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Implementation Guide for the Protocol to the CETA Agreement between Canada, the European Union and its Member States regarding the mutual acceptance of the results of conformity assessment

(2021/C 351/01)

Introduction

In the area of technical barriers to trade, the European Union (EU) -Canada Comprehensive Economic and Trade Agreement ('CETA') provides for an ambitious Protocol on the mutual acceptance of the results of conformity assessment ('the Protocol'). ⁽¹⁾

Since 1998, Canada and the EU have recognised the results of their respective conformity assessment bodies through a Mutual Recognition Agreement. ⁽²⁾ Such cooperation is possible as the EU and Canada have similar safety and health requirements. Thus by establishing a mutual recognition agreement, the Parties ensured the safety and health of consumers, while alleviating their businesses of redundant additional costs by mutual acceptance of the results of conformity assessment.

The Protocol, replacing the mutual recognition agreement from 1998, goes further in extending the scope of product sectors covered and, as a first within conformity assessment cooperation, makes accreditation of conformity assessment bodies mandatory. In this way, the Protocol strengthens public oversight and serves as an inspiration for future international cooperation within conformity assessment activities.

This document intends to facilitate the swift implementation of the core elements of the Protocol. It provides practical guidance on the actions and steps to be taken by EU accreditation bodies, the Commission, Member State notifying authorities as well as the Canadian authorities.

This guidance document was drafted in consultation with the Expert Group on the Internal Market for Products working group on accreditation and conformity assessment ('IMP expert group') at meetings on 8 December 2020 and 20 January 2021.

The document focuses on the steps that the EU and its Member States need to undertake when interested conformity assessment bodies seek recognition to carry out conformity assessment according to EU and Canadian legislative requirements for the EU and Canadian market, including information on market surveillance and safeguards. Moreover, with the courtesy of the Canadian authorities, the guidance also explains how the Canadian authorities will process foreseen EU requests under the Protocol.

⁽¹⁾ CETA has been provisionally applied since 2017, including the Protocol. See Council Decision (EU) 2017/38 of 28 October 2016 on the provisional application of the Comprehensive Economic and Trade Agreement (CETA) between Canada, of the one part, and the European Union and its Member States, of the other part (OJ L 11, 14.1.2017, p. 1080).

⁽²⁾ OJ L 280, 16.10.1998, p. 1, OJ L 278, 16.10.2002, p. 19.

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A) Scope of the Protocol

According to Article 2.1, the scope of the Protocol covers the product groups listed in Annex 1 ⁽³⁾. As a result, EU accreditation bodies and, in some cases, Standards Council of Canada ⁽⁴⁾ can accredit Canadian conformity assessment bodies to assess conformity within the following EU harmonised legislation:

- Directive 2014/53/EU: Radio Equipment
- Directive 2014/30/EU: Electromagnetic compatibility
- Directive 2009/48/EC: Safety of Toys
- Regulation (EU) No 305/2011: Construction products
- Directive 2006/42/EC: Machinery
- Directive 2014/32/EU: Measuring Instruments
- Directive 92/42/EEC: Hot-water boilers
- Directive 2014/34/EU: Equipment and protective systems intended for use in potentially explosive atmospheres (ATEX)
- Directive 2000/14/EC: Noise emission in the environment by equipment for use outdoors
- Directive 2013/53/EU: Recreational craft

In Canada the legislation covering the scope corresponding to the EU legislation listed above is more complex to list, as Canadian legislation is not directive-based but made up of so-called 'Acts' and 'regulations', which both contain mandatory regulatory requirements. Depending on the product sector, the national government or the provinces and territories ('PTs') are responsible for determining the regulatory requirements applicable in their jurisdiction.

As such, for some Annex 1 product categories the PTs are responsible for determining the regulatory requirements for their province or territory, while there are other product categories determined by the national government and thus applied in all PTs.

More information, including federal authorities for a number of federal Acts, can be found here: <http://www.ic.gc.ca/eic/site/oca-bc.nsf/eng/ca03084.html>

Moreover, voluntary codes and standards are often incorporated by reference to the Acts and regulations, which makes them mandatory and legally binding. In this regard, Canada's 'National Codes' are developed nationally but implemented at the level of the PTs, with modifications deemed necessary for legitimate purposes.

More information on Canada's National Codes can be found here:

<https://nrc.canada.ca/en/certifications-evaluations-standards/codes-canada/codes-development-process/how-national-codes-are-developed>

Another important aspect for European conformity assessment bodies operating on the Canadian market is to establish and maintain a relationship with so-called 'Authorities Having Jurisdiction' at the federal or PTs level for a given product category in which the accreditation is sought. This requirement may, alternatively, be met by establishing a relationship with the relevant 'Regulatory Authority Advisory Body', which is composed of the applicable Canadian regulatory authorities in a specific field.

