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(Acts whose publication is obligatory)

**REGULATION (EC) No 852/2004 OF THE EUROPEAN PARLIAMENT
AND OF THE COUNCIL
of 29 April 2004**

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 Commission¹,

Having regard to the Opinion of the Economic and Social Committee²,

Having consulted the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty³,

¹ OJ C 365 E, 19.12.2000, p. 43.

² OJ C 155, 29.5.2001, p. 39.

³ Opinion of the European Parliament of 15 May 2002 (OJ C 180 E, 31.7.2003, p. 267), Council Common Position of 27 October 2003 (OJ C 48 E, 24.2.2004, p. 1), Position of the European Parliament of 30 March 2004 (not yet published in the Official Journal) and Council Decision of 16 April 2004.

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 178/2002¹. 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 foodstuffs² 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.

¹ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1). Regulation as amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p. 4).

² OJ L 175, 19.7.1993, p. 1. Directive as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

- (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 /2004 of the European Parliament and of the Council of laying down specific hygiene rules for food of animal origin ¹ 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.

¹ See page of this Official Journal.

- (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 ¹, 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.

¹ OJ L 37, 13.2.1993, p. 1. Regulation as amended by Regulation (EC) No 1882/2003.

- (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.
- (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 ¹,

HAVE ADOPTED THIS REGULATION:

¹ OJ L 184, 17.7.1999, p. 23.

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 the Community, 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.

3. Member States shall establish, under national law, rules governing the activities referred to in paragraph 2(c). Such national rules shall ensure the achievement of the objectives of this Regulation.

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 of a Member State 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;
- (g) "potable water" means water meeting the minimum requirements laid down in Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption ¹;
- (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;
- (k) "packaging" means the placing of one or more wrapped foodstuffs in a second container, and the latter container itself;
- (l) "hermetically sealed container" means a container that is designed and intended to be secure against the entry of hazards;

¹ OJ L 330, 5.12.1998, p. 32. Directive as modified by Regulation (EC) No 1882/2003.

- (m) "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;
- (n) "unprocessed products" means foodstuffs that have not undergone processing, and includes products that have been divided, parted, severed, sliced, boned, minced, skinned, ground, cut, cleaned, trimmed, husked, milled, chilled, frozen, deep-frozen or thawed;
- (o) "processed products" means foodstuffs resulting from the processing of unprocessed products. These products may contain ingredients that are necessary for their manufacture or to give them specific characteristics.

2. The definitions laid down in Regulation (EC) No 178/2002 shall also apply.

3. In the Annexes to this Regulation the terms "where necessary", "where appropriate", "adequate" and "sufficient" shall mean respectively where necessary, where appropriate, adequate or sufficient to achieve the objectives of this Regulation.

CHAPTER II

FOOD BUSINESS OPERATORS' OBLIGATIONS

Article 3

General obligation

Food business operators shall ensure that all stages of production, processing and distribution of food under their control satisfy the relevant hygiene requirements laid down in this Regulation.

Article 4

General and specific hygiene requirements

1. Food business operators carrying out primary production and those associated operations listed in Annex I shall comply with the general hygiene provisions laid down in Part A of Annex I and any specific requirements provided for in Regulation (EC) No/2004 *.
2. Food business operators carrying out any stage of production, processing and distribution of food after those stages to which paragraph 1 applies shall comply with the general hygiene requirements laid down in Annex II and any specific requirements provided for in Regulation (EC) No/2004 *.

* Note to Official Journal: insert No of Regulation laying down specific hygiene rules for food of animal origin.

3. Food business operators shall, as appropriate, adopt the following specific hygiene measures:

- (a) compliance with microbiological criteria for foodstuffs;
- (b) procedures necessary to meet targets set to achieve the objectives of this Regulation;
- (c) compliance with temperature control requirements for foodstuffs;
- (d) maintenance of the cold chain;
- (e) sampling and analysis.

4. The criteria, requirements and targets referred to in paragraph 3 shall be adopted in accordance with the procedure referred to in Article 14(2).

Associated sampling and analysis methods shall be laid down in accordance with the same procedure.

5. When this Regulation, Regulation (EC) No/2004 * and their implementing measures do not specify sampling or analysis methods, food business operators may use appropriate methods laid down in other Community or national legislation or, in the absence of such methods, methods that offer equivalent results to those obtained using the reference method, if they are scientifically validated in accordance with internationally recognised rules or protocols.
6. Food business operators may use the guides provided for in Articles 7, 8 and 9 as an aid to compliance with their obligations under this Regulation.

Article 5

Hazard analysis and critical control points

1. Food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.
2. The HACCP principles referred to in paragraph 1 consist of the following:
 - (a) identifying any hazards that must be prevented, eliminated or reduced to acceptable levels;
 - (b) identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels;

* Note to Official Journal: insert number of Regulation laying down specific hygiene rules for food of animal origin.

