

NAFTA TWG on Pesticides Stakeholder Meeting
December 4, 2003
Vancouver, British Columbia

1) 5-Year Plan and Workplan

Janice Hopkins (Canada)

- Workplan was created to complement the second 5-Year Strategy and summarizes the key points of all ongoing and new projects.
- The 5-Year Strategy has been completed and will continue for a five year period.
- Workplan will be updated periodically to reflect changes to projects and any progress.
- Workplan will allow stakeholders the opportunity to contact country specific individuals responsible for each project.

2) GHS Implementation

Janice Hopkins (Canada) - Attached presentation slides

- GHS implementation will harmonize the classification of chemicals based on health and environmental hazards.
- Current status:
 - Canada held workshop in October 2003 with stakeholders directly affected by GHS implementation.
 - Canada is currently developing a pesticide sectoral working group.
 - Health Canada will be federal lead on GHS for all chemicals.
 - The federal U.S. and Mexican leads are to be determined.
- Issues of concern consist of how governments will harmonize, what will be the cost, how will it be implemented, education, and classification criteria.
- The TWG requests more stakeholder input on the development of this project.

3) NAFTA Label

Debbie Edwards (USA) - Attached presentation slides

- Growing interest to pilot a non-agricultural NAFTA label.
- NAFTA label will act as a standard to eliminate different labels in each country and reduce trade irritants.

4) Update on Joint Reviews

Richard Aucoin (Canada) - Attached presentation slides

- Update on number of registrations and current submissions.

5) Minor Use

Bob Holm (IR-4 USA)

- Canada has developed a minor use program similar to the U.S. IR-4.
- New projects are being explored between Canada and IR-4.
- Increasing collaboration with Mexico.
- Four new projects will be piloted as minor use Joint Reviews.
- IR-4 continues to share information with Agriculture Agri-Food Canada (AAFC) on chemical reviews and residue trials.

6) Formulant Programs

Brad Bergen (Canada) - Attached presentation slides

- Update provided on Canadian status and release of the Canadian Formulants Program and the list of formulants in Canadian registered products.

7) Electronic Harmonization

Kate Bouvé (USA) and Micheline Zdunich (Canada) - Attached presentation slides

- Canadian electronic assembly of submissions (E-index) will be piloted with three registrants (Bayer, Dow, Syngenta).
- Program uses an Excel spreadsheet for simplicity.
- Guidance document will be released in next two months and all Canadian indexes will be required to be submitted in this form.

8) Canadian proposal to revoke 0.1 ppm

Janice Hopkins (Canada)

- Revocation of the MRL will ensure that a scientific based MRL is established for every pesticide.
- Canada released a consultation document to revoke the default tolerance; thirty-six comments were received.
- Comments will be analyzed over the next few months.
- Results of the comments will be discussed with the TWG.
- Next steps include the development of a Regulation.

9) Worker Safety (Train-the-trainer)

Luis Mercado (Mexico) and Anne Lindsay (USA)

- Program has proved to be a great success in Mexico for training and information.
- Established courses for users / applicators / medical staff that teaches the risk of using pesticides, training of the trainer, diagnostic approaches, poisoning issues, etc.
- EPA has continually provided support to Mexico due to the established U.S. program.
- EPA is currently reassessing program for improvements to the quality of training.

10) Pulse and Tomato Projects

Debbie Edwards (USA) - Attached presentation slides

- Update and status of projects.

11) Harmonization of Assessments

Diana Somers (Canada) and Margaret Stasikowski (USA)

- MTD harmonization
 - Intention to expand project to all organ systems after successful completion on the liver and kidneys.
 - Project has moved under ILSI umbrella to facilitate broad participation by academia, industry (national and international), and regulators.
 - ILSI will publish guidance document by December 2004.
- Electronic Templates
 - Templates have been developed and piloted successfully.
 - Success of templates has been recognized on the international forum (OECD has launched a project to harmonize templates)
- MRLs
 - Currently existing harmonization project between Canada and the U.S.
 - Mathematical approach being implemented to eliminate the “case-by-case” approach.
 - Testing with existing data sets will occur in late January 2004.
 - Proposal to be released to stakeholders by late May / early June 2004.
 - Harmonized guidance document expected for October / November 2004.
- DNT Guidance
 - Project has moved under ILSI umbrella to facilitate broad participation by academia, industry (national and international), and regulators.
 - Guidance document will be finalized for publication by March 2004.

