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Guidance document on the implementation of certain provisions of Regulation (EC) No 853/2004 on the hygiene of food of animal origin

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Guidance document on the implementation of certain provisions of

Regulation (EC) No 853/2004

on the hygiene of food of animal origin

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PURPOSE OF THIS DOCUMENT

This document is mainly directed at food businesses and competent authorities in the Member States, and aims to give guidance on the implementation of the new food hygiene requirements and on related subjects.

Readers in third countries may find useful elements in the document so as to better understand the scope and the purpose of EU food hygiene rules.

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[1]. 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 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 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 these meetings and discussions 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[2] (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[3], and

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1 OJ No L 226, 25.6.2004, p.22
2 OJ No L 31, 1.2.2002, p. 1
3 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[4],

- Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs[5],

- Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004, for the organisation of official controls under Regulations (EC) No 854/2004 and (EC) No 882/2004, derogating from Regulation (EC) No 852/2004 and amending Regulations (EC) No 853/2004 and (EC) No 854/2004[6],

- Commission Regulation (EC) No 2075/2005 of 5 December 2005 laying down specific rules on official controls for *Trichinella* in meat[7],

- Commission Regulation (EC) No 2076/2005 of 5 December 2005 laying down transitional arrangements for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and No 854/2004[8].

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)

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4 OJ No L 165, 30.4.2004, p.1
5 OJ No L 338, 22.12.2005, p. 1
6 OJ No L 338, 22.12.2005, p. 27
7 OJ No L 338, 22.12.2005, p. 60
8 OJ No L 338, 22.12.2005, p. 83

2. OBLIGATIONS OF FOOD BUSINESS OPERATORS

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

Food businesses that handle food of animal origin must implement the appropriate requirements of Regulation (EC) No 853/2004 in addition to the requirements laid down in Regulation (EC) No 852/2004.

3. SCOPE (ARTICLE 1 OF THE REGULATION)

3.1. Small businesses

Until 1 January 2006, certain small businesses were only able to place their products on the national or local market although they had 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 7 of Directive 71/118/EEC (the poultry meat Directive), slaughterhouses handling under 150 000 birds per year

- Under Article 3, point A(7) of Directive 77/99/EEC (the meat products Directive), when establishments use meat that has been marked with a national health mark.

These Directives have been repealed as from 1 January 2006. From this date onwards these establishments can place their products on the Community market if they are approved by the competent authority.

From 1 January 2006, there is therefore no restriction any more as to the supply of meat for the production of meat products and the placing on the market thereof if the slaughterhouse is approved by the competent authority.

Since it was unlikely that all the administrative steps to approve small businesses would have been taken on 1 January 2006, a transitional measure was adopted that allowed the then current practices to continue for those small businesses that had not been approved on that date and the national mark to be used in the meanwhile.

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).

Since for these products there are no requirements in Annex III of Regulation (EC) No 853/2004, establishments handling the products need not be approved nor need they apply an identification mark on the food.

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

Regulation (EC) No 853/2004 only applies to **unprocessed and processed food** 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 hereto.

- **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 hereto.

In determining whether a product of animal origin is processed or unprocessed it is important to have regard to **all** the relevant definitions contained in the hygiene regulations, in particular, the definitions of 'processing', 'unprocessed products' and 'processed products' in Article 2 of Regulation 852/2004, and the definitions of certain processed products in Section 7 of Annex I of Regulation 853/2004. The interrelationship between these definitions will impact on the decision reached.

3.4. Food containing both products of plant origin and products of animal origin

Annex III gives an overview of the scope of Regulations (EC) No 852/2004 and 853/2004. The overview is non exhaustive and therefore purely indicative. It may be subject to review in function of experience gained with these rules.

Unless expressly indicated to the contrary, the Regulation does not apply to the production of food containing both products of plant origin and **processed** products of animal origin. Such exclusion from the scope is based upon the observation that the risk posed by the ingredient of animal origin can be controlled by implementing the rules of Regulation (EC) No 852/2004 without there being a need to apply more detailed specific requirements. However, Article 1, paragraph 2 of Regulation (EC) No 853/2004 clearly spells out that the **processed products of animal origin** used in foods containing both

products of plant origin and processed products of animal origin that are as such exempted from the scope of Regulation 853/2004, shall be obtained and handled in accordance with the requirements of Regulation (EC) No 853/2004 e.g.