- (c) establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards;
- (d) establishing and implementing effective monitoring procedures at critical control points;
- (e) establishing corrective actions when monitoring indicates that a critical control point is not under control;
- (f) establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively; and
- (g) establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f).

When any modification is made in the product, process, or any step, food business operators shall review the procedure and make the necessary changes to it.

3. Paragraph 1 shall apply only to food business operators carrying out any stage of production, processing and distribution of food after primary production and those associated operations listed in Annex I.

4. Food business operators shall:

- (a) provide the competent authority with evidence of their compliance with paragraph 1 in the manner that the competent authority requires, taking account of the nature and size of the food business;
- (b) ensure that any documents describing the procedures developed in accordance with this Article are up-to-date at all times;
- (c) retain any other documents and records for an appropriate period.

5. Detailed arrangements for the implementation of this Article may be laid down in accordance with the procedure referred to in Article 14(2). Such arrangements may facilitate the implementation of this Article by certain food business operators, in particular by providing for the use of procedures set out in guides for the application of HACCP principles, in order to comply with paragraph 1. Such arrangements may also specify the period during which food business operators shall retain documents and records in accordance with paragraph 4(c).

Article 6

Official controls, registration and approval

1. Food business operators shall cooperate with the competent authorities in accordance with other applicable Community legislation or, if it does not exist, with national law.

2. In particular, every food business operator shall notify the appropriate competent authority, in the manner that the latter requires, of each establishment under its control that carries out any of the stages of production, processing and distribution of food, with a view to the registration of each such establishment.

Food business operators shall also ensure that the competent authority always has up-to-date information on establishments, including by notifying any significant change in activities and any closure of an existing establishment.

3. However, food business operators shall ensure that establishments are approved by the competent authority, following at least one on-site visit, when approval is required:

- (a) under the national law of the Member State in which the establishment is located;
- (b) under Regulation (EC) No/2004^{*}; or
- (c) by a decision adopted in accordance with the procedure referred to in Article 14(2).

Any Member State requiring the approval of certain establishments located on its territory under national law, as provided for in subparagraph (a), shall inform the Commission and other Member States of the relevant national rules.

* Note to Official Journal: insert number of Regulation laying down specific hygiene rules for food of animal origin.

CHAPTER III

GUIDES TO GOOD PRACTICE

Article 7

Development, dissemination and use of guides

Member States shall encourage the development of national guides to good practice for hygiene and for the application of HACCP principles in accordance with Article 8. Community guides shall be developed in accordance with Article 9.

The dissemination and use of both national and Community guides shall be encouraged. Nevertheless, food business operators may use these guides on a voluntary basis.

Article 8

National guides

1. When national guides to good practice are developed, they shall be developed and disseminated by food business sectors:

- (a) in consultation with representatives of parties whose interests may be substantially affected, such as competent authorities and consumer groups;

- (b) having regard to relevant codes of practice of the Codex Alimentarius; and
 - (c) when they concern primary production and those associated operations listed in Annex I, having regard to the recommendations set out in Part B of Annex I.
2. National guides may be developed under the aegis of a national standards institute referred to in Annex II to Directive 98/34/EC¹.
3. Member States shall assess national guides in order to ensure that:
- (a) they have been developed in accordance with paragraph 1;
 - (b) their contents are practicable for the sectors to which they refer; and
 - (c) they are suitable as guides to compliance with Articles 3, 4 and 5 in the sectors and for the foodstuffs covered.
4. Member States shall forward to the Commission national guides complying with the requirements of paragraph 3. The Commission shall set up and run a registration system for such guides and make it available to Member States.
5. Guides to good practice drawn up under Directive 93/43/EEC shall continue to apply after the entry into force of this Regulation, provided that they are compatible with its objectives.

¹ Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations (OJ L 204, 21.7.1998, p. 37). Directive as amended by Directive 98/48/EC (OJ L 217, 5.8.1998, p. 18).

Article 9

Community guides

1. Before Community guides to good practice for hygiene or for the application of the HACCP principles are developed, the Commission shall consult the Committee referred to in Article 14. The objective of this consultation shall be to consider the case for such guides, their scope and subject matter.

2. When Community guides are prepared, the Commission shall ensure that they are developed and disseminated:
 - (a) by or in consultation with appropriate representatives of European food business sectors, including SMEs, and other interested parties, such as consumer groups;
 - (b) in collaboration with parties whose interests may be substantially affected, including competent authorities;
 - (c) having regard to relevant codes of practice of the Codex Alimentarius; and
 - (d) when they concern primary production and those associated operations listed in Annex I, having regard to the recommendations set out in Part B of Annex I.

