

( DRAFT )  
ON

**POSSIBLE CRITERIA IN ESTABLISHING THE POSITIVE  
LIST OF ADDITIVES FOR PLASTICS AND COATINGS FOR  
FOOD APPLICATIONS AND THEIR RESTRICTIONS**

(updated to 10 October 1993)

**INTRODUCTION**

The aim of this document is to inform the concerned parties about the criteria likely to be used by the Commission services in amending the Directive 90/128/EEC to include:

- a) the first Community list of additives (the related amending Directive will be conventionally called for brevity and clarity "Directive on additives");
- b) the products actually excluded by the field of application of Directive 90/128/EEC i.e. varnishes and the majority of the laminates (the related amending Directive will be conventionally called for brevity and clarity "Directive on coatings").

Although the criteria, and particularly the dates indicated here may be subject to changes following the consultation of the interested parties (SCF, Member States, professional organizations etc.), the Commission services underline the need to seriously consider the indicated criteria and dates in order to avoid future difficulties.

This document supercedes the "Synoptic 6" and any other EEC document dated before the 10 October 1993.

## **FIRST PART: PLASTICS**

### **1. DIRECTIVE ON ADDITIVES: COMMUNITY POSITIVE LIST**

The Commission services intend to prepare, as soon as possible and not later than 31 December 1993, a first preliminary working document on a proposal for a Directive amending the Directive 90/128/EEC in order to extend the positive list to additives (see definition of additives in Synoptic 6, pages 138-139). This extension will be called briefly below "Directive on additives".

In principle, this (proposal for a) Directive will have the following characteristics:

- a) the field of application will be the same as that of Directive 90/128/EEC;
- b) the list of additives will be restricted only to the definitive Community list (equivalent to the Section A for the Directive on monomers). In principle therefore, contrary to the monomers list in Directive 90/128/EEC, the proposal will not include a provisional list of additives which may continue to be used at national level pending a decision on their inclusion in Section A (equivalent to the Section B for Directive on monomers);
- c) the substances not appearing in the Community positive list for additives will be forbidden 3 years after the adoption of the Directive.

The Commission services intend to transmit for adoption by the Standing Committee for Food a proposal of Directive on additives as soon as possible but not before the 1st January 1995.

The dates considered in this document assume that the Directive is adopted on 1st January 1995 and that the substances not in the positive list will be forbidden since 1 January 1998.

### **2. SUBSTANCES WHICH WILL BE INCLUDED IN THE COMMUNITY POSITIVE LIST OF ADDITIVES**

In principle only the substances used for plastics for which the requested data have been received before the 31 December 1993 or evaluated and classified by the SCF into lists L0-L4 before the 30 June 1994 will be included in the Community positive list.

N.B. It has to be stressed that for many substances the deadlines indicated in the synoptic 5 (five) have been largely exceeded. Moreover in "Synoptic 6" the Commission services strongly recommended that industry must provide the requested data as soon as possible in order to obtain the evaluation of the substances before the 31 March 1994. Therefore only the substances for which the Commission services recognize the impossibility for the concerned parties to transmit in due time the data requested by SCF could be subject to particular rules (see later).

### 3. SUBSTANCES NOT INCLUDED IN THE COMMUNITY POSITIVE LIST

These substances, classified in SCF lists 5-9, may continue to be authorized or to be used at national level until 1 January 1998 according to the assumptions. Therefore, for these substances, the current legal situation will remain unchanged until 1 January 1998.

In future, these substances may be included in the Community positive list, if the data requested by the SCF are supplied and the SCF classified them in L0-L4. The Commission services will propose every year an amendment to the Directive in order to include before the 1st January 1998 these substances as much as possible.

A particular situation is that of certain substances for which:

- a) the evaluation was postponed due to lack of time of the SCF or
- b) the SCF requested further data or data different from those previously provided and then the deadlines indicated by the SCF have not been exceeded (see Annex 1).

The Commission services believe that the substances already authorized at national level before the issue of Synoptic 6 and not yet evaluated by SCF due to lack of time will no longer exist after the 30 June 1994 and in any case before the proposal of Directive is adopted by the Standing Committee for Food. Therefore it is highly probable that these substances, if they are classified by the SCF in L0-L4, will appear in the proposal of Directive.

