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HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate D - Food Safety: production and distribution chain
D3 - Chemical and physical risks; surveillance

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FOOD CONTACT MATERIALS

PRACTICAL GUIDE

"A PRACTICAL GUIDE FOR USERS OF EUROPEAN DIRECTIVES "

(Updated to 15 April 2003)

1. This document may be also found at the following Internet address: *http://cpf.jrc.it/webpack/*. It replaces the previous version dated ***1st March 2002***.
2. The Unit D3 "Chemical and physical risks; surveillance" of the Health & Consumer Protection Directorate-General of the European Commission has prepared this document. It reflects the opinion of the Unit and not necessarily that of the European Commission and Member States.
3. ***Changes compared to the previous version are indicated in bold and italic characters (with the exception of Chapter III).*** However editorial and minor changes are not indicated.
4. ***Warning: This document is not legally binding***

TABLE OF CONTENT

NOTE FOR READER

1. This document is subject to continuous change due to the increasing harmonisation of the rules on food contact materials across the European Union. The dates of the latest changes are given in the table of contents (see column 3). The relevant changes are also indicated in the Section "NEWS" at the beginning of the Guide.

2. Careful reading of the homepage of the website will help the reader to understand its structure.

3. To be clear, please note that Appendices are the annexes of Annexes. All annexes and appendices are now listed in the Table of Contents.

4. For the meaning of some abbreviations and words, consult the document "**List of abbreviations and explanations"** in the EC-JRC website (**http://cpf.jrc.it/webpack**).

5. If you notice mistakes or have suggestions for improvements, e.g. insertion of new sections or texts, please inform the European Commission services (mark your message for the attention of Mr Luigi Rossi – for the address, see document **"EU and National Authorities"** in the EC-JRC website: **http://cpf.jrc.it/webpack**)

NEWS

The **main** amendments compared to the previous version of the Guide dated 1 March 2002 are:

- The Table of Contents now contains more references to help you to find information on specific issues more easily.
- Radical changes have been made to chapters I and II. Sections 1, 2, 5 of Chapter II in the last edition of the Guide and that related to the regulation of plastic materials and articles are transferred into Chapter I in order to put all the issues mainly related to plastics together. Only the Sections 3 and 4 related to the Scientific Committee on Food remain in Chapter II as they provide the information you may need onall the materials and articles included in a positive list.
- The appendix 4 of Chapter I of the previous version of "Practical Guide" which dealt with the "mutual recognition" has been deleted.
- The Chapter II, Section 1 of the previous version of "Practical Guide", which dealt with the "positive list of monomers", has been re-written to better explain on the identification of the starting substances used in the manufacture of thermoset polymers (see the new version in Chapter I, Section 3, paragraph 3.1.2).
- Chapter I, Section 3.2 of this version of "Practical Guide" now contains information about the Commission services intention to transform the list of authorised additives into a "positive list"
- Chapter I, Section 3, paragraph 7.2 of the previous version of "Practical Guide" which dealt with overall migration is now clearer about the interpretation of “analytical tolerance” and this now appears in (see the addition of the interpretation in Chapter I, Section 3 (Plastics – Part 1), paragraph 8.2).
- Chapter I, Section 3, paragraph 7.1 of the previous version of "Practical Guide" now has an interpretation of the second paragraph of Article 4 of Directive 2002/72/EC. This paragraph establishes the date of the enforcement of the SMLs for the additives listed in Section B of Annex III of the Directive. This clarification appears in Chapter I, Section 3, paragraph 8.1
- Chapter I, Section 3, paragraph 10.1 of this version of the “Practical Guide” explains where we are with developing the concept of Fat (consumption) Reduction Factors.
- Chapter I, Section 16 contains an update on the situation of the Adhesives.
- Chapter III contains an update on the activities of CEN.

GENERAL INTRODUCTION

WARNING

<u>This document is not legally binding</u>.

This "Practical Guide" is intended to be used by all those involved in the application of EU Directives on materials and articles intended to come into contact with foodstuffs.

It is intended to provide:

a) Information on the current situation in the European Union, national legislations, as well as other EU and non-EU documents, e.g. from the Council of Europe, which have no legal status, but provide useful guidance;

b) Guidelines on the correct application of legislation in the EU and Member States;

c) Guidelines on the practical application of general principles and rules for which the legislation does not give sufficient details;

d) Guidelines on issues for which there is no legal solution yet (e.g. regulation on dyes or catalysts for plastics) or issues not lending themselves to a legislative solution (e.g. modification of organoleptic properties of the foodstuffs);

e) Guidelines for checking compliance of the food contact material, particularly where the Directive does not give sufficient instructions (e.g. where the check on overall migration for plastics fails for technical reasons);

f) Guidelines on the procedures to be followed and data to be submitted for authorisation of a new substance to be included on the EU lists or for the re-evaluation of a substance already authorised;

g) Indications on EU legislation envisioned for the future.

This document has been prepared by the Unit D3 “Chemical and physical risks; surveillance” of the Health & Consumer Protection Directorate-General of the European Commission, which is responsible for the EU legislation. The document was transmitted for advice to the representatives of the Member States. This version has taken into account some of these remarks. This document represents the view of this Unit, and not necessarily that of the Commission and of the Member States (MS). Other guidance may be obtained from National Authorities as well as from the European professional organisations, whose addresses are listed in two separate documents of the EC website (*http://cpf.jrc.it/webpack)*.

CHAPTER I

EU LEGISLATION

A. Basic directives

[A1] 76/893/EEC
O.J. n° L340, of 09.12.1976 *(Old framework directive, repealed by Directive 89/109/EEC [A11])*

[A2] 78/142/EEC
Council Directive of 30 January 1978 on the approximation of the laws of the Member States relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs.
O.J. n° L44, of 15.02.1978, p.15 *(Plastics: limits on vinyl chloride monomer (VCM))*

[A3] 80/590/EEC
Commission Directive of 9 June 1980 determining the symbol that may accompany materials and articles intended to come into contact with foodstuffs.
O.J. n° L151, of 19.06.1980, p.21 *(Symbol for materials and articles)*

[A4] 80/766/EEC
Commission Directive of 8 July 1980 laying down the Community method of analysis for the official control of the vinyl chloride monomer level in materials and articles which are intended to come into contact with foodstuffs.
O.J. n° L213, of 16.08.1980, p.42 *(Plastics: determination of VCM in finished products)*

[A5] 81/432/EEC
Commission Directive of 29 April 1981 laying down the Community method of analysis for the official control of vinyl chloride released by materials and articles into foodstuffs.
O.J. n° L167, of 24.06.1981, p.6 *(Plastics: Determination of VCM in foods)*

[A6] 82/711/EEC
Council Directive of 18 October 1982 laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs.
O.J. n° L297, of 23.10.1982, p.26 *(Plastics: Basic rules for testing migration)*

[A7] 83/229/EEC
Council Directive of 25 April 1983 on the approximation of the laws of the Member States relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs.
O.J. n° L123, of 11.05.1983, p.31 *(Cellulose regenerated)*

[A8] 84/500/EEC
Council Directive of 15 October 1984 on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs.
O.J. n° L277, of 20.10.1984, p.12 *(Ceramics)*

[A9] 85/572/EEC
Council Directive of 19 December 1985 laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs.
O.J. n° L372, of 31.12.1985, p.14 *(Plastics: list of simulants for testing migration)*

[A10] 86/388/EEC
Commission Directive, of 23 July 1986, amending Council Directive 83/229/EEC on the approximation of the laws of the Member States relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs.
O.J. n° L228, of 14.08.1986, p.32 *(Cellulose regenerated: limits on MEG and DEG)*

[A11] 89/109/EEC
Council Directive 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.
O.J. n° L40, of 11.02.1989, p.38 *(New framework directive)*
Corrigendum O.J. n° L347 of 28.11.89, p.37

[A12] 90/128/EEC
Commission Directive of 23 February 1990 relating to plastic materials and articles intended to come into contact with foodstuffs.
O.J. n° L75, of 21.03.1990, p.19 *(Plastics: monomers)*
Corrigendum O.J. n° L349 of 13.12.1990, p.26 *(Replaced in its entirety by Directive 2002/72/EC)*

[A13] 92/15/EEC
Commission Directive of 11 March 1992, amending Council Directive 83/229/EEC on the approximation of the laws of the Member States relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs.
O.J. n° L102, of 16.04.1992, p.44 *(Additives, new substances)*

[A14] 92/39/EEC
Commission Directive of 14 May 1992, amending Directive 90/128/EEC concerning plastic materials and articles intended to come into contact with foodstuffs.
O.J. n° L168, of 23.06.1992, p.21 *(Replaced in its entirety by Directive 2002/72/EC)*

[A15] 93/9/EEC
Commission Directive of 15 March 1993 amending for the second time Directive 90/128/EEC relating to plastic materials and articles intended to come in contact with foodstuffs
O.J. n° L90, of 14.04.93, p.26 *(Replaced in its entirety by Directive 2002/72/EC)*

[A16] 93/11/EEC
Commission Directive of 15 March 1993 concerning the release of the N-nitrosamines and N-nitrosatable substances from rubber teats and soothers
O.J. n° L93, of 17.04.93, p.37 *(Rubber: Limits for nitrosamines)*

[A17] 93/8/EEC
Commission Directive of 15 March 1993 amending Council Directive 82/711/EEC laying down the basic rules necessary for testing migration of the constituents of plastics materials and articles intended to come into contact with foodstuffs
O.J. n° L90, of 14.04.93, p.22 *(Plastics: Basic rules for testing migration - 1st amendment)*

[A18] 93/10/EEC
Commission Directive of 15 March 1993 relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs
O.J. n° L93, of 17.04.93, p.27 *(Cellulose regenerated: Consolidation of 83/229/EEC)*

[A19] 93/111/EEC
Commission Directive of 10 December 1993, amending Directive 93/10/EEC relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs.
O.J. n° L310 of 14.12.1993, p.41 *(Cellulose regenerated: Amendment)*

[A20] 95/3/EC
Commission Directive of 14 February 1995, amending Directive 90/128/EEC relating to plastics materials and articles intended to come into contact with foodstuffs.
O.J. n° L41 of 23.02.1995, p.44 *(Replaced in its entirety by Directive 2002/72/EC)*

[A21] 96/11/EC
Commission Directive of 5 March 1996, amending Directive 90/128/EEC relating to plastics materials and articles intended to come into contact with foodstuffs.
O.J. n° L61 of 12.03.1996, p.26 *(Replaced in its entirety by Directive 2002/72/EC)*

[A22] 97/48/EC
Commission Directive of 29 July 1997 amending for second time Council Directive 82/711/EEC laying down the basic rules necessary for testing migration of the constituents of plastics materials and articles intended to come into contact with foodstuffs
O.J. n° L222, of 12.08.97, p 10 *(Plastics: Basic rules for testing migration - 2nd amendment)*

[A23] 1999/91/EC
Commission Directive of 23 November 1999, amending Directive 90/128/EEC relating to plastics materials and articles intended to come into contact with foodstuffs.
O.J. n° L310 of 4.12.1999, p.41 *(Replaced in its entirety by Directive 2002/72/EC)*

[A24] 2001/61/EC
Commission Directive of 8 August 2001 on the use of certain epoxy derivatives in materials and articles intended to come into contact with foodstuffs.
O.J. n° L215 of 9.08.2001, p.26 *(Badge/Bfdge/Noge, repealed by 2002/16/EC)*

[A25] 2001/62/EC
Commission Directive of 9 August 2001 amending Directive 90/128/EEC relating to plastics materials and articles intended to come into contact with foodstuffs.
O.J. n° L221 of 17.08.2001, p.18 *(Replaced in its entirety by Directive 2002/72/EC)*

[A26] 2002/16/EC
Commission Directive of 20 February 2002 on the use of certain epoxy derivatives in materials and articles intended to come into contact with foodstuffs.
O.J. n° L51 of 22.02.2002, p.27 *(Badge/Bfdge/Noge)*

[A27] 2002/17/EC
Commission Directive of 21 February 2002 amending Directive 90/128/EEC relating to plastics materials and articles intended to come into contact with foodstuffs.
O.J. n° L58 of 28.02.2002, p.19 *(Replaced in its entirety by Directive 2002/72/EC)*

[A28] 2002/72/EC
Commission Directive of 6 August 2002 relating to plastics materials and articles intended to come into contact with foodstuffs.
O.J. n° L220 of 15.08.2002, p.18 (Plastics : Codification of 90/128/EEC + 7 amendments)

[A29] Corrigendum to 2002/72/EC
Corrigendum to Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs.
O.J. n° L39 of 13.02.2003, p.1 (Plastics : Codification of 90/128/EEC + 7 amendments)

B. Some of the most important other EU Directives related to food contact materials

[B1] 85/591/EEC
Council Directive of 20 December 1985 concerning the introduction of Community methods of sampling and analysis for the monitoring of foodstuffs intended for human consumption
O.J. n° L372 of 31.12.1985, p 50 *(Foodstuffs and Food Contact Materials: Control)*

[B2] 89/397/EEC
Council Directive of 14 June 1989 on the official control of foodstuffs
O.J. n° L186, of 30.6.89, p 23 *(Foodstuffs and Food Contact Materials: Control)*

[B3] 93/99/EEC
Council Directive of 29 October 1993 on the subject of additional measures concerning the official control of foodstuffs
O.J. n° L290 of 24.11.93, p 14 *(Foodstuffs and Food Contact Materials: Control)*

C. Juridical instruments on general aspects of foodstuff legislation

[C1] 69/414/EEC
Council Decision of 13 November 1969 setting up a Standing Committee for Foodstuffs
O.J. n° L291, of 19.11.1969, p. 9 *(Setting up the Standing Committee for Foodstuffs)*

[C2] 74/234/EEC
Commission Decision of 16 April 1974 relating to the institution of a Scientific Committee for Food
O.J. n° L136, of 20.05.1974, p. 1 *(Setting up the Scientific Committee on Foodstuffs)*

[C3] 80/1073/EEC
Commission Decision of 24 October 1980 establishing a new statute of the Advisory Committee on Foodstuffs
O.J. n° L318, of 26.11.1980, p. 28 *(Repeals old Commission Decision 75/420/EEC as amended by Commission Decision 78/758/EEC)*

[C4] COM (85) 603 final
Completion of the internal market: Community legislation on Foodstuffs
(Communication from the Commission to the Council and the European Parliament)
(New strategy for harmonisation of laws in the sector of foodstuffs)

[C5] 86/241/EEC
Commission Decision of 16 April 1986, amending Decision 74/234/EEC with respect to the number of members of the Scientific Committee for Food
O.J. n° L163, of 19.06.1986, p. 40 *(Scientific Committee on Foodstuffs)*

[C6] 89/C271/03
Communication on the free movement of foodstuffs within the Community
O.J. n° C271, of 24.10.1989, p. 3 *(Rules applicable in the absence of EU provisions)*

[C7] 93/5/EEC
Council Directive 93/5/EEC of 25 February 1993 on assistance to the Commission and co-operation by the Member States in the scientific examination of questions relating to food
O.J. n° L52, of 4.3.93, p. 18 *(Co-operation between Scientific Committee for Food and institutes in the Member States)*

D. Other related Directives

[D1] 178/2002
Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
O.J n° L31, of 1.2.2002, p.1 ***(Food Law)***

SECTION 1

GENERAL INFORMATION

1. Background

With the establishment of the Single Market by 31 December 1992, the European Economic Community has set up an area where, among other things, the free exchange of goods, services and capital is assured.

In the sector of materials and articles intended to come into contact with foodstuffs, the legislative work needed to implement the necessary harmonisation is focusing on two essential goals:

- Removal of technical barriers to trade;
- Protection of the health of consumers.

For achieving these goals, a strategy has been designed and laid down in the Commission Communication: 'Completion Of The Internal Market: Community Legislation On Foodstuffs' [C4] as well as in the 'Commission Communication On The Free Movement Of Foodstuffs Within The Community' [C6]. This strategy includes:

a) Priority for harmonisation work in those sectors having a great field of application,[1] i.e. covering the entire foodstuff sector, e.g. food additives, food contact materials, methods of control (‘horizontal sectors’);

b) Priority for the adoption of health standards as regards methods of analysis;

c) Adoption of more rapid procedure for approving the specific directives in the sector (i.e. the so-called 'simplified procedure').

Materials intended to come into contact with foodstuffs (which is a broader concept than just packaging materials) form a priority area among the horizontal sector.

Since almost all the EU countries have more or less binding regulations in this field, manufacturers faced with differing standards in force ask for harmonised legislation.

Consumers, on the other hand, express increasing concern about migration of possibly harmful substances from packaging or other material into foodstuffs. Scientific knowledge is a prerequisite for the distinction of real issues from unjustified fears.

[1] In the 'vertical approach', all the aspects considered in the horizontal sector are covered for a specific product or class of foodstuffs.

As a consequence, a new corpus of legal instruments is emerging, with the following features:

1. Following the letter and the meaning of the Treaty of the European Union ('Treaty" i.e. Treaty of Rome as modified until the Treaty of Amsterdam) restrictions to the Free Trade of Foodstuffs in the Single Market are banned. Art. 28, according to its interpretation by the European Courts ('Cassis de Dijon'), confers upon the Commission the power to demand the deletion or amendment of a national provision hindering the import of products from the other Member States. However, the Commission favours removing such barriers, where they exist, through approximation of the laws of the Member States, pursuant to Art. 95 of the Treaty.

2. Definitions of health standards, as elaborated with the contribution of the Scientific Committee on Food[2] (in 2003, it will be replaced by the "Panel on food additives, flavourings, processing aids and materials in contact" of the new European Food Safety Authority (EFSA), are intertwined with the methods of analysis required to check them. In the past, the Commission has spent much effort laying down these methods and has now delegated the tedious task of elaborating validated and approved methods of analysis to the CEN. Also DG Research and mainly the Joint Research Centre (JRC-Ispra) collaborate in this issue.

3. Following the adoption of the Directive 89/109/EEC [A11], the Commission is empowered by the Council to adopt Directives through a 'simplified procedure'. This procedure excludes the transmission of the proposal to the European Parliament and to the Council. The Commission adopts the proposal, after a vote in a regulatory body called Standing Committee for Foodstuffs, composed by the representatives of the Member States. The standard procedure is described in figure 1 (not all the references are mentioned) and includes essentially the following steps:

   - Preparation of a draft by the Commission services;
   - Consultation of the Scientific Committee on Food on "provisions liable to affect public health"[3]
   - [Consultation of the Advisory Committee for Food][4]
   - Vote inside the Standing Committee on the Food Chain and Animal Health[5]

2 The Scientific Committee on Food investigates the risk connected to hygienic and toxicological aspects of the legislation proposed.

3 The last sentence of Article 3 of Dir. 89/109/EEC states:
'Provisions liable to affect public health shall be adopted after consulting the Scientific Committee for Food. They must fulfill the criteria set out in Annex II.'

4 The Advisory Committee on Foodstuffs was composed by 10 permanent members and 20 experts, representing agriculture, commerce, consumers, industry and employees. A new Committee is under preparation.

5 The Standing Committee on the Food Chain and Animal Health, a regulatory committee, comprises delegates from the Member States' government authorities: new Directives or Regulations, proposed by the Commission for the approximation of existing national legislation, are submitted to it for approval on behalf of the Member States.

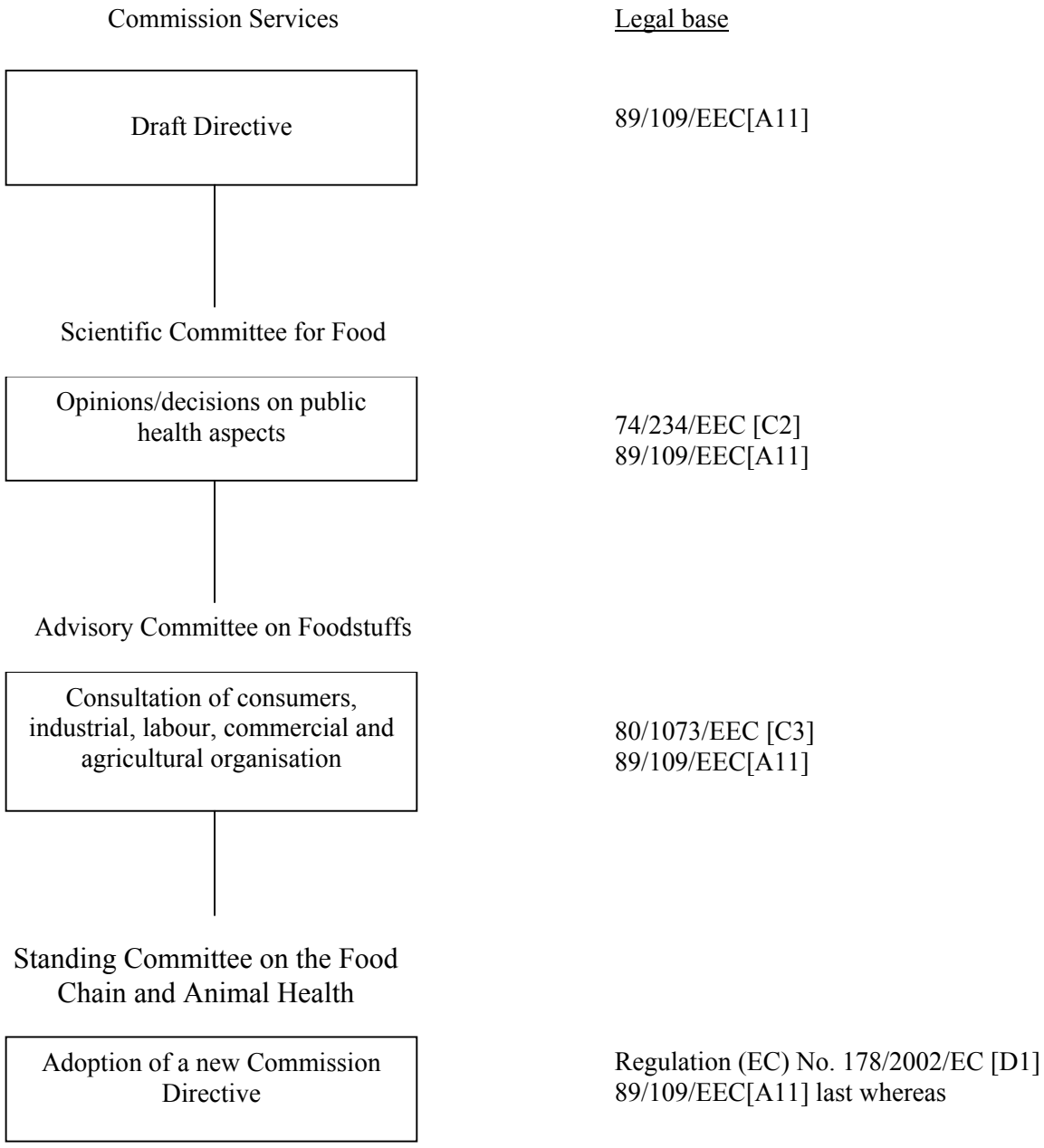

Figure 1 : Simplified procedure for the adoption of specific directives as set out in [C4]

As a matter of fact, direct collaboration between the Commission and the Member States in the established concertation organs is the adequate frame for developing the legislation on materials and articles in contact with food.

2. Free trade, approximation of legislation and public health

Achievement of the Single Market is associated with the removal of barriers to free trade, such as tariffs and equivalent taxes, quantitative restrictions to imports, or technical rules with an equivalent effect, as well as with control of the Members States' funding to national industries. However, the completion of the Single Market requires many additional issues to be addressed by the ongoing harmonisation of national legislations.

- Where national laws and regulations aim at protecting the consumer, and when the Member States recognise each other's measures as equivalent. In this way, they avoid the tedious task of designing a new and consolidated legislation for the European Union as a whole and act in agreement with the subsidiarity principle that the Commission should not legislate on matters satisfactorily handled in national legislation. They guarantee the free trade in their country of products enjoying legal recognition in another EC Member State (principle of 'mutual recognition')**.**

- Where existing national norms and technical rules impair the functioning of the Single Market, whether as a result of deliberate protectionism or differences in cultures or traditions, the Commission shall propose harmonised regulations. The provision in Art. 95, point 3[6] that approximation of national laws must take into account a high level of protection of health, security and environment, is of great importance to the sector of materials and articles intended to come into contact with foodstuffs.

- Where a Member State deems it necessary to set out new technical rules (in a broad meaning, as defined in Dir. 83/189/EEC) to face a new situation, or in a field where no EU legislation exists, the Member State must notify these rules to the Commission, which has the duty to check them against the Treaty. These new rules must further comply with the so-called 'principle of proportionality' now recognised in the European Court jurisprudence, i.e. their effect must not go beyond the enunciated objective; in particular, no discrimination or no new barrier to free trade, whether open or disguised, may result from these measures. The instruments available to the Commission in order to guarantee free trade are numerous and range from initiating proceedings against the Member State pursuant to Art. 28, to revising EU legislation;

- In addition, where a Member State believes that measures are required in order to protect public health, security, human or animal life, according to Art. 28, these new measures (which may only have a provisional character) must be notified to the Commission which will investigate them (Art. 95, points 4 and 5)[7]; they must also comply with the 'principle of proportionality'.

3. Architecture of the legislation on food contact materials

The directives adopted can be divided into three categories:

- Framework Directive 89/109/EEC applicable to all materials and articles

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6 Art. 95 has been added to the Treaty according to the Single Market Act and takes into account many particularities of the approximation of the national legislations.

7 Art. 95 point 5, also states that the harmonisation measures taken by the Council may include, as appropriate, a 'safeguard clause' as well as a EU procedure to verify the provisional regulations taken by the Member State pursuant to Art. 30.

- Specific Directives applicable to one group of materials and articles
- Individual Directives relating to individual substances.

Moreover a certain number of Guidelines are given in this document and, even though they are not legally binding, the Commission services invite the interested parties to follow them.

The Framework Directive of the Commission establishes:

- General principles applicable to all materials and articles, such as 'purity' of foodstuffs, 'inertness' of the materials and articles in food contact, 'good manufacturing practice',
- Criteria and procedures to be followed in drafting specific directives, i.e. directives for individual sectors (plastics, ceramics) or substances (vinyl chloride, nitrosamines, BADGE, ...);
- Criteria for adopting new rules, directives, provisions and for revising the existing ones, including the limited and conditional delegation of power upon the Commission by the Council in the legislating area (see above, 'simplified procedure').

The Specific Directives concern materials and articles (often globally referred to as products) mentioned in Annex I of Directive 89/109/EEC.

The Individual Directives refer to single substances or groups of substances used in the fabrication of the above-mentioned materials and articles or their components. They usually come into being as a result of an urgent need, but might also address a specific issue.

Practical Guide, Note for Guidance, Synoptic document and other documents contained in the JRC website (*http://cpf.jrc.it/webpack*) provide guidance to the enforcement laboratories and professional organisations for a correct application of the legislation or to assist them in areas not clearly described in the legislation.

4. Relations with other international organisms

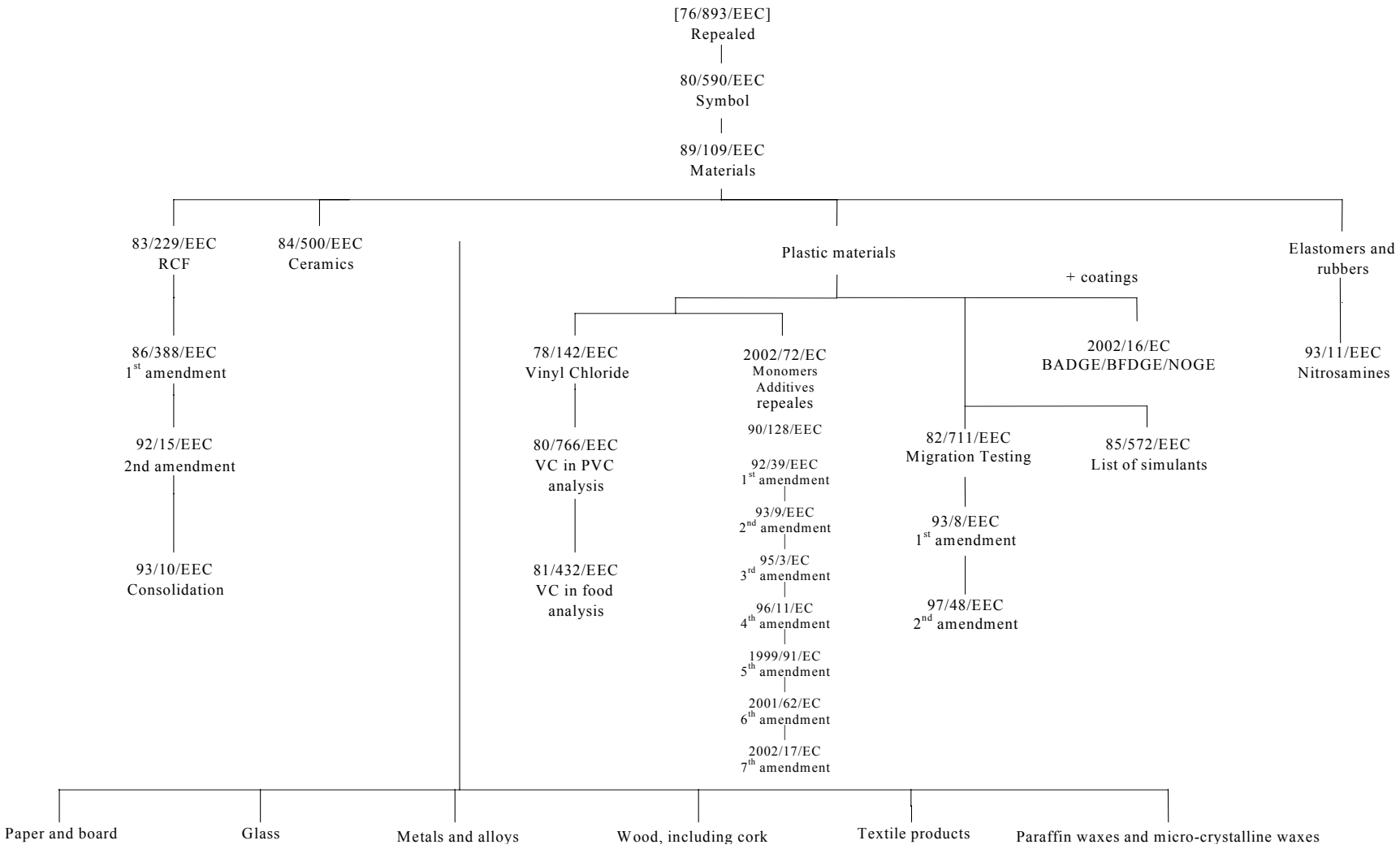
CEN

In the past, considerable effort has been devoted to the development and validation of test methods. This is all the more true for migration tests, which are complex by the great number of parameters involved and the need for simplifications. The Commission has supported the development and standardisation of a certain number of methods for the determination of substances for which an SML or QM was established in EU Directives. Later the Commission mandated CEN (European Committee for Standardisation) to establish validated method of analysis for the determination of overall and specific migration limits. See **Chapter III** for further information.

COUNCIL OF EUROPE

Due to the lack of human resources, it was agreed that the Council of Europe establishes Resolutions in the areas not covered by an EC activity. See **Chapter IV** for further information.

DIRECTIVES CONCERNING MATERIALS AND ARTICLES IN CONTACT WITH FOODSTUFFS



SECTION 2

FRAMEWORK DIRECTIVE

1. EU legislation: List of pertinent Directives

89/109/EEC [A11]		Council	Framework Directive
Corrigendum O.J. n° L347 of 28.11.89, p.37			
80/590/EEC [A3]		Commission	Symbol

2. Field of application (Art. 1)

Article 1

1. This Directive shall apply to materials and articles which, in their finished state, are intended to be brought into contact with foodstuffs or which are brought into contact with foodstuffs and are intended for that purpose hereinafter referred to as 'materials and articles'.

   Covering or coating substances, such as the substances covering cheese rinds, prepared meat products or fruit, which form part of foodstuffs and may be consumed together with those foodstuffs, shall not be subject to this Directive.

2. This Directive shall apply to materials and articles, which are in contact with water, which is intended for human consumption. It shall not, however, apply to fixed public or water supply equipment.

3. This Directive shall not apply to antiques.

Comments:

This Directive applies to all materials and articles in contact with foodstuffs, not just to packaging materials. According to this definition, forks, cups, processing machines, at factory level or at home, transportation pipes, containers, and also private water tanks, etc. are concerned. Moreover, it applies not only to the materials listed in Annex 1, but to all possible materials, e.g. recycled materials, bio-polymers, either single layer or multi-layer, whether or not the different layers consist of different materials (for the specific situation of multi-layer materials and articles, see discussion and comments in **10.3 Multi-layer articles;** for plastics materials, see **Section 3 - 2.1 Products covered under the field of application of the Directive 2002/72/EC**).

'In their finished state' means 'as they are sold or used', not in some intermediate state of their production; for plastics, this means not the pure resin, but the ready-made plastics article, with additives, colouring matters, and other aids, after thermosetting or any other treatment such as washing, etc.

The second indent of paragraph 1, "*Covering or coating substances shall not be subject to this Directive",* stated that material layers in such intimate contact with the foodstuff that they may be ingested together with the food, are excluded by this Directive. Due to the difficulty in the interpretation of this indent, the professional organisations were requested to establish guidelines on cheesewax. The text was prepared by the European Wax Federation and agreed by the representatives of the Member States during the October 93 meeting. In

2001, at unanimity it was decided to insert these guidelines as well as those regarding the "covering prepared meat products" in Practical Guide (see **Annex I to Section 2 of this Chapter**).

This directive does not concern fixed public or private water supply systems. However, 'fixed system' in this context means 'physically continuous'. Thus, if at some point water is discharged into a tank, the water supply ceases to be fixed from the tank and will be subject to this directive (see in this Chapter **Section 3 - 2.3 Comments**).

Finally, it has to be noted that other rules could apply, concomitantly or not, to materials and articles intended to come into contact with foodstuffs as a consequence of regulations on specific foods (drinking water, milk products etc.) or other aspects (e.g. hygienic aspects). A few examples of such other rules are in the Directives on drinking water, vegetables, fruits, or milk (packaging provisions). In this case, no contradiction should exist between the rules and the highest level of protection for the consumer has to be considered.

3. Aim of the Directive (Art. 2)

Council Directive 89/109/EEC on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs is regarded as the Framework Directive and aims at the protection of human health and the safeguard of the purity of the foodstuffs.

This Directive repeals the old frame Directive 76/893/EEC, all references to which are to be read as references to the new Framework Directive; a correlation table for the articles of both Directives can be found in Annex III of the Directive 89/109/EEC.

Article 2

Materials and articles must be manufactured in compliance with good manufacturing practice so that, under their normal or foreseeable conditions of use, they do not transfer their constituents to foodstuffs in quantities, which could:

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

Comments:

The wording of Art. 2 implies not only that any danger for human health shall be avoided, but also that a substantial ("unacceptable") contamination of foodstuffs due to massive migration of substances is forbidden, even if the substances released were demonstrated to be harmless.

The choice of the word "unacceptable" (change in the composition) was justified by some circumstances where a change in the composition is accepted or even wanted by the consumer (e.g. fermentation of the wine in wooden tanks for the preparation of "Cognac").

"Good Manufacturing Practice' and the extent of migration control are further dealt with in this Section at **10.2**; organoleptic characteristics are treated in **10.4.**

4. Specific Directives (Art. 3)

Article 3

1. The groups of materials and articles listed in Annex I and, where appropriate, combinations of these materials and articles shall be subject to specific Directives.

.....

Annex I

Plastics, including varnish and coatings
Regenerated cellulose
Elastomer and rubber
Paper and board
Ceramics
Glass
Metals and alloys
Wood, including cork
Textile products
Paraffin waxes and micro-crystalline waxes

This Annex can be seen as a 'positive list of domains' for which the Commission has received an explicit mandate from the Council, whereby the latter is entitled to take legislating initiatives whenever appropriate. In this procedure, the Commission acts in accordance with the rules and general criteria set out by the Council and laid down in Annex II of this Directive. This list implies no limitation of action for the Commission in other fields than those listed above.

3. The specific Directives may include:

(a) A list of the substances the use of which is authorised to the exclusion of all others (positive list);

Examples

- Lists (Section A and B) of Directive 2002/72/EC [A29] relating to plastic materials and articles intended to come into contact with foodstuffs.

- List of approved substances for use in regenerated cellulose films (Directive 93/10/EEC [A18].

