

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

(2000/C 365 E/02)

(Text with EEA relevance)

COM(2000) 438 final — 2000/0178(COD)

*(Submitted by the Commission on 14 July 2000)*

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 95 and 152(4)(b) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the Economic and Social Committee,

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,

Whereas:

(1) The protection of human health is of paramount importance.

(2) In the context of the internal market, Council Directive 93/43/EEC of 14 June 1993 on the hygiene of foodstuffs<sup>(1)</sup> has been adopted in order to ensure the safety of foodstuffs for human consumption in free circulation.

(3) This Directive fixes the principles with regard to food hygiene and in particular:

— the standard of hygiene throughout all stages of preparation, processing, manufacturing, packaging, storing, transportation, distribution, handling and offering for sale or supply to the final consumer,

— the need to base the standard of hygiene on the use of hazard analysis, risk assessment and other management techniques to identify, control and monitor critical points,

— the possibility of adopting microbiological criteria and temperature control requirements for certain classes of foodstuffs in accordance with scientifically accepted general principles,

— the development of guides to good hygiene practice to which food businesses may refer,

— the need for the competent authorities of the Member States to ensure the observance of the hygiene rules with the aim of preventing the final consumer from

being harmed by foodstuffs unfit for human consumption,

— the obligation on food operators to ensure that only foodstuffs not harmful to human health are placed on the market.

(4) Experience has shown that these principles constitute a sound basis for ensuring food safety.

(5) In the context of the common agricultural policy, specific health rules affecting the production and placing on the market of products included in the list contained in Annex I to the Treaty have been established.

(6) These health rules have ensured that barriers to trade for the products concerned were removed, thus contributing to the creation of the internal market, whilst ensuring a high level of protection of public health.

(7) These specific rules are contained in a large number of Directives.

(8) With regard to public health, these Directives contain common principles such as those related to the responsibilities of manufacturers of products of animal origin, the obligations of the competent authorities, the technical requirements for the structure and operation of establishments handling products of animal origin, the hygiene requirements which must be complied with in these establishments, the procedures for the approval of establishments, the conditions for storage and transport, the health marking of the products, etc.

(9) Many of these principles are the same as the principles laid down in Council Directive 93/43/EEC.

(10) The principles laid down in Directive 93/43/EEC can therefore be considered to be a common basis for the hygienic production of all food, including products of animal origin included in Annex I to the Treaty.

(11) In addition to this common basis, specific hygiene rules are needed in order to take the specificity of certain foodstuffs into account. The specific hygiene rules for products of animal origin are contained in European Parliament and Council Regulation ... laying down specific hygiene rules for food of animal origin.

