



COMMISSION OF THE EUROPEAN COMMUNITIES

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Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on materials and articles intended to come into contact with food

(presented by the Commission)

EXPLANATORY MEMORANDUM

BACKGROUND

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 (Framework Directive) establishes the general principles applicable to all food contact materials:

- (a) The principles of “inertness” of the materials and “purity of the food”, i.e.
 - migration of substances from the material or article into the food shall not endanger human health,
 - migration shall not bring an unacceptable change in the composition of the food or deteriorate its organoleptic characteristics.
- (b) The principle of “positive labelling”, stating that materials and articles intended to come into contact with food must be accompanied by the words ‘for food’ or by a symbol determined in Directive 80/590/EEC.

Directive 89/109/EEC also lays down:

- (c) the principle of lists of authorised substances used in the manufacture of food contact materials to the exclusion of all others (positive lists);
- (d) the groups of materials and articles to be regulated by implementing measures (specific directives);
- (e) procedures and criteria to be followed in drafting and adopting the specific directives for the different groups of materials and articles, including the evaluation of substances by the Scientific Committee on Food (SCF) and the opinion of the Standing Committee on Foodstuffs.

OBJECTIVES OF THE PROPOSAL

Since the adoption of Council Directive 89/109/EEC a number of new issues have emerged that need to be considered in the existing legislation:

- important technological developments have occurred in the area of food packaging,
- traceability as well as labelling of materials and articles intended to come into contact with food need to be better ensured,
- the transparency of the authorisation process should be improved by specifying the various phases of the procedure,
- the Commission must be given the possibility to adopt for the implementing measures not only directives, but also decisions or regulations, as the latter are more appropriate for provisions such as positive lists,
- better enforceability of the rules must be ensured through the establishment of Community and national Reference Laboratories,

- the symbol which should accompany materials and articles suitable for food contact, and which has been determined in Directive 80/590/EEC, should be for reasons of simplicity included in this proposal. Directive 80/590/EEC should be consequently repealed.

To this end and in the interest of clarity and efficiency, a new Regulation is proposed which will repeal Directive 89/109/EEC. This new Regulation introduces the following main modifications.

1. Legal instrument for implementing provisions

A detailed examination of the provisions of the specific implementing directives adopted so far in the sector of food contact materials leads to the following conclusions:

- the specific directives are purely technical provisions, aimed at implementing the general principles laid down in the Framework Directive in accordance with previously established criteria and procedures;
- they require frequent technical amendments to adapt them to the rapid technological progress in the sector (new materials, analytical methods, technological processes, food conservation and processing techniques, etc.);
- they mostly contain simple, repetitive provisions consisting of additions or amendments to the lists of substances authorised for use (positive lists) or laying down the conditions for their use. These annual additions or amendments are always put forward after consulting the SCF.

For these reasons, it is more appropriate to draw up regulations than directives. In fact, so far the Member States have mostly reproduced verbatim the content and format of the Community directives. This situation will occur even more frequently in the near future, when amendments to existing directives or new directives on other groups of materials (paper and board, varnishes, elastomers) are prepared.

It should also be pointed out that the use of regulations as legal instruments for the implementing provisions will ensure uniform and timely application of the rules for the benefit both of the consumers and of the competitiveness of the industry. For implementing procedures, the proposed Regulation changes from the compulsory system of issuing directives to a more flexible one enabling a decision about the legal nature of the act to be adopted – directive, regulation or decision – according to the content. Replacing the term "directive" by "measure", as provided in Article 95 of the Treaty, would achieve such flexibility. This approach has also been requested by some Member States.

2. Active and intelligent food contact materials and articles ("active and intelligent materials and articles")

The main purpose of food packaging is to protect the food against physical, biological and chemical risks. Food packaging materials have traditionally been developed to avoid interactions with food and, in particular, to minimise the release of their components ("migration") into the food. Accordingly, current Community legislation asks for maximum inertness of the food contact materials and minimised food contamination. Packaging materials must not cause unacceptable changes in the composition of the food or in its organoleptic characteristics.

