



CODE OF PRACTICE¹ FOR COATED ARTICLES WHERE THE FOOD CONTACT LAYER IS A COATING

WORKING DOCUMENT

**Note : some Annexes are in the process of being finalised, whilst those
on the CEPE web site will be periodically updated**

EDITION 4

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This version has amendments resulting from a joint meeting between industry and some Member State experts. These affect Articles 1, 3 4, and 5. **Major changes are indicated in red**

In addition minor editorial changes have been made.

¹ This Code and included Guidelines are of a voluntary nature. Individual companies may decide to apply these either in full or partly, or not according to their own judgement.

Contents

	List of associations recommending this Code of Practice
	Introduction
Article 1	Subject matter and scope
Article 2	Good Manufacturing Practice
Article 3	List of substances authorised
Article 4	Incomplete list of monomers and other starting substances
Article 5	Incomplete list of additives
Article 6	Substances having multiple functions
Article 7	Specific restrictions of substances (SML)
Article 8	Overall migration limit (OML)
Article 9	Rules for multilayer coatings
Article 10	Labelling requirements, declaration of conformity and supporting documents
Article 11	Demonstration of compliance with OML, SML and QMA and evaluation of results

ANNEXES	
<i>Annex I</i>	<i>Overview of how coated food contact articles are manufactured</i>
<i>Annex II</i>	<i>Monomers and other starting substances</i>
	<i>List A - monomers and other starting substance assessed by SCF/EFSA</i>
	<i>List B - monomers and other starting substances not assessed by SCF/EFSA</i>
<i>Annex III</i>	<i>Additives</i>
	<i>List C -additives assessed by SCF/EFSA</i>
	<i>List D - additives not assessed by SCF/EFSA</i>
<i>Annex IV</i>	<i>Generic description of resins used in food contact applications and their components</i>
<i>Annex V</i>	<i>Food and food simulants to be used for testing coatings in contact with foods</i>
<i>Annex VI</i>	<i>Risk assessment for migrants from coated articles in contact with foodstuffs</i>
<i>Annex VII</i>	<i>Basic rules for demonstrating compliance with the OML</i>
<i>Annex VIII</i>	<i>Basic rules for demonstrating compliance with SMLs</i>
<i>Annex IX</i>	<i>Glossary</i>
<i>Annex X</i>	<i>References to GMP's</i>
<i>AnnexXI</i>	<i>List of substances considered as dual additives</i>



LIST OF ASSOCIATIONS RECOMMENDING THIS CODE OF PRACTICE

Those trade associations listed below are recommending this Code of Practice to their member companies. Individual companies may decide to apply this, either in full or partly or not, according to their own judgement.

- APEAL – The Association of European Producers of Steel for Packaging
- CEFIC FCA – The CEFIC Food Contact Additives Panel
- CEPE - The European Council of Paint, Printing Ink and Artists' Colours Industry
- CiAA – The Confederation of the food and drink industries of the EU
- EAA – The European Aluminium Association
- EMPAC – The European Metal Packaging Association (former SEFEL : European Secretariat of Manufacturers of Light Metal Packaging)
- EPRA – The European Phenolic Resins Association
- EWF - The European Wax Federation
- CEFIC HARRPA – The CEFIC Hydrocarbon and Rosin Resins Producers Association
- PlasticsEurope Epoxy Resins Committee

INTRODUCTION

Today in the EU there are no harmonized regulations for coatings in direct contact with foodstuffs. All coated food contact articles have to comply with Article 3 of the Framework Regulation 1935/2004/EC (replacing Framework Directive 89/109/EEC) which states that migrants must not endanger human health.

Thus the coatings' manufacturing industry has taken the initiative to develop a Code of Practice which describes how compliance with the Framework Regulation can be demonstrated for direct food contact coatings.

This Code of Practice is of voluntary nature, each company taking their individual decision to apply it (partly or in full), or not. It is not an exclusive system and companies may decide to use other ways of ensuring the protection of Health, Safety and the Environment.

Companies when applying this Code of Practice along the chain of supply should ensure that the way it is applied is in strict compliance with competition law.

This code of practice applies to coated articles (which are within the scope of this code of practice – see Article 1) in contact with food where the food contact layer is derived from a coating.

Coatings are prepared by mixing raw materials. Coatings are applied to a substrate before being transformed to form the food contact layer. It is necessary to distinguish between the coating as applied to the substrate and the coating layer in contact with the foodstuff.

Coatings can be waterborne (water dispersible or water soluble), solventborne, solid particles (powder) or liquid which contains neither organic solvents nor water. If water and /or organic solvents are present then it is necessary for these to evaporate before the food contact coating layer is formed. In the case of solid particles, it is necessary for them to fuse together in order that they can form the food contact coating layer.

If the formation of the food contact layer solely depends upon the removal of water or organic solvent or the fusing of particles, then this is a thermoplastic coating. If the formation of the food contact layer depends upon a chemical reaction (crosslinking) of one or more components of the coating, to increase

the overall molecular weight, then it is a thermoset coating. Chemical reactions can be induced over a wide range of temperatures. The final performance properties can be attained only on completion of this process.

Article 1

Subject matter and scope

1.1 This Code of Practice describes how compliance with the Framework Regulation (EC) No 1935/2004 and subsequent amendments can be demonstrated for direct food² contact coatings.

1.2 a more precise and more legal definition of coatings than that used in AP(2004)1 has been requested by DGSANCO.

1.3 This Code of Practice shall only apply to the food contact surfaces of the following:

- a. Coated light metal packaging up to a volume of 10 litres
- b. Coated metal pails and drums with volumes ranging from 10 to 250 litres
- c. Coated articles with volumes 250 to 10,000 litres
- d. Heavy duty coated articles having a volume >10,000 litres
- e. Coated flexible aluminium packaging
- f. Printing inks and coatings in direct food contact

Those sectors to be incorporated at a later date when more details are available

- a. Coatings primarily used to seal food packaging
- c. Coatings for flexible packaging
- d. Coatings and inks for paper and board

Note that a more detailed overview of Coatings is given in Annex I

² Foodstuffs are as defined in EU Regulation(EC) No 178/2002 – see glossary

EXPLANATORY NOTE

Coatings for light metal packaging, pails and drums

With few exceptions coatings for light metal packaging are transformed into the food contact layer at elevated temperatures. Most coatings for light metal packaging are thermoset in nature, although some thermoplastic ones are used. Coatings can be applied to the fabricated light metal packaging article or most likely at some stage during the manufacture of the light metal packaging article. Further details are given in ILSI (International Life Science Institute) Monograph on metal packaging for foodstuffs .

Coatings for articles with volumes 250 to 10,000 L

The IBCs (Intermediate bulk containers) that are widely used for transport are generally either uncoated stainless steel or plastic. Other storage containers made from mild steel are rarely used for food contact.

Coatings for Heavy duty articles with volumes >10,000 L

Heavy duty coatings are normally applied in situ to large transport containers or storage tanks of volume >10,000L and all associated pipe work. Heavy duty articles are generally too large to be heated in an oven. Typical coatings consist of thermoset materials often applied as two-component and multilayer systems. Therefore they need to form the food contact layer at around ambient temperatures. Due to being reactive at ambient temperatures the reactive components are often mixed only shortly before application to the substrate.

Coatings for flexible aluminium packaging.

Coatings for aluminium for flexible packaging normally undergo a thermal process. In the case of thermoset coatings this enables cure to be achieved, whilst in the case of thermoplastic coatings this enables any organic solvents etc to be removed to enable a food contact layer to be formed.

Printing inks and coatings in direct food contact

Although described as inks, in many cases these descriptions are in fact coatings. The industry practice is that ink companies, or some converters, supply these products. In some cases they may be pigmented. The substrate, aluminium, plastic, paper and board, dictates subtle differences in their use and application, hence there is a separate entry for each. See Annex1 for further details.

PLEASE NOTE – COATING THICKNESS

The coatings on light metal packaging, pails and drums, flexible aluminium and plastics are typically very thin layers being of the order of 3-15 μm . In contrast, heavy duty coatings are typically very thick layers being of the order of 200 - 500 μm .

1.4. This Code of Practice shall not apply to

- a. Repeated use non-stick coatings, which remain regulated by the specific chapters of BfR, VGB, and FDA applicable to them.
- b. Extrusion coated materials or articles where the extrusion coating, being a plastic, should comply with the provisions of Directive 2002/72/EC as amended.
- c. Laminated packaging articles or components where the food contact layer, being a plastic, should comply with the provisions of 2002/72/EC, as amended.
- d. Printing inks and coatings applied to the non-food contact surface of food packaging materials and articles intended to come into contact with foodstuffs.
- e. Adhesives.
- f. Coatings on paper and board which remain regulated by specific chapters of BfR, VGB and FDA applicable to them.
- g. Coatings on regenerated cellulose which are covered under Commission Directive 93/10/EEC and its amendments.
- h. Can end sealants based upon rubbers and elastomers which remain covered by rules applicable under national legislation.
- i. Tin coatings.
- j. Wax coatings
- k. Gaskets for metal closures which are covered by the Plastics Directive 2007/19/EC.

Article 2
Good Manufacturing Practice (GMP)

2.1 Materials and articles shall be manufactured in compliance with the Framework Regulation (EC) No 1935/2004 and with the GMP Regulation (EC) No 2023/2006.

2.2 Materials and articles shall be manufactured in compliance with the GMP Regulation (EC) No 2023/2006. GMPs can be company specific, but for reference relevant industry GMPs are listed in Annex X, where relevant web-links are given

EXPLANATORY NOTE

Different sectors have different GMPs, some of which are more advanced than others. Due to the differences between coatings, substrates and industry practices, it is impractical to have one GMP to cover all coated articles in contact with food.

Article 3
Lists of substances authorised

1. Those substances referred to in Articles 4 and 5 may be used in the manufacture of coatings intended to come into contact with foodstuffs subject to the conditions and restrictions specified therein. The substances covered belong to the following categories
 - a) monomers and other starting substances (see Annex II)
 - b) additives (see Annex III)
2. Additionally, non-listed monomers and other starting substances and additives which are intentionally added may be used provided
 - a. they do not migrate³and
 - b. they are not Class 1 and 2 CMRs as defined by the CLP Regulation (the former 1,2,3 CMR Class of 67/548/EEC and its amendments)and
 - c. the Declaration of Compliance contains a statement that the no-migration principle is used for compliance.

EXPLANATORY NOTE

Non-listed monomers and other starting substances and additives, which are knowingly added and which are not carcinogenic or mutagenic or reprotoxic to mankind, are considered not to pose a threat to human health, provided they do not migrate at a detection limit of 10µg/kg. Declaring the presence of such substances, which are knowingly added, in the Declaration of Compliance ensures that all in the supply chain know of their existence and are aware of what is required to meet this no migration requirement.

³ The migration of the substances under paragraph 2(b) into food or stimulant shall not exceed 0,01mg/kg, measured with statistical certainty by a method of analysis in accordance with Article 11 of Regulation (EC) 882/2004. This limit shall always be expressed as concentration in foods or simulants. It shall apply to a group of compounds, if they are structurally and toxicologically related.

