



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

**Non-Agricultural Working Group Break-out Group
Summary**

Participants: Warren Stickle (CPDA), Bob Kiefer (CSPA), Frank Sanders (EPA), Yasmin Mekhel (EPA), Valerie Robertson (PMRA), Mark Brohm (PMRA), Dasha Pelka (PMRA), Ian Chisholm (TPD), Has Shah (ACC) Moises Capetillo (COFEPRIS), Patricia Pineda (COFEPRIS), Sue Crescenzi (Steptoe and Johnson, LLP), Norma Pangilinan (Bayer CropScience)

1. Overview of Regulatory Structure

Each country gave a summary of regulations and regulatory structure.

Mexico

The Comisión Intersecretarial para el Control del Proceso y Uso de Plaguicidas, Fertilizantes y Sustancias Tóxicas (CICOPLAFEST) includes representatives from the following secretariats: health, environment, agriculture and economy.

- Disinfectants fall under health legislation (Secretaría de Salud) and are not regulated as pesticides (i.e., products used in surgical procedures).
- Under the current framework, product registration is based on other countries' registration.
- Mexico is developing a new process for registration through legislation for pesticides (clarification is needed whether the scope will cover disinfectants).
- This process will enable Mexico to harmonize under NAFTA.

Canada

- Hard surface disinfectants are regulated by Health Canada.
- These products are subject to the same jurisdiction as pharmaceuticals (defined as a drug under the *Food and Drugs Act*).
- No harmonization of data requirements is being sought at this point in time— simply the label.

United States

- NOM189 labelling standard under the Consumer Product Safety Commission.

Other issues discussed

- Frank inquired whether parts of the label could be used to harmonize in the three countries.
- Since disinfectants are not classified as pesticides in Mexico, it is not possible to harmonize the label with Canada and the United States.

Action: Moises to send a sample copy of a Mexican label to Cleo Pizana as well as to provide legislative framework/information

- Cleaning products in Mexico are not subject to formal registration.
- Need to clarify who is the responsible body in Mexico regulating turf, golf course and ornamental products.

Action: Moises to inquire and report back on the turf/ornamental issue

- Are there separate registration processes in Mexico for agricultural products and non-agricultural products for domestic uses?

Action: Moises to send Frank information on what Mexico would like to see on the label in order to be able to market a product.

2. Review Label Requirement Matrix for Hard Surface Disinfectants

Ian Chisholm provided a brief summary of the pilot project for a NAFTA label:

- Two companies have been selected for the pilot project.
- In Jan 2005, the companies will go through the pilot submission process.
 - ▶ Presubmission conference call to take place to discuss requirements.
 - ▶ 45-day screening; 210-day review period in Canada; 90 days in the United States under the *Pesticide Registration Improvement Act (PRIA)*.
 - ▶ As a result, a 90-day screening/review period was selected.
 - ▶ Will be using the United States Environmental Protection Agency's (EPA) hazard symbols on labels.
 - In Canada, disinfectants are considered drugs and Workplace Hazardous Materials Information System/Consumer Chemicals and Containers Regulations (WHIMS/CCCR) do not apply.
 - ▶ Single label will be eligible for use in Canada and the United States.
 - Hope to add Mexico to the list of eligible countries.
 - To be eligible for the NAFTA label pilot, label must already be registered (Drug Identification Number [DIN] and EPA registration number).

3. Update on Formulants

- The Pest Management Regulatory Agency (PMRA) published a Regulatory Directive on formulants this year.
- Phase-in of new requirements will be over three years, beginning January 2005.
- Industry has expressed concern about List 2 labelling requirements targeted for implementation in 2006.
- The PMRA is actively talking to industry.
- Need to focus on how/where to disclose on label.
- New *Pest Control Products Act* will require disclosure of Formulants of health concern.
- The EPA targets to complete the re-assessment of food-use chemicals by August 2006.
- Chemical Producers and Distributors Association (CPDA; Warren Stickle) and Inert Steering Committee gave the EPA a list of verified CAS numbers.

Action: EPA agreed to provide this list to PMRA (Valerie)

- There are approximately 60 List 2 food use inerts under review in the United States.
- The United States raised a need to synchronize listings with the PMRA. Valerie indicated that the PMRA will liaise with the EPA on the reassessment activities.
- List 2 is not applicable to hard surface disinfectants; only to sanitizer-only products.
- CPDA/Warren indicated that they had hired a consultant to help with obtaining information about surfactants for the EPA for the purposes of reassessment

4. Industry Thoughts on Projects for Mexico

- Industry suggested that the next label harmonization project could be rodenticides for public health.

5. Update on Joint Reviews (JR)

- Industry indicated that new use JRs need to be addressed.
- Industry is driving force for JR in the United States; unless there is a reduced timeframe, there is no incentive for this process.
- For the United States, the JR timeframes are less than the PRIA timeframes.
- The United States and the Therapeutic Products Directorate are looking at potentially harmonizing data requirements for disinfectants (MRA and TPD); need to engage stakeholders.

6. 40 Code of Federal Regulations (CFR) Part 158, Subpart W

- Industry is concerned with the delays in the publication of these antimicrobial data requirements and suggested that this be a priority.
- Frank suggested that there is a need to hold workshops related to Subpart 158 W as a mechanism for reaching out to user communities.

7. Additional Steps

- Industry suggested that there is a need to consider other non-agricultural insecticides, household products and rodenticides for the NAFTA label, if the hard surface disinfectant NAFTA label can be used as model, and if we should move to the next candidate.

Action: Frank to liaise with Lois Rossi in order to get a contact for the above.

- There is also a need to flag the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) coordination.
- Need to be aware of what changes will be required as a result of GHS implementation.