



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

**Twenty-third Session**

**DISCUSSION PAPER ON THE POSSIBLE DEVELOPMENT OF GUIDANCE ON THE USE**  
**OF SYSTEMS EQUIVALENCE**

*Prepared by an electronic working group<sup>1</sup> led by New Zealand, the United States of America and Chile*

**INTRODUCTION**

1. During discussion at its 21<sup>st</sup> session, in 2013, on emerging issues and the future direction of its work, the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) agreed to consider a discussion paper, to be prepared by New Zealand, on the possible development of guidance on the use of systems equivalence/comparability (para. 63, REP15/FICS), especially as a means to further facilitate safe trade while better utilizing and risk targeting inspection resources.

2. At its 22<sup>nd</sup> session CCFICS considered<sup>2</sup> the discussion paper (CX/FICS 16/22/7) and a project document (CRD11). The Committee noted that while systems equivalence was a complex topic, it was important to expand the suite of tools that recognized the ability of a competent authority to provide assurances regarding the safety of food. This work would represent the next stage of evolution of existing CCFICS texts on equivalence. With regards to the scope of the document, the following suggestions were made:

- To improve the consistency of the paper, the text should clearly distinguish between equivalence for a set of measures versus equivalence on a system wide basis.
- There should be a thorough discussion involving both developing and developed countries on: the reasons for new guidance, the gaps to be filled to identify the problems that require solutions, and the benefits of additional guidance.
- The Committee should attain a better understanding of some of the issues of the previous CCFICS work that attempted to cover technical barriers to trade in the context of equivalence as this could inform the Committee's thinking and ensure that past difficulties were avoided.

3. The Committee further noted that the development of guidance in the area of system equivalence should address the dual mandate of Codex, the term equivalence should be used instead of "comparability", and this work will assist trade facilitation.

4. The Committee considered it necessary to further refine the scope, prerequisites and procedures of the discussion paper and project document. The Committee agreed to establish an electronic Working Group (not precluding a physical Working Group prior to the next Committee meeting), led by New Zealand with the United States of America and Chile acting as co-chairs, working in English and Spanish and open to all Codex members and observers, to revise the discussion paper and the project document taking into account the above discussion.

5. The present discussion paper has taken into account the above comments and the membership of the working group has facilitated the discussion between developing and developed countries as suggested. CCFICS23 is invited to consider the current version of the discussion paper and the attached project document.

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<sup>1</sup> The electronic working group comprised representatives from: Australia, Argentina, Brazil, Belgium, Belize, Canada, Chile, Denmark, Ecuador, European Commission, India, Indonesia, Iran, Japan, Republic of Korea, Malaysia, New Zealand, Norway, Philippines, Singapore, Spain, Switzerland, Thailand, United States of America, Uruguay, FAO, FoodDrink Europe, Harvest Plus, SSAFE, INC.,

<sup>2</sup> Paras. 49-52, REP16/FICS.

6. With the continuing globalization of the food trade and an associated rise in consumer concerns, countries are increasingly wanting assurances greater than those that can be achieved through the specifying and enforcing of product standards. Effectively some countries have attempted to extend the regulatory requirements and approval approach that they apply to those facilities operating within their territories to those operating outside of their territory but also wishing to export to them. Where well-developed and functioning National Food Control Systems (NFCS)<sup>3</sup> are already in place in the exporting country the imposition of additional detailed external requirements and approval processes can often result in an unnecessary duplication of controls. As such the imposition of the additional requirements can potentially place unnecessary resource burdens on both countries and result in significant barriers to trade.

7. An increased consideration of the equivalence of the systems already in place in the exporting country as a basis for all or part of any assurances required has the potential to facilitate trade and also to free up resources in both importing and exporting countries alike. Such resources could then potentially be targeted to manage more pressing areas of risk.

