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COMMISSION
OF THE
EUROPEAN COMMUNITIES

CS/PM/1021

Directorate General
for
Industrial Affairs and Internal Market

III/C/1

III/3141/89-EN (Rev. 5)
LR/LR
Brussels, 1 August 1991

DRAFT

SYNOPTIC DOCUMENT 5
on
PLASTICS MATERIALS AND ARTICLES
INTENDED TO COME INTO CONTACT WITH FOODSTUFFS

(updated to 1 August 1991)

NOTA BENE

The amendments to the text of the previous version
(Synoptic 4) are written in bold characters or underlined.

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NOTA BENE

The amendments to the text of the previous version (Synoptic 4) are written in bold characters or underlined.

IN ANY CORRESPONDENCE WITH THE EEC SERVICES AND THE SCF ON A SUBSTANCE INCLUDED IN THIS DOCUMENT, IT IS ABSOLUTELY NECESSARY TO FOLLOW STRICTLY THE INSTRUCTIONS INDICATED IN THE DOCUMENT "NOTE FOR GUIDANCE OF APPLICANTS..." (III/3568/89 Final) AVAILABLE ON REQUEST TO THE FOLLOWING ADDRESS:

Commission of the European Communities
(for the attention of Mr Gontier) DIV. III/C/1
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EXPLANATORY NOTE

1. The Commission of the European Communities ("CEC") is in the process of completing the Community law in the sector of plastics materials, as laid down by Annex 1 to the Council Directive 89/109/EEC of 21 December 1988 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs (O.J. N. L 40, 11 February 1989 (hereinafter called "new framework Directive"). In principle, it is provided that the final Community regulation will contain rules concerning the following aspects:

- a) a positive list of substances authorized;
- b) a global migration limit;
- c) the basic rules for testing migration (list of simulants, conditions for testing migration (time, temperature));
- d) the criteria for purity of certain substances;
- e) the methods of analysis;
- f) other.

2. Because of the complexity of the subject and the number of discrepancies between the national laws, the CEC decided to proceed step by step, proposing for adoption Directives on the specific aspects of the regulation. Six Directives have already been adopted in this sector:

- 78/142/EEC concerning the limits for vinyl chloride monomer (VCM) (OJ n. L 44 of 15.02.1978);
- 80/766/EEC concerning the determination of VCM in the finished products (OJ n.L 213 of 16.08.1980);
- 81/432/EEC concerning the determination of VCM in the foodstuffs (OJ n. 167 of 24.06.1981);
- 82/711/EEC Directive on plastics "basic rules for testing migration" (OJ n. L 297 of 23.10.1982);
- 85/572/EEC Directive on plastics "list of simulants to be used for testing migration" (OJ n.L.372 of 31.12.1985);
- 90/128/EEC Directive on plastics "monomer" (OJ n. L 128 of 21.3.1990 rectified by OJ n.349 of 13.12.90).

3. Other Directives are either being prepared or being planned. Such Directives will take the legal form of Commission Directives (adopted by a qualified majority (54/76 votes) by the Standing Committee for Food, according to the new procedure laid down in Article 3 of the new framework Directive). In principle they will consist of:

- a) a first modification of the Directive on monomers in order to:
 - include "new" monomers
 - amend the legal status of the listed monomers, if a re-evaluation of a substance makes it necessary.

A draft is now ready (III/3274/91 Rev.1) and is planned to be available for adoption before 31 December 1991.

- b) a modification of Directive 82/711/EEC in order to add the test conditions for high temperature contact and the use of microwave (planned for 1992)(doc. III/3278/91 Rev.1);
- c) an extension of the positive list of the adopted Directive on monomers in order to include the monomers used to

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manufacture varnishes, lacquers, paints, including epoxy resins as well as the additives of the mentioned products (planned for the end of 1992).

- d) some Directives which will
- codify, complete (e.g. purity criteria) and, in some cases, amend (e.g. basic rules for migration tests) the previously adopted Directives.

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The problem of the official control of plastics materials and articles and the methods of analysis will be examined later, taking account of the development of Directive 89/397/EEC. At present there are the following two initiatives:

- a) the European Committee for Normalization (CEN) is preparing methods of determination of the global migration and for controlling the quantitative restrictions on some monomers set out in Directive 90/128/EEC;
- b) the Council of Europe is preparing a compilation of the methods actually available for the determination of specific migration in foods or foods simulants. For further information, please, contact Mr. Baum, Council of Europe, Partial Agreement, Division, BP 431 R6, F-67006 STRASBOURG, Cedex-France (phone: 8614961; fax: 8367057).