Active materials and articles are new concepts in packaging, designed to interact with food in order to maintain or improve the condition of the food during storing and prolong its shelf life. Such applications include oxygen scavengers, flavourings, preservative or antioxidant emitters, ethylene absorbers from fresh food, etc. Another innovative type of packaging called intelligent materials and articles are developed to provide information about the actual condition of the food.

The proposed Regulation provides the legal framework, which introduces the possibility to take into account these new technological solutions to food packaging and sets some basic requirements for their use.

- The proposal defines the active and intelligent materials and articles and specifies that the Regulation should apply to these materials and articles (Article 2).
- Article 2 of Directive 89/109/EEC states that materials and articles should not bring about unacceptable changes to the composition or deteriorate the organoleptic properties of the food. Active materials and articles, however, due to their intended use may change these properties of the food. Therefore, this Article has been modified to clarify that compositional and organoleptic changes brought to the food by active materials and articles are allowed provided these changes comply with any other Community legislation applicable to food (Article 4).
- Labelling requirements are proposed to inform the user of active materials and articles (food packers) about the interaction of these applications with the food in order to comply with any relevant food legislation (Article 12(1)(e)).
- Since active and intelligent materials and articles include sophisticated systems composed of different materials, such as plastic, paper, metal, adhesives etc, more detailed rules might be needed in specific measures. For this reason, these materials and articles are added to the list of materials to be regulated by specific measures (Annex I).

3. Authorisation procedure

Directive 89/109/EEC lays down the principle of positive lists of authorised substances and the groups of materials and articles to be regulated by specific measures implementing the basic principles. It also sets the procedures and criteria to be followed in drafting and adopting the implementing measures, including the evaluation of substances by the SCF.

The proposed Regulation establishes more detailed procedures for the safety assessment and authorisation of substances to be used in the manufacture of food contact materials.

Where a positive list is drawn up, the procedure proposed in the draft Regulation (*Articles 8-11*) can be summarised as follows:

- those interested in placing a new substance for a food contact material on the market submit an application to the national competent authority of a Member State;
- the national competent authority informs the European Food Safety Authority (“Authority”) about the receipt of an application and makes available to the Authority the application and any supplementary information provided by the applicant;

- the Authority informs the Commission and the other Member States of the application and makes the application and any supplementary information submitted by the applicant available to them;
- the Authority expresses an opinion within a defined limited time, forwards it to the Commission, the Member States and the applicant, and makes it public after adoption;
- based on the opinion of the Authority, the Commission proposes a draft measure.

Confidentiality for sensitive data is provided if requested by the applicant, which is subject to the decision of the Commission (*Article 18*).

4. Labelling

- Article 6(3) of Directive 89/109/EEC states that materials and articles, which by their nature are obviously intended to come into contact with food, do not need to be labelled with the words ‘for food use’ or the symbol. However, since there are also materials and articles of a shape or nature suggesting that they can be used for food contact, without being manufactured for this purpose, the proposed Regulation replaces Article 6(3) of 89/109/EEC with the requirement that all materials or articles suitable for food contact should be labelled by the words “suitable for food contact” or a symbol. For simplicity, this symbol, specified by Directive 80/590/EEC, should be integrated into the draft Regulation (Annex II) and Directive 80/590/EEC should be repealed.
- A labelling provision for active and intelligent materials and articles has been mentioned above (Article 12(1)(e)).

5. Traceability (*Article 15*)

The provisions on traceability established in Article 18 of Regulation (EC) No 178/2002 of the European Parliament and of the Council 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, do not apply to food contact materials and articles. It is, therefore, necessary to establish general requirements to ensure traceability of all materials and articles in contact or intended to come into contact with food at all stages.

In line with Regulation (EC) No 178/2002, this draft Regulation requires all food contact material businesses to have in place systems to identify at every given stage of production and trade, their supplier(s) and to whom materials and articles are supplied, whereby at least one step “above” and one “below” must be identifiable, unless specific provisions require further traceability. Importers are also concerned.

