
TAB #2
Background on the North American Free Trade Agreement (NAFTA)
Technical Working Group On Pesticides

Introduction

In view of the increasing globalization in trade it is clear that the regulatory decisions of one country can have immediate effects on others. To address the need for closer cooperation, information and work sharing among Canada, the United States and Mexico, the NAFTA Technical Working Group on Pesticides (TWG) was formally established in March 1996. At its meeting in June 1997, the NAFTA TWG formalized its operational framework with the establishment of four technical subcommittees and a series of project teams.

Technical Working Group Structure

Technical Subcommittees have been established in four key areas. These subcommittees provide opportunity for stakeholder involvement in the development and implementation of specific projects:

- 1) *Joint Review of Chemical Pesticides*: develops compatible review programs to facilitate routine sharing of the work of pesticide regulation.
- 2) *Food Residues*: entails work that will create a process for establishing North American MRLs or tolerances for pesticide residues on foods, thereby helping to reduce agricultural impediments to trade.
- 3) *Risk Reduction*: coordinates work on alternative approaches to pest management, including facilitating access to biopesticides and supporting integrated pest management (IPM).
- 4) *Regulatory Capacity Building*: includes a diverse range of projects which contribute to the infrastructure necessary to achieve work sharing as the way to do business and create a North American market for pesticides.

The NAFTA Executive Board meets twice annually and the full NAFTA TWG once a year; detailed progress/status reports are published every six months. The most recent report was published in November 1998. These reports are available on the Internet, along with detailed project sheets and work plans. The US EPA site is:

<http://www.epa.gov/oppfead1/international/naftatwg>, while the PMRA site is <http://www.hc-sc.gc.ca/pmra-arla> under "international activities".

The next session of the full NAFTA TWG is scheduled for May 25-26, 1999 in San Antonio, Texas.

Highlights of the Activities/Achievements of the NAFTA TWG on Pesticides

Food Residues Subcommittee

- , In February 1999, the Subcommittee issued its annual call for the identification of NAFTA Category A pesticide trade irritants in conjunction with the publication of a revised version of “*Procedures for the Identification and Resolution of NAFTA Pesticide Trade Irritants*”.
- , The PMRA and EPA have agreed on a common approach to the use of probabilistic assessment methodology for acute dietary risk assessment.
- , Residue zone maps established for Canada and the US are being expanded to include Mexico. These scientifically defined common crop zones will facilitate the development of residue data.
- , Residue chemistry data requirements have been harmonized between Canada and the US. In June 1998, Canada published the *Residue Chemistry Guidelines (Regulatory Directive 98-02)* which provides details on the information required for the evaluation and assessment of pesticide residues in foods.
- , In October 1998, at the US Department of Agriculture Interregional 4 (IR-4) Planning Meeting, Canada and the US selected five pesticide/crop combinations as joint minor use projects for the 1999 field season. These include tebuconazole on green onions, pirimicarb on celery, pyridaben on cherries and azoxystrobin on broccoli and on cabbage.

Joint Review of Chemical Pesticides Subcommittee

- , Based on experiences gained through the implementation of the joint review process, the Joint Review Subcommittee published “*Revised Procedures for Joint Review*” in August 1998.
- , The first joint review, for the compound ***cyprodinil*** (Vanguard), was completed in April 1998. Cyprodinil is a fungicide developed by Novartis for use on fruit and nut crops.
- , The second joint review examined ***diflufenzopyr*** (Distinct, BASF), a herbicide developed for use on corn. The review was completed in January 1999
- , A final decision is pending for ***fenhexamid*** (Elevate, Tomen/Bayer), a fungicide for the control of grey mold on grapes, strawberries and ornamentals
- , Progress has also been demonstrated through work sharing activities:
 - < A final decision is pending for ***sulfosulfuron***, a herbicide for use in wheat (Monsanto). This is the first chemical jointly reviewed on an international basis by with Canada, the United States, Australia and the European Union (with Ireland as competent authority).

