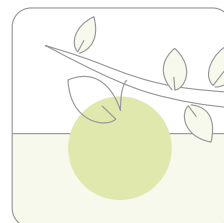
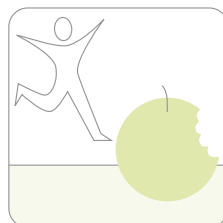
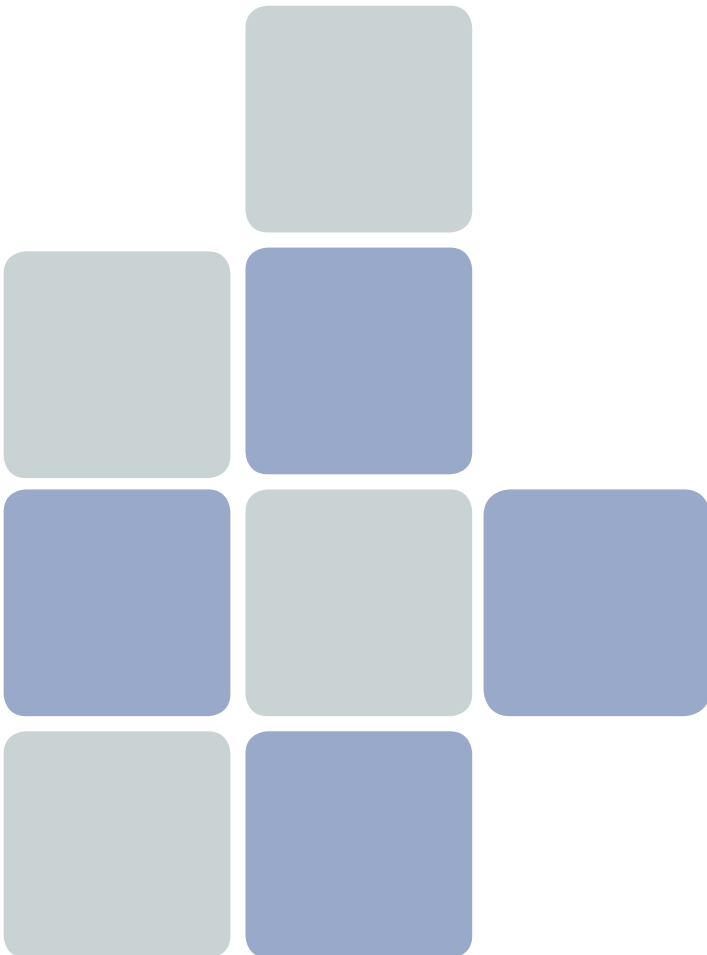


GUIDANCE DOCUMENT

Key questions related to import requirements
and the new rules on food hygiene and official
food controls





**EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL**

Brussels, 5.1.2006

GUIDANCE DOCUMENT

**on certain key questions related to import requirements
and the new rules on food hygiene and on official food controls**

PURPOSE OF THIS DOCUMENT

This document is mainly directed at competent authorities and food businesses in the Member States and in third countries and aims to give guidance on certain key questions with regard to the implementation of the new food hygiene import requirements and on related subjects.

NOTE

This document is an evolving document and will be updated to take account of experiences and information from the Member States, from competent authorities and food businesses in third countries, from food importers and from the Commission's Food and Veterinary Office.

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1. INTRODUCTION

Since the adoption of the new rules on the hygiene of foodstuffs (Regulations (EC) No 852/2004, 853/2004 and 854/2004), and of the rules on official controls (Regulation (EC) No 882/2004), the Commission has been requested to clarify a number of aspects related to food imports covered by these Regulations. This document aims to follow-up these requests.

The Commission's Health and Consumer Protection Directorate General has held a series of meetings with experts from the Member States in order to examine and reach consensus on a number of issues concerning the implementation of the new Regulations.

In the interest of transparency, the Commission has also promoted discussion with stakeholders so as to allow different socio-economic interests to express an opinion. To this end the Commission has organised a meeting with representatives from producers, industry, commerce and consumers to discuss issues related to the implementation of the Regulations.

It was considered that these meetings and discussions should continue in the light of the experience gained by the full application of the Regulations from 1 January 2006.

It should be noted that matters relating to the non-compliance of national legislation with the Regulation remain outside the scope of this exercise and will continue to be dealt with in accordance with established Commission procedures.