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 such 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 synthesize them are included in the list;
 - (c) mixtures of the authorised substances.
 - (d) Aids to polymerisation which are covered in Council of Europe Resolution AP(92)2
 - (e) Polymerisation production aids

The materials and articles which contain the substances indicated under (a), (b), (c), (d) and (e) shall comply with the requirements stated in Article 3 of the Framework Regulation (EC) No 1935/2004.

Article 4
Monomers and other starting substances

1. Those monomers and other starting substances listed in Annex II may be used for the manufacture of coatings for direct food contact, subject to the restrictions set out therein.
2. The list in Annex II is subdivided into list A and list B.

List A: monomers and other starting substances assessed:

- 2.1 Substances evaluated by SCF/EFSA, classified in list SCF 0-4 and used in compliance with specific migration limits or other restrictions, if any
- 2.2 Monomers and starting substances approved by member states or any competent authorities based upon an evaluation of a toxicological dossier which meets the present SCF/EFSA criteria.

List B: temporary appendix to List A (incomplete list of monomers and other starting substances).

- 2.3 List of monomers and other starting substances approved by EU Member states or by FDA, not meeting the criteria of 2.2.
- 2.4 The substances on the temporary appendix should be subjected to additional toxicological information depending on their migration into foodstuffs or the level of exposure to those substances. Exposure assessments may only be used when all relevant food contact sources of exposure are identified.
 - a. migration below 10 ppb (10^{-9}) - substances do not need further testing **provided the SAR (Structural Activity Alert) does not indicate potential for mutagenicity. In this case mutagenicity data will be required.**
 - b. migration below 50 ppb – these substances should have the mutagenicity tests according to REACH timeframes
 - c. migration above 50 ppb – the supply chain needs to set up common interest groups in order to submit a dossier to EFSA.
 - d. Whilst the migration may exceed 10ppb, if it can be demonstrated that the exposure is below 10 µg/person/day, then no further testing is required.
 - e. It may also be possible to revise the requirements for cases b and c by the use of exposure assessments.

EXPLANATORY NOTE

A number of the monomers and other starting substances currently used have not been fully assessed by SCF/EFSA, mainly because they are specifically used for coatings. In order that they can continue to be used, they must have authorisation by at least one member state or be listed by the FDA. It is intended that the substances, which are used and are not on SCF Lists 0-4, will be subjected to toxicological testing or exposure assessments as described above.

3. In addition to those substances in the list in Annex II, any substances which have an SCF or EFSA opinion (list SCF 0-4) may be used for the manufacture of the coatings for direct food contact, subject to any restrictions applicable to them.

EXPLANATORY NOTE

The current list of monomers and other starting substances reflects those currently used to manufacture coatings, which are in contact with food. Industry reserves the right to use any fully evaluated (SCF 0-4) substance, but not-listed in Annex II, in future developments, as an SCF/EFSA opinion exists. As this list is regularly updated these substances, will eventually appear on a future revision.

4. Substances authorised as direct food additives, which can also be used in direct food contact coatings are listed in Annex XI. If the migration exceeds 10 µg per 6 dm² then their identity will be given in the Declaration of Compliance.

EXPLANATORY NOTE

In this context the dual use additive is used as a monomer thereby being consumed in the preparation of the polymer. Residual levels are typically very low. The supplier has the option not to declare the identity if it can be demonstrated that the migration is below 10 µg per 6 dm².

5. Authorised monomers and starting substances may be chemically reacted and the resulting product (resin, polymer or pre-polymer) may be used in coatings for direct food contact.

EXPLANATORY NOTE

Generic descriptions of how these monomers and starting substances could be used to generate materials incorporated into coatings for direct food contact are given in Annex IV.

Article 5 Additives

1. The present article does not apply to colorants and solvents.
2. Those additives listed in Annex III may be used for the manufacture of coatings for direct food contact subject to the restrictions set out therein.
3. The list in Annex III is sub-divided into Lists C and D

List C: list of additives assessed:

- 3.1 Substances evaluated by SCF/EFSA, classified in list SCF 0-4 and used in compliance with specific migration limits or other restrictions, if any
- 3.2 Additives approved by member states based or by any competent authorities upon an evaluation of a toxicological dossier which meets the present SCF/EFSA criteria.

EXPLANATORY NOTE

In the case of polymeric additives made from complex raw materials, such as petroleum distillates, HARRPA has discussed this issue with the Commission and a distinction between polymers which can form articles and those which cannot was agreed. A similar debate will be needed to resolve this issue for coatings.

List D: temporary appendix to List C (incomplete list of additives assessed).

- 3.3 Substances approved by EU Member states or by FDA, not meeting the criteria of 3.2.
- 3.4 The substances on the temporary appendix should be subjected to additional toxicological information depending on their migration into foodstuffs or the level of exposure to those substances. Exposure assessments may only be used when all of the potential food contact applications are identified.
 - a. migration below 10 ppb - substances do not need further testing **provided the SAR does not indicate potential for mutagenicity. In this case mutagenicity data will be required.**

- b. migration below 50 ppb – these substances should have the mutagenicity tests according to REACH timeframes
- c. migration above 50 ppb – the supply chain needs to set up common interest groups in order to submit a dossier to EFSA.
- d. Whilst the migration may exceed 10ppb, if it can be demonstrated that the exposure is below 10 µg/person/day, then no further testing is required.
- e. It may also be possible to revise the requirements for cases b and c by the use of exposure assessments.

EXPLANATORY NOTE

A number of the additives currently used have not been fully assessed by SCF/EFSA, mainly because they are specifically used for coatings. In order that they can continue to be used, they must have authorisation by at least one member state or be listed by the FDA. It is intended that the substances, which are used and are not on SCF Lists 0-4, will be subjected to additional toxicological testing or exposure assessment as described above.

- 4. In addition to those substances in the list in Annex III any substances which have an SCF or EFSA opinion (list SCF 0-4) may be used for the manufacture of coatings for direct food contact, subject to any restrictions applicable to them.

EXPLANATORY NOTE

The current list of additives reflects those currently used to manufacture coatings, which are in contact with food. Industry reserves the right to use any fully evaluated (SCF 0-4) substance, but not-listed in Annex III, in future developments, as an SCF/EFSA opinion exists. As this list is regularly updated these substances, will eventually appear on a future revision.

- 5. When used as additives, natural or synthetic polymeric substances provided their monomers are listed in Annex II and they comply with the requirements of this Code of Practice may be used.

6. Substances authorised as direct food additives, which could be used in direct food contact coatings are listed in Annex XI. When used as an additive their identity must be given in the Declaration of Compliance.

Article 6

Substances having multiple functions

1. Substances referred to in Articles 4 and 5, which are listed in Annex XI should be subject to the rules in Articles 4.4 and 5.6 with the relevant information being given in the Declaration of Compliance (see Article 10).

Article 7

Specific restrictions of substances

1. Coated articles for direct food contact shall not transfer their constituents to the foods or food simulants as set out in Annex V in quantities exceeding the restrictions established in Annexes II and III.
2. Wherever possible TDIs should be used as the SMLs are derived from their use in plastics. However in order to use TDIs it is necessary to have supporting exposure data. In the absence of exposure data the default assumption of 1 kg food packaged in 6 dm² is applicable, thus the SMLs apply.
3. The SMLs (Specific Migration Limits) in the lists set out in Annexes II and III are expressed in mg (of substance)/kg (of food or food simulant). However, such limits and the levels of migration measured are expressed in mg/6dm² (of surface area of material or article in food contact) in the following cases:
 - a containers and other articles which can be filled, with a capacity of less than 500 ml or 500 g
 - b Coated films and sheets and other articles which cannot be filled or for which it is impossible to estimate the relationship between the surface area of such material or articles and the quantity of food in contact therewith.
4. In the cases described under 2(a) and 2(b), the limits set out in Annexes II and III expressed in mg/kg shall be divided by the conventional conversion

factor of 6 in order to express them in mg/dm². This conversion is based on the assumption that 1 kg of food is in contact with 6 dm² of packaging.

5. The use of non-regulated simulant substitutes can only be used to demonstrate compliance but cannot be used to demonstrate non-compliance. Non-regulated simulants can only be used when it has been demonstrated that they represent worse or equal case than regulated simulants.
6. For repeat use articles refer to the rules in Annexes VII & VIII.

Article 8 **Overall migration limit (OML)**

1. Coated articles for direct food contact shall not transfer their constituents to foods or the food simulants set out respectively in Annex V in quantities exceeding 60 mgs / 6dm². It should be noted that the test protocols defined for plastics in 2002/72/EC and its amendments and other relevant legislation may not be appropriate for all coated articles.

EXPLANATORY NOTE

3% acetic acid as a stimulant for acidic foodstuffs is inappropriate for both heavy duty coatings and coatings for light metal packaging due to the fact that a significant part of the substrate can be corroded and contribute to the OML. This is further discussed in Annex VII.

2. For coatings for heavy duty articles the OML is expressed in mgs (of substance)/ Kg (of food or food simulant) and may not exceed 60 mgs/ Kg food or food simulant.
3. For closures, stoppers or similar devices for sealing the overall migration from the coated surface is expressed in mgs / Kg (of food or simulant) and must not exceed 60 mgs/Kg of food or food simulant taking account of the analytical tolerance

Article 9

Rules for multilayers of coatings for direct food contact

In some instances more than one layer of a coating may be applied to the food contact side of the coated article.

1. Each coating layer shall comply with the rules given in Articles 3, 4 and 5.
2. The SMLs apply to the coated article independent of the coating layer where the substance is present.
3. The finished article shall comply with the OML

Article 10

Labelling requirements, compliance declaration and record-keeping of compliance supporting documentation

1. The labelling requirements in Article 15 of the Framework Regulation (EC) No 1935/2004 shall apply.
2. In the application of Article 16(1) of the Regulation (EC) No 1935/2004, at the marketing stages other than the retail stages, coated materials and articles, coatings and their raw materials shall be accompanied by a written declaration, appropriate to their position in the supply chain.

The written compliance declaration shall provide adequate and relevant information at each stage of the supply chain to help ensure the suitable use and safety of the materials and articles subject to the declaration and their compliance with relevant regulations. The written declaration shall be reviewed regularly and/or when there is a significant change in the composition of the material and article. The declaration of compliance shall contain the following information:

- a. Name and address of the company which manufactures or imports the finished material or article;
- b. Trade name;
- c. Identity of the raw material, coating or coated article;
- d. Date of the declaration;
- e. The confirmation that the material or article complies with, this code of practice, the requirements of appropriate EU Regulation and, when appropriate, of national law under the conditions of use

identified under sub-paragraph (g) hereunder. The references of the legislation complied with shall be quoted.

- f. Adequate information relative to the substances used for which specific restrictions are in place under this Code of Practice and relevant Community or national legislation to allow the downstream user to ensure compliance with those restrictions and list of substances used for which an SML or specifications are established.
- g. Depending upon their position in the supply chain, specifications on the use of the material or article such as
 - (i) type or types of food;
 - (ii) time and temperature of storage or treatment of the said material or article;
 - (iii) surface volume ratio used for compliance assessment.