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

- (12) The principle objective of the general and specific hygiene rules is to ensure a high level of consumer protection with regard to food safety, taking into account in particular:
- the principle that primary responsibility for food safety rests with the manufacturer,
  - the need to ensure food safety throughout the food chain, starting with primary production,
  - maintaining the cold chain for food that cannot safely be stored at ambient temperatures,
  - general implementation of the hazard analysis critical control points system which, together with the application of good hygiene practice, should reinforce the responsibility of food business operators,
  - that codes to good practice are a valuable instrument for guiding food business operators at all levels of the food chain on the compliance with food hygiene rules,
  - the need to carry out official controls at all stages of production, manufacture and placing on the market,
  - the establishment of microbiological criteria and temperature control requirements based on a scientific assessment of risk,
  - the need to ensure that imported foods are of at least the same or an equivalent health standard.
- (13) Food safety from the place of primary production up to the point of sale to the consumer requires an integrated approach where all food business operators must ensure that food safety is not compromised.
- (14) Food hazards already present at the level of primary production must be identified and adequately controlled.
- (15) Hygiene at farm level can be organised through the use of codes of good practice, supplemented where necessary with specific hygiene rules to be observed during the production of primary products.
- (16) Food safety is a result of several factors including the respect of mandatory requirements, the implementation of food safety programmes established and operated by food business operators and the implementation of the Hazard Analysis Critical Control points system (HACCP).
- (17) The hazard analysis critical control point system in food production should take account of the principles already laid down by the Codex Alimentarius allowing at the same time the flexibility needed for its application in all situations, and in particular in small businesses.
- (18) Flexibility is also needed so as to take account of the specific character of traditional ways of food production and of the supply difficulties that may arise due to geographical constraints; such flexibility must not however compromise the objectives of food safety.
- (19) For food which cannot be safely stored at ambient temperatures, the maintenance of the integrity of the cold chain is a basic principle of food hygiene.
- (20) The implementation of the hygiene rules can be guided by the setting of objectives such as pathogen reduction targets or performance standards and it is necessary to foresee the procedures for that purpose.
- (21) The traceability of food and food ingredients along the food chain is an essential element in ensuring food safety.
- (22) Food businesses should be registered with the competent authority in order to allow official controls to be performed efficiently.
- (23) Food operators shall give all assistance required in order to ensure that official controls can be carried out efficiently by the competent authorities.
- (24) Food imported into the Community shall be of the same hygiene level as the food obtained in the Community, or be of level equivalent thereto.
- (25) In order to ensure a high level of protection and to prevent deflections of trade, food obtained in the Community and exported towards third countries shall not be of a lesser hygiene standard than the food produced and consumed within the Community.
- (26) Scientific advice must underpin Community legislation on food hygiene; to this end, the scientific committees in the field of consumer protection and food safety set up by Commission Decision 97/579/EC of 23 July 1997 <sup>(1)</sup> and the Scientific Steering Committee set up by Commission Decision 97/404/EC of 10 June 1997 <sup>(2)</sup> should be consulted wherever necessary.
- (27) In order to take account of technical and scientific progress, a procedure should be available to adopt certain requirements called for in the present Regulation.

<sup>(1)</sup> OJ L 237, 28.8.1997, p. 18.

<sup>(2)</sup> OJ L 169, 27.6.1997, p. 85.

(28) The present Regulation takes into account the international obligations laid down on the WTO-Sanitary and Phytosanitary Agreement and in Codex Alimentarius.

(29) The present recast of existing Community hygiene rules means that the existing hygiene rules can be repealed; this is achieved through Council Directive .../.../EC 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.

(30) Since the measures necessary for the implementation of this Regulation are measures of general scope within the meaning of Article 2 of Council Decision 1999/468/EEC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission <sup>(1)</sup>, they should be adopted by use of the regulatory procedure provided for in Article 5 of that Decision,

HAVE ADOPTED THIS REGULATION:

#### 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 offering for sale or supply of a foodstuff to the final consumer. This Regulation shall apply without prejudice to more specific requirements relating to food safety, and does not cover issues relating to nutrition or compositional matters.

It applies to food businesses and 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,
- 'food safety' means the assurance that food will not cause adverse health effects to the final consumer when it is prepared and eaten taking into account its intended use,
- 'food business' means any undertaking, whether for profit or not and whether public or private, carrying out any or

all of the stages from and including primary production up to and including the offering for sale or supply of foodstuffs to the final consumer,

— '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 products of the soil, of stock farming, of hunting and fisheries,

— '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,

— 'certification' means the procedure by which the competent authorities provide written or equivalent assurance of conformity to requirements,

— 'equivalence' means the capability of different systems to meet the same objectives,

— 'hazard' means a biological, chemical or physical agent with the potential to compromise food safety,

— 'contamination' means the presence of a substance not intentionally added to the food or present in the food environment, which may compromise the safety or fitness for human consumption of the food,

— 'marketing' means holding, displaying and offering for sale, selling, delivering or any other form of placing on the market in the Community,

— '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, shops, supermarket distribution centres, wholesale outlets selling wrapped and packaged foodstuffs,

— 'final consumer' means the ultimate consumer of a foodstuff who shall not use the food as part of any food business operation or activity,

— '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,

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

- '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 can be considered to be packaging,
- 'products of animal origin' means foodstuffs obtained from animals, including honey,
- 'product of plant origin' means foodstuffs obtained from plants,
- '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,
- '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; substances necessary for their manufacture or for giving specific characteristics to the products may be added,
- 'hermetically sealed container' means a container that 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.

