3.1.8 Standards and other technical requirements

3.65. Canada's standardization system is composed of over 350 organizations and 15,000 members involved in standards development, product or service certification, testing and management systems registration. Established under the Standards Council of Canada Act, the Standard Council of Canada is a federal Crown corporation with the mandate to promote an efficient and effective standardization in Canada. It assumes its mandate by prescribing policies and procedures for the development of national voluntary standards, coordinating Canada's participation in the international standards system, and accrediting the various bodies of the system.[50] The Technical Barriers and Regulations Division of the DFATD is Canada's SPS and TBT notification authority and enquiry point. There has been no major change to the Canadian standardization system since the last Review.

3.66. Standards development is carried out by Standards Development Organizations (SDOs), accredited by the SCC. There are currently eight SDOs: the Canadian Standards Association (CSA); the Underwriters' Laboratories of Canada (ULC); the Canadian General Standards Board (CGSB); the Bureau de normalisation du Québec; Air-Conditioning, Heating & Refrigeration Institute; ASTM International; NSF International; and ULC Standards. Although these institutions may develop standards in any area, they generally operate in agreed areas of specialty reflecting the expertise of their technical committees. Once a SDO makes the decision to develop a standard, it establishes a technical committee that generally includes consumer representatives, general interest group representatives, government officials and producers. The committee typically reviews existing (international) standards first for possible adoption or adjustment. Standards are developed through a consensus-based decision making process. Once a draft standard is developed, the public is invited for review and comments. A minimum time-frame of 60 days is prescribed for the submission of comments by interested parties (including those outside Canada) before the publication of the standard.

3.67. A standard may be further submitted to the SCC for consideration as a National Standard of Canada. Key criteria in the SCC's decision include: the composition of the committee and the degree of consensus in the development of the standard; the consistency of the standard with existing international or relevant foreign standards; and, the extent to which the standard does not act as a barrier to trade. National standards are to be reviewed and updated every five years. They can be further submitted to international organisations for consideration and adoption as international standards. Over the past four years, the number of active standards has declined, from 3,482 in 2010-11 to 2,901 by mid-2014. As of mid-2013, there were 141 national standards and 98 adoptions of international standards.

3.68. The SCC also has the mandate to grant accreditation to organizations delivering services such as testing, certification, and management systems registration. Certification bodies are accredited on a fee-for-service basis. As of 2014, there were 37 certification bodies (including U.S.-based bodies), more than 350 testing organizations, and 27 management systems registrars accredited by the SCC.

3.69. Canada's participation in international standardization activities is generally governed by ISO/IEC statutes, rules of procedures and directives. Mutual recognition agreements are generally negotiated by the SCC. The SCC has agreements with a number of foreign standards bodies, including the American National Standards Institute (ANSI), the Korean Agency for Standards and Technology (KATS), the Mongolian Agency for Standardization and Metrology (MASM), The Standardization Administration of China (SAC), the European Committee for Standardization (CEN), and the European Committee for Electro-Technical Standardization (CENELEC). In addition, SCC is a signatory to a number of voluntary accreditation agreements, including the International Accreditation Forum (IAF), the Asia-Pacific Laboratory Accreditation Cooperation (APLAC), and the Inter-American Accreditation Cooperation (IAAC).

3.70. The process of preparing technical regulations is decentralized. Various federal and provincial authorities develop regulations, including technical regulations. When developing technical regulations, federal authorities must carry out consultations with interested parties as early as possible, and, in general, it is expected that the extent of the consultations be

[50] More information may be obtained at the SCC's website. Viewed at: https://www.scc.ca/en/standards/committees/get-involved-standardization.

proportional to the regulation's impact. Federal authorities must publish proposals in the *Canada Gazette Part I*, to allow for a public comment period (pre-publication stage). In some cases, this requirement is explicitly specified in the enabling legislation. For all other regulations that do not have a fixed statutory comment period, the Treasury Board, which is the Cabinet Committee in charge of reviewing and approving regulations, may, upon request by a federal authority, waive the pre-publication requirement or shorten the comment period. However, the authorities have indicated that this is rare and may occur only in circumstances where the expected value from pre-publication is limited (for instance, proposals that are straightforward harmonization with international standards). In fact, in most instances of harmonization with international technical standards, pre-publication has been pursued to ensure that affected stakeholders are notified of the implementation timelines and requirements. The period for comments is typically 30 days. In accordance with Canada's obligations of notification under various trade agreements, a longer period for comments (at least 75 days) is observed for technical regulations that affect trade.

