


EU legislation: Food contact materials

Introduction

 Materials and articles intended to come into contact with food are to be interpreted in the broadest sense of the word: legislation applies to packaging materials for foodstuffs but also to materials and articles like kitchen utensils and plastic party plates. Manufacturers that produce food packaging materials and articles or other materials and articles coming into contact with food that are intended for the European Market will have to conform to the requirements of the Framework Regulation and possibly also to requirements laid down in specific Directives.

1. The Framework Regulation 1935/2004 setting general requirements for all food contact materials;
2. Directives covering specific groups of food contact materials and articles listed in Annex 1 of the Framework Directive, and;
3. Directives on Specific Substances used in the manufacture of materials and articles intended for food contact.

Please note: In November of 2004 Framework Directive 89/109/EC has been repealed by a Framework Regulation (EC) No. 1935/2004. Since a Regulation is directly applicable to the Member States, the EU countries do not have to transpose these requirements into national legislation. The new Regulation entered into force on December 3rd, 2004. The new Regulation addresses various new topics, including active food contact materials, and food contact materials produced from recycled material. It furthermore establishes 17 groups of materials and articles which may be covered by specific measures, in stead of the 10 listed in the Directive that was repealed and replaced.

Table 1 depicts the groups of materials and substances that are currently covered by European legislation.

Table 1: overview of current Directives on food contact materials

Scope legislation	Materials/ substances and reference	Main issues covered by the legislation
All food contact materials	<ul style="list-style-type: none"> • All food contact materials (Regulation (EC) No. 1935/2004) 	<ul style="list-style-type: none"> • Scope • General safety provisions • Marking/labelling requirements • Establishes groups of materials which may be covered by specific measures • Procedure to be followed for the authorisation of substances to be used in food contact materials and articles • Traceability of food contact materials and articles (not yet in force, will enter into force as of October 27, 2006)
Directives covering specific groups of food contact materials	<ul style="list-style-type: none"> • Plastics (2002/72/EC) • Regenerated cellulose film (93/10/EEC) • Ceramics (84/500/EEC) 	<ul style="list-style-type: none"> • Scope (for example type of plastics) • Quantity and/or migration limits • Specifications and restrictions • Conditions for use substances • Reference to relevant directives for testing methods
Directives on Specific Substances	<ul style="list-style-type: none"> • Vinyl chloride monomer (78/142/EEC) • N-nitrosamines and N-nitrosatable (93/11/EEC) • BADGE, NOGE, BFDGE (2002/16/EC) 	<ul style="list-style-type: none"> • Scope • Migration limits • Testing methods

In the following part the legal requirements set out in the Framework Regulation and the various Directives are described. Through hyperlinks you can click to the Directive and substance of your choice.

➔ [For more information](#) you can find links to relevant Directives and other documents of the European Commission in the external links section. For other relevant documents please consult the related documents.

Outline of the legislation

The following issues are discussed in this document:

1. Framework Regulation
2. Directives on groups of materials and articles
 - Plastic materials
 - Regenerated cellulose film
 - Ceramics
3. Directives on specific substances
 - Vinyl chloride monomer
 - N-nitrosamines and N-nitrosatable substances
 - BAGDE, NOGE, BFDGE (epoxy derivatives)

The checklist below (figure 1) can be used to check the relevance of EU requirements for your products intended to come into contact with food. For food contact materials made of plastics a separate flow-chart is given for a step by step approach.

In case you produce food packaging materials, besides legal requirements for food contact materials you will also have to comply with EU legislation on packaging.