EXPLANATORY NOTE

The above will be updated in line with any future changes in Article 9 of The Plastics Directive 2002/72/EC and its amendments, subject to agreement by the signatories to this Code of Practice. The content of the Declaration of Compliance is still under debate, and it is the intention that this Article will reflect whatever is agreed in the wider arena. The major concern is confidentiality of proprietary information.

Current discussions between sectors in the supply chain show a preference for a two part Declaration of Compliance. The first part will be generic and available to anyone. The second part will contain confidential information exchanged between parties under appropriate secrecy agreement.

- h. in the absence of specific community implementing measures, reference shall be made to national legislation applicable.
- i. A statement whether or not non-listed monomers and other starting substances or additives referred to in Article 3.2, are intentionally used.
- j. A statement whether or not substances, which are also dual additives as listed in Annex XI, are intentionally used in line with the requirements given in Articles 4.4 and 5.6.

- k. On request, a statement whether or not substances in temporary lists B or D are present.

EXPLANATORY NOTE

The content of the Declaration of Compliance is still under debate. Depending upon the outcome, either the presence or identity of the substances referred to in k will be declared, subject to confidentiality.

Sub-sections i,j and k are additional to the requirements in 2007/19/EC.

3. Appropriate documentation to demonstrate that the products comply with the relevant requirements shall be made available by the business operator to the national competent authorities on demand. This documentation shall contain, as is relevant for the product and their place in the supply chain:
- (a) information as regards their compliance with this code of practice
 - (b) results of testing, calculation, other analysis, evidence on the safety or reasoning demonstrating compliance. (Internationally recognized scientific principles, including exposure assessment, may be used)

Article 11

Compliance with OML, SML and QMA and evaluation of results

1. Compliance testing regarding OML and SML in food or food simulants shall be carried out in accordance with the rules laid down in Annexes VII and VIII respectively.
2. Compliance with QMA shall be carried out in accordance with the rules laid down in Annex VII.
3. Compliance with the SML can be demonstrated also on the basis of other conclusive experimental data or scientific evidence or a scientific reasoning. Some indications for the application of this Article are referred to in Annexes VIII.
4. The results obtained in migration testing with food prevail over the results obtained with any type of simulant and simulant substitute.
5. The results obtained in migration testing with a regulated simulant, i.e. reference food simulant or regulated simulant D substitutes prevails over the results obtained with a non-regulated simulant.



6. Non-regulated simulants / organic solvents / extractants can be used to demonstrate compliance, provided they represent the worse case or equal for appropriate regulated simulants, but not non-compliance.
7. For repeated use articles, the rules are given in Annexes VII & VIII.

ANNEX I OVERVIEW OF HOW COATED FOOD CONTACT ARTICLES ARE MANUFACTURED

A. COATED LIGHT METAL PACKAGING

1. Definition of coatings for light metal packaging

These are coatings applied onto rigid metal, typically steel or aluminium, to manufacture food cans, beverage cans, can ends, metal closures, aerosols and tubes. For canned food and beverage, aerosols and tubes, volumes would be in the range 25 – 5,000 cm³.

2. Production

Coatings for light metal packaging are produced by batch processes using good manufacturing processes.

3. Application and curing

Coatings for light metal packaging are applied under controlled factory conditions using good manufacturing practice. Coatings can be applied either on pre-formed / partially formed or on flat substrates using suitable methods of application before undergoing thermal treatment. Suitability of the application method is based on the performance of the process and the coated product. In most cases some degree of deformation occurs after curing the coating in order to form the finished article. Film thicknesses typically vary between 5 – 15 µm. The coatings are typically cured at high temperatures.

4. Conditions of use

Coatings for light metal packaging are developed taking into account a number of parameters, such as :

Type of application – sheet vs coil, roller coat vs spray

Type of metal – aluminium, steel (tinplate, tin-free steel)

Deformation(s) required to form finished article

Type of food to be packaged and its processing, if any, during the filling and treatment operations.

Migrants from the cured coating

Surface to volume ratios can vary from < 6dm²/kg to about 19 dm²/kg, depending whether it is a catering pack or a small fish can. In the case of metal closures the range is about 0.1 to 4.0 dm²/kg.

B. DRUMS AND PAILS

1. *Definition of coatings for drums and pails.*

These are coatings applied onto rigid metal, typically steel, to manufacture pails and drums. Pails are open top containers with volumes between 5 and 25 L; drums can be open top or tight head with volumes up to 250 L.

2. *Production*

Coatings for pails and drums are produced by batch processes using good manufacturing processes.

3. *Application and curing*

Coatings for pails and drums are applied under controlled factory conditions, using good manufacturing practice. Coatings are generally spray-applied on separate drum components with a typical film thickness between 12 and 20 microns and are cured at 220 to 230°C for 10 minutes.

4. *Conditions of use*

Coatings for pails and drums are developed, taking into account the type of food to be packaged and other requirements.

Surface to volume ratios can vary from $<1 \text{ dm}^2/\text{kg}$ to about $2.5 \text{ dm}^2/\text{kg}$, depending on the size of the pail or drum.

C. COATINGS FOR ARTICLES WITH VOLUMES 250 TO 10,000L

Not applicable

D. HEAVY DUTY COATINGS

1. *Definition of heavy duty coatings*

These are coatings applied on containers or storage tanks with a volume capacity of 10,000 litres or more and on all pipelines belonging to or connecting them.

2. *Production*

Heavy duty coatings are normally produced via a batch process under good manufacturing practices.

3. *Application and curing*

Heavy duty coatings are normally applied in situ on large containers like ship tanks, rail/road containers and land storage tanks. They must be applied on a well prepared surface under controlled conditions. Generally they are applied at a total thickness of 250 microns either as one- or multi-layer systems.

Curing of heavy duty coatings is normally at ambient temperatures (but hot cure is also possible under some circumstances).

4. Conditions of use

Large containers are continuously emptied and refilled (so-called repeat use). This means that migration into foodstuffs will be gradually reduced. The total service life of a heavy duty coating system may be more than 20 years. Typical migration would be expected to become very low during the service life.

The surface to volume ratio has a positive influence by reducing the migration into foodstuffs. The surface to volume ratio of a typical 10,000 litre container is 0.42 dm²/kg, compared with the convention of 6 dm²/kg used in the EU for food packaging materials. This means that the EU convention of assuming a factor of 6 between migration expressed as mg/dm² packaging material and that expressed as mg/kg (ppm) food is 14-fold greater than the worst case (i.e. smallest volume) for containers protected with heavy duty coatings. Of course, many containers (e.g. ship tanks, land storage tanks) are far larger than the 10,000 litre minimum used to define heavy duty coatings.

Examples:

Container: 10,000 litres
Dimensions 10 by 10 by 100 dm
Surface area: 4200 dm²

Container 10,000 litres
Road container 3 metres long and 1.03 metre radius
Surface area: 2600 dm²

These typical conditions of use have resulted in an exemption of heavy duty coatings from the Epoxy Directive 2002/16/EC and its amendments, including Directive 2004/13/EC and Regulation (EC) No /1895/2005.

E. COATED FLEXIBLE ALUMINIUM PACKAGING

1. Definition

Coated Flexible Aluminium Packaging consists of products where coatings are applied to aluminium or multilayer substrates where one layer is aluminium. Aluminium used for this purpose is typically of thicknesses up to 200 µm.

Applications would include: individual wrappers, lidding, diaphragms, caps, blister packs composite cans and food containers.

2. Production

Coatings for flexible aluminium packaging are produced in batch processes using good manufacturing practices.

3. Application

Coatings for flexible aluminium packaging are applied under controlled production conditions using good manufacturing practices.

Coatings may consist of thermoplastic, thermo set, or organic solvent / water free liquids (e.g. post lubrication).

These coatings may be applied by various means such as, but not limited to, roller coating, printing, spraying and dipping.

4. Conditions of Use

Coated flexible aluminium packaging may be used in retail, domestic or catering sectors.

Depending on the type of specification, the packaging may be subjected to sterilization, retorting or cooking processes at filler stages. Likewise, storage could be at ambient, refrigerated or at frozen conditions. The specific packaging may be subjected to defrosting or re-heating before the end of its life cycle.

Suitability of the flexible aluminium packaging should be ascertained for specific applications prior to its use.

F. Direct Food contact coatings and inks

Although described as inks, in many cases these descriptions are in fact coatings. The industry practice is that ink companies supply these. In some cases they may be pigmented. The substrate, aluminium, plastic, paper and board, dictates subtle differences in their use and application, hence there is a separate entry for each.

a. COATED AND PRINTED PLASTIC PACKAGING

1. Definition of Coatings and Printing Inks for coated and printed plastic packaging

Coatings can include Coldseals, Antimists and Barrier Coats/Primers, Heatseals and promotional inks. These coatings and inks are applied onto the flexible packaging films such as uncoated or coated OPP, PET and PE to give a seal (coldseal or heatseal) or properties such as non-fogging (Antimists).

Primers are used to protect aluminium surfaces especially on metallised OPP prior to coldseal coating. Direct food contact Inks are used for information and competitions. Heatseals may be used in plastic lidding applications for example to give peelable seals.

2. Production

Coatings and Inks for plastic packaging are produced by batch process using good manufacturing practices (GMP).

3. Application and Curing

Coatings and Inks are applied under controlled factory conditions using good manufacturing practice, primarily by the gravure or flexo printing method onto the substrate and dried by the evaporation of solvent/water by heat.

4. Conditions of Use

Coatings and Printing Inks for plastic packaging are developed taking into account a number of parameters as follows:-

Coldseal Adhesives	Substrate, seal strength and mode of seal failure required, release from homopolymer OPP or release lacquer (laminated or mono-web).
Heatseals	Substrate, pack style, seal strength
Printing Inks	Substrate, resistance to foodstuffs concerned.

Typical uses:

- Coldseal: Confectionery, Iced Confectionery and Biscuit packaging to provide a seal.
- Heatseal: Confectionery, Snack and Biscuit packaging to provide a seal.
- Printing Inks: Confectionery packaging, mainly for promotional competitions.
- Antimists: Fresh salad packaging.
- Primers: Used to prevent direct contact between metallised surfaces and foodstuffs and to enable coldseal adhesives to be applied and adhere to metallised film surfaces.

Coldseals are usually pattern applied with a relatively small area of direct contact with the foodstuff but on some ice cream packaging 100% coverage may occur; therefore the area of contact will vary. From a toxicology and migration point of view, a worst case scenario should be assumed i.e. 5g/m² dry weight of coldseal, 100% coverage, 100% transfer of the coldseal to the foodstuff, a typical wrapper size (12cm x 14cm) and a consumption of 3 bars/day. This scenario should not pose a threat to human health.

For Printing Inks, the same criteria would apply but at a dry coating weight of 2g/m².

b. COATED AND PRINTED PAPER AND BOARD

1. Definition of Coatings and Printing Inks for Paper and Board

These are coatings and printing inks applied to paper and board to manufacture food trays/cartons and packaging material. Coldseal and heatseal coatings may also be used as in (a) above.