4. This document is a working document containing the monomers (see Annex 1) and additives (see Annex 2) listed by the Commission services until 1 August 1991. In particular it contains:

- a) in Annex 1 the draft of a complete positive list of monomers for all types of plastics (including varnishes and excluding only silicones). Therefore this list includes:
 - the monomers contained in the Directive;
 - the "new" requested monomers;
 - monomers (as individual compound) derived from generic terms classified in list 9 by SCF and, therefore, destined to be deleted in the draft of first modification of Directive 90/128/EEC. These monomers can be recognised because in column "REMARKS" the abbreviation S1(PM/REF.N) appears.
- all the monomers for varnishes (which now include epoxy resins).

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- This list does not contain the monomers for silicones, as these products will be considered in later stage.
- This list does not contain the monomers notified by UK on 4 April 1991 (CS/PM/950) and on 9 July 1991 (CS/PM/978) as these substances were not accompanied by a technical dossier according to the "NOTE FOR GUIDANCE" or accompanied by a documentation showing that these substances are included in a national positive list or in FDA before 31 December 1990. Also in this last case the substances will be included only provisionally waiting for a technical dossier.

- b) In Annex 1 bis the requested products obtained by means of

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bacterial fermentation and submitted for approval to CEC are listed;

In principle the columns 2, 4, 5 and 12 are equal to columns 1,2,3 and 4 of the Directive on monomers. In certain cases a difference can be noted as some monomers were re-evaluated by SCF after the adoption of the Directive on monomers and the Commission services proposed to modify the current restrictions in order to take account of the new evaluations. It has also to be noted that the list is presented in another format, which allows for listing the monomers in alphabetical and progressive PM/REF Number order and to provide supplementary information;

c) in Annex 2 the draft of the updated list of additives.

At present this list contains:

- all the additives (according to the definition which appear in Annex 2) referring to the plastics regulated by the Directive 90/128/EEC; therefore it includes also all the polymers used as additives as the SCF recently recommended that the technical dossiers, particularly the specifications for the identity) should be provided in order to evaluating them.
- all the additives for epoxy resins (they are included under the column MAT_C);

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This list does not yet contain:

- a) a large majority of additives for varnishes. They will be added in the next version according to the document in preparation at the Council of Europe;
- b) all the additives for silicones, as these products will be considered in later stage.

N.B. In the document some items appear such as "coatings", "epoxy resins", "silicones" which are intended to be deleted. They are introduced only for recording the documents (cs/pm/...) referring to them.

5. This document represents a working document and, therefore, it may be subject to modifications. However, it reflects with regard to the substances included and to the restrictions going with a number of substances the present opinion of the Commission services.

6. This document is based on the previous document III/3141/89-EN (Rev.4) (15 January 1991), modified to take account of:

- a) the requests on "new" monomers and additives received by the Commission services before the 1 August 1991 according to the "NOTE FOR GUIDANCE";
- b) the results of the evaluations made by SCF during 1991 and their consequences on the EEC status of the compound;
- c) some of the new information submitted to the Commission by the Member States and by industry until the date of update;
- d) the new deadlines fixed according to the general rules set out in Appendix 1.

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7. The Commission services believe that they have considered all documents received before 1 August 1991. Any comment to this document should be addressed to the following address:

COMMISSION OF THE EUROPEAN COMMUNITIES
DG III
(for the attention of Mr Rossi Luigi)
200, RUE DE LA LOI
1049 BRUSSELS
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ADDENDUM TO THE EXPLANATORY NOTE

INFORMATION OR ABBREVIATIONS INCLUDED IN THE COLUMNS OF THE TABLES OF THE ANNEXES 1 and 2 OF THE SYNOPSIS DOCUMENT

1. EXPLANATION OF THE COLUMNS

Column "U"

If the column "U" appears in the document, the sign + indicates that the "relevant" (not redactional) content of at least one column of the item has been modified not only with regards to the "synoptic" document III/3141/89 (rev.4) but also to consolidated SCF report on monomers (CS/PM/663) and SCF report on additives (CS/PM/664). The modifications of documents CS/PM/1022 and 1023 appear only in the corresponding documents e.g. CS/PM/1022 and 1023 although the sign + appears in synoptic document too.

Column "PM/REF. N."

It contains the EEC packaging materials reference number of the substances on the list; conventionally the following numbers have been assigned:

monomers: 10000-29999

additives: >30000

These numbers will be used not only in the Directive on plastics materials but also in Directives relating to other materials eg. paper, rubber, etc. A substance listed as monomer as well as an additive will be assigned two different PM/REF numbers. In order to avoid frequent modification of the lists, a PM/REF_N. will only be assigned when the chemical or legislative status of that substances is clear for the CEC.

