Regulation (EC) No 852/2004 of the european parliament and of the council of 29 April 2004 on the hygiene of foodstuffs

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on the hygiene of foodstuffs

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 95 and 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) The pursuit of a high level of protection of human life and health is one of the fundamental objectives of food law, as laid down in Regulation (EC) No 178/2002[(4)]. That Regulation also lays down other common principles and definitions for national and Community food law, including the aim of achieving free movement of food within the Community.

(2) Council Directive 93/43/EEC of 14 June 1993 on the hygiene of foodstuffs[(5)] laid down the general rules of hygiene for foodstuffs and the procedures for verification of compliance with these rules.

(3) Experience has shown that these rules and procedures constitute a sound basis for ensuring food safety. 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 and procedures 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 all food, including products of animal origin listed in Annex I to the Treaty.

(6) In addition to this common basis, specific hygiene rules are necessary for certain foodstuffs. 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[(6)] lays down these rules.

(7) The principal objective of the new general and specific hygiene rules is to ensure a high level of consumer protection with regard to food safety.

(8) An integrated approach is necessary to ensure food safety from the place of primary production up to and including placing on the market or export. Every food business operator along the food chain should ensure that food safety is not compromised.

(9) 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, they should apply only to undertakings, the concept of which implies a certain continuity of activities and a certain degree of organisation.

(10) Food hazards present at the level of primary production should be identified and adequately controlled to ensure the achievement of the objectives of this Regulation. However, in the case of the direct supply of small quantities of primary products, 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.

(11) The application of hazard analysis and critical control point (HACCP) principles to primary production is not yet generally feasible. However, guides to good practice should encourage the use of appropriate hygiene practices at farm level. Where necessary, specific hygiene rules for primary production should supplement these guides. It is appropriate for the hygiene requirements applicable to primary production and associated operations to differ from those for other operations.

(12) Food safety is a result of several factors: legislation should lay down minimum hygiene requirements; official controls should be in place to check food business operators' compliance and food business operators should establish and operate food safety programmes and procedures based on the HACCP principles.

(13) Successful implementation of the procedures based on the HACCP principles will require the full cooperation and commitment of food business employees. To this end, employees should undergo training. The HACCP system is an instrument to help food business operators attain a higher standard of food safety. The HACCP system should not be regarded as a method of self-regulation and should not replace official controls.

(14) While the requirement of establishing procedures based on the HACCP principles should not initially apply to primary production, the feasibility of its extension will be one element of the review that the Commission will carry out following implementation of this Regulation. It is, however, appropriate for Member States to encourage operators at the level of primary production to apply such principles as far as possible.

(15) The HACCP requirements should take account of the principles contained in the *Codex Alimentarius*. They should provide sufficient flexibility to be applicable in all

situations, including in small businesses. In particular, it is necessary to recognise that, in certain food businesses, it is not possible to identify critical control points and that, in some cases, good hygienic practices can replace the monitoring of critical control points. Similarly, the requirement of establishing 'critical limits' does not imply that it is necessary to fix a numerical limit in every case. In addition, the requirement of retaining documents needs to be flexible in order to avoid undue burdens for very small businesses.

(16) Flexibility is also 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 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.

(17) The setting of objectives such as pathogen reduction targets or performance standards may guide the implementation of hygiene rules. It is therefore necessary to provide procedures for that purpose. Such objectives would supplement existing food law, such as Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food[7], which provides for the establishment of maximum tolerances for specific contaminants, and Regulation (EC) No 178/2002, which prohibits the placing on the market of unsafe food and provides a uniform basis for the use of the precautionary principle.

(18) 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. This Regulation takes account of international obligations laid down in the WTO Sanitary and Phytosanitary Agreement and the international food safety standards contained in the *Codex Alimentarius*.

(19) The registration of establishments and the cooperation of food business operators are necessary to allow the competent authorities to perform official controls efficiently.

