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 and repealing Directives 80/590/EEC and 89/109/EEC

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 and repealing Directives 80/590/EEC and 89/109/EEC

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee[(1)],

Acting in accordance with the procedure laid down in Article 251 of the Treaty[(2)],

Whereas:

(1) Council Directive 89/109/EEC of 21 December 1988 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs[(3)] established general principles for eliminating the differences between the laws of the Member States as regards those materials and articles and provided for the adoption of implementing directives concerning specific groups of materials and articles (specific directives). This approach was successful and should be continued.

(2) The specific directives adopted under Directive 89/109/EEC in general contain provisions which leave little room for the exercise of discretion by the Member States in their transposition besides being subject to frequent amendments required to adapt them rapidly to technological progress. It should therefore be possible for such measures to take the form of regulations or decisions. At the same time it is appropriate to include a number of additional subjects. Directive 89/109/EEC should therefore be replaced.

(3) The principle underlying this Regulation is that any material or article intended to come into contact directly or indirectly with food must be sufficiently inert to preclude substances from being transferred to food in quantities large enough to endanger human health or to bring about an unacceptable change in the composition of the food or a deterioration in its organoleptic properties.

(4) New types of materials and articles designed to actively maintain or improve the condition of the food (active food contact materials and articles) are not inert by their design, unlike traditional materials and articles intended to come into contact with food. Other types of new materials and articles are designed to monitor the condition of the food (intelligent food contact materials and articles). Both these types of materials and

articles may be brought into contact with food. It is therefore necessary, for reasons of clarity and legal certainty, for active and intelligent food contact materials and articles to be included in the scope of this Regulation and the main requirements for their use to be established. Further requirements should be stated in specific measures, to include positive lists of authorised substances and/or materials and articles, which should be adopted as soon as possible.

(5) Active food contact materials and articles are designed to deliberately incorporate 'active' components intended to be released into the food or to absorb substances from the food. They should be distinguished from materials and articles which are traditionally used to release their natural ingredients into specific types of food during the process of their manufacture, such as wooden barrels.

(6) Active food contact materials and articles may change the composition or the organoleptic properties of the food only if the changes comply with the Community provisions applicable to food, such as the provisions of Directive 89/107/EEC[(4)] on food additives. In particular, substances such as food additives deliberately incorporated into certain active food contact materials and articles for release into packaged foods or the environment surrounding such foods, should be authorised under the relevant Community provisions applicable to food and also be subject to other rules which will be established in a specific measure.
In addition, adequate labelling or information should support users in the safe and correct use of active materials and articles in compliance with the food legislation, including the provisions on food labelling.

(7) Active and intelligent food contact materials and articles should not change the composition or the organoleptic properties of food or give information about the condition of the food that could mislead consumers. For example, active food contact materials and articles should not release or absorb substances such as aldehydes or amines in order to mask an incipient spoilage of the food. Such changes which could manipulate signs of spoilage could mislead the consumer and they should therefore not be allowed. Similarly, active food contact materials and articles which produce colour changes to the food that give the wrong information concerning the condition of the food could mislead the consumer and therefore should not be allowed either.

(8) Any material or article intended to come into contact with food which is placed on the market should comply with the requirements of this Regulation. Nevertheless, materials and articles supplied as antiques should be excluded as they are available in restricted quantities and their contact with food is therefore limited.

(9) Covering or coating materials forming part of the food and possibly being consumed with it should not fall within the scope of this Regulation. On the other hand, this Regulation should apply to covering or coating materials which cover cheese rinds, prepared meat products or fruit but which do not form part of food and are not intended to be consumed together with such food.

(10) It is necessary to lay down various types of restrictions and conditions for the use of the materials and articles covered by this Regulation and the substances used in their manufacture. It is appropriate to establish those restrictions and conditions in specific

measures having regard to the technological characteristics specific to each group of materials and articles.

(11) Pursuant to 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[(5)], the European Food Safety Authority (the Authority) should be consulted before provisions liable to affect public health are adopted under specific measures.

(12) When specific measures include a list of substances authorised within the Community for use in the manufacture of materials and articles intended to come into contact with food, those substances should undergo a safety assessment prior to their authorisation. The safety assessment and authorisation of those substances should be without prejudice to the relevant requirements of the Community legislation concerning the registration, evaluation, authorisation and restriction of chemicals.

