
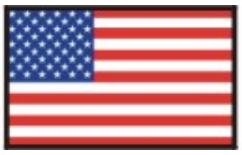


Trilateral Cooperation Charter

Between

The Health Products and Food Branch,
Health Canada
Canada,

The Food and Drug Administration,
Department of Health and Human Services
The United States of America,

and

The Federal Commission for the Protection from
Sanitary Risks,
Secretaria de Salud
Mexico

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Trilateral Cooperation Charter

PURPOSE

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.

MISSION

To protect and promote public health through a trilateral forum that shares information and works collaboratively on issues of mutual interest.

MEMBERSHIP (Participants to the Trilateral Cooperation)

United States:	Food and Drug Administration (USFDA)* and the Federal Trade Commission (FTC).
Canada[1] :	Health Products and Food Branch (HPFB)*, Canadian Food Inspection Agency (CFIA), and the Commissioner of Competition (Competition Bureau).
Mexico:	Federal Commission for the Protection from Sanitary Risks (COFEPRIS),* Federal Office of the Judge Advocate General of Consumers (PROFECO).

*Signatories

This Charter recognizes that others may be invited to participate (based on the issues before the Trilateral Cooperation). It also recognizes that non-signatory organizations have mandates in the areas of drugs, medical devices, food safety, and nutrition (to protect and promote human health) as well as in the areas of general marketplace competition and consumer benefit.

STRATEGIC OBJECTIVES

In pursuit of this mission, members intend to actively engage in achieving the following strategic objectives:

- Identifying and solving problems;
- Sharing information and best practices, and establishing harmonized positions on issues of mutual interest;
- Identifying emerging issues of common interest;
- Promoting capacity building;
- Developing confidence/capacity and trust among members of the trilateral;
- Increasing public confidence;
- Developing partnerships; and
- Developing mechanisms for cooperation and working collaboratively to implement solutions for issues of mutual interest.

PRINCIPLES

To achieve these objectives, the Parties to the Trilateral Cooperation should be guided by the following principles:

- A focus on health and safety issues;
- Equal participation for all stakeholders;
- Serving the interests of all three countries;

- The use of joint problem-solving techniques and consensual decision-making processes; and
- The advancement of public health.

GOVERNANCE STRUCTURE

A. Heads of Delegation

The Trilateral Heads of Delegation Team is the decision-making body of the Trilateral Cooperation. It comprises the leaders of HPFB (Assistant Deputy Minister), the FDA (Commissioner of Food and Drugs), and COFEPRIS (Federal Commissioner). The role of the Trilateral Heads of Delegation is to provide overall leadership for and direction to the Trilateral Cooperation.

B. Steering Committee

Reporting to the Heads of Delegation, the Steering Committee sets the agenda for each meeting in line with the principles and strategic objectives, focusing on priorities that benefit all countries.

The Steering Committee consists of an equal number of members from each country, with the selection being the responsibility of the individual countries. The Committee provides leadership to the Working Groups and recommends high-level policy issues to the Heads of Delegation. As well, it identifies and discusses new and emerging issues confronting the three countries. The Steering Committee is led by country Co-chairs who serve as liaisons to the Working Groups.

Specifically, the Steering Committee

- draws upon the expertise of its members and others to provide advice and recommendations on high-level issues to the Heads of Delegation;
- garners support and promotes the Trilateral Cooperation by communicating objectives and accomplishments to senior management in its respective organizations;
- establishes ad hoc sub-committees and/or task forces to undertake specific work;
- invites experts to submit information to the Committee, when and as required;
- is the forum for joint proactive Trilateral Cooperation planning; and
- refers unresolved issues to the Heads of Delegation, as required.

