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HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL
Directorate E – Safety of the food chain
E3 – Chemicals, contaminants and pesticides

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WORKING DOCUMENT:
DOES NOT NECESSARILY
REPRESENT THE VIEWS OF
THE COMMISSION

Working document on a

Draft Regulation

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

(Version updated to 16 June 2006)

Note

This revision takes into account comments received in the working group meeting on March 2006 and includes comments received until 12 June, Therefore:

- A definition of absorbing active substance was introduced
- Article 3 was redrafted
- Article 9 was redrafted, in accordance to the other proposals on food contact materials

The comments that were not taken into account are mentioned in the third column in italic, together with the justification.

Relevant changes from the previous version are indicated in bold and highlighted in yellow.

Explanatory Note

BACKGROUND

Regulation (EC) No 1935/2004 sets out the general principles applicable to Food Contact Materials (FCM) and empowers the Commission to adopt specific measures concerning specific group of materials and articles. This proposal for a Regulation establishes the general principles for active and intelligent materials and articles i.e. materials or articles which are intended to extend the shelf-life, to maintain, improve or monitor the condition of packaged food.

The Regulation 1935/2004 sets out for active and intelligent materials general provisions such as:

- They shall be safe (Article 3(1a)).
- They may bring changes to the composition and organoleptic properties of the food on the condition that these changes comply with the food legislation (Article 4.1¹).
- Until the adoption of a specific measure on active and intelligent materials and articles, only substances explicitly authorised by the food legislation (e.g. food additives or flavours) may be intentionally released by active materials and articles (“releasing active materials and articles”). These substances shall be considered as ingredients and be labelled according to Directive 2000/13/EC on food labelling (Article 4 (2)).
- Changes to the food must not mislead consumer for instance by masking spoilage of the food (Article 4 (3)).
- Labelling of non-edible parts is required (Article 4 (5)).
- Labelling of the active and intelligent materials and articles as ‘active’ or ‘intelligent’ (Article 4 (6)).
- Consumer must be informed how to use active and intelligent materials and articles safely and appropriately (Article 15 (1) (b)).
- Food packer must be informed how to use active materials and articles safely and in compliance with food law (e.g. name and quantity of released component to be provided to the food packer). (Art. 15 (1) (e)).

The Framework Regulation (EC) No 1935/2004 on FCM also establishes that further requirements for active and intelligent materials and articles should be set out in a specific Commission measure.

¹ See whereas (4) of this proposal for a Regulation

OBJECTIVES OF THE WORKING DOCUMENT

In accordance with the recommendations of legal service (June 2004 meeting), this working document does not repeat any provision adopted in the Regulation (EC) No 1935/2004 unless there is a need for their correct application. Therefore this text contains only the additional requirements for active and intelligent materials to ensure their safe use. Other editorial changes have been suggested by the legal service (February 2005) into the text to harmonise the format of this version with the draft on recycled plastics (EMB/955 Rev.5). The procedure to establish a positive list of active and intelligent components is taking into account the outcome internal discussion on authorisation procedures. This draft considers some specific issues related to the safety assessment, the authorisation and control of such materials and articles and clarifies the enforcement in practice of the specific (SML) and overall (OML) migration limits.

- **Requirements for the materials and articles that contain or incorporate the active and intelligent component**

The further additional specific provisions necessary to regulate the active and intelligent materials are mentioned below.

- The active and intelligent materials shall have efficacy and suitability.
- In addition to the general rules of Regulation (EC) No 1935/2004 abovementioned (see background), the active and intelligent materials shall comply with the rules applicable to the same materials and articles when they do not contain the active and intelligent components by virtue of certain adopted implementing measures of that Regulation such as directives on ceramics, regenerated cellulose films and homogenous plastics. Moreover they shall comply with any future legislation related to non-active and no-intelligent food contact materials.

