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Subject: Proposed Regulation of the European Parliament and of the Council on the hygiene of foodstuffs

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The Annex to this document contains a consolidated text of the proposed Regulation of the European Parliament and of the Council on the hygiene of foodstuffs.

The annexed draft incorporates:

- amendments reflecting the outcome of discussions within the Working Party up to and including at its meeting on 20 June 2002;
  - editorial adjustments to ensure internal consistency and to clarify ambiguities; and
  - footnotes indicating how the text compares to the amendments proposed in the opinion of the European Parliament (document 8868/02) and some technical or drafting changes to align the text with certain of these amendments.
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**PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT**

**AND OF THE COUNCIL ON THE HYGIENE OF FOODSTUFFS**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,<sup>1</sup>

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<sup>2</sup>,

Having regard to the opinion of the Economic and Social Committee<sup>3</sup>,

Having regard to the opinion of the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty<sup>4</sup>,

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<sup>1</sup> Two delegations have a parliamentary scrutiny reservation.

<sup>2</sup> OJ C 365 E , 19.12.2000, p. 43.

<sup>3</sup> OJ C 155, 29.5.2001, p. 39.

<sup>4</sup> Opinion of the European Parliament of ... May 2002 (not yet published in the Official Journal), Council Common Position of ... (not yet published in the Official Journal) and Decision of the European Parliament of ... (not yet published in the Official Journal). In addition to the EP amendments referred to in the footnotes, the draft Regulation is consistent with amendments 11, 18, 24, 50, 54 and 59, which propose the deletion of superfluous provisions.

Whereas:

- (1)<sup>1</sup> 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<sup>2</sup>. 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<sup>3</sup> established hygiene principles to ensure the fitness for human consumption of food in free circulation within the internal market. In particular, it laid down the following principles:
- that hygiene rules should apply to all stages of production, processing and distribution of food after primary production;
  - the need to base the hygiene rules on hazard analysis, risk assessment and other management techniques to identify, control and monitor critical points;
  - that it should be possible to adopt microbiological criteria and temperature control requirements for certain classes of food in accordance with scientifically accepted general principles;
  - the development of guides to good hygiene practice to which food business operators may refer;
  - the need for Member States' competent authorities to enforce the hygiene rules to protect the final consumer from food unfit for human consumption;
  - food business operators' duty to place on the market only food that is not harmful to human health.

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<sup>1</sup> This recital incorporates EP amendment 1, with drafting changes.

<sup>2</sup> OJ L 31, 1.2.2002, p. 1. Regulation 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.

<sup>3</sup> OJ L 175, 19.7.1993, p. 1.

- (3) Experience has shown that these principles constitute a sound basis for ensuring food safety.
- (4) 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.
- (5)<sup>1</sup> 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.
- (6) With regard to public health, these Directives contain common principles. In particular, they establish similar rules 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.
- (7) Many of these principles are the same as the principles laid down in Council Directive 93/43/EEC.
- (8) The principles laid down in Directive 93/43/EEC therefore constitute a common basis for the hygienic production of all food, including products of animal origin listed in Annex I to the Treaty.
- (9) In addition to this common basis, or general rules, specific hygiene rules are necessary for certain foodstuffs. A separate Regulation of the European Parliament and of the Council will lay down such specific hygiene rules for food of animal origin.

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<sup>1</sup> This recital is broadly consistent with the objective of EP amendment 2.

- (10)<sup>1</sup> 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, taking particular account of the following principles:
- that primary responsibility for food safety rests with the food business operator;
  - the need to ensure food safety throughout the food chain, starting with primary production;
  - the importance, for food that cannot be stored safely at ambient temperatures, particularly frozen food, of maintaining the cold chain;
  - general implementation of procedures based on the principles of hazard analysis and critical control points (HACCP) which, together with the application of good hygiene practice, should reinforce food business operators' responsibility;
- that 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;
- the establishment of microbiological criteria and temperature control requirements based on a scientific risk assessment;
  - the need to ensure that imported foods are of at least the same health standard as food produced in the Community or are of an equivalent standard.
- (11)<sup>2</sup> 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 must ensure that food safety is not compromised.

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<sup>1</sup> This recital incorporates EP amendments 3 and 4, with drafting changes to the latter.

<sup>2</sup> This recital incorporates EP amendment 5, with drafting changes.

