European Food Safety Authority

FOOD CONTACT MATERIALS

NOTE FOR GUIDANCE

("NOTE FOR GUIDANCE FOR PETITIONERS PRESENTING AN APPLICATION FOR THE SAFETY ASSESSMENT OF A SUBSTANCE TO BE USED IN FOOD CONTACT MATERIALS PRIOR TO ITS AUTHORISATION")

(Updated on 08 June 2006)

ADDITIONS, AMENDMENTS TO THE PREVIOUS VERSION ARE MARKED IN TURQUOISE

This document is available only in English.

NOTE FOR THE READER

1. It has to be stressed that the Chapter II of this document contains the current official version of the so-called "SCF guidelines for Food Contact Materials" as it was issued in the Health & Consumer Protection Directorate-General (DG SANCO) website:
   http://europa.eu.int/comm/food/fs/sc/scf/outcome_en.html

   These guidelines have been endorsed by the EFSA Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) in its second meeting
   http://www.efsa.eu.int/science/afc/afc_meetings/248/minutes_afc_02_adopted_en1.pdf

2. It should be recalled that the meaning of some abbreviations and terms not explained in this document appears in the other document of the website called "List of abbreviations and explanations"
   http://europa.eu.int/comm/food/food/chemicalsafety/foodcontact/abbrev_ref_en.pdf

3. If you notice mistakes, or you have suggestions to improve this document, please send your suggestions to the European Food Safety Authority (for the attention of Mr Dimitrios Spyropoulos, Largo N. Palli 5/A, 43100 Parma)
   Email: dimitrios.spyropoulos@efsa.eu.int – Fax: +39 0521 036360)

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NEWS

The current table includes the main amendments to the previous version (dated 28.09.2005) of the EFSA "Note for Guidance", available on the EFSA website. The amendments are indicated in bold characters and a turquoise background. However, minor editorial changes are not specified.

By technical dossier is meant the WHOLE TECHNICAL INFORMATION (also summaries of studies) divided in technical annexes and submitted by the petitioner in support of his request for evaluation of a substance by the EFSA.
The technical dossier has to be submitted by model letter No 1 or 2 to a Member State competent Authority.
A document, called Petitioner Summary Data Sheet (P-SDS), containing the whole information in summary and THE REFERENCES to the annexes has to be included in the technical dossier.

Since EFSA is the competent Authority for the risk assessment in Europe while the risk management decisions remain to the Commission it is clarified that:
The classification into a SCF_List is a tool used for tackling authorisation dossiers and do not prejudice the management decisions that will be taken on the basis of the scientific opinions of the AFC Panel and in the framework of the applicable legislation

CHAPTER 0

GENERAL INTRODUCTION

This document is the result of the compilation of the following documents, described below with their abbreviated titles:

-	Administrative Guidance	Chapter I
-	SCF Guidelines	Chapter II
-	AFC-FCM-WG Explanatory Guidance	Chapter III
-	Commission Explanatory Guidance	Chapter IV

The aim of this document is to provide:

a) guidelines for presentation of an application for the safety assessment of a substance prior to its authorisation and subsequent inclusion in the relevant EU Directives (as a first step the substance is included in the "Synoptic Document"[1]);

b) guidelines for requesting the re-evaluation of substances already included in the "Synoptic document";

c) guidelines for the submission of technical dossiers accompanying such requests;

d) explanation of the criteria used by the AFC Panel in the classification of substances to one of the SCF Lists.

As regards the Chapter I, see the remarks in the Note for the Reader.

1 Synoptic document is an EC working document where all the substances evaluated by SCF or EFSA AFC Panel or to be evaluated by the EFSA AFC Panel are listed. Along each substance appear their legal status at EU level, as well as the evaluation, if any, of the SCF and AFC Panel, available also on internet. The full SCF opinions can be found on the DG SANCO website: http://europa.eu.int/comm/food/fs/sc/scf/outcome_en.html**.**
Those of the AFC Panel can be found on the EFSA website: http://www.efsa.eu.int/science/afc/afc_opinions/catindex_en.html.

CHAPTER I

EFSA ADMINISTRATIVE GUIDANCE ON HOW TO PRESENT AN APPLICATION FOR EVALUATION BY THE EFSA AFC PANEL AND FOLLOW UP.

(Called briefly "EFSA Administrative Guidance")

1. INTRODUCTION

The general procedure for the authorisation of substances in food contact materials is laid down in Article 8 – 12 of Regulation (EC) 1935/2004[2] (Framework Regulation)

The aim of this document, prepared by EFSA in cooperation with the Commission, is to explain:

a) the practical aspects of the administrative procedure to be followed by a petitioner requiring the evaluation or re-evaluation of a substance;

b) the follow-up of the request.

In this document the term "petition" or "application" means the official request from a company to obtain an evaluation, or a re-evaluation by the EFSA AFC Panel of a substance for the purpose of introducing it into, or for a change of its classification/restriction in the "Synoptic document" and subsequently in a EU Directive.

This document deals mainly with plastics used in food contact materials. However it may also be used for the evaluation of a substance for other food contact materials (e.g. regenerated cellulose films, rubber etc.).

A typical petition consists of the following separate documents described below:

a) a letter requesting the evaluation or re-evaluation of the substance. For model letters, see Chapter I, Annexes 2 & 3;

b) a technical dossier compiled following the "SCF Guidelines" as well as the AFC-FCM-Explanatory Guidance;

c) a Petitioner Summary Data Sheet (P-SDS). See Chapter III, Annex 6.

Each document should be prepared as set out here in order to facilitate the examination of a petition by the EFSA AFC Panel and to avoid delays.

2 Regulation (EC) No 1935/2004 of the European Parliament and the Council of 27 October 2004 on materials and articles intended to come into contact with food, OJ No L 338/4, 13.11.2004

To avoid any loss in the mail the above mentioned documents should be transmitted by express courier.

2. EVALUATION OF A SUBSTANCE

2.1 EVALUATION OF A NEW SUBSTANCE

To obtain the insertion of a new substance into the "Synoptic document" and later into EU Directive, Regulation or Decision, any person concerned is invited to submit a petition to the competent Authority of a Member State. A list of the competent authorities of the Member States is inserted in Annex 1 of this Chapter. For substances originating from countries other than the Member States, a petition has to be submitted to the competent Authority of any Member State. **The technical dossier should be submitted with the use of the model letter n° 1 and will always include the Petitioner Summary Data Sheet (P-SDS), a document, which will provide the full information in summary and make reference to the technical annexes contained in the technical dossier.** The full information should be submitted on paper and in electronic format on standard physical media (CD-ROM).

The electronic version of the petition should be certified as being identical to the one on paper. Common electronic formats should be used, such as "MS Word" or "Adobe Acrobat Reader". The files should be searchable using the search facilities of standard software packages. It is highly recommended to make the P-SDS available on a "Word" format to facilitate the work of EFSA

Appropriate labels should be attached on the CD jewel case, including the following information: Name of the substance, REF No (when it is known), company, date of submission and CD-ROM number (if more than one per dossier, eg disk # of #).

Each CD-ROM should contain a file detailing the name of the files contained in the disk and their contents. A print out of this file should accompany the CD-ROM, clearly indicating the different files and where they can be found.

In addition to the complete version with all information applicants should provide a second version of the CD- ROM without the confidential information. This version will be made available to anyone who might submit a request to EFSA according to Regulation (EC) No 1935/2004, art. 19.

The applicant should keep at least 3 additional paper and electronic copies readily available in cases when the Secretariat of the AFC Panel or a Member State requires them. The petitioner may be asked to send additional copies or sections of the dossier and CD-ROM to additional addresses.

2.1.1 TECHNICAL DOSSIERS

The technical dossier should contain the data mentioned in "SCF Guidelines", taking into account the other documents included below:

a) The document "AFC-FCM-WG Explanatory Guidance" (see Chapter III);

b) The document "Commission Explanatory Guidance" (see Chapter IV);

If all these documents are insufficient to establish the database to be submitted to the national competent authority for a specific substance, the petitioner may consult the EFSA

services for further advice. Because it is highly probable that the secretariat will have to consult the AFC-FCM-WG, it is recommended that the use of this option is restricted entirely to cases where the substance or the group of substances require special consideration. Some delay must be expected for this procedure (generally 2-6 months).

2.2. RE-EVALUATION OF A SUBSTANCE

The re-evaluation of substances can be requested in three different situations:

a) During the evaluation of the dossier, EFSA may consider necessary to require further information including additional studies. Such *additional* tests should be presented by the original petitioner using the model letter n° 2 related to a request of re-evaluation.

b) The petitioner has obtained further information on a substance currently classified in SCF lists 0-5 and believes that the additional data might permit a different classification or restriction for that substance.

c) A new petitioner has obtained further information on a substance currently in the Synoptic Document and believes that the additional data might permit a different classification. In that case, the article 21 on data sharing of Regulation (EC) No 1935/2004 applies. The new applicant should enquire with the Commission and the European professional organisations about an agreement on data sharing with the original applicant. If such an agreement is reached the petitioner should include the written agreement signed by all involved parties in the application and supply only the new data using model letter n° 2 related to a request of re-evaluation. If the original and new applicant have not agreed on data sharing the new petitioner has to submit a new petition including all data using model letter n° 2.

In any case the petitioner has to check the dossier to be submitted against the requirements of the latest version of the Note for Guidance. This is imperative if more than 4 years have elapsed from the time of the last evaluation of the substance by the SCF or EFSA. It is quite possible that the scientific approach to the safety evaluation of a substance has changed in meanwhile and additional or different data may be needed or inversely some data may no more be considered necessary. If in doubt the petitioner is invited to ask EFSA.

For the re-evaluation of a substance the petitioner is invited to submit a request to the national competent authority. **The technical dossier should be submitted with the use of the model letter n° 2 and will always include the Petitioner Summary Data Sheet (P-SDS), a document which will provide the full information in summary and make reference to the technical annexes contained in the technical dossier.** The full information should be submitted on paper and in electronic format on standard physical media (CD-ROM).
3 paper and electronic copies of all documents should be held available to be sent to the persons indicated by the Secretariat of the AFC Panel of EFSA or a Member State as indicated in the model letter n° 2.

For petitions concerning re-evaluation of substances the following practical advises have to be followed to avoid misunderstandings and delays in the evaluations:

a) The petitioner should always prepare a new, complete Summary Data Sheet (P-SDS), to replace the previous one. In this P-SDS the new data should be highlighted, e.g. by the use of bold or coloured characters or background etc.
b) The technical dossier should only include the new data to be considered by EFSA.
c) In addition to the model letter n° 2, another letter should accompany the petition to explain briefly the reasons for the request for re-evaluation.

