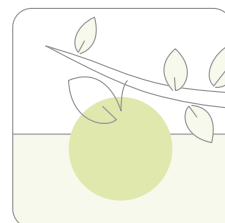
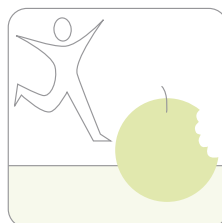
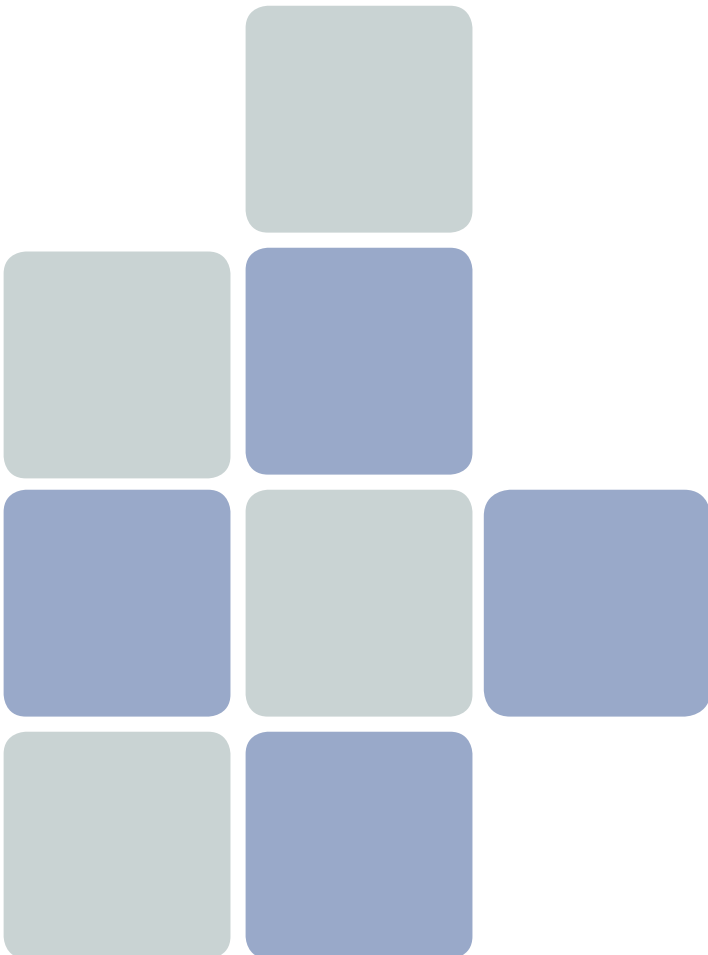


# GUIDANCE DOCUMENT

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





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**COMMISSION STAFF WORKING DOCUMENT**

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

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and the EU 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 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 Food and Veterinary Office of the Commission's Health and Consumers Directorate General.

*The Court of Justice of the European Union constitutes the judicial authority of the EU and is the institution which interprets European Union law as last resort.*

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## 1. INTRODUCTION

Since the adoption of the 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 Consumers 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 above 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 Regulations 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 foodstuffs<sup>1</sup>,
- 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 origin<sup>2</sup>,

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<sup>1</sup> OJ L 226, 25.6.2004, p. 3.

<sup>2</sup> OJ L 226, 25.6.2004, p. 22.

- 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 safety<sup>3</sup> (also referred to as the General Food Law), and
- 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<sup>4</sup>.

A separate guidance document has been established on Regulations (EC) Nos 178/2002, 852/2004, 853/2004 and on flexibility with regard to HACCP-based systems and small and medium size enterprises.

(See [http://ec.europa.eu/food/food/biosafety/hygienelegislation/index\\_en.htm](http://ec.europa.eu/food/food/biosafety/hygienelegislation/index_en.htm))

## 2. GENERAL REMARKS

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 processed ingredients of animal origin and ingredients of 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.

The food hygiene conditions for food imports are laid down in several parts of EU law.

Apart from Regulations (EC) Nos 852/2004, 853/2004, 178/2002 and 882/2002, consideration should be given to:

- 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<sup>5</sup>
- 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<sup>6</sup>.

This document supplements other guidance documents and in particular:

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<sup>3</sup> OJ L 31, 1.2.2002, p. 1.

<sup>4</sup> OJ L 191, 28.5.2004, p. 1.

<sup>5</sup> OJ L 226, 25.6.2004, p.83.

<sup>6</sup> OJ L 24, 30.1.1998, p.9.

