

EN

**SANCO/1514/2005**  
**25 May 2005**

**Wording document: does not necessarily represent the opinion of the European Commission.**

**Preliminary version: may be subject to changes and amendments.**



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 17.5.2005

**DRAFT**

**Guidance document on the implementation of certain provisions of**

**Regulation (EC) No 853/2004**

**on the hygiene of food of animal origin**

## **PURPOSE OF THIS DOCUMENT**

This document is mainly directed at food businesses and competent authorities, and aims to give guidance on the implementation of the new food hygiene 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, food businesses and the Commission's Food and Veterinary Office.

## 1. INTRODUCTION

Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin (hereafter “the Regulation”) was adopted on 29 April 2004<sup>1</sup>. It lays down the hygiene requirements to be respected by food businesses handling food of animal origin at all stages of the food chain. Since the adoption of the Regulation, the Commission has been requested to clarify a number of aspects thereof. 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 and interpretation of the Regulation.

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 Regulation.

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 Regulation. 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.

For a complete understanding of the different aspects of Regulation (EC) No 853/2004, it is essential to be also familiar with other parts of Community legislation, and in particular with the principles and definitions of :

- 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>2</sup> (also referred to as the General Food Law),
- Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April on the hygiene of foodstuffs<sup>3</sup>, and

---

<sup>1</sup> OJ No L 226, 25.6.2004, p.22

<sup>2</sup> OJ No L 31, 1.2.2002, p. 1

<sup>3</sup> OJ No L 226 of 25.6.2004, p. 3

- 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>.

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

(See [http://europa.eu.int/comm/food/food/foodlaw/guidance/index\\_en.htm](http://europa.eu.int/comm/food/food/foodlaw/guidance/index_en.htm))

---

<sup>4</sup> OJ No L 165, 30.4.2004, p.1

## **2. OBLIGATIONS OF FOOD BUSSINESS OPERATORS**

The Regulation is addressed to, and must be implemented by, food businesses. They must ensure that all the requirements are properly implemented in order to ensure food safety.

The role of the competent authority is to verify whether the food hygiene rules are properly implemented. This verification must be carried out in accordance with the general principles laid down in Regulation (EC) No 882/2004 and in accordance with Regulation (EC) No 854/2004.

## **3. SCOPE (ARTICLE 1 OF THE REGULATION)**

### **3.1. Small businesses**

Under current Community law, certain small businesses can only place their products in the national market although they have to respect food hygiene criteria, e.g.

- Under Article 4 of Directive 64/433/EEC (the fresh meat Directive) meat from low capacity slaughterhouses handling not more than 20 livestock units per week, and cutting plants which produce not more than five tonnes of boned meat per week;
- Under Article 9 of Directive 77/99/EEC (the meat products Directive), establishments producing less than 7.5 tonnes of finished product per week.

Under Regulation (EC) No 853/2004, these establishments can place their products on the Community market without having to respect severe new requirements.

### **3.2. Establishments handling food of animal origin for which no detailed requirements are laid down**

For certain products of animal origin (e.g. honey), the Regulation does not lay down detailed rules. In that event, the food of animal origin must be handled in accordance with the relevant requirements laid down in Regulation (EC) No 852/2004 and also with the general rules for products of animal origin laid down in Regulation (EC) No 853/2004 (in particular the rules on products from outside the Community referred to in Article 6).

### **3.3. Products covered under Regulation (EC) No 853/2004**

The scope of the Regulation includes unprocessed products and processed products of animal origin.

- **A (non-exhaustive) list of unprocessed products of animal origin** [as defined in Article 2, point 1(n) of Regulation (EC) No 852/2004] is given in Annex I.

- A (non exhaustive) list of processed products of animal origin [as defined in Article 2, point 1(o) of Regulation (EC) No 852/2004] is given in Annex II.

### 3.4. “Composite products”

Although the term “composite products” is commonly used to indicate food containing both products of plant origin and processed products of animal origin, that term is not defined as such in the Regulation.

Unless expressly indicated to the contrary, the Regulation does not apply to food containing both products of plant origin and processed products of animal origin e.g. chocolate, bakery products, pizzas etc.

However, the ingredient of animal origin used for the manufacture of such products must comply with EC law, i.e. have been obtained in accordance with Regulation (EC) No 853/2004.

Annex III gives an overview of composite products. The overview is non exhaustive and therefore purely indicative.

