

## II

(Acts whose publication is not obligatory)

## COUNCIL

## COUNCIL DIRECTIVE

of 20 June 1989

on hygiene and health problems affecting the production and the placing on the market of egg products

(89/437/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 43 thereof,

Having regard to the proposal from the Commission <sup>(1)</sup>,

Having regard to the opinion of the European Parliament <sup>(2)</sup>,

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

Whereas, in order to ensure the smooth operation of the common market and more especially of the common organization of the market in eggs established by Regulation (EEC) No 2771/75 <sup>(4)</sup>, as last amended by Regulation (EEC) No 3907/87 <sup>(5)</sup>, and of the common system of trade for ovalbumin and lactalbumin introduced by Regulation (EEC) No 2783/75 <sup>(6)</sup>, as amended by Regulation (EEC) No 4001/87 <sup>(7)</sup>, it is essential that the marketing of egg products should no longer be hindered by disparities existing between Member States in respect of health requirements in this area; whereas this will enable production to be better harmonized and bring about competition on equal terms while assuring consumers of a quality product;

Whereas the marketing of certain egg products which are not covered by Annex II to the Treaty is closely linked with the marketing of egg products for which a market organization exists; whereas distortions of competition should be eliminated for all egg products;

Whereas it appears appropriate to exclude from the scope of this Directive egg products which are obtained in small scale enterprises, shops or restaurants and used for the manufacture of foodstuffs intended for direct sale to the final consumer or to be consumed on the spot;

Whereas health requirements should be laid down for the production, storage and transport of egg products; whereas, in particular, it is important that rules be laid down governing the approval of establishments;

Whereas it is important also that the health requirements to be met by egg products be laid down;

Whereas the said rules must apply in an identical manner to intra-Community trade and to trade within the Member States;

Whereas it is the responsibility primarily of producers to ensure that egg products meet the health requirements laid down in this Directive; whereas the competent authorities of the Member States must, by carrying out checks and inspections, see to it that producers comply with the abovementioned requirements; whereas the rules governing these checks and inspections must take account of the demands of the internal market;

Whereas a random check must be made to detect the presence of residues of substances liable to be harmful to human health;

<sup>(1)</sup> OJ No C 67, 14. 3. 1987, p. 9 and OJ No C 53, 2. 3. 1989, p. 10.

<sup>(2)</sup> OJ No C 187, 18. 7. 1988, p. 184.

<sup>(3)</sup> OJ No C 232, 31. 8. 1987, p. 1.

<sup>(4)</sup> OJ No L 282, 1. 11. 1975, p. 49.

<sup>(5)</sup> OJ No L 370, 30. 12. 1987, p. 14.

<sup>(6)</sup> OJ No L 282, 1. 11. 1975, p. 104.

<sup>(7)</sup> OJ No L 377, 31. 12. 1987, p. 44.

Whereas Community control measures should be introduced to guarantee the uniform application in all Member States of the standards laid down in this Directive;

Whereas, in the context of intra-Community trade, the consignor, the consignee or their representative must be given the opportunity, where a dispute arises with the competent authorities of the Member States of destination, of seeking an expert's opinion;

Whereas egg products manufactured in a third country intended to be placed on the market on Community territory must not qualify for more favourable arrangements than those laid down in this Directive; whereas provision should be made for a Community procedure for inspecting establishments in third countries;

Whereas the Commission should be entrusted with the task of adopting certain measures for implementing this Directive; whereas, to that end, procedures should be laid down introducing close and effective cooperation between the Commission and the Member States within the Standing Veterinary Committee,

HAS ADOPTED THIS DIRECTIVE:

#### Article 1

This Directive lays down hygiene and health requirements concerning the production and the placing on the market of egg products for direct human consumption or for the manufacture of foodstuffs.

However, this Directive shall not apply to:

- finished foodstuffs manufactured from egg products, as defined in Article 2 and which meet with the provisions of Article 3,
- egg products which are obtained in small scale enterprises and which, without having undergone any treatment, are used for the manufacture of foodstuffs intended for direct sale, without any intermediary, to the consumer or consumed on the spot immediately after having been prepared.

