

COMMISSION OF THE EUROPEAN COMMUNITIES

COM(92) 547 final - SYN 376

Brussels, 10 December 1992

Amended proposal for a

COUNCIL DIRECTIVE

on the hygiene of foodstuffs

(presented by the Commission pursuant to Article 149(3)
of the EEC-Treaty)

Explanatory memorandum

1. This proposal introduces wholly or partly those amendments voted on 29 October 1991 by the European Parliament which the Commission, subject to changes in drafting, can accept.

The table below summarizes the content of the amendments and the Commission's comment on them.

RECITAL ARTICLE	AMEND- MENT	CONTENT	ACCEPT Y/N	COMMENT
Recital	1	Paramount concern protection human health	Y	
Recital	2	Exclusion of primary production and introduction of preparation stage	Y	Increase of clearness - with editorial changes
Recital	3	Hygiene requirement for products exported to third countries	Y	In line with Commission policy
Recital	4	Elaborates HACCP Principles	Y	Increase of clearness with editorial changes
Recital	5	Relationship with more specific Community rules	N	Superfluous
Recital	6	Extension of Community microbiological criteria to other criteria	Y/N	Commission can accept to include criteria for temperature control but no others
Recital	7	Makes reference of documents of good hygiene practice to Codex Alimentarius obligatory	Y	With editorial changes
Recital	8	Makes documents of good hygiene practice binding	N	It is essential that these documents are voluntary
Recital	9	Precedence of public health over legitimate rights of food businesses	N	Does not make sense
Recital	10	Indicates that a high level of safety is the reason why the Commission needs to be aware of the competent authorities in the Member States	Y	Stands to reason
Recital	11	Need for Community standards for education and training for workers in the food industry	N	Commission will carry out feasibility study on this subject
Article 1	12	Directive supplements and overrides more specific Community rules	N	Commission will study relationship and if necessary make proposals
Article 1	13	Consolidation of more specific Community rules in this Directive	N	Superfluous
Article 2	14	Exclusion of primary production and introduction of preparatory stage	Y	Increase of clearness with editorial changes
Article 2	15	Define "food business" more clearly	Y	With editorial changes
Article 3	16	Introduces preparation stage to the scope of the Directive	Y	Increase of clearness with editorial changes
Article 3	17	Introduces process safety and extends use of HACCP to similar systems	Y/N	First part outside scope - second part with editorial changes
Article 3	18	Keeping of adequate documentation by food businesses for the purpose of facilitating enforcement	N	Requirement is unreasonable and subject to fraude
Article 4	19	Makes rules of the Annex subject to the nature of the foodstuff involved	N	Escape possibilities too many

RECITAL ARTICLE	AMEND- MENT	CONTENT	ACCEPT	COMMENT
Article 4	20	See amendment 6	Y/N	
Article 5	21, 22 23, 24	Changes the basis of the documents of good hygiene practice	N	Commission will redraft this article completely
Article 6	25	Requires compliance with EN 29000 standards	N	Too demanding
Article 7	26	Requires competent authorities to be government accredited	N	This Directive is not the right place for such an amendment
Article 7	27	Requires certain frequency of inspection for all food businesses	N	This Directive is not the right place for such an amendment
Article 8	28	Requires closure of the undertaking until food produced is deemed by the competent authorities to satisfy the requirements of the Directive	N	Unnecessary may contravene with product liability rules
Article 9	29	Gives the undertaking the right to compensation if on appeal it is found that incorrect action has been enforced	Y	Seems fair
Article 9	30, 31	Obliges Member State to report to the Commission annually on levels of compliance	N	Superfluous, is already foreseen under art.14 of Directive 89/397/EEC on the official control of foodstuffs
Article 10	32	Asks Commission to undertake study on Community wide standards for education and training of food handlers	Y	Commission needs more time than proposed 2 years with editorial changes
4 Article 10	33	Modification of the Committee procedure of Directive 87/379/EEC	N	This Directive is not the right place to do so
New Article	34	Safety clause on imported foodstuffs from third countries	Y	
Annex - Chapter I	35	Refers to health and safety of the workers	N	This directive is not the right place to do so
Annex - Chapter I	36	Extends scope of this paragraph	Y/N	Water and materials are acceptable rest not
Annex - Chapter I	37	Location and number of lavatories and washbasins	Y/N	Improves scope, partly unnecessary with editorial changes
Annex - Chapter I	38	Requires temperature controlled running water	N	Either superfluous or inadequate
Annex - Chapter I	39	Introduces temperature requirements for perishable foodstuffs	N	Adequately covered with new article 4
Annex - Chapter II	40	Requirements for storage	N	Too demanding
Annex - Chapter II	41	Floors must be able to be kept clean and made of non-slip materials	Y/N	First part acceptable with editorial changes, second part not because this Directive is not the right place for it