3.71. Draft regulations must be accompanied by a "regulatory impact analysis statement" describing their estimated benefits and costs, the results of the consultations with stakeholders, and the proposed regulations' monitoring and enforcement instruments. Upon approval by the Treasury Board, the Governor General signs the regulation, and the Registrar of Statutory Instruments registers it. Regulations enter into force immediately after registration or on a day specifically stipulated. The Regulation can only be enforced once published in the *Canada Gazette Part II*. Such publication must occur within 23 days of registration.

3.72. The development of technical regulations must follow, to the extent possible, the *Cabinet Directive on Regulatory Management*, which applies to all federal departments, agencies, and entities over which the Cabinet has either general authority or a specific authority relating to regulation making.[51] Under the *Directive*, federal authorities are expected to make use of all or parts of relevant international standards, guidelines, and recommendations when seeking to fulfil the intended policy objectives sought by the country. The development of technical regulations (and other regulations) must be preceded by an identification of policy issues, their assessment and the determination of the need for government intervention. Once the public policy issues are identified, responsible departments and agencies must: set measurable objectives that address the public policy issue and its causes; establish linkages to enabling legislation and government priorities to ensure relevance and consistency; and develop and use performance indicators on an ongoing basis to monitor and report on progress against performance expectations, with a particular emphasis on high impact proposals. Departments and agencies are also responsible for assessing the benefits and costs of regulatory and non-regulatory measures, including government inaction.

3.73. To ensure compliance with international commitments, the *Directive* encourages agencies and departments preparing the technical regulations to seek the advice of the DFATD concerning the compatibility of the proposed regulations with Canada's trade obligations. Departments and agencies are to take advantage of opportunities for cooperation, either bilaterally or through multilateral fora, by reviewing and influencing international best practices, sharing knowledge, adopting or contributing to the development and updating of international standards and conformity assessment procedures, and developing and pursuing compatible approaches with international counterparts. Agencies are also instructed to limit the number of specific Canadian regulatory requirements or approaches to instances when they are warranted by specific Canadian circumstances and when they result over time in the greatest overall benefit to Canadians, and to minimize regulatory differences with key trading partners (e.g., the United States) including through regulatory alignment, mutual recognition, and the development of compatible approaches.

3.74. Canada does not maintain a catalogue of technical regulations. However, *Canada Gazette's Consolidated Index of Federal Statutory Instruments* includes (but does not specifically categorize or indicate) technical regulations.

[51] The Directive, which came into effect in December 2012, updated and replaced the *Cabinet Directive on Streamlining Regulation* (dated 1 April 2007) and the *Government of Canada Regulatory Policy* (dated November 1999). Treasury Board of Canada Secretariat online information. Viewed at: http://www.tbs-sct.gc.ca/rtrap-parfa/cdrm-dcgr/cdrm-dcgr01-eng.asp.

3.75. Canada relies on a variety of tools to ensure compliance with technical regulations, depending on a number of factors, including risks and the particular characteristics of the sector. Conformity assessment procedures are generally specified in Canadian technical regulations. In sectors subject to third-party conformity assessment, most Canadian regulatory authorities rely on conformity assessment bodies accredited by the SCC, whose criteria are based on ISO/IEC standards and include additional requirements to fulfil the needs of Canadian regulatory authorities. Third-party conformity assessment is used in a number of sectors, including electrical safety, some medical devices, and construction products. Canada uses suppliers' declaration of conformity for motor vehicles, electromagnetic compatibility, and some telecommunications products. Regulatory authorities are directly responsible for conformity assessment for certain products (pharmaceutical products and medical devices for instance).

3.76. Between 2011 and 2014, Canada raised 26 specific trade concerns (STC) in the TBT Committee.[52] The concerns were related to measures maintained by a variety of partners, including Ecuador (5 STCs), China (3 STCs), European Union (3 STCs), and Viet Nam (3 STCs). The most frequent issues were related to discrimination and requests for clarification or further information.

3.77. Canada has regularly notified its draft technical regulations, ordinances, and conformity assessment procedures to the TBT Committee. During the 2011-14 period, Canada submitted 115 new technical regulation notifications (excluding corrections and appendices).[53] Canada participates in a number of conformity assessment agreements (Table A3.1).

3.1.9 Sanitary and phytosanitary requirements

3.78. The Food and Drugs Act (FDA) and regulations remain the main federal statute applying to the safety of food sold in Canada (including those that are marketed exclusively within the provinces). The legislation is supplemented by the *Fish Inspection Act*, the *Canada Agricultural Products Act*, the *Meat Inspection Act*, and the food provisions of the *Consumer Packaging and Labelling Act*.

3.79. Health Canada and the Canadian Food Inspection Agency (CFIA) are the main regulators for food safety, animal health and plant health. In October 2013, the Federal Government announced the transfer of the reporting relationship of the CFIA from the Minister of Agriculture and Agri-Food to the Minister of Health, bringing under the same department the main federal food safety authorities. The Minister of Agriculture and Agri-Food retains its responsibility over non-food safety agricultural activities, including economic and trade issues, as well as animal health and plant protection work.