The present document aims to assist all players in the food chain to better understand and to apply correctly and in a uniform way the Regulations. However, this document has no formal legal status and in the event of a dispute, ultimate responsibility for the interpretation of the law lies with the Court of Justice.

The main documents referred in this document are:

- € Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April on the hygiene of foodstuffs¹,
- € Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April laying down specific hygiene rules for food of animal origin²,
- € Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety³ (also referred to as the General Food Law), and

¹ OJ No L 226, 25.6.2004, p. 3

² OJ No L 226, 25.6.2004, p. 22

³ OJ No L 31, 1.2.2002, p. 1

€ 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 welfare⁴.

Other relevant documents are:

€ Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs⁵,

€ Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 and for the organisation of official controls under Regulations (EC) No 854/2004 and No 882/2004, derogating from Regulation (EC) No 852/2004 and amending Regulations (EC) No 853/2004 and No 854/2004⁶,

€ Commission Regulation (EC) No 2075 of 5 December 2005 laying down specific rules on official controls for *Trichinella* in meat⁷,

€ Commission Regulation (EC) No 2076/2005 of 5 December 2005 laying down transitional measures for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004⁸.

Separate guidance documents ha been established on Regulations (EC) No 178/2002, No 852/2004, No 853/2004 and on flexibility with regard to HACCP-based systems .

(See http://europa.eu.int/comm/food/food/foodlaw/guidance/index_en.htm)

⁴ OJ No L 191, 28.5.2004, p. 1

⁵ OJ No L 338, 22.12.2005, p. 1

⁶ OJ No L 338, 22.12.2005, p. 27

⁷ OJ No L 338, 22.12.2005, p. 60

⁸ OJ no L 338, 22.12.2005, p. 83

2. GENERAL REMARKS

2.1. **In the EU the food hygiene import systems for food of animal origin (such as meat, fish and dairy products) are not entirely the same as for food of non-animal origin (such as fruit, vegetables) or as for food containing both ingredients of animal origin and plant origin etc.**

This document aims to clarify in general terms and with regard to food hygiene, the import systems for different food commodities, and in particular for:

- ∅ Food of non-animal origin,
- ∅ Food of animal origin, and
- ∅ Food containing both processed ingredients of animal origin and ingredients of plant origin.

2.2. **The food hygiene conditions for food imports are laid down in several parts of Community law. The main elements are included in the following:**

- ∅ 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 (Official Journal L 31 of 1.2.2002, p.1)
- ∅ Regulation (EC) No 882/2002 of the European Parliament and of the Council of 29 April 2004 on official controls to be performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (Official Journal L 191 of 28 May 2004, p. 1)
- ∅ Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (Official Journal L 226 of 25 June 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 (Official Journal L 226 of 25 June 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 (Official Journal L 226 of 25 June 2004, p. 83)
- ∅ 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.
- ∅ Other legislation concerning animal health, animal welfare, plant health and several food standards (e.g. food additives, maximum residue levels etc.)

2.3. Food hygiene and other sanitary requirements

This document refers mainly to the new EU food hygiene requirements and the consequences for food imports.

It must be borne in mind that in addition to food hygiene requirements, other sanitary measures may apply such as animal health and plant health requirements. Where appropriate, this document refers to such sanitary measures.

2.4. This document supplements other guidance documents and in particular:

€ *General guidance for third country authorities on procedures to be followed when importing live animals and animal products into the European Union.*

For more information see:

http://europa.eu.int/comm/food/fvo/pdf/guide_thirdcountries_en.pdf

€ *Guidelines on the implementation of the main General Food Law requirements.*

For more information see:

http://europa.eu.int/comm/food/food/foodlaw/guidance/index_en.htm

3. FREQUENTLY ASKED QUESTIONS

3.1. **Must third countries, in order to be eligible for food exports to the EU after 1 January 2006, have a competent authority in place?**

Regulation (EC) No 882/2004 does not require third countries to have competent authorities in place. However, more specific veterinary and phytosanitary legislation requires that competent authorities must have been established. In general the following applies:

∄ With regard to food of animal origin, the EU has always taken into consideration the guarantees on compliance with EU food law given by the competent authorities in third countries. ***That system has not been changed and will therefore continue after 1 January 2006.***