- (12) In accordance with the principles of proportionality and subsidiarity, Community rules should apply neither to primary production for private domestic use nor to the domestic preparation, handling or storage of food for private domestic consumption. Moreover, Community requirements apply only to undertakings, which implies a certain continuity of activities and a degree of organisation.
- (13) Food hazards present at the level of primary production must be identified and adequately controlled to ensure that they present no risk from a public health point of view. However, in the case of the direct supply of small quantities of primary products to the final consumer or to a local shop or restaurant, it is appropriate to protect public health through national law, in particular because of the close relationship between the producer and the consumer.
- (14)<sup>1</sup> The full application of HACCP principles to primary production is not currently 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.
- (15)<sup>2</sup> Food safety is a result of several factors. Legislation must lay down minimum hygiene requirements. Official controls must be in place to check food business operators' compliance. In addition, food business operators must establish and operate food safety programmes and procedures based on the HACCP principles.

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<sup>1</sup> This recital incorporates part of EP amendment 7.

<sup>2</sup> This recital incorporates part of EP amendment 8, with drafting changes.

- (16) While the requirement to establish 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 the Regulation.
- (17)<sup>1</sup> HACCP is an instrument to help food business operators attain a higher standard of food safety. HACCP should not be regarded as a method of self-regulation and does not replace official controls.
- (18)<sup>2</sup> Successful implementation of the HACCP principles will require the full cooperation and commitment of food business' employees. To this end, employees must undergo training.
- (19) The requirements concerning HACCP 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 to establish "critical limits" does not imply that it is necessary to fix a numerical limit in every case. The requirement to retain documents needs to be flexible to avoid undue burdens for very small businesses.
- (20) 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. However, such flexibility must 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 must be fully transparent. It should provide for discussion within the Standing Committee on the Food Chain and Animal Health where necessary to resolve disagreements.
- (21) Flexibility is particularly important for regions suffering from special geographical constraints, including the outermost regions referred to in Article 299(2) of the Treaty.

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<sup>1</sup> This recital reflects EP amendment 6.

<sup>2</sup> This recital reflects part of EP amendment 9.

- (22)<sup>1</sup> The setting of objectives such as pathogen reduction targets or performance standards should guide the implementation of hygiene rules. It is therefore necessary to foresee procedures for that purpose.
- (23) Such objectives would supplement existing food law, such as Regulation (EC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food, 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.
- (24) The registration of establishments and the co-operation of food business operators are necessary to allow the competent authorities to perform official controls efficiently.
- (25)<sup>2</sup> 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.
- (26)<sup>3</sup> Food imported into the Community must satisfy the general requirements laid down in Regulation (EC) No 178/2002 and the specific requirements laid down in this Regulation.
- (27)<sup>4</sup> Community products exported to third countries must satisfy the general requirements laid down in Regulation (EC) No 178/2002 and the specific requirements laid down in this Regulation.
- (28)<sup>5</sup> Scientific advice must underpin Community legislation on food hygiene. To this end, the European Food Safety Authority should be consulted whenever necessary.

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<sup>1</sup> This recital incorporates EP amendment 10.

<sup>2</sup> This recital is consistent with EP amendment 11.

<sup>3</sup> This recital reflects EP amendment 12.

<sup>4</sup> This recital reflects EP amendment 14.

<sup>5</sup> This recital is consistent with the objective of EP amendment 15.

- (29) To take account of technical and scientific progress, close and effective co-operation should be ensured between the Commission and the Member States within the Standing Committee set up by Regulation (EC) No 178/2002.
- (30) 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.
- (31) The adoption of this Regulation means that Directive 93/43/EEC can be repealed.
- (32) The requirements of this Regulation should apply one year after its entry into force, to allow the affected industries time to adapt.
- (33) 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<sup>1</sup>,

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<sup>1</sup> OJ L 184, 17.7.1999, p. 23.

HAVE ADOPTED THIS REGULATION:

## CHAPTER I

### GENERAL PROVISIONS

#### Article 1

##### Scope

- 1.<sup>1</sup> This Regulation lays down general rules for food business operators on the hygiene of foodstuffs. It shall apply to all stages of production, processing and distribution of food and to exports. It shall apply 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.
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.

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<sup>1</sup> This paragraph is consistent with the objective of EP amendment 16.