The list of Regulatory Authority Advisory Bodies can be found here:

<https://www.scc.ca/en/accreditation/scc-accreditation-regulatory-authority-advisory-bodies>

Given the nature of the Canadian system, Standards Council of Canada does not maintain a knowledge base of regulatory requirements for product certification. Instead when a conformity assessment body's client requests certification of their product in order to meet regulatory requirements, they are responsible, with or without the conformity assessment body's assistance, to identify the correct technical standard required by the Canadian authorities. For EU conformity assessment bodies and accreditation bodies, the European co-operation for Accreditation and Standards Council of Canada Steering

⁽³⁾ For the scope of relevant EU legislation, the Protocol specifies that the product groups are dependent on the EU recognising non-governmental bodies for the purpose of assessing conformity of goods with the EU's harmonised legislation. Currently, such requirement of only recognising non-governmental bodies does not have any implications for the product groups listed in Annex 1.

⁽⁴⁾ Currently, as per Article 15 of the Protocol, Standards Council of Canada can accredit Canadian conformity assessment bodies for Directive 2014/53/EU: Radio Equipment and Directive 2014/30/EU: Electromagnetic compatibility, however, for the remaining EU legislation listed, Standards Council of Canada will need to be recognised pursuant to Article 12 of the Protocol, please see more under section C.

Group, described in sections C and F of this document, is available to assist them in finding information on regulatory requirements. Moreover, Standards Council of Canada remains available and offers assistance to interested EU accreditation bodies and conformity assessment bodies regarding the regulatory system in Canada.

Importantly, regarding Canadian requirements, the Standards Council of Canada may accredit interested EU conformity assessment bodies as it does to Canadian conformity assessment bodies. Standards Council of Canada's accreditation is available outside the terms of the Protocol, hence, some EU conformity assessment bodies have already taken advantage and be accredited by Standards Council of Canada before the Protocol's provisional application. Under the terms of the Protocol, EU national accreditation bodies will now be able to accredit conformity assessment bodies in their territory for relevant product sectors to certify to Canadian requirements.

The Protocol provides that the EU and Canada will consult with a view to broadening the scope of application of the Protocol by modifying Annex 1. In this regard, Article 2.2 provides that priority should be given to the product groups listed in Annex 2.

Annex 2 foresees the following categories of products:

- Medical devices including accessories
- Pressure equipment, including vessels, piping, accessories and assemblies
- Appliances burning gaseous fuels, including related fittings
- Personal protective equipment
- Rail systems, subsystems and interoperability constituents
- Equipment placed on board a ship

B) Accreditation, designation, (lack of) objections and additional requirements for the recognition of conformity assessment bodies

Compared to traditional mutual recognition agreements on the mutual acceptance of conformity assessment results, the Protocol introduces a novel obligatory requirement for conformity assessment bodies to be accredited by recognised accreditation bodies. By making accreditation mandatory for Canadian and EU conformity assessment bodies, the Protocol strengthens public oversight of conformity assessment activities between Canada and the EU.

Article 4 of the Protocol provides that a conformity assessment body should seek accreditation from an accreditation body in its territory if the other Party has recognised that accreditation body pursuant to Articles 12 or 15. However, when there are no accreditation bodies recognised pursuant to Articles 12 or 15, conformity assessment bodies can seek accreditation in the territory of the other Party. Hence, Article 4 of the Protocol sets that conformity assessment bodies seek accreditation within their own territory from the recognised accreditation bodies there as the 'preferred way'.

The following sections seek to first explain the road to recognition for Canadian conformity assessment bodies and then secondly for EU conformity assessment bodies. Recognition of Canadian and EU Accreditation bodies is further explained in Section C.

Recognition of Canadian conformity assessment bodies

Article 3.2 of the Protocol sets out the recognition procedure for Canadian conformity assessment bodies. Once a Canadian conformity assessment body has gone through the procedure foreseen in Articles 3.2(a) or 3.2(b), the body will be listed on the public NANDO website with its assigned identification number and thus be able to operate on the EU market for the product categories for which it has been designated.

The recognition procedures in Articles 3.2(a) and 3.2(b) are almost identical, in fact, only the first step of the accreditation process differs.

The procedures include five cumulative steps, these are: i) accreditation, ii) designation, iii) (lack of) objections; iv) no withdrawal, and v) continuous compliance over time.

1) Accreditation:

Article 3.2(a): ‘(i) the conformity assessment body is accredited, by an accreditation body appointed by one of the Member States of the European Union, as competent to assess conformity with those specific European Union technical regulations;’

or:

Article 3.2(b): ‘(i) the third-party conformity assessment body established in Canada is accredited, by an accreditation body that is recognised pursuant to Articles 12 or 15, as competent to assess conformity with those specific European Union technical regulations;’

According to the paragraph in Article 3.2(a)(i), Canadian conformity assessment bodies can seek accreditation from EU Member State accreditation bodies.

As explained above, in the event that there is a Canadian accreditation body recognised pursuant to Articles 12 or 15, and the conformity assessment body holds an accreditation certificate from such a body, the recognition process will be that of Article 3.2(b), which is reflected in Article 3.2(b)(i). For further information about the recognition of Canadian accreditation bodies, please see section C.

Article 4 of the Protocol provides that accreditation bodies should accredit Canadian conformity assessment bodies under conditions no less favourable than those applied to EU conformity assessment bodies. Therefore, EU accreditation bodies should apply the same conditions and procedures – nothing more, nothing less – to accredit Canadian conformity assessment bodies, as they would apply to EU conformity assessment bodies seeking accreditation.