On the other hand, the Directive on ceramics does not contain any positive list (see Annex II, point 3 of Dir. 89/109/EEC [A11]).

See in this Section, **paragraph 5, EU positive lists and other regulatory instruments** on the proper significance of the positive lists.

(b) Purity standards for such substances;

Example:

The Directive 2002/72/EC [A29] states that the substances used in the manufacture of these materials and articles must be of 'good technical quality'. The interpretation of 'good technical quality' is difficult and can be given only case by case. Criteria must be specified for individual substances.

(c) Special conditions of use for these substances and/or the materials and articles in which they are used;

Example:

Special conditions may include restrictions on use (QM, QMA) or sanitary measures such as washing operations.

(d) Specific limits on the migration of certain constituents or groups of constituents into or onto foodstuffs;

Example:

The migration limits for cadmium and lead in Directive 84/500/EEC [A8] or for vinyl chloride monomer in Directive 78/142/EEC [A1] or all the SML in Sections A or B of Directive 2002/72/EC [A29].

(e) An overall limit on the migration of constituents into or onto foodstuffs;

Example:

Art. 2 of Directive 2002/72/EC [A29] (see **Section 3, paragraph 6. Overall migration limits**) specifies such a limit for plastics materials, specifying a quantitative content to the notion of 'no unacceptable change in the composition' (see in this Section in **paragraph 3, Comments** above).

See **Section 3, paragraph 8. Implementation of the legislation**, where the compliance of plastic materials with overall and specific migration limits is further discussed.

(f) If necessary, provisions aimed at protecting human health against any hazards, which might arise through oral contact with materials and articles;

Example:
This provision was inserted in order to take into account the existence of a rule in Denmark and Germany, which established for the external surface of ceramic an SML for cadmium.

(g) Other rules to ensure compliance with Article 2;

This provision has been included for the sake of completeness.

(h) The basic rules necessary for checking compliance with the provisions of points (d), (e), (f) and (g);

Example:
Ceramics: the basic test conditions, including the simulants, have been defined in the Annex I of the Directive 84/500/EEC [A8].

Plastic: the simulants and basic test conditions have been defined in the Directive 82/711/EEC [A6].

(i) Detailed rules concerning sample taking and the methods of analysis required checking compliance with the provisions of points (a) to (g).

Examples:

Ceramics: the methods of analysis have been defined in the Annex II of Directive 84/500/EEC [A8].

Directive 81/432/EEC [A5] lays down the Community methods for the analysis of vinyl chloride.

The Commission mandated CEN to establish validated methods of analysis (**see Chapter III**).

5. EU positive lists and other regulatory instruments

Lists of substances authorised in materials and articles in contact with foodstuffs may exist at three levels:

5.1 In EU Directives.

Inclusion (or rejection) of substances in a positive list at EU level is the final stage of the process of harmonising national legislation and protection of public health. Consumers are then assured that authorised substances are in agreement with the best currently available knowledge on risk assessment. Manufacturers, resellers, marketers are given guarantees that no other restrictions than those mentioned in the positive lists will be imposed on the materials they would like to place on the market.

5.2 In national positive lists.

Member States may maintain their national positive lists in fields where harmonisation by the EU legislation has not taken place yet. Since the EU list has been derived from the national lists and must be transposed in national law, no contradiction should exist between EU harmonisation and implementation of national lists. If a material complying with a national positive list is rejected by a country into which the material is exported, either because a substance used is not authorised in the importing country or a more severe restriction exists, the problem should be examined in the light of the Framework Directive. The country refusing the importation should justify the measures taken (prohibition of the substance or more severe restriction) by health concerns. The opinion on the substance expressed by the SCF will usually decide.

5.3 In provisional EU lists.

Synoptic document contained in JRC website is a working document made by the Commission services, which contains the substances authorised or used in the Member States. It is not a legal binding text but only an informative document. Beside any substance the opinion of the SCF is reported. The restrictions suggested by the SCF can orientate the Member States and the industry in managing these substances.

The inclusion of a new substance in the Community lists requires an application at the Commission services (first and third level) or the national authorities (second level). See For further explanation and details on the administrative procedure to follow, see **"Note for Guidance"** in the JRC website (*http://cpf.jrc.it/webpack*).

6. Provisional authorisation at national level (Art. 4)

Under certain conditions the Member States have the right to allow within their territories the use of a substance not yet included in positive lists of EU Directives (Art. 4 of Dir. 89/109/EEC [A11]). Conditions are specified by Directive 2002/72/EC [A29] in its Art. 3.3. Other derogations from existing positive lists may only be granted in specific instances by specific directives, such as Directive 83/229/EEC [A7] in the case of dyes and pigments or adhesives in regenerated cellulose films (see Art. 2.2 of Dir. 83/229/EEC)

Regarding the other Member States and the Commission, a Member State making use of the provision of Article 4 has to comply with the following obligations:

- The authorisation can be granted for a maximum of 2 years, during which a verification may take place for a final decision on inclusion or rejection of the substance;
- Verification is carried out by the Commission in accordance with the established procedures, such as consultation of the Scientific Committee on Food; this procedure should come to a conclusion within 18 months from submission of the request by the Member State;
- The materials and articles thus manufactured must bear a distinctive indication, which will be defined in the authorisation of the substance.

7. Temporary suspension of a substance contained in a EU positive list ('safeguard clause') (Art. 5)

Article 5

Where a Member State, as a result of new information or of a reassessment of existing information made since one of the specific directives was adopted, has detailed grounds for establishing that the use of a material or article endangers human health although it complies with the relevant specific directive, that Member State 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 thereof and give reason for its decision.

The 'safeguard clause' of Art. 5 reasserts and implements provisions made in Articles 30 i.e. protection of human health and 95 Point 5 i.e. harmonisation of legislation. A Member State may restrict the use of a substance in the positive lists. As the Commission has the duty to harmonise the legislation, it tries to bring the Member States to a consensus positions. If a change in the Directives is deemed necessary, the procedure laid down in Article 9 is to be followed.

Article 5 only applies to the substances covered by a European Directive. Moreover, the onus of proof rests with the Member State.

8. Labelling (Art. 6)

The provisions for labelling the materials and articles complying with the legislation are listed in Article 6. Many materials and articles considered are likely to have several uses. Whenever one of these uses is for foodstuffs and another for non-foodstuff articles, positive labelling may be needed.

In the current state of the legislation, three cases are distinguished:

- If materials and articles are already in contact with foodstuffs (e.g. packaged foodstuffs) no specific labelling is required;
- If materials and articles are not contact with foodstuffs specific labelling provisions of Article 6.1, 6.2, 6.5 and 6.6 of Directive 89/109/EEC is required;
- If materials and articles are clearly intended for foodstuffs, such as forks, corks, saucers, pans, coffee-machines, the Member States may decide whether or not a positive labelling is required. Even if the Commission proposed a positive labelling such as " for food use" some Member States were against because they believed that this new obligation was unnecessary.

When labelling is required (first indent) or optional (third indent), the materials and articles are labelled 'for food use'. This label must be clearly visible throughout the marketing stages. Where intended for consumers, it must appear in an easily understandable form. A written declaration shall attest the compliance of the products with the rules applicable to them. These rules may be those specified in the specific EC Directives or in absence of them, in the national provisions.

9. Free trade clause (Art. 7)

Article 7

1. Member States shall not, for reasons relating to composition, behaviour in the presence of foodstuffs or labelling, prohibit or restrict either trade in or the use of materials and articles complying with this directive or with the specific Directives.

2. Paragraph 1 shall not affect national provisions, which are applicable in the absence of the specific directives.

This Article reasserts Article 28 of the Treaty in the sector of materials and articles intended to come into contact with foodstuffs. Materials or articles complying with the rules on composition, labelling and migration stated in the framework Directive, in particular in Article 2 are deemed to conform to the rules for the free trade throughout the European Union. A Member State must not hinder the importation of a material or article not complying with its internal (also specific) rules, if it complies with the general rules provided by the Framework Directive and it cannot demonstrate a risk for the health in accordance with the procedure in Art. 5. Possible conflict situations are subject to Art. 28, 30 and 95 of the Treaty, a more precise interpretation of which is given by the new jurisprudence evolved from numerous arrests by the European Court of Justice.

10. Further comments on the current legislation

10.1 Migration units

Specific Directives may set out an overall migration limit and specific migration limits for the release of substances from the given material or article. Migration limits may be expressed in mg/dm², mg/kg or mg/l. A limit in mg/dm² emphasises the inertness of the surface, whereas a limit in mg/kg or mg/l underlines the contamination of the foodstuffs. Limits in mg/kg or mg/l are directly related to the exposure of the consumers and the risk of

an unacceptable contamination of a food. The choice of the units reflects the evaluation of the testing conditions and assessment of the risk connected to exposure.

10.2 Purity, extent of migration control and 'GMP'

The question may arise as to what extent migration must be reduced in order to comply with the 'principle of inertness' ascertained in Article 2 of Directive 89/109/EEC. Is the manufacturer required to lower the migration into foodstuffs to the lowest level technically possible, or is he only expected to comply with the migration limits established by the specific Directives?

The relevant directives do not oblige to reduce the migration to the lowest possible level, but manufacturers must comply with the concept of GMP ('Good Manufacturing Practice' - Art. 2 of Dir. 89/109/EEC) even when the ensuing obligations are more stringent than the migration limits. A more specific definition of 'GMP' should be prepared to enforce adequately this obligation.

As example of 'GMP' see (a) the Documentedited by British Plastic Federation entitled "Plastic in contact with food": a Guide" (publication N° 341/3 November 1999)[8] and (b) - Document edited by Flexible Packaging Europe and CITPA " Code for good manufacturing practices for flexible and fibre-based packaging for food[9]

10.3 Multi-layer articles

A problem of interpretation has recently been raised on the materials and articles composed by two or more layers, e.g. paper/plastic/food or paper/aluminium/plastics/food. Do directive 89/109/EEC and its specific Directives also apply to the layers not in direct contact with foodstuffs, or only to the layer in direct contact with foodstuffs?

Although the interpretation of a Directive belongs to the competence of the Court of Justice, an analysis of the wording of Directive 89/109/EEC is attempted here. The sentences to be analysed are the following:

Article 1

1. This Directive shall apply to materials and articles which, in their finished state, are intended to be brought into contact with foodstuffs or which are brought into contact with foodstuffs and are intended for that purpose hereinafter referred to as 'materials and articles'.

Sixth whereas

> Whereas the principle underlying this Directive should be that any material or article intended to come into contact or which is intentionally in contact either directly or indirectly with foodstuffs, must be sufficiently stable not to transfer.....

In the case of a multi-layer structure, Directive 89/109/EEC and its specific Directives (unless providing other specific rules) apply to all layers, whether in direct or indirect contact with the foodstuffs. Indirect contact may be relevant because of possible migration into food through the layer in direct food contact. Therefore, at first for the legislator the layers in direct or indirect contact are subject to the same rules.

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The directives mentioned above should not apply to the layers only in indirect contact with foodstuffs, if any migration of substances through the direct food contact layer can be ruled out, i.e. if the food contact layer acts as a "functional barrier". The duty to prove the absence of migration from indirect food contact remains with the producer of the article. In the absence of experimental proof of a functional barrier, all the layers should comply with the rules applicable to them. The Commission intends in future to define the concept of functional barrier to clarify the legal status of multi-layers.

10.4. Deterioration of organoleptic properties

At this time, no validated method for assessing deterioration of the organoleptic properties of foodstuffs exists. As a reference, it may be noted that the following tests are carried out at national level:

Germany

- DIN 10955 (1983): 'Sensory testing of packaging materials and packages for food products'

Netherland

- ***Sensory analysis; Packaging and Food Utensils regulation Staatscourant No 88 of 12/05/98***

United Kingdom

- S 3755 (1964): 'Methods of test for the assessment of odour from packaging materials used for foodstuffs'

- S 5929, Part 3 (1984, ISO 4120 - 1983): 'Sensory analysis of food'

Other national and international references will be provided as soon as made available to the Commission.

Since no method for the sensory evaluation of materials for use in ordinary and microwave ovens is described in the literature, in 1992 the Fraunhofer-Institut für Lebensmitteltechnologie und Verpackung (ILV) elaborated on request of the Commission the methods described in appendices 1 and 2.

ANNEX I TO SECTION 2 OF CHAPTER I

GUIDELINES FOR THE INTERPRETATION OF ARTICLE 1 OF DIRECTIVE 89/109/EEC

CHEESEWAX

Cheesewax is a formulated product largely based on solid hydrocarbons or fatty acid derivatives, additives and pigments. It is applied to cheese in order to prevent microbiological deterioration and protect cheese from contamination during handling, storage and transport.

In accordance with Article 1 of Directive 89/109/EEC, cheesewax is considered as a food contact material for the reason that it does not “form part of the foodstuffs" and it is not consumed together with those foodstuffs.

In fact,

(a) It hardly adheres to the untreated rind of cheese;
(b) It does not adhere to untreated rindless cheese;
(c) It will be taken off cheese pre-treated with polymeric film together with this film.

Involuntary ingestion of cheesewax should be avoided. Therefore, the consumer should be informed, e.g. by a label or a distinct colour of the wax.

COVERING PREPARED MEAT PRODUCTS

“Covering prepared meat products” are considered as a food contact materials for the reason that they do not “form part of the foodstuffs” and they are not consumed together with those foodstuffs.

Involuntary ingestion of this covering should be avoided. Therefore, the consumer should be informed, e.g. by a distinct colour of covering

ISSUE RELATED TO POP CORN AND OTHER "EDIBLE" MATERIAL USED AS FOOD CONTACT MATERIALS

Pop corn and other edible materials used as packaging for food applications are considered as foodstuffs and submitted to the foodstuffs rules.

ANNEX II TO SECTION 2 OF CHAPTER I

GUIDELINES FOR SENSORY TESTING AT MICROWAVE CONDITIONS

Warning: This appendix is added just for information and does not represent necessarily Commission guidelines. This appendix was not discussed with Member States.

Sensory testing of food contact materials for use in microwave ovens is carried out with food simulants. For ready-to-eat-packages, the test can also be performed with the packed food. The object to be tested has to be cleaned as usual in the household or suggested by the producer. As food simulants, drinking water or neutral frying oil are used.

For testing with drinking water (at temperatures below 100 °C), the testing object is filled to half of its volume; for testing with fat or oil (at temperatures between 100 and 150 °C), with 100 g fat per dm² bottom area, which corresponds to a layer of about 1 cm highness.

Covers and covering films are tested over appropriate vessels filled with water.

Heating is carried out in a microwave oven under the following conditions:

- Drinking water (max. 100 °C): 600 Watt, 2 min/100 ml;
- Frying fat (max. 121 °C): 600 Watt, 3 min/100 g;
- Frying fat (max. 150 °C): 600 Watt, 4 min/100 g.

After heating, the food simulants are allowed to cool in the object tested to a temperature of 40-50 °C and tasted at that temperature against reference samples, which were treated the same way in glass.

Otherwise the test is carried out according to DIN 10955 (Sensory testing of packaging materials and packages for food products).

If a food simulant is evaluated with the mark 3 (distinct deviation from the reference sample) it is to assume that real food is also reduced in its odour and/or taste quality, which means an offence against Article 2 of Directive 89/109/EEC.

ANNEX III TO SECTION 2 OF CHAPTER I

GUIDELINES FOR SENSORY TESTING AT OVENS CONDITIONS

Warning: This annex is added just for information and does not represent necessarily Commission guidelines. This appendix was not discussed with Member States.

Sensory testing of baking papers and boards is carried out with a neutral sponge mixture, which is spread on the baking tray as suggested by the producer and covered with the mixture.

The standardised mixture contains:
200 g wheat flour
150 g margarine
1 egg
2 tablespoons of water

and has to be cooled for at least 1 hour at 4-8 °C.

After cooling, the mixture is rolled out on the baking paper or board covered by the testing material, over an area of about 12 dm² and about 0.5 cm thick. For smaller testing areas, correspondingly less dough is used.

The baking conditions are chosen corresponding to the instructions of the producer or selected from the following possibilities:
180 °C / 30 min,
200 °C / 25 min or
220 °C / 20 min.

For the reference sample, the mixture is baked on aluminium foil covered by testing material, applying the same conditions.

After baking, the “cakes" are allowed to cool to about 40 °C on the testing material. Then the testing material is tasted against the reference sample.

Alternatively the test is carried out according to DIN 10955 (Sensory testing of packaging materials and packages for food products).

If the testing material is evaluated with the mark 2.5 (remarkable deviation from the reference sample), it is assumed that also a real food is reduced in its odour and/or taste quality, which means an offence against Article 2 of Directive 89/109/EEC.

SECTION 3

PLASTICS – Part 1

1. EU legislation: List of pertinent Directives

Corrigendum			
2002/72/EC	***[A29]***	***Commission***	***Codification of 90/128 and its 7 amendments***
2002/72/EC	***[A28]***	***Commission***	***Codification of 90/128 and its 7 amendments***
Directives repealed:			
90/128/EEC	[A12]	Commission	General rules, positive list of monomers
92/39/EEC	[A14]	Commission	1st Amendment of Directive 90/128/EEC
93/9/EEC	[A15]	Commission	2nd Amendment of Directive 90/128/EEC
95/3/EEC	[A20]	Commission	3rd Amendment of Directive 90/128/EEC
96/11/EEC	[A21]	Commission	4th Amendment of Directive 90/128/EEC
1999/91/EC	[A23]	Commission	5th Amendment of Directive 90/128/EEC
2001/62/EC	[A25]	Commission	6th Amendment of Directive 90/128/EEC
2002/17/EC	[A27]	Commission	7th Amendment of Directive 90/128/EEC
82/711/EEC	**[A6]**	**Council**	**Basic rules for migration testing**
93/8/EEC	[A17]	Commission	1st Amendment of Directive 82/711/EEC
97/48/EC	[A22]	Commission	2nd Amendment of Directive 82/711/EEC
85/572/EEC	**[A9]**	**Council**	**List of simulants**
78/142/EEC	**[A2]**	**Council**	**Limits for vinyl chloride (VC)**
80/766/EEC	[A4]	Commission	Method of analysis of VC in products
81/432/EEC	[A5]	Commission	Method of analysis of VC migration
2002/16/EC	***[A26]***	***Commission***	***Use of certain epoxy derivatives (BADGE, BFDGE, NOGE)*** ***(See Section 4 Part 2 of Chapter I)***

Directive 2002/72/EC [A29] is a specific Directive in the sense of the Framework Directive 89/109/EEC. Like similar specific directives, its provisions are not restricted to packaging materials (see **Section 2, paragraph 2. Field of application of the Framework Directive**). Monomers or other starting substances used to manufacture these plastic materials and articles are addressed specifically.

Directive **2002/72/EC [A29]** establishes:

- The field of application;
- The global migration limit for all plastic materials and articles;

- A positive list of authorised monomers and other starting substances, with restrictions on their use (such as specific migration limits) where applicable;
- An incomplete list of authorised additives and for some of them, restrictions on their use (such as specific migration limits),
- The dates of enforcement of the legislation;
- The procedures for adapting, revising and/or completing the positive list of its Annexes.

The Directives **82/711/EEC** and its amendments, as well as Directive **85/572/EEC** provide the basic rules for overall and specific migration testing.

The Directives on **vinyl chloride** establishe a QM and an SML for this monomer and the methods for their enforcement (see **Plastics – Part 2**).

2. Directive 2002/72/EC [A29]: field of application

2.1. Plastics covered

Article 1.2.

This Directive shall apply to plastic materials and articles and parts thereof:

(a) Consisting exclusively of plastics; or

(b) 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 their finished product state, are intended to come into contact or are brought into contact with foodstuffs and are intended for that purpose.

On the meaning of 'finished state', see **Section 2, paragraph 2. Field of application of the Framework Directive.**

The definition of plastics, in the sense of this Directive, is provided in

Article 1.3.

For the purposes of this Directive, 'plastics' shall mean the 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 matter may be added to such macromolecular compounds.

2.2. Plastics not covered

2.2.1. Products already dealt with in other Directives

Article 1.3.

(i) Varnished or unvarnished regenerated cellulose film, covered by Council Directive 83/229/EEC [A7] as amended by Directives 86/388/EEC [A10] and 92/15/EEC [A13]; [10]

2.2.2. Other products

Article 1.3.

However, the following shall not be regarded as 'plastics':

[10] Only varnished regenerated cellulose film with a coating of less than 50 mg/dm² is covered in the above-mentioned Directives. Regenerated cellulose films with a higher proportion of coating will probably be included in a Directive specifically dedicated to varnishes, coatings etc. in contact with food.

(i) (See **2.2.1.** above)
(ii) Elastomers and natural and synthetic rubber;
(iii) Paper and paperboard, whether modified or not by the addition of plastics;
(iv) Surface coatings obtained from:
- Paraffin waxes, including synthetic paraffin waxes, and/or microcrystalline waxes,
- Mixtures of the waxes listed in the first indent with each other and/or with plastics;
(v) Ion exchange resins.
(vi) Silicones

Article 1.4

This Directive shall not apply, until further action by the Commission, to materials and articles composed of two or more layers, one of which does not consist exclusively of plastics, even if the one intended to come into direct contact with foodstuffs does consist exclusively of plastics.

2.2.3 Comments

The reasons for the exclusions may be of two types:
- Technological properties of the materials, which require specific rules, e.g. silicones, ion-exchange resins;
- Reasons of opportunity.

The possibility of including these materials, e.g. materials and articles composed of two or more layer, will be considered later.

For domains excluded from the field of application, the Framework Directive and national legislations apply.

In accordance with Art. 1.2 of Directive 89/109/EEC, private or fixed public water supply systems are not concerned by this directive (see **Chapter I, Section 2, paragraph 2. Field of application of the Framework Directive** on the meaning of 'fixed systems').

For plastic materials and articles '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', the considerations made on the multi-layer articles in **Section 2, paragraph 10.3 Multi-layer articles** apply.

Nota bene n. 1
Biodegradable plastics are included in the field of application as well as the plastics manufactured with the use of monomers obtained by the so-called “chemical recycling" processes (see Chapter I, Section 3, paragraph 10.3)

Nota bene n. 2
Refillable plastics are included in the field of application of Directive2002/72/EC [A29] and moreover for the substances not regulated by the specific Directive such as oligomers, reaction products etc. they should comply with Article 2 of Directive 89/109/EEC.

3. EU "lists of substances" and their field of application

Introduction

The EU approach to ensure the safety of food contact materials originates from previous national legislation and historic developments. In the 1970s, the legislators were

confronted with the overwhelmingly complex task of dealing with substances that migrated into foodstuffs e.. Their first efforts concerned the preparation of a positive list of the ingredients (monomers and additives) used for the manufacture of food contact materials and articles. The toxicological evaluation of these substances was made following the criteria of the time, these differ from those used today.

The Commission services decided not to change the criteria in listing the substances and compiled all the national lists in an "EU inventory list" of substances, which may be included at the end in an EU positive list. Obviously, this approach neglects that the migrants into foods may include substances that were not ingredients but which may be derived from them during the manufacturing process, the so-called reaction products, or impurities not integrated into the polymer. The safety requirement laid down by Article 2 of the Framework Directive 89/109/EEC is only fully achieved when these components are also under control. For this reason, this issue is largely debated at the EU and Council of Europe level to find the appropriate legislative solutions.

3.1. Positive list of monomers and other starting substances

The Directive 2002/72/EC [28] states:

"Art. 3.1.

Only those monomers and other starting substances listed in Annex II, section A and B may be used for the manufacture of plastic materials and articles subject to the restrictions specified.

Annex II, paragraph 3

The list also does not include the following substances although they may be present:

(a) Substances which could be present in the finished product as:

- Impurities in the substances used,
- Reaction intermediates,
- Decomposition products;

(b) Oligomers and natural or synthetic macromolecular substances as well as their mixtures, if the monomers or starting substances required to synthesise them are included in the list;

(c) Mixtures of the authorised substances.

The materials and articles, which contain the substances indicated under (a), (b) and (c), shall comply with the requirements stated in Article 2 of Directive 89/109/EEC."

The aim of a positive list is to protect the consumer against health risks from the exposure to substances migrating into the food. They should contain all substances migrating into foodstuffs, but this is a demanding task, because of many migrants neither the identity nor the potential impact on health is known.

The EU positive list of "monomers and other starting substances" includes substances deliberately used in the manufacture of the finished material and article and constituting a repeating unit of a polymer chain or polymer network and the substances used to modify existing natural or synthetic macromolecular materials. All these substances should be the subject of a request for authorisation (application). Directive 2002/72/EC defines them in the following way.

"- Substances undergoing polymerisation, which include polycondensation, polyaddition or any other similar process, to manufacture macromolecules;

- Natural or synthetic macromolecular substances used in the manufacture of modified macromolecules, if the monomers or the other starting substances required to synthesise them are not included in the list;
- Substances used to modify existing natural or synthetic macromolecular substances."

Consequently, components such as:

- Impurities of starting materials
- Reaction intermediates (e.g. oligomers, products of side reactions)
- Decomposition products

are not included in this list.

The identification of substances to be included in the EU list is not so easy and some explanation is given below (see 3.1.1 and 3.1.2). However, it should be remembered here that in the new version of the "Note for Guidance", the SCF requires for monomers "… information on the migration of oligomers and reaction products from polymers produced from new monomers or which are produced by means of polymerisation aids that influence the molecular structure or molecular weight of the polymer. In the first instance there is a need for information on the identity and level of substances that migrates as a consequence of the use of a new monomer…"

3.1.1. Monomers and other starting substances in thermoplastics polymers

Thermoplastic polymers: Polymers which are capable of being repeatedly softened by heat and hardened by cooling. Typical of the thermoplastic family are the styrene polymers and copolymers, acrylics, cellulosics, polyethylenes, polypropylene, vinyls and nylons. (Plastics Engineering, Handbook of The Society of the Plastics Industry, Inc., edited by Michael L. Berins, 1991).

For thermoplastics, the identification of what are the "monomers and other starting substances" is relatively simple. Petitions should be presented for all those components deliberately added to a polymerisation medium, which will be integrated into the polymer. The only permitted exceptions provided by Directive 2002/72/EC are:

- ***"The oligomers and natural or synthetic macromolecular substances as well as their mixtures, if the monomers or starting substances required to synthesise them are included in the list;***
- ***The mixtures of the authorised substances."***

Examples:

1. ***If an ester derived from an acid and an alcohol contained in Section A of the positive list is used as a monomer, it has to be the subject of a petition in order to be listed as a new monomer. The ester has a toxicological profile different from that of the acid and the alcohol from which it is formed. However, the technical dossier accompanying the petition does not need to contain toxicological data if it is demonstrated that metabolism completely hydrolyses the ester.***

2. ***If oligomers formed from positive-listed monomers are used as a starting material, they do not normally need to be listed. This is because they often have the same***

structural elements and functional groups as the toxicologically investigated monomers and, therefore, the toxicological profile is assumed to be the same.

3.1.2 Monomers and other starting substances for thermoset polymers.

Thermoset polymers (often called "resins"): Polymers that will undergo a chemical reaction through the application of heat and pressure, catalysts, ultraviolet light, etc., leading to an infusible state. Typical of the plastics in the thermosetting family are the aminos (melamine, benzoguanamine and urea), most polyesters, alkyds, epoxies, acrylics, polyurethanes and phenolics. (Plastics Engineering Handbook of The Society of the Plastics Industry, Inc., edited by Michael L. Berins, 1991).

Thermoset systems: These are systems based on thermoset polymers which after polymerisation (crosslinking, drying, curing, hardening) solidify to a three dimensional crosslinked matrix that cannot be remelted without destroying its original characteristics. Typical examples are organic coatings, composites, etc.

Figure 1 shows the manufacturing process of a crosslinked thermoset food contact material e.g. a cured organic coating

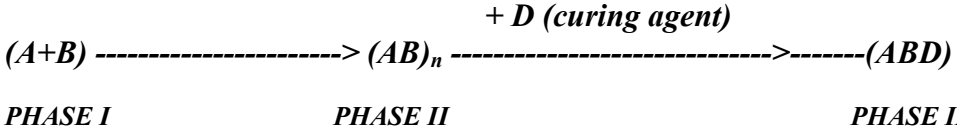

Figure 1. Phases of manufacturing of a crosslinked thermoset food contact material.
(A, B) = starting substances for the manufacturing of thermoset polymers;
$(AB)_n$ = thermoset polymer often called "resin", incorporating a variable number of base units (AB);
(ABD) = final product of the polymerisation process e.g. a crosslindek/cured coating.

The manufacturing of the crosslinked thermoset food contact material can be described as follows:

Phase I describes the manufacturing process of the thermoset polymers $(AB)_n$ from the starting substances A and B. Depending on the number of repeating units in the backbone, the thermoset polymers $(AB)_n$ may be oligomeric or polymeric. Phase I also includes the manufacturing of oligomeric or polymeric curing or crosslinking agents (D) which are also considered thermoset materials.

The thermoset polymers $(AB)_n$ as such are not used as food contact materials, they are merely used as reactive intermediates or prepolymers that require further polymerisation/curing in a second stage (Phase II) to form the final crosslinked thermoset food contact material e.g. a cured organic coating (Phase III)

Phase II describes the manufacturing (curing) process of the final crosslinked thermoset food contact material by reacting the thermoset polymers $(AB)_n$ with curing/crosslinking agents (D) or by other means of polymerisation (heat, pressure, UV light, catalyst activated cure). As mentioned before, the curing/crosslinking agent is also a thermoset material that can be monomeric, oligomeric or polymeric in nature.

<u>Phase III</u> is the crosslinked thermoset food contact material e.g. a cured organic coating.

The starting substances A, B as well as monomeric curing agents D should be listed as starting substances. The various resulting pre-polymers $(AB)_n$ (e.g. components of a resin) are oligomers and currently do not need to be listed according to Annex II, paragraph 3, under b) of Directive 2002/72/EC. However, the producer shall carry out a risk assessment in accordance to the principle of "responsible care".

The legislator can establish a restriction to the migration of these prepolymers if they migrate in a quantity, which might endanger human health. This restriction may become either a specification of the finished material (see for example Annex V of Directive 2002/72EC) or a specification of the starting substances. Other different legislative solutions can be suggested on a case by case basis. In the majority of the national legislations, the pre-polymers $(AB)_n$ do not appear and their relevant precursors (A, B) are listed.

In the new version of the "Note for Guidance", the SCF requires for monomers "… information on the migration of oligomers and reaction products from polymers produced from new monomers or which are produced by means of polymerisation aids that influence the molecular structure or molecular weight of the polymer. In the first instance there is a need for information on the identity and level of substances that migrates as a consequence of the use of a new monomer…"

3.1.3 <u>Exclusions from the EU positive list of monomers and other starting substances</u>

Article 3.5

However the lists appearing in Annex II, Section A and B do not yet include monomers and other starting substances used only in the manufacture of:

- Surface coatings obtained from resinous or polymerised products in liquids, powder or dispersed form, such as varnishes, lacquers, paints, etc.,
- Epoxy resins
- Adhesives and adhesion promoters,
- Printing inks.

As described in the abovementioned article, not all the momomers for plastics are listed. A certain number of monomers used to manufacture the above listed materials are not yet included because the professional organisations claimed for specific rules for them or because their lists were not completed when the Directive was adopted. These monomers will be added as soon as possible.

It must further be reminded that the list of monomers is subdivided into two Sections:

- Section A, which contains all the monomers fully harmonised at EU level;

- Section B, which contains monomers authorised only in at least one Member State and not yet harmonised at EU level pending the submission of the data requested by SCF for their evaluation. This Section has a temporary existence until 31 December 2004.

3.2 List of authorised additives

3.2.1 The Directive 2002/72/EC [A29] states:

Article 3a

An incomplete list of additives, which may be used for the manufacture of plastic materials and articles, together with the restrictions and/or modifications on their use, is set out in Annex III, Sections A and B.

"Additives" are substances added to polymers ("Category I") or to the polymerisation medium ***(so called "Polymer production aids")*** to achieve a technical effect ("Category II").

In order to assist the petitioner in the request for an authorisation, the Commission has prepared the following indicative list of types of substance falling into the definition of "additives", grouped in the two Categories.

"Category I"
"Additive" means a substance which is incorporated into plastics to achieve a technical effect in the finished product; they are intended to be present in the finished articles."

[- Antifoaming agents] [11]
- Antiskinning agents
- Antioxidants
- Antistatic agents
- Dryers
[- Emulsifiers][12]
- Fillers
- Flame-retardants
[- Foaming agents] [12]
- Hardening agents
- Impact modifiers
- Lubricants
- Miscellaneous additives
- Optical brighteners
- Plasticizers
- Preservatives
- Protective colloids
- Reinforcements
- Release agents
- Stabilisers
- Thickeners
- UV absorbers

"Category II"
"Polymer production aids" means any substance used to provide a suitable medium in which polymerisation occurs (e.g. emulsifiers, surfactants, buffering agents, etc.)

- Anti-foam reagents/degassing agents
- Blowing agents
- Buffering agents
- Build-up suppressants
- Dispersing aids

[11] To be verified whether they should be inserted between the additives

- Emulsifiers
- Flow control agents
- Nucleating agents
- PH regulators
- Solvents
- Surfactants
- Suspension agents
- Stabilisers
- Thickening agents
- Water treatment reagents

Specific explanation is given about the polymers used as additives (see paragraph 3.3 below)

3.2.2 The EU list of additives is not yet a positive list because the additives not included in this list may be used if they comply with a national list. However, the Commission services has undertaken to transform the national lists into a positive list before the 31 December 2005. In the first amendment of Directive 2002/72/EC, now in preparation, the Article 4 of the Directive 2002/72/EC is replaced by the following:

WARNING
This text is not an official text and it is not yet adopted and, therefore, can be subject to important amendments. The reader should check if the text remains unchanged or has been modified during the long EU procedure for the adoption of a Directive (send an e-mail to catherine.iffenecker@cec.eu.int).

"Article 4

1. An incomplete list of additives which may be used for the manufacture of plastic materials and articles, together with the restrictions and/or specifications on their use, is set out in Annex III, Sections A and B.

2. For the substances in Annex III, Section B, the verification of the compliance of the specific migration limits in simulant D or in test media of substitute tests as laid down in Directive 82/711/EEC and 85/572/EEC is applied as from 31 December 2005.

3. The lists appearing in Annex III, Sections A and B do not yet include the following additives:

a) additives used only in the manufacture of:

- **surface coatings obtained from resinous or polymerised products in liquid, powder or dispersion form, such as varnishes, lacquers, paints, etc.,**
- **epoxy resins,**
- **adhesives and adhesion promoters,**
- **printing inks**

b) colorants

c) solvents

4 The list of additives referred to in paragraph 1 shall become a Community list of authorised additives to the exclusion of all others (positive list). In view of the establishment of the positive list, any person interested in the authorisation of an additive, which is already placed on the market in one or more of the Member States, shall submit data for its safety evaluation by the "European Food Safety Authority"

('EFSA') not later than 31 December 2004. For the submission of the required data the applicant 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"[12]

5 The Commission will establish not later than 31 December 2005:

a) the date when the list of authorised additives will become a positive list;

b) a provisional list of additives which may continue to be used until the EFSA has evaluated them. They shall fulfil the following conditions:

(i) they are permitted in one or more of the Member States not later than 31 December 2004;

(ii) the data mentioned in paragraph 4 have been supplied in accordance with EFSA requirements not later than 31 December 2004;

(iii) they shall be used in accordance with the national law.

If during the examination of the data the EFSA requires supplementary information, these substances shall continue to be used subject to national law, even after the positive list is established and until the EFSA has issued an opinion, provided that the information is submitted within the time limits specified by the EFSA.

6. "New additives", i.e. additives never evaluated by the SCF or EFSA may always be added to the list of substances authorised at Community level following the safety evaluation by the EFSA."

The list is also subdivided in two lists:

- Section A contains additives fully harmonised at EU level;
- Section B contains additives not yet fully harmonised at EU level, because the SML set out in the Directive should be not yet applied when the simulant D is used.

Section B has been provisionally introduced (until 31 December 2003**, but now a deadline of 31 December 2005 is under discussion)** because the discussion on Fat (consumption) Reduction Factors is not yet finished and the application of the SML without these factors may exclude some applications already authorised at national level.

As regards the impurities, reaction intermediates and decomposition products the same considerations made for monomers apply.