< Two other compounds, *Helix* and *Zoximide* are under review. *Helix* (Novartis) is an insecticide to be used as a seed treatment, and for ornamental, turf and greenhouse applications. *Zoximide* (Rohm and Haas) is a fungicide for use on potatoes and grapes.

, The process of cooperative reevaluation of older organophosphate and carbamate insecticides has led to an agreement to share information on the associated tolerance reassessment process to minimize trade problems.

Regulatory Capacity Building Subcommittee

, Efforts to harmonize environmental fate and toxicology protocols are nearing completion. Work remains to be done in the areas of non-target plant testing, and terrestrial field dissipation study protocols. Implementation of harmonized protocols will facilitate work sharing activities.

, A prototype of a Canada-US map of ecoregions for terrestrial field studies has been completed. The use of such a map will lead to reduced data development costs.

, Evaluators at the PMRA are in the process of assessing a pilot electronic submission, comparing three different electronic formats – CADDY, PDF and web-based.

, The first complete versions of the OECD Guidance documents to the preparation of industry data submissions and country data reviews will be released in the first quarter of 1999.

, A harmonized (US EPA - California EPA - PMRA) guideline document *Post application Exposure Monitoring Guidelines (Pro 98-04)* was released for comment in September 1998. The purpose of the document is to provide harmonized guidance in designing and implementing studies required to assess postapplication exposure.

, The redesign of the Pesticide Handlers and Exposure Database (PHED) has been completed. Release of the software is targeted for 1999.

, The Subcommittee has initiated a new project to formalize a process to exchange information of formulants, and to develop a harmonized formulants policy.

Risk Reduction Subcommittee

, The Subcommittee has developed stakeholder projects to promote IPM strategies for canola and for cranberry production.

, Data requirements for pheromones (semiochemicals) have been harmonized between Canada and the US and work is also underway on microbials. This work will support that of the OECD Pesticide Forum in this area.

, Joint reviews of a pheromone and a microbial are underway. The first biopesticide joint review for a pine shoot moth pheromone, for use in forestry, has just been completed.

, Draft guidelines for resistance management labeling have been developed.

A North American Initiative for Pesticides: Operation of the NAFTA Technical Working Group on Pesticides (NAI)

At the meeting of the NAFTA Technical Working Group on Pesticides in June 1997, a vision was discussed that within five years work sharing would be routine between the three NAFTA countries. This vision has now been articulated in a document called *A North American Initiative for Pesticides: Operation of the NAFTA Technical Working Group on Pesticides*. This document serves as a framework within which to pursue harmonization activities and ensure that individual activities of government and industry are coordinated and are effectively contributing to the longer term goal.

Through the North American Initiative, the federal governments of Canada, US and Mexico are striving to make work sharing the way of doing business by 2002 and to develop a North American market for pesticides, while maintaining current high levels of protection of public health and the environment and supporting the principles of sustainable pest management.

Objectives include encouraging a pesticide product designed with the North American market in mind, a common data submission and format for country data reviews, a coordinated review process, utilizing each country's reviews to the fullest, and a minimization of trade problems resulting from different Maximum Residue Limits (MRLs or tolerances) on agricultural commodities traded among the three countries.

Summary

This work has already begun to pay dividends by addressing specific trade irritants, often caused by national differences in Maximum Residue Limits, developing a better understanding of each regulatory agency's assessment practices, working to harmonize each country's procedures and requirements, and encouraging pesticide registrants (product owners) to make coordinated data submissions to the three NAFTA countries. NAFTA TWG partners include the Canadian Pest Management Regulatory Agency, a consortium of Mexican agencies (CICOPLAFEST) responsible for pesticide regulation, and the US EPA Office of Pesticide Programs.