## Article 2

### Definitions

The following definitions shall apply for the purposes of this Regulation:

- 1.<sup>1</sup> the definitions laid down in Regulation (EC) No 178/2002; and
2. the following definitions:
  - (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) “establishment” means any unit of a food business;
  - (c) “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;
  - (d) “equivalent” means, in respect of different systems, capable of meeting the same objectives;
  - (e) “contamination” means the presence or introduction of a hazard;

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<sup>1</sup> This point is consistent with EP amendment 17.

- (f) “potable water” means water meeting the minimum requirements laid down in Directive 98/83/EC for water intended for human consumption;
- (g) “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;
- (h) “clean water” means clean seawater and fresh water of a similar quality;
- (i)<sup>1</sup> “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;
- (j) “packaging” means the placing of one or more wrapped foodstuffs in a second container, and the latter container itself;
- (k) “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;
- (l) “unprocessed products” means foodstuffs that have not undergone processing, including products that have been divided, parted, severed, sliced, boned, minced, skinned, ground, cut, cleaned, trimmed, husked, milled, chilled, frozen, deep-frozen or thawed;
- (m) “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;
- (n) “hermetically sealed container” means a container that is designed and intended to be secure against the entry of micro-organisms.<sup>2</sup>

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<sup>1</sup> This definition is consistent with EP amendment 25.

<sup>2</sup> It might be appropriate to move the definitions of “wild game”, “fishery products” and “bivalve molluscs” from the draft Regulation laying down specific hygiene rules for food of animal origin to this Article. Annexes I and II use these terms. There is no need to define the terms, however, if they are not ambiguous in the context 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.<sup>1</sup>

#### 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 in Community legislation laying down specific hygiene rules for food of animal origin.
2. Food business operators carrying out any stage of production, processing and distribution of food after those to which paragraph 1 applies shall comply with the general hygiene requirements laid down in Annex II and any specific requirements in Community legislation laying down specific hygiene rules for food of animal origin.

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<sup>1</sup> This wording is consistent with EP amendments 27 and 107.

- 3.<sup>1</sup> Food business operators shall:
- (a) comply with microbiological and temperature criteria; and
  - (b) take measures or adopt procedures necessary to meet targets set to achieve the objectives of this Regulation.
4. The criteria 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, Community legislation laying down specific hygiene rules for food of animal origin and their implementing rules 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 to 9 as an aid to compliance with their obligations under this Regulation.

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<sup>1</sup> Paragraphs 3 and 4 are broadly consistent with the objective of EP amendment 106.

## 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 principles of hazard analysis and critical control points (HACCP).
  
2. The HACCP principles referred to in paragraph 1 are:
  - (a) to identify any hazards that must be prevented, eliminated or reduced to acceptable levels;
  - (b) to identify 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;
  - (c) to establish critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards;
  - (d) to establish and implement effective monitoring procedures at critical control points;
  - (e) to establish corrective actions when monitoring indicates that a critical control point is not under control;
  - (f) to establish procedures to verify that the measures outlined in subparagraphs (a) to (e) are working effectively. Verification procedures shall be carried out regularly; and
  - (g) to establish 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 necessary changes to it.

3. The requirement of 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.<sup>1</sup>
4. (a)<sup>2</sup> Food business operators shall provide the competent authority with evidence of their compliance with the requirement of paragraph 1 in the manner that the competent authority requests taking account of the nature and size of the food business.
  - (b) Food business operators shall ensure that any documents describing the procedures developed in accordance with this Article are up-to-date at all times.
  - (c) Food business operators shall retain any other documents 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 certain food business operators' implementation of this Article, in particular by providing for the use of procedures set out in guides for the application of HACCP principles developed in accordance with Article 7 to 9 in order to comply with the requirement of paragraph 1. Such arrangements may also specify the period during which food business operators shall retain documents in accordance with paragraph 4(c).

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<sup>1</sup> One delegation has a reservation on this paragraph, wishing it to make explicit provision for each Member State to have the option of applying the requirement under national law to primary production and associated operations carried out on its territory.

<sup>2</sup> This subparagraph is consistent with part of EP amendment 36.

## Article 6

### Official controls, registration and approval

1. Food business operators shall co-operate with the competent authorities in accordance with other applicable Community legislation or, where there is none, national law.

2.<sup>1</sup> In particular, every food business operator shall notify the appropriate competent authority of each establishment under its control carrying out any of the stages of production, processing and distribution of food in the manner that the competent authority requires with a view to its registration.