#### Article 2

For the purposes of this Directive, the definition given in Article 1 (2) of Regulation (EEC) No 2772/75<sup>(1)</sup> shall apply. The following definitions shall also apply:

1. egg products: products obtained from eggs, their various components or mixtures thereof, after removal of the shell and membranes, intended for human consumption; they may be partially supplemented by other foodstuffs or additives; they may be liquid, concentrated, dried, crystallized, frozen, quick-frozen or coagulated;

2. farm of production: without prejudice to Regulation (EEC) No 2782/75<sup>(2)</sup>, farm for the production of eggs intended for human consumption;
3. establishment: establishment approved for the manufacture and/or treatment of egg products;
4. cracked eggs: eggs with a damaged but unbroken shell, with intact membranes;
5. batch: a quantity of egg products which have been prepared under the same conditions and in particular treated in a single continuous operation;
6. consignment: a quantity of egg products for a single delivery to one destination for further processing by the food industry or intended for direct human consumption;
7. country of dispatch: the Member State or third country from which egg products are dispatched to another Member State;
8. country of destination: the Member State to which egg products are dispatched from another Member State or from a third country;
9. packing: the placing of egg products in any form of package;
10. competent authority: the veterinary department or any other equivalent department designated by the Member State concerned to monitor compliance with the provisions of this Directive;
11. placing on the market: the marketing of egg products, as defined in point 5 of Article 1 of Regulation (EEC) No 2772/75.

#### Article 3

Member States shall ensure that only egg products which meet the following general requirements are produced as foodstuffs or used in the manufacture of foodstuffs:

- (a) they must have been obtained from hens', ducks', geese's, turkeys's, guinea fowl's or quail's eggs, but not a mixture of eggs of different species;
- (b) they must bear an indication of the percentage of egg ingredients they contain when they are partially supplemented by other foodstuffs or, provided they fulfil the requirements of Article 12, by additives;
- (c) they must have been treated and prepared in an establishment approved in accordance with Article 6 which complies with Chapters I and II of the Annex, and satisfy the requirements of this Directive;
- (d) they must have been prepared under hygiene conditions complying with Chapters III and V of the Annex, from

(<sup>1</sup>) OJ No L 282, 1. 11. 1975, p. 56.

(<sup>2</sup>) OJ No L 282, 1. 11. 1975, p. 100.

eggs meeting the requirements laid down in Chapter IV of the Annex;

- (e) they must have undergone a treatment process authorized under the procedure laid down in Article 14 which enables them to meet *inter alia* the analytical specifications laid down in Chapter VI of the Annex.

However, where it is necessary for technological reasons associated with the preparation of certain foodstuffs obtained from egg products, the competent authority shall decide, on the basis of criteria to be determined in accordance with the procedure laid down in Article 14, that certain egg products need not undergo treatment; in such a case, the egg products must be used without delay in the establishment where they are intended for the manufacture of other foodstuffs;

- (f) they must comply with the analytical specifications set out in Chapter VI of the Annex;
- (g) they must have undergone a health check in accordance with Chapter VII of the Annex;
- (h) they must have been packed in accordance with Chapter VIII of the Annex;
- (i) they must be stored and transported in accordance with Chapters IX and X of the Annex;
- (j) they must bear the mark of wholesomeness provided for in Chapter XI of the Annex and, where intended for direct human consumption, must meet the requirements of Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer<sup>(1)</sup>, as last amended by Directive 86/197/EEC<sup>(2)</sup>.

#### Article 4

The competent authorities shall ensure that the manufacturers of egg products adopt all measures necessary to comply with this Directive, and in particular that:

- samples for laboratory examination are taken in order to check that the analytical specifications set out in Chapter VI of the Annex have been observed,
- egg products that may not be kept at the ambient temperature are transported or stored at the temperatures stipulated in Chapters IX and X of the Annex,
- the period during which the conservation of egg products is assured is laid down,
- the results of the various checks and tests are recorded and kept for presentation to them for a period of two years,
- each batch marked in such a way that its date of treatment can be identified; this batch mark must appear on the

treatment record and on the mark of wholesomeness provided for in Chapter XI.

#### Article 5

1. Member States shall ensure that checks are effected to detect any residues of substances having a pharmacological or hormonal action, and of antibiotics, pesticides, detergents and other substances which are harmful or which might alter the organoleptic characteristics of egg products or make their consumption dangerous or harmful to human health.

2. If the egg products examined show traces of residues in excess of the permitted levels fixed in accordance with paragraph 4, they must not be allowed to be used in food for human consumption or placed on the market, either for the manufacture of foodstuffs or for direct human consumption.

3. Tests for residues must be carried out in accordance with proven and scientifically recognized methods, in particular those prescribed in Community Directives or other international standards.

It must be possible to assess the tests for residues using reference methods laid down in accordance with the procedure set out in Article 14 after the Scientific Veterinary Committee has expressed its opinion.

In accordance with the same procedure, at least one reference laboratory must be designated in each Member State to carry out the examination for residues in the event of application of Articles 7 and 8.

The Commission shall publish the reference methods and the list of reference laboratories in the *Official Journal of the European Communities*.

4. Acting by a qualified majority on a proposal from the Commission, the Council shall adopt:

- the detailed arrangements for monitoring,
- the tolerances for the substances referred to in paragraph 2,
- the frequency of sampling.