***Remark:*** *an establishment manufacturing both products of animal origin and composite products may apply the identification mark required for product of animal origin also on the composite products concerned (see Annex II, Section I, point B.7 of Regulation (EC) No 853/2004).*

### 3.5. Retail

Unless expressly indicated to the contrary, **Regulation (EC) No 853/2004 does not apply to retail** [Article 1, paragraph 5(a)].

The definition of retail sale is in Article 3, point 7 of Regulation (EC) No 178/2002. It reads as follows:

*“retail” means the handling and/ or processing of food and its storage at the point of sale or delivery to the final consumer, and includes distribution terminals, catering operations, factory canteens, institutional catering, restaurants and other similar food service operations, shops, supermarket distribution centres and wholesale outlets.*

As explained in recitals 12 and 13 of Regulation (EC) No 853/2004, this definition which includes wholesale operations was considered to be too wide for food hygiene purposes. In the context of food hygiene, retail should generally have a more limited meaning as follows: “activities involving direct sale or supply of food of animal origin to the final consumer”. This means that:

- For activities involving direct sale or supply of food of animal origin to the final consumer, Regulation (EC) No 852/2004 would suffice.
- With regard to wholesale activities (i.e. when a wholesale or retail establishment carries out operations with a view to supplying food of animal

origin to another establishment), Regulation (EC) No 853/2004 applies except for:

- Establishments for which the wholesale activities consist only of storage and transport. In that case, the requirements of Regulation (EC) No 852/2004, and the temperature requirements laid down in Regulation (EC) No 853/2004 apply,
- The supply is, in accordance with national law, a **marginal, localised and restricted** activity of a retail establishment that mainly supplies the final consumer. In that event, only Regulation (EC) No 852/2004 applies.

However, in accordance with Article 1, paragraph 5(c), Member States may decide to extend the rules of Regulation (EC) No 853/2004 to retail establishments situated on their territory to which it would not apply pursuant to derogations provided for in the Regulation.

### 3.6. The notion “*marginal, localised and restricted activity*” as referred to in Article 1 paragraph 5, point b)ii of Regulation (EC) No 853/2004.

That notion allows genuine retail shops supplying the final consumer (e.g. a butcher) to deliver food of animal origin to another local retail business under the requirements of Regulation (EC) No 852/2004 only. The requirements of Regulation (EC) No 853/2004 (e.g. the approval of the establishment, the application of an identification mark) would not apply.

*In general terms, the notion “marginal, localised and restricted activity” should:*

- *allow current practices as they exist in the Member States to continue,*
- *be applied in such a way that there is no unfair competition with food establishments carrying out similar activities and that are subjected to the full impact of Regulation (EC) No 853/2004*

The notion “marginal, localised and restricted supply” stems from the observation that retail establishments supplying the final consumer as their main trade should in effect trade their products locally (even if the destination is in another Member State) and so are not engaged in long distance trade which require more attention and supervision in particular as regards transport and cold chain conditions. In the case of a large Member State it would therefore not be in line with the Regulation to extend geographically the notion “marginal, localised and restricted supply” to the entire territory of that Member State.

The notion is further explained in recital (13), where it is spelled out that such supply should be only a small part of the supplying establishment’s business; the establishment supplied should be in its immediate vicinity, and the supply should concern only certain types of products or establishments.

In some cases retailers (e.g. butchers) may produce small quantities (in absolute terms) of food, most of which is supplied to caterers and/or to other retailers. In such cases it would be in line with the intention of the Regulation to enable the continued use of traditional methods of distribution, considering that “marginal” should include the notion of small quantities. “Marginal” should therefore be interpreted as a small amount of food of animal origin in absolute terms **or** as a small part of the establishment’s businesses, whichever is the greater amount. At any rate, the combination of the three criteria provided for by the Regulation should allow an appropriate qualification of most situations.

### **3.7. Primary production covered under Regulation (EC) No 853/2004**

For certain products of animal origin, the notion “primary production” referred to in Regulation (EC) No 852/2004 is further developed under Regulation (EC) No 853/2004:

#### **Live bivalve molluscs** [Annex III, Section VII, point 4(a)]

With regard to live bivalve molluscs, primary production covers operations that take place before live bivalve molluscs arrive at a dispatch or purification centre.