12) NAFTA Import Tolerance Document

Ariff Ally (Canada)

- Comments have been received and are currently being analyzed with the intent of incorporating them into the document.
- Common data submission, OECD guidance and OECD dossier will be the common format that will be used.
- Document expected final release in December 2004.

13) Adverse Effects reporting

Diana Somers (Canada) - Attached presentation slides

- Update on the status in Canada.

14) Break Out Group Report Back to Plenary

a) BOG 1: NAWG

- Facilitator: Lisa Lange (Therapeutic Products Directorate, Canada)
- Rapporteur: Brad Bergen (PMRA, Canada)
- Reporter back to plenary: Robert Kiefer, CSPA USA

Joint Review Submission Process for Non-Ag Products:

In order to facilitate increased submission of non-agricultural products into Canada and the U.S., the Canadian Therapeutic Products Directorate proposed that the existing Joint Review procedures be used as a model for developing a process for non-agricultural products. Industry indicated concerns, which hinder the submission of a non-agricultural candidate jointly to Canada, the U.S. and Mexico. These issues revolved around the differences in regulatory jurisdictions, fees, and data requirements all of which generate trade irritants.

Further discussion would be required to determine incentives to promote joint submissions, which could involve reduced fees and timelines (e.g. a joint fee for sharing). Industry proposed that the joint review process be expanded to include new end uses for existing active ingredients. The joint review process is a catalyst for the development of harmonized data requirements between the NAFTA countries, thus industry was invited to propose a non-agricultural candidate that could be piloted.

Industry proposed that an industry / government task force be created to facilitate the identification of a process to move forward on these issues.

Action: Industry was tasked to propose a non-agricultural candidate for a pilot joint review.

Harmonization of Data Requirements:

Industry emphasized the need to complete the existing NAFTA TWG project on the harmonization of non-agricultural data requirements. The forward movement of this project is pending the finalization of 40CFR Part 158, new Subpart W and OPPTS Series 810 Product Performance (Efficacy) Test Guidelines.

Action: The U.S. to follow up on 40CFR Part 158, new Subpart W.

Public Health Pesticides:

Industry emphasized the importance to gain tri-lateral agreement on the Public Health pesticide definition. Recognition and identification of public health benefits provided by non-agricultural pesticides is important and industry proposed to develop a White Paper for NAFTA TWG consideration.

The NAFTA TWG and industry need to work together to promote the use of friendlier, less toxic, efficacious products while balancing risks with benefits of public health pesticides. In addition, the benefits of public health pesticides need to be communicated to the public while ensuring that risk

management is upheld - risk communication.

There is a need to establish a process to ensure that important public health uses are not removed through the re-evaluation process of agricultural pesticides with non-agricultural uses (e.g. pesticides for mosquito control).

Inerts / Formulants:

Industry emphasized their concern regarding Canada's new legislation requiring the disclosure of List 2 formulants on product labels. Disclosure on Canadian labels will be of most concern with respect to Confidential Business Information (CBI), liability issues, confidential formulation information, data compensation / data protection and the business of trade. This is not a requirement in the U.S. and would consequently cause trade irritants and potential unavailability of pesticide products in Canada.

Industry recommended that implementation of disclosure in Canada be put on hold until the U.S. tolerance reassessment is completed in 2006. Canada is open to receiving data for assessment prior to the close of EPA's reassessment process in order to facilitate review in Canada. Benefits could result in the transfer of a List 2 to another list if the data is supportive.

Opportunities for Mexican Involvement:

NAWG emphasized the importance of CICLOPLAFEST (Mexico) to harmonize test and labelling requirements with Canada and the U.S. in order to avoid and remedy trade irritants. It would be beneficial to streamline the Mexican review process for domestic products as well as differentiate and recognize the differences between agricultural and non-agricultural products in the registration process. Further identification of Mexican public health projects is needed.

There is progress in the Mexican government to distinguish urban use pesticides versus agricultural pesticides as well as domestic versus non-agricultural products. Several issues involving risk communication, labelling standards, less toxic products and alternatives are being explored and will impact on future policies.

Action: Industry to identify a public health product that could be done tri-laterally in a joint manner (e.g. mosquitoes, rodents).