Article 5.2 of the Protocol sets out the qualitative elements for Canadian conformity assessment bodies to be accredited in the EU. According to Article 5.2(a)-(b), a Canadian conformity assessment body will have to meet the requirements set out in Article R17 of Annex I to Decision 768/2008/EC and hold an accreditation certificate.

Table of requirements relating to conformity assessment bodies (not exhaustive ^(*)):

1	A conformity assessment body shall be established under national law and have legal personality.
2	A conformity assessment body shall be a third-party body independent of the organisation or the product it assesses.
3	A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the products which they assess, nor the authorised representative of any of those parties.
4	Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements.
5	A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by [reference to relevant part of the EU legislation] and in relation to which it has been notified.

(*) Please note that the requirements are not shown in full and thus for the exhaustive list of requirements, please see directly Article R17 of Annex I to Decision 768/2008/EC.

6	The personnel responsible for carrying out conformity assessment activities shall have the following: (a) sound technical and vocational training; (b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority; (c) appropriate knowledge and understanding of the essential requirements, of the applicable harmonised standards and of the [relevant EU legislation]; (d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.
7	The impartiality of the conformity assessment bodies, their top level management and of the assessment personnel, shall be guaranteed.
8	Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.
9	The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks.
10	Conformity assessment bodies shall participate in, or ensure that their assessment personnel are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under the relevant [EU] legislation and apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

It is important to note that these requirements are continuous, i.e. even if the EU recognises a Canadian conformity assessment body that can start operating on the EU market, it will continue to have to meet the requirements of Article 5.2. If the conformity assessment body does not meet these requirements following its recognition, the Canadian authorities shall withdraw its designation in accordance with Article 8 or Member State authorities can challenge its designation in accordance with Article 7 of the Protocol. See these points further elaborated under section D below.

2) Designation:

‘(ii) the third-party conformity assessment body established in Canada is designated by Canada in accordance with the procedures set out in Article 5;’

Article 5.1 provides that Canada will be allowed to use the EU’s electronic notification tool (NANDO) for the purpose of designating a conformity assessment body. When designating a conformity assessment body, Canada’s authorities will have to provide the information listed in Annex 3 to the Protocol, which is:

‘(i) the scope of designation (not to exceed that body’s scope of accreditation);

(ii) the accreditation certificate and the related scope of accreditation;

(iii) the body’s address and contact information;’

Thus, a Canadian conformity assessment body to be designated will have to be in possession of an accreditation certificate.

By designating the conformity assessment body, the relevant authority assures public oversight over the competence of the candidate conformity assessment body.

Regarding the concrete designation steps in NANDO, see also pages 50-72 of the ‘Guide To Using: NANDO-INPUT / New Approach Notified and Designated Organisations’ from 21 September 2017, which outlines the concrete technical steps for the Canadian authorities to designate Canadian conformity assessment bodies in the NANDO database.

3) Objections

‘(iii) there are no unresolved objections pursuant to Article 6;’

Article 6 entails the possibility to object to the designation of a Canadian conformity assessment body within 30 days of the notification/designation in NANDO.

As is the case under EU law, notifying authorities can raise such objections through the NANDO database.

The procedure and assessment for such objections should be done in accordance with Article 6. As such, the Commission and Member State notifying authorities can object if Canada failed to provide the information described in Annex 3 or if there is reason to believe that the Canadian conformity assessment body does not fulfil Articles 5.2 to 5.4 of the Protocol. In this regard, the designated conformity assessment body shall essentially meet the requirements set out in Article R17 of Annex I to Decision 768/2008/EC, see Articles 5.2 and 5.3 of the Protocol.

Following Article 6.2, it is also possible for the Commission and Member State notifying authorities to seek additional information from the Canadian authorities in relation to the fulfilment of Articles 5.2 to 5.4 of the Protocol of a designated Canadian conformity assessment body. To this extent, when the Canadian authorities reply, the Commission and Member State notifying authorities will have an additional 30 days to assess such information and likewise object to the designation of the Canadian conformity assessment body. A feature for NANDO will be made available for these purposes.

Additional requirements for the recognition:

- 4): '(iv) the designation made in accordance with the procedures set out Article 5 is not withdrawn by Canada;'

These requirements are self-explanatory, i.e. if Canada withdraws the designation, the Canadian conformity assessment body will subsequently be withdrawn from the NANDO database.

- 5): '(v) after the expiry of the 30 day period of time referred to in Article 6.1 or 6.2, the third-party conformity assessment body established in Canada continues to meet all the conditions described in Article 5.2;'

Similarly, as explained above, to be recognised and listed in NANDO, Canadian conformity assessment bodies have to continue to meet all of the conditions described in Article 5.2.

Designation and recognition of EU conformity assessment bodies

Article 3.1 of the Protocol concerns the recognition of conformity assessment bodies established in the EU. The procedure under Articles 3.1(a) and 3.1(b) are significantly different and differ as well from the recognition process for Canadian conformity assessment bodies as explained above.

