ANNEX

5. HEALTH AND CONSUMER PROTECTION

5.1. **Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food**[(1)]

As regards Regulation (EEC) No 315/93, the Commission should be empowered in particular to establish maximum tolerances for specific contaminants. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EEC) No 315/93 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.

Any delay in the establishment of maximum tolerances for specific contaminants could represent a threat to human or animal health. 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 have recourse to the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of those tolerances.

Accordingly Regulation (EEC) No 315/93 is hereby amended as follows:

1. the first subparagraph of Article 2(3) shall be replaced by the following:

> In order to protect public health and pursuant to paragraph 1, the Commission may where necessary establish the maximum tolerances for specific contaminants. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 8(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 8(4).;

2. Article 4(2) shall be replaced by the following:

2. The Commission shall examine the reasons given by the Member State referred to in paragraph 1 as soon as possible in the Standing Committee for Foodstuffs, set up by Council Decision 69/414/EEC[(2)], and shall deliver its opinion immediately and take any necessary measures aimed at confirming, amending or repealing the national measure, in accordance with the regulatory procedure laid down in Article 8(2).;

3. in the fourth subparagraph of Article 5(3), the words ‘Article 8’ shall be replaced by the words ‘Article 8(2)’;

4. Article 8 shall be amended as follows:

(a) paragraph 3 shall be replaced by the following:

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

(b) the following paragraph shall be added:

> 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..

5.2. Council Directive 93/74/EEC of 13 September 1993 on feedingstuffs intended for particular nutritional purposes[4]

As regards Directive 93/74/EEC, the Commission should be empowered in particular to adopt general provisions regarding the application of the indications contained in the list of intended uses and to adopt amendments, in line with developments in scientific and technical knowledge, to the list of intended uses and the general provisions regarding the application of the indications contained in the list of intended uses. Since those measures are of general scope and are designed to amend non-essential elements of Directive 93/74/EEC, *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.

Feedingstuffs intended for particular nutritional purposes are playing an increasing role in the diet of pet animals and are also used in the rearing of productive livestock. The composition and preparation of such feedingstuffs must be specially designed to meet the particular nutritional needs of categories of pets or productive livestock whose process of assimilation, absorption or metabolism could briefly be impaired or is temporarily or irreversibly impaired. Users of such feedingstuffs therefore need to be provided immediately with accurate and meaningful information so that they can make appropriate choices. 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 have recourse to the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of general provisions regarding the application of the indications contained in the list of intended uses and for the adoption of amendments, in line with developments in scientific and technical knowledge, to the list of intended uses and the general provisions regarding the application of the indications contained in the list of intended uses.

Accordingly, Directive 93/74/EEC is hereby amended as follows:

1. Article 6 shall be replaced by the following:

Article 6

The Commission shall adopt:

(a) a list of intended uses as set out in the Annex no later than 30 June 1994 in accordance with the regulatory procedure referred to in Article 9(2). That list shall contain:

— the indications referred to in points (b), (c), (d) and (e) of Article 5(1), and,

— where appropriate, the indications referred to in Article 5(2) and Article 5(4), second subparagraph,

(b) general provisions regarding the application of the indications referred to in point (a), including applicable tolerances;

(c) amendments to the measures adopted in accordance with points (a) and (b) in line with developments in scientific and technical knowledge.

The measures provided for in points (b) and (c), designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 9(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 9(4).;

2. Article 8(2) shall be replaced by the following:

2. The Commission shall initiate as soon as possible the regulatory procedure laid down in Article 9(2) with a view to adopting any appropriate measures aimed at confirming, amending or repealing the national measure.;

3. Article 9(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.

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..

5.3. **Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and products**[(5)]

As regards Directive 96/23/EC, the Commission should be empowered in particular to adopt amendments to the Annexes. Since those measures are of general scope and are designed to amend non-essential elements of Directive 96/23/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.

Accordingly, Directive 96/23/EC is hereby amended as follows:

1. Article 6 shall be replaced by the following:

Article 6

1 The plan must conform to the sampling levels and frequencies laid down in Annex IV. However, at the request of a Member State the Commission may, in accordance with the regulatory procedure referred to in Article 33(2), adjust for the Member States concerned the minimum control requirements laid down in Annex IV provided that it is clearly established that such adjustments increase the overall effectiveness of the plan in respect of the Member State concerned and in no way reduce its ability to identify residues of, or cases of illegal treatment with, substances listed in Annex I.

2 Re-examination of the groups of residues to be checked for in accordance with Annex II and determination of the sampling levels and frequencies covering the animals and products referred to in Article 3 and not already laid down in Annex IV shall be carried out by the Commission and on the first occasion within a maximum of 18 months of the adoption of this Directive. In doing so, the Commission shall take account of experience gained under existing national measures and of information forwarded to the Commission under existing Community requirements making such specific product groups subject to monitoring for residues. 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 33(4).;

2. Article 8 shall be amended as follows:

(a) the second and third subparagraphs of paragraph 1 shall be replaced by the following:

Once the Commission has established their conformity, it shall submit the plans for approval in accordance with the regulatory procedure referred to in Article 33(3).

In order to take account of changes in the situation in a given Member State or in a region thereof, of the results of national surveys or of investigations carried out in the framework of Articles 16 and 17, the Commission may, at the request of the Member State concerned or on its own initiative, decide, in accordance with the regulatory procedure referred to in Article 33(2), to approve an amendment or addition to a plan previously approved pursuant to paragraph 2.;

(b) the fifth subparagraph of paragraph 2 shall be replaced by the following:

Where there are comments from Member States or where the Commission deems the update not to be in conformity or to be insufficient, the Commission shall submit the updated plans to the Standing Veterinary Committee, which must act under the regulatory procedure referred to in Article 33(3).;

3. the third subparagraph of Article 14(1) shall be replaced by the following:

A list of such designated laboratories shall be drawn up in accordance with the regulatory procedure referred to in Article 33(3).;

4. the second subparagraph of Article 15(1) shall be replaced by the following:

The detailed rules for the taking of official samples and the routine and reference methods to be employed for the analysis of such official samples shall be specified 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 33(4).;

5. the sixth subparagraph of Article 20(2) shall be replaced by the following:

In the light of the experts' opinion, appropriate measures may be taken in accordance with the regulatory procedure referred to in Article 33(2).;

6. the second subparagraph of paragraph 1 and paragraph 2 of Article 21 shall be replaced by the following:

The Member State concerned shall take the measures necessary to take account of the results of those verifications and shall notify the Commission of the measures taken. Where the Commission considers that the measures taken are insufficient, it shall, after consultation with the Member State in question and having regard to the measures necessary to safeguard public health, take appropriate measures in accordance with the regulatory procedure referred to in Article 33(2).

