

NAFTA TWG on Pesticides Meeting

December 5th, 2002

New Orleans

Introduction:

Marcia Mulkey, Director, Office of Pesticide Programs, EPA, United States:

Began by welcoming everyone to the meeting and thanking the Secretariat for putting everything together. She proceeded to introduce the TWG members sitting at the table.

- Janice Hopkins, Director, Alternative Strategies and Regulatory Affairs Division, PMRA, Canada.
- Leonor Cedillo, Director of Risk Analysis, Ministry of Environmental Health, Mexico.
- Jim Jones, Deputy Director, Office of Pesticide Programs, US EPA.
- Anne Lindsay, Director, Field and External Affairs Division, OPP, US EPA.
- Diana Somers, Director, Health Evaluation Division, PMRA, Canada.
- Ian Chisholm, Evaluator, Therapeutic Products Division, Canada.
- Amada Vélez, Director of Service and Technical Support, Ministry of Agriculture, Mexico.
- Armando Flores, Director of Residues and Hazardous Activities, Ministry of Environment, Mexico.

She gave a brief overview of what the day would look like, and moved on to the short updates.

Short updates:

i) Canada's Minor Use Program:

Janice Hopkins:

- There has been a concern in Canada surrounding the availability of pesticides for minor crops.
- This spring, additional funding was made available for a reduced risk program that incorporated minor uses.
- This program is similar to IR-4 in the US, and would allow Canada to work with IR-4 as well as with registrants.
- Imme Gerke was appointed as the minor use coordinator.
- This program will continue to emphasize joint reviews among NAFTA countries.

ii) IR-4/ Mexico activities:

Amada Vélez:

- During more than 5 years, our main concern has been the setting of MRLs that would facilitate trade.
- Mexico needs to develop an infrastructure that would ensure that the best agricultural practices are commonplace.
- IR-4 has offered to work with researchers in Mexico so that Mexico can develop MRL program.

Dan Kunkel, IR-4:

- IR-4's joint research with Canada has resulted in more than 100 trials. They are happy to start work with Mexico.
- IR-4 worked with Mexican scientists to give an overview of the IR-4 activities, the goal of the organization.
- The Mexican scientists then went to IR-4 facilities in New Jersey to see the laboratory practices. They also toured IR-4 facilities in Florida.
- IR-4 is looking forward to future activities with Mexico.

iii) Update on Joint Review Activities:

Charalyn Kriz, PMRA:

- 10 joint reviews completed in 2002, resulting in 3 new active ingredients and a total of 7 end-use products were granted registration.
- Reduced risk insecticide acetamiprid was registered in March 2002 by EPA, and in June 2002 by PMRA, with four affiliated end-use products - Pristine RTU (for homeowner use), Assail 70WP, Chipco Tristar 70WSP, and Adjust 70WP.
- Pyraclostrobin was registered by EPA in September 2002; it should be registered by PMRA by the end of 2002, with two end-use products- Headline EC and Cabrio EC.
- *Pseudozyma flocculosa* and its end-use product Sporodex WP Biological Fungicide have been registered by PMRA in May 2002 and by EPA in September 2002.
- We completed the first joint review minor use registration for the reduced risk fungicide fenhexamid in April 2002.
- For foramsulfuron, a work share review, EPA conducted a parallel review with Germany and EPA registered foramsulfuron and a safener in March 2002. PMRA will complete work on these submissions by winter 2003.
- Iodosulfuron methyl sodium was registered by EPA in September 2002 EPA. PMRA will complete work by winter 2003.
- An import MRL for iprovalicarb, a fungicide for imported grapes, raisins, and wine, was completed by PMRA in May 2001, while EPA completed the review in July 2002.
- The import MRL for tolylfluanid for use on imported apples, grapes, hops, and tomatoes was completed in August 2002 by EPA, and will be completed by PMRA in winter 2003.
- Potential joint review submissions expected in the next calendar year include a herbicide for use on corn, a fungicide for foliar use on wheat, barley, canola and pulse crops (rice and peanuts in US only), and some potential biopesticides.
- In October, EPA and PMRA met with registrants and each other to discuss the positive and negative aspects of the Joint Review process in detail.

iv) Update on OECD IT Workshop

Diana Somers:

- The objects of the sessions was to demonstrate value to both industry and regulatory agencies of:
 - standard formats (templates) for individual study reviews.

- templates for electronic document assembly / generation with efficiency.
- Some of the challenges that have to be overcome:
 - data received in variable formats.
 - variable level of detail in reviews.
- These lead to: inefficient peer review, inefficient document generation for reviewers and registrants, as well as difficulties in joint review and work shares.
- Therefore, the solution is Electronic Templates for:
 - Study Reviews:
 - developed standardized review templates, individual studies, available for each scientific discipline.
 - could be a NAFTA project.
 - Summary Documents:
 - developed additional critical templates and formats for summary science documents, summary tables, risk assessments, public consultation and decision documents.
 - Administrative documents:
 - memos, labels, correspondence, deficiency notes and registration letters.
- Benefit of Template Approach for the Regulatory Process:
 - consistent quality and level of detail.
 - minimize hunt and search.
 - transparent decision tree.
 - efficient for peer review.
- International Harmonization/ Work sharing:
 - common format for all review activity at international level.
 - facilitates international sharing of reviews.
 - acceptable level of detail for decisions.
 - efficiency gains.
- The use of electronic template as an efficient interface between an electronic submission and a PMRA review.
- These templates can be used to generate subsequent documents.

v) Update on cumulative risk assessment process:

Susan Lewis, US EPA:

- Comparison of Individual and Cumulative Risk Assessment.
 - Individual Assessment:
 - Focus is on specific chemical.
 - Goal- determine “safe” level for most sensitive endpoint.
 - Considers all effects and exposures.
 - Cumulative Assessment:
 - Emphasis on the effect shared by members of the common mechanism group.
 - Considers relative potency of chemicals in the group.
 - Must look at the likelihood of co-occurrence of exposures.

- Public Participation Process- OPs.
 - 5 Technical Briefings.
 - Drinking Water Methodology Workshop.
 - Many Science Advisory Panel meetings.
 - Preliminary assessment – public comment.
 - Release revised assessment 6/02 public comment.
- Next Steps for OP Cumulative.
 - Address comments received from the June 2002 assessment and SAP.
 - Complete remaining OPs for individual assessments- Dimethoate (DDVP), Methyl Parathion (Malathion).
- Additional information- www.epa.gov/pesticides/cumulative.

vi) NAFTA import tolerance document:

Lois Rossi, US EPA:

- Comments on the NAFTA import tolerance document have been received from government partners in Canada, Mexico and the United States.
- The NAFTA import tolerance document is currently undergoing revision.
- After stakeholder comments we are seeking to finalize the document.

vii) NAFTA Label

Terri Stowe, US EPA:

- Efforts currently focus on the harmonization of labeling requirements between EPA and PMRA with an ultimate goal of enabling registrants to submit a "NAFTA" label that will satisfy labeling requirements of all NAFTA countries.
- The NAFTA label workgroup reviewed two NAFTA labels, TI-435 and Sporodex L in an attempt to harmonize basic labeling elements and labeling language. The workgroup succeeded in developing a NAFTA label for the Sporodex L product; however, the registrant decided to use the NAFTA label in Canada only.
- Many of the issues requiring regulation changes for a NAFTA label may be resolved by the GHS implementation.
- EPA and PMRA labeling regulations require different toxicity endpoints to determine required precautionary signal words, which may be the biggest hurdle to implementing a NAFTA label.
- Growers need to provide input to industry/government regarding which product labels they would like to see proposed for a NAFTA label under the NAFTA joint review program.
- The Non-Agricultural Working Group (NAWG) has expressed interest in developing NAFTA labels for consumer products, offering a potential expansion of the NAFTA label program.
- We will continue to discuss and identify potential legal and enforcement issues with NAFTA labels and how to resolve them.

viii) Update on worker safety activities

Anne Lindsay:

- The train-the-trainer program with Mexico began three years ago, with the US and Mexico looking to integrate their programs.
- This project is still growing.
- The TWG has also been working on the Pesticide Applicator Core Exams, a project between the US and Canada.
- The project started in May 2000. Actual applicators participated in this, and developed the blue print of knowledge.
- We are currently field testing the exam and developing the grading system.
- The US will work with 6 of the states, and Canada with 2 of the provinces.

ix) Update on CEC activities:

Renée Salas, Ministry of Health, Mexico:

- The North American Commission for Environmental Cooperation is currently promoting a sound management of chemicals initiative.
- North American Regional Action Plans (NARAP) include Lindane- new initiative, DDT- closing stage and Chlordane- closing stage.
 - The objective of the DDT project is to reduce human and environmental exposure to this compound and its metabolites.
 - Goals include reducing the use of DDT in Mexico for malaria control by 80% in 5 years, eliminating the illegal use of DDT in agricultural activities and increasing international cooperation to improve the implementation of international controls over production, export and use of DDT.
 - NARAP objectives have been accomplished, Mexico's experience has been shared throughout the Central and South American region and a new proposal for a "GEF program" will include 9 demonstration projects.
- The objective of the chlordane project is to reduce human and environmental exposure to this compound through the elimination of its currently authorized uses.
 - Objectives were accomplished to a certain extent, but there are still some specific details that each country must deal with on an individual basis.
- Children's Environmental Health (CEH) has implemented an indicators project to document pesticide acute poisoning cases. The CEH is also sponsoring a workshop on child-based pesticide risk assessment.

