NAFTA Technical Working Group on Pesticides Meeting
Merida, Mexico, December 2, 2004
SUMMARY

1. Welcome and Country Updates

Amada Vélez welcomed everyone to Day 2 of the Stakeholder Meeting of the NAFTA Technical Working Group on Pesticides and indicated that there would be an update from each of the three countries.

Canada: Wendy Sexsmith, Acting Executive Director of the Pest Management Regulatory Agency (PMRA), provided an update on the new Canadian *Pest Control Products Act* (PCPA), which will strengthen health and environmental protection. As an example, the new legislation will codify aggregate exposure levels and cumulative effects, require special protection for infants and children, and require reporting of adverse effects. Also provided was an update on the proposed revocation of the 0.1 ppm default maximum residue limit (MRL) and the proposed amendment to the *Food and Drugs Act*, which would enable the PMRA to set MRLs under the PCPA. These initiatives support the work of the NAFTA Technical Working Group and support international regulatory co-operation.

United States: Jim Jones, Director of the Office of Pesticide Programs, United States Environmental Protection Agency (EPA), provided an update on the *Pesticide Registration Improvement Act* (PRIA) and the upcoming Organisation for Economic Co-operation and Development (OECD) Workshop on Worksharing being hosted in the United States on January 31, 2006. He indicated that the PRIA is a new law that requires pesticide manufacturers to pay a fee to the government in order to have a pesticide reviewed. The following key issues were raised:

1. data needs to be submitted in a harmonized manner;
2. NAFTA countries need to prospectively work together in a harmonized way (i.e., joint review); and
3. retrospectively, how do we bring together approaches that have been around for many years?

Mexico: Dr. Miguel Lombera, Comisionado de Evidencia y Manejo de Riesgos of the Comisión Federal para la Protección contra Riesgos Sanitarios/Secretaría de Salud (COFEPRIS/SSA), gave an update on the proposed new regulations in Mexico that will apply to human health, plant and animal health as well as environment. These provisions will also include a new MRL regulation. He stressed the importance of harmonization. Support is needed both from government and industry to build a regulation that will improve both the health and the environment.

2. Non-Agricultural Status Report

NAFTA Label for Hard Surface Disinfectants
The American and Canadian governments began working on this project after receiving a request from the Non-Agricultural Working Group (NAWG). The purpose of this project was to enhance both free trade and regulatory cooperation between Canada and the United States, as well as to have one label in three countries for hard surface disinfectants. Currently, a guidance document is being developed.

Pilot Joint Review
The product involved in this pilot joint review is a heavy duty wood preservative. The process has provided an opportunity for the EPA and the PMRA to work closely together in the area of antimicrobials. Registrants are encouraged to submit other joint review candidates.

3. Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

The GHS is an internationally agreed system of hazard classification criteria, standardized label elements (pictograms, signal words and hazard statements) as well as guidance on other aspects of hazard communication. The goals are to enhance safer tranport, handling and use of all types of chemicals and to facilitate trade by promoting greater consistency in chemical hazard classification as well as hazard communication worldwide. The NAFTA TWG is committed to work toward coordinated approaches to the GHS for pesticides as part of the Five-Year Strategy.

The potential impact of GHS on pesticides is significant. After initial consultation with NAFTA partners at the last meeting, the United States has made available for public comment a white paper outlining initial thinking for applying the system to pesticide labels. Canada has conducted a number of conference calls with stakeholders in the pesticide sector. (The GHS has also become fully available in Spanish, an important step in advancing implementation considerations in Mexico.)

Next steps will include analyses of stakeholder input received to date, coupled with ongoing consultation among NAFTA countries and continued work with stakeholders to address the many issues that have been identified.

4. Food Residue Subcommittee

Prospective Strategies
Prospective strategies involve harmonization of data requirements through collaborative review (i.e., joint review/workshare). Minor use is a key activity under this umbrella. This work is aided significantly by NAFTA templates. A NAFTA Guidance document for import tolerances has been drafted and is proposed to be published by the end of February. Retrospective strategies exploring the potential for harmonizing uses and MRLs for registered pesticides are being examined on a pilot basis through projects with the pulse and tomato sectors.
In all strategies (retrospective and prospective), there is a need to engage all stakeholders.