#### Article 6

1. Member States shall draw up lists of their approved establishments, each of which shall have an approval number. Member States shall forward this list to the other Member States and to the Commission.

No Member State shall approve an establishment unless compliance with this Directive is assured. A Member State shall withdraw approval if the conditions for granting it cease

<sup>(1)</sup> OJ No L 33, 8. 2. 1979, p. 1.

<sup>(2)</sup> OJ No L 144, 29. 5. 1986, p. 38.

to be fulfilled. The other Member States and the Commission shall be informed of the withdrawal of approval.

2. The inspection and monitoring of establishments and packaging centres shall be carried out regularly on the responsibility of the competent authority, which shall at all times have free access to all parts of the establishments, in order to ensure that this Directive is being observed.

If such inspections reveal that not all the requirements of this Directive are being met, the competent authority shall take the appropriate action to remedy the situation.

#### Article 7

1. Experts from the Commission may, in cooperation with the competent authorities, make on-the-spot checks insofar as that is indispensable for ensuring uniform application of the Directive; they may in particular verify whether establishments and packing centres approved in accordance with Article 5 (3) of Regulation (EEC) No 2772/75 are actually complying with the Directive.

A Member State within the territory of which a check is being carried out shall give all necessary assistance to the experts in carrying out their duties. The Commission shall inform the Member State concerned of the results of the checks.

The Member State concerned shall take any measures required to take account of the results of the check. If the Member State does not take those measures, the Commission may, in accordance with the procedure laid down in Article 13, decide that the Member State in question must suspend the placing on the market of egg products from the establishment which fails to comply with this Directive.

2. Before the checks referred to in paragraph 1 are carried out, in accordance with the procedure laid down in Article 14, the general provisions for applying this Article shall be determined and a Commission recommendation shall be established, containing the rules to be followed for the purpose of the checks provided for in paragraph 1.

#### Article 8

1. Without prejudice to Articles 6 and 7, the country of destination may, where there are serious grounds for suspecting irregularities, carry out non-discriminatory inspections of egg products in order to check that a consignment meets the requirements of this Directive.

2. The inspections referred to in paragraph 1 shall be carried out at the place of destination of the goods or at another suitable place, provided that in the latter case the choice of the place interferes as little as possible with the routing of the goods.

Such inspections must be carried out as soon as possible so as not unduly to delay the placing of egg products on the market, or cause delays which might impair their quality.

3. If, during an inspection carried out in accordance with paragraphs 1 and 2, it is found that the egg products do not comply with this Directive, the competent authority of the country of destination may give the consignor, the consignee or their representative the choice of withdrawing the consignment from the market in order that it may undergo further treatment or of using it for other purposes if this is permissible on health grounds. If not, the alternative offered must be the destruction of the egg products. In any event, precautionary measures shall be taken by the competent authority to prevent improper use of such egg products.

4. (a) Decisions and the grounds for taking them must be notified to the consignor, the consignee or their representative. Should such person so request, reasons must be given for such decisions and must be notified to him immediately in writing together with particulars of the remedies available to him under the law, their forms and the time limits within which action must be taken.

Remedies available to the consignor, the consignee or their representative shall not be affected by this Directive.

(b) If such decisions are based on the existence of a particularly serious risk to human health, they shall be communicated forthwith to the competent authority of the Member State of dispatch and to the Commission.

(c) Following such communication, appropriate measures may be taken in accordance with the procedure laid down in Article 13, in particular for the purpose of coordinating the measures taken in other Member States with regard to the egg products concerned.

5. Member States shall grant consignors whose egg products may not be placed on the market as a result of an inspection as provided for in paragraph 1 the right to obtain an expert's opinion.

The expert must be a national of a Member State other than the country of dispatch or the country of destination.

The Commission, acting on a proposal from the Member States, shall draw up a list of experts who may be instructed to prepare such opinions. The detailed rules for the application of this paragraph shall be adopted according to the procedure laid down in Article 14.

#### Article 9

Where a Member State considers, after carrying out an inspection in accordance with Article 8, that the provisions of

this Directive are no longer being observed in an establishment in another Member State it shall so inform the competent authority of that State. The said authority shall take all necessary measures and notify the competent authority of the first Member State of the decisions taken and of the reasons for such decisions.

If the first Member State fears that such measures have not been taken or are inadequate, the two Member States shall together seek ways and means of remedying the situation, if necessary by means of an inspection visit of the establishment.

The Member States shall inform the Commission of disputes and of the solutions reached.

If the Member States are unable to reach agreement, one of them shall refer the matter within a reasonable period to the Commission, which shall instruct one or more experts to deliver an opinion.