3.80. Health Canada is responsible for establishing standards and policies governing the safety and nutritional quality of all food sold in Canada.[54] Its mandate also includes conducting food-related health risk assessment, approving and regulating pest control products and setting maximum residue limits (MRLs) for pesticides that may remain in or on food; and, evaluating the safety of veterinary drugs used in food-producing animals and establishing corresponding MRLs.

3.81. The enforcement of food safety-related standards and policies is within the purview of the CFIA. The CFIA is responsible for enforcing all federally mandated inspection, compliance, and quarantine requirements related to food, animal health and plant health. The CFIA is also the lead agency for risk assessments related to animal health and plant health.[55] The CFIA is responsible for administering a number of acts and their regulations. These include: the Agriculture and Agri-Food Administrative Monetary Penalties Act, the Canada Agricultural Products Act, the Canadian Food Inspection Agency Act, the Feeds Act, the Fertilizers Act, the Fish Inspection Act, the Food and Drugs Act (as it relates to food), the Health of Animals Act, the Meat Inspection Act, the Plant Breeders' Rights Act, the Plant Protection Act, the Safe Food for Canadians Act, and the Seeds Act.

[52] WTO TBT Information Management System. Viewed at: http://tbtims.wto.org/web/pages/search/stc/Search.aspx.

[53] WTO documents G/TBT/N/CAN/326, 7 January 2011 to G/TBT/N/CAN/435, 11 December 2014.

[54] Health Canada online information. Viewed at: http://www.hc-sc.gc.ca/index-eng.php.

[55] More information on the CFIA's activities can be found at: http://www.inspection.gc.ca/about-the-cfia/eng/1299008020759/1299008778654.

3.82. SPS-related requirements for imports into Canada are the responsibility of the Federal Government given its constitutional jurisdiction over international trade. Provinces and territories have jurisdiction within their respective borders and have legislation for some food safety issues, including for food manufactured and sold within their borders.

3.83. In 2012, the *Food and Drugs Act* (FDA) was amended to include two new tools: *Marketing Authorizations* (MA) and *Incorporation by Reference*. The MA framework gives the Minister of Health the authority to issue authorizations for the use of specific substances in foods (e.g. food additives) and health/nutrition representations/claims for foods under certain conditions. The amendments also provided an expanded authority to incorporate by reference technical and non-technical standards, methods, guidelines or any other documents, into MAs, or directly into the Food and Drug Regulations. These amendments were intended to allow the Minister to act rapidly on certain science and safety decisions, and to improve efficiency in the food regulatory system, ultimately making it more responsive to emerging health and safety issues.

3.84. Canada is in the midst of important changes to its food safety system. On 22 November 2012, the *Safe Food for Canadians Act (SFCA)* received Royal Assent. The SFCA aims at stronger food safety rules and more consistent and effective inspection, and provides for increased penalties for non-compliance. The Act will consolidate and replace existing food legislation, other than the FDA[56], and enhance inspection powers. It applies to all food commodities that are traded inter-provincially and internationally, but not to natural health products. The new legislative framework prohibits food tampering, deceptive practices and hoaxes. Parties may still have recourse to a judicial review by the Federal Court if they are unsatisfied with the appeal mechanism.

3.85. The SFCA will be brought into force through implementing regulations. Consultations on the proposed regulations were under way as of February 2015. The proposed regulations would apply international standards for preventive controls (such as the Hazard Analysis and Critical Control Points and Good Manufacturing Practices) to all food traded inter-provincially, exported and imported. New traceability requirements would allow for more timely removal of unsafe food from the supply chain. Like domestic manufacturers, food importers would need to be licensed and have preventive control plans that demonstrate that imported products meet Canadian requirements. The authorities indicated that the CFIA will be working with small and medium enterprises to explore approaches tailored to their operational needs and to assist them in achieving compliance.

3.86. In the transition period before the SFCA comes into force, the CFIA implemented some changes using existing authorities and administrative guidelines. For instance, in the quest of a more effective inspection, the CFIA embarked in a process to design a new and Improved Food Inspection Model to modernize its regulatory oversight under existing legislation. A final round of consultations on the Integrated Agency Inspection Model (iAIM) was concluded in August 2014[57] with a multi-year implementation underway.[58]

3.87. The iAIM is serving as the policy basis for the proposed regulatory framework under the SFCA, including requirements for licensing and preventive control plans. The Model also calls for a consistent and risk-based approach to inspection that will focus its activities on food commodities and establishments that pose the greatest risk for consumers. It has also established Inspection Verification Teams to oversee food inspection performance. The iAIM does not cover foreign facilities, but applies to them through domestic importers. It calls for extending licensing requirements to all businesses and individuals involved in the importation or preparation of food for export or interprovincial trade. The iAIM also proposes requirements for businesses to develop, implement and maintain preventive control plans based on the Codex Alimentarius, IPPC and OIE principles and standards.