C. Working Groups

The Trilateral Cooperation undertakes its work through Working Groups. Three Co-chairs representing each country head each Working Group. The Co-chairs are responsible for identifying issues for discussion and for seeking the Steering Committee's support. Current Working Groups include the following:

1. Canada-US-Mexico Compliance Information Group (CUMCIG): Its purpose is to increase the exchange of emergency preparedness and response, compliance and enforcement information between the three countries. The Group coordinates related enforcement activities with counterpart agencies in appropriate cases. Lead Country: United States of America.
2. Mexico-US-Canada Health Fraud Group (MUCH): Its purpose is to maintain a formal framework for cooperation in combating health fraud and to identify appropriate lines of communication to ensure a continual exchange of information on compliance and enforcement activities among the three countries. Lead Country: Mexico.
3. Laboratory Cooperation Working Group: Its purpose is to establish and maintain cooperation in the area of regulatory laboratory operations. Through continual discussions, this group is expected to share information with a view to building confidence in our respective analytical results. Lead Country: Canada.
4. Canada-US-Mexico Training Working Group: Its purpose is to share existing training information, establish a communication strategy between the Training Working Group and the other Working Groups, and to assist in identifying training needs of staff who will be engaged in Trilateral work. Lead Country: United States of America.

D. Country Coordinators (Secretariat)

Management and support services are provided by each of the countries to the Trilateral Cooperation. Country Coordinators coordinate input and develop agendas for the Trilateral meetings. They are also responsible for selecting a facilitator, creating a record of decisions at each Committee meeting, establishing schedules for Steering Committee conference calls and meetings, and developing and tracking action items from each meeting.

SCOPE OF WORK

The Trilateral Cooperation serves the mutual interests of all three countries and provides a forum for participants to discuss effective means for achieving its mission. Joint problem-solving techniques and consensual decision-making processes are used in reaching resolution of issues in a way that advances public health and gives consideration to the economic impact of health fraud. To avoid duplication and overlap, the Trilateral Cooperation should not deal with issues that are being discussed in other fora unless requested to do so as a means of solving a specific

problem affecting the three countries or unless directed to do so by the Heads of Delegation. The Committee recognizes that the work under the Trilateral Cooperation is not a substitute for bilateral cooperation, nor does it impose obligations on its counterparts. Countries should use existing and new fora to discuss bilateral issues.

CRITERIA FOR IDENTIFYING ISSUES FOR DISCUSSION

To prioritize its discussions, the Steering Committee uses the following criteria in selecting issues for discussion. Each issue must

- be a public health concern;
- be of common concern to all three countries;
- be solvable with realizable outcomes and within a reasonable time frame; and
- not detract from discussions or processes in other fora.

MEETINGS

The Steering Committee and the Working Groups should meet in the spring and fall of each year, with any additional meetings (teleconferences or videoconferences) called by the Steering Committee as required. Meetings should be hosted by each country on a rotating basis (Canada-Mexico-US). The host country is responsible for all scheduling, logistics, and management of the meetings.

The spring meeting will be devoted to reviewing progress, resolving any impediments to progress, and evaluating accomplishments.

The fall meeting, which includes a meeting of the Heads of Delegation, will be devoted to a year-end review, the assessment of outcomes, the identification of new issues, and the setting of priorities for the following year.

A tracking system (Action Plan) is to be developed by each Working Group to track major projects including action items, performance measurements, progress and accomplishments. The system should be updated regularly with summaries provided to the Steering Committee and the other Working Groups ahead of the spring and fall meetings. The Steering Committee expects to use these meetings to determine whether to renew its procedures and/or to make changes in any aspect of the partnership.

Agenda Development and Dissemination

Meeting agendas (subject to the Steering Committee's final approval) are developed by the host country in collaboration with the other two countries. All potential agenda items should be submitted to the country Coordinators who will forward them to the host country. The host country develops a mutually agreeable agenda for the spring and fall meetings. The final agenda should be distributed to all participants at least 10 working days prior to the meeting. For issues that require the Steering Committee to make a decision, all related information must be distributed to participants no later than 10 calendar days prior to the meeting.

SUMMARY OF OPERATING PROCEDURES

Meeting Process

1. Country Coordinators are responsible for coordinating input for the development of agendas, and for selecting facilitators and scribes for the meetings.
2. New business agenda items may be proposed by any member of the Steering Committee or Working Groups and should be submitted for consideration to the Coordinators for inclusion on the agenda 14 days before the meeting.
3. Meetings are to be held as required, but at least twice each year (spring and fall).
4. The Steering Committee may allot time for presentations by non-members regarding agenda items.
5. Meeting records should clearly indicate any members responsible for leading any action arising along with report back dates.