If an active and intelligent material is not regulated at Community level e.g. paper, rubber, metals etc. it shall comply with the current national legislation. Divergences between the national provisions will be regulated as usual by the application of Articles 28 to 30 of the Treaty (ex articles 30 and 36 of the Treaty of Rome). Therefore the legal situation related to the inactive or no-intelligent “FCM” applicable before the adoption of this Regulation is not affected when this text is adopted. At the same time the legal situation of the active and intelligent components is clarified as their use will be harmonised at Community level.

- In the case of “releasing active materials”, if a Community implementing measure or, in its absence, a national legislation such as Dutch, Italian, French legislations provides for an OML, the amount of the ”released active substance” in or onto the food or food simulants shall not be included in the overall migration value.
- In the case of ”releasing active materials”, if a Community legislation on food or, in its absence, a national legislation provides for the “released active substance” a limit in food the total quantity of this substance shall not exceed this limit independently from the source from which it derives.

- **Community list of active and intelligent components**

The active and intelligent component(s), which may be a quite complex mixture of substances including the “released active substance” authorised as food additive or

flavours or by EU legislation, shall be authorised and inserted in a special list subdivided in accordance with their function (Releaser active component – Absorber active component – Intelligent component). It was objected that in the case of an active component composed only by a “released active substance” it would be not necessary to re-assess such substance as it was already evaluated and authorised in the context of its use as food additive or flavour. However it was also stressed the need to maintain the approach of a “positive list” for the active and intelligent components in order to know the substances used and their conditions of use and to permit the European Food Safety Authority (EFSA) to evaluate, when appropriate, the formation of new reaction or degradation products during the manufacture of active and intelligent materials. Therefore a new authorisation is requested always for the active components. It is logic that the petition for the active components should contain only data not already evaluated to avoid any double toxicological assessment. EFSA is drafting specific guidelines for active and intelligent components, to better specify the data to be transmitted for an authorisation of an active and/or intelligent component.

A system of authorisation delivered only to the applicant and his clients is proposed to protect the propriety of these new innovative components (authorisation holder). The authorisation will include the chemical composition, the trade name and references of the authorisation holder as well as the conditions and, when necessary, restrictions of use of the system and/or of the food contact material in which the active and intelligent system is incorporated.

A period of 18 months is proposed for applications to be submitted for the evaluation and authorisation of active and intelligent components. After all the components, for which a valid application has been submitted within this period, have been evaluated by EFSA, the Commission shall establish the initial Community list.

Labelling

In application of Article 4(5) of Regulation (EC) No 1935/2004 it is specified that non edible parts of active and intelligent materials that may be mistaken as part of the food shall be labelled with the words ‘do not eat’ and shall be accompanied, where technically possible, by a symbol.

- **Declaration of compliance and record-keeping of supporting documents**

In application of Article 16 of the Regulation (EC) No 1935/2004, the draft confirms the need for a declaration of compliance and the maintaining of the documentation which demonstrate this compliance.

Whereas or Article	Text	<i>Comments</i>
(1)	Regulation (EC) No 1935/2004 establishes that active and intelligent food contact materials and articles (hereinafter referred to as active and intelligent materials and articles) i.e. materials and article which are designed to extend the shelf-life, to maintain or improve or monitor the condition of packaged food are included in its field of application and, therefore, all the provisions provided for any type of materials and articles intended to come into contact with food (hereinafter referred to as “food contact materials”, FCM) are also applicable to these new materials. Similarly, other provisions provided in other measures such as Directive 2001/95/EEC on general product safety ² and its implementing measures, and Directive 87/357/EEC concerning products which, appearing to be other than they are, endanger the health and safety of the consumers ³ are also applicable, when appropriate. Therefore the relevant provisions of all these EU measures are not repeated in this Regulation, unless there is a need for their correct application.	
(2)	Regulation (EC) No 1935/2004 sets out the general principles applicable to FCM and provides for the adoption of implementing measures to define the specific rules to apply these principles in practice and to eliminate the differences between the laws of the Member States. That Regulation empowers the Commission to adopt specific measures concerning specific group of materials and articles mentioned in the Annex (specific measures) 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)	General rules applicable only to active and intelligent materials and articles are set out in Regulation (EC) No 1935/2004. These include provisions for released active substances that have to comply with relevant food legislation and labelling rules.	