8. The concept of equivalence can be applied when evaluating whether any measure or set of measures applied by an exporting country achieve the same level of effect as the corresponding measures applied by the importing country<sup>4</sup> (measure by measure equivalence). Alternatively it can be applied at the system level when evaluating whether the overall design and functioning of a food control system<sup>5</sup>, in whole or in part, is likely to deliver a comparable overarching level of consumer protection (systems equivalence). For example:

- a) A measure by measure assessment could be used to objectively evaluate whether the specified decontamination procedures or treatments achieve the regulatory objective (e.g. microbiological reduction in a defined food processing system) of the importing country. Whereas a system equivalence assessment could be used to objectively evaluate the seafood regulatory system, focusing on whether the policy setting, system design, implementation, monitoring and system review functions of the exporting country system deliver a comparable overarching level of consumer protection as the importing country system.
- b) A measure by measure TBT equivalence consideration may directly compare whether two separate sets of procedures are likely to achieve the same regulatory objective e.g. procedures used to certify individual organic farms. Whereas the system equivalence consideration for the comparison of the entire organic assurance programmes may focus on whether the two assurance systems: operate under similar principles; have transparent standard setting and arbitration processes; have the necessary infrastructure and resources; are supported by suitable documented quality assurance framework; and generate sufficient performance and compliance metrics to allow for appropriate enforcement and continued improvement.

9. CCFICS has recently developed *Principles and Guidelines on the Exchange of Information between Importing and Exporting Countries to Support the Trade in Food* (CAC/GL 89-2016). While this guidance covers the potential full scope of possible information exchanges to initiate or maintain trade there is a lack of specific guidance on how countries can adapt the process and type of information exchanged where they want to, as appropriate, develop relationships to attain broader system equivalence recognition. Similarly the recently developed *Guidelines for National Food Control Systems* (CAC/GL 82-2013) provides useful recommendations on the characteristics of NFCS which when applied may form a useful basis for countries to have confidence in the design and functioning of an exporting country's NFCS or parts thereof.

#### **Evaluation of existing CCFICS text relating to Equivalence**

10. There are three existing CCFICS text that relate directly to equivalence:

- *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CAC/GL 26-1997)
- *Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems* (CAC/GL 34-1999)
- *Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems* (CAC/GL 53-2003)

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<sup>3</sup> CAC/GL 82-2013 describes the key principles and core elements of an efficient and effective NFCS. FAO publication *Assuring Food Safety and Quality: Guidelines for Strengthening National Food Control Systems* (Food & Nutrition paper 76) also provides useful information.

<sup>4</sup> Section 6 of CAC/GL 53/2003

<sup>5</sup> A National Food Control System includes import and export inspection and certification systems and has the objective of both protecting public health and ensuring fair practices in trade (CAC/GL 82/2013 para 2 and para 6).

**Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (CAC/GL 26-1997)**

11. "Equivalence" is defined in CAC/GL 26-1997 as "*the capability of different inspection and certification systems to meet the same objectives*". These objectives may relate to either the protection of consumer health or ensuring fair practices in the food trade.

12. Section 5 (para. 9) of CAC/GL 26-1997 states: "*The recognition of equivalence of inspection and certification should be facilitated where it can be objectively demonstrated that there is an appropriate system for inspection and certification of food by the exporting country in accordance with these guidelines*".

13. In relation to equivalence agreements, Section 5 (para. 14) of CAC/GL 26-1997 states that: "*The application of equivalence principles may be in the form of agreements or letters of understanding established between governments either for inspection and/or certification of production areas, sectors or parts of sectors. Equivalence may also be established through the administration of a comprehensive agreement which would cover inspection and certification of all food commodity forms traded between two or more countries.*"

14. CAC/GL 26-1997 further states (para. 15) that: "*Agreements on the recognition of equivalence of inspection and certification systems may include provisions concerning:*

- *the legislative framework, control programmes and administrative procedures;*
- *contact points in inspection and certification services;*
- *demonstration by the exporting country of the effectiveness and adequacy of its enforcement and control programmes, including laboratories;*
- *where relevant, lists of products or establishments subject to certification or approval, accredited facilities and accredited bodies;*
- *mechanisms supporting continued recognition of equivalence, e.g., exchange of information on hazards and monitoring and surveillance*".

15. CAC/GL 26-1997 clearly indicates an intention that equivalence of systems is something that can be considered. However it only provides high level guidance on the scope of considerations and does not elaborate on the purpose of such agreements.

**Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems (CAC/GL 34-1999)**

16. "Equivalence" is defined in CAC/GL 34-1999 exactly as it is in CAC/GL 26-1997.

