

ALINORM 01/30A
Appendix III**PROPOSED DRAFT GUIDELINES ON THE JUDGEMENT OF EQUIVALENCE OF SANITARY MEASURES ASSOCIATED WITH FOOD INSPECTION AND CERTIFICATION SYSTEMS
(Advanced to Step 5/8 of the Codex Procedure)****SECTION 1 - PREAMBLE**

1. It is often the case that importing and exporting countries operate different food inspection and certification systems. The reasons for such differences include differences in prevalence of particular food safety hazards, national choice about management of food safety risks and differences in the historical development of food control systems.
2. In such circumstances, and in order to facilitate trade, there is a need to determine the effectiveness of sanitary measures of the exporting country in achieving the appropriate level of sanitary protection of the importing country. This has led to recognition of the principle of equivalence as provided for in the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (WTO SPS Agreement).
3. Application of the principle of equivalence has mutual benefits for both exporting and importing countries.

SECTION 2 - SCOPE

4. 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 (refer paragraph 7).

SECTION 3 - DEFINITIONS

5. The definitions presented in this document are derived from and consistent with those of the Codex Alimentarius Commission and the WTO SPS Agreement.

Sanitary measure: Any measure applied to protect human life or health within the territory of the country from risks arising from additives, contaminants, toxins or disease-causing organisms in food or feedstuffs, or from risks otherwise arising from diseases carried by foods which are animals, plants or products thereof.

Hazard: A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.³³

Risk: A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.¹

Risk Assessment: A scientifically-based process consisting of the following steps: (i) hazard identification; (ii) hazard characterisation; (iii) exposure assessment; and (iv) risk characterisation.¹

Appropriate level of sanitary protection (ALOP): The level of protection deemed appropriate by the country establishing a sanitary measure to protect human life or health within its territory. (This concept may otherwise be referred to as the “acceptable level of risk”.)

Equivalence (of sanitary measures)³⁴: Equivalence is the state wherein sanitary measures applied in an exporting country, though different from the measures applied in an importing

³³ Codex Alimentarius Commission: Procedural Manual (11th Edition), pages 48-49.

³⁴ Equivalence is defined in CAC/GL 26-1997: “Equivalence is the capability of different inspection and certification systems to meet the same objectives”.

country, achieve, as demonstrated by the exporting country, the importing country's appropriate level of sanitary protection.

SECTION 4 - SANITARY MEASURES AND THE DETERMINATION OF EQUIVALENCE

6. To facilitate judgement of equivalence between countries and promote harmonisation of food safety standards, Codex members should base their sanitary measures on Codex standards and related texts.³⁵
7. 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. For the purposes of determining equivalence, the sanitary measures associated with a food inspection and certification system can be broadly categorised as:
 - a) infrastructure; including the legislative base (e.g., food and enforcement law), and administrative systems (e.g., organisation of national and regional authorities);
 - b) programme design, implementation and monitoring; including documentation of systems, monitoring, performance, decision criteria and action, laboratory capability, transportation infrastructure and provisions for certification and audit; and/or
 - c) specific requirements; including individual facilities (e.g., premises design), equipment (e.g., design of food contact machinery), processes (e.g., HACCP plans), procedures (e.g., ante- and post-mortem inspection), tests (e.g., laboratory tests for microbiological and chemical hazards) and methods of sampling and inspection.
8. A sanitary measure proposed for determination of equivalence may fall into one or more of these categories, which are not mutually exclusive. A single measure, however, on which an equivalence determination may be made, cannot be considered in a vacuum. In other words, whether the importing country's ALOP is likely to be achieved can only be determined in most cases through an evaluation of all relevant components of an exporting country's food inspection and certification system. For example, a determination of equivalence for a specific sanitary measure at the programme design, implementation and monitoring level will require in most cases a prior determination of an equivalent infrastructure. A determination of equivalence for a specific sanitary measure at the specific requirements level will require in most cases a prior determination of an equivalent infrastructure and equivalent programme design, implementation, and monitoring.
9. An objective basis for comparison of sanitary measures must be established to allow an equivalence determination to be made, and this may include the following elements:
 - a) the reason/purpose for the sanitary measure;
 - b) the relationship of the sanitary measure to the ALOP, i.e., how the sanitary measure achieves or contributes to the achievement of the ALOP;
 - c) where appropriate, an expression of the level of control of the hazard in a food that is achieved by the sanitary measure;
 - d) the scientific basis for the sanitary measure under consideration, including risk assessment where appropriate.

SECTION 5 - GENERAL PRINCIPLES FOR THE DETERMINATION OF EQUIVALENCE

10. Determination of the equivalence of sanitary measures associated with food inspection and certification systems should be based on application of the following principles:

³⁵ Article 3 of the WTO SPS Agreement states, *inter alia*, that WTO Members may introduce or maintain sanitary measures which result in a higher level of sanitary protection than would be achieved based on Codex standards, if there is a scientific justification, or as a consequence of the member's chosen level of protection. Such measures must be based on a risk assessment appropriate to the circumstances.