There were no questions for the presenters.

Presentation on draft 5 yr initiative:

Anne Lindsay:

- Provided a short introduction to the document:
 - The NAFTA TWG was established to address pesticide regulatory harmonization concerns of the three countries.
 - Our original goals were: 1- make work sharing the way of doing business in North America; 2- develop a North American market for pesticides, while maintaining a high

standard for the protection of human health and the environment.

- Our new document reflects a vision of North America as the world's model for safety.
- The draft came from: stakeholder comments, government findings, last year's meeting's break out groups, and individual recommendations.
- The objectives were made to encompass the suggestions we received.
- There was a high diversity of themes from the comments we received, which makes drafting a vision document difficult. We are going to be working towards finalizing the document with these suggestions.
- Many of the comments call for more frequent trilateral work, and mention that developing specific milestones would be of great benefit.
- The topics for the break out groups today reflect our desire to get more in depth comments on the 5 year initiative.
- During the public comment period at the end of the day, stakeholders will have the chance to make final remarks.
- The floor was opened for comments/questions.

Mark Goodwin, Pulse Canada:

- Expressed a very firm belief that the TWG needs a road map, and not a compass. The document as it stands, does not provide this. It needs more detail.

Chuck Beach, CCSPA, SC Johnson, Canada:

- Does the minor use initiative in Canada apply to non-agricultural products?
- Canada is almost committed to GHS. Would that guide the development of a NAFTA label, or is it going to be the other way around?
- Would GHS apply to labeling standards in Health Canada as a whole?

Janice Hopkins:

- The minor use initiative is directed towards agricultural products only.
- Regarding GHS, there will be a common approach across Health Canada. Not only that, but Health Canada will be working with Transport Canada as well. There will be a common approach to all products that will be affected by GHS. It is anticipated that GHS will be adopted in Canada before 2008. They are now preparing a consultation document and are forming a stakeholder group.

Marcia Mulkey:

- The NAFTA label would not wait for GHS. It may serve as an opportunity to pilot GHS.

Louis Arnold, grower from North Dakota:

- NAFTA TWG began in order to address agricultural trade and is now moving to bring in non-agricultural stakeholders. It is not in the mandate of the TWG to address non-agricultural issues.

Patricia Ballamingie, WWF Canada:

- Her concerns are with health and environmental protection.

- Risk reduction and movement to safer pesticide goals should be stated explicitly in the 5 year initiative document.
- Cited NAFTA environmental side agreement.

Has Shah, ACC, and NAWG:

- Strongly disagrees with Louis Arnold. The agricultural activities have a direct impact on the non-agricultural industry. Therefore the non-agricultural industry should be taken into consideration.

Break out groups :

More detailed notes on the break out group discussions can be found in the appendices.

Group 2:

MRLs & Minor Use

Harmonization of MRL's:

- Harmonized MRLs for all new use and reassessments.
- Common MRL solves shipping issues when growers are unaware of final destination.
- Simultaneous MRL establishment important for reducing trade barriers.
- Regulatory agencies need to reduce barriers to trade, pesticide use and access to pest management tools.
- Use of databases (both public and private) for tracking crop uses, MRLs and violations will help to define priorities. Most important is the need to understand grower priorities.

Minor Use:

- High expectations on Canada's minor use program to address existing issues. No definition of minor use and no program in Mexico, but grower impact is trilateral.
- Need a harmonized minor use submission process.
- Trilateral prioritization of minor uses and trilateral efficacy issues need to be determined.
- Differences in incentives (i.e., FQPA), marketing strategies and costs will affect priorities.
- Impact of emergency exemptions or special local registration needs to be addressed.
- Harmonized crop group definitions and residue zones (CODEX, OECD).

Group 3

Work Sharing & Non-Agricultural Issues

Single Forum:

- NAFTA
 - People feel that NAFTA is a good mechanism for this discussion.
 - Many common ingredients (both active & inert).
 - Legislation and regulation largely similar between ag and non-ag pesticides.
- Basic approach to risk assessment is common between ag and non-ag.
 - Exception is use sites.

- Industry not separable into distinct segments.
- Synergies possible.
- Coordination and consistency is possible.
- Do not foresee a dilution of resources as there are common issues, priorities are unique as is division of labor.

Conclusions:

- Harmonization of risk assessment models needed for inerts and low toxicity pesticides.
- Identify and harmonize data requires for all agricultural pesticides.
- Trilateral agreement on definition and recognition of contribution to public health.
- Harmonize label requirements.
- Increase work sharing incentives.
- Industry should be doing some of the work and presenting it to government.
- Increase communication with industry- provide more information.
- Acceptance of formulations across countries.
- Keep communication open between regulators and regulated community.

Group 4

Safety and Sustainability & MRL's

General:

- Increase information distributed to stakeholders.

Worker Safety:

- Prioritize education, training and safe practices, which is of specific interest in the Mexico training program.
- Take home exposure from farm workers, as examined in the farm family study.
- Pesticide incident information- how it is gathered and how it is reported.
- Industry stewardship- PESP in USA, EFP in Canada, Agricultural Department safety program to meet EPA requirements.
- Language and cultural perspectives taken into consideration.
- Sending certain production abroad can decrease job opportunities and increase risks from imported foods.

Risk Assessment:

- Want harmonization among all three countries.
- Evaluation of health effects, how they are conducted and what is taken into account.
- Mexico to start with joint risk assessments.
- Including safety factor for children as mandatory.
- Increased stakeholders' input from workers and their families.
- The use of as much real exposure data and information as possible, as opposed to assumptions.

MRL's:

- Potential for pilot project on two old chemicals, one which has comparable use patterns in

North America and one that does not. This way information could be provided to stakeholders.

- Harmonization to the highest possible standards based on scientific information.
- Risk cup consideration for imports.
- Need for the harmonization of MRL's within NAFTA.
 - Resolve issues when one country has remaining uses while the other two countries have cancelled use.
- The use of the residue zone maps and how it plays in the harmonization activities.

Reduced Risk:

- Unclear definition of risk reduction.
- There is unanimous support for risk reduction.
- Better facilitation for the registration of reduced risked chemicals.

Group 1

Work Sharing & Minor Use

Minor Use:

- Inter-relationship among MU programs in NAFTA countries:
 - Grower needs to be documented by growers on crop by crop basis- alternatives, emergencies and resistance.
 - Need strong leadership team.
 - Ensure needs prioritized.
 - Need all 3 countries at table.
 - Develop North American data set.
 - Consider MU as a North American initiative- both and domestic and import uses.
 - Suggest industry/grower/government working group to meet 2 - 3 times a year.
 - Mexico is in the process of implementing a MU program- will assign an official.
 - Issue for Mexico- no MRLs for some Mexican MU crops.
- Residue sub-zone requirements:
 - Proposal that TWG consider a project to revisit North American residue zone map.
 - Reduce the number of trials.
 - Reduce number of sub-zones.
 - Industry is looking at residue data to see differences in zones.
 - OECD also looking at what impacts residue levels.
- Efficacy requirement for MU's the following proposals were made:
 - Consider relaxing efficacy requirements for MUs.
 - Propose reduction in number of trials required.
 - Consider groupings.
 - Efficacy reviewing in Mexico.
- Minor Use second entry uses in joint review program:
 - How to add second entry uses into joint review process?
 - Can uses be added mid-stream.

- Industry desire that agencies not lose sight of addition of uses.
 - Should consider bundling MU's together.
- In Canada, MU's not submitted by company, but a sponsor.
 - Can these be folded into JR process?
- General:
 - Need to expand communication.
 - Industry working on position paper on efficacy requirements for MU.
 - Have a standing Work Group on Minor Crops.
 - Producers should meet on a NAFTA level.

Work Sharing:

- Communication with stakeholders:
 - Ability to share information on submission with stakeholders.
 - Develop a template letter.
 - Need more communication/interface between industry and other stakeholders.
 - Propose annual (or quarterly) meetings with all agencies in one city to hold presubmission meeting- unless videoconferencing a possibility.
- Changes to JR process:
 - Eliminate requirement for multiple summary documents for each country.
 - Standardize summary documents, workflow, formatting and binders.
 - Unpredictability in PMRA screening process.
 - Differences in EPA workplan versus PMRA timelines- schedules need to be harmonized.
 - Difference in safety factors.
 - Need more involvement of growers.
- How to integrate Mexico into JR process.
 - Request that Mexican government provide continuity to JR involvement.
 - Need a dedicated representative in the process.
 - Integrate farmers/stakeholders into process.
 - Mexican government invited to coordination meeting in March to schedule 2004 work, EPA meeting in September.
 - Some major crops in Mexico are MUs in other NAFTA countries.
 - Will tolerances/MRLs for Mexico be acceptable in US/Canada?
 - US/Canada have started to work on crop groupings- representative crops.
- NAFTA labels:
 - Need to reconsider benefits/needs of this project.
 - Support NAFTA label if it is functional and not too long.
 - Useful to distribute a draft dummy label.

Questions/Comments:

Karen Pither, IWG, Bayer:

- Is the front end screen for Reduced Risk chemicals adequate? Do you have all of the reports that you need? Do you still need the front end screen?

- Working relationship should be more interactive.

Ingrid Maciel, BASF, Mexico:

- An official regulation is needed to establish MRL's in Mexico.

Angel Saavedra, DOW AGROSciences, Mexico:

- Mexican participation in the joint review process should follow a clear procedure. Formats need to be harmonized among countries.