Additional provisions for specific groups of materials and articles may be adopted, if necessary, in specific measures.

6. Safeguard measures

Emergency measures for food are established in Articles 53 and 54 of Regulation (EC) No 178/2002. They are applicable also when serious risk to human health derives from migration of substances from food contact materials and articles into food. In addition to these

emergency measures foreseen for food by Regulation (EC) No 178/2002, a safeguard clause specific to materials and articles as such is included in *Article 16*.

7. Reference laboratories (*Article 23*)

In order to ensure enforceability of the rules, it is proposed to establish a Community Reference Laboratory and national reference laboratories, in accordance with Regulation of the European Parliament and of the Council on official feed and food controls¹.

8. New materials which may be regulated by specific measures

Further to active and intelligent materials and articles, three more groups of materials, i.e. ion-exchange resins, adhesives, printing inks, are proposed to be added to the list of groups of materials, which may be regulated by specific measures (*Annex I*).

IMPACT OF THE PROPOSAL ON THE ACCEDING COUNTRIES

The proposed Regulation will have no specific impact on the acceding countries in particular, nor will it affect the enlargement of the Union in general.

The new provisions aim at introducing more clarity and transparency to the currently existing provisions as laid down in Directive 89/109/EEC. The core principles of Directive 89/109/EEC remain unchanged in this proposal. The new provisions are in line with Regulation (EC) No 178/2002 which is part of the *acquis* accepted by the acceding countries under the Accession Treaty.

Notably in relation to active and intelligent materials and articles the proposal simply establishes the legal frame for regulating these new types of packaging. The description of the authorisation procedure is introduced for reasons of transparency and does not change the current practice. Finally the traceability provisions are aligned with the requirements established by the above mentioned Regulation (EC) No 178/2002.

Practically all acceding countries have already transposed most of the *acquis* on food contact materials, including Directive 89/109/EEC or are in the process of doing so. They have been fully informed on the principles of the above-mentioned Regulation (EC) No 178/2002 which will be directly applicable upon accession. Further, in the context of the monitoring exercise of the Commission, DG SANCO is currently actively co-operating with these countries to assist them and to ensure their national texts are fully conform with EU law, including the *acquis* on food contact materials.

In view of the nature of the changes introduced in the proposal and of the maintaining of exactly the same policy as in the past the proposed Regulation should not have cause any specific problems of transposition or implementation in the acceding countries, as compared to the existing *acquis*.

¹ Commission proposal COM(2003) 52 final. References will be added when the Regulation is adopted by the European Parliament and the Council.

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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 Commission¹,

Having regard to the opinion of the European Economic and Social Committee²,

Acting in accordance with the procedure laid down in Article 251 of the Treaty³,

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 foodstuffs⁴, replacing Directive 76/893/EEC, 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 should be that any material or article intended to come into contact with food must be sufficiently inert to preclude substances 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.

¹ OJ C

² OJ C

³ OJ C

⁴ OJ L 40, 11.2.1989, p. 38.

- (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, contrary to 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.
- (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) Any material and 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 manufactured and placed on the market before 1 January 1980, when the rules of Directive 76/893/EEC became applicable, and which are supplied as antiques, should be excluded.
- (7) Covering or coating products forming part of the food and possibly being consumed with it should not fall within the scope of this Regulation.
- (8) 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.
- (9) 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 safety⁵, the European Food Safety Authority ("the Authority") should be consulted before provisions liable to affect public health are adopted under specific measures.
- (10) 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.
- (11) Differences between national laws, regulations and administrative provisions concerning the safety assessment and the 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.

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).