IN CORRESPONDENCE WITH THE COMMISSION SERVICES AND THE SCF, THE PM/REF.N., IF ANY, THE CAS N., IF ANY AND THE CHEMICAL NAME (FOLLOWING THE RULES SET OUT IN THE EXPLANATION FOR COLUMN "NAME"), SHOULD ALWAYS BE MENTIONED. CORRESPONDENCE NOT INCLUDING SUCH NUMBERS COULD BE REJECTED.

Column "COUNTRY"

It contains the country(ies) which, in principle, authorize(s) and/or use(s) (at least for one of the products included in the field of application of the consolidated Directive) the substance(s) or a part of the substances included in the item. In a few cases SCF appears. It means that the SCF splits the substance requested by the countries indicated in 2 substances. Because it is impossible to describe the complex national legal situation, the content of this column is not very precise. In order to know exactly how the legal system actually applies to a substance at national level, it is imperative to refer to the national legislation. DK,H,IRL,L,P do not appear in column COUNTRY" because these countries have no lists of substances authorized. There is no positive list for monomers in France, but admission of some particular monomers has been requested officially. Therefore F appears in the columns only for those monomers.

Abbreviations used:

B Belgium

D Federal Republic of Germany

DK Denmark

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E Spain
F France
H Greece
I Italy
IRL Ireland
L Luxembourg
N Netherlands
P Portugal
UK United Kingdom

Column "CAS N"

It contains the CAS (Chemical Abstracts Service) registry number, if any; if the substance is a mixture of substances, the CAS number refers to the mixture. Where an indent has been placed in the column, it means that a research for CAS N. has been made, but that the result was negative. If the result of the search was found to be doubtful a question mark was set to the result. If no CAS number or indent has been placed in the column it means that the research has not yet been made.

Where there is inconsistency between the CAS number and the chemical name, the chemical name shall take precedence over the CAS number. If there is inconsistency between the CAS number reported in EINECS and the one in the CAS-Register, the CAS-number in the CAS-Register shall apply.

Column "NAME"

It contains the chemical name.

In principle, the substances labelled with an asterisk are included in Section B of the Directive. For these substances the SCF recommends the requested data (see the SCF consolidated report on monomers (CS/PM/1022) as well as the one on additive CS/PM/1023) to be submitted in accordance with the rules set out in the "NOTE FOR GUIDANCE OF APPLICANTS.." (III/3568/89 Final) and taking account of the deadlines laid down in Appendix 1. The data requested are set out in Appendix 2.

In principle, the substances are listed according to their common name. The following general criteria have been applied:

1. The substances are listed in English version in alphabetical order with the following conventions:

- a) - special characters such as numerals, Greek letters (alpha, beta, epsilon, omega);
- prefixes indicating substituted locations (m, o, p, C-, N-) stereochemicals (cis, trans) or other structural features (n-, tert., sec.);
- plural as well as words or expressions which do not indicate a chemical structure e.g. "derived from..", or "substituted.." or "with..".

are ignored;

- b) the following prefixes are considered to form part of the name: bis, cyclo, iso, and the numerals mono, di, tri, tetra, penta etc. In the main name they should be written in capitals. The following prefixes should be considered as additions and should not be printed in capitals in the main

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name: ortho (o-), meta (m-), para (p-), alpha, beta, gamma etc. cis, trans, dextro (d-), laevo (l-), normal (n-), N- (=link to nitrogen atom), primary (prim.), secondary (sec.) and tertiary (tert.);

- c) generic terms describing aliphatic organic acids are indicated according to the following sequence: acids, aliphatic, mono- or polycarboxylic, saturated or unsaturated, linear or branched, (Cx-Cy);
- d) generic terms describing aliphatic alcohols are indicated according to the following sequence: alcohol, aliphatic, mono- or polyhydric, saturated or unsaturated, linear or branched, primary or secondary or tertiary (Cx-Cy);
- e) esters of monohydric aliphatic alcohols are usually listed under the corresponding acids followed by the radical corresponding to the alcohol followed by the term "ester(s)";
- f) esters of polyhydric alcohols are usually listed under the corresponding acids followed by the terms "esters with" and the name of the polyhydric alcohol. In certain cases the esters are indicated, starting from the polyhydric alcohols (eg. polyglycerol monostearate);
- g) polymeric additives are expressed in terms of the monomers which constitute them, in alphabetical order and separated by a hyphen, followed by the term "polymer" or "copolymer";
- h) salts (including double salts and acid salts) of aluminium, ammonium, calcium, iron, magnesium, potassium, sodium and zinc of an authorized acid, alcohol or phenol shall be automatically authorized. However, names containing for example ".....acid(s), salts" appear in the lists if the corresponding free acid(s) is(are) not separately mentioned. In such cases the meaning of the term "salts" is "salts of aluminium, ammonium, calcium, iron, magnesium, potassium, sodium and zinc". Only in a few cases salts are listed starting by the metal;
- i) following common names are, for example, used:
 - arachidic acid
 - behenic acid
 - caprylic acid
 - lauric acid
 - myristic acid
 - oleic acid
 - palmitic acid
 - ricinoleic acid
 - stearic acid