2.2. CHECK LIST WITH THE DOCUMENTS TO BE PROVIDED

For facilitating the petitioner in compiling a valid dossier for evaluation by the AFC Panel the following check list of documents to be submitted is attached:

1	Model letter	No.1 for evaluation and No.2 for re-evaluation
2	Letter explaining the background of the request for evaluation (*for re-evaluations only*)	Alternatively the reasons for asking the re-evaluation can be given in the model letter
3	**P-SDS**	Document summarising all data with marked appropriately the confidential information and in the case of re-evaluation the new data. **Reference to the technical annexes attached has to be made in every section of the P-SDS.** Verifiable justification should be provided as to why the disclosure of information marked as confidential would significantly harm the petitioner's competitive position.
4	Technical annexes	The necessary technical information, e.g. scientific reasoning, full reports of experiments, bibliographic references cited
5	Table of contents for the annexes	A table which will give the contents of each Annex and the relevant point on the SDS, e.g. Annex 1, Gene mutation in bacteria, 8.1.1
6	CD-ROM With the complete information	All the information in hard copy should also be on the CD. The P-SDS should be provided in Word format. The other files may be either in Word format or in Adobe Acrobat Reader. Appropriate labels should be attached on the CD jewel case, including the following information: Name of the substance, REF No (when it is known), company, date of submission and CD-ROM number (if more than one per dossier, eg disk # of #). Each CD-ROM should contain a file detailing the name of the files contained in the disk and their contents. A print out of this file should accompany the CD-ROM, clearly indicating the different files and where they can be found.
7	CD-ROM With only the non-confidential information	Only the information which is not considered as confidential by the petitioner should be on this CD-ROM. This information will be readily available to anyone who might so request, according to Regulation (EC) No. 1935/2004, art. 19

3. FOLLOW UP OF A PETITION

3.1. ACKNOWLEDGMENT OF THE RECEIPT OF THE PETITION

The competent authority will acknowledge the receipt of the application in writing within 14 days of its receipt. The acknowledgment will state the date of the receipt of the application.

3.2. TRANSMISSION OF THE PETITION TO EFSA

The competent authority will inform without delay EFSA and make the application and any supplementary information supplied by the applicant available to EFSA
The paper copy and the electronic version should be sent by express courrier to :

European Food Safety Authority
AFC Panel – FCM Working Group
Largo N. Palli 5/A
I-43100 Parma
Italy

3.3. INFORMATION TO THE COMMISSION AND MEMBER STATES

EFSA will inform without delay the other Member States and the Commission of the application and make the application and any supplementary information supplied by the applicant available to them

3.4. CONFIRMATION OF ADMINISTRATIVE ACCEPTABILITY OF THE PETITION (=AAP)

After the receipt of a petition by EFSA and its analysis, the petitioner will receive a letter to acknowledge the receipt of the request. In this letter, the allocated substance reference number and the document reference number are mentioned as well as the official name as allocated by the Commission services. It is essential to quote both reference numbers and the official name in any future correspondence with the any Member State and EFSA. The letter will confirm whether or not the request is in compliance with the instructions set out in this Note for Guidance (administrative acceptability of the petition = AAP). If the request does not comply with these instructions, the applicant will be asked to modify the request appropriately (transmission to the petitioner of an AAP negative). Note that if the petition does not contain the full dossier also in electronic format (CD-ROM) the petitioner will receive an AAP negative. Note that the acceptance of the petition (AAP positive) does not imply that the documentation provided necessarily fully complies with the guidelines of the SCF and the guidance set out in this document. EFSA reserves the right to request additional information as necessary for complete assessment of the substance. It has to be stressed that any deviation from the SCF guidelines or AFC-FCM-WG guidance must be justified both in the technical dossier and in the Petitioner Summary Data Sheet (P-SDS).

3.5. AFC PANEL EVALUATION

After each meeting, the AFC Panel prepares an opinion with all the evaluations. The opinion will be made publicly available on the following Internet address:

http://www.efsa.eu.int/science/afc/afc_opinions/catindex_en.html

3.6. TIME FOR EXAMINATION OF TECHNICAL DOSSIERS

According to the Regulation (EC) No 1935/2004, EFSA shall give an opinion within six months of the receipt of a valid application, as to whether the substance under the intended conditions of use of the material or article in which it is used, complies with the safety criteria laid down in Article 3 and 4 of the Framework Regulation.
EFSA may extend the said period by a maximum of a further six months. In this case they shall provide an explanation for the delay to the applicant, the Commission and the Member States.
However EFSA may, where appropriate, request the applicant to supplement the particulars accompanying the application within a time limit specified by EFSA. In case of the request of such supplementary information, the time limit is suspended until the information is provided. Likewise, the time limit is suspended for time allowed to the applicant to prepare oral or written explanations.

3.7. PUBLIC ACCESS TO PETITIONS

Petitions for authorisation, supplementary information from applicants and opinions from the Authority, excluding confidential information, shall be made accessible to the public in accordance with Articles 38, 39 and 41 of Regulation (EC) No 178/2002 and Articles 2, 4, 7, 8 and 10 of Regulation (EC) No 1049/2001.

Applicants should provide 2 versions of the CD- ROM. One with the whole information, identical to the hard copy, and a second version which will contain again the P-SDS and all technical annexes but without the confidential sections.

The complete information will be made available to the Commission and Member States which have to respect the confidentiality of commercial and industrial information provided.
The Commission will determine, after consultation with the applicant, which information should be kept confidential, as stated in Article 20 of the Regulation (EC) No. 1935/2004. However, the following information can not be considered confidential:

- the name and address of the applicant and the chemical name of the substance
- information of direct relevance to the assessment of the safety of the substance
- the analytical method or methods

Verifiable justification has to be provided as to why disclosure of the information considered as confidential would harm the competitive position of the petitioner.

4. MODEL LETTERS

To facilitate this procedure, petitioners should always use the model letters contained in Annexes 2 and 3. An explanation on how to fill in the model letters is given in Annex 4 of this Chapter.
Petitioners are advised to mention on the letter addressed to the competent Authority of a Member State that the whole package should be transmitted to EFSA AFC Panel

as foreseen in the Regulation (EC) No 1935/2004, art. 9.

Annex 1 to Chapter I

Member States Contact Points for Petitions

The updated list can be found at the Commission website at the following address:

http://europa.eu.int/comm/food/food/chemicalsafety/foodcontact/nat_contact_points_en.pdf

Annex 2 to Chapter I

MODEL LETTER N° 1

REQUEST FOR THE EVALUATION OF A NEW SUBSTANCE (1)

NAME OF THE RELEVANT NATIONAL AUTHORITY (2)
For the attention of : name of the responsible

Our reference:..... Date:.....……..

Subject: Request for the evaluation of a monomer /additive (3)

The undersigned.....(4)……...requests the addition of the following new substance:…… (5).....
on behalf of ……..(6)……

The person responsible for answering any detailed questions on the technical dossier is:
.....(7).....….....

Enclosed are the following:
a. the technical dossier (8)
b. the Petitioner Summary Data Sheet (P-SDS)(9)
c. CD-ROM with the full information
d. CD-ROM with the non-confidential information

The information on the CD-ROM is certified as being identical to the one on paper except for the confidential parts in the case of the documentation under point d.. Moreover, three complete sets of the documentation under point a., b., and c. will be held available and sent to the persons indicated by the Secretariat of the AFC Panel of EFSA on request.

A sample of 250 g of the substance, the relevant product safety sheet, the spectroscopic data and a copy of the model letter belonging to it have been transmitted to Ms C. Simoneau, at the EC-Joint Research Centre (10).

Yours sincerely,
.....

Annex 3 to Chapter I

MODEL LETTER N° 2

REQUEST FOR THE RE-EVALUATION OF A SUBSTANCE (1)

NAME OF THE RELEVANT NATIONAL AUTHORITY (2)
For the attention of : ……(name of the responsible)

Our reference:..... Date.....:.....

Subject: Request for the re-evaluation of a monomer/additive (3) REF.N.....

The undersigned.....(4).....
requests re-evaluation of the following substance:
.....(5).....
on behalf of …….. (6)…….
The person responsible for answering detailed questions on the technical dossier is:
.....(7).....
Enclosed are the following:

a. Technical dossier (8)
b. Petitioner Summary Data Sheet (P-SDS) (9)
c. CD-ROM with the full information
d. CD-ROM with the non-confidential information

The information on the CD-ROM is certified as being identical to the one on paper except for the confidential parts in the case of the documentation under point d.. Moreover, three complete sets of the documentation under point a., b., and c.will be held available and sent to the persons indicated by the Secretariat of the AFC Panel of EFSA on request.

If not yet supplied in the past, a sample of 250 g of the substance, the relevant product safety sheet, the spectroscopic data and a copy of the model letter belonging to it have been transmitted to Ms C. Simoneau, at the EC-Joint Research Centre (10)

Yours sincerely,
.....

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Annex 4 to Chapter I

LEGEND TO MODEL LETTERS

The numbers between brackets in model letters n°1 and 2 have the following meaning:

(1) submit a separate request for each substance (except when a group of substances is being considered for a group evaluation and group restriction)

(2) write the name and the address of the National competent authority of the member state appointed to receive the petitions for the evaluation of substances. You can find the list of these Authorities in Annex 1 and on the website:

(3) delete monomer or additive as appropriate

(4) specify name, address, telephone, fax and E-mail of petitioner

(5) specify the chemical name, main chemical synonyms (e.g. IUPAC name) and trade names, CAS number

(6) specify name, address, telephone, fax and E-mail of the manufacturer(s) or the user(s) of the substance on whose behalf the application is filed, if different from point (4)

(7) specify name, address, telephone, fax and E-mail of the person responsible for the technical dossier

(8) see Annex 5 of this Chapter

(9) see Chapter III, Annex 6

(10) Dr Simoneau's full address and communication details are: Dr C. Simoneau, at the EC-Joint Research Centre, Institute for Health and Consumer Protection, Physical and Chemical Exposure Unit, T.P. 260, I-21020 ISPRA, Italy (Tel: +39-0332-785889 –Fax: +39-0332-785707 - E-mail: Catherine.Simoneau@jrc.it).

Annex 5 to Chapter I

TECHNICAL DOSSIER

1. Technical dossiers, submitted to the national competent authorities should contain the data detailed in Chapter III.

2. New substances

For obtaining authorisation for the use of a new substance as a constituent of food contact materials, the petitioner is invited to submit to the national competent authority the data requested in the "SCF Guidelines" in a format as outlined in the AFC-FCM-WG Explanatory guidance.

3. Substances already evaluated by the SCF or EFSA

For re-evaluation of a substance for use as a constituent of food contact materials, that has already been examined but not fully evaluated by the SCF or EFSA because of lack or insufficiency of technical data, or to clarify questions arisen during the evaluation the petitioner is invited to submit the additional data requested by SCF or EFSA (Substances classified in SCF list 7 and substances still under evaluation). For the substances classified in list 6 and 8, unless there is a specific request of the data in the SCF or EFSA opinion, the data to be submitted are those mentioned in SCF guidelines (see Chapter II). For the substances classified in list 9 a better description of the identity of the substance is requested. For further explanation of the SCF lists see Annex 5 of Chapter III.

Article 21 on data sharing of Regulation (EC) No 1935/2004 applies. The new applicant should enquire with the Commission and the European professional organisations about an agreement on data sharing with the original applicant. If such an agreement is reached the petitioner should include the written agreement signed by all involved parties in the application and supply only the new data. If the original and new applicant have not agreed on data sharing the new petitioner has to submit a new petition including all data.