- Milk powder used to prepare ice cream must have been obtained in accordance with Regulation (EC) No 853/2004, however the manufacture of ice creams falls under Regulation (EC) No 852/2004;

- Processed products of animal origin, such as meat, dairy and/or fishery products, used to prepare a pizza must have been obtained in accordance with Regulation (EC) No 853/2004, but the manufacture of the pizza falls under Regulation (EC) No 852/2004;

- Meat and/or dairy products used to prepare ready-to-eat meals composed of such processed products and vegetables must have been obtained in accordance with Regulation (EC) No 853/2004, but the manufacture of these ready-to-eat meals falls under Regulation (EC) No 852/2004;

- Egg products used to prepare mayonnaise must have been obtained in accordance with Regulation (EC) No 853/2004, however the manufacture of mayonnaise falls under Regulation (EC) No 852/2004.

However, the addition of a product of plant origin to a processed product of animal origin does not automatically mean that the resulting food falls within the meaning of Article 1, paragraph 2 of Regulation (EC) No 853/2004, e.g.:

- Cheeses to which herbs are added or yogurts to which fruit is added remain dairy products, and their manufacture must be performed under Regulation (EC) No 853/2004;

- Sausages to which garlic or soya is added remain meat products, and their manufacture must be performed under Regulation (EC) No 853/2004.

When the ingredient of plant origin, which is added to a processed animal product, has a technological function and modifies the initial product to such an extent that the resulting food cannot remain within the definition of "processed products of animal origin" as laid down in Article 2(1), point (o) of Regulation (EC) No 852/2004, then such products fall within the meaning of Article 1, paragraph 2 of Regulation (EC) No 853/2004, e.g.:

- Spreadable fats where all or part of the milk fats have been replaced by fats of plant origin.

Remark: *an establishment manufacturing both products of animal origin and other products may apply the identification mark required for products of animal origin also on the other products (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. In accordance with the definition of "retail", the term "activities" includes processing (e.g. the preparation of bakery products containing products of animal origin, the preparation of meat products in a local butcher shop) at the point of sale to the final consumer.

- 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,

  - if 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 provisions of Regulation (EC) No 853/2004 to retail establishments situated on their territory to which they would not apply. In applying this possibility, Member States should be led by the general principles of food law, i.e. proportionality and the need to have rules that are risk based.

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 supply 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.

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 requires 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. At any rate, the combination of the three criteria provided for by the Regulation should allow an appropriate qualification of most situations.

The national rules to be adopted pursuant to Article 1, paragraph 5, point c) of Regulation (EC) No 853/2004 must be subject to the general rules of the Treaty, and in particular Articles 28, 29 and 30 thereof.

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, purification centre or processing establishment.

Fishery products [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/collection of live fishery products (*whether from sea water or fresh water*) with a view to their being placed on the market, and
- Includes the following associated operations:
  - Slaughter, bleeding, heading, gutting, removing fins, refrigeration and wrapping for transport 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 (*whether from sea water or fresh water*) the nature of which has not substantially been altered, including live fishery products, from the place of production to the first establishment of destination.

Raw milk [Annex III, Section IX, Chapter 1]

The Regulation covers requirements to be respected at the farm, in particular with regard to the health of the animals, hygiene on milk production holdings, and criteria to be respected for raw milk.

Eggs [Annex III, Section X, Chapter 1]

The Regulation covers the handling of eggs at the producer's premises, and lays down that eggs must be kept clean, dry, free of extraneous odour, effectively protected from shocks and out of direct sunshine.

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

4.1. Establishments subject to approval

Establishments [except those carrying out only primary production, transport operations, the storage of products not requiring temperature controlled storage conditions or retail operations other than those to which this Regulation applies pursuant to Article 1(5)(b)] handling those products for which Annex III of Regulation (EC) No 853/2004 lays down requirements must be approved. This

entails a wide range of establishments, including establishments handling non-processed products and processed products of animal origin.