2 The general rules for implementing this Article, especially as regards the frequency and method of carrying out the verifications referred to in the first subparagraph of paragraph 1 (including cooperation with the competent authorities), shall be determined in accordance with the regulatory procedure referred to in Article 33(3).;

7. Article 29 shall be amended as follows:

(a) the fourth subparagraph of paragraph 1 shall be replaced by the following:

The Commission shall approve the plan in accordance with the regulatory procedure referred to in Article 33(3). Under the same procedure, guarantees other than those resulting from the implementation of this Directive may be accepted.;

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

2. Where the requirements of paragraph 1 are not complied with, inclusion of a third country on the lists of third countries laid down by Community legislation or as a result of the benefit of pre-listing may be suspended in accordance with the regulatory procedure referred to in Article 33(3), at the request of a Member State or by the Commission on its own initiative.;

8. the first subparagraph of Article 30(3) shall be replaced by the following:

3. If, in cases involving third countries which have concluded equivalence agreements with the Community, the Commission, after making enquiries of the competent authorities of the third countries concerned, concludes that they have failed to fulfil their obligations and the guarantees given by the plans referred to in Article 29(1), it shall cease to allow the country concerned, under the regulatory procedure referred to in Article 33(2), to benefit from the said agreements for the animals and products in question until that third country has made good its shortcomings. The suspension shall be revoked under the same procedure.;

9. Article 32 shall be deleted;

10. Articles 33, 34 and 35 shall be replaced by the following:

Article 33

1 The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health set up pursuant to Article 58 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matter of food safety[(6)].

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

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at fifteen days.

3 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 laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

4 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.

Article 34

Without prejudice to Article 6(2), Annexes I, III, IV and V may be amended or supplemented by the Commission. In particular, those Annexes may be amended with a view to risk assessment of the following factors:

— potential toxicity of residues in foodstuffs of animal origin,

— likelihood of residues occurring in foodstuffs of animal origin,

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 33(4).

Article 35

The Commission may adopt transitional measures required for the implementation of the arrangements laid down by this Directive.

Transitional measures of general scope, designed to amend non-essential elements of this Directive, *inter alia*, by supplementing it with new non-essential elements, and in particular further specifications of the requirements laid down in this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(4).

Other transitional measures may be adopted in accordance with the regulatory procedure referred to in Article 33(2)..

5.4. **Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients**[8]

As regards Regulation (EC) No 258/97, the Commission should be empowered in particular to adopt data protection arrangements. Since those measures are of general scope and are designed to supplement Regulation (EC) No 258/97 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, Regulation (EC) No 258/97 is hereby amended as follows:

1. in Article 1(3), the words ‘Article 13’ shall be replaced by the words ‘Article 13(2)’;

2. in the second subparagraph of Article 3(4), the words ‘Article 13’ shall be replaced by the words ‘Article 13(2)’;

3. in Article 4(5), the words ‘Article 13’ shall be replaced by the words ‘Article 13(2)’;

4. in Article 7(1), the words ‘Article 13’ shall be replaced by the words ‘Article 13(2)’;

5. in Article 8(3), the words ‘Article 13’ shall be replaced by the words ‘Article 13(2)’;

6. Article 10 shall be replaced by the following:

Article 10

Detailed rules for the protection of the information provided by the applicant shall be adopted by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 13(3).;

7. Article 12(2) shall be replaced by the following**:**

2. The Commission shall examine the grounds referred to in paragraph 1 as soon as possible within the Standing Committee for Foodstuffs. It shall take the appropriate measures aimed at confirming, amending or repealing the national measure in accordance with the regulatory procedure laid down in Article 13(2). The Member State which took the decision referred to in paragraph 1 may maintain it until the measures have entered into force.;

8. Article 13(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..

5.5. **Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community**[(9)]

As regards Decision No 2119/98/EC, the Commission should be empowered in particular to establish the communicable diseases and the criteria for selection of those diseases to be covered by the Community network, as well as the epidemiological and microbiological surveillance methods. Since those measures are of general scope and are designed to amend non-essential elements of Decision No 2119/98/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 an emergency situation occurs with regard to the appearance or to new developments of a serious communicable disease, the epidemiological surveillance system should be triggered as soon as possible, in order to ensure protection of the population and public health. 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 have recourse to the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of decisions determining the communicable diseases, the criteria for the selection of those diseases and the epidemiological and microbiological surveillance methods, as well as for the amendments to the Annex to Decision No 2119/98/EC containing the list of categories of communicable diseases.

Accordingly, Decision No 2119/98/EC is hereby amended as follows:

1. Article 3 shall be amended as follows:

(a) the introductory words shall be replaced by the following:

> With a view to the effective operation of the Community network with regard to epidemiological surveillance and to achieving uniform information within this framework, the following shall be adopted by the Commission:;

(b) the following paragraphs shall be added:

> The measures referred to in points (a), (b) and (e), designed to amend non-essential elements of this Decision, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 7(4).

The measures referred to in points (c), (d), (f), (g) and (h) shall be adopted in accordance with the regulatory procedure referred to in Article 7(2).;

2. Article 6(5) shall be replaced by the following:

5. Procedures concerning the information and consultation referred to in paragraphs 1, 2 and 3 and procedures concerning the coordination referred to in paragraphs 1 and 4 shall be established in accordance with the regulatory procedure referred to in Article 7(2).;

3. Article 7 shall be amended as follows:

(a) paragraph 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.;

(b) the following paragraph shall be added:

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.;

4. Article 8 shall be replaced by the following:

Article 8

The Annex may be amended or supplemented by the Commission. Those measures, designed to amend non-essential elements of this Decision, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 7(4)..

5.6. Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs[(10)]

As regards Directive 2000/13/EC, the Commission should be empowered in particular to adopt certain measures necessary for its implementation. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2000/13/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 have recourse to the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the amendment of the lists of certain categories of ingredients.

