Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 853/2004 of the European Parliament and of the Council, SECTION VIII:. (See end of Document for details)

[X1ANNEX III

SPECIFIC REQUIREMENTS

Editorial Information

X1 Substituted by Corrigendum to Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (Official Journal of the European Union L 139 of 30 April 2004).

SECTION VIII:

FISHERY PRODUCTS

[F1]. This Section does not apply to bivalve molluscs, echinoderms, tunicates and marine gastropods if they are still alive when placed on the market. With the exception of Chapters I and II, it applies to such animals when not placed on the market live, in which case they must have been obtained in accordance with Section VII.

It applies to thawed unprocessed fishery products and fresh fishery products to which food additives have been added in accordance with the appropriate [F2 legislation in force in the relevant constituent territory of Great Britain.].]

Textual Amendments

F2 Words in Annex 3 Section 8 para. 1 substituted (31.12.2020) by S.I. 2019/640, reg. 19(7)(a) (as substituted by The Food and Feed Hygiene and Safety (Miscellaneous Amendments etc.) (EU Exit) Regulations 2020 (S.I. 2020/1504), regs. 1(2), 9(11)(b))

Textual Amendments

- **F1** Substituted by Commission Regulation (EU) No 558/2010 of 24 June 2010 amending Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin (Text with EEA relevance).
- [F32] Chapter III, Parts A, C and D, Chapter IV, Part A and Chapter V apply to retail.]

Textual Amendments

- F3 Substituted by Commission Regulation (EC) No 1020/2008 of 17 October 2008 amending Annexes II and III to Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin and Regulation (EC) No 2076/2005 as regards identification marking, raw milk and dairy products, eggs and egg products and certain fishery products (Text with EEA relevance).
- 3. The requirements of this Section supplement those laid down in Regulation (EC) No 852/2004:
- (a) In the case of establishments, including vessels, engaged in primary production and associated operations they supplement the requirements of Annex I to that Regulation.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 853/2004 of the European Parliament and of the Council, SECTION VIII:. (See end of Document for details)

- (b) In the case of other establishments, including vessels, they supplement the requirements of Annex II to that Regulation.
- (c) [F4In the case of water supply, they supplement the requirements of Annex II, Chapter VII to that Regulation; clean seawater may be used for the handling and washing of fishery products, the production of ice used to chill fishery products and the rapid cooling of crustaceans and molluscs after their cooking.]

Textual Amendments

F4 Inserted by Commission Regulation (EC) No 1020/2008 of 17 October 2008 amending Annexes II and III to Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin and Regulation (EC) No 2076/2005 as regards identification marking, raw milk and dairy products, eggs and egg products and certain fishery products (Text with EEA relevance).

[F5By way of derogation from point (a), point 7 of Part A of Annex I to Regulation (EC) No 852/2004 may not apply to operators engaged in small-scale coastal fishing within the meaning of Article 26(1) of Council Regulation (EC) No 1198/2006⁽¹⁾, and carrying out their activities only for short periods of less than 24 hours.]

Textual Amendments

- F5 Inserted by Commission Regulation (EC) No 1243/2007 of 24 October 2007 amending Annex III to Regulation (EC) No 853/2004 of the European Parliament and the Council laying down specific hygiene rules for food of animal origin (Text with EEA relevance).
- 4. In relation to fishery products:
- (a) primary production covers the farming, fishing and collection of live fishery products with a view to their being placed on the market;

and

- (b) associated operations cover any of the following operations, if carried out on board fishing vessels: slaughter, bleeding, heading, gutting, removing fins, refrigeration and wrapping; they also include:
 - 1. the transport and storage of fishery products the nature of which has not been substantially altered, including live fishery products, within fish farms on land;

and

2. the transport of fishery products the nature of which has not been substantially altered, including live fishery products, from the place of production to the first establishment of destination.

