irritants.

- The member country that does not have the registered use should receive an application for the registration of the use and for the establishment of an

¹ Including the General Regulation Limit in Canada if applicable

² Note that an import MRL/tolerance may allow for the importation of the treated crop even though the pesticide is not allowed for use in the importing country

MRL/tolerance from the representative company/user group. The company/user group should then work with the country in which the pesticide is registered for the use, to provide sufficient data

- At the time of submission of the application, the company should request that the evaluations from the country in which the pesticide is registered are forwarded to the country wishing to register the pesticide-commodity combination.
- The country registering the pesticide-commodity combination should utilize the reviews to the greatest extent possible in making the regulatory decision. It is recognized, however, that in certain areas where unique data requirements exist, e.g. residue trial data requirements, crop rotation data requirements, etc., additional data and subsequent review will be required.
- The NAFTA member countries' regulators will then work together to establish, to the extent possible, MRLs/tolerances that are harmonized and cover the registered use patterns.

CATEGORY D

An MRL/tolerance discrepancy resulting from a non-registered use in the exporting country

1. Criteria

A registration and an MRL/tolerance have NOT been established in the exporting country and an MRL/tolerance does not exist in the importing country.

2. Actions needed for resolution of Category D trade irritants

The following action is needed in order to resolve a trade irritant of this type:

- the use for the commodity must be registered in the exporting country, and an MRL/tolerance must be established for the commodity in the exporting country.
- an MRL/tolerance must be established in the importing country that is at least as high as the MRL/tolerance in the exporting country.

3. Identification of Category D trade irritants

The exporting authorities, growers and company representatives are responsible for identifying this type of trade irritant. Growers are encouraged to work with the company representatives in order to provide sufficient information to both register the specific use of the product in the country of origin and to establish an MRL/tolerance in the importing country. For import tolerances, the USA has recently provided guidance in this area through their "Import Tolerances Guidelines". These guidelines are presently being examined to determine whether they could be adopted as NAFTA guidelines.

4. Procedures for the resolution of Category D trade irritants

There will not be any direct involvement of the Food Residues Subcommittee in the resolution of Category D trade irritants.

- The exporting country contacts the manufacturer of the product to initiate discussions on the registration process. The company should then work with the exporting country to provide sufficient data to register the use.
- The company should provide sufficient data not only for the NAFTA country

in which the commodity is grown but also sufficient data to support the establishment of an MRL/tolerance in the importing country.

- The company should then simultaneously submit the data package to all NAFTA member countries. The cover letter should identify the submission as having been submitted simultaneously.
- The NAFTA member countries' regulators will then coordinate the reviews of the submitted data with the goal of establishing a harmonized MRL/tolerance level.

CATEGORY E

An MRL/tolerance discrepancy resulting from a registered use with a time-limited tolerance in the exporting country (with or without a compliance violation)

1. Criteria

A time-limited MRL/tolerance has been established in an exporting country and the MRL/tolerance is lower or does not exist in the importing country.

2. Actions needed for resolution of Category E trade irritants

a. Full registration (*FIFRA Section 3 in the U.S.*)

This type of trade irritant will be handled as described for Categories A and B. The reader is referred to the appropriate section based on other criteria for the trade irritant. It is advised that interested groups/individuals make efforts to resolve the issue that has caused the tolerance to be time-limited as soon as possible, since a lack of information that causes the exporting country to set a time-limited tolerance could interfere with establishing an MRL/tolerance in the importing country.

b. Emergency exemption (*FIFRA Section 18 in the U.S.*) and Experimental Use Permits (*EUPs, FIFRA Section 5 in the U.S.*)

The pesticide regulatory agencies of Canada and Mexico do not have mechanisms for the establishment of tolerances for these types of situations in which there is not sufficient data for full registration. Further, in the U.S., emergency exemptions and special local needs registrations are intended for limited use in restricted situations in which there is not complete data to support full registration. Therefore, before these trade irritants can be resolved, full registration of the pesticide use and an MRL/tolerance must be obtained in the exporting country.