- 10.1 An importing country has the sovereign right to set a level of sanitary protection it deems appropriate in relation to the protection of human life and health.³⁶ The ALOP may be expressed in qualitative or quantitative terms.
- 10.2 An importing country should be able to describe how its sanitary measure achieves, or contributes to the achievement of, its ALOP.
- 10.3 An importing country should recognize that sanitary measures different from its own may be capable of achieving its ALOP, and can therefore be found to be equivalent.
- 10.4 The sanitary measures applied by the exporting country must achieve the importing country's ALOP.
- 10.5 Countries should, upon request, enter into consultations with the aim of achieving bilateral or multilateral recognition of the equivalence of specified sanitary measures³⁷.
- 10.6 It is the responsibility of the exporting country to demonstrate that its sanitary measures can achieve the importing country's ALOP.
- 10.7 The comparison of countries' sanitary measures should be carried out in an objective manner.
- 10.8 Where risk assessment is used in the demonstration of equivalence, countries should strive to achieve consistency in the techniques applied so as to ensure that findings can be objectively compared.
- 10.9 When judging the equivalence of sanitary measures, the importing country should take into account any knowledge it has of the food inspection and certification systems in the exporting country and of the performance of those systems.
- 10.10 The exporting country should provide access to enable the inspection and certification systems which are the subject of the equivalence determination to be examined and evaluated upon request of the food control authorities of the importing country.
- 10.11 Countries should ensure transparency in both the demonstration and judgement of equivalence, consulting all interested parties to the extent practicable and reasonable.

SECTION 6 - PROCEDURE FOR THE DETERMINATION OF EQUIVALENCE

11. The importing country should make available details of its sanitary measures to the exporting country on request. The exporting country should review all applicable sanitary measures of the importing country for the food involved and identify those it will meet and those for which it seeks determination of equivalence. The importing and exporting countries should then use an agreed process for exchange of the relevant information to facilitate the determination of equivalence. This information should be limited to that which is necessary for this purpose.
12. The determination of equivalence is facilitated by both exporting and importing countries following a sequence of steps, such as those described below and illustrated in Figure 1:
- 12.1 The exporting country identifies the sanitary measure of the importing country for which it wishes to apply a different measure, and requests the reason/purpose for the measure.
- 12.2 The importing country provides the reason/purpose for the identified sanitary measure.
- 12.3 On the initiative of the exporting country, the importing and exporting countries should enter into a dialogue concerning an objective basis for comparison.

³⁶ The SPS Agreement sets out the rights and obligations of WTO Members in relation to the determination of an appropriate level of sanitary protection.

³⁷ Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems CAC/GL 26- 1997.

12.4 The exporting country develops the submission to demonstrate that the application of the different sanitary measure achieves or contributes to the achievement of the ALOP of the importing country, and presents it to the importing country.³⁸

12.5 The importing country determines whether the exporting country's measure achieves the importing country's ALOP.

12.6 If the importing country has any concerns with the submission as presented, it should notify them to the exporting country at the earliest opportunity and should detail the reasons for concern. If possible, the importing country should suggest how the concerns might be addressed.

12.7 The exporting country should respond to such concerns by providing further information as appropriate.

12.8 The importing country notifies the exporting country of its judgement within a reasonable period of time and provides the reasoning for its decision, should the judgement be that the sanitary measure(s) is not equivalent.

12.9 An attempt should be made to resolve any differences of opinion over judgement of a submission, either interim or final.

SECTION 7 - JUDGEMENT

13. Judgement of equivalence by the importing country should be based on a transparent analytical process that is objective and consistent, and includes consultation with all interested parties to the extent practicable and reasonable.

14. Experience and detailed knowledge of an exporting country's food inspection and certification systems may in itself be sufficient to allow an objective judgement of equivalence by the importing country. For example, a sanitary measure categorized as a specific requirement (refer paragraph 7) may be able to be judged equivalent without consideration of the supporting programme design, implementation and monitoring, and infrastructure.

15. Where countries have no previous history of significant trading in foods or detailed knowledge of each other's food inspection and certification systems, the determination of equivalence may require a detailed side-by-side comparison of all relevant sanitary measures.

16. Judgement of equivalence should take into account those Codex texts relevant to the food safety matters under consideration.

17. Following any judgement of equivalence, exporting and importing countries should advise each other of significant changes in their supporting programmes and infrastructure that may affect the original determination of equivalence.

³⁸ Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems; CAC/GL 34-1999.

Figure I: Simplified flow chart for the determination of equivalence (individual steps may be iterated)