∄ With regard to food of non-animal origin :

○ As far as phytosanitary requirements are concerned, the need for a competent authority is spelled out in the relevant legislation. ***That system has not been changed and will therefore continue after 1 January 2006.***

○ Compliance with EU requirements other than phytosanitary ones has been ensured in most cases by non governmental bodies and imports were allowed upon the guarantees offered by the importer of the food into the EU. ***The new rules do not change that situation and imports will continue to be organised as before 1 January 2006.***

3.2. **Must third countries, in order to be eligible for food exports after 1 January 2006, be approved by the EU?**

∄ With regard to food of animal origin only a third country that appears on list established by the Community can export to the EU. ***That system has not been changed and will continue after 1 January 2006.***

∄ With regard to food of non-animal origin, third countries do not need to appear on a list for being eligible for export. ***The new rules do not change that situation and imports will continue to be organised as before 1 January 2006.***

3.3. **Must third countries, in order to be eligible for food exports after 1 January 2006, have submitted a control plan to the EU?**

Regulation (EC) No 882/2004 does not require third countries to submit a control plan before 1 January 2006.

Regulation (EC) No 882/2004 authorises the Commission to request third countries to provide accurate and up-to-date information on their sanitary and phytosanitary regulations, control procedures and risk assessment procedures with regard to products exported to the EU.

This is fully in line with Article 7 and Annex B of the World Trade Organisation's Agreement on the Application of Sanitary and Phytosanitary Measures (15 April 1994).

It may be the case that, in the future, the Commission will request third countries to present information on the issues referred to above. To assist third countries, the Commission intends to establish guidelines on how such information shall be presented. When there is no request from the Commission, there is no need for third countries to submit information.

That new procedure would supplement the system whereby information is requested from third countries before and during inspection visits of the Commission's Food and Veterinary office.

It must be borne in mind that EU food law requires mandatory submission of information with respect to:

- ∅ Residues of veterinary medicinal products and other pharmacological active substances used to treat animals.
- ∅ Zoonotic diseases.

3.4. **Must food establishments in third countries, in order to be eligible for food exports after 1 January 2006, be registered with the competent authority?**

∅ With regard to food of animal origin, in most cases only products from establishments (including factory and freezer vessels) that appear on a list approved by the Community can export to the EU. That system has not been changed and *exports of food of animal origin may therefore continue to be organised as before 1 January 2006.*

∅ With regard to food of non-animal origin, it is in many cases sufficient that exporting establishments in third countries are known to and accepted as suppliers by importers of food into the Community. *Exports of food of non-animal origin towards the EU can therefore continue to be organised as before 1 January 2006.* For consignments containing plants or plant products which are covered by the EU plant health acquis, the exporter must obtain a phytosanitary certificate issued by his competent national authorities. This will normally involve registration (see under 6.5).

3.5. Must food establishments in third countries, in order to be eligible for food exports after 1 January 2006, implement procedures based on the HACCP principles?

The competent authorities in the Member States had to ensure already before 1 January 2006 that foodstuffs imported into the Community were submitted to official controls for the purpose of ensuring that the relevant provisions of the food hygiene rules, including the requirement of putting in place, implementing and maintaining HACCP-based procedures were observed (see Article 8, paragraph 3 of Directive 93/43/EEC on food hygiene).

The new EU rules on food hygiene confirm that all food businesses after primary production must put in place, implement and maintain a procedure based on the HACCP principles. These rules are however more flexible than the old system, as the HACCP based procedures can be adapted to all situations.

3.6. Must third countries, in order to be eligible for export after 1 January 2006, have reference laboratories in place?

There is no requirement for third countries to have reference laboratories.

However, Regulation (EC) No 882/2004 requires laboratories that are engaged in verifying compliance with EU food standards to be accredited.

Such laboratories may be private laboratories that have been designated for the purpose of verifying compliance with EU food standards by the body in charge of official controls.

In order to facilitate the accreditation of laboratories, the Commission has adopted a Regulation that grants **a transitional period of four years** during which laboratories in third countries can adapt to the new situation.

3.7. What role will the Food and Veterinary Office of the directorate general for health and consumer protection play after 1 January 2006?

The Food and Veterinary Office (FVO) will continue to carry out inspection missions in both Member States and third countries as before 1 January 2006.