However the following systematic names of radicals have been retained:

- n-dodecyl instead of lauryl
- n-hexadecyl " " cetyl

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- n-octadecyl	" "	stearyl
- n-tetradecyl	" "	myristyl
- 2,3-epoxypropyl	" "	glycidyl

Similarly the following systematic names of alcohols have been retained:

- n-dodecanol	instead of lauryl alcohol
- n-hexadecanol	" " cetyl alcohol
- n-octadecanol	" " stearyl alcohol
- n-tetradecanol	" " myristyl alcohol

Column "EEC L"

It contains the following abbreviations which are useful for computer retrieval:

AX= substances allocated to Section A in one of the future EEC Directive ("Directive x");

AD= substances allocated to Section A in EEC Directive 90/128/EEC;

A1= substances allocated to Section A in 1st modification of EEC Directive 90/128/EEC;

A1*= substances maintained in Section A in 1st modification of EEC Directive 90/128/EEC subject to amendment of their restriction;

A1S= substances, derived by a generic deleted item, allocated to Section A in 1st modification of EEC Directive 90/128/EEC;

BX= substances allocated to Section B in one of the future EEC Directive ("Directive x");

BD= substances allocated to Section B in Directive 90/128/EEC;

B1= substances allocated to Section B in 1st modification of Directive 90/128/EEC;

B1*= substances maintained in Section B in 1st modification of EEC Directive 90/128/EEC subject to amendment of their restriction;

B1S= substances, derived by a generic deleted item, allocated to Section B in 1st modification of EEC Directive 90/128/EEC;

BD/B1 substance in section B in Directive 90/128/EEC and maintained in Section B in the first modification of the Directive 90/128/EEC;

BD/B1*= substance in section B in Directive 90/128/EEC and maintained with a different restriction in Section B of the first modification of the Directive 90/128/EEC;

DX= substances deleted from the list in a future Directive ("Directive x");

D1= substances deleted in the first modification of the Directive 90/128/EEC;

D= "new" substances never authorized (corresponding to substances in waiting list ("W") in SCF lists (see later)

The criteria applied for the allocation into Section A and B is the following: if the substance is classified by SCF in lists 0, 1, 2, 3, 4 it is allocated in Section A; if the substance is classified by SCF in lists 6, 7, 8, 9 it is allocated in Section B, unless the substance is

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not deleted; if you note inconsistency, please inform the Commission services.

Column "RESTRICTIONS"

In principle it may include:

- the types of plastic materials for which the substance is authorized to be used (see abbreviations of the type of plastic later. Where no indication is given, the substance is authorized for use in all types of plastic materials);
- specific migration limit (SML or SML(T)) in food or in food simulants (FS), unless it is specified otherwise;
- the maximum quantity (QM or QM(T)) of substance permitted in the finished product (FP);
- any other restriction specifically mentioned.

The following expression "See PM/REF.N" may also appear. It means that the substance(s) mentioned in column "NAME" is(are) identical to the substance(s) mentioned in column "RESTRICTIONS" and that the preferred name in correspondence of which all the information is reported is that indicated in column "RESTRICTION", which will appear in extenso in Directive.

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.

In principle, the relevant criteria used by CEC for putting a restriction are the following:

- 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 mg/kg b.w., is subject to a quantitative restriction;
- b) a substance, used only in a few polymers (e.g. less than 3) which cannot be mixed with other polymers, could be subject to a restriction on use ("only for PVC");
- c) a substance having an ADI or TDI less than 1 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 weights 60 kg and that he eats one kilo of foods in contact with the plastics containing always the substance under reference;
- d) a substance contained in list 4A (in the SCF report on monomers) or in list 4 (in the SCF report on additives) will be subject, in principle, to a limit of detection in food or in simulating liquids (FS) equal to 0.010 mg/kg (for some substances eg. acrylonitrile, methacrylonitrile, butadiene it was fixed a value 0.020 mg/kg for taking account of the value of the reproducibility established in a collaborative test);
- e) a substance contained in list 6 A or in list 9 (in this last case only if the substance contains a group suspect to be carcinogenic ("allyl" "vinyl" "epoxy" etc.) will be subject, in principle, to a limit of detection in food or in food simulants equal to 0.050 mg/kg;
- f) a substance contained in list 3 or in list 6B and having a restriction expressed in a limit of migration will be subject to this limit of migration;
- g) a substance contained in list 3 or in list 6B and having a

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restriction expressed in mg/kg b.w. will be subject to a limit of migration obtained by multiplying the ADI or TDI by 60.