Accordingly, Directive 2000/13/EC is hereby amended as follows:

1. Article 4(3) shall be replaced by the following:

3. The Community provisions referred to in paragraphs 1 and 2 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 20(3).;

2. Article 6 shall be amended as follows:

(a) point (d) of the second subparagraph of paragraph 3a shall be replaced by the following:

(d) as regards other products, being measures designed to amend non-essential elements of this Directive, in accordance with the regulatory procedure with scrutiny referred to in Article 20(3).;

(b) the second subparagraph of paragraph 6 shall be amended as follows:

(i) the first indent shall be replaced by the following:

— ingredients which belong to one of the categories listed in Annex I and are constituents of another foodstuff need only be designated by the name of that category.

Alterations to the list of categories in Annex I may be effected by the Commission. 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 20(3).

However, the designation “starch” listed in Annex I must always be complemented by the indication of its specific vegetable origin, when that ingredient may contain gluten,;

(ii) the second indent shall be replaced by the following:

— ingredients belonging to one of the categories listed in Annex II must be designated by the name of that category, followed by their specific name or EC number; if an ingredient belongs to more than one of the categories, the category appropriate to the principal function in the case of the foodstuff in question shall be indicated.

Amendments to Annex II based on advances in scientific and technical knowledge, being measures designed to amend non-essential elements of this Directive, shall be adopted by the Commission in accordance with the regulatory procedure with scrutiny referred to in Article 20(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 20(4).

However, the designation “modified starch” listed in Annex II must always be complemented by the indication of its specific vegetable origin, when that ingredient may contain gluten,;

(c) the third subparagraph of paragraph 7 shall be replaced by the following:

The Community provisions referred to in this paragraph 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 20(3).;

(d) the third subparagraph of paragraph 11 shall be replaced by the following:

Without prejudice to the second subparagraph, Annex IIIa may be amended by the Commission, after an opinion has been obtained from the European Food Safety Authority issued on the basis of Article 29 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety[11]. 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 20(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 20(4).;

3. Article 7 shall be amended as follows:

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

(d) in the cases determined by the Commission; determination of such cases, being a measure designed to amend non-essential elements of this Directive by supplementing it, shall be carried out in accordance with the regulatory procedure with scrutiny referred to in Article 20(3).;

(b) paragraph 3(d) shall be replaced by the following:

(d) in the cases determined by the Commission; determination of such cases, being a measure designed to amend non-essential elements of this Directive by supplementing it, shall be carried out in accordance with the regulatory procedure with scrutiny referred to in Article 20(3).;

(c) the third sentence of paragraph 4 shall be replaced by the following:

‘Such provisions shall be adopted by the Commission. That measure, 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 20(3).’;

4. Article 8 shall be amended as follows:

(a) the third subparagraph of paragraph 4 shall be replaced by the following:

This list may be supplemented by the Commission. That measure, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 20(3).;

(b) paragraph 6 shall be replaced by the following:

6. The Community provisions referred to in paragraphs 1, second subparagraph, 2(b) and (d) and 5, second subparagraph, shall be adopted by the Commission. That measure, 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 20(3).;

5. in Article 11(2), the third subparagraph shall be replaced by the following:

The Community provisions referred to in this paragraph shall be adopted by the Commission. That measure, 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 20(3).;

6. in Article 12, the second paragraph shall be replaced by the following:

In the case of other beverages containing more than 1,2 % by volume of alcohol, these rules shall be laid down by the Commission.

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 20(3).;

7. Article 16(1) shall be replaced by the following:

1. Member States shall ensure that the sale is prohibited within their own territories of foodstuffs for which the particulars provided for in Article 3 and Article 4(2) do not appear in a language easily understood by the consumer, unless the consumer is in fact informed by means of other measures, determined as regards one or more labelling particulars. Determination of such measures, being a measure designed to amend non-essential elements of this Directive by supplementing it, shall be carried out in accordance with the regulatory procedure with scrutiny referred to in Article 20(3).;

8. Article 20 shall be amended as follows:

(a) paragraph 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.;

(b) the following paragraph shall be added:

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.;

9. Article 21 shall be replaced by the following:

Article 21

The Commission shall adopt temporary measures, if these prove necessary in order to facilitate the application of this Directive.

Temporary measures of general scope designed to amend non-essential elements of this Directive, including those supplementing it with new non-essential elements, in particular further specifications of the requirements laid down in the provisions of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 20(3).

Other temporary measures may be adopted in accordance with the regulatory procedure referred to in Article 20(2)..

5.7. Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products[(12)]

As regards Directive 2001/37/EC, the Commission should be empowered in particular to adopt rules for the use of colour photographs or the illustrations on tobacco products and to adapt the provisions on the measurement methods and on the health warnings to scientific and technical progress. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2001/37/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.

Accordingly, Directive 2001/37/EC is hereby amended as follows:

1. the first subparagraph of Article 5(3) shall be replaced by the following:

3. The rules for the use of colour photographs or other illustrations to depict and explain the health consequences of smoking shall be adopted by the Commission with a view to ensuring that internal market provisions are not undermined. 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).;

2. Article 9 shall be replaced by the following:

Article 9

Adaptations

1 The adaptation to scientific and technical progress of the measurement methods laid down in Article 4 and the definitions relating thereto shall be decided 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).

2 The adaptation to scientific and technical progress of health warnings to be shown on unit packets of tobacco products as set out in Annex I and the frequency of rotation of the health warnings shall be decided 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).

3 The Commission shall, in accordance with the procedure laid down in Article 10(2), adapt to scientific and technical progress the marking for identification and tracing purposes of tobacco products.;

3. Article 10 shall be replaced by the following:

Article 10

Committee procedure

1 The Commission shall be assisted by a committee.

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.

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..

5.8. Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety[(13)]

As regards Directive 2001/95/EC, the Commission should be empowered in particular to set out and adapt the principal rules and procedures of notification of serious risks from products. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2001/95/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 and in particular because the adequacy of the principal rules and procedures regarding notifications of serious risks from products is a precondition for the proper functioning of the rapid alert system, the time-limits for the regulatory procedure with scrutiny should be curtailed.