² OJ L 11 of 15.1.2002, p.4.

³ OJ L 192 of 25 June 1987, p.1

	Specific rules should be laid down in a specific measure.	
(4)	This Regulation is a specific measure within the meaning of Article 5 of Regulation (EC) No 1935/2004. This specific Regulation should establish the specific rules for these materials and articles to be applied in addition to the general requirements established in Regulation (EC) No 1935/2004 for their safe use.	
(5)	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 board or coatings and varnishes. These last materials may be either harmonised or only partially harmonised or not yet harmonised at Community level. The present rules should apply without prejudice to Community and/or national provisions that regulate these materials.	
(6)	There is the possibility of exceeding the overall and specific migration limits that may apply to the migration of the “released active substance(s)” by virtue of specific measures such as plastics Directive 2002/72/EC. The overall migration limit (OML) may be exceeded due to migration of the “released active substance(s)”. In this case exceeding the overall migration limit should be permitted if the level of migration of the “released active substance(s)” complies with restrictions existing in the food law. If a specific restriction in FCM exists for the “released active substance”, exceeding this restriction should be permitted if the “released active substance(s)” complies with restrictions existing in the food law.	
(7)	The authorisation procedure established in Regulation (EC) No 1935/2004 needs to be adapted to make it appropriate for the specific technical nature of the active and intelligent materials and articles. The structure of these materials and articles is quite complex. It includes active and intelligent components, which may be constituted by a mixture of substances able to release substances into the food or to absorb substances from the food or to monitor the status of the food. These components are often incorporated or contained in multi-material systems. The safety, the function and the efficacy of the active and intelligent components depend among other factors on the material or article in which they are incorporated. Therefore, an individual	

	authorisation of these components within the active and intelligent material in which they are incorporated that stipulates conditions and restrictions of use is a more appropriate means to reaching the objectives of this Regulation.	
(8)	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 ⁴ and Council Regulation (EC) No 2232/96 of the European Parliament and of the Council of 28 October 1996 laying down a Community procedure for flavouring substances used or intended for use in or on foodstuffs ⁵ , provide for the authorisation of these substances in foodstuffs. In addition to this authorisation procedure, such substances which are incorporated as active components in a material or article to be released into or onto the food (“released active substance”), should also be authorised by this Regulation in order to effect their control through a Community list and for the safety assessment possible breakdown or reaction products arising during the manufacture of active and intelligent materials and articles in which they are incorporated.	
(9)	This authorisation should not cover the legal status of the materials and articles in which the active and intelligent component is incorporated.	
(10)	It is appropriate that the person (“the applicant”) who intends to place on the market active and intelligent components should submit all the information necessary for the safety assessment. The applicant should also propose appropriate specific testing to be used for control of compliance with the provisions of this Regulation (“dedicated tests”).	
(11)	In order to ensure harmonisation, safety assessments of active and intelligent components should be carried out by the European Food Safety Authority (“the Authority”), after the submission of a valid application as set in Articles 8 to 10 of Regulation (EC) No 1935/2004. In order to inform the applicant of an authorisation	

⁴ OJ L 40, 11.2.1989, p. 27. Directive as amended by Directive 94/34/EC of the European Parliament and of the Council (OJ L 237, 10.9.1994, p. 1).

