United States – Canada – Mexico
Trilateral Seminar and Annual Meeting
October 18-21, 2004

Final Report

[Approved by the Steering Committee on February 2, 2005]

1. INTRODUCTION

The Trilateral Cooperation is a formal mechanism for the development of relations and harmonization initiatives between the Health Products and Food Branch (HPFB) of Health Canada, the United States' Food and Drug Administration (FDA), and Mexico's Federal Commission for the Protection From Sanitary Risks (COFEPRIS). The main purpose of the Trilateral Cooperation is to increase communication, collaboration, and the exchange of information among the three countries in the areas of drugs, biologics, medical devices, food safety and nutrition to protect and promote human health.

Heads of Delegation, steering committee, working groups and country coordinators constitute the governance structure of the Trilateral Cooperation. The U.S. Federal Trade Commission, Mexico's Federal Office of the Judge Advocate General of Consumers, the Canadian Food Inspection Agency and the Competition Bureau of Canada also actively participate in the Trilateral Cooperation via membership on the working groups. Two meetings are held each year and hosted by each country on an annual rotating basis.

Health Canada hosted the 2004 meetings. The Mid-Year Review meeting, which was held at the end of April 2004, was devoted to reviewing progress, evaluating accomplishments and planning for the Fall meeting. The **2004 Annual Trilateral Meeting** was held **on October 18-21, 2004,** in Ottawa. The program for the event included:

- a preparatory meeting of the Steering Committee (October 17)
- a training seminar (October 18);
- meeting of the Steering Committee and Working Groups (October 18-20); and
- meeting of the Heads of Delegation (October 21).

During the meeting of the Steering Committee and Working Groups, delegates defined long-term goals for the working groups, reviewed accomplishments and outcomes of their work to date, and identified priorities for 2005. The latter were presented by the Steering Committee to the Heads of Delegation on October 21st.

This report presents a summary of the Training Working Group's assessment of the training seminar (Section 2), and the key messages and directions from the Heads of Delegation to the Steering Committee and Working Groups (Section 3). The agendas for the meetings and list of participants are annexed to this report (Appendices A and B). The detailed reports from the Steering Committee and the Working Groups, and any other presentations decks, are available via your country coordinators.

2. SUMMARY OF THE TRILATERAL TRAINING SEMINAR - OCTOBER 18, 2004

2.1. Introduction

At the 2004 Trilateral Cooperation Annual Meeting, a Trilateral training seminar was conducted on October 18. This was an exercise in which Trilateral participants, working in small facilitated working groups, discussed how their respective countries would respond to a scenario involving a potentially dangerous unapproved pharmaceutical drug that claimed to produce rapid weight loss. This information sharing and interactive approach was a first time initiative within the Trilateral Cooperation and was deemed useful and helped countries interact in a more effective manner.

This training seminar, which was organized by the Training Working Group, aimed both (1) to increase the Trilateral participants' understanding of each other's regulatory and institutional frameworks and (2) to initiate confidence building among the participants.

This report summarizes the Training Working Group's assessment of the training seminar. In addition, the following documents are attached:

- Appendix C – Results of the Group Discussion from the Trilateral Seminar
- Appendix D – Summary Report – Trilateral Seminar Survey
- Appendix E – Additional Comments from Participants in the Trilateral Seminar

2.2. An Assessment

2.2.1. Results

The seminar's results relate to four fundamental aspects for the Working Group: 1) a closer relationship between the countries, 2) conception of the training work, 3) a preliminary list of training themes for the next seminars which were validated via an on-line survey among the three countries, and 4) recommendations for improving the next annual Trilateral Seminar.

2.2.2. Conclusions and Comments

The objective of the seminar was achieved and was perceived as satisfactory. The feedback received from the participants via the on-ling survey indicates that the exercise permitted development of a closer relationship between countries, and allowed participants to identify a significant number of similarities and some differences. However, they also emphasized that the scenario and the allocated timeframe permitted only a minimal degree of confidence-building. The Training Working Group had intended this workshop to be the "first step" in a confidence-building continuum process and had recognized that successful confidence-building will take time and would only be feasible through additional confidence-building experiences and different processes. To enable the participants to build a deeper and more meaningful level of confidence in the future, some participants commented that a training topic involving different type of scenarios such as a

minor illness or a mislabelling issue might be useful. Another recommendation was that future exercises should permit the participants to go deeper into the process that each country has developed for responding to a specific scenario, so as to understand the context in which the country acts.

The successful performance of the seminar improved the Working Group's position among the trilateral working group, and some capabilities of the training group were shown, which demonstrated the specific competencies and abilities that the Training Working Group brings to the Trilateral Cooperation. Furthermore, it has been possible, through the seminar evaluation forms, to obtain a list of the preferred themes for the next seminar, which can improve future actions. Finally, the recommendations will allow the Training Working Group to improve the performance of future seminars so to achieve the essential objective of "building confidence".

3. SUMMARY OF THE MEETING OF THE HEADS OF DELEGATION – OCTOBER 21, 2004

The participants at the Heads of Delegation meeting on the morning of October 21, 2004, included: Diane C. Gorman, Assistant Deputy Minister, HPFB, Health Canada; Lic. Ernesto Enríquez Rubio, COFEPRIS, Mexico; and Dr. Murray Lumpkin, Acting Deputy Commissioner, FDA, United States; the Steering Committee members and the Country Coordinators. Ms. Gorman chaired the meeting.

During the first part of the meeting, the Heads of Delegation gave brief overviews of key developments in their respective countries. The key points made by each country are summarized as follows:

Canada

- The new minority government, led by Prime Minister Paul Martin, has identified three broad objectives: strengthen the country's social foundations; build a 21st century economy on innovation and entrepreneurship; and show leadership both at home and on the international stage. Health Canada plays a key role in delivering these priorities. This new government also places increased focus on accountability and evidence-based advice.
- A new Health Minister and a Minister of State of Public Health were assigned after the elections. The Public Health Agency of Canada began operating on September 24th and Dr. David Butler Jones, was appointed the Chief Public Health Officer. The Government of
  Canada's priority for the Agency is to build strong emergency response systems and to establish the Pan-Canadian Public Health Network, which will strengthen the collaboration among public health organizations nationwide.
- During a recent meeting, the First Ministers committed to a 10-year plan to strengthen health care in Canada. This plan will be comprised of several key components including a National Pharmaceuticals Strategy, which will review the role of the regulators.

- The Health Products and Food Branch (HPFB) is continuing to improve its performance with respect to reducing drug submission backlog (which has been reduced by 70%) and progress is continuing to meet all targets.
- Information was also provided on several new Government of Canada initiatives (such as "Smart Regulations") that are currently at the forefront of federal policy.

United States

- The FDA has established an Office of Oncology Products within its Center for Drug Evaluation and Research. A national search is being carried out for a person to lead the new office.
- The area of "combination products" is a very active area, and the number of combination products is expected to continue to grow. FDA's Office of Combination Products provides companies with advice on which of FDA's review processes and requirements apply to particular products.
- FDA's Center for Veterinary Medicine has established a new Office of Minor Use and Minor Species (MUMS) Animal Drug Development. This follows on the enactment of the MUMS Animal Health Act.