A non-exhaustive list of establishment categories subject to approval in accordance with Regulation (EC) No 853/2004 is given in Annex IV to the present document.

As retail (activities involving direct sale or supply of food of animal origin to the final consumer) is not covered by the scope of Regulation (EC) No 853/2004, the approval of retail establishments is not required under that Regulation.

4.2. The approval of small establishments

Additionally small establishments handling food of animal origin must be approved by the competent authority.

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

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 registration but no approval.

4.3. 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.

Where it is felt that the infrastructural requirements of Regulations (EC) No 852/2004 and 853/2004 are disproportionate for on-the-farm slaughter Member States may adapt those requirements, by adopting national measures, in accordance with the procedure laid down for that purpose in Article 13 of Regulation (EC) No 852/2004 and/or 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, fall outside the scope of Regulation (EC) No 853/2004. Member States shall establish national rules to ensure the safety of such meat [see Article1, paragraph (3), point (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. Member States may have national rules in place with regard to this type of slaughter.*

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, e.g.:

- 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-wrapping), the cold stores remain establishments to be approved in accordance with Article 4.

4.5. Re-wrapping establishments

Re-wrapping establishments proceed to the unwrapping of products of animal origin that were previously wrapped in another establishment. Such unwrapping and re-wrapping operations may be combined with operations such as slicing and cutting of food.

Re-wrapping establishments handle exposed products of animal origin. It must be considered that, when they handle products of animal origin that are covered in Annex III of the Regulation, they fall within the scope of Article 4, paragraph 2 of the Regulation. Their approval is therefore required. This is a logical approach since new hazards may be introduced at the level of such establishments.

In order to ensure traceability, food business operators should not place on the market products of animal origin handled in rewrapping establishments unless the identification mark of the rewrapping establishment is applied.

4.6. Wholesale markets

It appears from Article 3, paragraph 3 of Regulation (EC) No 854/2004 that wholesale markets manufacturing products of animal origin need approval before they can place on the market their products. Since in a wholesale market several infrastructures and equipment (e.g. water supply, cold stores) are shared by several units, it seems appropriate that a person/body is held responsible for ensuring that the hygiene requirements for those common infrastructures and equipment are met.

5. TECHNICAL ISSUES

MEAT

5.1. Animal species

Definitions of certain animal species are provided for in Annex I of Regulation (EC) No 853/2004.

- With regard to point 1.2, 'domestic ungulates' are defined as *"domestic bovine (including Bubalus and Bison species) (...)"*. Yak or zebu animals are also domestic bovines.

- With regard to point 1.6, 'farmed game' is defined as *"farmed ratites and farmed land mammals other than those referred to in point 1.2"*. Reindeer which are traditionally farmed are also farmed game.

5.2. 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 that animals are 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 carcase contamination and subsequent food poisoning. Animals that are sent for slaughter must therefore be clean enough not to present an unacceptable risk for slaughter and dressing operations.

The objective of the requirement is indeed 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 an appropriate slaughter scheme, 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.

5.3. Lairage facilities and waiting pens

Annex III, Section I, Chapter II, point 1(a) of the Regulation lays down that *"Slaughterhouses must have adequate and hygienic lairage facilities or, climate permitting, waiting pens that are easy to clean and disinfect. These facilities must be equipped for watering the animals and, if necessary, feeding them."*

As is the case for other requirements, the principle of proportionality must be respected in deciding about the nature of lairages or waiting pens. For small slaughterhouses, slaughtering few animals, there is no need to require sophisticated or extensive infrastructures, and the equipment for watering and if necessary for feeding the animals may be simple (e.g. movable equipment).

5.4. Equipment for the sterilisation of knives

Annex III, Section I, Chapter II, point 3 of the Regulation lays down that slaughterhouses *"must have facilities for disinfecting tools with hot water supplied at not less than 82°C or an alternative system having an equivalent effect."*

Worries have been expressed by operators of small slaughterhouses that this requirement, with regard to the sterilisation of knives, may create the need for having available multiple facilities in the slaughter room.

