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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 meat⁷,

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

⁶ OJ L 338, 22.12.2005, p. 27

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 (for example eggs, raw milk, live bivalve molluscs if originating from A classified production areas or marine gastropods and echinoderms, from not classified production areas) or meat from poultry or lagomorphs (not from other species) slaughtered on the farm (including meat products and preparations made thereof on the farm), or wild game or wild game meat, **and**
- By the producer (the gatherer in the case of live bivalve molluscs, the fisherman or the farmer/primary producer, never somebody else) or hunter.

Member States shall establish national rules governing these activities and persons.

The local retail establishment (e.g. butcher, restaurant, supermarket, ...), delivering to the final consumer, may further process these products, without the obligation to apply Regulation (EC) No 853/2004, in accordance with Article 1.5(a) of that Regulation. The retailer may deliver food of non-animal origin to others than final consumers. The local retailer may only supply food of animal origin, including small quantities of meat of poultry, lagomorphs or wild game, to another establishment (including another retailer) if the local retailer complies with Regulation (EC) No 853/2004 or if the local retailer is excluded from that Regulation in accordance its Article 1.5(b) (i) or (ii).

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 and also used in Commission Regulation (EU) No 702/2014⁹. Staff headcount, turnover or balance sheet total can be used as determining factors.

Category	Staff headcount	Turnover	Balance sheet total
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) 2019/627¹⁰. In that Implementing Regulation, thresholds have been used for slaughterhouses and game-handling establishment, to apply flexibility, considering them as low-capacity establishments¹¹ 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), the Regulation does not lay down detailed rules. In that

⁸ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32003H0361>

⁹ Commission Regulation (EU) No 702/2014 of 25 June 2014 declaring certain categories of aid in the agricultural and forestry sectors and in rural areas compatible with the internal market in application of Articles 107 and 108 of the Treaty on the Functioning of the European Union (OJ L 193, 1.7.2014, p. 1).

¹⁰ 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)

¹¹ See also the definitions of ‘low-capacity slaughterhouse’ and ‘low-capacity game-handling establishment’ in Commission Delegated Regulation (EU) 2019/624 Article 2(17) and (18).

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.

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.

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. 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 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 (EC) No 852/2004, and the

definitions of certain processed products in Section 7 of Annex I of Regulation (EC) No 853/2004. The interrelationship between these definitions will impact on the decision reached.

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 (point (2) of the Section). Since these are still specific requirements in Annex III of the Regulation, all the establishments handling (producing, packaging, etc.) the highly refined products must be approved in accordance with Article 4(2) of Regulation (EC) No 853/2004, unless a derogation in Article 4(2) is applicable.

3.6. Food containing both products of plant origin and products of animal origin (composite products)

See the Commission Staff working document: guidance on general requirements on composite products and products which could erroneously be considered as composite products, including import conditions and controls¹².

3.7. Retail

Unless expressly indicated to the contrary, **Regulation (EC) No 853/2004, including approval of the establishment, 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.

Regulation (EC) No 853/2004 excludes in principle retail (i.e. the handling and/or processing of food and its storage at the point of sale) from its scope. This also means that where, as example, cheese is manufactured and sold at a retail premise (e.g. at a retail shop on the farm), these activities can be carried out in accordance with the requirements laid down in Regulation (EC) No 852/2004 only, requiring registration but no approval (See however also the second bullet below if this farmer/retailer is supplying to another retailer).

However, as explained in recitals 12 and 13 of Regulation (EC) No 853/2004, the above definition which includes wholesale where direct sale or supply of food is to the final consumer. This means that:

¹² See “Illustrative Guidance on import conditions for composite products” at https://food.ec.europa.eu/safety/biological-safety/food-hygiene/guidance-platform_en

- 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.
- With regard to retailers supplying any food of animal origin to another establishment Regulation (EC) No 853/2004 applies except:
 - for establishments for which the operations 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, or
 - if the supply is, in accordance with national law, a **marginal, localised and restricted** activity of the retailer to another retail establishment. In that event, only Regulation (EC) No 852/2004 applies.

Where infrastructures and equipment (e.g. water supply, cold stores) are shared by several FBOs, it seems appropriate that a person/body is held responsible for ensuring that the hygiene requirements for those common infrastructures and equipment are met.

A decision tree approach to verify if retail establishments are subjected to the requirements of Regulation (EC) No 853/2004 can be found in Annex III. Note that a retailer whose activities are not limited to transport and storage, supplying a product of animal origin to a non-retail food business, must comply with Regulation (EC) No 853/2004, including approval of the establishment, and the FBO cannot avail of an exemption under marginal, localised and restricted activity as the supply is not retail to retail (i.e. to the final consumer) e.g. a butcher providing minced meat to another FBO who uses the minced meat to make pastries for supply to other businesses.

While certain operation such as “wholesale” are not defined, the use of the decision tree in Annex III, based on the activity carried out, provides clear indications when the requirements of Regulation (EC) No 853/2004 apply.

In accordance with Article 1, paragraph 5(c), Member States may decide to extend the provisions of Regulation (EC) No 853/2004 to 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. 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.

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 centre, a purification centre, an approved intermediary operator or a 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 or slaughter at the sea, including for farmed tuna where stunning and bleeding may be carried out on board vessel supporting the harvesting operations. If the stunning is carried out in an on land farm with percussion, or bleeding after stunning, those activities cannot be considered as associated operations and, consequently, those activities cannot be considered as primary production activities.

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.

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 of animal origin 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 or 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 V to the present document.

