



**COUNCIL OF THE  
EUROPEAN UNION**

**Brussels, 4 January 2001 (16.01)  
(OR. fr)**

**13050/1/00**

**REV 1**

**LIMITE**

**DENLEG 56  
AGRILEG 165  
CODEC 845**

<p><b>Interinstitutional File: 2000/0178 (COD)</b></p>
--

## **OUTCOME OF PROCEEDINGS**

---

of :	Working Party of Veterinary Experts
on :	31 October 2000
No. prev.doc.	12383/00 DENLEG 55 AGRILEG 149 CODEC 778 + ADD 1 + ADD 1 COR 1(fr) 10427/00 AGRILEG 116 CODEC 562
Subject :	Proposal for a Regulation of the European Parliament and of the Council on the hygiene of foodstuffs

---

Delegations will find attached the text of the above proposal as agreed on at the meeting on 31 October 2000. Changes to the previous document (12383/00 ADD 1 DENLEG 55 AGRILEG 149 CODEC 778) are shown in bold type and deleted passages are marked: [...]. Comments by the delegations and by the Commission representative are contained in the footnotes. These have been amended so individual Member States cannot be identified.

The Annexes <sup>1</sup> are not included in this document since only the Articles were examined. The Chairman has asked delegations for their written comments on the Annexes.

---

<sup>1</sup> The Working Party decided, during examination of the second proposal of the "food hygiene" package, that the following additions could usefully be made to the above proposal:

- the words "working and" after "provide ... controlled" in paragraph 2(d) of Chapter I of Annex II, so as to read: "... provide suitable ... working and storage conditions ...";
- the words "and storage" in paragraph 2 of Chapter II of Annex II, so that the sentence reads: "Adequate facilities ... for the cleaning, disinfecting and storage of ... utensils ...".

Proposal for a

**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

on the hygiene of foodstuffs

*Article 1*

*Scope*

This Regulation lays down the rules to ensure the hygiene of foodstuffs at all stages from and including primary production up to and including the transfer, whether in return for payment or free of charge, or supply of a foodstuff to the final consumer. This Regulation shall apply without prejudice <sup>1</sup> to more specific requirements relating to food hygiene and does not cover issues relating to nutrition or compositional matters. It applies to food businesses.

It does not apply to the primary production of food for private domestic use or the domestic preparation of foodstuffs for private consumption.

*Article 2*

*Definitions*

For the purposes of this Regulation:

- "food hygiene", hereinafter called "hygiene" means the measures and conditions necessary to control hazards and ensure fitness for human consumption of a foodstuff taking into account its intended use, [...]

---

<sup>1</sup> Some delegations asked the Legal Service to clarify "without prejudice".

- "food business" means any natural or legal person <sup>1</sup> carrying out, whether for profit or not, any or all of the stages from and including primary production up to and including the transfer, whether in return for payment or free of charge, **presentation** or supply of foodstuffs to the final consumer;
- "establishment" means any **geographical** unit of a business where foodstuffs are prepared, processed, manufactured, wrapped, stored, transported, distributed, sold – including by telesale – or supplied to the final consumer; <sup>2</sup>
- "food business operator" means the person or persons responsible for ensuring that the requirements of this Regulation are met within the food business under his/their control;
- "primary products" means agricultural products of the soil, products of stock farming, of hunting, of aquaculture and of fisheries; <sup>3</sup>
- "primary production" means the production, rearing or growing of primary products up to and including harvesting, hunting, fishing, milking and all stages of animal production prior to slaughter;
- "competent authority/ies" means the central authority/ies of a Member State responsible for the purposes and controls set out in this Regulation or any other authority or body to which competence has been delegated by the central authority/ies;

[...] <sup>4</sup>

---

<sup>1</sup> A reservation on this definition, particularly in relation to the term "natural or legal person".

<sup>2</sup> Following the Working Party's discussion on the status of fishing vessels, the Commission representative said that under the present text these vessels are establishments which need to be registered.

<sup>3</sup> A number of delegations, asked that fruit and wild mushrooms be covered with a view to, inter alia, an inspection of imported mushrooms . An addition to Annex I Chapter III to cover picking was suggested.

<sup>4</sup> Deletion of the definition of "certification".