Mexico

- The public in Latin America is increasingly preoccupied by poverty and marginalization. Mexico has undertaken a health reform to provide universal access to health care. The new health care system will be modeled after the Canadian system and will include two main components: (2) health care services for those insured; and (2) health care services for those who don't have insurance coverage.
- The Mexican government sees a need for further research on orphan drugs that are particular to Mexico, and Mexico is interested in working with the U.S. and Canada to find more effective and less costly approaches to orphan drugs.
- Regulation of meat, milk, and eggs has been moved from the Agriculture Ministry to COFEPRIS.
- Under the new Mexican legislation, all drug registrations will expire in the next 4-5 years. To obtain renewal of their registrations, some drugs will have to go through Phase 2 trials again, and many drugs will have to go through Phase 3 again.

The second part of the meeting focused on the Trilateral Cooperation All three Heads of Delegation emphasized the importance of continuing the Trilateral Cooperation and their commitment to continuing to work towards its success. They also noted that the Trilateral Cooperation should become, as much as possible, the focal point for communicating and managing all issues that could have an impact on the three countries and that fall within the authority of the Trilateral partners. They indicated that the Steering Committee has proven to be a useful mechanism in moving the Trilateral Cooperation forward. The foundation for the cooperation has been solidified with the institutionalization of the governance structure and the processes.

The Heads of Delegation reviewed the reports of and provided directions to the Steering Committee and the Working Groups. The following table summarizes the reports and the key messages and directions from the Heads of Delegation by specific working group and their proposed activities.

Steering Committee			
Key Priority and Activities	**Lead**	**Key Milestones & Deliverable**	**Key Messages and Directions from the Heads of Delegation**
Strengthening the Trilateral Cooperation ➢ Review the balance in the responsibility regarding the country leads & chairs of working groups. ➢ Review and adopt the *Study of Terminology Used by Regulatory Agencies* as an official document of the Trilateral Cooperation. ➢ Develop and maintain a formal inventory of Trilateral Cooperation information and documents.		December 2004	The Heads of Delegation agreed that the Steering Committee mechanism has been very useful in moving the Trilateral Cooperation forward. They are requesting that the Steering Committee: ➢ develop metrics for assessing the activities of the Trilateral Cooperation, particularly the outcomes of the activities of the Working Groups; ➢ identify the impediments and barriers to increased information – sharing and cooperation for the Working Groups; ➢ develop Standard Operating Procedures to share confidential information; ➢ explore the potential of sharing classified information; and ➢ provide recommendations to the Heads of Delegation on the potential of Trilateral Cooperation addressing the following new topics: Combination products; paediatric research; organ transplants; orphan drugs; tissue regulations; medical devices; US's Critical Path Initiative; and risk analysis issues.
Common Definitions for Trilateral Cooperation Terminology ➢ Conclude common definitions and examples for terms that are used within the Trilateral Cooperation.	United States	**2005 Mid-Year Review Meeting**	Definitions of terminology needed to advance the work of CUMCIG, particularly in confidence-building.
2005 Trilateral Meetings ➢ Evaluate the 2004 Annual Trilateral Meeting and finalize -- and distribute -- the report and key directions of the 2004 Annual Training Meeting. ➢ Plan and deliver the Trilateral Mid-Year Review and the	All Canada Mexico Mexico	December 2004 End of April 2005 (Cancun,	The Heads of Delegation commended the Steering Committee for the successful meeting. They requested that the Steering Committee: ➢ Draft a thank you note to all working groups' members for their signature.

Annual Trilateral Meetings. ➢ Plan and deliver the Heads of Delegation Meeting ➢ Include information on new laws, legislation and guidance documents in the country updates at both meetings.	All	Mexico) Fall 2005 (Puerto Vallarta, Mexico)	
Information on other public health issues ➢ Discuss emergency alerts when they arise. This step should be included in the EPR Working Group's crisis communication procedures.	All	On-going	
Working Group – CUMCIG			
Key Priority and Activities	**Lead**	**Key Milestones & Deliverable**	**Key Messages and Directions from the Heads of Delegation**
Renewal of CUMCIG ➢ Revise the terms of reference to address the new long-term goal *"to build confidence in our respective regulatory processes and decision-making practices through the exchange of information to allow countries to make informed decisions on the protection of public health."*			The Heads of Delegation agreed that the issues and challenges identified by the Working Group could be generalized to the other working groups. They are requesting CUMCIG: ➢ identify the barriers that inhibit identifying cooperative activities under the Trilateral Cooperation; and ➢ define a focus and outcomes for CUMCIG.
DRAFT - **Information on Compliance Status** ➢ Establish mechanisms to share information that is legally permissible about compliance status of selected domestic manufacturing facilities for human drugs and food products.			The Heads of Delegation noted that sharing information on Good Manufacturing Practices is limited by the country's legal frameworks. They are requesting that CUMCIG: ➢ consider sharing the status of the inspections only so that each country can ask the companies to provide details.
DRAFT **- Information on Inspections and their Findings** ➢ Notify in advance of			The Heads of Delegation noted the importance of sharing information about upcoming for cause

scheduled regulatory inspections on our respective countries and exchange information regarding inspections findings by home country authority. (to be further discussed and defined)			inspections.
DRAFT -**Maintain an Inventory of Relevant Information** ➢ Develop mechanisms to collect and track existing and relevant information on legislation, regulations, and policies affecting human drugs, dietary supplements, and processes food products and ingredients, and share updates and pending changes affecting these products.			
Share Information or Product Recalls and Significant Safety Issues/ Problems *Such information is to be exchanged in advance, as much as possible, of any public notice so as to permit partner regulators to initiate any action they deem necessary in the protection of their public health.* ➢ Establish working mechanism and criteria to share: *a.* product recalls of human drugs, dietary supplements / natural health products, and processed food products and ingredients requiring public notification of a significant and/or potential risk to public health. *b.* Significant safety issues/problems (such *information may arise from verified inspection findings and verified defect/problem complaints reports)*			
Working Group – Emergency Preparedness and Response			
Key Priority and Activities	**Lead**	**Key Milestones & Deliverables**	**Key Messages and Directions from the Heads of Delegation**
Trilateral Emergency Procedures ➢ Develop trilateral procedures for sharing information during emergencies and assess need			The Heads of Delegation agreed that they should ensure to communicate/get in touch. They requested that EPR :

for international communications Annex. ➢ Develop trilateral procedures for sharing information on consumer complaints and adverse events.			➢ examine the capacity of response for each country and, building on that knowledge, define a procedure for response; and ➢ identify technology challenges.
Emergency Exercises ➢ Conduct an emergency communications drill. ➢ Increase opportunities for exchanges and participation in future national exercises.			The Heads of Delegation recognized other areas where countries work together to prevent disaster. They requested that EPR: ➢ review lessons learned in emergency preparedness exercises (e.g., G-8 Summit, Olympics in Athens, US Presidential conventions and debates).

