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## **Russian Federation**

**Post:** Moscow

### **Customs Union Publishes Inspection Guidelines for Public Comment**

**Report Categories:**

Sanitary/Phytosanitary/Food Safety

FAIRS Subject Report

Trade Policy Monitoring

Livestock and Products

Poultry and Products

Dairy and Products

Fishery Products

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**Report Highlights:**

The Russia-Kazakhstan-Belarus Customs Union (CU) published draft inspection guidelines for determination of SPS equivalence on its website. These guidelines cover the inspection of products and establishments subject to CU veterinary control. There is a 60-day public comment period, starting November 16, 2012, and ending January 15, 2013. Interested U.S. parties are encouraged to share their comments and concerns with USDA's enquiry point ([IRSD@fas.usda.gov](mailto:IRSD@fas.usda.gov)).

## **General Information**

The Russia-Kazakhstan-Belarus Customs Union (CU) published the following draft document regarding inspection guidelines for determination of SPS equivalence on its website: [Guidelines for Inspectors for Confirming Equivalence of Applied Veterinary Measures during Inspections of Objects that are Subject to Veterinary Control in Third Countries.](#)

Unofficial English translation of the above draft document can be found below. There is a 60-day public comment period, starting November 16, 2012, and ending January 15, 2013. Interested U.S. parties are encouraged to share their comments and concerns with USDA's enquiry point ([IRSD@fas.usda.gov](mailto:IRSD@fas.usda.gov)). USDA, in turn, will share collected comments/concerns with the Eurasian Economic Commission.

As of the date of publication of this report, FAS/Moscow does not believe this measure has been notified to the World Trade Organization.

BEGIN UNOFFICIAL TRANSLATION:

Annex to Decision  
of Collegium of Eurasian Economic  
Commission  
No.     dated

### **Guidelines for Inspectors for Confirming Equivalence of Applied Veterinary Measures during Inspections of Objects that are Subject to Veterinary Control in Third Countries.**

#### **I. Preamble**

These guidelines are designed taking into account:

1. The fact that some importing and exporting countries have different systems for inspection of objects controlled by veterinary supervision. These differences are due to differences in the prevalence of certain risks selected by the country risk management activities, and the differences in the historical development of systems of veterinary supervision.
2. In such circumstances, in order to facilitate trade and thus to protect animal and human health, the exporting and importing country can organize a joint analysis of the efficiency of veterinary and sanitary measures of the exporting country in achieving the appropriate level of veterinary and sanitary protection in the importing country consistent with the principle of equivalence under the Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization (WTO SPS Agreement).<sup>2</sup>
3. Application of the principle of equivalence is mutually beneficial for both the importing country and the exporting country. Protecting animal and human health, it facilitates trade and reduces the costs of regulation to governments, industry, producers and consumers, enabling the exporting

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<sup>2</sup> In accordance with the definition of "equivalence" in Section 3, the equivalent measures (i.e. measures that are different from those used by the importing country, but, nevertheless, ensuring appropriate level of protection of the importing country) must be different from measures that coincide with those in the importing country.

country to use the most effective means in the circumstances in order to achieve an adequate level of protection of the importing country.<sup>3</sup>

4. Importing countries must avoid application of unnecessary measures if they are already carried out by the exporting country. Importing countries should be able to reduce the frequency and volume of confirming measures following the decision on the equivalence of measures applied in the exporting country.

5. Normative legal acts of the Customs Union:

- Agreement on the Customs Union on veterinary and sanitary measures of 11 December 2009;

- Decision of the Customs Union Commission of June 18, 2010 No. 317 "On the application of veterinary and sanitary measures in the Customs Union" (as amended by the decision of the Commission of the Customs Union No. 342 of August 17, 2010, No. 455 of November 18, 2010, No. 623 of April 7, 2011, No. 724 of June 22, 2011);

- Decision of the Customs Union Commission No. 625 of April 7, 2011 "On ensuring the harmonization of legislation of the Customs Union on the application of sanitary, veterinary and phytosanitary measures with international standards";

- Decision of the Customs Union Commission No. 721 of June 22, 2011 "On the application of international standards, recommendations and guidelines";

- Decision of the Customs Union Commission No. 801 of September 23, 2011 "On the Regulation on the common procedure of the examination of legal acts of the Customs Union on the application of sanitary, veterinary and phytosanitary measures";

- Decision of the Customs Union Commission No. 834 of October 18, 2011 "On the Regulation of a single system of joint inspections of sites and sampling of goods (products) subject to veterinary control (supervision)."