3. The Committee referred to in Article 14 shall assess draft Community guides in order to ensure that:

- (a) they have been developed in accordance with paragraph 2;
- (b) their contents are practicable for the sectors to which they refer throughout the Community;
and
- (c) they are suitable as guides to compliance with Articles 3, 4 and 5 in the sectors and for the foodstuffs covered.

4. The Commission shall invite the Committee referred to in Article 14 periodically to review any Community guides prepared in accordance with this Article, in cooperation with the bodies mentioned in paragraph 2.

The aim of this review shall be to ensure that the guides remain practicable and to take account of technological and scientific developments.

5. The titles and references of Community guides prepared in accordance with this Article shall be published in the C series of the Official Journal of the European Union.

CHAPTER IV

IMPORTS AND EXPORTS

Article 10

Imports

As regards the hygiene of imported food, the relevant requirements of food law referred to in Article 11 of Regulation (EC) No 178/2002 shall include the requirements laid down in Articles 3 to 6 of this Regulation.

Article 11

Exports

As regards the hygiene of exported or re-exported food, the relevant requirements of food law referred to in Article 12 of Regulation (EC) No 178/2002 shall include the requirements laid down in Articles 3 to 6 of this Regulation.

CHAPTER V

FINAL PROVISIONS

Article 12

Implementing measures and transitional arrangements

Implementing measures and transitional arrangements may be laid down in accordance with the procedure referred to in Article 14(2).

Article 13

Amendment and adaptation of Annexes I and II

1. Annexes I and II may be adapted or updated in accordance with the procedure referred to in Article 14(2), taking into account:
 - (a) the need to revise the recommendations set out in Annex I, Part B, paragraph 2;
 - (b) the experience gained from the implementation of HACCP-based systems pursuant to Article 5;
 - (c) technological developments and their practical consequences and consumer expectations with regard to food composition;

(d) scientific advice, particularly new risk assessments;

(e) microbiological and temperature criteria for foodstuffs.

2. Derogations from Annexes I and II may be granted, in particular in order to facilitate the implementation of Article 5 for small businesses, in accordance with the procedure referred to in Article 14(2), taking into account the relevant risk factors, provided that such derogations do not affect the achievement of the objectives of this Regulation.

3. Member States may, without compromising achievement of the objectives of this Regulation, adopt, in accordance with paragraphs 4 to 7 of this Article, national measures adapting the requirements laid down in Annex II.

4.(a) The national measures referred to in paragraph 3 shall have the aim of:

(i) enabling the continued use of traditional methods, at any of the stages of production, processing or distribution of food; or

(ii) accommodating the needs of food businesses situated in regions that are subject to special geographical constraints.

(b) In other cases, they shall apply only to the construction, layout and equipment of establishments.

5. Any Member State wishing to adopt national measures as referred to in paragraph 3 shall notify the Commission and other Member States. The notification shall:

- (a) provide a detailed description of the requirements that that Member State considers need to be adapted and the nature of the adaptation sought;
- (b) describe the foodstuffs and establishments concerned;
- (c) explain the reasons for the adaptation, including, where relevant, by providing a summary of the hazard analysis carried out and any measures to be taken to ensure that the adaptation will not compromise the objectives of this Regulation; and
- (d) give any other relevant information.

6. The other Member States shall have three months from the receipt of a notification referred to in paragraph 5 to send written comments to the Commission. In the case of the adaptations arising from paragraph 4(b), this period shall, at the request of any Member State, be extended to four months. The Commission may, and when it receives written comments from one or more Member States shall, consult Member States within the committee referred to in Article 14(1). The Commission may decide, in accordance with the procedure referred to in Article 14(2), whether the envisaged measures may be implemented, subject, if necessary, to appropriate amendments. Where appropriate, the Commission may propose general measures in accordance with paragraph 1 or 2.

7. A Member State may adopt national measures adapting the requirements of Annex II only:
- (a) in compliance with a decision adopted in accordance with paragraph 6; or
 - (b) if, one month after the expiry of the period referred to in paragraph 6, the Commission has not informed Member States that it has received written comments or that it intends to propose the adoption of a decision in accordance with paragraph 6.

Article 14

Committee procedure

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health.
2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

Article 15

Consultation of the European Food Safety Authority

The Commission shall consult the European Food Safety Authority on any matter falling within the scope of this Regulation that could have a significant impact on public health and, in particular, before proposing criteria, requirements or targets in accordance with Article 4(4).

