3.18. *Annex 5*

The heading is incorrect; the provisions of the Annex are actually designed to govern the 'vaccines' used and not the 'vaccination conditions'. Moreover, the contents of the Annex will no longer be relevant after the adoption of the proposed Directive on the establishment of additional provisions for immunological veterinary medicinal products (COM(88) 779 final—SYN 190), implementing Directive 81/851/EEC. Work on this is currently in progress, and it is hoped that the Directive will soon be finalized.

For this reason, it is recommended that this Annex be deleted, together with any references to it in the Regulation proper.

Done at Brussels, 31 May 1989.

The Chairman

of the Economic and Social Committee

Alberto MASPRONE

Opinion on the proposal for a Council Directive on the approximation of the laws of the Member States concerning food ingredients treated with ionizing radiation

(89/C 194/06)

On 26 December 1988, the Council decided to consult the Economic and Social Committee, under Article 100A of the Treaty establishing the European Economic Community, on the abovementioned proposal.

The Section for Industry, Commerce, Crafts and Services, which was responsible for preparing the Committee's work on the subject, adopted its Opinion on 3 May 1989. The rapporteur was Mr Gardner.

At its 266th plenary session (meeting of 31 May 1989), the Economic and Social Committee adopted the following Opinion by 85 votes to 43 with 16 abstentions (vote recorded).

1. Introduction

1.1. Ionization of food [1] is used to kill dangerous bacteria and larger pathogens, as well as infesting insects. It is also used to increase the shelf life of some foods. For this purpose, the food is exposed to ionizing radiation, either from electric machines or from isotope sources, in each case under carefully controlled conditions. The process is technologically complex and expensive, so its application will be limited to specific cases.

1.2. Many ordinary people have considerable concerns about the consumer acceptability of food ionization and about worker protection associated with the ionization facilities. This applies in particular to (a) the acceptability on health grounds and the technological need for this preservation technique, (b) the danger of the ionization procedure and of disregard for hygiene standards, (c) the rise in the number of jobs exposed to radiation and (d) the nutritional-physiological aspects of any reduction in the nutritional value of food as a result of ionization.

1.3. The food ionization technique up to 10 kGy has been subjected to very intensive nutritional and toxicological tests over the last 30 years, including multigeneration ones on animals. Much of these comprehensive scientific and technical data were produced by an international project funded by 25 governments. Consequently the standard of the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) (CODEX) 'recog-

[1] Six Member States, Belgium (± 10 foods), Denmark (2), Spain (2), France (± 9), Italy (3), Netherlands (± 40), permit food irradiation to different degrees (different products). Ireland, Greece and Portugal have no legislation either prohibiting or permitting ionization of food. The position in Luxembourg is unclear. The UK prohibits ionization. Germany in principle prohibits ionization but administrative permission can be given for individual foods (e.g. spices).

nizes that the process of food irradiation has been established as safe for general application to an overall average level of absorbed dose of 10 kGy'. These findings were further endorsed by the EEC Scientific Committee for Food (SCF).

Like all safety evaluations, this of course is an assessment of the relative importance of proven and possibly unproven risks.

1.4. The availability of the technique of ionization must not lead to unhygienic production or processing of food.

2. Present ionization plants

2.1. There are currently at least 150 ionization plants, operating on a world-wide basis with a number of these within the EEC. Other plants are planned within Member States of the EEC and elsewhere in the world.

Since ionization cannot be detected in the final food, products from all these ionization plants, both EEC and others, will continue to be able to move freely throughout the Community, unless controls on these plants are internationally agreed.

3. Detection of ionized food

3.1. Food ionization under controlled conditions, as proposed by the Commission and by CODEX, is a very mild treatment and generally these changes are not significant enough to be detected by current methods. Also, present potential detection methods are too indefinite, costly and complex to form a practical basis for international control of ionized food.

3.2. However, as a result of these problems of detectability, various representatives of trade unions, European-level agricultural organizations and consumer organizations within the EEC are concerned about the international control aspects of ionized food.

3.3. The Committee recognizes that considerable Research and Development (R & D) effort is currently being expended within the Member States on solving the detection problem. In view of its central importance, the Committee strongly urges the Commission to increase substantially funding for research in the interests of finding a viable and practical method of detection very rapidly. The Committee would much prefer that the implementation of this draft Directive should be delayed until acceptable tests for the detection of irradiation are available.

4. EC trade

4.1. Based on current practice, the Commission proposes a system of approval and inspection of plants to overcome the present problems associated with the detection of ionization in food products.

4.2. Given that after 1992 there will be free movement of food products throughout the Community, there seem to be only two options:

a) to continue to leave the control of food ionization to national legislation, which effectively means free movement of ionized food from those countries which permit the process;

b) to initiate a Community framework, such as the Commission is proposing.

4.3. Furthermore, it is particularly important to ensure that Member States can only import ionized food products from non-EEC countries in line with an agreed Community standard (as proposed in Article 8).

5. General comments

In the above circumstances, the Committee deems it inadvisable to endorse a Community framework for food ionization, apart from ionization of spices, until such time as the EC Commission has submitted conclusive evidence as to the technical need for and acceptability on health grounds of this preservation method.

The Committee therefore requests the EC Commission to draft a report on:

— assessments of food ionization by certain international organizations,

— the development of alternative preservation methods,

— the scope for detecting ionization,

— international ionization practice,

— imports of products which are frequently subjected to ionization,

— ascertainment of the capacity of Community plants which are suitable for carrying out food ionization, and

— the state of discussions on food ionization in the Community Member States, the Commission and the Council.

6. Detailed comments

Article 1.2 (a)

This should be changed to 10 MeV, only for the development of anti-terrorist devices at airports. This covers the detection of weapons in food consignments by X-ray equipment.