3.2.3 There are several additives contained in the current list, which are also included in the lists of additives or flavouring substances for food. The new ongoing amendment of Directive 2002 establishes the general rule that the more severe restrictions should be enforced in those foods for which the rules apply. Therefore, if an SML is more restrictive than the maximum level allowed of this substance as food additive or flavouring for a certain food, the SML applies. If the SML is less restrictive than the maximum authorised

12 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" is updated on 13 December 2001 and it is available on: http://europa.eu.int/comm/food/fs/sc/scf/out82_en.pdf

level of this additive in the respective food the latter prevails. It is provided for that for these substances information on the level of migration should be supplied to enable the user of these materials and articles to comply with the relevant Community provisions or, in their absence, with national provisions applicable to food. This rule is especially important for additives such as 54880/59280/87840/88240/87600 etc. for which the maximum level of additive authorised in some foods is less than 60 ppm.

3.3 List of polymers used as starting substances or additives

3.3.1 Explanation of important terms

Since the Directive 2002/72/EC does not define the related terms, the Commission consulted the SCF and decided to use the terms according to the descriptions set out below.

3.3.1.1 "Polymeric substance used as additive" generic expression which is used when it is impossible to indicate if a substance is covered by the definition of "polymeric additive" or by the definition of "basic substance".

Note
This expression intends to overcome the difficulty to define the situation where a polymeric substance (substance B) is mixed/added to another polymeric substance (substance A). How the two components should be considered? Should B be considered "additive"? If not, why not if it is mixed/added to A to achieve a technical effect in the finished product as requested by the definition of "additive" of sub-paragraph 2.2.11.

3.3.1.2. "Polymeric additive" means any polymer and/or prepolymer and/or oligomer, which may be added to plastics in order to achieve a technical effect but which cannot be used in the absence of other polymers as the main structural component of finished materials and articles."

3.3.1.3 "Polymeric monomer" means any polymer (including prepolymer and oligomer), which may used as starting substance in a polymerisation process.

3.3.1.4 "Monomer and starting substance" means any starting substance (regardless of its chemical nature (compound, mixture, monomer, oligomer, prepolymer natural or synthetic macromolecules etc.) used in any type of polymerisation process including the modification of natural or synthetic substances. According to the Directive 2002/72/ EC the substances to be listed as monomers and starting substances are: substances undergoing polymerisation, which includes polycondensation, polyaddition or any other similar process, to manufacture macromolecules,

- ***natural or synthetic macromolecular substances used in the manufacture of modified macromolecules, if the monomers or the other starting substances required to synthesise them are not included in the list,***
- ***substances used to modify existing natural or synthetic macromolecular substances.***

3.3.1.5 "Oligomer" means any substance consisting of a few repeating units of a monomer and/or starting substance.

3.3.1.6 "Prepolymer" ***means a macromolecule or oligomer molecule capable of entering, through reactive groups, into further polymerisation, thereby contributing more than one monomeric unit to at least one chain of the final macromolecule (IUPAC definition)***

3.3.1.7 "Polymer" means any macromolecular compound obtained by polymerisation (polyaddition, polycondensation or any other similar process) of monomers and other starting substances.

3.3.1.8 "Plastic" means the organic macromolecular compounds obtained by polymerization, polycondensation, polyaddition or any other similar process from molecules with a lower molecular weight or by chemical alteration of natural macromolecules. Other substances or matter may be added to such macromolecular compounds

Note
This definition of "plastic"appears in Directive 2002/72/EC.

3.3.1.9 "Blend" means any mixture of polymers and/or plastics in the same physical state, each of which can be used as such for the manufacture of finished materials and articles.

3.3.1.10 ***"Basic polymer" means any polymeric substance, such as plastic or polymer, which is capable of functioning as the main structural component of finished materials and articles."***

Note
The definition of "basic polymer" includes both definitions of "plastic" (…which may contain additives) and "polymer"(…which does not contain additives). It should be remembered that basic polymers should comply with the requirements specified in sub-paragraph 4.2 i.e. - in practice - they should follow the rules of Directive 2002/72/EC.

3.3.1.11 "Additive" means a substance, which is incorporated into plastics to achieve a technical effect in the finished product; they are intended to be present in the finished articles.

Note
Sometimes in the text is used the expression "conventional additive" to indicate the additives which have no a polymeric structure.

3.3.1.12 ***"Polymer production aids" means any substance used to provide a suitable medium in which polymerisation occurs (e.g. emulsifiers, surfactants, buffering agents, etc.)***

3.3.2. Status of oligomers and pre-polymers used as "monomers or starting substances"

Annex 2 of Directive 2002/72/EC establishes that the list of monomers and other starting substances includes natural or synthetic macromolecular substances used for the manufacture of modified macromolecules, if the monomers or the other starting substances required for their synthesis are not listed (e.g. polyvinylalcohol, as vinylalcohol is non existent)[13].

It has been stated in 2.1.2 and 2.1.3 of Annex 2 of Directive 2002/72/EC that oligomers and natural or synthetic macromolecular substances (e.g. pre-polymers), as well as their mixtures, are not listed if the monomers or starting substances required for their synthesis are included in the list.

It must be stressed that "blends of the approved polymers used as starting substances" are automatically authorised and, therefore, are not listed.

3.3.3 Status of polymeric additives as defined under 4.1

When used as additives, oligomers and natural or synthetic macromolecular substances as well as their mixtures are all included in the list, even if the monomers or starting substances required for their synthesis are included in the list.

Nota bene
It must be stressed that any polymer which can be used as such for the manufacture of finished materials and articles is excluded by the definition of polymeric additive.

3.3.4 Why the difference in treating oligomers and (pre-)polymers?

Why are oligomers and polymers treated differently when their monomers are listed compounds? When oligomers and pre-polymers are used as "monomer or starting substances", they are largely converted to high molecular weight polymers, which are no risk

13 See Annex 2 of the Directive.

to the consumers' health. However, when used as polymeric additives, they remain unchanged and are more likely to migrate. In the interest of better control, they must be listed. In fact, they may have a somewhat different toxicity than the monomers used for their synthesis.

3.3.5. SCF Guidelines on polymeric additives

See explanation on **Section 3, paragraph 3.3.3** of this document and mainly **"Note for Guidance"** in JRC website: **http://cpf.jrc.it/webpack**.

3.4. Biocides

Recently some petitions asking for authorisation of substances acting as biocides on the surface of articles have been submitted to the Commission. At the request of the Commission, in December 2001 the SCF adopted guidelines on the additional data to be submitted for these substances. For further explanation see **"Note for Guidance"** Chapter II

3.5 List of colorants

There is no decision of the Commission on the listing of colorants at EU level. Therefore, for colorants, the general provisions of the framework Directive 89/109/EEC [A11] apply and, where they exist (e.g. in France), specific national legislations apply. The Committee of Experts of the Council of Europe adopted on 13 September 1989 Resolution AP(89)1 on this issue. See **Chapter IV**.

4. Impurities in substances and constituents of mixtures

Impurities of authorised substances are not listed and therefore do not require specific authorisation according to Annex II point 3 of the Directive, but they should comply with the specification of Art. 2 of Directive 89/109/EEC, i.e. should not

- Endanger human health
- Bring about an unacceptable change in the organoleptic characteristics thereof.

The Directive 2002/72/EC has not differentiated between impurities in the listed substances and specifications of mixtures i.e. constituents of mixtures. Therefore some practical guidance is given below. Further explanations can be found in the document "SCF-WG Explanatory Guidance", included in the document **"Note for Guidance".**

The main differences between impurities and constituents of mixtures are summarised below.

Substance	Impurity	Constituent of mixture
Presence is deliberate	No	Yes
With a technological function	No	Yes
Requires an authorisation	No[14]	Yes

[14] In some exceptional cases an impurity may appear in general purity criteria (to be established later) or in the positive list itself.

Specified on the positive list	No[15]	Yes

4.1 Restrictions on impurities

For many substances it will be necessary to specify impurities, in some cases with restrictions. Impurities are often enriched in the migrate, since they tend not to be integrated into the polymer and, therefore, remain easily extractable.

Due to the large number of authorised substances, the often several ways that they synthesise (giving rise to different impurities) and the difficulties of legally and toxicologically defining specifications, Directives or drafts of Directives have so far established such specifications in only a few cases. The matter therefore mostly remains regulated at national level. The Commission intends to approach this problem later, unless specific health concerns come to light.
In fact Annex II, paragraph 3 of Directive 2002/72/EC states that the impurities in authorised materials are not to be listed and, therefore, do not require specific authorisation.

- If the impurity is a substance included in the positive list, its migration should comply with specific migration limits and other restrictions, as far as existing in Directive 2002/72/EC and its amendments.

- If the impurity consists of a substance which is not included in the positive list, the finished material or article containing the impurity should comply with Article 2 of Directive 89/109/EEC, i.e. it should not transfer the impurity to the foodstuffs in a quantity which could

    - Endanger human health or

    - Bring about an unacceptable change in the composition of the foodstuffs or a deterioration in the organoleptic characteristics thereof."

The "SCF Guidelines" state that the petitioner should submit the information “on any decomposition or transformation which the substance may undergo while the material or article is being manufactured; an indication of the decomposition or transformation products which may be formed in the finished material or article during production“ in the dossier to introduce a substance into the positive list.

The Commission, following the SCF opinion, may decide to introduce restrictions on impurities, appearing as specifications of the starting substance.

Nota bene n. 1: Data base on authorised substances

A database on certain monomers and other starting substances as well as on additives of Directive 2002/72/EC has been prepared at the EC-Joint Research Centre and is extended to any new substance in the list. For every substance listed, it includes purity data, physical properties and spectra of commercial samples. The data on purity could provide the basis for a specification of the substances. Further information may be obtained from:

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15 See Annex 2, paragraph 3.

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Nota bene n. 2: Impurities in fats and fatty acids derived from natural raw materials

It is generally recognised by the legislators that the presence of minor amounts of certain fatty acids in natural oils e.g. fatty acids with odd numbers of carbon atoms should be dealt with as impurities of the natural oil and therefore they form part of the specification of the individually listed major components. In this way it is not necessary for all these "rare" acids to be included in the positive list.

4.2 Information on mixtures

This section is to help industry to plan dossiers for the evaluation of mixtures.

4.2.1 Defined mixtures

a) Synthetic mixture: mixture made by combining defined substances.

The applicant should present a separate petition for every substance in the mixture, independently of its concentration in the mixture.

b) Defined process mixture: mixture obtained from a reproducible process and with a composition, which can be determined, e.g. a mixture consisting of a limited number of isomers.

4.2.2 Non-defined mixtures

a) Mixture from natural sources: mixtures typically of high complexity and variability, or of high complexity resulting from further physical or chemical treatment, such as distillation, ethoxylation or hydrogenation. Examples: edible oils and fats, rosin esters.

The applicant is requested to provide a specification of the non-defined mixture regarding the relevant aspects.

b) Process mixture: mixture obtained from a reproducible process and with a composition which cannot reasonably be determined. Example: diisononylphthalate, often showing a widely varying composition of isomers, depending on the manufacturing process.

The applicant is requested to provide a specification of the non-defined mixture regarding the relevant aspects.

The petitioner has three options:

a) Presenting a petition for the individual component of a mixture (Procedure A)

b) Presenting a petition for the mixture (Procedure B);

c) Presenting a petition for the mixture based on the toxicological data for one or several representative components of the mixture (Procedure C).

The advantages and disadvantages of the possible procedures are summarised below:

Procedure A.

The petitioner submits a petition for those individual components of the mixture, which are not included in the EU lists so far. The toxicological tests should be performed on purified components.

Advantages:

- Future petitions for mixtures containing the same components, but in different ratios, are avoided.

- The need for complicated specification of the mixture and problems concerning the definition of restrictions are avoided.

Disadvantage: the supply of toxicological data for individual components may be expensive.

Procedure B

The petitioner specifies the commercially produced mixture, as described in the "SCF-WG Explanatory Guidance", and provides the data from the toxicological tests carried out on the commercial mixture.

For the petitioner, the advantage is that the toxicological testing is limited to the commercial mixture.

Authorisation will be restricted to the mixture of the petition and products of similar composition. The consequences are:

(i) The Commission needs a detailed description/analysis of the mixture to be authorised;

(ii) Mixtures of the same components, but of different quantitative composition need to be authorised separately;

(iii) If restrictions are required, the SCF and the Commission must find a way for their expression. It may be analytically demanding to enforce the resulting SML.

Approximations will be necessary. For instance, if the mixture consists of substances of similar structure and molecular weight, it may be assumed that all components migrate to the same extent and the composition of the migrated material will correspond to that of the original mixture.

If it is analytically not feasible to determine the mixture as a whole, selected components of the mixture must be measured and the totals calculate from there. This approach again presupposes that all relevant components of the mixture migrate to the same extent.

Procedure C

The petitioner submits a petition for the mixture, but only presents toxicological and migration data for one or a few components, selected as representatives of the mixture. As an example, if the mixture consists of homologous compounds, the evaluation might be based on the following information:

- Set of toxicity data on one or on a few components of the mixture;

- Scientific evidence (e.g. structure-activity correlation) showing how the toxicological profile of the other components is related to that of the compound investigated.

This procedure combines the advantages of both previous procedures and avoids their disadvantages. However, it remains at the SCF to decide whether the data on one or a few components enables the evaluation of the whole mixture.

The SCF prefers Procedure A, because it facilitates the examination of the technical dossier of the "process mixtures" and, if necessary, the definition of restrictions, but it is aware of the possible difficulties in strictly applying Procedure A and recognises that no "a general rule" can be established.

4.2.3 Recommended procedure for the evaluation of a mixture

In conclusion, the Commission recommends to either follow Procedure A or to proceed in steps. In the latter case, a petition accompanied by a technical dossier is submitted, characterising the mixture and proposing a strategy to obtain toxicological data. For instance, if the petitioner intends to follow Procedure C, he presents evidence on how the toxicological profile of the component(s) proposed to be tested is related to that of all others. The SCF will respond whether the chosen strategy is acceptable or alternative routes should be followed.

1st step: The petitioner submits a technical dossier describing the mixture and proposes a procedure (A, B or C).

2nd step: The SCF examines the dossier and decides on the most appropriate procedure.

3rd step: The petitioner carries out the toxicity and migration testing.

4th step: Final evaluation by SCF.

4.2.4 Other questions on mixtures and individual components in mixture

Question: If a mixture appears in the EU positive lists, are then the individual components automatically authorised?

Answer: Not always, because the toxicity of a substance depends on the dose ingested by the animals examined in the toxicological test. The data obtained for a whole mixture cannot always be extrapolated to a minor component in this mixture.

Question: If the various components of a mixture are listed individually in the positive list, are all of their mixtures automatically authorised?

Answer: Yes.

5. Aids to polymerisation

They are defined as "Substances, which directly influence the formation of polymers" and constitute a separate class of substances planned to be regulated by specific rules. They include, for example:

- Accelerators
- Catalysts
- Catalyst deactivators
- Catalyst supports
- Catalyst modifiers
- Chain scission reagents
- Chain transfer or extending agents
- Chain stop reagents
- Cross-linking agents
- Initiators and promoters
- Molecular weight regulators
- Polymerisation inhibitors
- Redox agents

6. Overall migration limits

The restrictions on use of plastic materials and articles are given in Art. 2.

Article 2

Plastic materials and articles shall not transfer their constituents to foodstuffs in quantities exceeding 10 milligrams per square decimetre of surface area of material or article (mg/dm²) (overall migration limit). However, this limit shall be 60 milligrams of the constituents released per kilogram of foodstuff (mg/kg) in the following cases:

(a) 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 (1);

(b) Articles which can be filled and for which it is impracticable to estimate the surface area in contact with foodstuffs;

(c) Caps, gaskets, stoppers or similar devices for sealing.

This limit must not be exceeded for plastic materials and articles intended to come in contact with foodstuffs. For the method of determination of the overall migration limit, see in this Section, **paragraph 11. "Enforcement of legislation and methods of analysis"** and **"Analytical info"** in JRC website: *http://cpf.jrc.it/webpack/analytic.htm*).

The limits are expressed in different units in accordance with the different volumes of the articles. In fact, the articles having a capacity less than 0.5 litre normally contain foods consumed in low quantity and therefore result in a low exposure to the consumer. As the migration of a low amount into a low volume result in a relatively high concentration, the migration expressed in mg/dm² provides a more appropriate indication of the contamination and avoids that articles are rejected in the absence of an appreciable risk for the consumer.

The opposite refers to articles having a capacity greater than 10 litres, since even the migration of a large amount results in a low concentration. Moreover, foodstuffs contained in these articles during their storage or transport are transferred into other articles for sale and hence are subject to additional contamination by migrants. Therefore, to stop the manufacture of articles of poor quality, the units chosen in these cases are mg/dm².

7. Specific migration limits

Specific migration limits (SML) are specified for some of the substances in the lists for monomers and additives. They are based on the opinions expressed by the SCF and are obtained by multiplying the ADI/TDI values by a factor of 60 This factor is derived from the convention that a person of 60 kg daily could ingest up to 1 kg of foodstuffs in contact with a plastic article always containing the considered substance at a concentration corresponding to the SML. The Council of Europe adopted this convention in '60. Recently the Commission examined the possibility of changing this convention, since European professional organisations consider them as excessively severe. See **Chapter I, Section 3, paragraph 10.1. "Fat (Consumption) Reduction Factors"**. For the method of determination of the SML see in this Section, **paragraph 11. "Enforcement of legislation and methods of analysis"** (and annexes), **Chapter III "CEN"** and **"Analytical info"** in JRC website: *http://cpf.jrc.it/webpack/analytic.htm*).

8. Implementation of the legislation (Directives 82/711/EEC and 85/572/EEC)

8.1. Verification of compliance with the migration limits

Article 4

An incomplete list of additives, which may be used for the manufacture of plastic materials and articles, together with the restrictions and/or specifications on their use, is set out in Annex III, Sections A and B.

For the substances in Annex III, Section B, the specific migration limits are applied as from 1 January 2004 when the verification of compliance is carried out in simulant D or in test media of substitute tests as laid down in Directives 82/711/EEC and 85/572/EEC.

Article 5

1. Verification of compliance with the migration limits shall be carried out in accordance with the rules laid down in Directives 82/711/EEC [A6] and 85/572/EEC [A9] and the further provisions set out in Annex I.

2. Verification of compliance with the specific migration limits provided for in paragraph 1 shall not be compulsory, if it can be established that compliance with the overall migration limit laid down in Article 2 implies that the specific migration limits are not exceeded.

3. Verification of compliance with the specific migration limits provided in paragraph 1 shall not be compulsory, if it can be established that, by assuming complete migration of the residual substance in the material or article, it cannot exceed the specific limit of migration.

4. The verification of compliance with the specific migration limits provided for in paragraph 1 may be ensured by the determination of the quantity of a substance in the finished material or article provided that a relationship between that quantity and the value of the specific migration of the substance has been established either by an adequate experimentation or by the application of generally recognised diffusion models based on scientific evidence. To demonstrate the non-compliance of a material or article, confirmation of the estimated migration value by experimental testing is obligatory.

Annex 1

1. Where the migration tests are carried out on samples taken from the material or article or on samples manufactured for the purpose, and the quantities of foodstuff or simulant placed in contact with the sample differ from those employed in the actual conditions under which the material or article is used, the results obtained should be corrected by applying the following formula:

$$M = \frac{m.a_2}{a_1.q}.1000 \qquad (1)$$

Where:

M	is the migration in mg/kg;
m	is the mass in mg of substance released by the sample as determined by the migration test;
a_1	is the surface area in dm² of the sample in contact with the foodstuff or simulant during the migration test;
a_2	is the surface area in dm² of the material or article in real conditions of use;
q	is the quantity in grams of foodstuff in contact with the material or article in real conditions of use.

5. Where a material or article is intended to come into repeated contact with foodstuffs, the migration test(s) shall be carried out three times on a single sample in accordance with the conditions laid down in Directive 82/711/EEC using another sample of the food or simulant(s) on each occasion. Its compliance shall be checked on the basis of the level of the migration found in the third test. However, if there is conclusive proof that the level of the migration does not increase in the second and third tests and if the migration limit(s) is (are) not exceeded on the first test, no further test is necessary.

Nota bene 1
It should be stressed the difference which exists between the conditions of contact in the experimental migration tests and the conditions of contact in the real conditions. These last ones should be considered in order to assess the compliance with the restrictions in the Directive. ***Therefore, with the only exception of the cases where it is impossible to estimate the ratio S/V, it is always necessary to apply the formula described under (1) to calculate the value of migration to be compared with the SML.***

Nota bene 2
As regards the above-mentioned paragraph 5, it should be stressed that if the migration value exceeds the SML at the first attack, the migration testing should continue until the third attack as only the difference between the migration value at third and second attack shall be compared to the SML to judge the compliance of a material or article.

Various documents have been prepared or mandated by the Commission to interpret and enforce the Directives 82/711/EEC and 85/572/EEC. They are included entirely or referenced in these documents or website addresses:

- **Chapter I, Section 3, § 11. "Enforcement of legislation and methods of analysis"**
- **Chapter III "CEN"**
- **Chapter IV "Council of Europe"**
- **"Analytical info" in JRC website :** http://cpf.jrc.it/webpack/analytic.htm

However, on the request of some Member States it is necessary to add here the interpretation of the second indent of Article 4.

For the additives appearing in the EU Community list (Annex III), there are <u>two</u> different dates for the enforcement of the SML i.e.:

a) <u>As from 1 December 2002</u> (date of the application of the Directive 2001/62/EC)
- ***(i) when the plastic is in contact with any type of foodstuffs (aqueous, acidic, alcoholic and fatty) and the analysis is made in foodstuffs itself or***
- ***(ii) when the plastic is in contact with aqueous, acidic, and alcholic foodstuffs and the analysis is carried out by using the simulants A, B and C.***

b) <u>As from 1 January 2004</u> when the verification of compliance is carried out in simulant D or in test media of substitute tests as laid down in Directives 82/711/EEC and 85/572/EEC.

This means that for the substances in Annex III, Section B, the specific migration limits shall not be applied during the period 1 December 2002 – 31 December 2003 when the following two conditions exist:

a) When the plastic is in contact with a fatty food for which the simulant D is provided in Directive 85/572/EEC and

b) When the analysis is carried out in simulant D (or in its substitute).

During this period the national restrictions, if any, apply to the substances in Annex III, Section B.

<u>Note bene 2</u>
This was the compromise reached during the discussions for the preparation of the Directive 2001/16/EC ("Sixth amendment of Directive 90/128/EEC). There were two positions: the first one which required the enforcement of the SMLs in all the simulants (including the simulant D) for all the additives as from 1 December 2002. The second one required the application of the SMLs in simulant D only when the Fat (consumption) Reduction Factors" (FRF) were introduced in the Directive 85/572/EEC. The final compromise was to postpone until 1 January 2004 the enforcement of the SMLs only when simulant D is used. In fact the Commission believed that the decision on the introduction (if any) of the FRF could be taken before the 1 January 2004. This intepretation is confirmed also by recital 10 to the Directive which states:

" (10) For certain additives the restrictions established in this Directive cannot yet be applied in all situations. This is pending the collection and evaluation of all the data needed for a better estimation of consumer exposure in particular situations. Therefore, these additives appear in a separate list from additives fully regulated at Community level."

8.2. <u>Compliance with the SML through the determination of the overall migration</u>

It is possible to check the compliance with the SML through the determination of the overall migration. However the following conditions should be respected:

a) The substance having the SML should be non-volatile because the overall migration can not determine the volatile substances;

b) The value of the overall migration shall be diminished by the value 3 which is the analytical tolerance affecting conventionally any determination of the overall migration;

c) The resulting value obtained under b) shall be lower than the SML.

The term "analytical tolerance" is not a technically defined parameter such as " repeatability " or "reproducibility". It was introduced in the Directive to avoid a choice between the two mentioned parameters. It encompasses all the possible sources of imprecision or inaccuracy during sampling, treatment and analysis.

It does, however, give rise to the question of which limit should not be exceeded to ensure the compliance with the overall migration limit? The answer depends on whether a substraction is made from the value of the analytical tolerance (=3 mg/dm²) during analysis. If the factor of 3 is not substracted the limit not to be exceeded is 13 mg/dm². If the value 3 is substracted the limit to be not exceeded 10 mg/dm². It is irrelevant to the verification of compliance if the real value of the analytical tolerance is greater or less than 3.

9. Further comments on Directive 2002/72/EC [A29]

9.1 Scheme describing the step sequence to apply the Directive

A simple scheme explaining the sequence of steps involved in the application of Directive 2002/72/EC [A29] and its amendments is given overleaf.

9.2 Compliance with the Directive

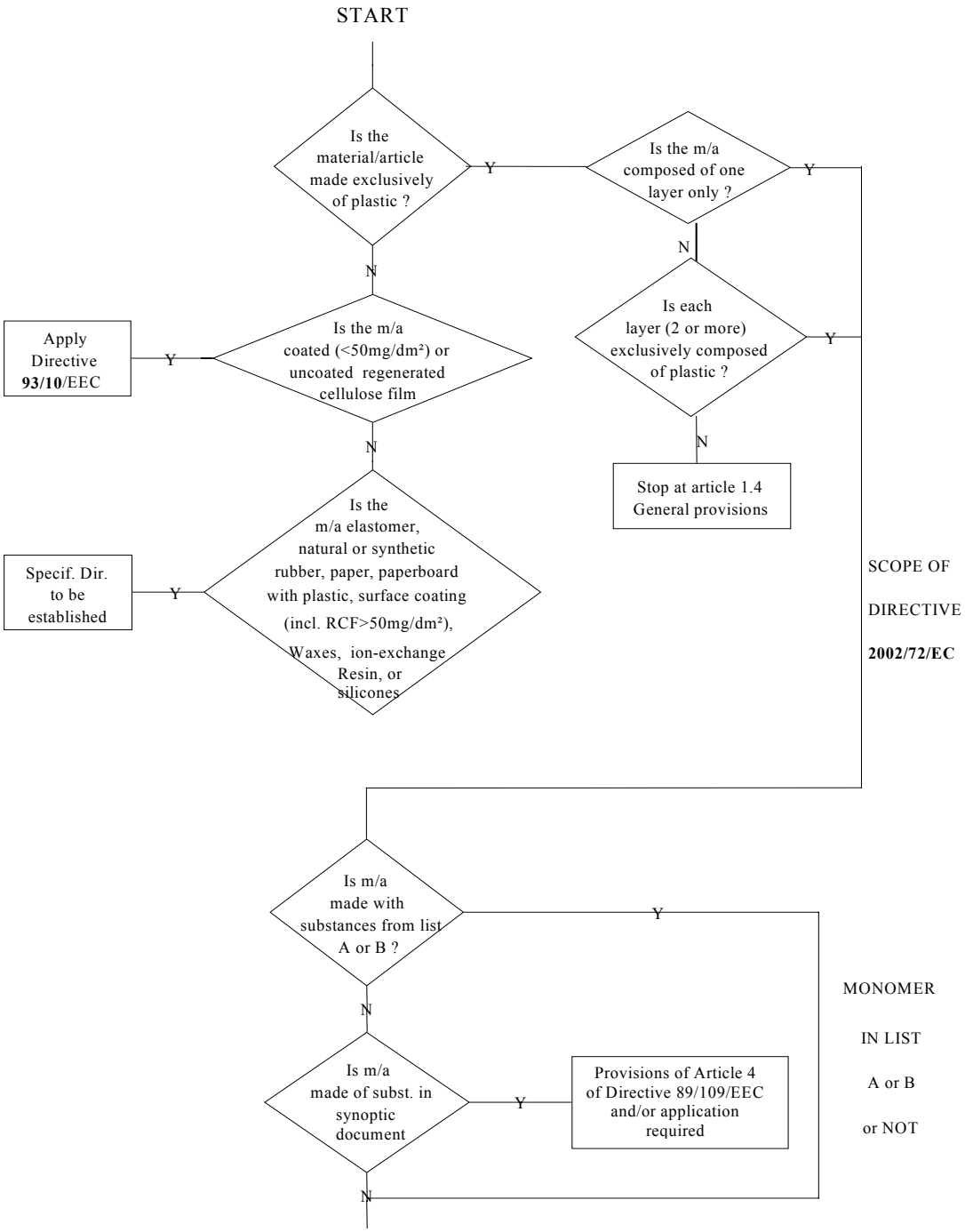
To certify compliance, it should be identified whether:

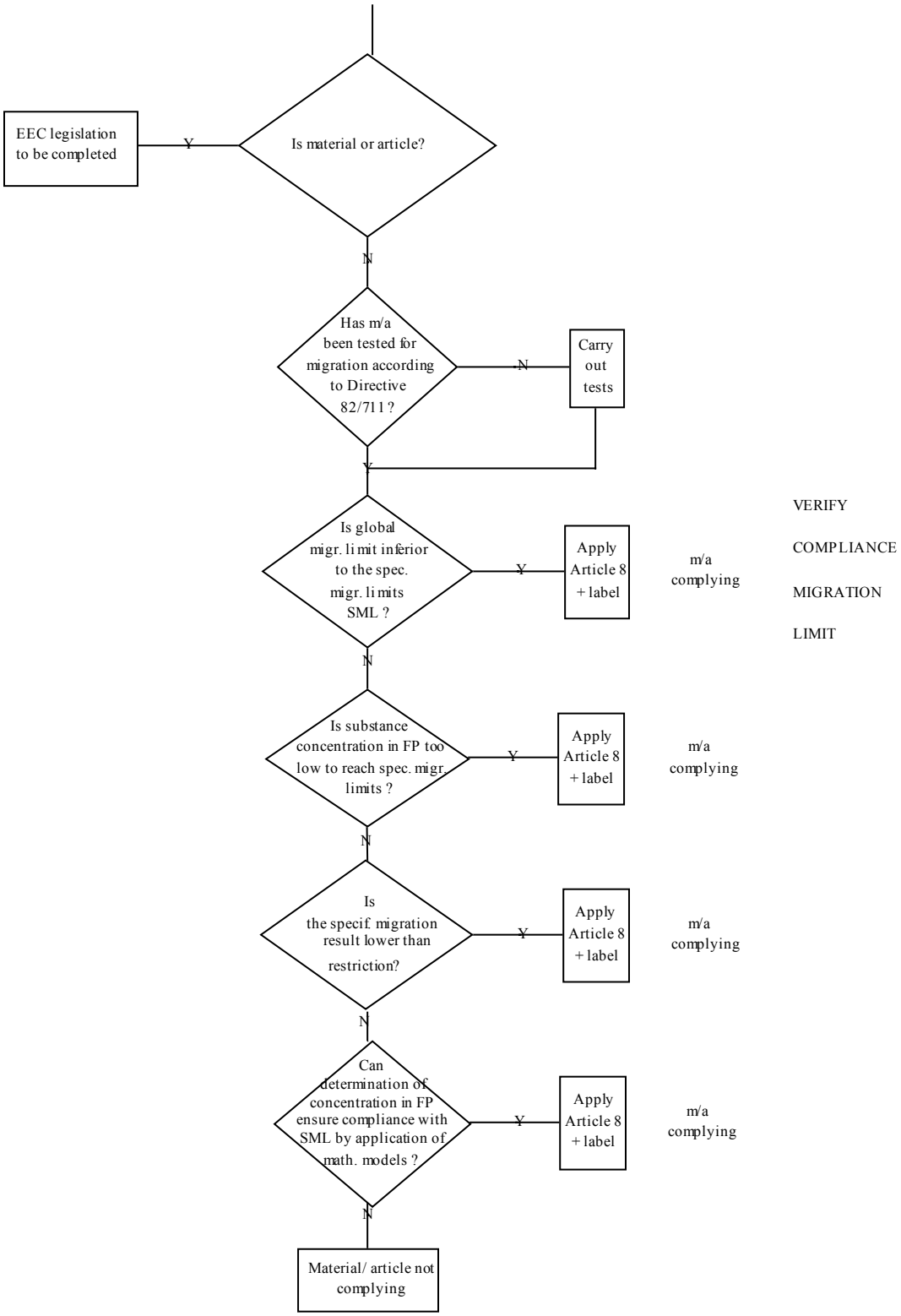
A. The plastic material or article is within the scope of the Directive according to Art 1.2. and the definitions given or whether it is beyond the scope of the Directive as indicated in Art. 1.3. and 1.4.

B. The monomer(s) and additives used to manufacture the plastic article either
   - Are contained in Sections A or B of Annex II and III to the Directive, or
   - Not or only partially contained in lists A or B, but are accepted at the national level as a new substance, in which case the provisions of Art. 4 of Directive 89/109/EEC [A11] have to be taken into account;

C. The material or article fulfils the limit of overall migration and the monomers and additives comply with SML, QM or QMA restrictions.

Procedure for complying with the provisions of Directive 2002/72/EC on plastic materials and articles in contact with foodstuffs




EEC legislation to be completed
Y
Is material or article?
N
Has m/a been tested for migration according to Directive 82/711 ?
N
Carry out tests
Y
Is global migr. limit inferior to the spec. migr. limits SML ?
Y
Apply Article 8 + label
m/a complying
N
Is substance concentration in FP too low to reach spec. migr. limits ?
Y
Apply Article 8 + label
m/a complying
N
Is the specif. migration result lower than restriction?
Y
Apply Article 8 + label
m/a complying
N
Can determination of concentration in FP ensure compliance with SML by application of math. models ?
Y
Apply Article 8 + label
m/a complying
N
Material/ article not complying
VERIFY
COMPLIANCE
MIGRATION
LIMIT

10. Other issues of EU plastic regulation

Other problems have been considered at EU level, even though there may not be specific rules on them yet. Further information on the current status of these discussions is given below.

10.1. Fat (consumption) Reduction Factor (FRF)

As a first step towards introducing consumption-related reduction factors, the European professional organisations requested that the Commission introduce a Fat (consumption) Reduction Factor (FRF). They asked that it should take into account that at least 95% of the population consumes less than 200 g of fat per day as a long term average. A task force was constituted by the Commission services to analyse the implications of the industry proposal and to propose a workable formula on which the SCF could be consulted.

In December 2002 the SCF expressed an opinion favourable to the introduction of FRFs variables from 1 to 5 in accordance with the quantity of fat) present in the fatty foodstuffs (i.e if the fat content is 20% the FRF = 1, if the fat content is 100% the FRF = 5. However the factor will only be applied to lipophilic substances in certain prescribed situations (see SCF opinion: http://europa.eu.int/comm/food/fs/sc/scf/out149_en.pdf)

During 2003, the Commission services will examine the problems raised by the SCF and by certain Member States that concern the introduction of the FRF in Directive 2002/72/EC to find a legislative solution.

10.2. Threshold of Regulation

The "Threshold of Regulation" (ToR) was introduced by the US-FDA and means a concentration of a migrating substance calculated for the whole diet (= 0.5 ppb) below which the FDA assumes that the risk for human health becomes negligible even when the substance is highly toxic. Extremely toxic compounds (e.g. carcinogens) are excluded, however.

For a compound migrating into foods in a quantity representing less than 0.5 ppb in the whole diet, the petitioner no longer needs a formal approval from the FDA. He only needs to "notify" the new substance to the FDA, accompanied by a reduced technical dossier containing:

a) The identity data of the substance;
b) The migration data;
c) A literature research on the toxicity data for the substance examined.

If there is no opposition from the FDA on the use of the substance, the latter may be marketed after 90 days. The substance is listed in a specific FDA document.

10.3 Concept of "no migration"

Repeatedly, the Commission services were requested to accept that the use of a substance, which is not detectable in food or food simulants by an "agreed sensitive analytical method", is permitted without toxicological investigation and without authorisation. This request will be re-considered in future.

10.4. Recycling for food application

Recently, an increased interest has been noted in Europe for recycled and/or reused materials in the sector of materials and articles in contact with foodstuffs. The matter will be considered during 2003.

Chemical recycling

New procedures for recovering monomers from recollected used articles have been introduced, e.g. involving depolymerization. The Commission considers that these monomers can be used as starting substances for the manufacture of plastics intended to come into contact with foodstuffs, provided they comply with the applicable EEC Directives. As regards the purity criteria of the mentioned monomers, see Directive 2002/72/EC[16].

10.5 Irradiation, microwave and other physical treatment

These specific issues are not yet considered by the Directive 82/711/EEC [A6] laying down the basic rules for testing migration properties.

11. Enforcement of legislation and methods of analysis

11.1. Enforcement of legislation on food contact materials belongs to the more general issue of enforcement of legislation on foodstuffs, and all the rules applicable to the latter are, mutatis mutandis, applicable to the former.