- Decision of the Customs Union Commission No. 835 of October 18, 2011 "On the equivalence of sanitary, veterinary and phytosanitary measures, and risk assessment."

6. The need to consider when inspecting the controlled the Codex Alimentarius guidelines, such as the CAC / RCP 1-1969 (recommended international general principles of food hygiene), CAC / RCP 58 - 2005 (code of hygienic practice for meat), CAC / RCP 57-2004 (Code Hygienic Practice for Milk and milk products), CAC / RCP 52-2003 (Code of practice for fish and fishery products) and other relevant international standards, guidelines and related documents.

## II. Sphere of application

7. Definitions present in the document correspond to the Codex Alimentarius and the WTO SPS Agreement.

***Veterinary and sanitary measure:*** any measure applied to protect animal and human health in the country from risks arising from the entry, establishment or spread of diseases, pests - vectors of diseases, or disease-causing organisms, additives, and the presence of contaminants, toxins or disease-causing organisms in controlled goods, as well as due to the risks arising from diseases transmitted with the controlled goods, or because of the risks associated with other hazards in controlled goods.

*Note:* Veterinary and sanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, the relevant requirements relating to controlled goods,

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<sup>3</sup> Benefits to the exporting country on the application of the principle of equivalence can be rejected if the request for equivalence is used as an excuse for breaking the existing trade. Such action of the importing country would be contrary to the principles of international trade.

methods of production and processing, testing procedures, inspection, certification and granting of permits, sampling procedures and risk assessment, as well as the requirements for packaging and labeling, directly related to food safety.

**Hazard:** Biological, chemical or physical agents in the controlled products that have the potential to cause adverse effects on health.<sup>4</sup>

**Risk:** The probability of adverse effects on health and the severity of the impact, which follows logically from the dangerous controlled goods.

**Risk assessment:** assessment of the likelihood of entry, establishment, or spread of a pest or disease within the territory of the importing country with respect to sanitary or phytosanitary measures which might be applied, and the associated potential biological and economic consequences; or assessment of the possible adverse effects on human or animal health, arising from the presence of additives, contaminants, toxins or disease-causing organisms in controlled goods.

Scientific-based process consisting of the following steps: 1) hazard identification, 2) hazard characterization and 3) exposure assessment, and 4) risk characterization.<sup>4</sup>

**The appropriate level of veterinary and sanitary protection (ALOP):** The level of protection that is deemed appropriate for the protection of human life and health in the country establishing veterinary and sanitary measures. (In other words, this concept can be defined as an "acceptable level of risk").

**Equivalence of veterinary and sanitary measures:**<sup>5</sup> Equivalence - a condition in which the veterinary and sanitary measures applied in the exporting country, although different from those used in the importing country, achieve the level of veterinary and sanitary protection, corresponding to the level of the importing country, as demonstrated by the exporting country.

### III. General principles for determination of equivalence

8. Determination of equivalence of veterinary and sanitary measures relating to inspection of the controlled objects is based on the application of the following principles:

a) The importing country has the right to determine the level of veterinary and sanitary protection, which it considers necessary for the protection of animal and human health.<sup>6</sup> ALOP may be expressed in qualitative and quantitative terms.

b) Veterinary and sanitary measure<sup>7</sup> used in the importing country, shall actually achieve the ALOP of the importing country and should be applied in accordance with article 2.3 of the WTO SPS Agreement.<sup>8</sup>

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<sup>4</sup> Commission "Codex Alimentarius": Procedures Manual (Version 12), pages 43-44.

<sup>5</sup> Equivalence is defined in CAC / GL 26-1997 as "the ability of different systems of inspection and certification meet the same objectives."

<sup>6</sup> Agreement on SPS measures defines the rights and obligations of WTO Members in respect of determining the appropriate level of sanitary protection.

<sup>7</sup> A reference to "measure" in this section in the singular can also mean a reference to "measures" or "a package of measures", depending on the circumstances.

<sup>8</sup> Equivalent measures can achieve the ALOP of the importing country, or in combination with other measures, they can contribute to achieving the ALOP of the importing country. In the remainder of this guide, any reference to the latter should be regarded as including the feature.