- (12) 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.
- (13) Labelling supports users in the correct use of the materials and articles. Methods used for such labelling may vary according to the user.
- (14) A symbol was introduced by Commission Directive 80/590/EEC of 9 June 1980 determining the symbol that may accompany materials and articles intended to come into contact with foodstuffs⁶. It should, for reasons of simplicity, be incorporated in this Regulation.
- (15) Traceability of materials and articles intended to come into contact with food should be ensured at all stages. Business operators should at least be able to identify the businesses from which and to which the materials and articles have been supplied.
- (16) 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.
- (17) It is appropriate to protect the investment made by innovators in gathering the information and data supporting an application 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.
- (18) 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 [...] of the European Parliament and of the Council on official feed and food controls⁷.
- (19) The measures necessary for the implementation of this Regulation and amendments to Annexes I and II 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 Commission⁸.
- (20) The Member States should lay down rules on penalties applicable to infringements of the provisions of this Regulation and ensure that they are implemented. Those penalties must be effective, proportionate and dissuasive.
- (21) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States due 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.

⁶ OJ L 151, 19.6.1980, p. 21. Directive as last amended by the act of Accession of Austria, Finland and Sweden.

⁷ Commission proposal COM(2003) 52 final. References will be added when the Regulation is adopted by the European Parliament and the Council.

⁸ OJ L 184, 17. 7. 1999, p. 23

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

HAVE ADOPTED THIS REGULATION:

Article 1
Subject matter and scope

1. The purpose of this Regulation is to ensure the effective functioning of the internal market in relation to materials and articles intended to come into contact with foodstuffs, 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 (hereinafter referred to as ‘materials and articles’), including active and intelligent food contact materials and articles, which in their finished state:
 - (a) are intended to be brought into contact with food; or
 - (b) are already brought into contact with food and are intended for that purpose; or
 - (c) can reasonably be expected to be brought into contact with foods or to transfer their constituents to food.
3. This Regulation shall not apply to:
 - (a) materials and articles which were manufactured and placed on the market before 1 January 1980 and which are supplied as antiques;
 - (b) covering or coating products, such as the products covering cheese rinds, prepared meat products or fruits, which form part of food and may, be consumed together with this food;
 - (c) fixed public or private water supply equipment.

Article 2
Definitions

For the purposes of this Regulation, the definitions laid down in Regulation (EC) No 178/2002 shall apply, with the exception of the definition of “traceability”.

The following definitions shall also apply:

- (1) “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;
- (2) “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;

- (3) “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;
- (4) “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;
- (5) “traceability” means the ability to trace and follow a material or article through all stages of manufacture, processing and distribution.

Article 3
General requirements

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 a deterioration in the organoleptic characteristics thereof.

Article 4
Special requirements for active and intelligent materials and articles

- 1. Without prejudice to Article 3(a), active materials and articles may bring about changes in the composition or the organoleptic characteristics of the food only if the changes comply with the Community provisions or, in their absence, with the national provisions applicable to food.
- 2. Active materials and articles shall not bring about changes in the composition or the organoleptic characteristics of the food which could mislead the consumers.
- 3. Intelligent materials and articles shall not give information about the condition of the food which could mislead the consumers.

Article 5
Specific measures for groups of materials and articles

For the groups of materials and articles listed in Annex I and, where appropriate, combinations of those materials and articles, specific measures may be adopted in accordance with the procedure referred to in Article 21(2).

Those specific measures may include:

- (a) a list of the substances the use of which is authorised to the exclusion of all others (positive list);
- (b) purity standards for substances referred to in (a);

- (c) special conditions of use for substances referred to in (a) and/or the materials and articles in which they are used;
- (d) specific limits on the migration of certain constituents or groups of constituents into or onto food, taking due account of other possible sources of exposure to those constituents;
- (e) an overall limit on the migration of constituents into or onto food;
- (f) provisions aimed at protecting human health against hazards arising from oral contact with materials and articles;
- (g) other rules to ensure compliance with Articles 3 and 4;
- (h) basic rules for checking compliance with points (a) to (g);
- (i) rules concerning the collection of samples and the methods of analysis to check compliance with points (a) to (g);
- (j) additional provisions for ensuring traceability of materials and articles;
- (k) provisions requiring that the Commission establishes and maintains a publicly available Community Register (“Register”) of authorised substances, materials or articles.