(13) Differences between national laws, regulations and administrative provisions concerning the safety assessment and authorisation of substances used in the manufacture of materials and articles intended to come into contact with food may hinder the free movement of those materials and articles, creating conditions of unequal and unfair competition. An authorisation procedure should therefore be established at Community level. In order to ensure harmonised safety assessment of those substances, the Authority should carry out such assessments.

(14) The safety assessment of substances should be followed by a risk management decision as to whether those substances should be entered on a Community list of authorised substances.

(15) It is appropriate to provide for the possibility of an administrative review of specific acts or omissions on the part of the Authority under this Regulation. This review should be without prejudice to the role of the Authority as an independent scientific point of reference in risk assessment.

(16) Labelling supports users in the correct use of the materials and articles. Methods used for such labelling may vary according to the user.

(17) Commission Directive 80/590/EEC[(6)] introduced a symbol that may accompany materials and articles intended to come into contact with foodstuffs. This symbol should, for reasons of simplicity, be incorporated in this Regulation.

(18) The traceability of materials and articles intended to come into contact with food should be ensured at all stages in order to facilitate control, the recall of defective products, consumer information and the attribution of responsibility. Business operators should at least be able to identify the businesses from which, and to which, the materials and articles are supplied.

(19) In the control of the compliance of the materials and articles with this Regulation, it is appropriate to take into account the special needs of developing countries, and in particular of the least developed countries. The Commission has been committed

by 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[(7)] to support developing countries with regard to food safety, including the safety of the materials and articles in contact with food. Special provisions have therefore been established in that Regulation which should be applicable also to the food contact materials and articles.

(20) It is necessary to establish procedures for the adoption of safeguard measures in situations where a material or article is likely to constitute a serious risk to human health.

(21) Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents[(8)] applies to documents held by the Authority.

(22) It is appropriate to protect the investment made by innovators in gathering the information and data supporting an application made under this Regulation. In order to avoid unnecessary repetition of studies and in particular animal testing, however, sharing of data should be permitted provided there is agreement between the interested parties.

(23) Community and national reference laboratories should be designated to contribute to a high quality and uniformity of analytical results. This objective will be achieved within the framework of Regulation (EC) No 882/2004.

(24) The use of recycled materials and articles should be favoured in the Community for environmental reasons, provided that strict requirements are established to ensure food safety and consumer protection. Such requirements should be established taking also into account the technological characteristics of the different groups of materials and articles mentioned in Annex I. Priority should be given to the harmonisation of rules on recycled plastic material and articles as their use is increasing and national laws and provisions are lacking or are divergent. Therefore, a draft of a specific measure on recycled plastic materials and articles should be made available to the public as soon as possible in order to clarify the legal situation in the Community.

(25) The measures necessary for the implementation of this Regulation and amendments to Annexes I and II hereto should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[(9)].

(26) Member States should lay down rules on sanctions applicable to infringements of the provisions of this Regulation and ensure that they are implemented. Such sanctions must be effective, proportionate and dissuasive.

(27) It is necessary for business operators to have sufficient time to adapt to some of the requirements established by this Regulation.

(28) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States because of the differences between the national laws and provisions and can therefore be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the

Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

(29) Directives 80/590/EEC and 89/109/EEC should therefore be repealed,

HAVE ADOPTED THIS REGULATION:

Article 1

Purpose and subject matter

1 The purpose of this Regulation is to ensure the effective functioning of the internal market in relation to the placing on the market in the Community of materials and articles intended to come into contact directly or indirectly with food, whilst providing the basis for securing a high level of protection of human health and the interests of consumers.

2 This Regulation shall apply to materials and articles, including active and intelligent food contact materials and articles, (hereinafter referred to as materials and articles) which in their finished state:

a are intended to be brought into contact with food;

or

b are already in contact with food and were intended for that purpose;

or

c can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use.

3 This Regulation shall not apply to:

a materials and articles which are supplied as antiques;

b covering or coating materials, such as the materials covering cheese rinds, prepared meat products or fruits, which form part of the food and may be consumed together with this food;

c fixed public or private water supply equipment.

