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Agenda Item 5

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

Twelfth Session

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DISCUSSION PAPER ON THE JUDGEMENT OF EQUIVALENCE OF TECHNICAL REGULATIONS ASSOCIATED WITH FOOD INSPECTION AND CERTIFICATION SYSTEMS

Comments from Canada, Mexico, New Zealand, United States and European Community

CANADA

General Comment:

The paper provides a helpful analysis of the elements of the WTO/TBT Agreement on the judgement of equivalence and on options for dealing with TBT-related issues. It should help CCFICS reflect on key considerations to make informed decisions.

Canada believes that clarification from the WTO/TBT Committee on the operation of equivalence and mutual recognition within the TBT Agreement is critical to make informed decisions at CCFICS. At the time of submitting comments, this clarification was not available.

It is Canada's view that the "specific or potential examples of problems in trade that were or could be solved through the application of equivalence and mutual recognition agreements", provided as responses to Circular Letter 2002/54-FICS (Annex 2), show that trade problems related to technical regulations are very diverse. We also note that the examples in Annexes 3 and 4 regarding trade disputes or concerns invoking or relating to the TBT Agreement suggest that challenges reside more specifically with the legitimacy of a TBT measure rather than with its equivalence with another country's measure. Canada still questions the usefulness of developing general guidance in this area and, particularly, it appears unlikely that further guidance by CCFICS on the judgement of equivalence of technical regulations would alleviate such disputes or concerns.

Canada has had the opportunity to negotiate arrangements with other countries pertaining to the mutual recognition of food inspection and control systems. These arrangements are based on provisions included in the *Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems (CAC/GL 34- 1999)*, and the *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (CAC/GL 26-1997)*. We question whether there is a need for guidance from CCFICS in the area of MRAs to address TBT-related issues.

Canada's views on the questions raised in the Discussion Paper are as follows:

EQUIVALENCE OF TECHNICAL REGULATIONS AND CODEX**Paragraph 11:****Is there a need for practical guidance on how to judge equivalence of technical regulations?**

Canada maintains its view that the necessary resources to develop guidelines on the judgement of equivalence of technical regulations would greatly outweigh the benefits at the present time. We question whether further guidance by CCFICS on the judgement of equivalence of technical regulations would alleviate TBT-related disputes or concerns based on the examples provided in Annexes 3 and 4 which suggest that challenges reside more specifically with the legitimacy of TBT measures rather than their equivalence with another country's measure. We note that clarification from the TBT Committee would be useful to make an informed decision regarding this question.

Should work on equivalence on technical regulations be dependent on the request of the TBT Committee?

Although work within CCFICS on the judgement of equivalence of technical regulations is not dependent on the request of the TBT Committee, clarification from the TBT Committee in this area is critical for CCFICS to make an informed decision on the need for work in this area, either on the judgement of equivalence of technical regulations or of conformity assessment procedures.

Paragraphs 15 and 17:

Are food inspection and certification systems, in some circumstances, components of technical regulations?

Can judgement of equivalence usefully apply to technical regulation in these circumstances?

Can the process of judgement of equivalence of technical regulations be separated from formulation and legitimate objective of technical regulations?

The Committee should first reflect and decide on the questions posed in paragraph 11 before considering the questions in paragraphs 15 and 17. As the response from Canada to the first question in relation to paragraph 11, above, does not favour initiating the development of practical guidance for the judgement of equivalence of technical regulations, we find it neither necessary nor appropriate to answer Questions 15 and 17 at this time.

EQUIVALENCE OF CONFORMITY ASSESSMENT PROCEDURES AND CODEX**Paragraph 23:**

Is there a need for further practical guidance for the judgement of equivalence of conformity assessment procedures?

It may be that CCFICS guidance for the judgement of equivalence of conformity assessment procedures could be useful to alleviate TBT-related issues. Country responses to Circular Letter 2002/54-FICS (Annex 2) show some examples of TBT-related issues that appear to be related to conformity assessment procedures. We wonder, however, whether there would be sufficient benefit from developing guidance to justify the resources required.

Paragraph 24:

If a need is evident CCFICS, (in light of its terms of reference) should consider what its role is, in providing guidance to Codex members in the determination of the equivalence of the competence of conformity assessment bodies, (in terms of the TBT agreement) or whether this is sufficiently covered by other relevant codex committees (e.g. CCMAS) or other relevant international agencies, for example the international laboratory accreditation co-operation (ILAC), and the international accreditation forum (IAF).

The Committee should first reflect and agree on a direction from the question posed in paragraph 23 before considering the question in paragraph 24.

OTHER OPTIONS FOR DEALING WITH TBT RELATED TRADE ISSUES**Mutual Recognition Arrangements (MRAs)****Paragraph 31:**

CCFICS should consider whether there is a need for developing material to deal with TBT related issues that:

- is within its terms of reference and does not duplicate existing work
- involves mechanisms such as one way recognition, mutual recognition, either formally or informally.