NAFTA Technical Working Group on Pesticides
Grupo de Trabajo Técnico del TLCAN sobre plaguicidas
Groupe de travail technique de l'ALENA sur les pesticides

**A NORTH AMERICAN INITIATIVE FOR PESTICIDES:
OPERATION OF THE
NAFTA TECHNICAL WORKING GROUP
ON PESTICIDES**

November 6, 1998

A NORTH AMERICAN INITIATIVE FOR PESTICIDES: OPERATION OF THE NAFTA TECHNICAL WORKING GROUP ON PESTICIDES

In view of the increasing globalization in trade it is clear that the regulatory decisions of one country can have immediate effects on others. To address the need for closer cooperation, information and even work sharing among Canada, the United States and Mexico, the NAFTA Technical Working Group on Pesticides (NAFTA TWG) was formally established in March 1996. At its meeting in June 1997, the NAFTA TWG formalized its operational framework with the establishment of four technical subcommittees and a series of project teams. At the same time the countries articulated a vision for the future -- that within five years work sharing would be routine among them. This forward view has led to the development of the concept of a North American market for pesticides.

In order to work towards this objective, it is necessary to identify what needs to be done so that the work can be organized in the most efficient fashion. It is the purpose of this document to provide the conceptual framework for the work under way in the NAFTA TWG. The document may also be used as a tool by governments to help:

- < make decisions concerning the relative priority of projects;
- < ensure that the activities of government, industry and others are coordinated and are effectively contributing to the stated goals.

This proposed framework will evolve as a result of the ongoing review of the progress of the work of the NAFTA TWG.

Goals

1. To make work sharing the way of doing business among Canada, US and Mexico by 2002.
2. To develop a North American market for pesticides while maintaining current high levels of protection of public health and the environment and supporting the principles of sustainable pest management.

Objectives:

- C a pesticide product designed with the North American market in mind
- C a common data submission and format for country data reviews
- C a coordinated review process, utilizing each country's reviews to the fullest
- C a minimization of trade problems resulting from different Maximum Residue Limits (MRLs) on agricultural commodities traded among the three countries

To meet the objectives, consideration must be given to harmonizing (see attached graph):

- C data requirements
- C relevant test protocols
- C data submissions (dossiers) and study report formats (monographs)
- C data review and risk assessment practices
- C regulatory decision making
- C administrative processes and procedures

What is meant by harmonization?

Harmonization requires a complete understanding of the methods and practices used to regulate pesticides in other countries and a willingness on the part of all parties involved to work toward converging these approaches where necessary. This does not mean setting standards to the lowest common denominator, or simply accepting another country's decision, but rather finding acceptable approaches that will maintain current high levels of protection of the public health and the environment and support the principles of sustainable pest management.

The goal will be the minimization of any regulatory hurdles/impediments and the creation of a truly level playing field among NAFTA countries, so that if a manufacturer was to seek registration in only one country it would reflect a marketing decision rather than a difference in regulatory requirements.

Benefits arising from the activities of the NAFTA TWG:

- < Existing resources of both governments and industry will be used more effectively;
- < Resources needed to manage issues unique to national interests will become increasingly available;
- < Access to a wider range of safe and effective pest management tools will be facilitated;
- < Barriers to the trade in food resulting from differences in pesticide residue levels will be minimized;
- < Regulatory decisions will be consistent with the broader environmental and sustainable development goals of the NAFTA agreement

Incentives to public support: There will be an overall reduction in risk as newer, presumably, safer products will be available sooner to replace or supplement the use of older more "toxic" products; greater transparency in the regulatory processes and decision making; improved scientific assessments; enhanced environmental protection and the development of a North American approach to sustainable pest management.

Incentives to grower groups: There will be faster and simultaneous access to a wider range of pest control products, including those for minor use, which will facilitate effective pest management; alleviation of trade disruptions that arise as a result of technical differences in the levels of residues permitted in food.

Incentives to government participation include: increased efficiency in the regulatory process; decreased need for regulatory enforcement of trade irritants; enhanced scientific understanding of the nature of the risk, as reviewers learn from each other; resource savings that will enable a redirection of attention to those aspects of the submission or other issues unique to national interests, e.g. re-evaluation and risk reduction activities.

Incentives to pesticide industry participation include: greater efficiency with “integrated” review activity providing access to the North American market sooner than if three separate registration activities were undertaken; increased cost effectiveness of the process; good leverage to gain access to other markets being provided by North American registration.

Operation of the NAFTA TWG

The operational structure of the NAFTA TWG was amended in 1997 in order to meet the needs of the three countries and to ensure an effective and open process. The operation of the TWG will continue to evolve as experience is gained.