Article 2

Definitions

1 For the purposes of this Regulation, the relevant definitions laid down in Regulation (EC) No 178/2002 shall apply, with the exception of the definitions of ‘traceability’ and ‘placing on the market’, which shall have the following meanings:

a ‘traceability’: the ability to trace and follow a material or article through all stages of manufacture, processing and distribution;

b ‘placing on the market’: the holding of materials and articles for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution and other forms of transfer themselves.

2 The following definitions shall also apply:

a ‘active food contact materials and articles’ (hereinafter referred to as active materials and articles) means materials and articles that are intended to extend the shelf-life or to maintain or improve the condition of packaged food. They are designed to deliberately

incorporate components that would release or absorb substances into or from the packaged food or the environment surrounding the food;

b ‘intelligent food contact materials and articles’ (hereinafter referred to as intelligent materials and articles) means materials and articles which monitor the condition of packaged food or the environment surrounding the food;

c ‘business’ means any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of manufacture, processing and distribution of materials and articles;

d ‘business operator’ means the natural or legal persons responsible for ensuring that the requirements of this Regulation are met within the business under their control.

Article 3

General requirements

1 Materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:

a endanger human health;

or

b bring about an unacceptable change in the composition of the food;

or

c bring about a deterioration in the organoleptic characteristics thereof.

2 The labelling, advertising and presentation of a material or article shall not mislead the consumers.

Article 4

Special requirements for active and intelligent materials and articles

1 In the application of Article 3(1)(b) and 3(1)(c), active materials and articles may bring about changes in the composition or organoleptic characteristics of food on condition that the changes comply with the Community provisions applicable to food, such as the provisions of Directive 89/107/EEC on food additives and related implementing measures, or, if no Community provisions exist, with the national provisions applicable to food.

2 Pending the adoption of additional rules in a specific measure on active and intelligent materials and articles, substances deliberately incorporated into active materials and articles to be released into the food or the environment surrounding the food shall be authorised and used in accordance with the relevant Community provisions applicable to food, and shall comply with the provisions of this Regulation and its implementing measures.

These substances shall be considered as ingredients within the meaning of Article 6(4)(a) of Directive 2000/13/EC[(10)].

3 Active materials and articles shall not bring about changes in the composition or organoleptic characteristics of food, for instance by masking the spoilage of food, which could mislead consumers.

4 Intelligent materials and articles shall not give information about the condition of the food which could mislead consumers.

5 Active and intelligent materials and articles already brought into contact with food shall be adequately labelled to allow identification by the consumer of non-edible parts.

6 Active and intelligent materials and articles shall be adequately labelled to indicate that the materials or articles are active and/or intelligent.

Article 5

Specific measures for groups of materials and articles

[[F1]1 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.**]**

Those specific measures may include:

a a list of substances authorised for use in the manufacturing of materials and articles;

b list(s) of authorised substances incorporated in active or intelligent food contact materials and articles, or list(s) of active or intelligent materials and articles and, when necessary, special conditions of use for these substances and/or the materials and articles in which they are incorporated;

c purity standards for substances referred to in (a);

d special conditions of use for substances referred to in (a) and/or the materials and articles in which they are used;

e specific limits on the migration of certain constituents or groups of constituents into or on to food, taking due account of other possible sources of exposure to those constituents;

f an overall limit on the migration of constituents into or on to food;

g provisions aimed at protecting human health against hazards arising from oral contact with materials and articles;

h other rules to ensure compliance with Articles 3 and 4;

i basic rules for checking compliance with points (a) to (h);

j rules concerning the collection of samples and the methods of analysis to check compliance with points (a) to (h);

k specific provisions for ensuring the traceability of materials and articles including provisions regarding the duration for retention of records or provisions to allow, if necessary, for derogations from the requirements of Article 17;

l additional provisions of labelling for active and intelligent materials and articles;

m provisions requiring the Commission to establish and maintain a publicly available Community Register (Register) of authorised substances, processes, or materials or articles;

n specific procedural rules adapting, as necessary, the procedure referred to in Articles 8 to 12, or making it appropriate for the authorisation of certain types of materials and articles and/or processes used in their manufacture, including, where necessary, a procedure for an individual authorisation of a substance, process, or material or article through a decision addressed to an applicant.

[F2The 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).**]**

[F12 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).**]**

Textual Amendments

F1 Substituted by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.