4. Guidelines

The petitioner is invited to follow in both above-mentioned cases not only the “SCF Guidelines” but also the very detailed recommendations contained in Chapter III (“AFC-FCM-WG Explanatory Guidance”) and in Chapter IV (“Commission Explanatory Guidance”).

It has to be stressed that any reference to published information on the substance applied for and, where applicable, to related compounds critical to support the application should be accompanied by a copy of the relevant documents.

CHAPTER II

SCF GUIDELINES

PRESENTATION OF AN APPLICATION FOR SAFETY ASSESSMENT OF A SUBSTANCE TO BE USED IN FOOD CONTACT MATERIALS PRIOR TO ITS AUTHORISATION

VERSION ADOPTED IN DECEMBER 2001

EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Scientific Opinions
C3 – Management of scientific committees II; scientific co-operation and networks

Scientific Committee on Food

SCF/CS/PLEN/GEN/100 Final
19 December 2001

Guidelines of the Scientific Committee on Food

for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation

(updated on 13 December 2001)

NB: The numeration of the sections of the data to be provided has been changed in order to reflect exactly this of the Summary Data Sheet. So the microbiological properties have been transferred to section 7 from section 4. That is the only change to the original.

B-1049 Brussels - Belgium
Telephone: direct line (+32-2) 29 581.10/659.48/648.70, exchange 299.11.11. Fax: (+32-2) 299.48.91
Telex: COMEU B 21877. Telegraphic address: COMEUR Brussels.
http://europa.eu.int/comm/food/fs/sc/scf/index_en.html

INTRODUCTION

The general problem arising from the use of food contact materials derives from their content of substances capable of migrating into the contacted food. Therefore, to protect the consumer, an assessment of the potential hazards from oral exposure to those constituents that migrate into the food must be made.

To establish the safety from ingestion of migrating substances, both the toxicological data indicating the potential hazard and the likely human exposure data need to be combined. However, the Committee is aware that for most substances used in food contact materials, human exposure data are not readily available. The Committee will therefore continue to use data from studies on migration into food or food simulants and, for reasons of prudence, maintains the assumption that a person may consume daily up to 1 kg of food in contact with the relevant food contact material. The Committee is aware that studies on food consumption factors are ongoing and these may permit eventually more accurate estimates of intake.

These guidelines replace the ones published in the 26th Series of Reports of the SCF [3].

These revised guidelines were developed to provide guidance to the applicant on the scope of the data requirement, the latter depending on the extent of the likely migration into food, and to enable the SCF to evaluate any substance used in the intended application as food contact material.

It should be noted, however, that these guidelines should not be applied or interpreted too rigidly. For example, since the petitioner has knowledge of the identity, use of and potential exposure to the substance requested, and of the database available for it, the petitioner may deviate from the guidelines, provided valid, scientific reasons are given in the application. On the other hand, the petitioner should provide all available data, which are relevant for the evaluation by the SCF. In all cases the SCF may request additional data, if the data submitted are equivocal or warrant further investigation.

As a general principle, the greater the exposure through migration, the more toxicological information will be required.

(a) In case of high migration (i.e.5 - 60 mg/kg/food), an extensive data set is needed to establish the safety.

(b) In case of migration between 0.05 – 5 mg/kg food, a reduced data set may suffice.

(c) In case of low migration (i.e. <0.05 mg/kg food), only a limited data set is needed.

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3 The revised guidelines were adopted by the SCF on 22 November 2000, at its 124th Plenary meeting (Document reference SCF/CS/PLEN/GEN/90 Final). On 13 December 2001, at its 130th meeting, the Committee updated these revised guidelines to incorporate a section referring to biocides. The update also harmonised the presentation of the toxicological data, core set of studies, with the one in the guidelines relating to food additives, adopted by the Committee on 11 July 2001, at its 128th Plenary (Document "Guidance on submissions for food additive evaluations by the Scientific Committee on Food, reference SCF/CS/ADD/GEN 26 final) .

In determining the appropriate extent of the data set required the migration values should not be regarded as absolute limits but as indicative values.

It should be noted that these guidelines do not include any consideration of environmental aspects such as persistence in the environment, ecological impact of their constituents and their fate after the food contact material has been submitted to waste disposal treatment.

INFORMATION TO BE SUPPLIED WITH AN APPLICATION FOR A SUBSTANCE TO BE USED IN MATERIALS AND ARTICLES IN CONTACT WITH FOOD

For any document mentioned the latest version should be consulted. For example, if a Directive is referred to, then only the latest amended version should be considered. Justification for any deviation from this "SCF Guidelines" must be included. Further guidance on detail aspects from the Commission services, including administrative information, and from the SCF can be obtained in the document "Note for Guidance" [4].

1. IDENTITY OF THE SUBSTANCE

The name and all relevant information concerning the substance, its impurities, and its breakdown and reaction products.

2. PHYSICAL AND CHEMICAL PROPERTIES OF THE SUBSTANCE

All relevant physical and chemical information concerning the substance, its breakdown and reaction products

3. INTENDED USE OF THE SUBSTANCE

A statement of the intended use of the substance.

4. AUTHORISATION OF THE SUBSTANCE

Information concerning authorisation for use of the substance in EU Member States and other countries, e.g. USA, Japan.

4 This document is available on line on the Internet at the site of the European Food Safety Authority (EFSA) http://www.efsa.eu.int/science/afc/afc_guidance/catindex_en.html

5. MIGRATION DATA ON THE SUBSTANCE

To permit estimation of the likely maximum daily intake of the substance, its impurities, its breakdown and reaction products give, where practicable, information on their concentrations in the food itself. Alternatively, information on migration into food simulants under standard conditions of migration testing or applying the worst case scenario. If known, include exposure estimates from other non-food contact material sources

6. DATA ON THE RESIDUAL CONTENT OF THE SUBSTANCE IN THE FOOD CONTACT MATERIAL

All relevant information concerning the residual content of the substance in the food contact material.

7. MICROBIOLOGICAL PROPERTIES OF THE SUBSTANCE

All relevant information on microbiological properties of substance

8. TOXICOLOGICAL DATA

8.1 General requirements

The general requirements for toxicological studies that have to be supplied for substances in food contact materials are set out below. It should be recognised that not all chemicals used in the manufacture of a food contact material will migrate into food. Many will form a stable part of a polymer, some will migrate only in minute quantities, if at all, others will disappear during production, while yet others will decompose completely to yield either no or vanishingly small residues. While many substances migrate in the same chemical form in which they were incorporated into food contact materials, others will migrate partially or totally in another chemical form. In such cases the toxicological requirements may also apply to the transformation or reaction products.

8.2 Core set

The core set of tests comprises:

- 3 mutagenicity studies *in vitro*:

  i) A test for induction of gene mutations in bacteria

  ii) A test for induction of gene mutations in mammalian cells *in vitro* (preferably the mouse lymphoma to assay)

  iii) A test for induction of chromosomal aberrations in mammalian cells *in vitro*

- 90-day oral toxicity studies, normally in two species

- Studies on absorption, distribution, metabolism and excretion

- Studies on reproduction in one species, and developmental toxicity, normally in two species

- Studies on long-term toxicity/carcinogenicity, normally in two species

These studies should be carried out according to prevailing EU or OECD guidelines, including "Good Laboratory Practice". The substances tested should be of the same specification as described in section 1.

Health information on people exposed occupationally would be regarded as useful ancillary information.

8.3 Reduced core set

Under certain circumstances the core set of tests may not be required and only the tests indicated below may have to be provided.

8.3.1 In cases where migration is in the range from 0.05 - 5 mg/kg of food / food simulant, the following data are needed:

- The 3 mutagenicity tests mentioned in point 8.2
- A 90-day oral toxicity study
- Data to demonstrate the absence of potential for accumulation in man

8.3.2 In cases where migration is below 0.05 mg/kg of food / food simulant the following data are needed:

- The 3 mutagenicity tests mentioned in point 8.2.

8.4 Special investigations/additional studies

If the above-mentioned studies or prior knowledge or structural considerations indicate that other biological effects such as peroxisomal proliferation[5], neurotoxicity, immunotoxicity or endocrinological events may occur, additional studies may be required.

At present no validated methods are available for studies in laboratory animals which would allow assessment of a substance's potential to cause intolerance and/or allergic reactions in susceptible individuals following oral exposure. However, studies on dermal or inhalation sensitisation may give information relevant for possible hazards from occupational exposure and could be helpful in assessing consumer safety.

Under certain circumstances, particularly those relating to the chemical nature of the substance to be used in food contact materials, the tests normally to be provided for the safety evaluations and risk assessments may be modified as outlined below.

- [5] Peroxisome studies are no longer relevant to the evaluation of substances for Food Contact Materials

8.4.1 Hydrolysable substances

If the chemical structure suggests ready hydrolysis of the substance in food and/or the gastrointestinal tract into components which already have been toxicologically evaluated, the rate of hydrolysis and its degree of completeness will determine the extent of toxicological testing necessary for an evaluation. In particular, it will depend on these parameters. Whether the unhydrolysed substance needs also to be included in the testing program depends on the outcome of the hydrolysis studies.

8.4.2 Polymeric additives

Because only the fraction with molecular mass below 1000 D is regarded as toxicologically relevant, a distinction has been made between polymeric additives with a weight averaged molecular mass (MW) below 1000 D and those with MW above 1000 D. For those polymeric additives with a MW > 1000 D only a reduced set of data may be required. In deciding which data are needed, the data available on the monomers involved, the size of the fraction with molecular masses below 1000 D, and the proportion of the additive in the plastic will be taken into account.

8.4.3 Foodstuffs/Food ingredients

These can be used as monomers, as starting substances or as additives and will require only the data requested in sections 1 and 3.

8.4.4 Food additives

Those already evaluated by the SCF will, in the first instance, only require the data requested in sections 1, 3 and 6.

8.4.5 Antimicrobial Substances

Antimicrobial substances, intended to be present in food contact materials, require additional considerations to those applied to microbiologically inert substances of food contact materials. The petitioner should provide evidence that any migration into food is not intentional but only incidental; that its use does not exert any preservative effect on the food; that it does not allow the selection of non-sensitive organisms on the surface of the food contact materials; and that it does not allow the development of biocide resistance in sensitive micro-organisms.
The petitioner should also provide evidence that the substance is not used to reduce the normal hygienic measures required in handling foodstuffs.

CHAPTER III

AFC-FCM-WG EXPLANATORY GUIDANCE OF THE SCF GUIDELINES FOR FOOD CONTACT MATERIALS

0. Introduction

The aim of this document is to help petitioners in preparing a presentation of an application for assessment of a substance to be used in food contact materials prior to its authorisation. It amplifies and explains the information requested by the SCF in their guidelines (Chapter II) by giving a more detailed description of the data needed.

All these data should be provided in the order indicated in this document. The data requested in the first column should always be provided, either as indicated in the second column or as a statement such as 'yes', 'no', 'not applicable', 'no info', 'not relevant', etc.

