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COMMISSION STAFF WORKING DOCUMENT

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 business operators 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 audits.

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 2004¹ and is applicable since 1 January 2006. 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 Food Safety Directorate General regularly hold 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 also promotes discussion with stakeholders so as to allow different socio-economic interests to express an opinion. To this end the Commission can organise meetings with representatives from producers, industry, commerce and consumers to discuss issues related to the implementation of the Regulation.

This Guidance documents has been updated several times since the initial version was published in 2009, with the purpose to adapt to changes in the legal requirements or to provide additional clarification when considered appropriate to improve the understanding of legal requirements and harmonise the application in all Member States.

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 safety² (also referred to as the General Food Law),

¹ OJ No L 226, 25.6.2004, p.22

² OJ No L 31, 1.2.2002, p. 1

- Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April on the hygiene of foodstuffs³,
- Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation)⁴,
- Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs⁵,
- Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004, 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 854/2004⁶,
- Commission Implementing Regulation (EU) 2015/1375 of 10 August 2015 laying down specific rules on official controls for Trichinella in meat ⁷,

Separate guidance documents, including on (EC) No 852/2004 but also developed by national or European stakeholders' organisations have been established. See https://food.ec.europa.eu/safety/biological-safety/food-hygiene/guidance-platform_en . Additional guidance on Regulation (EC) No 178/2002 can be found at: https://food.ec.europa.eu/horizontal-topics/general-food-law/food-law-general-requirements_en , https://food.ec.europa.eu/horizontal-topics/general-food-law/food-law-general-principles_en and https://food.ec.europa.eu/horizontal-topics/general-food-law/food-law-procedures_en .

³ OJ No L 226 of 25.6.2004, p. 3

⁴ OJ L 95, 7.4.2017, p. 1

⁵ OJ No L 338, 22.12.2005, p. 1

⁷ OJ L 212, 11.8.2015, p. 7

2. OBLIGATIONS OF FOOD BUSINESS OPERATORS

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

Food business operators 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. Exclusions from Regulation (EC) No 853/2004 as regards the direct supply of certain food to the final consumer or to local retail establishments directly supplying such final consumer

These exclusions have been laid down in Articles 1.3 (c) to (e) of Regulation (EC) No 853/2004. The exclusions only apply if:

- Small quantities, **and**
- Primary products (eggs, raw milk, ...) or meat (including meat product and preparations) from poultry or lagomorphs (not from other species) slaughter on the farm, or wild game or wild game meat, **and**
- By the producer (this is only the farmer, never somebody else such as a retailer) or hunter.

3.2. Handling, activities, operations

The wordings “handling”, “activities” and “operations” are often used within Regulation (EC) No 853//2004. They have the same meaning and should be understood broadly covering (within the relevant context), rearing, slaughtering, processing, storage, transport, rewrapping or repackaging,

3.3. Small businesses

Regulation (EC) No 853/2004 does not lay down criteria to define small establishments. Although not binding, small (and medium) sized enterprises are defined in EU recommendation 2003/361⁸. Staff headcount, turnover or balance sheet total can be used as determining factors.

Category	Staff headcount	Turnover	Balance sheet total
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⁸ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32003H0361>

Medium-sized	< 250	< 50 Mio €	< 43 Mio €
Small	< 50	< 10 Mio €	< 10 Mio €
Micro	< 10	< 2 Mio €	< 2 Mio €

Another example can be found in Commission Implementing Regulation (EU) 2019/627⁹. In that Implementing Regulation, thresholds have been used for slaughterhouses and game-handling establishments, to apply flexibility, considering them as low-capacity establishments when slaughtering or handling less than 1000 livestock units or less than 150 000 bird, lagomorphs and small wild game per year.

The above criteria can give an orientation in case adaptations under national law are considered for small establishments in accordance with Article 10(3) of Regulation (EC) No 853/2004.

3.4. Establishments handling food of animal origin for which no detailed requirements are laid down

For certain products of animal origin (e.g. honey, insects, reptile meat, cultivated meat, aquatic mammals such as seals), 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 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).