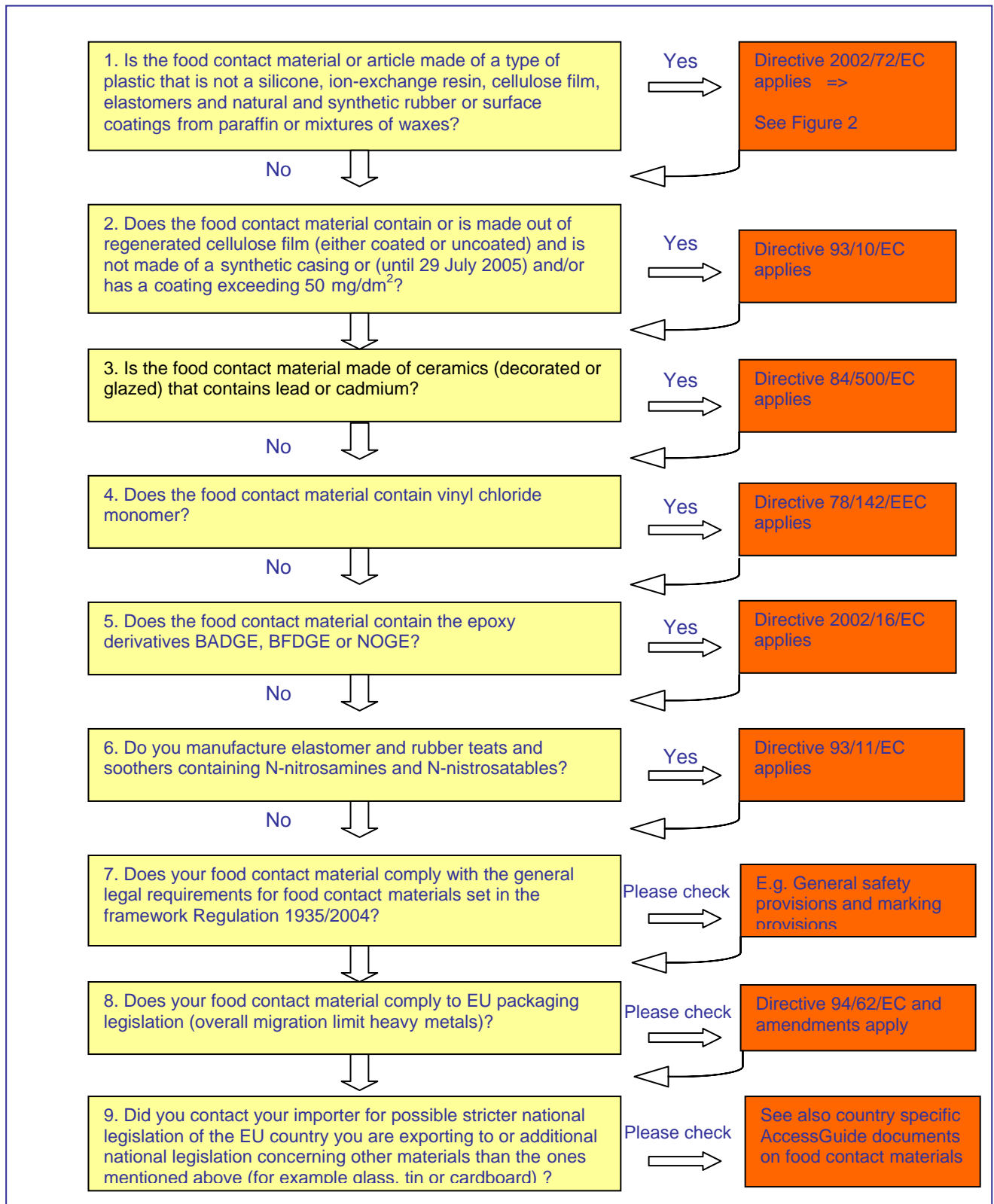
➔ [For more information on](#) this legislation, please refer to the related documents.

Also, individual EU countries may (still) have stricter or additional legislation for groups of food contact materials the EU has not yet drafted legal provisions for (for example glass or paper and board). Although most countries strive towards harmonisation with EU legislation, it is always advisable to contact your importer for more information on additional (or stricter) national legislation in the country you want to export to.

Please note that the European Commission made information pages available on “food contact materials”. Among others you will find a “practical guide” explaining the requirements.

➔ [For more information on](#) this document and other interesting pages please refer to the external links section.

Figure 1: checklist for compliance to EU legislation on food contact material



1. Framework Regulation

Regulation (EC) 1935/2004 serves as a framework Regulation setting out the common principles and rules for the composition of materials and articles intended to come into contact with foodstuffs. Please note that this Regulation replaces and repeals Framework Directive 89/109/EEC.

Regulation (EC) 1935/2004 applies to:

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 in contact with food and were intended for that purpose, or
- c. can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use.

The Regulation does not apply to:

- d. covering or coating substances, such as the materials covering cheese rinds, prepared meat products or fruit, which form part of the food and may be consumed together with the foodstuffs.
- e. antiques.
- f. fixed public or private water supply equipment.