- c) The importing country must describe how its veterinary and sanitary measure achieves the ALOP.
- d) The importing country must recognize that the veterinary and sanitary measures other than its own, can achieve the ALOP of the importing country.
- e) Veterinary and sanitary measure, proposed by the exporting country as equivalent must achieve the ALOP of the importing country.
- f) At the request of the exporting country the importing country within a reasonable time should rapidly begin consultations to determine the equivalence of certain veterinary and sanitary measures<sup>9</sup>.
- g) The exporting country should objectively demonstrate that its veterinary and sanitary measure can achieve the ALOP of the importing country.
- h) A comparison of veterinary and sanitary measures of the countries should be done in an objective way.
  - i) If during the demonstration of equivalence a risk assessment is used, countries should make every effort to achieve consistency in the methods used, using, where appropriate, the internationally accepted methodology and taking into account the relevant texts of the "Codex Alimentarius" Commission (hereinafter - the Codex).
  - j) The importing country must take into account the knowledge and experience gained by the inspection of controlled objects in the exporting country in order to carry out the determination in a more effective way and faster.
  - k) The exporting country should provide access to the inspection and certification systems, which are the subject of the equivalence determination, for their review and evaluation at the request of the importing country bodies supervising the control goods.
  - l) All equivalence assessments should take into account the means, by which equivalence is maintained.
  - m) Countries should ensure transparency both in the demonstration, and the evaluation of equivalence, providing consultations to all interested parties, in cases where this is feasible. Exporting and importing countries should consider the procedure for evaluating the equivalence in coordination with each other.
  - n) The importing country should consider favorably the request of a developing country exporting country to provide appropriate technical assistance that will contribute to a better determination of equivalence.

#### **IV. Conditions for determination of equivalence**

9. The determination of equivalence may be required for any veterinary and sanitary measure or series of measures relating to controlled goods. Appropriate veterinary and sanitary measures, which form a system of veterinary control in the exporting country, which are not the object of equivalence determination, must meet the requirements of the importing country.

10. The scope of determination of equivalence should depend on previous experience, knowledge, and confidence that the importing country takes into account the measures of veterinary control of the exporting country.

11. When the importing country has accumulated experience, knowledge, and confidence in the veterinary control measures, in respect of which equivalence is evaluated, and the countries agree that

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<sup>9</sup> Guidelines for the development, implementation, evaluation, and accreditation of the systems of inspection and certification of imports and exports of food, CAC / GL 26 - 1997.

the import requirements are fully met (for example, when there is an experience of trade), determination of equivalence of veterinary and sanitary measures can be carried out without further consideration of other relevant measures constituting the system of veterinary control.

12. If the importing country has no accumulated experience, knowledge, or confidence in the veterinary control measures, whose equivalence is being assessed, and the countries have not established that the import requirements are fully met (for example, if the proposal on trade in controlled goods is made for the first time), determination of equivalence of veterinary and sanitary measures would require further consideration of the relevant measures, which form the basis of the system of veterinary control.

13. In order to determine the equivalence, the veterinary and sanitary measures associated with the system of inspection can be roughly classified as follows:

a) Infrastructure: including the legal framework (e.g., food legislation and implementing laws) and administrative systems (e.g., organization of national or regional authorities, the law enforcement system, etc.);

b) a draft program, implementation and monitoring: including documents on systems, monitoring, implementation, criteria for decision-making and action, laboratory facilities, transport infrastructure and regulations on certification and audits, and / or

c) specific requirements, including requirements applicable to individual facilities (e.g. premises, structures), equipment (e.g. models of mechanisms that come into contact with food products), processes (e.g. HACCP plans), procedures (e.g. pre-and post-mortem inspections), tests (e.g. laboratory tests for microbiological and chemical hazards), and the methods of sampling and inspection.

14. This categorization is likely to facilitate an agreement between the countries based on a comparison of veterinary and sanitary measures that are the subject of determination of equivalence (see Section V). In the future, breaking measures into certain categories can help countries to simplify determination of equivalence relating to other veterinary and sanitary measures that make up the control system of controlled goods.

## **V. Objective basis of comparison**

15. Since veterinary and sanitary measures applied by importing country are designed to achieve its ALOP, the exporting country can demonstrate achievement of the ALOP of the importing country by demonstrating that the measures, which it proposes as equivalent, have the same effect in achieving the ALOP of the importing country, as the appropriate veterinary and sanitary measures applied by importing country with the help of an objective basis of comparison.