CHAPTER I:

REQUIREMENTS FOR VESSELS

Food business operators must ensure that:

1. vessels used to harvest fishery products from their natural environment, or to handle or process them after harvesting, comply with the structural and equipment requirements laid down in Part I;

and

- 2. operations carried out on board vessels take place in accordance with the rules laid down in Part II.
- I. STRUCTURAL AND EQUIPMENT REQUIREMENTS
- A. Requirements for all vessels
- 1. Vessels must be designed and constructed so as not to cause contamination of the products with bilge-water, sewage, smoke, fuel, oil, grease or other objectionable substances.
- 2. Surfaces with which fishery products come into contact must be of suitable corrosion-resistant material that is smooth and easy to clean. Surface coatings must be durable and non-toxic.
- 3. Equipment and material used for working on fishery products must be made of corrosion-resistant material that is easy to clean and disinfect.
- 4. When vessels have a water intake for water used with fishery products, it must be situated in a position that avoids contamination of the water supply.
- B. Requirements for vessels designed and equipped to preserve fresh fishery products for more than 24 hours
- 1. Vessels designed and equipped to preserve fishery products for more than 24 hours must be equipped with holds, tanks or containers for the storage of fishery products at the temperatures laid down in Chapter VII.
- 2. Holds must be separated from the engine compartments and from the crew quarters by partitions which are sufficient to prevent any contamination of the stored fishery products. Holds and containers used for the storage of fishery products must ensure their preservation under satisfactory conditions of hygiene and, where necessary, ensure that melt water does not remain in contact with the products.
- 3. In vessels equipped for chilling fishery products in cooled clean seawater, tanks must incorporate devices for achieving a uniform temperature throughout the tanks. Such devices must achieve a chilling rate that ensures that the mix of fish and clean seawater reaches not more than 3 °C six hours after loading and not more than 0 °C after 16 hours and allow the monitoring and, where necessary, recording of temperatures.
- C. Requirements for freezer vessels

Freezer vessels must:

- 1. have freezing equipment with sufficient capacity to lower the temperature rapidly so as to achieve a core temperature of not more than -18 °C;
- 2. have refrigeration equipment with sufficient capacity to maintain fishery products in the storage holds at not more than -18 °C. Storage holds must be equipped with a temperature-recording device in a place where it can be easily read. The temperature sensor of the reader must be situated in the area where the temperature in the hold is the highest;

and

- 3. meet the requirements for vessels designed and equipped to preserve fishery products for more than 24 hours laid down in Part B, point 2.
- D. Requirements for factory vessels
- 1. Factory vessels must have at least:
- (a) a receiving area reserved for taking fishery products on board, designed to allow each successive catch to be separated. This area must be easy to clean and designed so as to protect the products from the sun or the elements and from any source of contamination;
- (b) a hygienic system for conveying fishery products from the receiving area to the work area;
- (c) work areas that are large enough for the hygienic preparation and processing of fishery products, easy to clean and disinfect and designed and arranged in such a way as to prevent any contamination of the products;
- (d) storage areas for the finished products that are large enough and designed so that they are easy to clean. If a waste-processing unit operates on board, a separate hold must be designated for the storage of such waste;
- (e) a place for storing packaging materials that is separate from the product preparation and processing areas;
- (f) special equipment for disposing waste or fishery products that are unfit for human consumption directly into the sea or, where circumstances so require, into a watertight tank reserved for that purpose. If waste is stored and processed on board with a view to its sanitation, separate areas must be allocated for that purpose;
- (g) a water intake situated in a position that avoids contamination of the water supply;and
- (h) hand-washing equipment for use by the staff engaged in handling exposed fishery products with taps designed to prevent the spread of contamination.
- 2. However, factory vessels on board which crustaceans and molluscs are cooked, chilled and wrapped, need not meet the requirements of point 1 if no other form of handling or processing takes place on board such vessels.
- 3. Factory vessels that freeze fishery products must have equipment meeting the requirements for freezer vessels laid down in Part C, points 1 and 2.

II. HYGIENE REQUIREMENTS

- 1. When in use, the parts of vessels or containers set aside for the storage of fishery products must be kept clean and maintained in good repair and condition. In particular, they must not be contaminated by fuel or bilge water.
- 2. As soon as possible after they are taken on board, fishery products must be protected from contamination and from the effects of the sun or any other source of heat. [F6] When they are washed, the water used must be either potable water or, where appropriate, clean water.]