Furthermore, food safety will be ensured for a number of products (insects, cultivated meat) due the need for an assessment by the European Food Safety Authority within the frame of a novel food authorisation. Laying down specific requirements in Annex III of Regulation (EC) No 853/2004 may however be considered in future if:

- The market share would increase and significant specific hazards to be addressed are identified;
- New techniques have sufficiently evolved to lay down common specific requirements, not blocking further innovation.

⁹ Commission Implementing Regulation (EU) 2019/627 of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls (OJ L 131, 17.5.2019, p. 51)

Since for these products there are no requirements in Annex III of Regulation (EC) No 853/2004, establishments handling the products do not need to be approved or to apply an identification mark on the food.

For a number of highly refined products (Section XVI of Annex III), only limited specific requirements are laid down such as the origin of the raw materials. Since there are requirements, all the establishment producing the highly refined products must be approved.

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

Regulation (EC) No 853/2004 applies to **unprocessed and processed food of animal origin**.

The definition of “products of animal origin” (Point 8.1 of Annex I to Regulation (EC) No 853/2004) must be understood very broadly as any product derived from animals intended for human consumption. The products of animal origin can be either unprocessed or processed. after possible processing. Even if there are several robust processing steps substantially changing the original product of animal origin, the product remains a product of animal origin since there is no endpoint in Regulation (EC) No 853/2004 (e.g. transition from lanolin from wool to Vitamin D3). Composite products are not considered as included in the definition of “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 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.

3.6. 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 the new 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, so called composite products¹⁰. 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 the 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. When the ingredient of plant origin, which is added to a processed animal product, has a technological function and modifies the main characteristics of the final product, the resulting food cannot remain within the definition of "processed products" as laid down in Article 2, 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 and they are considered as a composite product 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 (if produced without involving a heat treatment of the milk powder);
- 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. When the addition does not modify the main characteristics of the initial processed product of animal origin, the food is not considered as a composite product, e.g.:

¹⁰ Detailed description on the rules for production and import conditions of composite products can be found in the Commission Staff Working Document published at https://food.ec.europa.eu/system/files/2016-10/biosafety_fh_legis_guidance_reg-2004-852_comp-prods_en.pdf and at https://food.ec.europa.eu/horizontal-topics/international-affairs/eu-entry-conditions/composite-products_en

- 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;
- Cooked sausages to which garlic or soya is added remain meat products, and their manufacture must be performed under Regulation (EC) No 853/2004.
- Canned tuna to which olive oil is added remain fishery products, and their manufacture must be performed under Regulation (EC) No 853/2004.
- The addition of some minerals, vitamins, carotenoids, ... to capsules with fish oil, does not change the fact that the product maintains the characteristics of fish oil, so it does not become a composite product but remains a product of animal origin. If (also) vegetable oil is mixed with the fish oil, the same principle needs to be applied although there is no clear cut-off limit. In such cases the decision will be a case by case decision and in case of doubts, the exact composition of the product, including the treatments of the raw materials, should be provided in order to allow the CAs to take the appropriate decision.

Remark:

- The product obtained by the addition of a product of plant origin to an unprocessed product of animal origin (e.g. fresh meat) is not a composite product but remain a product of animal origin and need to fully comply with Regulation (EC) No 853/2004;
- an approved establishment manufacturing both products of animal origin to which Regulation (EC) 853/2004 applies and other products to which it does not, 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).e.g.: approved establishment manufacturing canned tuna and producing also tuna salad (composite product) may apply the identification mark also on the salad.

3.7. 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, the above 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 to the final consumer”. This means that:

- For activities involving direct sale or supply of food 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.
- When a wholesale or other establishment carries out retail 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.

3.8. 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 b)ii 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.

Note that a retailer whose activities are not limited to transport and storage, but supplying (even if this a marginal, localised and restricting activity), to another food business operator, not being a retailer, must be approved e.g. a butcher providing his minced meat to another FBO making pastries of it for placing on the market).

3.9. 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, approved intermediary operators 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 if 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.
 - The stunning at farm level if carried out by an electrical method or thermal shock¹¹.

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 conditions of the dairy 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 unintended extraneous odour, effectively protected from shocks and out of direct sunshine.