Article 16

Report to the European Parliament and the Council

1. The Commission shall, not later than^{*}, submit a report to the European Parliament and the Council.
2. The report shall, in particular, review the experience gained from the application of this Regulation and consider whether it would be desirable and practicable to provide for the extension of the requirements of Article 5 to food business operators carrying out primary production and those associated operations listed in Annex I.
3. The Commission shall, if appropriate, accompany the report with relevant proposals.

^{*} Five years after the entry into force of this Regulation.

Article 17

Repeal

1. Directive 93/43/EEC shall be repealed with effect from the date of application of this Regulation.
2. References to the repealed Directive shall be construed as being made to this Regulation.
3. However, decisions adopted pursuant to Articles 3(3) and 10 of Directive 93/43/EEC shall remain in force pending their replacement by decisions adopted in accordance with this Regulation or Regulation (EC) No 178/2002. Pending the setting of the criteria or requirements referred to in Article 4(3), points (a) to (e) of this Regulation, Member States may maintain any national rules establishing such criteria or requirements that they had adopted in accordance with Directive 93/43/EEC.
4. Pending the application of new Community legislation laying down rules for official controls on food, Member States shall take all appropriate measures to ensure the fulfilment of the obligations laid down in or under this Regulation.

Article 18

Entry into force

This Regulation shall enter into force twenty days after the date of its publication in the Official Journal of the European Union.

It shall apply 18 months after the date on which all of the following acts have entered into force:

- (a) Regulation (EC) No .../2004 *;
- (b) Regulation (EC) No .../2004 of the European Parliament and of the Council of laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption ¹; and
- (c) Directive 2004/41/EC of the European Parliament and of the Council of 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 ².

However, it shall apply no earlier than 1 January 2006.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 29 April 2004.

For the European Parliament
The President
P. COX

For the Council
The President
M. McDOWELL

* Note to Official Journal: insert number of Regulation laying down specific hygiene rules for food of animal origin.

¹ See p. of this Official Journal.

² See p. of this Official Journal.

PRIMARY PRODUCTION

PART A: GENERAL HYGIENE PROVISIONS FOR PRIMARY PRODUCTION AND ASSOCIATED OPERATIONS

I. SCOPE

1. This Annex applies to primary production and the following associated operations:
 - (a) the transport, storage and handling of primary products at the place of production, provided that this does not substantially alter their nature;
 - (b) the transport of live animals, where this is necessary to achieve the objectives of this Regulation; and
 - (c) in the case of products of plant origin, fishery products and wild game, transport operations to deliver primary products, the nature of which has not been substantially altered, from the place of production to an establishment.

II. HYGIENE PROVISIONS

2. As far as possible, food business operators are to ensure that primary products are protected against contamination, having regard to any processing that primary products will subsequently undergo.

3. Notwithstanding the general duty laid down in paragraph 2, food business operators are to comply with appropriate Community and national legislative provisions relating to the control of hazards in primary production and associated operations, including:
 - (a) measures to control contamination arising from the air, soil, water, feed, fertilisers, veterinary medicinal products, plant protection products and biocides and the storage, handling and disposal of waste; and
 - (b) measures relating to animal health and welfare and plant health that have implications for human health, including programmes for the monitoring and control of zoonoses and zoonotic agents.

4. Food business operators rearing, harvesting or hunting animals or producing primary products of animal origin are to take adequate measures, as appropriate:
 - (a) to keep any facilities used in connection with primary production and associated operations, including facilities used to store and handle feed, clean and, where necessary after cleaning, to disinfect them in an appropriate manner;
 - (b) to keep clean and, where necessary after cleaning, to disinfect, in an appropriate manner, equipment, containers, crates, vehicles and vessels;

- (c) as far as possible to ensure the cleanliness of animals going to slaughter and, where necessary, production animals;
- (d) to use potable water, or clean water, whenever necessary to prevent contamination;
- (e) to ensure that staff handling foodstuffs are in good health and undergo training on health risks;
- (f) as far as possible to prevent animals and pests from causing contamination;
- (g) to store and handle waste and hazardous substances so as to prevent contamination;
- (h) to prevent the introduction and spread of contagious diseases transmissible to humans through food, including by taking precautionary measures when introducing new animals and reporting suspected outbreaks of such diseases to the competent authority;
- (i) to take account of the results of any relevant analyses carried out on samples taken from animals or other samples that have importance to human health; and
- (j) to use feed additives and veterinary medicinal products correctly, as required by the relevant legislation.

5. Food business operators producing or harvesting plant products are to take adequate measures, as appropriate:
 - (a) to keep clean and, where necessary after cleaning, to disinfect, in an appropriate manner, facilities, equipment, containers, crates, vehicles and vessels;
 - (b) to ensure, where necessary, hygienic production, transport and storage conditions for, and the cleanliness of, plant products;
 - (c) to use potable water, or clean water, whenever necessary to prevent contamination;
 - (d) to ensure that staff handling foodstuffs are in good health and undergo training on health risks;
 - (e) as far as possible to prevent animals and pests from causing contamination;
 - (f) to store and handle wastes and hazardous substances so as to prevent contamination;
 - (g) to take account of the results of any relevant analyses carried out on samples taken from plants or other samples that have importance to human health; and
 - (h) to use plant protection products and biocides correctly, as required by the relevant legislation.