Share Information ➢ Share Crises Communications Plan and exercise. ➢ Update on changes in national emergency management structures. ➢ Continue commitment to joint meetings with Laboratory Cooperation Working Group and sharing information on laboratory EP&R measure.			The Heads of Delegation recognized the need to identify the laboratory capacity in North America for dealing with emergencies. They requested that the EPR and Laboratory Working Groups: ➢ identify the capabilities and capacities of each country (e.g., labs, methods, pathogens and toxins)? ➢ identify ways in which they could cooperate in emergency situations.
Training ➢ Provide information to the training group on EP&R training needs			
Working Group - Laboratory Cooperation			
Key Priority and Activities	**Lead**	**Key Milestones & Deliverables**	**Key Messages and Directions from the Heads of Delegation**
Share Method Information ➢ Sharing specific methods targeting agreed food commodities including cilantro and guacamole.			The Heads of Delegation commended the Working Group for the successful advancements in the last year. They also recognized the need to identify the laboratory capacity in North America

Target analytes include *Shigella spp* and *Listeria monocytogenes.* ➢ Building a standard template to effectively communicate and exchange method information covering sample matrix/analyte, performance standards, quality assurance, decision process and confirmation. ➢ Exploring the use of the ELEXNET methods module			for dealing with emergencies. They requested that the EPR and Laboratory Working Groups: ➢ identify the capabilities and capacities of each country (e.g., labs, methods, pathogens and toxins)? ➢ identify ways in which they could cooperate in emergency situations.

Proficiency Test Sample Program ➢ Utilizing the 2004 FERN training, Canada and Mexico will participate in the upcoming *Bacillus anthracis* proficiency test sample ➢ Continue participating in the quarterly US FDA Pharmaceutical Drug Check Sample Program. ➢ Share a list of current proficiency testing programs and move toward sharing results.	Canada & Mexico Canada & Mexico All		
eLEXNET ➢ Continue progress on implementing eLEXNET. ➢ Explore use of eLEXNET methods module to facilitate all three countries sharing methodology information including quality attributes, data fields and functionality for communication.	All countries		
Working Group – MUCH			
Key Priority and Activities	**Lead**	**Key Milestones & Deliverables**	**Key Messages and Directions from the Heads of Delegation**
Trilateral Enforcement Initiative for Weight Loss Products and		2005 Annual Trilateral Meeting in	The Heads of Delegation supported the suggestion that they release a joint

Services ➢ Issuance of a joint public outreach communication to present the MUCH initiative and to warn/educate consumers about deceptive and fraudulent weight loss products.		Mexico - joint press release	communiqué at the 2005 Annual Meeting. The communiqué should be available in Spanish, English and French.
Enforcement Actions and Public Outreach Against "Cure all" ➢ Take enforcement actions and public outreach activities against "Cure all" products including those with deceptive and fraudulent weight loss claims.			The Heads of Delegation support this initiative.

Working Group – Training			
Key Priority and Activities	**Lead**	**Key Milestones & Deliverables**	**Key Messages and Directions from the Heads of Delegation**
Identifying Training Needs for the Trilateral Cooperation ➢ Prioritize training topics/seminar collected at the 2004 Pre-Trilateral Seminar. ➢ Conduct a survey with the 2004 participants to prioritize results.	All countries		The Heads of Delegation requested that the Working Group review Mexico's request for training on risk analysis.
Exchange Information on Available Courses ➢ Compile list of existing training courses relevant/applicable to Trilateral Cooperation ➢ Offer FERN courses to Canada and Mexico	United States	December 2004 On-going	
2005 Annual Training Seminars ➢ Develop, organize and deliver two pre-trilateral seminars.		April 2005 October 2004	The Heads of Delegation support the development and delivery of two seminars per year.

Internet Site for the Trilateral Cooperation ➢ Develop a proposal to address cost and technical issues.			The Heads of Delegation support the development of an internet site and believe it will be an important infrastructure for the Trilateral Cooperation.

Appendix A

Agendas

United States – Canada – Mexico

Annual Trilateral Meeting

October 18-20, 2004
Fairmont Château Laurier Hotel
1 Rideau Street
Ottawa (Ontario) Canada

Monday, October 18, 2004
TRILATERAL SEMINAR – "Confidence Building"
Canadian Room

Objective: To help build confidence in each others' decision-making processes through information sharing and interactive discussions.

Proposed Agenda

7:45 AM **Registration/Continental Breakfast** (Canadian Room)

8:15 AM **Welcoming Remarks**
- **Diane Gorman**, Assistant Deputy Minister, Health Products and Food Branch (HPFB), Health Canada

8:30 AM **Opening Remarks**
- **Ginette Workman**, Director General, Office of Management Services, Health Products and Food Branch, Health Canada

8:45 AM **Overview of Draft Common Definitions for the Trilateral Cooperation**
- **Melinda Plaisier**, Assistant Commissioner for International Programs, Food and Drug Administration (FDA)

9:00 AM **Building Confidence through the Sharing of Information on Our Decision-Making Processes** (45 min. presentation per country based on a scenario and common question template)
- U.S.

9:45 AM **HEALTH BREAK**

10:00 AM **Building Confidence through the Sharing of Information on Our Decision-Making Process**

- Mexico
- Canada

11:30 AM **Rules for the Breakout Groups Session**

11:35 AM **Breakout Groups Session**

12:30 PM **LUNCH (**Wilfrid's Restaurant)

1:30 PM **Feedback Session**

2:15 PM **Conclusions of the Trilateral Seminar**

- **Ginette Workman**, Director General, Office of Management Services, HPFB, Health Canada

2:30 PM **HEALTH BREAK**

Monday, October 18, 2004
TRILATERAL MEETING – Plenary Session
Canadian Room

Proposed Agenda

2:45 PM **Welcoming Remarks**

- **Judith Lockett**, Director General, Office of Regulatory and International Affairs, HPFB, Health Canada

3:00 PM **Presentations of Delegations and Country Updates**

- **Canada:** Judith Lockett, Director General, Office of Regulatory and **International** Affairs, HPFB, Health Canada
  Andrea Rosen, Assistant Deputy Commissioner, Fair Business Practice Branch, Competition Bureau
  Paul Haddow, Executive Director, International Affairs, Canadian Food Inspection Agency

- **United States:** **Melinda Plaisier**, Assistant Commissioner for International **P**rograms, Food and Drug Administration
  John Marzilli, Deputy Associate Commissioner, Office of Regulatory Affairs, Food and Drug Administration

Mexico: **Lic. Luis Alfonso Caso Gonzalez**, Comisionado de Fomento Sanitario, COFEPRIS,
Lic. José Rodrigo Roque Díaz Subprocurador de Verificación de la Produraduria Federal del Consumidor, PROFECO

4:15 PM **Steering Committee Report**

- **Judith Lockett**, Director General, Office of Regulatory and International Affairs, HPFB, Health Canada

5:00 PM **Review of Logistics for October 19 & 20**

5:15 PM **Adjournment of Plenary Session**

Tuesday - October 19, 2004
TRILATERAL MEETING - Working Groups' Sessions

Proposed Agenda

Objectives:

- Discuss draft common definitions for the Trilateral Cooperation.
- Finalize the deliverables for the Heads of Delegation.
- Link with other working groups if necessary.
- Identify priorities for 2005.