Pursuant to Article 3.1(a), an EU conformity assessment body accredited by the Standards Council of Canada shall immediately be recognised as competent to certify products to technical standards on its scope of accreditation, which are required by the regulators in the jurisdictions of the intended markets in Canada. Thus, there is no objection period, designation or other cumulative requirements foreseen in the recognition procedure under Article 3.1(a).

After having obtained the accreditation from the Standards Council of Canada, the Canadian authorities through the Standards Council of Canada will list the EU conformity assessment body on the Standards Council of Canada's website. The link to such list will be also made publically available in NANDO.

Pursuant to Article 3.1(b), if a recognised EU accreditation body accredits the EU conformity assessment body, then the five cumulative steps explained above for Canadian conformity assessment bodies are almost analogous.

As such, in addition to seeking accreditation from a recognised EU accreditation body (Article 3.1(b)(i)), the EU conformity assessment body will also have to be designated by a Member State notifying authority in accordance with Article 5.

- For Member State notifying authorities this entails ensuring compliance with Articles 5.1 and 5.5. As such, Member State notifying authorities need to include the information in Annex 3 as described above and ensure that the EU conformity assessment body is accredited by a recognised EU accreditation body (Article 3.1(b)(ii)).
- Member State notifying authorities shall designate EU conformity assessment bodies directly to the Canadian authorities via the following functional mailbox: cetainfo@scc.ca. Please note that for the areas of telecommunications and electromagnetic compatibility a specific procedure applies ⁽⁶⁾.
- When designating EU conformity assessment bodies, Member State notifying authorities shall remember to copy and inform the Commission through the following functional mailbox: GROW-NANDO-ADMINISTRATOR@ec.europa.eu
- The EU conformity assessment body will have to have no unresolved objections from the Canadian authorities following the 30 days objection period in accordance with Article 6.1 (Article 3.1(b)(iii)). During the 30-day period, Standards Council of Canada will liaise with the appropriate regulatory authority in Canada having jurisdiction for the product sector in question and will facilitate the administrative processes needed for recognition in Canada;
- The EU conformity assessment body will have to comply with the additional requirements analogous to those applying to Canadian conformity assessment bodies as explained above (Articles 3.1(b)(iv)-(v)).

At the latest 30 days after having received the designation from a Member State notifying authority, the Canadian authorities will recognise the EU conformity assessment body or in accordance with Article 6 of the Protocol decline to recognise the EU conformity assessment body. The Canadian authorities will provide their reply directly to the Member State notifying authority via e-mail. If Canada recognises the EU conformity assessment body, it will then list the EU conformity assessment body at its relevant website.

If the reply is negative, the Member State notifying authority should inform the Commission through the following functional mailbox:

GROW-NANDO-ADMINISTRATOR@ec.europa.eu

If the negative reply raises questions of concern to all Member States, the Commission will call a meeting of the IMP expert group.

Similarly to Canadian conformity assessment bodies, as described above, the relevant Member State notifying authority that designates the EU conformity assessment body will assure public oversight over the competence of it, regardless of where it has obtained its accreditation certificate.

C) Recognition of the Parties' accreditation bodies

The novelty of the Protocol compared to traditional mutual recognition agreements is that it makes accreditation mandatory for the recognition of conformity assessment bodies under the Protocol, thus strengthening public oversight. Because of this, conformity assessment bodies will either have to seek accreditation from a recognised accreditation body within their own territory or from the accreditation bodies of the other Party.

⁽⁶⁾ If the CAB is looking at Testing Equipment to RSS-102, there is no recognition involved and the lab simply needs to register by following the steps below:

If the CAB is looking at certifying equipment, procedure CB-01 and CB-02 needs to be followed.

Company numbers can be obtained by creating a new web account through the Spectrum Management System.

1. Click on 'Register a new Web Account for a new or existing Licensee or Certification/Registration clients or Broadcaster'.

2. Under the Equipment Certification and Registration list, select 'New Applicant' or 'New Agent Applicant' and then click on the 'Next' button.

3. Fill in the 'Web User Information', 'Applicant Information' and 'Certification Letter Contact'.

4. Review the information and then submit your request.

If you already have a web account, you can request additional company numbers.

1. Login to your account

2. select 'list my application'

3. click on the 'Add Client', which is located to the right of your name at the top of the page.

4. Select 'New Applicant' and then the 'Next' button.

5. Fill in the company information and then click on the 'Next' button.

6. Review the information and then submit your request.

Articles 12 and 15 of the Protocol set out the recognition procedure for accreditation bodies to accredit conformity assessment bodies for the other Party's market. Article 15 sets out that for technical regulations related to telecommunications terminal equipment, information technology equipment, apparatus used for radio communication and electromagnetic compatibility, from the date of entry into force of the Protocol ⁽⁷⁾, Canada recognises all national accreditation bodies of the EU's Member States and, similarly, the EU recognises the Standards Council of Canada (SCC).