However, the Commission is responsible under Regulation (EC) No. 882/2004 for requesting third countries intending to export food to the Community to provide accurate and up-to-date information on the general organisation and management of sanitary control systems. While this is largely the situation at present in relation to food of animal origin, there will be an increase in the Commission's responsibility in the area of food of non-animal origin. The role of the FVO will reflect this increased responsibility. Guidelines on how such information should be presented will be produced in Autumn of 2006.

The natural contact point for the Commission in third countries is the competent authority. In practice, initial requests for information will be addressed to the representation of the third country in the EU. Depending on the reply given by the third country, further contacts will be either directly with the competent

authority(ies) in the third country concerned and/or with the relevant control body.

4. THE NOTIONS “FOOD”, “FOOD OF ANIMAL ORIGIN”, “FOOD OF NON-ANIMAL ORIGIN” AND “COMPOSITE PRODUCTS”

In EU law, the requirements and introduction procedures for importing food of non-animal origin, food of animal origin and composite products are different. It is important therefore to have an understanding of what these notions include.

4.1. What is food?

Food is defined in Article 2 of Regulation (EC) No 178/2002 referred to in Section 2.2 of this document. That definition is duplicated in Annex I to the present document.

4.2. What are products of animal origin?

The notion “products of animal origin” covers food that has been derived from animals or coming from animals, whether processed or not. In certain cases this may include live animals (e.g. lobsters or live bivalve molluscs) that are placed on the market for consumption.

Annex II gives a general (non-exhaustive) overview of what is to be considered as products of animal origin.

4.3. What is food of non-animal origin?

Food of non-animal origin **includes items such as fruits, vegetables, cereals, tubers, drinks**, (apart from drinks prepared from products of animal origin such as milk and certain milk based drinks), **food of mineral origin** (such as salt), **spices, condiments** etc.

4.4. What are composite products?

For food hygiene purposes, food containing both products of plant origin and processed products of animal origin are called “**composite products**”.

Sections 6, 7 and 8 of this document give the essential elements that must be taken into account when importing food of non-animal origin, food of animal origin and composite products respectively into the EU.

5. BASIC REQUIREMENTS OF FOOD LAW

Certain basic food law requirements applying to all food are laid down in Regulation (EC) No 178/2002. These include in particular:

5.1. Compliance or equivalence (Article 11 of Regulation (EC) No 178/2002)

Food imported into the Community for placing on the market within the Community shall comply with:

- ∅ The relevant requirements of food law, or
- ∅ Conditions recognised by the Community to be **at least equivalent** thereto, or
- ∅ Where a specific agreement exists between the Community and the exporting country, with requirements contained therein.

5.2. Responsibilities of food importers (Article 19 of Regulation (EC) No 178/2002)

If a food business operator considers or has reason to believe that a food which it has imported is not in compliance with the food safety requirements, it shall immediately initiate procedures to withdraw the food in question from the market where the food has left the immediate control of that initial food business operator and inform the competent authorities thereof.

6. IMPORTS OF FOOD OF NON-ANIMAL ORIGIN

6.1. Food hygiene requirements

The relevant requirements with regard to the hygiene of food of non animal origin are contained in Articles 3 to 6 of Regulation (EC) No 852/2004, which means that the following rules need to be respected by food business operators in third countries:

- ∅ A general obligation on the operator to monitor the food safety of products and processes under his responsibility (Article 3 of Regulation (EC) No 852/2004),
- ∅ General hygiene provisions for primary production (Article 4.1 of, and Part A of Annex I to Regulation (EC) No 852/2004),
- ∅ Detailed requirements after primary production (Article 4.2 of and Annex II to Regulation (EC) No 852/2004),
- ∅ For certain products, microbiological requirements (Article 4.3 of Regulation (EC) No 852/2004) and Commission Regulation (EC) No 2073/2005 ,

- ∄ Procedures based on the HACCP principles (Article 5 of Regulation (EC) No 852/2004) ,
- ∄ Registration of establishments (Article 6 of Regulation (EC) No 852/2004).