8:00 AM **Continental Breakfast** (Canadian Room)

8:30 AM **Working Groups' Sessions**
[Specific agendas, location of meeting and background material for each of the working group can be found in Tab 5 of the binder]

10:15 AM **HEALTH BREAK**

10:30 AM **Working Groups' Sessions (continued)**

12:00 PM **LUNCH** (Wilfrid's Restaurant)

1:15 PM **Working Groups' Sessions (continued)**

3:00 PM **HEALTH BREAK**

4:30 PM **Adjournment**

Wednesday, October 20, 2004
TRILATERAL MEETING - Working Groups' Sessions (cont'd)

8:00 AM **Continental Breakfast** (Canadian Room)

8:30 AM **Working Groups' Sessions (continued)**

10:15 AM **HEALTH BREAK**

10:30 AM **Working Groups' Sessions – Conclusions and Group Photograph**
- Finalize report and deliverables
- Picture taking

12:00 PM **LUNCH** (Wilfrid's Restaurant)

Wednesday, October 20, 2004
TRILATERAL MEETING - Plenary Session
Canadian Room

1:15 PM **Working Groups and Steering Committee Reports**
- Progress report on activities, deliverables for the Heads of Delegations and 2005 Priorities

2:30 PM **Common Definitions for the Trilateral Cooperation**
- Facilitated discussion to obtain final comments on the draft common definitions.

3:15 PM **Meetings in 2005** - Mexico

3:30 PM **Closing Remarks**

3:45 PM **Adjournment of Trilateral Meeting**

7:00 PM **Cocktail and Dinner at the Canadian Museum of Civilization**
- Bus will leave the hotel at 6:30 pm (see Tab 8)

United States – Canada – Mexico

Heads of Delegation Meeting

October 21, 2004

Boardroom 6
Government of Canada Conference Center
2 Rideau Street
Ottawa (Ontario) Canada

Proposed Agenda

8:00 AM **Continental Breakfast**

8:30 AM **Welcoming Remarks**

- Diane C. Gorman, Assistant Deputy Minister, Health Product s and Food HPFB, Health Canada

8:45 AM **Opening Remarks and Country Updates**

- **Canada:** Diane C. Gorman, Assistant Deputy Minister, Health Product s and Food HPFB, Health Canada
- **United States**: Dr. Murray Lumpkin, Associate Commissioner of International Affairs, Food and Drug Administration
- **Mexico:** Lic. Ernesto Enríquez Rubio, Comisionado Federal, Comisión Federal Para La Protección Contra Riesgo Sanitarios (COFEPRIS), Secretaría de Salud

9:30 AM **Common Definitions for the Trilateral Cooperation -** United States

9:45 AM **Steering Committee Report** - Canada

10:00 AM **HEALTH BREAK**

10:15 AM **Working Groups' Recommendations and Deliverables**

- CUMCIG - United States
- Emergency Preparedness and Response - United States

- MUCH - Mexico
- Laboratory Cooperation - Canada
- Training - United States

11:10 AM **Heads of Delegation Feedback and Next Steps on Working Groups' Recommendations**

11:45 AM **Closing Remarks**

- **Canada:** Diane C. Gorman, Assistant Deputy Minister, Health Product s and Food Branch (HPFB), Health Canada

- **United States**: Dr. Murray Lumpkin, Associate Commissioner of International Affairs, Food and Drug Administration

- **Mexico:** Lic. Ernesto Enríquez Rubio, Comisionado Federal, Comisión Federal Para la Protección Contra Riesgo Sanitarios (COFEPRIS), Secretaría de Salud

12:00 PM **Photograph**

12:30 PM **LUNCH** (Wilfrid's Restaurant, Fairmont Château Laurier Hotel)

Appendix B

United States – Canada – Mexico

Annual Trilateral Meeting

October 18-21, 2004
Fairmont Château Laurier Hotel
1 Rideau Street
Ottawa (Ontario) Canada

Final List of Participants

(Revised: October 21, 2004)

CANADA		
NAME AND TITLE	**ORGANIZATION**	**COORDINATES**
Head of Delegation:		
Diane C. Gorman Assistant Deputy Minister	HPFB	Ph: (613) 957-1804 Fax: (613) 957-3954 Email: diane_gorman@hc-sc.gc.ca

CANADA		
NAME AND TITLE	**ORGANIZATION**	**COORDINATES**
Steering Committee:		
Robert Asare-Danso A/Director	Office of Regulatory and International Affairs, HPFB	Ph: (613) 941-9379 Fax: (613) 941-8322 Email: robert_asare-danso@hc-sc.gc.ca
Judith Lockett **(Co-Chair)** Director General	Office of Regulatory and International Affairs, HPFB	Ph: (613) 957-6349 Fax: (613) 941-8322 Email: judith_lockett@hc-sc.gc.ca
Country Coordinator:		
Nathalie Lévesque Policy Analyst	Office of Regulatory and International Affairs, HPFB[1]	Ph: (613) 957-3469 Fax: (613) 941-8322 Email: nathalie_levesque@hc-sc.gc.ca

[1] Legend:

CFIA: Canadian Food Inspection Agency
HPFB: Health Products and Food Branch, Health Canada
FBPB: Fair Business Practices Branch, Competition Bureau

Working Groups:		
CUMCIG		
Danièle Dionne **(Co-Chair)** Acting Executive Director	Assistant Deputy Minister Office, HPFB	Ph: (613) 954-0513 Fax: (613) 952-9805 Email: daniele_dionne@hc-sc.gc.ca
Sharon Flack A/Senior Bilateral Officer	International Affairs, CFIA	Ph: (613) 228-6634 Fax: (613) 225-2342 Email: sflack@inspection.gc.ca
Claude Lesage Senior Counsel/Manager	Legal Services Health Canada	Ph: (613) 954-1428 Fax: (613) 957-1327 Email: claude_s_lesage@hc-sc.gc.ca
Greg Orriss Director	Bureau of Food Safety and Consumer Protection, CFIA	Ph: (613) 221-7162 Fax: (613) 221-7295 Email: orrissgr@inspection.gc.ca
Dennis Shelley Operational Manager	HPFB Inspectorate British Columbia/Yukon Regional Office Health Canada	Ph: (604) 666-3704 Fax: (604) 666-1398 Email: dennis_shelley@hc-sc.gc.ca
Chris Palmer Associate Director	International Program, Bureau of Food Regulatory, International and Interagency Affairs, HPFB	Ph: (613) 941-4616 Fax: (613) 941-3537 Email: chris_palmer@hc-sc.gc.ca
Emergency Preparedness and Response		
Gerald R. Nixon National Manager	Food Safety Investigations Program	Ph: (613) 221-7158 Fax: (613) 221-7295 Email: gnixon@inspection.gc.ca

Jennifer Hill **(Co-Chair)** Director	Office of Emergency Management Liaison, Preparedness and Policy Coordination, CFIA	Ph: (613) 225-2342 ext. 3799 Fax: (613) 228-6619 Email:: hilljs@inspection.gc.ca
Nicholas Trudel Director	Emergency, Security and Facilities Management Office of Management and Program Services, HPFB	Ph: (613) 948-2654 Fax: (613) 952-8852 Email: nicholas_trudel@hc-sc.gc.ca
Laboratory Cooperation		
Andrew Adams Director	Ontario Laboratories Network, CFIA	Ph: (613) 228-6698 ext. 4899 Fax: (613) 228-6660 Email: adamsa@inspection.gc.ca
Colin Broughton **(Co-Chair)** Regional Director	Ontario and Nunavut Region, HPFB	Ph: (416) 973-1452 Fax: (416) 973-1554 Email: colin_broughton@hc-sc.gc.ca
Terry D. Cyr Research Scientist	Centre for Biologics Research, BGTD, HPFB	Ph: (613) 957-1068 Fax: (613) 941-8933 Email: terry_cyr@hc-sc.gc.ca
MUCH		
Christian Boulianne Competition Law Officer	Compliance and Enforcement Coordination Division, HPFB Inspectorate	Ph: (819) 994-6039 Fax: (819) 953-2557 Email: boulianne.christian@cb-bc.gc.ca
Joan Korol Compliance Officer	Inspectorate, Investigation & Coordination Unit, HPFB	Ph: (613) 946-5090 Fax: (613) 954-0941 Email: joan_korol@hc-sc.gc.ca