General safety provisions

Among others, the framework Regulation 1935/2004 defines that "materials and articles must be manufactured in compliance with good manufacturing practice so that, under their normal and foreseeable conditions of use they do not transfer their constituents to food in quantities which could:

- Endanger human health, or
- Bring about an unacceptable change in the composition of the food, or
- Bring about a deterioration in the organoleptic characteristics of the food.

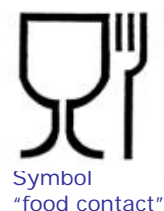
The "Code for Good Manufacturing Practices for flexible and fibre-based packaging materials, version 1.0, May 2003" is an example of Good Manufacturing Practice according to Commission Guidelines (see external links section).

Presentation of food contact materials or articles

The Regulation furthermore requires that the labelling, advertising and presentation of a material or article shall not mislead consumers. In addition to this general provision, Article 15 sets out requirements for labelling.

Article 15 on labelling is applicable to materials and articles which are not already in contact with food, but meant for food contact applications. When placed on the market, they must be accompanied by:

- a. the words 'for food contact', or a specific indication as to their use, such as a coffee machine, wine bottle, soup spoon, or the symbol which is reproduced in Annex II to Regulation 1935/2004. (However, if the article is clearly intended to come into contact with food (because of its characteristics) this information is not obligatory); and
- b. If necessary special instructions to be observed for safe and appropriate use; and
- c. The name or trade name and, in either case, the address or registered office of the manufacturer, processor or seller responsible for placing on the market established within the EU; and
- d. Adequate labelling or identification to ensure traceability of the material or article; and
- e. In the case of active materials and articles, information on the permitted use or uses and other relevant information (e.g. name and quantity of the substances released by the active component)



The information provided for under a), b) and e) is limited to materials and articles that comply with article 3 (general safety requirements) and, if applicable, article 4 (active and intelligent materials and articles).

The specifications mentioned under a) to e) must be conspicuous (clearly noticeable), clearly readable and indelible (can not be brushed of). Moreover, if products are meant for retail the information under a), b) and e) should be given in a language easily understood by purchasers. Please note that Member States can stipulate the language, as long as they do not preclude the possibility of particulars being indicated in several languages.

In the retail stage, the specifications:

- must be put on the materials and articles or on the packaging,
- or on the labels fixed to the materials and articles or to their packaging
- or on a notice in the immediate vicinity of the materials and articles and clearly visible to purchasers. In this case, for the specification under c) (name and address of the registered office, or the registered trade mark) is only allowed to be listed on such a notice if a label bearing them cannot, for technical reasons, be affixed to the materials and articles included at either the manufacturing or marketing stage.

In the marketing stages other than the retail stage, the specifications:

- must be on the accompanying documents,
- on the labels or packaging,
- or on the materials and articles themselves.

Active and intelligent materials and articles

New requirements are laid down in the Regulation so as to include requirements for active and intelligent food contact materials and articles.

What are **active** and **intelligent** food contact materials and articles?

In the definitions of the Regulation it is explained:

Active refers to materials and articles that are intended to extend the shelf-life or to maintain or improve the condition of the 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.

Intelligent food contact materials and articles means materials and articles which monitor the condition of packaged food or the environment surrounding the food

The framework Regulation sets requirements on the following:

- that pending the adoption of rules in a specific measure for these types of materials and articles, substances deliberately incorporated and to be released in the food or the environment surrounding the food, these substances need to be authorised and used in accordance with relevant legislation. Such substances are considered food ingredients (as laid down in Directive 2000/13/EC on food labelling).
- Active materials may not bring about changes that could mislead the consumer. For instance by changing the organoleptic characteristics of food to mask spoilage.
- Intelligent materials may not give information about the condition of the food to mislead consumers.
- Active and intelligent materials which are already in contact with food at the moment they are put on the market should be adequately labelled so the consumer can identify the non-edible parts. In addition they need to be labelled to indicate that the materials or articles are active and/or intelligent.