In the lay-out below which is in fact the form that the P-SDS has to follow (that is why the word Ref: is included in the table) , it is explained what information is expected to be contained in the Technical Dossier.
A clear document that should be used for the preparation of the Petitioner Summary Data Sheet (P-SDS) is also provided in Annex 6 of this chapter (Chapter III) and should be an independent document containing a summary of all information that has been provided in the technical annexes as well as a reference to these technical annexes where the detailed information is provided in full. As an example: A summary should be given for the test method for the determination of the migration and also migration results should be presented as mean values with standard deviations. This information is sufficient, as individual values are available from the TD. Also a reference to the technical annex(es) shall be given where the migration method and the actual migration tests are described.

In case of a re-evaluation an updated (complete) P-SDS should be provided. In this updated P-SDS the added or modified information shall be marked as new information

Justification of any deviation from the “AFC-FCM-WG Explanatory Guidance” must be given in the Technical Dossier and in the P-SDS.

Note that, because the migration testing is subject to the EU Directives, detailed guidelines on migration testing have been prepared by the Commission under its own responsibility and have not been included in this part of the document, but have been inserted in the document called “Commission Explanatory Guidance on Migration Testing for Food Contact Materials” (see Chapter IV). However the AFC PANEL will verify whether the data submitted in the Technical Dossier are in compliance with the above-mentioned guidelines and whether these are in accordance with the general criteria established in this document.

For transparency reasons, a summary of the information provided in a dossier and the conclusions of the evaluation will be published on the EFSA internet site. Dossiers however, may

contain strictly confidential information such as information on production processes. Information considered essential, confidential company property should be clearly marked. Properly marked information will be retained from disclosure. (see also Chapter I, 3.7)

If any document is mentioned, only its updated version should be considered. For example, if a reference to a Directive appears in the text or in the bibliography and meanwhile the Directive has been amended, only the amended version should be taken into account.

Data requested		Guidance for providing the data requested
1.	**IDENTITY OF SUBSTANCE**	
1.1	**individual substance:**	Answer 'yes' or 'no' If 'no' go to 1.2, if 'yes' give information requested in 1.1.1 to 1.1.11 as complete as possible.
1.1.1	**chemical name**:	Give chemical name of substance.
1.1.2	**synonym(s):**	Set out synonyms, if any.
1.1.3	**trade name(s):**	Set out trade name(s), if any.
1.1.4	**CAS Nr:**	Set out CAS number, if any.
1.1.5	**molecular and structural formula:**	Give molecular and structural formula.
1.1.6	**molecular weight:**	Give molecular weight.
1.1.7	**spectroscopic data:**	Give spectroscopic data which allow identification of the substance, e.g. FTIR, UV, NMR and/or MS. ***Ref:***
1.1.8	**manufacturing details**	Set out production process, including starting substances, production control and reproducibility of the process If known, indicate any alternative production process and product that can be used, and whether such products have the same characteristics. ***Ref:***
1.1.9	**purity (%):**	Set out percentage purity. Set out how the purity was established. Supporting documentation (e.g. chromatogram) should be provided. The substance will be evaluated for the stated level of purity. ***Ref:***
1.1.10	**impurities (%):**	Set out: - identity and typical range of percentage of impurities, - origin of the impurities (eg starting substance, side reaction product, degradation product) - individual impurity levels, - describe the analytical methods to determine the impurities. Supporting documentation (e.g. chromatograms) should be provided. If there might be some concern about impurities, migration and/or toxicity data on these impurities might be requested, and specifications set by authorities.

1.1.11	**specifications:**	Where appropriate, submit a proposal for a specification (eg level of purity, nature and percentage of impurities, type of polymer to be used …) to be included in the Directive. ***Ref:***
1.1.12	**other information:**	Set out any other information that may be relevant for evaluation. ***Ref:***
1.2	**defined mixture:**	Answer 'yes' or 'no' If 'no' go to 1.3, if "yes" give information requested in 1.2.1 to 1.2.13 as completely as possible. This section only deals with "process mixtures", obtained from a reproducible process and where the detailed composition can be easily determined (e.g. mixture of isomers). "Synthetic mixtures", made up by intentionally of individual identified components are not considered in this section. See also the explanation given in the Document "Practical Guide".
1.2.1	**chemical name:**	Give chemical name of mixture, if any.
1.2.2	**synonym(s):**	Set out synonyms, if any.
1.2.3	**trade name(s):**	Set out trade name(s), if any.
1.2.4	**CAS Nr:**	Set out CAS number (s), if any.
1.2.5	**constituents:**	Set out chemical name(s) of constituents of the mixture.
1.2.6	**proportions in the mixture:**	Set out proportions of substances in the mixture. ***Ref:***
1.2.7	**molecular and structural formula:**	Give molecular and structural formula of each component including isomers.
1.2.8	**molecular weight (Mw) and range:**	Give molecular weight (weight averaged molecular mass) and molecular mass range. ***Ref:***
1.2.9	**spectroscopic data:**	Give spectroscopic data which allow identification of the mixture, e.g. FTIR, UV, NMR and/or MS. ***Ref:***
1.2.10	**manufacturing details**	Set out production process, including starting substances, production control and reproducibility of the process. If known, indicate any alternative production process and product that can be used, and whether such products have the same characteristics. ***Ref:***

1.2.11 purity (%):

Set out percentage purity.
Set out in what way the purity was established. Supporting documentation (e.g. chromatogram) should be provided
The substance will be evaluated for the stated level of purity.

Ref:

1.2.12 impurities (%):

Set out:

- identity and typical range of percentage of impurities,
- origin of the impurities (eg starting substance, side reaction product, degradation product)
- individual impurity levels,
- describe the analytical methods to determine the impurities. Supporting documentation (e.g. chromatograms) should be provided.

If there might be some concern about impurities, migration and/or toxicity data on these impurities might be requested, and specifications set by authorities.

Ref:

1.2.13 specifications:

Where appropriate, give a proposal for a specification to be included in Directives.

Ref:

1.2.14 other information:

Set out any other information that may be relevant for evaluation.

Ref:

1.3 Non-defined mixture:

Answer 'yes' or 'no'
If 'no' go to 1.4, if “yes” give information requested in 1.3.1 to 1.3.16 as complete as possible.
Non defined mixtures are mixtures which may vary from batch to batch, but which have a composition within certain specifications. Typical examples of non-defined mixtures are products derived from natural sources. Their composition will depend on the origin of source, climate and treatment. Also technical processes like ethoxylation, epoxydation or hydrogenation may create a large number of individual components. The best available specification of the non-defined mixture should be submitted for authorisation.

1.3.1 chemical name:

Give description as complete as possible.

1.3.2 synonym(s):

Set out synonyms, if any.

1.3.3 trade name(s):

Set out trade name(s), if any.

1.3.4 CAS nr:

Set out CAS number(s), if any.

1.3.5 starting substances:

Set out substances or raw materials used in manufacturing the mixture.

1.3.6	**manufacturing details:**	Set out production process, production control and reproducibility of the process. If known, indicate any alternative production process and product that can be used, and whether such products have the same characteristics. *Ref:*
1.3.7	**substances formed:**	Set out substances formed during the process. *Ref:*
1.3.8	**purification by:**	Set out details of purification of the end product. *Ref:*
1.3.9	**by-products:**	Give qualitative and quantitative information on by-products, if any. *Ref:*
1.3.10	**molecular and structural formula:**	Give molecular and structural formula. For non-defined mixtures this information may be complicated. In some cases the information requested could be described as e.g. “oil of natural origin” with range of fatty acids and further treatment, if any.
1.3.11	**molecular weight (M_W) and range:**	Give Mw (weight averaged molecular mass) and molecular weight range. *Ref:*
1.3.12	**purity (%):**	Set out percentage purity. Set out how the purity has been established. Supporting documentation (e.g. chromatogram) should be provided. The substance will be evaluated for the stated level of purity. *Ref:*
1.3.13	**impurities (%):**	Set out: - identity and typical range of percentage of impurities, - origin of the impurities (eg starting substance, side reaction product, degradation product) - individual impurity levels, - describe the analytical methods to determine the impurities. Supporting documentation (e.g. chromatograms) should be provided. If there might be some concern about impurities, migration and/or toxicity data on these impurities might be requested, and specifications set by authorities. *Ref:*
1.3.14	**spectroscopic data:**	Give spectroscopic data which allow identification of the substance, for example FTIR, UV, NMR and/or MS. *Ref:*
1.3.15	**specifications:**	Where appropriate, give a proposal for a specification to be included in the Directive.
1.3.16	**other information:**	Set out any other information that may be relevant

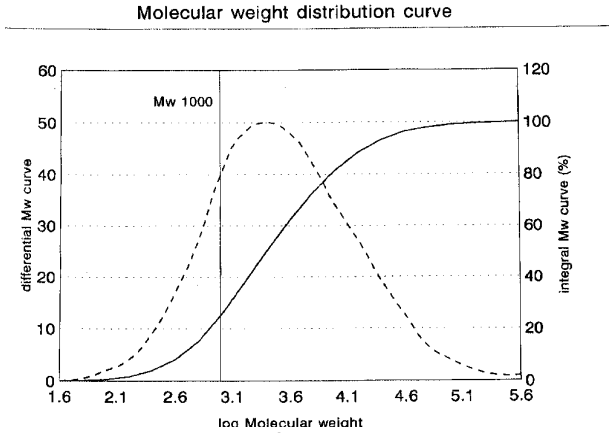
		for evaluation. *Ref:*
1.4	**polymer used as additive:**	Answer 'yes' or 'no' If 'no' go to 2, if “yes” give information requested in 1.4.1 to 1.4.19 as complete as possible. Polymeric additive means any polymer and/or prepolymer and/or oligomer, which may be added in plastics in order to achieve a technical effect but which cannot be used as such for the manufacture of finished materials and articles. It includes also polymeric substances which may be added to the medium in which polymerisation occurs.
1.4.1	**chemical name:**	Give chemical name of substance, if any.
1.4.2	**synonyms:**	Set out synonyms, if any.
1.4.3	**trade name(s):**	Set out trade name(s), if any.
1.4.4	**CAS Nr:**	Set out CAS number, if any.
1.4.5	**starting substances:**	Set out monomers and/or other starting substances.
1.4.6	**manufacturing details**	Set out production process, production control and reproducibility of the process. If known, indicate any alternative production process and product that can be used, and whether such products have the same characteristics. *Ref:*
1.4.7	**additive(s):**	Set out additives used, if any.
1.4.8	**structure of polymer:**	Give structure of polymer.
1.4.9	**weight averaged molecular mass:**	Give weight averaged molecular mass. *Ref:*
1.4.10	**number averaged molecular mass:**	Give number averaged molecular mass. *Ref:*
1.4.11	**molecular mass range:**	Give molecular mass range, distribution curve inclusive: Curve of the distribution of the molecular masses (see figure below). This should be obtained by GPC or by another agreed method. - The GPC calibration supplied should include as standards samples of the same polymer, having their molecular mass accurately determined by an adequate technique (their molecular mass should lie around 1000 D). Determine the weight averaged

molecular mass in weight (M_W) and the number averaged molecular mass (M_n).