Pending that opinion, the Member State of dispatch shall intensify checks on egg products coming from the establishment in question and, at the request of the Member State of destination, the Commission shall immediately instruct an expert to go to the consignor establishment in order to propose appropriate interim protective measures.

In the light of the opinion provided for in the fourth subparagraph, or the result of the check performed in accordance with Article 7 (1), Member States may be authorized, under the procedure laid down in Article 13, temporarily to deny access to their territory for egg products coming from that establishment.

Such authorization may be withdrawn under the procedure laid down in Article 13 on the basis of a further opinion delivered by one or more experts.

The experts shall be nationals of a Member State other than those involved in the dispute.

Detailed rules for the application of this Article shall be adopted in accordance with the procedure laid down in Article 14.

#### Article 10

The Annex to this Directive shall be amended by the Council acting by a qualified majority on a proposal from the Commission.

#### Article 11

1. Pending the application of the provisions of this Directive, national provisions governing imports of egg products from third countries shall continue to apply and must not be more favourable than those governing intra-Community trade.

2. On-the-spot inspections shall be carried out by experts from the Member States and the Commission. Member

States' experts instructed to carry out these inspections shall be appointed by the Commission on proposals from the Member States. Inspections shall be carried out on behalf of the Community, which shall bear the costs relating thereto.

3. A list of the establishments which meet the requirements set out in the Annex shall be drawn up in accordance with the procedure laid down in Article 14.

4. The health certificate accompanying the products on importation and the form and nature of the mark of wholesomeness applied to the products shall correspond to a model to be determined in accordance with the procedure laid down in Article 14.

#### Article 12

The Council, acting by a qualified majority on a proposal from the Commission, shall decide which additives contained in the list of additives authorized by the Community rules in force on additives which may be used in foodstuffs may be used for the egg products defined in Article 3 (a) and the detailed rules on such use.

Pending such decision, national rules governing such use shall continue to apply.

#### Article 13

1. Where the procedure laid down in this Article is to be applied, the matter shall be referred forthwith to the Standing Veterinary Committee set up by the Council Decision of 15 October 1968 (hereinafter referred to as 'the committee') by its chairman on his initiative or at the request of a Member State.

2. The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

3. The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.

4. If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, within 15 days of the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission, save where the Council has decided against the said measures by a simple majority.

#### *Article 14*

1. Where the procedure laid down in this Article is to be applied, the chairman shall refer the matter without delay to the committee on his own initiative or at the request of a Member State.
2. The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member State within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.
3. The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.
4. If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, within three months of the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission, save where the Council has decided against the said measures by a simple majority.

#### *Article 15*

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 December 1991. They shall inform the Commission thereof forthwith.

The Commission shall, no later than 31 December 1994, submit a report to the Council on the experience acquired on the subject, accompanied, where appropriate, by proposals aimed at adapting the Annex to this Directive taking special account of scientific and technological developments.

#### *Article 16*

This Directive is addressed to the Member States.

Done at Luxembourg, 20 June 1989.

*For the Council*  
*The President*  
C. ROMERO HERRERA

## ANNEX

## CHAPTER I

## GENERAL CONDITIONS OF APPROVAL AND OPERATION

Establishments must possess at least:

1. in areas where eggs are stored and where egg products are manufactured or stored:
  - (a) waterproof flooring which is easy to clean and disinfect, rotproof and laid in such a way as to facilitate the draining of water; the water must be channelled towards drains fitted with gratings and traps to prevent odours;
  - (b) smooth, durable, impermeable walls, with a light-coloured, washable coating up to a height of at least two metres and up to at least storage height in chilling or refrigeration rooms and in stores. Wall to floor junctions must be rounded or similarly finished in such a way as to facilitate cleaning;
  - (c) doors in material that does not deteriorate and, if of wood, with a smooth and impermeable covering on both sides;
  - (d) ceilings which are easy to clean and which have been built and finished in such a way as to prevent the accumulation of dirt and the formation of mould, the possible peeling of paint-work and the condensation of water vapour;
  - (e) adequate ventilation and, if necessary, good steam extraction;
  - (f) adequate natural or artificial lighting;
  - (g) as near as possible to the work stations:
    - an adequate number of facilities for the cleaning and disinfecting of hands and the cleaning of equipment with hot water. Taps must not be operable by hand or the arms. For the cleaning of hands, these facilities must be provided with hot and cold running water or water premixed to a suitable temperature, cleaning and disinfecting products and hand towels which can be used once only,
    - facilities for the disinfecting of tools;
2. an appropriate number of changing rooms, with smooth, impermeable and washable walls and floors, wash basins and flush lavatories. The latter must not give directly on to the work area. Wash basins must have hot and cold running water or water premixed to a suitable temperature, materials for cleaning and disinfecting the hands, and hand towels which can be used once only. Wash basin taps must not be hand-operable. There must be a sufficient number of wash basin close to the lavatories;
3. a separate area and adequate facilities for cleaning and disinfecting fixed and mobile containers and tanks. However, this area and these facilities shall not be required if there are provisions for the cleaning and disinfecting of containers and tanks at other centres;
4. facilities for the supply of exclusively potable water within the meaning of Council Directive 80/778/EEC of 15 July 1980 relating to the quality of water intended for human consumption <sup>(1)</sup>;