2. Production

Coatings and printing inks for paper and board are produced by batch processes using good manufacturing practices

3. Application and Curing

Coatings and inks for paper and board are applied under controlled factory conditions using good manufacturing practice. Applied typically by gravure, flexo or offset printing processes and are dried by evaporation of solvent/water by heat.

4. Conditions of use

Coatings and printing inks for paper and board are developed for the following typical applications:

Fast Food containers/wrappers for barrier and decorative properties.
Iced Confectionary and Cone wrappers for sealing, barrier and promotional competitions.
Teabags and speciality teabag sachets
Confectionery wrappers for competitions.
Inserts, into cereal packets.

c. COATED AND PRINTED FLEXIBLE ALUMINIUM PACKAGING

1. Definition of Coatings and Printing Inks for Flexible Aluminium Packaging

Coatings in the form of heatseals are applied onto aluminium to form the lidding material for yoghurt containers and small portion packs of butter, milk, jam and stock cubes. Such coatings can also be used in pharmaceutical packaging (blister packs). Barrier Coatings may also be applied to the metallised side of metallised plastic films. Printing Inks may be used for information and competitions on such packaging and also on confectionery products wrapped in aluminium foil.

2. Production

Coatings and Inks for Flexible Aluminium Packaging are produced by batch processes using good manufacturing practices

3. Application and curing

Heatseal coatings are applied under controlled factory conditions using good manufacturing practice. These heatseals are mostly applied by the gravure, flexo or roller coating method, either by the supplier of the aluminium or by the converter, and drying is by heat evaporation of solvents/water. Coating weights will depend on specification but can typically be between 1.0g/m² and 6.0g/m² dry.

Printing Inks for this type of work are usually applied by the gravure or flexo process and will dry solely by solvent/water evaporation using heat.

4. Conditions of Use

Heatseals for Printed Aluminium Packaging are developed taking into account the material to be sealed to (PS, PP, PVC, PET) and the seal/peel strength required.

The food stuff to be packed will determine the resistance properties of the heatseal.

Typical surface areas of yoghurt lidding vary between 22cm² and 30cm² for contents of yoghurt between 100gm and 250gm.

ANNEX II

INCOMPLETE⁴ LIST OF MONOMERS AND OTHER STARTING SUBSTANCES

1. This Annex contains the list of monomers or other starting substances. The list includes:
 - substances undergoing polymerisation, which includes polycondensation, polyaddition or any other similar process, to manufacture macromolecules,
 - natural 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,
 - starting substances used to modify existing natural or synthetic substances.

2. This list is subdivided into list A and list B.

List A contains substances which have been assessed by SCF or EFSA and for which there is an opinion (classified in list SCF 0-4) and used in compliance with specific migration limits or other restrictions if any and substances approved in member states or by FDA, based on an evaluation of a toxicological dossier, which meets the present SCF/EFSA criteria

List B contains substances which have been approved by member states or by FDA, applying evaluation criteria at the time of their approval

3. The following substances are not included even if they are intentionally used and are authorised:
 - (a) Salts (including double salts and acid salts) of aluminium, ammonium, calcium, iron, magnesium, potassium and sodium of authorised acids, phenols or alcohols. However, names containing '... acid(s), salts' appear in the lists, if the corresponding free acid(s) is (are) not mentioned;

⁴ ***The list is claimed as being incomplete as it is based on the Council of Europe documents which are updated on regular basis. It does not contain other substances which have an SCF or EFSA opinion (lists SCF 0-4) e.g. substances which are authorised for other food contact sectors.***

- (b) Ionic salts (including double salts and acid salts) of metals of authorised acids, phenols or alcohols. For these salts the restrictions applicable to the acid and cationic metal shall apply independently from their source'
4. Substances shall be of good technical quality as regards the purity criteria.
 5. The list contains the following information:
 - column 1 (PM/REF. No) : the EEC packaging material reference number of the substances on the list,
 - column 2 (CAS No) : the CAS (Chemical Abstracts) Registry number,
 - column 3 (Name) : the chemical name,
 - column 4 (Restrictions and/or specifications): These may include:
 - specific migration limit (SML),
 - maximum permitted quantity of the substance in the finished material or article (QM),
 - maximum permitted quantity of the substance in the finished material or article expressed as mg per 6 dm² of the surface in contact with foodstuffs (QMA),
 - any other restriction specifically mentioned,
 - any type of specifications related to the substance or to the polymer,
 -
 6. If a substance appearing on the list as an individual compound is also covered by a generic term, the restrictions applying to this substance shall be those indicated for the individual compound.
 7. Where there is any inconsistency between the CAS number and the chemical name, then the chemical name shall take precedence over the CAS number. If there is an inconsistency between the CAS number reported in EINECS and the CAS Registry, then the CAS number in the CAS Registry shall apply.
 8. A number of abbreviations or expressions are used in column 4 of the table, the meanings of which are as follows:

- DL = detection limit of the method of analysis;
- FP = Whilst strictly speaking FP refers to finished plastic in this context it is referring to any finished material or article;
- NCO = isocyanate moiety;
- ND = Not detectable. For the purpose of this Code of Practice "not detectable" means that the substance should not be detected by a validated method of analysis which should detect it at the detection limit (DL) specified. If such a method does not currently exist, an analytical method with appropriate performance characteristics at the detection limit may be used, pending the development of a validated method;
- QM = maximum permitted quantity of the 'residual' substance in the material or article;
- QM(T) = Maximum permitted quantity of the 'residual' substance in the material or article expressed as total of moiety or substance(s) indicated. For the purpose of this Code of Practice the quantity of the substance in the material or article should be determined by a validated method of analysis. If such a method does not currently exist, an analytical method with appropriate performance characteristics at the specified limit may be used, pending the development of a validated method;
- QMA = Maximum permitted quantity of the "residual" substance in the finished material or article expressed as mg per 6 dm² of the surface in contact with foodstuffs. For the purpose of this Code of Practice the quantity of the substance in the surface of the material or article should be determined by a validated method of analysis. If such a method does not currently exist, an analytical method with appropriate performance characteristics at the specified limit may be used, pending the development of a validated method;
- QMA(T) = Maximum permitted quantity of the "residual" substance in the material or article expressed as mg of total of moiety or substance(s) indicated per 6 dm² of the surface in contact with foodstuffs. For the purpose of this Code of Practice. the quantity of the substance in the surface of the material or article should be determined by a validated method of analysis. If such a method does not currently exist, an analytical method with appropriate performance characteristics at the specified limit may be used, pending the development of a validated method;
- SML = Specific migration limit in food or in food simulant, unless it is specified otherwise. For the purpose of this Code of Practice the specific migration of the substance should be determined by a validated method of analysis. If such a method does not currently exist, an analytical method with appropriate performance characteristics at the specified limit may be used, pending the development of a validated method;



SML(T) = Specific migration limit in food or in food simulant expressed as total of moiety or substance(s) indicated. For the purpose of this Code of Practice the specific migration of the substances should be determined by a validated method of analysis. If such a method does not currently exist, an analytical method with appropriate performance characteristics at the specified limit may be used, pending the development of a validated method.

Lists A and B, including their updates, are available on the publication part of CEPE website (under paint documents) at following link :

<http://www.cepe.org/>

These are also available on the Council of Europe website.

ANNEX III

INCOMPLETE⁵ LIST OF ADDITIVES

1. This Annex contains the list of substances which are incorporated into coatings to achieve a technical effect in the finished product, including 'polymeric additives'. They are intended to be present in the finished articles;

For the purpose of this Annex, 'Polymeric additives' means any polymer and/or prepolymer and/or oligomer which may be added to coatings in order to achieve a technical effect but which cannot be used in absence of other polymers as the main structural component of finished materials and articles. It includes also substances which may be added to the medium in which polymerisation occurs.

The list does not include:

- (a) the substances which directly influence the formation of polymers;
- (b) the substances only used to provide a suitable medium in which polymerisation occurs ('polymerisation production aids')
- (c) colourants and many pigments.

2. This list is sub-divided into Lists C and D

List C contains additives which have been assessed by SCF or EFSA and for which there is an opinion (classified in list SCF 0-4) and used in compliance with specific migration limits or other restrictions if any and substances approved in member states or by FDA, based on an evaluation of a toxicological dossier, which meets the present SCF/EFSA criteria

List D contains additives which have been approved by member states or by FDA, applying evaluation criteria at the time of their approval

⁵ ***The list is claimed to be incompleated as it is based on the Council of Europe documents which are updated on regular basis. It does not contain other substances which have an SCF or EFSA opinion (lists SCF 0-4) e.g. substances which are authorised for other food contact sectors.***

3. The following substances are not included even if they are intentionally used and are authorised:
 - (a) Salts (including double salts and acid salts) of aluminium, ammonium, calcium, iron, magnesium, potassium and sodium of authorised acids, phenols or alcohols. However, names containing '... acid(s), salts' appear in the lists, if the corresponding free acid(s) is (are) not mentioned;
 - (b) Ionic salts (including double salts and acid salts) of metals of authorised acids, phenols or alcohols. For these salts the restrictions applicable to the acid and cationic metal shall apply independently from their source.'

4. The current list of additives includes also some polymerisation production aids (PPA). Some of the PPA's can also act as additives and, therefore they are included in Lists C and D. The others acting solely as a PPA will be regulated later, therefore they are excluded from the current definition of additives.

5. Substances shall be of good technical quality as regards the purity criteria.

6. The list contains the following information:
 - column 1 (PM/REF. No): the EEC packaging material reference number of the substances on the list,
 - column 2 (CAS No): the CAS (Chemical Abstracts Service) registry number,
 - column 3 (Name): the chemical name,
 - column 4 (Restrictions and/or specifications). These may include:
 - specific migration limit (SML),
 - maximum permitted quantity of the substance in the finished material or article (QM),
 - maximum permitted quantity of the substance in the finished material or article expressed as mg per 6 dm² of the surface in contact with foodstuffs (QMA),
 - any other restriction specifically laid down,
 - any type of specification related to the substance or polymer.

7. If a substance appearing on the list as an individual compound is also covered by a generic term, the restrictions applying to this substance shall be those indicated for the individual compound.

8. Where there is any inconsistency between the CAS number and the chemical name, the chemical name shall take precedence over the CAS number. If there is an inconsistency between the CAS number reported in EINECS and the CAS registry, the CAS number in the CAS registry shall apply.

Lists C and D, including their updates, are available on the publication part of CEPE website (under paint documents) at following link :

<http://www.cepe.org/>

These are also available on the Council of Europe website.

ANNEX IV

GENERIC DESCRIPTION OF COATINGS TYPICALLY USED IN FOOD CONTACT APPLICATIONS AND THEIR COMPONENTS

ANNEX IV.I - DESCRIPTION OF COATINGS

Coatings typically consist of:

1. Resins (synthetic or natural), polymers or prepolymers
2. Crosslinking agents or crosslinking prepolymers or crosslinking resins.
Note that these are present only in thermoset (or predominately) systems.
3. Additives, such as waxes, pigments, lubricants, flow aids and defoamers
4. Organic solvents and or water (not always)
 - Items 1-3 are designed to remain in the final film. In the case of thermoset systems, the cured coating comprises a (densely) crosslinked polymeric matrix resulting from the reaction of items 1 with 2.
 - Coatings are normally applied in the wet state (although powder coating systems can also be used in contact with food), and cannot fulfil their desired functions until organic solvent and or water (if present) has been removed, and, in the case of thermoset coatings, crosslinking of items 1 with 2 has occurred.
 - Organic solvent and water-free thermoplastic coatings rely on melting and re-solidifying to form the food contact layer.
 - Organic solvent and water-free thermoset coatings rely on crosslinking to form the food contact layer, which may or may not involve a melting process.