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.<sup>2</sup> 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;<sup>3</sup>
- (b) under Community legislation laying down specific hygiene rules for food of animal origin; or
- (c) by a decision adopted in accordance with the procedure referred to in Article 14(2).

Any Member State intending to require the approval of certain establishments located on its territory under national law, as provided for in subparagraph (a), shall first notify the Commission and other Member States.

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<sup>1</sup> This paragraph is broadly consistent with the objective of EP amendment 49.

<sup>2</sup> This paragraph is consistent with the objectives of EP amendments 51 and 52.

<sup>3</sup> One delegation has a reservation on this provision.

## CHAPTER III

### GUIDES TO GOOD PRACTICE

#### Article 7

##### Development, dissemination and use of guides

1. 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.
2. The dissemination and use of both national and Community guides shall be encouraged.
- 3.<sup>1</sup> Nevertheless, food business operators may use these guides voluntarily.

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<sup>1</sup> This paragraph is consistent with EP amendments 40 and 45.

## Article 8

### National guides

- 1.<sup>1</sup> When national guides to good practice are developed, they shall be developed and disseminated:
  - (a)<sup>2</sup> by food business sectors, 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, 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 I to Directive 98/34/EC.<sup>3</sup>
3. Member States shall assess national guides to ensure that:
  - (a)<sup>4</sup> they have been developed in accordance with paragraph 1;
  - (b) the contents of such guides are practicable for the sectors to which they refer; and
  - (c) they are suitable as guides to compliance with the provisions of Articles 3, 4 and 5 in the sectors and for the foodstuffs covered.

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<sup>1</sup> This paragraph is consistent with EP amendment 41.

<sup>2</sup> This paragraph is consistent with part of EP amendment 42.

<sup>3</sup> OJ L 204, 21.7.1998, p. 37. Directive 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. Directive as amended by Directive 98/48/EC (OJ L 217, 5.8.1998, p. 18).

<sup>4</sup> This paragraph is consistent with the objective of EP amendment 43.

4. Member States shall forward national guides complying with the requirements of paragraph 3 to the Commission. The Commission shall set up and run a registration system for such guides and make this available to Member States.
- 5.<sup>1</sup> 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.

## Article 9

### Community guides

1. Before Community guides to good practice for hygiene or for the application of 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.<sup>2</sup> Where 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, having regard to the recommendations set out in Part B of Annex I.

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<sup>1</sup> This paragraph is consistent with EP amendment 44.

<sup>2</sup> This paragraph is consistent with the objective of EP amendment 46.

3. The Committee referred to in Article 14 shall assess draft Community guides to ensure that:
- (a) they have been developed in accordance with paragraph 2;
  - (b) the contents of such guides are practicable for the sectors to which they refer throughout the Community; and
  - (c) they are suitable as guides to compliance with the provisions of 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.<sup>1</sup>
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 Communities.

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<sup>1</sup> This paragraph is broadly consistent with the objective of EP amendment 47, which the Commission has not accepted, but unlike that amendment does not specify the frequency of reviews.

## CHAPTER IV

### IMPORTS AND EXPORTS

#### Article 10

##### Imports<sup>1</sup>

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<sup>2</sup>

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.

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<sup>1</sup> This Article is consistent with the objective of EP amendment 56.

<sup>2</sup> This Article is consistent with the objective of EP amendment 57.

## 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).<sup>1</sup>

#### Article 13

##### Amendment and adaptation of Annexes I and II

1. The provisions of Annexes I and II may be repealed, amended, adapted or supplemented, in accordance with the procedure referred to in Article 14(2), to take account of:
  - (a) the development of codes of good practice;
  - (b) the experience gained from the implementation of HACCP-based systems pursuant to Article 5;
  - (c) technological developments;
  - (d) scientific advice, particularly new risk assessments; and
  - (e) the setting of food safety targets.<sup>2</sup>

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<sup>1</sup> This Article is consistent with the objective of EP amendment 60.

<sup>2</sup> This provision is now consistent with Article 18(1) of the draft Regulation laying down specific hygiene rules for food of animal origin (documents 5035/02 and 5806/02).