Insects

With regard to insects, primary production includes:

- growing live insects, including egg and larvae production,
- collection and packaging if without slaughter or processing, with a view to their being placed on the market, and
- transport from the farm of live insects.

¹¹ If the stunning is carried out at farm level with percussion, or bleeding after stunning is carried out at farm level, those activities cannot be considered as associated operations and, consequently, those activities cannot be considered as primary production activities

4. THE KILLING OF INSECTS AND OTHER PROCESSING ACTIVITIES - INCLUDING HANDLING OPERATIONS DIRECTLY ASSOCIATED WITH THESE ACTIVITIES - ARE NOT CONSIDERED AS 'PRIMARY PRODUCTION' ACTIVITIES, EVEN IF CARRIED OUT IN THE SAME REARING PLANT, SINCE THESE STEPS LEAD TO A CHANGE IN THE SHAPE AND/OR STRUCTURE OF THE PRODUCT. SUCH ACTIVITIES DO NOT REQUIRE APPROVAL OF THE ESTABLISHMENT AS LONG AS THERE ARE NO SPECIFIC CONDITIONS LAID DOWN IN ANNEX III OF REGULATION (EC) NO 853/2004. 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.

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, including the use of mobile slaughter units

There has been an increasing demand for the possibility to allow slaughter on farm in order to avoid animal welfare issues during transport to the slaughterhouse. The purpose of Regulation (EC) No 853/2004 must however maintain the insurance of good hygiene/safety of the meat. Nevertheless, a number of possibilities are included in Regulation (EC) No 853/2004 to allow slaughter on the farm subject to certain conditions, as illustrated in Table 1

Table 1 Possibilities for full slaughter on the farm

Species	Full slaughter
All domestic species and farmed game	Approved fixed (small) slaughterhouse
	Approved full mobile slaughterhouse
	Semi-mobile, approved in conjunction with fixed parts e.g. for lairage or cooling
	For private domestic consumption without placing on the market
Poultry and lagomorphs	Small quantities of meat directly supplied to the final consumer or local retail establishment directly supplying to the final consumer

Table 2 Possibilities for stunning and bleeding (+ possible removal of intestines) on the farm subject to certain conditions

Species	Stunning and bleeding (+ possible removal of intestines)
Domestic ungulates	Emergency slaughter
Domestic bovine, porcine and animals and solipeds	Limited number to avoid any risk for handler or prevent injuries of animals during transport
Farmed ratites and (game) ungulates	To avoid any risk for handler or prevent injuries of animals during transport
Delayed eviscerated poultry, geese and ducks reared for the production of 'foie gras', farmed (small) game	Allowed

Full 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. The exceptions to approval are slaughter for the purpose of private domestic consumption without placing on the market and in case of small quantities of meat of poultry and lagomorphs, directly

supplied to the final consumer or local retail establishment directly supplying to the final consumer in accordance with Article 1.3 of Regulation (EC) No 853/2004.

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 Article 1, paragraph (d) of the Regulation].

In the case of “**domestic 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 regarding this type of slaughter.

The possibility to **stun and bleed ungulates at the holding of provenance**, introduced in 2021 might be quite challenging from hygiene perspective e.g. risk cross-contamination of carcasses during transport to the slaughterhouse and therefore a prudent approach has been taken by a limitation of the species and of the number of animals, by the condition related to the risk for the handler and the animals and by the obligatory presence of an official veterinarian. [Consequently, such slaughter at the holding of provenance cannot be systematically applied to all animals on a farm unless very extensive rearing is applied to all animals.]

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.

Cross-border slaughterhouse activities are subject to certain restrictions:

- approval of a full mobile slaughterhouse within each MS where the slaughterhouse operates (with application of different health/identification mark) since approval of an establishment on a territory is the competence of each national authority;
- there are no additional restrictions in case of cross-border use of mobile slaughter boxes in accordance with Chapter VIa of Section I to Annex III of Regulation (EC) No 853/2004: Ante-mortem inspection can take place in country A by an first official veterinarian of country A, while post-mortem inspection can take place in the slaughterhouse in country B by, under supervision or under the responsibility of another official veterinarian of country B.