It is important that there is adequate crosslinking and / or removal of organic solvent and or water otherwise this will result in the finished article being unsuitable for its intended application.

The resins or polymers used in coatings can be either thermoplastic or thermoset.

Thermoplastic resins or polymers undergo little if any further intentional chemical reactions with other components in the coating. As such they are typically of high molecular weight and the final properties of the coating are normally inherent in the thermoplastic resins or polymers as mixed into the applied coating.

Thermoset resins or polymers or prepolymers are specifically designed to undergo chemical reactions (normally crosslinking or curing) either with other components in the coating such as crosslinking agents or crosslinking prepolymers or crosslinking resins or with themselves or any combination to form a final film which will be in contact with foodstuffs. Crosslinking agents can also be considered thermoset starting materials. Typically the components intended to react with each other or themselves are of lower molecular weight than a thermoplastic resin or polymer. Thermoset coatings develop their optimum mechanical properties and performance requirements only when sufficient crosslinking reactions between the functional groups have occurred, which results in an increase in molecular weight.

Resins or polymers or prepolymers or crosslinking agents or crosslinking prepolymers or crosslinking resins are prepared only from monomers and other starting substances included in Annex II Lists A and B or are themselves on these lists.

Thus it is necessary to describe how these substances are used to prepare relatively complex mixtures of resins or polymers or prepolymers as well as crosslinking resins or crosslinking agents or crosslinking prepolymers. Due to their complexity, it is impracticable to individually list all of the potential components present in the resins or prepolymers or polymers or crosslinking agents or crosslinking prepolymers or crosslinking resins mixed in the applied film. This is also the case for oligomers and isomers of substances in Lists A&B, even if some are relatively low molecular weight species. Thus to ensure uniformity of treatment for all resins or prepolymers or polymers or crosslinking agents or crosslinking prepolymers or crosslinking resins only the building blocks for resins or polymers or prepolymers or crosslinking agents or crosslinking prepolymers or crosslinking resins are listed. This informative Annex describes how these building blocks are combined and, as its name suggests, is for informative purposes only. It is not exhaustive and in this context it is not a positive list, but contains as much compositional information as is reasonably possible.

Additives, including polymeric additives, cover a wide range of materials, many of which are designed to improve the integrity of the final film. These would typically be flow aids, defoamers, plasticisers, whilst additives such as waxes are present to improve the lubricity of the dried film. Waxes may also be used as a coating rather than an additive. In addition pigments could be present. Additives used are in Annex III Lists C and D or are polymeric being prepared from substances in Annex II Lists A and B.

The approach used in the informative annex consists of families of resins, further defined by the types of substances in the inventory List of Monomers and other starting substances and Additives normally used in their

manufacture and the typical combinations of the substances. An indication of the typical functional groups is also given.

The informative Annex consists of 2 sections in total:

1. Overview of resins typically used
2. Generic description of composition of typical resins, with functional groups possibly present
3. Overview of how the resins in 1 and 2 may be combined in a coating.

ANNEX IV.II – OVERVIEW OF DIFFERENT TYPES OF RESINS TYPICALLY USED IN FOOD CONTACT COATINGS

Resins which may be used in coatings for direct food contact can be subdivided into :

1. Acrylics
2. Alkyds
3. Aminos
4. Anhydrides
5. Cellulosics
6. Epoxies
7. Hydrocarbon resins
8. (Poly)Isocyanates
9. Polyamides / polyamines
10. Polyesters
11. Phenolics
12. Polyurethanes
13. Vinylics
14. Rosins and rosin derivatives
15. Miscellaneous
16. Polyethers
17. Shellacs, ketone and latex

ANNEX IV.III - GENERIC DESCRIPTIONS OF COMPOSITION OF RESINS TYPICALLY USED IN FOOD CONTACT COATINGS AND POTENTIAL FUNCTIONAL GROUPS WHICH COULD BE PRESENT.

Note : Where resins are used to modify other resins then any of the functional groups present in the original resins may also be present

1. Acrylics

- 1.1 Acrylics prepared from a combination of monomers (co-monomers) on the Inventory list of Monomers and Additives, such as methyl methacrylate (PM 21130), styrene (PM 24610) or ethyl hexyl acrylate (PM 11500).

Functional groups potentially present:

Ester, aromatic and / or aliphatic residual $>C=C<$ unsaturation

- 1.2 Functional acrylics prepared from a combination of monomers (co-monomers) on the Inventory list of Monomers and Additives (as in 1.1) with functional co-monomers from the Inventory list of Monomers and Additives, such as acrylic or methacrylic acids (PM 10690 or 20020) or hydroxy ethyl methacrylate (PM 20950).

Functional groups potentially present:

Ester, -OH, -COOH, -NH₂, oxirane, aromatic and / or aliphatic residual $>C=C<$ unsaturation

- 1.3 Acrylic resins (1.1 or 1.2) further modified by reaction with other types of resins prepared from substances on the Inventory list of Monomers and Additives, such as epoxies (6.1) or polyesters (10.1).

Functional groups potentially present:

Ester, -OH, -COOH, -NH₂, oxirane, aromatic and / or aliphatic residual $>C=C<$ unsaturation

2. Alkyds

- 2.1 Saturated or unsaturated fatty acids or oils in the Inventory list of Monomers and Additives, such as coconut oil (PM 14685), soya bean oil (PM 24520), linseed oil (PM 19532), soya fatty acids (PM 17200), tall oil fatty acids (PM 17230) or mixtures thereof, and possibly monofunctional acids, such as benzoic acid (PM 13090) reacted with glycerol (PM 18100) and other polyols, such as pentaerythritol (PM 22840).

Functional groups potentially present:

Esters, -OH, Ar-COOH, R-COOH,

- 2.2 Alkyds (2.1) further modified by reaction with substances in the Inventory list of Monomers and Additives, such as styrene (PM) or other resins, such as acrylics or phenolics.

Functional groups potentially present:
Esters, -OH, Ar-COOH, R-COOH, groups from modifying monomers or resins

3. Amines

- 3.1 Formaldehyde (PM 17260) reacted with certain amines in the Inventory list of Monomers and Additives, such as benzoguanamine (PM 15310), melamine (PM 25420) or urea (PM 25960).

Any of the above further reacted (partially or fully) with methanol (PM 21550), isobutanol (PM 18970) or other aliphatic alcohols (PM 12375).

Functional groups potentially present:
residual -NH₂ (coming from the monomers); -NH-CH₂OH ; - N (CH₂OH)₂ ;
-NH-CH₂OR ; -N (CH₂OR)₂

4. Anhydrides

- 4.1 Anhydride functional substances in the Inventory list of Monomers and Additives, such as trimellitic anhydride (PM 25550) either by itself or reacted with a polyol in the Inventory list of Monomers and Additives, such as ethylene glycol (PM 16990).

Functional groups potentially present:
Aromatic and/or aliphatic Esters, R-OH, Ar-COOH, Ar-anhydride

5. Cellulosics

- 5.1 Nitrocellulose (PM 22450) is the nitration product of cellulose. For coatings a product with a nitrogen content less than 12,6% is used

Functional groups potentially present:
Hydroxyl, nitro (-NO₂)

- 5.2 Modified nitrocelluloses

Modified celluloses, such as cellulose acetopropionate (CAP) (PM?) and cellulose acetobutyrate (CAB) (PM?) can be used. They are, respectively, the mixed esters with acetic and propionic acid (PM Ref. 14512) and with acetic and butyric acid (PM Ref. 14508 – 43300).

Functional groups potentially present:
hydroxyl, nitro (-NO₂).

6. Epoxies

- 6.1 Standard aromatic epoxy resins prepared from Epichlorohydrin (PM 16750) and bifunctional phenols included in the Inventory list of Monomers and Additives, such as Bisphenol A (PM 13480) or Bisphenol F (PM 13455/ 13457) to form an epoxy, which may be further reacted with the original phenol monomer and/or other phenolic monomers, such as p-t-butyl phenol (PM 14020).

Functional groups potentially present:
Oxirane, -OH, -ArOH, -C-N-C-

- 6.2 Epoxy novolac resins prepared from Epichlorohydrin (PM 16750) and novolac precursor resin made from formaldehyde (PM 17260) and phenols included in the Inventory list of Monomers and Additives, typically Phenol (PM 22960).

Functional groups potentially present:
Oxirane, Ar-OH, -C-N-C-, -Ar-CH₂-Ar-, -Ar-CH₂-O-CH₂-Ar-

The use of epoxy novolacs in can coatings is not permitted, but they can be used in heavy duty coatings. For further details refer to Regulation (EC) No 1895/2005.

- 6.3 Epoxy-acrylic resins prepared from epoxies (6.1) which are further modified by reaction with acrylic/vinyl monomers included on the Inventory list of Monomers and Additives, such as Acrylic or Methacrylic acids (PMs 10690 or 20020) and Styrene (PM 24610), or further reacted with an acrylic resin (1.1 or 1.2) prepared from substances on the Inventory list of Monomers and Additives. Acid functionality may be neutralised by reaction with a (semi-) volatile amine, such as dimethylaminoethanol (PM 16150).

Functional groups potentially present:
Oxirane, ester, -OH, R-COOH, aromatic and/or aliphatic residual >C=C< unsaturation

- 6.4 Epoxy-ester resins prepared from epoxies (6.1) which are further modified by reaction with acid functional substances included in the Inventory list of Monomers and Additives, such as a fatty acid, like

hydrogenated coconut fatty acid (PM 17175), or a diacid such as adipic acid (PM 12130), or other acid functional intermediates or resins, prepared from substances in the Inventory list of Monomers and Additives, such as an acid functional polyester (10.3), or acid functional acrylic (1.2).

Functional groups potentially present:

Oxirane, ester, -OH, Ar-COOH, R-COOH, aromatic and/or aliphatic residual >C=C< unsaturation

- 6.5 Epoxy-amine adducts prepared from epoxy resins (6.1) which are further reacted with amine functional substances included in the Inventory list of Monomers and Additives, such as ethylene diamine (PM 16960) or an amine functional intermediate or resin (9.1), prepared from substances included in the Inventory list of Monomers and Additives, to form an epoxy adduct with residual amine functionality.