F2 Inserted by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.

Article 6

National specific measures

In the absence of specific measures referred to in Article 5, this Regulation shall not prevent Member States from maintaining or adopting national provisions provided they comply with the rules of the Treaty.

Article 7

Role of the European Food Safety Authority

Provisions liable to affect public health shall be adopted after consulting the European Food Safety Authority, hereinafter referred to as ‘the Authority’.

Article 8

General requirements for the authorisation of substances

1 When a list of substances as referred to in points (a) and (b) of the second subparagraph of Article 5(1) is adopted, anyone seeking an authorisation for a substance not yet included in that list shall submit an application in accordance with Article 9(1).

2 No substance shall be authorised unless it has been adequately and sufficiently demonstrated that, when used under the conditions to be set in the specific measures, the final material or article satisfies the requirements of Article 3 and, where they apply, Article 4.

Article 9

Application for authorisation of a new substance

1 To obtain the authorisation referred to in Article 8(1), the following procedure shall apply:

a an application shall be submitted to the competent authority of a Member State accompanied by the following:

(i) the name and address of the applicant;

(ii) a technical dossier containing the information specified in the guidelines for the safety assessment of a substance to be published by the Authority;

(iii) a summary of the technical dossier;

b the competent authority referred to in (a) shall:

(i) acknowledge receipt of the application in writing to the applicant within 14 days of its receipt. The acknowledgement shall state the date of receipt of the application;

(ii) inform the Authority without delay;

and

(iii) make the application and any supplementary information supplied by the applicant available to the Authority;

c the Authority shall without delay inform the other Member States and the Commission of the application and shall make the application and any supplementary information supplied by the applicant available to them.

2 The Authority shall publish detailed guidelines concerning the preparation and the submission of the application[(11)].

Article 10

Opinion of the Authority

1 The Authority shall give an opinion within six months of the receipt of a valid application, as to whether, under the intended conditions of use of the material or article in which it is used, the substance complies with the safety criteria laid down in Article 3 and, where they apply, Article 4.

The Authority may extend the said period by a maximum period of a further six months. In such a case it shall provide an explanation for the delay to the applicant, the Commission and the Member States.

2 The Authority may, where appropriate, request the applicant to supplement the particulars accompanying the application within a time limit specified by the Authority. Where the Authority requests supplementary information, the time limit laid down in paragraph 1

shall be suspended until that information has been provided. Similarly, the time limit shall be suspended for the time allowed the applicant to prepare oral or written explanations.

3 In order to prepare its opinion, the Authority shall:

a verify that the information and documents submitted by the applicant are in accordance with Article 9(1)(a), in which case the application shall be regarded as valid, and examine whether the substance complies with the safety criteria laid down in Article 3 and, where they apply, Article 4;

b inform the applicant, the Commission and the Member States if an application is not valid.

4 In the event of an opinion in favour of authorising the evaluated substance, the opinion shall include:

a the designation of the substance including its specifications;

and

b where appropriate, recommendations for any conditions or restrictions of use for the evaluated substance and/or the material or article in which it is used;

and

c an assessment as to whether the analytical method proposed is appropriate for the intended control purposes.

5 The Authority shall forward its opinion to the Commission, the Member States and the applicant.

6 The Authority shall make its opinion public, after deletion of any information identified as confidential, in accordance with Article 20.

Article 11

Community authorisation

1 The Community authorisation of a substance or substances shall take place in the form of the adoption of a specific measure. The Commission shall, where appropriate, prepare a draft of a specific measure, as referred to in Article 5, to authorise the substance or substances evaluated by the Authority and specify or change the conditions of its or their use.

2 The draft specific measure shall take into account the opinion of the Authority, relevant provisions of Community law and other legitimate factors relevant to the matter under consideration. Where the draft specific measure is not in accordance with the opinion of the Authority, the Commission shall provide without delay an explanation for the reasons for the differences. If the Commission does not intend to prepare a draft specific measure after a favourable opinion by the Authority, it shall inform the applicant without delay and provide the applicant with an explanation.

[[F1]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).**]**

4 After the authorisation of a substance in accordance with this Regulation, any business operator using the authorised substance or materials or articles containing the

authorised substance shall comply with any condition or restriction attached to such authorisation.