Regulation (EC) No 853/2004 does not apply in principle to retail establishments directly supplying food of animal origin to the final consumer (e.g. butcher shops, supermarkets, production of cheese on the farm, etc, (see point 3.7)). Therefore, such retail establishments need not to be approved.

4.2. Slaughter exempted from approval

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. Domestic consumption should be understood as the consumption by the owner of the animal within his/her household, including temporary private guests, but without any marketing of the obtained products.

4.3. The approval of cold stores

4.3.1. Cold stores at retail

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***”.

Cold stores being part of a retail establishment are not subject to the Regulation unless approval is required for the retail activity (See Section 3.7 of this guidance),

Standalone cold stores that are involved in wholesale operations which are limited to transport and storage, do not need to be approved but remain subject to the temperature requirements. However, when such wholesale operations include more than storage and transport (for instance portioning, slicing, re-wrapping, freezing within the frame of food donations), the cold stores are establishments to be approved in accordance with Article 4.2. In other words, when Regulation (EC) No 853/2004 applies to the retail operation (see decision tree in Annex III), approval of the cold store is required.

4.3.2. Other cold stores (not related to retail)

Irrespective of the activity carried out in a cold store, the exemptions under Art. 1(5)(b) of Regulation (EC) No 853/2004 do not apply when these cold stores are obviously not retailers e.g. standalone cold stores storing carcasses or meat cuts for further supply to establishments (cutting plants, meat processing plants) that are

subject to approval under Art. 4(2) of this Regulation. Such cold stores must always be approved as well as cold storage as part of an establishment requiring approval (e.g. slaughterhouse, cutting plant, establishment processing fish, dairy products, ...).

Annex IV provides a decision tree to verify applicable requirements to cold stores.

4.4. 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.

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 (*Rangifer tarandus tarandus*) which are traditionally farmed are also farmed game. Farmed llamas and alpacas are also farmed game since they do not fall under the definition of domestic ungulates.

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 carcass 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 safety required by Union 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, and/or
- The sorting of the animals in accordance with cleanliness and developing an appropriate slaughter scheme, and/or
- Developing procedures for the hygienic dressing of animals that must protect carcasses from unnecessary contamination, and/or
- Other appropriate procedures.

Guides to good practice may be an appropriate tool to assist slaughterhouse operators in defining these means. See the “Guidance on sharing Good Practices in slaughter hygiene”¹³

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

¹³ https://food.ec.europa.eu/safety/biological-safety/food-hygiene/guidance-platform_en

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 beyond the evaluation of measures he has to implement in accordance with his standard operating procedures since a further evaluation can only be performed in a professional way by the official veterinarian.

5.7. Possibilities for slaughter on the holding of provenance, including mobile slaughterhouses

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, several possibilities are included in Regulation (EC) No 853/2004 to allow slaughter on the holding of provenance subject to certain conditions, as illustrated in Tables 1 and 2.

Table 1 Possibilities for slaughter and dressing at the holding of provenance

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, reindeer (<i>Rangifer tarandus tarandus</i> , in certain areas of Finland and Sweden)	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 stomach and intestines) on the holding of provenance subject to certain conditions

Species	Stunning and bleeding (+ possible removal of stomach and intestines)
Domestic ungulates	Emergency slaughter
Domestic bovine, caprine, ovine and porcine animals and solipeds	Limited number
Farmed ratites, farmed game ungulates and bisons	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 and dressing activities at the farm must be carried out in accordance with the appropriate general hygiene 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 the 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 possibility to **stun and bleed ungulates at the holding of provenance** 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 and by the obligatory presence of an official veterinarian.

Where 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 units (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 a 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. The approval number/health mark is the one of the slaughterhouse of which the mobile units are part.

5.8. Freezing of fresh meat “without undue delay”

Point 4 of Chapter VII to Section I (meat of domestic ungulates) of Annex III to Regulation (EC) No 853/2004 lays down that “*Meat intended for freezing must be frozen without undue delay, taking into account where necessary a stabilisation period before freezing*”. The stabilisation period refers to the time period which is normally a few days. During this period, the meat can be cut and/or transported to a cold store. Freezing without undue delay also applies to meat of poultry and lagomorphs (point 5 to Chapter V to Section II of Annex III to the Regulation).

Consequently, freezing of meat must happen shortly after slaughter and is not allowed on meat:

- approaching its use-by date as a way to longer store such meat for further processing,
- being vacuum-packed for storing as chilled meat beyond the stabilisation period.

An exception was made for the purpose of food donations at retail under certain conditions laid down in the above requirements, to facilitate the safe redistribution of food within that framework. In addition, dry-ageing of beef results in sensory changes of the meat, after which freezing is allowed without undue delay.

5.9. Rolling window as regards carcase aerobic colony count

A maximum daily mean carcase aerobic colony count applies in case of transport of carcasses of domestic ungulates at a temperature higher than 7°C. A rolling window of 10 weeks needs to be used to calculate this mean. Generally, this rolling windows of 10 weeks corresponds to 10 consecutive sampling sessions considering that Regulation (EC) No 2073/2005 provides that FBOs shall take samples for microbiological analysis at least once a week for aerobic colony count. In accordance with Regulation (EC) No 2073/2005, the frequency of sampling of carcasses for aerobic colony count analyses may be reduced to fortnightly testing if satisfactory results are obtained for six consecutive weeks. In such case and in view of a harmonised approach throughout the EU, 10 weeks should be understood as 10 sampling weeks or 10 sampling sessions.

