



Health & Consumer Protection Directorate-General

General guidance on EU import and transit rules for live animals and animal products from third countries













EUROPEAN COMMISSION HEALTH AND CONSUMERS DIRECTORATE-GENERAL

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General guidance on EU import and transit rules for live animals and animal products from third countries

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INTRODUCTION

Detailed EU legislation in the veterinary field lays down the conditions that apply to the imports of live animals and products of animal origin from third countries. The responsibility for this area lay within the domain of the Health and Consumers Directorate-General (DG SANCO). The legislation of the European Union in this field is fully harmonised (apart from certain import certificates which have not yet been established) and the main relevant Union law is listed under Section 16. The EU takes particular care to ensure that this legislation is fully compliant with its international obligations and especially with the requirements of the Sanitary and Phytosanitary Agreement of the World Trade Organisation.

This legislation imposes a series of health and supervisory requirements, designed to ensure that imported animals and products meet standards at least equivalent to those required for production in, and trade between Member States. In the few areas, where no harmonised certification yet exists, as indicated under Section 16 of this Guidance, third countries should take contact with Member States authorities to obtain information on national import conditions.

This document provides guidance primarily to the national authorities in third countries who are interested in exporting live animals and/or products thereof to the European Union.

Interested parties should always take contact with the European Commission (for contact details see Section 15) to check whether there have been any changes to the procedures described in this document, and for more detailed guidance in respect of particular production sectors.

It is also foreseen that other interested stakeholders can benefit from the information provided in this Guidance. In such a case they are advised to contact their national authorities if they wish further assistance, information and/or initiate approval procedures concerning imports into the European Union.

It should also be noted that, in view of the very wide range of products covered by this Guidance, some elements will not apply to all imports. Some of the key issues related to imports, especially from the public health point of view are highlighted in another guidance which is available on the webpage of the European Commission¹.

1. GENERAL PRINCIPLES

A detailed description of the sequence of individual steps and actions to be followed where a third country seeks approval is given in Section 8. In most cases, an on-the-spot inspection by the Commission inspection service of the Health and Consumers Directorate General, DG SANCO (FVO - Food and Veterinary Office located in Grange - Ireland) is required before approval can be considered. This is designed to evaluate whether the animal and public health situation, the official services, the legal provisions, the control systems and production standards, etc., meet EU requirements.

When the lists of authorised third countries or parts of third countries for animal health purposes are drawn up or amended, particular account is taken of:

¹ <u>http://ec.europa.eu/food/international/trade/interpretation_imports.pdf</u>

- (1) the health status of livestock, other domestic animals and wildlife in the third country, with special regard to exotic animal diseases and any aspects of the general health and the environmental situation in the third country which may pose a risk to the health and the environmental status of the Union;
- (2) the legislation of the third country on live animals and products of animal origin;
- (3) the organisation of the competent veterinary authority and its inspection services, the powers of those services, the supervision to which they are subject, and the means at their disposal, including staff and laboratory capacity, to apply national legislation effectively;
- (4) the assurances which the competent veterinary authority of the third country can give regarding compliance or equivalence with the relevant animal health conditions applicable in the Union;
- (5) whether the third country is a member of the World Organisation for Animal Health (OIE) and the regularity and rapidity of the information supplied by the third country relating to the existence of infectious or contagious animal diseases in its territory, in particular OIE listed diseases;
- (6) the guarantees given by the third country directly to inform the Commission and the Member States:
 - (a) within 24 hours of the confirmation of the occurrence of major serious diseases of concern and of any change in the vaccination policy concerning such diseases;
 - (b) within an appropriate period, of any proposed changes in the national health rules concerning relevant type of live animals, in particular regarding importation;
 - (c) at regular intervals, of the animal health status of its territory;
- (7) any experience of previous imports from the third country and the results of any import controls carried out;
- (8) the results of FVO inspections and/or audits carried out in the third country, in particular the results of the assessment of the competent authorities or, where the Commission so requests, the report submitted by the competent authorities on the inspections which they have carried out;
- (9) the rules on the prevention and control of infectious or contagious animal diseases in force in the third country and their implementation, including rules on the importation from other third countries.

When the lists of authorised third countries or parts of third countries for public health purposes are drawn up or amended, in addition to most of the above provisions, amended as applicable to the public health field, particular account is taken of:

- (1) the training of staff in the performance of official controls;
- (2) the resources, including diagnostic facilities available to the competent authorities;
- (3) the existence and operation of documented control procedures and control systems based on priorities;
- (4) the extent and operation of official controls on imports of animals and their products;
- (5) the assurances which the third country can give regarding compliance with, or equivalence to, Union requirements;

- (6) the hygiene conditions of production, manufacture, handling, storage and dispatch actually applied to products of animal origin destined for the European Union;
- (7) any experience of marketing of the product from the third country and the results of any import controls carried out;
- (8) the results of FVO inspections carried out in the third country, in particular the results of the assessment of the competent authorities, and the action that competent authorities have taken in the light of any recommendations addressed to them following a FVO inspection;
- (9) the existence, implementation and communication of an approved zoonoses control programme;
- (10) the use of veterinary medicinal products, including rules on their prohibition or authorisation, their distribution, their placing on the market and the rules covering administration and inspection;
- (11) the preparation and use of feedingstuffs, including the procedures for using additives and the preparation and use of medicated feedingstuffs, as well as the hygiene quality of the raw materials used for preparing feedingstuffs and of the final product;
- (12) the existence, implementation and communication of an approved residue control programme.

These lists drawn up for animal health and public health purposes may be but not necessarily combined with each other. In relation to the establishments of origin of animal products the national competent authorities must also guarantee that:

- (1) the conditions applied to the establishments from which feed and food may be imported into the EU comply with or are equivalent to the requirements in Union feed and food law;
- (2) a list of such establishments is drawn up and kept up to date;
- (3) the list of establishments and its updated versions are communicated to the Commission without delay;
- (4) the establishments are the subject of regular and effective controls by the competent authority of the third country.

For most commodities, where a request for approval is received by the Commission, a preliminary questionnaire, relating to the animals/products in question, will be sent to the national authorities. This is designed to assess whether EU requirements can be satisfied and to gather information prior to a possible on-the-spot inspection by the FVO. For further information a model of this questionnaire is included, under Section 16 of this Guidance.

Where the information provided by the national competent authorities is considered satisfactory, and the FVO inspection leads to a favourable recommendation, the Commission will adopt the necessary legislation to grant approval for imports after receiving a favourable opinion of the Standing Committee on the Food Chain and Animal Health² (comprising representatives of the Chief Veterinary Officers of the Member States). Approvals may cover all or part of a third country, reflecting the animal and public health situation and the nature of the animals/products for which approval is sought.

² http://ec.europa.eu/food/committees/regulatory/index_en.htm

2. ANIMAL HEALTH SITUATION

The third country must be a member of the OIE and have systems in place for the rapid detection, reporting and confirmation of the OIE listed diseases. It will also have to give a formal undertaking to notify the European Commission of outbreaks of major serious diseases within 24 hours of confirmation or any change in the vaccination policy concerning such diseases.

The third country must either have its own laboratory facilities that will allow this detection and confirmation to take place, or have formal agreements in place with suitable laboratories in other countries. Laboratories involved in official controls need to be accredited as of 1 January 2006. The competent authority may designate a non-accredited laboratory to perform official controls provided quality control schemes are in place and accreditation will be completed by 1 January 2010. From that date on laboratories must be accredited according to the international standards.

The extent, to which the animal disease situation will affect whether approval can be considered, or what conditions are linked to the approval, varies according to the type of animal or product concerned. For example, imports of live domestic biungulate animals have not been authorised from countries which vaccinate against foot and mouth disease (FMD), or where the disease is present. On the other hand, for fully treated meat products and milk based products, this would not cause a problem, because the causative pathogen is destroyed by appropriate heat or other specified treatments or by other risk mitigating factors. Further details are given in the legislation under Section 16 dealing with specific imports.

Animal disease control systems, whose operation and outcome must be recorded and demonstrable, must be in place. These would, for example, have to include the registration of holdings, animal identification and movement controls (traceability) so that compliance with EU health certification requirements can be confirmed. These certification requirements may provide, for example, that before slaughter an animal has spent a certain time period on a holding and in a region which is free of certain diseases.

Contingency plans for the control and/or eradication of outbreaks of certain OIE listed diseases of great importance should be in place and operational (the nature and extent of these plans will depend upon the nature of the animals or products for which approval is sought).

For live animal imports, a range of supplementary disease control/eradication programmes, as well as testing to demonstrate freedom from certain diseases, and reflecting the type of animals concerned, will have to be in place. Further details may be seen in the relevant chapters under Section 16 of this Guidance.

It should also be noted that for some animal products, additional animal health controls or risk management measures may be required, or risk management measures can be applied. For example, meat from countries where FMD vaccination is practised may undergo additional maturation procedures (including de-boning) to ensure virus destruction. In other cases, e.g. for the management of avian influenza or classical swine fever minimum treatment requirements are established for meat products to reflect the animal disease situation in the country concerned.

Without compromising the overall objective of ensuring the safety of the import, flexibility is shown wherever possible. For example, regarding outbreaks of highly

infectious animal diseases like FMD, while imports under unsafe conditions can not be accepted but where it is feasible, the principle of regionalisation is applied. This means that imports of live animals and products can be allowed from those defined regions of countries which satisfy the requirements, while banning imports from certain other regions in those countries which do not. With other words in case of the outbreak of an animal disease, restrictions are applied in the regions affected, with free movement of animals and products outside the affected regions. Only animals or products from nonaffected zones can be considered fit for export under certain conditions. The European Union is convinced that regionalisation is the best approach to maintain adequate disease control with minimum restrictions to trade.

Furthermore, there is also a possibility to import certain live animals from the nonauthorised countries, as it is allowed to move them from their country of birth to a third country appearing on the lists with a view of subsequent movement to the EU. In this case the minimum residency period in the authorised third country is six months. It is also worthy to note that St. Pierre and Miquelon is a listed third country in which the situation is ideal for this kind of import. Further to that, it even has a quarantine station where certain types of animals can remain under the satisfactory control of the official veterinary services within the facilities and can be subsequently imported into the EU after as little as two months.

The exporting country's import policy, including controls, and the animal health situation in neighbouring countries, will also be taken into account.

To illustrate the application of these provisions in practice, the reader is referred to detailed animal health import requirements for animals/products of currently approved countries, which can be found in the model certificates attached to the relevant EU legislation listed under Section 16 of this Guidance.

3. RESIDUES, CONTAMINANTS AND ADDITIVES CONTROLS

The EU has detailed legislation in place to control the use of, and monitoring for, a wide range of veterinary drugs and other substances in all classes of animals and products intended for human consumption. Legal controls over prohibited substances in respect of the animals and products intended for export must be in place in the third country.