Mark Goodwin, Pulse Canada:

- Where does this input go from here, where do stakeholders find out the outcome and how does it get integrated?

Marcia Mulkey:

- Agencies will try and give some answers by the end of the day.
- Agencies anticipate a revision to the 5 year initiative and other documents by the middle of 2003. Agencies hope to have feedback about the desire to have a great deal more detail about activities, work plans and projects. Agencies also want to capture the commitments of industry and grower groups.

Karen Pither, IWG, Bayer:

- Industry would like a residue zone explanation and clarification.
- The agencies have taken a statistical approach with a scientific determination being climate. OECD is taking approaches towards MRLs, etc. such as thinking that the physical location has a lesser role than application technique.
- In North America, the zones are very specific. This is the time to step back and look at whether our rationale fits with what the OECD is proposing, and that maybe North America does not need so many residue zones.

Judy Shaw, Syngenta, Canada:

- Industry submitted that Agencies should go with the OECD way of determining zone maps, that OECD was moving in the right direction and that application technology was the main flux in residues.

Bill Ballek, ISSA, NAWG:

- The approach to the NAFTA label should be to take a well defined product group and then create a label from that point. Surface disinfectants could be an example. One of the things that they noted was that the methods of application were similar across NAFTA countries and therefore easier to regulate than agricultural products. A NAFTA label would provide more safety due to enhanced communication.

Blanca Sierra, GLP, Mexico:

- Would like TWG to consider the harmonization of non-agricultural product data requirements.

These are currently very similar to agricultural requirements.

BREAK

Public Comment Period:

Wally Ewart, Minor Crop Farmer Alliance, California Citrus Council:

- Minor Crop Farmer alliance has been working with NAFTA since its inception.
- A lot has been accomplished, but a lot more needs to be done. From the growers' perspective the focus has been lost.
- The changes that the TWG has implemented have given growers challenges they did not have before. There have been regulation change in Canada and Mexico.
- Newer chemistries are available faster, but they limit the export markets.
- Canada and Mexico are the major export markets for the US for speciality crops. There are trade irritants in specialty products.
- He is heartened by the IR-4 expansion in the NAFTA countries.

Louis Arnold, North Dakota Barley Council:

- Grower from North Dakota.
- Congratulations because at this meeting he heard that accomplishments are being made.
- Thinks that, looking at the 5 year initiative, there are some things the TWG has been abandoning in the past 5 years.
- When the committee started, he thought the purpose was to have a correlation of all the things the registrants had to do, and that they would be the same in all three countries. He thought that Agencies would continue doing the same things they did during the last five years.
- The NAFTA label is a direct result of the pricing issue. He is disheartened by the pricing differentials between the US and Canada. There are people who are buying chemicals across the border and are now facing jail time. He thought the NAFTA label would resolve this.
- Then NAWG came to the picture and he wonders if the resources are going to be taken away from the agricultural activities.
- There is a committee in North Dakota set for government exchanges, and yet none of them are at the NAFTA meeting.

Karen Pither, IWG, Bayer:

- Harmonization is key. She believes in harmonization. But the level of frustration is rising and could compromise the effectiveness of these meetings. This could be a result of the multiple stakeholders involved. There are different expectations from different groups.
- The main thing to do is keep the main focus the main focus.
- Industry is pleased with:
 - Canadian minor use program.
 - Predictability of the joint review time lines.
 - The continued expansion of the joint reviews/work shares.
 - Development of harmonized science based protocols.

- Participation of the Mexican delegation.
- The number of government representatives at the meeting.
- There are some industry irritants:
 - Lack of communication with industry outside of the yearly meeting. Stakeholders do not see the results from the meetings.
 - Lack of response to industry's initiatives.
 - Project to regionalize the residue zone maps.
 - Lack of harmonization in administrative programs.
 - Elimination of multiple summary documents: this translates to major investments by the companies.
 - EPA non-acceptance of OECD format.
 - Differences in e-submissions formats.
 - Creation of new trade barriers.
 - Differences in MRLs: there is no temporary setting of MRLs.
 - Canadian gazetting policy.
 - Emergency use MRLs.
 - Import tolerance.
 - Mexico requiring US MRLs before starting registration process.
 - The survey for trade barriers has been done and it is available.
 - Dilution of resources and delay in deliverables.
 - Lack of progress in the harmonization of MRLs.
 - Lack of emphasis in eliminating trade barriers.
- Do agencies have a philosophical problem with the mutual acceptance of MRLs? Is there a scientific reason behind this non-acceptance or is it just due to regulation? If separate reviews are required, what can industry do?
- Industry vision:
 - Regulations established on a national level that do not disrupt international trade.
 - Eliminate any regulatory barriers to free trade which have been formed by discordant regulation.
- Trade barriers are more than just a violation and they are important to the growers.
- If growers cannot trade between the US and Canada, they will go out of business.
- The issues that all stakeholders face must be understood.

Angel Saavedra, Dow, Mexico:

- He is speaking on behalf of the Mexican industry.
- Applauds the creation of the zone maps, although now it is time to implement them.
- Mexico needs to establish a program for emergency uses.
- Representation from the Mexican government is very encouraging.
- These are some areas that need work:
 - Minor uses. There needs to be constancy and a clear policy for producers. There should be an official letter to producers letting them know about a process for registration, etc. There also needs to be a government official appointed to do minor uses.

- They need clear rules for emergency uses.
- Procedures for Mexico need to be integrated. Also, what is specific to the country of origin, should be added to the joint review procedures.
- Mexico accepts US MRLs. Industry wants them to do the same with Canadian MRLs.
- COFEPRIS and SENASICA are good developments. Under these two, priorities should be given to products that are methyl bromide alternatives, OP alternatives and other types of reduced risk. This should be defined in the procedures.
- There are different MRLs for national and export bound products. These should be defined.
- There should be more transparency for all registration processes.
- Agencies should be more flexible in their policies if they truly want to harmonize.
- There should be improved communication with Mexican stakeholders, specially producers.
- Thanked Karen Pither for her help.

Jennifer Ballantine, Monsanto, Canada:

- Industry has some operational concerns:
 - Residue zone map regionalization.
 - Proposal by IWG.
 - Utilizes same scientific criteria to determine number and location of crop residue trials.
 - Elimination of residue zone maps.
 - Development of data to compare crop residues between residue sub zones.
 - Report presented to TWG.
 - Clarification of report templates.
 - Environmental fate report templates were well done and requirements were clear.
 - Need for similar process for residue study templates, and other scientific report templates.
 - Determination of what reviewers require to be included for report templates.
- The industry group has provided information in detail and if there is any information required, it will also be submitted to the TWG.

Mark Goodwin/Don Sissons, Pulse Canada:

Don Sissons:

- He is a 5th generation farmer.
- More grower groups should try to make themselves available. The work of the TWG is worthwhile for growers.
- Made a proposal to the TWG to consider pulse crops as NAFTA case studies. These include lentils, beans, peas and chick peas. Requested TWG feedback.
- These crops would serve as a focussing point to work on a few issues.
- Pulse growers have already spoken with EPA.
- Klaus Neverman and Don Sissons have already met with the Mexican Bean Council in Durango to develop a relationship with Mexican growers.
- They have already developed crop profiles for the US and Canada, and established pest

- priorities. This last item will soon go up in EPA's website.
- Considers that MRLs that are not yet trade barriers are ticking bombs.

Mark Goodwin:

- There are many benefits for using pulse crops as case studies.
- This would provide: external opinions of end users, growers that are involved in regulatory decisions, getting back to understanding what others are doing.
- Reiterated the desire to receive feedback from the TWG.

Ted Menzies, Western Canadian Wheat Growers:

- Canadian Agri-Food Trade Alliance President, and also grows spices.
- This organization needs to hear what the TWG has done.
- He is interested in pulse proposal. Would like response.
- Farmers' livelihood depends on trade and they therefore need MRL harmonization, and and results.
- MRLs should not be another non-tariff barrier to trade.
- Things have to move faster than how they have been moving.
- There are few infractions because farmers would not risk having one. Therefore, there is the perception that there are less problems.
- Farmers want faster access to safer chemicals. They also want to be proactive.
- Expressed disappointment at the lack of farmer representation at the meeting. TWG should further open the dialogue to farmers.

Patricia Ballamingie, World Wildlife Fund Canada:

- The work of the TWG has had many positive outcomes, i.e.: elimination of trade barriers, access to lower risk pesticides.
- Believes that harmonization should have a continental agenda focussing on risk reduction, risk assessments, residue reduction, children's health and lowering reliance on pesticides.
- These are undermined by the trade goal.
- Risk reduction is stated as a point to the market and not as a main focus of the 5 year initiative. It should be one of the main goals.
- The sub-goals should be: continental tracking of residues, IPM implementation, reducing the reliance on pesticides.
- NAFTA TWG should target specific crops. WWF has already worked with apple and potato growers.
- When harmonizing MRLs, the TWG should harmonize to the highest possible safety standard.
- Rather than having MRL harmonization as a priority, the TWG should pursue aggressive continental reduction of residues, as a way of reducing trade irritants.
- The OP cumulative risk assessment should wait until developmental neurotoxicity data is available. An additional 10 fold safety factor should be applied.
- Worker safety and other public interest organizations should be more involved. There is disappointment within the public sector because of what is seen as a lack of possible

accomplishments with this dialogue.