In some cases, a specific migration limit could be deleted or replaced by a limit in the amount of residue (QM) in the finished product (FP). The reasons of this decision are indicated in the column "REMARKS", when this column appear in the printed document.

Column "REMARKS"

In principle, this column (which will disappear in the Directive) may include the information requested and/or other remarks (included as pro-memoria) made by CEC (eg. the type of polymer or material in which is used). For the meaning of the expressions used (for example Ex L9, or N1(PM/REF.N) or of the abbreviations, see later paragraph 2.

Column "SCF L"

It contains the number of the list in which the substance is classified by the SCF or other abbreviations. The meaning of the number or other abbreviations which appears in this column is as following:

List 0:

Substances which may be used in the production of plastic materials and articles, e.g. food ingredients and certain substances known from the intermediate metabolism in man and for which an ADI need not be established for this purpose.

List 1

Substances for which an ADI, a temporary ADI (t-ADI), a MTDI, a PMTDI, or a PTWI or the classification "acceptable" has been established by this Committee or by JECFA.

List 2

Substances for which a TDI or t-TDI has been established by this Committee.

List 3

Substances for which an ADI or TDI could not be established, but where the present use could be accepted; some of these substances are self-limiting because of their organoleptic properties or are volatile and therefore unlikely to be present in the finished product. For other substances with very low migration, a TDI has not been set but the maximum level to be used in any packaging material is stated. This is because the available toxicological data would give a TDI very much higher than the maximum likely intakes arising from present uses of the additive.

List 4 (for additives)

Substances for which an ADI or TDI could not be established, but which could be used if the substance migrating into food or food simulants is not detectable by an agreed sensitive method.

List 4 (for monomers):

List 4A (for monomers)

Idem list 4 for additives (see above)

List 4B (for monomers)

Substances for which an ADI or TDI could not be established, but which could be used if the levels of monomers residues in materials and articles intended to come into contact with foodstuffs are reduced, as much as possible

List 5

Substances which should not be used.

List 6

Substances for which there exists suspicion about their toxicity and for

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which data are lacking or are insufficient.

List 6A

Substances suspected to have carcinogenic properties. These should not be detectable in foods or in food simulants by an appropriate sensitive method for each substance.

List 6B

Substances suspected to have toxic properties (other than carcinogenic). Restrictions may be indicated.

List 7

Substances for which some toxicological data exist, but for which an ADI or TDI could not be established. The additional specified information should be furnished.

List 8

Substances for which no or only scanty and inadequate data were available.

List 9

Substances and groups of substances which could not be evaluated due to lack of specificity.

These groups should be replaced by individual substances actually in use.

List W

"Waiting list". Substances not yet included in the Community list ("New substances"). Besides the W a number indicating the SCF list (allocated on the basis of data available at the moment) may appear.

List P

List of substances for which the evaluation is postponed as the SCF is preparing a toxicological sheet or by lack of time or for other reasons.

List P*

List of (new) substances for which the evaluation is postponed as the SCF is preparing a toxicological sheet by lack of time or for other reasons.

List .../P

When for a substance, already evaluated, new documentation is supplied, besides the number of the list ... may appear the letter P indicating that the substance is under re-evaluation.

Column "ADI"

It contains the value in mg/kg b.w. of the ADI or TDI. The asterisk besides to the value indicates that the ADI or TDI attributed is temporary.

Column "SCF M":

It contains the following information:

- M.. number of the meeting(s) of the working group "Packaging materials" of the SCF at which the item has been evaluated;
- R.. number of the Series of the SCF Report in which the opinion of the SCF on the item has been given or will given.
- R17= contains the evaluations for the monomers from the 1st until the 21 Meeting of the working group;
- R19= contains the evaluations for the monomers from the 22th until the 27th Meeting of the working group;
- R20= contains the evaluations for the monomers from the 28th until the 34th Meeting of the working group;
- Rx = contains the evaluations for the additives from the 21st (18 April 1985) until the 46th meeting (June 1991) of the working group "Packaging materials" of the SCF. The x will be replaced by the number of the report, when it will be published, probably in 1992.