- If standards of the same polymer are not available, then polystyrene standards should be used. An absolute value of M_W or M_n should then be determined by an adequate technique. The abscissa of the GPC molecular mass distribution curve should then be corrected by the factor:

M_n (absolute value)	or	M_W (absolute value)
M_n (GPC value relative to PS)		M_W (GPC value relative to PS)

On the integrated molecular mass distribution curve (determined according the above mentioned guidelines) determine the point corresponding to abscissa 1000 D (true value): this gives the percentage of polymeric additive with molecular mass less than 1000 D.



figure

Ref:

1.4.12	**constituents with molecular mass <1000 (%):**	Set out percentage constituents with molecular mass < 1000.
1.4.13	**viscosity, if available:**	Give intrinsic and/or relative viscosity, if any. *Ref:*
1.4.14	**melt flow index, if available:**	Give melt flow index, if any. *Ref:*
1.4.15	**density (g/cm^3)**	Give density, if any. *Ref:*

1.4.16 spectroscopic data: Give spectroscopic data, which allow identification of the subject substance, for example FTIR, UV, NMR and/or MS.

Ref:

1.4.17 residual monomers (mg/kg): Set out monomers as well as individual monomer contents. See also item 6.

Ref:

1.4.18 purity (%): Set out percentage purity.
Set out how the purity was established. Supporting documentation (e.g. chromatogram) should be provided.
The substance will be evaluated for the stated level of purity.

Ref:

1.4.19 impurities (%): Set out:

- identity and typical range of percentage of impurities,
- origin of the impurities (eg starting substance, side reaction product, degradation product)
- individual impurity levels,
- describe the analytical methods to determine the impurities. Supporting documentation (e.g. chromatograms) should be provided.

If there might be some concern about impurities, migration and/or toxicity data on these impurities might be requested, and specifications set by authorities.

Ref:

1.4.20 specifications: Where appropriate, give a proposal for the specification to be included in the Directive.

Ref:

1.4.21 other information: Set out any other information that may be relevant for evaluation.

Ref:

2. PHYSICAL AND CHEMICAL.PROPERTIES OF SUBSTANCE

2.1 physical properties

2.1.1 melting point (°C): Give melting point.

2.1.2 boiling point (°C): Give boiling point.

2.1.3 decomposition temperature (°C): Give decomposition temperature, if any.

Ref:

2.1.4 solubility (g/l): Set out solubility in solvents.

If available, solubility in organic solvents should be presented as well as in food simulants.
If in migration tests a fatty food simulant is replaced by a substitute volatile simulant then both solubility in the oil and in the substitute simulants is required. At least a semi-quantitative estimate of solubility should be presented to make the use of substitute solvents acceptable. The solubility may be given in g/l, or it may be indicated e.g. miscible, good, moderate, poor or insoluble etc. The intention here is that comparative information on solubility, which is one of the parameters that may influence migration, is obtained.

Ref:

2.1.5 octanol/water partition(log Po/w)

Set out partition coefficient, if available.
Information is obligatory in the following cases:
- Migration is > 0.05 mg/kg of food/food simulant
- Substance is requested to be subject to the Fat (consumption) Reduction Factor (FRF).

If the migration is > 0.05 mg/kg then information on accumulation in man is requested (see Annex 4). The log Po/w could be a tool to decide for the need of additional data.

Lipophilic substances may be marked as appropriate to apply the FRF. Proper evidence should be provided to demonstrate the lipophilic properties of a substance. A log Po/w may be one of the three criteria established to classify the substance as lipohilic. The other 2 are the following:

1. Migration into non-fatty simulants should not exceed 1/10 of the SML of the substance or
2 Solubility in the non-fatty simulants should be less than 10% of the SML

Ref:

2.1.6 other information related to lipophilicity:

Give any other relevant information.

Ref:

2.2 chemical properties

2.2.1 nature:

Answer 'acidic', basic' or 'neutral'.

2.2.2 reactivity:

Give information on reactivity of subject substance.

2.2.3 stability:

Give information on stability of subject substance in the polymer towards light, heat, moisture, air, ionising radiation, oxidative treatment, etc.
Provide a thermogravimetric analysis (for

		substances other than monomers) of the compound. For chemicals which are not deemed to react in the polymer, the onset of degradation should in general be 10% above the max. process temperature. If this is not met an explanation should be given why the substance can be used above or near the decomposition temperature. If any of the other parameters are relevant for authorization of the substance, then sufficient detailed information shall be provided for a proper evaluation. *Ref:*
2.2.4	**hydrolysis:**	Hydrolysis may simplify the petition if already evaluated chemicals are formed in high yield in body fluid simulants. If relevant, give results of hydrolysis tests carried out according to the guidelines of chapter III annex 1. If hydrolysis tests are carried out then full details shall be provided, including the analytical method. *Ref:*
2.2.5	**intentional decomposition/ transformation:**	Give information on intentional decomposition or transformation of substance, if any, during manufacture of a food contact material or article. If there might be some concern about decomposition products, migration and/or toxicity data on these products might be requested, and specifications or restrictions may be set. In this respect a monomer is considered to be transformed into a polymer Additives like scavengers will be transformed and anti-oxidants will be decomposed according to the intention of use. Other substances may be decomposed e.g. by oxidation or due to high temperature etc. *Ref:*
2.2.6	**unintentional decomposition/ transformation product(s):**	Where relevant, set out unintentional decomposition or transformation products - of the pure substance (see 2.2.3) - formed in the material during the manufacture of a final article - formed during various treatments likely to be applied to the finished material or article (e.g. ionising treatments) *Ref:*
2.2.7	**interaction with food substances:**	Give information on reaction of substance with food substances, if any. This item is very important for making decisions on the type of restriction to be established (SML, QM or QMA). If migration tests, including recovery tests (see 5.1.11), have been carried out then reference could be made to item 5.1. In any other situation stability of the substance in food simulants

should be provided, unless a QM or QMA limit is requested by the petitioner.

Ref:

2.2.8 other information: Set out any other information that may be relevant for evaluation.

Ref:

3. INTENDED APPLICATION OF SUBSTANCE

3.1 food contact material: Set out food contact material(s) in which substance is to be used.
Information should be provided in what type of polymers the substance is intended to be used, and/or in what type of food contact material, e.g. all kinds of polyolefins, ABS used for manufacture of household machines, only in PET beverage bottles. This information may be important for estimating the real exposure.
Indication of a very restricted or a very broad field of application may influence the final authorisation and the restrictions of the substance.

3.2 technological function: Set out function of substance in the production process or in the finished product. For example monomer, co-monomer in the production of polymer X, antioxidant, antistatic agent, preservative, etc. Provide any relevant information to demonstrate the functionality of the substance in the final product. If relevant, provide information on the production process.

3.3 maximum process temperature (°C): Set out maximum temperature in manufacturing process of polymer as well as final food contact material. (see also 2.2.3)

3.4 maximum percentage in formulation: Set out maximum percentage of the substance used in the formulation and/or related to the final food contact material (e.g. a substances added in an aqueous suspension should be related to the dry matter). The maximum percentage to achieve a technological property, as well as the level used in practice should be given, if relevant.
Typically in the case of additives, the maximum percentage will influence the migration of the substance. Materials submitted to migration testing should always contain the maximum percentage indicated.

3.5 conditions of contact in practice

3.5.1	**contact food:**	Set out foods to be in contact with finished products. Indicate any typical foodstuff or use for all types of foodstuff. Migration tests should be carried out accordingly.
3.5.2	**time and temperature:**	Set out approximate time and temperature of contact in practice. Set out any restriction of time and temperature. If “no restrictions“ is indicated then the food contact material should be able to withstand test conditions of 2 h at 175°C with olive oil. See Directive “82/711/EEC” and its amendments for further guidance.
3.5.3	**surface to volume ratio:**	Set out approximate ratio of dm^2 food contact materials to kg food in practice. For materials intended for general application the ratio is conventionally 6 dm^2/kg. For specific applications the ratio area/food may deviate significantly, e.g. tubing or large tanks, single portion package (see also 3.1) Information requested here should not be confused with the information requested in item 5.
3.5.4	**other information:**	Give any other relevant information.
3.6	**treatment of food contact material prior to use:**	Give information on treatment of food contact material prior to contact with food, e.g. sterilisation, cleaning with pressurised steam, rinsing, irradiation, e-beam or UV light treatment, etc.
3.7	**other uses:**	Set out other uses or intended uses of the substance additional to food contact materials, if any. If the substance is used in other domains than food contact materials, only a fraction of the ADI may be allocated to food contact materials.
3.8	**other information:**	Set out any other information that may be relevant for evaluation.

4. AUTHORISATION OF SUBSTANCE

4.1 EU countries

4.1.1	**in Member States:**	Answer 'yes' or 'no'. If 'yes' set out Member State(s), give relevant regulation(s) or other and give further details like restrictions and conditions.
4.1.2	**notified as “new substance” in the context of 6th Amendment of Directive 67/548/EEC:**	Answer 'yes' or 'no'. If 'yes' give details and data transmitted.

4.1.3 other information: Give any other relevant information.

4.2 non-EU countries

4.2.1 in USA: Answer 'yes' or 'no'. If 'yes' give relevant regulation(s) or other and give further details like restrictions and conditions.

4.2.2 in Japan: Answer 'yes' or 'no'. If 'yes' give relevant regulation(s) or other and give further details like restrictions and conditions.

4.2.3 in other countries: Answer 'yes' or 'no'. If 'yes' set out other countries, give relevant regulation(s) or other and give further details like restrictions and conditions.

4.2.4 other information: Set out any other information that may be relevant for evaluation.

4.3 other information: Set out any other information that may be relevant for evaluation, e.g. authorisation on other uses or environmental regulations.

5. DATA ON MIGRATION OF SUBSTANCE

If food simulants are used, the provisions concerning the specific and overall migration set out in the EU Directives6 and in the document "Commission Explanatory Guidance for Migration Testing" should be followed.

5.1 specific migration (SM): Answer 'SM determined' or 'SM not determined'. If SM is not determined give reasons. In general the determination of the specific migration will be requested to demonstrate worst case migration. Based on the level of migration the number of toxicity tests can be established. However there are a number of exceptions where specific migration can be replaced by the determination of the actual content of the substance followed by worst case calculation. In cases where it is impossible to measure specific migration because of the properties of the substance, e.g. polymeric additives, the overall migration can be used to demonstrate worst case migration of the substance.
All experiments required in specific migration testing should be performed in triplicate.

Ref:

5.1.1 substance: Set out substance(s) determined.

6 See the document “Eu and national Legislations” appearing in the homepage of EC-JRC website

Information on migration of decomposition products (e.g. antioxidant) and/or impurities –if any- may be required as well.

Ref:

5.1.2 test sample:

The test sample should always represent the worst case situation. This means the highest concentration of additive or co-monomer should be present. Also thickness of the test sample should represent the worst case situation. If the test sample is intended to represent a range of materials of different brands or grades, then it should be assured that material is selected that will represent the worst case situation in the migration testing. If the substance is used in different kinds of polymers then, in principle, each type of polymer should be tested. However if it is properly argued only migration tests with the polymer representing worst case can be acceptable. For example for an additive used in all types of polyolefins tests with LDPE may suffice.