- The agenda for children's health and risk assessments should be more substantive.
- There should be a workgroup on sustainable pest management rather than a workgroup on pesticides.

Dean Thomson, Canada Horticultural Council:

- From a Canadian perspective, there have been many good news.
- There have been definite improvements in the last year.
- Grower have been able to work proactively with regulatory agencies to develop helpful programs such as minor use initiative.
- MRL issue will increase in importance in next few months as registration discrepancies between Canada and US become more evident.
- Most growers do not see positive results outside of new chemistries made available.
- TWG should move forward on suggestions made this year and produce concrete results for next year's meeting.
- TWG should continue to build on the improvements made this year.
- TWG should get back on track in terms of deliverables.

Virginia Ruiz, Farm Worker Justice Fund:

- Under the objective of broadening of dialogue in the 5 year initiative, the TWG should work harder to be inclusive, especially of labor groups and new public interest groups.
- Agricultural labor is very diverse across all three countries.
- The input from agricultural workers adds to the dialogue, and TWG should be more inclusive.
- Workers have the highest exposure to pesticides and should be included in dialogue which directly impacts their well-being.

Closing Remarks

Marcia Mulkey:

- TWG is very pleased with what has been done. What we have harmonized is pretty amazing. We are very proud of our accomplishments and of the recognition from growers and industry. We have near complete harmonization of data requirements.
- The Executive Board session tomorrow will begin tackling the issues raised today.
- We look forward to the informal setting to discuss some issues this evening.
- We want to build and sustain areas of success, but also to rethink our purposes and adopt the best possible approach for the next five years. Goals need to be cost effective and practical. Transparency and responsiveness are important.
- We now require a vision and overarching goals. We need a 'vision' document in conjunction with concrete steps document. The concrete plan should have accountability, realistic priorities, overarching goals, measurements of success and action items.
- We understand that adjustments need to be made to create a separate concrete steps document to deal with trade impediments. The five year initiative should be a living, breathing

document.

- We need better communication and partnering-based approach. The workplan should include stakeholder interests and government deliverables.
- The overall thrust of NAFTA is trade. That includes trade in treated commodities and in pesticide products. We need to keep in mind what the regulatory standards are. The NAFTA label needs promotion. MRLs are a central issue and governments need to focus on them as such. Trade includes non-agricultural products as well, and governments need to look at how these will be incorporated into the dialogue.
- There is a consensus that trade must be sustainable, and that it should not be seen as conflicting with safety and sustainability. Trade must be credible, sustainable and work in conjunction with safety, environmental concerns and health. We need to continue to improve our risk reduction approach.
- Working on a commodity specific basis is a way to get things accomplished. Canola is an example of this. We are looking to expand commodity projects.
- The break out groups might have taken away our way to let stakeholders know where we are with project-specific updates. We moved from project updates to engage stakeholders more, but will need to evaluate in regards to accountability.
- We will look to find government closure on 5 year initiative document tomorrow.

Leonor Cedillo:

- There are a couple of proposals to the Mexican government.
- CICOPLAFEST will meet to address issues raised at meeting.
- As soon as the Mexican government reorganization is done, they will make it public, together with an explanation of impacts.
- There were a lot of good ideas from producers and industry.
- The main themes do not differ from what is already in the 5 year initiative. We will need to see which ones are priorities in environment and health areas. This will help to identify potential barriers.
- We need to strengthen public participation and include public and producers more. NGOs did not participate as much. We will need to broaden the dialogue further in the future.
- Thanked the host country and everyone for participating.

Janice Hopkins:

- Thanked the hosts for choosing location and venue.
- Expressed appreciation of stakeholder participation. The preparation that went on in the stakeholder meetings (prior to the full meeting) was very useful. There were specific recommendations.
- We need to continue to improve on the dissemination of information about our meetings. We will need to further advertise to a greater diversity of groups. We welcome suggestions on how to improve this.
- There is some trepidation about the break out groups. Why do we accept some recommendations and not others?
- There are a high expectations about the Canadian minor use initiative. Minor uses need to be

addressed from a North American perspective.

- We need to find incentives for industry to participate in Joint Reviews.
- MRLs came up regularly and need more attention.
- The Canadian gazetting process is outside of the control of PMRA. They will look for innovative ways to approach 'smart regulation' over the long term.
- The work sharing recommendations made clear that the goals have not been reached yet.
- Non-agricultural group organization brought discipline to this issue with specific listing of topics to be discussed. A new name for the groups would be useful.
- Recognized of the work of the Secretariat.

Marcia Mulkey:

- Expressed appreciation of Dr. Carlos Santos-Burgoa for his efforts to include Mexico and Dr. Claire Franklin while she attends Parliamentary hearings.
- Public service is often joyful, but also a humbling experience when attempting to give deliverables with limited means.
- Further recognized Karen Pither's efforts on this committee over the years.

Highlights from the TWG Executive Board Discussions

- Different representatives from the Mexican agencies described the reorganization of the Mexican government. CICOPLAFFEST will have a rotating two year presidency, alternating between the Ministry of the Environment and the Ministry of Agriculture. The Ministry of Health will continue to hold the TWG Executive Board co-chair position.
- The Five Year Initiative will be finalized, based on input received during the public comment period and at the meeting. The Secretariat will be responsible for preparing a new draft. The TWG will also draft a work plan for the next 12-18 months, which will be an accompanying document to the new Five Year Initiative.
- Mexico indicated that they will not participate in the NAFTA label activities for the time being. They are currently revising their labeling regulations.
- The TWG will encourage trilateral discussions and active exchange of information regarding GHS implementation in North America. The Joint Review Subcommittee will be in charge of these discussions.
- There is a possibility of an early April meeting of Executive Board members to meet the new Mexican Executive Board co-chair. This meeting would likely take place in Mexico.
- The TWG was interested in determining whether different MRLs resulted from joint reviews completed to date. Mexico expressed a need for assistance in developing procedures that

would assist in considering Mexican dietary intakes in setting MRLs. The TWG will begin efforts to better communicate how it is addressing the MRL issue.

- Priorities were given to responding to the proposals set forth by the IWG and the pulse growers.
- The next Executive Board meeting will take place in Hermosillo, Mexico in May 2003.

Appendix 1

Break out group 1

Minor use and work share

Facilitating team:

Lisa Lange, PMRA, Canada

Patricia Pineda, Ministry of Health, Mexico

Terri Stowe, US EPA

Vera Soltero, US EPA

Flip chart notes:

Minor Crops:

Inter-relationship of minor use programs

- Key: grower needs to be documented by growers
- Need strong leadership team
- Ensure needs are prioritized.
 - List alternatives (if available)
 - New pest?
 - Emergency?
- Bring needs of all three countries to the table.
- Develop North American data set.
- Need input from chemical industry too, with all countries represented.
- Producers must be represented as well.
- Crops may not be grown in all three countries, still need to allow imports to other countries.

Subzones (for residues):

- Is there scientific justification for these subzones?
- Consider North America as a region
 - Can this reduce the number of trials?
 - Zones previously set based on climate, soil, etc.
 - Maybe need to rethink this.
 - Will TWG consider this as a project?

Efficacy requirements for minor crops:

- Efficacy requirements present an obstacle.
 - Consider relaxing efficacy requirements.
 - Propose reduction in the number of trials.
 - Consider grouping uses.
- Mexico is in the process of implementing minor use program. Will assign an official.
- Efficacy is required in Mexico as well.

Second entry uses in joint review program (as minor use program):

- Cannot make a submission to Mexico until tolerance is established in the US.
 - How to fit this into minor use program?
- Agencies should consider subsequent uses.
- Useful to bundle multiple minor uses into 1 package.
- For minor uses, possibility for EPA to work on minor use while main submission is still in progress, and share risk assessment with PMRA.
- Coordination of import MRLs.
 - Need to consider submitting to PMRA before trade issue arises (if registered in US only).
- Want a Mexican representative to minor use issues.
- Proposal for a standing committee on minor uses.
- Need strong involvement of IR-4.
 - Maybe not an agricultural need, but a trade need.
- Emergency use applications should be coordinated on a NAFTA basis.
- Need a NAFTA zone map with table for data requirements.
- Subzone issue needs to be addressed.
- Minor use issue very important to growers.
- Growers need to be more active in minor use area, residue issues.

Work share issues:

Sharing of info on a submission with a stakeholder.

- Develop a template letter to allow stakeholder X to be included in discussion on submission.
- Industry and stakeholders need to communicate more, not just depend on agencies to provide info.
- Proposal that agencies get together in one city (quarterly?) to allow companies to come in for pre-submission meetings with all in one place.
- Additional use of videoconference meetings
 - AAFC has facilities.
- Need more interface between industry and growers.
- Ability to include minor use submissions to major new uses.
 - Can minor use submission come during screening, after primary submission? How much lag time would be acceptable?

Changes to the JR process:

- Requirements for multiple summary documents to each agency.
 - Creates additional work for industry.
 - Would like to see one format for summary documents.
- Need to standardize workflow, formatting, etc. Binder types should be the same.
- Unpredictability of the PMRA screen, preliminary review.
 - Can industry be involved in screen as per OECD process?
- Differences in scheduling- EPA workplan vs. PMRA set timelines
- Expense of efficacy data.

- Different safety factors lead to different risk cups.
- Sharing of DERs during the review process.
- Templates need to be finalized.
- Growers need these products, need to work together to get harmonized, need to get more involved.

How to involve Mexico in the JR process?