6.2. Other health requirements

- ∄ Under relevant requirements of EU food law, a number of rules apply that complement or are in addition to food hygiene. These include in particular and where appropriate requirements concerning:
 - Contaminants,
 - Maximum residue levels for pesticides,
 - The use of food additives,
 - Materials and articles in contact with foodstuffs,
 - Food irradiation,
 - Novel foods,
 - Radioactivity.
- ∄ Product specific requirements also exist concerning :
 - Quick frozen foodstuffs,
 - Foodstuffs for particular nutritional purposes,
 - Genetically modified organisms (GMOs).

For more information, see:

http://europa.eu.int/comm/food/index_en.htm

6.3. Plant health requirements

Before they can be introduced into the Community, certain plants, plant products or other objects must comply with phytosanitary requirements. See also under point 6.5.

For more information, see:

<http://europa.eu.int/comm/food/plant>

6.4. Import procedures related to food hygiene

When importing food of non-animal origin, **it is incumbent upon the importer to ensure compliance with the relevant requirements of food law or with conditions recognised equivalent thereto by the Community.**

- ∄ Food of non-animal origin may be submitted to controls in accordance with a control plan drawn up in the light of potential risks (see Article 15, paragraph 1 of Regulation (EC) No 882/2004). Such controls must take place in accordance with national law in the different Member States. This may be at the point of entry, the point of release for free circulation, the importer's premises, retail outlets etc.

Apart from food hygiene, these import controls may also cover other food safety issues such as: additives, materials in contact with food, contaminants etc.

Certain food commodities of non-animal origin need to be presented at a designated point for being submitted to checks. See point 6.6 and Annex III.

- ∄ Generally, food of non-animal origin:
- Can enter the EU without certification by the competent authorities of the third country of dispatch, and
 - Is not subjected to a pre-notification procedure on arrival.

6.5. Import procedures related to plant health

Certain plants and plant products (listed in Part B of Annex V to Directive 2000/29/EC) must be accompanied by a phytosanitary certificate, issued by the National Plant Protection Organisation of the exporting country. Upon entry into the Community, the phytosanitary certificate may be replaced by a plant passport (for those imported plants, plant products or other objects which are also listed in Part A of Annex V).

These plants and plant products are subjected to compulsory plant health, identity and documentary checks with a view to ensuring compliance with the EC's general and specific import requirements, before being released for circulation within the Community. Such checks could take place at specified entry points situated at the outer border of the Community or in the case of identity and plant health checks also at places of destination inside the Community when meeting special conditions. The importers of such goods should be registered by the responsible official authorities of the Member State.

Airport authorities, harbour authorities or either importers or operators, as arranged by them, shall give as soon as they are aware of the imminent arrival of consignments of relevant plants or plant products advance notice to the customs office of the point of entry and to the responsible official authorities. Member States may also apply this latter provision to cases of land transport, in particular where the arrival is expected outside the normal working hours of the relevant official bodies.

For more information, see: <http://europa.eu.int/comm/food/plant>

6.6. Food of non-animal origin subject to in increased level of controls

In accordance with Article 15, paragraph 5 of Regulation (EC) No 882/2004, the Commission may establish a list of food of non-animal origin (including composite products) that, on the basis of known or emerging risks, should be subjected to an increased level of official controls upon introduction into the EU.

For such food, the following would apply:

- ∅ Particular points of entry shall be designated,
- ∅ Food business operators shall give prior notification of the arrival of the goods and of their nature.

The Commission has not yet established a list of such food. In the meanwhile, the safeguard measures establishing an increased level of control with regard to certain food commodities remain in place. *Annex III gives an overview of the safeguard measures currently maintained.*

7. IMPORTS OF PRODUCTS OF ANIMAL ORIGIN

7.1. Import procedures

In accordance with Directive 97/78/EC:

- ∄ Products of animal origin must be presented at a Community border inspection post for being submitted to an import control,
- ∄ Prior notice of the arrival of the products in the border inspection post must be given in accordance with National rules of the Member State in which the border inspection post is situated.
- ∄ The consignments must be presented to the border inspection post accompanied by all the relevant certificates required in EU veterinary legislation
- ∄ Consignments will only be accepted if the products are derived from approved countries , regions and establishments as appropriate
- ∄ In certain cases, safeguard measures introducing special import conditions or restrictions may apply.
- ∄ The procedures as laid down in Commission Regulation (EC) No 136/2004 are to be followed.