11.2. The main rules are those provided by the Directives 89/397/EEC, 93/99/EEC and 85/591/EEC. The references can be found in the document **"EU and national legislation"**. Other rules and guidelines can be found as regards the checking of the migration in the texts:

a) Directive 2002/72/EC, Annex 1;

b) Directive 82/711/EEC and its amendments;

c) "Commission Explanatory Guidance on Migration Testing", Chapter IV in **"Note for Guidance"**.

11.3. In the absence of binding rules at the EU level, the Member States are responsible for the enforcement of the EC Directives.

11.4. In the Annexes, guidelines are given on two problems intensely debated at EU level:

a) The use of mathematical models to replace migration testing (see Annex 1);

b) The methods recommended for the verification of the quantitative restrictions established in the Directives, such as SML, QM, QMA, OM (see Chapter III).

11.5. A short summary of an EC research is reported in Annex 2 to assist the industry and official laboratories in enforcing the legislation.

16 See Annex 2, paragraph 4.

ANNEX I

MATHEMATICAL MODELS

1. Directive 2002/72/EC, Article 5, paragraph 4, provides the following clause:

The verification of compliance with the specific migration limits provided for in paragraph 1 may be ensured by the determination of the quantity of a substance in the finished material or article provided that a relationship between that quantity and the value of the specific migration of the substance has been established either by an adequate experimentation or **by the application of generally recognised diffusion models based on scientific evidence**. To demonstrate the non-compliance of a material or article, confirmation of the estimated migration value by experimental testing is obligatory.

2. A research project subventioned by the Commission (DG Research) has established the mathematical equations to be applied and the conditions for their application. The appendix 1 describes the result of this research.

3. Commission guidelines

The Commission recommends to the enforcement authorities the application, when appropriate, of the "modelling", as a tool to avoid very long and expensive analysis. However it reminds also that if there is discrepancy between the results obtained by experimental testing and by application of a generally recognised diffusion model, the judgement for compliance should be based on the experimental results.

Nota bene

Even if there is only a very low probability that the results of the experimental testing exceed the value obtained by the application of the "modelling", any person that noted this discrepancy are invited to inform the Commission.

APPENDIX 1 TO ANNEX I

ESTIMATION OF MIGRATION BY GENERALLY RECOGNISED DIFFUSION MODELS IN SUPPORT OF EU DIRECTIVE 2002/72/EC

('Migration modelling')

This document contains the conclusions of the European project SMT-CT98-7513
'*Evaluation of Migration Models in Support of Directive 90/128/EEC*'
(now 2002/72/EC)

Contents

1 Introduction

To check the compliance of a polymeric food contact material with the existing EU/EC regulations specific and overall migration tests shall be carried out using the food simulants under the test conditions specified in the Directive 97/48/EC. On the other hand, the experimental determination of the specific migration into food (food simulants) requires a considerable amount of time and is even in many cases impossible due to technical/analytical problems, chemical degradation/volatilisation of the migrant or non-availability of corresponding analytical methods.

Numerous scientific investigations have demonstrated during the last two decades that migration from food contact materials into food and food simulants are foreseeable physical processes. Mass transfer from a plastic material into foodstuffs is predictable and obeys in most cases to Fick´s laws of diffusion. Hence, in addition to the abovementioned alternative experimental methods a new alternative tool appears based on theoretical migration estimations. In fact, whereas modelling of potential migration has been used in the United States as an additional tool in support of regulatory decisions since several years, the European Union has introduced this tool recently with EU Directive 2001/62/EC (the 6th amendment of Directive 90/128/EEC) as a conformity and quality assurance tool. Article 5 of this Directive is amended by the following paragraph:

> *The verification of compliance with the specific migration limits provided for in paragraph 1 may be ensured by the determination of the quantity of a substance in the finished material or article, provided that a relationship between that quantity and the value of the specific migration of the substance has been established either by an adequate experimentation or by the application of generally recognised diffusion models based on scientific evidence. To demonstrate the non-compliance of a material or article, confirmation of the estimated migration value by experimental testing is obligatory.*

A generally recognised model must be based on scientific evidence.

The realisation of this requirement which is a great scientific challenge due to the enormous complexity and variety of polymer and chemical structures involved has been recently finished within the European project SMT-CT98-7513 '*Evaluation of Migration Models in Support of Directive 2002/72/EC'*.

The major objectives of this project were

(i) To demonstrate that a correspondence between the specific migration limit (SML) and a permitted maximum initial concentration (MIC) of a substance in the finished product can be established and

(ii) To establish documentation that demonstrates the validity of underlying migration models for compliance purposes.

The final report of this project has been recently finalised /1/ and a presentation of the project results will be published in a scientific journal from the field /2/.

The practical consequences of introducing migration modelling as a novel tool for migration evaluation are not completely overseeable at this moment due to the inherent novelty character. However, one of the foreseeable advantages of migration modelling is that it will allow high speed computer-aided access to upperbound migration values independent of analytical limitations and manage any given individual food packaging system (geometry, ratio mass/contact area, shelf life etc.). Moreover, migration modelling is completely

insensitive to chemical degradation and reactivity or physical volatilisation of test migrants as occuring in real migration testing. It can therefore not only be used for plausability considerations with respect to the extent and amplitude of obtained migration results but also for identification of otherwise hardly detectable false-negative test results. Consequently, migration modelling offers not only a very economic approach for industry for taking quick decisions in relation to packaging development and design but also to surveillance laboratories who have quick and may be unique access to otherwise inaccessible migrational evaluation informations. The conclusions of the thematic network take into account both industrial and legal requirements as well as scientific considerations.

The aim of this document is to describe the results on an upperbound migration prediction as an outcome from the above mentioned EU project and to assist the possible users of the described model by providing sufficient explanatory guidance, tables, practical examples and an experimental procedure for verification purposes. According to the current state-of-the-art, the scope and applicability of migration prediction comprises the mass transfer of migrants listed in Annex A and other organic substances from packaging polymers mentioned in this report when in contact with food simulants according to Directive 97/48/EU. The above list is derived from reference /13/.

However, it should be noted that the procedure described in Annex B offers a possibility to expand the scope also to other polymers or polymer modifications.
Further reading can be found in the bibliographic references.

2 Migration modelling

Currently existing predictive mathematical models for migration estimation are essentially based on diffusion theory and consideration of partitioning effects. The underlying key parameters are the diffusion coefficient of the migrant in the plastic D_P as well as the partition coefficient of the migrant between the plastic and the food (simulant) $K_{P,F}$. Although these models are still under further scientific discussion, refinement or development, they provide an estimation of worse case migration scenarios for monolayer, homogeneous materials, and without any modification in time and interaction with food. One of these models has been used in an approach to predict upperbound migration values, which has been validated within the EU project SMT-CT98-7513 /1, 2/. It is based on some general requirements (see 2.1) and is designed such that it enables migration prediction with sufficient safety margins.
A list of chemical substances, which includes monomers and other starting substances as well as additives from the European positive list for plastics intended to come into contact with foodstuffs is given in Annex A of this report /13/.

2.1 General scientific considerations

Theoretical specific migration estimations can only be accepted on a case by case basis using scientific evidence. A useful model for many situations occurring in food contact material is based on following general requirements.

1. In most cases of practical relevance a plastic food contact material or article (monolayer, homogenous) (P), can be regarded as a polymer film/sheet, of finite and constant thickness (d_P) being in contact with a food or food simulant (F), of finite volume (V_F).

2. It is assumed that during the manufacturing process of P the migrant is distributed homogeneously in P.

3. It is assumed that there is no boundary resistance for the transfer of the migrant between P and F.

4. It is assumed that the interaction between P and F is negligible and no swelling of P by uptake of F occurs during the migration process.

5. A partition coefficient between food and polymer is assumed and defined as

$$K_{P,F} = \frac{c_{P,\infty}}{c_{F,\infty}} \frac{\rho_P}{\rho_F}$$

6. The migrant is homogeneously distributed in F. The sum total amount of the migrant in P and F is constant during the migration process.

7. The diffusion equation - also known as Fick's 2nd equation - describing a migration process corresponding to the general requirements 1 to 5 is /3/:

$$\frac{\partial c}{\partial t} = D_P \frac{\partial^2 c}{\partial x^2} \qquad (1)$$

where: c is the concentration of migrant in the food contact material or article (P) at time t at distance x from the origin of the x-axis and Dp is the constant diffusion coefficient in the food contact material or article.

8. With requirements from 1 to 5 the analytical solution of Eq (1) is Eq (2) /3/:

$$\frac{m_{F,t}}{A} = 0.1 c_{P,0} \rho_P d_P \left(\frac{\alpha}{1+\alpha}\right)\left[1 - \sum_{n=1}^{\infty} \frac{2\alpha(1+\alpha)}{1+\alpha+\alpha^2 q_n^2} \exp\left(-D_P t \frac{q_n^2}{d_P^2}\right)\right] \qquad (2)$$

where: $\alpha = \frac{1}{K_{P,F}} \frac{V_F}{V_P} = \frac{c_{F,\infty}}{c_{P,\infty}} \frac{\rho_F}{\rho_P} \frac{V_F}{V_P}$ $\qquad$ $K_{P,F} = \frac{c_{P,\infty}}{c_{F,\infty}} \frac{\rho_P}{\rho_F}$

and respectively

$$\tan q_n = -\alpha\ q_n \qquad (2^*)$$

where: $m_{F,t}$ - mass of migrant from P into F after time t, (mg)
A - area of P in contact with F , (dm^2)
$c_{P,0}$ - initial concentration of migrant in P, (mg/kg)
ρ_P - density of P, (g/cm^3)
ρ_F - density of F, (g/cm^3)
D_p - diffusion coefficient of migrant in P, (cm^2/s)
t - migration time, (s)
d_P - thickness of P, (cm)
V_P - volume of P, (cm^3)
V_F - volume of F, (cm^3)
$c_{P,\infty}$ - equilibrium concentration of migrant in P (mg/kg)
$c_{F,\infty}$ - equilibrium concentration of migrant in F (mg/kg)
$K_{P/F}$ - the partition coefficient of the migrant between P and F
q_n - the non-zero, positive roots of equation (2*)

(9) Equation (2) can be rearranged to give equation (3), which can be used to estimate the maximum initial concentration of migrant (MIC) in the food contact material or article.

$$MIC = \frac{SML}{100}\frac{V_F}{A}\frac{\rho_F}{}\left\{\rho_P d_P\left(\frac{\alpha}{1+\alpha}\right)\left[1-\sum_{n=1}^{\infty}\frac{2\alpha(1+\alpha)}{1+\alpha+\alpha^2 q_n^2}\exp\left(-D_P t\frac{q_n^2}{d_P^2}\right)\right]\right\}^{-1} \qquad (3)$$

where: all parameters as for equation (2) apply, except
SML - Specific Migration Limit, (mg/kg)
MIC - maximum initial concentration in P, (mg/kg).

2.2 Migration estimation

As mentioned above the key parameters necessary for migration modelling are the diffusion coefficient of the migrant in the plastic, D_P, as well as the partition coefficient of the migrant between the plastic and the food (simulant), $K_{P,F}$. Both parameters play a crucial role in determining the level of migration in a real food packaging application /4, 5/. Due to a lack of knowledge of the exact values in any specific case, it is recommended to establish these values in more generalized and conservative way so that reliably worst case scenarios with respect to migration are estimated which, in fact, is of primary interest from regulatory stand point. To meet this requirement the described migration model has the two following implications:

1. In absence of specific data, the partition coefficient of the migrant between the polymeric material and the food can be taken as $K_{P,F} = 1$ when the substance is well soluble in food ; this option leads to the highest migration values. For all other cases, that means where the migrant is not soluble in food and/or food simulants, one can take $K_{P,F} = 1000$. Deviation from these values could strongly influence the estimated migration values. If experimental $K_{P,F}$ values are available they shall be used.

2. The actual diffusion coefficient D_P of a migrant in a polymer matrix can be replaced with a polymer specific upperbound diffusion coefficient, D_P^*. Using such a D_P^* for migration estimations leads to "worst case" values. From phenomenologic derivations and a statistical evaluation of experimental diffusion and migration data /6/ D_P^* can be estimated by the following Eq. (4) /5/:

$$D_P^* = 10^4 \exp\left[A_P - 0.1351 M_r^{2/3} + 0.003 M_r - \frac{10454}{T} \right] (\mathrm{cm^2/s}) \qquad (4)$$

where: $A_P = A_P^{'} - \frac{\tau}{T}$ (5)

where: M_r : relative molecular mass of migrant in Dalton
T : temperature, K
A'_p : a polymer specific "diffusion conductance" parameter
τ : a polymer specific "activation energy" parameter

3 Polymer specific migration modelling

From equation (4) it can be recognised that there are key variables which determine the diffusion in a polymer. Two of them are not linked to the polymer and are the relative molecular mass of the migrant, M_r, and the absolute temperature, T, respectively.

The third parameter, the A_P value, is linked to the polymer and describes the basic diffusion behaviour or a „conductance" of the polymer matrix towards the diffusion of migrants. Higher values of A_P in such polymers as PE lead to increased D_P^* values and increasing migration while in stiff chain polymers such as polyesters and polystyrenes lower A_P values account for smaller diffusion coefficients for the same migrant and lower migration.

In the following, the requirements for polymer specific migration modelling are described.

In this context it must be stressed that for polyolefines (PO), the experts participating to the European project SMT-CT98-7513 'Evaluation of Migration Models in Support of Directive 2002/72/EC' agreed to consider the prediction tool fully validated on the basis of the large number of consistent results.

For PC and PVC, the abovementioned experts in the same meeting (Brussels, March 26-27, 2001) considered that the data are « insufficient to create a reliable set of parameters for migration modelling ».

Moreover, the majority of the abovementioned experts agreed on the following : «Although, much less data are available for the non-PO (like PS, HIPS, PET, PEN, PA) compared to PO, the basis has been considered sufficiently solid due to the fact that well defined migration

experiments have been selected, which have been performed in recent years by internationally recognised laboratories . For the non-PO samples covering the market situation at present date, it could be shown that these equations overestimate the experimental migration values. »

3.1 Polyolefines

The polyolefines (PO) used for food packaging are: low density polyethylenes (LDPE and LLDPE), high density polyethylene (HDPE) and various types of polypropylenes (PP-random, PP-homo and PP-rubber). The copolymers with non-olefinic monomers (eg acrylics, vinylics, etc) are not yet evaluated. Using product knowledge of these PO's, the temperature range for the applicability of migration modelling, as required by the general requirements given before, is listed in Table 3.1.1. In these cases the migration process in PO's follows the generally accepted physical law of diffusion (Eq. 1) with the solution given in Eq. (2).

Table 3.1.1 Parameter ranges for the applicability of the migration model for selected PO.

Polymer	**T (^{o}C)**	**$c_{P,0}$ (%)**	**$K_{P/F}$**
LDPE	< 80	< 1.0 for all PO	1 for high solubility of migrant in food, 1000 for low solubility of migrant in food for all selected PO's
LLDPE	< 100		
HDPE	< 90		
PP (homo)	< 120		
PP (random)	< 120		
PP (rubber)	< 100		

For the above PO's the actual values of A'_p and τ from Eq. (5) have been determined empirically using a data base consisting of more than 600 well defined diffusion experiments reported in the literature over the last four decades /6/ (Table 3.1.2). Using these values of A'_P and τ in Eqs. (4) and (5) produces "upper limit" diffusion coefficients, D_P^* , which lead to an overestimation of the 95% of the diffusion coefficients available within the current database /7, 8/.

Table 3.1.2 Parameters for selected Polyolefins

Polymer	**A'_p**	**τ**
LDPE/LLDPE	11.5	0
HDPE	14.5	1577
PP (homo and random)	13.1	1577
PP (rubber)	11.5	0

3.2 Polystyrenes

Polystyrenes used for food packaging applications are general purpose polystyrene (PS) and high impact polystyrene (HIPS). Using product knowledge of these polymers the temperature range for the applicability of migration modelling, as required by the general requirements given before, is listed in Table 3.2.1. In these cases the migration process in PS's follows the generally accepted physical law of diffusion, Eq. (1), with the solution given in Eq. (2).

Table 3.2.1 Ranges of parameters for the applicability of the migration model for PS and respectively HIPS.

Polymer	**T (^oC)**	**$c_{P,0}$ (%)**	**$K_{P/F}$**
PS	< 70	< 1 for all PS	1 for high solubility of migrant in food, 1000 for low solubility of migrant in food
HIPS	< 70		

For PS and HIPS the actual values of A'_p and τ could be determined empirically from the data base of diffusion coefficients and verified by well defined migration experiments reported in recent years by internationally recognized laboratories /1, 2/. Applying these values of A'_P and τ (see table 3.2.2) in Eqs. (4) and (5) results in "upper limit" diffusion coefficients, D_P^*. These D_P^* when introduced in Eq. 2, lead to overestimations (in most cases largely) of the experimental migration data available.

Table 3.2.2: Parameters for PS and HIPS

Polymer	**A'_p**	**τ**
PS	0	0
HIPS	1.0	0

3.3 Polyesters

The polyesters used for food packaging applications are polyethylene therephthalate (PET), polybutylene therephthalate (PBT) and polyethylene naphthalate (PEN). Using product knowledge of these polyesters the temperature range for the applicability of migration modelling, as required by the general requirements given before, is listed in Table 3.3.1. In these cases the migration process in these polyesters follows the generally accepted physical law of diffusion, Eq. (1), with the solution given in Eq. (2).

Table 3.3.1. Ranges of parameters for the applicability of the migration model for PET and PEN.

Polymer	**T (^oC)**	**$c_{P,0}$ (%)**	**$K_{P/F}$**
PET	< 175	< 1 for all Polyesters	1 for high solubility of migrant in food, 1000 for low solubility of migrant in food
PEN	< 175		

For PET and PEN the actual values of A'_p and τ from Eq. (5) were determined empirically using migration data from well defined migration experiments reported in recent years by internationally recognized laboratories /1, 2/. Using these values of A'_P and τ (see table 3.3.2) in Eqs. (4) and (5) results in "upper limit" diffusion coefficients, D_P^*, which, introduced in Eq. (2), lead to overestimations (in most cases largely) of the experimental migration data.

Table 3.3.2: Parameters for PET and PEN

Polymer	A'_p	τ
PET	6.0	1577
PEN	5.0	1577

3.4 Polyamides 6,6

For polyamide only few data are available both for diffusion coefficients and migration. Furthermore, the relative humidity can strongly influence the mechanism of the transfer. Pending new data the value reported in Table 3.4.1 can be a first tool to estimate migration.

Table 3.4.1. Ranges of parameters for the applicability of the migration model for PA 6,6.

Polymer	T (^oC)	$c_{P,0}$ (%)	$K_{P/F}$
PA 6,6	< 100	< 1	1

For PA 6,6 the actual values of A'_p and τ from Eq. (5) were determined empirically using migration data from well defined migration experiments reported in recent years by internationally recognized laboratories /1, 2/. Using these values of A'_P and τ (see table 3.4.2) in Eqs. (4) and (5) results in "upper limit" diffusion coefficients, D_P^* , which, introduced in Eq. (2), lead to overestimations (in most cases largely) of the migration database values.

Table 3.4.2: Parameters for PA

Polymer	A'_p	τ
PA	2.0	0

3.5 Other polymers

Besides the polymers described above other packaging polymers or polymer modifications can be found on the market and, in addition, new polymer developments may be developed. In principal, migration modelling is also applicable to those polymers for migrants listed in Annex A or other organic chemical substances. In those cases, the procedure described in Annex B can be applied to establish experimentally the relationship between the initial concentration of a migrant in a polymer and its specific migration or with other words the basic diffusivity of the polymer expressed as the polymer specific A_P value.

4 Procedures, practical applications and examples

For migration modelling as described above corresponding home made computer programs may be established and applied. For conveniency reasons, it should be noted that a specifically tailored and userfriendly computer program is available on the market (MIGRATEST Lite 2001, FABES GmbH Munich, Germany) or can be freely downloaded from the internet (SMEWISE, INRA Reims, France at:

http://www.inra.fr/Internet/Produits/securite-emballage)

Two principal procedures can be followed with the model:

(i) Based on knowledge of the existing initial concentration of a migrant of known molecular weight in a polymer its specific time and temperature dependent migration into a given food simulant or food can be calculated from Eq. (2).

(ii) Reversely, based on a given migration limit or SML value, the maximum initial concentration (MIC) of a migrant of known molecular weight in a polymer that can be used in a food contact can be estimated from Eq (3).

As a general rule: In cases where the migration estimation scheme outlined above leads to results which are above the legal limits (SML), an experimental test of compliance is compulsory. In case of doubt or that the polymer specific A'_P value is not known or applicable from the tables given in paragraph 3, a kinetic study should be carried out as described in the procedure given in Annex B to establish the Q versus SM relationship /10/.

4.1 Compliance testing of substances with specific migration limits (SML)

One major objective of this report is to give guidance for compliance testing. Consequently, one major field of application is concerned with the control of substances found in the positive lists of the Directive 2002/72/EC. From the many compounds listed, all the substances were extracted which can be considered to fulfil the assumptions in the foregoing paragraphs /13/. That means for example, only organic compounds, soluble in the polymeric matrix are considered and all the external applicable additives, as antistatics, lubricants, etc. are excluded for modelling. In addition, all the electrolytes, salts, oxides, metals, are excluded, and only compounds with well defined molecular weight or mixtures with well defined ranges of molecular weights are considered. But even with this selection criteria, a considerable number of compounds remains.

It must be emphasised that at the present stage of knowledge the migration model is suitable for polymers in paragraph 3. The Annex A lists the compounds considered for migration modelling extracted from the Directive 2002/72/EC and its amendments. Therefore this list is a useful reference for those users, who need or desire to perform estimations without any uncertainty in the right selection of the appropriate parameters. In fact, under these conditions the problem of swelling is not relevant because it is inherently included in the model. It must be underlined that the model cannot be used for migration predictions in iso-octane or other test media with a high swelling power. In such cases it is recommended to consider reference /9/. Moreover, the problem of blooming is not relevant because substances, which are accumulated at the surface of the plastic article are not listed in Annex A.

Finally it should be noted that by using Eq.(3) a value for the maximum initial concentration (MIC) of a migrant in P can be estimated for which a specific migration limit (SML) for an additive cannot be exceeded.

4.2 Optimising compliance control

Migration models can be used to optimise compliance control strategies. In fact there is an infinite variety of packages to be tested, with different geometry, size, type and thickness of polymer, food, shelf life of food, temperature etc and the effort to check all these influences is huge. By using the migration model one can find out relatively easily the worst case system, (covering all the less severe situations) and then reduce the experimental migration measurement just to those cases or samples where it is possible to be in non-compliance at all. In order to find this system, one can use the equations and parameters given above (see paragraphs 2 and 3).

Having the experimental result from one selected test, all the different conditions and parameters, as mentioned above, are then modelled without a supplementary experimental test. In this manner a significant increase of the quality assurance is possible with many samples controlled during the same time compared to one experiment without the additional tool of modelling. Of course, the nature of the plastic material must be known as well as the initial concentration of the concerned migrant (known or disclosed by producer or experimentally tested). If not, a reasonable upper limit can be used.

Models must be applied properly. That means the results obtained by modelling can be only as good as the assumptions of the model are fulfilled. If it cannot be assumed that the concerned sample is a polymer as specified in table 2 or 3, the model is not properly applied. In this case a quick kinetic study can be recommended as proposed in the procedure described in Annex B.

Crucial questions for enforcement laboratories in connection with compliance control, especially on the retail market, are: *Which migrateable compounds (additives, rest-monomers) are present in the objects to control? What substances from the positive list can be used in practice in PO?* This, however, is not a specific issue of modelling, but represents an inherent requirement to any control lab. It is not so uncommon that no knowledge about the manufacture of the material exists from the producer, but is indeed impossible to test all substances from the positive lists with SML values < 60 mg/kg. Following the traditional experimental way, several analyses often with different techniques (MS/GC, MS/HPLC, FTIR) should be performed to try to identify the components in the materials; in this situation, migration models can help to restrict the number of experimental analyses /11/.

It is well known that for a given polymer only a very limited number of substances from the positive lists in the Directive 2002/72/EC and their Amendments are used. In the following tables 4.2.1 (PO) and 4.2.2 (non-PO) some of such substances are extracted from the table in Annex A. These tables were prepared by consulting the most important producers of plastic materials and the newest secondary literature referring additives for plastic materials /12/. In addition to the identification numbers the upper limits of initial concentrations claimed to be used in materials and articles for food contact are shown. Nevertheless, as fully specified in reference /13/ this table should be considered only as an example to offer a first guide in selecting specific additives if no other information is available about the composition of a sample to be tested

Table 4.2.1 PM/REF-numbers, chemical names, M_r-, SML-values and highest concentrations, $C_{P,0}$ of some additives usually used in polyolefines.

PM/ REF	Chemical name	M_r	SML (mg/kg)	$C_{P,0}$ (%)
38560	2,5-bis(5-tert-butyl-2-benzoxazolyl)thiophene	431	0.6	
38800	N,N'-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionyl)-hydrazide	553	15	HDPE 0.2
38820	Bis(2,4-di-tert-butylphenyl)penta-erythritol diphosphite	605	0.6	PP 0.1; LDPE 0.06
38840	Bis(2,4-dicumylphenyl)pentaerythritol diphosphite	853	5	LDPE 0.06
39890	Bis(methylbenzylidene) sorbitol	386	60	
46480	Dibenzylidene sorbitol	358	60	
46640	2,6-Di-tert-butyl-p-cresol (BHT)	220	3	PP 0.2
48640	2,4-Dihydroxybenzophenone	214	6	
48720	4,4'-Dihydroxybenzophenone	214	6	
48880	2,2'-Dihydroxy-4-methoxy benzophenone	244	6	
53670	Ethylenglycol-bis(3,3-bis(3-tert-butyl-4-hydroxyphenyl)butyrate)	795	6	PP 0.2; HDPE 0.1
54300	2,2'-Ethylidene-bis(4,6-di-tert-butyl-phenyl)-fluorophosphonite	487	6	PP 0.1; LDPE 0.06
60320	2-(2-Hydroxy-3,5-bis(1,1-dimethylbenz-yl)phenyl)benzo-triazole	448	1.5	
60400	2-(2'-Hydroxy-3'-tert-butyl-5'-methyl-phenyl)-5-chlorobenzotriazole	316	30	PP 0.4; HDPE 0.3
60480	2-(2'-Hydroxy-3,5'-di-tert-butylphenyl)-5-chlorobenzotriazole	358	30	PP 0.5
61600	2-Hydroxy-4-n-octylbenzophenone	326	6	PP 0.5; HDPE 0.3; LDPE 0.5
68320	Octadecyl 3-(3,5-di-tert-butyl-4-hydroxy-phenyl)propionate	531	6	PP 0.2; HDPE 0.1; LDPE 0.3
71680	Pentaerythritol tetrakis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionate]	1178	60	PP 0.2; HDPE 0.25; LDPE 0.03
74010	Phosphorous acid, bis(2,4-di-tert-butyl-6-methylphenyl) ethyl ester	514	5	PP 0.1; HDPE 0.05; LDPE 0.06
74240	Phosphorous acid, tris(2,4-di-tert-butylphenyl)ester	647	60	PP 0.1; HDPE 0.5; LDPE 0.12
80480	Poly(6-morpholino-1,3,5-triazine-2,4-diyl)-[(2,2,6,6-tertamethyl-4-piperidyl)imino]-hexamethylene-[(2,2,6,6-tertamethyl-4-piperidyl)-imino]	2600 -	1.8	PP 0.5
81200	Poly[6-[(1,1,3,3-tetramethylbutyl)-amino]-1,3,5-triazine-2,4-diyl]-[(2,2,6,6-tertamethyl-4-piperidyl)imino]-hexamethylene-[(2,2,6,6-tertamethyl-4-piperidyl)imino]	2000-3100	3	PP 0.5; HDPE 0.2; LDPE 0.5
81220	Poly-[[6-[N-(2,2,6,6-tetramethyl-4-piperidinyl)-n-butylamino]-1,3,5-triazine-2,4-diyl][(2,2,6,6-tetramethyl-4-piperidinyl)imino]-1,6-hexanediyl[(2,2,6,6-tetramethyl-4-piperidinyl)imino]]-alpha-[N,N,N',N'-tetrabutyl-N''-(2,2,6,6-tetramethyl-4-piperidinyl)-N''-[6-(2,2,6,6-tetramethyl-4-piperidinylamino)-hexyl]-[1,3,5-triazine-2,4,6-	2600-3400	5	PP 0.2; HDPE 0.1; LDPE 0.1

	triamine]-omega-N,N,N',N'-tetrabutyl-1,3,5-triazine-2,4-diamine]			
83595	Reaction product of di-tert-butyl phosphonite with biphenyl, obtained by condensation of 2,4 di-tert-butylphenol with Friedel-Crafts reaction product of phosphorus trichloride and biphenyl	991	18	PP 0.1; HDPE 0.05 ; LDPE 0.06
92880	Thiodiethanol-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate)	643	2.4	
93120	Thiodipropionic acid, didodecyl ester	515	5	PP 0.1 – 0.5
93280	Thiodipropionic acid, dioctadecyl ester	683	5	PP 0.5
93520	Alpha-Tocopherol	431	60	
94960	1,1,1-Trimethylol-propane	134	6	
95200	1,3,5-Trimethyl-2,4,6-tris(3,5-di-tert-butyl-4-hydroxybenzyl)benzene	775	60	PP 0.2; HDPE 0.1
95270	2,4,6-Tris(tert-butyl)phenyl 2-butyl-2-ethyl-1,3-propanediol phosphite	450	2	HDPE 0.05;LDPE 0.06
95360	1,3,5-Tris(3,5-di-tert-butyl-4-hydroxybenzyl)-1,3,5-triazine-2,4,6-(1H,3H,5H)-trione	784	5	PP 0.1; HDPE 0.1
95600	1,1,3-Tris(2-methyl-4-hydroxy-5-tert-butylphenyl) butane	545	5	PE 0.1

Table 4.2.2 PM/REF-numbers, names, Mr-, SML-values and highest concentrations, CP,0 of some additives usually used in some non-polyolefines

PM/ REF	**1.1. Chemical name**	**M_r**	**SML (mg/kg)**	**$C_{P,0}$ (%)**
1.2.				
40020	2,4-Bis(octylthiomethyl)-6-methyl-phenol	425	6	0.2
61440	2-(2;-Hydroxy-5'-methylphenyl)benzotri-azole	225	30	0.25
61600	2-Hydroxy-4-n-octylbenzophenone	326	6	0.2
68320	Octadecyl 3-(3,5-di-tert-butyl-4-hydroxy-phenyl)propionate	531	6	0.15
74240	Phosphorous acid, tris(2,4-di-tert-butylphenyl)ester	646	60	0.2
83595	Reaction product of di-tert-butyl phosphonite with biphenyl, obtained by condensation of 2,4 di-tert-butylphenol with Friedel-Crafts reaction product of phosphorus trichloride and biphenyl	595	18	0.2
94400	Triethyleneglycol-bis[3-(3-tert-butyl-4-hydroxy-5-methylphenyl) propionate]	587	18	0.2
95600	1,1,3-Tris(2-methyl-4-hydroxy-5-tert-butylphenyl) butane	545	5	0.2

1.3.				
31520	Acrylic acid, 2-tert-butyl-6-(3-tert-butyl-2-hydroxy-5-methylbenzyl)-4-methyl-phenyl ester	395	6	0.5
38560	2,5-bis(5-tert-butyl-2-benzoxazolyl)thiophene	431	0.6	0.05
40000	2,4-Bis(octylmercapto)-6-(4-hydroxy-3,5-di-tert-butylanilino)-1,3,5-triazine	589	30	0.1
40020	2,4-Bis(octylthiomethyl)-6-methyl-phenol	425	6	0.2
61440	2-(2;-Hydroxy-5'-methylphenyl)benzotri-azole	225	30	0.4
68320	Octadecyl 3-(3,5-di-tert-butyl-4-hydroxy-phenyl)propionate	531	6	0.5
94400	Triethyleneglycol-bis[3-(3-tert-butyl-4-hydroxy-5-methylphenyl) propionate]	587	3	0.04
1.4.				
51700	2-(4,6Diphenyl-1,3,5-triazin-2-yl)-5-(hexyloxy)phenol)	425	0.05	0.5
60320	2-(2-Hydroxy-3,5-bis(1,1-dimethylbenz-yl)phenyl)benzo-triazole	448	1.5	0.5
71680	Pentaerythritol tetrakis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionate]	1178	60	0.1
74240	Phosphorous acid, tris(2,4-di-tert-butylphenyl)ester	647	60	0.1
94400	Triethyleneglycol-bis[3-(3-tert-butyl-4-hydroxy-5-methylphenyl) propionate]	587	3	0.1
1.5.				
51700	2-(4,6Diphenyl-1,3,5-triazin-2-yl)-5-(hexyloxy)phenol)	425	0.05	0.2
60320	2-(2-Hydroxy-3,5-bis(1,1-dimethylbenz-yl)phenyl)benzo-triazole	448	1.5	0.2
60480	2,2'-Methylenebis(4-methyl-6-tert-butyl-phenol)	358	30	0.2
71680	Pentaerythritol tetrakis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionate]	1178	60	0.08
1.6.				
38820	Bis(2,4-di-tert-butylphenyl)penta-erythritol diphosphite	605	0.6	0.125
53200	2-Ethoxy-2'-ethyloxanilide	312	30	0.5

59120	1,6-Hexamethylene-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionamide	637	45	0.5
60320	2-(2-Hydroxy-3,5-bis(1,1-dimethylbenz-yl)phenyl)benzo-triazole	448	1.5	0.5
60480	2,2'-Methylenebis(4-methyl-6-tert-butyl-phenol)	358	30	0.5
68320	Octadecyl 3-(3,5-di-tert-butyl-4-hydroxy-phenyl)propionate	531	6	0.5
71680	Pentaerythritol tetrakis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionate]	1178	60	0.5
74240	Phosphorous acid, tris(2,4-di-tert-butylphenyl)ester	647	60	0.5
81200	Poly[6-[(1,1,3,3-tetramethylbutyl)-amino]-1,3,5-triazine-2,4-diyl]-[(2,2,6,6-tertamethyl-4-piperidyl)imino]-hexamethylene-[(2,2,6,6-tertamethyl-4-piperidyl)imino]	2000-3100	3	0.5
81220	Poly-[[6-[N-(2,2,6,6-tetramethyl-4-piperidinyl)-n-butylamino]-1,3,5-triazine-2,4-diyl][(2,2,6,6-tetramethyl-4-piperidinyl)imino]-1,6-hexanediyl[(2,2,6,6-tetramethyl-4-piperidinyl)imino]]-alpha-[N,N,N',N'-tetrabutyl-N''-(2,2,6,6-tetramethyl-4-piperidinyl)-N''-[6-(2,2,6,6-tetramethyl-4-piperidinylamino)-hexyl]-[1,3,5-triazine-2,4,6-triamine]-omega-N,N,N',N'-tetrabutyl-1,3,5-triazine-2,4-diamine]	2600-3400	5	0.5
83595	Reaction product of di-tert-butyl phosphonite with biphenyl, obtained by condensation of 2,4 di-tert-butylphenol with Friedel-Crafts reaction product of phosphorus trichloride and biphenyl	991	18	0.25
92880	Thiodiethanol-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate)	643	2.4	0.5
93120	Thiodipropionic acid, didodecyl ester	515	5	0.25
94400	Triethyleneglycol-bis[3-(3-tert-butyl-4-hydroxy-5-methylphenyl) propionate]	587	3	0.5
95200	1,3,5-Trimethyl-2,4,6-tris(3,5-di-tert-butyl-4-hydroxybenzyl)benzene	775	60	0.5

For most of the substances in the table 1 there are no official and validated migration test methods available. Taking this into account migration modelling is of great help for a first orientation and a further selection of the most appropriate strategy of testing.

4.3 Examples

In this section the use and potential of migration modelling is demonstrated with a few examples obtained from reference /13/. These examples are presented with the aid of a market available software which is specifically tailored (MIGRATEST Lite 2001), according to the requirements mentioned above and includes all the equations given in this report.

Example 1:

A film of LDPE with a thickness of 100 μm is used for sandwiches with fatty substances on the surface. This kind of food is stored at 4° C for maximum 7 days. It is known that the film contains Irganox 1076 and Irgafos 168 as additives.

What information can be obtained about the specific migration of the two additives by mathemical modelling?