5.10. Meat preparations and meat products

5.10.1. 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 since they are within the definition of fresh meat. However, they cannot be used to produce meat preparations made from minced meat (or produce minced meat).

5.10.2. 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'. Meat preparations fall within the definition of 'unprocessed products'. Indeed, even if an action mentioned in the definition of 'processing' is done on fresh meat which it is insufficient to modify the internal muscle fibre structure of the meat, thus not eliminating the characteristics of fresh meat, the end-product is a meat preparation, thus an unprocessed product. If this action, however, has been sufficient to modify the internal fibre structure of the meat and thus has substantially altered the product, the end-product is a meat product (or processed product).

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 they should be manufactured according to the relevant hygiene requirements. In addition, rules on marketing standards, additives and labelling refer to these definitions and, as such, harmonisation of application to the extent possible 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’.

Some processing visually eliminates the characteristics of fresh meat (e.g., heating, smoking, drying) and make it possible to distinguish with certainty meat preparations (e.g., meat cooked only on the surface) from meat products (meat cooked through).

In other cases, the disappearance of the characteristics of fresh meat is more subtle and gradual with processing techniques such as salting, curing and marinating. In such cases, the elimination of the characteristics of fresh meat should be assessed at the moment of placing on the market to decide if such placing should be as meat preparation or meat product. The mere adding of the seasonings, ingredients or additives (sometimes incorrectly referred to as marinating) itself is not processing. Only when the addition of organic acids and/or salt is accompanied with a processing effect with the loss of the characteristics of fresh meat in the core of the product before placing on the market, it is a meat product.

The following examples can therefore be provided:

- a) Minced meat to which other foodstuffs, seasonings or additives have been added without effect on the characteristics of fresh (minced) meat becomes a meat preparation¹⁴.
- b) Marinade is an exogenous liquid preparation incorporating at least organic acids or their salts and used to tenderize meat, preserve it: it may be salty and/or sweet, condimented, possibly oily and/or alcoholic. Brine is a solution of at least water and salt used for curing: it may only contain ingredients and additives permitted in the product to which it is added. Marinating and curing are considered as processing because they substantially alter the initial product as regards pH, salt content (see point 1(m) of Article 2 to Regulation ((EC) No 852/2004). However, a meat preparation only becomes a meat product when it has been thoroughly processed and as a consequence, the internal muscle fibre structure of the meat has been modified (see definition of meat product) at any place in the product. Consequently:
 - i. Fresh meat that has been marinated completely through to the core generally falls within the definition of ‘meat products’ as this process results in a denaturising of muscle fibre proteins which constitutes modification of the internal muscle fibre structure. It is necessary to

¹⁴ If only salt has been added and the salt content is less than 1%, it remains fresh meat and is not a meat preparation.

ensure that the application process of the marinade guarantees a homogeneous diffusion of the marinade to the core of the meat (e.g. by injection using a multi-head marinade injector, by mechanical treatment by a meat tumbling machine, by prolonged immersion in order to secure the most uniform distribution of the marinade).

- ii. Fresh meat that has not been marinated completely through to the core 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.
 - iii. Fresh meat that has been cured with brine completely through to the core may in an initial phase still be a meat preparation and only falls within the definition of ‘meat products’ when the added salt has resulted in a drying effect which results in a gradual disappearance of the characteristics of fresh meat before placing on the market. It is necessary to ensure that the application process of the brine guarantees a homogeneous diffusion of the brine to the core of the meat (e.g. by injection using a multi-head brine injector, by mechanical treatment by a meat tumbling machine, by prolonged immersion in order to secure the most uniform distribution of the brine).
 - iv. Fresh meat that has not been cured completely through to the core falls within the definition of ‘meat preparations’ as the modification of the internal muscle fibre structure is never complete and the cut surface still shows the characteristics of fresh meat.
- c) Flash fried meat which remains raw in the core 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.
 - d) 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

5.11. 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 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).

5.12. Labelling

Annex III, Section IX, Chapter IV of Regulation (EC) No 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 applied to dairy products made from raw milk to reduce possible microbiological hazards linked to raw milk (e.g. microfiltration). There are no EU rules applicable to the specific labelling of such dairy products as regards the nature or the denomination of the treatment applied.

5.13. Criteria for cow's milk

Annex III, Section IX, Chapter II, Part 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 rationale 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. This requirement applies to situations involving an unintended discontinuity in the process. It is not the intention therefore to require processed milk that has already entered into a new planned processing step (e.g. to which additional flora has been added for processing reasons - production of yoghurt or cheese) or is submitted to a continuous process (e.g. raw milk > pasteurised milk > milk powder) 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.

FISHERY PRODUCTS

5.15. 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 EFSA¹⁵, 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.

5.16. Methods to kill larval stages of parasites

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. The visual examination, carried out on eviscerated and not eviscerated fishery products according to Regulation (EC) No 2074/2005, has the objective to avoid that obviously contaminated fishery products are placed on the market for human consumption. Fishery products are often placed on the market as fresh fishery products which, before eaten, are heat-treated or frozen by the consumer in a way that ensures the killing of viable parasites. Fishery products must be visually examined in the state the food operator handles them (whole, eviscerated, filleted, sliced). Regulation (EC) No 2074/2005 contains definitions related to the visual examination, as well as more detailed rules for the visual examination of eviscerated, filleted, and sliced fish.

The legislative text specifies the temperature and time for the treatment to be applied by food business operators to kill viable parasites. Reaching such a core temperature depends on the thickness and composition of the product. For instance, it has been estimated that a 3 cm thick fillet should be heated for 10 minutes to ensure that *Anisakis* spp. larvae are destroyed. However, the larval stage (metacercaria) of trematodes (including *Opisthorchis* species and *Clonorchis* species) that occur in freshwater fish in certain geographical areas is more resistant to temperatures.