Therefore, SCC is already recognised to accredit Canadian conformity assessment bodies within the following scopes: Directive 2014/53/EU on radio equipment and Directive 2014/30/EU on electromagnetic compatibility. To this extent, some Canadian conformity assessment bodies are already listed in NANDO today and are operating within the EU market. ⁽⁸⁾

Similarly, all EU accreditation bodies are already able to accredit EU conformity assessment bodies for the Canadian Telecommunications Act, Radiocommunication Act and the Radio Communication Regulations, including technical requirements for radio apparatus and related innovation, science and economic development procedures. ⁽⁹⁾

For all other product sectors listed in Annex 1, Article 12 of the Protocol sets out a recognition procedure for interested accreditation bodies. ⁽¹⁰⁾

To seek recognition of their accreditation bodies, the Canadian and EU authorities ⁽¹¹⁾ may notify each other according to Article 12.2, a request for recognition, which should include an exhaustive list of items, notably for an accreditation body:

- its name, address and contact details;
- evidence that its authority is derived from the government;
- whether it acts on a non-commercial and non-competitive basis;
- evidence of its independence from the conformity assessment bodies it assesses and from commercial pressures, in order to ensure that no conflicts of interest with conformity assessment bodies occur;
- evidence that it is organised and operated so as to safeguard the objectivity and impartiality of its activities and the confidentiality of the information it obtains;
- evidence that each decision relating to the attestation of competence of conformity assessment bodies is taken by a competent person different from those who carry out the assessment;
- the scope for which its recognition is requested;
- evidence of its competence to accredit conformity assessment bodies within the scope for which its recognition is requested, referring to applicable international standards, guides and recommendations, and applicable European or Canadian standards, technical regulations and conformity assessment procedures;
- evidence of its internal procedures to ensure efficient management and appropriate internal controls, including the procedures in place for documenting the duties, responsibilities and authorities of personnel who can affect the quality of the assessment as well as the attestation of competence;
- evidence of the number of competent personnel at its disposal, which should be sufficient for the proper performance of its tasks, and of the procedures in place for monitoring the performance and competence of the personnel involved in the accreditation process;
- whether or not it is appointed for the scope for which its recognition is requested in the territory of the nominating Party;

⁽⁷⁾ CETA has been provisionally applied since 2017, including the Protocol. See footnote 1.

⁽⁸⁾ A complete list of Canadian conformity assessment bodies currently recognised can be found here: https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=country.notifiedbody&cou_id=124

⁽⁹⁾ The acts can be found via the following hyperlinks: *Telecommunications Act*, *Radiocommunication Act* and the *Radiocommunication Regulations*. For a full list of the relevant technical requirements for radio apparatus and related innovation, science and economic development procedures, please contact Standards Council of Canada.

⁽¹⁰⁾ Please note that on 18 February 2021, Standards Council of Canada was recognised to accredit conformity assessment bodies for equipment, machines, apparatus, devices, control components, protection systems, safety devices, controlling devices and regulating devices, and related instrumentation and prevention and detection systems for use in potentially explosive atmospheres (ATEX equipment). See the following website for a complete list of sectors, where Standards Council of Canada is recognised: https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=ab.detail&ab_id=243324

⁽¹¹⁾ Please see the below sub-heading 'On the process for recognition requests of EU accreditation bodies' for the relevant procedure and involved EU authorities.

- evidence of its status as a signatory to the International Laboratory Accreditation Cooperation (ILAC) or International Accreditation Forum (IAF) multilateral recognition arrangements and to any related regional recognition arrangements; and
- any other information that the Parties may decide is necessary.

Article 12.3 of the Protocol provides for solutions when the parties recognise that differences may exist between their respective standards, technical regulations and conformity assessment procedures. In this regard, the Standards Council of Canada and the European co-operation for Accreditation (EA) association concluded a bilateral co-operation agreement in accordance with Article 12.3. See section F for more information.

According to the bilateral co-operation agreement signed by the Standards Council of Canada and the European Co-operation for Accreditation (EA), a request for recognition shall be based on a recommendation from the 'EA – Standards Council of Canada Steering Group'. This was set up in 2018 to assess the competence of the Standards Council of Canada and EU accreditation bodies to accredit conformity assessment bodies for Canada's and the EU's markets ⁽¹²⁾.

Once a recognition notification request is received, Canada and the EU have 60 days to respond in writing and provide the information requested in Article 12.5 of the Protocol. This written reply can inform the other Party of the following:

- that it recognises the accreditation body competent to accredit conformity assessment bodies for the scope proposed (Article 12.5(a));
- that amendments or legislative and regulatory changes are required to recognise the accreditation body (Article 12.5(b));
- that specific information required as per Article 12.2 of the Protocol is missing (Article 12.5(c));
- that it refuses to recognise the accreditation body for the proposed scope and the reasons for such refusal (Article 12.5(d)).

Moreover, in accordance with Article 12.6, the EU and Canada shall publish the names of the accreditation bodies that they recognise, and for each accreditation body, the scope of the technical regulations for which they recognise them. The EU will use NANDO for these purposes, while Canada will publish the list of recognised EU accreditation bodies on the website of the Standards Council of Canada.