It is a fundamental requirement for all third countries wishing to export to the EU that they have in place a monitoring programme for these substances that meets the requirements of this legislation in respect of the animals and/or animal products concerned. This programme must be submitted to the European Commission where it is evaluated and if the evaluation is favourable, approved.

Subsequently, the results of each year's programme, together with an updated programme for the coming year, must be submitted to the European Commission on an annual basis.

The relevant laboratory facilities must fulfil the same requirements as detailed in the second paragraph of Section 2 of this Guidance.

It may be acceptable for the monitoring programme and controls over prohibited substances, to be limited to specific sectors and individual holdings. However, such a separate export-oriented system would require effective registration, control, tracing and identification procedures, with a reliable, transparent, monitoring system in place, to be established. These procedures and system would be the subject of special evaluation as part of the approval process.

4. MICROBIOGICAL CONTROL

In order to be authorised for import of certain live animals and hatching eggs, third countries shall submit a *Salmonella* control programme for approval to the Commission. This requirement is gradually introduced to guarantee equivalence with EU requirements. Control programmes must be submitted already for the import of hatching eggs as well as for the import of day-old chicks and breeding and productive poultry of *Gallus gallus* and turkeys intended for breeding or egg production. The same requirement applies to import of day-old chicks for production (both for laying and fattening purposes).

Food safety criteria for several zoonotic pathogens such as *Salmonella* and *Listeria* apply to the import of certain foodstuffs.

5. FOOD SAFETY STANDARDS IN PROCESSING ESTABLISHMENTS

Standards in individual establishments proposed for approval must be at least equivalent to the requirements of the relevant EU legislation. These are the same as those laid down for establishments in Member States. The main legislation for each production sector is given in the relevant chapter of Section 16 of this Guidance.

The national competent authority should be confident that the above standards are met before an establishment is put forward to the Commission for approval. If this is found not to be the case at any subsequent on-the-spot inspection, this will reflect unfavourably on the evaluation of the authority's ability to deliver EU standards. The Commission has a variety of "pro formas" which should be completed by the competent authorities to request approval of processing establishments and confirm that they meet the relevant Union requirements.

Particular attention must be paid to the installation and operation of the permanent procedures of the establishment based on the HACCP principles, microbiological controls and an effective official control system, including documented records of control actions and their outcome. As from 1 January 2006, the implementation of HACCP based control systems are mandatory in all food production, processing and distribution establishments (except for establishments involved in primary production).

To avoid any conflict of interest and possible fraud, officials in processing establishments must be able to act independently of operators. There must be supervisory systems over these officials at regional and central levels.

As a general principle, establishments must meet EU standards during EU production runs, and may meet other standards at other times for their own national markets but such product must be kept strictly separate from product destined for the EU. In all cases, this issue should be clarified during inspection visits by the FVO.

6. **BSE-RELATED IMPORT CONTROLS**

Regulation (EC) No 999/2001 lays down rules for the determination of the BSE status of Member States, of third countries and of their regions which result in the classification in three categories: negligible BSE risk, controlled BSE risk and undetermined BSE risk.

The OIE should play a leading role in this process of the categorisation of countries. Pending the outcome of the OIE evaluation and the final decision on the BSE status of the importing country, the country has to comply with the import requirements applicable to countries with an undetermined BSE risk.

Commission Decision 2007/453/EC lays down the list of countries according to their BSE risk status in the three categories i.e. negligible BSE risk, controlled BSE risk and undetermined BSE risk.

The import measures regarding all forms of Transmissible Spongiform Encephalopathies (TSE) are laid down in Annex IX to Regulation (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies, as last amended. The import requirements into the Community of live animals, embryos, ova and products of animal origin are based on the BSE risk status of the countries and in line with the international standards adopted at the OIE.

7. NATIONAL AUTHORITY STANDARDS

It is essential that the national authority (often referred to as the "competent authority") is able to deliver the level of veterinary controls required. Any shortfall would mean that approval could not be considered, or that an existing approval might have to be revoked. As part of the approval process, a detailed questionnaire, relating to the sector for which approval is sought, is sent to the national authority. Amongst the various issues raised, the following are of particular importance in evaluating the authority's performance:

- (1) *Management structure*. This must ensure that there are adequate communication links between central, regional and local official services. The central authorities, who are answerable for standards, must be able to exercise control over regional and local services.
- (2) *Independence*. The official services must be independent of outside pressures, and be able to carry out their duties without undue restrictions. Individual officials must enjoy a status that ensures their independence from commercial concerns, and must not be dependent upon them for their livelihood, i.e. no conflict of interest and high ethical standards.
- (3) *Resources.* All levels of the official services, including border controls and laboratories, must have sufficient personnel, financial and equipment resources to allow them to carry out their control functions.
- (4) *Personnel.* All staff must enjoy an independent status within the official services. Where external staff is used, arrangements must be in place to ensure that they have the same degree of independence and accountability as full-time officials.

- (5) *Recruitment and training.* The competent authority must be able to show that vacancies are promptly filled, and that the operation of the official services is not damaged by shortages of suitably qualified personnel. Training programmes, so that staff can carry out their duties properly, should be in place, and properly recorded.
- (6) *Legal/enforcement powers.* These must be available to, and used by, the official services. The powers must be enshrined in national legislation and allow these services to carry out their control functions in an effective manner.
- (7) *Prioritisation and documentation of controls.* Official services should have in place written systems to prioritise their control activities, reflecting the risks posed by the different stages of the production chain. The planning, performance and outcome of these controls at central, regional and local levels should be recorded so that compliance with EU standards can be demonstrated. Ideally, internal audit systems should be in place to monitor the operation of these controls.
- (8) Laboratory services. There should be a properly resourced laboratory network, including a central reference laboratory, enjoying a status independent from producers/processors, and covering the whole country. It might, however, be acceptable to use laboratory facilities in other countries where these can be shown to offer the same level of service. Specific EU rules governing the operation and capabilities of these laboratories for particular production sectors must be respected. The duties of the laboratory network should be clearly established, as should reporting procedures when non-compliant results are detected. Links with international or EU reference laboratories should be established. The central competent authority must be able to direct the activities of the laboratory service which are relevant to the production sector concerned, even where it is not part of the same management structure. The relevant laboratory facilities must also fulfil the same requirements as detailed in the second paragraph of Section 2 of this Guidance.
- (9) *Import controls.* There must be effective import controls in place at the points of entry to the third country to safeguard the health status of the country. These must be properly staffed and resourced, and provided with the necessary legal powers to take control and enforcement action. In particular, the reception, handling, storage and onward transmission of animals and products intended for despatch to the EU, or for use in the production of EU-status products, must meet EU requirements and avoid risk of cross-contamination by non-eligible animals and products. The import policy of the country will also be assessed to ensure that the health status of the country is not jeopardised.
- (10) Animal health controls. There must be an effective system for the detection and notification of animal diseases relevant to the animals/products for export. This should include surveillance measures, farm registration, animal identification and movement controls, so that the eligibility of animals used in the manufacture of EU status products can be demonstrated (traceability). It may also require disease monitoring and control or eradication programmes to be in place. The prompt notification of confirmation of diseases must also be demonstrated.
- (11) *Food safety controls.* Details of the zoonoses covered by national legislation, and the control action taken, should be provided. Co-ordination procedures between

animal and public health authorities should be in place. Systems should be in place to record the actions taken, and their outcome, when zoonotic pathogens are identified. Traceability must be assured throughout the whole process of food of animal origin production.

8. COUNTRY APPROVAL PROCEDURE

The following sequence is generally followed (although it may vary according to the animal/product concerned):

- (1) The national authority submits a formal request for approval to the Commission services. This should include at least the following information:
 - (a) Type of animal/product for which approval is sought. Full details of all animal-origin products should be given;
 - (b) Anticipated volume of trade and main importing Member States;
 - (c) Class of animals (e.g. breeding, fattening, slaughter) involved;
 - (d) Description of minimum treatment (heat, maturation, acidification etc) applied to the products;
 - (e) Number and type of establishments considered to meet EU requirements

It should also include confirmation that all proposed establishments satisfy EU requirements. References to the appropriate EU legislation must be given.

- (2) Commission acknowledges request and sends the relevant pre-mission questionnaire.
- (3) National authority submits completed questionnaire, with the proposed residues monitoring programme for approval, and with copies of the national legislation applicable to the animals/products concerned (if English or French translations are provided this will speed up the processing of the dossiers).
- (4) Bilateral contacts between the national authorities and the Commission to resolve outstanding issues.
- (5) If the Commission is satisfied with the information provided, an on-the-spot inspection is (in most cases) organised by the FVO.
- (6) Following completion of the FVO inspection, a copy of its report is sent to the national authorities, the relevant Commission services, the European Parliament and the Member States.³
- (7) If the outcome of the mission is satisfactory, and any other outstanding issues have been resolved, the Commission prepares draft legislation:
 - (a) to add the third country to the list of third countries from which imports of the animal/product are approved;

³ Reports of the FVO are also published on the website of DG SANCO: <u>http://ec.europa.eu/food/fvo/index_en.cfm</u>

- (b) to draw up if necessary animal health certification based on the country or part of the country's health situation to accompany imports, (a number of model health certificates are already laid down in Union legislation);
- (c) to approve the residues monitoring programme;
- (d) to set up an initial list of approved establishments.⁴

It must be noted however that the approval of residue programs, the adding a country on a list for animal health purposes, the requirements for public health purposes and the listing of the approved establishments are done by different Commission services and often under different legal acts. Appearance in one of them is not a precondition for the inclusion on another list. For example, the inclusion on the residue list does not affect in any way the possible inclusion on the animal health list. In this regard the third country can choose its approach as to how and in what order to launch applications for approval, some of their elements can be done parallel. Generally, it is advised to start with the animal health listing because usually this may be the most difficult to comply with, and it would not be cost effective to build a slaughterhouse and then discover that export of meat cannot be authorised for animal health reasons.

- (8) The proposed legislative texts are adopted by the Commission, and published in the Official Journal, after a favourable opinion of the Standing Committee on the Food Chain and Animal Health has been received.
- (9) If an implementation date is not specified in the legislative text then it will be the date of official notification of the text by the Commission to Member States.

9. ANIMAL WELFARE PROVISIONS

The EU animal welfare requirements are also applicable in relation to the import of live animals and products of animal origin. They have paramount importance in particular in two major areas that are the handling of animals during slaughter for human consumption and the welfare requirements concerning the transport of most of live animals.

