Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004 (Text with EEA relevance)

COMMISSION REGULATION (EC) No 2074/2005

of 5 December 2005

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(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs[(1)], and in particular Article 13(2) thereof,

Having regard 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[(2)], and in particular Articles 9, 10 and 11 thereof,

Having regard to Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption[(3)], and in particular Articles 16, 17 and 18 thereof,

Having regard to Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the compliance with feed and food law, animal health and animal welfare rules[(4)], and in particular Article 63 thereof,

Whereas:

(1) Regulation (EC) No 853/2004 lays down specific requirements concerning hygiene rules for food of animal origin. It is necessary to lay down certain implementing measures for meat, live bivalve molluscs, fishery products, milk, eggs, frogs' legs and snails, and processed products thereof.

Changes to legislation: *There are outstanding changes not yet made to Commission Regulation (EC) No 2074/2005. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(2) Regulation (EC) No 854/2004 lays down specific rules for the organisation of official controls on products of animal origin intended for human consumption. It is necessary to develop certain rules and further specify other requirements.

(3) Regulation (EC) No 882/2004 establishes at Community level a harmonised framework of general rules for the organisation of official controls. It is necessary to develop certain rules and further specify other requirements.

(4) Commission Decision 20XX/2005/EC[(5)] repeals certain Decisions implementing measures provided for in the Directives repealed by Directive 2004/41/EC of the European Parliament and of the Council of 21 April 2004 repealing certain Directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC[(6)]. Certain parts of the relevant Decisions should therefore be retained in this Regulation.

(5) Regulation (EC) No 852/2004 requires the food business operator to keep and retain records and on request to make relevant information in these records available to the competent authority and receiving food business operator.

(6) Regulation (EC) No 853/2004 also requires the slaughterhouse operator to request, receive, check and act upon the food chain information for all animals, other than wild game, sent or intended to be sent to the slaughterhouse. In addition, he should make sure the food chain information provides all the details required under Regulation (EC) No 853/2004.

(7) The food chain information assists the slaughterhouse operator to organise slaughter operations and assists the official veterinarian to determine the required inspection procedures. The food chain information should be analysed by the official veterinarian and used as an integral part of the inspection procedures.

(8) Existing systems for information flow should be used as much as possible and adapted to comply with the requirements for the food chain information laid down in Regulation (EC) No 854/2004.

(9) In order to improve animal management at holding level and in accordance with Regulation (EC) No 854/2004, the official veterinarian should record and, if necessary, communicate, to the food business operator of the holding of provenance and to any veterinarian attending the holding of provenance or any competent authority involved, any disease or condition observed at the slaughterhouse in respect of individual animals or the herd/flock and which may affect public or animal health or endanger animal welfare.

(10) Regulations (EC) Nos 853/2004 and 854/2004 set out the requirements governing parasite checks during handling of fishery products on shore and on board vessels. It is up to food business operators to carry out their own checks at all stages in the production of fishery products in accordance with the rules in Chapter V(D) of Section VIII of Annex III to Regulation (EC) No 853/2004 so that fish which are

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obviously infested with parasites are not released for human consumption. The adoption of detailed rules relating to visual inspections calls for the concepts of visible parasites and visual inspection to be defined and the type and frequency of the observations to be determined.

(11) The checks provided for in Regulation (EC) No 853/2004 to prevent fishery products which are unfit for human consumption from being placed on the market may comprise certain chemical checks, including checks of total volatile basic nitrogen (TVB-N). It is necessary to set levels of TVB-N that are not to be exceeded in the case of certain species categories and to specify the analysis methods to be used. The analysis methods that are scientifically recognised for checking TVB-N should continue to be used as a matter of routine, but a reference method should be specified for use where there is doubt regarding the results or in the event of dispute.

(12) The limits for Paralytic Shellfish Poison (PSP), Amnesic Shellfish Poison (ASP) and lipophilic toxins are laid down in Regulation (EC) No 853/2004. Bioassays are the reference method for detecting certain toxins and preventing toxic shellfish from being harvested. Maximum levels and methods of analysis should be harmonised and implemented by the Member States to protect human health. In addition to biological testing methods, alternative detection methods, such as chemical methods and *in vitro* assays, should be allowed if it is demonstrated that the performance of the chosen methods is at least as effective as the biological method and that their implementation provides an equivalent level of public health protection. The proposed maximum levels for lipophilic toxins are based on provisional data and should be reassessed once new scientific evidence becomes available. A lack of reference material and the sole use of non-bioassay tests currently means that the level of public health protection provided in respect of all toxins specified is not equivalent to that afforded by biological tests. Provision should be made for the replacement of biological tests as soon as possible.

(13) Mechanically separated meat (MSM) produced using techniques that do not alter the structure of the bones used in the production of MSM should be treated as different from MSM produced using techniques that alter the structure of the bones.

(14) MSM of the former type produced under specified conditions and of a specified composition should be permitted in meat preparations that are clearly not intended to be consumed without first undergoing heat treatment. These conditions are linked in particular to the calcium content of MSM, which should be specified in accordance with Article 11(2) of Regulation (EC) No 853/2004. An adjustment should be made to the specified maximum calcium content set in this Regulation once detailed information is available on variations occurring where different types of raw material are used.