- "equivalence" means the capability of different systems to meet the same objectives;
- "hazard" <sup>1</sup> means a biological, chemical or physical agent with the potential **adversely to affect health**; <sup>2</sup>
- "contamination" means the addition of a hazard to, or its presence in, food or its environment, [...];
- "marketing" means holding, displaying with a view to sale and offering for sale, selling, delivering or any other form of placing on the market, whether in return for payment or free of charge [...];
- [– "retail trade" means the handling and processing of food and its storage:
  - at the point of sale or delivery to the final consumer, and includes mass catering operations, factory canteens, institutional catering, restaurants and other similar food service operations,
  - in shops mainly concerned with storage with a view to [...] sale to the final consumer, including distribution **terminals** [...];] <sup>3</sup>

[...] <sup>4</sup>

- "final consumer" means the ultimate consumer of a foodstuff who will not use the food as part of any food business operation or activity;

---

<sup>1</sup> English being the language of drafting of the Commission proposal, some delegations pointed out that the translation of "danger" ("hazard") and of "risque" ("risk") was not always consistent.

<sup>2</sup> Wording close to that of the Codex Alimentarius and agreed by the Working Party.

<sup>3</sup> Reservations by two delegations, which thought that this definition was unnecessary here; the definition could be reviewed during examination of the 2nd proposal (specific rules of hygiene for animal products).

<sup>4</sup> In view of the insufficient support for the definition of "local market", the Presidency suggested that this notion be dealt with in the context of Article 4(4).

- "private consumption" means [the consumption of food in a non-commercial setting by a selected public]; <sup>1</sup>
- "clean seawater" means seawater or brackish water without microbiological contamination, harmful substances and/or toxic marine plankton in quantities capable of affecting the health quality of fishery products; <sup>2</sup>
- ["wrapping" means the protection of a product by the use of an initial wrapping or initial container in direct contact with the product concerned, and the initial wrapper or initial container itself;
- "packaging" means the placing of one or more wrapped foodstuffs in a second container, and the latter container itself; if wrapping is strong enough to ensure effective protection, it may be considered to be packaging;] <sup>3</sup>
- "products of animal origin" means foodstuffs obtained from animals, including honey;
- "unprocessed product" means foodstuffs which have not undergone a treatment, including products which have been, for example, divided, parted, severed, boned, minced, skinned, ground, cut, cleaned, trimmed, husked or milled, chilled, frozen or deep-frozen;

---

<sup>1</sup> Proposal from the Presidency. The Presidency explained that the term "selected public" meant invited guests; clarification of the term "non-commercial setting" was sought. Two delegations pointed out that catering in private clubs or associations and free catering for charitable purposes should be covered by the Regulation. One delegation called for this definition to be deleted.

In conclusion, the Presidency called on delegations to consider proposals for possible texts for this definition.

<sup>2</sup> A request that the definition of "seawater" be transferred to the 2nd Regulation proposal.

<sup>3</sup> Definitions to be reviewed or deleted, depending on the text adopted in Chapter X of Annex II.

- "processed product" means foodstuffs resulting from the application to unprocessed products of a treatment such as heating, smoking, curing, maturing, pickling, drying, marinating, extraction, extrusion, etc. or a combination of these processes and/or products; these products may contain ingredients necessary for their manufacture in order to give them specific characteristics;
- "hermetically sealed container" means a container which is designed and intended to be secure against the entry of micro-organisms;
- "where necessary", "where appropriate", "sufficient" mean where revealed necessary, appropriate or sufficient after hazard analysis in the context of the HACCP system.

1

### *Article 3*

#### *General obligation*

Food business operators shall guarantee that all stages for which they are responsible from and including primary production up to and including the offering for sale or supply of foodstuffs to the final consumer are carried out in a hygienic way in accordance with this Regulation.

### *Article 4*

#### *General hygiene requirements and specific hygiene requirements*

1. Food business operators at the level of primary production shall comply with the general hygiene provisions in Annex I hereto, any other specific provisions in Regulation ... (laying down specific hygiene rules for food of animal origin), and in any other Annexes which may be added in accordance with the procedure laid down in Article 15.

---

<sup>1</sup> Two delegations asked if the term "shelf life" should be defined, possibly in line with Directive 2000/13/EC.

2. Food business operators, other than referred to in paragraph 1, shall comply with the general hygiene provisions in Annex II, any other specific provisions laid down in Regulation ... (laying down specific hygiene rules for food of animal origin) and in any other annexes which may be added in accordance with the procedure laid down in Article 15.
3. Exemptions from provisions of the Annexes referred to in paragraphs 1 and 2 may be granted by the Commission in accordance with the procedure laid down in Article 15, provided that such exemptions do not affect the achievement of the objectives of this Regulation.
4. Member States may, with due regard for the food hygiene objectives, adapt the requirements laid down in Annex II with a view to:<sup>1</sup>
  - accommodating the needs of food businesses situated in regions suffering from special geographical constraints or affected by supply difficulties the products from which are serving the local market<sup>2</sup> only or
  - taking account of traditional methods of production or distribution.

Member States having recourse to this possibility shall inform the Commission and the other Member States thereof. Member States shall have three months from the receipt of the notification to send written comments to the Commission. Where written comments are made, the Commission shall take a decision in accordance with the procedure referred to in Article 15(2).