¹⁵ Opinion of the Scientific Panel on Biological hazards (BIOHAZ) on parasites in fishery products adopted on 11 March 2010. <http://www.efsa.europa.eu/it/scdocs/doc/1543.pdf>

Food business operators placing freshwater fish on the market must therefore also take into account the risk that such products may contain metacercariae that may represent a health hazard if meant to be eaten without a treatment that kills such parasites. Various reports indicate different parameters for the freezing treatment that kill various trematode metacercariae, which again have been reflected in different legislative provisions worldwide. EFSA refers in its Opinion on Parasites in Fishery Products to WHO statements that the metacercaria of *Opisthorchis* spp. and *Clonorchis* spp. are killed by freezing at -10°C for 5 days.

Other temperature-time parameters for various metacercariae can inter alia be found in FAO Fisheries Technical Paper 444¹⁶. These data include references that it shall take 3-4 days to kill the larvae of *Clonorchis sinensis* if frozen at -20°C and 32 hours to kill the larvae of *Opisthorchis felinus* at -28°C.

Regarding the heat treatment that will kill metacercariae, EFSA refers in its Opinion on Parasites in Fishery Products to a temperature of 70°C for 30 min for killing the *Clonorchis* and *Opisthorchis* metacercariae.

In case the FBO places on the market fishery products intended to be consumed raw or marinated, salted or treated with a treatment insufficient to kill the viable parasite, the legislation specifies that food business operators need not carry out the freezing treatment for fishery products that have been preserved as frozen fishery products for a sufficiently long period to kill the viable parasites. According to the legislation frozen fishery products must be kept at a temperature of not more than -18°C in all parts of the product. For parasites other than trematodes the freezing treatment must consist of lowering the temperature in all parts of the product to at least:

(a) – 20 °C for not less than 24 hours;

or

(b) – 35 °C for not less than 15 hours

Though larvae of trematodes are somewhat more resistant it can be concluded that the time that frozen fishery products are normally kept at -18 °C during cold storage, transport and the distribution chain shall kill all parasites that may represent a health hazard to the consumer. If fresh fishery products are frozen for a short period of time for technological reasons such as freezing treatment to eliminate viable parasites of public health concern, they can still be considered as fresh fishery products.

Methods other than freezing or heat treatment, as for example dry salting for a certain period, may also kill parasites present in fishery products. If such other methods are used by food business operators to kill parasites that may represent a health hazard to the consumer the treatment must be performed in line with a risk

¹⁶ FAO Fisheries Technical Paper 444, Assessment and management of seafood safety and quality: Chapter 5.1.4 Parasites. <http://www.fao.org/docrep/006/y4743e/y4743e0c.htm>

assessment documenting its efficiency. Further data on methods to kill larval stages of parasites of public health concern can be found in various documents. These include the Opinion of EFSA on parasites in fishery products, the Opinion of EFSA on Fish parasites of the Baltic Sea¹⁷, the FAO Fisheries Technical Paper 444 and Opinion 2007-SA-0379¹⁸ from the French risk assessment body, AFSSA.

5.17. Wild catches of fishery products

Point D.3(c) of Chapter III of Section VIII of Annex III to Regulation (EC) No 853/2004 provides for the competent authority of a Member State to authorise that the freezing treatment need not be carried out when epidemiological data are available indicating that the fishing grounds of origin do not present a health hazard with regard to the presence of parasites.

EFSA has concluded that all wild caught seawater and freshwater fish must be considered at risk of containing viable parasites of human health hazard if these products are to be eaten raw or almost raw. Consequently, an evaluation of new documentation that wild caught fish, whether from salt water or fresh water, is free from parasites should be based on an appropriate risk assessment. An assessment of whether fishery products from a fishing ground is likely to present a health hazard should take into account the prevalence, abundance, as well as species and geographical distributions of the parasites and their hosts together with results from monitoring systems and trends in parasite presence and abundance. It should also be noted that a Member State has to respect its obligation to notify any such national measure in accordance with Directive (EU) 2015/1535¹⁹.

5.18. Farmed fishery products

Point D.3(d) of Chapter III of Annex III to Regulation (EC) No 853/2004 states that certain farmed fishery products can be exempted from the freezing requirement even if intended to be consumed raw or marinated, salted or treated with a treatment insufficient to kill the viable parasites. Procedures and measures to ensure the absence of parasites should be designed according to the risk for infection. Guides to good practices may be appropriate tools to assist food business operators in defining means to ensure that fishery products are not infected with parasites that may represent a health hazard.

¹⁷ Opinion of the Scientific Panel on Biological hazards (BIOHAZ) on assessment of epidemiological data in relation to the health risks resulting from the presence of parasites in wild caught fish from fishing grounds in the Baltic Sea adopted on 7 July 2011. <http://www.efsa.europa.eu/en/efsajournal/pub/2320.htm>

¹⁸ Opinion of the French Food Safety Agency (Afssa) on a risk assessment request concerning the presence of anisakidae in fishery products and the extension of the exemption from the freezing sanitary obligation of fishery products whose feeding is under control and for certain species of wild fish. (Afssa – Request no. 2007-SA-0379). <http://www.anses.fr/Documents/MIC2007sa0379EN.pdf>

¹⁹ Directive of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (codification) OJ L 241, 17.9.2015, p. 1–15

5.18.1. Farming systems that by nature exclude any possibility for infection

These are systems where the design of the facilities and the farming system by nature protect against the access of any source of infection. Such systems include onshore tank systems supplied with water that can be demonstrated to be free from parasites. Open systems as floating cages, etc. do not belong to this category. When reared in fresh water, the water should be flowing continuously and should not come from lakes or reservoirs. When these requirements are not met, or when fish are reared in salt water, water should be filtered in a way that prevents the access of any source of infection. For farming systems that by nature exclude any possibility for infection of the fishery product it is sufficient to document the compliance with good practices for such farming systems that ensures the absence of parasites that represent a health hazard.