Textual Amendments

- **F6** Deleted by Commission Regulation (EC) No 1020/2008 of 17 October 2008 amending Annexes II and III to Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin and Regulation (EC) No 2076/2005 as regards identification marking, raw milk and dairy products, eggs and egg products and certain fishery products (Text with EEA relevance).
- 3. Fishery products must be handled and stored so as to prevent bruising. Handlers may use spiked instruments to move large fish or fish which might injure them, provided that the flesh of the products suffers no damage.
- 4. Fishery products other than those kept alive must undergo chilling as soon as possible after loading. However, when chilling is not possible, fishery products must be landed as soon as possible.
- [F36. Where fish are headed and/or gutted on board, such operations must be carried out hygienically as soon as possible after capture, and the products must be washed immediately and thoroughly. In that event, the viscera and parts that may constitute a danger to public health must be removed as soon as possible and kept apart from products intended for human consumption. Livers and roes intended for human consumption must be preserved under ice, at a temperature approaching that of melting ice, or be frozen.]
- 7. Where freezing in brine of whole fish intended for canning is practised, a temperature of not more than -9 °C must be achieved for the product. The brine must not be a source of contamination for the fish.

CHAPTER II:

REQUIREMENTS DURING AND AFTER LANDING

- 1. Food business operators responsible for the unloading and landing of fishery products must:
- (a) ensure that unloading and landing equipment that comes into contact with fishery products is constructed of material that is easy to clean and disinfect and maintained in a good state of repair and cleanliness;

and

- (b) avoid contamination of fishery products during unloading and landing, in particular by:
 - (i) carrying out unloading and landing operations rapidly;
 - (ii) placing fishery products without delay in a protected environment at the temperature specified in Chapter VII;

and

- (iii) not using equipment and practices that cause unnecessary damage to the edible parts of the fishery products.
- 2. Food business operators responsible for auction and wholesale markets or parts thereof where fishery products are displayed for sale must ensure compliance with the following requirements.
- (a) (i) There must be lockable facilities for the refrigerated storage of detained fishery products and separate lockable facilities for the storage of fishery products declared unfit for human consumption.
 - (ii) If the competent authority so requires, there must be an adequately equipped lockable facility or, where needed, room for the exclusive use of the competent authority.
- (b) At the time of display or storage of fishery products:
 - (i) the premises must not be used for other purposes;
 - vehicles emitting exhaust fumes likely to impair the quality of fishery products must not have access to the premises;
 - (iii) persons having access to the premises must not introduce other animals; and
 - (iv) the premises must be well lit to facilitate official controls.
- 3. When chilling was not possible on board the vessel, fresh fishery products, other than those kept alive, must undergo chilling as soon as possible after landing and be stored at a temperature approaching that of melting ice.
- [F74. Food business operators must cooperate with relevant competent authorities so as to permit them to carry out official controls in accordance with Regulation (EC) No. 854/2004 and notify the competent authority of where the fishery products are landed.]

Textual Amendments

F7 Annex 3 Section 8 Ch. 2 para. 4 substituted (31.12.2020) by The Specific Food Hygiene (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/640), regs. 1, 19(7)(b); 2020 c. 1, Sch. 5 para. 1(1)

CHAPTER III:

REQUIREMENTS FOR ESTABLISHMENTS, INCLUDING VESSELS, HANDLING FISHERY PRODUCTS

Food business operators must ensure compliance with the following requirements, where relevant, in establishments handling fishery products.

- A. REQUIREMENTS FOR FRESH FISHERY PRODUCTS
- 1. Where chilled, unpackaged products are not distributed, dispatched, prepared or processed immediately after reaching an establishment on land, they must be stored under ice in appropriate facilities. Re-icing must be carried out as often as necessary.

Packaged fresh fishery products must be chilled to a temperature approaching that of melting ice.