17. Section 3 of CAC/GL 34-1999 describes the purpose of an equivalence agreement and states (para.2) that: "*Countries may wish to enter into agreements concerning food import and export inspection and certification systems to:*

- a) *provide an enhanced means of assuring that exported products conform to importing country requirements;*
- b) *eliminate duplication of activities and use collective resources more efficiently and effectively;*
- c) *provide a mechanism for the cooperative exchange of expertise, assistance and information to help assure and enhance conformity with requirements*".

18. It goes on to further state (para. 3) that "*equivalence agreements are not generally intended as a condition for trade but rather as a means for ensuring that importing country requirements are met with minimal trade impediments. For example, such agreements may result in reducing the importing country's rate of physical checks or sampling to test against standards or to avoid additional certification in the country of origin*".

19. CAC/GL 34-1999 again provides some high-level guidance as to the potential scope, purpose, consultative process and format of equivalence agreements, but falls short of detailed guidance on how countries might practically implement such a process particularly where a wider systems equivalence agreement is being considered.

**Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems (CAC/GL 53-2003)**

20. CAC/GL 53/2003 Section 2 (para. 5) states: *“This document provides guidelines on the judgement of the equivalence of sanitary measures associated with food inspection and certification systems. For the purpose of determining equivalence, these measures can be broadly characterized as infrastructure; programme design, implementation and monitoring; and/or specific requirements.*

21. The note within the definition of ‘Sanitary measure’ states: *Sanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, inter alia, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety.*

22. CAC/GL 53/2003 has limited application to more overarching system equivalence processes because its focus is on specified measure by measure comparisons. This is especially evident in para. 16 of Section 6 in which the development of the “objective basis of comparison” is described.

**Previous work relating to equivalence of technical regulation (food trade related measures falling under the WTO/TBT Agreement definitions)**

23. The need for guidance on the judgement of equivalence was first raised in 1997 at CCFICS5 (para.53, ALINORM 97/30A). CCFICS6 (February 1998) considered a discussion paper on issues relating to the judgement of equivalence<sup>6</sup>. The paper promoted the elaboration of guidelines relating to the judgement of equivalence of sanitary measures only. CCFICS6 generally supported the development of guidelines addressing sanitary (i.e. health related) measures but was divided on development of guidelines addressing non-health related measures. Several delegations also supported the development of guidelines that took a systems approach. (ALINORM 99/30, paras. 41-52)

24. CCFICS7 (February 1999) agreed to request the CAC to initiate formal work on the elaboration of guidelines on the judgement of equivalence of sanitary measure (para.81 ALINORM 99/30A). Due to the variation of views on the proposal to develop guidance on the judgement of equivalence of technical regulations CCFICS7 requested advice from the Executive Committee and the Commission on how to proceed (para.84 ALINORM 99/30A).

25. CCFICS8 (February 2000) having received advice from CAC23 and EXEC46 that CCFICS should proceed to develop guidance on the equivalence of technical regulations other than sanitary measures in parallel with food safety issues considered a discussion paper<sup>7</sup> on the matter. During the discussion at CCFICS8 it was suggested that the focus of the work should be on the equivalence of systems rather than on the equivalence of technical measure expressed in terms of specific values. The Committee agreed to progress the proposed work into the step process. (ALINORM 01/30, paras. 66-69)

26. CCFICS9 (December 2000) considered a proposed draft guideline on the judgment of equivalence of technical regulations<sup>8</sup> at step 3. The draft guideline attempted to maintain a level of consistency in format and language with the draft guideline on the judgement of sanitary measures that was also being considered by the Committee. It was noted that this meant the draft presented a high degree of complexity due to the differences in how the WTO TBT Agreement defined the terms technical regulation and standard. Further although the process for determining equivalence was similar in both WTO Agreements the basis for determining equivalence was different. The Committee agreed to maintain a level of consistency between the two draft documents in general and where appropriate and returned the draft technical regulations document to step 2. (ALINORM 01/30A, paras. 93-100)

27. CCFICS10 (March 2002) briefly considered a proposed draft guideline on the judgment of equivalence of technical regulations<sup>9</sup> at step 3. It was suggested that the document needed further work. The Committee was informed that the paper was intimately linked to the ongoing discussion on the draft guideline on the judgement of sanitary measures. The Committee agreed to give priority to the judgement of sanitary measures document and to defer for the time being further work on the draft guidelines on the judgement of equivalence of technical regulations. The Committee agreed to consider at its next meeting a discussion paper examining the need for guidance. (ALINORM 03/30, paras. 69-75)