(20) The traceability of food and food ingredients along the food chain is an essential element in ensuring food safety. Regulation (EC) No 178/2002 contains rules to ensure the traceability of food and food ingredients and provides a procedure for the adoption of implementing rules to apply these principles in respect of specific sectors.

(21) Food imported into the Community is to comply with the general requirements laid down in Regulation (EC) No 178/2002 or satisfy rules that are equivalent to Community rules. The present Regulation defines certain specific hygiene requirements for food imported into the Community.

Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 852/2004 of the european parliament and of the council. (See end of Document for details)*

(22) Food exported to third countries from the Community is to comply with the general requirements laid down in Regulation (EC) No 178/2002. The present Regulation defines certain specific hygiene requirements for food exported from the Community.

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

(24) Since this Regulation replaces Directive 93/43/EEC, the latter should be repealed.

(25) 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 affected industries time to adapt.

(26) 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[8],

HAVE ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Scope

1 This Regulation lays down general rules for food business operators on the hygiene of foodstuffs, taking particular account of the following principles:

a primary responsibility for food safety rests with the food business operator;

b it is necessary to ensure food safety throughout the food chain, starting with primary production;

c it is important, for food that cannot be stored safely at ambient temperatures, particularly frozen food, to maintain the cold chain;

d general implementation of procedures based on the HACCP principles, together with the application of good hygiene practice, should reinforce food business operators' responsibility;

e guides to good practice are a valuable instrument to aid food business operators at all levels of the food chain with compliance with food hygiene rules and with the application of the HACCP principles;

f it is necessary to establish microbiological criteria and temperature control requirements based on a scientific risk assessment;

g it is necessary to ensure that imported foods are of at least the same hygiene standard as food produced in **[**F1Great Britain**]**, or are of an equivalent standard.

This Regulation shall apply to all stages of production, processing and distribution of food and to exports, and without prejudice to more specific requirements relating to food hygiene.

2 This Regulation shall not apply 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 collection centres and tanneries which fall within the definition of food business only because they handle raw material for the production of gelatine or collagen.

F2 3 . . . . . .

Textual Amendments

F1 Words in Art. 1(1)(g) substituted (31.12.2020) by The General Food Hygiene (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/642), regs. 1, **3(a)** (as substituted by S.I. 2020/1504, regs. 1(2), **11(2)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F2 Art. 1(3) omitted (31.12.2020) by virtue of The General Food Hygiene (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/642), regs. 1, **3(b)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 2

Definitions

1 For the purposes of this Regulation:

a ‘food hygiene’, hereinafter called ‘hygiene’, means the measures and conditions necessary to control hazards and to ensure fitness for human consumption of a foodstuff taking into account its intended use;

b ‘primary products’ means products of primary production including products of the soil, of stock farming, of hunting and fishing;

c ‘establishment’ means any unit of a food business;

d ‘competent authority’ means the central authority F3... competent to ensure compliance with the requirements of this Regulation or any other authority to which that central authority has delegated that competence; it shall also include, where appropriate, the corresponding authority of a third country;

e ‘equivalent’ means, in respect of different systems, capable of meeting the same objectives;

f ‘contamination’ means the presence or introduction of a hazard;

[F4 g “potable water” means—

i as regards England, water meeting the requirements laid down in the Private Water Supplies (England) Regulations 2016;

ii as regards Wales, water meeting the requirements laid down in the Private Water Supplies (Wales) Regulations 2017;

iii as regards Scotland, water meeting the requirements laid down in the Water Intended for Human Consumption (Private Supplies) (Scotland) Regulations 2017;**]**

h ‘clean seawater’ means natural, artificial or purified seawater or brackish water that does not contain micro-organisms, harmful substances or toxic marine plankton in quantities capable of directly or indirectly affecting the health quality of food;

i ‘clean water’ means clean seawater and fresh water of a similar quality;

j ‘wrapping’ means the placing of a foodstuff in a wrapper or container in direct contact with the foodstuff concerned, and the wrapper or container itself;