16. The importing country on request of the exporting country shall specify as precisely as possible, the objective basis for comparison of the veterinary and sanitary measures, proposed by the exporting country with its own measures<sup>11</sup>. The dialogue between the exporting country and the importing country will promote understanding and agreement on the objective basis for comparison. Additional information provided by the importing country, may include:

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<sup>11</sup> The objective basis for comparison of veterinary and sanitary measures that are classified as "Infrastructure" is likely to have a qualitative nature, for example, ability of legislation to control food and to achieve the main objectives of food security. Objective basis for comparison of veterinary and sanitary measures that are classified as "Specific requirements" is likely to have a quantitative nature, for example, comparison of the level of control of hazards, achieved by this measure. The objective basis for comparison of veterinary and sanitary measures that are classified as "the program" is likely to contain a mixture of qualitative and quantitative elements, for example, correct application of principles and the corresponding critical limits in the food control system HACCP.

- a) the reason / purpose of veterinary and sanitary measures, including identification of specific risks, which are addressed by the measure;
- b) the interrelationship of the veterinary and sanitary measures and the ALOP, i.e. how the veterinary and sanitary measure achieves the ALOP;
- c) if necessary, the expression of the level of hazard control in controlled goods, achieved by the veterinary and sanitary measure;
- d) scientific basis for the veterinary and sanitary measure under consideration, including risk assessment, if necessary;
- e) any additional information that may assist the exporting country in presenting an objective demonstration of equivalence.

## **VI. Procedure for determination of equivalence**

17. The importing country should make public the details of its veterinary and sanitary measures to the exporting country on request. The exporting country should review all applicable veterinary and sanitary measures of the importing country with respect to the controlled goods in question and identify those that meet the requirements and those, which require determination of equivalence. Importing and exporting countries should use agreed processes for the exchange of relevant information to assist in determining equivalence. This information must be limited to that, which is necessary for this purpose.

18. Determination of equivalence is ensured both by the exporting country and the importing country, following the successive stages, such as those described below and illustrated in Figure 1. The Parties must work together on these steps in order to reach agreement:

- a) The exporting country indicates the veterinary and sanitary measure of the importing country, which she would like to replace with another measure, and asks about the reason / ground for application of that measure.
- b) The importing country provides the reason / ground for the application of that measure and other relevant information in accordance with paragraph 8.
- c) In accordance with paragraph 8 the importing country should indicate as accurately as possible an objective basis for a comparative analysis of veterinary and sanitary measures proposed by the exporting country and its own. At the initiative of the exporting country, the importing and exporting countries should enter into a dialogue on the objective basis for the specified comparison in order to reach agreement.
- d) The exporting country prepares a package of documents, using a risk assessment or other relevant methodology (based on feasibility), to demonstrate that with the application of other veterinary and sanitary measure an appropriate level of veterinary and sanitary protection (ALOP) of the importing country is achieved, and provides it to the importing country.
- e) The importing country analyzes the documents and, if this is enough, uses the specified documents to determine whether the appropriate level of protection (ALOP) of the importing country is achieved by the measure of the exporting country.
- f) If the importing country has any concerns about the package of documents submitted, it should in no time notify the exporting country thereof and should elaborate on the reasons for its concerns. If possible, the importing country should submit proposals for the way, in which these concerns can be addressed.
- g) The exporting country should respond to these concerns by providing additional information, changes in its proposals, or taking other action as appropriate.

h) The importing country notifies the exporting country of its view over the relevant time period, and provides arguments for its decision on the fact that the mentioned sanitary measure is not equivalent, i.e. when it is used an appropriate level of sanitary protection (ALOP) of the importing country is not achieved.

i) Efforts should be made to resolve differences of opinion concerning the evaluation of the submitted documents, both preliminary, and final.

## **VII. Assessment of equivalence**

19. Assessment of equivalence by the importing country should be based on the transparent analytical process that is objective and consistent, and includes consultations with all interested parties, to the extent practicable and appropriate.