⁵ OJ L 299 of 28 October 1996, p.1

	on the data to be provided for the risk assessment, the Authority should be requested to publish a detailed guidance concerning the preparation and the submission of the application.	
(12)	The safety assessment of a specific active and intelligent component should be followed by a risk management decision as to whether the component should be granted or refused an authorisation. That decision should be adopted in accordance with the regulatory procedure described in article 23(2) of Regulation (EC) No 1935/2004 ensuring close cooperation between the Commission and the Member States.	
(13)	A Community list of active and intelligent components authorised under this Regulation should be established, including the description of their conditions of use and, where necessary, of the material or article in which they are incorporated.	
(14)	Since several active and intelligent materials are already on the market in the Member States, provision should be established to ensure that the transition to a Community authorisation procedure is smooth and does not disturb the existing active and intelligent materials and articles market. Sufficient time should be allowed for the applicant to make available to the Authority the information necessary for the safety assessment of the relevant active and intelligent components. Therefore, a certain time period, hereinafter referred to as the “initial authorisation phase”, should be fixed during which the information for existing active and intelligent materials and articles should be submitted by the applicant to the Authority.	
(15)	Applications for authorisation of new active and intelligent components may also be submitted during the initial authorisation phase. The Authority should evaluate without delay all applications for existing as well as new active and intelligent materials and articles for which sufficient information has been submitted during the initial authorisation phase.	

(16)	An initial Community list of these active and intelligent components should be drafted by the Commission after the completion of the safety assessment of all active and intelligent components for which sufficient information was submitted during the initial authorisation phase. In order to ensure fair and equal conditions for all applicants, this initial authorisation should be done at the same time in a single step.	
(17)	Active and intelligent components e.g. oxygen absorbers may be present in form of sachets in the packaged food. If they are not sufficiently labelled they could be mistaken as a part of the food and a risk of ingestion exists. Therefore active and intelligent materials and articles should be labelled and accompanied, where technically possible, by the symbol reproduced in the Annex, whenever the materials and articles may be mistaken as part of the food.	
(18)	The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,	
Article 1	<p style="text-align: center;"><i>Article 1</i> <i>Subject matter and Scope</i></p> <ol style="list-style-type: none"> 1. This Regulation deals in particular with individual authorisations of active and intelligent components used in active and intelligent food contact materials and articles. 2. This Regulation is a specific measure within the meaning of Article 5(1) of Regulation (EC) No 1935/2004. 3. It shall apply to active and intelligent food contact materials and articles as they are defined in Article 2(2)(a) and (b) of the Regulation (EC) No 1935/2004. <p>They may be composed of one or more layer(s) or part(s) made of the same or</p>	

	different materials.	
Article 2	<p style="text-align: center;"><i>Article 2</i> <i>Definitions</i></p> <p>For the purpose of this Regulation, the relevant definitions laid down in Regulation (EC) No 1935/2004 and in its specific implementing measures shall apply.</p> <p>The following definitions shall also apply:</p> <ol style="list-style-type: none"> 1. “releasing active materials and articles” means active materials and articles which deliberately incorporate components intended to release substances into or onto the packaged food or the environment surrounding the food. 2. “released active substance” means the substance of an active component intended to be released into the packaged food or the environment surrounding the food. 3. “absorbing active materials and articles” means active materials and articles which deliberately incorporate components intended to absorb substances from the packaged food or the environment surrounding the food. 4. “absorbing active substance” means the substance of an active component intended to absorb substances from the packaged food or the environment surrounding the food. 5. “active component” means an individual substance or a combination of substances which cause the active function of a material or article. 6. “intelligent component” means an individual substance or a combination of substances of an intelligent material or article which provide the intended information. 	

