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COMMISSION OF THE EUROPEAN COMMUNITIES

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draft
GUIDANCE DOCUMENT ON IMPORT REQUIREMENTS
and the new rules on food hygiene and on official controls

Draft
GUIDANCE DOCUMENT ON FOOD HYGIENE IMPORT REQUIREMENTS
and the new rules on food hygiene and on official controls

PURPOSE OF THIS DOCUMENT

This document is mainly directed at competent authorities and food businesses in the Member States and in third countries, in particular developing countries and aims to give guidance on 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.

TABLE OF CONTENTS

draft GUIDANCE DOCUMENT ON IMPORT REQUIREMENTS and the new rules on food hygiene and on official controls Draft GUIDANCE DOCUMENT ON FOOD HYGIENE IMPORT REQUIREMENTS and the new rules on food hygiene and on official controls.....	2
1. INTRODUCTION	5
2. GENERAL REMARKS	7
2.1. The sanitary conditions for food imports are laid down in several parts of Community law. The main elements are included in the following:	7
2.2. This document supplements other guidance giving advice on food imports and in particular the following document:	7
3. FREQUENTLY ASKED QUESTIONS	8
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?	8
3.2. Must third countries, in order to be eligible for food exports after 1 January 2006, be approved by the EU?	8
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?	9
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?	9
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?	10
3.6. Must third countries, in order to be eligible for export after 1 January 2006, have reference laboratories in place?	10
3.7. What role will the Food and veterinary office of the directorate general for health and consumer protection play after 1 January 2006?	10
4. THE NOTIONS “FOOD OF ANIMAL ORIGIN”, “FOOD OF NON-ANIMAL ORIGIN” AND “COMPOSITE PRODUCTS”	11
4.1. What are products of animal origin?	11
4.2. What is food of non-animal origin?	11
4.3. What are composite products?	11
5. IMPORTS OF FOOD OF <u>NON-ANIMAL ORIGIN</u>	12
5.1. Food hygiene requirements	12

5.2.	Other health requirements	12
5.3.	Import procedures related to food hygiene.....	13
5.4.	Import procedures related to plant health.....	13
5.5.	Food of non-animal origin subject to in increased level of controls	14
6.	IMPORTS OF PRODUCTS OF ANIMAL ORIGIN	15
6.1.	Import procedures.....	15
6.2.	Food hygiene requirements	15
6.3.	Animal health requirements.....	16
6.4.	Other health requirements	17
7.	IMPORTS OF COMPOSITE PRODUCTS	18
7.1.	Basic food hygiene requirements	18
7.2.	Other food hygiene requirements:	18
7.3.	Other health requirements	19
7.4.	Animal health requirements.....	19
	ANNEX I	20
	ANNEX II.....	22

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 this is a useful procedure, which should continue in the light of the experience gained by the full application of the Regulation 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.

Separate guidance documents have been established on Regulations (EC) No 178/2002, 852/2004, 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

2. GENERAL REMARKS

2.1. **The sanitary 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.)

2.2. **This document supplements other guidance giving advice on food imports and in particular the following document:**

“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

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.
 - 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.

This is fully in line with Article 7 and Annex B of the World Trade Organisation's Agreement on the Application of Sanitary measures 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.

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 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 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.*

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?

Food establishments were already before 1 January 2006 subject, in most cases, to the requirement of putting in place, implementing and maintaining HACCP-based procedures (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.

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 2005.

However, the Commission is responsible under Regulation (EC) No. 882/2004 for requesting third countries intending to export goods 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 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 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 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.

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

4.2. What is food of non-animal origin?

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

4.3. 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**”).

Examples of “composite products” are given in Annex II.

Sections 5, 6 and 7 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. IMPORTS OF FOOD OF NON-ANIMAL ORIGIN

5.1. 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),
- 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 .../2005) (in preparation),
- 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.

5.2. 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,
 - The use of food additives,
 - Materials and articles in contact with foodstuffs,
 - Food irradiation.
- 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

http://europa.eu.int/comm/agriculture/foodqual/quali1_en.htm

- Before they can be introduced into the Community, certain plants, plant products or other objects must comply with phytosanitary (plant health) requirements.

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

5.3. 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.**

- Generally, food of non-animal origin:
 - Can enter the EU without certification by the competent authorities of the third country of dispatch,
 - Is not subjected to a pre-notification procedure on arrival, and
 - Does not have to be presented systematically at a designated point of entry.
- 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 do not necessarily require the presentation of the products to a designated point of entry, and may take place at different locations in accordance with national law in the different Member States: the point of free release for circulation, the importer's premises, retail sale units etc.