5.18.2. Fish farming with negligible risk for infection

Such production systems must also meet the basic criteria that the fish is cultured from embryos and fed their whole life on a diet that cannot contain viable parasites. However, the systems are not totally secluded from their environment with regard to the possible presence of parasites. For example, the fish may live at least part of its life in an environment where the presence of parasites cannot be excluded. According to the scientific opinion of EFSA Atlantic salmon farmed in a specific way represents a negligible risk with regard to parasites of public health importance. Practical experience with other species than farmed Atlantic salmon have also shown that other fishery products farmed in certain ways and/or in specified areas, both in fresh water and salt water, may be free from parasites that represent a risk to the consumers. Before food business operators apply the derogation from the freezing treatment for such production it must have been demonstrated that the procedures applied ensure that the production does not represent a health hazard with regard to the presence of live parasites. The competent authority must approve those procedures. In some cases it is sufficient to refer to EFSA's risk assessment for that kind of production, the procedures applied and have a generic monitoring programme at national level to ensure that the information on which the favourable risk assessment was based does not change.

If the type of production cannot exclude the risk for parasites as a general rule more intensive monitoring of fishery products, at farm level or even at batch level, could be deemed necessary. Methods applied for checking for the absence of parasites should be adjusted to the type of parasites, type of fish species, etc., ranging from plain visual inspection, via candling (visual inspection on a light table) to artificial digestion in Pepsin/HCl. If any parasites that may represent a health hazard should be revealed through monitoring programmes, or in any other way, these products should be excluded from the freezing exception until the production system has been checked and the farm has returned to the original situation that allowed the food business operator to make use of the exception.

5.19. Documents accompanying fishery products which have not undergone freezing treatments.

Each batch of fishery products subject to the derogation referred to in point D 3 (c) and (d) of Chapter III Section VIII of Annex III to Regulation (EC) No 853/2004 (no need to freeze it) shall be accompanied by documentation demonstrating that the competent authorities authorised the procedures applied for ensuring that the production does not represent a health hazard with regard to the presence of parasites. This could include a sentence in the commercial document granting the approval of the procedures by the competent authorities of the country where the fishery products are originating from, or copies of the approval of the procedures provided by the competent authorities or any other document proving the authorisation of the competent authorities to avoid the prescribed freezing treatment.

5.20. 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 examination' and 'candling'.

Destructive methods, like the digestion method, cannot be used in visual examination for determining whether fishery products are 'obviously contaminated' with parasites. An examination of the abdominal cavity after incision for visual examination of viscera and peritoneum is not considered as a destructive method. The visual examination must be performed by the food operator on the fishery product in the state the operator handles the product in (whole, eviscerated, filleted, sliced). If a food operator only handles non-eviscerated fish, the visual examination encompasses the surface of the fish, e.g. skin, eyes, mouth and gills. If the food operator eviscerates the fishery product, the examination also includes the abdominal cavity, viscera and peritoneum. If the fishery product is filleted and/or sliced, the fillets and slices should be examined.

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.

5.21. Processed/non processed fishery 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 a solution of water and additives to fresh or defrosted fishery products, asserting that this is “marinating”. Their objective is to use unauthorised additives or other ingredients, forbidden in fresh or unprocessed raw products with the ultimate goal to change the colour or texture of the fish, claiming that this activity is a processing. The fishery products after these treatments appear as fresh/raw, and not processed and this misleads consumers because they do not expect that the fresh appearance could be due to the addition of unauthorized additives in a fresh product. The use of unauthorised additives or other ingredients in unprocessed fishery products, which does not substantially alter their nature, cannot be said to 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 considered as processed, taking into account that the injection of water with additives is an action that not substantially alters the initial product, and cannot be labelled as such.

IDENTIFICATION MARKING

5.22. 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 of an ID mark on a product does not necessarily imply that it is ready for sale to the final consumer 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) No 853/2004 products to B (not a retailer) without labelling and without an ID-mark 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. So there might be two ID marks on the wrapping. It should be clear what activity was carried out by A and by B.

5.23. Multiple ID marking

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

Several identification marks on a single package may exceptionally be applied if 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.

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**
- **Fresh blood**
- **Fresh fishery products or frozen fishery products made from fresh 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**
- **Live snails**
- **Honey, propolis, pollen and royal jelly (if unprocessed).**

An unprocessed product with a product of plant origin remains a raw product (if the addition of a product of plant origin does not substantially alters the initial product) e.g.

- **Skewer containing fresh meat and vegetables**

- **Fresh fishery products or frozen fishery products made from fresh fishery products whole or prepared (e.g. fish fillets or loins) with the addition of additives authorised for unprocessed fishery products**

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 made from unprocessed raw materials 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 made from fresh 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.