On the process for recognition requests of Standards Council of Canada

In order to adequately handle the recognition notification requests within the 60-day deadline foreseen in Article 12.5, a new feature in the NANDO database will be developed, which will make it possible for the Canadian authorities to notify their accreditation body recognition request, including all the information requested as listed in Article 12.2 through this database. If no objections are raised within 60 days of the receipt of the relevant notification, the Canadian authorities will receive a written reply recognising the accreditation body's competency to accredit conformity assessment bodies for the scope proposed (Article 12.5(a)).

The Commission will liaise with EA on the process leading up to the request for recognition and inform Member States of EA's assessment of the request for recognition, which is preceded by the work of the EA and Standards Council of Canada Steering Committee. See for more information sections C and F of this document. If required, the Commission will call a meeting of the IMP expert group.

If a Member State wants to raise objections regardless of the findings of EA, it will be able to do so via its notifying authority. Objections may be directly encoded in the NANDO database, attaching a statement, which will inform other Member States and the Commission. When doing so the Member State shall give reasons for its objections and is required to state the conditions under which recognition could, in their view, be granted.

Upon reception of such individual Member State objection and if considered necessary, the Commission's services would immediately call a meeting of the IMP expert group to discuss the concerns of the relevant Member State. In order to comply with the 60-day deadline, Member States will only be able to submit objections until 40 days after reception of the recognition notification request submitted by the Canadian authorities.

⁽¹²⁾ A model/framework for mutual recognition of Canada's and the EU's accreditation bodies was agreed by EA and Standards Council of Canada on 18 June 2018. Find more information in section F.

Upon the expiry of the 60-day deadline, if the objections remain, an automated feature would then be created in NANDO as a written reply to the Canadian authorities, inserting the statement from the objecting Member States(s), and providing the information requested in Article 12.5(b), (c) and/ or (d). The Commission will steer the subsequent dialogue with the Canadian authorities.

On the process for recognition requests of EU accreditation bodies

EU accreditation bodies interested in seeking recognition in Canada should inform EA and the Commission accordingly. Any notification request for recognition for EU accreditation bodies would follow a positive recommendation by the EA – Standards Council of Canada Steering Group. Please see section F for more information.

The Commission will submit on behalf of the EU the recognition notification request to Canada via NANDO, which will automatically inform Member States via an e-mail alert.

The recognition notification request and the accompanying information will be submitted to the Canadian authorities in accordance with Article 12 of the Protocol. The Canadian authorities would have 60 days to provide a written reply to the recognition request.

The Canadian authorities, having access to NANDO and having received the notification for recognition, will reply in accordance with Article 12.5 of the Protocol via e-mail to the following functional mailbox: GROW-NANDO-ADMINISTRATOR@ec.europa.eu.

Once the Commission's services have received the reply, they will dispatch it to the relevant Member State and the concerned EU accreditation body and will inform EA and other Member States. Moreover, if the Canadian authorities reject the notification request or require amendments or legislative and regulatory changes or seek additional specific information, the Commission's services may call a meeting of the IMP expert group to discuss the rejection decision or the request for additional information.

D) Challenges and withdrawals of conformity assessment bodies and accreditation bodies

Following the recognition of a conformity assessment body, it is possible to challenge its competence or withdraw its designation in accordance with Articles 7 and 8 of the Protocol. Moreover, Articles 13 and 14 of the Protocol concern the cessation or challenge of recognition of a recognised Canadian accreditation body.

Challenges to conformity assessment bodies

Article 7 of the Protocol concerns challenges and sets out the challenge procedure, including in Article 7.5, for the Parties ceasing to recognise a concerned conformity assessment body.

Article 7.1 provides that conformity assessment bodies can be challenged if the relevant authorities fail to take action as a result of the complaint procedure foreseen in Article 11.3 of the Protocol (see below section E for more information on Article 11.3 of the Protocol). Moreover, conformity assessment bodies can be challenged if there are reasons to believe that the results of such bodies' conformity assessment activities do not provide sufficient assurances that the products assessed are in conformity with relevant legislation.

Member State notifying authorities may submit their challenges directly via NANDO, thus, informing the other Member States and the Commission. After 15 days, if there is no reaction from the Commission or other Member States, an automated feature in NANDO will immediately send the challenge to the Canadian authorities. This process will allow transparency between the Commission and other Member State notifying authorities and ensure relevant follow up in the NANDO database, i.e. if action needs to be taken as a result of the challenge process.

Before notifying a challenge to the Canadian authorities in accordance with Article 7.2, the Commission's services will assist in verifying the requirements in Articles 7.1 and 7.2 in cooperation with the concerned Member State.

After having notified the challenge to the Canadian authorities, for coordination purposes, the Commission's services will enable the dialogue foreseen in Article 7.4 of the Protocol between the Canadian authorities and the notifying authority having submitted the challenge.

If a concerned Member State wishes to take measures in accordance with Article 7.3 of the Protocol, it shall inform the Commission's services, so that a coordinated approach can be established between all Member States.

Similarly, the Commission's services will steer any action foreseen under Article 7.5 of the Protocol, in close coordination with Member State notifying authorities. In this regard, the Commission's services intend to utilise the IMP expert group as the forum for any discussion relating to Article 7.5.