Modelling with the software
… requires to provide the following informations:

1. Information about the polymer → polymer thickness (**0.01 cm**) → polymer density (**0.945 g/cm^3**) → pre-defined polymer → LDPE → OK
   (the density value 0.945 is the highest density for LDPE and gives a worst case for the amount of migrant per volume of PO. The density ranges for each class of polymer are shown when the pre-defined polymer is selected).
2. Information about the migrateable substance → migrateable substance from Synoptic Document → search PM-Ref No (**68320**) → search → (Octadecyl-3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) → select → relative molecular weight (**531**) → OK → substance concentration in polymer (**5000** mg/kg) → calculation of diffusion coefficient → migration process takes place at one (1) constant temperature level T_1 → temperature T_1 (**5° C**) → estimation of the diffusion coefficient with eq. (4) → calculate diffusion coefficient D_1 → OK.

   (The above initial concentration of 5000 mg/kg can be assumed as an upper limit for all the additives from table 4.2.1 for PO. From a practical and economical standpoint this value is exaggerated.)

3. Information about the foodstuff or food simulant → food simulant → D olive oil → OK.
   Information about the packaging → Conventional EEC Packing → yes → OK.
   Information about the contact between material and food → T_1 → solubility of migrant → soluble → OK → user defined contact data → days (**10**) → OK.

Calculation of migration:

Conditions: One side migration → estimation → time dependent migration (TDM) → TDM with effect of partitioning (E1). (Remark that TDM with effect of partitioning is the selection that is usually is the right one for these situation of modelling, This is useful because there are several options in the software)

Result: $m_{F,t}/A = 2.8$ mg/dm^2.

Discussion of the result:

Save the above result of modelling in a corresponding file, denoted for example as Ex1.

In conformity with Article 4 (b) in Directive 2002/72/EC, the specific limits expressed in mg/kg shall be divided by the conventional conversion factor of 6 in order to express them in mg/dm^2. For the above additive (Irganox 1076) the specific limit is now 6/6 = 1 mg/dm^2 < 2.8 mg/dm^2. The sandwiches with fatty substances on the surface belong to the category of food with the reference number 08.08 in the Directive 85/572/EEC and the reduction factor X/5 can be used. This means in the above example: $(m_{F,t}/A)/5 = 0.56 < 1$ mg/dm^2 and, consequently, it is in compliance with the Directive 2002/72/EC.
For the second additive, Irgafos 168 (PM/REF = 74240), with the molecular weight $M_r = 647$ a smaller migration rate results (Eq.2) as for Irganox 1076 with $M_r = 531$. With the tenfold higher migration limit (SML = 60 mg/kg) no further investigation of the specific migration is necessary.

Example 2:

A film of LDPE (100 µm) is used in the same way as in example 1 but the origin of the plastic is unknown.

Which informations can be obtained from mathematical modelling about the specific migration of any additives possibly contained in the film?

From the previous example we know that a reduction factor X/5 can be used. That means the film is in compliance with the Directive 2002/72/EC if $(m_{F,t}/A)/5 \leq SML/6 = 1$ mg/dm^2 because for most additives in table 4 the specific migration limits are SML ≥ 6 mg/kg. Let us start with the additive with the smallest molecular weight, $Mr_i = 214$ and SML = 6. As in the first example an initial concentration of 0.5% (5000 mg/kg) is assumed as an upper limit.

Modelling with the software:
…can be done with the aid of the previous File Ex1 (saved under Example1) and requires to provide the following informations:

1. Information about the migrateable substance → user defined migrateable substance → molecular weight **(214)** → OK

   Calculation of migration:

   → Estimation → TDM → TDM + E1.
   Result: $m_{F,t}/A = 4.7$ mg/dm^2.

   Discussion of the result:

   With the reduction factor X/5 the final result is $(m_{F,t}/A)/5 = 0.94 < 1$ mg/dm^2. Consequently, for all additives in table 4.2.1 with $M_r > 214$ and SML ≥ 6 the film can be considered to be in compliance with the Directive 2002/72/EC because the migration decreases with increasing M_r.
   By repeating the calculations in the same manner for the remaining additives in table 4.2.1 the estimated migration values exceed the corresponding SML values for 5 additives with the following PM/REF: 38560, 38820, 46640, 60320, 95270.
   If one decides to extract all the migrants from the LDPE film using an adequate method, e.g. hot toluene for solving and methanol for re-precipitation, then a quick semi-quantitative analysis is sufficient for a decision of necessary further investigation.

So long as the initial concentrations of all additives from table 4.2.1 are significantly below 5000 mg/kg, no migration tests are necessary. For the above 5 additives knowledge of the initial concentrations, $c_{P,0}$, is necessary for a prediction of migration.

Example 3:

An empty baker made of PS is to be evaluated with respect to its compliance when intended for being in contact with milk products (yoghurt, and such products in association with fruit and fruit products) as categorised with the reference number 07.02 in the Directive 85/572/EEC. The product must be stored at 8°C. The baker with a volume of 500 ml has a conic geometry and a wall thickness of ≤ 1 mm.
The needed test conditions in conformity with the EEC Directives are: 10 days at 20° C with simulant B.

Which informations can mathematical modelling provide with respect to specific migration of any additives?

From the 8 additives listed in table 4.2.2 for PS, Tinuvin P has the smallest M_r and it can be assumed that it migrates with the highest rate. Therefore it is recommendable to start with this compound.

Modelling with the software:
…requires to provide the following informations:

1. Information about the polymer → polymer thickness (**0.1 cm**) → polymer density (**1.1 g/cm^3**) → user defined polymer → PS → OK.

2. Information about the migrateable substance → migrateable substance from user defined substance → search PM-Ref No (**61440**) → search → (Tinuvin P) → select → relative molecular weight (**225**) → OK → substance concentration in polymer (**5000** mg/kg) → calculation of diffusion coefficient → migration process takes place at one (1) constant temperature level T_1 → estimation of the diffusion coefficient with eq. (4) → temperature T_1 (**20° C**) → Polymer specific constant A_P' (**0**) → Activation energy constant τ (**0**) → calculate diffusion coefficient D_1 → OK.

3. Information about the foodstuff or food simulant → food simulant → B 3% Acetic acid → OK.

4. Information about the packaging → user defined packaging → conic trunk packing (**d = 6.8 cm, D = 8.8 cm, h = 10.5 cm**) → OK.

5. Information about the contact between material and food → T_1 → solubility of migrant → soluble → OK → user defined contact data → days (**10**) → OK.

Calculation of migration

Conditions: One side migration → estimation → time dependent migration (TDM) → TDM with effect of partitioning (E1)
Result: $C_{F,t}$ = 0.84 mg/kg < 6 mg/kg (SML).

Discussion of the result

The migration rate is significantly smaller than the SML value even if the additive is considered to be soluble in the simulant (which is equivalent to a fat test). The other 7 additives from table 4.2.2 have higher molecular weights. It is therefore extremely unlikely that one of these additives exceeds the respective SML value under the above conditions of use. An overall migration test may be a good additional investigation for confirmatory purposes.

Example 4:

A steam sterilizable container with a capacity of 500 ml and a cylindrical form, with a maximum wall thickness of 2 mm is used for liquid or paste with fatty substances on the surface, according to reference number 08.03 in the Directive 85/572/EEC. The container has a PP label. The additives used are Irganox 1076 (0.06 %) and Irgafos 168 (0.1 %). This information was obtained from the producer of the article.

Compliance testing of the above article according to Directive 97/48/EEC requires test conditions of 2 h at 121° C 2 h followed by 10 days at 40° C using simulant D, olive oil.

Which informations can be obtained by mathematical modelling?

In the following two procedures are described:

Procedure 1 (two separate migration effects):

Modelling with the software:
…requires to provide the following informations:

1. Information about the polymer → polymer thickness (**0.2 cm**) → polymer density (**0.91 g/cm^3**) → pre-defined polymer → PP → OK

2. Information about the migrateable substance → migrateable substance from Synoptic Document → search PM-Ref No (**68320**) → search → (Octadecyl-3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) → select → relative molecular weight (**531**) → OK → substance concentration in polymer (**600** mg/kg) → calculation of diffusion coefficient → migration process takes place at one (1) constant temperature level T_1 → temperature T_1 (**121° C**) → estimation of diffusion coefficient with eq. (4) → calculate diffusion coefficient D_1 → OK.
(in this way the migration effect attributed by the high temperature condition alone is considered)

3. Information about the foodstuff or food simulant → food simulant → D olive oil → OK.

4. Information about the packaging → user defined packaging → cylindric packing (**D = 10 cm, H = 6.5 cm**) → OK.

5. Information about the contact between material and food → T_1 → solubility of migrant → soluble → OK → user defined contact data → hours (**2**) → OK.

Calculation of migration

Conditions: One side migration → estimation → time dependent migration (TDM) → TDM with effect of partitioning (E1)
Result: $C_{F,t}$ = 17.5 mg/kg.
Now, for calculation of the pure low temperature (40°C) migration effect further information is needed:

6. Information about the contact between material and food → T_1 → user defined contact data → T_1 **(40)** °C → days (**10**) → OK.

Calculation of migration

Conditions: One side migration → estimation → time dependent migration (TDM) → TDM with effect of partitioning (E1)
Result: $C_{F,t}$ = 3.77 mg/kg.

Discussion of the result

The sum of the two separate migration effects at 121° C and 40° C amounts to 17.5 + 3.77 = 21.27 mg/kg > 6 mg/kg = SML for Irganox 1076. For the conformity check with the Directive 85/572/EE the reduction factor is X/3 and the result is 21.27 / 3 = 7.09 > 6 mg/kg.

Now, to calculate the Irgafos 168 it needs to provide further informations:

7. Information about the migrateable substance → migrateable substance from Synoptic Document → search PM-Ref No (**74240**) → search → (phosphorous acid, tris(2,4-di-tert-btylphenyl)ester) → select → relative molecular weight (**647**) → OK → substance concentration in polymer (**1000** mg/kg) → calculation of diffusion coefficient → migration process takes place at one (1) constant temperature level T_1 → temperature T_1 (**121° C**) → estimation of diffusion coefficient with eq. (4) → calculate diffusion coefficient D_1 → OK.

8. Information about the contact between material and food → T_1 → user defined contact data → hours (**2**) → OK.

Calculation of migration

Conditions: One side migration → estimation → time dependent migration (TDM) → TDM with effect of partitioning (E1)
Result: $C_{F,t}$ = 18.8 mg/kg.
And, again for calculation of the pure low temperature (40°C) migration effect further information is needed:

9. Information about the contact between material and food → T_1 → user defined contact data → T_1 **(40)** °C → days (**10**) → OK.

Calculation of migration
Conditions: One side migration → estimation → time dependent migration (TDM) → TDM with effect of partitioning (E1)
Result: $C_{F,t}$ = 4.02 mg/kg.

Discussion of the result

The sum of both migration effects at 121° C and 40° C amounts to 18.8 + 4.02 = 22.82 mg/kg < 60 mg/kg = SML for Irgafos 168.

Procedure 2 (consecutive migration effect)

Modelling with the software:
…requires to provide the following informations:

1. Information about the migrateable substance → migrateable substance from Synoptic Document → search PM-Ref No (**68320**) → search → (Octadecyl-3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) → select → relative molecular weight (**531**) → OK → substance concentration in polymer (**600** mg/kg) → calculation of diffusion coefficient → migration process takes place at two (2) consecutive temperature levels T_1 T_2 → estimation of diffusion coefficient with eq. (4) → T_1 (**121**) → T_2 (**40**) → calculate diffusion coefficients → OK.

2. Information about the contact between material and food → T_1 T_2 → user defined contact data → t_1 **(2)** hours → t_2 (**10**) days → OK.

Calculation of migration

Conditions: One side migration → estimation → time dependent migration (TDM) → TDM with effect of partitioning (E1)
Result: $C_{F,t}$ = 17.9 mg/kg.

Discussion of the result

With the second procedure the result is smaller as with the first one because in the first procedure the two migrations are considered as independent processes with two separate samples. The calculated specific migration for Irganox 1076 exceeds the

corresponding SML value. Therefore, a migration test is necessary. The calculated specific migration value for Irgafos 168 is significantly smaller as the SML value. A migration test is not necessary in this case.

5 Experimental verification of migration modelling

Since the migration model decribed in this report has not been fully validated for each and every polymer type or polymer modification or food packaging application, it is essential to provide a possibility for experimental verification of modelled migration results. This requirement is also addressed by Article 5 of the 6th amendment of Directive 2002/72/EC which says that *'...that a relationship between the quantity of a substance in the finished material or article and the value of the specific migration of the substance has been established either by an adequate experimentation…'* .

In Annex B of this report a guidance document is given which describes an experimental procedure which allows industry and enforcement laboratories to confirm compliance with an SML through the verification of compliance with the corresponding maximum initial quantity in the plastic. More specifically, this method describes how to measure and derive experimentally/theoretically the basic diffusivity behaviour (A_P value) of a given test plastics material using one or more selected test migrants only. Based on the determined A_P value, Q/SM or MIC/SML relationships can be calculated for any other migrant in dependency of its molecular weight and for the applicable temperature range.

This method is not only applicable for verification purposes but should also be applied in case of doubt when for instance the polymer specific A'_P value is not known or applicable from the tables given in paragraph 3.

Annex A: List of substances with SML values from the positive list system of Directive 2002/72/EC, including 6th Amendment, for which migration modelling is applicable. (This list is reported in reference /13/)

PM/ REF no.	CAS No	Chemical name	SML IN MG/KG	M_r	Remarks
10060	75-07-0	Acetaldehyde	6	44	SML(T)
10120	108-05-4	Acetic acid, vinyl ester	12	86	
10630	79-06-1	Acrylamide		71	SML=ND (DL=0,01)
10660	15214-89-8	2-Acrylamido-2-methylpropanesulphonic acid	0,05	207	
11000	50976-02-8	Acrylic acid, dicyclopentadienyl ester			QMA=0,05 mg/6dm²
11245	2156-97-0	Acrylic acid, dodecyl ester	0,05	240	
12100	107-13-1	Acrylonitrile		53	SML=ND (DL=0,02)
12265	4074-90-2	Adipic acid, divinyl ester		198	QM=5
12670	2855-13-2	1-Amino-3-aminomethyl-3,5,5-trimethylcyclohexane	6	170	
12761	693-57-2	12-Aminododecanoic acid	0,05	215	
12788	2432-99-7	11-Aminoundecanoic acid	5	201	
13000	1477-55-0	1,3-Benzene dimethaneamine	0,05	136	
13060	4422-95-1	1,3,5-Benzenetricarboxylic acid trichloride		265	QMA=0,05 mg/6dm²
13180	498-66-8	Bicyclo(2.2.1)hept-2-ene norbornene)	0,05	94	
13210	1761-71-3	Bis(4-aminocyclohexyl)-methane	0,05	210	
13395	4767-03-7	2,2-Bis(hydroxymethyl)propionic acid	0,05*	134	QMA mg/6 dm²
13480	80-05-7	2,2-Bis(4-hydroxyphenyl)propane	3	228	
13510	1675-54-3	2,2-Bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl ether (=BADGE)	1	340	SML(T)
13530	38103-06-9	2,2-Bis(4-hydroxyphenyl) propane bis phthalic anhydride	0,05	521	
13600	47465-97-4	3,3-Bis(3-methyl-4-hydroxyphenyl)2-indolinone	1,8		
13614	38103-06-9	Bisphenol A bis(phthalic anhydride)		521	See 13530
13630	106-99-0	Butadiene		54	QM=1 or SML=ND (DL=0,02)
13780	2425-79-8	1,4-Butanediol bis(2,3-epoxypropyl)ether		202	QM=1
13810	505-65-7	1,4-Butanediolformal	0,05*	102	
14020	98-54-4	4-tert-Butylphenol	0,05	150	
14200	105-60-2	Caprolactam	15	113	SML(T)
14230	2123-24-2	Caprolactam, sodium salt	15		SML(T)
14380	75-44-5	Carbonyl chloride		99	QM=1
14650	79-38-9	Chlorotrifluoroethylene		116	QMA=0,05 mg/6dm²
14841	599-64-4	4-Cumylphenol	0,05	212	
14950	3173-53-3	Cyclohexyl isocyanate		125	QM(T)=1
15030	931-88-4	Cyclooctene	0,05	110	Aqueous foodstuffs
15070	1647-16-1	1,9-Decadiene	0,05	138	
15130	872-05-9	1-Decene	0,05	140	
15565	106-46-7	1,4-Dichlorobenzene	12	147	
15700	5124-30-1	Dicyclohexylmethane-4,4'-di-isocyanate		262	QM(T)=1
15760	111-46-6	Diethyleneglycol	30	106	SML(T)
15790	111-40-0	Diethylenetriamine	5	103	
15820	345-92-6	4,4'-Difluorobenzophenone	0,05	218	
15880	120-80-9	1,2-Dihydroxybenzene	6	110	

15910	108-46-3	1,3-Dihydroxybenzene	2,4	110	
15940	123-31-9	1,4-Dihydroxybenzene	0,6	110	
15970	611-99-4	4,4'-Dihydroxybenzophenone	6	214	
16000	92-88-6	4,4'-Dihydroxybiphenyl	6	186	
16090	80-09-1	4,4'-Dihydroxydiphenylsulphone	0,05	250	
16150	108-01-0	Dimethylaminoethanol	18	89	
16240	91-97-4	3,3'-Dimethyl-4,4'-di-isocyanatobiphenyl		264	QM(T)=1
16360	576-26-1	2,6-Dimethylphenol	0,05	122	
16390	126-30-7	2,2-Dimethyl-1,3-propanediol	0,05	104	
16450	646-06-0	1,3-Dioxolane	0,05	74	
16570	4128-73-8	Diphenyl ether 4,4'-di-isocyanate		252	QM(T)=1
16600	5873-54-1	Diphenylmethane 2,4'-di-isocyanate		250	QM(T)=1
16630	101-68-8	Diphenylmethane 4,4'-di-isocyanate		250	QM(T)=1
16690	1321-74-0	Divinylbenzene	0,05*	130	
16694	13811-50-2	N,N'-Divinyl-2-imidazolidinone			QM=5
16704	112-41-4	1-Dodecene	0,05	168	
16750	106-89-8	Epichlorohydrin		93	QM=1
16960	107-15-3	Ethylenediamine	12	60	
16990	107-21-1	Ethyleneglycol	30	62	SML(T)
17005	151-56-4	Ethyleneimine		43	SML=ND (DL=0,01)
17020	75-21-8	Ethylene oxide		44	QM=1
17050	104-76-7	2-Ethyl-1-hexanol	30	130	
17160	97-53-0	Eugenol		164	SML=ND (DL=0,02)
17260	50-00-0	Formaldehyde	15	30	
18220	68564-88-5	N-Heptylaminoundecanoic acid	0,05		
18250	115-28-6	Hexachloroendomethylene tetrahydrophthalic acid		389	SML=ND (DL=0,01)
18280	115-27-5	Hexachloroendomethylene tetrahydrophthalic anhydrid		371	SML=ND (DL=0,01)
18430	116-15-4	Hexafluoropropylene		150	SML=ND (DL=0,01)
18460	124-09-4	Hexamethylenediamine	2,4	116	
18640	822-06-0	Hexamethylene diisocyanate		168	QM(T)=1
18670	100-97-0	Hexamethylenetetramine	15	140	
18820	592-41-6	1-Hexene	3	84	
19060	109-53-5	Isobutyl vinyl ether		100	QM=5
19110	4098-71-9	1-Isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane (Isophoronediisocyanate)	1**	222	QM mg/kg
19150	121-91-5	Isophthalic acid	5	166	
19210	1459-93-4	Isophthalic acid, dimethyl ester	0,05	194	
19490	947-04-6	Laurolactam	5	197	
19540	110-16-7	Maleic acid	30	116	Also 64800
19960	108-31-6	Maleic anhydride	30	98	
19990	79-39-0	Methacrylamide		85	SML=ND (DL=0,02)
20050	96-05-9	Methacrylic acid, allyl ester	0,05	126	
20410	2082-81-7	Methacrylic acid, diester with 1,4-butandiol	0,05	226	
20530	2867-47-2	Methacrylic acid, 2-(dimethylamino)ethyl ester		157	SML=ND (DL=0,02)
20590	106-91-2	Methacrylic acid, 2,3-epoxypropyl-ester	5**	142	
21490	126-98-7	Methacrylonitrile		67	SML=ND (DL=0,02)
21640	78-79-5	2-Methyl-1,3-butadiene (Isoprene)	1**	68	
21730	563-45-1	3-Methyl-1-butene		70	QMA=0,006 mg/6dm²

21765	106246-33-7	4,4'-Methylene-bis(3-chloro-2,6-diethylaniline)	0,05*	378	
21940	924-42-5	N-Methylolacrylamide		101	SML=ND (DL=0,01)
22150	691-37-2	4-Methyl-1-pentene	0,02	84	
22331	25513-64-8	Mixture of (40%w/w) 1,6-diamino-2,2,4-trimethyl hexane and (60%w/w) 1,6-diamino-2,4,4-trimethyl hexane		158	QMA=5 mg/6dm²
22337	141-43-5	2-Aminoethanol	0,05	61	
22360	1141-38-4	2,6-Naphthalenedicarboxylic acid	5	216	
22390	840-65-3	2,6-Naphtalenedicarboxylic acid, dimethyl ester	0,05	244	
22420	3173-72-6	1,5-Naphthalene diisocyanate		210	QM(T)=1
22550	498-66-8	Norbornene		94	See „Bi-cyclo(2.2.1)he pt-2-ene“
22570	112-96-9	Octadecyl isocyanate		296	QM(T)=1
22660	111-66-0	1-Octene	15	112	
22900	109-67-1	1-Pentene	5	70	
22937	1623-05-8	Perfluoropropyl perfluorovinyl ether	0,05	266	
23050	108-45-2	1,3-Phenylenediamine		108	QM=1
23175	122-52-1	Phosphorous acid, triethyl ester		166	QM=ND (DL=1mg/kg)
23230	131-17-9	Phthalic acid, diallyl ester		246	SML=ND (DL=0,01)
23547	9016-00-6 63148-62-9	Polydimethylsiloxane		>6800	
23770	504-63-2	1,3-Propanediol	0,05	76	
23920	105-38-4	Propionic acid, vinyl ester	6	100	SML(T)
24010	75-56-9	Propylene oxide		58	QM=1
24057	89-32-7	Pyromellitic anhydride	0,05	218	
24073	101-90-6	Resorcinol diglycidyl ether	0,005	222	
24130	8050-09-7	Rosin gum		-	See „Rosin“
24760	26914-43-2	Styrenesulphonic acid	0,05		
24887	6362-79-4	5-Sulphoisophthalic acid, monosodium salt	5	268	
24888	3965-55-7	5-Sulphoisophthalic acid, monosodium salt, dimethyl ester	0,05	296	
24910	100-21-0	Terephthalic acid	7,5	166	
24940	100-20-9	Terephthalic acid dichloride	7,5	203	SML(T)
25080	1120-36-1	1-Tetradecene	0,05	196	
25120	116-14-3	Tetrafluoroethylene	0,05	100	
25150	109-99-9	Tetrahydrofuran	0,6	72	
25210	584-84-9	2,4-Toluene diisocyanate		174	QM(T)=1
25240	91-08-7	2,6-Toluene diisocyanate		174	QM(T)=1
25270	26747-90-0	2,4-Toluene diisocyanate dimer			QM(T)=1
25360	-	Trialkyl(C5-C15) acetic acid, 2,3-epoxypropyl ester			QM=1
25380	-	Trialkyl acetic acid (C7-C17), vinyl esters	0,05*	146	Smallest M
25385	102-70-5	Triallylamine		137	
25420	108-78-1	2,4,6-Triamino-1,3,5-triazine	30	126	
25600	77-99-6	1,1,1-Trimethylolpropane	6	134	
25900	110-88-3	Trioxane	0,05	90	
25927	27955-94-8	1,1,1-Tris(4-hydroxyphenyl) ethane		306	QM=0,5
26110	75-35-4	Vinylidene chloride		97	QM=5 or SML=ND (DL=0,05)
26140	75-38-7	Vinylidene fluoride	5	64	
26155	1072-63-5	1-Vinylimidazole		94	QM=5
26170	3195-78-6	N-Vinyl-N-methylacetamide		99	QM=2
26320	2768-02-7	Vinyltrimethoxysilane		148	QM=5
31520	61167-58-6	Acrylic acid, 2-tert-butyl-6-(3-tert-butyl-2-hydroxy-5-methylbenzyl)-4-methyl-phenyl ester	6	385	

31530	128961-68-2	Acrylic acid, 2,4-di-tert-pentyl-6-[1-(3,5-di-tert-pentyl-2-hydroxy-phenyl)ethyl] phenyl ester	5	549	
31920	103-23-1	Adipic acid, bis(2-ethylhexyl)ester	18	370	
35160	6642-31-5	6-Amino-1,3-dimethyluracil	5	155	
35284	111-41-1	N-(2-aminoethyl)ethanolamine	0,05	104	
37520	2634-33-5	1,2-Benzoisothiazolin-3-one	0,05	151	
38240	119-61-9	Benzophenone	0,6	182	
38515	1533-45-5	4,4-bis(2-benzoxazollyl)stilbene	0,05	414	
38560	7128-64-5	2,5-bis(5-tert-butyl-2-benzoxazolyl)thiophene	0,6	431	
38700	63397-60-4	Bis(2-carbobutoxyethyl)tin-bis(isooctylmercaptoacetate)	18	784	
38800	32687-78-8	N,N'-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionyl)-hydrazide	15	553	
38820	26741-53-7	Bis(2,4-di-tert-butylphenyl)penta-erythritol diphosphite	0,6	605	
38840	154862-43-8	Bis(2,4-dicumylphenyl)pentaerythritol diphosphite	5	853	
39060	35958-30-6	1,1-Bis(2-hydroxy-3,5-di-tert-butyl phenyl)ethane	5	439	
39090	-	N,N-bis(2-hydroxyethyl)alkyl(C8-C18)-amine	1,2	217	
39680	80-05-7	2,2-Bis(4-hydroxyphenyl)propane (Bisphenol A)	3	228	
39890	87826-41-3 69158-41-4 54686-97-4	Bis(methylbenzylidene) sorbitol	60	386	
39925	129228-21-3	3,3-Bis(methoxymethyl)-2,5-dimethyl-hexane	0,05	158	
40000	991-84-4	2,4-Bis(octylmercapto)-6-(4-hydroxy-3,5-di-tert-butylanilino)-1,3,5-triazine	30	589	
40020	110553-27-0	2,4-Bis(octylthiomethyl)-6-methyl-phenol	6	425	
40720	25013-16-5	tert-Butyl-4-hydroxyanisole (BHA)	30	180	
40800	13003-12-8	4,4'-Butyliden-bis(6-tert-butyl-3-methyl-phenyl-ditridecyl phosphite)	6	1240	
42000	63438-80-2	(2-Carbobutoxyethyl)tin-tris(isooctyl-mercaptoacetate)	30	858	
43680	75-45-6	Chlorodifluoromethane	6	86	
43760	26172-55-4	5-Chloro-2-methyl-4-isothiazolin-3-one	0,01	150	
46480	32647-67-9	Dibenzylidene sorbitol	60	358	
46640	128-37-0	2,6-Di-tert-butyl-p-cresol (BHT)	3	220	
46720	4130-42-1	2,6-Di-tert-butyl-4-ethylphenol	4,8*	234	
47540	27458-90-8	Di-tert-dodecyl disulfide (containing 35% polysulfides)	0,05	403	
47600	84030-61-5	Di-n-dodecyltin-bis(isooctyl-mercaptoacetate)	12	862	
47680	111-46-6	Diethyleneglycol	30	106	
48620	123-31-9	1,4-Dihydroxybenzene	0,6	110	
48640	131-56-6	2,4-Dihydroxybenzophenone	6	214	
48720	611-99-4	4,4'-Dihydroxybenzophenone	6	214	
48800	97-23-4	2,2'-Dihydroxy-5,5'-dichlorodiphenyl-methane	12	269	
48880	131-53-3	2,2'-Dihydroxy-4-methoxybenzophenone	6	244	
49485	134701-20-5	2,4-Dimethyl-6-(1-methylpentadecyl)-phenol	1	347	
49600	26636-01-1	Dimethyltin-bis(isooctylmercapto-acetate)	0,18	554	expr. as tin
49840	2500-88-1	Dioctadecyl disulphide	3	571	
50240	10039-33-5	Di-n-octyltin-bis(2-ethylhexyl-maleate)	0,04	800	expr. as tin
50320	15571-58-1	Di-n-octyltinbis(2-ethylhexylmercapto-acetate)	0,04	752	expr.as tin
50360		Di-n-octyltin-bis(ethylmaleate)	0,04	716	expr. as tin
50400	33568-99-9	Di-n-octyltin-bis(isooctylmaleate)	0,04	800	expr. as tin
50480	26401-97-8	Di-n-octyltin-bis(isooctylmercapto-acetate)	0,04	752	expr. as tin
50560	-	Di-n-octyltin 1,4-butandiol-bis(mercaptoacetate)	0,04	585	expr. as tin
50640	3648-18-8	Di-n-octyltin dilaurate	0,04	744	expr. as tin
50720	15571-60-5	Di-n-octyltin dimaleate	0,04	575	expr. as tin
50960	69226-44-4	Di-n-octyltin ethyleneglycol-bis(mercaptoacetate)	0,04	554	expr. as tin
51040	15535-79-2	Di-n-octyltin mercaptoacetate	0,04	403	expr. as tin
51120	-	Di-n-octyltin thiobenzoate 2-ethylhexylmercaptoacetate	0,04	687	expr. as tin
51570	127-63-9	Diphenyl sulphone	3	218	
51680	102-08-9	N,N'-Diphenylthiourea	3	228	

51700	147315-50-2	2-(4,6Diphenyl-1,3,5-triazin-2-yl)-5-(hexyloxy)phenol)	0,05	425	
52000	27176-87-0	Dodecylbenzenesulphonic acid	30	326	
52320	52047-59-3	2-(4-Dodecylphenyl)indole	0,06		
52880	23676-09-7	4-Ethoxybenzoic acid, ethylester	3,6	194	
53200	23949-66-8	2-Ethoxy-2'-ethyloxanilide	30	312	
53650	107-21-1	Ethyleneglycol	30	62	
53670	32509-66-3	Ethylenglycol-bis(3,3-bis(3-tert-butyl-4-hydroxyphenyl)butyrate)	6	795	
54300	118337-09-0	2,2'-Ethylidenebis(4,6-di-tert-butyl-phenyl)fluorophosphonite	6	487	
55200	1166-52-5	Gallic acid, dodecyl ester	30	338	
55280	1034-01-1	Gallic acid, octyl ester	30	282	
55360	121-79-9	Gallic acid, propyl ester	30	212	
59120	23128-74-7	1,6-Hexamethylene-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionamide	45	637	
59200	35074-77-2	1,6-Hexamethylene-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate)	6	639	
59280	100-97-0	Hexamethylenetetramine	15	140	as formald.
60320	70321-86-7	2-(2-Hydroxy-3,5-bis(1,1-dimethylbenz-yl)phenyl)benzo-triazole	1,5	448	
60400	3896-11-5	2-(2'-Hydroxy-3'-tert-butyl-5'-methyl-phenyl)-5-chlorobenzotriazole	30	316	
60480	3864-99-1	2-(2'-Hydroxy-3,5'-di-tert-butylphenyl)-5-chlorobenzotriazole	30	358	
61360	131-57-7	2-Hydroxy-4-methoxybenzophenone	6	228	
61440	2440-22-4	2-(2;-Hydroxy-5'-methylphenyl)benzotri-azole	30	225	
61600	1843-05-6	2-Hydroxy-4-n-octylbenzophenone	6	326	
66400	88-24-4	2,2'-Methylenebis(4-ethyl-6-tert-butyl-phenol)	1,5	369	
66480	119-47-1	2,2'-Methylenebis(4-methyl-6-tert-butyl-phenol)	1,5	341	
66560	4066-02-8	2,2'-Methylenebis(4-methyl-6-cyclohexylphenol)	3	393	
66580	77-62-3	2,2'-Methylenebis[4-methyl-6-(1-methyl-cyclohexyl)phenol]	3	421	
66755	2682-20-4	2-Methyl-4-isothiazolin-3-one	ND	115	LD=0,02
67360	67649-65-4	Mono-n-dodecyltin-tris(isooctyl-mercaptoacetate)	24	897	
67420	141-43-5	Monoethanolamine	0,05	61	
67520	54849-38-6	Monomethyltin-tris(isooctylmercapto-acetate)	0,18	743	expr. as tin
67680	27107-89-7	Mono-n-octyltin-tris(2-ethylhexyl-mercaptoacetate)	1,2	841	expr. as tin
67760	26401-86-5	Mono-n-octyltin-tris(isooctyl-mercaptoacetate)	1,2	841	expr. as tin
68320	2082-79-3	Octadecyl 3-(3,5-di-tert-butyl-4-hydroxy-phenyl)propionate	6	531	
68400	10094-45-8	Octadecylerucamide	5	590	
69840	16260-09-6	Oleylpalmitamide	5	255	smallest M
71635	25151-96-6	Pentaerythritol dioleate	0,05	665	not sim. D
71680	6683-19-8	Pentaerythritol tetrakis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionate]	60	1178	
72160	948-65-2	2-Phenylindole	15	193	
72800	1241-94-7	Phosphoric acid, diphenyl 2-ethyl-hexyl ester	2.4	362	
73720	115-96-8	Phosphoric acid, trichloroethyl ester	ND	285	LD=0,02
74010	145650-60-8	Phosphorous acid, bis(2,4-di-tert-butyl-6-methylphenyl) ethyl ester	5	514	
74240	31570-04-4	Phosphorous acid, tris(2,4-di-tert-butylphenyl)ester	60	647	
74400	26523-78-4 1333-21-7 54771-30-1 8012-67-7	Phosphorous acid, trisnonyl ester (Irgafos TNPP) -and/or dinonylphenyl) ester	30	502	smallest M
74640	117-81-7	Phthalic acid, bis(2-ethylhexyl) ester	3	391	
74960	84-61-7	Phthalic acid, dicyclohexyl ester	6	330	

75040	-	Phthalic acid, diesters with hexadecanol and/or octadecanol	9	670	
75120	84-66-2	Phthalic acid, diethylester	12	222	
77895	68439-49-6	Polyethyleneglycol(EO=2-6)mono alkyl(C16-C18) ether	0,05	363	EO=4, C12
80480	82451-48-7	Poly(6-morpholino-1,3,5-triazine-2,4-diyl)-[(2,2,6,6-tertamethyl-4-piperidyl)imino]-hexamethylene-[(2,2,6,6-tertamethyl-4-piperidyl)-imino]	1,8		
81200	71878-19-8	Poly[6-[(1,1,3,3-tetramethylbutyl)-amino]-1,3,5-triazine-2,4-diyl]-[(2,2,6,6-tertamethyl-4-piperidyl)imino]-hexamethylene-[(2,2,6,6-tertamethyl-4-piperidyl)imino]	3	2000	
81220	192268-64-7	Poly-[[6-[N-(2,2,6,6-tetramethyl-4-piperidinyl)-n-butylamino]-1,3,5-triazine-2,4-diyl][(2,2,6,6-tetramethyl-4-piperidinyl)imino]-1,6-hexanediyl[(2,2,6,6-tetramethyl-4-piperidinyl)imino]]-alpha-[N,N,N',N'-tetrabutyl-N''-(2,2,6,6-tetramethyl-4-piperidinyl)-N''-[6-(2,2,6,6-tetramethyl-4-piperidinylamino)-hexyl]-[1,3,5-triazine-2,4,6-triamine]-omega-N,N,N',N'-tetrabutyl-1,3,5-triazine-2,4-diamine]	5	2600	
83595	119345-01-6	Reaction product of di-tert-butyl phosphonite with biphenyl, obtained by condensation of 2,4 di-tert-butylphenol with Friedel-Crafts reaction product of phosphorus trichloride and biphenyl	18	595	smallest M
83700	141-22-0	Ricinoleic acid	42	299	
84800	87-18-3	Salicylic acid, 4-tert-butylphenyl ester	12	270	
84880	119-36-8	Salycilic acid, methyl ester	30	152	
85280	52829-07-9	Sebacic acid, bis(2,2,6,6-tertamethyl-4-piperidyl) ester		481	not ev.
89440	-	Stearic acid, esters with ethylene- glycol	30	329	
92560	38613-77-3	Tetrakis(2,4-di-tert-butylphenyl)-4,4'-biphenylene diphosphonite	18	1035	see 83595
92800	96-69-5	4,4'-Thiobis(6-tert-butyl-3-methyl-phenol	0,48	350	359
92880	41484-35-9	Thiodiethanol-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate)	2,4	643	
92930	120218-34-0	Thiodiethanol-bis(5-methoxycarbonyl-2,6-dimethyl-1,4-dihydropyridine-3-carboxylate)	6		
93120	123-28-4	Thiodipropionic acid, didodecyl ester	5	515	
93280	693-36-7	Thiodipropionic acid, dioctadecyl ester	5	683	
93520	59-02-9	alpha-Tocopherol	60	431	
93720	108-78-1	2,4,6-Triamino-1,3,5-triazine (Melamine)	30	126	
93930	3380-34-5	2,4,4'-Trichloro-2'-hydroxydiphenyl ether	5	290	
94400	36443-68-2	Triethyleneglycol-bis[3-(3-tert-butyl-4-hydroxy-5-methylphenyl) propionate]	3	569	
94560	122-20-3	Triisopropanolamine	5	191	
94960	77-99-6	1,1,1-Trimethylolpropane	6	134	
95200	1709-70-2	1,3,5-Trimethyl-2,4,6-tris(3,5-di-tert-butyl-4-hydroxybenzyl)ben-zene	60	775	
95270	161717-32-4	2,4,6-Tris(tert-butyl)phenyl 2-butyl-2-ethyl-1,3-propanediol phosphite	2	450	
95280	40601-76-1	1,3,5-Tris(4-tert-butyl-3-hydroxy-2,6-dimethylbenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione	6	664	
95360	27676-62-6	1,3,5-Tris(3,5-di-tert-butyl-4-hydroxybenzyl)-1,3,5-triazine-2,4,6-(1H,3H,5H)-trione	5	784	
95600	1843-03-4	1,1,3-Tris(2-methyl-4-hydroxy-5-tert-butylphenyl) butane	5	545	

Annex B: Guidance for establishing an experimental relationship between the quantity (Q) of a substance in the finished material or article and its specific migration (SM)

Preface:

The aim of this document is to give an answer to the following question:

How can industry and the enforcement laboratories confirm compliance with an SML through the verification of compliance with the corresponding maximum initial quantity in the plastic using an experimental procedure?