RECITAL ARTICLE	AMEND-MEND	CONTENT	ACCEPT Y/N	COMMENT
Annex Chapter II	42	Walls must be easy to clean and disinfect and maintained in sound condition	Y	Improves clearness
Annex Chapter II	43	Requirements on overhead fixtures and prevention of infestation	Y/N	Improves scope (first part) Second part too demanding
Annex Chapter II	44	Accumulation of pathogenic micro-organisms and food debris	N	Too demanding
Annex Chapter II	45	Requires temperature controlled running water	N	Superfluous and inadequate
Annex Chapter II	46	Potable water only for sinks designated for washing of foodstuffs	Y	Improves text
Annex Chapter II	47	Requires separate hand and food washing facilities	N	Too demanding
Annex Chapter III	48	Articles, fittings and equipment must be readily cleanable	Y/N	Principle accepted, will be covered by general clause
Annex Chapter III	49	Removes escape-clause and covers also design of equipment	N	Too demanding
Annex Chapter III	50	Provisions for prefabricated kitchens	N	Superfluous
Annex Chapter IV	51	Food waste and refuse in closable containers	Y	More hygienic
Annex Chapter IV	52	Refuse to be removed by specialized undertakings	N	Too demanding and outside scope of this Directive
Annex Chapter V	53	Potable water only for washing of foodstuffs, preparation and handling	Y	With editorial changes
Annex Chapter VI	54	Detailed requirements for personal hygiene of foodhandling	N	To be dealt with in codes
Annex Chapter VI	55	Adequate supervision on persons suffering from a disease	N	Superfluous

RECITAL ARTICLE	AMEND- MEND	CONTENT	ACCEPT Y/N	COMMENT
Annex Chapter VII	56	Storage condition for packaging materials	N	Unnecessary
Annex Chapter VII	57	Changes "no cross contamination" into "minimize cross contamination"	Y	Improves text
Annex Chapter VII	58	Requirement for contaminated foodstuffs	N	Not the right place
Annex Chapter VIII	59	Deletes provision in training	Y	To be replaced by corresponding article
Annex New Chapter	60	Rejected by Parliament		
	61	Rejected by Parliament		
Article 3	62	Allows for derogations from the Annex via a Committee Procedure	Y	
	63	Rejected by Parliament		
Annex New Chapter	64	Defines conditions for transport of foodstuffs	N	Too demanding

Council Directive

on the hygiene of foodstuffs

In response to the opinion delivered by the European Parliament (1) on the proposal for a Council Directive on the hygiene of foodstuffs (2) and in accordance with the third paragraph of Article 149 of the Treaty establishing the European Community, the Commission has decided to amend the above-mentioned proposal as follows:

1. Add as a first recital (new)

Whereas the protection of human health is of paramount concern:

2. Replace the third recital by

Whereas after primary production the general rules of hygiene for foodstuffs to be respected at the time of processing, manufacturing, packaging, storing, transportation, distribution, handling, preparation and sale to the ultimate consumer of foodstuffs should be harmonised in order to protect human health;

(1)

(2) OJ No C24 31.1.1992 page 11

3. Introduce a new recital

Whereas it is appropriate for the hygiene rules applicable to foodstuffs for consumption in the European Community to be the same as the hygiene rules for foodstuffs intended for export to third countries;