However, facilities supplying non-potable water are authorized for steam-production, fire-fighting and the cooling of refrigeration equipment, provided that the pipes installed for this purpose preclude the use of such water for other purposes and present no risk of contamination to the egg products. The steam and water concerned may not come into contact with the egg products or be used for cleaning or disinfecting containers, plant or equipment which come into contact with the egg products. Pipes carrying non-potable water must be clearly distinguished from those carrying potable water;
5. appropriate equipment for protection against pests such as insects and rodents;
6. equipment, couplings and instruments or their surfaces which are intended to come into contact with egg products must be made of smooth material which is easy to wash, clean and disinfect, resists corrosion and does not transfer substances to the egg products in such quantities as to endanger human health, cause deterioration in the composition of the egg products or adversely affect their organoleptic characteristics.

<sup>(1)</sup> OJ No L 229, 30. 8. 1980, p. 11.

## CHAPTER II

## SPECIAL CONDITIONS FOR THE APPROVAL OF ESTABLISHMENTS

In addition to the general conditions laid down in Chapter I, establishments must have at least:

1. suitable rooms large enough for the separate storage of the eggs and the finished egg products, where necessary, with refrigeration equipment to keep the egg products at the appropriate temperatures; cold stores must be equipped with a thermometer or a remote recording thermometer;
2. where dirty eggs are used, facilities for washing and disinfecting the eggs; a list of products authorized for performing this disinfection shall be drawn up in accordance with the procedure laid down in Article 14;
3. (a) a special room with appropriate facilities for breaking eggs and collecting their contents and removing the parts of shell and membrane;  
(b) a separate room for operations other than those referred to in (a).  
Where egg products are pasteurized, pasteurization may be carried out in the room referred to in (a), when the establishment has a closed pasteurization system; in other cases pasteurization must be carried out in the room referred to in (b). In the latter case, every step must be taken to prevent the contamination of egg products after their pasteurization;
4. suitable facilities for in-plant conveying of egg contents;
5. in the cases provided for in this Directive, equipment approved by the competent authority for the treatment of egg products, fitted at least with:
  - (a) in the case of pasteurization:
    - automatic temperature control,
    - a recording thermometer,
    - an automatic safety device preventing insufficient heating;
  - (b) in the case of a continuous pasteurization system, the equipment must also be fitted with:
    - an adequate safety system preventing the mixture of pasteurized egg products with incompletely pasteurized egg products, and
    - an automatic safety recording device preventing the aforementioned mixture;
6. a room for the storage of other foodstuffs and additives;
7. where the products are packed in disposable containers, an appropriate and, if necessary, separate area for the storage of such containers and the raw materials intended for their manufacture;
8. facilities for the immediate removal and separate storage of empty shells, and of eggs and egg products which are unfit for human consumption;
9. suitable equipment for the hygienic packaging of egg products;
10. to carry out analyses and examinations in accordance with the requirements of this Directive on raw materials and egg products, an establishment must have an appropriate laboratory. If it does not, it must secure the services of a laboratory that fulfils those requirements. In the latter case it shall inform the competent authority accordingly;
11. where required, suitable equipment for the thawing of frozen egg products which must undergo treatment and further handling in an approved establishment;
12. a separate room for the storage of cleaning and disinfection products.

## CHAPTER III

## HYGIENE REQUIREMENTS RELATING TO THE PREMISES, EQUIPMENT AND STAFF OF ESTABLISHMENTS

The highest degree of cleanliness must be required of staff, premises and equipment:

1. staff who treat or handle eggs and egg products must, in particular, wear clean working clothes and headgear. They must wash and disinfect their hands several times in the course of each working day and on each resumption of work.