Accordingly, Directive 2001/95/EC is hereby amended as follows:

1. Article 4(1)(a) shall be replaced by the following:

(a) the requirements intended to ensure that products which conform to those standards satisfy the general safety requirement 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 15(4);;

2. the second subparagraph of Article 5(3) shall be replaced by the following:

The Commission shall adapt the specific requirements relating to the obligation to provide information laid down in Annex I. 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 15(5).;

3. Article 12(3) shall be replaced by the following:

3. Detailed procedures for RAPEX are set out in Annex II. They shall be adapted 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 15(5).;

4. Article 15 shall be replaced by the following:

Article 15

1 The Commission shall be assisted by a Committee.

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 laid down in Article 5(6) of Decision 1999/468/EC shall be set at 15 days.

3 Where reference is made to this paragraph, Articles 3 and 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 Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

5 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 laid down 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..

5.9. **Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety**[(14)]

As regards Regulation (EC) No 178/2002, the Commission should be empowered in particular to adopt provisions relating to the number and names of the Scientific Panels, the rules of procedure for submitting a request for an opinion to the Authority and the criteria for inclusion of an institute on the list of competent organisations designated by the Member States. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 178/2002, *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.

Accordingly, Regulation (EC) No 178/2002 is hereby amended as follows:

1. the second subparagraph of Article 28(4) shall be replaced by the following:

> The number and names of the Scientific Panels may be adapted in the light of technical and scientific development by the Commission, at the Authority's request. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 58(3).;

2. Article 29(6) shall be replaced by the following:

6. The implementing rules for the application of this Article shall be established by the Commission after consulting the Authority. Those rules shall specify in particular:

- a the procedure to be applied by the Authority to the requests referred to it;
- b the guidelines governing the scientific evaluation of substances, products or processes which are subject under Community legislation to a system of prior authorisation or entry on a positive list, in particular where Community legislation makes provision for, or authorises, a dossier to be presented for this purpose by the applicant.

The measure referred to in point (a), designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 58(3).

The guidelines referred to in point (b) shall be adopted in accordance with the regulatory procedure referred to in Article 58(2).;

3. Article 36(3) shall be replaced by the following:

3. The Commission, after consulting the Authority, shall lay down rules establishing the criteria for inclusion of an institute on the list of competent organisations designated by the Member States, arrangements for setting out harmonised quality requirements and the financial rules governing any financial support. Those measures, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 58(3).

Other implementing rules for the application of paragraphs 1 and 2 shall be laid down by the Commission, after consulting the Authority, in accordance with the regulatory procedure referred to in Article 58(2).;

4. paragraphs 2 and 3 of Article 58 shall be replaced by the following:

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 laid down 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..

5.10. **Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption[(15)]**

As regards Regulation (EC) No 1774/2002, the Commission should be empowered in particular to establish rules on the disposal, processing, importation/exportation and transformation of Category 1, 2 and 3 material of animal by-products, as well as rules on the placing on the market of animal by-products coming from territories subject to animal health restrictions and of organic fertilisers and soil improvers; to define the conditions for the importation from third countries of petfood and raw material for petfood production; and to define specific or alternative hygiene requirements laid down in the Annexes. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 1774/2002, *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 have recourse to the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of the rules regarding the placing on the market of animal by-products, or products deriving therefrom, coming from territories subject to animal health restrictions, for the adoption of alternative rules for specific situations regarding the placing on the market of animal by-products, or products deriving therefrom, coming from territories subject to animal health restrictions and for amendment of the Annexes.

Accordingly, Regulation (EC) No 1774/2002 is hereby amended as follows:

1. Article 3(2) shall be replaced by the following:

2. However, Member States may regulate under national law the importation and placing on the market of products not referred to in Annexes VII and VIII, pending the adoption of a decision by the Commission. That measure, designed to amend

non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3). Member States shall immediately inform the Commission of the use that they make of this possibility.;

2. Article 4 shall be amended as follows:

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

(e) in the light of developments in scientific knowledge, disposed of by other means that are approved by the Commission after consultation of the appropriate scientific committee. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3). Those means may either supplement or replace those provided for in points (a) to (d) of this paragraph.;

(b) the first sentence of paragraph 4 shall be replaced by the following:

'Category 1 material shall not be imported or exported except in accordance with this Regulation or with rules laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).';

3. Article 5 shall be amended as follows:

(a) paragraph 2 shall be amended as follows:

(i) in point (c), point (i) shall be replaced by the following:

(i) in the case of resulting proteinaceous material, used as an organic fertiliser or soil improver in compliance with requirements, if any, laid down by the Commission after consultation of the appropriate scientific committee. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3),;

(ii) point (d) shall be replaced by the following:

(d) in the case of material of fish origin, ensiled or composted in compliance with rules adopted by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3);;

(iii) in point (e), point (iii) shall be replaced by the following:

(iii) transformed in a biogas plant or composted in accordance with rules laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in

accordance with the regulatory procedure with scrutiny referred to in Article 33(3);;

(iv) point (g) shall be replaced by the following:

(g) disposed of by other means, or used in other ways, in accordance with rules laid down by the Commission after consultation of the appropriate scientific committee. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3). Those means or ways may either supplement or replace those provided for in points (a) to (f) of this paragraph.;

(b) paragraph 4 shall be replaced by the following:

4. Category 2 material shall not be placed on the market or exported except in accordance with this Regulation or with rules laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).;

4. points (g), (h) and (i) of Article 6(2) shall be replaced by the following:

(g) in the case of catering waste referred to in paragraph 1(l), transformed in a biogas plant or composted in accordance with rules laid down by the Commission, or, pending the adoption of such rules, in accordance with national law. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3);

(h) in the case of material of fish origin, ensiled or composted in accordance with rules laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3); or

(i) disposed of by other means, or used in other ways, in accordance with rules laid down by the Commission after consultation of the appropriate scientific committee; those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3). Those means or ways may either supplement or replace those provided for in points (a) to (h).;

5. Article 12(5) shall be replaced by the following:

5. The requirements of paragraphs 2 and 3 may be amended by the Commission in the light of developments in scientific knowledge, after consultation of the appropriate scientific committee. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).;

6. Article 16(3) shall be amended as follows:

(a) point (d) shall be replaced by the following:

(d) comply with the requirements laid down in Annexes VII and VIII, or with detailed rules to be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 33(4).;

(b) the first sentence of the second subparagraph shall be replaced by the following:

'Conditions alternative to those set out in the first subparagraph may be laid down in specific situations by decisions adopted by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 33(4).';

7. Article 20(2) shall be replaced by the following:

2. Member States shall ensure that organic fertilisers and soil improvers produced from processed products, other than those produced from manure and digestive tract content, are placed on the market or exported only if they meet requirements, if any, laid down by the Commission after consultation of the appropriate scientific committee. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3);

8. Article 22(2) shall be replaced by the following:

2. The Commission shall establish rules concerning control measures. Those measures, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).