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 (including standalone ones) 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, freezing within the frame of food donations), the cold stores remain establishments to be approved in accordance with Article 4.

Decision tree useful, see separate document?

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

Wholesale markets, when handling or 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 (Articles 11.4 and 43.2 of Commission Implementing Regulation (EU) 2019/627)

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. 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.

5.6. 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.

5.7. Meat preparations and meat products

5.7.1. Raw materials for meat preparations

The raw materials that can be used in meat preparations are laid down in point 2 of Chapter II to Section V of Annex III of Regulation (EC) No 853/2004. Fresh meat containing bones or skins can be used as raw materials for meat preparations (but not for minced meat) since they are within the definition of fresh meat.

5.7.2. Meat preparation or meat product?

Annex I 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 or which has undergone processes insufficient to modify the internal muscle fibre structure of the meat and thus to eliminate the characteristics of fresh meat."(point 1.15).
- 'Meat products' as "processed products resulting from the processing of meat or from the further processing of such processed products, so that the cut surface shows that the product no longer has the characteristics of fresh meat. (Point 7.1).

Definitions of 'processing', 'unprocessed products' and 'processed products' are laid down, respectively, in Article 2(1)(m), (n) and (o) of Regulation (EC) No 852/2004 and are applicable to all foodstuffs, including meat.

All meat products fall within the definition of 'processed products'. However, meat preparations can fall within the definition of 'unprocessed products' or that of 'processed products'. For example, a meat preparation will fall within the definition of 'processed products' if the actions mentioned in the definition of 'processing' that are applied are insufficient to modify the internal muscle fibre structure of the meat completely and the cut surface shows that the product has the characteristics of fresh meat.

The definitions of 'meat preparations' and 'meat products' (and others in Regulation (EC) No 853/2004) are intentionally broad because meat technology is innovative. There is, however, a need for products to fall within a particular definition and that they are manufactured according to the relevant hygiene requirements. In addition, rules on marketing standards, additives and labelling make reference to these definitions and, as such, harmonisation of application is essential.

Products may be placed on the market before the processing has resulted in complete changes to the meat/internal muscle fibre structure. In such cases, the degree to which the characteristics of fresh meat have been eliminated at the point where a product is placed on the market will determine the definition into which it

falls. If the characteristics of fresh meat are not completely eliminated, the product should be considered to fall within the definition of 'meat preparations'. If the characteristics of fresh meat are completely eliminated, it should be considered to fall within the definition of 'meat products'.

The following clarifications can therefore be provided:

- Fresh meat that has been 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.
- Fresh meat that has been marinated completely through to the centre falls within the definition of 'meat products' as the definition of 'processing' includes marinating and this process results in a denaturising of muscle fibre proteins which constitutes modification of the internal muscle fibre structure and elimination of characteristics of fresh meat at the cut surface.
- Fresh meat that has not been marinated completely through to the centre falls within the definition of 'meat preparations' as the modification of the internal muscle fibre structure is not complete and the cut surface still shows the characteristics of fresh meat.
- Salted or cured meat, even throughout the whole meat, placed on the market in the initial phase of the maturing process and which has not undergone any other processing, such as cooking or drying, falls under the definition of 'meat preparation', as characteristics of fresh meat still remain. When the product is submitted to further processing, such as drying, which results in the elimination of the characteristics of fresh meat, it will then fall within the definition of 'meat products'.
- Flash fried meat which remains raw in the centre falls within the definition of 'meat preparations', as the heating process was insufficient to modify the internal muscle fibre structure of the meat and eliminate the characteristics of fresh meat completely. The cut surface therefore still shows characteristics of fresh meat.
- Flash fried meat marinated through to the centre or completely cured before flash frying falls within the definition of a 'meat product', because the marinating/complete curing has eliminated the characteristics of fresh meat.
- Meat which has been completely fried but which still requires cooking before consumption falls within the definition of 'meat products', as the frying has modified the internal muscle fibre structure of the meat to the extent that the characteristics of fresh meat have been eliminated and the cut surface no longer shows the characteristics of fresh meat."