Decision Making

6. All decisions are to be made by consensus. Consensus is defined as an understanding by all members of the group, arrived at through discussion and compromise. Although it may not be each member's preferred result, it is a result that all members can "live with" and support.

Responsibilities of Members

7. Each member has a responsibility to participate actively in discussions and decision-making.
8. Each member of the Steering Committee and the Working Groups share responsibility for the effectiveness of the group's collaborative problem-solving and decision-making processes.
9. All members of the Steering Committee, regardless of whether they are present at meetings, are expected to support the Committee's decisions and assist in their implementation.

Sub-committees

10. The Steering Committee may establish sub-committees as necessary to undertake specific work.

Amendments

11. The Steering Committee, through mutual written consent and approval by the Heads of Delegation, may alter, amend, or revoke the Trilateral Cooperation Charter or any of its operating procedures at any time and may adopt additional procedures as it deems necessary.

Signed on this twenty-seventh day of February 2004, in the English, French and Spanish languages, each version being equally valid.

For The Health Products and Food Branch
HEALTH CANADA
CANADA:

_____
Diane C. Gorman
Assistant Deputy Minister
Head of Delegation (Canada)

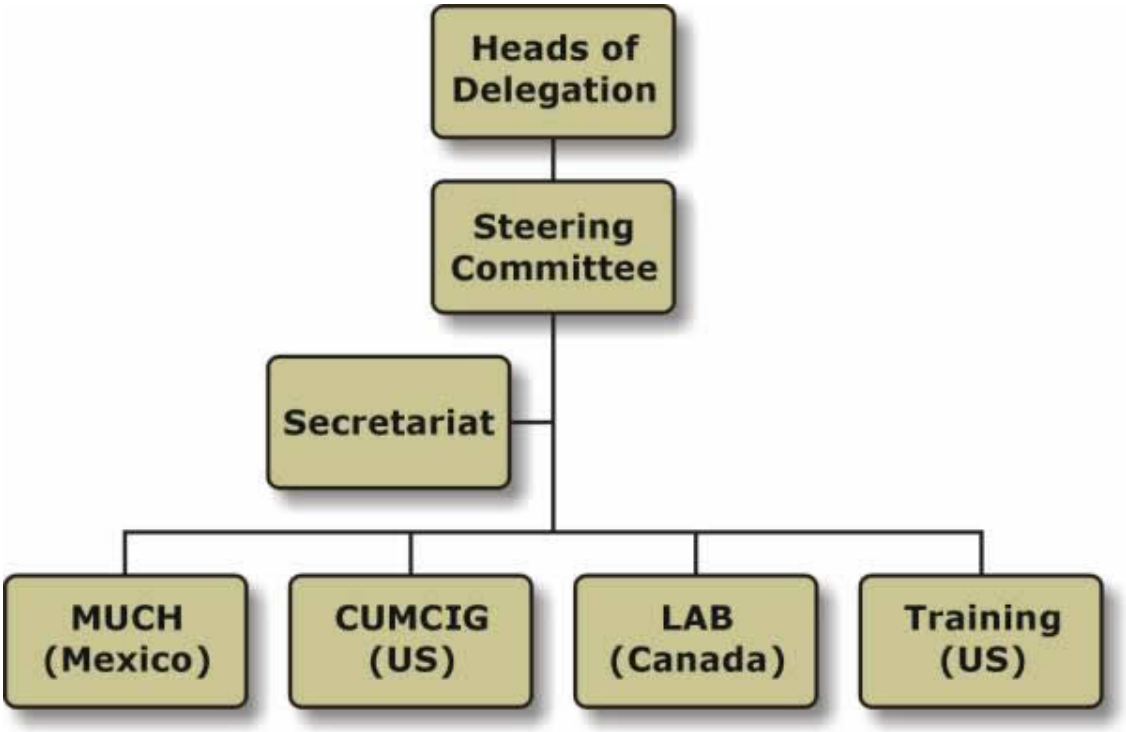
For The Food and Drug Administration
DEPARTMENT OF HEALTH AND HUMAN SERVICES,
THE UNITED STATES OF AMERICA:

_____
Mark B. McClellan, M.D., Ph.D.
Commissioner of Food and Drugs
Head of Delegation (United States of America)

For The Federal Commission for the Protection from Sanitary Risks
SECRETARIA DE SALUD
MEXICO:

_____
Ernesto Enríquez Rubio
Federal Commissioner
Head of Delegation (Mexico)

APPENDIX A: GOVERNANCE STRUCTURE



APPENDIX B: TERMS OF REFERENCE OF THE WORKING GROUPS

MUCH - TERMS OF REFERENCE

Purpose

To consolidate and maintain a formal framework for trilateral cooperation in combating health fraud, so as to protect and promulgate the health and economic well being of citizens of all three nations and to identify appropriate lines of communication to ensure a continual exchange of information on compliance and enforcement activities among the three countries.

Health Fraud Definition

For the purposes of this Working Group, health fraud may include the following:

The false, deceptive, or misleading promotion, advertisement, distribution, sale, possession for sale, or offering for sale of products or provision of services, intended for human use, that are represented as being safe and/or effective to diagnose, prevent, cure, treat, or mitigate disease (or other conditions), to rehabilitate patients or to provide a beneficial effect on health.

Objectives

To the extent compatible with their laws, enforcement policies, and other important interests, each member country shall

- develop and implement comprehensive collaborative approaches and mechanisms to deal with health fraud;
- share information describing current trends in health fraud and strategies for addressing emerging problems;
- cooperate in the detection of cross-border health fraud;
- inform counterpart agencies as soon as practicable of significant investigations and proceedings involving health fraud occurring or originating in the jurisdiction of each member country;
- consider counterpart agency requests to investigate domestic activities having harmful cross-border effects;
- consider coordinating related enforcement activities with counterpart agencies in appropriate cases;
- coordinate import surveillance activities and share information that would maximize surveillance efforts;
- develop and disseminate joint consumer and business education messages about health fraud;
- seek to promote cooperation among federal, state, provincial and local law enforcement agencies of all three member countries, and as appropriate, seek to include such agencies in cooperative efforts to combat health fraud; and
- develop further strategies to achieve coordinated compliance and enforcement; joint consumer and business education; trilateral communication and information exchanges; and the building of partnerships to combat health fraud.

Membership

The Working Group shall consist of the following:

- Representatives of the regulatory agencies relevant to the control of health fraud from the three signatory countries;
- Representatives of the regulatory and law enforcement agencies with authority or jurisdiction over health fraud issues; and
- Representatives from other government agencies as agreed to by the Co-chairs.

The Working Group shall be chaired by one representative from each country. These three Co-chairs shall be individuals with responsibility for implementing or recommending policy changes within their organizations.

Structure

The Co-chairs shall chair Working Group meetings and conference calls on a rotational basis.

Ad hoc committees shall be created or disbanded according to Working Group needs.

Ad hoc committee members are to be drawn from the Working Group membership, although non-members may be asked to contribute on the basis of specific expertise.

Each ad hoc committee shall develop Terms of Reference and structures as required. As a general rule, ad hoc committees shall report directly to the full Work Group membership unless urgency dictates a more immediate response. In such cases, the Working Group Chair shall determine the appropriate reporting process.

Secretariat Services

Secretariat services shall be provided through the offices of the Head of Delegation of the member country hosting the event. These services comprise the following:

- Agenda: Members shall be canvassed in advance of regularly scheduled meetings and an agenda made available a minimum of five working days in advance of each meeting.
- Logistics: The Secretariat shall assume responsibility for meeting rooms and other immediate requirements pertaining to the meeting itself. Members shall be responsible for their own travel and accommodation arrangements.
- Meeting Summary: A record of the meetings shall be kept and held to the appropriate level of detail required to summarize effectively the proceedings and to reflect decisions taken. Each member country is responsible for translating record of decision into the language of choice and for maintaining its own committee files.
- Disclosure: Members of the Working Group subscribe to the principles of accountability and disclosure. However, in view of the confidential information discussed and exchanged at the Working Group meetings that relate to ongoing investigations by law enforcement and regulatory agencies, the meeting summaries shall be kept confidential.

