Commission Regulation (EC) No 450/2009 of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food (Text with EEA relevance)

COMMISSION REGULATION (EC) No 450/2009

of 29 May 2009

on active and intelligent materials and articles intended to come into contact with food

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to 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[(1)], and in particular Article 5(1) (h), (i), (l), (m) and (n) thereof,

After consulting the European Food Safety Authority,

Whereas:

(1) Regulation (EC) No 1935/2004 establishes that active and intelligent food contact materials and articles (active and intelligent materials and articles) are included in its field of application and, therefore, all its provisions concerning materials and articles intended to come into contact with food (food contact materials) also apply to these materials and articles. Other Community measures, such as those provided for in Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety[(2)] and its implementing measures, and Council Directive 87/357/EEC of 25 June 1987 on the approximation of the laws of the Member States concerning products which, appearing to be other than they are, endanger the health or safety of the consumers[(3)], also apply, where appropriate, to such materials and articles.

(2) Regulation (EC) No 1935/2004 lays down the general principles for eliminating the differences between the laws of the Member States as regards food contact materials. Article 5(1) of that Regulation provides for the adoption of specific measures for groups of materials and articles and describes in detail the procedure for the authorisation of substances at Community level when a specific measure provides for a list of authorised substances.

(3) Certain rules applicable to active and intelligent materials and articles are set out in Regulation (EC) No 1935/2004. These include rules for released active substances that have to comply with Community and national provisions applicable to food and labelling rules. Specific rules should be laid down in a specific measure.

(4) This Regulation is a specific measure within the meaning of Article 5(1)(b) of Regulation (EC) No 1935/2004. This Regulation should establish the specific rules

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for active and intelligent materials and articles to be applied in addition to the general requirements established in Regulation (EC) No 1935/2004 for their safe use.

(5) Many different types of active and intelligent materials and articles exist. The substances responsible for the active and/or intelligent function can be contained in a separate container, for example, inclusion in a small paper sachet or, the substances can be directly incorporated into the packaging material, for example, incorporation in the plastic of a plastic bottle. Those substances, responsible for creating the active and/or intelligent function of those materials and articles (the components) should be evaluated in accordance with this Regulation. The passive parts, such as the container, the packaging into which that container is placed and the packaging material, in which the substance is incorporated, should be covered by the specific Community or national provisions applicable to those materials and articles.

(6) The active and intelligent materials and articles may be composed of one or more layers, or parts of different types of materials, such as plastics, paper and cardboard or coatings and varnishes. Requirements for those materials may be either fully harmonised, or only partially harmonised, or not yet harmonised at Community level. The rules laid down in this Regulation should apply without prejudice to Community or national provisions that regulate such materials.

(7) The individual substance or, if relevant, the combination of substances which constitute the components should be evaluated to guarantee that they are safe and comply with the requirements laid down in Regulation (EC) No 1935/2004. In some cases, it may be necessary to evaluate and authorise the combination of substances, when the active or intelligent function implies interaction between different substances leading to an enhancement of the function or the generation of new substances responsible for the active and intelligent function.

(8) Regulation (EC) No 1935/2004 provides that 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.

(9) It is appropriate that the person interested in placing on the market active and intelligent materials and articles or the components thereof, namely the applicant, should submit all the information necessary for the safety assessment of the substance or, if necessary, of the combination of substances which constitutes the component.

(10) The safety assessment of a substance or of a combination of substances which constitutes the components should be carried out by the European Food Safety Authority (the Authority), after the submission of a valid application, in accordance with Articles 9 and 10 of Regulation (EC) No 1935/2004. In order to inform the applicant of the data to be provided for the safety assessment, the Authority should publish detailed guidelines concerning the preparation and the submission of the application. In order to enable the enforcement of any possible restrictions, it is necessary that the applicant provides an appropriate analytical method for the detection and quantification of the substance. The Authority should evaluate if the analytical method is suitable for the purpose of enforcement of any proposed restriction.

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(11) The safety assessment of a specific substance or of a combination of substances should be followed by a risk management decision as to whether the substance should be included in the Community list of authorised substances that may be used in active and intelligent components (the Community list). That decision should be adopted in accordance with the regulatory procedure referred to in Article 23(2) of Regulation (EC) No 1935/2004 ensuring close cooperation between the Commission and the Member States.

(12) The Community list should include the identity, conditions of use, restrictions and/or specifications of use of the substance or of a combination of substances and, where necessary, of the component or of the material or of the article in which they are added to or incorporated into. The identity of a substance should include at least the name and, if available and necessary, the CAS numbers, particle size, composition or other specifications.