In relation to the import of certain products the animal welfare requirements are incorporated into the import certificates in the form of an attestation and the veterinary authority of the country of origin has to certify them together with the animal and public health requirements.

In relation to the transport of live animals from third countries the animal welfare requirements are both incorporated into the import certificates and also directly apply and are enforceable by the veterinary authorities of the Member States once the consignment reaches the veterinary border inspection post (BIP) of entry. In order to transport animals within the EU (including import and transit consignments) transporters need to be

⁴ Lists of currently approved establishments sorted either by country or by product are available under: <u>http://ec.europa.eu/food/international/trade/third_en.htm</u> Procedure on how to add them onto existing lists using a standard application form and contact details are available under: <u>http://ec.europa.eu/food/food/biosafety/establishments/third_country/information_en.htm</u>

authorised by a Member State, pre-approval of the vehicles is necessary and from January 2008 drivers will need a certificate of competence issued by a competent authority of a Member State or by a body designated by that competent authority. As these and other animal welfare requirements are thoroughly checked at the BIPs, veterinary authorities at the country of origin should be aware of them. Consignments that do not meet them (e.g. unfit animals, overstocked trucks, insufficient head space, transporters not authorised by a Member State, lack of journey log for leg of long distance journey within EU etc.) will, at the very least, be delayed.

10. HEALTH CERTIFICATION

Imports of animals and animal products into the EU must, as a general rule, be accompanied by the health certification laid down in EU legislation. This sets out the conditions that must be satisfied, and the checks that must have been undertaken, if imports are to be allowed. The details of the certification required are set out in specific EU legislation, which includes models of the certificates to be used.

The certification must be signed by an official veterinarian or official inspector (as indicated in the relevant certificate), and must respect the provisions of Council Directive 96/93/EC on the certification of animals and animal products. Strict rules apply to the production, signing and issuing of certificates, as they confirm compliance with EU rules. The original version of the certificate must accompany consignments on entry into the European Union. Certificates must normally be drawn up in the language of the country of dispatch and both of the Member State of destination and of the Member State in which the border inspection takes place although these Member States can agree if they so wish to accept any official EU language other than their own on the certificates.

Each category of animal and product has its own set of animal and/or public health requirements, which may include welfare requirements (e.g. at stunning and slaughter). Particular attention must be paid to ensure that the correct certification is used, and that all of its provisions have been met.

In some cases, especially for the import of animal by-products intended for technical use, the use of commercial document and/or a declaration by the importer is allowed instead of a veterinary certificate.

11. BORDER INSPECTION UPON ENTRY TO THE EU

For introduction into the European Union of import and transit consignments of animals or products of animal origin, they must enter via an approved BIP located in a Member State. BIPs are placed under the authority of official veterinarians, who are effectively responsible for health checks on incoming consignments.

According to EU legislation each consignment of live animals and products of animal origin must be subject to official veterinary checks in the border inspection. The official controls include at least a systematic documentary check, identity check and, as appropriate, a physical check. In some cases the frequency of physical checks can be reduced and they depend on the risk profile of the product and also on the results of previous checks.

Although the procedural aspects of the entry of consignments are mainly the responsibility of the importer, or as it is often the case shared between importer, exporter and transporter, including perhaps other agents, it must be mentioned that live animal consignments need to be pre-notified to the BIP 24 hours before arrival and product consignments before arrival in the BIP with the first part of the so-called common veterinary entry documents (CVED) filled in as appropriate. Due to a recently developed veterinary computer application (Trade Control and Expert System-TRACES) this could also be done by an electronic transmission. There is extensive EU legislation concerning many other aspects of the entry procedure.

Consignments which are found not to be compliant with EU legislation will either be destroyed or, under certain conditions, re-dispatched within 60 days. If any one of the checks however indicates that a consignment of animals or products is likely to constitute a danger to animal or human health, the consignment in question will be seized and destroyed by the competent authorities immediately.

Additional information on TRACES can be found at: <u>http://ec.europa.eu/food/animal/diseases/traces/index_en.htm</u>

12. TRANSIT REQUIREMENTS

In general and in accordance with the animal health rules laid down in the different sectoral legislation, consignments of live animals and animal products transiting or in the case of products, being temporarily stored in the EU must comply with the EU animal health requirements. This compliance is checked at the BIPs of entry and specific certification is required. The relevant detailed rules are contained in the list of legislation given in Section 16 of this Guidance. This applies only to the animal health requirements as there are no requirements for transit and/or storage for public health.

13. PERSONAL IMPORTS

Personal imports of meat and milk bought into the EU continue to present a real threat to animal health throughout the EU as it is known that dangerous pathogens that cause animal diseases such as foot and mouth disease and classical swine fever can reside in them. Hence pathogens could be introduced into the EU by such products originating in third countries where pathogens may be circulating, either in postal packages or in the baggage of travellers arriving from outside the EU.

The EU has measures in place to permanently prohibit all personal consignments of meat, meat products, milk and milk products from entering the EU, including packages sent to private persons, unless specifically authorised, certified as being eligible for EU entry and subject to declaration of the goods on arrival together with the necessary official veterinary documentation (i.e. the same as for commercial imports). The legislation also sets down specific provisions that allow the Member States the organisation of controls at EU entry points to detect the presence of illegal consignments, the deployment of appropriate detection aids such as scanning equipment and sniffer dogs where necessary, the seizure and destruction of personal consignments that are found to be in breach of the rules and to impose penalties on those travellers that are found to be breaking the rules.

Travellers are, however, allowed to bring in limited quantities of infant or specialist food required for medical purposes from all third countries, providing that those comply with

certain provisions and also special personal consignments from a very limited number of countries fall outside the scope of the Regulation.

There is also a requirement for international transport operators to inform passengers they carry into the European Union and postal services of the rules governing personal imports of meat and milk. This includes provisions to make use of existing means of passenger communication, such as web sites, leaflets, in-flight magazines and videos to publicise the rules.

14. NEW FRAMEWORK LEGISLATION

It should be noted that several new pieces of framework legislation have been adopted in recent years in the areas of animal and public health. Their aim is to merge, harmonise and simplify very detailed and complex requirements previously scattered over numerous EU Directives. The overall aim is to create a single, transparent policy applicable to all food and all food operators, together with effective instruments to manage food safety and prevent as much as possible potential future food crises, throughout the food chain (also known as "from stable to table" or "from farm to fork" approach. While these laws do not represent fundamental changes in the principles described above, they supersede the former legal frameworks by creating new ones for production, processing, distribution and introduction of live animals and products of animal origin and for their official control.

General hygiene rules have been laid down for the production of all food, while specific rules have been laid down for meat and meat products, bivalve molluscs, fishery products, milk and dairy products, eggs and egg products, frogs' legs and snails, animal fats and greaves, gelatine and collagen. The new hygiene laws and their official control⁵ are applicable as of 1 January 2006.

As regards to animal health rules, Council Directive 2002/99/EC laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption has been applicable since 1 January 2005⁶, while Council Directive 2004/68/EC laying down animal health rules for the importation into and transit through the Community of certain live ungulate animals has been applied since 20 November 2005.

15. INITIAL CONTACT

Inquiries from competent veterinary authorities of third countries concerning imports of animals and animal products into the European Union or their transit should be addressed, in the first instance, to:

Mr Bernard Van Goethem Director, DG Health and Consumers

⁵ Furter information is available under: http://ec.europa.eu/food/food/biosafety/hygienelegislation/index_en.htm

⁶ Detailed information on all animal health rules concerning products are available on the Internet under; http://ec.europa.eu/food/animal/animalproducts/index_en.htm

Directorate D - Animal Health and Welfare Rue Belliard 232, 03/085 B-1049 Brussels E-mail: Bernard.Van-Goethem@ec.europa.eu Internet: http://ec.europa.eu/food/index_en.htm

All other interested parties and private businesses should contact their competent veterinary authority.

The general guidance document can be found at the following website address:

http://ec.europa.eu/food/international/trade/index_en.htm

The European Union provides technical assistance and facilities for institutional capacity building to help developing countries comply with EU rules. Additional, national and regional development programmes of the EU are available in individual countries, as well as bilateral aid projects of the Member States. The delegations of the EU can provide detailed information on such assistance. For more details, see:

http://ec.europa.eu/external_relations/delegations/web_en.htm

The European Union may also assist third countries, particularly developing countries familiarise themselves with EU import requirements. For this purpose, training organised for Member States in the EU are often also open to participants from third countries. Specific training sessions may also be organised for third country participants on the spot. For more details, see:

http://ec.europa.eu/food/training_strategy/index_en.htm

16. EU LEGISLATION OF RELEVANCE

16.1. Official contact details

The following legal acts can be accessed:

- either through the free on-line EUR-Lex database: <u>http://eurlex.europa.eu</u> (a helpdesk is available for technical questions: <u>helpdesk-online-opoce@ec.europa.eu</u>) or
- by any of the official sales agents for persons interested in paper copies (list of the sales offices: <u>http://publications.europa.eu/eu_bookshop/index_en.htm</u>

Further information about these publications may be obtained through the Office for Official Publications of the European Union which is the publishing house of the institutions of the European Union and is responsible for publishing, distributing, promoting and marketing the publications of all the EU institutions by means of its distribution network:

Office for Official Publications of the European Union 2, rue Mercier 2985 Luxembourg Tel: (352) 2929-1 E-mail: <u>opoce-info-info@ec.europa.eu</u> Website: <u>http://bookshop.europa.eu/</u>

Practical advice

Given the necessity to maintain full knowledge of the consolidated legislation and considering the fact that any amending legislation contains in its title at least the number of the amended legislation, as a purely practical assistance for those who wish to use the Internet to obtain legislation, the following approach is recommended:

- 1. Visit the following site (click on or copy and paste into browser): <u>http://eur-lex.europa.eu/RECH_mot.do</u>
- 2. By pressing the *search* button, it will be possible to perform a *search using search terms*. If the number of the basic legislation is typed into the *search for* field, after pressing the *search* button again, the result will provide both the basic legislation, and all its every amendments still in force ordered by date. The legislation available in .pdf format can be studied right away. Nevertheless some of the legislation can be displayed in .html format and therefore will not be convenient to work with. Moreover such texts do not contain any tables, lists and certificates. However, even the data for this legislation will contain the reference to the Official Journal where it was published, including the relevant pages.
- 3. In the latter case, having the correct reference to the publication in the Official Journal, one can either obtain the relevant copy from the addresses above or visit the http://eur-lex.europa.eu/en/index.htm page and after pressing the Official Journal button in the top left corner, search for and download the official version.