MILK AND DAIRY PRODUCTS

5.8. 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 exclude 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).

5.9. 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 Regulation (EU) No 1169/2011 (Food Information to the Consumers). 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).

5.10. 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.

5.11. 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.

FISHERY PRODUCTS

5.12. Parasites of public health concern

Annex III, Section VIII, Chapter III, Point D of Regulation (EC) No 853/2004 contains provisions to ensure the killing of viable larval stages of parasites in fishery products that may represent a health hazard to the consumers. Fishery product-borne parasitic diseases in humans are caused by:

- An infection following ingestion of viable parasites of human health concern. The larval stages of such parasites representing a health hazard to the consumer are (1) nematodes, mainly larvae of *Anisakis* species and *Pseudoterranova decipiens*, (2) larvae (plerocercoids) of *Diphyllobothrium* cestodes and (3) larvae (metacercariae) of trematodes, or
- An allergic reaction linked to *Anisakidae*. According to EFSA, only *Anisakis simplex* has been clearly implicated with allergic reactions. EFSA stipulates that the primary initiator of allergy to *Anisakis* nematodes in humans is infection by live *Anisakis simplex* larvae.

5.13. The term 'obviously contaminated'

Annex III, Section VIII, Chapter V, Point D 'PARASITES' of Regulation (EC) No 853/2004 includes a general provision for food business operators regarding visual examination for visible parasites and rules for placing on the market of such fishery products:

'Food business operators must ensure that fishery products have been subjected to a visual examination for the purpose of detecting visible parasites before being placed on the market. They must not place fishery products that are obviously contaminated with parasites on the market for human consumption.'

Section I of Annex II to Regulation (EC) No 2074/2005 lays down, in Chapter II, more specific provisions for visual inspection of eviscerated fish and of fish fillets and slices for establishments on land and on-board factory vessels. It also defines, in Chapter I, the terms 'visible parasite', 'visual inspection' and 'candling'.

Destructive methods, like the digestion method, cannot be used in visual examination and visual inspection for determining whether fishery products are 'obviously contaminated' with parasites.

When considering whether a fishery product is 'obviously contaminated' with parasites, in order to assess whether it can be placed on the market or not, it must be distinguished between edible and non-edible parts of the fishery product:

- When visible parasites are only found in parts of the fishery product that are not to be consumed (**non-edible parts of the raw material**) the normal procedures (including gutting, etc.) ensure that the raw materials actually used

for products intended for human consumption are not obviously contaminated with visible parasites. When the non-edible parts are removed the raw materials are not considered as 'obviously contaminated'.

- When **edible parts (raw materials or products to be presented to the consumer)** are obviously contaminated with visible parasites, the food business operator has two possibilities: (i) either not to place the fishery product on the market, or (ii) hygienically apply normal sorting and/or preparatory or processing procedures in accordance with Point 1 of Chapter IX of Annex II to Regulation (EC) No 852/2004 to ensure that the product to be presented to the consumer is no longer 'obviously contaminated' with parasites by visible inspection and is thereby fit for human consumption. The procedures may include trimming of raw materials being particularly susceptible to parasites.

The Codex Alimentarius Commission has provided internationally recognized standards providing more details for certain specific fishery products contaminated with parasites. Though these texts for specific products cannot be applied for fishery products in general, they are relevant reference points for the specific products concerned.

The Codex Alimentarius texts indicate limits for non-viable visible parasites and defect levels for texture changes due to parasites for certain specific fishery products ready to be presented to consumers. The Codex also describes candling in a more detailed way than EU legislation.

Some parasites in fishery products may not be visible but decompose the fish flesh and may render it unfit for human consumption. In such cases the applicable provision is Point 1 of Chapter IX of Annex II to Regulation (EC) No 852/2004 and not the provisions on visible parasites in fishery products referred to in Annex III, Section VIII, Chapter V, Point D of Regulation (EC) No 853/2004.

