

ANNEX

8. HEALTH AND CONSUMER PROTECTION

8.1. Council Directive 89/108/EEC of 21 December 1988 on the approximation of the laws of the Member States relating to quick-frozen foodstuffs for human consumption⁽¹⁾

As regards Directive 89/108/EEC, the Commission should be empowered to determine the purity criteria to be satisfied by cryogenic media, the sampling procedures for quick-frozen foodstuffs and the procedures for monitoring the temperature of such feedstuffs and for monitoring temperatures in the means of transport, warehousing and storage. Since those measures are of general scope and are designed to amend non-essential elements of Directive 89/108/EEC by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Directive 89/108/EEC is hereby amended as follows:

1. the third paragraph of Article 4 shall be replaced by the following:

The purity criteria to be satisfied by those cryogenic media shall be determined, as far as necessary, by the Commission. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 12(2).;

2. Article 11 shall be replaced by the following:

Article 11

The sampling procedures for quick-frozen foodstuffs and the procedures for monitoring their temperature and for monitoring temperatures in the means of transport, warehousing and storage shall be determined by the Commission. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 12(2).;

3. Article 12 shall be amended as follows:

(a) paragraph 2 shall be replaced by the following:

2. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.;

(b) paragraph 3 shall be deleted.

8.2. Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs⁽²⁾

As regards Directive 90/496/EEC, the Commission should be empowered to adopt provisions necessary for changes to the list of vitamins, minerals and their recommended daily allowances; for a definition of fibre and its associated methods of analysis; for the restriction or prohibition of nutrition claims; for amendments and additions relating to the list of categories of nutrients and their conversion factors; and to establish rules concerning the extent of the information to be given and the manner of its communication for non-pre-packaged foodstuffs. Since those measures are of general scope and are designed to amend non-essential elements of Directive 90/496/EEC, *inter alia*, by supplementing it with new non-essential elements, they must be

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adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Directive 90/496/EEC is hereby amended as follows:

1. in Article 1(4)(a), the second subparagraph shall be replaced by the following:

Measures designed to amend non-essential elements of this Directive and changing the list of vitamins, minerals and their recommended daily allowances shall be adopted by the Commission in accordance with the regulatory procedure with scrutiny referred to in Article 10(3).;
2. in the third subparagraph of Article 1(4)(b), the words ‘Article 10’ shall be replaced by the words ‘Article 10(2)’;
3. Article 1(4)(j) shall be replaced by the following:
 - (j) “fibre” means a material to be defined by the Commission and measured by a method of analysis to be determined by the Commission. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(3).;
4. Article 3 shall be replaced by the following:

Article 3

The only nutrition claims permitted shall be those relating to energy, to the nutrients listed in Article 1(4)(a)(ii) and to substances which belong to, or which are components of, a category of those nutrients. Provisions restricting or prohibiting nutrition claims within the meaning of this Article may be adopted by the Commission. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(3).;
5. Article 5(2) shall be replaced by the following:
 2. Amendments to the conversion factors referred to in paragraph 1 and the addition to the list in that paragraph of substances which belong to, or are components of, one of the categories of nutrients referred to therein and their conversion factors, shall be adopted by the Commission in order to calculate more precisely the energy value of foodstuffs. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(3).;
6. in Article 6(3), the words ‘Article 10’ shall be replaced by the words ‘Article 10(2)’;
7. in Article 6(5)(b), the words ‘Article 10’ shall be replaced by the words ‘Article 10(2)’;
8. in the second subparagraph of Article 6(8), the words ‘Article 10’ shall be replaced by the words ‘Article 10(2)’;
9. Article 8 shall be replaced by the following:

Article 8

In the case of non-pre-packaged foodstuffs put up for sale to the final consumer or to mass caterers and foodstuffs packed at the point of sale at the request of the purchaser or pre-packaged with a view to immediate sale, the extent of the information referred to in Article 4 and the manner of its communication may be determined by national

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law until the eventual adoption of measures by the Commission. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(3).;

10. Article 10(3) shall be replaced by the following:

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

8.3. Directive 1999/2/EC of the European Parliament and of the Council of 22 February 1999 on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation⁽³⁾

As regards Directive 1999/2/EC, the Commission should be empowered to implement rules relating to food irradiation. Since those measures are of general scope and are designed to amend non-essential elements of Directive 1999/2/EC, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

On grounds of efficiency, the normal time limits for the regulatory procedure with scrutiny should be curtailed for the adoption of certain exceptions to rules relating to maximum radiation doses for foodstuffs and the use of irradiation treatment in combination with chemical treatment, as well as for the adoption of supplementary requirements for approval of irradiation facilities.

