

SANITARY AND PHYTOSANITARY MEASURES

APPENDIX 1

COMPETENT AUTHORITIES

1. Competent Authorities of the EU Party

Control competences are shared between the national services of the European Union Member States and the European Commission. In this respect the following applies:

- (a) as regards exports to Colombia and/or Peru, the European Union Member States are responsible for control of the production conditions and procedures, including statutory inspections and issuing health (or animal welfare) certifications attesting compliance with the standards and requirements established by the importing Party.
- (b) as regards imports from Colombia and/or Peru, the European Union Member States are responsible for the control of the compliance of such imports with the import conditions established by the European Union;

- (c) the European Commission is responsible for overall co-ordination, inspections and audits of inspection systems and the necessary legislative action to ensure uniform application of standards and requirements within the European Union.

2. Competent Authorities of Colombia

Control and surveillance are carried out jointly by the Instituto Colombiano Agropecuario (hereinafter referred to as "ICA") and the Instituto Nacional de Vigilancia de Medicamentos y Alimentos – (hereinafter referred to as "INVIMA"), in accordance with the competences assigned to each institution by law. In this respect the following applies:

- (a) as regards exports to European Union Member States, ICA and INVIMA are responsible for the surveillance and control of the sanitary and phytosanitary conditions and procedures, including statutory inspections and issuing sanitary and phytosanitary certificates attesting compliance with the standards and requirements established by the importing Party;
- (b) as regards imports from the European Union Member States into Colombia, ICA and INVIMA are responsible for the verification and control of the compliance with the established import conditions, including the inspections and the sanitary and phytosanitary certificates issued by the European Union Member States attesting the compliance of such imports with the standards and import requirements in force in Colombia;

- (c) ICA and INVIMA are responsible, in accordance with their respective competences, for the overall co-ordination, inspection and audits of inspection systems.

3. Competent Authorities of Peru

The competent authorities of Peru in sanitary and phytosanitary matters are the following institutions:

- (a) Servicio Nacional de Sanidad Agraria (hereinafter referred to as "SENASA")
- (b) Dirección General de Salud Ambiental (hereinafter referred to as "DIGESA")
- (c) Ministerio de Salud
- (d) Instituto Tecnológico Pesquero (hereinafter referred to as "ITP")
- (e) Ministerio de Comercio Exterior y Turismo (hereinafter referred to as "MINCETUR").

APPENDIX 2

REQUIREMENTS AND PROVISIONS FOR APPROVAL OF ESTABLISHMENTS FOR PRODUCTS OF ANIMAL ORIGIN

1. The competent authority of the importing Party shall draw up lists of approved establishments and shall make these lists publicly available.
2. The requirements and procedures for approval are the following:
 - (a) the import of the animal product concerned from the exporting Party shall have been authorised by the competent authority of the importing Party; this authorisation shall include the import and certification requirements in force for the products concerned;
 - (b) the competent authority of the exporting Party shall approve the establishments intended to export and provide the importing Party with satisfactory sanitary guarantees that those establishments meet the relevant requirements of the importing Party;
 - (c) the competent authority of the exporting Party must have the effective power to suspend or withdraw the export approval of an establishment in the event of non-compliance of the relevant requirements of the importing Party;

- (d) the importing Party may carry out verifications in accordance with the provisions of Article 93 of this Agreement, as part of the approval procedure;
- (e) the verifications referred to in subparagraph (d), shall concern the structure, organisation and powers of the competent authority responsible for the approval of the establishments and the sanitary guarantees that such competent authority can provide regarding the compliance with the requirements of the importing Party;
- (f) the verifications referred to in subparagraph (d), may include on-the-spot inspection of a representative number of establishments appearing on the list or lists provided by the exporting Party;
- (g) taking into account the specific structure and distribution of competences within the EU Party, verifications referred to in subparagraph (d) carried out in the EU Party may concern individual European Union Member States;
- (h) based on the results of the verifications provided for in subparagraph (d), the importing Party may modify the list of establishments.