- Request that Mexican government provide continuity to the JR process.
- Need a dedicated person to JR/Work shares.
- A document on requirements should be published.
 - Integrate farmers and stakeholders into process.
- Canadian government will hold workshop in March with grower groups to schedule work for 2004- invite Mexican government.
- US meeting is in September.
- Mexico needs to establish a list of priorities.
 - Some minor uses in other countries are major crops in Mexico.
 - Will studies generated in Mexico be acceptable in US, Canada?
 - Need to establish list of minor uses that can be considered.
 - Have a procedure for biological efficacy.
- US/Canada have started to work on crop groupings, can generate residue data on representative crops: get registration for all uses in group.
 - Maybe can consider same approach for efficacy; can help Mexico.

NAFTA label:

- Look at crops where this is easiest. Example: seed treatment products; labels are relatively small.
- Support NAFTA label if it is usable/ not too long/ not causing increase in registration time (reviewed as part of the JR program, and no time added).
- Concern for misinterpretation of label rates (metric vs. imperial).
- Would be useful to distribute a draft dummy label for all to see.
- NAFTA label created to let growers know the product is registered in other countries, can be exported, has an MRL.
- Since voluntary, how to encourage companies to submit NAFTA labels?
 - Offer incentives? (Cost, review times, etc.?)
- Does NAFTA label offer advantages to growers? If so, let it be known to industry.
- Rather than putting MRLs on label, put them on Web. Always current.
- Is there a benefit to a NAFTA label in Mexico? Can info be shared in a better way?
- Long labels can be difficult for growers.
- Suggest use of an emblem on label to say it is a NAFTA label.
- Label is a good instrument for communicating risks of use.
- Mexican legislation needs to take JR's/Work shares into account.
- NAFTA label as a risk communication document.
- Need to determine if NAFTA label is still useful to industry and growers.

Raw notes:

Minor Uses

Point 1: Interaction among the minor use programs in the three countries

Craig Hunter: Canada embarked on a program similar to IR-4. Make sure that in each area the grower needs are documented by the grower. This can be done in a crop by crop basis, with strong leadership role for each region. Then we should bring them together.

Ensure that these needs are prioritized. Possible prioritization criteria are: no alternatives, outstanding issues (MRLs revoked due to FQPA), resistance issues, new pests, new crop, section 18 followed by minor use request to label that use.

Rather than 3 separate sets of data requirements, in those cases where product is needed in 3 countries, we should have a North American data set.

It is important to involve the chemical companies in this process. Then we can have one story, one set of discussions and one submission.

Jim Barron: Canada is rapidly coming along with this program. Now we need to focus on Mexico.

Angel Saavedra: They are working on it in Mexico, but there is the need to link the producers with the government in order to address their needs. Amada used to be the link for this issue, but she has many other responsibilities. Mexican producers were not able to come to this meeting.

We should have an organization between producers and industry, something like IR-4 NAFTA. Maybe not all the countries need the products, but it can still be a NAFTA process.

There should be a point of contact for industry and government, and they should meet 2-3 times a year.

Jim Barron: It is time to expand these IR-4 meeting to Canada and Mexico.

Point 2: Residue sub-zone requirements and minor use registrations

Jennifer Ballantine: There are some operational points regarding the residue subzone requirements. Residue subzone maps in Canada create problems because of minor uses. Industry is looking at possible differences in residue zone map subzones. They are looking at the differences in residues to see if there are data to validate combining the zones.

They are looking at North America as a region. Do you need as many trials as you would need in each country?

Karen Pither: There are some OECD studies that suggest that climate, soil type etc., have less of an impact on residue levels than application rate, type, etc. This brings into question the validity of the North American maps.

Jim Barron: Steve Funk said that OECD is very close to industry on the residue zone map issue.

Karen Pither: This is a source of frustration for industry. They have submitted a proposed project and they don't know if they can move forward because of lack of response from the Executive Board.

Louis Arnold: Asked when this map was finalized and when it was sent out. He never received it.

Vera Soltero: Map was sent out to stakeholders in the summer, and is currently posted on our website.

Cindy Smith: Offered a copy of the map to Louis Arnold.

Point 3: Efficacy requirements for minor use registrations

Jim Barron: There is also the issue of efficacy trials in Canada as they relate to minor crops. This is a significant obstacle for producers. There are some specific ideas they would like to take to PMRA:

- Consider using a crop grouping approach similar to the one developed for residue data.
- Reduce the number of trials required based on dietary risk factors and use rates.

Gustavo González: Amada has a compromise to establish a process for minor uses with the people

that visited IR-4.

It is quite common that what the Mexico consider minor uses are traditional crops in Mexico, with no tolerances at all in the US and Canada. The problem here is MRLs, not the lack of a minor use process.

Efficacy is required in Mexico, but it hasn't been decided if there is going to be a different requirement for minor uses.

Point 4: How second entry uses will be included in Joint Reviews

Jim Barron: There needs to be further clarification on this topic, and about what we mean.

Jim Barron: Second entry uses would then be more of a work share.

Cindy Smith: Prioritization is an issue.

Craig Hunter: There are differences in the treatment of data by the countries during a work share or a JR. GRAS products can't go through the PMRA registration process. Should EPA notify PMRA when they receive a GRAS products? Countries need to share a process to deal with this.

Lisa Lange: PMRA has a reduced risk initiative that came out this year, that will resolve this issue.

Jim Barron: What is the status of the tailgating policy?

Lisa Lange: This still happens. However, the trade off is time lines. If registrants want to be able to add uses mid-review, then they can't expect the same time line to remain.

Craig Hunter: If tailgated uses are done jointly, maybe we can work this through. If those additional uses were coming through IR-4, that would give credence to the argument.

Karen Pither: Part of the roll out of the minor use program includes money for resource for minor uses in PMRA. Shouldn't this take care of the resource constraints?

Lisa Lange: Resource are being added to another section. This would not alleviate the review burden.

Cindy Smith: Is it true that in Mexico you cannot make a submission until the MRL is

established in the US for export?

- Jim Jones: Hears a desire from industry that agencies focus on the uses that are subsequently submitted. Agencies should not lose sight of these.
- Craig Nelson: Would it help if these secondary submissions were bundled in more than one use, and then are prioritized according to the number of new uses?
- Terri Stowe: When the EPA's workplan is put out, minor uses are bundled up together.
- Lisa Lange: We are trying to get minor uses up-front.
- Karen Pither: All of the responsibility doesn't fall on the agencies. Minor uses in Canada are not submitted by company. Is there something in the procedures to combine different sources of data (primary use, and then added uses).
- Jim Jones: Hears a desire for IR-4 and companies to get together earlier.
- Karen Pither: The mandated time lines for minor uses should be Cat. A and not Cat. B. This should be understood.
- There should also be coordination of import MRLs. There should be addressed before they become trade irritants.
- Jim Barron: We should expand the communication process in the meetings, etc., on minor uses. It is time for Mexico to step up and join us. There should be Mexican representation at minor use meetings.
- There are lot of synergy opportunities.
- Industry meetings are going to include key people from Canada and Mexico.
- Industry is working on a position paper on efficacy requirements.
- There should be a standing workgroup on minor crops that includes governments, industry and growers.
- Angel Saavedra: Mexico needs the collaboration of IR-4. Producers in the south of Mexico asked directly the establishment of MRLs on pineapples. IR-4 said that there was no need from US producers and that they could therefore do nothing. There is a trade need.

Karen Pither: Emergency uses need to be considered on a NAFTA level. This has never been considered. Temporary MRLs for emergency uses and trade have not been in place.

Craig Hunter: The crop profiles also need to be updated to get an idea of the acreage. This changes yearly.

Don Sissons: Ag Canada should be complimented.

Subzone issue needs to be dealt with. Need to demand a response from the TWG on the residue zone map issues.

Residue issue: growers are responsible. Minor use is huge for farmers and they need to get organized. There are now inroads to have 3-country organization.

Harmonization among agencies has a huge impact on growers. TWG needs to move it forward.

Would like to see more producer involvement.

BREAK

Work Sharing

Point 1: Work sharing and communication with stakeholders

Craig Hunter: Do the governments require a letter from registrants to authorize the sharing of information. Need to link a blank form in the registration application package authorizing agencies to share information with the public, and maybe specify with whom.

Terri Stowe: Once a chemical is accepted as a joint review, the chemical is added to the project sheet. Information includes the submitting company. This enables the growers to call the company themselves.

Janice Hopkins: Canada's new pest control legislation will allow PMRA to be more open with registrants.

Karen Pither: Companies are willing to communicate with growers. It is difficult for companies to arrange pre-submission meetings. Would it be possible for agencies to set specific meeting times for pre-submission meetings? Video conferencing is much preferable.

- Lisa Lange: EPA and PMRA have done this 3 times. Ag Canada has video conferencing facilities, but PMRA does not.
- Jim Barron: The pre-submission meetings could be tied to the March 31st cut off date to make it into the EPA workplan.
- Karen Pither: On the communication between industry and growers groups: there needs to be more coordination with the submission of minor use packages. Could the minor use submission come during screening after the primary submission? How much lag time would be acceptable?
- Craig Hunter: There will be a different residue review stream in minor uses in Canada. However, this is not the case for efficacy.
- Cindy Smith: With regards to work share, is it true that PMRA would not accept import tolerance requests until review is done in another country?
- Craig Hunter: Maybe until the MRL review is done in the exporting country. Apple growers in Canada oppose import tolerances for products they want. Companies need to understand that growers have felt behind on registrations.
- Removal of the 0.1ppm default MRL in Canada would create an open season on new registrations.