Ref:

5.1.2.1 chemical composition:

Set out chemical composition of the test sample. Information should be provided particularly on the initial concentration of the substance, but also information on the total composition is required as the composition of the test specimen may influence the final migration of the substance.

5.1.2.2 physical composition:

Set out physical composition of test sample, such as homogeneous material, multi-layer material. In case of multi-layer material it should be indicated in which layer the substance is present. If this is not the direct food contact side, then also relevant information on the top-layers shall be given.

5.1.2.3 density, melt flow index of polymer:

Set out density and melt flow index (if relevant) of the polymer containing the substance. This information is required for mathematical modelling. In multi-layer constructions also the density of the barrier layers shall be given.

5.1.2.4 dimensions of test sample:

Set out dimensions of test sample.

Test sample is the sample manufactured for the purpose of the migration study. Provide information on shape, e.g.: bottle, film, sheet, etc. and thickness. For laminates the total thickness and the thickness of each relevant layer should be indicated. For articles with inhomogeneous thickness the thickness at various places should be given. The dimensions of an article should be set out (height, length, width and/or diameter).

5.1.2.5	**dimensions of test specimen:**	Describe briefly that part or section of the test sample from which the test specimen was taken particularly in case of inhomogeneous materials (e.g. bottle). Set out spatial dimensions of test specimen (length, height, width, diameter). Calculate the total area of the test specimen. In case of two-sided contact (see 5.1.5) also calculate the total area of both sides. If the test specimen does not come into contact completely with the simulant (with use of one side migration cells) then calculate the actual contact area.
5.1.3	**treatment of test sample prior to testing:**	Set out to what treatment food contact material was subjected prior to testing. E.g. cleaning, washing etc. Treatment of a test sample should be representative of use in practice.
5.1.4	**test food(s)/food simulant(s):**	Set out foodstuff(s) or food simulant(s) used in migration testing. For the selection of the food simulant Directive 82/711/EEC as amended should be followed. The "Commission Explanatory Guidance for Migration Testing" (see Chapter IV) should be taken into account. Especially when olive oil is replaced by substitute food simulants this document should be studied carefully. Also data on solubility as requested in item 2.1.4 shall be provided in those cases. Replacement of olive oil by substitute simulants is only allowed in case of technical problems. Therefore the necessity of the use of substitute simulants should be clarified, preferably supported by some analytical data. Olive oil should not be replaced for convenience only. Arguments will be considered for validity. Poor analytical chemistry or lack of facilities may not appear acceptable arguments for replacement of olive oil by substitute simulants. In the special case of migration of metal ions where ion exchange is the driving force, migration experiments should also be performed in the following simulants: 40 mM sodium acetate buffer at pH 5 and 50 mM sodium phosphate buffer at pH 7.
5.1.5	**contact mode:**	Set out whether sample was tested on one or on two sides Set out in which way contact with the simulants was achieved, e.g.: cell, pouch, total immersion etc. If tested on two sides set out whether one or both sides of the test specimen are used in the calculation of the contact area.
5.1.6	**contact time and temperature:**	Set out duration of test and test temperature. In case of short contact times (≤2 hours) at high

temperature (≥100°C), describe in acceptable manner or demonstrate maintenance of the temperature over the test period.

5.1.7 surface to volume ratio:

Set out dm^2 test sample per kg food or per L simulant. Give the actual contact area and the volume of simulant. Calculate from these data the actual surface to volume ratio applied in the migration test. Conventionally the ratio is 6 dm^2/kg simulant. For analytical reasons it is often necessary to deviate from that ratio, which in principle is acceptable. However it should be carefully considered whether or not the migration, using a higher ratio of area to volume, could influence the final migration due to saturation of the simulant.

5.1.8 analytical method:

Set out principle of analytical method used, and submit a copy of the method in standard format.
Guidance for the description of a method in standard format is given in the document "Commission Explanatory Guidance for Migration Testing" (Chapter IV)**.** In addition, the technical dossier shall contain e.g. actual data concerning the preparation of calibration solutions, typical chromatograms, calibration curves, correlation coefficients and all relevant data needed for a proper evaluation of the method and the migration data provided. It should be realised that the method of determination may be used by enforcement laboratories in order to enforce any restriction established to the substance. Therefore the method should use generally available equipment. Use of very sophisticated methods should be justified.

Ref:

5.1.9 detection/ determination limit:

Give detection and/or determination limit of method, and set out the way the detection limit was established. Detection limits are particularly important when migration is not detectable or at the level of the detection limit. Where relevant, visual information such as typical chromatograms, calibration curve, blank values should be provided.

Ref:

5.1.10 precision of test method:

Give repeatability (r) of method at migration level. For example, repeatability of the method can be obtained from the standard deviation of the triplicate migration experiments or from recovery experiments.

Ref:

5.1.11 recovery:

Set out percentage recovery of substance as determined in recovery experiments under time-temperature conditions of migration test. To obtain

data both on the suitability of the analytical method as well as the stability of the substance in the food simulants, recovery experiments (triplicate) shall be performed with food simulants spiked with the substance at a level of interest (e.g. 50 μg/kg) or at the actual level of the migration values. The spiked food simulants shall be stored under the same conditions of time and temperature, in the same or equivalent containers as used in the migration experiments. Provide all actual data, to allow proper evaluation of the results presented, such as method of standard addition (solvent used, volume added) amount of substance added to a known volume of simulant (x μg/y ml), storage condition, etc.
If low recovery values are obtained, reasons for this should be explained.
Results of the recovery test may influence the type of restriction to be established.

Ref:

5.1.12 other information: Set out any other information that may be relevant for evaluation.

Ref:

5.1.13 results: Give all individual migration data obtained, blank and recovery data inclusive. Preferably the data should be presented in a table, which should contain sufficient details to follow the way the final results are obtained. For example it should contain:

- test conditions of time and temperature
- simulant
- contact area
- volume of food simulant used in the test
- actual concentration of the substance in the simulant as obtained from the migration experiment
- migration in the food simulant expressed in mg/dm²
- migration in the food simulant using the conventional factor of 6 dm²/kg or any other relevant ratio
- amount of substance added in the recovery tests.

Ref:

5.2 overall migration (OM): Answer 'determined', 'not determined'
In general the determination of the OM as described in CEN methods EN 1186 is not required for petitioning of an additive or a monomer. The overall migration may be used as a replacement for specific migration in those cases where the specific migration is impossible to measure because of the properties of the substance, e.g. polymeric additives. The overall migration may be used to demonstrate worst case migration of the substance.

In special cases the AFC Panel may require OM data, e.g. when larger amounts of oligomers are suspected (see 5.3).

Ref:

5.2.1 test sample: Set out what food contact material sample was subjected to testing, e.g.: composition, shape (bottles, film, cups, tins, etc.), thickness and dimensions. For selection of test samples etc., see 5.1.2. Where relevant use the same grade of test material in specific and overall migration testing. However there may be reasons to take different grades of material. Where the overall migration of one grade gives highest results while from another grade the specific migration is the highest, then different test samples could be used.

Ref:

5.2.2 treatment of sample prior to testing: Set out to what treatment food contact material was subjected prior to testing.

5.2.3 food simulant(s): Set out food simulant(s) used in testing.
For the selection of food simulants Directive "82/711/EEC', as amended, should be followed. The "Commission Explanatory Guidance for Migration Testing" should be taken into account. The necessity of the use of substitute test medium should be explained, preferably supported by some analytical data.

5.2.4 contact mode: Set out whether sample was tested on one or on two sides. Set out in which way contact with the simulants was achieved, like cell, pouch, total immersion etc. If tested on two sides set out whether one or both sides of the test specimen are used in the calculation of the contact area.

5.2.5 contact time and temperature: Set out duration of test and test temperature in °C. In case of short contact times (≤2 hours) at high temperature (≥100°C), describe in acceptable manner or demonstrate maintenance of the temperature over the test period.

5.2.6 surface to volume ratio: Set out area of test sample in dm^2 per L simulant.
Conventionally the ratio is 6 dm^2/kg simulant. The actual ratio in the migration tests may deviate. For guidance on the CEN methods consult the document "Methods of Analysis".

5.2.7 test method: Set out analytical methods used. Reference to CEN methods as they appear in the document "Methods of Analysis" should be given, where relevant. Any deviation from those methods should be reported. If other methods are used to determine the overall migration, then a detailed description of the

analytical method should be provided.

5.2.8 other information: Set out any other information that may be relevant for evaluation.

5.2.9 results: Give all individual migration data obtained, if relevant, blanks inclusive. Preferably the data should be presented in a table, which should contain sufficient details to follow the way the final results are obtained. For example it should contain:

- test conditions of time and temperature (in °C)
- simulant
- contact area (dm^2)
- volume of food simulant used in the test (ml)
- migration in the food simulant expressed in mg/dm^2
- migration in the food simulant using the conventional factor of 6 dm^2/kg or any other relevant ratio.

Ref:

5.3 Quantification and identification of: a)migrating oligomers and b)reaction products derived from monomers and starting substances and additives

Answer 'determined', or 'not determined'. Where it is not determined, a justification should be given.

Experimental data show that in polymers the migration of oligomers (M_w<1000) or reaction products occurs and in some cases high levels were found. Therefore, there is a need for information on:

a) the migration of oligomers from polymers produced from monomers or which are produced by means of polymerisation aids that influence the molecular structure or molecular weight of the polymer.

b) the migration of reaction products from polymers produced from monomers or additives.

In the first instance there is a need for information on the identity and level of substances that migrate as a consequence of the use of a new monomer or additive (see also 2.2).

Tests with olive oil may not be suitable for identification purposes. Substitute simulants or alternative test media may be more convenient for identification purposes.

In principle the identity of the migratable substances may be required, however in some cases a simple characterisation by identification of the functional groups may be sufficient.

Ref:

5.3.1 test sample: The test sample composition and its thickness should always represent the worst case. In general, the highest concentration of the substance, and the largest thickness, should be used. If the substance is intended to be used in a range of materials of different polymers or grades, then each type of

material should be tested. However, if it is properly argued, only tests with the material representing the worst case may be acceptable.

Ref:

5.3.1.1 chemical composition: Set out chemical composition of the test sample. Information should be provided on the initial concentration of the substance(s), and also on the total composition, as this may influence the final migration of the substance(s).

5.3.1.2 physical composition: Set out physical composition of test sample, such as homogeneous material, multi-layer material.
In case for a multi-layer material it should be indicated in which layer the substance(s) is present. If this is not the direct food contact side, then also relevant information on the top-layers should be given.

5.3.1.3 density, melt flow index of polymer: Set out density and melt flow index (if relevant) of the polymer containing the substance(s).
This information is required for mathematical modelling. In multi-layer constructions the density of the barrier layers should be given also.