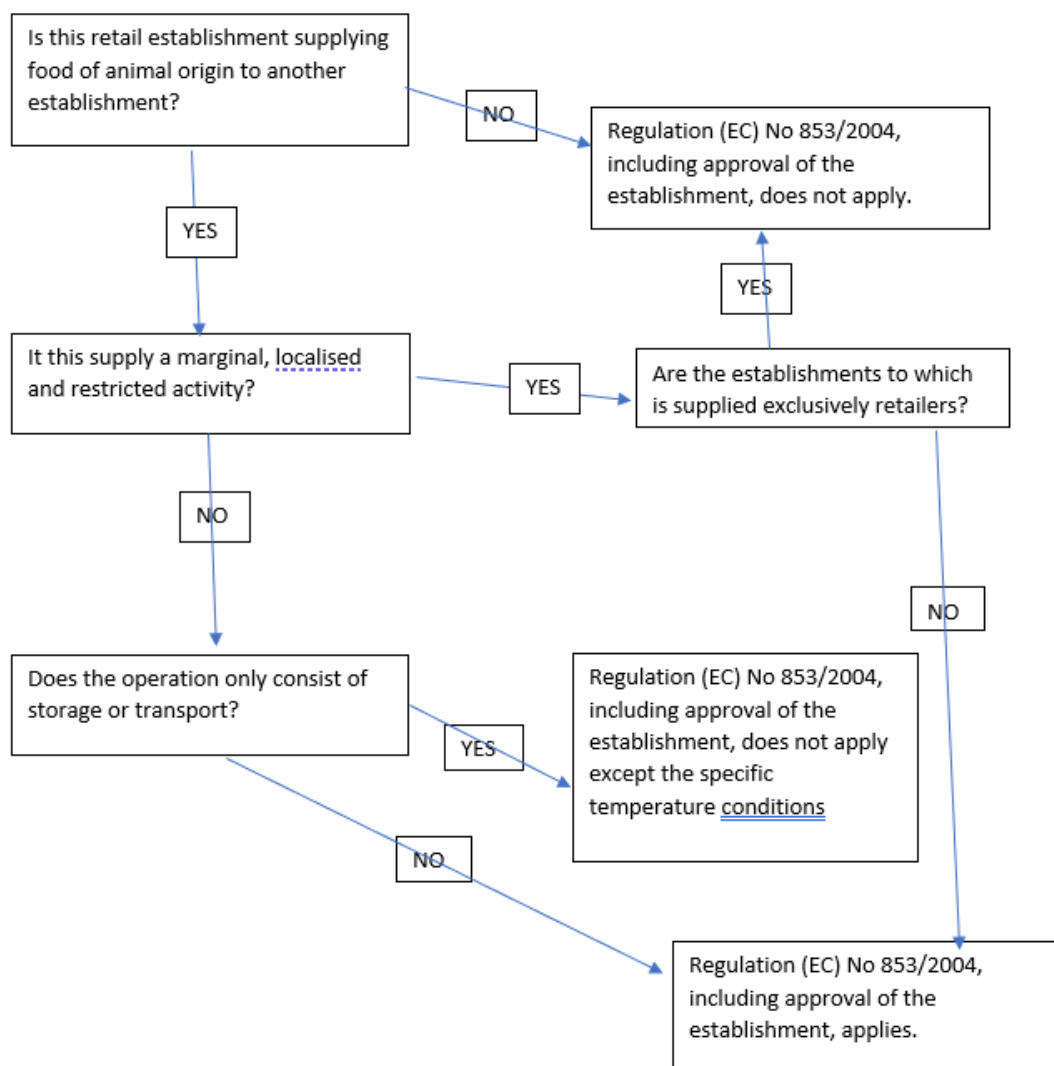
- Meat products (ham, salami, etc.)
- Processed fishery products (smoked fish, fish that has been marinated until the action substantially alters the initial unprocessed product including its appearance etc)
- Dairy products (pasteurised milk and other heat treated milk, cheese, yoghurt, etc.)
- Egg 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.