2. Specific Directives for single groups of food contact materials and articles

Annex I of framework Regulation 1935/2004 lists 17 specific materials and articles coming into contact with food. For these materials and articles specific measures may be adopted. Three of these materials are already regulated (see below, materials 3, 10, 12 written in bold). For the

other materials no harmonised legislation has been laid down yet. These materials and articles are:

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

These material specific requirements are laid down in the following Directives and its amendments:

- Directive 2002/72/EC and its amendments cover plastic materials and articles coming into contact with food.
- Directive 93/10/EEC relates to materials and articles of regenerated cellulose film intended to come into contact with foodstuffs.
- Directive 84/500/EEC covers ceramic articles intended to come into contact with foodstuffs

Please note that it can be possible that for those types of materials not yet regulated, Member States have set additional national legislation.

2.a. Plastic materials (Directive 2002/72/EC)

“Plastics” are defined as organic macromolecular compounds obtained by polymerisation, polycondensation, polyaddition or any other similar process from molecules with a lower molecular weight or by chemical alteration of natural macromolecules. Other substances or matters may be added to such macromolecular compounds.

The flowchart on the following page (figure 2) gives a step-by-step approach for applying to the legal requirements set by Directive 2002/72/EC.

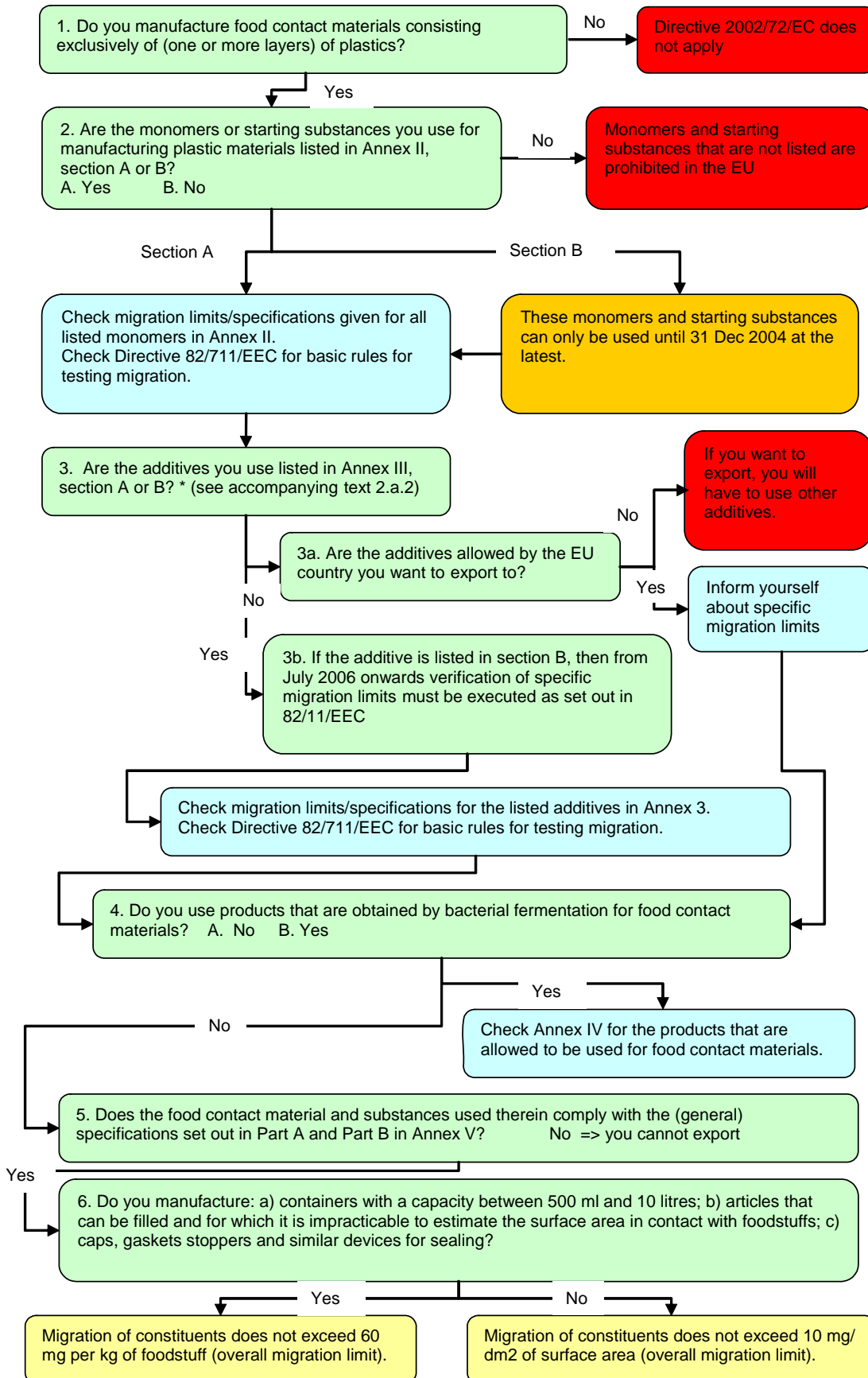
Scope of the Directive (Step 1 of flowchart figure 2)