The objective of the requirement is to ensure that meat is not contaminated through equipment, e.g. knives. This objective can be achieved through different means, such as:

- Having sterilising equipment for knives at key places in the slaughterhouses directly accessible by the workers. Such equipment may be the appropriate choice in the bigger slaughterhouses.

- Sterilising in a single operation a number of knives sufficient to ensure that clean knives are available throughout the slaughter operations. This solution may be appropriate in low capacity slaughterhouses.

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

Annex I, Chapter XIV, point 66 of Directive 64/433/EEC provided 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 carcases 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, and has even been broadened 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****."*

"Specific products" must be understood as any product for which the competent authority grants an authorisation and specifies the requirements to be respected.

5.6. Scrap trimmings and scrap cuttings

Annex III, Section V, Chapter II, point 1(c)(i) lays down that *"the raw material used to prepare minced meat must not derive from scrap trimmings and scrap cuttings (other than whole muscle cuttings)"*.

Since the word "scrap" may mean either "small pieces" or "waste", several requests have been made to clarify what is to be understood under the terms "scrap trimmings and scrap cuttings".

In general terms, it would not seem logical to ban products fit for human consumption from being used for human consumption. The use of small pieces (trimmings and cuttings) of meat that are fit for human consumption for the preparation of minced meat should therefore not pose a problem, it being understood that the microbiological quality of the minced meat must be guaranteed at all times, and that they have been obtained from whole muscle.

5.7. 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 on 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.

5.8. Mobile slaughterhouse

The wording of Regulation (EC) No 852/2004 and (EC) No 853/2004 does not prevent the use of mobile facilities for the slaughter of animals, provided that these facilities comply with the relevant requirements laid down in those Regulations.

Member States may adapt the requirements as regards the construction, layout and equipment of these establishments by adopting national measures in compliance with the procedure laid down in Articles 13 of Regulation (EC) No 852/2004 and 10 of Regulation (EC) No 853/2004.

5.9. Meat preparations

Annex I, point 1.15 of Regulation (EC) No 853/2004 defines 'meat preparations' as *"fresh meat, including meat that has been reduced to fragments, which has had foodstuffs, seasonings or additives added to it (...)"*.

Meat reduced to fragments includes minced meat. Therefore, minced meat to which other foodstuffs, seasonings or additives have been added falls within the definition of meat preparations.

MILK AND DAIRY PRODUCTS

5.10. Identification mark

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

The wording of Regulation (EC) No 853/2004 does not seem to prevent such practice.

5.11. Automatic milking installations

Annex III, Section IX, Chapter I, Part II, Subpart B, Point 1(b) of Regulation (EC) No 853/2004 lays down that milk from each animal must be “checked for organoleptic or physico-chemical abnormalities by the milker or a method achieving similar results”.

Traditionally the milker checks the milk from each animal by visual inspection. Other methods achieving similar results may be used.

Other methods are necessary if milking is performed using fully automated milking installations. In particular, it would be good practice that automatic milking installations should be able to detect abnormal milk automatically and separate it from the human consumption supply. An internationally recognised ISO standard concerning the requirements for automated milking installations has been developed and includes the methods used to check for organoleptic or physico-chemical abnormalities in the milk (ISO 20966:2007).

5.12. Labelling

Annex III, Section IX, Chapter IV of Regulation 853/2004 prescribes the labelling of raw milk and products made with raw milk intended for human consumption in the context of labelling Directive 2000/13/EC. This entails that the labelling information concerning products made from raw milk applies up to the point of sale.

They shall be given to the consumer to allow him to make his choice. They may be provided with packaging, document, notice, label, ring or collar accompanying or referring to the concerned products.

The terms “physical or chemical treatment” referred to in point 1(b) of the same chapter should be understood as treatments to reduce possible microbiological hazards linked to raw milk or raw milk products (e.g. microfiltration).