In accordance with Article 14 of Regulation (EC) No 882/2004 food of animal origin may also be submitted in border inspection posts to controls for other issues than food hygiene and animal health, such as:

- ∄ Food additives,
- ∄ Materials in contact with food,
- ∄ Food irradiation.

7.2. Food hygiene requirements

Obligations of food business operators in third countries

The relevant requirements with regard to the hygiene of food of animal origin are contained in:

- ∄ Articles 3 to 6 of Regulation (EC) No 852/2004, which means that the following rules need to be respected by food business operators in third countries:
 - A general obligation on the operator to monitor the food safety of products and processes under his responsibility (Article 3),

- General hygiene provisions for primary production (Article 4.1 of, and Part A of Annex I to, Regulation (EC) No 852/2004),
 - Detailed requirements after primary production (Article 4.2 of and Annex II to Regulation (EC) No 852/2004),
 - For certain products, microbiological requirements (Article 4.3 of Regulation (EC) No 852/2004) and Commission Regulation (EC) No 2073/2005),
 - Procedures based on the HACCP principles (Article 5 of Regulation (EC) No 852/2004) ,
 - Registration of establishments (Article 6 of Regulation (EC) No 852/2004). The approval of establishments is in principle necessary only for foods of animal origin.
- ∄ The requirements appropriate for the products that are exported and that are contained in Regulation (EC) No 853/2004.

Obligations of importers (Article 6 of Regulation (EC) No 853/2004)

Food business operators importing products of animal origin must ensure that the products:

- ∄ Come from a third country or a part of a third country that appears on a Community list,
- ∄ Where applicable, come from an establishment that appears on a list,
- ∄ Where applicable, carry a health or identification mark,
- ∄ Where applicable, are accompanied by a certificate issued by the representative of the competent authority of the third country,
- ∄ Are made available for control in a border inspection post,
- ∄ Comply with the animal health requirements of Directive 2002/99/EC,
- ∄ Operations carried out under their control that take place after importation are carried out in accordance with the appropriate requirements of Regulation (EC) No 853/2004.

Obligations of competent authorities in third countries

For products of animal origin, EU food law requires that the competent authority of the exporting country offers guarantees as to the compliance or equivalence with EU requirements. The competent authorities in the exporting third country shall in particular ensure that:

- ⊘ Their control services comply with the operational criteria laid down in EC law, in particular in Regulation (EC) No 882/2004,
- ⊘ The establishments that are authorised to export to the EU comply and continue to comply with the EC requirements and that the list of such establishments is kept up-to-date and communicated to the Commission (Article 12, paragraph 2 of Regulation (EC) No 854/2004),
- ⊘ The certification requirements are satisfied. Detailed rules with regard to certification are laid down in Council Directive 96/93/EC on the certification of animals and animal products (OJ No L 13, 16.1.1997, p. 28). Further details are laid down in Annex VI to Regulation (EC) No 854/2004 (e.g. that the certificate must be issued before the consignment to which it relates leaves the control of the competent authority or the third country of dispatch).

7.3. Animal health requirements

Food of animal origin from third countries must comply with requirements that prevent the introduction of animal diseases into the EU. These requirements emanate from 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.

For more information, see:

http://europa.eu.int/comm/food/animal/animalproducts/index_en.htm

7.4. Other health requirements

- ⊘ Under EU food law, a number of requirements may apply in complement or in addition to food hygiene. These include requirements concerning:
 - Contaminants and residues,
 - The use of substances having a hormonal effect,
 - The use of food additives,
 - Materials and articles in contact with foodstuffs,
 - Radioactivity.
- ⊘ Product specific requirements also exist concerning :
 - Quick frozen foodstuffs,
 - Foodstuffs for particular nutritional purposes,
 - Genetically modified organisms (GMOs)

For more information, see:

http://europa.eu.int/comm/food/index_en.htm

7.5. Animal welfare requirements

Council Directive 93/119/EC on the protection of animals at the time of slaughter sets out requirements with regard to humane slaughter of animals (solipeds, ruminants, pigs, rabbits and poultry) in slaughterhouses.

As a general rule, animals must be spared any avoidable excitement, pain or suffering during movement, lairaging, restraint, stunning, slaughter or killing.

Article 15 of the Directive lays down that during their visits in slaughterhouses in third countries, the Commission experts shall ensure that the animals have been slaughtered under conditions which offer guarantees of humane treatment at least equivalent to those provided for in Directive 93/119/EC.