Functional groups potentially present:

-OH, R-NH₂(from monomers), R-NH-R, imidazolines, tertiary amines, quaternary ammonium

- 6.6 Reactive diluents: low molecular weight glycidylether/ester compounds prepared from Epichlorohydrin (PM 16750) reacted with mono-, bi- or multifunctional alcohols, phenols or organic acids included in the Inventory list of Monomers and Additives. Reactive diluents are used as modifiers in epoxy based systems to adjust viscosity or improve flexibility, typical examples include 1,4-Butanediol diglycidylether (PM 13780) and Trialkyl (C5-C15) acetic acid glycidylester (PM 14390)

Functional groups potentially present:

R-Oxirane, R-OH, R-COOH

7. Hydrocarbon resins

Hydrocarbon resins are polymers manufactured from various types of monomers. The raw material for these resins may be pure monomers, e.g. styrene, but often are based on complex distillates. Due to the complex nature of the structures of many of the monomers, industry has submitted the final resins for evaluation by EFSA rather than their individual monomers. Due to the low molecular weight, these resins cannot be used, in the absence of other (polymeric) components, as the main structural compound of the finished articles.

Hydrocarbon resins may be hydrogenated or not.

8. (Poly)isocyanates

- 8.1 Isocyanates in the Inventory list of Monomers and Additives, such as hexamethylene diisocyanate (PM 18640) or diphenyl methane diisocyanate (PMs 16600, 16630) either reacted with themselves or with polyols in the Inventory list of Monomers and Additives, such as trimethylol propane (PM 25600).

Functional groups potentially present:

Aromatic / aliphatic –NCO ; urethane, biuret, allophanate

The isocyanate functionality may be further reacted with a 'blocking agent' to enable single component coating formulations to be prepared. The blocking agent evaporates on heating, thereby regenerating the isocyanate functionality.

9. Polyamides / polyamines

- 9.1 Amines in the Inventory list of Monomers and Additives, such as diethylene triamine (PM 15790), reacted with acid functional substances in the Inventory list of Monomers and Additives, such as dimerised fatty acid (PM 17233) and / or monofunctional acids, such as tall oil fatty acid (PM 17230) to produce an amine functional resin.

Functional groups potentially present:

-COOH, -NH₂, -NH-, CONH₂, imidazolines

- 9.2 Epoxy resins (6.1) reacted with an amine functional substance in the Inventory list of Monomers and Additives, such as ethylene diamine (PM 16960) or an amine functional intermediate or resin (9.1), prepared from substances in the Inventory list of Monomers and Additives, to form an epoxy adduct with residual amine functionality.

Functional groups potentially present:

Oxirane, -OH, -NH₂, -NH-, imidazolines

10. Polyesters

- 10.1 Polyesters prepared by the reaction of polyacids in the Inventory list of Monomers and Additives such as adipic acid (PM 12130), terephthalic acid (PM 24910), isophthalic acid (PM 19150) and possibly monofunctional acids, such as benzoic acid (PM 13090), with polyols listed in the Inventory list of Monomers and Additives, such as neopentyl glycol (PM 16390), ethylene glycol (PM 16990), butanediol (PMs 13690, 13720), trimethylol propane (PM 25600).

Functional groups potentially present:
R-OH, R-COOH, Ar-COOH, esters

- 10.2 Polyester polyols prepared from substances in the Inventory list of Monomers and Additives used to prepare polyesters (10.1), but with the stoichiometric composition altered to give a high residual hydroxyl functionality.

Functional groups potentially present:
R-OH, R-COOH, Ar-COOH, esters

- 10.3 Acid functional polyesters prepared from substances in the Inventory list of Monomers and Additives used to prepare polyesters (10.1), but with the stoichiometric composition altered to give a high residual carboxylic acid functionality. Acid functionality may be neutralised by reaction with a (semi-) volatile amine, such as dimethylaminoethanol (PM16150).

Functional groups potentially present:
R-OH, R-COOH, Ar-COOH, esters

- 10.4 Polyesters may undergo further modification by reaction with either an acrylic resin (1.1, 1.2) prepared from substances in the Inventory list of Monomers and Additives, or acrylic monomers listed in the Inventory list of Monomers and Additives, such as styrene (PM 24610) and acrylic or methacrylic acids (PMs 10690 or 20020). Acid functionality may be neutralised by reaction with a (semi-) volatile amine, such as dimethylaminoethanol (PM16150).

Functional groups potentially present:
R-OH, R-COOH, Ar-COOH, esters, >C=C<

- 10.5 Polyesters (10.1, 10.2, 10.3) prepared from substances in the Inventory list of Monomers and Additives may undergo further modification with phenolics (11.1) prepared from substances in the Inventory list of Monomers and Additives.

Functional groups potentially present:
Ar-CH₂OH, Ar-CH₂OR, Ar-CH₂-O-CH₂-Ar, R-OH, R-COOH, Ar-COOH, ester

11. Phenolics

- 11.1 Formaldehyde (PM 17260) reacted with phenols in the Inventory list of Monomers and Additives, such as phenol (PM 22960), cresols (PMs

14710, 14740, 14770), xylenols (PMs 16270, 16300, 16330, 16360, 16363, 16364), p-t butyl phenol (PM14020), BPA (PM 13480), p-tOP (25185), CNSL (CAS 8007-24-7) and any combination of them.

Any of the above resins further reacted (partially or fully) with methanol (PM 21550), isobutanol (PM 18970) or aliphatic alcohols (PM 12375).

Functional groups potentially present:

Ar-CH₂OH, Ar-CH₂OR, Ar-CH₂-O-CH₂ –Ar, Ar-OH, Ar-CH₂-Ar, -C-N-C-

- 11.2 Phenolics (11.1) prepared from substances in the Inventory list of Monomers and Additives further reacted with, for example, epoxies (6.1) prepared from substances in the Inventory list of Monomers and Additives.

Functional groups potentially present:

Ar-CH₂OH, Ar-CH₂OR, Ar-CH₂-O-CH₂ –Ar, oxirane, Ar-OH, ester, Ar-CH₂-Ar

- 11.3 Phenolics (11.1) prepared from substances in the Inventory list of Monomers and Additives further reacted with, for example, polyesters (10.1) prepared from substances in the Inventory list of Monomers and Additives.

Functional groups potentially present:

Ar-CH₂OH, Ar-CH₂OR, Ar-CH₂-O-CH₂ –Ar, Ar-OH, COOH, ester, Ar-CH₂-Ar

- 11.4 Modified phenolics (11.2 or 11.3) prepared from substances in the Inventory list of Monomers and Additives further reacted with acrylic resins (1.1) prepared from substances in the Inventory list of Monomers and Additives or acrylic monomers on the Inventory list of Monomers and Additives, such as methacrylic acid (PM 20020) and styrene (PM 24610).

12. Thermoplastic polyurethanes

- 12.1 Polyols in the Inventory list of Monomers and Additives, such as ethylene glycol (PM 16990), polypropylene glycol (PMs 23740, 23770), or polyether glycols, such as dipropylene glycol (PM 16660) or a polyester polyol (10.2), or polyols based on polybutadiene, prepared from substances on the Inventory list of Monomers and Additives, reacted with either an isocyanate in the Inventory list of Monomers and Additives, such as hexamethylene diisocyanate (PM 18640) or diphenyl methane diisocyanate (PMs 16600, 16630) or toluene diisocyanate (PM 25240) or toluene diisocyanate dimer (PM 25270), or a polyisocyanate (8.1)

prepared from substances in the Inventory list of Monomers and Additives.

Functional groups potentially present:

urethane, R-OH, esters, R-COOH, Ar-COOH, biuret, allophanate

- 12.2 Polyurethanes (12.1) prepared from substances in the Inventory list of Monomers and Additives further reacted with, for example, acrylics (1.1) prepared from substances in the Inventory list of Monomers and Additives or acrylic monomers in the Inventory list of Monomers and Additives, such as acrylic or methacrylic acids (PM 10690 or 20020).

Functional groups potentially present:

urethane, R-OH, esters, R-COOH, Ar-COOH, biuret, allophanate,

13. Vinylics

- 13.1 Vinylics prepared from vinyl monomers on the Inventory list of Monomers and Additives, such as vinyl chloride (PM 26050), vinyl acetate (PM 10090) and/or acrylic monomers on the Inventory list of Monomers and Additives, such as methyl methacrylate (PM 21130).

Functional groups potentially present:

Ester, aromatic and / or aliphatic residual $>C=C<$ unsaturation, C-Cl,

- 13.2 Functional vinylics resins prepared from vinyl monomers on the Inventory list of Monomers and Additives, such as vinyl chloride (PM 26050), vinyl acetate (PM 10090) and/or acrylic monomers on the Inventory list of Monomers and Additives, such as methyl methacrylate (PM 21130), with functional acrylic monomers such as glycidyl methacrylate (PM 20590) or other functional co monomers with unsaturation, such as maleic acid (PM 19540).

Functional groups potentially present:

Ester, R-OH, R-COOH, aromatic and / or aliphatic residual $>C=C<$ unsaturation, C-Cl, R-NH₂, oxirane

14. Rosin Resins

- 14.1 Rosin (wood, gum & tall oil) (PMs 24070, 24100, 24130, 24160, 24190) whether or not hydrogenated, dehydrogenated or disproportionated or dimerised/polymerised, whether or not reacted with maleic anhydride, acrylic-, fumaric- or maleic acids (PMs 19540, 10690, 17290, 19960), and/or formaldehyde (PM 17260).

Functional groups potentially present:
R-COOH, esters, methylol

- 14.2 Fortified rosin esters formed from rosin (wood, gum & tall oil) (PMs 24070, 24100, 24130, 24160, 24190) whether or not hydrogenated, dehydrogenated or disproportionated or dimerised/polymerised, reacted with maleic anhydride, acrylic-, fumaric- or maleic acids (PMs 19540, 10690, 17290, 19960), with mono- and / or polyhydric alcohols and /or glycols listed in the Inventory List of Monomers and other starting substances and Additives.

Functional groups potentially present:
R-COOH, esters, methylol

- 14.3 Rosins, esters or fortified esters from above reacted with phenolic resins (11.1).
- 14.4 Rosins, esters or fortified esters, or phenolic resins from above reacted with terpene resins (7.1, 7.2).
- 14.5 Rosin esters as described under PM/REF numbers 84000, 84080, 84210, 84240, 84320, 84400.

15. Miscellaneous

- 15.1 Modified polybutadiene rubbers, prepared from butadiene (PM 13630) and other substances on the Inventory list of Monomers and Additives.
- 15.2 Polychloroprenes based upon request to add details
- 15.3 Silicones based upon fluids or crosslinked elastomers and resins
- 15.4 Terpene-phenol resins prepared by the reaction of phenol (PM 22960) with terpenes listed in the Inventory list of Monomers and Additives such as alpha-pinene (PM 23470).

16. Polyethers

- 16.1 Polyethers prepared by the reaction of ethylene oxide (PM 17020) and/or propylene oxide (PM 24010) with mono/polyfunctional alcohols or mono/polyfunctional phenols included in the Inventory list of monomers and additives, such as 1,2-propylene glycol (PM 23770) , p-cresol (PM 14770), Bisphenol A (PM 13480).

Functional groups potentially present :
Ether, -OH

17. Shellac and ketone resins

Shellac

Shellac is the purified form of the secretion of the insect *Laccifer Lacca* and can be considered as a natural condensation product of aleuritic acid and schelloic acid. Also contains wax which can be precipitated and the resin can also be bleached.