#### Article 3

##### General obligation

Food business operators shall ensure 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.

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 adapt the requirements laid down in Annex II with a view to accommodate the needs of food businesses situated in regions suffering from special geographical constraints or affected by supply difficulties which are serving the local market, or with a view to take account of traditional methods of production. The objectives of food hygiene shall not be compromised.

Member States having recourse to this possibility shall inform the Commission and the other Member States thereof. Member States shall have one month 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).

#### Article 5

##### Hazard analysis and critical control points system

1. Food business operators other than at the level of primary 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.

2. Food business operators shall establish procedures to verify whether the measures outlined in paragraph 1 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.

3. Food business operators shall establish documents and records commensurate to the nature and size of the food business to demonstrate the effective application of the measures outlined in paragraphs 1 and 2, and to facilitate official controls. Such documents shall be kept by the food business operator for at least the time of the shelf life of the product.

4. As part of the system referred to in paragraphs 1, 2 and 3, 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.

5. In accordance with the procedure referred to in Article 15, the Commission may adopt measures in order to facilitate the implementation of this Article, in particular in small businesses.

#### Article 6

##### Specific food safety requirements

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

1. Microbiological criteria and temperature criteria for foodstuffs may be adopted and/or amended.
2. Targets and/or performance standards in order to facilitate the implementation of this Regulation may be set.

#### Article 7

##### National guides to good practice and guides to the application of HACCP

1. Member States shall encourage the development of guides to good practice which shall include guidance on the compliance with Article 3, 4 and where Article 5 applies, the application of the principles of HACCP (hereinafter referred to as national guides).

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,
- in consultation with interests 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,

- have been developed in association with representatives of the sector concerned and other interested parties, such as appropriate competent authorities and consumer groups,

- 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. Twelve months following the coming into force of this Regulation, and thereafter annually, the Member States shall forward to the Commission a report concerning the steps taken to develop national guides specified in paragraph 1.

5. Member States shall forward to the Commission those national guides which they have determined to comply with paragraphs 3 of this Article. The Commission shall keep a register of such guides and make this available to the Member States.

#### 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.

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

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

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 produced in accordance with Article 7 and subsequently Community guides are produced 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 such published guides are drawn to the attention of the relevant food business sectors and the appropriate authorities in their territories.

#### Article 9

##### Registration or approval of food businesses

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, the name and address of all premises where food business activities are carried out. The competent authority/ies shall allocate a registration number to each food establishment and keep an up to date list thereof.

2. Food business operators except those operating at retail level shall ensure that foodstuffs produced by them are identified with their registration number.

3. Where the competent authority/ies considers it necessary for the purposes of assuring that the requirements of this Regulation are met, or where required by more specific

Community rules, food businesses must be approved and shall not operate without such approval. The competent authority shall only approve those establishments where, after a visit by officials of the competent authority/ies it has been ascertained that all the requirements of this regulation are met.

#### 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 identifies that a foodstuff presents a serious risk to health it shall immediately withdraw that foodstuff from the market. When a serious risk has been identified and when a foodstuff has been withdrawn from the market due to risk to the health of the consumer, food business operators shall immediately inform the competent authority thereof.

2. Food business operators shall keep adequate records which enable them to identify the supplier of ingredients and foods used in their operation and where appropriate the provenance of the animals used for food production.

3. Where necessary to ensure appropriate traceability of food or food ingredients, the Commission shall lay down detailed rules in accordance with the procedure provided for in Article 15.

#### Article 11

##### Official controls

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,
- make available any documentation and record required under the present Regulation or considered necessary by the competent authority for judging the situation.