- A dedicated website which offers advice as well as assistance to third country trading partners intending to import food: [http://ec.europa.eu/food/international/trade/index\\_en.htm](http://ec.europa.eu/food/international/trade/index_en.htm)
- Guidelines on the implementation of the main General Food Law requirements: [http://ec.europa.eu/food/food/foodlaw/guidance/index\\_en.htm](http://ec.europa.eu/food/food/foodlaw/guidance/index_en.htm)

Importers of food need to consider also other requirements that need to be complied with:

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, enzymes and flavourings,
  - 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),
  - Approved residue control plans.

For more information, see:

[http://ec.europa.eu/food/food/index\\_en.htm](http://ec.europa.eu/food/food/index_en.htm)

Plant health requirements

Before they can be introduced into the EU, certain plants, plant products or other objects must comply with phytosanitary requirements.

For more information, see: [http://ec.europa.eu/food/plant/index\\_en.htm](http://ec.europa.eu/food/plant/index_en.htm)

Animal health requirements

Products of animal origin from third countries must comply with requirements that prevent the introduction of animal diseases into the EU. These requirements emanate from Council Directive 2002/99/EC of laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption<sup>7</sup>. For more information, see:

[http://ec.europa.eu/food/animal/animalproducts/index\\_en.htm](http://ec.europa.eu/food/animal/animalproducts/index_en.htm)

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<sup>7</sup> OJ L 18, 23.1.2003, p. 11.



The provisions in the hygiene regulations may be supplemented by additional animal health requirements or other provisions, such as the ones on novel food (Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients<sup>8</sup>).

### **3. FREQUENTLY ASKED QUESTIONS**

#### **3.1. Must third countries, in order to be eligible for food exports to the EU 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.
- 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.

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

With regard to food of animal origin only a third country that appears on a list established by the EU can export to the EU.

With regard to food of non-animal origin, third countries do not need to appear on a list for being eligible for export to the EU.

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

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

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)<sup>9</sup>.

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

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<sup>8</sup> OJ L 43, 14.2.1997, p. 1.

<sup>9</sup> Published on [http://www.wto.org/english/tratop\\_e/sps\\_e/spsagr\\_e.htm](http://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm)

- 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, 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 EU can export to the EU.
- 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 EU. 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, implement procedures based on the HACCP principles?**

The competent authorities in the Member States have to ensure that foodstuffs imported into the EU are 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 are observed.

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

**3.6. Must third countries, in order to be eligible for export, 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** during which laboratories in third countries can adapt to the new situation.

**3.7. What role will the Food and Veterinary Office of the Commission's Health and Consumers Directorate General play?**

The Food and Veterinary Office (FVO) carries out audits in both Member States and third countries.

However, the Commission is responsible under Regulation (EC) No. 882/2004 for requesting third countries intending to export food to the EU to provide accurate and up-to-date information on the general organisation and management of sanitary control systems.

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.

##### **4.2. What is food of animal origin?**

The notion “food 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 I gives a general (non-exhaustive) overview of what is to be considered as food 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 or including products of animal origin such as milk or egg products 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 5, 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. GENERAL REQUIREMENTS FOR ALL FOOD**

Certain basic food law and food hygiene requirements applying to all food are laid down in Regulation (EC) No 178/2002 and Regulation (EC) No 852/2004, respectively. These include in particular:

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

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

- The relevant requirements of food law, or
- Conditions recognised by the EU to be **at least equivalent** thereto, or

- Where a specific agreement exists between the EU 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.

## **5.3. General food hygiene requirements and microbiological criteria**

The relevant requirements with regard to the hygiene of all food are contained in Articles 3 to 6 of Regulation (EC) No 852/2004, which means that the following rules need to be respected by all 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 of 15 November 2005 on microbiological criteria for foodstuffs<sup>10</sup>,
- Procedures based on the HACCP principles (Article 5 of Regulation (EC) No 852/2004),
- Registration or approval of establishments (Article 6 of Regulation (EC) No 852/2004).

## **6. IMPORTS OF FOOD OF NON-ANIMAL ORIGIN**

### **6.1. Import procedures**

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

- Most (see points 6.2, 6.3 and 6.4) food of non-animal origin can enter the EU through any entry point and is not subject to specific import conditions, pre-notification requirement or certification by the competent authorities of the third country of dispatch.
- 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

<sup>10</sup> OJ L 338, 22.12.2005, p. 1.

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.

## **6.2. Food of non-animal origin subject to increased level of controls**

In accordance with Article 15, paragraph 5 of Regulation (EC) No 882/2004, the Commission established a list of food of non-animal origin that, on the basis of known or emerging risks, must 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 to the competent authority at the point of entry into the EU.

The list of the products subject to controls at the point of entry into the EU has been laid down in Annex I to Commission Regulation (EC) No 669/2009 of 24 July 2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC<sup>11</sup> and can be consulted at:

[http://ec.europa.eu/food/food/controls/increased\\_checks/index\\_en.htm](http://ec.europa.eu/food/food/controls/increased_checks/index_en.htm)

## **6.3. Food of non-animal origin subject to specific import requirements and to specific import procedures**

In application of Article 53 of Regulation (EC) 178/2002, safeguard measures have been taken as regards the import of certain food of non-animal origin from certain third countries imposing special conditions to the import of these products into the Union.