---

<sup>1</sup> Reservation by one delegation regarding the approach to this paragraph; the delegation thought that exceptions or derogations should be linked to risk, not size of business.

<sup>2</sup> Reservations by two delegations on the part of the sentence referring to the local market. One delegation proposed that "local" be replaced by "situated in the vicinity of their location". The Commission representative thought that no definition of "local market" was required. The Presidency suggested that the circumstances in which businesses needed exceptions should be considered.

*Article 5*

*Hazard analysis and critical control points system*

1. Food business operators other than at the level of primary <sup>1</sup> production shall put in place, implement and maintain a permanent procedure developed in accordance with the following principles of the system of hazard analysis and critical control points (HACCP):
  - (a) identify any hazards that must be prevented, eliminated or reduced to acceptable levels;
  - (b) identify the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or reduce it to acceptable levels;
  - (c) establish critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards;
  - (d) establish and implement effective monitoring procedures at critical control points;
  - (e) establish corrective actions when monitoring indicates that a critical control point is not under control;
  - (f) establish procedures to verify whether the measures outlined in (a) to (e) above are working effectively. Verification procedures shall be carried out regularly and whenever the food business operation changes in a manner that could adversely affect food safety;
  - (g) establish documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in (a) to (f) above with a view to facilitating official controls.

---

<sup>1</sup> Reservation by one delegation regarding the exception made in the case of primary production.

2. Food business operators shall keep permanently the documents describing their plans based on the HACCP system. Other documents concerning, inter alia, manufactured or marketed products must be kept for at least six months<sup>1</sup> following expiry of the product's shelf life<sup>2</sup>.
3. As part of the system referred to in paragraphs 1 and 2, food business operators may use guides to good practice in conjunction with guides on the application of HACCP, as developed in accordance with Articles 7 and 8. Such guides must be appropriate for the operations and foods to which they are applied by the food business operator.
4. Measures to facilitate the implementation of **the system provided for in** this Article, in particular in small businesses, may be adopted in accordance with the procedure referred to in Article 15<sup>3</sup>.

#### *Article 6<sup>4</sup>*

##### *Specific food hygiene requirements*

In accordance with the procedure referred to in Article 15 and after consulting the competent Scientific Committee or Committees:

1. microbiological criteria (including sampling and analysis methods) and temperature criteria for foodstuffs may be adopted and/or amended on the basis of risk analysis;

---

<sup>1</sup> Period to be discussed.

<sup>2</sup> See page 6, note 1.

<sup>3</sup> Four delegations called for the adoption of measures to assist small businesses, where necessary by the Member States also, prior to the application of this Regulation. Two delegations thought that all businesses should follow the HACCP system. The Commission representative stated that a study was under way but that some flexibility for small businesses was essential straightaway. However, he expressed a reservation on the possibility that the Member States should adopt measures in this area.

<sup>4</sup> Reservation on this Article by one delgation which would like the Commission to submit a proposal on temperature and microbiological criteria before the Regulation enters into force. Commission reservation on this request (see note 3 on next page).

2. [guidelines]<sup>1</sup> may be drawn up in order to achieve this Regulation's objectives;
3. Pending the setting of the criteria referred to in paragraph 1, the relevant requirements and standards laid down in the Directives referred to in Articles 1 and 2 of Directive ... (repealing certain Directives on the hygiene of foodstuffs and on the health conditions for the production and placing on the market of certain products of animal origin intended for human consumption, and amending Directives 89/662/EEC and 91/67/EEC), or their implementing rules **or relevant national measures**, shall continue to apply<sup>2</sup>.

#### *Article 7*

#### *National guides to good practice*<sup>3</sup>

1. Member States shall encourage the development of guides to good practice for hygiene and use of the **principles** of the HACCP system, which **guides** may be used voluntarily by food businesses and shall include, inter alia, guidance on compliance with Articles 3 and 4 and, where Article 5 applies, the application of HACCP principles.
2. Where the guides to good practice referred to in paragraph 1 are developed, they shall be developed as follows:
  - by food business sectors and representatives of other interested parties, such as appropriate authorities and consumer groups,

---

<sup>1</sup> The Commission representative and four delegations thought that the term "guidelines" was not forceful enough and wanted to revert to the original English of the Commission proposal, which spoke of "performance standards".

<sup>2</sup> With regard to temperature and microbiological criteria, one delegation asked that a date be set for the submission of a proposal by the Commission. The Commission representative expressed a reservation on this request. In this connection, one delegation proposed the introduction of another Annex in the second proposal which would adopt the criteria currently in force.

<sup>3</sup> Proposal that the title of this Article be clarified by the addition of the word "hygiene": "national guides to good hygiene practice".