Other rules for the implementation of this Article shall be adopted in accordance with the regulatory procedure referred to in Article 33(2).

Derogations from paragraph 1(a) may be granted in relation to fish and fur animals, after consultation of the appropriate scientific committee. Those measures, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).;

9. Article 23 shall be amended as follows:

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

(d) In addition, Member States may authorise the use, under the supervision of the competent authorities, of Category 1 material referred to in Article 4(1)(b)(ii) for the feeding of endangered or protected species of necrophagous birds in accordance with rules laid down by the Commission after consultation of the European Food Safety Authority. Those measures, designed to amend non-

essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).;

(b) paragraph 5 shall be replaced by the following:

5. Detailed rules concerning verification measures may be adopted by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).;

10. Article 25(3) shall be replaced by the following:

3. The Commission may lay down rules concerning the frequency of checks and reference methods for microbiological analyses. Those measures, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).

Any other detailed arrangements for implementing this Article may be laid down under the regulatory procedure referred to in Article 33(2).;

11. Article 26(5) shall be replaced by the following:

5. The Commission may lay down rules concerning the frequency of checks and reference methods for microbiological analyses. Those measures, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).

Any other detailed arrangements for implementing this Article may be laid down under the regulatory procedure referred to in Article 33(2).;

12. the second paragraph of Article 28 shall be replaced by the following:

However, the importation from third countries of petfood and raw material for petfood production, derived from animals which have been treated with certain substances prohibited in accordance with Directive 96/22/EC, shall be permitted provided that such raw material is permanently marked and under specific conditions laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).;

13. Article 32(1) shall be replaced by the following:

1. After consultation of the appropriate scientific committee on any question that could have an impact on animal or public health, the Annexes may be amended or supplemented and any appropriate transitional measures may be adopted by the Commission.

Transitional measures and measures amending or supplementing the Annexes, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, in particular further specifications of the requirements laid down in this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 33(4).

Other transitional measures may be adopted in accordance with the regulatory procedure referred to in Article 33(2).;

14. Article 33 shall be replaced as follows:

Article 33

Committee procedure

1 The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, hereinafter referred to as "the Committee".

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 laid down in Article 5(6) of Decision 1999/468/EC shall be set at 15 days.

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.;

15. in Annex III, Chapter II, Part B, point 11 shall be replaced by the following:

11. Waste water must be treated to ensure, as far as is reasonably practicable, that no pathogens remain. Specific requirements for the treatment of waste water from Category 1 and Category 2 intermediate plants may be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).;

16. Annex V shall be amended as follows:

(a) point 4 of Chapter II shall be replaced by the following:

4. Waste water originating in the unclean sector must be treated to ensure, as far as is reasonably practicable, that no pathogens remain. Specific requirements for the treatment of waste water from processing plants may be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).;

(b) point 5 of Chapter V shall be replaced by the following:

5. Validation procedures based on testing methods may be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).;

17. Annex VI shall be amended as follows:

(a) point 8 in Part C of Chapter I shall be replaced by the following:

8. Processed products derived from Category 1 or 2 material, with the exception of liquid products destined for biogas or composting plants, must be permanently marked, where technically possible with smell, using a system approved by the competent authority. Detailed rules for such marking may be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).;

(b) point 2(b) of Chapter III shall be replaced by the following:

(b) in a continuous process at 140 °C 2 bars (2 000 hPa) for eight minutes, or under equivalent conditions laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).;

18. Annex VII shall be amended as follows:

(a) point 13(b) in Part C of Chapter II shall be replaced by the following:

(b) reprocessed in a processing plant approved pursuant to this Regulation or decontaminated by a treatment authorised by the competent authority. A list of permitted treatments may be established by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3). The consignment must not be released until it has been treated, tested for salmonella by the competent authority in accordance with Chapter I, paragraph 10, and a negative result obtained.;

(b) Chapter V shall be amended as follows:

(i) point 5 of Part A shall be replaced by the following:

5. Raw milk and colostrum must be produced under conditions offering adequate guarantees as regards animal health. Such conditions may be established by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).;

(ii) point 3 of Part B shall be replaced by the following:

3. Where a risk of introduction of an exotic disease or any other risk to animal health is identified, additional conditions for the protection of animal health may be established by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in

accordance with the regulatory procedure with scrutiny referred to in Article 33(3).;

(c) point 3(c) in Part B of Chapter VI shall be replaced by the following:

(c) an equivalent production process approved by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).;

(d) point 1 in Part A of Chapter VII shall be replaced by the following:

1. Dicalcium phosphate must be produced by a process that:

(a) ensures that all Category 3 bone-material is finely crushed and degreased with hot water and treated with dilute hydrochloric acid (at a minimum concentration of 4 % and a pH of less than 1,5) over a period of at least two days;

(b) following the procedure provided for in point (a), applies a treatment of the obtained phosphoric liquor with lime, resulting in a precipitate of dicalcium phosphate at pH 4 to 7; and

(c) finally, air-dries the precipitate of dicalcium phosphate with inlet temperature of 65 °C to 325 °C and end temperature between 30 °C and 65 °C, or

by an equivalent process approved by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).;

(e) point 1 in Part A of Chapter VIII shall be replaced by the following:

1. Tricalcium phosphate must be produced by a process that ensures:

(a) that all Category 3 bone-material is finely crushed and degreased in counter-flow with hot water (bone chips less than 14 mm);

(b) continuous cooking with steam at 145 °C during 30 minutes at 4 bars;

(c) separation of the protein broth from the hydroxyapatite (tricalcium phosphate) by centrifugation; and

(d) granulation of the tricalcium phosphate after drying in a fluid bed with air at 200 °C; or

by an equivalent production process approved by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).;

19. Annex VIII shall be amended as follows:

(a) point 2(e) in Part A of Chapter VI shall be replaced by the following:

(e) preserved by a process other than tanning specified by the Commission. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).;

(b) point 4(a)(iii) in Part A of Chapter VII shall be replaced by the following:

(iii) preserved by a treatment other than tanning approved by the Commission. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3)..