5 The applicant or any business operator using the authorised substance or materials or articles containing the authorised substance shall immediately inform the Commission of any new scientific or technical information, which might affect the safety assessment of the authorised substance in relation to human health. If necessary, the Authority shall then review the assessment.

6 The granting of an authorisation shall not affect the general civil and criminal liability of any business operator in respect of the authorised substance, the material or article containing the authorised substance, and the food that is in contact with such material or article.

Textual Amendments

F1 Substituted by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.

Article 12

Modification, suspension and revocation of authorisation

1 The applicant or any business operator using the authorised substance or materials or articles containing the authorised substance may, in accordance with the procedure laid down in Article 9(1), apply for modification of the existing authorisation.

2 The application shall be accompanied by the following:

a a reference to the original application;

b a technical dossier containing the new information in accordance with the guidelines referred to in Article 9(2);

c a new complete summary of the technical dossier in a standardised form.

3 On its own initiative or following a request from a Member State or the Commission, the Authority shall evaluate whether the opinion or the authorisation is still in accordance with this Regulation, in accordance with the procedure laid down in Article 10, where applicable. The Authority may, where necessary, consult the applicant.

4 The Commission shall examine the opinion of the Authority without delay and prepare a draft specific measure to be taken.

5 A draft specific measure modifying an authorisation shall specify any necessary changes in the conditions of use and, if any, in the restrictions attached to that authorisation.

[[F1]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).**]**

Textual Amendments

F1 Substituted by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.

Article 13

Competent authorities of Member States

Each Member State shall notify to the Commission and to the Authority the name and address, as well as a contact point, of the national competent authority or authorities designated to be responsible in its territory for receiving the application for authorisation referred to in Articles 9 to 12. The Commission shall publish the name and address of the national competent authorities as well as the contact points notified in accordance with this Article.

Article 14

Administrative review

Any act adopted under, or failure to exercise, the powers vested in the Authority by this Regulation may be reviewed by the Commission on its own initiative or in response to a request from a Member State or from any person directly and individually concerned.

To this effect a request shall be submitted to the Commission within two months from the day on which the party concerned became aware of the act or omission in question.

The Commission shall take a decision within two months requiring, if appropriate, the Authority to undo its act or to remedy its failure to act.

Article 15

Labelling

1 Without prejudice to the specific measures referred to in Article 5, materials and articles, which are not yet in contact with food when placed on the market, shall be accompanied by:

a the words ‘for food contact’, or a specific indication as to their use, such as coffee machine, wine bottle, soup spoon, or the symbol reproduced in Annex II;

and

b if necessary, special instructions to be observed for safe and appropriate use;

and

c the name or trade name and, in either case, the address or registered office of the manufacturer, processor, or seller responsible for placing on the market established within the Community;

and

d adequate labelling or identification to ensure traceability of the material or article, as described in Article 17;

and

e in the case of active materials and articles, information on the permitted use or uses and other relevant information such as the name and quantity of the substances released by the active component so as to enable food business operators who use these materials and articles to comply with any other relevant Community provisions or, in their absence, national provisions applicable to food, including the provisions on food labelling.

2 The information referred to in paragraph 1(a) shall not, however, be obligatory for any articles which, because of their characteristics, are clearly intended to come into contact with food.

3 The information required by paragraph 1 shall be conspicuous, clearly legible and indelible.

4 Retail trade in materials and articles shall be prohibited if the information required under paragraph (1)(a), (b) and (e) is not given in a language easily understood by purchasers.

5 Within its own territory, the Member State in which the material or article is marketed may, in accordance with the rules of the Treaty, stipulate that those labelling particulars shall be given in one or more languages which it shall determine from among the official languages of the Community.

6 Paragraphs 4 and 5 shall not preclude the labelling particulars from being indicated in several languages.

7 At the retail stage, the information required under paragraph 1 shall be displayed on:

a the materials and articles or on their packaging;

or

b labels affixed to the materials and articles or to their packaging;

or

c a notice in the immediate vicinity of the materials and articles and clearly visible to purchasers; for the information referred to in paragraph 1(c), however, this option shall be open only if, for technical reasons, that information or a label bearing it cannot be affixed to the materials and articles at either the manufacturing or the marketing stage.

