

EC-Canada Regulatory Cooperation Roadmap 2007 - 2008

1. Chemicals

Cooperation between the European Commission and Canada regarding: (1) the regulation of substances, and (2) the effective implementation of their respective regulatory frameworks.

Objective:

Led by the European Commission's Directorate-General Enterprise and Industry and Directorate-General Environment and Environment and Health Canada, the European Commission and Canada are seeking to establish and implement cooperative arrangements, both bilaterally and in particular also in the framework of international organisations, to facilitate the achievement of their respective regulatory objectives and to promote the sound management of chemicals.

Cooperation activities under this roadmap are subject to the availability of appropriate resources, to the applicable laws and regulations, policies and programmes of each jurisdiction, and to the terms of the arrangement.

All costs resulting from cooperation under this roadmap are to be borne by the jurisdiction that incurs them, including participation in meetings, unless otherwise determined by both jurisdictions.

Potential areas of regulatory cooperation include:

- Examination of potential options for the secure exchange of data and assessment outcomes and increased cooperation in the sound management of chemicals that may eventually lead to a more formal agreement pursuant to the European legislation concerning the Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) article 120 and the *Canadian Environmental Protection Act, 1999* (CEPA 1999) sections 75 and 316.

- Encouraging cooperation and promoting mutual recognition of the outcomes of assessments of chemicals.
- Regular consultations about risk assessment/management regulatory priorities and approaches to encourage cooperation wherever possible to maximize effectiveness of environmental and human health protection measures and minimize potential trade issues.
- Staff exchanges between the European Chemical Agency and Canadian agencies responsible for chemical management.

Potential areas of scientific and technical collaboration include:

- Regular consultations and the exchange of information on programmes, practices, laws and regulations relevant to cooperation under this roadmap, including possible work sharing.
- Advancing scientific tools and quality assurance systems, in particular good laboratory practice (GLP).
- Development and validation of intelligent/integrated testing strategies in order to promote, for example, alternatives to animal testing.
- Sharing Data and Assessments Outcomes in accordance with existing rules on confidentiality within each jurisdiction.
- Development of standardized analytical methods to support regulatory prohibitions or restrictions of chemicals in preparations/mixtures or products.
- The use and application of computational tools.
- Emerging issues including: respective chemicals-related stewardship with manufactured nanomaterials; the monitoring and surveillance of chemicals in the environment; and environmental and health linkages.
- Exchange of information on and co-operation in the implementation of the GHS criteria in the classification of chemicals – including where feasible practical examples, as well as the further development of the criteria within the appropriate international bodies.

Progress/Results: EC and Canadian technical experts have met on several occasions to exchange information regarding their respective regulatory systems and to identify areas of potential collaboration.

Next Steps: DG Enterprise and Industry and DG Environment and Environment Canada to further elaborate an informal cooperation arrangement including the above items and to prepare plans for a staff exchange program.

A workshop on REACH, including also REACH-IT and on Reach Implementation Projects (RIPs) may be organized for interested stakeholders in Canada and/or the United States, involving the European Commission and the Agency.

2. Electrical and Electronic Equipment and Waste (e-waste)

Cooperation between EC and Canadian counterparts to share experiences and information on respective life cycle approaches for the management of electrical and electronic products and waste including: regulating certain hazardous substances in electrical and electronic equipment (EEE), environmental design, labelling of electrical and electronic equipment, collection and take-back practices, and material recovery and recycling practices for used and end-of-life products.

Objectives:

Life Cycle Management of Electrical and Electronic Equipment and e-waste

Goal: Achieve an effective exchange of information and experiences on policies for minimizing the negative environmental impact over the life cycle of EEE by promoting clean technology and green design and for minimizing the generation of e-waste.

Considering existing international on-going work such as through the Basel Convention, the OECD Working group on Waste Prevention and Recycling, the Solving the e-waste Problem initiative (StEP), and environmental standardization in the IEC Technical Committee 111; share information and experiences on life cycle management approaches to extended producer responsibility, including on:

2.1 Eco-design of electrical and electronic equipment

- improving the recycle-ability of EEE,
- maximizing resource recovery from end-of-life EEE management,
- strategies for extending the life of e-equipment,
- promoting clean technologies,
- approaches to promote and encourage eco-design,
- selecting criteria for eco-design,
- setting targets for the environmental performance of products,
- eco-design to address occupational health and safety issues;

2.2 Eco-labels for electrical and electronic equipment

- life-cycle impact assessments criteria for environmental product declarations,
- the development of EEE eco-labels and eco-labelling programs,
- environmental labels and certification approaches with view to achieve mutual recognition of similar types labels and certificates;

2.3 Used and end-of-life electrical and electronic equipment

- criteria and standards for testing and labelling,
- collection approaches and take-back requirements,
- strategies, criteria and standards for promoting and facilitating the environmentally sound material recovery and recycling,
- performance measurement.