## **6.4. Sprouts and seeds intended for the production of sprouts**

Apart from the above requirements on food of non-animal origin, certification applies to the import of consignments of sprouts or seeds intended for the production of sprouts, excluding sprouts which have undergone a treatment which eliminates the microbiological hazards (for example canned (pasteurized) sprouts) in accordance with Commission Regulation (EU) No 211/2013 of 11 March 2013 on certification requirements for imports into the Union of sprouts and seeds intended for the production of sprouts<sup>12</sup>.

Apart from the requirement in section 5 and 6.1, certification is needed as regards provisions on:

- Traceability in accordance with Commission Regulation (EU) No 208/2013 of 11 March 2013 on traceability requirements for sprouts and seeds intended for the production of sprouts<sup>13</sup>.

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<sup>11</sup> OJ L 194, 25.7.2009, p. 11.

<sup>12</sup> OJ L 68, 12.3.2013, p. 26.

<sup>13</sup> OJ L 68, 12.3.2013, p. 16.

- Approval of establishments producing sprouts in accordance with Commission Regulation (EU) No 210/2013 of 11 March 2013 on the approval of establishments producing sprouts pursuant to Regulation (EC) No 852/2004 of the European Parliament and of the Council<sup>14</sup>.

## **7. IMPORTS OF FOOD OF ANIMAL ORIGIN,**

### **7.1. Import procedures**

In accordance with Directive 97/78/EC and 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<sup>15</sup>:

- Products of animal origin, must be presented at an EU approved border inspection post for being submitted to an import control,
- Prior notification of the physical arrival of the products on the EU territory must be provided to the border inspection post of arrival using the Common Veterinary Entry Document (CVED),
- The consignments must be presented to the border inspection post accompanied by all relevant certificates/documents required in EU legislation,
- Consignments will only be accepted if the products are derived from approved third countries, regions thereof and establishments as appropriate and if veterinary checks had favourable results,
- In certain cases, safeguard measures introducing special import conditions or restrictions may apply,
- The procedures as laid down in Regulation (EC) No 136/2004 are to be followed.

Additional information regarding import controls in border inspection posts is available at: [http://ec.europa.eu/food/animal/bips/index\\_en.htm](http://ec.europa.eu/food/animal/bips/index_en.htm)

### **7.2. Specific food hygiene requirements**

It should be noted that when the hygiene package (including implementing acts such as Regulation (EC) No 2073/2005) came into force, the previous specific public health conditions on imports of food of animal origin based on 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<sup>16</sup> (Annex II) were among those repealed.

#### *7.2.1. Obligations of importers (Article 6 of Regulation (EC) No 853/2004)*

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

- Come from a third country or a part of a third country that appears on an EU list,
- Where applicable, come from an establishment that appears on an EU list,

<sup>14</sup> OJ L 68, 12.3.2013, p. 24.

<sup>15</sup> OJ L 21, 28.1.2004, p.11

<sup>16</sup> OJ L 62, 15.3.1993, p. 49.

- 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 an EU approved border inspection post,
- Comply with the animal health requirements of Council 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.

#### 7.2.2. *Obligations of competent authorities in third countries*

For food 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 EU 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 EU 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. Common (e.g. including animal health requirements) model certificates have been made available for almost all food for which specific requirements have been laid down in Annex III to Regulation (EC) No 853/2004.

As regards food of animal origin not covered by Annex III to Regulation (EC) No 853/2004, an EU list of eligible countries and the model health certificate have been laid down for honey (apiculture products).

The models can be found at: [http://ec.europa.eu/food/international/trade/index\\_en.htm](http://ec.europa.eu/food/international/trade/index_en.htm)

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).

#### 7.2.3. *Transitional measures for import of certain food of animal origin*

Import conditions for food of animal origin are considered fully harmonised at EU level if for the relevant food, the import conditions include the presence of:

- a) An EU list of eligible third countries
- b) A model health certificate (public health statements often combined with animal health statements in the same certificate)
- c) An EU list of eligible establishments in third countries (only for establishments falling under Annex II to Regulation (EC) No 852/2004 and for which Annex III to Regulation (EC) No 853/2004 lays down requirements).

For certain food of animal origin, the lists of eligible countries, the model certificates and/or the lists (if required) of eligible establishments have not yet been established at EU level (insects, meat of marine mammals, meat of reptiles, ...). Therefore, transitional provisions apply until 31 December 2016<sup>17</sup>.