3. Approval pursuant to paragraphs 1 and 2 shall initially be limited to the following categories of establishments:
- (a) all establishments for fresh meat of domestic species;
 - (b) all establishments for fresh meat of wild and farmed game;
 - (c) all establishments for poultry meat;
 - (d) all establishments for meat products of all species;
 - (e) all establishments for other products of animal origin for human consumption (eg. casings, meat preparations, minced meat);
 - (f) all establishments for milk and milk products for human consumption; and
 - (g) processing establishments and factory/freezer vessels for fishery products for human consumption including bivalve molluscs and crustaceans.

APPENDIX 3

GUIDELINES FOR CONDUCTING VERIFICATIONS

Verifications may be carried out on the basis of audits and/or on-the-spot inspections.

For the purposes of this Annex:

- The "auditee" is the Party subject to the verification;
- The "auditor" is the Party that carries out the verification.

1. General Principles of Verification

- (a) verifications shall be carried out in cooperation between the auditor and the auditee in accordance with the provisions set out in this Appendix;

- (b) verifications shall aim at verifying the effectiveness of the controls of the auditee rather than at rejecting individual animals, groups of animals, consignments of food establishments or individual lots of plants or plant products; where verification reveals a serious risk to animal, plant or human health, the auditee shall take immediate corrective action. The process may include the study of the relevant regulations, the method of implementation, the assessment of the end result, the level of compliance and subsequent corrective actions;
- (c) the frequency of verifications shall be based on performance. A low level of performance should result in an increased frequency of verifications. Unsatisfactory performance shall be corrected by the auditee to the auditor's satisfaction;
- (d) verifications, and the decisions based on them, shall be made in a transparent and consistent manner.

2. Principles Relating to the Auditor

The auditors shall prepare a plan, preferably in accordance with recognised international standards, that covers the following points:

- (a) the subject, depth and scope of the verification;

- (b) the date and place of the verification, along with a timetable up to and including the issue of the final report;
- (c) the language or languages in which the verification will be conducted and the report written;
- (d) the identity of the auditors including, if a team approach is used, the leader; specialised professional skills may be required to carry out verification of specialised systems and programmes; and
- (e) a schedule of meetings with competent officials and visits to the establishments or facilities, as appropriate; the identity of establishments or facilities to be visited need not be stated in advance.

Subject to provisions on freedom of information, respect of commercial confidentiality shall be observed by the auditor. Conflicts of interest must be avoided.

3. Principles Relating to the Auditee

In order to facilitate verification, the following principles shall apply to actions taken by the auditee:

- (a) the auditee shall cooperate fully with the auditor and shall designate personnel responsible for this task; cooperation may include, for example:
 - (i) access to all relevant regulations and standards;
 - (ii) access to compliance programmes and relevant records and documents;
 - (iii) access to audit and inspection reports;
 - (iv) access to documentation concerning corrective actions and sanctions; and
 - (v) facilitating entry to establishments;
- (b) the auditee shall carry out a documented programme to demonstrate to the auditor that standards are being met on a consistent and uniform basis.

4. Procedures

(a) Opening meeting

An opening meeting shall be held between representatives of the Parties. At this meeting, the auditor shall be responsible for reviewing the verification plan and confirming that adequate resources, documentation, and any other necessary means are available for conducting the verification.

(b) Document review

The document review may consist in the examination of the documents and records referred to in subparagraph 3(a), the structures and competences of the auditee, and any relevant changes to inspection and certification systems since the entry into force of this Agreement or after the last verification, with emphasis on the implementation of elements of the system of inspection and certification for animals, animal products plants or plant products of interest. This may include an examination of relevant inspection and certification records and documents.

(c) on-the-spot inspections

- (i) to decide if an on-the-spot inspection should be carried out, the risk of the relevant animal, plant or animal or plant product should be considered, taking into account factors such as the history of conformity of the industry sector or exporting Party with requirements, the volume of product produced and imported or exported, changes in infrastructure and the domestic inspection and certification systems;
- (ii) on-the-spot inspections may involve visits to production and manufacturing facilities, food-handling or storage areas and control laboratories to check on compliance with the information contained in the documentary material referred to in subparagraph (b) above.