2. Exemptions from provisions of Annexes I and II may be granted in accordance with the procedure referred to in Article 14(2), provided that such exemptions do not affect the achievement of the objectives of this Regulation.
- 3.<sup>1</sup> Member States may, without compromising food hygiene objectives, adopt national measures adapting the requirements laid down in Annex II in accordance with paragraphs 4 to 7.
4. The national measures referred to in paragraph 3 shall:
  - (a) have the aim of enabling the continued use of traditional methods at any of the stages of production, processing or distribution of food;
  - (b) concern the construction, layout and equipment of establishments; or
  - (c) have the aim of accommodating the needs of food businesses situated in regions suffering from special geographical constraints.
- 5.<sup>2</sup> Any Member State wishing to adopt national measures adapting the requirements laid down in Annex II as referred to in paragraph 4 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;

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<sup>1</sup> This paragraph is consistent with the objective of EP amendment 31.

<sup>2</sup> This paragraph is consistent with the objective of EP amendment 32.

- (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 hygiene objectives); and
  - (d) give any other relevant information.
- 6. 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 adaptations referred to in 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, where necessary, to appropriate amendments. Where appropriate, the Commission may propose measures of general application in accordance with paragraphs 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 referred to in subparagraph (a).

## Article 14

### Standing Committee procedure

- 1.<sup>1</sup> The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health established by Regulation (EC) No 178/2002.
2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, in compliance with Article 8 thereof.

The period laid down in Article 5(6) of that Decision shall be 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 within the scope of this Regulation that could have a significant impact on public health and, in particular, before proposing criteria or targets in accordance with Article 4(4).

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<sup>1</sup> This paragraph is consistent with EP amendment 61.

## Article 16

### Report to Council and Parliament

- 1.<sup>1</sup> The Commission shall, within five years of this Regulation entering into force, submit a report to the European Parliament and the Council.
- 2.<sup>2</sup> The report shall in particular review the experience gained from the implementation 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.<sup>3</sup>
3. The Commission shall, if appropriate, accompany the report with relevant proposals.

## Article 17

### Repeal

1. Directive 93/43/EEC is repealed with effect from the date of application of this Regulation.
2. However, decisions adopted pursuant to Articles 3(3) and 10 of that Directive shall remain in force until replaced by decisions adopted in accordance with the present Regulation or Regulation (EC) 178/2002.<sup>4</sup> Pending the setting of the criteria referred to in Article 4(3)(a) Member States may maintain any national rules establishing such criteria that they had adopted in accordance with Directive 93/43/EEC.

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<sup>1</sup> The substitution of five years for seven implements EP amendment 62.

<sup>2</sup> This paragraph partly implements EP amendment 131.

<sup>3</sup> The representative of the Commission has a reservation on the words between square brackets.

<sup>4</sup> With two exceptions, all the delegated legislation adopted under Directive 93/43/EEC consists of safeguard measures under Article 10 concerning certain imports (e.g., Commission Decisions 2002/75/EC, 2002/79/EC and 2002/80/EC). Article 53 of Regulation (EC) No 178/2002 now provides a legal base for the adoption of such measures. The exceptions are Directives 96/3/EC and 98/28/EC (adopted under Article 3(3)), which provide derogations for the bulk carriage by sea of oils and sugar respectively.

3. 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 on the date of its publication in the Official Journal of the European Communities.

It shall apply one year after the entry into force of this Regulation.<sup>1</sup>

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

Done at,

*For the European Parliament*  
*The President*

*For the Council*  
*The President*

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<sup>1</sup> This provision is consistent with EP amendment 56.

## ANNEX I

### PRIMARY PRODUCTION

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

##### I. SCOPE

- 1.<sup>1</sup> The provisions of this Part apply 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;
  - (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; and
  - (d) the direct supply of small quantities of primary products to the final consumer at the place of production.<sup>2</sup>

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<sup>1</sup> With the exception of subparagraph (c), this paragraph has the same objective as EP amendment 64.

<sup>2</sup> Three delegations and the Commission representative have a reservation on this provision. They believe that such direct supply ought to fall outside the scope of the Regulation, as EP amendment 103 proposes. The wording “direct supply of small quantities of primary products to the final consumer” comes from the EP amendment.

## II. HYGIENE PROVISIONS

- 2.<sup>1</sup> Food business operators must ensure, as far as possible, that primary products are protected against contamination (having regard to any processing that primary products will subsequently undergo).
- 3.<sup>2</sup> Notwithstanding the general duty laid down in paragraph 2, food business operators must comply with appropriate Community and national legislative provisions relating to the control of hazards in primary production, 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.<sup>3</sup>
4. Food business operators rearing, harvesting or hunting animals or producing primary products of animal origin must take adequate measures, as appropriate:
- (a) to keep any facilities used in connection with primary production, 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;

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<sup>1</sup> This paragraph is consistent with EP amendment 65.

