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

[[X1]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**]**

[[X1]THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 152(4)(b) thereof,

Having regard to the proposal from the Commission[(1)],

Having regard to the opinion of the European Economic and Social Committee[(2)],

Having consulted the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty[(3)],

Whereas:

(1) Pursuant to Regulation (EC) No 852/2004[(4)], the European Parliament and the Council laid down general rules for food business operators on the hygiene of foodstuffs.

(2) Certain foodstuffs may present specific hazards to human health, requiring the setting of specific hygiene rules. This is particularly the case for food of animal origin, in which microbiological and chemical hazards have frequently been reported.

(3) In the context of the common agricultural policy, many Directives have been adopted to establish specific health rules for the production and placing on the market of the products listed in Annex I to the Treaty. These health rules have reduced trade barriers for the products concerned, contributing to the creation of the internal market while ensuring a high level of protection of public health.

(4) With regard to public health, these rules contain common principles, in particular in relation to the manufacturers 'and competent authorities' responsibilities, structural, operational and hygiene requirements for establishments, procedures for the approval of establishments, requirements for storage and transport and health marks.

(5) These principles constitute a common basis for the hygienic production of food of animal origin, permitting the simplification of the existing directives.

(6) It is desirable to achieve further simplification by applying the same rules wherever appropriate to all products of animal origin.

(7) The requirement in Regulation (EC) No 852/2004 whereby food business operators carrying out any stage of production, processing and distribution of food after primary production and associated operations must put in place, implement and maintain

procedures based on hazard analysis and critical control point (HACCP) principles also permits simplification.

(8) Taken together, these elements justify a recasting of the specific hygiene rules contained in existing directives.

(9) The principal objectives of the recasting are to secure a high level of consumer protection with regard to food safety, in particular by making food business operators throughout the Community subject to the same rules, and to ensure the proper functioning of the internal market in products of animal origin, thus contributing to the achievement of the objectives of the common agricultural policy.

(10) It is necessary to maintain and, where required to ensure consumer protection, to tighten detailed hygiene rules for products of animal origin.

(11) Community rules should not apply either to primary production for private domestic use or to the domestic preparation, handling or storage of food for private domestic consumption. Moreover, where small quantities of primary products or of certain types of meat are supplied directly by the food business operator producing them to the final consumer or to a local retail establishment, it is appropriate to protect public health through national law, in particular because of the close relationship between the producer and the consumer.

(12) The requirements of Regulation (EC) No 852/2004 are generally sufficient to ensure food safety in establishments carrying out retail activities involving the direct sale or supply of food of animal origin to the final consumer. This Regulation should generally apply to wholesale activities (that is, when a retail establishment carries out operations with a view to supplying food of animal origin to another establishment). Nevertheless, with the exception of the specific temperature requirements laid down in this Regulation, the requirements of Regulation (EC) No 852/2004 should suffice for wholesale activities consisting only of storage or transport.

(13) Member States should have some discretion to extend or to limit the application of the requirements of this Regulation to retail under national law. However, they may limit their application only if they consider that the requirements of Regulation (EC) No 852/2004 are sufficient to achieve food hygiene objectives and when the supply of food of animal origin from a retail establishment to another establishment is a marginal, localised and restricted activity. Such supply should therefore be only a small part of the establishment's business; the establishments supplied should be situated in its immediate vicinity; and the supply should concern only certain types of products or establishments.

(14) In accordance with Article 10 of the Treaty, Member States are to take all appropriate measures to ensure that food business operators comply with the obligations laid down in this Regulation.

(15) The traceability of food is an essential element in ensuring food safety. In addition to complying with the general rules of Regulation (EC) No 178/2002[(5)], food business operators responsible for establishments that are subject to approval in accordance with

this Regulation should ensure that all products of animal origin that they place on the market bear either a health mark or an identification mark.

(16) Food imported into the Community is to comply with the general requirements laid down in Regulation (EC) No 178/2002 or to satisfy rules that are equivalent to Community rules. This Regulation defines specific hygiene requirements for food of animal origin imported into the Community.

(17) The adoption of this Regulation should not reduce the level of protection provided by the additional guarantees agreed for Finland and Sweden on their accession to the Community and confirmed by Commission Decisions 94/968/EC[(6)], 95/50/EC[(7)], 95/160/EC[(8)], 95/161/E[(9)] and 95/168/EC[(10)], and Council Decisions 95/409/EC[(11)], 95/410/EC[(12)] and 95/411/EC[(13)]. It should establish a procedure for the granting, for a transitional period, of guarantees to any Member State that has an approved national control programme which, for the food of animal origin concerned, is equivalent to those approved for Finland and Sweden. Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents[(14)] provides for a similar procedure in respect of live animals and hatching eggs.

(18) It is appropriate for the structural and hygiene requirements laid down in this Regulation to apply to all types of establishments, including small businesses and mobile slaughterhouses.