4. Replace the fourth recital by

Whereas the use of hazard analysis, risk assessment and other management techniques to identify, control and monitor critical control points is recognised;

5. Replace the 5th recital by

Whereas microbiological and temperature control criteria for certain classes of foodstuffs should be adopted in accordance with scientifically accepted general principles, in order to protect human health;

6. Replace the 6th recital by

Whereas the use of documents on good hygiene practice within the Community shall be recommended and where appropriate be based on the relevant codes of practice of the Codex Alimentarius;

7. Replace the 12th recital by

Whereas in order to ensure a high level of safety the Commission must be aware of the competent authorities in the Member States responsible for the official control of food hygiene;

8. Replace the 1st Indent of Article 2 by

"food hygiene" means all measures necessary to ensure the safety and wholesomeness of food at all stages after its primary production during processing, manufacturing, packaging, storing, transportation, distribution, handling, preparation and sale to the final consumer;

9. Replace the 2nd Indent of Article 2 by

"food business" means any undertaking, whether for profit or not and whether public or private, carrying out any or all of the following: preparation, processing, manufacturing, packaging, storing, transportation, distribution, handling or offering for sale or supply of foodstuffs;

10. Replace the first paragraph of Article 3 by

The processing, manufacturing, packaging, storing, transportation, distribution, handling, preparation and sale of foodstuffs shall be carried out in an hygienic way;

11. Replace the second paragraph of Article 3 by

Food business operators shall identify any step in their activities which is critical to ensuring food safety and ensure that adequate safety procedures are identified, implemented, maintained and reviewed using the principles which have been used in developing the system of HACCP (Hazard Analysis and Critical Control Points).

12. Replace the third paragraph of Article 3 by

Food businesses shall comply with the rules of hygiene for foodstuffs as listed in the Annex to this Directive. Derogations from certain provisions of the Annex may be granted according to the procedure laid down in article 10.

13. Replace Article 4 by

Microbiological criteria and temperature control criteria for certain classes of foodstuffs may be adopted in accordance with the procedure laid down in article 10 and after consulting the Scientific Committee for Foodstuffs as installed by Decision 74/234/EEC (10) or any other procedure provided for in more specific Community rules.

14. Replace Article 5 by

1. Member States shall encourage the development of documents on good hygiene practice which may be used voluntarily by food businesses as a guide to compliance with the provisions of Article 3.

2. Where the documents on good hygiene 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, for example, appropriate authorities and consumer groups;
- in consultation with interests substantially affected including competent authorities;
- where appropriate, having regard to the Recommended

International Code of Practice, General Principles of Food
(13) Codex Alimentarius Commission (13) International Code of Practice, General Principles of Food Hygiene, Second Revision (1985), Food and Agricultural Organization of the United Nations World Health Organization, Rome, 1988.

3. The documents referred to in paragraph 1 and 2 may be developed under the aegis of a national standards institute referred to in list 2 of the Annex to Directive 83/189/EEC.
4. Member States shall assess the documents on good hygiene practice referred to in paragraphs 1 and 2 with a view to determining to what extent they can be presumed to comply with article 3.
5. Member States shall transmit to the Commission those documents on good hygiene practice which they presume to comply with article 3. Likewise, the Commission shall assess these documents of good hygiene practice and make them available to the other Member States in case they comply with Article 3.

6. here one or more Member States, or the Commission consider that, for the purposes of harmonisation, there may be a need for the voluntary documents on good hygiene practice to be developed on a European basis (hereafter referred to as European documents on good hygiene practice), the Commission shall consult Member States in the framework of the Standing Committee on Foodstuffs in accordance with article 10 of this Directive to:

- consider the case for such voluntary documents in the sectors or activities concerned and, where it considers such documents are needed:
- indicate the intended scope, subject matter and timetable for development of such voluntary documents, taking into account the time needed for consultation with interests substantially affected by them; and
- refer such voluntary documents for development under the aegis of a European standards institute.