Guides to good practices may be appropriate tools to assist food business operators in relation to the issue fishery products 'obviously contaminated' with parasites

5.14. Processed/non processed fish products

Processing and processed products are defined in Article 2 (m) and (o) of Regulation (EC) No 852/2004. Article 2(m) of this Regulation states that "'processing' means any action that substantially alters the initial product, including heating, smoking, curing, maturing, drying, marinating, extraction, extrusion or a combination of those processes."

Certain operators inject water to fresh or defrosted fishery products, especially tuna, asserting that this is "marinating". The scope is to use unauthorised additives or other ingredients, forbidden in fresh or unprocessed raw products for the ultimate scope to

change the colour of the fish, claiming that this activity is a processing. The fishery products after these treatments appear as fresh/raw, and not processed. The use of unauthorised additives or other ingredients in unprocessed fishery products, which does not substantially alter their nature, cannot result in “processed fishery products” and placing those products on the market as “processed fishery products” for justifying the use of such additives is in breach of the EU legislation. Therefore, those products cannot be labelled as processed or transformed, taking into account that the injection of water with additives is an action that not substantially alters the initial product.

IDENTIFICATION MARKING

5.15. Who must apply its ID mark?

Article 5(1) of Regulation (EC) No 853/2004 lays down:

"Food business operators shall not place on the market a product of animal origin handled in an establishment subject to approval in accordance with Article 4(2) unless it has either:

(a) a health mark applied in accordance with Regulation (EC) No 854/2004; or

(b) when that Regulation does not provide for the application of a health mark, an identification mark applied in accordance with Annex II, Section I, of this Regulation"

Annex II, Section I Point A.2 of the Regulation further lays down that:

"However, when a products packaging and/or wrapping is removed or it is further processed in another establishment, a new mark must be applied to the product. In such cases, the new mark must indicate the approval number of the establishment where these operations take place."

The key issue is "subject to approval" according to Regulation (EC) No 853/2004. This excludes establishments carrying out only primary production, transport operations, storage of products not requiring temperature-controlled storage conditions and retail operations when excluded from the Regulation (EC) No 853/2004 and establishments handling foodstuff for which there are not specific requirements in Annex III to Regulation (EC) 853/2004. Annex II, Section I, Point A.2 makes clear that "handled" in the Article 5(1) must be understood broadly including removal of wrapping or packaging.

Therefore, the ID mark is associated with the approval of an establishment. It should be noted that the application on an ID mark on a product does not necessarily imply that it is fit for human consumption when it leaves the establishment.

On the other hand, if there is no removal of the packaging or the wrapping, and no processing in an establishment, the ID mark of the last establishment in the preceding steps of the production chain which is subject to ID marking, must be maintained and no new (additional) ID mark should be applied.

Examples

- A delivers wrapped temperature-stable processed foodstuff for which there are specific requirements in Annex III to Regulation (EC) 853/2004 products to B (not a retailer) without labelling and without an ID-mark out on the wrapped products but with its ID mark on the packaging. B takes the wrapped products out of a packaging and therefore must apply its own ID-mark on the

wrapping or on a new packaging. B must be approved because its activities are not limited to storage.

- A large package with an ID mark from A applied to the external surface of its packaging and on the wrapped products in the package, is received at B (not a retailer). The packaging is removed. The wrapped products are re-packaged. The packaging (or wrapping) must bear the ID-mark of B because of the removal of the packaging. The ID-mark on the wrapping and the packaging will be different or there might be two ID marks on the wrapping.
- B receives chilled meat or fish for which there are specific requirements in Annex III to Regulation (EC) 853/2004 with the ID mark of A, which carried out for example the cutting and the wrapping. In B, the product only undergoes a freezing treatment (no re-wrapping or re-packaging). B cannot apply its ID mark since there is no rewrapping/repackaging and freezing is not processing.
- B receives wrapped (prepacked) sliced meat products with the ID-mark of A on the wrapping. B is a standalone plant only carrying out high pressure processing on the product, sufficient to reduce bacterial load. B must apply its ID-mark on the (re-)packaging or on the wrapped product since HPP is processing. It should be clear what activity was carried out by A and by B.
- A (purification centre or intermediary operator) sends unwrapped live bivalve molluscs without ID-mark to B (another approved operator only mixing batches). B mixes the lots of live bivalve molluscs and sends it to C (dispatch centre placing live bivalve molluscs on the market). B may apply the ID mark, but this requirement is not compulsory.
- A (purification centre or approved intermediary operator) receives live bivalve molluscs from a class B production area. A rewraps the un-purified molluscs and may apply an ID-mark before sending them to B, (another approved operator) that mixes the lots of live bivalve molluscs, rewraps them and may apply a new ID mark .