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

5.4. Import procedures related to plant health

Certain plants, plant products or other objects (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).

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

5.5. Food of non-animal origin subject to an 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.*

6. IMPORTS OF PRODUCTS OF ANIMAL ORIGIN

6.1. 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.
- Commission Regulation (EC) No 136/2004⁵ gives more detailed information on procedures for veterinary checks at Community border inspection posts.
- 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.

6.2. 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 .../2005) (in preparation),

⁵ OJ L21, 28.1.2004, p. 11

- 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.

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.

6.3. 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

6.4. Other health requirements

- Under EU food law, a number of requirements may apply where appropriate in complement or in addition to food hygiene. These include requirements concerning:
 - Contaminants and residues,
 - The use of food additives,
 - Materials and articles in contact with foodstuffs.
- 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

http://europa.eu.int/comm/agriculture/foodqual/quali1_en.htm

7. IMPORTS OF COMPOSITE PRODUCTS

7.1. 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 .../2005) (in preparation),
- 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.

7.2. 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 will keep this requirement under review. 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.

7.3. 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.
- Product specific requirements also exist concerning :
 - Quick frozen foodstuffs,
 - Foodstuffs for particular nutritional purposes,
 - Genetically modified organisms (GMOs).

7.4. 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 will establish a risk based list of products that will be the subject of such checks.

For more information, see:

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

ANNEX I

PRODUCTS OF ANIMAL ORIGIN

I. Non-exhaustive list of non-processed products of animal origin

- **Fresh meat (meat of domestic ungulates, poultry meat, meat from lagomorphs, wild game meat, farmed game meat and other meat)**
- **Minced meat**
- **Meat preparations**
- **Mechanically Separated Meat**
- **Blood**
- **Fish and crustaceans (including live fish and crustaceans)**
- **Live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods**
- **Raw milk**
- **Eggs**
- **Frogs' legs**
- **Snails**
- **Honey**
- **Other**

A non-processed product of animal origin associated with a product of plant origin remains a non-processed product of animal origin e.g.

- **skewer containing fresh meat and vegetables**

ANNEX I (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

Processed products include:

- **Meat products (ham, salami,)**
- **Fish products (smoked fish, marinated fish etc)**
- **Milk products (heat treated milk, cheese, yoghurt,)**
- **Egg products**
- **Rendered animal fat**
- **Greaves**
- **Gelatine**
- **Collagen**
- **Treated stomachs and bladders etc.**

Processed products also include:

- **Combinations of processed products e.g. cheese with ham**
- **Products obtained after further processing of already processed products.**

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

- **sausage with garlic**
- **yoghurt with fruit**
- **cheese with herbs**
- **ice cream with chocolate**

ANNEX II

NON-EXHAUSTIVE LIST OF COMPOSITE PRODUCTS**

(i.e. a combination of food of non-animal origin such as fruit and vegetables with processed food of animal origin)

Bearing in mind that the ingredient of animal origin must be processed, composite products include:

- **Pizzas**
- **Pastry products such as ravioli**
- **Prepared dishes**
- **Bakery products/biscuits with butter, cream etc**
- **Sandwich with ham/cheese**
- **Chocolate**
- **Processed products of animal origin in which a component has been replaced by an ingredient of plant origin e.g. a milk product where the cream is replaced by plant oil/fat**
- **Preparations with eggs such as mayonnaise**
- **Etc.**

****NOTE: This list is for food hygiene purposes only. A separate list may apply for animal health purposes. The Commission will establish guidance on this issue in due time.**

ANNEX III

Commission Decisions imposing special conditions on imports

- 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 Egypt⁶ 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 China⁷ 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 Turkey⁸ 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 Brazil⁹ as last amended by Commission Decision 2004/428/EC of 29 April 2004¹⁰
- 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 Iran¹¹
- Commission Decision 2003/460/EC of 20 June 2003 on emergency measures regarding hot chilli and hot chilli products¹²
- Commission Decision 2004/92/CE of 21 January 2004 on emergency measures regarding chilli and hot chilli products
- Commission Decision (BT 10)

⁶ OJ L19, 25.1.2000, p.46

⁷ OJ L34, 5.2.2002, p.21

⁸ OJ L34, 5.2.2002, p.26

⁹ OJ L168, 5.7.2003, p.33

¹⁰ OJ L 154, 30.4.2004, p. 14

¹¹ OJ L 30, 3.2.2005, p.12

¹² OJ L 154, 21.6.2003, p.114