1. Introduction

The experimental determination of the specific migration into food(simulants) requires a considerable amount of time and cost and is even in many cases impossible due to technical/analytical problems, chemical degradation/volatilisation of the migrant or non-availability of corresponding analytical methods. From this it is obvious, that correlating SML restrictions with maximum initial concentration in a polymer (MIC) would not only be of great help but can also be considered to be a very economical alternative procedure to migration or compliance testing.

If for one given polymer type the basic Q/SM relationship (i.e. the basic diffusivity behaviour of this material) has been established using one or more typical migrants, then application of the migration/diffusion model (see Annex I) is possible to establish any specific MIC/SML relationship without further experimental migration testing within a (previously) well established and defined application range.

One of the foreseeable advantages of migration modelling is that it will allow high speed computer-assisted migrational access to any foodstuff matrix independent of its analytically limiting compositional complexity and manage any given individual food packaging system (geometry, ratio mass/contact area, shelf life etc.). Moreover, migration modelling is completely insensitive to chemical degradation and reactivity or physical volatilisation of test migrants as occuring in real migration testing. It can therefore not only be used for plausability considerations with respect to the extent and height of obtained migration results but also for identification of otherwise hardly detectable false-negative test results.

2. Scope

This method describes how to measure and derive experimentally/theoretically the basic diffusivity behaviour (A_P value, see below) of a given test plastics material using one or more selected test migrants only. Based on the determined A_P value, Q/SM or MIC/SML relationships can be calculated for any other migrant in dependency of its molecular weight and for the applicable temperature range.

3. General technical considerations

3.1 Test material

The test material is a polymeric material or article which has been synthesized in conformity with GMP (See also paragraphs 2 and 3 of this report). It contains at least one known migrateable compound with a relative molecular mass $M_r < 1000$. Such a migrant can be an additive, a residual monomer or an oligomer. Any thickness of the polymeric sample film or sheet can be used. It is preferable to use a sample with the highest expected thickness for practical applications.

3.2 Test migrants

It is preferable, if possible, to select a processing additive with well known properties for which well known and simple chromatographic analysis methods (HPLC or GC) can be used. A general requirement to the 'test migrant' is that it is sufficiently stable under the extraction and migration conditions. As an example, IRGAFOS 168 was found to be very useful although being always accompanied by its well-known oxidation product IRGAFOS 168 (ox.). The reproducible mass balance IRGAFOS168/IRGAFOS168(ox). and the analytical ease of detection allow the simultaneous determination of the sum of parent and degradation product in this case.

4. Test principle

The test involves principally three steps:

(i) Extraction of the test material to identify, select and determine quantitatively one or more suitable test migrants (initial quantity in the plastic, Q).

(ii) Kinetic migration experiment to measure the diffusion characteristics of the test material with respect of the time-dependency and extent of release of the test migrant(s) into a food simulant.

(iii) Migration/diffusion modelling to establish the basic diffusivity behaviour of the test sample in terms of an A_p value.

Depending on the knowledge about the polymeric test sample and its composition, step (i) and/or steps (ii) and (iii) may be omitted. For instance, in case the polymer is a polyolefin with well known diffusivity behaviour (defined A_p value) and if the identity and initial concentration of the test migrant is known, then calculation of the Q/SM or MIC/SML relationship according to paragraph 6 (see below) can immediately be applied.

5. Procedure

5.1 Extraction of the test material (step i)

Knowledge of the initial concentration, $c_{P,0}$, of the test migrant(s) in the polymer sample (homogeneous distribution) is necessary and can be measured following an adequate extraction procedure with a solvent or swelling agent. The conditions of this extraction procedure are primarily related to the physico-chemical properties of the test sample and, once available or established for a given migrant, the procedure can be applied or adapted for the extraction of any other test migrant.

Validated standard test procedures for determination of phenolic antioxidants such as Irganox 1010 and 1076 and erucamide slip additives in polyethylenes are given in ASTM standards D 5524-94 and D 5815-95.

Further useful guidance to extraction of polymers can be found in Paragraph 8 of the Final Report of EU Project AIR-94-1025 'Safety and quality control of plastics materials for food contact' dated April 1999 and literature given therein. Moreover, this document provides further instructions on analytical techniques to obtain analytical fingerprints of unknown plastics constituents and how to step forward to identification and quantification of these potential migrants in the test material expressed as initial concentration, $c_{P,0}$, or quantity in the plastic, Q.

It must be noted here that according to item 2 of the 'General requirements' (Annex I, B.) it is required that the test migrant is homogeneously distributed in the plastic. Blooming effects, i.e. the inhomogeneous deposition of a migrant on or in the plastics surface, lead to non-applicability of the migration model and need to be recognised and eliminated. One way to check blooming effects is to shortly (approx. 30 seconds) immerse the plastic with gentle movement into a solvent like 95 % ethanol and/or iso-octane followed by analysis of the rinsing solvent. Significant amounts of migrant found in that way indicate a blooming effect. Further indication can be obtained from an anormal kinetic migration curve measured under 5.2.

Based on the obtained results one ore more suitable test migrants need to be selected for step ii (5.2).

5.2 Kinetic migration measurements (step ii)

Depending on the thickness and structure of the polymeric test sample the migration experiment can be done either by total immersion or using a migration cell in the single sided mode. As a general rule and for guidance, high diffusivity polymers comparable to the behaviour of polyolefines should be thicker than 500 µm for being applied to the total immersion test; low diffusivity polymers comparable to the behaviour of PET can be totally immersed at a thickness higher than 100 µm. If the sample is not homogeneous and socalled edge effects may occur, then the one sided test is obligatory. As a general remark, the one sided test should always be the preferred one and carried out where possible.

Migration experiments are conducted at two different temperatures such that the full kinetic migration curve can be established by taking sufficient and suitably positioned time points. If necessary, a pre-experiment needs to be carried out. Ideally, the shape of the migration curve is expected to originate at time zero with zero migration and sloping linearly with square root of time until approximately 60% of maximum migration has occurred. Finally, the curve approaches asymptotically at equilibrium the maximum concentration. Blooming effect of a migrant can be recognised from the curve where significant migration is already observed at time zero. The tests should be carried out as follows:

Migration at temperature T1 at regular practical test conditions:
In general, migration may be measured after 1, 2, 4 and 10 days at 40 °C (obligatoric kinetic experiment). In case of very high diffusion and/or very thin materials the curve may be necessary to be established already within a few hours and may reach equilibrium very early.

In case of very low diffusion and/or thick materials, if necessary, one or two additional time points are measured between 10 and 20 days to reach or approach equlibrium.
Migration at temperature T2 at worse-case conditions: in dependence of the practical application a second kinetic migration experiment may be necessary selecting

- a temperature according to the highest foreseeable contact conditions and

- 3 suitable time points, for instance 0.5, 1.0 and 2.0 times the maximum time test conditions (97/48/EC, table 3).

Migration measurements are carried out applying duplicate test sample set-up with duplicate determination of each migration time point and using at least one appropriate food simulant (fat test using olive oil, if analytically and technically possible) or an alternative/substitute test medium.

5.3 Diffusion/migration modelling (step iii)

Step 1: From the kinetic curves measured under 4.2, the diffusion coefficient D_P and partition coefficients $K_{P/F}$ are derived on the basis of equation (2) of this report.
Step 2: The wanted basic diffusivity behaviour of the test sample, expressed as A_P-value, is derived on the basis of eq. (4) of this report.

Access to the wanted parameters from both steps can be achieved using a suitable computer programme (step 1) or directly calculated from eq. (4) (step 2), respectively.

6. Establishment of Q/SM or MIC/SML relationship

On the basis of the determined material diffusivity property (A_P value; Step 2 of 5.3) Q/SM or MIC/SML relationships can now be established for any other given migrant taking its molecular weight into account using eq. (3) of this report.

As a worst case, it is recommended to apply the partition coefficient $K_{P/F} = 1$. This is relevant in the case of high solubility of the migrant in food simulant. In case of low solubility of the migrant in food simulant a partition coefficient $K_{P/F} = 1000$ was found to be appropriate.

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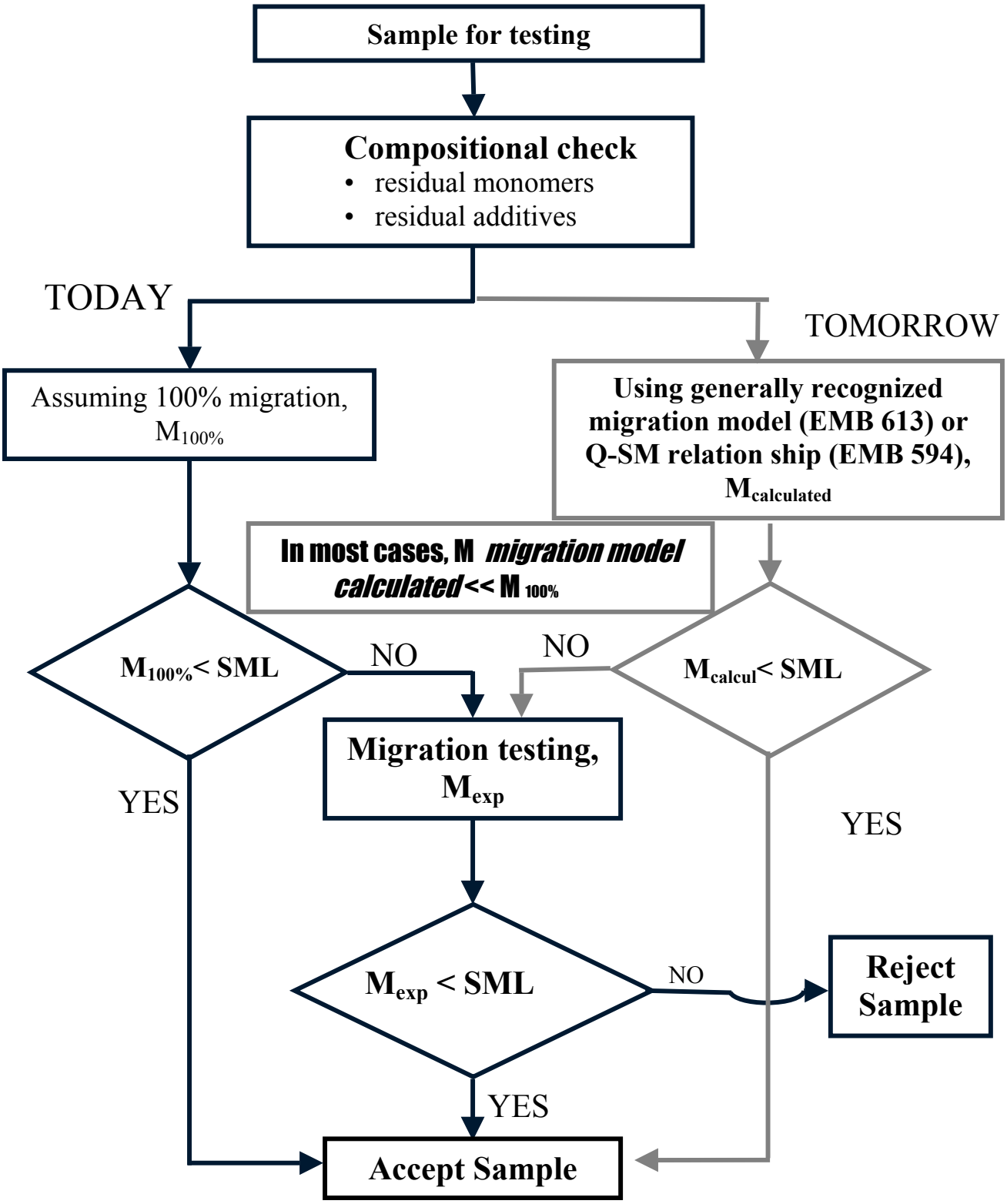
Benefit of Migration Models



ANNEX II

Safety and quality of food contact materials

(http://cpf.jrc.it/webpack/downloads/AIR%20941025%20Report-link%20from%20PG.doc)

Part 1: Evaluation of analytical strategies to introduce migration measurement into good manufacturing practice

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SUMMARY

Migration of packaging constituents into food can raise doubts about food safety. This paper describes conclusions of a research project conducted in the framework of the EU AIR research programme (AIR CT94-1025). It aims to facilitate introduction of migration control into good manufacturing practice and into enforcement policies. Representative polymer classes were defined, according to chemical structure, technological function, and importance on the market and behaviour in migration. These classes can be characterised by analytical methods. Analytical techniques were investigated for potential migrant identification. High temperature gas chromatography is a powerful method and ^{1}H magnetic resonance provides a convenient fingerprint of a plastic material.

Volatile compounds are characterised by head-space techniques. It is essential to differentiate volatile compounds desorbed and those generated during the thermal desorption. For metal trace analysis, the microwave mineralisation followed with Absorption Atomic technique seems to be powerful. These different techniques are introduced in a testing scheme, which can be adapted both for industrial control and for enforcement laboratories. Guidelines will be proposed in the second part of this paper.

The general strategy is summarised in Figure 1. Each step of this strategy was carefully optimised. For the box "quantification of migrants with an SML", reference is made to other, more dedicated work, such as CEN TC 194/SC1/ENV 13130.

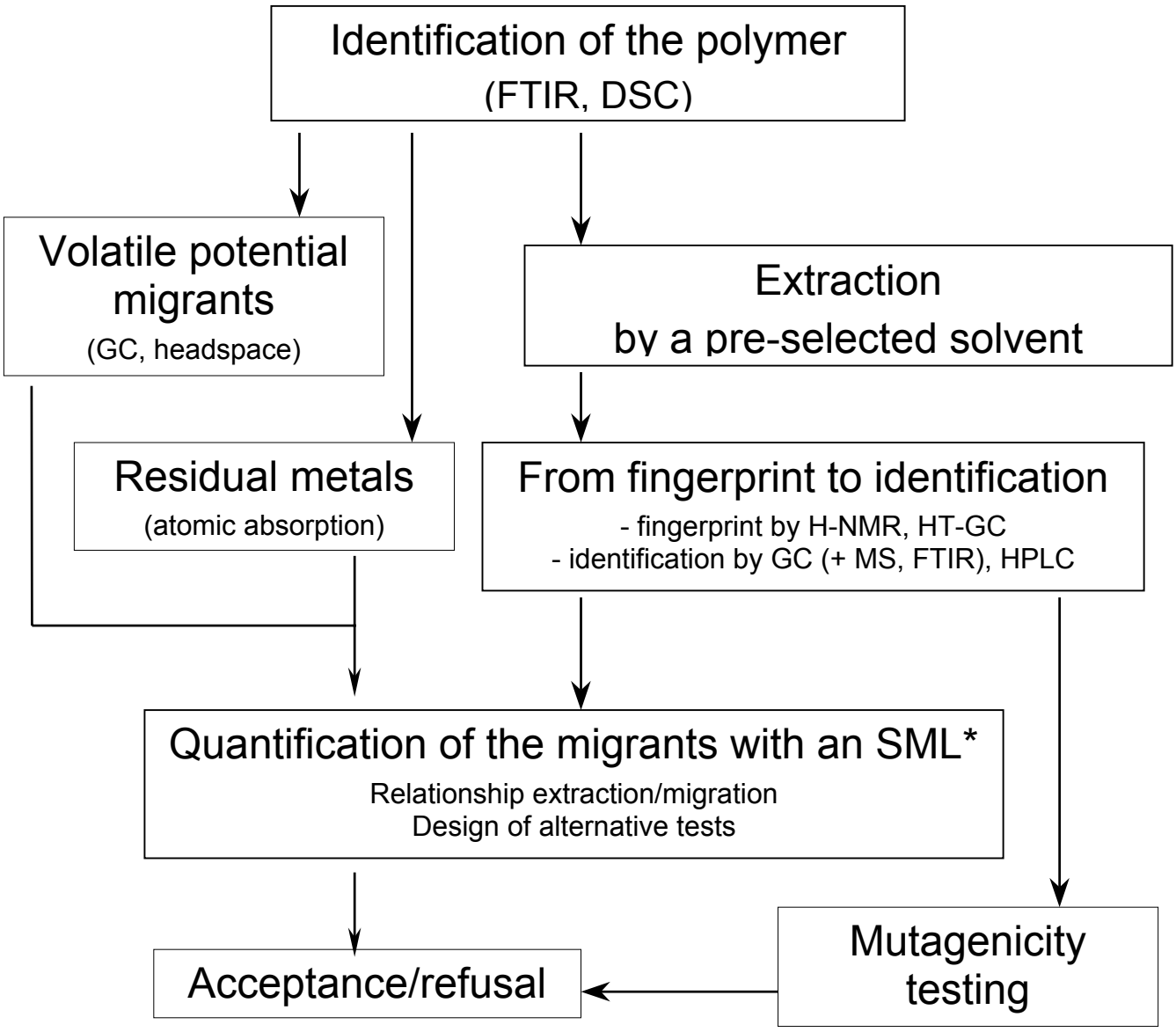

*Figure 1: the general scheme (*here general approaches are presented; for specific migration methods, refer to work of CEN TC 194/SC1/ENV 13130). Modelling and mutagenicity testing are presented respectively in parts 2 and 3 of this work.*

CONCLUSION

In Europe, it is the authorities that decide what is safe for the consumer and what is not. In most cases the industrial actors of packaging have only to comply with legislation, and do not have to decide themselves what is safe for the consumer. As we have seen in the introduction, the responsibility of compliance belongs to the industrial end user of the material and the most of the relevant knowledge is property of the resin manufacturer.

This work contributes to guidelines for introducing migration into good manufacturing practice. Full guidelines will be presented in the next paper. The fingerprint based strategy proposed here, is simple to use and will certainly become very useful. Extension of this work is likely to show that fingerprints of approved materials can help for the identification of quality defects.

Materials were classified by industry. They represent all the main structures on the market. Other materials may behave slightly differently, and it may be wise, if a good accuracy is required, to determine their actual extraction kinetic parameters (E) values (e.g. for a quality control scheme). For enforcement, the E values given in the document are probably sufficient. However in any case, it would be advisable that further research programmes corroborate the use and the scope of E values.

The selection of extraction solvents and of alternative test media relies on a large scientific literature. First the possible solvents are deduced from the identity of the polymer. As far as possible, we tried to recommend several solvents for each polymer. Then, the selection of the right solvent depends on the potential migrants, and on their solubility in the possible solvents. These selectivity effects play an important role, even at concentrations well below the solubility limits.

All the materials studied, in use in different European companies, did comply perfectly with the EU regulations and directives.

SECTION 3

PLASTICS – Part 2

Directives on vinylchloride monomer

Directive 78/142/EEC [A2] establishes the restrictions expressed as SML = 0.01 mg/kg and QM= 1 mg/kg in finished product to be applied to the vinylchloride monomer, which is the basic substance for the manufacture of PVC, largely used in food contact applications.

Directives 80/766/EEC [A4] and 81/432/EEC [A5] establish the method of analysis for the enforcement of the SML and QM.

SECTION 4

SURFACE COATINGS – Part 1

1. EU legislation

Coatings are not yet regulated at EU level by a specific Directive and, therefore, the general provisions of the Framework Directive 89/109/EEC [A11] apply. However, see Part 2 of this section in relation to the use of BADGE, BFDGE and NOGE together with their derivatives in surface coatings.

Nota bene : At the Council of Europe, a Resolution was adopted in the past. An amendment of this Resolution is now under study. See Paragraph IV.

2. Further information

At the moment, the European Commission Directive 2002/72/EC [A29] only applies to bulk plastics and multi-layer structures consisting solely of plastics. The Commission has not decided yet whether or not the Directive 2002/72/EC [A29] will be extended, with the needed changes, to cover also polymeric coatings on non-plastic substrates ("surface coatings"). In fact, such an extension would complicate the Directive, because the articles to be covered involve different technologies:

- Coated metal substrates, such as coated beverage and food cans;
- Polymeric coatings on a paper or paperboard substrate, such as plastic coated cartons;
- Non-stick hollowware, such as frying pans;
- Laminates with aluminium foil.

Some concepts of Directive 2002/72/EC [A29], such as overall migration, specific migration and positive lists should be applied also to surface coatings. However, there are analytical problems related to the use of certain simulants. 3 % acetic acid attacks aluminium and steel substrates far worse than actual foods. Olive oil for determining overall migration requires the accurate determination of small weight changes, which is difficult with heavy metal articles, such as frying pans or baking tins. The use of olive oil on articles with a polymeric coating on a metal substrate or on a paper or paperboard substrate shows relevant problems in the detrmination of the overall migration. Therefore the Commission mandated CEN to find appropriate solutions to these problems. In the above-mentioned two cases the CEN TC 194 SC1 replaces the olive oil with other volatile solvents, but testing conditions require adjustments. The Annexes 1 and 2 describe the methodologies to be applied and the background of the choices made.

3. Commission Guidelines

Pending the drafting of a Commission Directive, the Commission recommends the application of the methods described in the Annexes I and II at national level ***unless the national legislation establishes differently.*** The Commission methods were validated by task force groups including the best experts in the field as well as by inter-laboratory tests.

SECTION 4

BADGE/BFDGE/NOGE - Part 2

1. List of pertinent Directives

2002/16/EC	[A26]	Commission	Use of certain epoxy derivatives (BADGE, BFDGE, NOGE)

Nota bene. The Directive 2002/16/EC has replaced the previous one 2001/61/EC [A24], which is repealed. The comment refers to the new Directive.

2. Field of application (Art. 1)

Article 1

1. This Directive shall apply to the following materials and articles:

   (a) Materials and articles made of any type of plastics
   (b) Materials and articles covered by surface coatings
   (c) Adhesives

   manufactured with or containing one or more of the following substances:

   - 2,2-Bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether hereinafter called “BADGE”, and some of its derivatives,
   - Bis(-hydroxyphenyl)methane bis(2,3-epoxypropyl)ethers hereinafter called “BFDGE”, and some of their derivatives,
   - Other Novolac glycidyl ethers hereinafter called “NOGEs”, and some of their derivatives.

2. This Directive shall not apply to containers or storage tanks having a capacity greater than 10 000 litres or to pipelines belonging to or connected with them, covered by special coatings called “heavy-duty coatings”

3. Comments

The reasons for the exclusion of large containers are explained in (new) recital nr. 10. The definition of the capacity of 10,000 l was proposed by industry and accepted by the legislator. ***The migration of BADGE and particularly NOGE, which is largely used as starting substance, is not significant and therefore it was agreed that it was not necessary to establish a migration limit, which would be difficult to enforce.***

4. Aim of the Directive (Art. 2, 3 and 4)

Articles 2-4 establish restrictions to the use of BADGE, BFDGE, NOGE and derivatives having at least one epoxy or chlorohydrin group. The SML for BADGE and the corresponding derivatives was established on the basis of the SCF opinion. The SML for BFDGE and the corresponding derivatives was based on the similarity of its toxicological profile with BADGE. The restriction for NOGE was expressed as a maximum quantity in the

finished product (QM) because the determination of the many compounds involved in foodstuffs is exceedingly difficult.

Since no toxicological data are available for NOGE and the corresponding derivatives, the value of the restriction was chosen sufficiently low to exclude the use of NOGE as additive. The aim was to avoid the replacement of BADGE by NOGE, in agreement with the SCF, in December 1999 stating: *"The Committee therefore is of the opinion that, at present, it is not appropriate to use NOGE as an additive in organosols in food contact materials."*

The use of the three substances will be forbidden after 1 January 2005, unless further toxicological data permits their use. The Commission was informed by the professional organisations that they would provide new toxicological data in 2004 to maintain the use of BADGE.

5. Exhaustion of the stocks

The permission to sell out the existing stocks was requested by professional organisations and from countries outside the European Union, because of the long shelf life of canned food. The Directive established that its enforcement only starts from 1 March 2003. Articles brought into food contact before this date remain within the national legislation in force before this date, i.e. they can continue to be traded inside those Member States where they were in compliance with the existing rules. Member States, which did not allow the use of these compounds, may keep up their rules at least up to the end of 2004.

6. Methods of analysis

The Directive has established the use of validated methods of analysis for the official enforcement of the restrictions. The Commission has mandated the CEN to establish validated methods of analysis for the enforcement of the Directive.

ANNEX I TO SECTION 4 OF CHAPTER I

GUIDELINES FOR MIGRATION TESTING OF POLYMERIC COATINGS ON METALS

Warning: This document will be published as a CEN-EN (see Chapter III).

Extract from a CEN ENV draft document

"Materials and articles in contact with foodstuffs — Polymeric coatings on metal substrates — Guide to the selection of conditions and test methods for overall migration"

Foreword
This document has been prepared by CEN /TC 194, "Utensils in contact with food". This document is currently submitted to the CEN Enquiry. This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

Introduction
No single test method has been devised which can be used to determine overall migration, at all temperatures, in all food simulants. Indeed, owing to the practical difficulties inherent in testing with involatile extractants such as fats and the multitude of applications in which polymeric coatings on metal substrates come into contact with food, there are many methods and permitted variations to methods in this prestandard.

This European Prestandard is intended to give advice on the selection of the most appropriate type of test, test conditions and test method for a given application of a polymeric coating on a metal substrate and is intended to be read in its entirety before testing protocols are finalized. A test method for overall migration into aqueous simulants by article filling from polymeric coatings on food and beverage cans and non-stick coatings is given in clause 12. For many polymeric coated articles methods in EN 1186-2 to EN 1186-9 are suitable, according to the form in which the article is tested. The general criteria for the operation and assessment of testing laboratories as well as the general criteria for laboratory accreditation bodies are set out in EN 45001, EN 45002 and EN 45003. It is recommended that laboratories using this standard validate their procedures by testing certified reference samples and by taking part in a proficiency scheme. Suitable proficiency schemes are operated in Germany and in the United Kingdom, for example the German Assessment Scheme for Food Testing (GAFT) and the Food Analysis Performance Assessment Scheme (FAPAS) conducted by the Central Science Laboratory of the Department for the Environment, Food and Rural Affairs.

Scope

This European Prestandard provides a guide to the selection of the appropriate conditions and test methods for the determination of overall migration into food simulants and test media

from polymeric coatings on metal substrates, which are intended to come into contact with foodstuffs and a test method for overall migration into aqueous simulants by article filling from polymeric coatings on food and beverage cans and non-stick coatings.

NOTE Polymeric coatings on metal substrates are not yet included in the scope of any European Union Directive. This prestandard has been prepared to assist in the development of such a Directive.

Food simulants, test media and reagents

Aqueous food simulants

The aqueous food simulants shall be of the following quality:

- distilled water or water of equivalent quality, simulant A;

- 3 % acetic acid (w/v) in aqueous solution, simulant B;

For the purposes of this standard this means a solution prepared by diluting 30 g of acetic acid with distilled water to a volume of 1 l;

- 10 % ethanol (v/v) in aqueous solution, simulant C.

For liquids or beverages with an ethanol content greater than 10 % (v/v) the test is carried out with aqueous solutions of ethanol of a similar strength.
Each of the above food simulants shall give a non-volatile residue of less than 5 mg/l, when evaporated to dryness and dried to constant weight at 105 C to 110 °C.
For overall migration testing of a coating material which is applied to substrates which are not resistant to acid, 3 % acetic acid is an unsuitable simulant because of the interfering corrosion products. 10 % aqueous ethanol should be used instead, since intensive studies have demonstrated that they provide sufficient information to evaluate coating materials for the overall migration properties even under the condition of contact with acidic food. Only in certain cases would it appear necessary to use 3 % acetic acid as simulant, e.g. for samples containing inorganic constituents and testing specific migration of certain additive such as pigments, siccatives, amines and similar. In these cases the finished product can be tested with acetic acid only if the corrosion products do not interfere with the determination of the particular specific migrant. Otherwise it is recommended either to apply the coating on to an inert substrate prior to testing, or to test the unsupported film in the case of laminated metal.

ANNEX II TO SECTION 4 OF CHAPTER I

GUIDELINES FOR MIGRATION TESTING OF POLYMERIC COATINGS ON CELLULOSIC SUBSTRATES (PAPER AND BOARD)

Warning: This document will be issued as a CEN-EN (see Chapter III)

1. Introduction

The European Commission intends to extend the field of application of the Directive 2002/72/EC [A29] on plastic materials to polymeric coatings on paper and board in food contact. The aim of this document is to give guidance for the application of Directive 82/711/EEC, as last amended by Directive 97/48/EC regarding the determination of the specific and overall migration into fatty food simulants. A Glossary of the terms in use is added as Appendix 1 to this Annex.

Nota bene: In absence of a Directive for these products, the methodology here described can be used at national level.

2. Specific migration into fatty food simulants

The Directive 82/711/EEC[17], as last amended by Directive 97/48/EC[18], applies.

3. Guidance on the determination of the overall migration into fatty food simulants

3.1. Background

Many investigators have reported problems in measuring the overall migration from plastic-coated paper and board with fatty food simulants (1, 2, 3, and 4). The problems were:

- unreliable results: excessively high standard deviations, sometimes even negative values;
- technical problems: penetration of olive oil through pinholes in the polymeric layer, cell leakages, problems with conditioning to constant weight.

The technical problems are mainly caused by the water content of paper and board and the hygroscopic behaviour of these materials. Often the equilibrium moisture content could only be reached after long periods of drying or never at all. Furthermore, the samples rapidly pick up moisture from the air.

3.2. Use of the "Substitute tests" and "Alternative tests"

According to the rules provided by Chapter III of Directive 97/48/EC, the oil should be replaced by a substitute medium, i.e. isooctane, ethanol 95% or, at temperatures $\geq$ 100 °C, MPPO[19]. Moreover the same Directive permits the use of "alternative tests" at the conditions mentioned in Chapter IV.

CEN/TC 194/SC 1/WG 6 has carried out a research programme on the feasibility of these substitute and alternative tests (see Appendix 2) (3). This study has shown:

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[17] O.J. n. L 297, of 23.10.1982, p.26

[18] O.J. n. L 222, of 12.08.1997, p.10

[19] MPPO = modified polyphenylene oxide, traded under the name Tenax

a) The use of iso-octane in single side contact is recommended for polyolefin coatings, e.g. polyethylene and polypropylene;

b) For some coatings, e.g. polyesters and polyamides (5, 6), the use of ethanol 95% is recommended;

c) The use of MPPO is recommended at higher testing temperatures or if a single side test with solvents is impossible because of excessive penetration of the solvent through pinholes;

d) Total immersion in iso-octane for 1 day at 40 °C is considered the most severe test of Table IV in Directive 97/48/EC and may primarily be useful to establish the compliance of the material or article if the test results do not exceed the migration limits. When the limits are exceeded, this test has to be performed under single side contact condition.

A guide to the selection of methods and conditions for the test of overall migration from polymeric coatings on cellulosic substrates (paper and board) is given below.

3.3. Methods and conditions for determining overall migration from polymeric coatings on cellulosic substrates

Apply the following procedure.

3.3.1 Examine the sample and determine the type of coating. For the definition of different types of coatings see Annex 1.

3.3.2 As shown in *figure 1,* the sample can first be tested by total immersion according to ENV 1186-14 "Test methods for substitute tests" Section 3. Time and temperature are chosen according to Directive 97/48/EEC.

Note 1: The type of coating determines the choice of solvent. (Cf. Note for Guidance[20])

Note 2: Step 1 may be omitted and the test started at step 2.

Note 3: If the coating is partially or totally dissolved by the solvent, the test shall start at step 3 (MPPO).

3.3.3 If the test result from step 1 is above 10 mg/dm^2, the sample is tested in a migration cell according to ENV 1186-14 "Test methods for substitute tests" Section 4. Time and temperature are chosen according to Directive 97/48/EEC.

3.3.4 If the test according to step 2 is not possible, the sample may be tested according to ENV 1186-13 "Test method for overall migration at high temperatures", but using a lower temperature. Time and temperature are chosen according to 97/48/EEC.

3.3.5 For samples intended for use at high temperatures (e.g. microwave or conventional oven), migration should only be determined using MPPO (step 3). Time and temperature are chosen according to Directive 97/48/EEC.

3.3.6 "Alternative tests", as defined in Directive 97/48/EEC, may be used as an alternative to this test scheme: e.g. 1186-15 "Alternative test methods to migration into fatty food simulants by rapid extraction into iso-octane and/or 95 % ethanol" (see Chapter III).

20 See the last version of the document appearing in the EC website (**http://cpf.jrc.it/webpack/**)

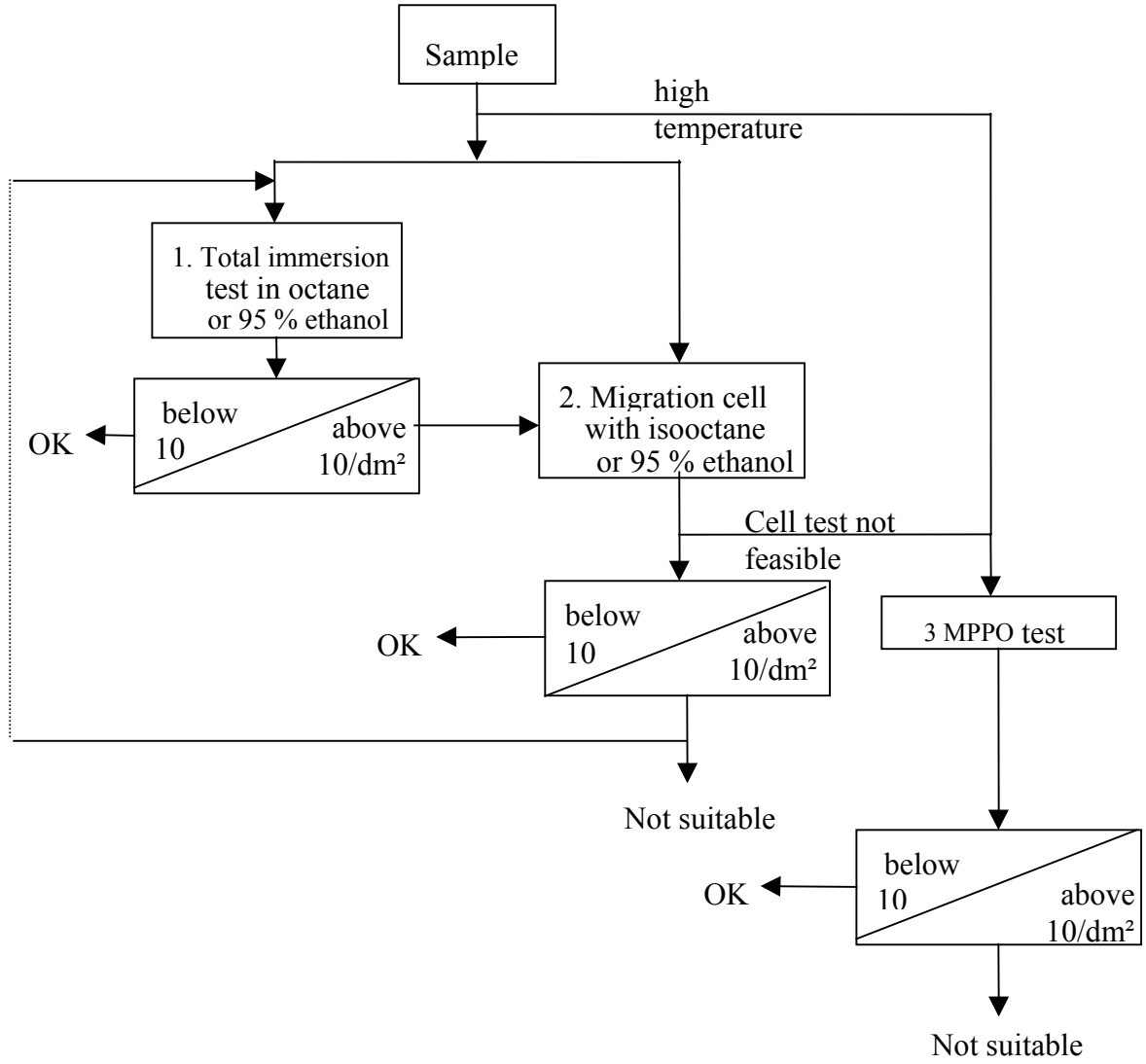

Figure 1. Test scheme for papers with polymeric coatings intended for fatty food contact.