The Directive and its amendments apply to plastic food contact materials and articles and parts thereof:

- consisting exclusively of plastics; or
- composed of two or more layers of materials, each consisting exclusively of plastics, which are bound together by means of adhesives or by any other means, which, in the finished product state, are intended to come into contact or are brought into contact with foodstuffs intended for that purpose

Not included in the definition are:

- varnished or unvarnished regenerated cellulose film;
- elastomers and natural and synthetic rubber;
- paper or paperboard, whether modified or not by the addition of plastics;
- surface coatings obtained from paraffin waxes or mixtures of waxes listed in the first indent with each other and/or with plastics;
- ion-exchange resins;
- silicones.



Migration limits

There are two types of migration limits set for plastic food contact materials:

1. Overall migration limit (step 6 flowchart)
2. Specific migration limits (step 2 and 3 flowchart)

1. Overall migration limit (step 6 flowchart figure 2)

Directive 2002/72/EC stipulates that plastic materials and articles intended to come into contact with foodstuffs shall not transfer their constituents to foodstuffs in quantities exceeding 10 milligrams per square decimetre of surface area of material or article (mg/dm²). This is the overall migration limit.

However, in the following three cases the overall migration limit is substituted by a limit of 60 milligrams of the constituents released per kilogram of foodstuff (mg/kg):

- For articles which are containers or are comparable to containers or which can be filled with a capacity of not less than 500 millilitres (ml) and not more than 10 litres (l);
- For articles which can be filled and for which it is impracticable to estimate the surface area in contact with foodstuffs;
- For caps, gaskets stoppers or similar devices for sealing.

2. Specific migration limits (step 2 and 3 flowchart figure 2)

Annex II of Directive 2002/72/EC, sections A and B, lists the monomers and starting substances that may be used for the manufacture of plastic materials and articles subject to the restrictions specified. Monomers and starting substances listed in Annex II, Section B, may only be used until 31 December 2004 at latest, pending their evaluation by the European Food Safety Authority (step 2).

Annex III, Sections A and B, provides an incomplete list of additives, which may be used for the manufacture of plastic material and articles. It is incomplete in as much it does not contain all substances currently accepted in one or more Member States. Those additives continue to be regulated by national laws pending a decision on inclusion into the EU list. The current list of additives is to become a positive list to the exclusion of all others, in order to harmonise the use of additives in the European Union (step 3).

For the additives listed in Annex III section B, the verification of compliance with the specific migration limits in simulant D or in test media of substitute tests as laid down in Directive 82/711/EEC (art 3) and Directive 85/572/EEC (art 1) shall apply from July 2006.

Please note that the lists in Annex III, sections A and B do not yet include the following additives:

- a) additives used only in the manufacture of:
 - surface coating obtained from resinous or polymerised products in liquid, powder or dispersion form, such as varnishes, lacquers, paints,
 - epoxy resins,
 - adhesives and adhesion promoters,
 - printing inks;
- b) colorants;
- c) solvents.

Restrictions and/or specifications on their use are also set out in Annex III.

The additives listed in Annex III which are authorised as food additives (Directive 89/107/EEC) or flavourings (Directive 88/388/EEC) shall not migrate into:

- Foodstuffs in quantities having a technological function in the final foodstuffs.
- Foodstuffs for which their use is authorised as food additives or flavourings, in quantities exceeding the restrictions mentioned in the Directives above or Annex III of this Directive 2002/72/EEC, whichever is the lowest.

- Foodstuffs for which their use is not authorised as food additives or flavourings, in quantities exceeding the restrictions set out in Annex III.

Annex IV specifies products obtained by means of bacterial fermentation listed that may be used in contact with foods (step 4 flowchart figure 2).

Annex V, Part A, gives general specifications related to plastic materials and articles. Annex V, Part B, sets out specifications for specific substances. The meaning of the numbers between brackets appearing in the column "restrictions and/or specifications" is explained in Annex VI (step 5 flowchart figure 2).