- in consultation with parties whose interests may be substantially affected, including competent authorities,
- where appropriate, having regard to the Recommended International Codes of Practice of the Codex Alimentarius.

National guides may be developed under the aegis of a national standards institute referred to in Annex I to Directive 98/34/EC <sup>1</sup> 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 as amended by Directive 98/48/EC <sup>2</sup>.

3. Member States shall assess national guides to ensure:

- that the contents of such guides are practicable for the sectors to which they refer,
- that they have been developed in association with representatives of the sector concerned and other interested parties, such as appropriate competent authorities and consumer groups,
- that they have been developed having regard to the Recommended International Code of Practice, General Principles of Food Hygiene, of the Codex Alimentarius,
- that all interested parties substantially affected have been consulted and the relevant comments taken into account,
- their suitability as guides to compliance with the provisions of Articles 3, 4, and 5 in the sectors and/or for the foodstuffs covered.

4. Member States shall forward to the Commission those national guides the compliance of which with paragraph 3 of this Article they have established. The Commission shall set up and run a registration system for such guides <sup>3</sup> and make this available to the Member States.

---

<sup>1</sup> OJ L 204, 21.7.1998, p. 37.

<sup>2</sup> OJ L 217, 5.8.1998, p. 18.

<sup>3</sup> Two delegations suggested that the Commission or the Member States set up an internet site for the publication of the guides.

5. The good practice guides drawn up under Directive 93/43/EC shall continue to apply after the entry into force of this Regulation provided that they comply with the objectives of this Article.

## *Article 8*

### *Community guides*

1. Where a Member State or the Commission considers that there is a need for uniform Community guides to good practice, and/or Community guides on the application of the principles of HACCP (hereinafter referred to as Community guides), the Commission shall consult the relevant Committee referred to in Article 15. The objective of this consultation shall be to consider the case for such guides, their scope and subject matter.
2. Where Community guides are prepared, steps shall be taken to ensure that they are developed with representatives of the sector concerned and other interested parties, such as appropriate competent authorities and consumer groups, taking into account the Recommended International Code of Practice, General Principles of Food Hygiene, of the Codex Alimentarius and any national guides developed in accordance with Article 7.
3. The relevant Committee or Committees referred to in Article 15 shall be responsible for assessing Community guides. Measures shall be taken by such Committee or Committees to ensure that:
  - the contents of such guides are practicable for the sectors to which they refer throughout the Community,
  - all interests substantially affected by such guides have been consulted and the relevant comments taken into account,
  - where they exist, national guides forwarded to the Commission under Article 7(5) have been taken into account,
  - their suitability as guides to compliance with the provisions of Articles 3, 4 and 5 in the sectors and/or for the foodstuffs covered.

4. Where national guides have been drawn up in accordance with Article 7 and subsequently Community guides are compiled in accordance with this Article, food business operators may refer to either.
5. The titles and references of Community guides prepared in accordance with the procedure in paragraphs 1 to 3 shall be published in the C series of *the Official Journal of the European Communities*. Member States shall ensure that the existence of such guides is drawn to the attention of the relevant food business sectors and the appropriate authorities in their territories.

*Article 9<sup>1</sup>*

*Registration or approval of food establishments*

1. Food business operators shall ensure that all establishments under their control and covered by this Regulation are registered with the competent authority/ies outlining the nature of the business, their name and their address. The competent authority/ies shall allocate a registration number to each of these establishments on the basis of a written declaration<sup>2</sup>. In order to facilitate controls by the competent authorities, the latter shall draw up a list of those establishments which they shall update at regular intervals.

[...]<sup>3</sup>

---

<sup>1</sup> The rewording of this Article proposed by the Presidency met with the backing of two delegations; several other delegations expressed reservations or misgivings over specific points (see following notes).

<sup>2</sup> Several delegations expressed reservations or misgivings on a written declaration.

<sup>3</sup> Certain delegations were opposed to the deletion of the paragraph providing for product identification by the registration number of the establishment since the provisions of the Labelling Directive (2000/13/EC) were insufficient to permit traceability.

2. [...] [Where required by more specific Community rules, in particular those referred in Regulation ... laying down specific hygiene rules for food of animal origin, food **establishments** must be approved and shall not operate without such approval. In such a case the approval number shall be substituted for the registration number. The competent authority/ies shall give their approval only where, after an on-site visit by their officials prior to the start-up of any activity, it has been ascertained that the establishment meets all the relevant requirements of this Regulation].<sup>1</sup>
3. The Commission shall consider ways of identifying foodstuffs from the registration number and, if necessary, make relevant proposals under the procedure provided for in Article 15<sup>2</sup>.