(15) Article 31(2)(f) of Regulation (EC) No 882/2004 provides for Member States to maintain up-to-date lists of approved establishments. A common framework should be laid down for the presentation of relevant information to other Member States and to the public.

(16) Section XI of Annex III to Regulation (EC) No 853/2004 sets out the requirements governing the preparation of frogs' legs and snails intended for human consumption.

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Specific requirements, including model health certificates, should also be laid down for imports from third countries of frogs' legs and snails intended for human consumption.

(17) Sections XIV and XV of Annex III to Regulation (EC) No 853/2004 lay down rules on the production and placing on the market of gelatine and collagen intended for human consumption. Specific requirements, including model health certificates, should also be laid down for imports from third countries of gelatine and collagen and raw materials for the production of gelatine and collagen intended for human consumption.

(18) Flexibility is needed so foods with traditional characteristics can continue to be produced. Member States have already granted derogations for a wide range of such foods under the legislation in force before 1 January 2006. Food business operators should be able to continue without interruption to apply existing practices after that date. A procedure allowing Member States to exercise flexibility is provided for in Regulations (EC) No 852/2004, (EC) No 853/2004 and (EC) No 854/2004. However, in most cases where derogations have already been granted it is only a question of continuing established practices, so applying a full notification procedure, including a complete hazard analysis, may place an unnecessary and disproportionate burden on the Member States. Foods with traditional characteristics should therefore be defined and general conditions applicable to such foods should be laid down, by way of derogation from the structural requirements laid down in Regulation (EC) No 852/2004, with due regard to food health objectives.

(19) Since Regulations (EC) Nos 853/2004 and 854/2004 were adopted before the accession on 1 May 2004, they did not refer to the new Member States. The ISO codes for those Member States and the abbreviations for the European Community in their languages should therefore be added to the relevant provisions of those Regulations.

(20) Section I of Annex III to Regulation (EC) No 853/2004 lays down rules on the production and placing on the market of meat from domestic ungulates. Exceptions to the complete skinning of the carcase and other parts of the body intended for human consumption are set out in Chapter IV, point 8 of that Section. Provision should be made to extend these exceptions to feet from adult bovine animals, provided they comply with the same conditions as those applying to feet of calves.

(21) Certain practices can mislead the consumer regarding the composition of certain products. In particular in order not to disappoint consumer expectations, the sale as fresh meat of poultrymeat treated with water retention agents should be banned.

(22) The opinion of the European Food Safety Authority adopted on 30 August 2004 has demonstrated that fishery products belonging to the family of *Gempylidae*, in particular *Ruvettus pretiosus* and *Lepidocybium flavobrunneum,* may have adverse gastrointestinal effects if consumed under certain conditions. The fishery products belonging to this family should therefore be subjected to marketing conditions.

(23) Section IX of Annex III to Regulation (EC) No 853/2004 lays down specific hygiene rules for raw milk and dairy products. According to Part II (B)(1)(e) of Chapter I, teat dips or other udder cleaning products may be used only if they have been approved by the competent authority. However, no detailed authorisation scheme is provided in this

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Part. It is therefore necessary, in order to ensure a harmonised approach by Member States, to clarify the procedures under which such authorisations should be given.

(24) Regulation (EC) No 853/2004 requires food business operators to ensure that heat treatments used to process raw milk and dairy products should conform to an internationally recognised standard. However, owing to the specificity of certain heat treatments used in this sector and their impact on food safety and animal health, clearer guidance should be given to food business operators in this regard.

(25) Regulation (EC) No 853/2004 introduces a new definition to cover products derived from eggs that, after removal of the shell, have not yet been processed. It is, therefore, necessary to clarify the rules applying to those products and amend Section X, Chapter II of Annex III to Regulation (EC) No 853/2004 accordingly.

(26) Section XIV of Annex III to Regulation (EC) No 853/2004 lays down specific health rules for gelatine. These rules include requirements covering the type of raw materials that may be used to produce gelatine and the transport and storage of such materials. They also lay down specifications applicable to the manufacture of gelatine. However, the rules applying to labelling of gelatine should also be laid down.

(27) Scientific progress has led to the establishment of ISO 16649-3 as an agreed reference method for analysis of *E. coli* in bivalve molluscs. This reference method is already established for live bivalve molluscs from areas A in accordance with Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs[7]. Consequently, ISO 16649-3 should be specified as the reference MPN (most probable number) method for analysis of *E. coli* in bivalve molluscs originating in areas B and C too. The use of alternative methods should be allowed only where they are considered equivalent to the reference method.

(28) Regulations (EC) Nos 853/2004 and 854/2004 should therefore be amended accordingly.

(29) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

[F1 Article 1

Requirements concerning food chain information for the purpose of Regulation (EC) No 853/2004

Requirements concerning food chain information as referred to in Section III of Annex II to Regulation (EC) No 853/2004 are set out in Annex I to this Regulation.**]**

Textual Amendments

F1 Substituted by Commission Implementing Regulation (EU) 2019/1139 of 3 July 2019 amending Regulation (EC) No 2074/2005 as regards official controls on food of animal origin in relation to requirements concerning food chain information and fishery products and to the reference to