The specific migration limits in the lists set out in Annexes II and III are expressed in mg/kg. However, such limits are expressed in mg/dm² in the following cases:

- Articles which are containers or are comparable to containers or which can be filled, with a capacity of less than 500 ml or more than 10 l;
- Sheet, film, or other material or articles which cannot be filled or for which it is impracticable to estimate the relationship between the surface area of such material or article and the quantity of food in contact therewith.

Testing migration limits (step 2,3 and 6 flowchart figure 2)

Directive 82/711/EEC and its amendments lay down the basic rules necessary for testing migration of the constituents of plastic materials intended to come into contact with foodstuffs.

➔ [For more information](#) on the legislation please refer to link to the Directive at the external links section.

2.b. Regenerated cellulose film (Directive 93/10/EC)

Scope of the Directive

Directive 93/10/EEC defines regenerated cellulose film as a thin sheet material obtained from a refined cellulose derived from unrecycled wood or cotton. To meet technical requirements, suitable substances may be added either in the mass or on the surface. Regenerated cellulose film may uncoated or be coated on one or both sides.

Directive 93/10/EEC applies to regenerated cellulose film which either:

- constitutes a finished product in itself; or
- forms part of a finished product containing other materials, and which is intended to come into contact with foodstuffs or which, by virtue of its purpose, does come into such contact.

The Directive does not apply to:

- synthetic casings of regenerated cellulose;
- until 29 July 2005 at the latest (amendment Directive 2004/14/EC) regenerated cellulose film intended to come into contact with foodstuffs has a coating exceeding 50 mg/dm².

Positive list of substances and migration limits

Directive 93/10/EEC covers regenerated cellulose films uncoated or coated with coatings manufactured only with substances listed in Annex II and conditions governing the use of substances allowed for the manufacture of regenerated cellulose film. Besides the substances, the Annex also gives limits to the quantities to be used in manufacturing regenerated cellulose films. Only in the case of ether and ethanediol a maximum authorised quantity in the foodstuffs itself is set, due to their liability to migrate extensively to foodstuffs (see Annex II of the Directive). As the list in Annex II is quite extensive, the list of substances with accompanying quantity limits is not submitted here, but can be found on the website of the EU using the links in this document (see external links).

From 29 July 2005 at the latest the Directive will also apply to coated regenerated cellulose film with coating consisting of plastics (besides uncoated or coated regenerated cellulose film

with coating derived from cellulose). Prior to coating, the regenerated cellulose film with coating consisting of plastics shall be manufactured only from substances or groups of substances listed in the first part of Annex II, subject to the restrictions listed in Annex II. The actual coating consisting of plastics to be applied to the regenerated cellulose film must be manufactured using only substances or groups of substances listed in the Annex II to IV of Directive 2002/72/EC referring to plastics coming into contact with foodstuffs (amendment Directive 2004/14/EC).

Annex II will be amended in accordance with the Annex in Directive 2004/14/EC by 29 July 2005 at the latest.

Directive 93/10/EEC stipulates that the printed side of regenerated cellulose films is not allowed to come into contact with foodstuffs.

2.c. Ceramics (Directive 84/500/EEC)

Ceramic articles can be capable of transferring lead and cadmium. In order to prevent risks from these substances Directive 84/500/EEC imposes a ceiling on the quantities of lead and cadmium allowed to pass into foodstuffs. These substances can be released from the decoration and/or glazing. The Directive also gives an analytical method for the determination of the migration of these substances. A ceramic article shall comply with the requirements of the Directive if the quantities of lead and/or cadmium extracted during the test carried out under the conditions specified in Annex I and II do not exceed the limits in the table below:

Ceramics	Lead (Pb)	Cadmium (Cd)
Category 1: Articles which cannot be filled and articles which can be filled, the internal depth of which measured from the lowest point to the horizontal plane passing through the upper rim, does not exceed 25 mm.	0.8 mg/dm ²	0.07 mg/dm ²
Category 2: All other articles which can be filled	4.0 mg/l	0.3 mg/l
Category 3: Cooking ware; packaging and storage vessels having a capacity of more than three litres	1.5 mg/l	0.1 mg/l

➡ [For more information on](#) the Directive for the limits concerning lead and cadmium please consult the external links.