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<sup>6</sup> CX/FICS 98/7

<sup>7</sup> CX/FICS 00/7 (February 2000)

<sup>8</sup> CCFICS/00/7 (August 2000)

<sup>9</sup> CCFICS/02/5

28. CCFICS11 (September 2002) considered a discussion paper on the judgement of equivalence of technical regulations<sup>10</sup>. The Committee noted the lack of examples of where the application of equivalence of technical regulations or conformity assessment procedures may have had a role in ensuring fair trade practices and remained divided on progressing work in this area. The discussion paper noted the definitions set out in the TBT Agreement as they relate to 'technical regulations'<sup>11</sup> and 'conformity assessment procedures'<sup>12</sup> and how 'equivalence' is discussed in respect of each<sup>13</sup>. The discussion paper went on to identify that while for technical regulations equivalence could be applied where the regulations are specified in terms of performance (which may include process and production methods), but would be less applicable when this is not the case (e.g. for nutritional objectives). In respect of conformity assessment procedures the challenge was in the often experienced lack of acceptance by importing countries of the results of tests undertaken by the exporting country. CCFICS11 decided to consider a revised paper at its next session and also to seek clarification from the WTO/TBT Committee on the operation of equivalence and mutual recognition within the TBT Agreement. (ALINORM 03/30A)

29. CCFICS12 (December 2003) considered a discussion paper on the judgement of equivalence of technical regulations<sup>14</sup>. The Committee remained divided on the need for guidance in this area and also if development of specific guidance was within its mandate. The Committee agreed not to pursue work on the judgement of equivalence of technical regulations at this time and that it might come back to this issue at a future time. (ALINORM 04/27/30)

30. In reviewing the previous work of CCFICS relating to TBT technical regulations (as summarised above paras 23-29) and with hindsight, it can be seen that while the definition of equivalence<sup>15</sup> clearly applies to the dual mandate of Codex, the desire to keep a consistency of language and the choice during the drafting of CAC 53/2003 to focus on measure by measure comparison level made it difficult to develop two similarly structured texts. What was perhaps missing was overarching guidance that focused more at a systems outcome level (system equivalence). At the systems equivalence level there is a much greater degree of commonality regardless of whether the objective of the inspection and certification system under consideration is solely focused on the protection of consumer health or solely focused on ensuring fair practices in the food trade or a combination of both.

### Need for further guidance

31. The original references to equivalence in both the *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CAC/GL 26-1997) and the *Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems* (CAC/GL 34-1999) incorporate a wider context for the concept and therefore can be said to explicitly contemplate the potential for systems equivalence determinations and agreements. However, neither document provides specific, practical guidance on how such evaluations should be made.

32. The *Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems* (CAC/GL 53-2003) was primarily developed to provide guidance on directly comparing the outcomes of a specified measure<sup>16</sup> or set of sanitary measures rather than recognizing the equivalence of the system as a whole. The appendix to CAC/GL 53-2003 does however provide examples of how 'experience, knowledge and confidence' can be developed and these examples can also be useful as ways to develop knowledge and confidence in a system as a whole.

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<sup>10</sup> CX/FICS 02/11/6

<sup>11</sup> Technical regulation: Document which lays down product characteristics or their related processes and production methods, including the administrative provisions, with which compliance is mandatory. It may also include or deal with exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method. TBT Agreement (Annex 1)

<sup>12</sup> Conformity assessment procedures: Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled. *TBT Agreement (Annex 1)*

<sup>13</sup> *Equivalence* - in respect of technical regulations Article 2.7 states, WTO Members "should give positive consideration to accepting as equivalent technical regulations of other Members, even if these regulations differ from their own, provided they are satisfied that these regulations adequately fulfil the objectives of their own regulations". In respect of conformity assessment procedures, Article 6.1 states "Members shall ensure, whenever possible, that results of conformity assessment procedures in other Members are accepted, even when they differ from their own, provided they are satisfied that those procedures offer an assurance of conformity with applicable technical regulation or standards equivalent to their own procedures"

<sup>14</sup> CX/FICS 03/5

<sup>15</sup> CAC/GL 26-1997: Equivalence is the capability of different inspection and certification systems to meet the same objectives

<sup>16</sup> CAC/GL 53/2003 solely refers to sanitary measures directly related to food safety and does not include other fair practices in the food trade as directly referenced in the objective of a NFCS (CAC/GL 82/2013 Section 2).