Point 2: Possible changes in the joint review process and implication for stakeholders

- Karen Pither: Industry made some recommendations in their submission of ideas for the 5 year plan. Agencies are currently requiring multiple summary documents. This is a cost issue for industry. There are different physical formats in agencies' administrative processes. They should standardize the work flow. OECD format is available. Use it.
- There are also new developing policies that proceed without being harmonized. E-submissions are an example of this.
- There is a problem with the unpredictability of the Canadian front end screening.
- Agencies need to focus on the elimination/creation of new trade irritants through work shares and joint reviews. A compound goes through the joint review process and still creates a trade irritant because of the gazetting policy.
- There is a scheduling problem: EPA schedules reviews on a yearly basis.

EPA releases DER's before completion of review. PMRA does not. This is a problem for registrants.

The risk cup is smaller in Canada. There needs to be a more detailed discussion about this. The different safety factors lead to different risk cups. This stops companies from trying to develop their products for joint registration.

There is confusion with the template and DER situation. Industry wants to support this but they need clarification.

Louis Arnold: Remember that as costs escalate and Agencies don't get their act together, growers are the ones that pay the bill. Same problems are still there.

Don Sissons: Would like the TWG to address Karen Pither's concerns right now. The meeting could be the place to do so.

Point 3: How to integrate Mexico into joint reviews

Angel Saavedra: Mexico was integrated in the joint review discussions last year/ There was someone assigned from Mexico in Salud. He's gone now. There needs to be continuity in the Mexican government. There is frustration in the Mexican industry because of all the changes. CICOPLAFEST need to publish a JR document. The new JR rules should integrate Mexico.

The Mexican industry also needs to work with growers. Growers from Canada and the US could meet with Mexican growers and try to integrate them.

Craig Hunter: Invited grower groups in Mexico to come to Canada in March for a grower meeting. The IR-4 food use workshop in September could also help Mexican producers.

Gustavo González: Efforts are being made to have Mexico participate in the JR program. What Mexico needs to do is establish a priority list and relationships. Once this list is established, these priorities would not be priorities for Canada and the US. Mexico needs to resolve their own problems. MRLs are the main problem. MRL setting is not equal to the processes in the US and Canada. Studies done in Mexico are not accepted in the US. Need to see which crops are needed and which crops are feasible.

Craig Hunter: Crop grouping concept can help.

Point 4: NAFTA label for Ag and Non-ag products

Craig Hunter: Let's pick the areas where there are issues and a NAFTA label would be useful. On the ag side, seed treatment uses would benefit from a NAFTA label. On the non-ag side, commercial uses.

Jim Gray: Supports NAFTA label for desegmenting the market, as long as it is an enforceable document. Is it going to add to the registration time line?

Terri Stowe: So far no.

Cindy Smith: Potential confusion due to unit differences. Asks for grower comments on this.

Terri Stowe: Sporodex: US market was main market, so US units were highlighted, with the Canadian units in parenthesis.

Jim Gray: To gain buy in from stakeholders, maybe we should distribute a dummy label to give an idea of the kind of document we are dealing with.

Terri Stowe: We did distribute it to states.

Ted Menzies: Is it possible to add MRLs from other countries to the label to ensure export capability? Wasn't this one of the original intents?

Karen Pither: This isn't an industry initiative except for stewardship purposes. Barriers to the NAFTA label were identified. Enforcement side is on the state level.

Jim Gray: How do we create incentives for industry to adopt a NAFTA label?

Don Sissons: Agencies should have financial and time line incentives.

Karen Pither: Does it have advantage for growers in North America?

Cindy Smith: Tolerance information could be put on a website.

Gustavo González: What is the objective of a NAFTA label? Who benefits? Is the harmonization complete in order to be able to do this? What is the benefit for the Mexican grower of having the US and Canada information? There could be a better way to disseminate this information.

Ted Menzies: Not all growers are connected to the internet. NAFTA label would not be feasible if too voluminous. Rapid decisions need to be made on the field, and a NAFTA label would get in the way.

Don Sissons: Maybe the label should have something that says the product is "NAFTA-ized"

do there's an assurance about exportation.

Luis A. Mercado: Use it as a way to communicate risks to health, etc., with a focus on prevention and management of possible emergencies, on a NAFTA label.

Guadalupe Salas: What's Mexico's position with respect to this project?

Angel Saavedra: Mexican government and industry don't support a NAFTA label. There are a lot of regulatory issues that need to be taken care of before they can move on a NAFTA label.

Luis A. Mercado: Mexico is currently generating a norm that will be proposed soon. It will correspond to what Mexico needs in terms of labeling.

Jim Barron: Should we get together to look at the pluses and minuses of this project?

Appendix 2
Break out group 2
MRLs and Minor Use

Facilitating team:

Debbie Edwards, US EPA
Dan Kunkel, IR-4, USA
Amada Vélez, Ministry of Agriculture, Mexico
Tyler Lane, US EPA

MRLs

- Luis Suguiyama: 300-400 tolerances are added yearly. Harmonization is therefore a major task. The regulatory agencies have ranked trade irritants A-E. Current work for category A trade irritants includes chlothalimine, methamidophos and acephate.
- Mark Goodwin: Why can't tolerances be harmonized quickly when there is the potential for public exposure?
- Dan Botts: The burden of knowing tolerance variances is on the importer and exporter when tolerances exist. The structure of trade irritant evaluation does nothing to preempt potential trade irritants. Growers would like a single MRL number for a [pesticide] product on a commodity. There will be an impact from Canada's phase out of default tolerance levels. Common MRLs would solve many shipping issues when growers are unaware of the potential shipping destination.
- Chris Warfield: The burden is on industry to provide data which will lead to harmonized regulatory decisions. The goal of NAFTA was to move from individual country decisions to a NAFTA wide tolerance. The government is not addressing barriers to trade, pesticide use, and access to pesticide products.
- Wally Ewart: [Commodities treated with] new products cannot be exported to primary trade regions due to lack of foreign import tolerances.
- Amada Velez: Mexico has products which do not have tolerances in importing countries. We are looking to move toward a common pesticide market.
- Janice Hopkins: [Canada] will soon be removing the 0.1 ppm default tolerance level. A consultation document will be available for public comment.
- Debbie Edwards: We need to identify these trade barriers.
- Wally Ewart: A USDA database for a comparison of the tolerances for 43 countries is being created with a grant to CropLife. Commodity groups already have MRL databases.
- Pat Boss: There is a problem with variances for labeled use patterns on products sold in multiple countries.
- Chris Warfield: CropLife Canada and CODEX web sites are also available for use in comparing MRLs.
- Luis Suguiyama: We should think in terms of a NAFTA MRL. This currently is only addressed

through Joint Reviews. Industry, growers and regulatory agencies need to think more in NAFTA terms.

- Chris Warfield: We need to take risk assessment (especially risk cup) issues to a NAFTA level of evaluation. This will facilitate harmonized MRL decision and eliminate trade barriers.
- Luis Suguiyama: MRLs are an enforcement tool. Harmonization means could occur through use of the residue zone map.
- Rafael Camacho: Pesticide use is very different in Mexico and it will take time to move toward MRL harmonization.
- Premjit Halarnkar: Acephate decision will not be taken until the cumulative risk assessment is completed in the U.S., thus causing a trade irritant.
- Unidentified: What are the principles of MRL setting? If MRLs are based on what the risk cup will bear, this will continue to cause trade irritants.
- Debbie Edwards: MRLs equal an enforcement tool. Differences will occur from percent crop treated acute and chronic toxicity inputs, etc. There is a possibility of a NAFTA risk assessment discussion.
- Unidentified: The slow process of creating import tolerances is preventing trade and the use of pesticide products.
- Rafael Camacho: Usage differences should be examined in order to make regulatory decisions.
- Imme Gerke: Regions are able to decide use patterns, thus making harmonized assessment difficult- but models do exist.
- Premjit Halarnkar: When product registration is delayed in one country, this creates a trade irritant across borders.
- Imme Gerke: We need to look at 'tailgating' issues and ask why minor use registrations do not come in up front.
- Tommy Wofford: There is a capacity issue.
- Imme Gerke: IR-4 and Canada minor use programs are ready to take chemicals up front to add the necessary information upon submission.
- Tommy Wofford: Time lag to registration makes this difficult.
- Judy Shaw: We need a project to decrease the time lines for simultaneous MRL establishment. Perhaps there can be a 'tailgating' exemption for minor use commodities.
- Imme Gerke: 'Tailgating' not necessary with a NAFTA MRL.
- Unidentified: Could there be the possibility of creating a NAFTA commission for the establishment of MRLs? Then, the company would have a clear idea of their registration options.
- Debbie Edwards: How should governments best determine trade barrier priorities?
- Wally Ewart: Growers were asked for priorities up front and these then ended up in lower trade irritant categories.
- Chris Warfield: These priority lists should be in the NAFTA files.
- Luis Suguiyama: A tracking table does exist.
- Debbie Edwards: The tomato pilot project demonstrates an alternative way of approaching NAFTA MRL issue. We need to look at the issue of import tolerances when the risk cup is full and how to resolve the resultant trade barriers.

Chris Warfield: This was originally dealt with in CODEX with industry priorities. Risk assessment must always be done with the best available data. This equals revising risk assessment when new data are available because one never wants to use the MRL for risk assessment.