Ketone Resin

Ketone resins are formed by the condensation of the cyclic ketones with formaldehyde using an alkali catalyst. This produces methyl cyclohexanones by substitution of the alpha-methylenes.

18. Natural and synthetic Rubber latex emulsions

Natural Rubber Latex

Chemically, natural rubber, sap from the rubber tree, is the unsaturated hydrocarbon, polyisoprene; $(C_5H_8)_n$. The cis isomer makes up about 99.9% of the rubber solids in natural rubber latex.

This has the structure:-



Natural rubber is listed under two EU PM numbers 24250 and 84560 and CAS number 009006-04-6.

ANNEX IV.IV - EXAMPLES OF TYPICAL FOOD CONTACT COATINGS

Note that in all of these examples additives have been omitted.

Thermoset coatings

Coatings for light metal packaging comprising epoxy resin (6.1) cured with phenolic resin (11.1, 11.2) or amino resin (3.1) or anhydride resin (4.1) or any combination of them.

Heavy duty coating comprising epoxy resin (6.1 or 6.2) cured with polyamide/polyamine resins (9.1, 9.2) or amines in the Inventory List of Monomers and additives.

Coatings for light metal packaging consisting of an epoxy resin modified with acrylic functionality (6.3), cured by reaction with itself and/or amino (3.1) and/or phenolic (11.1, 11.2, 11.4) resins or any combination of them.

Coatings for light metal packaging consisting of a polyester resin (10.1) cured with a phenolic resin (11.1, 11.3) and/or an amino resin (3.1) and/or an isocyanate resin (8.1) or any combination of them.

Flexible coating consisting of an acrylic resin (1.1, 1.2) cured by reaction with itself and/or another acrylic resin (1.2).

Electrodepositable coating consisting of epoxy resins with amine functionality (6.5) and a polyether resin (16.1), cured by reaction with a blocked polyisocyanate (8.1).

Thermoplastic coatings

Flexible coating consisting of nitrocellulose (5.1) and polyurethane resin (12.1) or acrylic resin (1.1, 1.2).

Flexible coating based on a vinylic resin (13.1, 13.2).

Coatings for light metal packaging primarily consisting of vinylic resin (13.1, 13.2) and possibly small amounts of other resins, such as amino (3.1), phenolic (11.1) or epoxy (6.1).

Flexible packaging coating based upon vinylic and acrylic resins.

Flexible packaging coating base upon nitrocellulose or modified celluloses, possibly in combination with acrylic and / or vinylic resins



Organic solvent and or water free coatings for light metal packaging consisting of powders based upon polyesters (10). In some instances other resins may be present to give a small degree of crosslinking to improve resistance properties.

ANNEX V
FOOD AND FOOD SIMULANTS TO BE USED FOR TESTING COATINGS
IN CONTACT WITH FOODS

REFERENCE FOOD SIMULANTS

As it is not always possible to use foods for testing food contact materials and articles, reference food simulants were introduced. They are classified by convention as having the characteristics of one or more food types. As these are sometimes updated, the rules for selection of suitable simulants applied in 2002/72/EC and its amendments will apply for coated articles and materials in contact with foodstuffs. However in some cases the selection of certain simulants is unsuitable and these are discussed in Annexes VII and VIII.

ANNEX VI

RISK ASSESSMENT FOR MIGRANTS FROM COATED ARTICLES IN CONTACT WITH FOODSTUFFS.

The migration behaviour into different foodstuffs for any specific migrant depends not only on the type of foodstuff, but also any thermal processing of the foodstuff once packed. The risk assessment should use internationally recognised scientific principles such as dietary exposure, toxicological or structure activity considerations. By convention, those substances with a molecular weight >1000D are considered not to be of toxicological concern as they are not considered to be absorbed in the gastro-intestinal tract.

Three different classes of migrants may be found:

- **Monomers and other starting substances and additives**, which are listed in Annexes II and III. Those substances having an SML must be identified and the compliance with the restriction demonstrated on the basis of conclusive experimental data using authorised food simulants under conditions of use. Alternatively strong organic solvent(s) may be used to extract all the substance(s) (worst case scenario). Compliance can also be demonstrated by correlating SML restrictions with maximum initial concentration in a polymer, assuming 100% migration or by modelling when considered appropriate⁶. In the case of impurities in monomers and other starting substances or additives any impurities present will have been considered during the dossier evaluation.
- **Oligomers, prepolymers and natural or synthetic macromolecular substances where the monomers or other starting substances required to synthesise them are included in Annexes II and III.** These substances do not appear in Annexes II or III as this list is restricted to monomers and other starting substances. These substances are expected to be of lower toxicological hazard than their starting substances, but should be taken account of in any risk assessment.
- **Decomposition or reaction products**, also known as non intentionally added substances (NIAS) are formed either during the manufacture of the resin or during the curing process. Their full characterisation

⁶ The Commission will be requested to ask EFSA to give an opinion on the suitability of modelling migrants from coatings. Note the use of modelling may be dependent upon film thickness.

including hazard and risk assessment of all individual identified peaks is not feasible.

In order to demonstrate compliance with article 3 of the Framework Regulation (EC) No 1935/2004, the following must be considered:

- By defining the end use application(s) of the coating, it may be possible to estimate a limit of migration equating to an exposure of < 1.5 µg/person/day. In this case, the reaction product does not deserve any further toxicological evaluation⁷. This process may utilise probabilistic modelling for exposure assessments⁸.

⁷ See ILSI Monographs, 'Threshold of Toxicological concern for chemical substances present in the diet, report of a workshop held in October 1999' Anon August 2000 and 'Threshold of toxicological concern (TTC) – a tool for assessing substances of unknown toxicity present at low levels in the diet' S. Barlow July 2005.

Further information is contained in I. C. Munro, J. J. Hlywka, E. M. Kennepohl - Risk assessment of packaging materials, Food Additives and Contaminants 19, Proceedings Supplement 3-12, 2002.

⁸ Industry has asked the Commission for an opinion on the suitability of probabilistic modelling for assessing exposure to migrants from food packaging materials. Examples of the use of probabilistic modelling for assessing exposure to migrants from food packaging may be obtained from the following:

ILSI Monograph 'Exposure from food contact materials. Summary report of a workshop held in October 2001'. K. Svennson 2002.

M.J. Holmes, A. Hart, P. Northing, P.K.T. Oldring, L. Castle, D. Stott, J. Smith, O. Wardman 'Dietary exposure to chemical migrants from food contact materials: a probabilistic approach Food additives and contaminants Oct 2005, 22, pp 907 - 919

L. Castle, A. Hart, M. Holmes, P.K.T. Oldring 'Stochastic modelling of consumer exposure for any substance from canned foods using simulant migration data' Food additives and contaminants May 2006, 23, pp 528 - 538 P.K.T. Oldring, L. Castle, A. Hart, M.J. Holmes 'Migrants from food cans revisited – application of a stochastic model for a more realistic assessment of exposure to BADGE' Packaging technology and science 2006, 19, pp 121 - 137.

Duffy, E., Gibney, M. J. 'Use of a food-consumption database with packaging information to estimate exposure to food-packaging migrants: epoxidized soybean oil and styrene monomer; food additives and contaminants, FEB 2007, 24, pp 216 - 225

Duffy, E., Hearty, A. P., McCarthy, S., Gibney, M. J. 'Estimation of exposure to food packaging materials. 3: Development of consumption factors and food-type distribution factors from data collected on Irish children'; food additives and contaminants, JAN 2007, 24, pp 63 – 74

Duffy, E, Hearty, AP, Gilsenan, MB, Gibney, MJ; 'Estimation of exposure to food packaging materials. 1: Development of a food-packaging database', food additives and contaminants, JUN 2006, 23, pp 623 - 633

Duffy, E, Hearty, AP, Flynn, A, McCarthy, S, Gibney, MJ; 'Estimation of exposure to food-packaging materials. 2: Patterns of intakes of packaged foods in Irish Children aged 5-12 years', food additives and contaminants JUL 2006, 23, pp 715 - 725

- If the level of 1.5 µg/person/day is exceeded, then it is necessary to apply other considerations using universally recognised techniques, such as SAR (Structural Activity Alerts) and Cramer classes for toxicological thresholds where if the structure of a substance is broadly known, higher levels of migration may not require toxicological testing of that substance.

For risk assessments made for foodstuffs stored in large containers, the size of the containers (volume ratio to contact area) should be taken into account.

ANNEX VII

BASIC RULES FOR DEMONSTRATING COMPLIANCE WITH THE OML

1. Heavy Duty

Migration studies with heavy duty coatings

Methods applied

- Samples were evaluated using directive 97/48/EC and 90/128/EEC, Annex 1, paragraph 2 and 5
 - o The curing of the coatings involved has been made according to the number of days and conditions as specified in the Technical Data sheet, 7 – 14 days, at 23°C, 50% relative humidity, alternative Hot-Cure, 5 days at 40 or 60°C.
 - o Cured panels have been washed immediately after curing with steam during 1 hour
 - o Ratio test area : volume simulant – 100 sq cm : 100 ml

Methods applied:

The investigation comprised the following determinations:

Determination of the overall migration into 10% ethanol, after a contact period of 10 days at 40°C.

Determination of the overall migration into olive oil, after a contact period of 10 days at 70°C.

As an alternative to olive oil isooctane (2 days at 20°C) has been used in one case.

Determination of the specific migration of solvents (xylene, benzylalcohol, ethylbenzene, butanol/iso-butanol) into 10% ethanol.

To determine the overall and specific migration into aqueous simulants from the samples, the test specimens were immersed in the food simulant, 3% acetic acid and 10% ethanol, and stored for 10 days at 40°C. After the contact period, the test specimens were emptied and the procedure was repeated twice, using the same panel and taking fresh simulant each time. After each storage period, the overall migration was determined following similar

methods as CEN method ENV 1186-3 (version May 1994) (aqueous simulant) as closely as possible.

To determine the overall migration into olive oil from the samples, the test specimens were immersed in the food simulant and stored for 10 days at 70°C, 20 days at 70°C and 30 days at 70°C, as follows:

- 1 panel for 10 days
- 1 panel for 20 days
- 1 panel for 30 days.

After the contact period, the overall migration was determined following the CEN method ENV 1186-2 (version May 1994) (fatty food stimulant) as close as possible. The infrared spectrum from the residue was determined. The results mentioned in the table are subtractions from these readings, i.e. 20 days = result 20 days – result 10 days.
30 days = result 30 days – result 20 days.

The specific migration of solvents was determined by wet analysis of simulant using HPLC or Headspace GC.

ANNEX VIII

BASIC RULES FOR DEMONSTRATING COMPLIANCE WITH SMLs

1. Heavy Duty

Heavy duty coatings are evaluated using methods described in Directives 97/48/EC, 85/572/EEC and 82/711/EEC.

Simulants:

Acetic acid:

Acetic Acid is not suitable as food simulant for Heavy Duty Coatings due to severe effect on the coating film (blistering and corrosion products) or in the case of light metal packaging due to corrosion of the metallic substrate. It is proposed to use 10% ethanol v/v as an alternative to 3% acetic acid.