5.13. Criteria for cow’s milk

Annex III, Section IX, Chapter II, III (1) (b) lays down that processed cow's milk used to prepare dairy products has a plate count of less than 100 000 per ml. The background of this requirement is that processed milk (e.g. pasteurised milk) that is used as a raw material has to comply with this limit before entering into a new processing step. It is not the intention therefore to require milk that has already entered into a new processing step (e.g. to which additional flora has been added for processing reasons - production of yoghurt or cheese) to comply with this criterion.

5.14. Animal species

Annex I, point 4.1 of Regulation (EC) No 853/2004 defines 'raw milk' as *"milk produced by the secretion of the mammary gland of farmed animals (...)"*. This definition covers therefore animals other than the common dairy species (cows, ewes and goats).

In practice, placing on the market of milk from mares, asses, camels or other farmed animals, including farmed game animals (e.g. reindeer), is possible provided that their production and processing comply with the relevant requirements laid down in Regulations (EC) No 852/2004 and (EC) No 853/2004.

ANNEX I
Non exhaustive list of unprocessed products of animal origin

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

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

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

Remarks:

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

ANNEX II
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. The process must lead to a substantial alteration of the initial product.

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

Processed products also include:

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

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

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

Remark:

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

ANNEX III
Classification in accordance with activities

Activity	Regulation (EC) No	Risk	Non-exhaustive list of examples
Assembly of food of plant origin with processed food of animal origin further processed together.	852/2004	The risk associated can be controlled by implementing the rules of Regulation (EC) No 852/2004.	• Canning food made from processed meat with vegetables • Assembly of pizzas containing processed ingredients of animal origin (such as cheese, processed fish or processed meat) • Producing soup made with meat extract
Assembly of food of plant origin with processed food of animal origin, and placed on the market as such.	852/2004	The risk associated can be controlled by implementing the rules of Regulation (EC) No 852/2004.	• Making sandwiches with ham or cheese • Manufacturing edible ices made from processed milk (heat treated milk, milk powder) • Making bakery products with dairy products • Assembling or manufacturing ready to eat meals composed of processed products of animal origin (e.g. processed meat) and vegetables • Manufacturing confectionery (e.g. chocolate containing processed milk) • Producing mayonnaise made with egg product

Assembly of food of plant origin with unprocessed food of animal origin further processed together.	853/2004	The risk is identical to the one posed when manufacturing processed food of animal origin, e.g. meat products. This justifies that the rules of Regulation (EC) No 853/2004 should apply. Approval of premises is required by EU rules and an identification mark may be applied to such foods**.**	• Canning products made from vegetables and fresh meat • Ice cream from raw milk **See remarks made under point 3.4**
Assembly of food of plant origin with unprocessed food of animal origin and placed on the market as such.	853/2004	The risk is identical to the one posed when handling raw products of animal origin, e.g. fresh meat etc. Approval of premises is required by EU rules and an identification mark may be applied to such foods.	• Assembling raw meat/fish skewer with vegetables

ANNEX IV
NON-EXHAUSTIVE LIST OF ESTABLISHMENTS SUBJECT TO APPROVAL

- Meat
  - Slaughterhouses
  - Cutting plants
  - Slaughter on farm (except in the case of the direct supply by the producer of small quantities of meat from poultry-lagomorphs slaughtered on the farm to the final consumer and to local retail establishments directly supplying the final consumer)
  - Game handling establishment
  - Establishments producing minced meat, meat preparations and MSM
  - Establishment manufacturing meat products
- Live bivalve molluscs
  - Dispatch centres
  - Purification centres
- Fishery products
  - freezer vessels and factory vessels
  - Establishments on land
- Milk and dairy products
  - Establishments processing raw milk into heat treated milk and into dairy products made from raw milk
  - Establishments making dairy products from already processed dairy products (e.g. butter from pasteurised cream, cheese from pasteurised milk or milk powder)
  - Milk collection centres
- Eggs and egg products
  - Egg packing centres
  - Establishments processing eggs

- Frogs' legs and snails
  - Establishments preparing and/or processing 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

- Establishments proceeding to the re-wrapping of the above products whether or not associated with other operations such as slicing, cutting.
- Cold stores insofar as they are used in relation to activities for which Annex III of Regulation 853/2004 lays down requirements.
- Wholesale markets insofar products of animal origin are manufactured.