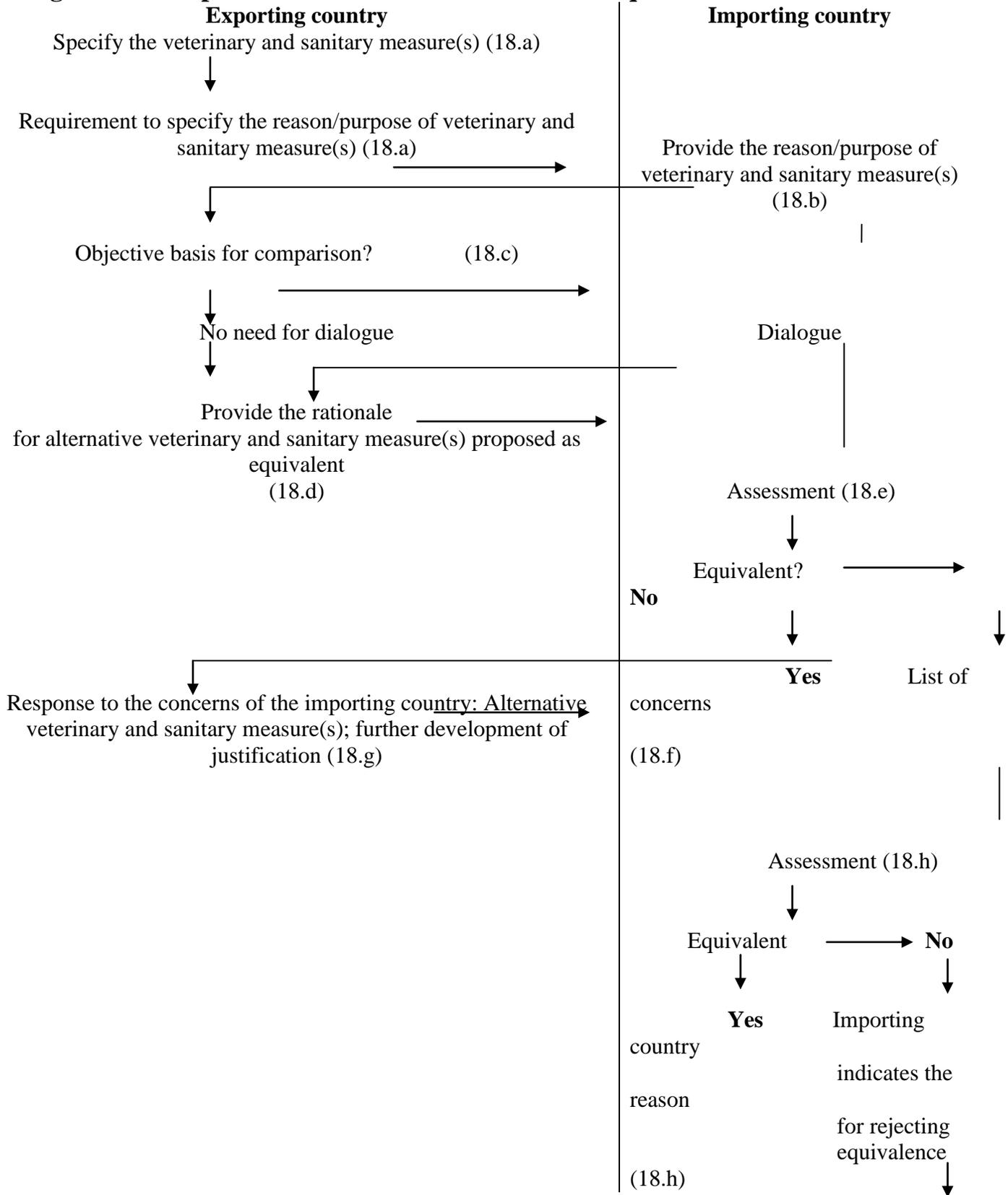
20. In assessing the equivalence of veterinary and sanitary measures the following should be taken into account:

- a) the experience, expertise and reliability of the systems of inspection and certification of food products in the exporting country (see Section IV);
- b) supporting data provided by the exporting country;
- c) analysis of the strength of the relationship between this veterinary and sanitary measure of the exporting country and the achievement of an appropriate level of veterinary and sanitary protection of the importing country, as reflected in an objective basis for comparison (see Section V);
- d) parameters must be specified in quantitative terms, to the extent possible;
- e) the adequacy of the quality characteristics in cases where the level of hazards control in controlled goods is not quantifiable;
- f) Analysis of variability and other sources of uncertainty in the data;
- g) analysis of the expected impact on animal and human health as a result of this veterinary and sanitary measure of the exporting country;
- h) Codex texts on the issues of safety of the controlled goods.

After conducting any assessment of equivalence, the exporting and importing countries should immediately inform each other of important changes in their support programs and infrastructure that may have an impact on the determination of equivalence.

21. Procedures Manual for carrying out assessments of the exporting country's systems by the importing country can be found in the Annex.

**Figure I: A simplified scheme for determination of equivalence**



resolution  
of opinion  
respect of  
(18.i)

Possible  
of differences  
in  
equivalence



Equivalent?