33. Given the diversity of trade, risk profiles, legislative instruments and administrative organizations among countries, the means utilized to objectively demonstrate equivalence among NFCSs need to be broader than when countries consider specific measure-by-measure comparisons. Import assurance programmes based on questionnaires, in-country individual establishment listing audits and product inspection are not the most efficient or effective use of resources. Higher levels of assurance can be gained through more direct cooperative relationships with other competent authorities based on appropriate shared knowledge and the development of confidence that the exporting country has an appropriate NFCS to deliver and maintain a comparable level of consumer protection relative to the traded commodities of interest.

34. Current determinations of equivalence based on the 'measure by measure approach' tend to establish equivalence at a certain point in time with the specific measures in place. Therefore any change to a measure by either party means the equivalence determination may need to be re-assessed, which could (depending on the nature of the change) involve recommencing the entire process. A systems equivalence approach is more dynamic in that it can allow for the development, including continuous improvement, of both parties systems, with periodic reassessments to ensure alignment is maintained. A systems equivalence approach incorporates the broader elements of the system (objectives, policy setting, system design, implementation, monitoring and system review), appropriate data gathering and performance monitoring, as well as science-based risk assessment tools (all of which support the continuous improvement of the control system).

35. While the use of other types of cooperative agreement may be more appropriate in many situations, developing relationships to full systems equivalence agreements covering one or more food commodities, on the basis of demonstrated performance, is a useful additional tool. It could be used to further reduce duplication of administrative processes and regulatory burden; support and enhance prioritisation and utilisation of regulatory resources within either or both trading parties; and build stronger ties, cooperation and transparent information sharing between countries. The food control system can be considered in its entirety or as applying only to a specific section of the food supply chain. The overarching consideration is whether the system as a whole, whatever the agreed scope, is both achieving and is likely to continue to achieve the required outcomes.

36. The recently promulgated *Guidelines for National Food Control Systems* (CAC/GL 82-2013) provide a basis for a more common understanding of the generic components of NFCS among countries. The new work proposed by this discussion document is not intended to suggest countries should either replicate the other country's NFCS design or submit a system equivalence case as a condition for trade. CAC/GL 82-2013 explicitly recognizes the need for countries to tailor their food control programmes to their own risk profiles and the existing context within their boundaries rather than to seek to duplicate several other national systems.

37. While some countries have successfully negotiated bilateral systems equivalence arrangements others have found the approach more challenging. There is therefore clearly a gap in guidance on how to initiate and conduct a systems equivalence assessment and guidance developed by Codex on this will deliver benefits to members. System equivalence is also a good and effective pre-border risk management option to facilitate trade in safe food products and reduce transaction costs.

### **Purpose and scope of proposed guidance**

38. The proposed draft guidance on systems equivalence is intended to work in conjunction with the existing texts, the *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CAC/GL 26-1997) and the *Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems* (CAC/GL 34-1999). It is not intended to replace CCFICS guidance on the judgment of the equivalence of more specific/targeted measures in terms of food safety outcomes<sup>17</sup>.

39. The new guidance could be an appendix to one of the existing CCFICS text or could be a standalone document.

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<sup>17</sup> Codex *Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems* (CAC/GL 53-2003).

40. The objectives of the proposed guidance are to facilitate better use and targeting of import and export assurance resources through the recognition of systems equivalence. This can help reduce the level of redundancy and duplication of assessment and control processes currently applied to international trade where competent control systems are already in place in the exporting country. The guidance will be designed to help importing and exporting countries develop an appropriate process to achieve the necessary confidence. It should also assist countries in addressing the key question of whether the design and operational performance of an identified food control system is likely to achieve the same or higher / comparable level of overall human health, food suitability and technical outcomes as achieved within the importing country.

41. The proposed guidance will provide a process for countries entering into consultations with the aim of considering the equivalence of the whole or parts of a NFCS. Considerations may apply to food safety, or those that relate to fair practices in the food trade such as suitability and technical outcomes. As system equivalence assessment is focussed at the comparability of the outcome of the entire system of controls (refer previous para. 8) there is a great deal more commonality in the applicable principles and processes regardless of whether specific outcomes relate more to food safety or ensuring fair practices in the food trade (other consumer protections).