[56] These include: the Fish Inspection Act, the Canada Agricultural Products Act, the Meat Inspection Act, and the food provisions of the Consumer Packaging and Labelling Act.

[57] Comments were solicited from WTO Members on various occasions. See WTO document G/SPS/N/CAN/613, 13 June 2012; and subsequent revisions.

[58] CFIA (2014), Integrated Agency Inspection Model. Viewed at: http://www.inspection.gc.ca/about-the-cfia/accountability/inspection-modernization/integrated-agency-inspection-model/iaim-consultation/eng/1390935174455/1390935603829.

3.88. Other SPS-related changes include the full implementation, by April 2013, of the aquatic animal health import programme. Under the programme, import permits are required for "susceptible species" of finfish, molluscs, and crustaceans.[59] Import permits contain specific requirements based on the disease risks associated with the animal, the origin, and other relevant health information. A health certification from the country of origin may be required.

3.89. CFIA's has developed an automated import system to assist importers and Customs in the management of their imported agriculture, fish, health and food products. The system consists of several modules including the Automated Import Reference System (AIRS) and a database of import requirements.

3.90. Between 2011 and 2014, Canada submitted 394 notifications under the SPS Agreement (excluding addenda and corrections).[60] This comprises 58 regular notifications of new or changed SPS regulations and five emergency notifications (compared to 208 regular and five emergency notifications over the 2007-10 period). Two STCs were raised about measures by Canada. In October 2012, Argentina expressed concerns regarding Canada's delay in opening its market to poultry and bovine meat from Argentina despite favourable risk assessments. Canada indicated that the delay was due to budgetary and staffing restrictions, but reaffirmed its intention to audit Argentina's beef and poultry meat inspection systems. In 2013, China raised, during a TBT Committee meeting, a STC regarding Canada's proposed food inspection model.[61] The representative of China requested the Canadian authorities to base any changes in their measures on relevant international standards, such as Codex standards. Canada indicated that it has provided Members the opportunity to comment on its proposed food inspection model on two occasions.[62] Furthermore, on 2 April 2013, Canada invited WTO Members to another round of consultation on the proposed draft.[63]

3.91. During the same period, Canada raised a STC about Mexico's imposition of bovine spongiform encephalopathy (BSE)-related restrictions on Canada's export of beef from cows, despite Canada being recognized by the OIE as a "controlled" BSE-risk country. The concern was supported by the European Union. Mexico expressed its willingness to work on the issue bilaterally with Canada.

3.2 Measures Directly Affecting Exports

3.2.1 Export procedures and requirements

3.92. Businesses and individuals are required to create an export or an import/export Business Number account with the Canada Revenue Agency before exporting commercial goods. The use of the services of a customs broker or freight forwarder is not mandatory.

3.93. In accordance with the Customs Act (Part V), exporters, carriers and customs service providers are, in general, required to report goods being exported from Canada. The main objectives of such reporting are statistical purposes and to control the export of strategic, dangerous, and other controlled and regulated goods. The minimum timeframe for export reporting depends on the mode of transportation and the nature of the goods to be exported. In general, the timeframe is two hours prior to loading for goods to be exported by air, rail or through the post office, and 48 hours for goods to be loaded onto a vessel in the marine mode. Goods exported through highways and time-sensitive goods may be reported immediately before they are exported. A variety of exemptions to the reporting requirement are in place and cover transactions such as exports to the United States, or transactions related to goods having a value of less than Can$2,000 (provided that they are non-restricted exports). There is a general exemption for items such as: personal and household effects; goods exported for repair or

[59] A list of susceptible species of aquatic animals may be viewed at: http://inspection.gc.ca/animals/aquatic-animals/diseases/susceptible-species/eng/1327162574928/ 1327162766981.

[60] WTO - SPS Information Management System (SPS IMS). Viewed at: http://spsims.wto.org/.

[61] WTO document G/TBT/M/59, 8 May 2013.

[62] In June 2012, Canada sought comments from Members on a document called "The Case for Change" - which outlined the proposed core components of an improved inspection model (WTO Document G/TBT/N/CAN/365, 18 June 2012). The second opportunity was in August 2012, when Canada sought feedback on its draft improved food inspection model (WTO document G/TBT/N/CAN/365/Rev.1, 24 August 2012).

[63] WTO Document G/SPS/N/CAN/613/Rev.1/Add.2, 3 April 2013.