Decisional Process

Decisions shall be based upon consensus rather than majority vote.

Meetings Schedule

The Much Working Group shall meet twice a year. The first meeting shall be held immediately prior to the Trilateral Heads of Delegation meeting, in order to provide a report at the latter on achievements and progress over the previous year and seek their guidance and direction on specific issues as required. The second meeting shall be held six months after the Trilateral Heads of Delegation meeting and will have to follow up on the commitments previously established.

Language

The meetings shall take place in the three official languages pertaining to the ensemble of the Working Group Membership: English, French, and Spanish. The host country shall be responsible for ensuring simultaneous translation as may be necessary.
With respect to press releases, communiqués, and other such materials, each member country shall be responsible for ensuring appropriate translation for dissemination within their own national boundaries obtaining necessary approvals within mutually agreeable time frames.
These terms of reference have been adopted simultaneously in versions prepared in the three official languages and are intended to have the same meaning in each version.

October 2003

CUMCIG — TERMS OF REFERENCE

Purpose

The purpose of CUMCIG is to increase the exchange of compliance and enforcement information and to increase cooperation between the

United States, Canada, and Mexico in the areas of drugs, biologics, medical devices, food safety, and nutrition.

Objectives

To the extent compatible with their respective statutory and regulatory authorities, policies, and other important priorities, each member country shall

- develop cooperation mechanisms for the solution and follow-up of the proposed issues in this Working Group;
- identify appropriate lines of communication to ensure a continual exchange of information on compliance and enforcement activities among the three countries;
- identify issues of common concern and develop approaches for dealing with them in a coordinated manner; and
- explore and develop areas where joint positions could be of mutual benefit.

Membership

The CUMCIG Working Group shall consist of the following:

- Representatives of the regulatory agencies relevant to compliance and enforcement activities from the three signatory countries; and
- Representatives from other bodies, as deemed appropriate by each member country.

The Working Group shall be chaired by one official government representative of the regulatory agencies from each country. The three Co-chairs shall be individuals with relevant expertise.

Structure

The Co-chairs shall chair the CUMCIG meetings and conference calls on a rotational basis. Issues requiring follow-up will be delegated by the Chair to Working Groups that are created on ad hoc basis.

The CUMCIG Co-chair reports to the Trilateral Steering Committee.

Individual participants brief their respective organizations on the discussions and action items resulting from the CUMCIG meeting.

Secretariat Services

Secretariat services shall be provided through the offices of the Head of Delegation of the member country hosting the event. These services comprise the following:

- Agenda: Members shall be canvassed in advance of regularly scheduled meetings and an agenda made available a minimum of five working days in advance of each meeting.
- Logistics: The Secretariat shall assume responsibility for meeting rooms and other immediate requirements pertaining to the meeting itself. Members shall be responsible for their own travel and accommodation arrangements.
- Meeting Summary: A record of the meetings shall be kept and held to the appropriate level of detail required to summarize effectively the proceedings and to reflect decisions taken. Each member country is responsible for translating record of decision into the language of choice and for maintaining its own Working Group files.
- Disclosure: Members of the Working Group subscribe to the principles of accountability and disclosure. However, in view of the confidential information discussed and exchanged at the Working Group meetings that relate to ongoing investigations by law enforcement and regulatory agencies, the meeting summaries shall be kept confidential.

Decisional Process

Decisions shall be based upon consensus rather than majority vote.

Meetings Schedule

The CUMCIG Working Group shall meet twice a year. The first meeting shall be held immediately prior to the Trilateral Heads of Delegation meeting in order to provide a report at the latter on achievements and progress over the previous year and to seek guidance and direction on specific issues as required. The second meeting shall be held six months after the Trilateral Heads of Delegation meeting and will have to follow up on the commitments previously established.

Operating Principles

The CUMCIG Working Group's activity will be based on the following principles:

An appropriate agenda will be developed jointly. However, the host country will be responsible for developing, distributing, and maintaining the Action Items. The agenda will be made available a minimum of five working days in advance of each meeting.