(19) Flexibility is appropriate to enable the continued use of traditional methods at any of the stages of production, processing or distribution of food and in relation to structural requirements for establishments. Flexibility is particularly important for regions that are subject to special geographical constraints, including the outermost regions referred to in Article 299(2) of the Treaty. However, flexibility should not compromise food hygiene objectives. Moreover, since all food produced in accordance with the hygiene rules will normally be in free circulation throughout the Community, the procedure allowing Member States to exercise flexibility should be fully transparent. It should provide, where necessary to resolve disagreements, for discussion within the Standing Committee on the Food Chain and Animal Health established by Regulation (EC) No 178/2002 and for the Commission to coordinate the process and take appropriate measures.

(20) The definition of mechanically separated meat (MSM) should be a generic one covering all methods of mechanical separation. Rapid technological developments in this area mean that a flexible definition is appropriate. The technical requirements for MSM should differ, however, depending on a risk assessment of the product resulting from different methods.

(21) There are interactions between food business operators, including the animal feed sector, and connections between animal health, animal welfare and public health considerations at all stages of production, processing and distribution. This requires adequate communication between the different stakeholders along the food chain from primary production to retail.

(22) In order to ensure proper inspection of hunted wild game placed on the Community market, bodies of hunted animals and their viscera should be presented for official post-mortem inspection at a game-handling establishment. However, to preserve certain hunting traditions without prejudicing food safety, it is appropriate to provide for training for hunters who place wild game on the market for human consumption. This should enable hunters to undertake an initial examination of wild game on the spot. In these circumstances, it is not necessary to require trained hunters to deliver all viscera to the game-handling establishment for post-mortem examination, if they carry out this initial examination and identify no anomalies or hazards. However, Member States should be allowed to establish stricter rules within their territories to take account of specific risks.

(23) This Regulation should establish criteria for raw milk pending the adoption of new requirements for its placing on the market. These criteria should be trigger values, implying that, in the event of any overshooting, food business operators are to take corrective action and to notify the competent authority. The criteria should not be maximum figures beyond which raw milk cannot be placed on the market. This implies that, in certain circumstances, raw milk not fully meeting the criteria can safely be used for human consumption, if appropriate measures are taken. As regards raw milk and raw cream intended for direct human consumption, it is appropriate to enable each Member State to maintain or establish appropriate health measures to ensure the achievement of the objectives of this Regulation on its territory.

(24) It is appropriate for the criterion for raw milk used to manufacture dairy products to be three times as high as the criterion for raw milk collected from the farm. The criterion for milk used to manufacture processed dairy products is an absolute value, whereas for raw milk collected from the farm it is an average. Compliance with the temperature requirements laid down in this Regulation will not halt all bacterial growth during transport and storage.

(25) The present recasting means that the existing hygiene rules can be repealed. Directive 2004/41/EC of the European Parliament and of the Council of 21 April 2004 repealing certain directives on food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption[(15)] achieves this.

(26) In addition, the rules of this Regulation on eggs replace those of Council Decision 94/371/EC of 20 June 1994 laying down specific public health conditions for the putting on the market of certain types of eggs[(16)], which the repeal of Annex II to Council Directive 92/118/EEC[(17)] renders void.

(27) Scientific advice should underpin Community legislation on food hygiene. To this end, the European Food Safety Authority should be consulted whenever necessary.

(28) To take account of technical and scientific progress, close and effective cooperation should be ensured between the Commission and the Member States within the Standing Committee on the Food Chain and Animal Health.

(29) The requirements of this Regulation should not apply until all parts of the new legislation on food hygiene have entered into force. It is also appropriate to provide for at least 18 months to elapse between entry into force and the application of the new rules, to allow the industries affected time to adapt.

(30) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[(18)],

HAVE ADOPTED THIS REGULATION:

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).

CHAPTER I

GENERAL PROVISIONS

Article 1

Scope

1 This Regulation lays down specific rules on the hygiene of food of animal origin for food business operators. These rules supplement those laid down by Regulation (EC) No 852/2004. They shall apply to unprocessed and processed products of animal origin.

2 Unless expressly indicated to the contrary, this Regulation shall not apply to food containing both products of plant origin and processed products of animal origin. However, processed products of animal origin used to prepare such food shall be obtained and handled in accordance with the requirements of this Regulation.

3 This Regulation shall not apply in relation to:

a primary production for private domestic use;

b the domestic preparation, handling or storage of food for private domestic consumption;

c the direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer;

d 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 as fresh meat;

e hunters who supply small quantities of wild game or wild game meat directly to the final consumer or to local retail establishments directly supplying the final consumer.

4 **[**[F1]The appropriate authority**]** shall establish, according to [F2]... law, rules governing the activities and persons referred to in paragraph 3(c), (d) and (e). Such [F2]... rules shall ensure the achievement of the objectives of this Regulation.

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