#### Article 12

##### Imports/exports

1. Foodstuffs imported into the Community shall comply with the provisions of Articles 3, 4 and 5 and any provision laid down pursuant to Article 6, or with provisions that are equivalent to those laid down in this Regulation.

2. Foodstuffs for exportation out of the Community shall comply with the provisions of Articles 3, 4, 5, 9 and any provisions laid down under Article 6, except where the importing country specifies otherwise.

*Article 13***Amending of annexes and implementing measures**

1. Provisions in the Annexes to this Regulation may be repealed, adapted, supplemented and/or amended in accordance with the procedure laid down in Article 15.
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 international standards contained in this Regulation, such as those of the Codex Alimentarius, may be adopted in accordance with the procedure referred to in Article 15.

*Article 15***Standing committee procedure**

1. The Commission shall be assisted by the Standing Veterinary Committee instituted by Council Decision 68/361/EEC <sup>(1)</sup> and by the Standing Committee for foodstuffs, instituted by European Parliament and Council Decision 69/414/EEC <sup>(2)</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 provided for in Article 5(6) of Decision 1999/468/EC shall be 3 months.

*Article 16***Report to Council and Parliament**

1. 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, reviewing the experience gained from implementing this Regulation.
2. In order to allow the Commission to establish the report referred to in paragraph 1, Member States shall submit all necessary information to the Commission 12 months before the period referred to in paragraph 1.

*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*.

It shall apply from 1 January 2004.

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

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

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

## 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, etc).

## CHAPTER I

**Requirements for all food**

1. Possible hazards occurring in primary production and methods to control such hazards shall, where possible, be addressed in the guides to good practice referred to in Articles 7 and 8. These guides may be combined with other guides or codes of practice required in particular under other relevant Community legislation.
2. Primary production shall be carried out in accordance with good practice and managed in such a way that hazards are monitored and where necessary eliminated or reduced to an acceptable level, taking into account normal processing procedures carried out after primary production. This includes, where appropriate,
  - adopting practices and measures to ensure that food and food sources are produced under appropriate hygienic conditions,
  - adopting measures with regard to hazards from the environment,
  - controlling contaminants, pests, diseases and infections of animals and plants,
  - the obligation to inform the competent authority if a problem that may affect human health is suspected.

## CHAPTER II

**Requirements for products of animal origin**

1. In the codes of good practice, actions to be taken in order to ensure the hygiene of food shall be described. This includes, where appropriate:
  - implementing suitable cleaning and disinfection procedures for animal housing, equipment, premises, transport crates and vehicles, etc.,
  - taking precautions when introducing new animals onto a farm, fish farm, molluscs growing area, etc.,
  - proper use of veterinary medicinal products and feed additives,
  - proper disposal of dead animals, waste and litter,
  - implementing effective pest-control programmes,
  - isolating diseased animals,
  - the cleanliness of slaughter animals,
  - protective measures to prevent the introduction of contagious diseases or diseases transmissible to humans,
  - the possible hazards associated with feedingstuffs,
  - a description of the problems that may affect human health and that need to be reported to the competent authority,
  - the implementation of hygiene control programmes, zoonoses control programmes and herd health surveillance programmes.
2. Farmers shall keep records or documentation containing information relevant to health protection. They shall in particular include information on:
  - the nature and origin of feedingstuffs,
  - the animal health status and the welfare of the animals at the farm,

- the use of veterinary medicinal products (nature of the treatment and date of application),
- the occurrence of diseases which may affect the safety of products of animal origin (e.g. udder infections),
- the results of any analyses carried out on samples taken from animals or other samples that have importance to human health, in particular with regard to control programmes for certain zoonotic agents,
- any reports from the slaughterhouse about ante- and post-mortem findings.

Farmers shall be assisted by the those responsible for the animals at the farm (veterinarians, agronomists, farm technicians. etc.) for completing the above records or documentation.