When, on imperative grounds of urgency, the normal time limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to apply the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of amendments to Directive 1999/2/EC or to its implementing directive by means of prohibitions or restrictions as compared to the previous legal situation to the extent necessary to ensure the protection of public health.

Accordingly, Directive 1999/2/EC is hereby amended as follows:

1. Article 5(2) shall be replaced by the following:

2. Exceptions to paragraph 1 may be adopted by the Commission. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 12(4).;

2. Article 7(2) shall be replaced by the following:

2. Approval shall be granted only if the facility:

- meets the requirements of the joint FAO/WHO Codex Alimentarius Commission Recommended International Code of Practice for the operation of irradiation facilities used for the treatment of foods (reference FAO/WHO/CAC, Vol. XV, edition 1), and any supplementary requirement which may be adopted by the Commission. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 12(4),
- designates a person responsible for compliance with all the conditions necessary for the application of the process.;

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3. in Article 8(3), the words ‘Article 12’ shall be replaced by the words ‘Article 12(2)’;
4. in the first subparagraph of Article 9(2)(a), the words ‘Article 12’ shall be replaced by the words ‘Article 12(2)’;
5. Article 12 shall be replaced by the following:

Article 12

1 The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health instituted by Regulation (EC) No 178/2002 of the European Parliament and of the Council⁽⁴⁾.

2 Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period provided for in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3 Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

4 Where reference is made to this paragraph, Article 5a(1) to (4) and (5)(b) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The time limits provided for in Article 5a(3)(c) and (4)(b) and (e) of Decision 1999/468/EC shall be set at two months, one month and two months respectively.

5 Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.;

6. in Article 14(2), the words ‘Article 12’ shall be replaced by the words ‘Article 12(2)’;

7. Article 14(3) shall be replaced by the following:

3. Adaptations of this Directive or of its implementing directive may be made by the Commission only to the extent necessary to ensure the protection of public health and shall in any event be limited to prohibitions or restrictions as compared to the previous legal situation. Those measures, designed to amend non-essential elements of this Directive, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 12(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 12(5).

8.4. Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements⁽⁵⁾

As regards Directive 2002/46/EC, the Commission should be empowered to adopt specific rules for vitamins and minerals used as food supplements, including the setting of specific values for maximum and minimum levels for vitamins and minerals present in food supplements, as well as their purity criteria. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2002/46/EC, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

When, on imperative grounds of urgency, the normal time limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to apply the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of measures prohibiting the use of a vitamin or mineral the use of which was previously authorised.

Accordingly, Directive 2002/46/EC is hereby amended as follows:

1. Article 4(2) shall be replaced by the following:
 2. The purity criteria for substances listed in Annex II to this Directive shall be adopted by the Commission, except where such criteria apply pursuant to paragraph 3. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 13(3).;
 2. Article 4(5) shall be replaced by the following:
 5. Modifications to the lists referred to in paragraph 1, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 13(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 13(4) in order to remove a vitamin or a mineral from the list referred to in paragraph 1 of this Article.;
 3. Article 5(4) shall be replaced by the following:
 4. The maximum and minimum amounts of vitamins and minerals referred to in paragraphs 1, 2 and 3 shall be adopted by the Commission. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 13(3).;
 4. Article 12(3) shall be replaced by the following:
 3. In order to remedy the difficulties described in paragraph 1 and to ensure the protection of human health, adaptations of this Directive or of its implementing measures shall be adopted by the Commission. Those measures, designed to amend non-essential elements of this Directive, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 13(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 13(4) in order to adopt those adaptations. The Member State that has adopted safeguard measures may in that event retain such measures until the adoption of the adaptations.;
 5. Article 13 shall be replaced by the following:

Article 13
 1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health instituted by Regulation (EC) No 178/2002 of the European Parliament and of the Council⁽⁶⁾
 2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.
- The period provided for in Article 5(6) of Decision 1999/468/EC shall be set at three months.

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3 Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

4 Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof..

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- (1) OJ L 40, 11.2.1989, p. 34.
- (2) OJ L 276, 6.10.1990, p. 40.
- (3) OJ L 66, 13.3.1999, p. 16.
- (4) OJ L 31, 1.2.2002, p. 1.';
- (5) OJ L 183, 12.7.2002, p. 51.
- (6) OJ L 31, 1.2.2002, p. 1.'.

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