(d) Follow-up verification

Where a follow-up verification is being conducted in order to verify the correction of deficiencies, it may be sufficient to examine only those points which have been found to require correction.

5. Working documents

Forms for reporting audit findings and conclusions should be standardised as much as possible in order to make the approach to verification more uniform, transparent and efficient. The working documents may include any checklist of elements to evaluate. Such checklists may cover:

- (a) legislation;
- (b) structure and operations of inspection and certification services;
- (c) establishment details and working procedures, health statistics, sampling plans and results;
- (d) compliance action and procedures;
- (e) reporting and complaint procedures; and
- (f) training programmes.

6. Closing Meeting

A closing meeting shall be held between representatives of the Parties involved, including, where appropriate, officials responsible for the national inspection and certification programmes. At this meeting, the auditor shall present the findings of the verification. The information shall be presented in a clear and concise manner, so that the conclusions of the audit are clearly understood. An action plan for correction of any deficiencies noted shall be drawn up by the auditee, preferably with target dates for completion.

7. Report

The draft report of verification shall be forwarded to the auditee within 45 working days following the closing meeting referred to in paragraph 6. The auditee shall have 30 working days to comment on the draft report. Comments made by the auditee shall be attached to and, where appropriate, included in the final report. However, where a significant public, animal or plant health risk has been identified during the verification, the auditee shall be informed as soon as possible and, in any case, within 10 working days following the end of the verification.

APPENDIX 4

CONTACT POINTS AND WEB-SITES

A. Contact Points

<p>For the European Union</p> <p>European Commission Postal Address: Rue de la Loi 200 - B-1049 Brussels –Belgium Tel. + 322 2963314 Fax. +322 2964286</p>
<p>For Colombia</p> <p>Instituto Colombiano Agropecuario (ICA) Postal Address: Calle 37 N° 8-43 Edificio Colgas, Bogotá, D.C. – Colombia Tel. +57 1 3203654 Fax. +57 1 2324695 E- mail: subgerencia.pecuaria@ica.gov.co</p>
<p>Instituto Nacional de Vigilancia de Medicamentos y Alimentos (INVIMA) Postal Address: Carrera 68D N° 17 – 11/21, Bogotá, D.C. - Colombia Tel. +57 1 2988700 E-mail: invimagr@invima.gov.co</p>
<p>Ministerio de Comercio, Industria y Turismo Postal Address: Calle 28 N° 13 A - 15, piso 3° - Bogotá, D.C. – Colombia Tel. +57 1 6064775</p>

<p>For Peru</p> <p>SENASA</p> <p>Postal Address: Avenida la Molina N° 1915-Lima 12 – La Molina – Lima - Perú</p> <p>Tel. +511 3133300</p> <p>Fax. +511 3401486</p>
<p>DIGEMID</p> <p>Postal Address: Las Amapolas N° 350 Urbanización San Eugenio – Lince – Lima – Perú</p> <p>Tel. +511 4428335, 4210146, 4210258</p> <p>Fax. +511 4226404</p>
<p>ITP</p> <p>Postal Address: Carretera a Ventanilla Km. 5.2 - Callao – Perú</p> <p>Tel.+511 5770116, 5770118</p> <p>Fax.+511 5770908</p>
<p>MINCETUR</p> <p>Postal Address: Calle Uno Oeste N° 050, Urbanización Córpac, San Isido, Lima – Perú</p> <p>Tel. +511 5136100, anexos 8020, 8021</p> <p>Fax. +511 5136100, anexo 8002</p> <p>E-mail: webmaster@mincetur.gob.pe</p>

B. Free websites

For the European Union http://europa.eu.int/comm/dgs/health_consumer/index_en.htm
For Colombia www.ica.gov.co www.invima.gov.co www.mincomercio.gov.co
For Peru www.senasa.gob.pe www.digesa.minsa.gob.pe www.itp.gob.pe www.mincetur.gob.pe