GHS Implementation:

The NAFTA TWG and industry are working together to obtain a standardized label that will apply to all products including pesticides. Canada is currently very coordinated in their development of a process for implementation. EPA is in preliminary stages of development while Mexico is participating to determine the acceptability and applicability of GHS in Mexico. Industry indicated that work in this area needs to be done in a harmonized approach in order to avoid development of a different labelling standard.

NAFTA Label:

A NAFTA label working group was formed which analyzed the requirements by each country in the

context of GHS, agricultural and non-agricultural products. Results from the working group provided a clear indication of differences and similarities as well as possible impediments.

Industry proposed the initiation of a pilot project to address a non-agricultural NAFTA label. The TWG was supportive of the proposal and indicated the need to obtain commitment from all governments as well as industry to go forward. A hard surface disinfectant was suggested as a potential candidate due to its similar use pattern across all countries. Secretariat should follow-up on identifying this pilot as a potential NAFTA project.

Other:

NAWG emphasized the desire to form a non-agricultural subcommittee to be part of the NAFTA TWG.

b) BOG 2A: Minor Use and Risk Reduction

- Facilitator: Anne Lindsay (EPA, USA)
- Rapporteur: Brian Belliveau (PMRA, Canada)
- Reporter back to plenary: Karen Pither (Pither Consulting, LLC - USA) and Marian Partridge (BC Greenhouse Growers Association - Canada)

Minor uses:

Industry raised the issue of the need for import tolerances – otherwise a country encounters trade barriers when exporting a minor crop. Collaboration in minor use among growers on a North American basis, and ways to integrate government and industry efforts, were discussed.

Submission barriers:

Efficacy and crop tolerance data requirements were raised, particularly for Canada, where active ingredients, registered in the U.S. and not Canada, are inaccessible to Canadian growers. Zone maps and data requirements, especially in border areas, need to be addressed. There are also differences in the way that occupational exposure is addressed between Canada and the United States.

Crop grouping / MRL setting needs to be North-America-wide. Some obstacles were mentioned in the lack of a crop grouping process in Mexico where a U.S. tolerance is required before submissions are received. Since in Mexico there must be evidence of a U.S. MRL before the application, and before products are exported, barriers to submission arise and Mexican growers are precluded from using products available in the U.S. and Canada. Mexico would like to see more US and Canadian registered products registered in Mexico, especially microbial pesticides.

Mexican growers would like standardized registration for all three countries. Due to excessive paperwork and inefficiency, many Mexican companies have difficulty getting registration. One reason for this problem is that there are no timelines set for registration.

Through IR-4's efforts, registrants are being encouraged to register their crops. IR-4 is working well and sharing experiences with the AAFC.

In regards to MRL submissions, in Canada efforts are underway to address the length of time that is required to establish an MRL. Canada and Mexico should consider using mechanisms similar to Section 18 (Emergency Use Exemption) and 24C in the U.S., which are useful tools for addressing minor use problems.

How can grower associations coordinate and work together to obtain an import MRL? There was also a question regarding how to advise growers in Mexico regarding what pesticides to use on their products (e.g. apples) to avoid problems at the border.

Risk Reduction:

Increased submission of reduced risk products and the prioritization of reduced risk pesticides for regulatory review was another issue raised in this group. EPA works with IR-4 on a process that allows growers to prioritize reduced risk products (including import MRLs).

Challenges are being experienced in meeting reduced risk criteria and therefore, categorization, because of inability to prove a product is better than an alternative for a new pest.

Integrated Pest Management (IPM) centers support grower groups in developing pest management strategic plans and crop profiles to get more grower input and to prioritize strategies. There were questions about how these plans are used and by whom. There is a need for feedback on the use of crop profiles and strategies.

Efficacy testing has to be done on a “real” crop basis – how can this be done when the crops are very valuable?