More complicated is the case of the substances of (b). It is the intention of the Commission services to prepare in an EEC working document a list of these substances ("First provisional list of pending substances") at the same time of the Community list of additives and to underline the particular situation of these substances to avoid for them a discrimination on a commercial point of view. However the Commission does not intend to insert the list of these substances in the Directive on additives as made in the past for the monomers (the so called "Section B", which will disappear the 1 January 1997 at latest). The reason for this decision is to maintain the pressure on these substances in order to receive as soon as possible the requested data as well as to maintain the responsibility to the authorities which have authorized such substances and which have specific data on these substances not available to the Commission services. Only on 1 January 1997 will an amendment of the Directive on additives establish a very restricted list of substances for which the time limit of 1 January 1998 is postponed because the deadlines recommended by the SCF are not yet exceeded and the experiments are ongoing ("Section B for additives").

### 4. QUANTITATIVE RESTRICTIONS IN THE POSITIVE LIST OF ADDITIVES

In principle the Commission services intend to apply to additives the same criteria already applied to monomers and which are described below:

- a) a substance contained in lists 4 or 6 of the SCF reports or having an ADI (list 1) or a TDI (list 2)  $< 1\text{mg/kg b.w.}$ , may be subject to a quantitative restriction;
- b) a substance having an ADI or TDI less than  $1\text{ mg/kg b.w.}$  will be subject to a specific migration limit in food or in food simulants equal to the value obtained by multiplying the

ADI or TDI by 60. It is assumed that a man weighs 60 kg and that he eats one kilo of foods in contact with the plastics which always contain the substance under reference;

- c) a substance contained in SCF list 4A will be subject to a limit of detection in food or in simulating liquids equal to 0.01 mg/kg;
- d) a substance contained in SCF list 6 A will be subject to a limit of detection in food or in food simulants equal to 0.05 mg/kg;
- e) a substance contained in SCF list 3 or in SCF list 6B and having a restriction expressed in a limit of migration will be subject to this limit of migration;
- f) a substance contained in SCF list 3 or in SCF list 6B and having a restriction expressed in mg/kg b.w. will be subject to a limit of migration obtained by multiplying the restriction by 60.

However, in order to avoid an excessive number of specific limits of migration, the Commission services, on the proposal of the concerned parties, may accept as alternative to put in some restricted and justified cases other type of restrictions (limits in finished plastic, restriction on the type of plastic etc.), if it is shown that they are equivalent.

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## SECOND PART: COATINGS

### 5. DIRECTIVE ON COATINGS AND LAMINATES

After the adoption of the Directive on additives (1995?) the Commission services intend to prepare an amendment to the Directive 90/128/EEC (called "Proposal for a Directive on coatings"), in order to include all the products now provisionally excluded .i.e.

- the varnishes and paints;
- the materials consisting of two or more layers, of which at least one does not consist solely of plastic material, even if the layer intended to come into contact with foodstuffs does consist entirely of plastic material.

In principle this amendment to the Directive 90/128/EEC will include among others:

- a) an additional list of monomers and additives to the Community positive list for plastics;
- b) the introduction of the concept of "functional barrier";
- c) if necessary, the amendment to the conditions of testing of migration in order to take into account the specificity of the new materials.

The Commission services intend to prepare this document in 1995 in order for it to be adopted by 1 January 1996.

### 6. SUBSTANCES WHICH WILL BE INCLUDED IN THE COMMUNITY POSITIVE LIST OF ADDITIVES

Because there will be only a list for plastics and coatings, all the substances already authorized for plastics by the Directive 90/128/EEC and following amendments will be also authorized for coatings. Moreover all the other substances used only for coatings and classified by the SCF before the 30 June 1995 or before the date of the preparation of the proposal of Directive on coatings will be included.