The information provided below is not intended to be an exhaustive list of legislation. It is provided for guidance purposes only and interested parties should always refer to the legislation as last amended. The authorities of the country seeking approval to export to the European Union are responsible for ensuring that all relevant EU legislative requirements are met. Some of this legislation can be frequently amended therefore care is needed in particular to ensure that any modifications to the legislation are taken into account. Copies of the legislation can be obtained from the contact points given above.

16.2. General legislation in force

Council Directive 88/407/EEC of 14 June 1988 laying down the animal health requirements applicable to intra-community trade in and imports of **semen of domestic animals** of the bovine species

OJ L 194, 22.7.1988, p. 10

Council Directive 89/556/EEC of 25 September 1989 on animal health conditions governing intra-Community trade in and importation from third countries of **embryos** of domestic animals of the **bovine** species

OJ L 302, 19.10.1989, p. 1

Council Directive 90/429/EEC of 26 June 1990 laying down the animal health requirements applicable to intra-Community trade in and imports of **semen of** domestic animals of the **porcine** species

OJ L 224, 18.8.1990, p. 62

Council Directive 2009/158/EC on animal health conditions governing intra-Community trade in and imports from third countries of **poultry and hatching eggs**

OJ No. L 343, 22.12.2009, p. 74

Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organization of **veterinary checks on animals entering the Community** from third countries and amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC

OJ L 268, 24.9.1991, p.56

Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of **animals, semen, ova and embryos** not subject to animal health requirements laid down in specific Community rules referred to in Annex A (I) to Directive 90/425/EEC

OJ L 268, 14.9.1992, p. 54

Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC, (see also section 16.6)

OJ L 62, 15.3.1993, p. 49

Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products

OJ L 13, 16.1.1997, p. 28

Council Regulation (EC) No 2406/96 of 26 November 1996 laying down common marketing standards for certain **fishery products**

OJ L 334, 23.12.1996, p. 1

Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of **veterinary checks on products entering the Community** from third countries

OJ No L 24, 30.1.1998, p. 9

Council Directive 98/83/ECof 3 November 1998 relating to the **quality of water** intended for human consumption

OJ L 330, 5.12.1998, p. 32

Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain **transmissible spongiform encephalopathies**

OJ L 147, 31.05.2001, p. 1

Commission Regulation (EC) No 2065/2001 of 22 October 2001 laying down detailed rules for the application of Council Regulation (EC) No 104/2000 as regards **informing consumers about fishery and aquaculture products**

OJ L 278, 23.10.2001, p. 6

Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the **general principles and requirements** of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

OJ L 31, 1. 2.2002, p. 1

Regulation (EC) No 1069/2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation)*OJ No. L 300, 14.10.2009, p. 1*)

Council Directive 2002/99/EC of 16 December 2002 laying down the **animal health rules** governing the production, processing, distribution and introduction of **products of animal origin for human consumption**

OJ L 18, 23.1.2003, p. 11

Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of **salmonella** and **other specified food-borne zoonotic agents**

(OJ L 325, 12.12.2003, p. 1)

Council Directive 2004/68/EC of 26 April 2004 laying down animal health rules for the importation into and transit through the Community of certain **live ungulate animals**, amending Directives 90/426/EEC and 92/65/EEC and repealing Directive 72/462/EEC

OJ L 139, 30. 4.2004, p. 321, corrigendum by OJ, L 226, 25. 6.2004, p. 128

Commission Decision 2004/407/EC of 26 April 2004 on transitional sanitary and certification rules under Regulation (EC) No 1774/2002 of the European Parliament and of the Council as regards import from certain third countries of **photographic gelatine**

OJ L 151, 30. 4.2004, p. 11

Commission Regulation (EC) No 878/2004 of 29 April 2004 laying down transitional measures for certain animal by-products defined as Category 1 and Category 2 materials, in accordance with Regulation (EC) No 1774/2002 of the European Parliament and of the Council,

OJ L 162, 30.4.2004, p.62.

Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the **hygiene of foodstuffs**

OJ L 139, 30. 4.2004, p. 1 corrigendum by OJ L 226, 25. 6.2004, p. 3

Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down **specific hygiene rules for food of animal origin**

OJ L 139, 30. 4.2004, p. 55 corrigendum by OJ L 226, 25. 6.2004, p. 22

Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of **official controls** on products of animal origin intended for human consumption

OJ L 139, 30. 4.2004, p. 206, corrigendum by OJ L 226, 25. 6.2004, p. 83

Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on **official controls** performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules

OJ L 165, 30. 4.2004, p. 1, corrigendum by *OJ L* 191, 28. 5.2004, p. 1

Commission Regulation (EC) No 2073/2005 of 15 November 2005 on **microbiological criteria** for foodstuffs

OJ L 338, 22.12.2005, p. 1

Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down **implementing measures** for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004

OJ L 338, 22.12.2005, p. 27

Commission Regulation (EC) No 2075/2005 of 5 December 2005 laying down specific rules on **official controls for Trichinella** in meat

OJ L 338, 22.12.2005, p. 60

Commission Regulation (EC) No 2076/2005 of 5 December 2005 laying down **transitional arrangements** for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004

OJ L 338, 22.12.2005, p. 83

Commission Regulation (EC) No 1192/2006 of 4 August 2006 implementing Regulation (EC) No 1774/2002 of the European Parliament and of the Council as regards lists of approved plants in Member States,

OJ L 215, 5.8.2006, p.10.

Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for **aquaculture animals and products thereof**, and on the prevention and control of certain diseases in aquatic animals

OJ L 328, 24.11.2006, p. 14

Directive 2006/113/EC of the European Parliament and of the Council of 12 December 2006 on the **quality required of shellfish waters**

OJ L 376, 27.12.2006, p. 14

Commission Directive 2008/5/EC of 30 January 2008 concerning the compulsory indication on the **labelling of certain foodstuffs** of particulars other than those provided for in Directive 2000/13/EC of the European Parliament and of the Council

OJ L 27, 31.1.2008, p. 12

Council Regulation (EC) No 1005/2008 of 29 September 2008 establishing a Community system to prevent, deter and eliminate illegal, unreported and unregulated fishing, amending Regulations (EEC) No 2847/93, (EC) No 1936/2001 and (EC) No 601/2004 and repealing Regulations (EC) No 1093/94 and (EC) No 1447/1999

OJ L 286, 29.10.2008, p. 1

16.3. Animal welfare legislation

Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing

(OJ No. L 303, 18.11.2009, p. 1)

Council Regulation (EC) No 1/2005 of 22 December 2004 on the **protection of animals during transport** and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97

OJ L 3, 5.1.2005, p. 1

Council Directive 2007/43/EC of 28 June 2007 laying down minimum rules for the **protection of chickens** kept for meat production

OJ L 182, 12.7.2007, p. 19

16.4. Materials in contact with foodstuffs

Council Directive 78/142/EEC of 30 January 1978 on the approximation of the laws of the Member States relating to **materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs**

OJ L 44, 15.2.1978, p. 15

Council Directive 85/572/EEC of 19 December 1985 laying down the list of **simulants to be used for testing migration of constituents of plastic materials** and articles intended to come into contact with foodstuffs

OJ L 372, 31.12.1985, p. 14

Commission Directive 2002/72/EC of 6 August 2002 relating to **plastic materials and articles** intended to come into contact with foodstuffs

OJ L 220, 15.8.2002, p. 18

Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on **materials and articles intended to come into contact with food** and repealing Directives 80/590/EEC and 89/109/EEC

OJ L 338, 13.11.2004, p. 4

Commission Directive 2007/42/EC of 29 June 2007 relating to materials and articles made of **regenerated cellulose film** intended to come into contact with foodstuffs

OJ L 172, 30.6.2007, p. 71

16.5. Residue and contaminant controls

Council Directive 96/23/EC of 29 April 1996 on measures to monitor **certain substances and residues thereof** in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC

OJ L 125, 23.5.1996, p. 10

Commission Decision 98/179/EC of 23 February 1998 laying down detailed rules on official sampling for the monitoring of certain substances and residues thereof in live animals and animal products

OJ L 65, 5.3.1998, p. 31

Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on **undesirable** substances in animal feed

OJ L 140, 30.5.2002, p. 10

Commission Decision 2002/657/EC of 12 August 2002 implementing Council Directive 96/23/EC concerning the performance of **analytical methods and the interpretation of results** *OJ L 221, 17.8.2002, p. 8*

Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the **methods of** sampling and analysis for the official control of the levels of **mycotoxins** in foodstuffs

OJ L 70, 9.3.2006, p. 12

Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for **certain contaminants** in foodstuffs

OJ L 364, 20.12.2006, p. 5

Commission Regulation (EC) No 1883/2006 of 19 December 2006 laying down methods of **sampling and analysis** for the official control of levels **of dioxins and dioxin-like PCBs** in certain foodstuffs

OJ L 364, 20.12.2006, p. 32

Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the **methods of** sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs

OJ L 88, 29.3.2007, p. 29

Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on **food additives**

OJ L 354, 31.12.2008, p. 16

Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of **residue limits of pharmacologically active substances in foodstuffs of animal origin**, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council

OJ L 152, 16.6.2009, p. 11

Commission Regulation (EU) No 37/2010 of 22 December 2009 on **pharmacologically active substances** and their **classification regarding maximum residue limits** in foodstuffs of animal origin

OJ L 15, 20.1.2010, p. 1

16.6. Lists of approved third countries, certification requirements, and in addition for germinal products, list of approved centres and teams

Commission Regulation (EU) 206/2010 of 12 March 2010 laying down lists of **third countries**, territories or parts thereof authorised for the introduction into the European Union of certain animals and fresh meat and the **veterinary certification** requirements

OJ L 73, 20.03.2010, p. 1

Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of **products not subject to the said requirements laid down in specific Community rules** referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC

OJ L 62, 15.3.1993, p. 49

Commission Decision 92/260/EEC of 10 April 1992 on animal health conditions and veterinary certification for **temporary admission of registered horses**

OJ L 130, 15.5.1992, p. 67

Commission Decision 93/195/EEC of 2 February 1993 on animal health conditions and veterinary certification for the re-entry of registered horses for racing, competition and cultural events after temporary export

OJ L 86, 6.4/1993, p. 1

Commission Decision 93/196/EEC of 5 February 1993 on animal health conditions and veterinary certification for imports of equidae for slaughter

OJ L 86, 6.4.1993, p. 7

Commission Decision 93/197/EEC of 5 February 1993 on animal health conditions and veterinary certification for imports of registered equidae and equidae for breeding and production

OJ L 86, 6.04.1993, p. 16

Commission Decision 96/539/EC of 4 September 1996 on animal health requirements and veterinary certification for imports into the Community of semen of the equine species

OJ L 230, 11.9.1996, p. 23

Commission Decision 96/540/EC of 4 September 1996 on animal health requirements and veterinary certification for imports into the Community of ova and embryos of the equine species OJ L 230, 11.9.1996, p. 28

Commission Decision 2000/572/EC of 8 September 2000 laying down animal and public health conditions and veterinary certification for imports of meat preparations from third countries and repealing Decision 97/29/EC

OJ L 240, 23.9.2000, p. 19

Commission Decision 2001/183/EC of 22 February 2001 laying down the sampling plans and diagnostic methods for the detection and confirmation of certain fish diseases and repealing Decision 92/532/EEC

OJ L 67, 9.3.2001, p. 65

Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation.