5.16. Multiple ID marking

In a number of cases a wrapping may carry more than one ID mark (see last example above on HPP treated wrapped sliced meat products).

It is rather common in the dairy sector to apply several identification marks on a single package with a clear indication as to which mark is the valid one. This is the case when the same product can be produced in different establishments. It has also been observed in other sectors.

The wording of Regulation (EC) No 853/2004 does not prevent such practice as long as it is clear which establishment produced or processed the product. In

addition, a multiple ID mark should remain exceptional and avoided to the extent possible to exclude confusion on the establishment that produced the product.

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**
- **Fresh blood**
- **Fresh or frozen fishery products**
- **Live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods**
- **Raw milk**
- **Whole eggs and not heat-treated liquid egg**
- **Frogs' legs**
- **Snails**
- **Honey, propolis, pollen and royal jelly (if unprocessed).**

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

- **Skewer containing fresh meat and vegetables**
- **Fresh or frozen fishery products whole or prepared (e.g. fish fillets or loins) with the addition of additives authorised for unprocessed fishery products or other ingredients from plant or other 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.**

- **Frozen fishery products are unprocessed products that can be whole or prepared. They should be generally classified as raw products as set out in the first bullet point.**

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, fish that has been marinated until losing the characteristics of raw fishery products. etc)**
- **Dairy products (pasteurised milk and other heat treated milk, cheese, yoghurt, etc.)**
- **Egg products (egg powder etc.)**
- **Rendered animal fat**
- **Greaves**
- **Gelatine**
- **Collagen**
- **Treated intestines, stomachs and bladders etc.**
- **Vitamin D3 and its precursors derived from lanolin**
-

Processed products also include:

- **A combination of processed products of animal origin e.g. cheese with ham, fish oil in bovine gelatine capsules, ham omelette made from egg products.**
- **Products that have undergone several processing operations e.g. cheese from pasteurised milk.**
- **The addition of substances to give special characteristics do not change the classification of processed products of animal origin e.g. sausage with garlic**
- **yoghurt with fruit**
- **cheese with herbs**
-

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.	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • 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

<p>Assembly of food of plant origin with unprocessed food of animal origin further processed together.</p>	<p>853/2004</p>	<p>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 must be applied to such foods.</p>	<ul style="list-style-type: none"> • Canning products made from vegetables and fresh meat • Ice cream from raw milk • Spanish omelette made with raw eggs, potatoes and onions. <p>See remarks made under point 3.6</p>
<p>Assembly of food of plant origin with unprocessed food of animal origin and placed on the market as such.</p>	<p>853/2004</p>	<p>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 must be applied to such foods.</p>	<ul style="list-style-type: none"> • Assembling raw meat/fish skewer with vegetables
<p>Assembly of processed food of animal origin</p>	<p>853/2004</p>	<p>Approval of premises is required by EU rules and an identification mark must be applied to such foods.</p>	<ul style="list-style-type: none"> • Assembly of processed food of animal origin

ANNEX IV

NON-EXHAUSTIVE LIST OF ESTABLISHMENTS SUBJECT TO APPROVAL

- General
 - Establishments manufacturing food supplements being considered as products of animal origin if requirements are laid down in Annex III of the Regulation (EC) No 853/2004 e.g. filling capsules with fish oil.
- 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
 - Wild game collection centres, when receiving bodies from other collection centres
- Live bivalve molluscs
 - Intermediary operators when they have a cold store or they group or split batches of live bivalve molluscs or they carry out conditioning or re-immersion
 - Dispatch centres
 - Purification centres
- Fishery products
 - Freezer, reefer 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 or egg products

- 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 handled or manufactured.