**No**

**Yes**

In assessing the systems of state inspection and certification, the following additional principles shall be applied.

**Principles to the actions by inspectors and experts of the competent authorities of the importing and exporting country in the process of assessment**

- A. Assessments should focus on the result, they should be transparent, constructive, and should be conducted in an agreed, ethical, and professional manner, as necessary, with respect to confidential information.
- B. The importing and exporting countries should apply an agreed process for reviewing all the issues that may arise during the process assessment.
- C. The importing and exporting countries should agree on the appropriate method of assessment before its start, based on the agreed scope and purpose.

**Principles of the process of assessment**

- D. The process of assessment should be planned, it should be systematic, transparent, consistent, fully documented, and communicated.
- E. The plan, including the rationale, objectives, scope, requirements and evaluation methods for assessing the system of state inspection and certification should be clearly defined by the importing country, communicated to the competent body(ies) of the exporting country and agreed with him within a reasonable time prior to the start of assessment.

**Principle of accounting for assessment**

- F. Agreed corrective actions, timeframes and subsequent verification procedures should be clearly established and documented.
- G. The final report on assessment should be clear and transparent, it can be published, if necessary, subject to confidentiality.

**Principle A**

**Assessments should focus on the result, they should be transparent, constructive, and should be conducted in an agreed, ethical, and professional manner, as necessary, with respect to confidential information.**

1. Inspectors and experts from the competent authority of the importing country should be able to demonstrate that the results of the assessment, conclusions and recommendations are focused on whether there is a likelihood that the desired results will be achieved by the system and that they are supported by objective data or the data that have been approved as accurate and reliable.
2. During the assessment, all arising issues should be solved by the inspectors and experts of the competent authorities in an agreed, ethical and professional manner.

3. Inspectors and experts from the competent authorities of the importing country should observe impartiality. Inspectors and experts should have the appropriate qualifications, experience, and must be trained both in the relevant field of expertise, and in the field of audit methods.

4. During the assessment the inspectors and experts of the importing country should ensure that confidential information is protected.

### **Principle B**

**The importing and exporting countries should apply an agreed process for reviewing all the issues that may arise during the process assessment**

5. Prior to the start of assessment, the key elements of the process of addressing issues that may arise during the assessment should be agreed upon. The competent authorities of the importing and exporting countries should seek to resolve all issues arising in the assessment together in an open and transparent manner. If any questions remain unresolved, they should be included in a report on the assessment with appropriate explanations.

### **Principle C**

**The importing and exporting countries should agree on the appropriate method of assessment before its start, based on the agreed scope and purpose.**

6. The most efficient and effective method should be chosen, that which can evaluate the effectiveness of the public system for inspection and certification of the exporting country, including the possibility for the competent body(ies) of the exporting country to organize and implement control, and provide the necessary guarantees to the importing country.

7. When choosing a method of assessment, it is important to consider the reason for the assessment. For example, assessments may be part of a risk analysis conducted before trade is launched, they can assess a system of state inspection and certification or control of a single element (e.g., chemical residues) or special exporting establishments.

8. When choosing a method of assessment, the experience, knowledge and reliability<sup>1</sup> of the importing country regarding the system of state inspection and certification of the exporting country should be taken into account.

### **Audit Methods**

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<sup>1</sup> Paragraph 9-14 of Appendix to the *Guidelines for assessing the equivalence of sanitary measures associated with the system of inspection and certification of food products* (CAC / GL 53-2003) provide additional guidance as to what is the experience, expertise and reliability, as well as expanding the information out in paragraph 10.12 of this manual.

9. The method of the audit, which is often called a "system audit," should focus on the assessment whether the system of state inspection and certification, or its components, of the exporting country serves its purpose.

10. In contrast to the study of all the procedures, system audits are based on the study of an example system procedures, documents or records and, if required, a number of sites within the scope of the system being audited.

11. The system approach focuses on the system(s) of control and according to it, all items identified as compliant/incompliant should be considered in the context of the whole system.

12. A system audit may include the study of the elements (legal framework, means of control, procedures, facilities, equipment, laboratories, vehicles, communications equipment, personnel and training to achieve the objectives of the inspection and certification program), or, if necessary, other elements.

### **Method of inspection**

13. In some cases, a method of inspection may be used to confirm the efficiency of control inspections conducted by a competent body(ies) in the exporting country.