(13) Active materials and articles may deliberately incorporate substances, which are intended to be released into food. As these substances are intentionally added to the food, they should only be used under the conditions set out in the relevant Community or national provisions for their use in food. Where the Community or national provisions provide for an authorisation of the substance, the substance and its use should comply with the requirements of the authorisation under the specific legislation on food, such as legislation on food additives. Food additives and enzymes could also be grafted or immobilised on the material and have a technological function on the food. Such applications are covered by legislation on food additives and enzymes and should, therefore, be treated in the same way as released active substances.

(14) Intelligent packaging systems provide the user with information on the conditions of the food and should not release their constituents into the food. Intelligent systems may be positioned on the outer surface of the package and may be separated from the food by a functional barrier, which is a barrier within food contact materials or articles preventing the migration of substances from behind that barrier into the food. Behind a functional barrier, non-authorised substances may be used, provided they fulfil certain criteria and their migration remains below a given detection limit. Taking into account foods for infants and other particularly susceptible persons, as well as the difficulties of this type of analysis affected by a large analytical tolerance, a maximum level of 0,01 mg/kg in food should be established for the migration of a non-authorised substance through a functional barrier. New technologies that engineer substances in particle size that exhibit chemical and physical properties that significantly differ from those at a larger scale, for example, nanoparticles, should be assessed on a case-by-case basis as regards their risk until more information is known about such new technology. Therefore, they should not be covered by the functional barrier concept.

(15) The specific Community measure covering the passive part of an active or intelligent material may lay down requirements for the inertness of the material, for example, an overall migration limit applicable to plastic materials. If a releasing active component is incorporated into a food contact material covered by a specific Community measure, there may be a risk of exceeding the overall migration limit due to the release of the

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active substance. As the active function is not an inherent feature of the passive material, the amount of released active substance should not be calculated in the value of overall migration.

(16) Article 4(5) of Regulation (EC) No 1935/2004 provides that active and intelligent materials and articles already brought into contact with food are to be adequately labelled to allow identification by the consumer of non-edible parts. Consistency of such information is indispensable in order to avoid confusion at consumer level. Therefore, active and intelligent materials and articles should be labelled with appropriate words and accompanied, where technically possible, by a symbol, whenever materials and articles or parts of them are perceived as edible.

(17) Article 16 of Regulation (EC) No 1935/2004 provides that materials and articles are to be accompanied by a written declaration of compliance attesting that they comply with the rules applicable to them. In accordance with Article 5(1)(h) and (i) of that Regulation, to strengthen the coordination and responsibility of the suppliers at each stage of the manufacturing process, the responsible persons should document compliance with the relevant rules in a declaration of compliance which is made available to his customer. In addition, at each stage of the manufacturing process, supporting documentation, substantiating the declaration of compliance, should be kept available for the enforcement authorities.

(18) Article 17(1) of Regulation (EC) No 178/2002 of the European Parliament and of the Council[(4)] requires food business operators to verify that foods satisfy the relevant requirements of food law. Article 15(1)(e) of Regulation (EC) No 1935/2004 provides that active materials and articles, which are not yet in contact with food when placed on the market, are to be accompanied by information on the permitted use or uses and other relevant information such as the name and maximum 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. To this end, subject to the requirement of confidentiality, food business operators should be given access to the relevant information to enable them to ensure that the migration or intentional release from active and intelligent materials and articles to food complies with the specifications and restrictions laid down in Community or national provisions applicable to food.

(19) Since several active and intelligent materials and articles are already on the market in the Member States, provisions should be established to ensure that the transition to a Community authorisation procedure is smooth and does not disturb the existing market for those materials and articles. Sufficient time should be allowed for the applicant to make available the information necessary for the safety assessment of the substance or the combination of substances which constitutes the component. Therefore, an 18 month period should be allowed, during which time the information on active and intelligent materials and articles should be submitted by the applicants. It should also be possible to submit applications for authorisation of a new substance or of a combination of substances during that 18 month period.

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(20) The Authority should evaluate, without delay, all applications for existing as well as new substances which constitute the components for which a valid application was submitted on time and in accordance with the guidelines of the Authority during the initial application phase.

(21) A Community list of authorised substances should be drawn up by the Commission after the completion of the safety assessment of all substances for which a valid application was submitted in accordance with the guidelines of the Authority, during the initial 18 month period. In order to ensure fair and equal conditions for all applicants, this Community list should be drawn up in a single step.

(22) The rules concerning the declaration of compliance and the specific labelling rules should only apply six months after the date of entry into force of this Regulation to give business operators sufficient time to adapt to these new rules.

(23) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter

This Regulation establishes specific requirements for the marketing of active and intelligent materials and articles intended to come into contact with food.

These specific requirements are without prejudice to Community or national provisions applicable to the materials and articles to which active or intelligent components are added or into which they are incorporated.

Article 2

Scope

This Regulation shall apply to active and intelligent materials and articles which are placed on the market within the Community.

Article 3

Definitions

For the purpose of this Regulation, the following definitions shall apply:

(a) ‘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