

**THE EUROPEAN UNION'S APPROACH TO SPS AUDITS
AND INSPECTIONS IN THIRD COUNTRIES**

Communication from the European Union

The following communication, received on 22 June 2011, is being circulated at the request of the Delegation of the European Union.

The European Union is pleased to share its experience on its systems-based approach to audits and/or inspections in the assessment of exporting partners' control systems. This approach is built on recognition of the ability of exporting countries to provide sufficient guarantees to demonstrate that their exports meet the EU's level of sanitary protection. The system promotes the idea that establishments in third countries can be listed as being eligible for export to the European Union on the basis of these guarantees, with a view to facilitate trade flows and to avoid undue delays or overly burdensome costs. It applies predominantly to imports of animal products.

I. INTRODUCTION

1. In general, to have access to markets for animals, plants and their products, it is necessary to provide guarantees that the appropriate level of sanitary protection (ALOP) set by the importing country is satisfied. Importing countries often verify these guarantees by carrying out spot audits and/or inspections in exporting countries.
2. While significant human, material and financial resources are needed to perform such audits and/or inspections, the use of these resources must be balanced with other considerations such as the need to facilitate market access, to avoid unjustified delays and to avoid exorbitant costs.
3. Parameters for audits and/or inspections are set out by the Codex Alimentarius which gives clear preference to the evaluation of official inspection and certification systems rather than specific commodities or establishments.¹
4. In keeping with this, the European Union relies on an audit system that seeks to provide full confidence in the exporting country's competent authorities and their ability to provide guarantees that meet the appropriate level of sanitary protection (ALOP) set by the European Union for those products they are seeking to export to the European Union.
5. This audit system relies on the official controls performed by the competent authorities of exporting countries. By building confidence in the inspection and certification systems of these third

¹ Principles and Guidelines for the Conduct of Assessment of foreign Inspection and Certification systems, Annex to CAC/GL 26-1997.

countries, the European Union does not engage in the overly burdensome task of inspecting each and every establishment seeking to export to the European Union.

6. The system mainly applies to animal products which are perceived to pose the highest risks.

II. DESCRIPTION OF THE EU SYSTEM

7. To be authorized to export a certain commodity to the European Union, an exporting country first has to demonstrate that its official controls fulfil EU requirements.² Once this is proven to be the case and after the European Union has verified the guarantees including where necessary an on-the-spot audit - the country is formally approved to export to the European Union.

8. The competent authority of the exporting country is subsequently able to set in motion a process of assessing the eligibility of establishments within its territory to export to the European Union. If the exporting country's competent authority sees that an establishment meets the relevant EU import conditions, it can place the establishment on a list (often termed a "*pre-list*") of exporting establishments that meet relevant EU conditions. This list is subsequently proposed to the European Union and thereon serves as a list of establishments from which EU member States are authorised to import. The list is also published on the Internet.³

9. The competent authority of the exporting country is responsible for keeping the list updated by adding or deleting establishments or by modifying information pertaining to an approved establishment, as appropriate.

10. Subsequent audits to the exporting country are carried out by the European Union on a regular basis to check if the exporting country's official control systems continue to provide the necessary guarantees for export.

11. This system is informally referred to in the European Union as the "*pre-listing system*" which underlines the recognition of the competence and authority of a third country to list its own establishments eligible to export to the European Union. It is applicable to all trading partners.

III. CONFORMITY TO INTERNATIONAL STANDARDS

12. EU audits follow international standards laid down by the Codex Alimentarius which give a clear preference to the evaluation of official inspection and certification systems rather than specific commodities or establishments.⁴

13. EU audits also include inspections of a sample of the establishments involved. These inspections are planned, open to scrutiny, and performed on the basis of internationally recognised audit methodologies (in line with ISO 19011).

14. They are carried out by the EU's audit and inspection service: the Food and Veterinary Office. The costs of travelling and the accommodation of EU auditors are fully paid for by the European Union. There are no audit fees to be paid - before, during or after the audits - by the visited

² The EU import conditions referred to in this note correspond to the general conditions as described under Article 11 of Regulation (EC) No: 178/2002, including the equivalence principle of the WTO SPS Agreement.

³ Third country establishments lists - http://ec.europa.eu/food/international/trade/third_en.htm.

⁴ Principles and Guidelines for the Conduct of Assessment of foreign Inspection and Certification systems, Annex to CAC/GL 26-1997.

countries or establishments. Both the audit body and audit process are independent in order to guarantee objective and un-biased results. Audit reports are made publicly available on the Internet.⁵

15. By developing a system to manage audits and inspections and the authorization of establishments in this manner, the European Union not only guarantees a high level of safety of traded agri-food commodities, it also respects its appropriate level of sanitary protection in a resource and trade-friendly manner.

IV. THE SITUATION TO DATE AMONGST WTO MEMBERS

16. According to the experience of the European Union, audit and inspection approaches which do not follow the *Codex Alimentarius* guidelines result in unjustified delays, create discriminatory treatment between trading partners and are not in line with WTO requirements, in particular as set in Annex C of the WTO SPS Agreement.