14. Inspections may include the study of the following:

- (a) How the company meets the requirements, including consideration of specific activities and product specifications, supervision and review of the company's activities and the relevant records of activities;
- (b) The number of employees in the company, if it is specified in the request;
- (c) What inspectors are allowed to do, if it is particularly pointed out in the requirements.

### **Principle D**

**The process of assessment should be planned, it should be systematic, transparent, consistent, fully documented, and communicated.**

15. Documents confirming the findings, conclusions and recommendations should be executed so that the efficiency of the assessment and presentation of its results were uniform, transparent, and reliable.

16. The competent authorities of the importing and exporting countries should be consulting each other in preparation for and during the assessment on all points of the process, from development of a plan for the assessment to the final report and decisions on all issues that arise during the assessment. To ensure regular and transparent communication, the competent authorities of the importing and exporting countries should designate contact persons or points of contact for the assessment.

## Principle E

**The plan, including the rationale, objectives, scope, requirements and evaluation methods for assessing the system of state inspection and certification should be clearly defined by the importing country, communicated to the competent body(ies) of the exporting country and agreed with him within a reasonable time prior to the start of assessment.**

17. In determining the rationale, objectives, scope, frequency, and methods of assessment the competent authority of the importing country should take into account the established level of experience, knowledge, and reliability, along with a history of previous assessments for the period since the last assessment, and any other relevant factors.

18. The procedure of systematic evaluation for the assessment should be based on the pre-defined and structured program in accordance with the purpose of assessment.

## Notice

19. The following information should be exchanged at the time of initial request and before the start of assessment of an existing system of state inspection and certification:

- a) Rationale for or the need for assessment may occur for several reasons, including the legal obligations of the importing country or the need to understand the respective roles of the competent authorities of the importing country and the exporting country or the need to ensure the ability of the exporting country's system or facilities for food production/processing to ensure compliance with the requirements.
- b) The purpose of assessment may, for example, be as follows: to confirm the effective application / implementation of special measures or technical requirements of the system of inspection and certification of the exporting country; to confirm compliance by the exporting country with the measures of the importing country; to assess compliance of equivalence agreements or other types of mutual acceptance of the systems, investigate outbreaks of diseases transmitted through food and related to imported / exported food products and monitor corrective actions arising from the previous assessments or situations that have arisen in connection with the problems in the area of food safety. If necessary, an audit of a risk assessment component of the food safety control system of the exporting country to support risk management practices may be conducted.
- c) It is necessary to define the scope of assessment, that is: whether the assessment covers the entire system, or only some of its components, measures, technical requirements, or products.
- d) It is necessary to define the intended method of assessment, including requirements, which will be covered by the assessment of the state system of inspection and certification of the exporting country.

20. In all cases, the competent authority of the importing country shall inform the competent authority of the exporting country of the proposed assessment so that the competent authority could organize the necessary activities, such as logistics and information gathering. If the rationale for the assessment is an important public health problem, the notice shall reflect the urgency associated with the risk to human health.

## **Preparation for assessment**

21. It is necessary to prepare a plan for carrying out the assessment, including methods of assessment, timing, and exchange of necessary information, and submit it to the competent authority of the exporting country within a reasonable period of time. The plan should include the following:

- a) Objectives and scope of assessment, including whether it is a separate assessment or if it is related to another assessment (for example, control of the previous assessment) or a series of assessments;
- b) Areas / elements for review / analysis, which may include the records and evaluation of checklists;
- c) The expected period for carrying out the assessment and drawing the report;
- d) The criteria for assessment of the public system for inspection and certification of the exporting country;
- e) Contact person for the members of the assessment team, who can negotiate the details of the assessment plan, and - if necessary - the members of the assessment team, including foreign auditors / inspectors, chief auditor / inspector, technical experts and interpreters;
- f) The language that will be used during the assessment, including translation, availability of the competent and impartial interpretation and resources.
- g) Specification of the type, and if possible / necessary the places of visits (e.g., offices, laboratories, or other facilities), and the timing and responsibility for the notification about the places if necessary (although this can be done at the opening meeting prior to the assessment);
- h) Date of assessment, dates of the opening and final meetings and the expected date for communicating the comments on the assessment;
- i) route and other logistics necessary for the assessment visit, and
- j) Methods of protection of confidential information.

22. Since it is necessary to ensure compliance with the assessment plan, it should be flexible so that it would be possible to make changes based on the information collected prior to or at the time of the assessment. Proposed significant changes to the assessment plan should be made only under mitigating circumstances, and they should be reported as soon as possible to the appropriate authority.