8 At the marketing stages other than the retail stage, the information required by paragraph 1 shall be displayed on:

a the accompanying documents;

or

b the labels or packaging;

or

c the materials and articles themselves.

9 The information provided for in paragraph 1(a), (b) and (e) shall be confined to materials and articles which comply with:

a the criteria laid down in Article 3 and, where they apply, Article 4;

and

b the specific measures referred to in Article 5 or, in their absence, with any national provisions applicable to these materials and articles.

Article 16

Declaration of compliance

1 The specific measures referred to in Article 5 shall require that materials and articles covered by those measures be accompanied by a written declaration stating that they comply with the rules applicable to them.

Appropriate documentation shall be available to demonstrate such compliance. That documentation shall be made available to the competent authorities on demand.

2 In the absence of specific measures, this Regulation shall not prevent Member States from retaining or adopting national provisions for declarations of compliance for materials and articles.

Article 17

Traceability

1 The traceability of materials and articles shall be ensured at all stages in order to facilitate control, the recall of defective products, consumer information and the attribution of responsibility.

2 With due regard to technological feasibility, business operators shall have in place systems and procedures to allow identification of the businesses from which and to which materials or articles and, where appropriate, substances or products covered by this Regulation and its implementing measures used in their manufacture are supplied. That information shall be made available to the competent authorities on demand.

3 The materials and articles which are placed on the market in the Community shall be identifiable by an appropriate system which allows their traceability by means of labelling or relevant documentation or information.

Article 18

Safeguard measures

1 When a Member State, as a result of new information or a reassessment of existing information has detailed grounds for concluding that the use of a material or article endangers human health, although it complies with the relevant specific measures, it may temporarily suspend or restrict application of the provisions in question within its territory.

It shall immediately inform the other Member States and the Commission and give reasons for the suspension or restriction.

2 The Commission shall examine as soon as possible, where appropriate after obtaining an opinion from the Authority, within the Committee referred to in Article 23(1) the grounds adduced by the Member State referred to in paragraph 1 and shall deliver its opinion without delay and take appropriate measures.

3 If the Commission considers that amendments to the relevant specific measures are necessary in order to remedy the difficulties referred to in paragraph 1 and to ensure the protection of human health, those amendments shall be adopted in accordance with the procedure referred to in Article 23(2).

4 The Member State referred to in paragraph 1 may retain the suspension or restriction until the amendments referred to in paragraph 3 have been adopted or the Commission has declined to adopt such amendments.

Article 19

Public access

1 Applications for authorisation, supplementary information from applicants and opinions from the Authority, excluding confidential information, shall be made accessible to the public in accordance with Articles 38, 39 and 41 of Regulation (EC) No 178/2002.

2 Member States shall process applications for access to documents received under this Regulation in accordance with Article 5 of Regulation (EC) No 1049/2001.

Article 20

Confidentiality

1 The applicant may indicate which information submitted under Articles 9(1), 10(2) and 12(2) is to be treated as confidential on the ground that its disclosure might significantly harm its competitive position. Verifiable justification must be given in such cases.

2 Information relating to the following shall not be considered confidential:

a the name and address of the applicant and the chemical name of the substance;

b information of direct relevance to the assessment of the safety of the substance;

c the analytical method or methods.

3 The Commission shall determine, after consultation with the applicant, which information should be kept confidential and shall inform the applicant and the Authority of its decision.

4 The Authority shall supply the Commission and the Member States with all information in its possession on request.

5 The Commission, the Authority and the Member States shall take the necessary measures to ensure appropriate confidentiality of the information received by them under this Regulation, except for information which must be made public if circumstances so require in order to protect human health.

6 If an applicant withdraws or has withdrawn an application, the Authority, the Commission and the Member States shall respect the confidentiality of commercial and industrial information provided, including research and development information as well as information on which the Commission and the applicant disagree as to its confidentiality.

Article 21

Sharing of existing data

Information given in an application submitted in accordance with Articles 9(1), 10(2) and 12(2) may be used for the benefit of another applicant, provided that the Authority considered that the substance is the same as the one for which the original application was submitted, including the degree of purity and the nature of impurities, and that the other applicant has agreed with the original applicant that such information may be used.