<sup>2</sup> This paragraph is consistent with the objectives of EP amendment 66.

<sup>3</sup> This provision now makes clear that it does not create any new requirements for primary producers. The final few words use language consistent with the Commission's proposals on zoonoses (document 11405/01).

- (c) to ensure, as far as possible, 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) to prevent, as far as possible, 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)<sup>1</sup> to use feed additives and veterinary medicinal products correctly, as required by the relevant legislation.

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<sup>1</sup> With the addition of this subparagraph, this paragraph is consistent with EP amendment 68.

5.<sup>1</sup> Food business operators producing or harvesting plant products must take adequate measures, as appropriate:

- (a) to keep clean and, where necessary after cleaning, to disinfect in an appropriate manner facilities, equipment, containers, crates and vehicles;
- (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) to prevent, as far as possible, 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.

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<sup>1</sup> This paragraph is consistent with EP amendment 70.

### III. RECORD-KEEPING<sup>1</sup>

6. Food business operators must 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 must make relevant information contained in these records available to the competent authority and receiving food business operators on request.
7. Food business operators rearing animals or producing primary products of animal origin must, in particular, keep records on:
  - (a) the nature and origin of feed fed to the animals;
  - (b) veterinary 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 to human health; and
  - (e) any relevant reports on checks carried out on animals or products of animal origin.

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<sup>1</sup> The provisions on record keeping are broadly consistent with EP amendments 72 and 73, in particular as a result of the addition of paragraph 10 and changes to paragraph 9.

8. Food business operators producing or harvesting plant products must, in particular 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.
9. Other persons, such as veterinarians, agronomists and farm technicians, may assist the food business operator with the keeping of records.

## **PART B: RECOMMENDATIONS FOR GUIDES TO GOOD HYGIENE PRACTICE<sup>1</sup>**

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.
2. Guides to good hygiene practice should include appropriate information on hazards that may arise in primary production 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;

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<sup>1</sup> This Part of Annex I is broadly consistent with EP amendment 73.

- (g) protective measures to prevent the introduction of contagious diseases transmissible to humans through food, and any obligation to notify the competent authority;
- (i) 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;
- (j) measures relating to the cleanliness of slaughter and production animals; and
- (k) measures relating to record-keeping.

## ANNEX II

### GENERAL HYGIENE REQUIREMENTS FOR ALL FOOD BUSINESS OPERATORS

#### (EXCEPT WHEN ANNEX I APPLIES)

#### INTRODUCTION

1. Subject to Article 4(2), 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 rooms to which Chapter III applies;
  - Chapter III applies to those premises listed in the heading to the Chapter; and
  - Chapter IV applies to all transportation.
2. In this Annex, the terms “where necessary”, “where appropriate”, “adequate” and “sufficient” mean respectively where necessary, where appropriate, adequate or sufficient to achieve the aims of this Regulation.

## CHAPTER I

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

1. Food premises must be kept clean and maintained in good repair and condition.
2. The layout, design, construction, siting and size of food premises must:
  - (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)<sup>1</sup> 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 must be available and connected to an effective drainage system. Lavatories must not open directly into rooms in which food is handled.

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<sup>1</sup> This subparagraph is consistent with EP amendment 75.

4. An adequate number of washbasins must be available, suitably located and designated for cleaning hands. Washbasins for cleaning hands must be provided with hot and cold running water, materials for cleaning hands and for hygienic drying. Where necessary, the facilities for washing food must be separate from the hand-washing facility.
5. There must be suitable and sufficient means of natural or mechanical ventilation. Mechanical airflow from a contaminated area to a clean area must be avoided. Ventilation systems must be so constructed as to enable filters and other parts requiring cleaning or replacement to be readily accessible.
6. Sanitary conveniences must have adequate natural or mechanical ventilation.<sup>1</sup>
7. Food premises must have adequate natural and/or artificial lighting.
8. Drainage facilities must be adequate for the purpose intended. They must be designed and constructed to avoid the risk of contamination. Where drainage channels are fully or partially open, they must be so designed to ensure that waste does not flow from a contaminated area towards and into a clean area or area where foods likely to present a high risk to the final consumer are handled.
- 9.<sup>2</sup> Where necessary, adequate changing facilities for personnel must be provided.
- 10.<sup>3</sup> Cleaning agents and disinfectants must not be stored in areas where food is handled.