Residue Trial Efficiencies
In order to decrease number of trials without compromising the ability to carry out an assessment, an approach has been agreed to which represents a significant savings (25%) within the joint review environment. Some considerations of this proposal include the following:

- the use patterns must be similar; and
- there is no further reduction for unquantifiable residues.

Next steps include updating acreage statistics in Canada and in the United States. It was noted that this 25% reduction of trials would at no time be less than the maximum required by the NAFTA countries, individually.

Analyzing MRLs — Statistical Methodology
This project originated with potential differences in MRLs between countries. There was a need to develop a more statistically based guidance with a harmonized approach for establishing tolerances. Next steps include a draft guidance document.

Subzones
The feasibility of merging crop subzones 5 and 5a is being examined.

5. Joint Review Subcommittee

A status report of the Joint Review/Workshare process was given. This program continues to be successful, with a total of 55 registrations granted. Current joint reviews include fully electronic submissions. A revised public document describing the joint review process is expected to be published in the near future. New American legislation (i.e., PRIA) is not expected to affect joint review timelines.

6. Re-evaluation

The Canadian re-evaluation program is designed to maximize the use of international reviews, in particular those from the EPA. A total of 401 active ingredients are subject to the current re-evaluation program, initiated in 2001. This program is a highly successful example of worksharing. The target date for food use chemicals is the fiscal year 2006–2007, and the target completion date for non food chemicals is fiscal year 2008–2009. In order to achieve the proposed target, the PMRA needs to do on average 50 chemicals/year. Worksharing (e.g., dimethoate, 2,4-D) is currently underway, and the discussions between the EPA and the PMRA on re-evaluation/re-registration are ongoing. A project on cooperative re-evaluation/re-registration of Heavy Duty Wood Preservative (HDWP) has resulted in harmonized preliminary assessments.

To date, approximately 80% of Canadian decisions are harmonized with the EPA.

7. Minor Use

A framework for developing pilot minor use submissions by Inter-regional Research Project Number 4 (IR-4) and Agriculture and Agri-Food Canada (AAFC) submitting them to the EPA and the PMRA simultaneously is being developed. This will build on existing joint minor use development work. IR-4 in the United States is working in collaboration with AAFC with new funding obtained in Canada for minor use. IR-4 and Mexico are also involved in food uses. Currently, there are 21 joint studies underway based on joint development work. The four pilot projects anticipated for joint submission to the EPA and the PMRA are the following:

- Fenhexamid/pomefruit
- Fenhexamid on ginseng
- Acetamiprid/greenhouse tomato
- S-metalochlor on squash

These pilot projects are anticipated to have an eight-month review timeframe once submitted. The goal is to have minor use data development and submission review carried out jointly on a routine basis. IR-4/EPA and the PMRA/AAFC continue to collaborate on crop groupings development.

8. Regulatory Capacity Building Subcommittee

a) Electronic Harmonization Information

The e-PRS (PMRA Electronic Regulatory System) was released in Canada in the fall of 2004 and is gradually being phased in starting with enrolment of major registrants. This is a web-based system with internal databases/infrastructures that will allow most business transactions and submissions between the PMRA and industry to be conducted on-line. The United States and Mexico visited the PMRA in September 2004 to review this system.

b) OECD Templates

The EPA presented on the introduction of NAFTA submission templates to the OECD. The NAFTA format will be used as a model to develop OECD templates. An OECD workshop on templates will be held in Washington in January 2005.

c) Terrestrial Field Dissipation Studies

The PMRA and the EPA have jointly developed a harmonized guidance document on conducting terrestrial field dissipation studies. The current guidance reflects inputs from many consultations. Currently this document is in the publication process in the PMRA and the EPA, Office of Pesticide Programs (OPP). The target is to have the guidance document simultaneously published by the PMRA and the OPP in 2005 in order to obtain stakeholder comments. Next steps include work on triggers for these studies.

d) MTD Project

The goal of this project is to develop harmonized guidance for industry on approaches to dose selection for chronic bioassays and to develop guidance for evaluators on adequacy of the dose selection; with a special focus on maximum tolerated dose.