3. Directives on specific substances

The third type of Directives regulating food contact materials and articles are the Directives on specific substances or groups of substances used in the manufacture of materials and articles intended for food contact. These Directives deal with substances that have raised special concern for the protection of the health of the consumer.

The substances regulated in these Directives (up till now) are:

- Vinyl chloride monomer in food contact materials and articles (Directive 78/142/EEC).
- Nitrosamines in rubber teats and soothers (Directive 93/11/EEC)
- BADGE, BFDGE and NOGE in plastics, coatings and adhesives (Directive 2002/16/EC)

3.a. Vinyl chloride monomer (Directive 78/142/EEC) (á back to Introduction)

Materials and articles which are intended to come into contact with foodstuffs can transfer vinyl chloride monomer to these articles in quantities liable to endanger human health. Therefore, Directive 78/142/EEC specifies that such materials and articles must not contain vinyl chloride monomer in a quantity exceeding 1 mg/kg of finished product and must not pass on to foodstuffs more than 0.01 mg/kg of vinyl chloride monomer. The method of analysis used to check the limits are also laid down in the Directive.

3.b. N-nitrosamines and N-nitrosatable substances (elastomer, rubber teats and soothers)
(Directive 93/11/EEC) (ā back to Introduction)

Directive 93/11/EEC defines that the migration of N-nitrosamines and N-nitrosatable substances from elastomer or rubber teats and soothers must not exceed the following limits as by virtue of their toxicity they are potentially hazardous to human health:

- mg of the total quantity of N-nitrosamines released per kg (parts of elastomer or rubber teats and soothers).
- 0.1 mg of the total quantity of N-nitrosatable substances released per kg (parts of elastomer or rubber teats and soothers).

These limits must be checked by means of a test, subject to the conditions set out in the annex to this Directive.

3.c. Certain epoxy derivatives (BADGE, BFDGE, NOGE) (Directive 2002/16/EC)
(ā back to Introduction)

Directive 2002/16/EC specifies the limits for the substances 'BADGE', 'BFDGE' and 'NOGE' and certain of their derivatives in materials and articles in the finished product state that are brought into contact with food and are intended for that purpose.

The Directive applies to materials and articles made of:

- any type of plastics;
- materials and articles covered by surface coatings;
- adhesives.

Migration limits are set in Annex I of the Directive. Materials and articles referred to in this Directive, manufactured with one or more of the substances mentioned in Annex I shall not release these substances in quantities exceeding the migration limits set in Annex I. Also the materials and articles shall not release substances listed in Annex II in a quantity which, when added to the sum of BADGE and it's derivatives listed in Annex I, exceeds the limit laid down in Annex II.

As from 1 March 2003, the quantity of NOGE components with more than two aromatic rings and at least one epoxy group as well as their derivatives containing chlorohydrin functions and having a molecular mass less than 1000 daltons shall not be detectable in the materials and articles covered by this Directive at the detection limit of 0,2 mg/6 dm², including analytical tolerance. For the purpose of this Directive, the detection limit specified in the first paragraph should be verified by a validated method of analysis. If such a method does not exist, an analytical method with appropriate performance characteristics may be used, pending the development of a validated method.

The use and/or presence of BDFGE and NOGE in the manufacture of materials and articles which this Directive applies to, may only be continued until 31 December 2004. In the case of the use and/or presence of BADGE, the date until use is allowed is set on 31 December 2005 by amendment 2004/13/EC.

The migration testing and method of analysis are to be carried out in accordance with the rules established in Directive 82/711/EEC and Directive 90/128/EEC and their amendments.

The requirements of this Directive shall not apply to materials and articles covered by surface coatings or adhesives which are brought into contact with foodstuffs before 1 March 2003. These materials and articles may be placed on the market provided that the date of filling appears on the on the materials and articles, taking into account the requirements of Directive 2000/13/EC. However, amendment 2004/13/EC stipulates that the date of filling may be replaced by another indication, provided that this indication permits the identification of the date of filling. Upon request, the date of filling shall be made available to the competent authorities and any person enforcing the requirements of this Directive.

EU member states have had until 28th February 2003 to comply national legislation with Directive 2002/16/EC. They will have until 29 January at the latest to comply with amendment Directive 2004/13/EC.

All relevant provisions and migration limits can be found in Directive 2002/16/EC on the website of the European Union (see links).