For more information, see:

http://europa.eu.int/comm/food/animal/welfare/international/index_en.htm

8. IMPORTS OF COMPOSITE PRODUCTS

8.1. Basic food hygiene requirements

The relevant requirements with regard to the hygiene of composite products are contained in Articles 3 to 6 of Regulation (EC) No 852/2004, which means that the following rules need to be respected by food business operators in third countries:

- ∄ A general obligation on the operator to monitor the food safety of products and processes under his responsibility (Article 3),
- ∄ General hygiene provisions for primary production (Article 4.1 of, and Part A of Annex I to, Regulation (EC) No 852/2004),
- ∄ Detailed requirements after primary production (Article 4.2 of and Annex II to Regulation (EC) No 852/2004),
- ∄ For certain products, microbiological requirements (Article 4.3 of Regulation (EC) No 852/2004) and Commission Regulation (EC) No 2073/2005),
- ∄ Procedures based on the HACCP principles (Article 5 of Regulation (EC) No 852/2004) ,
- ∄ Registration of establishments (Article 6 of Regulation (EC) No 852/2004). The approval of establishments is in principle necessary only for foods of animal origin.

8.2. Other food hygiene requirements:

In accordance with Article 6, paragraph 4 of Regulation (EC) No 853/2004, food business operators established in the Community and importing food containing both products of plant origin and processed products of animal origin must ensure that the processed components of animal origin contained in such food **satisfy the requirements for products of animal origin**, i.e.

- The components comes from a third country that appears on a Community list, and satisfy the product specific requirements applicable upon import in the Community,
- The establishment (or the production area for molluscs and the like) from which the components of animal origin used for producing the composite product have been dispatched, obtained or prepared, appears on a list from which imports are permitted,
- The importing food business operator must be able to demonstrate that the above is respected (using documentation or otherwise).

The Commission is reviewing this question in order to develop a risk based approach. Pending the establishment of a risk based list of composite

products that are to be subject to the above requirements, a transitional measure will allow current practices to continue.

8.3. Other health requirements

∄ Under EU food law, a number of requirements may apply where appropriate that complement or are in addition to food hygiene. These include in particular requirements concerning:

- Contaminants,
- The use of food additives,
- Materials and articles in contact with foodstuffs,
- Food irradiation,
- Radioactivity.

∄ Product specific requirements also exist concerning :

- Quick frozen foodstuffs,
- Foodstuffs for particular nutritional purposes,
- Genetically modified organisms (GMOs).

8.4. Animal health requirements

In addition, composite products may need a check at a border inspection post in order to verify compliance with animal health requirements.

The Commission is reviewing this question with the intention of introducing a measure to establish principles for the clarification and selection of which composite products that are considered to be a potential animal health risk and that therefore must be submitted to veterinary controls. Pending this requirement the application of national Rules as laid down in Commission Decision 2002/349/EC will continue.

For more information, see:

http://europa.eu.int/comm/food/animal/animalproducts/index_en.htm

8.5. Plant health requirements

Composite products are rather unlikely to be subject to plant health requirements. Indeed, for the purpose of the plant health acquis, plants shall be considered to mean living plants and specified living parts thereof, including seeds, while plant products are products of plant origin, unprocessed or having undergone simple preparation, in so far as these are not plants.

If composite products fall within the definition of plants or plants products, the provisions as laid out in 6.5 (import procedures related to plant health for food of non-animal origin) apply.

For more information, see:

<http://europa.eu.int/comm/food/plant>

ANNEX I
Definition of 'food'

'Food' means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.

'Food' includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC and without prejudice to the requirements of Directives 80/778/EEC and 98/83/EC.

'Food' shall not include:

- (a) feed;
- (b) live animals unless they are prepared for placing on the market for human consumption;
- (c) plants prior to harvesting,
- (d) medicinal products within the meaning of Council Directives 65/65/EEC and 92/73/EEC;
- (e) cosmetics within the meaning of Council Directive 76/768/EEC;
- (f) tobacco and tobacco products within the meaning of Council Directive 89/662/EEC;
- (g) narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs 1961, and the United Nations Convention on Psychotropic Substances, 1971;
- (h) residues and contaminants.