23. It is necessary to agree beforehand on the language to be used during the assessment, including translation, availability of the competent and impartial interpretation and resources.

24. To the extent possible, documentary information required for the planning, conducting and completion of the assessment is to be sought and provided prior to assessment using means of electronic communication as possible.

- a) A request for the preparation of an assessment should specify the scope of assessment and its purpose.
- b) If this is a verification assessment, then the exporting country will only need to provide information that has changed since the previous assessment, or has not been requested in the previous assessment;

- c) If the purpose of a request for information is not clear to the exporting country, and there are several problems associated with the requested information, the exporting country may require that the importing country provide explanations of the purpose and use of such information.
- d) If a visit to a facility is proposed as a method for assessment, prior to the visit, it is necessary to analyze the documents that describe the system, including legislative support.

25. In some cases, the assessment can be suspended or terminated prior to a facility visit, depending on the nature of the information provided by the competent authority of the exporting country, and in this case the competent authority of the importing country should clearly inform the competent authority of the exporting country of the cause. The competent authority of the exporting country should have the opportunity to receive explanations on the information provided, if deemed necessary.

### **Starting / Opening Assessment Meeting**

26. If the assessment includes a visit, it is necessary to hold a starting or introductory meeting.

- a) The meeting shall be held at a place designated by the competent authority of the exporting country.
- b) The meeting should address all aspects of the assessment plan, including final adjustments; the purpose of the meeting - to review the system of state inspection and certification in the country and to confirm the parameters and logistics of the assessment.
- c) It is necessary to agree on ways to ensure continuous interaction and communication between the parties during the assessment.

### **Closing / Summary Meeting**

27. If the assessment includes a visit, it is necessary to hold a closing or summary meeting.

- a) The meeting shall be held at a place designated by the competent authority of the exporting country.
- b) The evaluation team should summarize and present the main findings and preliminary conclusions. It is necessary to specify any inconsistencies and bring objective evidence to support the conclusions. Correction of inconsistencies should be the responsibility of the competent authority of the exporting country and verified by the competent authority of the importing country, including the verification assessment if necessary.
- c) At the meeting the competent authority of the exporting country shall be given the opportunity to ask questions and get clarification on the results and the comments made at the meeting.

### **Principle F**

**Agreed corrective actions, timeframes, and verification procedures should be clearly established and documented.**

### **Principle G**

**The final report on assessment should be clear and transparent, and it can be published subject to confidentiality of information, where applicable.**

28. The side, which was assessed, should be given the opportunity to review a draft report during an agreed period of time, to submit comments and to correct factual errors prior to compiling the final version of the report. The final report shall include or be accompanied by comments of the competent authority of the exporting country.

29. The assessment report should present a balanced picture of results, and include conclusions and recommendations that accurately reflect the results. The report should:

- a) contain the purpose, scope, and results;
- b) contain the criteria and the process of assessment;
- c) include assessment results with supporting evidence for each conclusion along with the importance, which was discussed at the final meeting;
- d) be accessible by prior agreement with the competent authority of the exporting country, including comments from the competent authority of the exporting country in order to improve the accuracy of the report;
- e) consider the time frame for finalizing the report and for response measures, as agreed between the competent authorities of the importing country and the exporting country;
- f) include a description of how corrective actions will be communicated and agreed upon, including the way for carrying out a verification assessment;
- g) if necessary, include a checklist of elements to be assessed, to support the findings;
- h) include the list of results of the assessment;
- i) include the key issues and problems that arose during the assessment if there is no agreement on the findings and corrective actions;
- j) include uncertainties and / or any obstacles that have arisen and may have affected the reliability of the conclusion of the assessment, and
- k) contain description of the areas not covered in the assessment report, although falling within the scope, and the reasons for the deviation from the agreed scope.

30. It is necessary to clearly indicate the timing and the protocol of the verification assessment. Confirmation of corrective actions may include:

- a) guarantees provided by the competent authority of the exporting country;
- b) documents submitted by the competent authority of the exporting country, or
- c) the declared corrective actions in the subsequent assessment.

31. In compiling and subsequent distribution of the assessment report, confidential information should be considered.

32. After drawing up the final report the competent authorities of the importing and exporting country should discuss and possibly agree on whether the report will be published and how it should be done in view of the confidentiality of information, if any.

END UNOFFICIAL TRANSLATION.