Next Steps: With respect to Life Cycle Management of EEE and e-waste, DG Environment and Environment Canada to pursue information exchange, and share studies and key findings in the area of e-waste management.

DG Environment and Environment Canada to share the coordinates of other regulatory officials involved in areas identified in the roadmap and organise another regulatory cooperation meeting on hazardous substances and life cycle management in fall 2007.

3. Organics equivalency

Cooperation between the European Commission and the Canadian Food Inspection Agency (CFIA) to obtain mutual equivalency for each respective Party's organic regulations and regimes in order to facilitate the smooth trade of organic agricultural products.

Objective: To start discussions on the assessment of Canada's submission package.

Progress/Results: On December 19, 2006 Canada submitted the required documents (a comparison table that compares the Canadian Regulations to the EU Regulations, the Canadian standard and permitted substances list) to the EU Commission to initiate the process of being added to the EU's approved third-country equivalency list. The EU Commission has assigned two Member States to examine Canada's submission package of December 19, 2006. Canada has updated the December 19 table that compares the Canadian *Organic Products Regulations* to the EU organic regulations to reflect the *Canada Gazette Part II* final version of the *Organic Product Regulations* published on December 21, 2006, highlighting the changes in the table so that the Member States will not have to review twice information that has not changed. The updated highlighted table was delivered to the European Commission on March 19, 2007.

Next Steps: Canada is looking forward to the results of the EU's assessment with the hope that initial discussions will take place soon.

4. Canada-EC Veterinary Agreement

Cooperation between the EC Directorate General for Health and Consumer Protection (SANCO) and the Canadian Food Inspection Agency (CFIA) to facilitate trade in live animals and animal products between the Community and Canada.

Objective: Continued progress on the action plan of the Joint Management Committee (JMC) of the Agreement between the European Community and the Government of Canada on sanitary measures to protect public and animal health in respect of trade in live animals and animal products (the EC-Canada Veterinary Agreement).

Progress/Results: The JMC has met regularly since the Agreement was signed in December 1998. Past results include the agreement to recognize equivalency of EC and Canadian public health measures pertaining to fresh and frozen pork and animal health measures for bovine semen, which came into force in April 2005.

The current action plan of the JMC includes ongoing cooperation in numerous areas as well as efforts to bring into force the recommended amendments to the Veterinary Agreement, which should serve to facilitate trade in a number of products.

Next Steps: European Commission's DG Health and Consumer Protection and CFIA will continue ongoing cooperation, as co-chairs of the JMC, and through exchanges between meetings of the JMC. The next meeting of the JMC is anticipated for the Fall of 2007, to be hosted by the EC.

5. Pesticides

Increased cooperation between the European Commission and Health Canada (Pest Management Regulatory Agency) in relation to the operational aspects of pesticide regulation:

Objectives:

- Promote good governance by sharing best practices:
 - Increase contacts between regulators of both countries on regulatory policy issues and practices related to pesticide regulation
- Exchange information and cooperative actions related to pesticide regulatory matters of mutual interest with focus on such elements as:
 - information exchanges on developments of legislation and regulatory structure;
 - information exchanges on upcoming regulatory issues;
 - promote scientific exchange and staff involvement in cooperative efforts;
 - exchange lists of new pesticides under evaluation and existing pesticides under re-evaluation;
 - information and experience in relation to information technology, particularly in the area of electronic submission and templates.

Next Steps: Officials to meet to discuss recent changes to regulatory structure in their respective jurisdiction and discuss opportunities for cooperative efforts in the regulation of pesticides. In addition to a fuller understanding of each others regulatory regime and recent legislative changes, this may include identification of opportunities for joint reviews or work sharing activities and similar mechanisms to further improve the timeliness and efficiency of regulatory processes.

6. Pharmaceuticals

Cooperation between EU and Canadian counterparts under two distinct initiatives related to pharmaceuticals:

- 1) Cooperation between the European Union (European Medicines Agency (EMA) and EC) and Health Canada's Health Products and Food Branch (HC) on matters related to the authorization of pharmaceutical products, site inspections and pharmacovigilance (i.e. studying the adverse effects of medicines).
- 2) Cooperation between the European Directorate for the Quality of Medicines (EDQM) and HC regarding the assessment of substances used in pharmaceutical products.

Objectives:

1. (a) Facilitate sharing of information including legislation and guidance documents, pharmacovigilance data, and information related to marketing authorization and post-authorization assessments.
2. (b) Through the implementation of the MOU signed in March, 2007, pool resources to reduce duplication and speed up access to medicines without any compromise to high standards of safety and quality.