Concerns were raised regarding problems of disposal of pesticide products in Mexico. The “Clean Fields” initiative in Mexico is based on a shared responsibility approach where all actors (government, consumers) have a certain degree of responsibility to deal with these types of products. In the U.S., state agencies are working on “Clean Sweep” programs for disposal of discontinued / leftover products. The EPA is also working on a national standard using programs adopted by states and manufacturers. In Canada, CropLife Canada has a stewardship program with provinces for agricultural pesticides focusing on disposable containers. There are also warehouse standards for agricultural use as well as an industry stewardship program being developed for homeowners.

c) BOG 2B: MRLs and NAFTA label

- Facilitator: Debbie Edwards (EPA, USA)
- Rapporteur: Trish MacQuarrie (PMRA, Canada)
- Reporter back to plenary: Chris Warfield, Bayer Canada

Outcomes of the San Antonio Meeting:

Industry reiterated the outcomes of the NAFTA TWG meeting held in San Antonio, Texas in May 1999. The barriers identified consisted of different regulatory requirements in each country (e.g. efficacy tolerance studies for tank mixes), differing labeling requirements, varying application rates in each country, and different review times. The positive incentives identified consisted of the

centralization of the administration of registrations and submissions in each country, the removal of formal efficacy reviews in Canada, the introduction of a notification process in Canada for efficacy data, and the development of a base label that would contain registration information from all NAFTA countries. The latter would allow for free product movement and country specific labels would be provided at the point of sale or use.

NAFTA Label:

Industry emphasized that the creation of a NAFTA label would allow free movement of products over borders, could facilitate crop marketing, curb illegal use of pesticide products, reduce price disparities, and aid in the harmonization of MRLs.

Issues relating to the creation of a NAFTA label would consist of creating the need to produce instructions for each country in three languages and consequently increase the illegal use of products.

Industry proposed that NAFTA labels could be used only for regional issues in order to simplify rates and label complexities. Consideration could be given to simultaneous submission for all crops in all countries. Pesticide agencies should conduct a legal review to identify necessary regulatory changes to support a NAFTA label. A non-agricultural product could be used to pilot the NAFTA label since there are no concerns relating to MRLs and labels tend to be simpler. Work should be done with existing labels, which would allow the products to be sold until the NAFTA label was finalized. Industry proposed that other options be explored that deal with pricing issues (e.g. Canada's Own Use Import Program - OUI, Dorgan Bill, create U.S. version).

Industry indicated that NAFTA countries should ensure the same end-points are chosen and that GHS be implemented simultaneously.

MRL Discrepancies:

Industry expressed the need to standardize MRLs in the NAFTA countries due to the differences that often arise in the way MRLs are determined in each country. Suggestions were made to harmonize methodologies and administrative processes for the establishment of MRLs. Emphasis was put on the need for the establishment of procedures for National MRLs and import tolerances in Mexico.

In the situation that an MRL issue is related to a reduced risk product, the NAFTA governments should be notified immediately in order to facilitate this item as a priority issue to be addressed. NAFTA should also harmonize with the Joint Meeting on Pesticides Residues (JMPR) and the Organization for Economic Cooperation and Development (OECD) in the determination of MRLs and evaluation procedures.

Industry requested that Canada consider the possibilities of time-limited emergency tolerances as well as revisit the Canadian policy that does not allow acceptance of applications for import tolerances until registration is obtained in another country.

Actions:

- Industry will make available the minutes of San Antonio meeting to the NAFTA TWG.
- Growers will choose existing products to pilot, preferably something done as a joint review.

d) BOG 2C: Joint Review and Electronic Issues

- Facilitator: Mark Brohm (PMRA, Canada)
- Rapporteur: Kate Bouvé (EPA, USA)
- Reporter back to plenary: Craig Hunter, Canadian Horticultural Council

NAFTA Label:

Participants identified some barriers to the development of a NAFTA label. There are disparities in label requirements among the three countries (e.g. different rates in each country). Should all three approve identical labels? A unique NAFTA label would require harmonization of signal words and symbols and directions in three languages. GHS would solve some problems, although metric versus imperial remains. The label benefit would be to facilitate movement of product across borders.

Joint Review:

Discussion focused on the benefits and constraints of joint reviews and work sharing. Mexico cited the benefits of a stepwise approach to joint reviews and Canada noted efforts in efficacy harmonization with Mexico.

There are many benefits from simultaneous joint reviews, but implementation depends on agreement by companies for information sharing among countries.

The use of the zone maps was put forward as a method of facilitating the registration process by reducing the number of trials required. Regionalized zone maps with Mexico are a NAFTA project and have been finalized. Mexico has harmonized several zones with the U.S., but these are not yet finalized. There was also a suggestion to reduce the number of trials required on a North American basis.