<sup>3</sup> [ Article 10

*Withdrawal of products/traceability*

1. Food business operators shall ensure that adequate procedures are in place to withdraw food from the market where such food presents a serious risk to the health of consumers. Where a food business operator becomes aware that a foodstuff presents a serious risk to human health, it shall inform the competent authority as soon as possible and immediately withdraw that foodstuff from the market. The operator shall also be obliged to inform consumers by appropriate means<sup>4</sup>.

---

<sup>1</sup> Reservations by several delegations on the rewording of this paragraph. Three delegations which supported the original Commission proposal, were in favour of a system of prior authorisation; they wanted it to be possible for the competent authorities to fix stricter conditions. Two delegations thought that approval should apply also to primary and/or plant production and to processing businesses where there was a health risk. One delegation underlined the importance of this paragraph for the second proposal. Another delegation was in favour of a general registration system; however, it was against any approval which would not be consistent with the concept of producer liability.

<sup>2</sup> Scrutiny reservation by the Commission representative.

<sup>3</sup> Discussion of this Article has been deferred pending a decision on the question of traceability in the framework of the proposal regarding the general principles and requirements of food legislation; the Commission representative said that the Commission would amend its proposal accordingly.

<sup>4</sup> A recital will be added on the application of the Directive relating to general product safety.

2. Food business operators shall keep an adequate registration system enabling them to identify the ingredients and foods used in their establishment [and, where appropriate, the provenance of the animals used for food production] together with the suppliers, and also the nature of products leaving their establishment and their destination, except where they are handed direct to consumers. They shall keep the registered data for a period which is appropriate to the products' shelf life. The period for which these data must be kept shall be determined by the Commission in accordance with the procedure laid down in Article 15.
  
3. Where necessary to ensure appropriate traceability of food or food ingredients, the Commission shall lay down detailed rules in accordance with the procedure laid down in Article 15].

### *Article 11*

#### *Assistance to control authorities*

Food business operators shall give all assistance needed to ensure that official controls carried out by the competent authority can be performed efficiently. They shall in particular:

- give access to all buildings, premises, installations or other infrastructures used for business purposes,
  
- make available any documentation or registration system required under the present Regulation or considered necessary by the competent authority.

## *Article 12*

### *Imports/exports*

1. Foodstuffs imported into the Community must have been produced in accordance with the provisions of Articles 3, 4, 5 [9 and 10]<sup>1</sup> and any provision laid down pursuant to Article 6, or with provisions which are equivalent to those laid down in this Regulation.
2. Foodstuffs for export out of the Community shall comply with the provisions of Articles 3, 4, 5 and 9 and any provisions laid down under Article 6 and with any additional conditions which may be required by the importing country<sup>2</sup>.

## *Article 13*

### *Amending of annexes and implementing measures*

1. [Provisions in the Annexes to this Regulation may be adapted, supplemented and/or amended in accordance with the procedure laid down in Article 15]<sup>3</sup>.
2. Implementing measures in relation to Articles 4, 5, 9, 10 and 12 may be adopted in accordance with the procedure laid down in Article 15.

## *Article 14*

### *References to international standards*

Amendments to references to standards of the Codex Alimentarius contained in this Regulation may be adopted in accordance with the procedure referred to in Article 15.

---

<sup>1</sup> [Opinion of the Council and Commission Legal Services requested on whether traceability can be required for imported products.](#)

<sup>2</sup> [Reservations by two delegations, which preferred the text of the original proposal.](#)

<sup>3</sup> [Reservations by most delegations](#), which wondered whether the Commission should be given such competence.

Commission reservation on the square brackets.

*Article 15*

*Standing Committee procedure*

1. The Commission shall be assisted by the Standing Veterinary Committee set up by Council Decision 68/361/EEC <sup>1</sup> and by the Standing Committee for foodstuffs set up by European Parliament and Council Decision 69/414/EEC <sup>2 3</sup>.
2. Where reference is made to this paragraph, the Regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Article 7(3) and Article 8 thereof.
3. The period laid down in Article 5(6) of Decision 1999/468/EC shall be three months.

*Article 16*

*Report to Council and Parliament*

The Commission shall submit a report to the European Parliament and the Council, where appropriate with any relevant proposals, within seven years of this Regulation entering into force, concerning any difficulties, in implementing this Regulation.

*Article 17*

*Entry into force*

This Regulation shall enter into force on the date of its publication in the *Official Journal of the European Communities*.

---

<sup>1</sup> OJ L 255, 18.10.1968, p. 23.

<sup>2</sup> OJ L 291, 19.11.1969, p. 9.

<sup>3</sup> The Commission representative announced the planned merger of the two Committees.

It shall apply from [one year after the entry into force of this Regulation].