It must be forbidden to smoke, eat, spit or chew in areas where eggs and egg products are handled and stored;



2. no animals may enter the establishments. Any rodents, insects or other vermin found must be systematically destroyed;
3. premises, equipment and instruments used for working on egg products must be kept clean and in a good state of repair. Equipment and instruments must be carefully cleaned and disinfected several times if necessary during the working day, at the end of the day's work and before being re-used where they have been soiled. Closed pipe-line systems for conveying egg products must be provided with an appropriate cleaning system which ensures their cleaning and disinfection in all parts. After having been cleaned and disinfected, pipes must be rinsed out with potable water;
4. premises, instruments and equipment must not be used for purposes other than the processing of egg products except the processing of other foodstuffs either simultaneously or at different times after the authorization of the competent authority has been obtained, provided that all appropriate measures are taken to prevent contamination of or adverse changes in the products covered by this Directive;
5. potable water must be used for all purposes: however, non-potable water may be used in exceptional cases for steam production provided that the pipes installed for this purpose preclude the use of this water for other purposes and present no danger of contamination of eggs or egg products. In addition, the use of non-potable water may be authorized in exceptional cases for the cooling of refrigeration equipment. Non-potable water pipes must be clearly distinguished from pipes used for potable water;
6. detergents, disinfectants and similar substances must be used and stored in such a way that instruments, equipment and egg products are not adversely affected. Their use must be followed by thorough rinsing of such instruments and equipment with potable water;
7. persons who are possible sources of contamination must be prohibited from working with or handling eggs or egg products;
8. any person employed to work with or handle eggs or egg products must be required to produce a medical certificate to show that there is no reason why he or she should not engage in such work. The medical certificate must be renewed yearly unless another staff medical check-up scheme offering similar guarantees is recognized in accordance with the procedure laid down in Article 14.

#### CHAPTER IV

#### REQUIREMENTS CONCERNING EGGS INTENDED FOR THE MANUFACTURE OF EGG PRODUCTS

1. Eggs used for the manufacture of egg products must be put up in packaging which complies with Commission Regulation (EEC) No 95/69 of 17 January 1969 implementing Regulation (EEC) No 1619/68 on marketing standards for eggs <sup>(1)</sup>, as last amended by Regulation (EEC) No 3906/86 <sup>(2)</sup>.
2. (a) For the manufacture of egg products, only non-incubated eggs which are fit for human consumption may be used; their shells must be fully developed or contain no breaks;  
(b) by way of derogation from (a), cracked eggs may be used for the manufacture of egg products provided they are delivered directly from the packing centres and the farm of production to an approved establishment, where they shall be broken as quickly as possible.
3. Eggs and egg products which are unfit for human consumption must be removed and denatured in such a way that they cannot be re-used for human consumption. They must immediately be placed in the room provided for in point 8 of Chapter II.

#### CHAPTER V

#### SPECIAL HYGIENE REQUIREMENTS FOR THE MANUFACTURE OF EGG PRODUCTS

All operations must be carried out in such a way as to avoid all contamination during the production, handling and storage of egg products, and in particular;

<sup>(1)</sup> OJ No L 13, 18. 1. 1969, p. 13

<sup>(2)</sup> OJ No L 364, 23. 12. 1986, p. 20.

1. eggs and egg products presented for subsequent treatment at an approved establishment must be stored immediately on arrival in the rooms provided for in Chapter II point 1 until they are processed. The temperature of these rooms must be such as to ensure that they are not contaminated. Trays of shell eggs must not be placed directly on the floor;
2. eggs must be unpacked, and, if necessary, washed and disinfected, in a room which is separate from the breaking room; packaging material must not be taken into the breaking room;
3. eggs must be broken in the room provided for in Chapter II, point 3 (a); cracked eggs as mentioned in Chapter IV, point 2 (b) must be processed without delay;
4. dirty eggs must be cleaned before being broken; this must be carried out in a room which is separate from the breaking room or from any room where exposed egg contents are handled. Cleaning procedures must be such as to prevent contamination or adulteration of the egg contents. Shells must be sufficiently dry at the time of breaking to prevent adulteration of the egg contents by the remains of the cleaning water;
5. eggs other than hen eggs or those of turkeys or guinea fowl must be handled and processed separately. All equipment must be cleaned and disinfected when processing of hen eggs and those of turkeys and guinea fowl is resumed;
6. breaking, whatever procedure is used, must be carried out in such a way as to avoid as far as possible contamination of the egg contents. To that end, the contents of eggs may not be obtained by the centrifugation or crushing of eggs, nor may centrifugation be used to obtain the remains of egg whites from empty shells. The remains of shells or membranes must be kept out of the egg product as far as possible and must not exceed the quantity specified in point 2 (c) of Chapter VI;
7. after breaking, each particle of egg product must undergo treatment as quickly as possible; heat treatment consists of treating the egg product at an appropriate temperature for an appropriate period in order to eliminate any pathogenic organisms present. During heat treatment, temperatures must be registered continuously. The records of each batch having undergone treatment must be kept at the disposal of the competent authority for two years. A batch which has been insufficiently treated may immediately undergo treatment again in the same establishment provided that the new treatment renders it fit for human consumption; should it be found to be unfit for human consumption, it must be denatured in accordance with point 3 of Chapter IV;
8. if treatment is not carried out immediately after breaking, the egg contents must be stored under satisfactory hygiene conditions, either frozen or at a temperature of not more than 4 °C. The storage period at 4 °C must not exceed 48 hours, except in the case of ingredients to be desugared;
9. where certain production practices so require, the Commission shall determine, pursuant to Article 14 and by 31 December 1991, the existence of special cases and shall lay down specific conditions according to which egg products coming from an approved establishment may be treated in another approved establishment, on the understanding that the following general conditions are complied with:
  - (a) as soon as the egg products have been obtained, they must be either deep frozen or chilled to a temperature of not more than 4 °C in the latter case, they must be treated at their place of destination during the 48 hours following the day of the breaking of the eggs from which they were obtained, except in the case of ingredients to be desugared;
  - (b) they must be packaged, checked, transported and handled in accordance with the requirements of the Directive;
  - (c) they must be labelled in accordance with the requirements laid down in Chapter XI. The nature of the goods must be indicated as follows: 'non-pasteurized egg products — to be treated at place of destination — date and time of breaking —';
10. further processing operations after treatment must ensure that there is no recontamination of the egg product; liquid products or concentrated products which have not been stabilized so as to keep at room temperature must be either dried or cooled to a temperature not exceeding 4 °C immediately, or after undergoing a fermentation process; products for freezing must be frozen immediately after treatment;
11. egg products must be kept at the temperatures required by this Directive until they are used for the manufacture of other foodstuffs;
12. in approved establishments, the preparation of egg products from raw materials which are not suitable for the manufacture of foodstuffs is prohibited, even for non-food purposes.