Timelines for joint reviews were raised. It was noted that the U.S. may have service standards as a result of fee-for-service legislation.

Mexico noted that it is clear for everyone that joint review is a benefit now and in the future, although there are concerns regarding data protection, and the Mexican government will have to think about a mechanism. There was a suggestion that exclusive use of data and compensation should be the same among the three countries.

Participants raised concern about the need for more efficacy data for Canada and that such data could drive the maximum rate, as well as the need for efficacy data up-front. Submission of a “staggered submission” with efficacy data submitted later was proposed.

There was interest in increasing the number of biopesticide products, especially in Canada. One

suggestion was for government staff to help biopesticide applicants prepare good submissions.

In summary, with respect to joint reviews:

- Industry noted that they applaud joint reviews.
- Residue zone map work should be finished and applied in the registration process.
- Import tolerance guidelines need to be completed.
- Data compensation / exclusive use needs to be addressed in Mexico, in procedural rules that are harmonized with the U.S. and Canada.
- Permission from industry to share reviews across countries, and to work share is very important - especially for biopesticides and antimicrobials.

Electronic Submission and Review:

There was discussion of the ability to submit electronic submissions in a secure fashion that will soon be possible in Canada. The E-index was also discussed. The use of templates for studies by industry in preparing their reports was identified as important in reducing submission rejection rates. The value of OECD Tier summaries was questioned.

15) Public Comment Period

- Pulse Canada (Don Sissons and Mark Goodwin) / North Dakota Department of Agriculture and North Dakota Dry Pea and Lentil Association (Jim Gray and Richard Haugeberg)
 - Pulse growers in Canada and the U.S. presented the perspective shared by growers across North America illustrating concerns that there is a need to have better and increased access to the appropriate tools for pest management. Some of the current older tools / pesticides are under regulatory threat due to re-evaluations / re-registrations. Lack of attention given to pulse crops will result in pulses becoming a “minor crop”. Resolution of these issues may be met by the following: increasing free trade and movement of pesticide-treated commodities through harmonization of MRLs, market de-segmentation and price equity; providing equal access to pesticide uses; and regulatory harmonization. Pulse growers emphasized the need to provide rapid access to reduced risk pest management alternatives. Pulse growers indicated the enthusiasm to work with the regulatory bodies to resolve these issues.
- IWG - Mexico (Angel Saavedra)
 - The Mexican industry has commented on many of the projects, which are currently ongoing. This is all based on the elimination of barriers. Agricultural products have been the main focus. However, we should be focussing on issues that require objective responses. Mexico urgently wants to harmonize MRLs and needs to work intensely in order to link to the other regulators for on-site studies (e.g. zone maps). For three years, Mexico has been trying to include this procedure, but nothing has been written down. This issue is very important in the case of emergency uses. Mexico hopes that it will be established in 2004 and that experience from the other countries can be learned as well as increasing Mexican participation in existing processes. Mexico wants to work with the TWG as much as possible in areas such

as Joint Review.

- IWG - USA (Jo Wisk)
 - Concerns were reiterated about MRLs including different levels and different timing for publishing them. Some of the causes suggested include different processes for setting MRLs, the Canadian Gazetting policy, delay in reviewing a Canadian import tolerance petition until a U.S. registration is granted, delay in Mexican registration process until a U.S. tolerance is established, and the elimination of the Canadian default tolerance at 0.1 ppm possibly causing future problems. The IWG-USA suggested that the TWG prioritize the projects underway, but they were also encouraged by the current Analyzing MRLs project.

- IWG - Canada (Jennifer Ballantine)
 - The primary objective of the TWG was reiterated as follows: “Facilitate cost effective pesticide regulation and trade among the three countries through harmonization and work sharing, while recognizing the environmental, ecological and human health objectives of the NAFTA.” The IWG’s goal is to eliminate trade barriers through a focus on the harmonization of MRLs and the establishment of NAFTA MRLs. Some of the process concerns identified by IWG-Canada included the tail-gating policy and import tolerance applications. Some concerns related to the assessment of pesticides included different MRLs being set despite using the same data sets, even in Joint Reviews, and less crops being put on labels due to the Canadian risk cup being smaller. Another concern raised by the IWG-Canada is the cost of import tolerance submissions. The IWG-Canada recommended that the 5-Year Strategy focus on addressing trade issues and that the TWG prioritize the projects being undertaken by the NAFTA countries.