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Ry= contains the evaluations for the monomers from the 35th until the 46th meeting of the SCFwg. They will be replaced by the number of the report, when it will be published, probably in 1992-1993.

Column "DEADLINE"

See appendix 2.

In principle the deadlines which appear in this column take account of the deadlines suggested by SCF in appendix 2). However they could differ in order to taking account also of other elements, for example:

- a) the need of avoiding too many deadlines; therefore a grouping of the deadlines in 30.6.199X or 31.12.199X is made;
- b) the possibility of submitting information in a time shorter of that indicated by SCF;
- c) the need of providing deadlines longer of those suggested by SCF, if there are valuable reasons for doing so. Normally this action will require a "quick" consultation of the wg "Packaging Materials" of the SCF.

It has to be noted that the application of the general rule described in Appendix 2, CASE II is not automatic when the substance is re-evaluated. For instance the deadline previously set out could be maintained if the data to be supplied at the "next" deadline are the same.

N.B.

1. It has to be noted that the deadlines indicated refer to the substance independently of the use of the substance (plastics, varnishes) and of the existence or not of a Directive adopted. That means that the substances for which the deadline is exceeded and that are not "retained" (B1 in column EEC_L1), could not appear longer or never appear in the Directive adopted or in future Directives, for example in the Directive which will include the additive list or in the Directive extending the field of application of Directive 90/128/EEC to varnishes.
2. Because a substance may be used as monomer and as additive, different deadlines can appear besides the same substance.
3. The deadlines suggested by industry in some letters for retaining the monomers in Section B are not accepted by CEC, if they are different from the general rules set out in appendix 2 of this document. In future only a letter of acceptance from CEC of the new delay proposed by applicants and addressed to them is a proof that the delay has been officially postponed. This explanation is necessary as the Commission services can not make a statement for each request transmitted to them.

Column "DEADLINE 1"

It contains the new precise deadline for retaining substance in Section B.

Column "DEADLINE 2"

It will contain the new precise deadline for submitting some of the data requested by SCF.

Column "DEADLINE 3"

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It will contain the new precise deadlines for submitting the remaining data requested by SCF.

Column "AGENDA"

It contains the number of the meeting where the substance is planned to be examined. If appear S means that the evaluation of substance is suspended as the CEC, after a first examination of SCF wg, has received or, at request of SCF wg, will receive new information. These substances will be included in the list of substances to be evaluated or re-evaluated by SCF.

Column "CS PM"

This column contains the progressive number of the document received or transmitted by the Commission which refers to the substance (see annexes of the minutes of the meetings of the SCF wg). If the number is followed by a stroke that means that all the documents listed at the left of the stroke have been examined by SCF. The letters for retaining a substance in Section B are indicated by an asterisk besides the reference number, although in some cases a technical dossier has been received.

2. EXPLANATION OF THE EXPRESSIONS OR ABBREVIATIONS USED IN THE TABLES OR IN THE DOCUMENT, LISTED IN ALPHABETICAL ORDER

N.B. The abbreviations used in the column "COUNTRY" are included in the explanatory note for this column (see paragraph 1 of the addendum).

A	-	in the column EEC_1 means substance which will be put in the Directive in Section A (= substances authorized at EEC level)
	-	in the column REMARKS means that the substance is requested for general use;
AD		See explanation in point 1, under column EEC_1
A1		"
A1*		"
A1S		"
Ax		"
AD		Additive
ACC		Acceptable for use
ALIPH.		Aliphatic
ADI		Acceptable Daily Intake
AP		Aids to polymerization (which only include, conventionally, the substances which directly influence the formation of polymers, see Annex 3).
B		means that the substance will be put in the Directive in Section B (=substances which may continue to be used at national level pending a decision on inclusion in Section A) if its deadline is not exceeded.
B0		See explanation in point 1, under column EEC_1
B1		"
B1*		"
B1S		"
Bx		"
Bx1		means substance for which an appropriate request (model letter 3 of the "Note for guidance") for retaining in Section B of the Directive 90/128/EEC has been transmitted to EEC services. These substances will appear in the Section B of the future draft of a modification of the Directive

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90/128/EEC. These substances could be disappear if the results of the requested tests to be carried out are not supplied within the dates which will appear in future in a new column "DEADLINE 2" (see appendix 1).

C* Coatings (varnishes and lacquers, including epoxy resins)

CEC Commission of the European Communities

"COVERED BY..(PM/REF.N)"

Means that the substance(s) mentioned in column "NAME" is (are) included in the substance(s) mentioned in column "REMARKS".

