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

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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

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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

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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

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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