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

=====



**COUNCIL OF THE  
EUROPEAN UNION**

**Brussels, 20 October 2000 (30.10)  
(OR. fr)**

**12383/00**

**ADD 1**

**Interinstitutional File:  
2000/0178 (COD)**

**LIMITE**

**DENLEG 55  
AGRILEG 149  
CODEC 778**

**ADDENDUM TO OUTCOME OF PROCEEDINGS**

---

of : Working Party of Veterinary Experts  
on : 25 and 26 July and 26 September 2000

---

No. Cion prop. : 10427/00 AGRILEG 116 CODEC 562 - COM(2000) 438 final

---

Subject : Proposal for a Regulation of the European Parliament and of the Council on the hygiene of foodstuffs

---

Delegations will find attached a Presidency drafting suggestion for the above proposal taking into account, as far as possible, their comments at the meeting. Changes in relation to the Commission proposal are underlined and deleted passages marked [...].

*[N.B. For the draft Articles, see document 13050/1/00.]*

ANNEX I

GENERAL HYGIENE RULES FOR PRIMARY PRODUCTION

Preface

This Annex applies to the production of primary products and includes any activity carried out to that effect at that level (farms, hunting, fisheries, aquaculture, etc).

**CHAPTER I**

**Requirements for all food**

[...]

2. Primary production operations [...] must be managed in such a way that hazards that may be presented by the relevant products are monitored and where necessary eliminated or reduced to an acceptable level, taking into account where necessary the specific requirements of normal processing procedures carried out at all stages after primary production. To that end food business operators operating in this area must, where appropriate:

- prevent contamination and control parasitic and infectious diseases of animals and plants;
- adopt practices and measures to ensure that food and food sources are produced and despatched to downstream production centres under appropriate hygienic conditions, in accordance with good agricultural and hygiene practices;

[...]

- inform the competent authority if a problem that may affect human health is suspected.

## CHAPTER II

### Requirements for animals and products of animal origin

1. In the primary production sector for animals and products of animal origin, food business operators must, in order to control the hazards that may be presented by the relevant products and, where necessary, eliminate or reduce them to an acceptable level in accordance with Chapter I above, organise production operations so as to, where appropriate:
  - clean and, where necessary, disinfect in an appropriate manner all animal housing as well as their surroundings and places where animals are brought together, the premises where milk or other animal products are stored and processed, those where animal feed is prepared and those where breeding material is stored;
  - clean and, where necessary, disinfect the equipment needed to care for animals and collect products from them and the vehicles and equipment to transport animals or animal products;
  - take precautions when introducing new animals onto a farm, fish farm, mollusc growing area etc.;
  - make proper use of veterinary medicinal products, complying with prescriptions;
  - make proper and appropriate use of feed additives;
  - dispose of dead animals, waste and litter in a proper manner;
  - take effective insect- and pest-control measures;
  - isolate diseased animals;
  - ensure the cleanliness of slaughter animals;

- ensure that, when animals are collected on the farm, the means of transport used is not likely to damage their health or welfare and that it will permit their transport under the best possible hygienic conditions;
- take protective measures to prevent the introduction of contagious diseases, or diseases transmissible to humans, by external (human, animal, material, etc.) vectors;
- ensure the traceability of feedingstuffs and treatments used;
- produce, prepare, distribute and store animal feedingstuffs under suitable hygienic conditions;
- feed animals a wholesome diet suited to their physiological needs;
- report to the competent authority any major problem on the farm capable of affecting human health if animal products are consumed;
- implement on the farm hygiene control programmes, zoonoses control programmes and herd health surveillance programmes drawn up by health organisations and/or the control authorities.

2. Farmers shall keep records and/or documentation on information relevant to health hazard control, which they shall update regularly.

These records shall contain, inter alia:

- particulars of animals or consignments thereof, the nature and origin of feedingstuffs;
- the animals' health status [...] in regard to controlled diseases;
- a chronological inventory of health, zootechnical and medical data on the animals farmed;

- treatments (veterinary medicinal products) administered to animals, with details of the nature of the treatment, the date on which it was administered and the waiting period;

[...]

- the results of any analyses carried out on samples taken from animals or other samples, taken for pathological purposes, that are relevant to human health, [...]
- any reports from the slaughterhouse about ante- and post-mortem findings.

[...]

3. The records and/or documentation referred to under 2 may replace or supplement records required under other Community or national acts.

These records [...] must be kept for submission to the competent authority on demand during a period to be set by the latter.

4. Information relevant to food hygiene which is contained in these records or documentation must accompany slaughter animals to the slaughterhouse or, where appropriate, animal products to processing factories in order to inform the competent authority and the receiving food operator about the health status of the herd.