ANNEX III

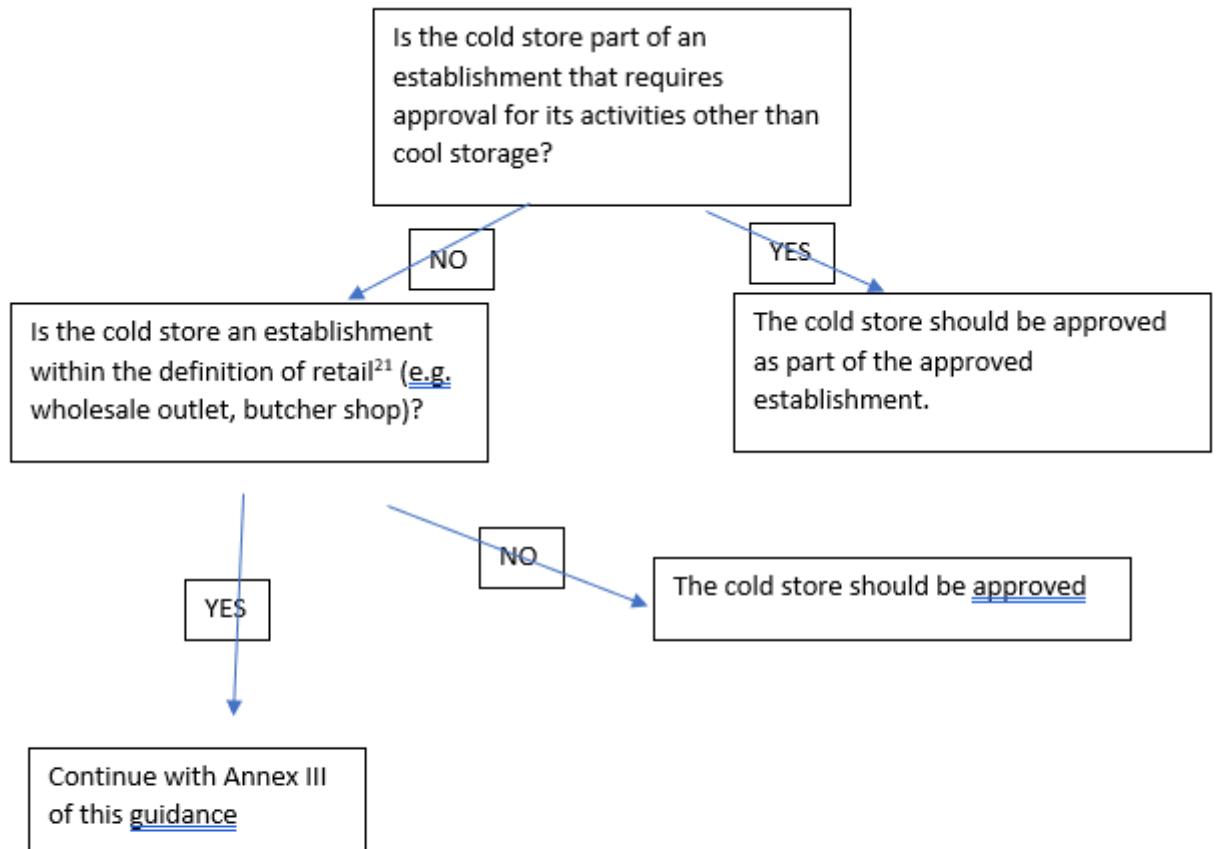
Application of Regulation (EC) No 853/2004 to retail²⁰ operations, including approval of the establishment



²⁰ As defined in Article 3.7 of Regulation (EC) No 178/2002: ‘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

ANNEX IV

Approval of cold stores storing food of animal origin



²¹ As defined in Article 3.7 of Regulation (EC) No 178/2002: '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

ANNEX V

Non-exhaustive list of establishments subject to approval

- General
 - Establishments proceeding to the re-wrapping/re-packaging of the products of animal origin for which Annex III to Regulation (EC) No 853/2004 lays down requirements, even if not associated with other operations such as slicing, cutting.
 - Establishments manufacturing food supplements being considered as products of animal origin if requirements are laid down in Annex III to Regulation (EC) No 853/2004 e.g. filling capsules with fish oil
 - Cold stores if required based on Annex IV

- Meat
 - Slaughterhouses
 - Cutting plants
 - Slaughter on the holding of provenance (except in the case of the direct supply by the producer of small quantities of meat from poultry, lagomorphs and reindeer (*Rangifer tarandus tarandus*, only in certain areas of Finland and Sweden) 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 (small and large) 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

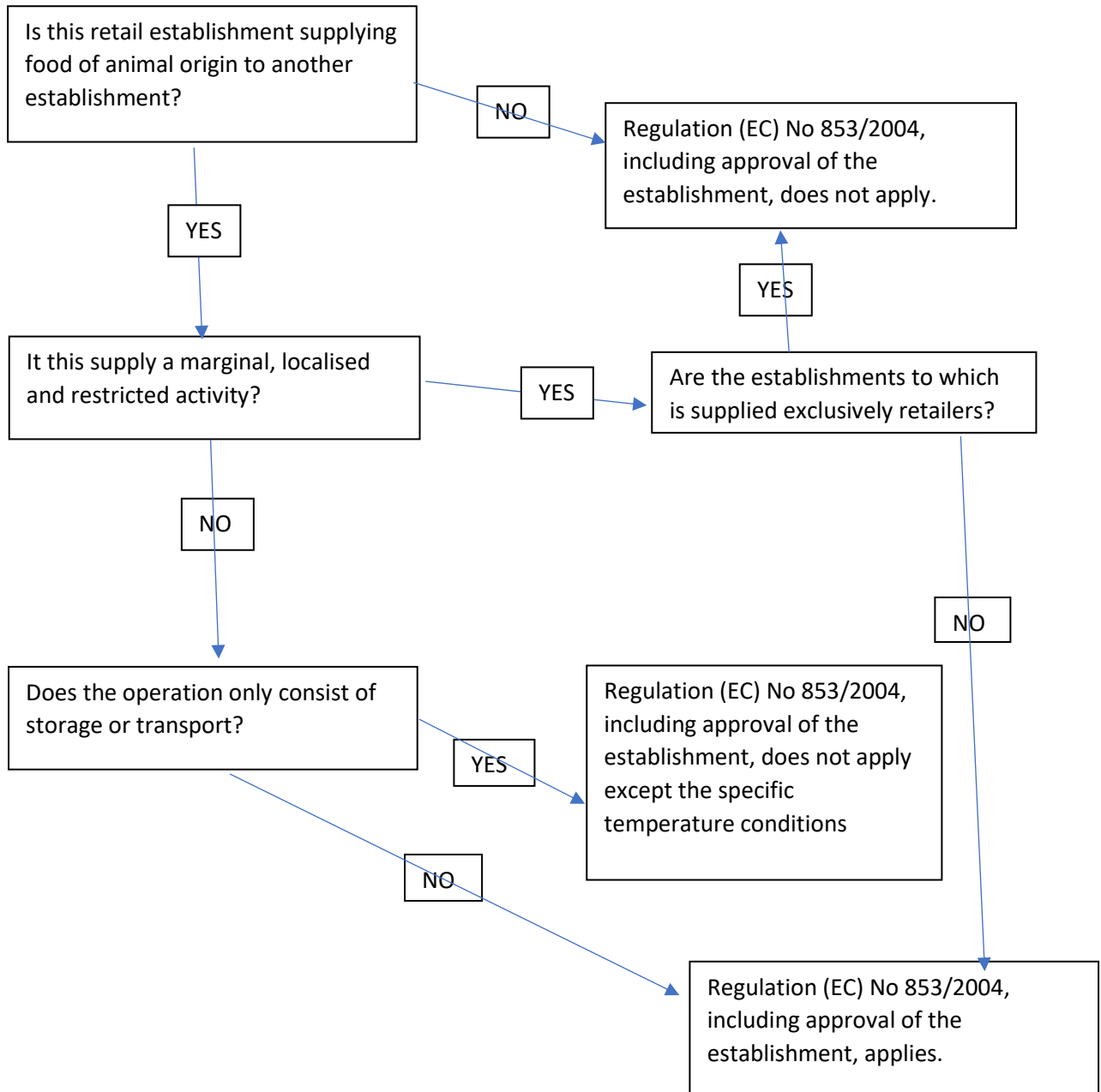
- Fishery products
 - Freezer, reefer and factory vessels
 - Establishments on land