The Working Group will not duplicate work being carried out by other Working Groups or committees.

The agency raising an issue shall lead the discussion.

The Working Group should focus on the exchange of information on compliance and enforcement activities. This exchange may be of a general nature, health protection policy issues, safety and quality issues or specific issues (e.g., canned mushrooms).

- The Working Group should limit the number of issues discussed at a meeting and should establish priorities jointly.
- The Working Group should identify each issue to be resolved, with defined objectives, an outline of the working arrangements, and a time frame for resolution of a given issue.
- Any structure (e.g., sub-committee, task force, etc.) established to handle a particular issue should be flexible and responsive.

Language

The meetings shall take place in the three official languages pertaining to the ensemble of the Working Group membership: English, Spanish, and French. The host country shall be responsible for ensuring simultaneous translation as may be necessary.

With respect to press releases, communiqués, and other such materials, each member country shall be responsible for ensuring appropriate translation for dissemination within their own national boundaries-obtaining necessary approvals and/or clearances within mutually agreeable time frames.

The Terms of Reference have been adopted simultaneously in versions prepared in the three official languages and are intended to have the same meaning in each version.

October 2003

LABORATORY COOPERATION WORKING GROUP — TERMS OF REFERENCE

Purpose

The purpose of the Laboratory Cooperation Working Group (LCG) is to identify and share analytical methods with the long-term goal of building a trustworthy analytical network. The LCG is also to work closely with and provide support to CUMCIG and MUCH, in their investigations of fraudulent products, counterfeit or unsafe drugs, and shortages of legitimate drugs.

Objectives

To the extent compatible with their respective statutory and regulatory authorities, policies and priorities, each member country shall
· identify and establish lines of communication to ensure a continual exchange of information on laboratory and regulatory science issues among the three countries;

- identify issues of common concern, and develop and implement approaches for dealing with them in a coordinated manner;
- explore and develop areas where joint or complementary positions and operations could be of mutual benefit; and
- support the work of the other Working Groups by providing laboratory support.

Membership

The LCG shall consist of one lead representative of each of the Heads of Delegation and representatives from other bodies as deemed appropriate by all member countries.

Structure

From the membership, a representative of one of the three Heads of Delegation shall chair the LCG on a rotational basis such that the period shall end with the conclusion of the meeting in the Chairperson's country.

The last item of business of each meeting shall be to elect the next Chairperson who will be the member in whose country the next LCG meeting is to be held.

Issues requiring follow-up may be delegated by the Chair to ad hoc groups.

The Chairperson of the LCG reports to the Trilateral Heads of Delegation.

Secretariat Services

Secretariat services shall be provided through the offices of the Head of Delegation of the member country hosting the event. These services comprise:

- Agenda: Members shall be canvassed in advance of regularly scheduled meeting and an agenda made available a minimum of five working days in advance of each meeting.
- Logistics: The Secretariat shall assume responsibility for meeting rooms and other immediate requirements pertaining to the meeting itself. Members shall be responsible for their own travel and accommodation arrangements.
- Meeting Summary: A record of the meetings shall be kept and held to the appropriate level of detail required to summarize effectively the proceedings and to reflect decision into the language of choice and for maintaining its own committee files.
- Disclosure: Members subscribe to the principle of disclosure. However, in view of the confidential information discussed and exchanged at the task force meetings that relate to ongoing investigations by law enforcement and regulatory agencies, the meeting summaries shall be kept confidential.

Decision Process

Decisions shall be based upon consensus of lead representatives rather than majority vote.

Meetings Schedule

The Working Group shall conduct its business on a continual basis and shall meet as required, either face-to-face or by telephone and then face-to-face immediately prior to the Trilateral Heads of Delegation meeting to report on its achievements and progress over the previous year and to seek guidance and direction on specific issues, as required.