Progress/Results:

- 1)
 - The EC and Canada participate in the International Conference on Harmonisation (ICH)
 - In the context of EU enlargement, the EC and Canada are building upon an existing sectoral annex to their MRA regarding the conformity assessment of good manufacturing practices for pharmaceuticals.

- Canada has participated in the EMEA's Visiting Experts Programme with a view to increasing mutual understanding of each others' pre- and post-market authorization systems.
 - A joint HC-EMEA guideline on pharmaceutical quality requirements for inhalation and nasal products has been developed and implemented.
- 2) A memorandum of understanding was signed March 20, 2007 between EDQM and HC which provides a framework for the exchange of information related to the assessment of substances used in pharmaceutical products. The MOU sees HC employing certificates issued by EDQM when conducting assessments while in turn, HC contributes to an international pool of experts which performs assessments on behalf of the EDQM.

Next Steps:

- 1) Health Canada will continue working with the EC/EMEA in support of the objectives listed above including aiming to establish confidentiality arrangements for the exchange of information by early 2008.
- 2) Health Canada and EDQM will focus discussion on the effective implementation of the March, 2007 MOU.

7. Radiation emitting devices

Dialogue between Health Canada (Consumer and Clinical Radiation Protection) and DG Enterprise and Industry, for its areas of responsibility, on the management of devices employing ionizing and non-ionizing radiations in their use application. Because of the overlapping areas of expertise, this also includes the issues of potential health concerns and effects arising from sources of environmental noise and environmental electric and magnetic fields deriving from electrical power transmission lines.

Objectives:

- Exchange of scientific, technical, and regulatory information on devices using or producing electric and magnetic fields, lasers or high-intensity light sources of various spectra, x-rays (medical and non-medical) and acoustical radiation (including noise and ultrasound). Devices include, but are not limited to, wireless communication devices and infrastructure, ultrasound diagnostic and therapeutic instrumentation, lasers and sources of UV radiation, security screening devices and diagnostic and therapeutic x-ray units. (Note: Canada does not foresee the inclusion of devices using radioisotopes as these are regulated by the Canadian Nuclear Safety Commission).
- Outline the details of the Canadian regulatory frameworks for the various areas of mutual interest and establish ongoing additional points of contact.
- Discuss the joint development of standards and prospects for cooperation in the comparative assessment of product specific standards and specifically on the safety and safe use of devices.

Progress/Results: At the May 2005 meeting of the EC-Canada Regulatory Cooperation Committee, DG Enterprise and Industry and Health Canada officials met to exchange information on the management of electric and magnetic fields (EMFs), learn best practices, establish appropriate contacts, and identify priority areas for bilateral cooperation. Participants agreed to:

- explore cooperation on issues related to environmental noise, UV exposure/phototoxicity, and mammography as well as continuing further discussions on EMFs;
- establish other appropriate contact points on EMFs, environmental noise, UV exposure, and mammography (managed by 4 DGs at the Commission);
- discuss a potential workplan for the next meeting of the Regulatory Cooperation Committee.

Next Steps:

Identify the appropriate officials and exchange contact information to initiate dialogue on on-going activities in this area, and develop a work plan, as appropriate.

8. Chemical Contaminants in Food

Cooperation between DG Health and Consumer Protection and Health Canada regarding the management of chemical contaminants in food, including natural toxins.

Objective: Increased cooperation in the development of maximum limits for natural toxins and other chemical contaminants in food and feed, and associated underlying risk assessment activities.

Progress/Results: At the May 2005 meeting of the EC-Canada Regulatory Cooperation Committee, DG Health and Consumer Protection and Health Canada officials exchanged information on jurisdictional responsibilities in the EU and Canada. Participants agreed to:

- enhanced information sharing on development of positions related to chemical contaminants in food;
- hold a yearly EC / Canada information exchange session prior to the Codex Committee on Food Additives and Contaminants (CCFAC) meeting;
- cooperate / exchange data in support of position development / evaluation for: Ergot and Ergot Alkaloids (Data to be sent from Canada to the EC) Data in support of the evaluation of non-dioxin-like PCBs (from the EC to Canada);
- use the WG on risk analysis / risk communication (formed at the recommendation of the international Workshop on Risk Analysis/Risk Communication – Ottawa, March 2005) as the forum to exchange information and coordinate actions on: workplans and priorities, status of on-going evaluation of selected chemicals in foods, risk management and risk communication strategies related to selected chemicals in food.