[*F1 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).**]**

Textual Amendments

F1 Substituted by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.

Article 23

Committee procedure

1 The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health instituted by Article 58(1) of Regulation (EC) No 178/2002.

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.

[F1 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.**]**

[F2 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.**]**

Textual Amendments

F1 Substituted by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of

the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.

F2 Inserted by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.

Article 24

Inspection and control measures

1 Member States shall carry out official controls in order to enforce compliance with this Regulation in accordance with relevant provisions of Community law relating to official food and feed controls.

2 Where necessary and on the request of the Commission, the Authority shall assist in developing technical guidance on sampling and testing to facilitate a coordinated approach for the application of paragraph 1.

3 The Community reference laboratory for materials and articles intended to come into contact with food and national reference laboratories established as laid down in Regulation (EC) No 882/2004 shall assist Member States in the application of paragraph 1 by contributing to a high quality and uniformity of analytical results.

Article 25

Sanctions

Member States shall lay down the rules on sanctions applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The sanctions provided for must be effective, proportionate and dissuasive. Member States shall communicate the relevant provisions to the Commission by 13 May 2005 and shall communicate to it without delay any subsequent amendment affecting them.

Article 26

Repeals

Directives 80/590/EEC and 89/109/EEC are repealed.

References to the repealed Directives shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex III.

Article 27

Transitional arrangements

Materials and articles that have been lawfully placed on the market before 3 December 2004 may be marketed until the stocks are exhausted.

Article 28

Entry into force

This Regulation shall enter into force on the 20 th day following that of its publication in the *Official Journal of the European Union*.

Article 17 shall apply from 27 October 2006.

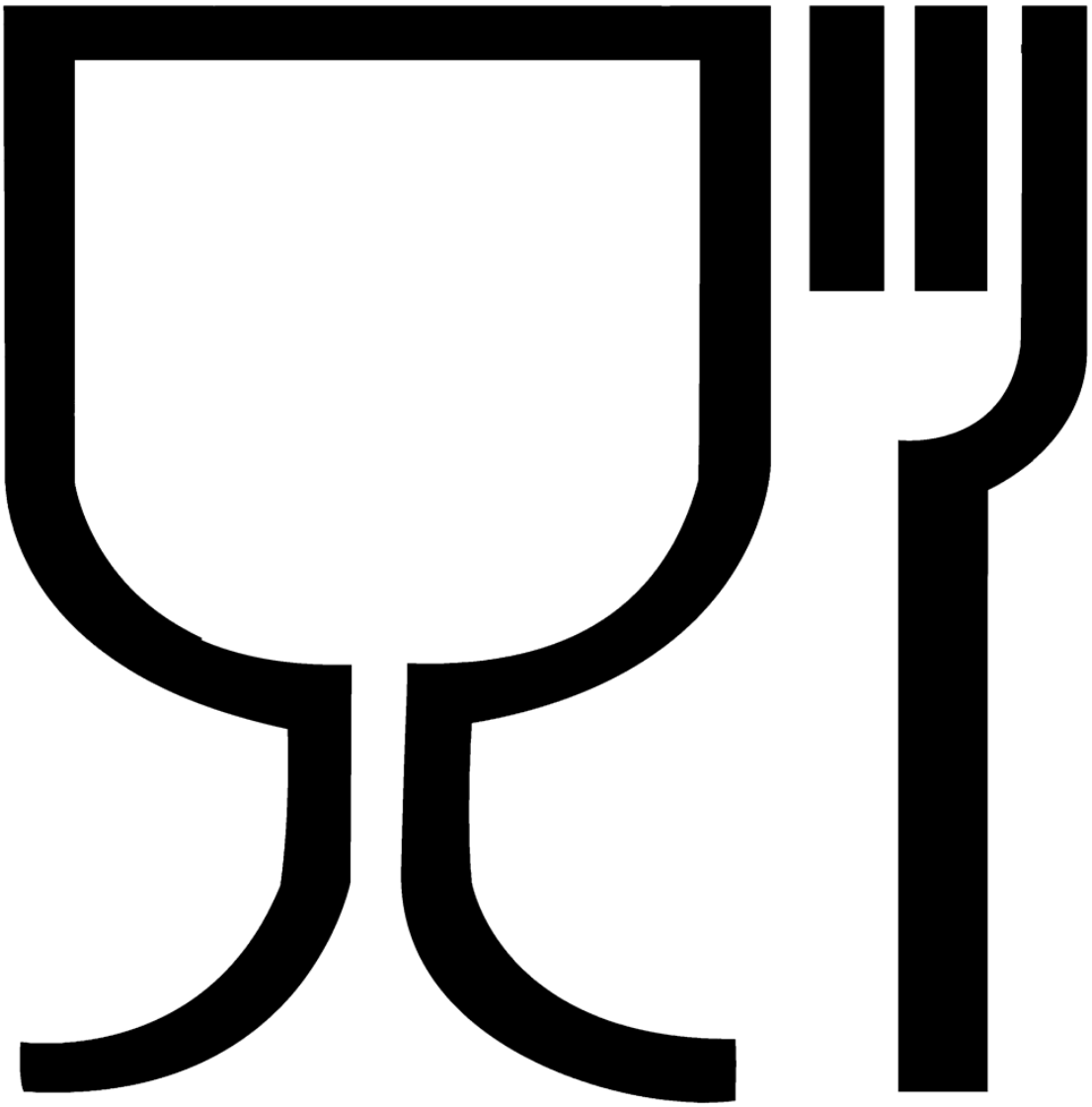
This Regulation shall be binding in its entirety and directly applicable in all Member States.