5.11. Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components[16]

As regards Directive 2002/98/EC, the Commission should be empowered in particular to adapt the technical requirements set out in Annexes I to IV to technical and scientific progress. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2002/98/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.

In the event that scientific and technical developments indicate that additional information should be provided to or obtained from donors, in order, for instance, to exclude donors presenting a health risk to others, an adaptation should be made without delay. Similarly, if scientific progress suggests new eligibility criteria concerning the suitability of blood and plasma donors, new deferral criteria should be added to the list immediately. 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 have recourse to the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adaptation to scientific and technical progress of the technical requirements concerning information to be provided to or obtained from donors, as well as requirements related to the suitability of blood and plasma donors, set out in Annexes I to IV.

Accordingly, Directive 2002/98/EC is hereby amended as follows:

1. Article 28 shall be replaced by the following:

Article 28

Committee procedure

1 The Commission shall be assisted by a Committee.

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 referred to 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), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.;

2. Article 29 shall be amended as follows:

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

> The adaptation of the technical requirements set out in Annexes I to IV to technical and scientific progress shall be decided 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 28(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 28(4) as regards technical requirements set out in Annexes III and IV.;

(b) the introductory wording in the second paragraph shall be replaced by the following:

> The following technical requirements and their adaptation to technical and scientific progress shall be decided by the Commission:;

(c) the following paragraphs are added:

> Technical requirements referred to in points (a) to (i) of the second paragraph, being 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 28(3).
>
> On imperative grounds of urgency the Commission may have recourse to the urgency procedure referred to in Article 28(4) as regards technical requirements referred to in points (b), (c),(d), (e), (f) and (g) of the second paragraph..

5.12. Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition[(17)]

As regards Regulation (EC) No 1831/2003, the Commission should be empowered in particular to establish, as a result of technological progress or scientific development, additional feed additive categories and functional groups, to adopt amendments to Annex III and to the general conditions of Annex IV to take technological progress and scientific development into account and to adopt amendments to Annex II. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 1831/2003, *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.

Accordingly, Regulation (EC) No 1831/2003 is hereby amended as follows:

1. Article 3(5) shall be replaced by the following:

5. Where necessary, as a result of technological progress or scientific development, the Commission may adapt the general conditions set out in Annex IV. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 22(3).;

2. Article 6(3) shall be replaced by the following:

3. Where necessary, as a result of technological progress or scientific development, the Commission shall establish additional feed additive categories and functional groups. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 22(3).;

3. the second subparagraph of Article 7(5) shall be replaced by the following:

After the Authority has been consulted, further rules for the implementation of this Article may be established.

Rules to allow for simplified provisions for the authorisation of additives which have been authorised for use in food shall be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 22(3).

Other implementing rules may be adopted in accordance with the regulatory procedure referred to in Article 22(2). Those rules should, where appropriate, differentiate between requirements for feed additives in respect of food-producing animals and requirements in respect of other animals, in particular pets.;

4. Article 16(6) shall be replaced by the following:

6. The Commission may adopt amendments to Annex III to take technological progress and scientific development into account. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 22(3).;

5. the third paragraph of Article 21 shall be replaced by the following:

Detailed rules for implementing Annex II shall be adopted in accordance with the regulatory procedure referred to in Article 22(2).

Annex II may be amended by the Commission. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 22(3).;

6. Article 22(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..

5.13. Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods[(18)]

As regards Regulation (EC) No 2065/2003, the Commission should be empowered in particular to adopt amendments to the Annexes. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 2065/2003, *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.

Accordingly, Regulation (EC) No 2065/2003 is hereby amended as follows:

1. Article 17(3) shall be replaced by the following:

3. If necessary, the Commission shall, after requesting scientific and technical assistance from the Authority, adopt quality criteria for validated analytical methods proposed in accordance with point 4 of Annex II, including substances to be measured.

Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 19(3).;

2. Article 18 shall be replaced by the following:

Article 18

Amendments

1 Amendments to the Annexes shall be adopted by the Commission following a request to the Authority for scientific and/or technical assistance. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 19(3).

2 Amendments to the list referred to in Article 6(1) shall be adopted in accordance with the regulatory procedure referred to in Article 19(2) following a request to the Authority for scientific and/or technical assistance.;

3. Article 19(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..

5.14. **Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents[19]**

As regards Regulation (EC) No 2160/2003, the Commission should be empowered in particular to adopt Community targets for the reduction of the prevalence of zoonoses and zoonotic agents, specific control methods and specific rules concerning the criteria for the evaluation of the testing methods, and to lay down the responsibilities and tasks of the reference laboratories and the rules for the implementation of Community controls. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 2160/2003, *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.

Accordingly, Regulation (EC) No 2160/2003 is hereby amended as follows:

1. Article 4 shall be amended as follows:

(a) the second subparagraph of paragraph 1 shall be replaced by the following:

The targets, and any amendments thereto, shall be established by the Commission. Those measures, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).;

(b) paragraph 6(a) shall be replaced by the following:

(a) Annex I may be amended by the Commission for the purposes listed in point (b), after taking account in particular of the criteria listed in point (c). Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).;

(c) paragraph 7 shall be replaced by the following:

7. Annex III may be amended or supplemented by the Commission. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).;

2. Article 5(6) shall be replaced by the following:

6. The requirements and minimum sampling rules laid down in Annex II may be amended, adapted or supplemented by the Commission, after taking account in particular of the criteria listed in Article 4(6)(c). Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).;

3. Article 8(1) shall be amended as follows:

(a) the introductory words shall be replaced by the following:

At the initiative of the Commission or at the request of a Member State:;

(b) the following subparagraph shall be added:

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).;

4. Article 9(4) shall be replaced by the following:

4. Without prejudice to Article 5(6), specific rules concerning the setting by Member States of the criteria referred to in Article 5(5) and in paragraph 2 of this Article may be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).;