- [F32. Operations such as heading and gutting must be carried out hygienically. Where gutting is possible from a technical and commercial viewpoint, it must be carried out as quickly as possible after the products have been caught or landed. The products must be washed thoroughly immediately after these operations.]
- 3. Operations such as filleting and cutting must be carried out so as to avoid contamination or spoilage of fillets and slices. Fillets and slices must not remain on the worktables beyond the time necessary for their preparation. Fillets and slices must be wrapped and, where necessary, packaged and must be chilled as quickly as possible after their preparation.
- 4. Containers used for the dispatch or storage of unpackaged prepared fresh fishery products stored under ice must ensure that melt water does not remain in contact with the products.
- 5. Whole and gutted fresh fishery products may be transported and stored in cooled water on board vessels. They may also continue to be transported in cooled water after landing, and be transported from aquaculture establishments, until they arrive at the first establishment on land carrying out any activity other than transport or sorting.

B. REQUIREMENTS FOR FROZEN PRODUCTS

Establishments on land that freeze fishery products must have equipment that satisfies the requirements laid down for freezer vessels in Section VIII, Chapter I, part I. C, points 1 and 2.

C. REQUIREMENTS FOR MECHANICALLY SEPARATED FISHERY PRODUCTS

Food business operators manufacturing mechanically separated fishery products must ensure compliance with the following requirements.

- 1. The raw materials used must satisfy the following requirements.
 - (a) Only whole fish and bones after filleting may be used to produce mechanically separated fishery products;
 - (b) All raw materials must be free from guts.
- 2. The manufacturing process must satisfy the following requirements:
 - (a) Mechanical separation must take place without undue delay after filleting.
 - (b) If whole fish are used, they must be gutted and washed beforehand.
 - (c) After production, mechanically separated fishery products must be frozen as quickly as possible or incorporated in a product intended for freezing or a stabilising treatment.

I^{F8}D. REQUIREMENTS CONCERNING PARASITES

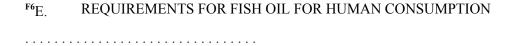
- 1. Food business operators placing on the market the following fishery products derived from finfish or cephalopod molluscs:
 - (a) fishery products intended to be consumed raw; or
 - (b) marinated, salted and any other treated fishery products, if the treatment is insufficient to kill the viable parasite;

must ensure that the raw material or finished product undergo a freezing treatment in order to kill viable parasites that may be a risk to the health of the consumer.

- 2. 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.
- 3. Food business operators need not carry out the freezing treatment set out in point 1 for fishery products:
 - (a) that have undergone, or are intended to undergo before consumption a heat treatment that kills the viable parasite. In the case of parasites other than trematodes the product is heated to a core temperature of 60 °C or more for at least one minute;
 - (b) that have been preserved as frozen fishery products for a sufficiently long period to kill the viable parasites;
 - (c) from wild catches, provided that:
 - (i) there are epidemiological data available indicating that the fishing grounds of origin do not present a health hazard with regard to the presence of parasites; and
 - (ii) the competent authority so authorises;
 - (d) derived from fish farming, cultured from embryos and have been fed exclusively on a diet that cannot contain viable parasites that present a health hazard, and one of the following requirements is complied with:
 - (i) have been exclusively reared in an environment that is free from viable parasites; or
 - (ii) the food business operator verifies through procedures, approved by the competent authority, that the fishery products do not represent a health hazard with regard to the presence of viable parasites.
- 4. (a) When placing on the market, except when supplied to the final consumer, fishery products referred to in point 1 must be accompanied by a document issued by the food business operator performing the freezing treatment, stating the type of freezing treatment that the products have undergone.
 - (b) Before placing on the market fishery products referred to in points 3(c) and (d) which have not undergone the freezing treatment or which are not intended to undergo before consumption a treatment that kills viable parasites that present a health hazard, a food business operator must ensure that the fishery products originate from a fishing ground or fish farming which complies with the specific conditions referred to in one of those points. This provision may be met by information in the commercial document or by any other information accompanying the fishery products.]