## CHAPTER VI

## ANALYTICAL SPECIFICATIONS

## 1. Microbiological criteria

All batches of egg products must, after treatment, undergo microbiological checks by sampling in treatment establishments in order to guarantee that they meet the following criteria:

- (a) salmonellae: absence in 25 g or ml of egg product;
  - (b) other criteria:
    - mesophilic aerobic bacteria:  $M = 10^5$  in 1 g or 1 ml,
    - enterobacteriaceae:  $M = 10^2$  in 1 g or 1 ml,
    - staphylococci: absence in 1 g of egg product,
- M = maximum value for the number of bacteria; the result is considered unsatisfactory if the number of bacteria in one or more sample units is M or more.

## 2. Other criteria

All batches of egg products must undergo checks by sampling in treatment establishments in order to guarantee that they meet the following criteria:

- (a) the concentration of 3 OH-butyric acid must not exceed 10 mg/kg in the dry matter of the unmodified egg product;
- (b) in order to ensure the hygienic handling of eggs and egg products before treatment, the following standards shall apply:
  - the lactic acid content must not exceed 1 000 mg/kg of egg product dry matter (applicable only to the untreated product),
  - the succinic acid content must not exceed 25 mg/kg of egg product dry matter.In the case of fermented products, however, these values are those recorded before the fermentation process;
- (c) the quantity of eggshell remains, egg membrane and any other particles in the egg product must not exceed 100 mg/kg of egg product;
- (d) the residual quantities of the substances mentioned in Article 5 (1) may not exceed the tolerances mentioned in Article 5 (4);

## 3. before 31 December 1991, the Commission will, in accordance with the procedure laid down in Article 14, determine:

- the analysis and test methods,
- the sampling plans,
- the number of samples to be taken,
- the analytical tolerances.

Pending those decisions the Member States will recognize as reference methods all analysis and test methods recognized internationally.

## CHAPTER VII

## HEALTH CONTROL AND SUPERVISION OF PRODUCTION

## 1. Establishments will be subject to supervision by the competent authority.

Supervision by the competent authority will include any supervision measures considered necessary to ensure that manufacturers of egg products meet the requirements of this Directive, and in particular:

- checks on the origin of eggs and the destination of egg products and of the records referred to in the fourth indent of Article 4,

- inspection of eggs intended for the manufacture of egg products,
  - inspection of egg products on dispatch from the establishment,
  - verification of the cleanliness of the premises, facilities and instruments and of staff hygiene,
  - taking of any samples required for laboratory tests to ensure that eggs and egg products comply with the requirements of this Directive; the results of such tests must be entered in a register and notified to the egg products manufacturer.
2. At the request of the competent authority, manufacturers of egg products must increase the frequency of the laboratory tests referred to in the first indent of Article 4 where this is considered necessary to ensure hygienic production of the egg products.