6. Food business operators are to take appropriate remedial action when informed of problems identified during official controls.

III. RECORD-KEEPING

7. Food business operators are to keep and retain records relating to measures put in place to control hazards in an appropriate manner and for an appropriate period, commensurate with the nature and size of the food business. Food business operators are to make relevant information contained in these records available to the competent authority and receiving food business operators on request.
8. Food business operators rearing animals or producing primary products of animal origin are, in particular, to keep records on:
 - (a) the nature and origin of feed fed to the animals;
 - (b) veterinary medicinal products or other treatments administered to the animals, dates of administration and withdrawal periods;
 - (c) the occurrence of diseases that may affect the safety of products of animal origin;
 - (d) the results of any analyses carried out on samples taken from animals or other samples taken for diagnostic purposes, that have importance for human health; and
 - (e) any relevant reports on checks carried out on animals or products of animal origin.

9. Food business operators producing or harvesting plant products are, in particular, to keep records on:
 - (a) any use of plant protection products and biocides;
 - (b) any occurrence of pests or diseases that may affect the safety of products of plant origin;
and
 - (c) the results of any relevant analyses carried out on samples taken from plants or other samples that have importance to human health.

10. The food business operators may be assisted by other persons, such as veterinarians, agronomists and farm technicians, with the keeping of records.

PART B: RECOMMENDATIONS FOR GUIDES TO GOOD HYGIENE PRACTICE

1. National and Community guides referred to in Articles 7 to 9 of this Regulation should contain guidance on good hygiene practice for the control of hazards in primary production and associated operations.
2. Guides to good hygiene practice should include appropriate information on hazards that may arise in primary production and associated operations and actions to control hazards, including relevant measures set out in Community and national legislation or national and Community programmes. Examples of such hazards and measures may include:
 - (a) the control of contamination such as mycotoxins, heavy metals and radioactive material;
 - (b) the use of water, organic waste and fertilisers;
 - (c) the correct and appropriate use of plant protection products and biocides and their traceability;
 - (d) the correct and appropriate use of veterinary medicinal products and feed additives and their traceability;
 - (e) the preparation, storage, use and traceability of feed;

- (f) the proper disposal of dead animals, waste and litter;
 - (g) protective measures to prevent the introduction of contagious diseases transmissible to humans through food, and any obligation to notify the competent authority;
 - (h) procedures, practices and methods to ensure that food is produced, handled, packed, stored and transported under appropriate hygienic conditions, including effective cleaning and pest-control;
 - (i) measures relating to the cleanliness of slaughter and production animals;
 - (j) measures relating to record-keeping.
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GENERAL HYGIENE REQUIREMENTS FOR ALL FOOD BUSINESS OPERATORS
(EXCEPT WHEN ANNEX I APPLIES)

INTRODUCTION

Chapters V to XII apply to all stages of production, processing and distribution of food and the remaining Chapters apply as follows:

- Chapter I applies to all food premises, except premises to which Chapter III applies;
- Chapter II applies to all rooms where food is prepared, treated or processed, except dining areas and premises to which Chapter III applies;
- Chapter III applies to those premises listed in the heading to the Chapter;
- Chapter IV applies to all transportation.

CHAPTER I

GENERAL REQUIREMENTS FOR FOOD PREMISES
(OTHER THAN THOSE SPECIFIED IN CHAPTER III)

1. Food premises are to be kept clean and maintained in good repair and condition.

2. The layout, design, construction, siting and size of food premises are to:
 - (a) permit adequate maintenance, cleaning and/or disinfection, avoid or minimise air-borne contamination, and provide adequate working space to allow for the hygienic performance of all operations;
 - (b) be such as to protect against the accumulation of dirt, contact with toxic materials, the shedding of particles into food and the formation of condensation or undesirable mould on surfaces;
 - (c) permit good food hygiene practices, including protection against contamination and, in particular, pest control; and
 - (d) where necessary, provide suitable temperature-controlled handling and storage conditions of sufficient capacity for maintaining foodstuffs at appropriate temperatures and designed to allow those temperatures to be monitored and, where necessary, recorded.
3. An adequate number of flush lavatories are to be available and connected to an effective drainage system. Lavatories are not to open directly into rooms in which food is handled.
4. An adequate number of washbasins is to be available, suitably located and designated for cleaning hands. Washbasins for cleaning hands are to be provided with hot and cold running water, materials for cleaning hands and for hygienic drying. Where necessary, the facilities for washing food are to be separate from the hand-washing facility.