5. Article 10(5) shall be replaced by the following:

5. The Member State of final destination may be authorised, in accordance with the regulatory procedure referred to in Article 14(2), to require for a transitional period that the results of the testing referred to in paragraph 4 of this Article fulfil the same criteria as those laid down under its national programme, in accordance with Article 5(5). The authorisation may be withdrawn and, without prejudice to Article 5(6), specific rules concerning such criteria may be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).;

6. Article 11 shall be amended as follows:

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

2. The responsibilities and tasks of the Community reference laboratories, in particular with regard to coordination of their activities and those of the national reference laboratories, shall be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).;

(b) paragraph 4 shall be replaced by the following:

4. Certain responsibilities and tasks of the national reference laboratories, in particular with regard to coordination of their activities and those of the relevant laboratories in the Member States designated under Article 12(1)(a), may be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).;

7. the third subparagraph of Article 12(3) shall be replaced by the following:

Where necessary, other methods for testing may be approved by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).;

8. Article 13 shall be replaced by the following:

Article 13

Implementing and transitional measures

Appropriate transitional or implementing measures, including the necessary amendments to the relevant health certificates, may be adopted by the Commission. Transitional measures of general scope designed to amend non-essential elements of this Regulation, including those supplementing it with new non-essential elements, in particular further specifications of the requirements laid down in the provisions of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).

Other implementing or transitional measures may be adopted in accordance with the regulatory procedure referred to in Article 14(2).;

9. Article 14(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.;

10. Article 17(2) shall be replaced by the following:

2. Practical arrangements for the implementation of this Article, in particular those governing the procedure for cooperation with national competent authorities, shall be laid down under the regulatory procedure referred to in Article 14(2)..

5.15. **Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement,**

testing, processing, preservation, storage and distribution of human tissues and cells[(20)]

As regards Directive 2004/23/EC, the Commission should be empowered in particular to establish traceability requirements for tissues and cells and the related procedures of enforcement as well as certain technical requirements regarding, *inter alia*, an accreditation system for tissue establishments and the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2004/32/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.

In the event that scientific and technical developments on selection criteria and laboratory tests for donors provide for new evidence of diseases transmissible through donation, prompt adaptation of Community legislation should follow consequently. 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 have recourse to the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of decisions concerning the criteria for selection of the donor of tissues and/or cells and the laboratory tests required for donors.

Accordingly, Directive 2004/23/EC is hereby amended as follows:

1. Article 8 shall be amended as follows:

   (a) paragraph 5 shall be replaced by the following:

   > 5. The traceability requirements for tissues and cells, as well as for products and materials coming into contact with those tissues and cells and having an effect on their quality and safety, 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 29(3).;

   (b) paragraph 6 shall be replaced by the following:

   > 6. The procedures for ensuring traceability at Community level shall be established 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 29(3).;

2. Article 9(4) shall be replaced by the following:

4. The procedures for verifying the equivalent standards of quality and safety in accordance with paragraph 1 shall be established by the Commission 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 29(3).;

3. Article 28 shall be amended as follows:

   (a) the introductory wording shall be replaced by the following:

   > The following technical requirements and their adaptation to scientific and technical progress shall be decided by the Commission:;

   (b) the following paragraphs shall be added:

Technical requirements referred to in points (a) to (i), being 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 29(3).

On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 29(4) as regards technical requirements referred to in points (d) and (e) of this Article.;

4. Article 29 shall be amended as follows:

(a) paragraph 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.;

(b) the following paragraph shall be added:

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..

5.16. **Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules[(21)]**

As regards Regulation (EC) No 882/2004, the Commission should be empowered in particular to adopt implementing measures concerning methods of sampling and analysis, to lay down the conditions in which special treatment may take place, to update the minimum rates for any fees or charges, to determine the circumstances in which official certification is required, to amend and update the lists of Community reference laboratories, and to lay down the criteria for assessing the risk of products exported to the Community and specific import conditions. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 882/2004, *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.

Accordingly, Regulation (EC) No 882/2004 is hereby amended as follows:

1. Article 11(4) shall be amended as follows:

(a) the introductory wording shall be replaced by the following:

The following implementing measures may be taken by the Commission:;

(b) the following subparagraph shall be added:

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4).;

2. Article 20(2) shall be replaced by the following:

2. The competent authority shall ensure that special treatment takes place in establishments under its control, or under the control of another Member State, and in accordance with conditions laid down by the Commission. Those measures, designed

to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4). In the absence of such conditions, the special treatment shall take place in accordance with national rules.;

3. the second subparagraph of Article 27(3) shall be replaced by the following:

> The rates in Annex IV, Section B and Annex V, Section B shall be updated by the Commission at least every two years, in particular to take account of inflation. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4).;

4. Article 30(1) shall be amended as follows:

(a) the introductory wording shall be replaced by the following:

> Without prejudice to requirements concerning official certification adopted for animal health or animal welfare purposes, requirements may be adopted by the Commission concerning:;

(b) the following subparagraphs are added:

> The measures referred to in point (a), designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4).
>
> The measures referred to in points (b) to (g) shall be adopted in accordance with the regulatory procedure referred to in Article 62(3).;

5. Article 32 shall be amended as follows:

(a) paragraph 5 shall be replaced by the following:

> 5. Other Community reference laboratories relevant to the areas referred to in Article 1 may be included in Annex VII by the Commission. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4). In accordance with the same procedure, Annex VII may be updated.;

(b) paragraph 6 shall be replaced by the following:

> 6. Additional responsibilities and tasks for Community reference laboratories may be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4).;

6. Article 33(6) shall be replaced by the following:

6. Additional responsibilities and tasks for national reference laboratories may be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4).;

7. the second subparagraph of Article 46(3) shall be replaced by the following:

The criteria for determining risk for the purpose of the risk assessment referred to in point (a) shall be decided by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4).;

8. Article 48(1) shall be replaced by the following:

1. To the extent that the conditions and detailed procedures to be respected when importing goods from third countries or their regions are not provided for by Community law and in particular by Regulation (EC) No 854/2004, they shall, if necessary, be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4).;

9. Article 62(4) shall be replaced by the following:

4. 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.;

10. Article 63 shall be replaced by the following:

Article 63

Implementing and transitional measures

1 Transitional measures of general scope, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it with new non-essential elements, in particular

— any modification of the standards referred to in Article 12(2),

— a definition of what feed is to be regarded as feed of animal origin for the purpose of this Regulation,

and further specifications of the requirements laid down in the provisions of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4).