The wide range of projects associated with the NAFTA TWG clearly demonstrates the commitment on the part of the national governments to working toward a North American market for pesticides. It is also evident that reaching this goal depends upon the commitment and cooperation of government and industry (the pesticide registrants, grower, user groups) and the public. We need to continue to identify further opportunities to work cooperatively on the activities of the NAFTA TWG.

1. Role of Government

Each government has both individually and collectively examined its pesticide regulatory process, including: data requirements; scientific review processes; and decision-making criteria. As a first step, governments have committed to building on the current program of joint review and work sharing. This work will be facilitated by making full use of activities currently under way in other international fora such as the OECD Pesticide Forum and the Codex Alimentarius.

Data requirements: Governments are committed to the harmonization of data requirements. The data requirements for the use of agricultural chemicals on food commodities are being harmonized between Canada and the US. This represents the largest data set and will be a useful basis from which to approach other use site

categories for chemical pesticides. In the meantime, work is progressing to develop harmonized requirements for microbial pesticides and pheromones. In those instances where differences are warranted due to legal mandate or considerations such as climate, pest complexes, application methods or environmental concerns, a supporting rationale will be developed.

For example, Canada routinely requires submission and review of efficacy data while the US only routinely requires review of efficacy data for public health uses. For those chemicals subject to a joint review, however, Canada will be reviewing the efficacy data and the US will be using its reviews. In the case of the joint review of cyprodinil, the result was a lowering of the application rates originally proposed for use both in the US and Canada.

Study protocols/Test guidelines: Governments are working to identify those areas where there are differences in the way in which data are generated. The areas where there is perhaps the greatest difference are those of environmental fate and toxicology. A NAFTA project is in place to reconcile these differences and governments are working to ensure that their pesticide priorities are reflected in the work of the OECD Test Guidelines Program. The development of protocols/test guidelines through the OECD may be one area where a greater role could be played by pesticide manufacturers.

Data submissions and study report formats: In order to move forward the work of data generation and review, governments are examining the merits of adopting common formats for data submissions (dossiers) and the preparation of country data reviews (monographs). The OECD Pesticide Forum has adopted guidelines on the preparation of common formats for industry data submission (dossier) as well as for country data reviews (monographs). The OECD guidelines are based on work initiated within the European Community and are compatible with the formats utilized in its pesticide review program. The NAFTA countries are considering the adoption of the OECD formats as the basis for North American data submissions and country data reviews. Common formats are a fundamental factor in optimizing efficiencies from joint reviews and work sharing.

Data review/risk assessment: Governments are working to harmonize risk assessment procedures by: developing guidance to data reviewers for evaluation of specific studies/end points; and harmonizing the way exposure assessments (dietary and occupational) are conducted. Progress has been made in harmonizing the approach to the review of sub-chronic toxicology studies between Canada and the US through the OECD. A similar approach is under consideration for chronic toxicity and reproduction.

These activities are supported through the practical experience gained in the joint review program between Canada and the US and through the ad hoc exchange of reviews to

promote sharing of work with a broader range of OECD countries. This experience is helpful in refining the terminology and level of detail and promoting a true understanding of the relative significance of apparent differences. This process is a key component in developing a fuller knowledge of how countries conduct risk assessments.

Regulatory decision making: The experience gained in working together through the NAFTA TWG will lead to coordinated regulatory decision making among NAFTA countries. In keeping with the stated objective, governments aim to be in a position to issue coordinated decisions on a pesticide by 2002, recognizing that there may be national variations on specific product approvals or use patterns. There may be fundamental disagreements on the risks associated with a given substance; however, the reason for those differences will be transparent and will be supported by sound science.

Administrative processes and procedures: A coordinated process for making regulatory decisions and identifying opportunities for improvement will be best achieved through the ongoing program of joint reviews. The utilization of a common format for country data reviews (monographs) and decision documents will contribute to this process improvement. This will require further discussion and agreement on the procedures involved in the preparation of decision documents. Decision documents will need to state clearly the basis for regulatory decisions taken in the NAFTA countries. In those instances where different decisions are taken, the underlying rationale will be clearly explained.