5. There is to be suitable and sufficient means of natural or mechanical ventilation. Mechanical airflow from a contaminated area to a clean area is to be avoided. Ventilation systems are to be so constructed as to enable filters and other parts requiring cleaning or replacement to be readily accessible.
6. Sanitary conveniences are to have adequate natural or mechanical ventilation.
7. Food premises are to have adequate natural and/or artificial lighting.
8. Drainage facilities are to be adequate for the purpose intended. They are to be designed and constructed to avoid the risk of contamination. Where drainage channels are fully or partially open, they are to be so designed as to ensure that waste does not flow from a contaminated area towards or into a clean area, in particular an area where foods likely to present a high risk to the final consumer are handled.
9. Where necessary, adequate changing facilities for personnel are to be provided.
10. Cleaning agents and disinfectants are not to be stored in areas where food is handled.

CHAPTER II

SPECIFIC REQUIREMENTS IN ROOMS WHERE FOODSTUFFS ARE PREPARED, TREATED OR PROCESSED (EXCLUDING DINING AREAS AND THOSE PREMISES SPECIFIED IN CHAPTER III)

1. In rooms where food is prepared, treated or processed (excluding dining areas and those premises specified in Chapter III, but including rooms contained in means of transport) the design and layout are to permit good food hygiene practices, including protection against contamination between and during operations. In particular:
 - (a) floor surfaces are to be maintained in a sound condition and be easy to clean and, where necessary, to disinfect. This will require the use of impervious, non-absorbent, washable and non-toxic materials unless food business operators can satisfy the competent authority that other materials used are appropriate. Where appropriate, floors are to allow adequate surface drainage;
 - (b) wall surfaces are to be maintained in a sound condition and be easy to clean and, where necessary, to disinfect. This will require the use of impervious, non-absorbent, washable and non-toxic materials and require a smooth surface up to a height appropriate for the operations unless food business operators can satisfy the competent authority that other materials used are appropriate;
 - (c) ceilings (or, where there are no ceilings, the interior surface of the roof) and overhead fixtures are to be constructed and finished so as to prevent the accumulation of dirt and to reduce condensation, the growth of undesirable mould and the shedding of particles;

- (d) windows and other openings are to be constructed to prevent the accumulation of dirt. Those which can be opened to the outside environment are, where necessary, to be fitted with insect-proof screens which can be easily removed for cleaning. Where open windows would result in contamination, windows are to remain closed and fixed during production;
 - (e) doors are to be easy to clean and, where necessary, to disinfect. This will require the use of smooth and non-absorbent surfaces unless food business operators can satisfy the competent authority that other materials used are appropriate; and
 - (f) surfaces (including surfaces of equipment) in areas where foods are handled and in particular those in contact with food are to be maintained in a sound condition and be easy to clean and, where necessary, to disinfect. This will require the use of smooth, washable corrosion-resistant and non-toxic materials, unless food business operators can satisfy the competent authority that other materials used are appropriate.
2. Adequate facilities are to be provided, where necessary, for the cleaning, disinfecting and storage of working utensils and equipment. These facilities are to be constructed of corrosion-resistant materials, be easy to clean and have an adequate supply of hot and cold water.
 3. Adequate provision is to be made, where necessary, for washing food. Every sink or other such facility provided for the washing of food is to have an adequate supply of hot and/or cold potable water consistent with the requirements of Chapter VII and be kept clean and, where necessary, disinfected.

CHAPTER III

REQUIREMENTS FOR MOVABLE AND/OR TEMPORARY PREMISES (SUCH AS MARQUEES, MARKET STALLS, MOBILE SALES VEHICLES), PREMISES USED PRIMARILY AS A PRIVATE DWELLING HOUSE BUT WHERE FOODS ARE REGULARLY PREPARED FOR PLACING ON THE MARKET, AND VENDING MACHINES

1. Premises and vending machines are, so far as is reasonably practicable, to be so sited, designed, constructed and kept clean and maintained in good repair and condition as to avoid the risk of contamination, in particular by animals and pests.
2. In particular, where necessary:
 - (a) appropriate facilities are to be available to maintain adequate personal hygiene (including facilities for the hygienic washing and drying of hands, hygienic sanitary arrangements and changing facilities);
 - (b) surfaces in contact with food are to be in a sound condition and be easy to clean and, where necessary, to disinfect. This will require the use of smooth, washable, corrosion-resistant and non-toxic materials, unless food business operators can satisfy the competent authority that other materials used are appropriate;
 - (c) adequate provision is to be made for the cleaning and, where necessary, disinfecting of working utensils and equipment;

- (d) where foodstuffs are cleaned as part of the food business' operations, adequate provision is to be made for this to be undertaken hygienically;
- (e) an adequate supply of hot and/or cold potable water is to be available;
- (f) adequate arrangements and/or facilities for the hygienic storage and disposal of hazardous and/or inedible substances and waste (whether liquid or solid) are to be available;
- (g) adequate facilities and/or arrangements for maintaining and monitoring suitable food temperature conditions are to be available;
- (h) foodstuffs are to be so placed as to avoid the risk of contamination so far as is reasonably practicable.