The Canadian authorities will submit their challenges to EU conformity assessment bodies to the Commission, which will subsequently communicate such a challenge to the concerned Member State notifying authority, EA and the EU accreditation body if relevant. If required and of interest to other Member States, the Commission will call a meeting of the IMP expert group.

Withdrawals of conformity assessment bodies and cessation of recognitions

Article 8 of the Protocol concerns withdrawals and sets out when the Parties shall withdraw or modify the scope of a previous conformity assessment body designation. For example, the Parties shall withdraw a conformity assessment body's designation if the conformity assessment body no longer fulfils the requirements in Article 5.2 of the Protocol.

Member State notifying authorities, which need to withdraw or modify the scope of a previously designated EU conformity assessment body, can do so directly to the Canadian authorities via the following functional mailbox: cetainfo@scc.ca

The Member State notifying authority shall put the Commission's services in copy of such communication via the following functional mailbox:

GROW-NANDO-ADMINISTRATOR@ec.europa.eu

Canada will request the withdrawal or modify the scope of its designated conformity assessment body directly via NANDO.

Moreover, Article 8.5 of the Protocol deals with five scenarios, without prejudice to Article 7.5, where the Parties can immediately cease to recognise a conformity assessment body that had been previously designated. For example, if the accreditation of a Canadian conformity assessment body lapses and the Canadian authorities do not withdraw its designation or submit a new accreditation certificate, the Commission and Member States may take measures in accordance with Article 8.5 of the Protocol, and cease to recognise the conformity assessment body whose competence is in question. Member States intending to cease to recognise a Canadian conformity assessment body shall inform the Commission, which may delist the concerned conformity assessment body from the list of recognised conformity assessment bodies in NANDO and inform the Canadian authorities accordingly.

Challenges and cessation of the recognition of accreditation bodies

Articles 13 and 14 of the Protocol provide for the possibility to cease to recognise or challenge the recognition of an accreditation body.

Article 13 sets out that if the accreditation body ceases to be a signatory of a multilateral or regional arrangement referenced in sub-paragraph (l) of Article 12.2 or a cooperation arrangement described in Article 12.3, the recognising Party may cease to recognise such an accrediting body.

Article 14 sets out the procedure to challenge the recognition of an accreditation body following its recognition.

If a Member State wants to challenge the recognition of the Canadian accreditation body, it shall inform the Commission's services, EA, and the other Member States via e-mail and justify in an objective and reasoned manner the underlying grounds for its request.

The process of challenging or ceasing to recognise the Standards Council of Canada, as well as the process aiming to resolve a challenge, shall be heavily reliant on the work carried out by EA and the Standards Council of Canada, as foreseen in Article 14.2 of the Protocol. Thus, EA will keep the Commission and the Member States duly informed of any developments, which could prompt a challenge or cease the recognition of the Standards Council of Canada and the conformity assessment bodies recognised on that basis.

When the Commission's services receive such information, it will immediately call a meeting of the IMP expert group to discuss how to proceed.

Similarly, if Canada intends to cease to recognise or challenge an EU accreditation body and any conformity assessment bodies recognised on that basis, it will inform the Commission, which will immediately inform and liaise with EA and the respective Member State, EU accreditation body and, as appropriate, subsequently call a meeting of the IMP expert group.

E) Market surveillance, enforcement and safeguards

Article 11 of the Protocol provides how market surveillance or enforcement authorities shall verify conformity for products assessed by a recognised conformity assessment body established in the other's territory and what enforcement and safeguard measures they may take in this regard.

According to Article 11.1, the verification of a product's compliance with relevant legislation shall be conducted under conditions no less favourable than those conducted with respect to products assessed by conformity assessment bodies in their own territory.

Article 11.2 of the Protocol provides that national authorities may adopt or maintain measures against a product, such as withdrawing the product from the market, if the product's placement or use on the market could compromise the fulfilment of a legitimate objective. According to Article 1 of the Protocol, legitimate objectives are those listed in Article 2.2 of the WTO Technical Barriers to Trade Agreement, for example the protection of human health and safety or of the environment. The measure(s) taken against a particular product will have to be consistent with CETA and the Protocol specifically. In this regard, in addition to the withdrawal of the product from the market, a few other examples of appropriate measures are explicitly listed in Article 11.2 of the Protocol. These are measures that are prohibiting the product's placement or use or are restricting its movement on the market.

Importantly, if a Member State market surveillance or enforcement authority wishes to adopt or maintain measures against a particular product, which have been assessed by a conformity assessment body designated by the Canadian authorities under the Protocol, they shall inform the Canadian authorities promptly via the following functional mailbox: cetainfo@scc.ca

When writing to the Canadian authorities, Member States shall always put in copy the Commission with the following functional mailbox:

GROW-NANDO-ADMINISTRATOR@ec.europa.eu

If the Canadian authorities so requests, the Member State authority, having already submitted the communication to the Commission's services, may be asked to provide reasons for adopting or maintaining these measures. For coordination purposes, the Commission's services would liaise the foreseen dialogue between the concerned Member State(s) authorities and Canada.