Operating Principles

The Working Group's activity will be based on the following principles:

- When a lead representative wishes to propose that a representative of another body attend one meeting or become a member of the LCG, such a proposal shall be made well in advance of the meeting.
- The agenda will be developed jointly by member countries.
- When used by the LCG, the word "accreditation" means accreditation to the ISO 17025 standard.
- The Chairperson will be responsible for ensuring that the action items are recorded, the lead person and time frame identified, and the action items distributed.
- The agency raising an issue shall lead the discussion.
- The group should establish priorities jointly.
- For significant issues, the committee should identify each issue to be resolved, with defined objectives, an outline of the working arrangements, and a time frame for resolution of a given issue.
- Any structure (e.g., sub-committee, task force, etc.) established to handle a particular issue should be flexible and responsive.
- Individual participants will brief their respective organizations on the discussions and action items resulting from any meeting.

Language

The meetings shall be conducted in the three official languages pertaining to the ensemble of the Working Group Membership: English, French, and Spanish. The host country shall be responsible for ensuring simultaneous translation as may be necessary.

With respect to press releases, communiqués, and other such materials, each member country shall be responsible for ensuring appropriate translation for dissemination within their own national boundaries obtaining necessary approvals within mutually agreeable time frames.

These terms of reference have been adopted simultaneously in versions prepared in the three official languages and are intended to have the same meaning in each version.

November 2003

TRAINING WORKING GROUP — TERMS OF REFERENCE

Purpose

To share existing and future information, to establish a communication strategy between the Training Working Group and the other Working Groups and to assist the Trilateral leadership in identifying training needs of common interest for the three countries of staff who will be engaged in activities related to initiatives of the Trilateral Cooperation.

Objective

1. To develop or assist in the development and delivery of training intended to further the purpose of the Trilateral Cooperation, in line with its strategic objectives, which are to

- identify and solve problems;
- share information;
- identify emerging issues;
- share best practices;

- promote capacity building;
- develop partnership; and
- establish harmonized positions on issues.

2. To organize a pre-trilateral seminar prior to each annual meeting. The pre-trilateral seminar will be managed by the host country.

Membership

One person from each country will serve on the Working Group.

Structure

A chairperson will be elected for a term of two years.

Secretariat Services

The Chairperson will provide secretariat services to include the following:

- Meeting Summaries: The chairperson will issue meeting notes via e-mail.
- Information Sharing: All members will be responsible for sharing current and future information with fellow Working Group members on an as-needed basis.
- Reports and Recommendations: Reports and recommendations to the Trilateral and Working Group leadership will be developed by the chairperson, with input of members on an as-needed and as-requested basis.
- Logistics: The secretariat shall assume responsibility for meeting rooms and other immediate requirements to a meeting and shall advise other members of appropriate details in advanced of the meeting; he/she will seek the support of the other members of the Working Group as appropriate in obtaining needed facilities, equipment and materials.
- Agenda: Members will be canvassed in advance of any meeting (teleconference or face-to-face) and the chairperson shall share an agenda in advance of any meeting.

Decisional Process

Decisions shall be based upon consensus rather than majority vote.

Meetings Schedule

The Working Group will meet, if possible, two times per year in person at the two trilateral meetings, and via e-mail and conference call as often as necessary to meet the objective of the Working Group.

Operating Procedures

- The Training Working Group will be responsible for developing a communication strategy to communicate training needs issues between the Trilateral Working Groups and the Steering Committee.
- The Training Working Group will be responsible for developing and sharing with the Steering Committee and each Trilateral Working Group, the training needs request template and process. Evaluation criteria will be developed to assess training needs requests.
- The Steering Committee will be responsible for assessing, prioritizing, and vetting the submitted training requests. The training should be of common interest to the three countries in order for the Trilateral Cooperation to carry out its purpose and objective.
- Where there are numerous training needs identified, the Steering Committee will take into consideration the priority/ranking and develop a list of topics and share that plan with the Training Working Group. This plan will include budgetary considerations.
- A Training Working Group representative will be assigned to a specific Working Group and will participate in conference calls/meetings of that particular group in order to support the Working Group with their training needs identification, if deemed necessary. The representation will be as follows:
  a) MUCH (representative from Mexico)
  b) CUMCIG (representative from the United States)
  c) Lab Cooperation (representative from Canada)
- If within a Trilateral Working Group, a training need is identified, the lead Co-chair of the Trilateral Working Group will complete and submit the Trilateral Training Request to the Steering Committee. The Leader of the Trilateral Workgroup will also advise its Training Working Group representative.
- The Leadership/Trilateral Working Group will identify an individual or individuals who should be contacted to serve as the technical expert or experts on the training subject.
- Once receiving specific training from the Steering Committee, a representative or representatives of the Training Working Group will contact/ meet with the technical expert or experts to develop a course plan. This course plan will be shared and discussed with the other Training Working Group members to ensure that it meets the needs of the three countries. This plan will include the following:
  a) Topic.
  b) Rationale (why needed).
  c) What is to be accomplished as a result of the course/event (learning objectives).
  d) Who
    i. Course advisory group (CAG) to plan, develop, and eventually deliver the training;
    ii. Intended audience; and
    iii. Others needed to deliver training (e.g., studio staff; on-site facilitators).
  e) When (development and delivery time lines)