Gilles Morissette Senior Competition Law Officer	Competition Bureau Fair Business Practices Branch Division B	Ph: (613) 997-1484 Fax: (613) 994-2240 Email: morissette.gilles@cb-bc.gc.ca
Etienne Ouimette **(Co-Chair)** Director	Compliance and Enforcement Coordination Division, HPFB Inspectorate	Ph: (613) 952-5804 Fax: (613) 952-9805 Email: etienne_ouimette@hc-sc.gc.ca
Andréa Rosen Assistant-Deputy Commissioner	Competition Bureau Fair Business Practices Branch Division A	Ph: (819) 953-4300 Fax: (819) 953-2557 Email: rosen.andrea@cb-bc.gc.ca
Raymond W. Tsang Manager	Natural Health Products , HPFB	Ph: (416) 952-4610 Fax: (416) 973-7794 Email: raymond_w_tsang@hc-sc.gc.ca
Training		
Christine Labaty A/Director	Office of Continuing Education, HPFB	Ph: (613) 941-5442 Fax: (613) 941-5534 Email: christine_labaty@hc-sc.gc.ca
Céline Savard Project Officer	Office of Continuing Education, HPFB	Ph: (613) 946-3581 Fax: (613) 941-5534 Email: celine_savard@hc-sc.gc.ca
Ginette Workman **(Co-Chair)** Director	Office of Management and Program Services, HPFB	Ph: (613) 952-0868 Fax: (613) 952-8872 Email: ginette_workman@hc-sc.gc.ca
Other:		
Paul Haddow Executive Director	International Affairs, CFIA	Ph: (613) 225-2342 Fax: (613) 228-6649 Email: phaddow@inspection.gc.ca
Secretariat:		
Tillie Andrews Executive Assistant	Office of Regulatory and International Affairs, HPFB	Ph: (613) 948-2758 Fax: (613) 941-8322 Email: tillie_andrews@hc-sc.gc.ca
Zydra Gestautaite Program Officer	Office of Regulatory and International Affairs, HPFB	Ph: (613) 948-6330 Fax: (613) 941-8322 Email: zydrune_gestautaite@hc-sc.gc.ca

Amberine Sheikh Administrative Assistant	Office of Regulatory and International Affairs, HPFB	Ph: (613) 948-6873 Fax: (613) 941-8322 Email: oria_ea@hc-sc.gc.ca
UNITED STATES		
NAME AND TITLE	**ORGANIZATION[2]**	**COORDINATES**
Head of Delegation:		
Murray M. Lumpkin, M.D. Deputy Acting Commissioner	International and Special Programs Office of the Commissioner, FDA	Ph: (301) 827-5709 Fax: (301) 443-3100 Email: mlumpkin@oc.fda.gov
Steering Committee:		
John Marzilli **(Co-Chair)** Deputy Associate Commissioner	Office of Regulatory Affairs, FDA	Ph: (301) 827-3101 Fax: (301) 443-6591 Email:john.marzilli@ora.fda.gov
Melinda K. Plaisier **(Co-Chair)** Assistant Commissioner for International Programs	Office of International Programs, FDA	Ph: (301) 827-4480 Fax: (301) 827-1451 Email: mplaisie@oc.fda.gov
Country Coordinator:		
Charles Gaylord Associate Director of the Americas	Office of International Programs, FDA	Ph: (301) 827-0909 Fax: (301) 827-0003 Email: cgaylord@oc.fda.gov
Working Groups		
CUMCIG		
Joe Baca Director, Office of Compliance	Center for Food Safety and Applied Nutrition, FDA	Ph: (301) 436-2359 Fax: (301) 436-2717 Email: jbaca@cfsan.fda.gov
Mildred Barber **(Co-Chair)** International Affairs	Office of Regulatory Affairs FDA	Ph: (301) 827-1135 Fax: (301) 443-3757

[2]Legend:

FDA: Food and Drug Administration
ORA: Office of Regulatory Affairs

Program Manager		Email: mbarber@ora.fda.gov
Brian Hasselbalch Consumer Safety Officer, Office of Compliance	Center for Drug Evaluation and Research	Ph: (301) 827-9046 Fax: (301) 827-8908 Email: hasselbalchb@cder.fda.gov
Dan McChesney Director, Office of Surveillance and Compliance	Center for Vetinary Medicine	Ph: (240) 453-6830 Fax: (240) 453-6880 Email: Daniel.mcchensey@fda.hhs.gov
Michael C. Rogers Director, Division of Field Investigations	Office of Regulatory Affairs, FDA	Ph: (301) 827-5658 Fax: (301) 443-3757 Email: mrogers2@ora.fda.gov

Emergency Preparedness and Response		
Ellen Morrison **(Co-Chair)** Director, Office of Crisis Management	Office of Crisis Management, Office of the Commissioner, FDA	Ph: (301) 827-5660 Fax: (301) 827-3333 Email: ellen.morrison@fda.gov
Emergency Prepardness and Response (cont'd)		
Israel Santiago Staff Manager, Office of Crisis Management	Office of Emergency Operations, FDA	Ph: (301) 827-5670 Cell: (301) 801-1091 Fax: (301)827-3333 Email: isantiago@oc.fda.gov
Laboratory Cooperation		
Carl Sciacchitano Senior Microbiologist	Office of Regulatory Operations, ORA FDA	Ph: (301) 827-1028 Fax: (301) 443-6388 Email: csciacc1@ora.fda.gov
MUCH		
Richard Cleland Assistant Director, Division of Advertising Practices	Federal Trade Commission	Ph: (202) 326-3088 Fax: Email: releland@ftc.gov
Joyce Wein Iliya Assistant Attorney General	State of Texas, Office of the Attorney General, Consumer Protection Division, Dallas Regional Office	Ph: (214) 969-7639 ext. 111 Fax: (214) 969-7615 Email: Joyce.Iliya@OAG.State.Tx
Gary Coody National Health Fraud Coordinator	Office of Enforcement, FDA	Ph: (240) 632-6806 Fax: Email: gary.coody@fda.gov

Training		
Gary German **(Co-Chair)** Director	Division of Human Resource Development, ORA FDA	Ph: (301) 827-8672 Fax: (301) 827-3737 Email: ggerman@ora.fda.gov
Other:		
Naomi Kawin Associate Director for International Policy	Office of International Programs, FDA	Ph: (301) 827-0590 Fax: (301) 480-0716 Email: nkawin@oc.fda.gov
Lonzell (Bud) Locklear Specialist	Environment, Science & Technology Embassy of the United States 490 Sussex Drive, Ottawa, Ontario	Ph: (613) 688-5244 Fax: (613) 234-2588 Email: locklearl@state.gov
MEXICO		
NAME AND TITLE	**ORGANIZATION**[3]	**COORDINATES**
Head of Delegation:		
Lic. Ernesto Enriquez Rubio Comisionado Fedeal para la Protección contra Riesgo Sanitarios	COFEPRIS	Ph: Fax: Email:

[3] Legend:

COFEPRIS: Federal Commission for the Protection of Sanitary Risks
PROFECO: Federal Office of the Judge Advocate General of Consumers

Steering Committee:		
Lic. Luis Alfonso Caso González **(Co-Chair)** Comisionado de Fomento Sanitario	COFEPRIS	Ph: 52-55-55-14-85-85 Fax: Email: lacaso@salud.gob.mx
Lic. Marcela Madrazo Reynoso Coordinadora General del Sistema Federal Sanitario	COFEPRIS	Ph: 52-55-55-14-85-88 Fax: Email: mmadrazo@salud.gob.mx
Country Coordinator:		
Lic. Renée Salas Guerrero Subdirectora Ejecutiva de Operación Internacional	COFEPRIS	Ph: 52-55-55-14-85-86 Fax: Email: rsalas@salud.gob.mx
Working Groups		
CUMCIG		
Ing. Fermín Islas Director Ejecutivo de Supervisión y Vigilancia Sanitaria	COFEPRIS	Ph. 52-55-55-14-09-30 Fax: Email: ferminislas@salud.gob.mx
Q. Rosa María Morales Gerente de Fármacos y Medicamentos	COFEPRIS	Ph: 52-55-50-80-53-84 Fax: Email: rmoraleszuniga@yahoo.com.mx
M en B Sonia Zamudio Alonso **(Co-Chair)** Directora Ejecutiva de Autorización de Productos y Establecimientos	COFEPRIS	Ph: 52-55-50-80-53-54 Fax: 52-55-52-08-06-10 Email: soniaz@salud.gob.mx

Emergency Prepardness and Response		
Biol. Aķda Albuerne Piña (Co-Chair) Comisionada de Operación Sanitaria	COFEPRIS	Ph: 52-55-55-14-07-61 Fax: Email: aalbuerne@salud.gob.mx
Q en A María Esther Díaz Carrillo Subdirectora Ejecutiva de Supervisión Operativa	COFEPRIS	Ph: 52-55-50-80-52-52 Fax: 52-55-52-08-28-71 Email: ediaz@salud.gob.mx
Laboratory Cooperation		
M en B Elvira Espinosa Gutiérrez **(Co-Chair)** Comisionada de Control Analítico y Ampliación de Cobertura	COFEPRIS	Ph. 52-55-55-73-37-20 Fax: 52-55- Email: eespinosa@salud.gob.mx

MUCH		
Q.F.B. Maribel Bernal Encargada de la Dirección de Autorización, Comercio Exterior y Publicidad	COFEPRIS	Ph: 52-55-50-80-54-82 Fax: Email: mbernal@salud.gob.mx
Lic. Marisol Chicano Pérez Subdirectora Ejecutiva de Autorización Publicitaria	COFEPRIS	Ph. 52-55-52-08-08-85 Fax: Email: marisolchicano@salud.gob.mx
Lic. Verónica González Gerente Ejecutiva de Monitoreo de Medios	COFEPRIS	Ph: 52-55-50-80-52-88 Fax: Email: veronicajglz@salud.gob.mx
Lic. José Rodrigo Roque Díaz Subprocurador de Verificación de la Procuraduría Federal del Consumidor	PROFECO	Ph: Fax: Email:
Training		
M en C Guadalupe Ocampo Gómez **(Co-Chair)** Directora Ejecutiva de Comunicación de Riesgos y Capacitación	COFEPRIS	Ph. 52-55-55-14-85-90 Fax: Email: ocampogomez@salud.gob.mx
m **Other:**		
Dr. Marcelo Signorini Subdirector Ejecutivo de Efectos Poblacionales	COFEPRIS	Ph: 52-55-55-14-69-39 Fax: Email: msignorini@salud.gob.mx
Secretariat:		
M en C Patricia Pineda Zavaleta Gerente de Asuntos Internacionales en Agentes Químicos y Medicamentos	COFEPRIS	Ph: 52 55-55-14-85-91 Fax: 52-55-52-08-29-74 Email: ppineda@salud.gob.mx

Appendix C

RESULTS OF THE GROUP DISCUSSION FROM THE PRE-TRILATERAL SEMINAR

Scenario: You have just been informed of a potential dangerous unapproved pharmaceutical drug which claims to produce rapid weight loss in use in your country.
There have been deaths worldwide, apparently linked to this product.*

** (Caveat – the drug excludes Natural Health Products, Food or Vitamin Supplements)*
***** Additional details:*** The product (drug) is being promoted on infomercials and the internet with claims that guarantees a weight loss of 30 pounds in 20 days
and to be clinically proven safe.

Themes	**Outcome of the interactive session on similarities and differences**
I. Decision-making Process	
1 a) How do the science and the policy components of your organization connect (if at all) in your decision-making process?	**Identified similarities:** • All based on scientific-public health evidence • Unapproved product • Death/emergency/immediate action • Focus on risk assessment (deaths) 1. Communication/dissemination system • Risk/benefit assessment critical element of decision-making • Gather info from all partners • Very clear decision-making processes **Identified differences:** • Adverse reporting events 1. Canada & USA – Voluntary (strategic consideration only for health professionals) 2. Mexico – Mandatory (for health professional) • Internet activities ≠ access issues • Systems are different • Export requirements
1 b) How are health risks and benefits assessment built into your decision-making process?	

1 c) How are other relevant considerations (economic, legal, ethical, social, etc.) brought into the decision-making approach?	**USA** • Proper health care • Communication media (responsible to communicate) **Mexico** • Advertising and publicity **<u>Identified similarities:</u>** • Labelling / indication issues • Death / health issues (Agency – rapid response (24 hours) for serious health hazard) • Based on law • Social, ethical and political considerations – but not part of the decision-making • Act immediately based on the proposed scenario
II. Consultation	
2 a) Who are the domestic and international partners involved or consulted in the decision-making approach?	**USA** • Would find out what the reports indicate internationally **Mexico** • Because it is international, it makes a big difference in respect to action. • Telephone sales vs internet sales **<u>Identified similarities:</u>** • Common organisations 1. Health agencies, departments 2. Trade associations 3. Provincial states 4. Customs 5. Trade agencies (Industry Canada, COFEPRIS, Federal Trade Commission) 6. Professional associations 7. Laboratories, scientific expertise (includes third parties) 8. WHO, country specific foreign regulators • Simultaneous communication with international and national partners • Depends on agency involved, interpretation of the issue • Different sequence would be initiated if it is an approved drug, non-approved drug or health product **<u>Identified differences:</u>** • The level of the Trade Agencies involvement.
2 b) when are they involved [at what point]?	**USA** • Scientists would contact scientists in other country • Would contact sister agency in the other country • Office of Crises Management contact **Mexico** • As soon as alert is issued **Canada** • Use similar agency in other country for them to disseminate information **<u>Identified similarities:</u>** • All three countries would involve national/domestic partners at the beginning and throughout in order to gather information