**Fishery products** including live pectinidae harvested outside production areas [Annex III, Section VIII, point 4 and Annex III, Section VIII, points 3(a) and (b)].

With regard to fishery products, primary production:

- Includes farming/fishing/catch of live fishery products
- Includes the following associated operations:
  - Slaughter, bleeding, heading, gutting, removing fins, refrigeration and wrapping carried out on board fishing vessels,
  - The transport and storage of fishery products the nature of which has not been substantially altered, including live fishery products, within farms on land, and
  - The transport of fishery products the nature of which has not substantially been altered, including live fishery products, from the place of production to the first establishment of destination.
- Covers establishments, including fishing vessels, engaged in primary production and associated operations. Other establishments, including factory and freezer vessels, are not covered by primary production.

Freezer and factory vessels where fish is handled are not engaged in primary production, but they are establishments subject to approval since they are not merely engaged in transport operations, and store products requiring temperature control.

#### **4. APPROVAL OF ESTABLISHMENTS (ARTICLE 4 OF THE REGULATION)**

##### **4.1. Establishments subject to approval**

A non-exhaustive list of establishment categories subject to approval is given in Annex IV to the present document.

##### **4.2. The approval of small establishments**

Also small establishments handling food of animal origin must be approved by the competent authority. This is in particular the case for small establishments referred to in point 3.1 above.

The approval requirements for such establishments are largely the requirements that applied already to them under the current rules. The new approval requirement should not therefore impose an important new burden provided these establishments already complied with the food hygiene rules applicable to them under the relevant Community rules (e.g. Directives 64/433/EEC and 77/99/EEC).

The need for approval shall however not prevent an establishment from placing food on the market between the date of application of the Regulation (1.1.2006) and the first subsequent inspection by the competent authority (see Article 4, paragraph 5 of the Regulation)

##### **Remark:**

*Regulation (EC) No 853/2004 excludes retail (i.e. the handling and/or processing of food and its storage at the point of sale) from its scope. This means that where cheese is manufactured and sold at a retail premise (e.g. at the farm), these activities can be carried under the respect of the requirements laid down in Regulation (EC) No 852/2004 only, requiring no approval.*

##### **4.3. The placing on the market of meat from animals slaughtered at the farm**

Slaughter activities at the farm must be carried out in accordance with the appropriate requirements of Regulation (EC) No 852/2004 and with the specific food hygiene rules for meat production laid down in Regulation (EC) No 853/2004. This includes that the slaughter facilities must be approved by the competent authority.

Were it is felt that the infrastructural requirements of Regulations (EC) No 852/2004 and 853/2004 disproportionate for on-the-farm slaughter Member States may adapt those requirements in accordance with the procedure laid down for that purpose in Article 10 of Regulation (EC) No 853/2004.

##### **Remarks:**

- *The direct supply, by the producer, of **small quantities of meat from poultry and lagomorphs** slaughtered on the farm to the final consumer or to local*

*retail establishments directly supplying such meat to the final consumer as fresh meat, fall outside the scope of Regulation (EC) No 853/2004. Member States shall establish national rules to ensure the safety of such meat [see Article 1, paragraph “(d) of the Regulation].*

- *In the case of “**slaughter for private domestic consumption**”, such activity is undertaken by a private person who cannot be considered as being a food business operator. In addition, meat resulting from such slaughter is not placed on the market. Slaughter for private domestic consumption falls therefore out of the scope of Regulations (EC) No 852/2004 and 853/2004. It is up to the Member States to ensure that these activities are appropriate to ensure food safety.*

#### **4.4. The approval of cold stores**

Article 1, paragraph 5(a) of Regulation (EC) No 853/2004 lays down that “**Unless expressly indicated to the contrary, this Regulation shall not apply to retail**”.

Since cold stores could be considered as retail establishments in the broader sense of the definition in Article 3, paragraph 7 of Regulation (EC) No 178/2002, one might conclude that cold stores are generally excluded from the scope of Regulation (EC) No 853/2004 and are therefore not the subject of approval by the competent authorities (see Article 1, paragraph 5(a) of Regulation (EC) No 853/2004).