2. Role of Pesticide Industry

Data submissions will need to be developed with a North American market in mind. This means that industry must factor this approach into its strategic planning for product formulation, data development and registration submissions over the medium-to-long term. In order to maximize opportunities for work sharing and regulatory efficiency on the part of governments, manufacturers will need to work with the NAFTA TWG to develop mechanisms to:

- C provide the same data set to all three countries in line with the format adopted within the OECD Pesticide Forum
- C coordinate product development, data submission and product distribution within the three countries

The joint review process represents an opportunity to pilot these cooperative mechanisms.

Pesticide manufacturers are in a unique position to work together to identify the key regulatory differences among the NAFTA countries (e.g. data requirements/protocols) and to work with governments in the appropriate fora (e.g. OECD Test Guidelines Programme) for the resolution of these differences.

The pesticide industry associations within the NAFTA countries have recently formed a NAFTA Industry Technical Working Group with the overall objective of coordinating/ harmonizing the North American industry position on NAFTA TWG issues.

3. Role of Grower Groups

Grower groups have a great deal to gain from the successful operation of the NAFTA TWG, as one of the results will be faster and simultaneous access to a greater range of products across North America. Growers are in a position to assist in the identification of inconsistencies in registrations and to encourage the pesticide industry to coordinate its data submissions across the three NAFTA countries. In addition growers play an important role in the definition of priorities for MRL harmonization and the development of the relevant data, particularly with respect to minor uses.

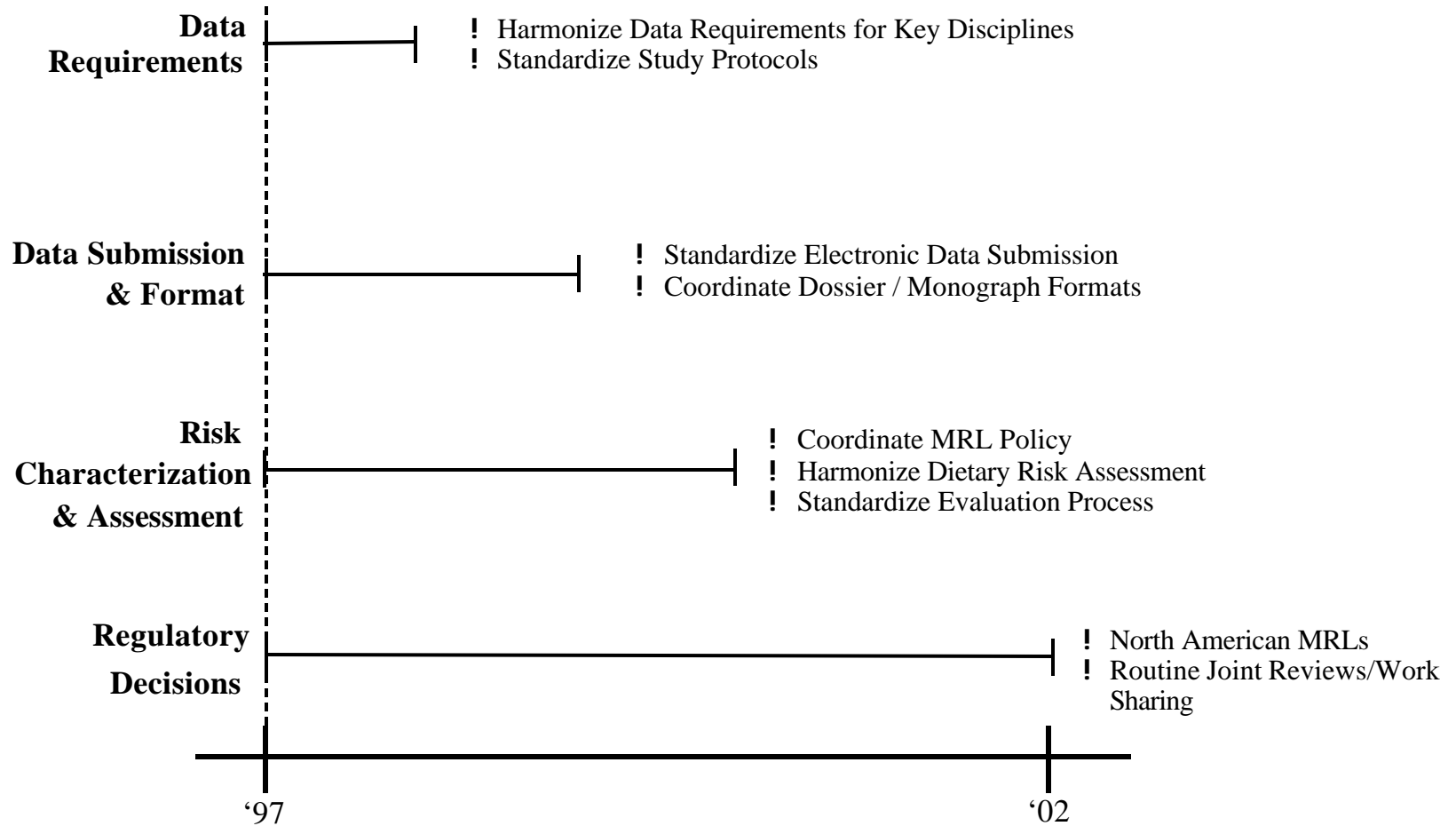
Grower groups along the US-Canada border have brought a number of pesticide harmonization issues to the attention of regulatory agencies within their countries, and at least one bilateral working group, representing the horticultural industry, has been formed.