ANNEX II
PRODUCTS OF ANIMAL ORIGIN

I. Non-exhaustive list of unprocessed products of animal origin

- **Fresh meat/minced meat/mechanically separated meat**
-
- **Untreated intestines, stomachs and bladders**
- **Meat preparations that have not been processed**
- **Blood**
- **Fresh fishery products**
- **Live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods**
- **Raw milk**
- **Whole eggs and liquid egg**
- **Frogs' legs**
- **Snails**
- **Honey**
- **Other**

An unprocessed product with a product of plant origin remains an unprocessed product of animal origin e.g.

- **skewer containing fresh meat and vegetables**
- **preparations of fresh fishery products (e.g. fish fillets) with food of plant origin**

Remarks:

- ∉ **Unprocessed products can be classified as “raw products”, i.e. they have not undergone processing (i.e. any action that substantially alters the initial product, including heating, smoking, curing, maturing, drying, marinating, extraction, extrusion, or a combination of those processes). Frozen products of animal origin remain unprocessed products.**
- ∉ **“Fresh” (with regard to meat) means meat that has not undergone any preserving process other than chilling, freezing or quick-freezing, including meat that is vacuum-wrapped in a controlled atmosphere.**
- ∉ **“Fresh” (with regard to fishery products) means unprocessed fishery products, whether whole or prepared, including products packaged vacuum or in a modified atmosphere, that have not undergone any treatment to ensure preservation other than chilling.**

ANNEX II (continued)

II. Non-exhaustive list of processed products of animal origin

Processed products are obtained by submitting raw material of animal origin to a process such as heating, smoking, curing, salting, maturing, drying, marinating, etc. The process must lead to a substantial alteration of the initial product.

Processed products include:

- Meat products (ham, salami, etc.)
- Processed fishery products (smoked fish, marinated fish etc.)
- Dairy products (heat treated milk, cheese, yoghurt, etc.)
- Egg products (egg powder etc.)
- Rendered animal fat
- Greaves
- Gelatine
- Collagen
- Treated intestines, stomachs and bladders etc.

Processed products also include:

- ∄ A combination of processed products e.g. cheese with ham
- ∄ Products that have undergone several processing operations e.g. cheese from pasteurised milk.

Products to give special characteristics may be added e.g.

- sausage with garlic
- yoghurt with fruit
- cheese with herbs

Remark:

- ∄ Processed products may include certain meat preparations such as marinated and cured meat.

ANNEX III

Commission Decisions imposing special conditions on imports of food of non-animal origin

- ∄ Commission Decision 2000/49/EC of 6 December 1999 repealing Decision 1999/356/EC and imposing special conditions on the import of peanuts and certain products derived from peanuts originating in or consigned from Egypt⁹ as last amended by Commission Decision 2004/429/EC of 29 April 2004
- ∄ Commission Decision 2002/79/EC of 4 February 2002 imposing special conditions on the import of peanuts and certain products derived from peanuts originating in or consigned from China¹⁰ as last amended by Commission Decision 2004/429/EC of 29 April 2004
- ∄ Commission Decision 2002/80/EC of 4 February 2002 imposing special conditions on the import of figs, hazelnuts and pistachios and certain products derived thereof originating in or consigned from Turkey¹¹ as last amended by Commission Decision 2004/429/EC of 29 April 2004
- ∄ Commission Decision 2003/493/EC of 4 July 2003 imposing special conditions on the import of Brazil nuts in shell originating in or consigned from Brazil¹² as last amended by Commission Decision 2004/428/EC of 29 April 2004¹³
- ∄ Commission Decision 2005/85/EC of 26 January 2005 imposing special conditions on the import of pistachios and certain products derived from pistachios originating in or consigned from Iran¹⁴
- ∄ Commission Decision 2055/402/EC of 23 May 2005 on emergency measures regarding chilli, chilli products, curcuma and palm oil¹⁵.

⁹ OJ L19, 25.1.2000, p.46

¹⁰ OJ L34, 5.2.2002, p.21

¹¹ OJ L34, 5.2.2002, p.26

¹² OJ L168, 5.7.2003, p.33

¹³ OJ L 154, 30.4.2004, p. 14

¹⁴ OJ L 30, 3.2.2005, p.12

¹⁵ OJ L 135, 28.5.2005, p. 34