Textual Amendments

F8 Substituted by Commission Regulation (EU) No 1276/2011 of 8 December 2011 amending Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council as regards the treatment to kill viable parasites in fishery products for human consumption (Text with EEA relevance).



[F3CHAPTER IV:

REQUIREMENTS FOR CERTAIN PROCESSED FISHERY PRODUCTS

Food business operators must ensure compliance with the following requirements in establishments handling certain processed fishery products.

- A. REQUIREMENTS FOR COOKING OF CRUSTACEANS AND MOLLUSCS
- 1. Rapid cooling must follow cooking. If no other method of preservation is used, cooling must continue until a temperature approaching that of melting ice is reached.
- 2. Shelling or shucking must be carried out hygienically, avoiding contamination of the product. Where such operations are done by hand, workers must pay particular attention to washing their hands.
- 3. After shelling or shucking, cooked products must be frozen immediately, or be chilled as soon as possible to the temperature set out in Chapter VII.
- B. REQUIREMENTS FOR FISH OIL INTENDED FOR HUMAN CONSUMPTION
- 1. Raw materials used in the preparation of fish oil for human consumption must:
- (a) come from establishments, including vessels, registered or approved pursuant to Regulation (EC) No 852/2004 or in accordance with this Regulation;
- (b) derive from fishery products which are fit for human consumption and which comply with the provisions set out in this Section;
- (c) be transported and stored in hygienic conditions;
- (d) be chilled as soon as possible and remain at the temperatures set out in Chapter VII.

By way of derogation from point 1(d), the food business operator may refrain from chilling the fishery products when whole fishery products are used directly in the preparation of fish oil for human consumption, and the raw material is processed within 36 hours after loading, provided that the freshness criteria are met and the total volatile basic nitrogen (TVB-N) value of the unprocessed fishery products do not exceed the limits set out in point 1 of Chapter I of Section II of Annex II to Commission Regulation (EC) No 2074/2005⁽²⁾.

2. The production process for fish oil must ensure that all raw material intended for the production of crude fish oil is subject to a treatment including, where relevant, heating, pressing, separation, centrifugation, processing, refining and purification steps before being placed on the market for the final consumer.

3. Provided that the raw materials and the production process comply with the requirements applying to fish oil intended for human consumption a food business operator may produce and store both fish oil for human consumption and fish oil and fish meal not intended for human consumption in the same establishment.

Textual Amendments

F9 Annex 3 Section 8 Ch. 4 Pt. B para. 4 omitted (31.12.2020) by virtue of The Specific Food Hygiene (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/640), regs. 1, 19(7)(c); 2020 c. 1, Sch. 5 para. 1(1)

CHAPTER V:

HEALTH STANDARDS FOR FISHERY PRODUCTS

In addition to ensuring compliance with microbiological criteria adopted in accordance with Regulation (EC) No 852/2004, food business operators must ensure, depending on the nature of the product or the species, that fishery products placed on the market for human consumption meet the standards laid down in this Chapter. [F4 The requirements of Parts B and D shall not apply to whole fishery products that are used directly for the preparation of fish oil intended for human consumption.]

A. ORGANOLEPTIC PROPERTIES OF FISHERY PRODUCTS

Food business operators must carry out an organoleptic examination of fishery products. In particular, this examination must ensure that fishery products comply with any freshness criteria.

B. HISTAMINE

Food business operators must ensure that the limits with regard to histamine are not exceeded.

C. TOTAL VOLATILE NITROGEN

Unprocessed fishery products must not be placed on the market if chemical tests reveal that the limits with regard to TVB-N or TMA-N have been exceeded.

D. 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. They must not place fishery products that are obviously contaminated with parasites on the market for human consumption.

E. TOXINS HARMFUL TO HUMAN HEALTH

[F31. Fishery products derived from poisonous fish of the following families must not be placed on the market: Tetraodontidae, Molidae, Diodontidae and Canthigasteridae.