<p>Article 3</p>	<p style="text-align: center;">Article 3 Requirements for active and intelligent materials and articles</p> <p>1. Active and intelligent materials and articles shall only be placed on the market if:</p> <p>(a) they comply with the requirements established by the Regulation (EC) No 1935/2004 and by this Regulation as well as by the implementing measures referred to in Article 5 of that Regulation. In absence of a Community implementing measure, national legislation applies.</p> <p>(b) they are suitable and effective for the intended purpose of use;</p> <p>(c) their active and intelligent components are included in the Community list.</p> <p>2. For active food contact materials and articles,</p> <p>(i) the amount of the released active substance(s) shall not be included in the value of the measured overall migration, in cases where an overall migration limit (OML) is established in a specific Community measure or, in the absence of a Community provision, in a national legislation;</p> <p>(ii) the amount of the released active substance(s) may exceed the specific restriction established in a specific Community measure related to food contact materials (FCM) or, in its absence, in national legislation, provided that its concentration in the food, originating from any source, complies with relevant Community legislation applicable to the food, or in its absence, with national legislation;</p> <p>(iii) substance (s), other than a released active substance also authorised as food additive by Council Directive 89/107/EEC or flavourings by</p>	<p><i>It was requested to introduce the wording of the framework regulation: released active substances being “considered as ingredients within the meaning of Article 6(4)(a) of Directive 2000/13/EC”.</i></p> <p>Since these provisions are already in the Framework Regulation, it should not be repeated here. Otherwise, we would have to include all relevant provisions of the Framework Regulation.</p> <p><i>A clarification was asked in relation to the absorbing active substances and it was requested to insert that absorbing active substances are considered as ingredients within the meaning of Directive 2000/13/EC.</i></p> <p>Only released active substances are considered as ingredients within the meaning of Directive 2000/13/EC. If, absorbing active substances are additives they will be treated similar to the dual additives in the Plastics Directive (see 2(iii)).</p> <p><i>It was suggested to include more detailed rules for intelligent components and in particular for TTI components (Time, Temperature Indicators) to check the effectiveness of the intelligent components to perform their function.</i></p> <p>Point 1(b) already mentions they should be suitable and effective for the intended purpose of use. This is a field in constant</p>
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	<p>Council Directive 88/388/EEC shall not have a technological function in the food. In case a specific restriction is established for these substances in a specific Community measure related to FCM or, in its absence, in national legislation, and a restriction is also established in food legislation, the lower restriction shall apply.</p>	<p>development. Therefore, it should not specify certain types of active and intelligent materials, to avoid becoming obsolete in a short period of time.</p> <p><i>Concerns were raised in relation to certain types of intelligent materials that can be misleading for the consumer in relation to the expiry date and in comparison to other products on the market.</i></p> <p>Article 4 (4) of the Framework Regulation already indicates that “Intelligent materials and articles shall not give information about the condition of the food which could mislead consumers”.</p> <p><i>It was proposed in 1(c) to end the sentence with “...in the Community list of pre-market approved active and intelligent components”.</i></p> <p>Since along the text the list is referred as “Community list”, the additional sentence would create confusion, especially during the transitional period.</p>
<p>Article 4</p>	<p style="text-align: center;"><i>Article 4</i></p> <p style="text-align: center;"><i>General conditions for inclusion and use of active and intelligent components in the Community list</i></p> <p>An active and intelligent component may be included in the Community list only if it meets the following conditions:</p>	

	<p>(a) it shall be suitable and effective for the intended purpose of use;</p> <p>(b) it shall enable the manufacture of materials and articles complying with the requirements of Article 3 of this Regulation.</p>	
<p>Article 5</p>	<p style="text-align: center;"><i>Article 5</i></p> <p style="text-align: center;"><i>The content of the Community list of active and intelligent components</i></p> <p>1. An active or intelligent component which complies with the conditions set out in Article 4 may, in accordance with the procedure on authorisation laid down in article 9 and 10 of Regulation (EC) No 1935/2004, be included in the Community list.</p> <p>2. The entry of an active or intelligent component in the Community list shall specify :</p> <p>(a) the name and the address of the authorisation holder(s),</p> <p>(b) the trade name of the component,</p> <p>(c) a description of the active and intelligent component in order to identify all relevant substances and their function,</p> <p>(d) the conditions of use of the active and intelligent component necessary to achieving the intended effect,</p> <p>(e) for active components, the food(s) in which the active component may be released and the maximum quantity released or references to similar restrictions set out in relevant food legislation,</p> <p>(f) specific restrictions related to application of releasing or absorbing active components,</p>	