### CHAPTER III

#### Requirements for products of plant origin

1. In the primary production sector for products of plant origin, food business operators must, in order to control the hazards that may be presented by the relevant products and, where necessary, eliminate or reduce them to an acceptable level in accordance with Chapter I above, organise production operations so as to, where appropriate:

- make correct and appropriate use of plant-protection products and fertilisers;
- [...] avoid contamination of products by biological, chemical or physical agents such as mycotoxins, heavy metals, radioactive material, etc., including those which could be introduced by water or fertilizer, waste and other organic residues used;

[...]

[...]

- use appropriate production, handling, storage and transport methods;
- clean and, where necessary, disinfect in an appropriate manner machinery, equipment and vehicles used for transport.

2. Operators [...] shall keep records and/or documentation containing information relevant to health hazard control, concerning inter alia:

- the correct and appropriate use of plant-protection products and fertilisers;
- the results of analyses carried out on samples taken on products or of other analysis made;

## **ANNEX II**

### **GENERAL HYGIENE REQUIREMENTS APPLYING TO ALL FOOD BUSINESSES** **(EXCEPT PRIMARY PRODUCTION)**

#### **Introductory remarks**

Chapters V to XII of this Annex apply throughout all stages after primary production during preparation, processing, manufacturing, packaging, storing, transportation, distribution, handling and offering for sale or supply to the final consumer.

The remaining Chapters of the Annex apply as follows:

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

#### **CHAPTER I**

##### **General requirements for food premises including outside areas and sites (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 shall:
  - (a) permit adequate maintenance, cleaning and/or disinfection, avoid or minimise air-borne contamination, and have 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 cross-contamination between and during separate operations from foodstuffs, wrapping and packaging materials, equipment, materials, water, air supply or personnel and external sources of contamination such as insects and other pests;
  - (d) Where it is necessary for the purposes of achieving the objectives of this Regulation, provide suitable temperature-controlled 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 washbasins must be available, suitably located and designated for cleaning hands. 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.
4. Washbasins for cleaning hands must be provided with hot and cold running water, materials for cleaning hands and for hygienic drying. Where necessary to avoid an unacceptable risk of contamination of food, 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 shall be provided with adequate natural or mechanical ventilation.
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 of foodstuffs. 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. Where required for the purposes of hygiene, a sufficient number of adequate changing facilities for personnel must be provided as necessary.

## **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) the design and layout shall permit good food hygiene practices, including protection against cross-contamination between and during operations, and in particular:

- (a) floor surfaces must be maintained in a sound condition and be easy to clean and, if necessary, 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, if necessary, 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 and overhead fixtures must be constructed and finished to prevent the accumulation of dirt and reduce condensation, the growth of undesirable moulds and the shedding of particles.
- (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 of foodstuffs, windows must remain closed and fixed during production.
- (e) doors must be easy to clean and, where necessary, 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.
- (f) 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, if necessary, disinfect. This will require the use of smooth, washable and non-toxic materials unless food business operators can satisfy the competent authority that other materials used are appropriate.

2. Adequate facilities must be provided for the cleaning and disinfecting of working utensils and equipment where this is required for the purposes of achieving the objectives of this Regulation. These facilities must be constructed of materials resistant to corrosion and must be easy to clean and have an adequate supply of hot and cold water.
3. Adequate provision must be made for any necessary washing of food where this is required to achieve the objectives of this Regulation. Every sink or other such facility provided for the washing of food must have an adequate supply of hot and/or cold potable water as required and be kept clean.

### **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 prepared for purposes other than private and domestic consumption, premises used occasionally for catering purposes, and vending machines**

1. Premises and vending machines shall be so sited, designed, constructed and kept clean and maintained in good repair and condition as to avoid the risk of contaminating foodstuffs and harbouring insects and pests, so far as is reasonably practicable.
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) surfaces in contact with food must be in a sound condition and be easy to clean and, if necessary, disinfect. This will require the use of smooth, washable, 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, if necessary, disinfecting of working utensils and equipment;
- (d) where foodstuffs are cleaned as part of the food business's operations adequate provision must be made for this to be undertaken hygienically;
- (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 in order 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 of foodstuffs.

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".

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 must be effective separation of products where necessary in order to protect against the risk of contamination.
4. 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.
5. Foodstuffs in conveyances and/or containers must be so placed and protected as to minimise the risk of contamination.
6. Where it is necessary for the purposes of achieving the objectives of this Regulation, conveyances and/or containers used for transporting foodstuffs must be designed so, that they are capable of maintaining foodstuffs at appropriate temperatures and [...] allow those temperatures to be monitored.

## **CHAPTER V**

### **Equipment requirements**

All articles, fittings and equipment with which food comes into contact shall be kept clean and:

- (a) be so constructed, be of such materials and be kept in such good order, repair and condition as to minimise any risk of contamination of the food;
  - (b) 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 thoroughly cleaned and, if necessary, disinfected, sufficient for the purposes intended;
- be installed in such a manner as to allow adequate cleaning of the surrounding area.