As noted in the general comments we question whether there is a need for guidance from CCFICS in the area of MRAs to address TBT-related issues. Canada has had the opportunity to negotiate arrangements with other countries pertaining to the mutual recognition of food inspection and control systems. These arrangements are based on provisions included in the *Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems (CAC/GL 34- 1999)*, and the *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (CAC/GL 26-1997)*.

We also note and agree with the comment from the United States in their response to Circular Letter 2002/54-FICS (Annex 2) that MRAs should be discussed independent of the discussion relating to equivalence. Canada views MRAs as tools to formalize various types of arrangements whether related to equivalence or compliance with import/export trade requirements.

MEXICO

Mexico recognises the analytical work on the topic carried out by the Working Group and makes the following comments:

The position presented in document CX/FICS 02/11/6 – Add. 1 in which Mexico states that it sees no need to develop guidelines on the judgement of equivalence of technical regulations associated with inspection and certification systems for food imports and exports is reiterated.

A review of the examples provided in the discussion paper (CX/FICS 03/5 Annex 2), does not, in our view, provide evidence of the usefulness of guidelines for the judgement of equivalence of technical regulations in resolving the potential conflicts presented.

Further, the information given in Annexes 3 and 4 of the discussion paper, shows that a large proportion of the issues refer to product labelling, for which there already exist specific guidelines developed by the Codex Committee on Food Labelling (CCFL), which include food naming aspects.

Further, there being disputes in this area, it is considered that this is the appropriate Committee for developing more specific principles and guidelines to harmonise issues in this area.

The application of the equivalence of compliance assessment procedures, agreements of mutual recognition of compliance assessment procedures and results, as well as the recognition of food inspection and certification systems, provide alternatives for resolving disputes arising from technical regulations, however, it is probable that the situation should be addressed on a case-by-case basis.

It is also possible that the compliance assessment procedures should be dealt with in the Codex Committee on Methods of Analysis and Sampling (CCMAS), to provide guidelines and principles to harmonise methodology and provide recognition of alternative procedures for product assessment and analysis.

With regard to compliance assessment and certification organisations, it is suggested considering the work carried out by other international organisations, and determining whether this work is sufficient to guarantee equivalence or recognition of the performance of such compliance assessment and certification organisations, by the competent authorities of importing countries, and consequently, of the assessment procedures applied and the results published by such organisations.

Similarly, it is suggested requesting from the Committee on Technical Barriers to Trade (TBT) of the World Trade Organisation (WTO) clarification of the need for a directive for the judgement of equivalence of technical regulations.

Further, given the fact that the Committee has identified the usefulness of the application of the equivalence of technical regulations by the member countries, Mexico would like to restate the proposal formulated in CX/FICS 02/11/6 – Add. 1, which could also be applied for judging the equivalence of compliance assessment procedures, should the Committee identify the need to undertake work in this area. However, it is also suggested that other alternatives be explored so as not to duplicate work or claim to include subjects that are the domain of other Committees.

NEW ZEALAND

The New Zealand Government would like to make the following comments:

New Zealand remains unconvinced about the need to develop international guidelines on the judgement of equivalence of technical regulations associated with food inspection and certification systems.

We believe the examples provided, in CX/FICS 03/5, not only fail to provide sufficient justification for the development of a set of guidelines in this area, they do not offer any clear indication of how guidelines would resolve the issues. We believe the resolution of such issues is best left to arrangements at the bilateral level.

New Zealand supports the discontinuation by CCFICS of work in this area.

UNITED STATES

The United States respectfully submits comments to the Codex Committee on Food Import and Export Inspection and Certification Systems in response to a request for comments on the *Discussion Paper on the Judgment of Equivalence of Technical Regulations Associated with Food Inspection and Certification Systems*, CX/FICS 03/5.

Comments

The United States expresses its' thanks to the Working Group, and to Australia as the Chair of the Working Group, for developing the *Discussion Paper on the Judgment of Equivalence of Technical Regulations Associated with Food Inspection and Certification Systems*.

The United States believes that the primary issue surrounding the question as to whether CCFICS should engage in work on this subject (developing guidance on undertaking judgments of equivalence with respect to technical regulations and conformity assessment systems) is the need for work in this area. The United States has noted previously that it is not aware of problems in trade dealing with technical regulations or conformity assessment procedures where the concept of equivalence might have been employed to facilitate trade. We continue to hold this view. We also note that the information presented in the various annexes to the Discussion Paper contain no clear examples of the use or need for equivalence with respect to technical regulations or conformity assessment systems. We believe that CCFICS should hold in abeyance work in this area until such a need is clearly expressed.

Noting that a clear need for work in this area has not been expressed and that the WTO/TBT Committee has not yet provided its clarification on the operation of equivalence and mutual recognition within the TBT Agreement, the United States provides the following with respect to the various questions.

QUESTION (Paragraph 11): Is there a need for practical guidance on how to judge equivalence of technical regulations? Should work on equivalence on technical regulations be dependent on the request of the TBT Committee.