OJ L 273, 10.10.2002, p. 1

Regulation (EC) No 998/2003 of the European Parliament and of the Council of 26 May 2003 on the animal health requirements applicable to the non-commercial movement of pet animals and amending Council Directive 92/65/EEC

OJ L 146, 13.6.2003, p. 1

Commission Decision 2003/779/EC of 31 October 2003 laying down animal health requirements and the veterinary certification for the import of animal casings from third countries OJ L 285, 1.11.2003, p. 38

Commission Decision 2003/812/EC of 17 November 2003 drawing up lists of third countries from which Member States are to authorise imports of certain products for human consumption subject to Council Directive 92/118/EEC

OJ L 305, 22.11.2003, p. 17

Commission Regulation (EU) No 206/2010 of 12 March 2010 laying down lists of third countries, territories or parts thereof authorised for the introduction into the European Union of certain animals and fresh meat and the veterinary certification requirements

OJ L 73, 20.03.2010, p.1

Commission Decision 2004/211/EC of 6 January 2004 establishing the list of third countries and parts of territory thereof from which Member States authorise imports of live equidae and semen, ova and embryos of the equine species, and amending Decisions 93/195/EEC and 94/63/EC OJ L 73, 11.3.2004, p. 1

Commission Regulation (EU) 605/2010 of 2 July 2010 laying down animal and public health and veterinary certification conditions for the introduction into the European Union of raw milk and dairy products intended for human consumption

OJ L 175, 00.07.2010, p. 1,

Commission Decision 2004/595/EC of 29 July 2004 establishing a model health certificate for the importation into the Community for trade of **dogs, cats and ferrets**

OJ L 266, 13.8.2004, p. 11

Commission Decision 2004/639/EC of 6 September 2004 laying down the importation conditions of **semen of** domestic animals of the **bovine** species

OJ L 292, 15.9.2004, p. 21

Commission Decision 2005/64/EC of 26 January 2005 implementing Council Directive 92/65/EEC as regards import conditions for **cats, dogs and ferrets** for approved bodies, institutes or centres *OJ L 27, 29.1.2005, p. 48*

Commission Decision 2005/290/EC of 4 April 2005 on simplified certificates for the importation of **bovine semen and fresh pig meat** from Canada and mending Decision 2004/639/EC *OJ L 93, 12.4.2005, p. 34*

Commission Decision 2006/168/EC of 4 January 2006 establishing the animal health and veterinary certification requirements for imports into the Community of **bovine embryos** and repealing Decision 2005/217/EC

OJ L 57, 28.2.2006, p. 19

Commission Decision 2006/766/EC of 6 November 2006 establishing the lists of third countries and territories from which imports of **bivalve molluscs**, echinoderms, tunicates, marine gastropods and fishery products are permitted

OJ L 320, 18.11.2006, p. 53

Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004

OJ L 338, 22.12.2005, p. 2

Commission Regulation (EC) No 318/2007 of 23 March 2007 laying down animal health conditions for **imports of certain birds** into the Community and the quarantine conditions thereof (see also section 16.11)

OJ L 84, 24.3.2007, p. 7

Commission Regulation (EC) No 2007/2006 of 22 December 2006 implementing Regulation (EC) No 1774/2002 of the European Parliament and of the Council as regards the importation and transit of certain **intermediate products** derived from Category 3 material intended for technical uses in medical devices, in vitro diagnostics and laboratory reagents and amending that Regulation *OJ L 379, 28.12.2006, p. 98*

Commission Decision 2007/240/EC of 16 April 2007 laying down **new veterinary certificates** for importing live animals, semen, embryos, ova and products of animal origin into the Community pursuant to Decisions 79/542/EEC, 92/260/EEC, 93/195/EEC, 93/196/EEC, 93/197/EEC, 95/328/EC, 96/333/EC, 96/539/EC, 96/540/EC, 2000/572/EC, 2000/585/EC, 2000/666/EC, 2002/613/EC, 2003/56/EC, 2003/779/EC, 2003/804/EC, 2003/858/EC, 2003/863/EC, 2003/881/EC, 2004/407/EC, 2004/438/EC, 2004/595/EC, 2004/639/EC and 2006/168/EC

OJ L 104, 21.4.2007, p. 37

Commission Decision 2007/453/EC of 29 June 2007 establishing the **BSE status** of Member States or third countries or regions thereof according to their BSE risk *OJ L 172, 30.6.2007, p. 84*

Commission Decision 2007/777/EC of 29 November 2007 laying down the animal and public health conditions and model certificates for imports of **certain meat products and treated stomachs, bladders and intestines** for human consumption from third countries and repealing Decision 2005/432/EC

OJ L 312, 30.11.2007, p. 49

Commission Decision 2008/635/ECof 22 July 2008 on imports of **semen**, **ova and embryos of the ovine and caprine species** into the Community as regards lists of third countries and of semen collection centres and embryo collection teams, and certification requirements

OJ L 206, 2.8.2008, p. 17

Commission Decision 2008/636/EC of 22 July 2008 establishing the list of third countries from which Member States authorise imports of **ova and embryos of the porcine species** *OJ L 206, 2.8.2008, p. 32*

Commission Regulation (EC) 798/2008 of 8 August 2008 laying down a list of third countries, territories, zones or compartments from which **poultry and poultry products** may be imported into and transit through the Community and the veterinary certification requirements

OJ L 226, 23.8.2008, p. 1.

Commission Regulation (EC) No 1251/2008 of 12 December 2008 implementing Council Directive 2006/88/EC as regards conditions and certification requirements for the placing on the market and the import into the Community of **aquaculture animals and products** thereof and laying down a list of vector species

OJ L 337, 16.12.2008, p. 41

Commission Decision 2008/946/EC of 12 December 2008 implementing Council Directive 2006/88/EC as regards requirements for quarantine of aquaculture animals

OJ L 337, 16.12.2008, p. 94

Commission Regulation (EC) No 1291/2008 of 18 December 2008 concerning the approval of control programmes for salmonella in certain third countries in accordance with Regulation (EC) No 2160/2003 of the European Parliament and of the Council and listing of avian influenza surveillance programmes in certain third countries and amending Annex I to Regulation (EC) No 798/2008. *OJ L340, 19.11.2008, p. 22*

Commission Regulation (EC) No 119/2009 of 9 February 2009 laying down a list of third countries or parts thereof, for imports into transit through the Community of **meat of wild leporidae and of farmed rabbits** and the veterinary certification requirements

OJ L 39, 10.2.2009, p. 12

Commission Decision 2009/893/EC of 30 November 2009 on importation of **semen of domestic animals of the porcine species** into the Community as regards lists of third countries and of semen collection centres, and certification requirements.

OJ L 320, 05.12.2009, p. 12

Commission Regulation (EU) No 388/2010 of 6 May 2010 implementing Regulation (EC) No 998/2003 of the European Parliament and of the Council as regards the maxi-mum number of pet animals of certain species that may be the subject of non- commercial movement

OJ L 07.05.2010, p. 3.

Commission Decision 2010/57/EU of 3 February 2010 laying down health guarantees for the transit of equidae being transported through the territories listed in Annex I to Council Directive 97/78/EC *OJ L 32, 4.2.2010, p. 9*

List of approved **semen collection centres and semen storage centres** for imports of **bovine semen** from third countries:

http://ec.europa.eu/food/animal/semen_ova/bovine/index_en.htm

List of approved **embryo collection and production teams** for imports of **bovine embryos** from third countries:

http://ec.europa.eu/food/animal/semen_ova/bovine/ova_embryos_en.htm

List of approved **semen collection centres and semen storage centres** for imports of **equine semen** from third countries:

http://ec.europa.eu/food/animal/semen_ova/equine/index_en.htm

List of approved **embryo collection and production teams** for imports of **equine embryos** from third countries:

http://ec.europa.eu/food/animal/semen_ova/equine/index_en.htm

List of approved **semen collection centres and semen storage centres** for imports of **ovine and caprine semen** from third countries:

http://ec.europa.eu/food/animal/semen_ova/ovine/index_en.htm

List of approved **embryo collection and production teams** for imports of **ovine and caprine embryos** from third countries:

http://ec.europa.eu/food/animal/semen_ova/ovine/index_en.htm

List of approved **semen collection centres** for imports of **porcine semen** from third countries: <u>http://ec.europa.eu/food/animal/semen_ova/porcine/index_en.htm</u>

List of approved **embryo collection and production teams** for imports of **porcine embryos** from third countries:

http://ec.europa.eu/food/animal/semen_ova/porcine/ova_embryos_en.htm

16.7. Lists and provisional lists of approved third country establishments: products for human consumption

Commission Decision 97/252/EC of 25 March 1997 drawing up provisional lists of third country establishments from which the Member States authorize imports of **milk and milk products for human consumption.**

OJ L 101, 18.4.1997, p. 46

Commission Decision 97/365/EC of 26 March 1997 drawing up provisional lists of third country establishments from which the Member States authorize imports of **products prepared from meat of bovine animals, swine, equidae and sheep and goats**

OJ L 154, 12/06.1997, pP. 41

Commission Decision 97/467/EC of 7 July 1997 drawing up provisional lists of third country establishments from which the Member States authorize imports of **rabbit meat and farmed game meat**

OJ L 199, 26.7.1997, p. 57

Commission Decision 97/468/EC of 7 July 1997 drawing up provisional lists of third country establishments from which the Member States authorize imports of **wild game meat** *OJ L 199, 26.7.1997, p. 62*

Commission Decision 97/569/EC of 16 July 1997 drawing up provisional lists of third country establishments from which the Member States authorize imports of **meat products** *OJ L 234, 26.8.1997, p. 16*

Commission Decision 99/120/EC of 27 January 1999 drawing up provisional lists of third country establishments from which the Member States authorize imports of **animal casings** *OJ L 36, 10.2.1999 p. 21*

Commission Decision 99/710/EC of 15 October 1999 drawing up provisional lists of third country establishments from which the Member States authorise imports of **minced meat and meat preparations**

OJ L 28, 4.11.1999, p. 82

Commission Decision 2001/556/EC of 11 July 2001 drawing up provisional lists of third country establishments from which Member States authorise imports of **gelatine intended for human consumption**