Records or documentation may be combined with records that may be required under other Community or national acts. Farmers must keep the records or documentation referred to above for submission to the competent authority on demand during a period to be set by the latter.

Information relevant to food safety 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 codes of good practice, actions to be taken in order to ensure the hygiene of food shall be described. This includes, where appropriate:
    - the correct and appropriate use of plant-protection products and fertilisers,
    - appropriate production, handling, storage and transport methods,
    - practices and measures to avoid contamination with biological, chemical or physical hazards such as mycotoxins, heavy metals, radioactive material, etc.
    - the use of water in primary production,
    - the use of organic waste in primary production,
    - the cleaning and where necessary disinfection of machinery, equipment and vehicles used for transport.
  2. Farmers, where necessary assisted by those responsible for the hygiene at the farm (agronomists, farm technicians, etc.), shall keep records or documentation containing information relevant to health protection, and in particular on:
    - 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.
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## 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 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 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, 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 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 pests, so far as is reasonably practicable.
2. In particular and 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 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 capable of maintaining foodstuffs at appropriate temperatures and designed to 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;
- (c) be installed in such a manner as to allow adequate cleaning of the surrounding area.

## 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 pests.

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.
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.

## 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 known to be 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 enter any food-handling area in any capacity if there is any likelihood of directly or indirectly contaminating food with pathogenic micro-organisms. Any person so affected and employed in a food business and who is likely to come into contact with food shall immediately report illness or symptoms to the food business operator.

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

## CHAPTER IX

**Provisions applicable to foodstuffs**

1. No raw materials or ingredients 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. For processed foodstuffs 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 contamination.
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. Measures shall be taken to ensure that wrapping and packaging materials are not a source of contamination to foodstuffs. Wrapping and packaging materials must be manufactured transported and supplied to food businesses in such a manner that they are protected from any contamination that may present a risk to health.
2. Wrapping materials must be stored in such a manner that they are not exposed to a risk of contamination, in particular contamination arising from food, the storage environment, cleaning substances and pests.
3. In food businesses where packing operations are carried out in the presence of exposed products measures must be taken to avoid contamination of these products. In particular, the room where packaging operations are undertaken must be of sufficient size, construction and design to allow for hygienic operations. Packaging materials must be assembled prior being brought into the packaging area and used without delay. Where packaging materials are to be lined with a wrapping material this must be carried out hygienically.
4. Wrapping and packaging material must only be re-used for foodstuffs if it is made of materials that are easy to clean and where necessary for the purposes of food hygiene, disinfect.

## CHAPTER XI

**Special conditions for certain processing operations**1. *Processing by heat treatment*

- the food must be processed in accordance with a scheduled heat treatment possibly associated with other methods to control microbiological hazards; equipment for the heat-treatment must be fitted with all control devices necessary to ensure that an appropriate heat treatment is applied,
- if the heat treatment, possibly combined with other hurdles is not sufficient to ensure the stability of the products, a rapid cooling to the specified storage temperature must be applied after heating so that the critical temperature zone for spore germination and subsequent growth is passed through as rapidly as possible,
- if the heat treatment is applied before wrapping, measures must be taken to prevent recontamination of the food after heating and before filling,
- 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 confirmed before filling,
- where the 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. Chemical additives to prevent corrosion of equipment and containers must be used in accordance with good practices,
- in the case of a continuous heat treatment of liquid food, the mixture of heat-treated liquid with incompletely heated liquid must be adequately prevented.

2. *Smoking*

- fumes and heat must not affect other operations,
- materials used for smoke production must be stored and used in such a way as to avoid contamination of foodstuffs,
- the combustion for smoke production of wood which is painted, varnished, glued or has undergone any chemical preservation is prohibited.

3. *Salting*

Salts used for the treatment of foodstuffs must be clean and must be stored in such a way as to prevent contamination. Salts may be re-used after cleaning where HACCP procedures have demonstrated that there is no risk of contamination.

## 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.

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