5.3.1.4 dimensions of test sample: Set out dimensions of test sample.
Test sample is the sample manufactured or used for the study. Provide information on shape, e.g.: bottle, film, sheet, etc. and thickness. For laminates the total thickness and the thickness of each relevant layer should be indicated. For articles with non-homogeneous thickness, the thickness at various places should be given. The dimensions of an article should be set out (height, length, width and/or diameter).

5.3.1.5 dimensions of test specimen Describe briefly that part or section of the test sample from which the test specimen was taken particularly in case of variable thickness materials (e.g. bottle).
Set out spatial dimensions of test specimen (length, height, width, diameter).
Calculate the total area of the test specimen. In case of two-sided contact (see 6.3.1.4) also calculate the total area of both sides. If the test specimen does not come into contact completely with the simulant then calculate the actual contact area.
In case of extraction, the weight of the test sample may suffice.

5.3.2 treatment of test sample prior to testing: Set out to what treatment the food contact material was subjected prior to testing, e.g. cleaning, washing etc. Treatment of a test sample should be

		representative of use in practice.
5.3.3	**test food(s)/food simulant(s)/extraction solvent(s):**	Set out foodstuff(s) or food simulant(s) or extraction solvent(s) used in migration testing. For quantitative determinations, the use of food simulants selected according to Directive 82/711/EEC as amended should be followed. Identification or characterisation of migratable substances may be possible in aqueous food simulants. In general, use of olive oil may not be feasible for various reasons. The use of volatile simulants or extraction solvents may be required to allow identification or characterisation of the migratable substances.
5.3.4	**contact mode:**	Set out whether the sample was tested on one or on two sides. Set out in which way contact with the simulants was achieved, e.g.: cell, pouch, total immersion etc. If tested on two sides set out whether one or both sides of the test specimen are used in the calculation of the contact area. Set out conditions of extraction, if relevant.
5.3.5	**contact time and temperature:**	Set out test duration and temperature.
5.3.6	**surface to volume ratio in migration tests:**	Give the actual contact area and the volume of simulant used in the migration experiment. Calculate their ratio expressed as dm^2/kg food simulant In principle, the ratio should be equivalent to the ratio occurring in real use. If this ratio is not known then the conventionally 6 dm^2/kg simulant may be used. For analytical reasons it may be necessary to deviate from that ratio, which in principle is acceptable. However it should be carefully considered whether or not using a higher ratio of area to volume, could influence the final migration due to saturation of the simulant, which may occur with substances poorly soluble in the simulant used. In extraction experiments, this most likely will not occur.
5.3.7	**analytical method:**	Set out the principle of analytical method(s) used, and submit a full copy of the method in the technical dossier. Identification or characterisation of migratable substances usually require application of various sophisticated and complementary techniques. In the summary data sheet an outline of the analytical approach should be given. In the technical dossier the analytical methods applied should be described in such detail to allow appropriate evaluation of the

results. This requires information of e.g. chromatographic, mass spectrometric systems, or other means of isolation or detection. Chromatograms, spectra, etc should be provided with a proper legend. Information or conclusions that should be deduced from such documents should be accompanied by an explanatory text.
In quantitative gravimetric analysis details should be given on the method. When using quantitative chromatographic methods, all details of the method should be provided that may be relevant for evaluation of the results, e.g. actual data concerning the calibration procedure, typical chromatograms or spectra, calibration curves, correlation coefficients.

Ref:

5.3.8 detection/ determination limit: Give detection and/or determination limit of the method, and set out the way the detection limit was established for quantitative determinations. Where relevant, visual information such as typical chromatograms, calibration curve, blank values should be provided.
Also in qualitative analyses an indication on the detection limit should be provided.

Ref:

5.3.9 recovery: Set out percentage recovery of substance as determined in recovery experiments under time-temperature conditions of migration test.
Recovery experiments as required in specific migration testing may or may not be possible, as no reference substances may be available. If there are proper arguments, then the recovery tests are not required.

Ref:

5.3.10 other information: Set out any other information that may be relevant for evaluation.

Ref:

5.3.11 results: Describe the migratable substance(s) that have been characterised or identified and give there migration levels (expressed in mg/6 dm^2). The presentation of the results of the characterised or identified migratable substance(s) may not be a straightforward issue. Any conclusions drawn from the investigations will need some clear reasoning and explanation to justify these conclusions.

Ref:

6. DATA ON RESIDUAL CONTENT OF SUBSTANCE IN THE FOOD CONTACT MATERIAL

6.1 actual content: Answer ”actual content determined” or “actual content not determined”. The need for the determination of the

actual or residual content of the substance in the test material depends on the type of substance and the data provided in the specific migration determination. For guidance the following examples are given:

- monomer (case 1)
Full data on specific migration are provided. Determination of residual content is not required.

- monomer (case 2)
Specific migration is not determined, but calculation of migration based on residual content and assuming 100% migration is provided. Determination of residual content is required. Full details concerning the method and results shall be provided.

- monomer (case 3)
Worst case migration is based on the amount of monomer initially added to the polymerisation process, while assuming 100% migration
Determination of residual content is not required. However, a properly described method for the determination of the residual content shall be provided for enforcement purposes.

- additive
Migration of additive is determined by specific and/or overall migration. Presence of the additive at the intended level in the actual test material used in migration experiments (5) should be demonstrated by means of analytical data. In general it is sufficient to demonstrate by analytical experiments the presence of the additive at the intended level. In this situation validation of the analytical method and extensive description of the analytical method is of less importance. Nevertheless sufficient information should be provided to make the data provided transparent and acceptable.

- monomer or additive
Determination of the specific migration of monomer or additive is not possible because of e.g. instability of the substance in food simulants, or because a QM limit is more appropriate. The determination of the actual content should be described in full detail according to standard format. In addition the method should be validated, and, where relevant, visual information (e.g. chromatograms) should be added.

Ref:

6.2 substance: Set out substance.

6.3 test sample: Where relevant, the test sample shall be equivalent to

		the test sample used in the migration experiments. In other situations the sample shall represent a worst case situation. If the test sample is intended to represent a range of materials of different brands or grades, then it should be assured that a material is selected that will represent the worst case situation. If the substance is used in different kinds of polymers then, in principle, each type of polymer should be examined for the residual content of the substance. However if it is properly argued only determination of the residual content in a polymer representing the worst case can be acceptable. Criteria of selection will depend on the substance and the manufacturing process.
		Ref:
6.3.1	**chemical composition**	Set out chemical composition of the test sample. Information should be provided particularly on the initial concentration of the substance, but also information on the total composition is required as the composition of the test specimen may influence the applicability of the analytical method and/or the residual content.
6.3.2	**physical composition**	Set out physical composition of test sample, such as homogeneous material, multi-layer material. In case of multi-layer material it should be indicated in which layer the substance is present. If this is not the direct food contact side, then also relevant information on the top-layers shall be given.
6.3.3	**density, melt flow index of polymer**	Set out density and melt flow index (if relevant) of the polymer containing the substance. This information is required for mathematic modelling. In multi-layer constructions also the density of the barrier layers shall be given.
6.3.4	**dimensions of test sample**	Set out dimensions of test sample. The test sample is the sample manufactured for the purpose of the determination of the residual or actual content of substance. Provide information on shape, e.g.: bottle, film, sheet, etc. and thickness. For laminates the total thickness and the thickness of each relevant layer should be indicated. For articles with in-homogeneous thickness the thickness at various places should given. The dimensions of an article should be set out (height, length, width, diameter).
6.3.5	**dimensions of test specimen:**	Set out dimensions or weight of test specimen. The test specimen is the actual part of material submitted to the residual content determination. Set out actual dimensions (height, length, width,

diameter) or weight of the test specimen. If a sub-sample is taken from in-homogeneous materials (e.g. bottle), then set out which part was taken.

6.4 treatment of sample: Set out treatment of the test sample, if not included in the test method.

6.5 test method: If relevant, the technical dossier shall contain the following information e.g. actual data concerning the preparation of calibration solutions, typical chromatograms, calibration curves, correlation coefficients and all relevant data needed for a proper evaluation of the method and the data related to the residual content. Guidance for the description of a method in standard format is given in the document "Commission Explanatory Guidance for Migration Testing". The method of determination may be used by enforcement laboratories in order to enforce restriction set for the substance. Therefore the method should use generally available equipment. Use of very sophisticated methods should be justified.
Where relevant, visual information such as typical chromatograms, calibration lines, etc. should be included.

Ref:

6.5.1 detection/ determination limit: Give detection and/or determination limit of method, and set out the way the detection limit was established. Detection limits are particularly important when a substance is not detectable or at the level of the detection limit. Where relevant visual information such as typical chromatograms, calibration curve, blank values should be provided.

Ref:

6.5.2 precision of test method: Give repeatability (r) of method at residual content level. For example, repeatability of the method can be obtained from the standard deviation of the triplicate determination or from recovery experiments.

Ref:

6.5.3 recovery: Set out percentage recovery of substance as determined in recovery experiments. To obtain data on the suitability of the analytical method, recovery experiments (triplicate) shall be performed by standard addition of the substance to the polymer sample at a level of interest or at the level of the actual content. Also the use of similar test material not containing the substance may be allowed. The spiked samples shall be treated in the same way as the test samples itself. Where relevant, visual information should be provided. If low recovery values are obtained, reasons for this should be

provided.

Ref:

6.5.4	**other information:**	Give any other relevant information.
		Ref:
6.6	**results:**	Give individual test results, including blank and recovery data. Preferably the data should be presented in a table, which should contain sufficient details to follow the way the final results are obtained.
		Ref:
6.7	**calculated migration (worst case):**	Set out calculation of migration of substance assuming total migration. In case, worst case calculation is acceptable an analytical method for analysis has to be provided. See also document "Commission Explanatory Guidance for Migration Testing"
		Ref:
6.8	**residual content versus specific migration:**	Give the relationship between residual content and specific migration, if determined.
		Ref:

7 MICROBIOLOGICAL PROPERTIES OF SUBSTANCE

This section focuses on the use of antimicrobial substances incorporated into food contact materials. Biocidal products are defined in Directive 98/8/EC as "active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means." A harmful organism is understood to be any organism "which has an unwanted presence or a detrimental effect for humans, their activities or the products they use or produce, or for animals or for the environment." However Article 1, 2 excludes from the scope of this directive products defined or within the scope of Council Directive 89/109/EEC on the approximation of the laws of the member states relating to materials and articles intended to come into contact with foodstuffs.

The following guidelines provide information to applicants regarding documentation to be supplied in order to permit the assessment of the public health implications, i.e. safety, efficacy including the microbiological effects of the use of an antimicrobial substance incorporated into food contact materials. Deviations from these guidelines are allowed provided that an appropriate justification is given.

It is not possible to give more specific guidance as to the methods to be used, as no validated methodology has been agreed at international level. Furthermore, different approaches may have to be followed for different substances depending on their intended use.

It should be noted that any effect of the biocidal active substance incorporated into the food contact material on the microbial flora of the food is strongly dependent on the contact time of the food contact material with the food (dose-time relation). This should be taken into account when assessing the effect of the **antimicrobial substance** on the microbial flora.

The evaluation of the microbiological data may lead to a restriction of use or of migration. If there is also another restriction based on toxicology, the lower should apply.