CHAPTER IV

TRANSPORT

1. Conveyances and/or containers used for transporting foodstuffs are to be kept clean and maintained in good repair and condition to protect foodstuffs from contamination and are, where necessary, to be designed and constructed to permit adequate cleaning and/or disinfection.

2. Receptacles in vehicles and/or containers are not to be used for transporting anything other than foodstuffs where this may result in contamination.
3. Where conveyances and/or containers are used for transporting anything in addition to foodstuffs or for transporting different foodstuffs at the same time, there is, where necessary, to be effective separation of products.
4. Bulk foodstuffs in liquid, granulate or powder form are to be transported in receptacles and/or containers/tankers reserved for the transport of foodstuffs. Such containers are to be marked in a clearly visible and indelible fashion, in one or more Community languages, to show that they are used for the transport of foodstuffs, or are to be marked "for foodstuffs only".
5. Where conveyances and/or containers have been used for transporting anything other than foodstuffs or for transporting different foodstuffs, there is to be effective cleaning between loads to avoid the risk of contamination.
6. Foodstuffs in conveyances and/or containers are to be so placed and protected as to minimise the risk of contamination.
7. Where necessary, conveyances and/or containers used for transporting foodstuffs are to be capable of maintaining foodstuffs at appropriate temperatures and allow those temperatures to be monitored.

CHAPTER V

EQUIPMENT REQUIREMENTS

1. All articles, fittings and equipment with which food comes into contact are to:
 - (a) be effectively cleaned and, where necessary, disinfected. Cleaning and disinfection are to take place at a frequency sufficient to avoid any risk of contamination;
 - (b) be so constructed, be of such materials and be kept in such good order, repair and condition as to minimise any risk of contamination;
 - (c) with the exception of non-returnable containers and packaging, be so constructed, be of such materials and be kept in such good order, repair and condition as to enable them to be kept clean and, where necessary, to be disinfected; and
 - (d) be installed in such a manner as to allow adequate cleaning of the equipment and the surrounding area.
2. Where necessary, equipment is to be fitted with any appropriate control device to guarantee fulfilment of this Regulation's objectives.
3. Where chemical additives have to be used to prevent corrosion of equipment and containers, they are to be used in accordance with good practice.

CHAPTER VI

FOOD WASTE

1. Food waste, non-edible by-products and other refuse are to be removed from rooms where food is present as quickly as possible, so as to avoid their accumulation.
2. Food waste, non-edible by-products and other refuse are to be deposited in closable containers, unless food business operators can demonstrate to the competent authority that other types of containers or evacuation systems used are appropriate. These containers are to be of an appropriate construction, kept in sound condition, be easy to clean and, where necessary, to disinfect.
3. Adequate provision is to be made for the storage and disposal of food waste, non-edible by-products and other refuse. Refuse stores are to be designed and managed in such a way as to enable them to be kept clean and, where necessary, free of animals and pests.
4. All waste is to be eliminated in a hygienic and environmentally friendly way in accordance with Community legislation applicable to that effect, and is not to constitute a direct or indirect source of contamination.

CHAPTER VII

WATER SUPPLY

1. (a) There is to be an adequate supply of potable water, which is to be used whenever necessary to ensure that foodstuffs are not contaminated;

- (b) Clean water may be used with whole fishery products. Clean seawater may be used with live bivalve molluscs, echinoderms, tunicates and marine gastropods; clean water may also be used for external washing. When such water is used, adequate facilities are to be available for its supply.

- 2. Where non-potable water is used, for example for fire control, steam production, refrigeration and other similar purposes, it is to circulate in a separate duly identified system. Non-potable water is not to connect with, or allow reflux into, potable water systems.

- 3. Recycled water used in processing or as an ingredient is not to present a risk of contamination. It is to be of the same standard as potable water, unless the competent authority is satisfied that the quality of the water cannot affect the wholesomeness of the foodstuff in its finished form.

- 4. Ice which comes into contact with food or which may contaminate food is to be made from potable water or, when used to chill whole fishery products, clean water. It is to be made, handled and stored under conditions that protect it from contamination.