	• All three countries would notify international partners as soon as the information is available • All three countries would go to the country of origin to obtain more information
2 c) what are their roles?	**USA** • Risk evaluation – economic data • Accessing expertise • May access partner country • US examples – Aristolochin consulted Belgium, KAVA domestic information did not support "bail" or international info. No ban in USA • Would not solely be based on international info **Mexico** • Risk determination • Recall & would communicate to public • Product could be reformulated **Canada** • Risk assessment • Complaint driven • Recall seizure if required • Communication to Public – advisory letters to pharmacists & physicians **<u>Identified similarities:</u>** • Similar model being used by all 3 countries in regard to risk assessment • Each agency has a primary health agency that is expected to be the lead agency. Other agencies provide information, investigations, specific remedies and publicity/communication. **<u>Identified differences:</u>** • Trade associations' role and seizures. 1. Mexico can seize without a court order. 2. USA and Canada can not
2 d) What is the impact of your partners' decision? How does it influence your decision?	With internet, it is difficult to know who the legal agent might be. **USA** • Burden of proof is on importer • Can stop entry of product on "appearance of risk" with an import alert **Mexico** • If info is available, can stop product at the border, if no further research is required **Canada** • Domestically, we use our partners strategically **<u>Identified similarities:</u>** • Responsibility rests with the legal agent **<u>Identified differences:</u>** • Partners' decision 1. USA & Mexico - take into consideration the decision of their partners but the agency's decision is not driven by them. 2. Canada has a shared roles & responsibilities. The impact is therefore within the limitations of regulations and policies.

2 e) When in the process [and in what circumstances] does your agency touch base with your Trilateral partners?	**USA** • Evidence that the product was on its way to partner country • Consult on actions taken **Mexico** • When alert is issued • Risk information exchange **Canada** • "Common sense" tool aims for consistent action unless situation is different in Canada • Finding an expert and using this information in a case **Identified similarities**: • If a Trilateral partner is involved (import/export), notified as soon as possible. Notified by : e-mail, conference calls.
III. Implementation / Evaluation	
3a) What is your agency's strategy implementation process? (Describe key steps or aspects)	**Identified similarities:** All agreed on basic strategy for implementation as follows: • Receive / verify information • Assess risk • Decide legal jurisdiction • Contain immediate problem – recall or removal of product from commerce • Notify related agencies / government offices and public notification • Multi-agency effort / multi faceted response • Similar process at macro level • Similar risk management approach • Similar pursuit of legal recourse • Unclear "ownership" of problems / grey areas • Need / desire for evidence to support decisions • Direct consumer reporting of adverse events **Identified differences:** • Socio-cultural – perception & tolerance of risk • Micro-level process • Legal differences : e.g. pharmaceuticals vs food in USA
3b) What are the options?	**Identified similarities:** • Legal and regulatory options • Priority placed on protection of the public • Control the product/sales • Warnings / advisories • Recall / embargo /immobilize • Voluntary compliance • Control of claims & advertising

3c) How are the results of the strategy implementation monitored (over time)?	**Identified similarities:** • Very similar in purpose and process in monitoring risks • Market monitoring • Adverse event reporting • Inspections • Reporting by public organizations, private sector and consumers • Surveillance systems • Scientific literature
3 d) What measures has your agency put in place to make its decision-making more transparent or visible to the public and other agencies? (i.e. documentation of decisions)	**Mexico** • Sometimes needs to seek judicial clearance for releasing certain documents. **Identified similarities:** • Legal obligation • Organisational desire • Formal written agreement (Memorandum of Understandings (MOUs)) • Measures are not comprehensive • Publication/communication • Stakeholder engagement • Private sector (Mx) • All have internal government offices/staff dedicated to fulfilling public release requirements • All three countries agreed that being internally transparent/accountable is important, as is being externally transparent / accountable • All have internal action (regulatory /administrative) and approval procedures **Identified differences:** • Some differences in process of public transparency of documents.
3 e) What are potential compliance and enforcement actions?	**Identified similarities:** • All have the authority to control drugs • Voluntary • Seizures • Public warnings / advisories • Prosecution **Identified differences:** • Specific penalties • Procedures • Seizures 1. Canada & Mexico – can detain / seize with or without judicial clearance 2. US - has to engage courts to interdict / remove from commerce fraudulent product (most types) • Mexico - can take action against TV stations and other information carrier for illegal promotion of unapproved drugs

Within the Trilateral Cooperation context and given these similarities and differences, what initiatives could be undertaken to strengthen our confidence?

- Exchange of information, particularly in products that may be fraudulous or causing health risks.
- Advance sharing of approved press releases before posting on website.
- Exchange info on companies with fraudulent actions (past activities) (confidentiality agreement – exchange on investigation (operationalize))
- Communication (Alert, check-up, lessons learned, use existing structure. MUCH as one option)
- Case studies : risk assessment focus

- Exchange information on legislative and law enforcement techniques
- Exchange of scientific information using scientific nomenclature
- Exchange info on investigative techniques
- Worker exchange programs
- Where appropriate, joint law enforcement action
- System to inform our counterparts even though it does not affect all three countries.
- Share investigations of problematic websites

Appendix D

Summary Report- Pre-Trilateral Seminar Survey

Background: At the October 2004 meeting in Ottawa, the Training Working Group received a number of suggestions for training topics that could be delivered at future meetings. We have validated those training needs and asked the participants' input through the Pre-Trilateral Seminar on-line survey that was run in December 2004. Participants were invited to complete the questionnaire, to rank, from the suggested topics, their top 5 topics and to provide additional comments related to the expected course/session content.

Objective: The objective of the on-line survey was to collect information, start to develop a long term training plan of topics for the Trilateral Cooperation and make a recommendation to the Steering Committee for their concurrence. The survey's results are not intended to be the only means to identify future training needs; however, it could serve as the starting point for the development of our long term Trilateral Cooperation training curriculum.

Survey Development: The process used to achieve our objective was to:

- Develop the survey methodology,
- Develop a communication plan,
- Create an on-line survey,
- Administer the on-line survey,
- Collect and analyze the data, and
- Share survey's results.

Survey Tool Used: The on-line survey tool was Websurveyor (www.websurveyor.com). This tool allowed for:

- automated data collection,
- automated data analysis,
- cross-tabulation, and
- real-time representation of survey results.

The Websurveyor software requires no additional plug-ins or hardware and it is rated #1 for ease of use by PC Magazine. The collected data was stored on a secure server and the results were anonymous.

Ranking Process: The following weighted scale was used to rank the suggested topics based on the priority that survey respondents assigned to the topic:

Priority #1	5 points
Priority #2	4 points
Priority #3	3 points
Priority #4	2 points
Priority #5	1 point

For example, if Risk Assessment / Risk Analysis was rated as priority #1 by 3 respondents, priority #2 by 2 respondents and priority #3 by 1 respondent the over all weighted total would be calculated as (3x5) + (2x4) + (1x3) = 26 points.

The suggested topic with the highest weighted total was ranked first overall, the topic with the second highest weighted total was ranked second overall and so forth.

Survey Outcome: 33% (19 respondents) of the Pre-Trilateral Seminar participants completed the on-line survey. The Training WG identified, based on the weighted total, the top 5 topics along with their comments. The results are listed in *Appendix A*.