Conclusion

This paper identifies the elements that should be included in the short, medium- and longer-term plans being made to meet the objective, by 2002, of having work sharing become the way that business is done among NAFTA countries and creating a North American market for pesticides. The preparation of such a plan will facilitate a better understanding of how the work of the NAFTA TWG might be most effectively organized. An initial attempt has been made to group the representative activities of the NAFTA TWG according to four general themes leading to the ultimate goal of coordinated regulatory decision making by December 2002. The ongoing development of this planning framework will be a report item at the meetings of the NAFTA TWG.

November 6, 1998

North American Initiative





NAFTA Technical Working Group on Pesticides
Grupo de Trabajo Técnico del TLCAN sobre plaguicidas
Groupe de travail technique de l'ALENA sur les pesticides

**PROCEDURES FOR THE
IDENTIFICATION
AND
RESOLUTION
OF
NAFTA PESTICIDE TRADE IRRITANTS**

Version 2

December 18, 1998

**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:

- c. 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:

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

- C 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;
- C the exporting country
- C the importing country
- C 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.

- C any available information explaining how the pesticide-commodity combination fulfils any applicable criteria listed in Appendix B

- C 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:

- C an incomplete toxicology data base
- C 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:

- C 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.

- C 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.

- C 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.

- C If accepted, the importing country then evaluates the proposed MRL/tolerance and moves to establish the required MRL/tolerance.

- C 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.

- C 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:

- c 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:

- c 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.
- c 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.

- C The company/user group should then work with the exporting country to provide sufficient data to establish the MRL/tolerance.

- C 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.

- C 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:

- c. 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.

- c. The member country that does not have the registered use should receive 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

application for the registration of the use and for the establishment of an 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.

- C 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.
- C 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.
- C 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:

- C 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.
- C 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.

- C 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.

- C 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.
- C 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.
- C 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:

- C The type of trade irritant (i.e. Category B, Category C, or Category D).
- C The name of the pesticide.
- C The name of the commodity for which use of the pesticide is a trade irritant.
- C 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").
- C The name and e-mail, phone number, or address of the person submitting the proposed trade irritant.
- C The name of the pesticide manufacturer, and the name and e-mail, phone number, or address of a contact person for the pesticide manufacturer.
- C The exporting country (Categories B and D), or the country where the pesticide-commodity combination is registered (Category C).
- 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 Subcommittee

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/pmra/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

Kim Meegan, Canadian Federation of Agriculture (CFA)

Donald Stubbs, U.S. Environmental Protection Agency

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