Article 6

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 7

General requirements for placing on the market

1. If a list as referred to in point (a) of the second subparagraph of Article 5 is adopted, anyone seeking an authorisation for a substance not yet included in that list shall submit an application in accordance with Article 8(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 Articles 3 and 4.

Article 8

Application for authorisation of a new substance

1. To obtain the authorisation referred to in Article 7(1), an application shall be submitted in accordance with the following points:
 - (a) the application shall be sent to the national 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 national competent authority 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 without delay the Authority; and
 - (iii) make the application and any supplementary information supplied by the applicant available to the Authority;
- (c) the Authority shall inform without delay 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 guidance concerning the preparation and the submission of the application. Pending such publication, applicants shall 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”⁹.

Article 9
Opinion of the Authority

1. The Authority shall give an opinion within six months of the receipt of a valid application, as to whether the substance under the intended conditions of use of the material or article in which it is used, complies with the criteria laid down in Articles 3 and 4.
- The Authority may extend the said period. 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 such time, as that information has been provided. Likewise, the time limit shall be suspended for the time allowed to the applicant to prepare oral or written explanations.
3. In order to prepare its opinion, the Authority shall:

⁹ http://europa.eu.int/comm/food/fs/sc/scf/out82_en.pdf

- (a) verify that the information and documents submitted by the applicant are in accordance with Article 8(1)(a) in which case the application shall be regarded as valid, and examine whether the substance complies with the criteria laid down in Articles 3 and 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;
 - (b) where appropriate, any conditions or restrictions of use for the evaluated substance and/or the material or article;
 - (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 18.

Article 10
Community authorisation

1. The Commission shall prepare, where appropriate, a draft of a specific measure to authorise the substance or substances evaluated by the Authority and specify or change the conditions of 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 an explanation for the reasons for the differences.
3. The specific measure referred to in paragraph 1 shall be adopted in accordance with the procedure referred to in Article 21(2).
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 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 to the authorised substance, the material or article containing the authorised substance, and the food that is in contact with such a material or article.

Article 11
Modification, suspension and revocation of authorisation

1. The applicant may, in accordance with the procedure laid down in Article 8(1), apply for a 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 according to the guidelines as referred to in Article 8(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 deliver an opinion on whether an authorisation is still in accordance with this Regulation, in accordance with the procedure laid down in Article 9, where applicable.
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.
6. A final specific measure on the modification, suspension or revocation of the authorisation shall be adopted in accordance with the procedure referred to in Article 21(2).

Article 12
Labelling

1. Without prejudice to the specific measures, materials and articles, which are not yet in contact with food when placed on the market, shall be accompanied by:
 - (a) the words “suitable 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;
 - (b) where appropriate, special instructions to be observed for safe use;
 - (c) either the name or trade name and the address or registered office, or the registered trade mark of the manufacturer, processor, or seller established within the Community;

- (d) adequate labelling or identification to allow traceability of the material or article;
 - (e) in the case of active materials and articles, instructions on the permitted use or uses to enable the users of these materials and articles to comply with any other relevant Community provisions or, in their absence, national provisions applicable to food.
2. The information required by paragraph 1 shall be conspicuous, clearly legible and indelible.
 3. At the retail stage, the information required by 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.
 4. At the marketing stages other than the retail stage, the information required by paragraph 1 shall be displayed on:
 - (a) the accompanying documents;
 - (b) the labels or packaging; or
 - (c) the materials and articles themselves.
 5. 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 Articles 3 and 4;
 - (b) the specific measures or, in their absence, with any national provisions applicable to them.

Article 13

Labelling requirements in specific measures

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, Member States may retain existing provisions or adopt provisions to this effect.

Article 14
Language used for labelling

Retail trade in materials and articles shall be prohibited if the information required under Article 12(1)(a) and (b) is not given in a language easily understood by purchasers. This provision shall not preclude such information appearing in several languages.

Article 15
Traceability

1. The traceability of the materials and articles shall be established at all stages of manufacture, processing and distribution.
2. Business operators shall have in place systems and procedures to allow the identification of the businesses from which and to which the materials or articles and, where appropriate, substances or products used in their manufacture have been 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 adequately labelled or identified to facilitate their traceability through relevant documentation or information.