### 7. SUBSTANCES NOT INCLUDED IN THE COMMUNITY POSITIVE LIST

They may be continued to be used at national level until the time fixed in the Directive on coatings for the prohibition of the coatings not in compliance with the Directive (usually 3 years after the adoption of Directive). Assuming that the directive on coatings will be adopted 1 January 1996, the substances authorized or used in at least one Member State can be maintained at national level until 1 January 1999. In principle no other derogations will be provided by Directive, except in

very exceptional justified cases (e.g. substances for which the data requested by SCF requires time longer than that existing between the date of the issue of Synoptic 6 or the future supplements and the time necessary for producing the requested data (see annex 1). A directive amending the Directive on coatings to be adopted 1 January 1998 will establish a very restricted list of substances for which the time limit of 1 January 1999 is postponed because the deadlines recommended by the SCF are not yet exceeded and the experiments are ongoing (this list is conventionally called "Section B for coatings")

**N.B. (FOR COATINGS)**

In principle the Commission services consider that the document Synoptic 6 contains all the substances authorized or used at national level for the coatings (see page 21-22 of the "Practical Guide N.1"). Therefore the inclusion of other substances in this list can be accepted only if a technical dossier is provided according to the "Practical Guide N.1". Moreover it is strongly recommended that the concerned parties supply as soon as possible and not later the 31 December 1994 the data requested by SCF for the substances only used for coatings. As already stressed, only in very exceptional justified cases, indicated in the previous paragraph, the data can be supplied later than 31 December 1994.

**7. QUANTITATIVE RESTRICTIONS IN THE POSITIVE LIST OF MONOMERS AND ADDITIVES FOR COATINGS**

In principle the Commission services intend to extend the Directive 90/128/EEC to the coatings and, therefore, to extend the same positive list (substances and restrictions) to the coatings (see also paragraphe 6).

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**In annex 2 a scheme of the described situation for plastics and coatings is reported.**

ANNEX 1**DEADLINES FOR THE TRANSMISSION OF TOXICOLOGICAL DATA**

<b><u>List 9</u></b>	1 year after the evaluation of SCF
<b><u>List 8</u></b>	1 year after the evaluation of SCF* N.B. The deadlines for the transmission of the results of the tests requested are the same of those indicated for list 7.
<b>List 7</b>	1 year after the evaluation of SCF*
<b>Data on:</b>	
- hydrolysis	2 years after the evaluation of SCF
- mutagenesis	2 years after the evaluation of SCF
- migration	2 years after the evaluation of SCF
<b>Studies:</b>	
- 28-days	2 years after the evaluation of SCF
- 90-days	2 years after the evaluation of SCF
- reproduction	3 years after the evaluation of SCF
- teratogenesis	3 years after the evaluation of SCF
- long term	5 years after the evaluation of SCF
<b><u>List 6</u></b>	1 years after the evaluation of SCF* N.B. The deadlines for the transmission of the results of the tests requested are the same of those indicated for list 7.
<b><u>List 2</u></b>	For substances for which a temporary TDI (t-TDI) has been fixed, the data shall be transmitted as soon as possible.

\* The dates marked with an asterisk refer to the time inside which the Commission has to receive a letter where the interested person declares its intention of transmit the requested data and encloses, for example, copy of the contractual engagement with the laboratory (ies) of analysis

**ANNEX 2****SCHEME OF THE DEADLINES AND CHARACTERISTICS OF THE POSITIVE LIST OF  
ADDITIVES FOR PLASTICS AND COATINGS FOR FOOD APPLICATIONS****DIRECTIVE ON ADDITIVES FOR PLASTICS**

31 December 1993	Deadline for the transmission of data requested by SCF
30 June 1994	Only the substances classified by the SCF into lists 0-4 will be considered for the preparation of the Community positive list
1 January 1995	Estimated date for the adoption of Directive on additives for "plastics"
1 January 1997	Directive amending the Directive on additive in order to include a provisional list of substances which may continue to be used at national level pending a decision on their inclusion in the Community list.
1 January 1997	The plastics which comply with the Directive on additives shall circulate at Community level
1 January 1998	The plastics which do not comply with the Directive on additives shall not be circulated at Community level

**DIRECTIVE ON COATINGS**

31 December 1994	Deadline for the transmission of data requested by SCF
30 June 1995	Only the substances classified by the SCF into lists 0-4 will be considered for the preparation of the Community positive list
1 January 1996	Estimated date for the adoption of Directive on "coatings"
1 January 1998	Directive amending the Directive on coatings in order to include a provisional list of substances which may continue to be used at national level pending a decision on their inclusion in the Community list.
1 January 1998	The coatings which comply with the Directive on coatings shall be circulated at Community level
1 January 1999	The coatings which do not comply with the Directive on coating shall not be circulated at Community level