	<p>(g) the date from which it is authorised and the date on which the authorisation ceases, and</p> <p>(h) any other provisions that may be necessary.</p> <p>3. The Community list shall be amended in accordance with the procedure referred to in Article 9 to 11 of Regulation (EC) No 1935/2004.</p> <p>4. Without prejudice to Article 6 the authorisation granted to the applicant (“Authorisation holder”) in accordance with the procedure laid down in this Regulation shall be valid throughout the Community for ten years and shall be renewable in accordance with Article 7.</p> <p>5. The authorisation under this Regulation shall be without prejudice to other Community provisions governing the use and placing on the market of substances which may only be used if they are included in a list of substances authorised to the exclusion of all others.</p>	
Article 6	<p style="text-align: center;"><i>Article 6</i></p> <p style="text-align: center;"><i>Modification, suspension and revocation of authorisation of active and intelligent components</i></p> <p>Modification, suspension and revocation of the authorisation of an active and intelligent component can be obtained in accordance with Article 12 of Regulation (EC) No 1935/2004.</p>	
Article 7	<p style="text-align: center;"><i>Article 7</i></p> <p style="text-align: center;"><i>Renewal of authorisation</i></p> <p>1. Without prejudice to Article 6, authorisations under this Regulation shall be renewable for 10-year periods on application to the Commission by the</p>	

	<p>authorisation holder, at the latest 18 months before the expiry date of the authorisation. The procedure laid down in Articles 5 applies taking into account of the following paragraphs 2 and 3.</p> <p>2. The application shall be accompanied only by the following:</p> <p>(a) a copy of the authorisation for placing the active and intelligent component on the market;</p> <p>(b) a technical dossier containing any new information which supplements the information already provided to the Authority in the course of the previous evaluation(s) and updates this in the light of the most recent scientific and technical developments;</p> <p>(c) a reasoned statement affirming that the product complies with Article 3.</p> <p>3. Where, for reasons beyond the control of the authorisation holder, no decision has been taken on the renewal of an authorisation up until one month before its expiry date, the period of authorisation of the active and intelligent component shall automatically be extended by 6 months. The Commission shall inform the authorisation holder and the Member States about the reasons for the delay.</p>	
Article 8	<p style="text-align: center;"><i>Article 8</i></p> <p style="text-align: center;"><i>Labelling of active and intelligent materials and articles</i></p> <p>1. The requirements of Articles 4 and 15 of Regulation (EC) No 1935/2004 shall apply.</p> <p>2. In addition to the requirements referred to in paragraph 1, active and intelligent materials and articles placed on the market, shall be accompanied</p>	<p><i>It was requested to use the text only "DO NOT EAT", since it could be difficult to place the symbol on small items – or at least difficult to "read" when the symbol is given in a small format.</i></p> <p>Both provisions: "do not eat" and the symbol are only mandatory whenever the materials may be mistaken as a part of the food and a risk of ingestion exists. In case there is not</p>

	<p>by the words “DO NOT EAT” and, where technically possible, the symbol reproduced in the Annex, whenever the materials and articles may be mistaken as a part of the food and a risk of ingestion exists.</p>	<p>space to put both, the text prevails over the symbol.</p> <p><i>It was requested to replace the text “technically possible” that could be difficult to control, by “when appropriate”.</i></p> <p>The sentence “when appropriate” does not make it easier to control.</p> <p><i>Concerns were raised in relation to the need of further provisions on the labelling of these types of materials and liability related to cases of insufficient labelling.</i></p> <p>The labelling provisions in the Framework Regulation also apply. This regulation cannot go beyond its scope. All materials and articles shall comply with the Community law applicable to them.</p>
<p>Article 9</p>	<p style="text-align: center;">Article 9</p> <p style="text-align: center;"><i>Declaration of compliance</i></p> <ol style="list-style-type: none"> 1. At the marketing stages other than the retail stage, active and intelligent materials and articles as well as the substances intended for the manufacturing of these materials and articles, shall be accompanied by a written declaration in accordance with Article 16 of the Regulation (EC) No 1935/2004. 2. That declaration shall be issued by the business operator and shall contain the information laid down in Annex II to this Regulation. 3. Appropriate documentation to demonstrate that the active and intelligent materials 	