Article 16
Safeguard measures

1. When a Member State, as a result of new information or a reassessment of existing information made since one of the specific measures referred to in Article 5 was adopted, 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 21(1) the grounds adduced by the Member State referred to in paragraph 1 of this Article 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 21(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.

Article 17
Public access

1. The application for authorisation and supplementary information from the applicant and opinions from the Authority, excluding confidential information, shall be made accessible to the public.
2. The Authority shall apply the principles of Regulation (EC) No 1049/2001 of the European Parliament and of the Council¹⁰ *mutatis mutandis* when handling applications for access to documents held by the Authority.
3. Member States shall handle applications for access to documents received under this Regulation in accordance with Article 5 of Regulation (EC) No 1049/2001.

Article 18
Confidentiality

1. The applicant may indicate which information submitted under Article 8(1) is to be treated as confidential because its disclosure may significantly harm his 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.

¹⁰ OJ L 145, 31.5.2001, p. 43

Article 19
Data protection

The information in the application submitted in accordance with Article 8(1) may be used for the benefit of another applicant, provided 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.

Article 20
Amendments to Annexes I and II

Amendments to Annexes I and II shall be adopted in accordance with the procedure referred to in Article 21(2).

Article 21
Committee

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 (hereinafter referred to as “the Committee”).
2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

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

Article 22
Inspection and control measures

1. Member States shall ensure that inspections and other control measures, as appropriate, are carried out to ensure compliance with this Regulation.
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 co-ordinated approach for the implementation of paragraph 1.

Article 23
Reference laboratories

A Community reference laboratory for materials and articles intended to come into contact with food and a list of national reference laboratories shall be established as laid down in Regulation (EC) No [...] [of the European Parliament and of the Council on official feed and food controls].

Article 24
Penalties

The Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission by *[insert date six months after the date of publication of this Regulation]* at the latest and shall notify it without delay of any subsequent amendment affecting them.

Article 25
Repeals

Directives 89/109/EEC and 80/590/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 26
Entry into force

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

Article 15 shall apply from *[2 years after the adoption of the Regulation]*.

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

Done at Brussels, [...]

For the European Parliament
The President
[...]

For the Council
The President
[...]

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) Elastomers and rubbers
- (6) Glass
- (7) Ion-exchange resins
- (8) Metals and alloys
- (9) Paper and board
- (10) Plastics
- (11) Printing inks
- (12) Regenerated cellulose
- (13) Textiles
- (14) Varnishes and coatings
- (15) Waxes
- (16) Wood

ANNEX II



Symbol

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 6
-	Article 7
-	Article 8
-	Article 9
-	Article 10
-	Article 11
Article 4	-
Article 6	Article 12
-	Article 13
-	Article 14
-	Article 15
Article 5	Article 16
Article 7	-
-	Article 17
-	Article 18
-	Article 19
-	Article 20
Article 8	-
Article 9	Article 21

-	Article 22
-	Article 23
-	Article 24
Article 10	Article 25
Article 11	-
Article 12	-
Article 13	Article 26
Annex I	Annex I
Annex II	-
Annex III	Annex III
Directive 80/590/EEC	This Regulation
Annex	Annex II

PRELIMINARY ASSESSMENT STATEMENT

1. PROBLEM IDENTIFICATION

Directive 89/109/EEC provided the basis for the assurance of a high level of protection of human health and of consumers' interests in relation to materials and articles intended to come into contact with food whilst ensuring the effective functioning of the internal market.

Technological progress in the area of food packaging is though rapid and intense. New types of packaging have been recently developed. The so-called "active" food contact materials and articles have been designed to maintain or improve the condition of the food and prolong its shelf life. Other new packaging applications known as "intelligent" food contact materials and articles are used to give information about the condition of the food. It is currently unclear if these types of packaging are covered by national or Community legislation. The proposal clarifies that these two types of food contact materials and articles are covered by the Regulation and sets basic rules for their use. It also foresees the possibility of drafting specific implementing measures for them.