Article 4.1

This Article, which deals with re-irradiation is less than clear. The CODEX version relates to the maximum doses and the Committee would prefer this.

Article 5

This refers to the labelling Directive 79/112/EEC. The latter is currently being amended and the reference must be changed to the amended version. It is important to note that fresh fruit and vegetables do not always appear to be covered by the labelling Directive 79/112/EEC, as amended. Clear, categorical marking arrangements are necessary but so far no decision has been taken on the amended labelling Directive.

Article 5.2

While the labelling Directive, as amended, regulates descriptions for the final consumer, this Directive deals only with labelling for intermediate trade. As it is, Article 5.2 (e) should be changed to require the same description as the amended Directive 79/112/EEC, so that the manufacturer knows what to put on the label of the final product. The current version is 'irradiated' or 'treated with ionizing radiation'. The international logo, which can be used in addition to the declaration, may be confusing in some countries. The Committee recommends that the Commission consider another logo for products moved within the EEC.

Article 6

Here the Committee needs to make the important point of worker protection. Fortunately, suitable systems of worker protection have already been evolved for ionization plants used for sterilizing medical equipment throughout the Community. The same safeguards must apply to food ionization and other future uses.

Article 7

The Committee would prefer records to be kept for 20 years or in line with existing practices for such documentation.

Article 8.2

The Commission should include in this Article a paragraph recapitulating the statement in the explanatory note (page 4) that the Community must reserve the right to develop an independent system of inspection if the current international cooperation is not fully successful.

Change 'may' to 'should'.

Article 9

Add: 'In line with the food packaging Directive of 22 December 1988.'

Article 11

The procedure laid down in Article 11 applies to changes which may prove necessary in various circumstances, particularly those described in Articles 10, 12 and 13. The Committee considers that the procedure currently proposed should include consultation of the Economic and Social Committee and that it should be laid down that the Council is to decide on the changes to be made. The provisions of Article 11 would thus have to be amended accordingly.

Article 12

Add: 'Who should take into account the results of any FAO/WHO evaluations.'

Annex 1

The Committee is concerned that food ionization could be used to mask unhygienic food products and therefore strongly recommends that the Commission should develop EEC-wide microbiological criteria. Annex 1 should be reviewed critically in line with needs, as defined below (Annex 5(1), first indent).

The list differs in some respects from the evaluation by the SCF. We would want the following changes:

a) The purpose of ionization should be given in each case, e.g. reducing bacterial load, disinfestation, etc.

b) 'Cereal flakes' should be changed to 'cereals', as in the SCF report.

Annex 3

See comments on Article 5.2.

Annex 4

'Batch' needs to be defined for continuous operation. There are precedents for this in other Directives.

Annex 5.1

First indent

Change in line with the food additives Directive to read:

' 'Need' is defined as a demonstrable technological, economic or other advantage of benefit to the consumer.'

Second indent

Add:

'In line with SCF evaluation.'

Annex 5.2

The introductory phrase should be reworded to read as follows:

'Food irradiation may only serve the following purposes:'

Last indent

Change 'disinfect' to 'disinfect and/or disinfest'.

Done at Brussels, 31 May 1989.

The Chairman

of the Economic and Social Committee

Alberto MASPRONE

APPENDIX

to the Opinion of the Economic and Social Committee

The following members, present or represented, voted in favour of the Opinion:

Mr/Mrs/Miss: Amato, Aparicio Bravo, Ataide Ferreira, Bazianas, Bento Gonçalves, Beretta, Berger, Bleser, Boddy, Boisserée, Bos, Breyiannis, Briganti, Broicher, Burnel, Cal, Calvet Chambon, Carroll, Cavazzuti, Ceballo Herrero, Christie, Conde, Corell Ayora, Cortois, Dassis, Della Croce, De Tavernier, Dos Santos, Droulin, van Eekert, Elstner, Etty, Eulen, Flum, Forgas, Frandi, Freeman, Gayetot, Germozzi, Geuenich, Glesener, Gomez Martinez, Gredal, Haas, Hagen, Hilkens, Hörsken, Houthuys, Jaschick, Jenkins, Kirchfeld, Lappas, Larsen, Laur, Liverani, Machado von Tschusi, Maddocks, Marvier, Morselli, Mourgues, Muhr, Muller, Murphy, Neto Da Silva, Nierhaus, Orsi, Petropoulos, Polyzos, Proença, Raftopoulos, Rouzier, Santillan Cabeza, Schmitz, Schnieders, Silva, Smith L. J., Städelin, Vallejo Calderon, Vassilaras, Velasco Mancebo, Vercellino, Vidal, Wick, Williams, Yverneau.

The following members, present or represented, voted against the Opinion:

Mr/Mrs/Miss: Arena, Arets, Bagliano, Beltrami, Berns, Ceyrac, Clavel, Collas, Coyle, van Dam, Dodd, Donck, Flather, Gardner, Green, Hancock, Hovgaard Jakobsen, Kaaris, Lustenhouwer, Mainetti, Moreland, Noordwal, de Normann, Panizo Arcos, Pardon, Pearson, Pelletier, Perrin-Pelletier, Poëton, Proumens, Ribière, Robinson, Rolão Gonçalves, Roseingrave, Schade-Poulsen, Speirs, Storie-Pugh, Tamlin, Telles, Termes Carrero, Tukker, Wagner, Whitworth.

The following members, present or represented, abstained:

Mr/Mrs/Miss: Aspinall, Bordes-Pages, Bredima-Savopoulou, Campbell, Giacomelli, Kazazis, Kröger, Löw, Mantovani, Margot, Mayayo, Bello, Muñiz Guardado, Quevedo Rojo, Riera Marsa, Serra Caracciolo, Strauß.