OJ L 200, 25.7.2001, p. 23

COMMISSION DECISION 2002/840/EC of 23 October 2002 adopting the list of approved facilities in third countries for the irradiation of foods. *OJ L 287, 25.10.2002, p. 40*

16.8. Legislation related to pet animals

Regulation (EC) No 998/2003 of the European Parliament and of the Council of 26 May 2003 on the animal health requirements applicable to the non-commercial movement of **pet animals** and amending Council Directive 92/65/EEC

OJ L 146, 13.6.2003, p. 1

Commission Decision 2004/301/EC of 30 March 2004 derogating from Decisions 2003/803/EC and 2004/203/EC as regards the **format for certificates and passports** for the non-commercial movement of dogs, cats and ferrets and amending Decision 2004/203/EC

OJ L 98, 2.4.2004, p. 55

Commission Decision 2004/824/EC of 1 December 2004 establishing a **model health certificate** for non-commercial movements of dogs, cats and ferrets from third countries into the Community *OJ L 358, 3.12.2004, p. 12*

Commission Decision 2004/839/EC of 3 December 2004 establishing conditions for noncommercial movements of **young dogs and cats** from third countries into the Community *OJ L 361, 8.12.2004, p. 40*

16.9. Legislation related to border inspection post (BIP) procedures

Commission Decision 94/360/EC of 20 May 1994 on the **reduced frequency of physical checks** of consignments of certain products to be implemented from third countries, under Council Directive 90/675/EEC

OJ L 158, 25.6.1994, p. 41

Commission Decision 97/794/EC of 12 November 1997 laying down certain detailed rules for the application of Council Directive 91/496/EEC as regards **veterinary checks on live animals** to be imported from third countries

OJ L 323, 26.11.1997, p. 31

Commission Decision 2000/25/EC of 16 December 1999 establishing the detailed rules for the application of Article 9 of Council Directive 97/78/EC concerning the **transhipment of products** at a Border Inspection Post where the consignments are intended for eventual import into the European Community, and amending Commission Decision 93/14/EEC

OJ L 9, 13.1.2000, p. 27

Commission Decision 2000/208/EC of 24 February 2000 establishing detailed rules for the application of Council Directive 97/78/EC concerning the **transit of products** of animal origin from one third country to another third country by road only across the European Community *OJ L 64, 11.3.2000, p. 20*

Commission Decision 2000/571/EC of 8 September 2000 laying down the methods of veterinary checks for products from third countries destined for introduction into **free zones**, **free warehouses**, **customs warehouses** or operators supplying cross border means of sea transport *OJ L 240*, *23.9.2000*, *p. 14*

Commission Decision 2009/821/EC of 28 September 2009 drawing up a **list of border inspection posts**, laying down certain rules on the inspections carried out by Commission veterinary experts and laying down the veterinary unites in Traces

OJ L 296, 12.11.2009, p. 1

Commission Regulation (EC) No 136/2004 of 22 January 2004 laying down procedures for **veterinary checks** at Community border inspection posts **on products** imported from third countries

OJ L 21, 28.1.2004, p. 11

Commission Regulation (EC) No 282/2004 of 18 February 2004 introducing a **document for** the declaration of, and veterinary checks on, **animals** from third countries entering the Community *OJ L 49*, *19.2.2004*, *p. 11*

Commission Decision 2004/292/EC of 30 March 2004 on the introduction of the **TRACES** system and amending Decision 92/486/EEC

OJ L 94, 31.3.2004, p. 63

Commission Decision 2005/92/EC of 2 February 2005 as regards animal health conditions, certification and transitional provisions concerning the introduction and storage period for consignments of **certain products of animal origin in free zones, free warehouses and premises of operators supplying cross border means of sea transport** in the Community

OJ L 31, 4.2.2005, p. 62

Commission Decision 2005/93/EC of 2 February 2005 as regards transitional provisions concerning the introduction and the storage period for consignments of **certain products of animal origin in customs warehouses** in the Community

OJ L 31, 4.2.2005, p. 64

Commission Decision 2007/275/EC of 17 April 2007 concerning **list of animals and products to be subject to controls** at border inspection posts under Council Directive 91/496/EEC and 97/78/EC

OJ L 116, 4.5.2007, p. 9

Commission Regulation (EC) No 206/2009 of 5 March 2009 on the introduction into the Community of **personal consignments of products of animal origin** and amending Regulation (EC) No 136/2004

OJ L 77, 24.3.2009, p. 1

16.10. Zootechnical legislation

Council Directive 94/28/EC of 23 June 1994 laying down the **principles relating to the zootechnical and genealogical conditions** applicable to imports from third countries of animals, their semen, ova and embryos, and amending Directive 77/504/EEC on pure-bred breeding animals of the bovine species

OJ L 178, 12.7.1994, p. 66

Commission Decision 96/509/EC of 18 July 1996 laying down pedigree and zootechnical requirements for the importation of **semen** of certain animals

OJ L 210, 20.6.1996, p. 47

Commission Decision 96/510/EC of 18 July 1996 laying down the pedigree and zootechnical certificates for the importation of **breeding animals, their semen, ova and embryos**

OJ L 210, 20.6.1996, p. 53

Commission Decision 2006/139/EC of 7 February 2006 implementing Council Directive 94/28/EC as regards a list of authorities in third countries approved for the **keeping of a herd book or register** of certain animals

OJ L 54, 24.2.2006, p. 34

16.11 Safeguard or Protection measures

Commission Decision 2002/994/EC of 20 December 2002 concerning certain protective measures with regard to the products of animal origin imported from **China**

OJ L 348, 21.12.2002, p. 154

Commission Decision 2003/71/EC of 29 January 2003 on certain protective measures in respect of **infectious salmon anaemia** in the **Faeroe Islands**

OJ L 26, 31.1.2003, p. 80

Commission Decision 2003/459/EC of 20 June 2003 on certain protection measures with regard to **monkey pox virus**

OJ L 154, 21.6.2003, p. 112

Commission Decision 2005/692/EC of 6 October 2005 concerning certain protection measures in relation to **avian influenza** in **several third countries**

OJ L 263, 08.10.2005, p. 20

Commission Decision 2007/25/EC of 22 December 2006 as regards certain protection measures in relation to **highly pathogenic avian influenza** and movements of **pet birds accompanying their owners** into the Community

OJ L 8, 13.1.2007, p. 29.

Commission Decision 2007/82/EC of 2 February 2007 on emergency measures **suspending** imports from the **Republic of Guinea** of **fishery products** intended for human consumption *OJ L 28, 3.2.2007, p. 25*

Commission Regulation No 2007/318 of 23 March 2007 laying down animal health conditions for imports of **certain birds** into the Community and the **quarantine conditions** thereof

OJ L 84, 24.3.2007, p. 7

COMMISSION DECISION 2007/453/EC of 29 June 2007 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk.

OJ L 172, 30.06.2007, p. 84

Commission Decision 2007/642/EC of 4 October 2007 on emergency measures applying to **fishery products** imported from **Albania** and intended for human consumption.

OJL 260 5.10.2007, p. 21

Commission Decision 2008/630/EC of 24 July 2008 on emergency measures applicable to **crustaceous** imported from **Bangladesh** and intended for human consumption

OJ L 205, 1.8.2008, p. 49

Commission Decision 2008/698/EC of 8 August 2008 on the temporary admission and imports into the Community of **registered horses** from **South Africa**

OJ L 235, 2.9.2008, p. 16

Council Regulation (EC) No 733/2008 on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power station.

OJ L 201, 30.07.2008, p. 1

Commission Decision 2008/866/EC of 12 November 2008 on emergency measures suspending imports from **Peru** of certain **bivalve molluscs** intended for human consumption

OJ L 307, 18.11.2008, p. 4

Commission Regulation (EC) No 1252/2008 of 12 December 2008 derogating from Regulation (EC) No 1251/2008 and suspending imports into the Community from Malaysia of consignments of certain aquaculture animals

OJ L 337, 16.12.2008, p 76

Commission Regulation (EC) No 1135/2009 of 25 November 2009 imposing special conditions governing the import of **certain products** originating in or consigned from **China**, and repealing Commission Decision 2008/798/EC.

OJ L 311, 26.11.2009, p. 3

Commission Decision 2009/727/EC of 30 September 2009 on emergency measures applicable to crustaceans imported from India and intended for human consumption or animal feed

OJ L 258, 01.10.2009, p. 31

Commission Decision 2010/220/EU of 16 April 2010 on emergency measures applicable to consignments of farmed fishery products imported from Indonesia and intended for human consumption.

OJ L 97, 17.04.2010, p. 17

NB This list is not intended to be exhaustive and has been included as a reminder that some specific emergency decisions may have been taken to restrict imports from certain countries.

6.12 Labelling

Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the **labelling**, presentation and advertising of foodstuffs

OJ L 109, 6.05.2000, p. 29

Commission Directive 2008/5/EC of 30 January 2008 concerning the compulsory **indication on the labelling** of certain foodstuffs of particulars other than those provided for in Directive 2000/13/EC of the European Parliament and of the Council

OJ L 27, 31.1.2008, p. 12

16.13 Miscellaneous

Commission Decision 2007/142/EC of 28 February 2007 establishing a Community Veterinary Emergency Team to assist the Commission in supporting Member States and third countries in veterinary matters relating to certain animal diseases

OJ L 62, 1.3.2007, p. 27

17. PRE-MISSION QUESTIONNAIRE

EXAMPLE - PRE-MISSION QUESTIONNAIRE (excludes poultry or fish) THIRD COUNTRY VETERINARY, FOOD SAFETY AND ANIMAL HEALTH CONTROLS

Note to competent authority

This questionnaire should be completed and returned to: Mr Michael Scannell, Director Food and Veterinary Office Grange, Dunsany Co. Meath Ireland E-mail: Michael.Scannell@ec.europa.eu Where any questions cannot be completely answered, this should be clearly indicated, and the missing information provided before the start of any FVO mission.

1. GENERAL INFORMATION

- **1.1.** Name of country
- **1.2.** Geographical issues

Please provide a map of showing the following features:

- national borders
- internal administrative borders (regional and local)
- borders of any approved disease control areas (regionalisation)
- main cities/towns
- main roads/railways
- main geographical features (rivers, mountain ranges)
- sites of:
- headquarters of State Veterinary Service (SVS)
- regional and local offices of SVS
- central and regional official laboratories
- approved border inspection posts (airports, sea ports, land crossings)

2. LIVESTOCK POPULATION

Please complete the table for holdings and livestock numbers in Annex I to this report (information should be given for the last 3 years):

3. LEGISLATION

Give the titles of the national legislation which is considered to provide equivalent health controls/guarantees to those laid down in the relevant EU legislation (indicating the title and name of the EU legislation in each case) for each of the sections included in this questionnaire. These should indicate clearly the animals and commodities covered by the cited legislation. Legislation controlling the use and distribution of veterinary medicines and medicated feedstuffs, residues monitoring and permitted Maximum Residue Limits (MRLs) should be included.