- Unifrut Apple Growers - Chihuahua, Mexico (Carlos Chavez)
 - The Mexican apple growers would like to count on the same products that are available to Canada and the U.S. as there are currently a very limited number of available products in Mexico. This is a major disadvantage to Mexico when competing in the same market. Growers want to be informed of new products, applications, and residue chemistry. It is known that the information is available, but not so for Mexican growers. Growers are supportive of harmonization in order to reduce trade barriers. There are serious issues with respect to disposal of pesticide products, which needs to be addressed. The companies are not taking proper care of disposals and this affects growers as well due to the lack of education on the issues of contamination of the environment and water. Many of the pesticides sold in Mexico are very expensive which opens the market for the smuggling of products from the U.S., which are not registered in Mexico. Due to the lack of education, many pesticides that are high or low risk are handled in the same manner, with implications for worker safety, environment and persistent health problems. Over-use of bactericides in pest control is causing resistance in humans when treating common diseases. The TWG should consider these issues carefully as many of the

Mexican products are exported to other countries. Also growers would like imported commodities analyzed for residues in the same manner that is done when exporting to other countries.

- CCSPA Canada (Shannon Coombs)
 - There are major issues and concerns with respect to the List 2 formulant disclosures on Canadian labels since it is not required on U.S. labels. There are anticipated serious implications and repercussions due to this if allowed to follow through.

- Canadian Horticultural Council (Anne Fowlie and Craig Hunter)
 - Growers sometimes feel excluded in some of the decisions made and would like increased participation on the TWG decisions, progress and projects. There are currently thirty-eight projects that are in progress or new in the Workplan. These should be prioritized in order to distribute resources appropriately and to produce good results. Otherwise, the non-priority projects should be removed from the Workplan. The sub-zone problems and residue project need to be resolved. The TWG should make a strong commitment to complete projects instead of repeating them each year at the meetings. Growers want more tools to be made available to increase productivity and reduce trade irritants. Growers are supportive of increasing efficiency of registrations through electronic submissions.

16) Closing Remarks

The Co-chairs expressed their appreciation for the participation by stakeholders, and the extensive input and advice that has been offered to the TWG Executive Board.

Highlights from the Executive Board Meeting

- The Executive Board exchanged information on significant developments taking place domestically. The United States highlighted the proposed fee for service legislation. Mexico reported on rule-making efforts for pesticide registrations. Canada provided a status report concerning their efforts to implement the new *Pest Control Products Act* (PCPA).
- Following status reports from each of the TWG Subcommittees, the Executive Board approved the following new projects: Dietary Exposure Assessment Methodologies, Priority List for Minor Uses, Analyzing Maximum Residue Levels, Pulse and Tomato Pilot Projects, GHS Implementation, MTD Harmonization, and DNT Evaluation Guidance.
- After carefully considering the feasibility of establishing a new subcommittee focused on non-agricultural issues, the Executive Board decided that the current TWG structure adequately accommodates areas of interest and concern raised by the NAWG. Instead, ways of highlighting the importance and increasing the visibility of NAWG issues will be actively explored. For example, the TWG will work with the NAWG to encourage pilot joint reviews, including public health pesticides of importance (vector / mosquito control), and NAFTA label submissions. The governments will pursue harmonization opportunities on data requirements, particularly as the U.S. develops domestic requirements under 40 CFR 158W.
- In the area of minor use, the Executive Board approved several pilot Joint Review projects, including joint reviews of submissions prepared by the U.S. IR-4 and Agriculture and Agri-Food Canada (AAFC), and agreed to explore options for potential improvement in the use of zone maps and conduct of trials. Additionally, the governments will participate in a new U.S. initiative to expand croup groupings.
- The TWG will explore the development of NAFTA labels for products already registered through the Joint Review process, and will continue to encourage registrants to submit new Joint Reviews.
- Canada and the United States will pursue more capacity building activities with Mexico, specifically with respect to formulants / inerts and dietary risk assessments.
- The Executive Board also discussed several cross-cutting issues such as the importance of developing performance / accountability measures and broadening stakeholder participation in the work of the TWG.