As stated above, the United States believes that a demonstrated need for undertaking work on the judgment of equivalence with respect to technical regulations and/or conformity assessment systems should be a prerequisite for CCFICS undertaking work on the subject. We do not see this need being voiced by countries and the information presented in the annexes to the Discussion Paper also do not, in the judgment of the United States, present a need for such work.

QUESTION (Paragraph 15): Are food inspection and certification systems, in some circumstances, components of technical regulations? Can judgment of equivalence usefully apply to technical regulations in these circumstances?

In some instances, technical regulations can include an inspection and/or certification component, e.g., organic certification programs. More frequently, however, technical regulations do not include such a component and rely on separate conformity assessment programs to determine compliance with a technical regulation. The United States believes that it is very unlikely that equivalence would have a useful application in the area of technical regulations.

QUESTION (Paragraph 17): Can the process of judgment of equivalence of technical regulations be separated from formulation and legitimate objective of technical regulations?

The United States believes that process of the judgment of equivalence with respect to technical regulations must take into account the regulation's legitimate objective. For example, if the legitimate objective of a technical regulation is to prevent misleading the consumer (e.g., product labelling) or prevent fraud (e.g., percent milkfat), then a demonstration of equivalence for an alternative technical regulation must ensure that the same legitimate objective is met.

QUESTION (Paragraphs 23 and 24): Is there a need for further practical guidance for the judgment of equivalence of conformity assessment procedures. If a need is evident, CCFICS (in its terms of reference) should consider what its role is in providing guidance to Codex members in the determination of the equivalence of the competence of conformity assessment bodies (in terms of the TBT Agreement) or whether this is sufficiently covered by other relevant Codex committees (e.g., CCMAS) or other relevant international agencies, for example the International Laboratory Accreditation Co-Operation (ILAC), and the International Accreditation Forum (IAF).

The United States is not aware of a demonstrated or stated need for such guidance. Absent this indication, the United States believes there is not a need for CCFICS to undertake work on the judgment of equivalence of conformity assessment systems at this time.

QUESTION (Paragraph 31): CCFICS should consider whether there is a need for developing material to deal with TBT related issues that

- is within its terms of reference and does not duplicate existing work;
- involves mechanisms such as one way recognition, mutual recognition, either formally or informally.

We note that the Codex Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems (CAC/GL 34-1999) already deal with the issue of one way or mutual equivalence agreements. Again, we do not see the need for further work in this area.

Thank you for the opportunity to provide these comments.

EUROPEAN COMMUNITY

The European Community continue to believe that the mandate of the CCFICS is to deal with the inspection and certification systems, including the equivalence aspects of these systems. The equivalence of technical regulations seems to be outside of the competence of the CCFICS as established by the Procedural Manual.

Moreover, the EC is still waiting for a convincing example of equivalence between two technical regulations.

The question "Are food inspection and certification systems, in some circumstances, components of technical regulation?" should be answered taking into consideration the definition of technical regulation provided by the TBT Agreement (Annex I, paragraph 1):

"Technical regulation: Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method."

This definition does not include any component of inspection and certification and the EC considers that CCFICS should not continue developing guidelines on the judgement of equivalence of technical regulations.

EQUIVALENCE OF CONFORMITY ASSESSMENT PROCEDURES

Conformity assessment procedures is defined in Annex I paragraph 3 of the TBT Agreement as:

“Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled.”

The explanatory note states that conformity assessment procedures include, *inter alia*, procedures for sampling, testing and inspection; evaluation, verification and assurance of conformity; registration, accreditation and approval as well as their combinations.

Article 6.1 offers a possibility of recognition of equivalence between two different conformity assessment procedures if the results can be accepted when those different procedures provide the same assurance of conformity with mandatory technical regulations or standards.

The EC recognises that there is some need for practical guidance for the judgement of equivalence of conformity assessment procedures. However, the EC considers that this issue is sufficiently covered by Codex Committees and other relevant International Agencies.

Nevertheless, the EC also believes that the role, the efficiency and the technical competence of the conformity assessment bodies are the basis on which a confidence can be established and a judgement of equivalence reached. The Article 6.1.1 of the TBT Agreement recognises that prior consultations may be necessary in order to arrive at a mutually satisfactory understanding regarding, in particular, adequate and enduring technical competence of the relevant conformity assessment bodies in the exporting Member, so that confidence in the continued reliability of their conformity assessment results can exist.

The EC considers that the CCFICS has a role to play (in light of its terms of reference) in providing guidance to Codex Members in the determination of the equivalence of the competence of conformity assessment bodies. However, before initiating this new work, the EC suggests that the Commission should consider whether the existing *Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems CAC/GL 34-1997* cover the needs of guidance for the determination of equivalence. If necessary, these guidelines should be amended in order to take into account specific needs related to the conformity assessment bodies. The EC is of the opinion that there is no need for a separate text dealing specifically with conformity assessment bodies.

With regard to the mutual recognition, the EC believes that this issue does not appear within the terms of reference of the CCFICS, and that the Commission should establish a clear mandate.