Copies of the above legislation should be provided.

4. ANIMAL HEALTH SITUATION

4.1. Animal health legislation

- (1) Indicate the species covered by the definition of "livestock".
- (2) Give a list of notifiable diseases (OIE list, others)
- (3) Give details of legal obligations to notify suspect outbreaks of OIE listed diseases.
- (4) Give details of any legal requirements for the control and eradication of OIE listed diseases.
- (5) Give details of any compensation payments made available to farmers etc when animals are slaughtered for disease control/eradication purposes.

4.2. Routine animal health controls

- (1) Describe any routine monitoring programmes for the presence of OIE listed diseases.
- (2) Give details of controls over the use, feeding and disposal of waste food, including controls over waste food coming from international transport.
- (3) Give details of any vaccination programmes in operation in respect of OIE listed diseases.

4.3. Disease notification

Describe existing procedures for notification to:

- OIE
- European Commission

of outbreaks of former OIE list A diseases.

If no such procedures currently exist, indicate what action will be taken to ensure notification in the future, and indicate the timetable for its implementation

NB. OIE membership, and a formal commitment to notify outbreaks of former OIE list A diseases to the European Commission and Member States is a requirement for all third countries seeking to export to the European Union).

- (4) What action is required of farmers, private veterinarians, etc who suspect an outbreak of former OIE list A disease?
- (5) Give dates and details of the outbreaks of all OIE listed diseases within the last 5 years.
 - in farmed livestock population

- in wild animal population

4.4. Disease outbreaks (former OIE list A diseases)

- (1) Give details of any written guidelines available to the official services for dealing with outbreaks of former OIE list A diseases.
- (2) In the event of a former OIE list A disease outbreak:
 - indicate the sampling and testing procedures used to identify and confirm presence of the causative agent.
 - describe the actions taken to control the disease situation in and around any holdings found to be infected with a former OIE list A disease (where these vary with the disease concerned, the differences should be clearly signalled).
 - indicate the control and/or eradication procedures (e.g. vaccination, stamping out, partial slaughter/vaccination etc) that would be taken.
 - describe the procedures used to confirm that an outbreak has been successfully controlled/eradicated, including any restrictions on restocking.
- (3) Give details of the presence of any vector populations that might facilitate the spread of former OIE list A diseases.
- (4) If former OIE list A diseases are found in only part of the country, please indicate the reasons (e.g. natural boundaries, intervention by the official services etc) why this is considered to be the case. Details of any artificial internal barriers, e.g. game fences etc, should be provided.

4.5. Vaccination

- (1) Describe the legal rules applicable to the use of vaccination against animal diseases.
- (2) Give full details of any routine vaccination programmes against OIE listed diseases.
- (3) Where vaccination is practised, give details of any controls over the type (e.g. live, dead), strains, production, use, storage and distribution.

4.6. Pre-export checks

(1) Checks carried out on farms of origin in relation to animal health status

5. COMPETENT AUTHORITY CONTROL SYSTEMS

5.1. Management structures

Give the name, responsibilities and contact details of the Directors of:

- Animal Health Services

- Public Health Services (food safety)
- Controls on veterinary medicines and medicated feedstuffs
- Laboratory Services
- (1) Describe the structure of the above services, and provide an organigramme of each service. The procedures for co-ordination and co-operation between the above services should be given. The management lines from central to regional to local services should be clearly indicated.
- (2) Indicate to whom the Directors report, and their relationship with the relevant government Ministers.

5.2. Independence of the official services

- (1) Describe the procedures that are in place to ensure the independence of the above services.
- (2) What links exist between the official services and private or quasigovernmental bodies?
- (3) What powers of investigation and enforcement are given to the official services?

5.3. Resources

NB. The following information should be given separately for the central, regional and local levels of the official services.

- (1) Financial
- Indicate the budget available for the operation of routine health controls, of any special health programmes and for dealing with health emergencies.
- Indicate the proportion of the budget provided by government, and that provided by other sources (the status of any other sources should be clearly indicated).
- (2) Personnel

Complete the following tables.

Permanent staff							
	Veterinary staff		Admini	Administrative staff		Technical staff*	
	Filled posts	Vacant posts	Filled posts	Vacant posts	Filled posts	Vacant posts	
Central service							
Regional service							
Local service							
Border controls							

Laboratory service						
- central laboratory						
-regional laboratories						
* Staff employed as animal or public health auxiliaries, acting in support of veterinary staff in the performance of technical duties						

		Contract and temporary staff						
	Veter	inary staff	Admini	strative staff	Tec	hnical staff*		
	Filled posts	Vacant posts	Filled posts	Vacant posts	Filled posts	Vacant posts		
Central service								
Regional service								
Local service								
Border controls								
* Staff employe performance of		-	lth auxiliarie	es, acting in sup	port of vet	erinary staff in the		

(3) Equipment

Indicate the type and quantity of equipment (e.g. vehicles, radios, disease control equipment, disinfectant sprays, humane slaughtering equipment, protective clothing etc.) available at regional and local offices for the performance of routine and emergency veterinary controls.

5.4. Personnel

What rules apply to the private/professional activities of permanent officials (veterinary and auxiliaries) outside their official duties?

Which official duties may be undertaken by private veterinarians/auxiliaries?

What rules are in place to ensure the independence of private veterinarians/auxiliaries carrying out official duties?

5.5. Recruitment & training

Describe the recruitment procedures for veterinary and technical staff.

Describe the minimum qualifications (and years of experience, where appropriate) required for veterinary and technical staff.

Give details of routine or special training programmes available for newly recruited and established veterinary and technical staff.

Give details of the arrangements for continued professional development of veterinary and technical staff.

5.6. Legal/enforcement powers

Indicate the enforcement powers and sanctions available in the event of noncompliance with national legislation. This should indicate which branch(es) of the official services has/have the power to initiate and follow-up prosecutions.

Provide details of all prosecutions, and their outcomes, undertaken by the official services in the veterinary and food safety sectors in the last three years.

5.7. Prioritisation of controls (routine programmes)

Describe any formal, written, system for the identification and prioritisation of veterinary and food safety controls operated by the official services. Examples of this system should be provided, with particular reference to the sector(s) for which EC approval is being sought.

Indicate whether regular reviews are undertaken of the prioritisation systems. Details of the frequency and nature of these reviews should be provided.

Describe the procedures for modifying the prioritisation system to take account of changes in the health situation, and/or the results of the official control findings.

5.8. Documentation of controls (routine programmes)

Provide details of written official control programmes at national, regional and local levels.

Provide examples of the documented results of these programmes, and of the action taken in response to these results.

Provide details of any internal or external audit system designed to monitor the operation of these control programmes.

5.9. Laboratory service

NB. See also section 11 of the questionnaire, dealing with specific laboratory issues.

Indicate the number and sites of laboratories included in any official network. The status of the laboratories (private/official) should be given. Describe the duties of the central laboratory and regional/local laboratories in the veterinary and food safety sectors.

Describe the management structure of the laboratory service, and its relationship to the central veterinary services.

Describe any links with international or EU reference laboratories. This should include participation in ring tests, exchanges of officials etc.

5.10. Import controls

NB. This section relates to the operation of controls over imports of animals and animal products into the third country. See also section 10 of the questionnaire, dealing with specific import control issues

Is the official service responsible for import controls part of the official services described in section 5.1, or is it an independent body?

If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central veterinary services.

Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts

How are imported products destined for use in the manufacture of EU-export eligible products identified?

5.11. Animal disease notification & control systems

NB. See also section 4 of the questionnaire, dealing with specific animal health issues.

Indicate which OIE listed diseases are the subject of official controls.

Indicate the legal requirements for the notification of suspicion and/or outbreaks of the above diseases.

Give details of any routine surveillance programmes for the above diseases.

Give details of any documented programmes to respond to outbreaks of former OIE list A diseases.

5.12. Chemical food safety controls

NB. See also section 13 of the questionnaire, dealing with specific food safety issues.

Indicate which food-borne chemical risks are required to be notified to the official services

Describe the procedures in place for co-operation/co-ordination between the responsible Ministries/Agencies when a food-borne disease by a chemical risk is identified in either the human or animal population.

Give details of any documented programmes to respond to food-borne diseases by a chemical risk.

Describe the system in place for the recording of food-borne diseases by a chemical risk.

5.13. Microbiological food safety controls

- (1) Describe any monitoring and/or control programmes in operation for zoonotic agents in animals and foodstuffs.
- (2) Give details of national legislation covering:
 - obligation to notify suspect/confirmed cases in feed, animals and foodstuffs
 - action required of farmers, private veterinarians, etc
 - action required of official services
- (3) Give results of recording systems for food-borne zoonotic cases in feed, animals and foodstuffs in the last 3 years.
- (4) Give details of any documented contingency plans, and the procedures in place, for the investigation and control of food-borne zoonotic outbreaks (2 or more cases linked by the same source of infection) in human populations.
- (5) Give details of routine and emergency consumer awareness campaigns.

5.14. Residue controls

Where not already done, please provide a copy of the national residues monitoring programme in fulfilment of the provisions of Council Directive 96/23/EC.

5.15. Controls on the use and distribution of veterinary drugs

- (1) Is the sale, or use in any animal species, of stilbenes or substances having a thyrostatic action permitted? (See Council Directive 96/22/EC).
- (2) Which veterinary drugs are banned for use in food producing animals (including equidae)? Is the sale or administration to farm animals of substances having an oestrogenic, androgenic, gestagenic action or of beta-agonists permitted? If so, under what conditions?
- (3) Which veterinary medicines are 'prescription only medicines'? What provisions exist in the legislation as regards the "extra label use" of veterinary drugs in food-producing animals?
- (4) Where the use of Hormone Growth Promoters is permitted, describe any system in place to identify animals produced without their use.
- (5) Describe the controls on the production and distribution of medicated feedstuffs.

(6) Provide a list (vademecum) of all registered authorised veterinary drugs and premixes for medicated feedingstuffs with the name of the veterinary drug, active substance, type of treatment (oral, injection etc), the withdrawal period and which species are concerned.

6. FARM REGISTRATION

- (1) Describe the system used to register livestock holdings. Any exemptions from this system should be clearly indicated.
- (2) Describe the method used to identify individual holdings.
- (3) Describe the system for the recording of farm registrations.