Directive 89/109/EEC already sets the procedures and criteria to be followed in drafting and adopting the implementing measures for the different groups of materials and articles, including the evaluation of substances by the Scientific Committee on Food (SCF). Nevertheless, it is necessary, for reasons of transparency, to establish more detailed procedures for the safety assessment and authorisation of substances used for the manufacture of food contact materials.

Food contact materials and articles need to be traceable at all stages of manufacture, processing and distribution. It is therefore necessary to establish general rules of traceability for food contact materials, in line with similar traceability provisions for food and feed established in Article 18 of Regulation (EC) No 178/2002.

Some additional provisions of labelling are proposed to better inform the consumers and the users of the food contact materials.

The present proposal aims at modifying Directive 89/109/EEC to take into account the issues mentioned above. It also integrates for reasons of simplicity the symbol which should accompany food contact materials and articles determined in Directive 80/590/EEC. The proposed Regulation will therefore replace and repeal Directives 89/109/EEC and 80/590/EEC.

2. OBJECTIVE OF THE PROPOSAL

The overall policy objective in terms of expected impacts is to:

- secure a high level of protection of human health and the interests of the consumer,

- ensure the free movement of materials and articles intended to come into contact with food,
- take into account important technological developments in the area of food packaging,
- ensure better traceability as well as labelling of materials and articles intended to come into contact with food,
- improve the transparency of the authorisation process by specifying the various phases of the procedure,
- give the possibility to the Commission to adopt for the implementing measures not only directives, but also decisions and regulations, as the latter are more appropriate for provisions, such as positive lists,
- ensure better enforceability of the rules through the establishment of Community and national Reference Laboratories.

The provisions on active and intelligent food contact materials and articles are general and establish the regulatory status of these packaging applications in the Community to the benefit of the concerned industry, the consumers and the Member States.

The additional labelling requirements will ensure a more informed use of the food contact materials and articles by the purchaser and the final consumer.

Improving traceability of food contact materials will be beneficial for the consumer in case of a problem, and will allow a more limited withdrawal of deficient products by the companies.

3. POLICY OPTIONS

The basic approach suggested to reach the above-mentioned objectives is to improve and harmonise Community legislation on materials and articles intended to come into contact with food by introducing the proposed rules.

In terms of respecting the subsidiarity and proportionality principles the Framework Directive 89/109/EEC was adopted on the grounds that differences between national laws of the Member States impeded the free movement of these materials and articles. Directive 89/109/EEC approximated those laws to achieve the free movement of food contact materials and articles whilst protecting consumer's health and interests. This Directive also established a list of materials and articles to be covered by specific directives. This approach was successful and should be continued.

The adoption of a Regulation instead of a Directive is justified by the technical nature of the act and will lead to the direct application of the proposed rules throughout the Community. This is important in the perspective of an enlarged Community that will

soon comprise 25 Member States and that will certainly benefit from homogenous and directly applicable rules throughout its territory.

4. IMPACTS – POSITIVE AND NEGATIVE

All sizes of businesses related to the manufacture, processing and trade of materials and articles intended to come into contact with food will be affected by the proposed provisions. The food industry is also concerned.

The **new obligations** implied by this proposal are the following:

Community authorisation for the substances used in the manufacture of food contact materials is already foreseen in Directive 89/109/EEC. Thus, no new obligations arise for business from the provisions on the authorisation procedure.

The main new obligations will be:

General obligation for applicants:

To send the application for the authorisation of a substance to the national competent authority of a Member State, in first place.

To inform the Authority about new information which may influence the evaluation of the safety in the use of an authorised substance.

General obligations for business operators responsible for the manufacture, processing, importation, or distribution of food contact materials:

To label all materials and articles that are intended to come into contact with food, including those for which this use is obvious by their nature and which were so far excluded from this obligation by Directive 89/109/EEC.