- 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 eggs products

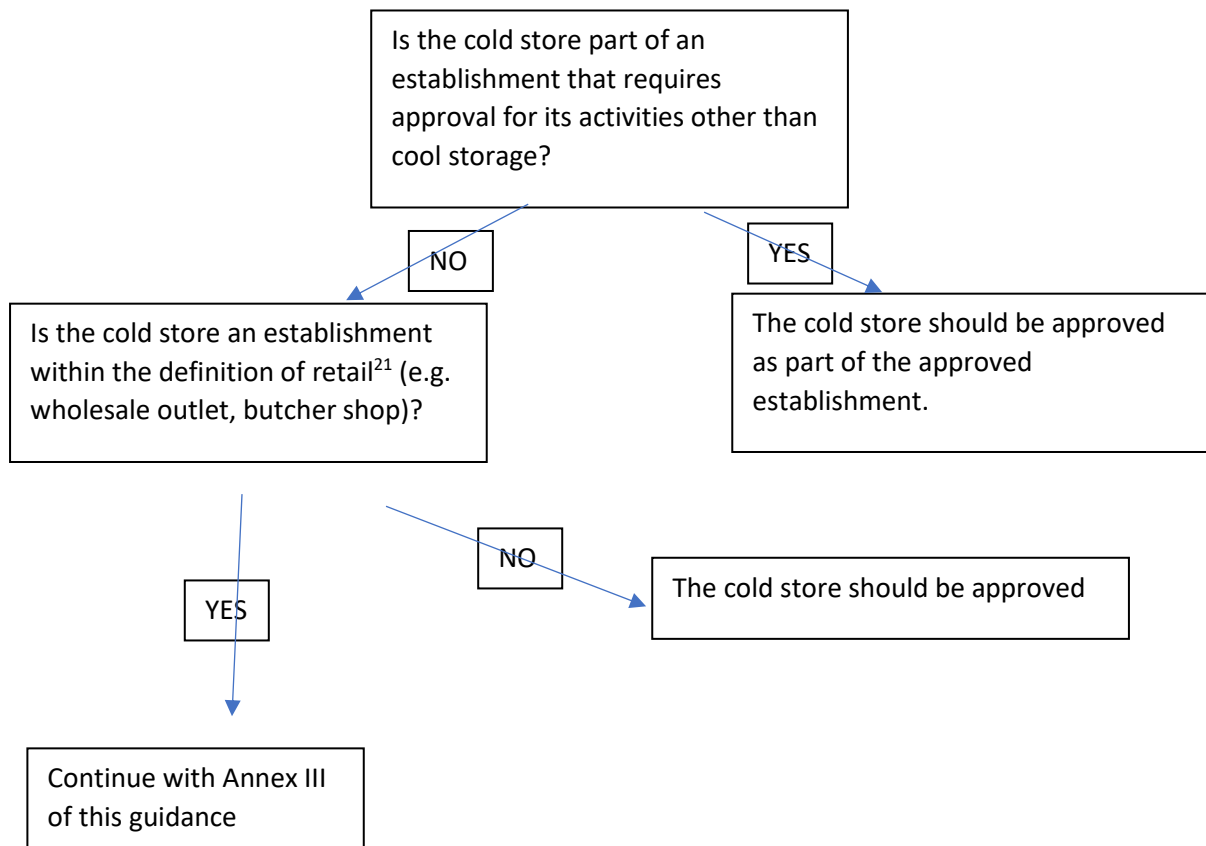
- Frogs' legs and snails
 - Establishments preparing and/or processing frogs' legs and snails
- Rendered animal fats and greaves
 - Establishments collecting, storing or processing raw materials
- Stomachs and bladders
 - Establishments treating bladders, stomachs and intestines
- Gelatine
 - Establishments processing raw materials
 - Establishments manufacturing gelatine capsules with or without filling them
- Collagen
 - Establishments processing raw materials

Annex III: Application of Regulation (EC) No 853/2004 to retail¹ operations, including approval of the establishment



¹ As defined in Article 3.7 of Regulation (EC) No 178/2002: ‘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

Annex IV: Approval of cold stores storing food of animal origin



²¹ As defined in Article 3.7 of Regulation (EC) No 178/2002: '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