CYCLOALIPH. Cycloaliphatic

Dx See explanation in point 1, under "Column EEC_1"

D1 "

D "

DEADLINE N. Dates within which the Commission should receive some specified information (see appendix 2)

DET Detectable

DL Limit of detection

Ex L9 Substance for plastics destined to disappear from the list because replaced by individual compound (see explanation in par. 4 of the explanatory note).

Ex L9* Substance used only for varnishes destined to disappear from the list because replaced by individual compound (see explanation in par. 4 of the explanatory note).

FP Finished product (= material and article in finished state)

FS Food simulants

gR Group Restriction. Restriction to be applied to all the substances indicated in the group as suggested by SCF in its reports.

m Meta

M Monomer

M.. Meetings (M followed by a number; see SCF_M)

MONOCARB. Monocarboxylic

MONOH. Monohydric

n Normal

NCO Isocyanate moiety

NEW SUBST. New substance. Substances requested to CEC for inclusion in the EEC positive list, but not yet authorized in at least one of the Member States of the European Communities (UK considered, in principle, "new" substance for "plastics" a substance not authorized in the USA before 31 December 1987 and for "varnishes" a substance not authorized in the USA before 31 December 1990). These substances will be evaluated by SCF only if the information requested by SCF in its Report (see "Note for guidance of applicants.." III/3568/89-updated version) has been transmitted to CEC). These substances will appear in synoptic documents but not in the drafts of Directives. The Member States are invited to not authorize these substances until the SCF has expressed its definitive opinion.

NS Not specified

o Ortho

p Para

P Substances for which the allocation in the columns "EEC_L" or "SCF_L" is postponed

P* <New> substances for which the allocation in EEC or SCF lists is postponed

POL or Pol Polymer

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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 substance(s) indicated

Rx Number (not yet known) of the Report of the SCF on additive.

Ry Number (not yet known) of the Report of the SCF on monomer.

S Substance in suspens.

S1(PM/REF.N) Substance which replaces the generic term (PM/REF.N) classified by the SCF in L9.

S2 Substance used only for varnishes which replaces the generic term (PM/REF.N) classified by the SCF in L9.

"SAME ..(PM/REF.N)" means that the substance(s) mentioned in column "NAME" is (are) identical to the substance(s) mentioned in column "RESTRICTIONS"

SAT. Saturated

SCF_L Number of the SCF list (see explanation in point 1)

SCF_M Number of the meeting of the SCF's working group "Packaging Materials" in which the substance was or will be examined. M41 means 41st meeting Number. Meetings planned since M40. (M41=19-20/VII/1990); (M42= 20-21/IX/1990); M43= 15-16/XI/1990); (M44= 20-21/II/1991) (M45= 23-24/IV/1991); (M46= 18-19/VI/1992); (M47 = 10-11/IX/1992); (M48 = 13-14/IX/1991)

"SIMILAR TO..(PM/SCF.N)" Means that the substance(s) is(are) not identical to or covered by the other substance(s) mentioned but that there is a certain similarity which has to be taken into account in the final decision on the status of the substance;

SML Specific migration limit in foods or in food simulant

SML(T) Specific migration limit in foods or in food simulant expressed as total of moiety/substance(s) indicated.

SML(Tp) Specific migration limit in foods or in food simulant for the group of substances having in COLUMN RESTRICTION the abbreviation SML(Tp); an explanation for these substances is given in CS/PM/956.

"SPEC(I)" Specification on identity of the substance(s) are requested (See the chapter "Identity" of the new SCF guidelines included in "Note for guidance of applicants");

"SPEC(P)" Specification on purity of the substance(s) is (are) requested by SCF or by a Member State indicated in parentheses;

"SPEC(U)" Specification on use of the substance are requested:

- is it a/monomer ("M") or additive ("A")
- is it really used in plastic materials? What type?
- is it technologically necessary (techn. nec.)? The Member State should provide by means of a letter addressed to CEC a report giving reasons for maintaining such substance(s) in the list. This letter must be provided to CEC as soon as possible and not later than 6 months after its apparition in synoptic document. After this period, the item could be deleted in the Directive; the final date will appear after the abbreviation;

T Single or in combination with substances of the same chemical moiety or individually indicated.

TDI Tolerable Daily Intake (new concept established by SCF in

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the definitions generally recognized, particularly to the International Standard ISO.472. It is to be noted that an abbreviation for a polymer refers both to the homopolymer and to various copolymers.