Moreover, Articles 11.3 and 11.4 of the Protocol foresee the possibility for Member State authorities and EU accreditation bodies to submit a written complaint to Canada should there be evidence that products assessed by a Canadian conformity assessment body do not comply with the applicable EU legislation for which it is recognised. Such a written complaint shall be supported by evidence, for example highlighting earlier measures taken under Article 11.2 of the Protocol. Ultimately, a complaint under Article 11.3 can be used to challenge the designation of the conformity assessment body concerned under Article 7, see section D above.

Member State authorities or EU accreditation bodies wishing to make a written complaint, shall inform and request the Commission's services to submit such a complaint on their behalf. Any such written complaints shall be submitted to the Commission's services via the following functional mailbox: GROW-NANDO-ADMINISTRATOR@ec.europa.eu

The Commission's services will monitor and advance the complaint with the Canadian authorities in close coordination with the Member State authority, EA, and the EU accreditation body concerned as well as inform other Member State authorities and EU accreditation bodies of the complaint.

Similarly, the Commission will be in contact with the concerned Member State and EU accreditation body, if Canada takes measures according to Article 11.2 of the Protocol or files a written complaint according to Articles 11.3 or 11.4 of the Protocol. The Commission's services will, for such purposes, use the IMP expert group as the relevant forum to discuss any issues relating to Article 11 of the Protocol, although it may consult the Member State market surveillance authorities as appropriate through the Union Product Compliance Network.

F) Bilateral agreements in relation to the accreditation process

Article 12.3 of the Protocol provides for the possibility of a cooperation arrangement either between the European and Canadian accreditation systems or in the absence of such an arrangement, between the nominated accreditation body and an accreditation body recognised as competent by the recognising Party. This arrangement should ensure that the nominated accreditation body is competent to accredit conformity assessment bodies as competent to assess conformity with the relevant regulations of the recognising authority. For these purposes, the European co-operation for Accreditation (EA) association and the Standards Council of Canada (SCC) signed a bilateral cooperation agreement on 10 June 2016 ⁽¹³⁾ to establish the conditions and procedures in terms of technical support aimed at mutual recognition of accreditation bodies and accredited conformity assessment bodies operating in the EU and Canada.

On 18 June 2018, EA and SCC established a model framework for the mutual recognition of Canadian and EU conformity assessment bodies and accreditation bodies. ⁽¹⁴⁾ The framework sets up a joint EA - SCC Steering Group, which oversees the recognition process and ensures the competence of conformity assessment bodies and accreditation bodies for the EU's and Canada's markets. Thus, the Steering Group administers the processes leading to the mutual recognition for each product category between SCC and EA, including:

- A list of product categories and related requirements for which the recognition has been established at national accreditation level.
- A list of accreditation bodies recognised with their scope of recognition.
- Updating, as needed, documentation and related forms to be used for the recognition processes.
- Maintaining regulatory currency and engagement with regulatory authorities.
- Acting as central point of contact for questions about the Protocol implementation and mutual recognition processes in application of the Protocol.

Moreover, in the absence of the recognition of Canadian accreditation body pursuant to Article 12, SCC may seek to conclude bilateral cooperation agreements with EU Member State accreditation bodies to facilitate the accreditation of Canadian conformity assessment bodies through EU accreditation bodies. Such bilateral cooperation agreements can facilitate the application of Article 4 of the Protocol. Typically, such an agreement could include ensuring site checks by SCC and the national EU accreditation body within their own territories and other measures which could proportionally lower the costs of accreditation while ensuring compliance with the relevant EU and Canadian requirements.

Although the conclusion of such agreements is not an obligation or pre-requisite foreseen in the Protocol, they could further facilitate the implementation of the Protocol pending the recognition of the Canadian accreditation body for specific product sectors.

G) Acceptance of results of recognised conformity assessment bodies

Articles 9 and 10 of the Protocol provide that the EU shall recognise the results of conformity assessment activities performed by conformity assessment bodies recognised pursuant to Article 3 (see section B) and by accredited in-house bodies established in Canada under conditions no less favourable than those applied to such bodies in the EU. Conversely, if a conformity assessment body has ceased to be recognised, Member State authorities may also cease to recognise its conformity assessment activities and following results.

Article 9.2 specifies that such refusal can start from the date when the conformity assessment body ceased to be recognised or if there are reasons to believe that such lack of competence prompting the withdrawal of recognition happened prior to that date, then prior to the cessation date. If there are no reasons to believe that the lack of competence happened before the cessation date, then Member State authorities shall accept the results of the relevant conformity assessment activities up until the cessation date.

Regarding accredited in-house bodies, according to Article 10.1 of the Protocol, only those in-house bodies accredited by an EU accreditation body or alternatively by Standards Council of Canada shall be given the no less favourable treatment.

⁽¹³⁾ More information can be found online in the attached brochure prepared by the European co-operation for Accreditation association: <https://european-accreditation.org/wp-content/uploads/2018/10/ceta-agreementand-conformity-assessment-accreditation-a-tool-to-enhance-tradebetween-the-european-union-and-canada.pdf>

⁽¹⁴⁾ Model/Framework for Mutual Recognition – CA Protocol, CETA, EA, Standards Council of Canada, 18 June 2018.