	<p>and articles as well as the substances intended for the manufacturing of these materials and articles comply with the requirements of this Regulation and Regulation (EC) No 1935/2004 shall be made available by the business operator to the national competent authorities on request. This documentation shall contain the conditions and results of testing, calculations, other analysis, and evidence on the safety or reasoning demonstrating compliance.</p>	
Article 10	<p style="text-align: center;"><i>Article 10</i></p> <p style="text-align: center;"><i>Inspection and control measures</i></p> <p><i>The provisions of Art.24 of Regulation (EC) n. 1935/2004 shall apply.</i></p>	
Article 11	<p style="text-align: center;"><i>Article 11</i></p> <p style="text-align: center;"><i>Transitional measure</i></p> <p style="text-align: center;"><i>Establishment of the Community list of active and intelligent components</i></p> <ol style="list-style-type: none"> 1. The Community list of active and intelligent components shall be drawn up on the basis of applications made pursuant to paragraph 2. 2. Interested parties may submit applications for the inclusion of an active or intelligent component in the Community list according to Article 9 of Regulation (EC) No 1935/2004. <p>The deadline for submitting such applications shall be 18 months after the date of entry into force of this Regulation.</p> <ol style="list-style-type: none"> 3. The Community list shall be adopted by the Commission in accordance with the procedure laid down in Article 10 and 11 of Regulation (EC) No 1935/2004, once the Authority has issued an opinion on each active and intelligent component for which a valid application has been submitted. 	

	<p>However, by way of derogation from that procedure:</p> <p>(a) Article 10(1) of Regulation (EC) No 1935/2004 shall not apply to the Authority's adoption of its opinion;</p> <p>(b) the Commission shall adopt the Community list for the first time after the Authority has delivered its opinion on all the active and intelligent components for which a valid application has been submitted.</p> <p>4. If necessary, any appropriate transitional measures for the purposes of this Article may be adopted in accordance with the procedure referred to in Article 23 of Regulation (EC) No 1935/2004.</p>	
Article 12	<p style="text-align: center;"><i>Article 12</i> <i>Entry into force</i></p> <p>This Regulation shall enter into force on the 20th day following that of its publication in the Official Journal of the European Union.</p> <p>Article 3 shall apply from the date of application of the Community list. Until this date, national provisions in force concerning active and intelligent materials and articles and active and intelligent components shall continue to apply in the Member States.</p> <p>This Regulation shall be binding in its entirety and directly applicable in all Member States.</p>	

<p><u>ANNEX I</u></p>	<p style="text-align: center;"><u>Symbol</u></p> <div style="text-align: center;">  <p style="text-align: center;">DO NOT EAT</p> </div>	
<p><u>ANNEX II</u></p>	<p style="text-align: center;"><u>DECLARATION OF COMPLIANCE</u></p> <p>The written declaration referred to in Article 9 shall contain the following information:</p> <ol style="list-style-type: none"> 1. the identity and address of the company which manufactures or imports the active and/or intelligent materials and articles as well as the substances intended for the manufacturing of these materials and articles; 2. the identity of the active and/or intelligent materials and articles as well as the substances intended for the manufacturing of these materials and articles; 3. the date of the declaration; 4. The confirmation that the active and/or intelligent materials and articles meets relevant requirements laid down in this Regulation, Regulation (EC) No 1935/2004 and in specific measures applicable; 5. Adequate information relative to the substances used for which restrictions are in place under this Regulation to allow the downstream business operators to ensure compliance with those restrictions; 	<p><i>It was requested to introduce points (c), (d), (e) and (f) of Article 5 in the declaration of compliance.</i></p> <p>These conditions are already in the Community list, according to the Article 5. That list will be published in the official Journal. In addition some of these requirements are already in the Framework Regulation 1935/2004, Article 15.</p>

	<p>6. Specifications on the use of the material or article, such as</p> <ul style="list-style-type: none">(i) type or types of food intended to be put in contact with;(ii) time and temperature of treatment and storage in contact with the food; <p>7. The written declaration shall permit an easy identification of the active and/or intelligent materials and articles as well as substances for which it is issued and shall be renewed when substantial changes in the production bring about changes in the migration or when new scientific data are available.</p>	
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