To instruct on the permitted uses of active and intelligent materials and articles, in order to enable the users of those materials and articles to comply with relevant legislation applicable to food.

General obligations for all business operators:

To comply with the conditions of use and restrictions attached to the authorisation of substances for manufacturing food contact materials.

To have in place systems to identify the suppliers to their businesses of materials and articles and where appropriate the substances and products used for their manufacture. On request, they should be able to make this information available to the competent authorities.

To identify to whom their products have been supplied and, upon request, to make this information available to the competent authorities.

To adequately label or identify the materials and articles placed on the market in the Community to allow their traceability.

In terms of **economic impact** the following aspects could be identified:

Already the current system requires the evaluation of substances used for the manufacture of food contact materials before their authorisation. Hence, the proposal will not introduce major changes in this respect.

The provisions on active and intelligent materials and articles are general and establish the regulatory status of these materials and articles in the Community to the benefit of the concerned industry, the consumers and the Member States.

Most of the labelling requirements already exist in Directive 89/109/EEC, and therefore should not have a major economic impact. It should also be noted that this Regulation offers different options for labelling.

The proposed regulation requires traceability of all food contact materials and articles. Since this presupposes systems enabling the identification of the products, it will involve some cost for the businesses manufacturing, processing and distributing food contact materials. It should be noted, however, that most companies have already established procedures for traceability as part of the requirements of modern quality management systems, such as ISO 9000, Good Manufacturing Practices etc. In addition, withdrawal of deficient products is more limited when these are traceable.

No **social** or **environmental** impacts are expected by this proposal.

5. FOLLOW-UP

A broad consultation has been carried out on a preliminary draft proposal in several meetings held with Member States and interested parties. Some specific issues, mainly technical such as traceability and “active” materials and articles, were additionally discussed within smaller consultation groups of experts. Most of the comments received as result of the consultations have been taken into consideration in the framework of this proposal.

The following professional and consumers’ organisations were constantly involved in the discussions, which led to the present proposal:

- APME (Association of plastics manufacturers in Europe)
- BEUC (The European consumers’ organisation)
- BLIC (Liaison Office of the E.U. Rubber Industry)
- CEFIC-FCA (European Chemical Industry Council-Food Contact Additives)
- CEI Bois (European Confederation of Woodworking Industries)

- CELiège (European Cork Confederation)
- CEPE (European Council of the Paint, Printing Ink and Artists' Colours Industry)
- CEPI (Confederation of European Paper Industries)
- CERAME-UNIE (Liaison office of the European ceramic industry)
- CIAA (Confederation of the food and drink industries of the EU)
- CIPCEL (International Rayon and Synthetic Fibres Committee)
- CITPA (International Confederation of Paper and Board Converters)
- EuPC (European plastics converters confederation)
- EPFMA (European Plasticized Film Manufacturers Association)
- ETS (European Tissue Symposium)
- EURATEX (European Apparel and Textile Organisation)
- EUROCOOP (European community of consumer cooperatives)
- EWF (European Wax Federation)
- FABRIMETAL / SEFEL (Metal Packaging Manufacturers Association)
- FEVE (European Container Glass Federation)
- FEICA (Association of European Adhesives Manufacturers)
- FLEXIBLE PACKAGING EUROPE (The European Forum for the Flexible Packaging Industry)

On the issue of active and intelligent materials and articles, the European consumers' organisation (BEUC) raised concerns in relation to correct labelling of these materials and articles. They also stressed the need for provisions to rule out that such systems mislead the consumers in relation to the quality or condition of the food. Their comments were taken into account.

The industry was concerned about the traceability provisions on which a broad consultation was held. A "Food Contact Materials Industry Liaison Committee" was created by the concerned industry to examine the proposed provisions. Finally the traceability requirements were generally accepted by the different industrial sectors. In addition the Liaison Committee works proactively on a volunteer basis for the preparation of guidelines for the application of the traceability rules.

An extended assessment on this proposal is not recommended as the proposal has already been subject to extended consultation with Member States and stakeholders. No further consultation is planned.