However, with regard to cold storage, Regulation (EC) No 853/2004 lays down requirements which must be considered as **expressly indicating** that cold storage operations fall within the scope of the Regulation:

- Annex III, Section I, Chapter VII of Regulation (EC) No 853/2004 contains requirements regarding cold storage for meat, and cold stores for meat are therefore establishments handling products for which Annex III to the Regulation lays down requirements. Such establishments shall not operate unless the competent authority has approved them;
- Article 4 of Regulation (EC) No 853/2004 expressly excludes storage of products not requiring temperature-controlled storage conditions from the approval obligations, it being understood that establishments proceeding to cold storage must be approved.

Cold stores must therefore be approved insofar as they are used in relation with activities for which Annex III of Regulation 853/2004 lays down requirements.

However, in the light of Article 1, paragraph 5(b), cold stores operated by genuine retail outlets not covered by the Regulation are not subject to the Regulation, and cold stores that are involved in wholesale operations which are physically limited to transport and storage, do not need to be approved but remain subject to the temperature requirements. When wholesale activities

include more than storage and transport (for instance re-packaging), the cold stores remain establishments to be approved in accordance with Article 4.

## 5. TECHNICAL ISSUES

### MEAT

#### 5.1. Clean animals

The requirement for animals to be clean is referred to in several parts of the new Hygiene rules:

- Farmers must take adequate measures, as far as possible, to ensure the cleanliness of the animals going to slaughter (Annex I, Part A, point II. 4(c) of Regulation (EC) No 852/2004);
- Slaughterhouse operators must ensure compliance with the following requirement: “animals must be clean” (Annex III, Section I, Chapter IV, point 4 of Regulation (EC) No 853/2004);
- The official veterinarian is to verify compliance with the requirement to ensure that animals that have such hide, skin or fleece conditions that there is an unacceptable risk of contamination of the meat during slaughter are not slaughtered unless they are cleaned beforehand (Annex I, Section II, Chapter III, point 3 of Regulation (EC) No 854/2004)

The background for this requirement is that there is substantial proof that unclean animals have been at the source of carcass contamination and subsequent food poisoning.

The objective of the requirement is to avoid contamination of the meat during slaughter so as to ensure that the microbiological quality required by Community law is achieved.

Developing the means for reaching the objective is a task to be achieved by the food business operators concerned. There are different means of reaching the objective, including:

- The effective cleaning of animals, or
- The sorting of the animals in accordance with cleanliness and developing a scheme for the separate slaughter of clean and dirty animals, or
- Developing procedures for the hygienic dressing of animals that must protect carcasses from unnecessary contamination, or
- Other appropriate procedures.

Guides to good practice may be an appropriate tool to assist slaughterhouse operators in defining these means.

It is the task of the competent authority to verify whether the procedures developed by the operators are carried out properly.

## 5.2. Transport of meat at temperatures that must enable the production of specific products

Annex I, Chapter XIV, point 66 of Directive 64/433/EEC lays down that:

*“Fresh meat must be chilled immediately after the post-mortem inspection and kept at a constant internal temperature of not more than + 7 °C for carcasses and cuts and + 3 °C for offal.*

*Derogations from this requirements may, for technical reasons relating to the maturation of meat, be granted by the competent authority on a case-by-case basis for the transportation of meat to cutting plants or butcher shops in the immediate vicinity of the slaughterhouse, provided that such transport takes not more than two hours”.*

At several occasions, the Commission has been questioned by food business operators who fear that this possibility has not been carried over in Regulation (EC) No 853/2004. However, the possibility of temperature derogations for the transport of meat has been maintained in Annex III, Section I, Chapter VII, point 3 of that Regulation which lays down that:

*“Meat must attain the temperature specified in point 1 before transport, and remain at that temperature during transport. However, transport may also take place if the competent authority so authorises to **enable production of specific products**, provided that:*

(a) *such transport takes place in accordance with the requirements that the competent authority specifies in respect of the transport from one given establishment to another,*

*and*

(b) *the meat leaves the slaughterhouse, or a cutting room on the same site as the slaughter premises immediately and **transport takes no more than two hours.**”*

## 5.3. Scrap trimmings and scrap cuttings

Annex III, Section V, Chapter II lays down that the following cannot be used as raw materials for the production of minced meat, meat preparations and mechanically separated meat:

*“scrap trimmings and scrap cuttings (other than whole muscle cuttings)”.*

Several requests have been made to clarify what is to be understood under this terminology.

In general terms, scrap trimmings and scrap cuttings refer obviously to meat trimmed from carcasses, meat cuts or offal which is then designated as either 'inedible' or 'unfit for human consumption'.