In addition, the response breakdown for the trilateral working groups and country representation were as follows:

Working Groups:

Response	# Count	%
Steering Committee	2	10.50 %
CUMCIG	2	10.50 %
MUCH	5	26.30 %
Lab. Coop.	3	15.80 %
EPR	3	15.80 %
Training	4	21.0 %

Country:

Response	# Count	%
USA	6	31.60 %
Mexico	7	36.80 %
Canada	6	31.60 %

Conclusion: This on-line tool was used for the first time within the Trilateral Cooperation context. It was felt, from the additional comments captured, that this communication tool has been useful and efficient. Furthermore, the information collected will benefit the Training Working Group to achieve its objective which is to develop or assist in the development and delivery of training intended to further the purpose of the Trilateral Cooperation.

As indicated, these results/priorities could serve as the basis of our long term training plan but not limited to only that. The identified priorities will, however, be subject to review, prioritization and vetting by the Steering Committee. The training activities must be of common interest to the three countries in order for the Trilateral Cooperation to carry out its purpose and objectives. Also, the training activities must support the Trilateral Cooperation annual priorities, result from an emergency issue or be identified by one of the working groups as a training need.

Appendix E

Additional Comments from Participants in the Pre-Trilateral Seminar

- Outstanding facilitation
- It was the right way to go!
- Scenario forces participants to internalize learning to be active participant rather than passive. Telling of scenario prior to presentation also helpful because pay attention better.
- Common depository of information/legislation/regulations/policy
- Full day training event more useful.
  Presentations were long enough; and enough time for discussions.
  Facilitation: good practice!
- Training topic should not be so black and white. A topic with a minor illness or a mislabeling issue might be useful.
- Thank you!
- I don't know what I don't know…
- This first exercise was satisfactory, but for the next one it would be interesting if it had more complexity and if the risk evaluation and risk management decisions had less obvious answers.
- Seek mechanisms that make other members of other tables participate more.
- The workshop was excellent for forging ties between the countries; in the future will help us remain closer.
- Many congratulations
- -- This type of practical case helps us interact in a more effective way.
  -- We need to exchange more experiences and innovative matters.
- The workshop helps a lot for better understanding and creating confidence between the agencies.
- It would be better in small rooms, because the discussion at one table mixed in with that of the neighboring table.
- Should ensure that appropriate staff from each agency/country present on scenarios and be involved in decision process exercises so that more benefit can be realized.
  Participants in exercises should also be given the scenario/case in advance and instructed to meet with responsible units/staff in their organizations to get answers to the pre-established questions -- This will ensure that they speak on behalf of their agency.
- The workshop was excellent for bringing the countries together, developing in the future this exercise will help bring us closer.
- Because we will run out of topics very soon, keep in mind year format limited to core international affairs contacts. It is very expensive to move that many resources.

Updated: Nov. 2004

Top 5 topics

Suggested Topic	Comments collected from Survey
1) Emergency Preparedness & Response (EPR) - Pre-Public communication process **(35 points)**	• La creación de un procedimiento trilateral de respuesta a emergencias (Create a trilateral procedure to respond to emergencies) • Conocer los procedimientos de otros paises en la preparación de respuesta a emergencias sanitarias (know what other countries do to prepare for health emergencies) • How each country acts in EPR in pre-public communication process • Obtain contact information for Emergency preparedness for each agency and understand processes that would be followed in the event of an emergency • To learn about the other countries systems and to gather ideas to improve our own EPR • El propósito es conocer los procedimientos de atención de emergencias de origen diverso y hacer del conocimiento público el progreso del grupo de trabajo, así como sus planes para el futuro. (the purpose is to find out how a rapid alert system is established with communication among the parties involved) • Estrategias para la comunicación y gestión del riesgo ante emergencias. (Strategies for communication and risk management before emergencies) • Learn about what is currently in place in each country and have a good discussion about what else could be done with a trilateral focus what info. is useful to share and can be shared; what tools (internet, etc) will be used-how to access and "store" information for continuity of access.
2) Facilitate exchange of technical information **(33 points)**	• Not looking fro training help on these topics • Scope of info collected; type of evaluation or analysis of info collected; understand what can be disclosed and when it can be disclosed with a foreign national regulatory agency; proper use of the information disclosed to ensure mutual balance in volume and in nature of subsequent action • Mecanismos para facilitar el intercambio de información técnica entre los tres países. (Mechanisms to facilitate sharing technical information among the three countries) • Intercambio oportuno de información (Timely exchange of information) • Establecer mecanismos de intercambio de información (Establish information-sharing mechanisms) • How each country act. • El intercambio de información técnica ha probado ser un tema de particular relevancia e interés para los grupos de trabajo, pero también ha presentado dificultades de distinta índole. El propósito de discutir el tema sería presentar las experiencias hasta el momento y buscar soluciones al problema, por lo que se propone que en lugar de ser un taller de II sea de SC. (The sharing of technical information is a topic of particular relevance and interest for the working groups, but various difficulties have arisen. The purpose of discussing the issue would be to present experiences up to now and to seek solutions to the problem, so it is suggested that the workshop be a training session instead of an information sharing session) • This might include information on science, exchange and

	assistance in enforcement activities
3) Share monitoring tools and inspection techniques / approaches **(25 points)**	• Understand one another's surveillance priorities and inspection approach(i.e., depth/scope) to determining product quality; understand enforcement tools and regulatory process for judging surveillance findings; understand why corrective/punitive action is taken or not. • Learn from other organizations about their tools and techniques for a more informed analysis of processes currently in place in my organization. Better understanding should facilitate efficient sharing of information. • Concluir ele intercambio de información, tal vez con ejercicios para reconocer nuestros sistemas (conclude information sharing, perhaps with exercises to recognize our systems) • How each country acts • Intercambio oportuno de información (Timely exchange of information) • Establecer mecanismos de intercambio de información (Establish information-sharing mechanisms)
4) Rapid notification alerts **(20 points)**	• To better understand how does each countries system of alerts work; to understand the process & criteria for notification; to understand the approval process & priorities within each country; to understand how the systems can best work together • El propósito es conocer cómo se establece un sistema de alerta rápida con su respectiva intercomunicación entre los actores involucrados. (the purpose is to find out how a rapid alert system is established with communication among the parties involved) • Envío oportuno de información.(Timely sending of information) • Conocerlo y retroalimentar para una respuesta oportuna (Know it and give feedback for a timely response) • How each country act • To gather ideas to improve our own systems
5) Risk assessment / risk analysis **(19 points)**	• Aplicaciones prácticas del análisis de riesgo a situaciones reales, considerando cuestiones como fuentes de información, principio precautorio, etc. (Practical applications of risk analysis to real situations, considering such issues as sources of information, precautionary principle, etc.) • Se busca aprender sobre la/las metodología(s) utilizada(s) para realizar análisis/evaluación de riesgos con el propósito de entender el fundamento del proceso de toma de decisión de las agencias. (Try to learn about method(s) used to analyze/assess risks in order to understand the basis of the agencies' decision-making process) • Entender cuales son los procedimientos de evaluación de riesgos, para un caso especifico (understand the risk assessment procedures for a specific case) • Understand national authorities use of formal and informal risk analysis: type of analysis and regulatory programs to which it is applied; limitations on use; anticipated future use; data management • Intercambio de técnicas (Technical exchange) • To learn, compare and contract the different risk analysis methods used in the 3 countries; to learn what a risk in a given country might mean for another • Continue some of the discussions we had in Ottawa with a specific case study