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<sup>1</sup> It is not clear what this paragraph adds to the general requirement laid down in paragraph 5, nor what “sanitary conveniences” are.

<sup>2</sup> This paragraph is consistent with EP amendment 78.

<sup>3</sup> This paragraph implements EP amendment 79.

## CHAPTER II

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

- 1.<sup>1</sup> In rooms where food is prepared, treated or processed (excluding dining areas and those premises specified in the title to Chapter III but including rooms contained in means of transport) the design and layout must permit good food hygiene practices, including protection against contamination between and during operations. In particular:
- (a) floor surfaces must 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 must allow adequate surface drainage;
  - (b) wall surfaces must 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)<sup>2</sup> ceilings (or, where there are no ceilings, the interior surface of the roof) and overhead fixtures must be constructed and finished so as to prevent the accumulation of dirt and to reduce condensation, the growth of undesirable moulds and the shedding of particles;

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<sup>1</sup> This paragraph is consistent with EP amendment 80.

<sup>2</sup> This subparagraph is consistent with EP amendment 81.

- (d) windows and other openings must be constructed to prevent the accumulation of dirt. Those which can be opened to the outside environment must, where necessary, be fitted with insect-proof screens which can be easily removed for cleaning. Where open windows would result in contamination, windows must remain closed and fixed during production;
- (e) doors must 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)<sup>1</sup> surfaces (including surfaces of equipment) in areas where foods are handled and in particular those in contact with food must 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.<sup>2</sup> Adequate facilities must be provided, where necessary, for the cleaning, disinfecting and storage of working utensils and equipment. These facilities must be constructed of corrosion-resistant materials, be easy to clean and have an adequate supply of hot and cold water.

3.<sup>3</sup> Adequate provision must be made, where necessary, for washing food. Every sink or other such facility provided for the washing of food must 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.

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<sup>1</sup> This subparagraph is consistent with EP amendment 82.

<sup>2</sup> This subparagraph implements EP amendment 83 in part.

<sup>3</sup> This subparagraph implements EP amendment 84 in part.

## 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.<sup>1</sup> Premises and vending machines must, so far as is reasonably practicable, 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 must be available to maintain adequate personal hygiene (including facilities for the hygienic washing and drying of hands, hygienic sanitary arrangements and changing facilities);
  - (b)<sup>2</sup> surfaces in contact with food must 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 must 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 must be made for this to be undertaken hygienically;

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<sup>1</sup> This paragraph is consistent with EP amendment 85.

<sup>2</sup> This paragraph is consistent with EP amendment 86.

- (e) an adequate supply of hot and/or cold potable water must 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) must be available;
- (g) adequate facilities and/or arrangements for maintaining and monitoring suitable food temperature conditions must be available;
- (h) foodstuffs must 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 must be kept clean and maintained in good repair and condition to protect foodstuffs from contamination and must, where necessary, be designed and constructed to permit adequate cleaning and/or disinfection.
2. Receptacles in vehicles and/or containers must not be used for transporting anything other than foodstuffs where this may result in contamination.
- 3.<sup>1</sup> Where conveyances and/or containers are used for transporting anything in addition to foodstuffs or for transporting different foodstuffs at the same time, there must, where necessary, be effective separation of products.
- 4.<sup>2</sup> Bulk foodstuffs in liquid, granular or powder form must be transported in receptacles and/or containers/tankers reserved for the transport of foodstuffs. Such containers must 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 must 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 must be effective cleaning between loads to avoid the risk of contamination.

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<sup>1</sup> This paragraph is consistent with EP amendment 87.

<sup>2</sup> This paragraph is consistent with EP amendment 88.

6. Foodstuffs in conveyances and/or containers must be so placed and protected as to minimise the risk of contamination.
7. Where necessary, conveyances and/or containers used for transporting foodstuffs must 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 must:
  - (a) be effectively cleaned and, where necessary, disinfected. Cleaning and disinfection must 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 must 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 must be used in accordance with good practice.