f) How (media to be used to deliver training (e.g., satellite, class room), agenda, learning materials, speakers; publicity and other elements, with the goal of ensuring and maximizing access to the learning).
g) Where (e.g., site and types of uplink, sites of downlinks, class room locations).

- Once a plan is developed the Training Working Group will gain concurrence from the Trilateral and Working Group leadership.
- The Training Working Group will assist other members of CAG in developing and delivering a specific training event.
- The Training Working Group will develop instruments to evaluate all sessions and courses. Evaluation results and other feedback will be given to CAG members, and to Trilateral and Working Group leadership.

Language

The meetings shall take place in the three official languages pertaining to the ensemble of the Working Group Membership: English, French, and Spanish. The host country shall be responsible for ensuring simultaneous translation as may be necessary.
With respect to press releases, communiqués, and other such materials, each member country shall be responsible for ensuring appropriate translation for dissemination within their own national boundaries obtaining necessary approvals within mutually agreeable time frames.
These terms of reference have been adopted simultaneously in versions prepared in the three official languages, and are intended to have the same meaning in each version.

January 2004

APPENDIX C: KEY PRIORITIES FOR 2004

Steering Committee

Complete Charter and Information Sharing Agreement for signature by Heads of Delegation

MUCH

- Enforcement Action on Fraudulent weight loss products
- Explore a web-based site to gather information from fraud cases on one site
- Develop criteria for selecting health fraud cases

CUMCIG

Emergency Response and Preparedness:

- Activities based on preventing and managing risk for public health protection
- Emergency preparedness and response activities are aligned with countries' priorities of public health protection
- Share response plans among the three countries
- Conduct another more detailed exercise (Canada will host)
- Update emergency contacts electronically (FDA to coordinate)
- Share organizational structures, including laboratories
- Extend exercise to broader membership
- Consider contingency plans for alternative communication mechanisms
- Explore the potential for sharing classified information

Laboratory Cooperation

- Enter data in eLEXNET and create respective reports
- "Play with the system" to become acquainted
- Further explore an exercise with the salmonella test
- Revisit priorities and purpose of this group: develop concrete priorities and an action plan for consideration by Heads of Delegation within six months

Training Working Group

- Organize and deliver a pre-trilateral seminar for 2004
- Develop a process for vetting training requests
- Establish as an activity of the training Working Group, a mechanism to exchange a list of the courses that each country offers, related to the topics of Trilateral Cooperation by December 2003

Heads of Delegation

" A" LIST (High-Priority Areas):

- GMPs
- Health claims
- Cross border safety issues (e.g., internet fraud, counterfeits, and unsafe medical products/practices, including wholesale drugs)
- Harmonization of new laboratory methods and validation of new agents

"B" LIST:

- Harmonized inspection systems
- Import/export risk management
- Direct-to-Consumer Advertising
- Emerging science issues

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[1]Health Canada and the CFIA share unique and complementary roles and responsibilities. Health Canada is responsible for food safety and nutrition policies, standards and regulations, including related labeling issues, while the CFIA is responsible for food inspection and compliance activities, as well as the development of regulations and policies related to other food labeling and compositional standards.