The final draft document was circulated to the working group members in August/September; comments and revisions are in progress. A peer review team is currently being assembled, with a Working Group/Peer team meeting targeted for early 2005 in order to finalize the document. It is expected that the final document will be released in the spring/summer of 2005.

e) Developmental Neurotoxicity (DNT)

The goal of this project is to develop harmonized guidance for industry and regulators to harmonize evaluation and interpretation of DNT studies. This project was moved into International Life Sciences Institute (ILSI), which facilitates broader participation.

An international working group was assembled and met in April 2004 to define the project scope. The working group members developed individual chapters and met again in November 2004 to begin collating document chapters.

f) Occupational Risk Assessment: Safety and Uncertainty Factors

The goal is to identify and resolve differences in the application of safety/uncertainty factors for occupational risk assessment.

Canada and the United States will develop a document on the policy of safety/uncertainty factors and how these are used. Each country will develop documents on occupational exposure risk assessment including selection of target margin of exposure, and how/whether occupational and other exposures are aggregated. An analysis of difference will be done in order to compare/contrast and define where differences exist, and, finally, the goal will be to address and resolve these differences.

A large policy component to this project may require public consultation at least in Canada. Timeframe, because of policy component, likely to be two years or more.

g) Harmonization: Dermal Absorption

The goal of this project is to resolve differences in the analysis of dermal absorption data and the derivation of dermal absorption values used in occupational and residential risk assessment. Specifically, the intent is to revisit and update the harmonized position on the derivation of dermal absorption values for use in occupational and residential risk assessments. An analysis of differences will be made (compare/contrast) with a view to initiating a process for the resolution of differences.

The possibility of moving this project to the OECD should be considered, while continuing the NAFTA work. The timeframe for this project is approximately two years in NAFTA.

9. Risk Reduction Subcommittee

a) Train the Trainer: Mexico

The 2004 National Program to Prevent Risks Derived from Pesticides was reviewed. Several components are part of this program, including Train the trainer, health promoters training, training for distribution facilities, SEVRA courses and health professional training. There are 360 courses given and 6,800 trainees.

This national program telesession was coordinated by SAGARPA, INCA-RURAL, COFEPRIS, Sonora, Puebla, Baja California, SEMARNAT and SEDESOL. A total of 2,000 binders have been printed for this program as well as 2,000 posters, 5,000 brochures and 1,000 booklets.

b) Applicator Core Exam

The EPA is responsible for pesticide product registration.

The label sets out the directions for use to pesticide applicators and must be adhered to. Applicators must be certified to use restricted pesticides. States must conform to, at minimum the standards set in CFR 171. However, many states go beyond this minimum.

The American Train the Trainer pilot project was completed in April 2004. Under PRIA, there are many other projects underway, such as incident data system, hazard communication pilots and new questions for core exam. At this point, there are no further activities under NAFTA. However, some areas for future cooperation include: aerial application, fumigation and rights of way.

c) Competency Standards for Certified Applicators

In Canada, the provinces are responsible for post registration control (i.e., sale, transportation, storage, use and disposal as well as training).

The PMRA assists in the development of national standards. There is a national standard for certification and recertification of applicators and vendors. Implementation of the training is done at the provincial level.

Certification is dependent on class of pesticide and type of pesticide use (i.e., commercial, non-commercial use)

10. Lindane Update

The EPA provided a country by country update.

Canada

By January 1, 2005, lindane will no longer be registered for agricultural pest control uses, including veterinary uses; however, some uses may remain for public health uses.

Mexico

Lindane is used for ectoparasite control and livestock (cattle and pigs).
Mexico is currently developing a phase-out plan, which includes public health uses.

United States

Lindane is used as a seed treatment on corn, wheat, oats and sorghum.

Over the next few months, the EPA will be revoking tolerances for lindane and reviewing additional data on residues found in food. One question remaining is whether to aggregate exposure resulting from pharmaceuticals with pesticidal uses as a part of the *Food Quality Protection Act*. It will be considered whether to assess the exposure from all isomers. The EPA will work towards registering alternative pesticides.

The European Union has proposed to eliminate all uses by January 2008; this may cause some trade irritants.

The regional action plan schedule will be available to the public in 2005.

11. Stakeholder Comments

The following is a summary of oral public comments provided by various stakeholder participants.

It was noted that there have been many completed workshares/joint reviews, and that the process is more inclusive (i.e., minor use). There was a recognition that section 18 tolerances apply to imports. It was expressed that work should be done towards streamlining the ecozone requirements across borders. Also, it was expressed that there is a need to enhance trade by eliminating MRL barriers. A suggestion was added that import tolerances should be established as a component of re-evaluation (consider CODEX).

Some trade solutions for the future were offered and are as follows:

- future new uses automatically establish import tolerances for NAFTA partners;
- Mexico to fully participate in Joint Review process;
- industry to participate in projects on ad hoc basis with key contacts; and
- improve information exchange within government.

It was also noted that access to tools is a key issue, with a concern that the technology pipeline may be slowing down and older tools are being under regulatory threat.

Pulse Crops

It was noted that export is of key significance to Canada, and there is a need to move the NAFTA Pulse project ahead. Rapid access to reduced risk pest management tools/alternatives is required. Work should be done with the Technical Working Group in order to resolve remaining barriers.

It was expressed that in 2003–2004, some products were blocked from entry to the United States due to vinclozolin. In comparison, "*Canada allows U.S. lettuce to enter with residue levels over the set MRL with total imports worth approximately $100 M*". Support was noted for harmonized MRLs/labels and for a collaborative approach to working with AAFC and the PMRA in order to develop a reduced risk strategy with which success has already been demonstrated. Several meetings have taken place with staff from these organizations. Proposals for broadleaf weed control have been suggested as well as alternatives to organophosphates for grasshoppers. An invitiation was extended to Mexican producers for their involvement in this process.

It was also noted that progress has occurred due to products such as pyraclostrobin and sulfatriazone. Other issues that were raised as a priority include the following:

- Free trade and movement of pesticides
- Equal access to all pesticide products
- Elimination of trade barriers through MRL harmonization and expediting the registration process
- Expand broadleaf weed control options for lentils and chickpeas
- Post harvest applied products
- Products to rotate with respect to strobilurins
- Retain full label for dimethoate on lentils and a label for thiabendazole on lentils
- Continue developing NAFTA labels
- Mutually accept MRLs for Canada and the United States and harmonizing MRLs for new products

Finally, next steps were expressed as a need to obtain a timely response to the priority list that has already been submitted.

Mexican Avocados

It was expressed that pesticides represent a very valuable tool that prevents economic disasters. However, a concern was noted that if these products are not properly handled, potential risks to the environment may occur. A need for the protection of balance through sustainable development was recognized. A concern was raised with respect to the lack of registration of new molecules for black raspberries in Mexico. Support for free trade under the NAFTA Technical Working Group was expressed.

Additional points

Additional points that were raised are as follows:

- There is a need to harmonize registrations
- IR-4 represents a process for obtaining uses most needed
- Mexican, American and Canadian industry groups should be formed
- Who are the representatives that need to be contacted?

Finally, it was noted that recently there has been much progress in projects under the NAFTA Technical Working Group. However, there is also a need to “continue to monitor” the progress of this ongoing work. With respect to the “Train the Applicators” project under the Risk Reduction Subcommittee, there were some questions as to how much more work can be done in this area under NAFTA.

In general, it was recognized that there is a need for industry to contribute to the development of NAFTA projects and to the future progress on harmonization.

12. Summary of Break-out Group Comments

See attachments.