- 5. Steam used directly in contact with food is not to contain any substance that presents a hazard to health or is likely to contaminate the food.

- 6. Where heat treatment is applied to foodstuffs in hermetically sealed containers it is to be ensured that water used to cool the containers after heat treatment is not a source of contamination for the foodstuff.

CHAPTER VIII

PERSONAL HYGIENE

1. Every person working in a food-handling area is to maintain a high degree of personal cleanliness and is to wear suitable, clean and, where necessary, protective clothing.
2. No person suffering from, or being a carrier of a disease likely to be transmitted through food or afflicted, for example, with infected wounds, skin infections, sores or diarrhoea is to be permitted to handle food or enter any food-handling area in any capacity if there is any likelihood of direct or indirect contamination. Any person so affected and employed in a food business and who is likely to come into contact with food is to report immediately the illness or symptoms, and if possible their causes, to the food business operator.

CHAPTER IX

PROVISIONS APPLICABLE TO FOODSTUFFS

1. A food business operator is not to accept raw materials or ingredients, other than live animals, or any other material used in processing products, if they are known to be, or might reasonably be expected to be, contaminated with parasites, pathogenic microorganisms or toxic, decomposed or foreign substances to such an extent that, even after the food business operator had hygienically applied normal sorting and/or preparatory or processing procedures, the final product would be unfit for human consumption.

2. Raw materials and all ingredients stored in a food business are to be kept in appropriate conditions designed to prevent harmful deterioration and protect them from contamination.
3. At all stages of production, processing and distribution, food is to be protected against any contamination likely to render the food unfit for human consumption, injurious to health or contaminated in such a way that it would be unreasonable to expect it to be consumed in that state.
4. Adequate procedures are to be in place to control pests. Adequate procedures are also to be in place to prevent domestic animals from having access to places where food is prepared, handled or stored (or, where the competent authority so permits in special cases, to prevent such access from resulting in contamination).
5. Raw materials, ingredients, intermediate products and finished products likely to support the reproduction of pathogenic micro-organisms or the formation of toxins are not to be kept at temperatures that might result in a risk to health. The cold chain is not to be interrupted. However, limited periods outside temperature control are permitted, to accommodate the practicalities of handling during preparation, transport, storage, display and service of food, provided that it does not result in a risk to health. Food businesses manufacturing, handling and wrapping processed foodstuffs are to have suitable rooms, large enough for the separate storage of raw materials from processed material and sufficient separate refrigerated storage.
6. Where foodstuffs are to be held or served at chilled temperatures they are to be cooled as quickly as possible following the heat-processing stage, or final preparation stage if no heat process is applied, to a temperature which does not result in a risk to health.

7. The thawing of foodstuffs is to be undertaken in such a way as to minimise the risk of growth of pathogenic microorganisms or the formation of toxins in the foods. During thawing, foods are to be subjected to temperatures that would not result in a risk to health. Where run-off liquid from the thawing process may present a risk to health it is to be adequately drained. Following thawing, food is to be handled in such a manner as to minimise the risk of growth of pathogenic microorganisms or the formation of toxins.
8. Hazardous and/or inedible substances, including animal feed, are to be adequately labelled and stored in separate and secure containers.

CHAPTER X

PROVISIONS APPLICABLE TO THE WRAPPING AND PACKAGING OF FOODSTUFFS

1. Material used for wrapping and packaging are not to be a source of contamination.
2. Wrapping materials are to be stored in such a manner that they are not exposed to a risk of contamination.
3. Wrapping and packaging operations are to be carried out so as to avoid contamination of the products. Where appropriate and in particular in the case of cans and glass jars, the integrity of the container's construction and its cleanliness is to be assured.
4. Wrapping and packaging material re-used for foodstuffs is to be easy to clean and, where necessary, to disinfect.

CHAPTER XI

HEAT TREATMENT

The following requirements apply only to food placed on the market in hermetically sealed containers:

1. any heat treatment process used to process an unprocessed product or to process further a processed product is:
 - (a) to raise every party of the product treated to a given temperature for a given period of time; and
 - (b) to prevent the product from becoming contaminated during the process;
2. to ensure that the process employed achieves the desired objectives, food business operators are to check regularly the main relevant parameters (particularly temperature, pressure, sealing and microbiology), including by the use of automatic devices;
3. the process used should conform to an internationally recognised standard (for example, pasteurisation, ultra high temperature or sterilisation).

CHAPTER XII

TRAINING

Food business operators are to ensure:

1. that food handlers are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity;
 2. that those responsible for the development and maintenance of the procedure referred to in Article 5(1) of this Regulation or for the operation of relevant guides have received adequate training in the application of the HACCP principles; and
 3. compliance with any requirements of national law concerning training programmes for persons working in certain food sectors.
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