42. As such it should be possible to develop guidance that is able to be used to support equivalence considerations that address both sanitary and other related technical matters as appropriate.

43. The guidance would provide:

- Principles and processes applicable during an initial consultative process in determining whether a more in-depth consideration of system equivalence is appropriate;
- Principles and processes relevant for use in an in-depth consideration of systems equivalence of whole or parts of a NFCS; and
- Linkages with other relevant Codex guidance such as the development of bilateral agreements documenting any recognition of systems equivalence, including expectations for maintenance.

#### **Considerations of requests for system equivalence associated with whole or parts of NFCS**

44. Without prejudice to any future work, the following is provided as a possible starting point for discussion of general principles and processes that could be included in a guidance document to be applied in determining and documenting systems equivalence for one or more sectors:

- a Initial consultations should occur to ensure any necessary prerequisite requirements including confidence in the performance of the exporting country's NFCS are able to be met and to ensure there is an agreement on the scope of the assessment (e.g. the whole or part of a NFCS).
- b Existing knowledge, confidence and experience can reduce the amount of information needing to be exchanged.
- c The decision criteria to be used in the consideration should be objective and outcome focussed and be made available to the requesting country.
- d Importing countries should provide in writing, with appropriate evidence and references, a description as to how their own NFCS or part thereof, as relevant, meets the objectives and outcomes outlined in the decision criteria.
- e Exporting countries need to be able to demonstrate in writing, with appropriate evidence and references, as to how their NFCS or part thereof, as relevant, meets the objectives and outcomes outlined in the decision criteria.
- f Communications should occur throughout the assessment process to ensure any necessary clarifications or additional information required can be provided.
- g Responses to requests for additional information should be provided as expeditiously as possible in order to facilitate a timely completion of assessments.
- h Cooperation and access should be provided to allow an in-country review where deemed necessary
- i Assessments should be completed in a transparent and timely manner.
- j The results of the assessment should be provided to the requesting party.
- k System equivalence recognitions should be documented in an agreement between the parties.

- I Maintenance of agreements should allow regulatory frameworks, programs and oversight to evolve, with appropriate dialogue and information exchange.

### **Recommendations**

45. The Committee is invited to support the recommendation for new work on the development of guidance on systems equivalence as set out in the attached project document through CCEXEC73 and then to CAC40.

46. The Committee is invited to establish an electronic Working Group (with the possibility of convening a physical working group) to prepare the proposed draft Codex guidance and/or principles on systems equivalence for circulation at step 3 and consideration at its 24<sup>th</sup> session.

## PROJECT DOCUMENT

### Proposal for new work to develop guidance on the use of systems equivalence

#### 1. Purpose and scope of the proposed standard

The purpose of the work is to provide guidance to competent authorities of importing and exporting countries on the use of systems equivalence recognition as a means to further facilitate protection of the health of consumers and ensuring fair practices in the food trade. It is intended to cover situations where it can be reasonably expected that the national food control system (NFCS) of the exporting country will, on an ongoing basis, likely reliably deliver food that meets similar overall human health, food suitability and technical outcomes as achieved within the importing country. The scope of the guidance is intended to apply to the process for importing and exporting countries to follow when a request has been made by an exporting country for the recognition of the equivalence of the whole or part of its NFCS.

#### 2. Relevance and timeliness

With the continuing globalization of the food trade and growth in associated consumer concerns, countries are increasingly prescribing not only standards for end products but also detailed production and processing requirements, resulting in increased requests for information, audit visits and product inspections. Better use of systems equivalence recognition where effective regulatory systems are already in place could reduce the burden on resources and unnecessary restrictions on trade caused by such processes. Specifically, it could provide for facilitated individual establishment listings, where required, and expedited border clearance processes based on confidence in the systems already in place in the exporting country to appropriately manage any risk associated with the trade to the level of protection required and achieved by the importing country.

The recognition of systems equivalence for all or part of the trade in food between countries has the potential not just to remove unnecessary restrictions on trade but also to free up resources in importing and exporting countries alike, which could be better allocated to manage more pressing areas of risk.

#### 3. The main aspects to be covered

This new work will provide principles and processes for the initial consultation process to determine if more in-depth consideration of systems equivalence is appropriate; principles and processes possibly appropriate to an in-depth consideration of systems equivalence; and any additional guidance as required on the development of bilateral agreements to document the recognition of systems equivalence.