7. The titles and references of European documents on good hygiene practice developed in accordance with the procedure in paragraphs 6 and 7 shall be published in the appropriate non-legislative series of the Official Journal of the European Communities. Member States shall ensure that such published documents are drawn to the attention of the relevant food business sectors and the appropriate authorities in their territories.

15. Add third paragraph to Article 8,

If on appeal it is found that the measures taken by the appropriate authorities cannot be substantiated the undertaking shall have a right to compensation.

16. Add new Article:

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

17. Add new Article

1. If a food hygiene problem likely to pose a serious risk for human health appears or spreads in the territory of a third country, the Commission, either on its own initiative or at the request of a Member State, shall, without delay, take one of the following measures depending on the seriousness of the situation:

- suspend imports from all or part of the third country concerned and, where necessary, from the transit third country;
- lay down special conditions for foodstuffs from all or part of the third country concerned.

2. The Commission may, in the situation provided for in paragraph 1, take interim protective measures regarding the foodstuffs concerned.
3. The Commission shall, whenever possible, consult with Member States before taking action in accordance with paragraphs 1 and 2.
4. The Commission shall immediately notify the Council and the Member States of any decision taken pursuant to paragraphs 1 and 2.

Any Member State may, within 30 days of notification, refer the Commission's decision to the Council. The Council, acting by a qualified majority, may confirm, amend or revoke the decision adopted by the Commission. If the Council has not taken a decision within 60 days the decision of the Commission shall be deemed to be revoked.

5. In the event that a Member state officially informs the Commission of the necessity of taking safeguard measures and the Commission has not had recourse to the provisions of paragraph 1 or 2, it may take interim protective measures with regard to imports of the foodstuffs in question.

When a Member State takes interim protective measures it shall immediately inform the other Member States and the Commission.

Within 10 working days the Commission shall put the matter before the Standing Committee for Foodstuffs with a view to a decision, in accordance with the procedure laid down in Article 10, on the extension, amendment or abrogation of the national interim protective measures.

18. Change chapter I, paragraph 1 (c) of the Annex in

permit good food hygiene practices, including protection against cross contamination between operations by foodstuffs, equipment, materials, water, air supply or personnel and external sources of contamination such as pests.

19. Change chapter I, paragraph 2 of the Annex in

an adequate number of washbasins must be available, suitably located and designated for cleaning hands. Adequate flush lavatories must be available and connected to an effective drainage system. Lavatories must not lead directly into rooms in which food is handled.

20. Change chapter II, paragraph 1 (a) of the Annex in

Floor surfaces must be maintained in a sound condition and they must be easy to clean and disinfect. This will require the use of impervious non-absorbent, washable and non-toxic materials.

21. Change chapter II, paragraph 1 (b) of the Annex in

walls must be constructed of impervious, non-absorbent, easy to clean and disinfect non-toxic materials; their surface must be smooth and maintained in a sound condition up to a height appropriate for the operations;

22. Change chapter II, paragraph 1 (c) of the Annex In

ceilings and overhead fixtures must be designed, constructed and finished to prevent the accumulation of dirt, to reduce condensation, the growth of moulds and the shedding of particles, and to prevent the risk of infestation.

23. Change chapter II, paragraph 3 of the Annex In

When appropriate, adequate provisions must be provided for any necessary washing of the food. Every sink or other such facility provided for the washing of food must have an adequate supply of water in accordance with Council Directive 80/778/EEC as required and be kept clean.

24. Add new paragraph to chapter IV of the Annex

Food waste and other refuse should be deposited in lidded containers. These containers should be of an appropriate construction, kept in sound condition, be easy to clean and appropriately labelled.

25. Change part V, paragraph 1 of the Annex In

There must be an adequate supply of potable water as specified in Council Directive 80/778/EEC relating to the quality of water intended for human consumption for use in the washing of foodstuffs, preparation and handling.

26. Change part VII, paragraph 3, second sub-paragraph In

In particular, food must be so placed as to minimise any risk of cross-contamination.

27. Delete part VIII of the Annex

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DOCUMENTS

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