Judy Shaw: Import tolerances do not include water assessment for importing country. We should have a science/industry working group for analysis due to regional/country differences.

Debbie Edwards: We are currently looking at commodity import from Europe, but it is difficult to add this to risk cup due to the drinking water issue.

Dan Botts: We used to address import MRL proposals through a public comment period. The time line for setting an import tolerance is usually dependent on the country requesting the MRL. We need to address products which are not used in the U.S.

Wally Ewart: Growers respond to [import tolerance issues] based on potential use in the U.S.

Chris Warfield: Decisions are often based on safety of use in the petitioning country and political issues.

Minor Use

Dan Kunkel: In 1995, IR-4 moved focus from FIFRA '88 to lower risk products. With the introduction of FQPA, minor use became a priority for the EPA. This program has created an import/export gap.

Dan Botts: FQPA changed research and development incentives. We need more emphasis on minor uses. The FQPA tolerance reassessment often impacts minor use crops. MRL driver needs a harmonized approach.

Amada Velez: Mexico needs to begin developing a minor use definition. We want to identify IR-4 priorities. Insight can be gained through the analysis of border state interactions and history. The costs of registration and MRL setting is low, but this will increase with NAFTA activities to support program expansion.

Unidentified: The new Canadian minor use program will improve IR-4 relationship, thus decreasing the gap between the U.S. and Canada. But, subzone requirements will need resolution. We are looking to show the lack of difference within these subzones.

Sue-Chi Shen: Need to determine how minor use programs will be utilized by industry in both countries.

Dan Kunkel: IR-4 would deal with EPA/PMRA, while industry should work through the presubmission consultation.

Sue-Chi Shen: Do risk reduction products have any priorities?

Judy Shaw: New use sites and new activities do have priorities.

Dan Botts: When will minor use move to a trilateral discussion?

Amada Velez: Mexico is introducing papaya as a pilot minor use crop. We are also now participating more in minor use activities.

Dan Kunkel: The minor use workshop determines priorities based on grower needs.

Tommy Wofford: We receive great benefit from the minor use program and have decreased time lines in this program to 30 months. However, there is a problem when IR-4

- has a tolerance before the use is added to a label. Canada and U.S. registrations are not in sync, causing problems.
- Judy Shaw: Lack of financial incentives determined by marketing departments. Minor Use more difficult in Canada due to time lines for registration. Also, with minor use registrations in Canada, the U.S. counterpart is not always the primary contact point within industry.
- Dan Kunkel: FQPA exemption allows the extension of exclusive use data for an additional 3 years.
- Chris Warfield: The regionalization of the residue zone map could reduce crop trials. PMRA needs to apply the same analysis to efficacy as in residue chemistry.
- Dan Botts: We need to consider product liability factors when moving into minor use areas. The further availability of a 10 year extension for the exclusive use of data has never been used with implementation of FQPA.
- Debbie Edwards: When growers request minor use for export, how does industry contact international counterparts?
- Dan Kunkel: We do not have a formal update.
- Dan Botts: When pests emerging, we should look at international registrations for control possibilities. To harmonize, emergency use process and 24 (c) registrations in U.S. need to be looked at.
- Amada Velez: SAGARPA will consult with Salud to register a pesticide when an emergency situation emerges.
- Chris Warfield: Regional and provincial governments drive minor use emergency exemptions in Canada. Approximately 3 per year.
- Dan Kunkel: IR-4 always uses crop groupings to increase registration potential. Nomenclature does have variance regionally.
- Wally Ewart: CODEX has different crop groupings, which will need to be harmonized with NAFTA countries.
- Sue-Chi Shen: Efficacy requirements in Canada and Mexico need harmonization resolution.
- Amada Velez: All products in Mexico and imported into Mexico must have efficacy trials. We want to harmonize our requirements with Canada.
- Chris Warfield: Canada will examine efficacy in relation to minor use. Canada looks at crop control efficacy as a group- i.e. if it works on 1 crop in the group, it will work on all crops.
- Judy Shaw: The global zone map with five zones will conflict with the North American zone map, causing more barriers.

Appendix 3

Break out group 3

Non-Agricultural & Worksharing

Facilitating team:

Anne Lindsay, US EPA

Renée Salas, Ministry of Health, Mexico

Charalyn Kriz, PMRA, Canada

Facilitator suggested that the BOG might want to add another topic for discussion, i.e., does harmonization on non-agricultural products belong under the NAFTA TWG?

Non-Agricultural Issues

Non-agricultural products vs. agricultural products

“Non-agricultural products” is a broad category including consumer products, antimicrobials, inerts, institutional and industrial products, lawn and garden products.

65-70% of all pesticide products are non-food; non-agricultural products include inerts.

Pesticide policies in the US affect non-agricultural products; legislation is the same across agricultural and non-agricultural products.

Various segments of the industry are not clearly separable; it would be burdensome to compare ag/non-ag products to find overlap; if separated, coordination of two programs could be more resource intensive than including them. Therefore they should be housed under the same umbrella (NAFTA TWG).

Use pattern is the only major difference between ag and non-ag areas; many non-ag products cross all three borders more than ag products and use patterns similar in all three countries.

Large overlap in actives in ag and non-ag areas.

The underlying risk assessment process is the same; ag and non-ag areas can derive synergies from each other; share internally thoughts and ideas, benefit from agricultural work.

Agricultural group is concerned because of potential dilution of resources; need to indicate that NAWG is not here to compete for resources but to work together; focus on issues that are the same.

Adjuvants and inerts need to be harmonized as affect both ag and non-ag products.

Many non-ag products are minor uses of tremendous value; harmonization in this area would be government contribution to minor use.

Public Health

Overriding concern is impact of non-ag products on public health; they have a significant impact in all three countries on public health.

Need to call attention to the public health benefits of lawn care products (see booklet); for example, weed control on road sides provides for safe highways.

Where pests are cross-border problems (foot and mouth disease), can have three contiguous countries on the same page; especially important when there is an emergency issue to be dealt with trilaterally.

Definition of public health pesticides need to be harmonized.

Include herbicides because there are public health issues with herbicides.

Disinfectants and sanitizers play an important role in public health.

Non-ag herbicides are used under powerlines, rights of way, waterways, edge of highways. Herbicides used on lawns across the country kill clover and dandelions. Hence bees would not be attracted to clover/dandelions and bee stings would be reduced.

Summary - 1) NAWG wants governments to reflect public health benefits of these products in vision statement; 2) next step would be a project to control a pest of public health importance.

Facilitator noted that NAWG has used a broad definition of public health benefits that includes indirect benefits.

Role of antimicrobials and some others in food processing and food handling facilities to reduce incidence of food-borne illness, e.g., rodenticides.

Need recognition of how products are of benefit to children's health.

Could try to codify information into a white paper to clarify public health benefits of non-ag products - NAWG willing to do this.

Facilitator's summary - NAFTA TWG needs to do better job of categorizing the diversity of non-ag products. Need clearer recognition that these products have both direct and indirect benefits to public health (broadly defined). This should be captured in the vision. Pests don't respect borders, therefore should be addressed in a trilateral way. There was a suggestion of a public health project to demonstrate what we've been talking about (put in parking lot). NAWG offered to produce a single

document to clarify public health benefits of non-ag products.

Inerts

Need harmonized comprehensive risk assessment model for inerts for NAFTA countries (including information and data required to satisfy the model). Refer to EPA's risk assessment model in their paper on inerts and low risk pesticides (June 2002).

Concern that PMRA about-to-be-released formulants policy may not be harmonized with EPA. Concern re labeling products containing List 2 formulants that "further testing may be required"; further testing should not be required until they move to List 1.

Preservatives issue where List 2 ingredients; difference in required labeling between Canada/US may impede North American label.

Some dates in Canadian formulants proposal have passed causing a problem with implementation, timelines and schedules.

Inerts is a cross-cutting issue not just non-ag issue. There are many more inerts in non-ag than in agricultural products. Harmonization on low risk inerts across ag/non-ag products should be a no-brainer.

In Canada, with the transfer of disinfectants from PMRA to Therapeutic Products Directorate, they are no longer be subject to the PCPA and the PMRA formulants policy, instead the FDA and CEPA.

The whole concept of a NAFTA label is not valid if industry has to formulate products differently in each country as a result of differences in formulant policies. American industry would not want to harmonize with statements regarding requirements for further testing.

EPA updated its comprehensive list of inerts; hopefully Canadian formulants policy will provide a list of all inerts and CAS numbers. It was suggested that a project between Canada/US be undertaken to assemble inert lists with CAS #'s.

Facilitator suggested a possible early activity, i.e., sharing information on basic approaches to evaluating and regulating inerts. There is a rich opportunity for harmonization in the area of inerts, especially if want common label. The topic of the risk assessment model used to evaluate inerts could intersect with worksharing topic. Inerts topic raises related issues around information and data harmonization, differences in policy approaches, particularly related to impacts on labeling, timelines for implementation, different statutes in Canada governing approaches to inert ingredients.

In October 11 comments on risk assessment model for inerts, NAWG tried to identify a couple of pilots for work share with Canada to clarify where we are with respect to Tier 1, Tier 2, Tier 3.

Facilitator stated we are in an early phase, and need more of an information exchange on what each country is doing.

NAFTA Label

NAWG is supportive of voluntary uniform NAFTA label; NAWG has compared and contrasted Canadian, US and Mexican labels for hard surface disinfectants/non-agricultural products. Differences exist in precautionary statements and warning symbols. There is a need to review the GHS and assess the potential for resolving labeling issues between the three countries.