## CHAPTER VIII

### PACKAGING OF EGG PRODUCTS

1. Egg products must be packaged in satisfactory hygiene conditions so as to ensure that they are not contaminated.

Containers must comply with all rules of hygiene, including the following:

- they must not be such as to impair the organoleptic characteristics of the egg products,
  - they must not be capable of transmitting to the egg products substances harmful to human health,
  - they must be strong enough to protect the egg products adequately.
2. The room in which containers are stored must be dust and vermin free; materials for making disposable containers must not be stored on the floor.
3. Containers used for egg products must be clean prior to being filled; re-usable containers must be cleaned, disinfected and rinsed before being filled.
4. Containers must be brought into the work room in a hygienic manner and must be used without undue delay.
5. Immediately after packaging, the containers must be closed and placed in the storage rooms referred to in Chapter II, point 1.
6. Containers intended for egg products may be used for other foodstuffs if required, provided they are cleaned and disinfected so as not to contaminate the egg products.
7. Containers which are to be used for the transport of egg products in bulk must comply with all the rules of hygiene, and in particular the following:
- their inside surfaces and any other part which may come into contact with the egg product must be made of a smooth material which is easy to wash, clean and disinfect, resists corrosion and does not transfer substances to the egg product in such quantities as to endanger human health, cause deterioration in the composition of the egg product or adversely affect its organoleptic characteristics,
  - they must be designed so that the egg product can be removed completely; if they are fitted with taps, these must be easy to remove, dismantle, wash, clean and disinfect,
  - they must be washed, cleaned, disinfected and rinsed immediately after each use and, if necessary, before re-use,
  - they must be appropriately sealed after being filled and remain sealed during transportation until they are used,
  - they must be reserved for the transport of egg products.

However, without prejudice to the provisions of this Chapter, for the first time and in this case by 31 December 1990, the Commission, according to the procedure provided for in Article 14 and to the extent that the egg products and the other foodstuffs concerned suffer no adverse effects as a result, shall fix, if necessary, the specific conditions with which such containers must comply in order to be used to transport other foodstuffs, in particular, conditions relating to:

- the washing, cleaning and disinfection of containers before they are re-used,
- transport conditions,
- the length of time during which they may be used.

Until the decisions provided for in the second subparagraph are brought into force and not later than 31 December 1991:

- the national rules authorizing the use of containers for transport on the national territory of foodstuffs other than egg products as well as bilateral agreements concluded by the Member States in this respect shall remain applicable, whilst complying with the general provisions of the Treaty,
- Member States, whose national rules make provision for such an authorization, may neither restrict nor prohibit the entry into their territory of transport from other Member States which provide for the same authorization,
- Member States which forbid the transport on their territory of other foodstuffs in containers designed for the transport of egg products may make the transport of egg products coming from other Member States to the same requirements.

## CHAPTER IX

### STORAGE

1. Egg products must be stored in the storage rooms referred to in point 1 of Chapter II.
2. Egg products for which certain storage temperatures are required must be maintained at those temperatures. The storage temperatures must be recorded continuously, the cooling rate must be such that the product reaches the required temperatures as quickly as possible and the containers must be stored in such a way that air can freely circulate round them.
3. The temperature in storage must not exceed the following values:
 

— deep frozen products:	-18° C,
— frozen products:	-12° C,
— chilled products:	+4° C,
— dehydrated products (excluding egg whites):	+15° C.

## CHAPTER X

### TRANSPORT

1. Vehicles and containers for the transport of egg products must be designed and equipped in such a way that the temperatures required by this Directive can be maintained continuously throughout the period of transport.
2. Egg products must be dispatched in such a way that they are adequately protected during transportation from anything which may be detrimental to them.
3. The temperatures prescribed in point 3 of Chapter IX, must be maintained during transport.

## CHAPTER XI

## MARKING OF EGG PRODUCTS

1. Without prejudice to the provisions of Directive 79/112/EEC, every consignment of egg products that leaves an establishment must have a label bearing the following particulars:
  - (i) either:
    - on the upper part, the initial letter or letters of the consigning country in capitals, i.e. B/D/DK/EL/ESP/F/IRL/I/L/NL/P/UK, followed by the approval number of the establishment,
    - on the lower part, one of the following sets of initials: CEE — EEC — EEG — EOK — EWG — EØF;
  - (ii) or:
    - on the upper part, the name of the consigning country in capitals,
    - in the centre, the approval number of the establishment,
    - on the lower part, one of the following sets of initials: CEE — EEC — EEG — EOK — EWG — EØF;
  - (iii) the temperature at which the egg products must be maintained and the period during which their conservation may thus be assured.

The label must be legible, indelible and in easily decipherable characters.
2. The transport documents must in particular include:
  - (a) the nature of the products with an indication of the species of origin;
  - (b) the batch numbers;
  - (c) the place of destination and the name and address of the first addressee.
3. This information, and that contained in the mark of wholesomeness, must be given in the official language or languages of the country of destination.