III. Monitoring of Current Trade Irritants

As detailed in Section I, the resolution of all types of trade irritants other than Category A will not directly involve the Food Residues Subcommittee. The Subcommittee does, however, intend to monitor the resolution of all types of trade irritants to ensure that the procedures specified in this document are effective. Therefore, the Food Residues Subcommittee requests that interested groups and/or individuals report the following information to one of the Food Residues Subcommittee co-chairs³ concerning Category B, Category C, and Category D trade irritants for which they are pursuing resolution:

- The type of trade irritant (i.e. Category B, Category C, or Category D).
- The name of the pesticide.
- The name of the commodity for which use of the pesticide is a trade irritant.
- Action that is being taken to attempt to resolve the trade irritant issue (e.g. "Submitted applications to Canada for registration and MRL on July 15, 1997").
- The name and e-mail, phone number, or address of the person submitting the proposed trade irritant.
- The name of the pesticide manufacturer, and the name and e-mail, phone number, or address of a contact person for the pesticide manufacturer.
- The exporting country (Categories B and D), or the country where the pesticide-commodity combination is registered (Category C).
- The importing country (Categories B and D), or the country in which registration of the pesticide-commodity combination is desired (Category C).

³ Appendix C contains the contact details for the Co-chairs of the Food Residues Committee

IV. Potential Trade Irritants

This document was developed to address trade irritants that have occurred over many years. It is clear that there is much that can be done by the NAFTA countries, working cooperatively through the NAFTA TWG, to minimize such problems in future.

The governments of Canada, Mexico and the United States have taken actions to reduce the development of further trade irritant issues by working together to develop common approaches to residue data requirements and evaluation. To facilitate the generation of data, a residue zone map has been developed which specifically defines crop regions or zones common to the three countries. The implementation of this zone map will reduce the number of residue trials required to support registration, and will facilitate the exchange of reviews. Projects to develop a minimum acceptable NAFTA protocol for residue trials, and uniform methodology for the assessment of dietary exposure to pesticides, have also been initiated

A consistent approach to data development and evaluation will facilitate the harmonization of MRLs/tolerances and increase the possibility of work sharing among the NAFTA countries. A programme on the Joint Review of pesticides is in place between Canada and the US. The opportunity to work cooperatively on real products has provided invaluable experience in understanding the how each country works to establish residue limits in food.

In addition to government initiatives, the pesticide industry and user groups have a role to play in preventing the development of trade irritants. The NAFTA Industry Working Group, established in June 1998 has representation from the pesticide industry associations in the three countries and has indicated its willingness to work with the NAFTA TWG. The coordinated submission of consistent data packages to NAFTA countries, in support of registration petitions for new MRLs/tolerances will be essential in order to avoid future trade irritants. Commodity groups and users are encouraged to work with pesticide registrants to ensure that appropriate applications are submitted. Pesticide user groups would benefit from becoming knowledgeable about the existing MRLs/tolerances in all three countries including an awareness of the appropriate application rates for the commodity so that the residue levels in the importing country are met.

Interested parties can monitor pending and newly established or revised MRLs/tolerances by accessing the Internet. In the U.S., a notice of the establishment or revision of a tolerance is published in the Federal Register. Notices of U.S. tolerances, published during 1994 or later, can be accessed at <http://www.gpo.ucop.edu> and then selecting "*Search Fed.Register*". The MRLs for Canada and Mexico can be obtained at <http://www.hc-sc.gc.ca/pmar/mainmrle.html>. For Canada, the MRLs are updated on a yearly basis.

APPENDIX A

ACRONYMS AND TERMS

CUSTA Canada-United States Trade Agreement

Food Residues Subcommittee

A subcommittee under the NAFTA TWG on Pesticides that works to resolve issues relating to pesticide residues in food.