Concern regarding the inability to get one labeling standard in Canada (pesticides/disinfectants/sanitizers); GHS could provide an opportunity for harmonization on a North American basis. Need inter-agency cooperation.

Not thinking of a one size fits all label. NAWG wants to draft a couple of templates to see if can get a North American label for non-ag products. A toilet bowl cleaner is the same in the Yukon and the Yucatan which may make it easier to derive a common label.

Suggest having a North American Working Group working on the GHS label.

Facilitator - Need good stakeholder involvement to progress well.

NAWG appreciates government willingness to explore North American working group.

Labeling in US needs to be in Spanish not just English. As well, there are different standards or norms in Mexico on disinfectants that do not need to be registered. This would make harmonized labels difficult.

Mexico is considering adopting GHS rulings; need to consider limitations as a country as far as actives are concerned.

Consumer, industrial and institutional products need to move forward hand in hand.

Facilitator summary - Heard an offer from NAWG to do analysis of GHS, matrix and standard label and a proposal for a working group to participate in implementation issues. There is a worker safety issue, need labels that people can read and understand. OECD has work that may influence our work and vice versa.

EPA has not required bilingual labels (Spanish precautionary statements)for Puerto Rico even though Spanish is official language of Puerto Rico.

In Mexico there is a high incidence of intoxication each year so they are considering including chronic effects on the label. Trying to incorporate these issues and inerts in GHS. Easily understandable labels

is not just a Mexican problem, rather a NAFTA problem.

Is it possible in Mexico to separate regulation of agricultural pesticides from non-agricultural pesticides?
- response: not possible under the Commission. This needs to be identified when proceed to draft regulation.

Facilitator's summary - There is an interest in understanding the reorganization in Mexico. There is a broad need for all three governments to share information on how they are currently working.

The NAWG would appreciate an opportunity to work with the Mexican government on pesticides of public health concern.

Worksharing

Work should not be duplicative.

In Canada, sanitizers are currently regulated under the PCPA with PMRA while disinfectants regulated by TPP; in Canada need TPP in NAWG; in Canada, efficacy standards are outdated for disinfectants and sanitizers.

Efficacy guidelines need to be updated in the US and data requirements for antimicrobials finalized. OECD working towards harmonization of efficacy guidelines.

There do not appear to be any incentives for worksharing. Will there be any reduction in fees because of a reduction in level of work due to worksharing?

What is incentive to provide DERs? In Canada, submission of DERs for non-ag products does not shorten timelines.

Will the Agencies accept 2nd entry Category B's for worksharing/JR? Some of the NAWG deal mostly with end use products, i.e., Category Bs in Canada.

Want to expand criteria for non-ag worksharing.

Facilitator - NAFTA agencies are open to worksharing on non-agricultural products. Efficiencies from electronic submissions in template format.

NAWG is interested in having some opportunity to influence Joint Review workplan. Is there a possibility of clustering information and doing a risk assessment on a chemical group or family (CBI protection)? Subsequent to first JR, perhaps second entry could be a work share.

NAWG will try to set up a couple of pilot projects on inerts with EPA; it makes sense to include Canada.

Action from NAWG

White paper to clarify public health benefits of non-ag products.
Pilot project on inerts.

Setting Priorities

Refer to Renée's presentation to plenary.

Appendix 4

Break out group 4

Safety and Sustainability & MRLs

Facilitating team:

Susan Lewis, US EPA

Leonor Cedillo, Ministry of Health, Mexico

Mark Brohm, PMRA, Canada

Worker Safety:

Mexico has trained 186 people in the Train-the-trainer Program. This program is done in conjunction with the EPA and is a program for teaching pesticide instructors. The idea is that there is an exchange of information as well as a training kit that would be used first in Mexico and the US and then in Canada.

Training courses were geared towards training the teachers so that they could train the applicators, and not towards training domestic farmers or farm workers going to the US to work.

It was suggested that worker safety should be included as part of the next 5 Year Plan and include more information about what is going on in Mexico regarding worker exposure.

Many would like to see more uniform training for workers and growers so that both understand the risks they are exposed to. Especially in the US, where workers could be geographically isolated, access to health care and information is limited if they experience adverse health effects.

“Take home exposure”- the exposure to pesticide residues on clothing etc., is of concern because it is unclear if it is considered in regulatory actions. NGO's feel this should be considered.

Risk Assessment:

Risk Assessment procedures should include more participation of the farmer community.

For intoxication cases, information is not being shared with the pesticide regulatory portion of the government at this time, as there is a separate organization that does the reporting in Mexico. They

only report on acute cases and there is no mandatory reporting in Mexico. Doctors have to report on more than 30 illnesses. They have to know the product that the patient was intoxicated with and sometimes cases go unreported due to the priorities of the medical staff. But there is a network of tox centers that maintains the statistics.

Species at risk, as well as human, infant and child health, are of concern.

Canada will make reporting of adverse effects mandatory for registrants.

Canada is far along in developing the 'uses data' so that they can have standardized methodology in developing Risk Assessment.

Mexico still needs to develop the infrastructure to be able to have a tox database that is centralized so doctors will have access to this information. This is currently being promoted across the country.

Prevention is the main concern for growers, as they have a long history of developing mandatory reporting. With respect to infant health, growers say that they do not allow children to be on the farm.

Risk assessment is part of every pesticide submission. Regulators look at the exposure and hazard identification (both short term and long term development) and take women in the work force into consideration when making their decisions. In addition, regulators consider data gaps within the risk assessment and this influences regulatory decisions.

The World Wildlife Fund would like for the third 10 fold safety factor to be mandatory.

Worker Safety Action would like to encourage the inclusion of more information from the workers themselves in the risk assessments. For example, with anti-sapstains industry and NGOs went to the unions and to the workers directly to speak with everyone.

US exposure evaluation takes into consideration: mixer loaders, applicators and harvesters.

Industry representatives stated that they submit information to the regulatory agencies and work with them to ensure that labels are correct and straightforward.

Industry monitors adverse effects through proactive product stewardship via labels and 1-800 numbers. In Canada mandatory incident reporting has been in effect since the 1980's under the Canadian Environmental Protection Act.

Regulators agreed that when they look at the use scenario, if children are affected then a higher risk assessment is considered.

An Agricultural Worker's Health study has been conducted by private industry. There was bio-monitoring on the child, partner and worker. The study found that take home exposure was of low

concern. The exposure from children performing pesticide applications was the exposure of concern.

Stewardship programs that are conducted have to resonate with the target group for them to be of any use. Therefore, they have to be tailored towards the language and educational level of the target audience.

When working on a risk assessment for Mexican workers, there are many small growers, many of whom are migrants themselves. Therefore, there is a lot of difference within Mexico itself regarding how farmers and growers work. Its very hard to generalize throughout the whole country, as there are many different dialects and literacy issues.

Mexico will be hosting a Risk Assessment workshop in 2003 so that they can have a standardized approach towards these issues.

In the last 5 years NAFTA countries have made significant gains: older chemicals are being reevaluated and regulatory bodies are working towards the harmonization of their risk assessments, re-evaluations and tolerances.

MRL's:

When conducting Joint Reviews it is important that there is harmonization of MRL's during this process so that there is a common standard across boarders.

A request was made to have a deadline for the elimination of differences within the regulatory process when determining MRL's. That deadline would be determined by the regulatory bodies.

Mexico must be taken into consideration when undertaking harmonization projects because even though the US and Canada are 99% harmonized, there are still many differences with Mexico.

There has to be more transparency with the NAFTA process and give growers some milestones so that they can understand the process of establishing MRL's.

Every difference in tolerances, becomes a trade barrier that has to be overcome. Therefore questions arise such as: how do you set tolerances if there is no standardized use pattern, so that there is safety to the consumer and still viability as a trade good?

Suggestions on how to proceed: strategic plans could be used within grower groups as ways of determining efficacy rates as well as use patterns. They can examine the use patterns so that MRL's are harmonized.

There is large difference in diets in the NAFTA countries and we have to study what should be considered for setting MRL's.

Canada, US and Mexico are harmonizing to the highest scientific denominator for MRL's so as to stay standardized.

Mexico needs legislation first to set the MRL's before using the Zone Maps. Developing this legislation should be a priority.

The length of the work day and the amount of residue that the worker becomes exposed to should also be taken into consideration, as this is different from country to country.

The duration of Canadian gazetting is becoming a problem. Canada is currently exploring how to reduce the time lines of gazetting.

When working with MRL's, it is important to concentrate on a chemical and not a commodity. How do regulators handle MRL's when the risk cup is full in one of the countries? An explanation would be appreciated to industry and growers.

US risk cups only include what is being used in the US.

Canada currently moving towards the elimination of the default 0.1ppm MRL.

When an MRL is dropped in the US but still in place in Canada, regulators work towards converging any discrepancies. But it is very rare for Canada and the US to have differences.

Reduced Risk:

Important to define what Reduced Risk (RR) means, as it means different things to different people and therefore we have to harmonize this language.

RR is based on how a chemical is used and its efficacy. This is important to growers and becomes an economic issue because high efficacy guarantees a quality crop. If you can only use the product at a rate that does not do the job, then there is no use in using it.

RR gives incentives to registrants to get new products out to markets to replace non RR pesticides already in use.

The criteria for an expedited review should be set according to lower toxicity ratings.

Other RR chemicals include organophosphate and/or methyl bromide alternatives.