Contacts between the EU and Health Canada's Food Standards teams in the area of chemical safety have been maintained and enhanced throughout 2006 and early 2007. On the margin of various international meetings, Meetings were organised on an ad hoc basis. In April 2006, on the margins of the CCFAC, the Canadian delegation met with European Commission representatives. Information was exchanged on respective positions developed for items on the agenda of this Codex meeting. Priorities of action in the areas of data gathering, risk assessment and risk management activities for contaminants in food were also exchanged. Informal discussions were also held during the UK FSA workshop on food incident reduction, in which representatives of the European Commission and Health Canada's Food Directorate were participants (London, UK, April 5-6, 2007)

In parallel, contacts and cooperation were enhanced with EU member states food safety authorities. A memorandum of understanding was developed and signed between Health Canada's Food Directorate and the UK Food Standards Agency (UKFSA), in March 2006. A similar agreement is being considered with the AFSSA (Agence Française de Sécurité Sanitaire des Aliments – France).

The Working Group on information sharing related to food chemical safety (initiated by Health Canada's Food Directorate in March 2005) has become the forum for regular information exchange and coordination of efforts on options of risk assessment, risk management and risk communication related to food chemical safety incidents e.g. Benzene in soft drinks, Sudan dyes in spices etc. This forum, now called "International Food Chemical Safety Liaison Group (IFCSLG), represents an opportunity for food safety regulators from several countries to exchange information on food surveillance data, and coordinate efforts of data gathering/assessment in support of standard setting and risk management decisions. The IFCSLG counts amongst its participants representatives of Health Canada's Food Directorate, the UK FSA, the European Food Safety Authority, Food Standards Australia New Zealand (FSANZ) and the US Food and Drugs Administration (US FDA). The European Commission's DG Health and Consumer Protection has recently agreed to join the IFCSLG, which meets / convenes every three months (by conference call) to discuss emerging priorities of food chemical safety initiatives.

Next Steps: Agreement on follow-up items subsequent to 2006-07 meetings / discussions:

- Continued information sharing on food monitoring data in the EU and Canada in support of standard setting and development of regulatory decisions, in particular for:
 - Persistent Organic Pollutants (POPs) both legacy and emerging chemicals (e.g. BDEs, PFCs)
 - Process induced chemicals
 - Mycotoxins in food
- Information sharing and coordination of positions on risk management decisions for detected mycotoxins in food e.g.: Ochratoxin A (OTA), deoxynivalenol (DON).

- Coordination of EC and Canadian positions prior to Codex committees, in particular the CCCF (sharing Codex positions prior to meetings as required)
- Continued enhancement of information sharing on risk assessment, risk management and risk communication initiatives with EU member states (UK FSA, AFSSA, AFSCA) along with the EC, during adhoc events:
 - Regular conference calls and face-to-face meetings of the IFCSLG;
 - Workshop on food Safety initiatives between AFSSA and HC/CFIA (November 2007);
 - MOU between Health Canada and AFSSA being developed in 2007;
 - Continued Canadian contribution in EC-driven food safety research projects such as BIOCOP and MONIQA (Harmonization of methods in support of monitoring and quality assurance in food supply chain), through the active participation of Health Canada's Food Directorate as a member of the BIOCOP consortium and the expert panel to MONIQA.

9. Food Allergen Labelling and Incident Prevention

Cooperation between DG Health and Consumer Protection and Health Canada regarding regulatory requirements for the declaration of priority allergens in pre-packaged foods and food allergen incident prevention.

Objective: Enhanced consultations on the assessment of labelling exemptions for priority allergens in processed foods; and cooperation on establishing review lists of priority allergens and further harmonise the development of risk management/enforcement strategies, and identified areas for future work.

Progress/Results: At the May 2005 meeting of the EC-Canada Regulatory Cooperation Committee, DG Health and Consumer Protection and Health Canada officials exchanged information on the current regulatory amendments of food labelling regulations to impose the declaration of priority allergens in pre-packaged foods. Participants agreed to:

- Study of the "temporarily exempted food ingredients from mandatory allergen declaration" based on the dossiers submitted to EFSA and the Commission;
- Better "frame" for the use of precautionary messages on food allergens ("May contain", " manufactured on same lines as .. Etc..").

Next Steps: Information sharing and enhanced cooperation will continue between Health Canada's Food Directorate and DG Health and Consumer Protection officials in this area. Areas of interest identified include:

- Further developments in the EU labelling directives related to food allergenic ingredients and possible next steps (implementation phase and subsequent decision to the requests of labelling exemptions made by the food industry and other stakeholders)
 - Current framework to distinguish ingredient labelling from cross-contamination/cross-contact issues and current/future risk management options
 - Current positions on the use of "allergen precautionary" labelling and "allergen-free" claims.
 - Consumer behaviour surveys on understanding of food allergen "precautionary statement" and issuance of guidance to the food industry.
-