MRL Maximum Residue Limit

NAFTA North American Free Trade Agreement

NAFTA TWG NAFTA Technical Working Group on Pesticides.

The TWG is comprised of individuals from the governments of Canada, Mexico, and the United States.

Trade Irritant Process Team

The Trade Irritant Process Team is a group of representative stakeholders formed to provide the Food Residues Subcommittee with views of industry and other government agencies regarding trade irritant issues. The current composition of the Trade Irritant Process Team is listed in Appendix D.

APPENDIX B

CRITERIA FOR PRIORITIZATION OF CATEGORY A TRADE IRRITANTS

Each proposed Category A trade irritant will be prioritized according to the four criteria detailed below. For each criterion, qualitative measures have been developed and assigned a given number of points. The pesticide-commodity combination with the largest number of total points will receive the highest review priority. The assignment of points and prioritization will be carried out by the NAFTA Food Residues Subcommittee cochair in the importing country in cooperation with their counterparts on the Food Residues Subcommittee. The Trade Irritant Process Team intends to meet annually to evaluate how well the prioritization system is working and to propose any needed modifications.

Criteria

1) *Frequency of Violations (35 points maximum)*

Violations for the most recent year for which statistics are available will be totalled for each pesticide-commodity combination. The combination that obtained the most violations will be assigned the full 35 points. Other combinations will be assigned an incremental percentage of points depending on how many violations occurred. For example, if the combination with the most violations was pesticide A on wonderfulfruit with 20 violations, and another combination, pesticide B on superveggie, had 10 violations, pesticide A on wonderfulfruit is assigned 35 points, and pesticide B on superveggie is assigned 17.5 points.

2) *Priority for Exporting Government (35 points maximum)*

Each government will determine how to distribute points for this category. Grower and pesticide user input will be taken into account.

3) *Support from the Data Submitter and Manufacturer (20 points maximum)*

- a) Submitter makes a commitment to submit all of the required data and the pesticide manufacturer does not object to the MRL/tolerance/registration action (20 points)
- b) Submitter makes a commitment to submit all of the required data, but the manufacturer objects to the MRL/tolerance/registration action (5 points)
- c) Submitter does not make a commitment to submit **all** of the required data (0 points)

- 4) *Amount of Work for Pesticide Regulatory Agency (10 points maximum)*
- a) MRL/tolerance is established in the importing country but lower than that of the exporting country, and a dietary risk assessment has been completed (10 points)
 - b) Technical grade of active ingredient is registered, residue data are needed, and a dietary risk assessment has been completed (9 points)
 - c) MRL/tolerance is established in the importing country but lower than that of the exporting country, and a dietary risk assessment has not been completed (7 points)
 - d) Technical grade of active ingredient is registered, residue data are needed, and a dietary risk assessment has not been completed (5 points)
 - e) Technical grade of active ingredient is not registered (0 points)

APPENDIX C

FOOD RESIDUE SUBCOMMITTEE CO-CHAIRS

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APPENDIX D

MEMBERS OF THE TRADE IRRITANT PROCESS TEAM

Allan Brown, Crop Protection Institute

Tobi Colvin-Snyder, U.S. Environmental Protection Agency

Lawrence Hall, U.S. Department of Agriculture (USDA)

Jose Laborde, Guanajuato Ministry of Agriculture

Javier Morgado Gutierrez, Ciba Mexico

Amada Velez Mendez, Secretaria de Agricultura, Ganaderia y Desarrollo Rural

Bill Murray, Pest Management Regulatory Agency

Douglas Mutch, Canadian Grain Council (CGC)

Klaus Neverman, AMIFAC

Karen Pither, American Crop Protection Association

Claire Regan, Grocery Manufacturers of America

Edward Ruckert, Minor Crop Farmers Alliance

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Donald Stubbs, U.S. Environmental Protection Agency

Stephen Whitney, Canadian Produce Marketing Association (CPMA)/
Canadian Horticultural Council (CHC)