7. ANIMAL IDENTIFICATION

(1) Describe the system for the identification of all classes of farm animals (cattle, sheep, goats, pigs, farmed game). Any exemptions from this system should be clearly indicated. Information on recording systems for the identification of animals should be given.

In particular, give details of the type of mark used (tags, tattoos etc), whether they allow individual animal or only farm identification, maximum age of animals at first identification, responsibility for application of marks, on-farm and official records of marks, re-application of lost marks, special marks for suspect or diseased animals etc.

- (2) Indicate any special rules for identification of pedigree animals.
- (3) Describe the official controls and records maintained to monitor the operation of the animal identification systems.
- (4) Indicate how the system allows traceback of animals and carcases to their farms of origin.

8. MOVEMENT CONTROLS

- (1) What controls exist over the movement of animals and animal products between regions of different health status?
- (2) Indicate if there is any official system for the authorisation of animal movements.
- (3) Give details of any requirements for the recording of animal movements (either by farmers, market authorities or the official services).
- (4) What additional controls are applied to animals with officially recognised disease-free status?
- (5) What additional controls are applied to animals despatched from farms which are not officially recognised to be free of specific diseases?

- (6) Describe the system for the updating and checking of movement record registers.
- (7) Describe the system for recording animal movements into and out of markets, and the procedures in place to avoid contact between animals of different health status.
- (8) Give details of any systems for the registration and authorisation of livestock vehicles and hauliers.
- (9) What records of animal movements are hauliers required to maintain?

9. CERTIFICATION

- (1) Describe the official controls over printing, storage and distribution of blank certificates. In particular, who is responsible for maintaining supplies of blank copies of certificates?
- (2) Describe the procedures for the completion of certificates.
- (3) Describe the procedures for the signature of certificates. In particular, who is responsible for signature?
- (4) Describe the procedures for the withdrawal or amendment of signed certificates.
- (5) Give details of any written instructions made available to certifying officials.
- (6) Give details of who is responsible for producing and checking support documentation for certificates.
- (7) Describe the procedures to be followed when the final health certificate that accompanies consignments exported to the EU is produced and signed.
- (8) Describe the controls over the movement of consignments within the country before final export to the EU.

10. IMPORT CONTROLS

- *NB.* This section relates to the operation of controls over imports of animals and animal products into the third country.
- (1) Describe the general controls over the import of live animals and animal products (legislation, approved countries and processing establishments, issue of import permits, quarantine requirements, animal and public health guarantees, certification, pre- and post-import testing etc).
- (2) Describe any controls on the import of animals having been treated with growth promoters.

- (3) Describe the type and frequency of checks carried out on imports of live animals and animal products at the point of entry into the country and/or their final destination.
- (4) Indicate the status and responsibility of the official in charge of import controls at border inspection posts.
- (5) Describe the action available under legislation, and actually taken, when an illegal import is detected.
- (6) Give details of any guidance given to officials, and the outcome of checks undertaken.
- (7) Describe the procedures for controls undertaken over animals and animal products that are:
 - entering the country
 - transitting the country

11. LABORATORY OPERATIONS

- (1) What procedures exist for the official accreditation of laboratories?
- (2) Give details of the financial resources available to the official laboratory network.
- (3) Give details of the type of tests undertaken by the laboratories in respect of the diagnosis and routine monitoring for former OIE list A diseases.
- (4) Is live virus handled in respect of former OIE list A diseases? If so, what precautions are in place to avoid accidental escape?
- (5) Give details of any ring tests organised and operated within the laboratory network, and/or with laboratories in other countries or international reference laboratories. What procedures are in place in the event of unsatisfactory results from these tests?
- (6) Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO etc. that exist in, or planned for, the laboratory system.
- (7) What procedures are in place for maintenance of equipment and replacement of reagents?
- (8) Describe qualifications of, and training programmes for, laboratory staff.

12. ZOONOSES AND FOOD POISONING CONTROLS

- (1) Describe any monitoring and/or control programmes in operation for zoonoses and food poisoning organisms.
- (2) Give details of national legislation covering:

- obligation to notify suspect/confirmed outbreaks
- action required of farmers, private veterinarians, etc
- action required of official services
- (3) Give results of recording systems for outbreaks of zoonoses and food poisoning in the last 3 years.
- (4) Describe any system in place for the rapid identification and notification of outbreaks of zoonoses and food poisoning.
- (5) Give details of any documented contingency plans, and the procedures in place, for the investigation and control of outbreaks of zoonoses and food poisoning in animal and human populations.
- (6) Give details of routine and emergency consumer awareness campaigns.

13. FOOD SAFETY STANDARDS (IN RELATION TO SECTORS FOR WHICH EXPORT APPROVAL IS SOUGHT, IF APPLICABLE)

NB. The following questions should be answered in relation to the sector(s) for which approval to export to the EU is being sought (if applicable).

13.1. Production details

The following information for each individual food processing establishment which is to be proposed for approval for the EU market should be provided.

- approval number
- trading name
- full address
- name of the official veterinarian in charge of the establishment
- type and volume of all products from the establishment
- type and volume of products intended for export to the EU
- confirmation by the official service of compliance with EU standards

13.2. All food processing premises

- (1) What national legislation is in place that will ensure equivalent standards to those laid down in EU legislation?
- (2) Give details of official control programmes, including internal audit systems for the official services, in the food safety sector. In particular, information on systems for the prioritisation and documentation of these programmes, and their results, should be provided.

- (3) Indicate the frequency and nature of official controls over the operation of processing establishments.
- (4) Describe the procedures for the granting, suspension and withdrawal of approval for processing and storage establishments.
- (5) Indicate the procedures for the monitoring of layout and structural conditions in establishments.
- (6) Describe controls over the use of health marks.
- (7) Describe controls over the use of health certificates.
- (8) What arrangements are in place for the provision of medical certificates for food handlers?
- (9) Describe the nature, frequency and extent of official controls within establishments.
- (10) Give details of the procedures in place to ensure traceability (back to farm level) of animal products intended for human consumption.
- (11) Indicate the legal requirements for water quality and safety.
- (12) Give details of any "own-check" systems (including HACCP) that operators and processors are required to implement. This should include the role of the official service in the development and checking of these systems.
- (13) Provide copies of any official guidelines and/or instructions on:
 - water testing programmes
 - cleansing and disinfection of establishments
 - pest control programmes
- (14) What access do the official services have to production records?
- (15) What action are operators and processors required to take if a serious threat to animal or consumer health is identified? What is the role of the official services in such cases?
- (16) What systems are in place to provide for the training of company operatives?
- (17) What are the qualifications, training and role of official auxiliaries in processing establishments? Indicate any restrictions on their activities. Indicate if the auxiliaries are paid by the processor or by the official services.

13.3. Red meat, farmed game and rabbit meat production

(1) What national legislation is in place that will ensure equivalent standards to those laid down in EU legislation?

- (2) Give details of any official programme of on-farm checks of suppliers to establishments exporting to the EU.
- (3) Describe the operation of any animal health checks and controls undertaken in slaughterhouses.
- (4) Give details of the ante and post mortem inspections undertaken by the official services, and of any records of the results of these inspections.
- (5) Describe the procedures for the identification, isolation and disposal of detained and unfit material.
- (6) Give details of the measures in place to protect the welfare of animals at slaughter.
- (7) Describe the official controls in place over hygienic standards of operation in processing establishment.
- (8) Give details of the procedures for health marking and certification of red meat carcases and offals.
- (9) What checks are undertaken to monitor temperature controls of storage and work rooms, and meat during storage and handling?
- (10) Where appropriate (pig, farmed "wild boar" and horse meat), give details of official checks, or temperature controls, undertaken in relation to the risks posed by trichinellosis in fresh meat, including the testing methods authorised for use.
- (11) What official controls exist over the slaughter and processing of casualty or sick animals for human consumption?
- (12) What procedures will be put in place to ensure adequate separation of EUeligible and non-EU eligible meat?

13.4. Wild game meat

- (1) What national legislation is in place that will ensure equivalent standards to those laid down in EU legislation?
- (2) Give the legal definition of wild game animals and meat derived therefrom
- (3) Are there any derogations that exclude certain classes of wild game, or certain processing establishments, e.g. low throughput, from legislative requirements?
- (4) Describe the controls over the hunting of wild game, including any restrictions on those allowed to hunt
- (5) Give details of the structural and facility requirements for game collecting centres and processing establishments
- (6) Give details of post mortem inspection requirements, including the handling and presentation of offals

- (7) Give details of any time and temperature constraints on the transfer of wild game from point of shooting to collection centre, and from collection centre to processing establishment.
- (8) What temperature controls are applicable to wild game during transport, storage and processing?
- (9) What hygiene rules apply to the transport, storage and processing of wild game?
- (10) What rules apply to the use and application of health marks? Are there restrictions on who is allowed to apply health marks?
- (11) Describe the health marks used on wild game, and how they differ from those used on farmed game.
- (12) What rules apply to the disposal of detained and condemned material?
- (13) What rules apply to ensure the separate identification of wild and farmed game?
- (14) Describe the procedures for trichinella testing, including:
 - species tested
 - supervision of testing procedures
 - test methods employed (indicate if they meet EU or particular international standards), including reagents, registration of results etc
 - who is allowed to carry out tests
 - minimum facilities required
 - marking of carcases that give negative results
 - action taken with carcases that give positive results

13.5. Meat products

- (15) What national legislation is in place that will ensure equivalent standards to those laid down in EU legislation?
- (16) Indicate if any, derogations from legal requirements are given to particular classes of processors, eg. low throughput, artisanal etc
- (17) What rules exist to ensure that only EU-status raw materials will be used?
- (18) What temperature controls are applied to raw materials and temperaturesensitive products?
- (19) What measures are in place to ensure traceability of meat products back to the premises of origin of raw materials?

- (20) What rules apply to the recording of treatment and storage conditions?
- (21) What microbiological checks are required on finished products?

Annex I

Livestock population:

	Cattle					
	Total number of holdings	Total number of adult dairy cattle			Number of bovines slaughtered	
Year						
Year						
Year						

	Pigs					
	Total number of holdings	Total number of breeding pigs		Total number of pigs slaughtered		
Year						
Year						
Year						

		Sheep/goats					
	Total number of holdings	Total number of dairy sheep/goats	Total number of breeding sheep/goats	Total number of fattening sheep/goats	Number of sheep/goats slaughtered		
Year							
Year							
Year							

	Farmed game						
	Total number of holdings	Total number of farmed game	Number of farmed deer	Number of farmed "wild boar"	Number of farmed game animals slaughtered (indicate species)		
Year							
Year							
Year							

	Wild game					
	Total number of wild deer	Total number of wild boar	Total number of other wild game (specify)	Number of wild game shot (indicate species)		
Year						
Year						
Year						