17. The European Union notes with regularity that many of its trading partners do not follow these guidelines with the negative consequences outlined below.

18. There are also differences in the import procedures and the frequency of audits/inspections from country to country.

19. While there are a number of trading partners applying "best practice" in their import control systems, there are also a wide range of trade-prohibitive practices, which the EU "pre-listing" system was specifically designed to avoid. In particular:

- (a) Unclear and cumbersome audit/inspection procedures - some audits and/or inspections lack planning: they are not systematic, poorly communicated, or not reported at all to the competent authority of the visited country.
- (b) Long delays for export approval to be granted - countries seeking to export to another country often have to wait a very long period of time for an inspection that will potentially allow market access. This is often due to a lack of - or the improper use of - human and/or financial resources. In some cases, it can take up to ten years for an exporting country to receive a visit from an importing country.
- (c) Excessive costs – costs that do not necessarily reflect the real cost of the audit/inspection are often charged to inspect establishments or competent authorities, or both;
- (d) Temporary approval granted - exporting establishments are often only approved on a temporary basis, many years after the original application.
- (e) Lists of establishments are updated only after long delays.
- (f) Differentiated treatment - trading partners in a similar situation are treated differently.
- (g) Lack of reciprocity - there is little, if any, reciprocity from trading partners despite the fact that the European Union applies its system equally to all.

20. Some WTO Members do manage imports and the authorization of establishments on the basis of an evaluation of official inspection and certification systems in a manner similar to that of the

⁵ The Food and Veterinary Office - http://ec.europa.eu/food/fvo/index_en.cfm.

European Union. This results in an efficient and effective use of human resources, facilitation of trade and is able to deliver the appropriate level of sanitary protection required.

V. ADVANTAGES OF THE EU SYSTEM

21. Rights and obligations of the WTO SPS Agreement - The European Union manages imports in general, and the lists of exporting establishments in particular, respecting the rights and obligations of the WTO SPS Agreement.
22. International standards - The EU approach recognizes, in line with the *Codex Alimentarius* (cf. CAC/GL 20-1995, CAC/GL 26-1997), that official and officially recognized inspection and certification systems are fundamentally important to build and maintain the necessary confidence in the inspection and certification system of an exporting country and to facilitate fair trade, taking account of the expectations of consumers.
23. Non-discrimination - The EU audit-based principles and the management of establishments are non-discriminatory as they apply equally to all the EU's trading partners.
24. Minimal disruptions to trade - The EU system is designed to minimize disruptions to trade while maintaining an appropriate level of sanitary protection.
25. Risk based approach - The audit system targets those commodities that pose the highest risk. This means that it is not imposed on *all* animals, plants and their products imported into the European Union. When a particular commodity or country, on the basis of an identifiable risk, requires an audit in order to verify that it meets the relevant EU import conditions, the procedures and objectives of the evaluation are communicated to the exporting competent authority in advance. This is an ongoing relationship which must be constantly assessed and maintained. Confidence in the competent authority of exporting countries is not only assessed by audits and/or inspection but also on the basis of controls at EU borders. The frequency of follow-up audits is limited to what is considered necessary to maintain confidence.
26. Transparency - The EU import conditions and lists of authorised establishments are publicly available, and on-the-spot inspections/audits are planned, systematic, consistent, fully-documented and well-communicated to trading partners.
27. Equivalence - The principle of equivalence is recognized whereby an exporting country may choose either to implement specific EU measures or to demonstrate that their own sanitary measures provide, at least, equivalent guarantees to achieve the EU's appropriate level of sanitary protection.
28. Efficiency and efficacy - The European Union applies a flexible, efficient and swift working system to manage lists of third countries and exporting establishments. The EU approach focuses on the performance of competent authorities, who are responsible to guarantee compliance with EU import requirements for exported products, including health verifications where necessary, rather than evaluating each and every exporting establishment. The EU approach makes the best possible use of limited human and financial resources and avoids unnecessary costs and unjustified delays.
29. Independence - To guarantee the independence of the audit body and the audit process, ensuring that it is sufficiently detached from entities which have a direct trade or commercial interest, the audit body is located in the European Commission's Directorate General responsible for Health and Consumers. All the costs of audits are also covered by the EU budget, to avoid any potential conflict of interest.

30. Evidence-based - The confidence needed for a swift listing of establishments is largely based on evidence collected during audits which rely on the examination of a sample of system procedures, documents or records and, where required, a selection of sites (including a representative sample of exporting establishments, *i.e.* not necessarily all establishments) within the scope of the system under audit. This is distinct from the necessity to inspect all procedures, records and production sites. The main objective of these audits is to build confidence in the competent authority of the exporting country and on-site verification is used only to the extent necessary to achieve that objective.

31. In conclusion, the European Union not only guarantees a high level of safety in traded agri-food commodities, it does this in a resource and trade-friendly manner.