ABS Acrylonitrile-butadiene-styrene
CA Cellulose acetate
CL Cellulose
CP Cellulose propionate
LCU Lignocellulose
MABS Methyl methacrylate-acrylonitrile-butadiene-styrene
MBS Methyl methacrylate-butadiene-styrene
MF Melamine-formaldehyde
MUF Melamine-urea-formaldehyde
NC Nitrocellulose
PA Polyamides
PAM Acrylic and methacrylic resins
PAN Polyacrylonitrile
PAR Polyarylates
PB Polybutene
PBT Polybutylene terephthalate
PC Polycarbonate
PCLD Polycaprolactone
PCTFE Polychlorotrifluoroethylene
PE Polyethylene
PEEK Polyetheretherketone
PEES Polyetherethersulphone
PEI Polyetherimide
PEK Polyetherketone
PEN Polyethylenenaphthenate
PES Polyethersulfone
PETH Polyether
PET Polyethylene terephthalate
PF Phenol-formaldehyde
PIB Polyisobutylene
PMMA Polymethyl methacrylate
PO Polyolefins
POM Polyoxymethylene= polyformaldehyde= polyacetal
PP Polypropylene
PPE Polyphenylene ether
PPO Polyphenylene oxide
PS Polystyrene
PT Polyterpenes
PTFE Polytetrafluoroethylene
PUR Polyurethanes
PVAC Polyvinyl acetate
PVB Polyvinyl butyral
PVC Polyvinyl chloride
PVCC Polyvinyl chloride chlorinated
PVDC Polyvinylidene chloride
PVDF Polyvinylidene fluoride
PVE Polyvinylether
RF Resorcinol-formaldehyde
SAN Styrene-acrylonitrile
SB Styrene-butadiene
UF Urea-formaldehyde
UP Unsaturated polyesters

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LIST OF ADDITIVES UPDATED TO 1 AUGUST 1991

U	PH/REF	CAS	NAME	SCF	EEC	SCF	AGE	CS/PM	ADI	RESTRICT	REMARKS	DEADLINE	MAT	MAT
N.	N.			L	L	M/R	NDA		mg/kg				PL	C
1	2	4	5	6	7	8	9	10	11	12	13	14	15	16
			30320 -	ACETYLACETIC ACID, SALTS	0	Ax	Rx							+
			30400 -	ACETYLATED GLYCERIDES	1	Ax	Rx		NS					+
			30480 DO140-04-5	*ACETYLRICINOLEIC ACID, BUTYL ESTER	7	Bx	Rx					31.12.91/1		+
			30560 -	*ACIDS, ALIPH. MONOCARB. (C6-C24)	9	Bx	Rx		351			31.12.91/1		+
			30640 -	*ACIDS, ALIPH., MONOCARB. (C8-C22), sec-BUTYL AND OLEYL ESTERS	9	Bx	Rx				PA, PAM, PS, PVC	31.12.91/1		+
			30720 -	*ACIDS, ALIPH., MONOCARB. (C8-C22), COMPOUNDS WITH DIETHANOLAMINE	9	Bx	Rx		351			31.12.91/1		+
			30800 -	*ACIDS, ALIPH., MONOCARB. (MORE THAN C6), ESTERS WITH MANNITOL	9	Bx	Rx					31.12.91/1		+
			30880 -	*ACIDS, ALIPH., MONOCARB. (MORE THAN C6), ESTERS WITH PENTAERYTHRITOL	9	Bx1	Rx		351, 547, 583			31.12.91/1		+
			30960 -	ACIDS, ALIPH., MONOCARB. (C6-C22) ESTERS WITH POLYGLYCEROL	1	Ax	Rx		ZET		Pe1			+
			31040 -	*ACIDS, ALIPH. MONOCARB., HYDROXYLATED (C12-C20) AND THEIR SULFONATED AND ACETYLATED DERIVATIVES	9	Bx	Rx		351			31.12.91/1		+
			31120 -	*ACIDS, ALIPH., MONOCARB. (C6-C24), Li, Na AND Sn SALTS	9	Bx	Rx					31.12.91/1		+
			31200 -	*ACIDS, ALIPH., MONOCARB., SAT. (MORE THAN C7), ESTERS WITH ALCOHOLS, ALIPH. MONOM.	9	Bx	Rx		351			31.12.91/1		+
			31280 -	*ACIDS, ALIPH., MONOCARB. (C8-C22), COMPOUNDS WITH TRIETHANOLAMINE	9	Bx	Rx		3517		PA, PS, PVC	31.12.91/1		+
			-	ACIDS, FATTY, OLIMERIZED, SALTS							PS			+

Glycolide 740, 742

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