## CHAPTER VI

### FOOD WASTE

- 1.<sup>1</sup> Food waste, non-edible by-products and other refuse must be removed from rooms where food is present as quickly as possible, so as to avoid its accumulation.
2. Food waste, non-edible by-products and other refuse must 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 must be of an appropriate construction, kept in sound condition, be easy to clean and, where necessary, to disinfect.
- 3.<sup>2</sup> Adequate provision must be made for the storage and disposal of food waste, non-edible by-products and other refuse. Refuse stores must 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 must be eliminated in a hygienic and environmentally friendly way in accordance with Community legislation applicable to that effect, and must not constitute a direct or indirect source of contamination.

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<sup>1</sup> This paragraph is consistent with EP amendment 90.

<sup>2</sup> Paragraphs 3 and 4 are consistent with EP amendment 91.

## CHAPTER VII

### WATER SUPPLY

1.
  - (a) There must be an adequate supply of potable water, which must 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 must 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 must circulate in a separate duly identified system. Non-potable water must not connect with, or allow reflux into, potable water systems.
3. Recycled water used in processing or as an ingredient must not present a risk of contamination. It must 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 must be made from potable water or, when used to chill whole fishery products, clean water. It must be made, handled and stored under conditions that protect it from contamination.

5. Steam used directly in contact with food must not contain any substance that presents a hazard to health or is likely to contaminate the food.
- 6.<sup>1</sup> Where heat treatment is applied to foodstuffs in hermetically sealed containers it must be ensured that water used to cool the containers after heat treatment is not a source of contamination for the foodstuff.

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<sup>1</sup> This paragraph is consistent with EP amendment 94.

## **CHAPTER VIII**

### **PERSONAL HYGIENE**

1. Every person working in a food-handling area must maintain a high degree of personal cleanliness and must 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 must 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 must immediately report the illness or symptoms to the food business operator.

## CHAPTER IX

### PROVISIONS APPLICABLE TO FOODSTUFFS

1. A food business operator must not 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.<sup>1</sup> Raw materials and all ingredients stored in a food business must be kept in appropriate conditions designed to prevent harmful deterioration and protect them from contamination.
3. All food which is handled, stored, packaged, displayed and transported must 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 must be in place to control pests. Adequate procedures must also 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).<sup>2</sup>

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<sup>1</sup> This paragraph is consistent with EP amendment 96.

<sup>2</sup> The additional words between parentheses seek to address concerns relating to guide dogs for the visually impaired and guard dogs.

5. Raw materials, ingredients, intermediate products and finished products likely to support the reproduction of pathogenic micro-organisms or the formation of toxins must not be kept at temperatures that might result in a risk to health. The cold chain must not 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 must 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 must 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 must 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 must 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 must be adequately drained. Following thawing, food must 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, must be adequately labelled and stored in separate and secure containers.
- [9. Liquid foodstuffs may be stored only in land tanks in use at tank installations if the three previous cargoes in the tanks, lines and pumps were foodstuffs.]<sup>1</sup>

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<sup>1</sup> One delegation has suggested the addition of this paragraph. The Working Party has yet to discuss the suggestion.

## CHAPTER X

### PROVISIONS APPLICABLE TO THE WRAPPING AND PACKAGING OF FOODSTUFFS<sup>1</sup>

1. Material used for wrapping and packaging must not be a source of contamination.
2. Wrapping materials must be stored in such a manner that they are not exposed to a risk of contamination.
3. Wrapping and packaging operations must 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 must be assured.
4. Wrapping and packaging material re-used for foodstuffs must be easy to clean and, where necessary, to disinfect.

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<sup>1</sup> This Chapter is broadly consistent with the objectives of EP amendments 99 and 100.

## CHAPTER XI

### HEAT TREATMENT

1. Any heat treatment process used to process an unprocessed product or to process further a processed product must:
  - (a) raise every party of the product treated to a given temperature for a given period of time; and
  - (b) prevent the product from becoming contaminated during the process.
2. To ensure that the process employed achieves the desired objectives, food business operators must regularly check 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 must ensure:

1. that food handlers are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity; [and]
- 2.<sup>1</sup> that those responsible for the development and maintenance of the procedure referred to in Article 5(1) or for the implementation 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.]<sup>2</sup>

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<sup>1</sup> This paragraph is consistent with EP amendment 102.

<sup>2</sup> One delegation has suggested the addition of this paragraph. The Working Party has yet to discuss the suggestion.