(c) Where necessary, the equipment must be fitted with any appropriate control device to guarantee fulfilment of this Regulation's objectives;

(d) Where chemical additives have to be used to prevent corrosion of equipment and containers, they must be used in accordance with good practices.

## CHAPTER VI

### Food waste

1. Food waste and other refuse must not be allowed to accumulate in food rooms except so far as is unavoidable for the proper functioning of the business.
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 if necessary disinfect.
3. Adequate provision must be made for the removal and storage of food waste and other refuse. Refuse stores must be designed and managed in such a way as to enable them to be kept clean and to protect against access by insects and other pests and contamination of food, potable water, equipment and premises.

Wastewater must be eliminated in a hygienic and environmentally friendly way in accordance with Community legislation applicable to that effect, and must not constitute a source of contamination of the food, either directly or indirectly.

## CHAPTER VII

### Water supply

1. There must be an adequate supply of potable water as specified in Council Directive 98/83/EC relating to the quality of water intended for human consumption <sup>1</sup>. This potable water must be used whenever necessary to ensure that foodstuffs are not contaminated. In the particular case of seafood products, clean seawater may be used where necessary.
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 system and be identified as such. Non-potable water shall not connect with, or allow reflux into, potable water systems.
3. Water which is recycled either to be used in processing or as an ingredient must not present a risk of contamination to the food from microbiological, chemical or physical hazards, and shall be of the same standard as potable water under Directive 98/83/EC, unless the competent authorities in the Member States are 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 lead to any contamination of food must be made from water which meets the specifications referred to in Directive 98/83/EC. It must be made, handled and stored under conditions which protect it from all contamination.
5. Steam used directly in contact with food must not contain any substance which 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 must be ensured that the water used for cooling the containers after heat treatment is not a source of contamination for the foodstuff.

---

<sup>1</sup> [OJ L 330, 5.12.1998, p. 32.](#)

## CHAPTER VIII

### Personal hygiene

1. Every person working in a food-handling area shall maintain a high degree of personal cleanliness and shall wear suitable, clean and, where necessary for the purposes of achieving the objectives of this Regulation, protective clothing.
2. No person suffering from, or [...] being a carrier of a disease likely to be transmitted through food or while afflicted for example with infected wounds, skin infections, sores or diarrhoea shall be permitted to handle food or enter any food-handling area in any capacity if there is any likelihood of directly or indirectly contaminating food [...]. Where necessary in order to achieve the objectives of this Regulation, every person required to handle food must undergo medical fitness checks at appropriate and regular intervals.

## CHAPTER IX

### Provisions applicable to foodstuffs

1. No raw materials or ingredients, or any other material used in processing products, such as wood used for smoking, shall be accepted by a food business if they are known to be, or might reasonably be expected to be, contaminated with parasites, pathogenic micro-organisms or toxic, decomposed or foreign substances that, after normal sorting and/or preparatory or processing procedures hygienically applied by food businesses, they would still be unfit for human consumption.
2. Raw materials and ingredients stored in a food business shall 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. Adequate procedures must be in place to ensure pests are controlled.
4. Raw materials, ingredients, intermediate products and finished products likely to support the growth of pathogenic micro-organisms or the formation of toxins must be kept at temperatures which would not 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, with sufficient separate refrigerated storage to prevent any proliferation. Provided that the objectives of this Regulation are attained, storage conditions may be adjusted in order to take account of the production capacity of the establishment.
5. 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 would not result in a risk to health.

6. The thawing of foodstuffs shall be undertaken in such a way as to minimise the risk of growth of pathogenic micro-organisms or the formation of toxins in the foods. During thawing foods shall be subjected to temperatures which 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 micro-organisms or the formation of toxins.
7. Hazardous and/or inedible substances, including animal feedstuffs, shall be adequately labelled and stored in separate and secure containers.
8. Raw materials used for the manufacture of processed products must have been produced and marketed or imported in accordance with this Regulation.

## **CHAPTER X**

### **Provisions applicable to the wrapping and packaging of foodstuffs**

1. Where necessary to attain the objectives of this Regulation, material used for wrapping and packaging may not be a source of contamination to foodstuffs [...].
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 checked before filling [...].
4. Wrapping and packaging material re-used for foodstuffs must be easy to clean and, where necessary for the purposes of food hygiene, to disinfect.

## **CHAPTER XI**

[...]

## **CHAPTER XII**

### **Training**

Food business operators shall ensure that food handlers are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity.

Food business operators shall ensure that those responsible for the development and maintenance of the HACCP system in a food business have received adequate training in the principles of HACCP.