4. References

1. H. Hainje, Results inventory of problems related to testing polymeric coatings on cellulosic substrates. CEN TC/194/SC1/WG6 Document N 11, August 1995

2. D. van Battum, Alternative fatty food simulants, a fact finding exercise. October 1994, revised February 1996 (EU Commission RESEARCH N 33)

3. R. Franz, Research programme of CEN TC194/SC1/WG6/TG2 on "The feasibility of alternative approaches to overall migration testing of coated cellulosic substrates for food contact". Final Report November 1997

4. M. Björklund Jansson, Alternative methods for the evaluation of migration from plastic coated paperboard to fatty food simulants. Lecture held on a workshop at JRC, Ispra, October 1997

5. ENV 1186 –15. Draft March 1998.

6. Practical Guide, CS/PM/2604 Rev 2, March 1997

APPENDIX 1 TO ANNEX II

GLOSSARY OF THE TERMS RELATING TO POLYMERIC LAYERS ON PAPER AND BOARD[21]

(Extract from a CEN document)

1. Scope and field of application

This document deals with terms used in the manufacture of polymeric or plastics layers and their application to paper and board. The following terms are used in the converting and packaging industries in respect of multi-layer materials.

Note: According to the field of application of Directive 2002/72/EC [A29] the surface intended to come into contact with foodstuffs is of polymeric or plastics origin.

2. Terms

2.1 BASIC MATERIALS

2.1.1 **Polymer**: Macromolecular compound obtained by polymerisation (polyaddition, polycondensation or any other similar process) of monomers and other starting substances or by fermentation with bacteria from other starting substances.

2.1.2 **Monomer and other starting substance**: Substance used in the manufacture of a macromolecule, which constitutes the repeating unit of a polymer chain or of a polymer network of any substance used for the manufacture of a plastics for food contact or used to modify existing natural or synthetic macromolecular substances.

2.1.3 **Plastics**: Polymer or mixture of polymers to which additives may have been added and which is used, as such, for the manufacture of finished materials and articles. Or as defined in 2002/72/EC the 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.

2.1.4 **Additive**: Substance, which is incorporated into plastics to achieve a technical effect in the finished product or used to provide a suitable medium in which polymerisation occurs

2.1.5 **Pre-polymer**: Reactive polymer with few repeating units, which has been prepared for use as monomer or starting substance.

Note: Usually there are approximately 2 to 20 repeating units.

2.1.6 **Paper:** Generic term for a range of materials in the form of a coherent sheet or web, excluding sheets or laps of pulp commonly understood for paper making or dissolving purposes and non-woven products, made by deposition, of vegetable, mineral, animal or synthetic fibres, or their mixtures, from a fluid suspension onto a suitable forming device, with or without the addition of other substances.

[21] This version does not take into consideration of the new definition of some terms, which appear in Chapter II, Section 1, paragraph 4.1

Note: They may be coated, impregnated or otherwise converted, during or after their manufacture, without necessarily losing their identity as paper. In conventional paper making processes, the fluid medium is water; new developments, however, include the use of air and other fluids.

2.1.7 **Board:** Generic term applied to certain types of paper frequently characterised by their relatively high rigidity.

Note1: In the generic sense the name "paper" can be used to describe both paper and board as defined.

Note 2: For some purposes, materials of a grammage of less than 225 g/m² are considered to be paper, and materials of a grammage of 225 g/m² or above are considered to be board. However, distinction between paper and board is primarily made on the basis of the characteristics of the material and, in some cases, its use. Many materials of a grammage of less than 225 g/m², such as certain grades of folding box board and corrugated raw materials, are generally referred to as "board" and many materials of a grammage greater than 225 g/m², such as certain grades of blotting paper, felt and drawing paper, are generally referred to as "paper".

2.1.8 **Binder**: Material that holds the pigment particles, in a pigment coating, together and fixes them to the surface of the paper or board.

2.1.9 **Dispersion:** Mixture of particles distributed in a vehicle. The particles can be in the form of hard aggregates or be flocculated, or both conditions could exist together.

2.1.10 **Emulsion**: Mixture of two mutually insoluble liquids in which one liquid is finely dispersed as droplets in the other.

2.1.11 **Paraffin wax**: Mixtures of high-boiling hydrocarbons derived from petroleum, solid at room temperature with a melting range from approximately 40-60^{o}C.

2.1.12 **Layer**: Continuous thickness of a material covering the surface of a substrate, forming a multi-component structure.

2.2 PROCESSES

2.2.1 **Coating**: Process by which one, or more, continuous layers of a material, in fluid or molten form, is applied to the surface of an existing material.

2.2.1.1 **Solvent coating**: Process by which a solution or dispersion of a polymeric material and additives, in an appropriate volatile solvent, is applied in one or more steps onto the moving web of the substrate. The film is formed by evaporation of the solvent.

Note: This process is also known under the name of lacquering or lacquer coating.

2.2.1.2 **Dispersion or emulsion coating**: Process by which an aqueous dispersion or emulsion and additives are applied in one or more steps onto the moving web of the substrate. The film is formed by evaporation of water.

Note: Wax is a common additive.

2.2.1.3 **Solvent free coating**: Process by which monomers or prepolymers in liquid form, with or without reaction agents, is applied onto the moving web of the substrate. The polymer is formed by a chemical reaction (curing) initiated by catalysis, radiation (ultraviolet or infra red radiation, heat), electron beam, high frequency, water, steam or high temperature.

2.2.1.4 **Extrusion or co-extrusion coating**: Process by which a molten polymeric material is forced (extruded) through a die positioned immediately above the nip between a supporting roll and chill roll and drawn down into this nip, where the molten film comes in contact with the moving web of the substrate. The polymer is solidified by cooling in the nip and remains tightly bonded to the substrate. When two or more polymeric materials are melted in two or more separate machines (extruders) and the melts are forced through one single die the process is called co-extrusion coating.

2.2.1.5 **Hot melt coating**: Process by which a molten mixture of waxes, polymers or other film forming materials is applied by means of rollers or dies onto the moving web of the substrate, where it is solidified by cooling and remains tightly bonded to the substrate.

Note: Hot melt coated paper or board does not come within the field of application of Directive 2002/72/EC.

2.2.1.6 **Paraffin or wax coating**: Process by which a molten paraffin or wax is applied by rollers or curtain onto the moving web of the substrate, where it is solidified by cooling.

Note: Paraffin or wax coated paper or board does not come within the field of application of Directive 2002/72/EC [A29].

2.2.1.7 **Pigment coating**: Process by which a layer of mineral or artificial pigments, together with binders and other additives, is applied in the form of a slurry (coating slip) onto the moving web of the substrate.

Note 1: This process is commonly used during paper or board production and is usually described as 'paper coating'.

Note 2: This type of coated paper or board does not come within the field of application of Directive 2002/72/EC and therefore is not seen as a polymeric coated material.

2.2.2 **Laminating**: Process by which two or more layers are joined together by a layer with an adhesive function to form a multi-layer structure.

Note 1: In the case of paper and board the adhesive layer can be, for example, a dispersion or solvent based or a solvent free adhesive, an extruded polymer, a hot melt, a wax, or a paraffin.

Note 2: In some countries the laminating process is called lining, when a surface layer of paper, plastics film, metal foil or any other material is pasted with an adhesive onto one or both sides of paper or board.

2.2.3 **Impregnation**: Process by which a moving web of an absorptive substrate is immersed in a liquid, which penetrates into the substrate. This can either be molten wax or paraffins or a dispersion of waxes, paraffins or polymeric materials.

Note: Film forming does not usually occur. Impregnated paper and board does not come within the field of application of Directive 2002/72/EC.

2.3 PRODUCTS

2.3.1 **Coated product**: Two or more layers of different materials produced by means of a coating process as mentioned under 2.2.1.

2.3.2 **Coated paper or board**: Coated product (2.3.1) in which at least one layer is paper or board. (See Note 2.2.1.7)

2.3.3 **Laminated product, laminate**: Two or more layers of similar or different materials combined by means of a laminating process (2.2.2)

2.3.4 **Laminated paper, laminated board:** Laminated product (2.3.3) in which at least one layer is paper or board.

2.3.5 **Impregnated product**: Substrate permeated with a liquid by impregnation. (2.2.3)

2.3.6 **Impregnated paper or board**: Impregnated product (2.3.5) in which the impregnated layer is paper or board (see Note under 2.2.3).

2.4 OTHERS

2.4.1 **Perforation:** Holes in the polymeric layer made by boring, piercing or stamping.

Note: Although these combinations come within the field of application of the Directive 2002/72/EC, testing with liquid simulants according the rules laid down in Directive 82/711/EEC is not possible.

2.4.2 **Pinholes**: Unintentional small holes in the polymeric layer occurring during the coating process.

Note: The presence of pinholes can sometimes make migration testing with liquid simulants impossible.

APPENDIX 2 TO ANNEX II
(Extract from a CEN document)

RESEARCH ON "SUBSTITUTE" AND "ALTERNATIVE" TESTS FOR POLYMERIC COATINGS ON PAPER AND BOARD

In this research 5 representative material structures were tested for extraction and migration with substitute simulants iso-octane, 95% ethanol and Tenax at different test conditions and the results were compared with conventional overall migration into olive oil.

The conclusions of this study were that

- Determination of the overall migration into olive oil from polymeric coatings on paper and board may be impossible in some cases (3 out of 5 in this study) due to technical difficulties and/or unreliable results;

- Test condition 1 day/40 °C was found to be more severe than 2 days/20 °C for both solvents iso-octane and 95% ethanol;

- Total immersion was confirmed as more severe test condition than exposure in single side contact;

- In those cases where the olive oil test was technically feasible as a reference, single side test procedure with iso-octane 95% ethanol and MPPO respectively provided results which were equal to or greater than those found with olive oil;

- 95% ethanol was found to be eventually not appropriate for some materials:

  a) When tested by total immersion which led to an extensive extraction of substances of the paper and board. This is a situation that does not occur under worst foreseeable conditions of use where such an extensive penetration of foodstuffs is prevented by the functional polymeric barrier covering the paper and board.

  b) When tested in single side contact for certain types of polymeric coatings (from polymer dispersions soluble in ethanol). In fact the polymeric layer causes penetration of the solvent and extraction of substances of the paper and board layer to an extent which does not occur under worst foreseeable conditions of use of these materials.

The final conclusion is that for testing overall migration from polymeric coatings on paper and board substitute tests can be used instead of olive oil under test conditions laid down in Chapter III, Table 4 (Conventional conditions for substitute tests) of Directive 97/48/EC. Use of iso-octane as fatty food simulant in single side contact is preferably recommended for polyolefin coatings, e.g. polyethylene and polypropylene. For some coatings, e.g. polyesters and polyamides, 95 % ethanol is recommended (5, 6). MPPO can be used as a verification test at higher temperatures or in cases where a single side test with solvents is impossible because of excessive penetration of the solvent through pinholes.

Since extraction tests by total immersion into iso-octane (2d/20 °C and 1d/40 °C) were clearly found to be an even more severe test condition it shall also be permissible - in accordance with Chapter IV of Directive 97/48/EC - to use these conditions. This cheap and

simple test procedure may be applied as a first approach in testing overall migration and may also be applied where single side testing with solvents is linked to technical problems like cell leakages or pinholes. Provided that the test results do not exceed the migration limits overall migration shall be regarded as being in compliance. In cases where overall migration limits are exceeded in the extraction test by total immersion, substitute test in single side contact has to be performed to verify compliance.

SECTION 5

REGENERATED CELLULOSE FILM (= RCF)

1. List of pertinent Directives

83/229/EEC	[A7]	Council	Positive list, restrictions on use
86/388/EEC	[A10]	Commission	Limits on MEG/DEG
92/15/EEC	[A13]	Commission	Additives (i.e. phthalate esters)
93/10/EEC	[A18]	Commission	Consolidation

2. Introduction

RCF is a thin sheet material obtained from refined cellulose derived from wood or cotton. Directive **83/229/EEC**, as amended by Directives **86/388/EEC** and **92/15/EEC**, listed the substances from which RCF for food contact use can be manufactured. In 1993, it was replaced by Directive **93/10/EEC** and amended by Directive **93/111/EC** to limit the transfer of diethylene or monoethylene glycol from coated RCF (such as boiled sweet wrappers) to food to 30 mg/kg. It listed, furthermore, the substances which may be used for the manufacture of RCF (some with quantitative restrictions) and the coatings that may be applied.

3. Field of application of Directive 83/229/EEC (as amended by Directives 86/388/EEC, 92/15/EEC) consolidated by 93/10/EEC [A18]

Article 1.2 of Directive 83/229/EEC - 93/10/EEC

This directive applies to regenerated cellulose film within the meaning of the description given in Annex I which either:
(a) Constitutes a finished product in itself; or
(b) Is a part of a finished product containing other materials and which is intended to or, in accordance with its purpose, does come into contact with foodstuffs.

Annex I of Directive 83/229/EEC - 93/10/EEC

Description of regenerated cellulose film
Regenerated cellulose film is a thin sheet material obtained from 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 be coated on one or both sides.

Article 1.3.

This directive does not apply to:
(a) Regenerated cellulose film which, on the side intended to come into contact with foodstuffs or, which, by virtue of its purpose does come into such contact, has a coating exceeding 50 mg/dm²;
(b) Synthetic casings of regenerated cellulose.

RCF with a higher degree of coating will probably be treated as a plastic material.

4. Positive list

A positive list of approved substances and, if necessary, restrictions on their use has been published in Annex II of Directive 83/229/EEC [A7].. Amendments on the limits for derivatives of ethylene glycols (MEG/DEG) can be found in Directive 86/388/EEC [A10]. Directive 92/15/EEC [A13] introduced several changes to the list and added new substances.

Purity criteria (in the sense of 'good technical quality') are now stated in the Annex II of the consolidated version, i.e. Directive 93/10/EEC [A18].

Restrictions in positive list

Some guidance in the determination of the restriction is given in Annex 1.

Colorants and adhesives

While colorants and adhesives for RCFs are not included in the published positive lists yet, their use is authorised, *'provided that there is no trace of migration of the substances into or onto foodstuffs, detectable by a method which shall be determined in accordance with the procedure laid down in Article 10 of Directive 76/893/EEC'* (Article 2.2 of Directive 83/229/EEC). However, the Directive does not specify the method to be used. Therefore, pending the establishment of a validated CEN method, it is useful to refer to the most appropriate existing method proposed by industry in 1992 (see Annex II to Section 5 of Chapter I)

The Framework Directive, the specific Directive or the amendments thereof provide additional provisions directly or indirectly referring to this subject, such as that 'printed surfaces of RCF shall not come into contact with the foodstuff' (Dir. 83/229/EEC, Art. 3), or the possibility for a Member State to maintain or adopt a positive list of colouring matters or adhesives.

Monoethylene and diethylene glycols (MEG/DEG)

MEG and DEG are included in the positive list of Directive 83/229/EEC with restrictions on their use being amended by Directive 86/388/EEC. Tetraethylene glycol has been added to the positive list by Directive 92/15/EEC. The restrictions have again been amended by Directive 93/10/EEC: migration is controlled by a compositional limit (QM) for the uncoated film.

ANNEX I TO SECTION 5 OF CHAPTER I

REMARKS CONCERNING THE DETERMINATION OF THE VARIOUS PERCENTAGE OF "CELLULOSE", "SOFTENERS" AND "OTHER ADDITIVES"

Warning: **This is a document prepared by CIPCEL and transmitted to the Commission services on 21 April 1992. It should not be considered as a Commission document.**

In the industrial manufacture of regenerated cellulose film (RCF), three main stages can be identified:

(a) Production of viscose (cellulose xanthate dissolved in sodium hydroxide solution).

(b) Coagulation of the viscose and regeneration of the cellulose from the cellulose xanthate. The resultant film is washed and the necessary additives incorporated. This is followed by controlled drying to provide an uncoated film.

(c) To provide additional properties (heat sealability, controlled water vapour permeability…..) to the cellulose film, the latter is often coated with lacquers based on cellulose nitrate, polyvinylidene chloride or polyvinyl chloride/acetate copolymers.

The colorants referred to in Article 2, paragraph 2, can consist of

- Pigments (e.g. titanium dioxide, iron oxide) introduced into the viscose, stage (a)

- Organic, soluble dyes, incorporated into the wet cellulose film, stage (b), or into the coating, stage (c)

Analytical precautions

When the percentages of "cellulose", "softeners" and "other additives" in an uncoated and/or coated cellulose film are measured, corrections have to be made for the various constituents (see later) It should also be noted that the presence of colouring matter (pigments or dyes) can interfere with some analytical procedures.

In order to measure the water content in the film (which varies with atmospheric humidity), direct drying must be avoided, as this may induce errors in the analysis through the loss of relatively volatile components.

It is recommended that several specimens of a sample be conditioned in the same manner (temperature, relative humidity and time). Some of them are used for the determination of the water content, e.g. according to Karl Fischer, while the others are used for further analyses.

Let W% be the water content of the film.
The amount of lacquer applied to the uncoated film (L%) is determined by a suitable technique, such as by spectrophotometry, back-scatter or an appropriate extraction method, using the conditioned specimens.

The colouring matter (M%) is also measured in the conditioned specimens. If inorganic pigments are identified, incineration enables the gravimetric determination. If soluble dyes are present, a spectrophotometric analysis is a suitable.

Corrections to be made on the percentages of cellulose (=C%), softeners (=S%) and other additives (=A%)

C% (corrected value) = C% x 100/(100-W-L-M)
S% (corrected value) = S% x 100/(100-W-L-M)
A% (corrected value) = A% x 100/(100-W-L-M)

Nota bene

The minimum cellulose content in the anhydrous RCF has been fixed at 72 % (Council Directive 83/229/EEC). This value refers to the anhydrous, uncoated RCF and it does not take into account the colouring matters.

ANNEX II TO SECTION 5 OF CHAPTER I

METHOD OF ANALYSYS FOR CONTROL OF MIGRATION OF COLORANTS ONTO FOODSTUFF

Warning: **This method was proposed by CIPCEL on 21 April 1992 as a proposal for a validated method of analysis. It should not be considered as a Commission document.**

INTRODUCTION

This test is to check the suitability of regenerated cellulose films containing colouring matter (dyes and pigments) against the requirements of Article 2.2. of the EEC Regenerated Cellulose Film Directive (Document 83/22WEEC - "Materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs").

APPARATUS

- Filter paper for qualitative analysis, of medium porosity, such as Weissband Mittel (Schleicher & Schull) ; Whatman N° 1 ; paper for chromatography (Archer 302),
- Glass dessicator,
- Oven capable of being regulated at 50 ± 2°C,
- Glass plates e.g. photographic type

LIQUID SIMULANTS FOR STANDARD TESTS

- Distilled water,
- Aqueous solution of acetic acid 3% (w/w),
- Aqueous solution of ethanol 15% (v/v),
- Decolorised edible oil or fat, or a comparable synthetic triglyceride,

If the foodstuff directly concerned does not correspond to the above simulants, e.g. owing to a higher percentage of acetic acid or ethanol, then the test simulant should be adapted to the particular requirements, or replaced by one which more closely corresponds to the foodstuff.

AREA OF CONTACT

At least 10 cm2.

TEST PROCEDURE

1. In the case of the aqueous simulants, and with the object of obtaining a test atmosphere saturated with the vapours of the liquid simulant at the test temperature, cover the bottom of the dessicator with the simulant concerned and maintain it a temperature of 50 ± 2°C in an oven for 30 minutes.

2. Impregnate strips of filter paper with the liquid simulant (aqueous or oil). These strips can conveniently be about 8 cm x 1,5 cm in dimensions, to provide an area of contact with the test film of the order of 10-15 cm². Eliminate excess simulant by squeezing the strips between two glass rods.

3. Place a 1 dm2 piece of the coloured film under test on to a glass plate, followed by a few strips of the filter paper impregnated with the appropriate simulating liquid, side by side and directly on top of the film. Cover with a second glasse plate, and on top of the latter place a few more strips of the impregnated filter paper to act as controls. Cover with a further glass plate, and place thereon a weight of about 1 kg.

4. Place the complete assembly referred to in 3. into the desiccator containing the appropriate simulant (L), and store the closed desiccator for 5 hours in the oven, regulated at a temperature of 50 ± 2°C. At the end of this test period, separate the strips of impregnated filter paper from the coloured film, and isolate the blank control strips.

CHECKING FOR MIGRATION

Compare the strips of impregnated filter paper that have been in contact with the coloured film sample with the control strips. This visual comparison should be done in daylight or under an artificial light source having the characteristics of daylight.

The control strips should have remained uncoloured, and, in order for the coloured test film to meet the requirements of Article 2.2. of the E.E.C. Regenerated Cellulose Film Directive, there should be no difference in colour, detectable to the eye, between the filter paper strips tested in contact with the coloured film and the control strips.

SECTION 6

CERAMICS

1. EU legislation: List of pertinent Directives

84/500/EEC [A8] Council Migration limits for Cd/Pb

2. Field of application of Directive 84/500/EEC

Article 1.2

This Directive concerns the possible migration of lead and cadmium from ceramic articles which, in their finished state, are intended to come into contact with foodstuffs, or which are in contact with foodstuffs, and are intended for that purpose.

Article 1.3

'Ceramic articles' means articles manufactured from a mixture of inorganic materials with a generally high argillaceous or silicate content to which small quantities of organic materials may have been added. These articles are first shaped and the shape thus obtained is permanently fixed by firing. They may be glazed, enamelled and/or decorated.

Possible migration of lead and cadmium from the inner surface of a ceramic lid underlies the same limits as ceramic vessels (Article 2.3).

3. Migration limits for lead and cadmium

Directive 84/500/EEC has established for lead and cadmium limits expressed according to the vessel type in mg/dm² (QMA) or in mg/l (SML).

Article 2.4

- 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/dm² for lead
  0.07 mg/dm² for cadmium

- All other articles which can be filled:
  4.0 mg/l for lead
  0.3 mg/l for cadmium

- Cooking ware; packaging and storage vessels having a capacity of more than three litres:
  1.5 mg/l for lead
  0.1 mg/l for cadmium

Variability of the lead and/or cadmium migration of individual ceramic articles has been taken in account:

Article 2.5

However, where a ceramic article does not exceed the above quantities by more than 50 %, that article shall nevertheless be recognised as satisfying the requirements of this Directive if at least three other articles with the same shape, dimensions, decoration and glaze are subjected to a test carried out under the conditions laid down in Annexes I and II and the average quantities of lead and/or cadmium extracted from those articles do not exceed the limits set, with none of those articles exceeding those limits by more than 50 %.

Nota bene. The Directive did not provide the procedure of the three consecutive attacks with the simulant, as the number of the samples to be checked is very large and the volatility of the acetic acid can create problems for the analysts.

4. Method for the determination of migration of lead and cadmium

Test conditions such as 'simulant' liquid composition, test duration, lighting conditions, surface determination, and contact between 'simulant' liquid and test article, are laid down in Annex I of the Directive.

The determination of the specific migration of lead and/or cadmium is carried out by atomic absorption spectrophotometry. Reagents, stock solutions, detection limits and other measurement specifications are set out in Annex II of the Directive.

A CEN standard (=EN 1388, Parts 1 and 2) established the details of the analytical procedure.

SECTION 7

ELASTOMERS AND RUBBER

Elastomers and rubber are not yet regulated at EU level by a specific Directive, with the exception of the Directive 93/11/EEC concerning the nitrosamines and N-nitrosatable substances released by rubber teats and soothers (see Annex). The general provisions of the framework Directive 89/109/EEC [A11] apply in all the other situations. The Committee of Experts of the Council of Europe is drafting a technical document in this issue (see Chapter IV).

Nota bene
The silicones have been treated at the levels of the Member States and the Council of Europe as a specific issue and are treated separately also here (see Section 8).

ANNEX TO SECTION 7 OF CHAPTER I

NITROSAMINES AND N-NITROSATABLE SUBSTANCES IN RUBBER TEATS AND SOOTHERS

1. EU legislation: List of pertinent Directives

93/11/EEC [A16]	Commission	Limits of nitrosamines and N-nitrosatable substances in teats and soothers

2. Limits of nitrosamines and N-nitrosatable substances in rubber teats and soothers

Researches carried out in Germany showed a possible release of nitrosamines and N-nitrosatable substances in rubber teats and soothers. Therefore the Commission, after the advice of the Scientific Committee on Food (SCF), drafted a proposal of Directive adopted as Directive 93/11/EEC.

Nitrosamines are formed in rubber teats and soothers during their production, nitroso- or NOx compounds reacting with secondary amines used as accelerators or stabilisers. Since modifications of the manufacturing process did not sufficiently reduce the migration of volatile nitrosamines, it seemed necessary to establish limits for the amides, amines and other nitrosatable substances which are as low as technically achievable. Directive 93/11/EEC (Article 2) limits the quantity of these substances in finished rubber teats and soothers.

3. Control of N-nitrosamines and N-nitrosatable substances

Annexes I and II of Directive 93/11/EEC provide basic rules and criteria for the method of analysis to be used to determine the release of these materials. A validated method is issued as EN (see Chapter III).

SECTION 8

SILICONES

1. EU legislation

Silicones are not yet regulated at EU level by a specific Directive and, therefore, the general provisions of the Framework Directive 89/109/EEC [A11] apply.

Nota bene
The Committee of Experts of the Council of Europe has adopted on 13 October 1999 a Resolution on this issue [AP(99)3]. See Chapter IV.

2. Background

Directive 2002/72/EC [A29] specifically excludes of silicones from the definition of "plastics". The reasons of this decision are:

a) 95 % of the silicones should be considered as elastomers rather than plastics according to classical definition;

b) The rules applied to plastics are not necessarily appropriate to silicones;

c) The existence of a Council of Europe Resolution recently approved.

3. Commission Guidelines

Pending the drafting of a Commission Directive and the absence of a national legislation, the Commission recommends the application of the Resolution of the Council of Europe as an instrument to apply the Article 2 of the framework Directive 89/109/EEC.

SECTION 9

PAPER AND BOARD

1. EU legislation

Paper and board food contact materials and articles are not yet regulated at EU level by a specific Directive and, therefore, the general provisions of the Framework Directive 89/109/EEC [A11] apply.

A Resolution of the Council of Europe was adopted by the Council of Ministers 18 September 2002 (Resolution AP (.2002)1. on paper and board materials and articles intended to come into contact with foodstuffs**: http://www.coe.fr/soc-sp/sante/pack/resol.htm**).

Moreover the Council's Public Health Committee adopted Technical Documents 2, 3 and 4 on 17 June 20002:

- Technical document No 2: Test conditions and methods of analysis for paper and board intended to come into contact with foodstuffs: **http://www.coe.fr/soc-sp/sante/pack/test.htm**
- Technical document No 3: Guidelines on paper and board, made from recycled fibres, intended to come into contact with foodstuffs : **http://www.coe.fr/soc-sp/sante/pack/fibres.htm**
- Technical document No 4: Good manufacturing practice for paper and board intended to come into contact with foodstuffs : **http://www.coe.fr/soc-sp/sante/pack/Res%20paper%20and%20board.htm**

See also **Chapter IV.**

2. Commission Guidelines

Pending the drafting of a Commission Directive and the absence of national legislation, the Commission recommends to applying at national level the above-mentioned Technical Documents to fulfil the requirements of Article 2 of the framework Directive 89/109/EEC. It should be reminded that the Committee of Experts, composed of representatives of the large majority of the Member States, has prepared and adopted these documents. The Commission services have also collaborated during the preparation of these documents. For further information, see Chapter IV.

SECTION 10

GLASS

EU legislation

Glass is not yet regulated at EU level by a specific Directive and, therefore, the general provisions of the Framework Directive 89/109/EEC [A11] apply.

The Committee of Experts of the Council of Europe is drafting a Technical Document on this issue. See Chapter IV.

SECTION 11

METALS AND ALLOYS

1. EU legislation

Metals and alloys are not yet regulated at EU level by a specific Directive and, therefore, the general provisions of the Framework Directive 89/109/EEC [A11] apply.

In March 2000, the Committee of Experts of the Council of Europe adopted a Technical Document called "Guidelines on metals and alloys used as food contact materials". This document lists international expert evaluations made on the individual metals (**http://www.coe.fr/soc-sp/sante/pack/metals.zip**). See also **Chapter IV.**

2. Commission Guidelines

Pending the drafting of a Commission Directive and the absence of national legislation, the Commission recommends applying at national level the above-mentioned Technical Document to fulfil the requirements of Article 2 of the framework Directive 89/109/EEC. It should be remembered that the Committee of Experts, composed of representatives of the large majority of the Member States, has prepared and adopted these documents. The Commission services have also collaborated during the preparation of these documents. For further information, see Chapter IV.

SECTION 12

CORK

EU legislation

Cork is not yet regulated at EU level by a specific Directive and, therefore, the general provisions of the Framework Directive 89/109/EEC [A11] apply.

The Committee of Experts of the Council of Europe is drafting a Technical document in this issue. See Chapter IV.

SECTION 13

TEXTILE PRODUCTS

EU legislation

Textiles are not yet regulated at EU level by a specific Directive and, therefore, the general provisions of the Framework Directive 89/109/EEC [A11] apply.

SECTION 14

PARAFFIN WAXES AND MICROCRYSTALLINE WAXES

EU legislation

Paraffin waxes are not yet regulated at EU level by a specific Directive and, therefore, the general provisions of the Framework Directive 89/109/EEC [A11] apply.

2. Wax (REF. N. 95859) and oils (REF.N. 95883)

The Directive 2002/72/EC [A29] contains some specifications of waxes, refined and white mineral oils, paraffinic.

Other information can be found:

a) For waxes in par. 172.886(b) of the Code of Federal Register of the US FDA

b) For white mineral oils in the European Pharmacopoeia as “Paraffinum Liquidum”

Nota bene 1
Since some of the waxes are also used as direct food additives, evaluations from the SCF can be found for certain qualities of waxes (specified by the EU directives).

Nota bene 2
The term “highly”, used in the SCF opinion does not appear in the current specifications because it is too generic and unnecessary for the definition of the product. In fact, the product should comply with the specifications appearing in the SCF opinion as well as with that of this document.

SECTION 15

ION EXCHANGE RESINS

1. EU legislation

Ion exchange resins are not yet regulated at EU level by a specific Directive and, therefore, the general provisions of the Framework Directive 89/109/EEC [A11] apply.

The Committee of Experts of the Council of Europe adopted Resolution AP(97)1 on this issue on 30 September 1997 (**http://www.coe.fr/soc-sp/sante/ap97e1.pdf**)

2. Commission Guidelines

Pending the drafting of a Commission Directive and the absence of national legislation, the Commission recommends applying at national level the above-mentioned Technical Document to fulfil the requirements of Article 2 of the framework Directive 89/109/EEC. It should be remembered that the Committee of Experts, composed of representatives of the large majority of the Member States, has prepared and adopted these documents. The Commission services have also collaborated during the preparation of these documents. For further information, see **Chapter IV**.

SECTION 16

ADHESIVES

This issue is not yet regulated specifically at EU level. Recently it was suggested to insert the adhesives between the types of materials to be regulated by Commission Directives. Pending the preparation of a specific Directive, the Commission requested the European professional organisation to prepare an inventory list of substances used in the manufacture of an adhesive and a professional Code of Practice. The documents are under preparation.

EU legislation

Adhesives are not yet regulated at EU level by a specific Directive and, therefore, the general provisions of the Framework Directive 89/109/EEC [A11] apply. However, see Part 2 of Section 4 in relation to the use of BADGE, BFDGE and NOGE together with their derivatives in adhesives.

SECTION 17

PRINTING INKS

EU legislation

Printing inks are not yet regulated at EU level by a specific Directive and, therefore, the general provisions of the Framework Directive 89/109/EEC [A11] apply.

The Commission services intend to insert printing inks into the list of materials and articles to be controlled by specifc directives.
The Committee of Experts of the Council of Europe is drafting a Technical document on this issue. See **Chapter IV**.

CHAPTER II

SCF: NOTE FOR GUIDANCE

("NOTE FOR GUIDANCE OF PETITIONER WHEN PRESENTING
AN APPLICATION FOR SAFETY ASSESSMENT OF A SUBSTANCE TO BE USED IN
FOOD CONTACT MATERIALS PRIOR TO ITS AUTHORISATION")

This document appears as a separate document in the homepage of the EC-JRC website (*http://cpf.jrc.it/webpack*)

CRITERIA APPLIED BY THE SCF FOR THE EVALUATION OF SUBSTANCES

1. INTRODUCTION

The "SCF Guidelines" not always explicitly inform about the criteria of SCF for the evaluation of a substance and the specification of quantitative restrictions. This document summarises these criteria as far as possible in order to provide basic information, but also as pro-memoria[2] to avoid discrepancies in future evaluations.

However it should be noted that this document was prepared many years ago and, therefore, does not necessarily represent now the SCF opinion.

2. ALLOCATION TO SCF LISTS.

2.1 The SCF classified the substances included in Synoptic document in ten lists ("SCF lists") defined as reported in the document "**Note for Guidance**". The criteria applied for this classification are included and will not be repeated here. However it could be useful

a) To repeat some criteria as a pro memoria and underline aspects for the allocation of substances in lists 6 (6A and 6B), 7, 8 and 9, because recently some detailed criteria have been defined for these lists;

b) To better explain the criteria used by the SCF for the establishment of a TDI or other quantitative restrictions.

2.2. List 6

The SCF stated that "allocations of substances to this list are mainly based upon similarity of structure of chemical substances already evaluated or known to have functional groups that indicate carcinogenic or other severe toxic properties".

2.2.1 List 6A

The SCF recently expressed the opinion that the following compounds are "suspected to have carcinogenic properties":

- Acrylamides and methacrylamides
- Allyl compounds
- Crotonyl compounds
- Epoxy compounds
- Hydrazides
- Vinyl compounds

In principle, all these compounds appear in list 6A, accompanied by the notation that "these substances should not be detectable in foods or in food simulants by an appropriate sensitive method", and the Commission established an SML equal to 0.05 mg/kg or a QM equal to 5 mg/kg in the Directive 2002/72/EC.

However, in the following cases, these substances may be classified in other lists:

Substances with sufficient data to allocate a TDI
These substances are classified in list 2. If mutagenicity data according to the guidelines and/or carcinogenicity data are missing, the TDI is temporary.

Generically termed substances
Substances just described in generic terms are classified in list 9, with the same restrictions as mentioned above (SML of 0.05 mg/kg or QM of 5 mg/kg)

Polymers made from the substances mentioned above
They are classified in list 9.