Olive Oil:

For heavy duty coatings, the determination of specific migration of organic solvents in olive oil is rather difficult and in case for xylene the specific migration value gives variable results. It is therefore recommended to use Isooctane (2 days at 20 deg C) as simulant. See conclusions in report migration studies from 12.02.1999

ANNEX I to Directive 90/12/EEC of 23 February 1990 relating to plastic materials and articles intended to come into contact with foodstuffs

Paragraph 2:

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:

$$1.2.3 // M = // m \cdot a_2 a_1 \cdot q // \cdot 1\ 000$$

Where:

1.2 // 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; // a1 // is the surface area in dm² of the sample in contact with the foodstuff or simulant during the migration test; // a2 // 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.

Paragraph 5:

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.

ANNEX IX

GLOSSARY

1. *"Additives" are substances which are incorporated into coatings for direct food contact to achieve a technical effect in the finished material or article. They are intended to be present in the finished materials or articles;*
2. *"Aids to Polymerisation" are substances, which directly enable the formation of the polymers or resins, used as components of coatings. They include initiators, polymerisation catalysts, chain transfer agents. They are usually reactive substances which are bound to the polymer. They are outside the definition of additives, but are currently covered in Council of Europe Resolution AP(92)2.*
3. *"Authorised substances" are substances in a community or national list, including the German recommendations.*
4. *"Authority" means European Food Safety Authority, as set by Regulation (EC) No 178/2002;*
5. *"Coated light metal packaging" comprises cans, ends, closures , aerosols and tubes for food and beverage, which have an organic coating applied to all or part of the food contact surface and pails (with a maximum volume of 40L).*
6. *"Coating" means a product mainly prepared from one or more mainly organic substances (raw materials), which in its finished state does not form a self-supporting layer or film, but when it is applied onto a substrate and forms a partial or an integral layer, which has certain intended technological effects in the material or article. Organic coatings are typically applied in a liquid (solution or dispersion) or powder state and need to dry, cure or solidify to reach their finished state. Inorganic coatings largely based on inorganic materials including metals and oxides are excluded from this definition.*
7. *"Coatings" may be formulated from resins/ polymers / prepolymers, crosslinking agents, as well as additives, such as waxes, defoamers, wetting aids, flow aids, organic solvents, pigments, etc. (See Annex IV).*
8. *"Crosslinking" is the process by which functional groups present in the thermoset polymers or pre-polymers react with those present in a crosslinking agent or prepolymer or themselves to form a crosslinked structure of increased molecular weight to form the final coating in contact with the foodstuff. Crosslinking is generally achieved by thermal treatment in high temperature ovens. It can also be obtained at ambient temperature by mixing reactive two pack systems.*

9. *“Curing” of coatings on light metal packaging is normally the high temperature process by which the applied coating layer to the metal is converted into the final coating (layer) (through crosslinking,) which is in contact with the foodstuff. In the case of heavy duty coatings, curing is typically achieved at ambient temperatures, using a two component system, mixed prior to application.*
10. *“Food” (or “foodstuff”), for the purposes of this Code of Practice, means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans (based on Regulation (EC) N° 178/2002)*
11. *“Food simulants” are authorised test media simulating foods in their behaviour of extracting substances from food contact materials.*
12. *“Good Manufacturing Practice (GMP)” is used in the manufacture of any coatings intended for contact with foodstuffs. The GMP’s are described in industry codes of practice (See Annex A)*
13. *“Heavy duty coatings” are coatings applied on containers or storage tanks with a volume capacity of 10,000 liters or more and on all pipelines belonging or connecting them.*
14. *“Migration test” means the determination of specific migration of a substance or the overall migration of substances either into food or into a food simulant;*
15. *“Monomer and other starting substance” means any starting substance such as compound, mixture, monomer, oligomer, pre-polymer natural or synthetic macromolecules etc., used as reactant in any chemical reaction during the production of coatings and their raw materials which become part of the polymeric structure of the final coating, which is in contact with foodstuffs.*
16. *“Non-intentionally added substances” [NIAS] are substances present in the finished product which were not deliberately added. NIAS’s include reaction and decomposition products, as well as impurities and oligomers.*
17. *“Non-regulated simulant substitutes” which may be used as substitutes for the reference simulant A, B, C and D for which equivalence with the regulated simulant must be demonstrated. Strong organic solvents are not considered to be non-regulated simulant substitutes, as they are significantly more extractive than foodstuffs.*
18. *“Oligomer” means any substance consisting of a number of repeating units of an individual monomer / starting substance or a combination of monomers or starting substances. Oligomers may be used as starting substances, but they may also remain as a low molecular weight fraction after crosslinking / curing process or in the case of thermoplastic coatings they may remain after evaporation of any organic solvent(s). Oligomers*

composed of authorised monomers and other starting substances are generally regarded as being of no greater toxicity than their repeating units..

19. *“Organic solvents” are processing aids, used in the formulation of many coatings to enable them to be applied to the substrate. In the case of light metal packaging organic solvents evaporate during the curing process, generally performed at high temperatures (ie 200°C), and are therefore not intended to remain in the final layer of coating in contact with foods. Organic solvents present in other coatings are removed during the formation of the final film. Organic solvents used to prepare resins, polymers, prepolymers and crosslinking resins are polymerisation production aids. Residual levels of solvents may be present in the finished film at levels which will not endanger human health or adversely affect organoleptic properties in accordance with Article 3 of Framework regulation (EC) No 1935/2004*
20. *“Overall migration” (OM) means the sum of the migration of all substances, except water, released from a material or article into food or food simulant;*
21. *“Overall migration limit” (OML) means the maximum permitted amount of all substances, except water, released from a material or article into food or food simulant;*
22. *“Plastics” are the organic macromolecular materials obtained by polymerisation, polycondensation, polyaddition, biological fermentation or similar processes from molecules with a lower molecular weight or by chemical alteration of natural and synthetic macromolecules. Other substances or matter may be added to such macromolecular compounds. Plastics are converted using standard technologies, such as extrusion, moulding, calendaring etc.; however, the following are not regarded as plastics: silicones, waxes, rubbers, ion exchange resins.*
23. *“Polymeric additive” means polymer and/or, prepolymer and/or oligomer which may be added to coatings in order to achieve a technical effect in the finished material or article, but which cannot be used in the absence of another polymer or prepolymer as principal coating component and normally does not take place in the crosslinking process.*
24. *“Polymerisation production aids” (PPA’s) means substances used to provide a suitable medium in which polymerisation occurs (e.g. emulsifiers, surfactants, buffering agents etc.). They may be used in the manufacture of some polymers or resins or polymeric additives used as components of the coating, but are neither intended to be present in the finished materials or articles nor to have a technical effect in the final materials or articles.*
25. *“Positive list” means a list of substances authorised for use in the manufacturing of materials and articles at the exclusion of all others..*

26. *“Prepolymer” refers to a low molecular weight reactive polymer used as a starting substance in the preparation of a coating formed from a combination of authorised monomers and other starting substances. They are generally regarded as being of no greater toxicity than their repeating units. They are designed to further react, with themselves or other reactive substances or prepolymers, resulting in a significant increase in their overall molecular weight.*
27. *“Product” means any goods sold in the supply chain for coated food contact articles.*
28. *“Processing aids” are substances, such as organic solvents, added to a coating to enable it to be applied to a substrate. In some cases a processing aid may also be a PPA. Consult Annex I for more detail.*
29. *“QMA” means maximal quantity of a substance permitted in a material or article expressed as mg (of substance) per 6 dm² of the surface in contact with foods; Note QM is not applicable for coated articles.*
30. *“Raw Agricultural Commodities” are pre-consumer food materials, for example bulk corn, wheat, rice etc.*
31. *“Reference food simulants” are distilled water or water of equivalent quality (simulant A), 3% acetic acid (w/v, simulant B) in aqueous solution, 10% ethanol in aqueous solution (v/v, simulant C), rectified olive oil (simulant D); a new simulant 50% ethanol is being introduced, e.g. for milk.*
32. *“Regulated simulant D substitutes” are iso-octane, 95% ethanol, sunflower oil, corn oil and modified polyphenylene oxide, used to substitute simulant D under specified conditions; See Simulant D oil substitutes.*
33. *“Resins” describes families of polymers / prepolymers. e.g. phenolic resins, epoxy resins , vinyl resins, used as components of coatings. Resins are further described in Annex IV.*
34. *“Rubber” means a family of materials showing the property of high elasticity. In an unaged state, rubber can be substantially deformed under stress, but recovers nearly to its original stage when the stress is removed. Rubber is usually made from a mixture of (solid and/or liquid) materials and can be subjected to a curing process, which changes its nature. It includes elastomers.*
35. SAR. Structural activity relationship.
36. *“Silicones” are a group of polymeric chemical substances and preparations, all based on polysiloxanes;*
37. *“Simulant D oil substitutes” are synthetic triglycerides or other edible oils with standardised specifications or 95% ethanol or modified polyphenylene oxide substituting the reference food simulant D under the same testing conditions. See Regulated simulant D substitutes.*

38. *"Specific migration" (SM) means the amount of a specific substance released from a material or article into food or food simulant;*
39. *"Specific Migration Limit" (SML) means the maximum permitted amount of a given substance released from a material or article into food or food simulants;*
40. *"Substitute test" means the determination of a specific migration or overall migration into a regulated or a non regulated simulant substitute;*
41. *"Supply chain" means all business operators, including the food business operators which participate directly or indirectly in the production, converting, distribution and use of materials and articles intended to come into contact with foodstuff such as ingredient supplier, raw materials manufacturer, converter and food packer.*
42. *"Thermoplastic coatings" are coatings which do not require crosslinking or curing. The heat treatment does not induce changes in the structure of the coatings but (similar to thermoset coatings) ensures that any organic solvents used for application purposes are no longer present in the finished film. Residual levels of solvents may be present in the finished film at levels which will not endanger human health or adversely affect organoleptic properties in accordance with Article 3 of Framework regulation (EC) No 1935/2004*
43. *"Thermoset coatings" are coatings which develop their mechanical and pack performance once the adequate crosslinking or curing has been achieved.*
44. *Water may be present in a wet coating, but in most cases it is not a solvent but a medium in which to carry the other coating materials which are dispersed into it. Frequently there will be an organic co-solvent present.*



ANNEX X

REFERENCES TO GMP's

For light metal packaging - Refer to '**Guide de bonnes pratiques d'hygiène et de fabrication des emballages métalliques**' by Syndicat National des Fabricants de Boîtes, Emballages et Bouchages Métalliques. This will be developed by 2007 into a European code of practice

For coatings for light metal packaging and heavy duty coatings – refer to Council of Europe RD 11-1-37 (May 2000).

For aluminium alloy semi and end products intended to come into contact with foodstuff – refer to the European Aluminium Industry (EAA) Code of Practice

For flexible packaging refer to www.flexpack-europe.org

For steel packaging, the GMP is available on APEAL website www.apeal.org, under "Library"



ANNEX XI

LIST OF DUAL USE SUBSTANCES

The list of substances considered to be dual use substances provided by CiAA is given on CEPE website.