Fresh, prepared, frozen and processed fishery products belonging to the family *Gempylidae*, in particular *Ruvettus pretiosus* and *Lepidocybium flavobrunneum*, may only be placed on the market in wrapped/packaged form and must be appropriately labelled to provide information

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 853/2004 of the European Parliament and of the Council, SECTION VIII:. (See end of Document for details)

to the consumer on preparation/cooking methods and on the risk related to the presence of substances with adverse gastrointestinal effects.

The scientific name of the fishery products must accompany the common name on the label.]

2. Fishery products containing biotoxins such as ciguatoxin or muscle-paralysing toxins must not be placed on the market. However, fishery products derived from bivalve molluscs, echinoderms, tunicates and marine gastropods may be placed on the market if they have been produced in accordance with Section VII and comply with the standards laid down in Chapter V, point 2, of that section.

CHAPTER VI:

WRAPPING AND PACKAGING OF FISHERY PRODUCTS

- 1. Receptacles in which fresh fishery products are kept under ice must be water-resistant and ensure that melt-water does not remain in contact with the products.
- 2. Frozen blocks prepared on board vessels must be adequately wrapped before landing.
- 3. When fishery products are wrapped on board fishing vessels, food business operators must ensure that wrapping material:
- (a) is not a source of contamination;
- (b) is stored in such a manner that it is not exposed to a risk of contamination;
- (c) intended for re-use is easy to clean and, where necessary, to disinfect.

CHAPTER VII:

STORAGE OF FISHERY PRODUCTS

Food business operators storing fishery products must ensure compliance with the following requirements.

- 1. Fresh fishery products, thawed unprocessed fishery products, and cooked and chilled products from crustaceans and molluscs, must be maintained at a temperature approaching that of melting ice.
- 2. [FIFrozen fishery products must be kept at a temperature of not more than -18 °C in all parts of the product; however, whole fish initially frozen in brine intended for the manufacture of canned food may be kept at a temperature of not more than -9 °C.]
- 3. Fishery products kept alive must be kept at a temperature and in a manner that does not adversely affect food safety or their viability.

CHAPTER VIII:

TRANSPORT OF FISHERY PRODUCTS

Food business operators transporting fishery products must ensure compliance with the following requirements.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 853/2004 of the European Parliament and of the Council, SECTION VIII: (See end of Document for details)

- 1. During transport, fishery products must be maintained at the required temperature. In particular:
 - (a) fresh fishery products, thawed unprocessed fishery products, and cooked and chilled products from crustaceans and molluscs, must be maintained at a temperature approaching that of melting ice;
 - (b) [F1 frozen fishery products, with the exception of whole fish initially frozen in brine intended for the manufacture of canned food, must be maintained during transport at an even temperature of not more than 18 °C in all parts of the product, possibly with short upward fluctuations of not more than 3 °C.1
- 2. Food business operators need not comply with point 1(b) when frozen fishery products are transported from a cold store to an approved establishment to be thawed on arrival for the purposes of preparation and/or processing, if the journey is short and the competent authority so permits.
- 3. If fishery products are kept under ice, melt water must not remain in contact with the products.
- 4. Fishery products to be placed on the market live must be transported in such a way as not adversely to affect food safety or their viability.]

- (1) $[^{X1}[^{F5}OJ L 223, 15.8.2006, p. 1.]]$
- (2) $[^{X1}[^{F3}OJ L 338, 22.12.2005, p. 27.]]$

Editorial Information

X1 Substituted by Corrigendum to Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (Official Journal of the European Union L 139 of 30 April 2004).

Textual Amendments

- F3 Substituted by Commission Regulation (EC) No 1020/2008 of 17 October 2008 amending Annexes II and III to Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin and Regulation (EC) No 2076/2005 as regards identification marking, raw milk and dairy products, eggs and egg products and certain fishery products (Text with EEA relevance).
- **F5** Inserted by Commission Regulation (EC) No 1243/2007 of 24 October 2007 amending Annex III to Regulation (EC) No 853/2004 of the European Parliament and the Council laying down specific hygiene rules for food of animal origin (Text with EEA relevance).

Changes to legislation:

There are currently no known outstanding effects for the Regulation (EC) No 853/2004 of the European Parliament and of the Council, SECTION VIII: