



## **A North American Initiative for Pesticides:**

**Operation of the NAFTA Technical Working Group on Pesticides**

**November 16, 1998**

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

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

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

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

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

### **Goals**

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

### **Objectives:**

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

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

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

### **What is meant by harmonization?**

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

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

### **Benefits arising from the activities of the NAFTA TWG:**

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

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

Incentives to grower groups: There will be faster and simultaneous access to a wider

range of pest control products, including those for minor use, which will facilitate effective pest management; alleviation of trade disruptions that arise as a result of technical differences in the levels of residues permitted in food.

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

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

## **Operation of the NAFTA TWG**

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

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

### **1. Role of Government**

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

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

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

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

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

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

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

These activities are supported through the practical experience gained in the joint

review program between Canada and the US and through the ad hoc exchange of reviews to promote sharing of work with a broader range of OECD countries. This experience is helpful in refining the terminology and level of detail and promoting a true understanding of the relative significance of apparent differences. This process is a key component in developing a fuller knowledge of how countries conduct risk assessments.

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

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

## 2. Role of Pesticide Industry

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

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

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

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

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

### **3. Role of Grower Groups**

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

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

### **Conclusion**

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

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# North American Initiative