In that context, scrap trimmings and scrap cuttings applies to e.g.:

- Material trimmed from meat and not harvested for purposes permitted by the relevant Directive, such as trimmings made during dressing arising from hair or other contamination;
- Trimmings from the point at which the sticking of the animal took place, injection areas
- Trimmings made, out of hygiene considerations, prior to cutting operations
- Bits of meat which have been deemed to be unfit for human consumption for sanitary reasons, e.g. pathological lesions, floor sweepings, etc.

#### **5.4. The evaluation of the food chain information by the slaughterhouse operator**

With regard to the food chain information, Annex II, Section III, point 5 of Regulation (EC) No 853/2004 lays down that the slaughterhouse operators must, in order to check whether or not to accept animals on their premises, evaluate the relevant information before making it available to the official veterinarian.

In practice, the slaughterhouse operator shall **check** that the food chain information that is presented is complete with no obvious errors or omissions, and can be deemed effective to support his decision. It does not impose to the slaughterhouse operator to make a professional evaluation of the information since such evaluation can only be performed in a professional way by the official veterinarian.

#### **5.5. Visible carcass contamination**

The food business operator must prevent faecal contamination of the carcass during the slaughter process (Annex III, Section I, Chapter IV, point 10). Every single carcass must be monitored visually by the food business operator to ensure absence of contamination with, in particular, faeces, grease and hair. In order to inspect the carcass visually in a proper way, the food business operator shall ensure that enough light is available at the point of inspection and that the carcass can be seen from all angles (mirrors can assist). If contamination is detected, it should be removed before the carcass will be inspected by the officials during the post mortem meat inspection.

#### **5.6. Udder removal**

As mentioned in Annex III, Section I, Chapter IV, the udder shall be removed during the slaughter process. If done before the carcass is inspected by the officials during the post mortem meat inspection, the udder shall accompany the carcass to enable the officials to examine at the same time the carcass and all its

organs (including udders in the case of cows) in order to properly judge the health status of the animal.

## **MILK AND MILK PRODUCTS**

### **5.7. Identification mark**

It is common use in the dairy sector to apply several identification marks on a single package with an indication as to what mark is the valid one.

The wording of the requirements with regard to identification marking in Annex III, Section IX, Chapter V of Regulation (EC) No 853/2004 allows continuation of such practice.

## **ANNEX I**

### **Non exhaustive list of**

#### **non-processed products of animal origin**

- Fresh meat/minced meat/Mechanically Separated Meat**
- Meat preparations**
- Blood**
- Fresh fishery products**
- Live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods**
- Raw milk**
- Eggs and liquid egg**
- Frogs' legs**
- Snails**
- Honey**
- Other**

**A non-processed product with a product of plant origin remains a raw product e.g.**

- skewer containing fresh meat and vegetables**

## ANNEX II

### Non-exhaustive list of processed products of animal origin

*Processed products are obtained by submitting raw products to a process such as heating, smoking, curing, maturing, drying, marinating, etc*

- 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:**

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

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

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

### ANNEX III

#### NON-EXHAUSTIVE LIST OF COMPOSITE PRODUCTS

**A composite products is 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. Other rules may apply for animal health purposes.**

**ANNEX IV**  
**NON-EXHAUSTIVE LIST OF**  
**ESTABLISHMENTS SUBJECT TO APPROVAL**

- Meat
  - Slaughterhouses
  - Cutting plants
  - Slaughter on farm (poultry-lagomorphs)
  - Game handling establishment
  - Establishments producing minced meat, meat preparations and MSM
  - Establishment manufacturing meat products
- Live bivalve molluscs
  - Dispatch centres
  - Purification centres
- Fishery products
  - Vessels not involved in primary production and associated operations (i.e. freezer vessels and factory vessels)
  - Establishments on land (including wholesale markets and auction halls where fishery products are displayed for sale; freezing establishments; establishments producing mechanically separated fish flesh; processing establishments)
- Milk and milk products
  - Establishments processing milk
  - Milk collection centres
- Egg products
  - Establishments processing eggs
- Frogs' legs and snails
  - Establishments preparing frogs' legs and snails
- Rendered animal fats and greaves

- Establishments collecting, storing or processing raw materials
- Stomachs and bladders
  - Establishments treating bladders, stomachs and intestines
- Gelatine
  - Establishments processing raw materials
- Collagen
  - Establishments processing raw materials