Other transitional and implementing measures necessary in order to ensure the uniform application of this Regulation may be laid down in accordance with the regulatory procedure referred to in Article 62(3). This applies in particular to:

— the delegation of control tasks to control bodies referred to in Article 5, where those control bodies were already in operation before the entry into force of this Regulation,

— non-compliance as referred to in Article 28 which gives rise to expense arising from additional official controls,

— expenditure incurred pursuant to Article 54,

— rules on microbiological, physical and/or chemical analysis in official controls, in particular in cases involving a suspicion of risk and including the surveillance of the safety of products imported from third countries,

2 In order to take account of the specificity of Regulations (EEC) No 2092/91, (EEC) No 2081/92 and (EEC) No 2082/92, specific measures to be adopted by the Commission may provide for the necessary derogations from, and adjustments to, the

rules laid down in this Regulation. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4).;

11. Article 64 shall be replaced by the following:

Article 64

Amendment of Annexes and references to European standards

The following measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4):

(1) the Annexes to this Regulation may be updated, except for Annex I, Annex IV and Annex V, without prejudice to Article 27(3), in particular in order to take account of administrative changes and scientific and/or technological progress;

(2) the references to the European standards mentioned in this Regulation may be updated in the event that CEN amends those references..

5.17. **Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food[(22)]**

As regards Regulation (EC) No 1935/2004, the Commission should be empowered in particular to adopt specific measures for groups of materials and articles, Community authorisation of a substance, and the modification, suspension or revocation of such authorisation. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 1935/2004, *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.

In order to strengthen the competitiveness and innovation of the European industry, materials and articles intended to come into contact with food should be marketed as soon as possible once their safety has been established. On grounds of efficiency, the normal time-limits for the regulatory procedure with scrutiny should be curtailed for the adoption of a list of substances authorised for use in the manufacturing of materials and articles; list(s) of authorised substances incorporated in active or intelligent food contact materials and articles, list(s) of active or intelligent materials and articles and, when necessary, special conditions of use for those substances and/or the materials and articles in which they are incorporated; purity standards; special conditions of use for certain substances and/or the materials and articles in which they are used; specific limits on the migration of certain constituents or groups of constituents into or on to food; amendments of existing specific directives on materials and articles; Community authorisations and the modification, suspension or revocation thereof.

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 have recourse to the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of specific measures regarding the modification, suspension or revocation of Community authorisations.

Accordingly, Regulation (EC) No 1935/2004 is hereby amended as follows:

1. Article 5 shall be amended as follows:

(a) the first subparagraph of paragraph 1 shall be replaced by the following:

> For the groups of materials and articles listed in Annex I and, where appropriate, combinations of those materials and articles or recycled materials and articles used in the manufacture of those materials and articles, specific measures may be adopted or amended by the Commission.;

(b) the following subparagraphs shall be added to paragraph 1:

> The specific measures referred to in point (m) shall be adopted by the Commission in accordance with the regulatory procedure referred to in Article 23(2).
>
> The specific measures referred to in points (f), (g), (h), (i), (j), (k), (l) and (n), designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 23(3).
>
> The specific measures referred to in points (a) to (e), designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 23(4).;

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

> 2. The Commission may amend the existing specific directives on materials and articles. Those measures, designed to amend the non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 23(4).;

2. Article 11(3) shall be replaced by the following:

3. Community authorisation in the form of specific measure, as referred to in paragraph 1, shall be adopted by the Commission. That measure, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 23(4).;

3. Article 12(6) shall be replaced by the following:

6. A final specific measure on the modification, suspension or revocation of the authorisation shall be adopted by the Commission. That measure, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 23(4). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 23(5).;

4. Article 22 shall be replaced by the following:

Article 22

Amendments to Annexes I and II shall be adopted by the Commission. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 23(3).;

5. Article 23 shall be amended as follows:

(a) paragraph 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.;

(b) the following paragraphs shall be added:

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 laid down in Article 5a(3)(c), (4)(b) and (4(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..

(**1**) OJ L 37, 13.2.1993, p. 1.

(**2**) OJ L 291, 19.11.1969, p. 9.';

(**3**) OJ L 184, 17.7.1999, p. 23.';

(**4**) OJ L 237, 22.9.1993, p. 23.

(**5**) OJ L 125, 23.5.1996, p. 10.

(**6**) OJ L 31, 1.2.2002, p. 1.

(**7**) OJ L 184, 17.7.1999, p. 23.'.

(**8**) OJ L 43, 14.2.1997, p. 1.

(**9**) OJ L 268, 3.10.1998, p. 1.

(**10**) OJ L 109, 6.5.2000, p. 29.

(**11**) OJ L 31, 1.2.2002, p. 1.';

(**12**) OJ L 194, 18.7.2001, p. 26.

(**13**) OJ L 11, 15.1.2002, p. 4.

(**14**) OJ L 31, 1.2.2002, p. 1.

(**15**) OJ L 273, 10.10.2002, p. 1.

(**16**) OJ L 33, 8.2.2003, p. 30.

(**17**) OJ L 268, 18.10.2003, p. 29.

(**18**) OJ L 309, 26.11.2003, p. 1.

(**19**) OJ L 325, 12.12.2003, p. 1.

(**20**) OJ L 102, 7.4.2004, p. 48.

(**21**) OJ L 165, 30.4.2004, p. 1.

(**22**) OJ L 338, 13.11.2004, p. 4.

Changes to legislation:
Regulation (EC) No 596/2009 of the European Parliament and of the Council, Division 5. is up to date with all changes known to be in force on or before 12 October 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to :

- Regulation partial repeal by EUDN 2013/1082 Decision
- Regulation partial repeal by EUDR 2014/24 Directive
- Regulation partial repeal by EUDR 2014/25 Directive
- Regulation partial repeal by EUDR 2014/40 Directive
- Regulation partial repeal by EUDR 2014/53 Directive
- Regulation partial repeal by EUDR 2014/90 Directive
- Regulation partial repeal by EUR 2011/1169 Regulation
- Regulation partial repeal by EUR 2014/376 Regulation
- Regulation partial repeal by EUR 2014/536 Regulation