During the transitional period, until the eventual adoption of harmonised EU import conditions, all imported food of animal origin must comply with the requirements of Regulation (EC) No 178/2002 (see section 5), and Regulation (EC) No 852/2004 (see Section 5.3). Imported food of animal origin must also comply with other conditions for food safety, if laid down in specific EU legislation applicable for certain food, such as, official controls for *Trichinella* according to Regulation (EC) No 2075/2005 of 5 December 2005 laying down specific rules on official controls for *Trichinella* in meat<sup>18</sup>, residue programmes according to Commission Decision 2011/163/EU of 16 March 2011 on the approval of plans submitted by third countries in accordance with Article 29 of Council Directive 96/23/EC<sup>19</sup>, the TSE legislation (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<sup>20</sup>), and specific safeguard measures. In line with general EU principles, it is the responsibility of the food business operators importing food of animal origin from third countries to ensure that importation takes place only if the product complies with these EU requirements. In addition, it is the responsibility of competent authorities in third countries to verify that food business operators exporting to the EU took their respective responsibility ensuring that exported products fulfil EU requirements.

The Commission is reflecting on a future solution for all food of animal origin to better clarify the import requirements for various types of products. before the end of the transitional period. The EU listing of establishments and the adoption of EU model certificates will, in any case, be continued as quickly as possible for food of animal origin for which specific requirements are laid down in Annex III to Regulation (EC) No 853/2004.

#### 7.2.4. National public health import conditions and the principle of free movement

In principle, a product lawfully marketed in one Member State can be placed on the market in all Member States. An exception to this general rule is that, according to Article 36 of the Treaty on the Functioning of the EU<sup>21</sup>, restrictions on trade between Member States can be justified, *inter alia*, for public morality or public health reasons, the protection of health and life of humans, animals and plants. However, since these restrictions are exceptional derogations from the principle of free movement, they must be thoroughly justified. Normally, serious risks are addressed by EU provisions ensuring the same high level of protection within the EU.

For food of animal origin for which full EU harmonisation (See 7.2.3) has not been completed yet, national public health import conditions may apply. However, before

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<sup>17</sup> Commission Regulation (EU) No 1079/2013 of 31 October 2013 laying down transitional measures for the application of Regulations (EC) No 853/2004 and (EC) No 884/2004 of the European Parliament and of the Council.

<sup>18</sup> OJ L 338, 22.12.2005, p. 60.

<sup>19</sup> OJ L 70, 17.3.2011, p. 40.

<sup>20</sup> OJ L 147, 31.5.2001, p. 1.

<sup>21</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2010:083:0047:0200:en:PDF>



laying down trade-restrictive national legislation, such national legislation must be notified at draft stage in accordance with the procedure under Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations<sup>22</sup>. In doing so, the Commission and other Member States shall have the possibility to provide comments on the possible restrictions on trade and import. Upon the successful completion of the notification procedure, these national rules must be complied with when placing the relevant food only on the market of the notifying Member State.

Member States importing food of animal origin for which full EU harmonisation has not been completed yet, do not need to lay down national rules for the application of the existing general EU import requirements (for instance, Regulation (EC) No 178/2002, or Regulation (EC) No 852/2004), as provisions in these EU Regulations are directly applicable. Only if additional national import requirements are laid down (see previous paragraph), cross-references to the relevant EU provisions should be made in the national rules without repeating the EU provisions and above mentioned notification under Directive 98/34/EC is required.

Regarding which national rules have to be notified, it should be observed that only the national rules themselves must be notified. For instance, national lists of eligible third country establishments which were established following these national rules should not be notified.

## **8. IMPORTS OF COMPOSITE PRODUCTS**

### **8.1. Specific food hygiene requirements**

In accordance with Article 6, paragraph 4 of Regulation (EC) No 853/2004, food business operators established in the EU 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 specific requirements for products of animal origin in section 7.2.**

The importing food business operator must be able to demonstrate that the above is respected (using documentation or otherwise).

### **8.2. Import procedure and certification of consignments of certain composite products.**

- Certain composite products provided for in Regulation (EU) No 28/2012 of 11 January 2012 laying down requirements for the certification for imports into and transit through the Union of certain composite products and amending Decision 2007/275/EC and Regulation (EC) No 1162/2009<sup>23</sup> have to undergo import controls in border inspection posts as described in section 7.1.
- The same Regulation specifies certification requirements taking into consideration animal and public health requirements.

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<sup>22</sup> OJ L 204, 21.7.1998, p. 37.

<sup>23</sup> OJ L 12, 14.1.2012, p. 1.

## FOOD OF ANIMAL ORIGIN

### I. Non-exhaustive list of non-processed food 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 food 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**
- **preparations of fresh fishery products (e.g. fish fillets) with food of plant origin**

## II. Non-exhaustive list of processed food 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.**

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

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