Vinyl compounds have been classified as follows:

(i) Vinyl compounds considered carcinogenic or suspect carcinogenic on the basis of experimental data: list 4A

(ii) Vinyl ethers of alcohols classified in SCF lists 0, 1, 2, and 3: List 7 (SML of 0.05 mg/kg or QM of 5 mg/kg). Needed: hydrolysis data

(iii) Vinyl ethers of alcohols in lists 6, 7 and 8: list 7 (SML of 0.05 mg/kg or QM of 5 mg/kg). Needed: data on corresponding alcohols, provided hydrolysis can be demonstrated

(iv) Vinyl esters of monocarboxylic acids classified in SCF lists 0, 1, 2 and 3: List 7. Needed: hydrolysis data.

(v) Monovinyl esters of polycarboxylic acids classified in SCF lists 0, 1, 2 and 3: List 7). Needed: hydrolysis data

(vi) Vinyl esters of monocarboxylic acids classified in SCF lists 6, 7 and 8: List 7). Needed: data on corresponding acid, provided hydrolysis could be demonstrated

(vii) Monovinyl esters of polycarboxylic acids classified in SCF lists 6, 7 and 8: List 7). Needed: data on corresponding acid, provided hydrolysis could be demonstrated

2.2.2. LIST 6B

The SCF classified the following compounds as "suspected to have toxic properties (other than carcinogenic)":

Esters of:

- Adipic
- Azelaic
- Citric
- Phosphoric
- Phosphorous
- Phthalic
- Sebacic
- Trimellitic

In principle, all these compounds appear in list 6B, with a few exceptions classified in

- List 2 (data available for allocating a TDI)
- List 7 (hydrolysis data justify the assessment of hydrolysates, see below)
- List 9 (better identification of the substances required before decisions can be taken).

Classification in list 6B is accompanied by a group TDI of 0.025 mg/kg b.w. and the request for studies on

- Peroxisome proliferation (with some exceptions)
- Reproduction and teratogenicity
- Mutagenicity
- Neurotoxicity

The allocation of a group TDI of 0.025 mg/kg bw is based on the following considerations.

- These compounds are suspected to have "severe toxic effects" and, therefore, their "migration should be kept as low as possible".

- Often these compounds have the same use (as plasticizers) and are applied as a mixture. It is, therefore, appropriate to define a restriction for the whole group.

- The majority of these additives are peroxisome proliferators, but there is not sufficient data to determine their potencies and compare them to that of DEHP, considered as the most potent peroxisome proliferator among these additives. Therefore the restriction for the whole group is fixed at the level of the TDI of DEHP (= 0.025 mg/kg bw).

The reasons for requesting further studies are summarised below.

Mutagenicity studies

Mutagenicity studies are useful primarily as a screening test to detect the substances "suspected to have carcinogenic properties". The recommended tests can be found in the "SCF-WG Explanatory Guidance".

Peroxisome proliferation study

See explanation given in the document "SCF-WG Explanatory Guidance".

Reproduction and teratogenicity studies

Studies on reproduction and teratogenicity have been requested for certain substances, because of evidence that a number of substances in the group have adverse effects on reproduction and/or are teratogenic. However, this data is only needed, if migration exceeds 5 mg/kg of food (see "SCF Guidelines").

Neurotoxicity studies

Neurotoxicity studies have been requested for phosphoric and phosphorous acid esters, because of evidence that a number of substances in this group have neurotoxic properties. Tests with chickens or measurements of anticholinesterase activity would be appropriate. However, such data is only needed, if migration exceeds 0.05 mg/kg of food (see "SCF Guidelines").

2.3. List 7

In principle, classification in list 7 is based on some data being available, but insufficient or inadequate to allow a classification into lists 0-4. Therefore the additional data specified in the notation "needed" should be furnished.

Hydrolysis data

The SCF asks for information about the hydrolysis rate with the objective of reducing the amount of toxicological testing required. Some chemical structures of monoesters suggest ready hydrolysis into substances, which are already in list 0, 1, 2 or 3. Hence the hydrolysis data is only requested for compounds specifically indicated.

As an example, the SCF required hydrolysis data only for acrylic and methacrylic esters of monohydric alcohols or monoesters of the same acids with polyalcohols, provided the alcohols were in lists 0, 1, 2 and 3. For all other esters of acrylic and methacrylic acids, the general rules for the classification of the substances in the SCF lists apply. The same for the esters of adipic, azelaic, citric, phosphoric, phosphorous, phthalic, sebacic and trimellitic acid: hydrolysis data are requested only for those monoesters, which may be hydrolysed to substances which are already in lists 0, 1, 2 and 3.

Hydrolysis may be demonstrated in foods or food simulants representing the range of foods with which the substance may come into contact. Alternatively, or in cases where

hydrolysis in food does not occur, hydrolysis can be evaluated in simulated saliva and/or gastrointestinal fluids.

The SCF underlined that the request for hydrolysis data does not imply that no other toxicity data will be needed. In some cases, moreover, other toxicity data may render the request for hydrolysis data superfluous.

2.4 List 8

The SCF classifies in this list "the substances for which none or only scanty and inadequate data is available".

The notation "inadequate data", which appears besides some compounds in List 8 (as well as in other lists), refers to the request made by the SCF in its guidelines. In these guidelines, the SCF recommended the petitioners to provide:

a) Only the data specified in "full" or "reduced" dossier (see "SCF Guidelines");

b) The data under a) according to EC Directives and/or OECD guidelines, including "Good Laboratory Practice".

Hence "inadequate" means that the data supplied (e.g. acute toxicity, inhalation studies) either do not correspond to those requested (e.g. subchronic or long-term studies, oral studies), or are not in conformity with EC/OECD guidelines (e.g. the number of animals or the number of biological parameters examined was insufficient).

2.5. List 9

In list 9, the SCF classified all the "substances and groups of substances which could not be evaluated due to lack of specifications (substances) or to lack of adequate description (groups of substances)", also the polymers for which the data on identity, as specified in "SCF Guidelines", are not available (see also "Note for Guidance).

2.5.1 Groups of substances or mixtures

According to the SCF, the evaluation and listing of groups of substances and mixtures should be replaced, where possible, by treatment of individual substances. If the petitioner is unable to specify the individual substances in a mixture, the SCF requires an explanation and will usually authorise only the mixture for which the petitioner supplied the technical data. Therefore, the petitioner should precisely describe the mixture.

No general criteria for the evaluation of mixtures have been established. The SCF decided to evaluate them on a case by case basis. For example, since phthalates, adipates and phosphates have been frequently requested as mixtures, for these substances a group restriction of 0.025 mg/kg has been fixed.

2.5.2 Polymers used as “basic polymers” or “polymeric additives”

The SCF divided polymers into two categories:

Cat. 1. “Basic polymers”

Cat. 2. “Polymeric additives”

The reason for this distinction is that the polymeric additives may not necessarily have the same degree of polymerisation as the basic polymers.

The basic polymers should be not listed “if the monomers or starting substances required to synthesise them are included in the list”.

The polymeric additives should be listed and the data requested in the "SCF Guidelines" should be provided. The criteria for their classification may be summarised as follows:

a) Polymers exclusively containing components with a molecular weight exceeding 1,000 D.

- If their monomers or starting materials are in lists 0, 1, 2, 3 and 4, they are toxicologically acceptable and classified in list 3 without specific individual evaluation.
- If their monomers or starting substances are in lists 6, 7, 8, 9 or not evaluated at all, they need an individual evaluation. Data should be supplied according to the "SCF Guidelines”

b) Polymers with part of the components having a molecular weight below 1,000 D.

They need an individual evaluation and data should be supplied according to the "SCF Guidelines”.

These categories are distinguished because of three main reasons.

a) The absorption by the gastrointestinal tract is negligible when the MW exceeds 1,000 Dalton.

b) The migration of high MW material from plastics is low.

c) Residual monomers and other low molecular weight components can be removed.

2.5.3 Fatty acids, their dimers and trimers

The SCF made the decisions listed below.

a) It is no longer necessary to add the notation "food grade quality" and, therefore, all the substances containing this specification have been suppressed.

b) All fatty acids derived from natural sources are classified in list 3, with the annotation "constituents of natural fats".

c) Fully hydrogenated or dehydrated fatty acids derived from natural sources are classified in list 3 with the annotation "identical with or similar to constituents of natural fats".

d) All edible oils (including castor oil, which has an ADI), fats and triglycerides with saturated monocarboxylic fatty acids with an even number of carbon atoms are classified in list 3, with the annotation "natural fats".

e) All fully hydrogenated and dehydrated oils and fats are classified in list 3, with the annotation "similar to natural fats".

f) Dimers of the materials described under b) are classified in list 8.

The SCF-WG decided that the minor fatty acids in natural edible oils should be dealt with as impurities and form part of the specification of the individually listed major components.

2.6. Salts

All SCF reports specify: "Whenever acids, phenols or alcohols have been evaluated, the assessment also includes aluminium, ammonium, calcium, iron, magnesium, potassium, sodium and zinc salts."

2.7 Foodstuffs and food ingredients

Foodstuffs or food ingredients, used either as monomers and starting substances or as additives to plastics, will be included in list 0 after the data requested by SCFI (Sections 1 and 3 of the SCF guidelines) have been supplied.

2.8. Food additives

Food additives listed in EC Directives or Reports of the SCF will be added to list 1 after the data requested by SCF (Sections 1, 3 and 6 of the SCF guideline) have been supplied. Migration data is still needed, because there are restrictions in terms of concentration in foods and types of food. Migration from plastic packaging must not lead to any infringement of these restrictions.

2.9 Biocides

(short extract from SCF-WG Explanatory Guidance of SCF Guidelines, see the full text in Note for Guidance in the same website (***http://cpf.jrc.it/webpack***)

"This section focuses on the use of biocides incorporated into food contact materials. ……The additional information to be provided by applicants relates particularly to documentation of the public health implications of the use of a biocide to be incorporated into food contact materials. The information to be supplied should enable an evaluation of the safety, efficacy, and the microbiological implications of the use of the biocide."

3. TOXICOLOGICAL DATA, QUANTITATIVE RESTRICTIONS

The conclusions from the toxicological data depend, first of all, on whether or not the set of mutagenicity tests indicates genotoxicity.

3.1. For non-genotoxic substances, usually a dose causing no observed adverse effects in laboratory animals (NOAEL) can be determined. If the NOAEL has already been evaluated by the SCF or JECFA, usually no reassessment is required. For further details, see "SCF Guidelines". For other substances a "tolerable daily intake" (TDI) for man is calculated, expressed in mg/kg body weight (b.w.) and applying a safety factor, which accounts for:

a) Possible differences between animals and man in their reaction to chemicals;

b) Possible differences in sensitivity to chemicals between individuals of a population;

c) Uncertainties in assessing the NOAEL in animals;

d) Uncertainties due to difficulties in carrying out adequate monitoring of human populations to detect unexpected adverse effects in man

If the toxicity data (e.g. referring to the "essential core set of tests" of the "SCF Guidelines") is considered adequate, usually a safety factor of 100 is applied.

3.2 Substances having a reduced technical dossier

3.2.1 If migration (M) is between 0.05 and 5 mg/kg food or food simulant, a "reduced dossier" is sufficient (see “SCF Guidelines”), and the SCF proposes a restriction less or equal to 5 mg/kg.

3.2.2 If migration remains below 0.05 mg/kg food or food simulant, a "reduced dossier" containing at least three specified mutagenicity tests may be supplied, and the SCF will propose a restriction below or equal to 0.05 mg/kg of food or food simulant.

3.3. Genotoxic substances or substances showing other high toxicity (e.g. sensitizers), for which the present scientific knowledge does not allow the establishment of a NOAEL, are usually classified in lists 4 or 5.

CHAPTER III

C E N

For further information concerning published standards, contact CEN, rue de Stassart 36, B-1050 Brussels, Belgium or your national standards body e.g. BSI, DIN, AFNOR, AENOR.

For other information on the standards work of CEN TC194/SC1, contact either the Secretary or the Chairman.

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CEN EN standard methods of test for materials and articles intended to come into contact with foodstuffs

(Text prepared by P. Tice, ex Secretary CEN TC194/SC1)

(Updated to 05 December 2002)

Warning

The parts amended are <u>not</u> indicated in bold and italics characters.

The responsibility for the development and establishment of standard test methods for the plastics substances or parameters for which the EC Directives have specified quantitative restrictions, was assigned to CEN by the European Commission/EFTA in 1994 by means of a mandate, with the necessary funding.

CEN is the European Committee for Standardization which produces harmonized EN standards to facilitate the exchange of goods and services within Europe by eliminating barriers to trade. CEN was established in March 1961 in Paris and moved to Brussels in 1975.

The members of CEN are the 19 national standards bodies of: the European Union (15 countries), the European Free Trade Association (3 countries) and the Czech Republic. In addition there are fourteen Affiliates, which are mainly standards bodies from East European countries. There are also four Corresponding Organisations: Egypt, South Africa, Ukraine and Yugoslavia.

CEN Technical Committee 194/Sub-Committee 1

The work to produce the standard (EN) test methods has been delegated by CEN to Sub-Committee 1 of Technical Committee 194 (CEN TC194/SC1). The title of the Sub-Committee is *General chemical methods of test for materials intended to come into contact with food.*

The development and drafting of the standard test methods is carried out by Working Groups under the direction of the Sub-Committee. The members of these Working Groups are appointed by the national standards bodies and are experts in the particular fields of analysis.

When a Working Group has completed drafting a Work Item/document it is circulated to members of CEN TC194/SC1 for technical approval. If the Work Item/document is approved it is then edited to comply with CEN rules and submitted to CEN Management Centre (CMC) for Enquiry/Formal Voting by CEN member national standard bodies for approval to become an EN standard. All documents produced by the Working Groups and approved by CEN TC194/SC1 are in English only. The final standard documents are translated into the other two CEN official languages - German and French. Where it is considered that the analytical test method in the document requires further development work it may be produced as a Technical Specification (CEN/TS *serves as a normative document in areas where the state of art is not yet stable enough*). Other documents aimed to provide information are produced as Technical Reports (CEN/TR *for information and transfer of knowledge*). The CEN/TS and CEN/TR are recently introduced classifications for documents. The CEN/TS classification has replaced the previous ENV classification. Work items which were scheduled to become ENV standards have been submitted to become CEN Technical Specifications. These are identified in the relevant sections below. The long term aim is for these Work Items to be established as full EN standards.

Following final Ratification and Implementation, all CEN/TS and CEN/TR documents and EN standards are published by the standards bodies of the individual member countries of CEN, usually

in one of the three official languages - English, German and French, For example in the UK as BSI EN 1186 and in Germany as DIN EN 1186.

Seven Working Groups have been formed with the following titles:

- Working Group 1 - *Overall Migration from plastics*
- Working Group 2 - *Methods of test for monomers*
- Working Group 3 - *Methods for metal release from ceramics*
- Working Group 4 - *Miscellaneous protocols and test methods* (see below)
- Working Group 5 - *Polymeric coatings on metal substrates for food contact*
- Working Group 6 - *Polymeric coatings on cellulosic substrates for food contact*
- Working Group 8 - *Test methods for BADGE, BFDGE plus reaction products, and NOGE*

The list of Work Items assigned to Working Group 4 is given below:

- methods for measurement of temperature at food/plastics interface
- method for determination of free fat on the surface of foodstuffs.
- method(s) for determination of molecular weights of polymeric additives

A reorganisation of the Working Groups took place early 2001 and the following Working Groups are currently active:

- Working Group 1 (includes any future work arising from Working Group 4 Work Items)
- Working Group 2
- Working Group 8

Working Groups 3, 4, 5 and 6 are currently not active having completed their work on the assigned Work Items.

In addition Task Group 9 is carrying out preliminary investigations on test methods for primary aromatic amines for Sub-Committee 1.

Task Group 9 was formed in October, 2001. The test methods are required for testing for compliance with the restriction for primary aromatic amines in European Commission Directive 2001/62/EC of 9th August 2001, which was the 6th amendment to Directive 90/128.EEC *relating to plastic materials and articles intended to come into contact with foodstuffs* (now incorporated in Annex V of codified Directive 2002/72/EC). An application for a new Work Item(s) is to be made by CEN TC194/SC1 for the test methods. It is intended that the test methods will become an EN standard.

Many of the Work Items in the Work Programme of Sub-Committee 1 have now been completed. These are detailed below. Work Items which are currently active include two Work Items for the BADGE/BFDGE/NOGE test methods assigned to Working Group 8.

Applications have recently been made for two new Work Items for documents to be produced as CEN Technical Reports (CEN/TR). It is intended that these Work Items will be assigned to Working Group 1.

The titles of the new Work Items are:

- Estimation of migration by generally recognized diffusion models in support of European Commission Directive 2002/72/EC

- Method of test for refillable PET bottles with respect to their chemical inertness

Some of the CEN TC194/SC1 Work Items are not covered by the current European Commission/EFTA mandate. These are identified in the relevant sections below.

Delays have occurred in the past in progressing the Work Items which resulted in most of the original Target Dates, particularly those specified in the European Commission/EFTA mandate, not being met.

New Target Dates for those Work Items covered by the European Commission/EFTA mandate were set in 2000, following a review meeting between CEN Management Centre and representatives from the European Commission/EFTA.

Progress against Target Dates currently set for all Work Items is given below.

Meetings of the active Working Groups and Task Groups usually take place twice per year (May and October) at various locations around Europe. CEN TC194/SC1 meetings also take place twice per year.

Progress with Work Items - December 2002

Working Group 1
Standard for overall migration test methods EN 1186

All 15 Parts of EN 1186 have been approved by CEN Members, ratified, implemented and published.

The overall migration test methods in standard EN 1186 are performed on plastics materials and articles to establish compliance with the overall migration limit in European Commission Directive 2002/72/EC *relating to plastic materials and articles intended to come into contact with foodstuffs*.

Fourteen parts of the standard were originally published as a preliminary/temporary ENV standard under the number ENV 1186 Parts 1 to 14.

Part 1 of the standard is the 'Guide' for use by the analyst to help select the appropriate test method, the method of exposure and the test conditions, and to assist in the interpretation of the test results.

Parts 2 to 13 cover overall migration testing with four food simulants: A - distilled water, B - 3% w/v aqueous acetic acid solution, C - 10% v/v aqueous ethanol solution, D - olive oil or other fatty food simulants, and with exposure of the plastic test specimens to the food simulants by: total immersion, single-side with cells, single-side with the plastic formed into pouches and single-side by filling articles/containers. The test methods are applicable to the measurement of overall migration from plastics which have been exposed to food simulants under all "conventional migration test conditions" specified in European Commission Directive 97/48/EC - the second amendment to Council Directive 82/711/EEC *laying down the basic rules necessary for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs*. These "conventional migration test conditions" cover *Test Times* from 0.5 hours to 10 days and *Test Temperatures* from 5°C to 175°C.

Part 14 contains test methods for *substitute fat tests* with test media iso-octane and 95% ethanol, as specified in European Commission Directive 97/48/EC.

Part 15 was not published as a Part of the preliminary/temporary ENV 1186 standard.

Part 15 contains 'extraction' test methods for *alternative fat tests* with *volatile media* iso-octane and 95% ethanol, as specified in European Commission Directive 97/48/EC.

Parts 14 and 15 were not included in the European Commission/EFTA mandate, as they were added to the Work Programme after the mandate was awarded in 1994.

The detailed titles of the fifteen Parts of EN 1186 are given below in Table 1:

Table 1 List of parts of EN 1186*: Overall migration tests methods for plastics materials and articles intended to come into contact with foodstuffs*

Part 1	Guide to selection of conditions and test methods for overall migration
Part 2	Test methods for overall migration into olive oil by total immersion
Part 3	Test methods for overall migration into aqueous food simulants by total immersion
Part 4	Test methods for overall migration into olive oil by cell
Part 5	Test methods for overall migration into aqueous food simulants by cell
Part 6	Test methods for overall migration into olive oil using a pouch
Part 7	Test methods for overall migration into aqueous food simulants using a pouch
Part 8	Test methods for overall migration into olive oil by article filling
Part 9	Test methods for overall migration into aqueous food simulants by article filling
Part 10	Test methods for overall migration into olive oil (modified method for use in cases where incomplete extraction of olive oil occurs)
Part 11	Test method for overall migration into mixtures of ^{14}C-labelled synthetic triglycerides
Part 12	Test method for overall migration at low temperatures
Part 13	Test methods for overall migration at high temperatures
Part 14	Test methods for 'substitute tests' for overall migration from plastics intended to come into contact with fatty foodstuffs using test media iso-octane and 95% ethanol
Part 15	Alternative test methods to migration into fatty food simulants by rapid extraction into iso-octane and 95% ethanol

NOTE: Part 1 has been extensively revised to take account of the changes to testing protocols made in European Commission Directive 97/48/EC - the second amendment to Council Directive 82/711/EEC *laying down the basic rules necessary for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs*, and to include new sections with advice on 'problems' identified in use of the test methods in the ENV standard.

For some of the test methods precision data - 'r' repeatability values and 'R' reproducibility values - have been acquired from various collaborative trials which have taken place with parts of the draft standard.

For the remainder of the test methods, collaborative trials were completed during 2001 to produce 'r' and 'R' precision data. These trials were covered by funding under the mandate and all reports were published by the Target Date of end December, 2001. As these precision data were produced after drafting of the corresponding test methods/parts of the standard had been finalised, it is intended to publish the data in the first revision of EN 1186 Part 1 and other relevant parts. These revisions are expected to be made within the next two/three years and will also take account of relevant changes made in amendments of the Commission's 'plastics' Directives.

The test method: *Determination of overall migration from polymeric coatings on metal substrates* has been approved by CEN members and ratified, implemented and published as a CEN/Technical Specification - CEN/TS 14235. (The draft of this test method was produced by Working Group 5 and finalised by Working Group 1).

The Working Group 1/Task Group 7 work to produce a report on in-house validation protocols to provide precision data for future test methods produced as EN standards by the Working Groups of the Sub-Committee, has been completed and is due to be published as a CEN Technical Report (CEN/TR) early 2003. Working Group 1 intend to use the data in the report to produce working protocols.

Working Group 2:
Standard for test methods for plastics monomers prEN 13130

The test methods for plastics monomers in the EN standard under preparation are performed on plastics materials and articles to establish compliance with the individual SML and/or QM restriction assigned to the particular plastics monomer in European Commission Directive 2002/72/EC *relating to plastic materials and articles intended to come into contact with foodstuffs*. The plastics monomers, for which test methods are included in the standard, were selected on the basis of extent of use, and potential consumer exposure.

There are eight initial Parts of the draft standard - seven plastics monomer test methods and a Part 1 'Guide' . The 'Guide' is for use by the analyst to help select the appropriate method of exposure and the test conditions, and to assist in the interpretation of the test results.

The eight Parts of the standard were published initially as an ENV standard under the number ENV 13130, in May 1999.

In the draft of the Part 1 'Guide' for the EN standard, extensive revisions have been made, taking account of experience in use of the ENV standard and also changes to testing protocols made in European Commission Directive 97/48/EC - the second amendment to Council Directive 82/711/EEC *laying down the basic rules necessary for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs*.

Minor changes have been made to the seven plastics monomer test methods in the drafts prepared for the EN standard.

The detailed titles of the eight parts of the ENV standard are given below in Table 2. The titles of the corresponding Parts of the EN standard are expected to be similar.

Table 2 List of parts of ENV 13130*: Monomer test methods for plastics materials and articles intended to come into contact with foodstuffs*

Part 1	Guide to the test methods for specific migration of substances from plastics into foods and food simulants and the determination of substances in plastics and the selection of conditions of exposure to food simulants
Part 2	Determination of terephthalic acid in food simulants (SML = 7.5 mg/kg)
Part 3	Determination of acrylonitrile in food and food simulants (SML = not detectable, DL = 0.02 mg/kg)
Part 4	Determination of butadiene in plastics (QM = 1 mg/kg)
Part 5	Determination of vinylidene chloride in food simulants (SML = not detectable, DL = 0.05 mg/kg)
Part 6	Determination of vinylidene chloride in plastics (QM = 5 mg/kg)
Part 7	Determination of monoethylene glycol and diethylene glycol food simulants (SML(T) = 30 mg/kg)
Part 8	Determination of isocyanates in plastics (QM = 1 mg/kg)

SML = specific migration limit in food or food simulant
QM = maximum permitted quantity of the 'residual' substance in the material or article
DL = detection limit of the method of analysis

Precision data ‘r’ and ‘R’ for test methods in Parts 2 to 8 have been obtained by means of collaborative trials.

Only the ENV standard was covered by the European Commission/EFTA mandate.

During 2000 a further 20 Work Items were added to the Working Group 2 Work Programme. These consisted of 20 monomer test methods which had been produced in the BCR Project *Development of Methods of Analysis for Monomers and Other Starting Substances with SML and/or QM Limits in Directive 90/128/EEC and 92/39/EEC* - Report No. EUR 17560 EN, Published 1997.

The number of monomer test methods published in the report was 35. The number was reduced to 20 for the new Work Items by removing the method for BADGE (now covered separately by Working Group 8), eliminating those for which further development work was required and consolidating a number of like methods. The 20 Work Items with corresponding prEN 13130 Part numbers are given in the Table 3, below.

Table 3 List of plastics monomers - test methods, prEN 13130 Parts 9 to 28

Test methods for:

9. acetic acid, vinyl ester (vinyl acetate)	19. dimethylaminoethanol
10. acrylamide	20. epichlorohydrin
11 11-aminoundecanoic acid	21. ethylenediamine and

	hexamethylene-diamine
12. 1,3-benzenedimethaneamine	22. ethylene oxide and propylene oxide
13. 2,2-bis(4-hydroxyphenyl) propane	23. formaldehyde and hexamethylene-tetramine
14. 3,3-bis(3-methyl-4-hydroxyphenyl)-2- indolinone	24. maleic acid and maleic anhydride
15. butadiene	25. 4-methy-pentene
16. caprolactam and caprolactam salt	26. 1-octene and tetrahydrofuran
17. carbonyl chloride	27. 2,4,6-triamino-1,3,5-triazine
18. 1,2-dihydroxybenzene, 1,3-dihydroxybenzene, 1,4-dihydroxybenzene, 4,4'-dihydroxybenzophenone and 4,4'-dihydroxybiphenyl	28. 1,1,1-trimethylopropane

The documents for Parts 1 to 8 reached CEN Stage 49 *Document available for formal vote* at end April, 2002 and were sent to CEN Management Centre for circulation for *Formal Voting* by CEN member national standards bodies. They are to be processed under the Unique Acceptance Procedure (UAP) which combines the Enquiry and Formal Voting stages.

If the Voting results give approval for the 8 Parts to become standard EN 13130 - Parts 1 to 8, and the expected progress schedule is achieved, these Parts of the standard should be *Ratified* early 2003. *Implementation* and publication should then follow mid 2003.

The re-drafting of the 20 test methods from the BCR Project into CEN format has been completed. It is not intended to initially publish these test methods as Parts of the standard ENV 13130. It is intended that they will be added to standard EN 13130 as Parts 9 to 28.

CEN Stage 40 *Document available for enquiry* is expected to be reached for Parts 9 to 28 early 2003, and Stage 49 *Document available for formal vote* towards the end of 2003. If the Voting results give approval for the 20 Parts to be added to standard EN 13130 and the expected progress schedule is achieved, these Parts of the standard should be *Ratified* at the beginning of 2004. *Implementation* and publication should then follow during the first half of 2004.

Some precision data ('r' with 2/3 laboratories) were produced for the Parts 9 to 28 test methods during the work under the BCR Project. No collaborative trials are currently planned to produce full 'r' and 'R' data for the 20 added to the Work Programme.

It is expected that future users of these Parts of the standard will establish precision and reliability data for test results produced by means of in-house protocols, to be produced by Working Group 1 from data in the CEN/TR produced by Task Group 7.

Working Group 3
Test methods for release of lead and cadmium from ceramics

Working Group 3, which had the task of producing test methods for the release of lead and cadmium from ceramics, completed the assigned Work Items in 1994 and an EN Standard has been published with two parts. The number of the standard and the titles of the two parts are:

EN 1388-1:1996 *Materials and articles in contact with foodstuffs - silicate surfaces, Part 1. Determination of release of lead and cadmium from ceramic ware*

EN 1388-2:1996 *Materials and articles in contact with foodstuffs - silicate surfaces, Part 2. Determination of release of lead and cadmium from silicate surfaces other than ceramic ware*

Working Group 4

1.7. Miscellaneous protocols and test methods

Working Group 4 is no longer active having completed all work required on the three assigned Work Items. The current positions and progress on the Work Items are given below:

Test method for: *Determination of temperature of plastics at the plastics/food interface during microwave and conventional oven cooking in order to select the appropriate temperature for migration cooking*, has been completed as standard EN 14233 and published.

The test method in EN14233 is performed on plastics materials and articles which are intended to come into contact with foodstuffs at elevated temperatures e.g. during microwave and conventional oven cooking, to establish the temperature to be used in migration tests - both overall and specific - with food simulants relevant to the foodstuff.

Test method for determination of free fat on the surface of foodstuffs reached CEN Stage 49 *Document available for formal vote* at end of December 2001 and was sent to CEN Management Centre for circulation for *Formal Voting* by CEN member national standards bodies. The document is to be processed under the Unique Acceptance Procedure (UAP) which combines the Enquiry and Formal Voting stages. There has been some delay in progressing this document but if the voting results give approval for this standard and the expected progress schedule is achieved, the standard should be *Ratified* early 2003. *Implementation* and publication should then follow mid 2003. The standard will have the number EN 14481.

The test method in EN 14481 determines whether free fat is present or not on the surface of foodstuff. Council Directive 85/572/EEC specifies that for certain classes of foodstuffs e.g. shelled and roasted nuts (Ref.No. 04.03B) where *there is no 'fatty contact' with the plastic, the test with simulant D may be dispensed with*.

Test method for the determination of the mass fraction of a polymeric additive that lies below 1000 Daltons reached CEN Stage 49 *Document available for formal vote* at end of May 2002 and was sent to CEN Management Centre for circulation for *Formal Voting* by CEN member national standards bodies. If the voting results give approval for this standard and the expected progress schedule is achieved, the standard should be *Ratified* early 2003. *Implementation* and publication should then follow mid 2003. It is intended that this document will be published as CEN/Technical Specification (CEN/TS).

This test method is intended to be performed on polymeric plastics additives to determine whether components are present with a molecular weight of 1,000 daltons or less. Polymeric additives with components present with molecular weights of 1,000 daltons or less may require additional toxicological data for classification.

Difficulties experienced in identifying suitable test methods is the reason why this test method is initially intended to be published as a CEN *Technical Specification* (CEN/TS). As mentioned above, the CEN/TS has recently replaced the ENV standard. Experience in use of the test method/methods during the period as a CEN/TS will allow any necessary amendments/changes to be made before it is converted to an EN standard

Working Group 5
Overall migration test methods for polymeric coatings on metal substrates

Working Group 5 is no longer active. After completing the initial drafting of the document for the assigned Work Item it was transferred to Working Group 1 to complete.

The document, CEN/TS 14235 *Determination of overall migration from polymeric coatings on metal substrates*, has been approved, ratified and published (see above).

The CEN/TS contains test methods intended to be performed on materials and articles consisting of metal substrates with polymeric coatings, to establish compliance with the overall migration limit expected to be incorporated in a future European Commission 'coatings' Directive.

The test methods determine overall migration from metal articles with polymeric coatings intended for contact with acidic and fatty foodstuffs.

At the meeting in 2000 between CEN Management Centre and the European Commission/EFTA, it was decided that as the Commission has not yet produced the 'coatings' Directive this Work Item should initially be produced as a preliminary/temporary ENV standard (now to be a CEN *Technical Specification* – CEN/TS).

It is expected that the CEN/TS will not be replaced by an EN standard until the European Commission has produced the 'coatings' Directive and any requirements for overall migration testing have been fully identified.

Working Group 6
Overall migration test methods for polymeric coatings on cellulosic substrates

Working Group 6 is no longer active having completed all work required on the assigned Work Item. The current positions and progress on the Work Item are given below:

The test method: *Determination of overall migration from polymeric coatings on cellulosic substrates* has been approved by CEN members, ratified, implemented and published as CEN/TS 14234.

The CEN/TS contains test methods intended to be performed on materials and articles consisting of cellulosic (paper and paperboard) substrates with polymeric coatings, to establish compliance with the overall migration limit expected to be incorporated in a future European Commission 'coatings' Directive.

The test methods determine overall migration from cellulosic materials with polymeric coatings intended for contact with fatty foodstuffs. A 'Guide ' has also been produced. The CEN/TS is a composite document consisting of the 'Guide' and the test methods.

The document has been produced as a CEN/TS, for similar reasons quoted for the Working Group 5 Work Item.

It is expected that the CEN/TS will not be replaced by an EN standard until the European Commission has produced the 'coatings' Directive and any requirements for overall migration testing have been fully identified.

Working Group 8
Test methods for BADGE and BFDGE plus reaction products, and NOGE

The Working Group has been assigned two Work Items. The first is for standard (EN) test method or methods to determine the substances BADGE [bisphenol A-diglycidyl ether, or alternative chemical name: 2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl ether] and BFDGE [bis(hydroxyphenyl)methane bis(2,3-epoxypropyl)ether], together with the hydrolysis products and chloro-derivatives, in foodstuffs and food simulants due to migration. The second Work Item is for a standard (EN) test method to determine the presence of Novolac glycidyl ethers [epoxy novalacs or NOGE] in finished materials.

All the above substances are/or have been used in coatings on food contact surfaces of food and beverage cans.

The EN standards will be required for testing foodstuffs/food simulants which have been in contact with metal materials and articles coated with epoxy derivatives, and for testing the coated materials and articles, to meet the requirements of the European Commission Directives 2001/61/EC and 2002/16/EC *on the use of some epoxy derivatives in materials and articles intended to come into contact with foodstuffs.*

Following publication of the first of the above mentioned European Commission Directives the testing requirements were fully identified and confirmed in the second Directive.

The drafting work by Working Group 8 on both the standards is due to be completed by the Target Date of July 2004 (Stage 40 *Document available for Enquiry*).

TASK GROUP 9

1.8. Test methods for primary aromatic amines

This Task Group was set up in October, 2001 to identify a suitable test method or methods for the determination of primary aromatic amines.

The 6th amendment to Directive 90/128/EEC – Directive 2001/62/EC – contained a restriction for primary aromatic amines. This restriction has now been incorporated in Annex V of codified Directive 2002/72/EC. Primary aromatic amines can arise during the curing process of isocyanate based adhesives and from colorants prepared by diazo-coupling.

The Directive specifies that such primary aromatic amines should not be detectable in foodstuffs/food simulants, when tested with an analytical method which has a detection limit of 0.02 mg/kg, analytical tolerance included. Specific primary aromatic amines listed in the Directive are excluded.

The Task Group is assessing the German BGVV test method for primary aromatic amines as a basis for a standard test method or methods to be used for testing for compliance with the restriction in the Directive.

An application for a new Work Item or Work Items will be made to CEN BT when the Task Group has selected the basic test method or methods and a programme of work agreed.

Once a programme of work has been agreed and Work Item(s) allocated, the work will be transferred to a new Working Group (9).

CHAPTER IV

COUNCIL OF EUROPE

To obtain information on the Council of Europe (CoE) activity and documents, see at the internet website:

http://www.coe.int/T/E/Social%5FCohesion/soc%2Dsp/Public%5FHealth/Food%5Fcontact/

Available documents	Click ⇩
Resolution AP (2002)1 on paper and board intended to come into contact with foodstuffs	http://www.coe.fr/soc-sp/sante/pack/resol.htm
Technical document No 2: Test conditions and methods of analysis for paper and board intended to come into contact with foodstuffs	**http://www.coe.fr/soc-sp/sante/pack/test.htm**
Technical document No 3: Guidelines on paper and board, made from recycled fibres, intended to come into contact with foodstuffs	**http://www.coe.fr/soc-sp/sante/pack/fibres.htm**
Technical document No 4: Good manufacturing practice for paper and board intended to come into contact with foodstuffs	**http://www.coe.fr/soc-sp/sante/pack/Res%20paper%20and%20board.htm**
Technical document: Guidelines on metals and alloys used as food contact materials	**http://www.coe.fr/soc-sp/sante/pack/metals.zip**
Resolution AP (96) 5 on surface coatings intended to come into contact with foodstuffs	**http://www.coe.fr/soc-sp/sante/surf1.zip**
Resolution AP (97) 1 on ion exchange and adsorbent resins used in the processing of foodstuffs	**http://www.coe.fr/soc-sp/sante/ap97e1.pdf**
Resolution AP (99) 3 on silicones used for food contact applications (incl. inventory list)	**http://www.coe.fr/soc-sp/sante/resol silicones.zip**

For further information, you are invited to consult the responsible of "Food Contact Materials" at CoE level:

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THE END