#### 4. An assessment against the *Criteria for the Establishment of Work Priorities*

The proposal is consistent with the criteria as follows:

**General Criterion: Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries.**

The proposed new work will further facilitate the trade of safe food while freeing up resources to allow better targeting of greater risk scenarios, thus meeting the general criterion of consumer protection.

##### **Criteria Applicable to General Subjects:**

*a) Diversification of national legislations and apparent resultant or potential impediments to international trade:*

Countries are increasingly prescribing not only standards for end products but also detailed production and processing requirements, resulting in increased requests for information, audit visits and product inspections. Recognition of systems equivalence, where competent regulatory systems are already in place, could reduce the burden on resources and unnecessary restrictions on trade caused by such processes.

*b) Scope of work and establishment of priorities between the various sections of work:*

Refer to Scope above.

*c) Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies):*

The WTO/SPS Committee's decision (G/SPS/19) provides for some further clarification on how WTO members should make use of the "equivalence" provisions of the SPS Agreement, i.e. Article 4. This decision strongly encourages the CAC to, on an ongoing basis, further progress its guidance covering the full scope of the decision. CCFICS has developed a number of standards that provide for the use of systems

equivalence but to date has only developed specific guidance more targeted to the judgement of the equivalence of specific sanitary measures (CAC/GL 53-2003). Specific guidance on a process for the potential recognition of the equivalence of whole food control systems, or those covering specific food, is however currently lacking. Development of such guidance would further facilitate and enable better use of the existing Codex guidance: *Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems* (CAC/GL 34-1999). The Committee will take into account any relevant international work in this area that is identified during the course of the work.

*d) Amenability of the subject of the proposal to standardisation:*

The Committee believes that principles and guidelines can be developed to address the issues identified.

*e) Consideration of the global magnitude of the problem or issue:*

The Committee has assessed that there is currently a significant burden imposed on importing and exporting countries due to a lack of practical international guidance in this area. The scarcity of notified equivalence agreements to the WTO/SPS Committee in accordance with G/SPS/7/Rev.2/Add.1 is further evidence that additional guidance in this area is both timely and relevant.

## **5. Relevance to Codex strategic objectives**

The proposed work is directly related to the purpose of the Codex Alimentarius Commission, according to its statutes, to protect the health of the consumers and ensure fair practices in the food trade, as well as to the first Strategic Goal of the Codex Alimentarius Commission's Strategic Plan 2014-2019 "establish international food standards that address current and emerging food issues", and is consistent with Objective 1.2 "proactively identify emerging issues and member country needs and, where appropriate, develop relevant food standards". Further, it contributes to Activity 1.2.2 "develop and revise international and regional standards as needed, in response to needs identified by Members and in response to factors that affect food safety, nutrition and fair practices in the food trade". It is also consistent with Objective 1.3 "strengthen coordination and cooperation with other international standards-setting organizations seeking to avoid duplication of efforts and optimize opportunities."

## **6. Information on the relation between the proposal and other existing Codex documents**

The proposed work will take into consideration the *Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems* (CAC/GL 34-1999); the *Principles and Guidelines for National Food Control Systems* (CAC/GL 82-2013); and the *Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems* (CAC/GL 53-2003). The finalized guidelines should be read in conjunction with the *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CAC/GL 26-1997) and the *Guidelines for Food Import Control Systems* (CAC/GL 47-2003). The proposed guidance would also fit nicely with, and is a natural extension and progression of the *Principles and Guidelines for the Exchange of Information between Importing and Exporting Countries to Support the Trade in Food* (CAC/GL 89-2016).

## **7. Identification of any requirement for and availability of expert scientific advice**

Not required.

## **8. Identification of any need for technical input to the standard from external bodies so that this can be planned for**

Not required at this time.

## **9. Completion of the new work and other conditions**

Subject to the Codex Alimentarius Commission approval at its 40<sup>th</sup> session in 2017, it is expected that the work can be completed in three to four years, depending on the future schedule of CCFICS meetings, which is currently meeting every 18 months:

- Consideration at Step 3 by CCFICS24;
- Consideration at Step 5 by CCFICS25; and
- Adoption of the proposed Guidelines by the Commission within a period of 4 years.