ANNEX I

List of groups of materials and articles which may be covered by specific measures

1. Active and intelligent materials and articles
2. Adhesives
3. Ceramics
4. Cork
5. Rubbers
6. Glass
7. Ion-exchange resins
8. Metals and alloys
9. Paper and board
10. Plastics
11. Printing inks
12. Regenerated cellulose
13. Silicones
14. Textiles
15. Varnishes and coatings
16. Waxes
17. Wood

ANNEX II



ANNEX III

CORRELATION TABLE

Directive 89/109/EEC	This Regulation
Article 1	Article 1
—	Article 2
Article 2	Article 3
—	Article 4
Article 3	Article 5

—	Article 7
—	Article 8
—	Article 9
—	Article 10
—	Article 11
—	Article 12
—	Article 13
—	Article 14
Article 4	—
Article 6	Article 15
—	Article 16
—	Article 17
Article 5	Article 18
Article 7	Article 6
—	Article 19
—	Article 20
—	Article 21
—	Article 22
Article 8	—
Article 9	Article 23
—	Article 24
—	
—	Article 25
Article 10	Article 26
—	Article 27
Article 11	—
Article 12	—
Article 13	Article 28
Annex I	Annex I
Annex II	—
Annex III	Annex III
Directive 80/590/EEC	This Regulation

Annex	Annex II

(**1**) OJ C 117, 30.4.2004, p. 1.

(**2**) Opinion of the European Parliament of 31 March 2004 (not yet published in the Official Journal) and Council Decision of 14 October 2004.

(**3**) OJ L 40, 11.2.1989, p. 38. Directive as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

(**4**) Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption (OJ L 40, 11.2.1989, p. 27). Directive as last amended by Regulation (EC) No 1882/2003.

(**5**) OJ L 31, 1.2.2002, p. 1. Regulation as amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p. 4).

(**6**) Commission Directive 80/590/EEC of 9 June 1980 determining the symbol that may accompany materials and articles intended to come into contact with foodstuffs (OJ L 151, 19.6.1980, p. 21). Directive as last amended by the 2003 Act of Accession

(**7**) OJ L 165, 30.4.2004, p. 1. Regulation as corrected in OJ L 191, 28.5.2004, p. 1.

(**8**) OJ L 145, 31.5.2001, p. 43.

(**9**) OJ L 184, 17.7.1999, p. 23

(**10**) 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 (OJ L 109, 6.5.2000, p. 29). Directive as last amended by Directive 2003/89/EC (OJ L 308, 25.11.2003, p. 15).

(**11**) Pending such publication, applicants may consult the ‘Guidelines of the Scientific Committee on Food for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation’. – http://europa.eu.int/comm/food/fs/sc/scf/out82_en.pdf.

Status:
Point in time view as at 31/01/2020.

Changes to legislation:
There are outstanding changes not yet made to Regulation (EC) No 1935/2004 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.