Substances with antimicrobial properties, which are intended to be incorporated into food contact materials will be evaluated on a case by case basis. Applicants shall provide all data required in items 1-7 of this Note for Guidance. Toxicological data shall be provided for new substances or substances not evaluated before by the EFSA-AFC panel. Active ingredients evaluated before will NOT need new toxicological data, provided the carrier system is inert and/or already approved and does not actively contribute to the antimicrobial properties of the food contact material. A typical example is the use of silver based antimicrobial agents where different supports for the silver ions may be used.

"Mutation tests in bacteria may not be appropriate for the evaluation of certain classes of chemicals, for example highly bactericidal compounds (e.g. certain antibiotics) .... In such cases, mammalian mutation tests may be more appropriate." (OECD Guideline 471, July 1997)

It should be emphasised that the use of the **antimicrobial substance** should not replace the need for good hygiene practices.

7.1	**Is the substance used as an antimicrobial agent?**	**Answer 'yes' or 'no'.** If 'no' go to 5, if 'yes' go to 7.2
7.2	**What is the intended microbiological function?**	Set out the technological function of the biocide. If the **antimicrobial substance** is used: a) as a "protection agent" during production process or storage of products to be used in the manufacture of the final article, go to 7.2.1 b) to reduce the microbiological contamination on the surface of the finished food contact material (FCM) and thereby improve hygiene in food preparation areas, go to 7.2.2
		Ref:
7.2.1	**Protection agent during production process or storage of products**	An **antimicrobial** substance may be added to protect from microbial spoilage the products to be used in the manufacture of the final article during production process or storage, e.g. an aqueous emulsion or process water containing these products. In this case, it should be argued from MIC values, migration data and/or concentrations in the final product that there could be no antimicrobial activity on the surface of the finished article. Alternatively it could be demonstrated using an appropriate method e,g, JIS Z 2801:2000[7] or EN DIN 1104 (adapted to use a wider range of microorganisms) Go to 8.

[7] Japanese Industrial Standard / Antimicrobial products – Test for antimicrobial activity and efficacy (Japanese Standards Association – 4-1-24, Akasaka, Minato-ku, Tokyo, 107-8440 JAPAN)

7.2.2	**Means of reducing microbial contamination on the surface of a FCM**	An antimicrobial substance may be added to a FCM to reduce the numbers of microorganisms on its surface and in turn to reduce the possibility of cross contamination. In this case, all information requested below should be provided.
7.2.2.1	**Intended applications of use**	Describe as far as possible the intended applications. Information should be provided on whether it is intended to be used for industrial food processing applications, consumer use (including catering) or both? Information should also be provided on each application, whether it is intended for "repeated use" or "single use"?
7.2.2.2	**Other information**	Give any information on the intended use other than those mentioned under 7.2.2.1 and in Section 3 if it may be useful for the risk assessment of the biocide.
7.3	**Spectrum of microbiological activity:**	Provide data on the spectrum of activity against various food-associated microorganisms, including pathogens. Any insensitive genera or species known or identified should be included. *Ref:*
7.4	**Level of activity:**	Provide information on Minimum Inhibitory Concentration (MICs) of the pure biocidal substance or preferably its active component e.g. silver ions, for the microorganisms likely to be exposed to the substance. The concentration of the microorganisms and the nature of the test medium in which they are exposed to the antimicrobial substance should be described. Include any dose-time-response information if available e.g. varying doses of antimicrobial substance for a constant time or a single concentration of antimicrobial substance for varying times. Describe the nature of the test medium in which the microorganisms are exposed to the biocide. Document the possibility of resistance arising to the antimicrobial substance in the sensitive population or cross-resistance to other antimicrobials developing. *Ref:*
7.5	**Possible consequences of the use of the**	Describe any possible encouragement to favour selective overgrowth of the flora on the surface of

	antimicrobial substance:	the food contact material containing the biocidal substance(s) by organisms that are insensitive to the biocidal substance(s).
		Ref:
7.6	**Efficacy:**	Efficacy strongly depends on migration of the antimicrobial substance to the surface of the material, and therefore on the type of polymer and on its antimicrobial substance content. On the other hand, migration should not be so high that there is a preservative effect on food (see section 7.8). Consequently, efficacy testing should be performed with polymers mentioned in 3.1, especially using that giving the highest and that giving the lowest migration (e.g. LDPE and PET respectively). The concentration of the antimicrobial substance in these test materials should not exceed that indicated in 3.4 and 5.1.2.1. Provide data to demonstrate the efficacy under the intended conditions of use describing the testing methodology that demonstrates this efficacy. When the biocide is to be used at low temperatures, e.g. in chill rooms, refrigerators, efficacy should be demonstrated at these temperatures. However, when this is technically impossible, e.g. in large scale industrial applications, provide data obtained from experiments that simulate the intended conditions of use. An alternative approach may rely for instance on comparison of predicted migration values with MICs, taking into account intrinsic and extrinsic conditions. The model should be properly validated.
		Ref:
7.7	**Efficacy upon repeated use**	Information should be provided to describe the behaviour of the biocidal surface after, for example, repeated cleaning procedures. Preferably, demonstration of efficacy under in-use conditions could be done using microbiological tests or by establishing the concentration of the active substance.
		Ref:
7.8	**Demonstration of the lack of antimicrobial activity against microbes in/on the food:**	Describe the evidence for absence of any effect on the microbiological flora in/on the food including comparison with data obtained from use of the same/comparable FCM not containing the biocidal substance(s). This should cover the worst case, which could include: The most sensitive micro-organism(s), The highest release level of the biocidal substance(s) or FCM with the highest concentration applied for,

		Foodstuffs spiked with the biocidal substance(s) at concentrations exceeding the observed or calculated migration levels. This consideration includes: Comparison of the observed or calculated migration levels with MIC values, Information on interaction of the biocidal substance(s) with food constituents which may lead to the inactivation of the biocide. *Ref:*
7.9	**Other information:**	Set out any other information that may be relevant for evaluation. *Ref:*
7.10	**Information on claim or disclaimer in accordance with the requirement of the relevant Directives.**	The claim should be consistent with the data described above on efficacy and activity.
7.11	**Information on authorization as biocidal product in the frame of Directive 98/8/EC**	Supply information if the substance is listed in Annex I or IA of Directive 98/8/EC or if it is a constituent of biocidal products authorised under Article 15(2) of Directive 98/8/EC or if it is a constituent of biocidal products allowed under the transitional measures or subject to the 10 year work programme provided for in Article 16 of Directive 98/8/EC

8. TOXICOLOGICAL DATA

The complete report of the toxicology studies performed should be provided. The studies should be performed following prevailing EC methods (1) and/or OECD guidelines (2) or other internationally agreed methods, and be in compliance with good laboratory practice (3).
The substances tested should be the commercial substances for which authorisation is requested. Especially the percentage of purity and the identity of impurities should be the same as those of the substances to be used in practice.
In any case, the substances used in any toxicological experiment should be described properly and their samples tested must be traceable.
In the absence of specifications on the identity (see section 1) of the substances tested, a justification should be provided.

8.1	**Genotoxicity**	In first instance, the following three in vitro mutagenicity assays should be performed:

8.1.1 Gene mutation in bacteria:	According to the EC Method B.13/14 and the OECD Guideline 471. It has to be noted that, the bacterial reverse mutation test may not be appropriate for the evaluation of certain classes of chemicals, for example highly bactericidal compounds (e.g. certain antibiotics). In such cases, mammalian mutation tests may be more appropriate. *Ref:*
8.1.2 *In vitro* mammalian cell gene mutation test:	According to the EC Method B.17 and the OECD Guideline 476. *Ref:*
8.1.3 *In vitro* mammalian chromosome aberration test :	According to the EC Method B.10 and the OECD Guideline 473. *Ref:*
8.1.4 Other information:	If any of the above tests yields a positive or equivocal result, further mutagenicity tests, including in vivo assays, may be required to elucidate the genotoxic potential of the substance. The choice of supplementary test(s) is decided case by case, on the basis of the results obtained and other relevant information. *Ref:*
8.2 General toxicity	
8.2.1 Subchronic (90d) oral toxicity:	According to the EC Method B.26 and the OECD guideline 408. *Ref:*
8.2.2 Chronic toxicity/ carcinogenicity:	According to the EC Method B.33 and the OECD guideline 453. *Ref:*
8.2.3 Reproduction/teratogenicity:	According to the EC Methods B.34–B.35 and the OECD guidelines 421-422. *Ref:*
8.2.4 Other information:	Set out any other information that may be relevant for evaluation, e.g. acute or subacute (28d) toxicity, dermal and inhalation effects should be provided when available. *Ref:*
8.3 Metabolism	
8.3.1 Absorption, distribution, biotransformation and excretion:	Give any relevant information when available. *Ref:*

8.3.2 Accumulation in man: To assess the potential for this consider the approaches listed in Annex 4. As detailed guidelines for methodology are absent the relevant sections of existing EU guidelines on veterinary drugs, additives in animal nutrition and human drugs may be consulted. Also IPCS (EHC 70 & EHC 57) as well as the FDA Red Book II may provide guidance.

Ref:

8.3.3 Other information: Set out any other information that may be relevant for evaluation.

Ref:

8.4 Miscellaneous

8.4.1 Effects on immune system: Give any relevant information, if any.

Ref:

8.4.2 Neurotoxicity: Phosphoric and phosphorous acid esters should be tested for neurotoxicity, if migration exceeds 0.05 mg/kg food/food simulants. According to OECD guideline 424.

Ref:

8.4.4 Other information: Set out any other information that may be relevant for evaluation.

Ref:

9. REFERENCES

1. Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, and subsequent adaptations to technical progress.

2. OECD Guidelines for Testing of Chemicals, Organisation for Economic Co-operation and Development, Paris.

3. OECD Principles of Good Laboratory Practice, Organisation for Economic Co-operation and Development, 1983, Paris.

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Annex 1 to Chapter III

MEASUREMENT OF HYDROLYSIS OF PLASTICS MONOMERS AND ADDITIVES IN DIGESTIVE FLUID SIMULANTS

Contents

Introduction
1 Scope
2 Principle
3 Reagents
3.1 Chemicals
3.2 Digestive fluid simulants
4 Apparatus
5 Samples
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6.2 Selection of simulants
6.3 Performance of hydrolysis test
6.4 Analysis of hydrolysate
7 Test report

INTRODUCTION

For the protection of human health, plastic food contact materials shall be in compliance with Directive 2002/72/EC updated with regard to composition and migration of constituents to foodstuffs coming into contact with these materials.

Constituents that may migrate to foodstuffs comprise residual monomers and other starting substances, residual process chemicals and additives as well as breakdown products and impurities of these substances.

Certain constituents may hydrolyse when ingested. The method described in this Guideline allows determination of the extent of hydrolysis, especially of esters, in order to assess whether the constituents break down into innocuous substances.

1 SCOPE

The method can be used to measure the extent of hydrolysis of monomers and additives in vitro, using standard digestive fluid simulants for saliva, gastric juice and intestinal fluid.

The method does not describe the analytical procedures required for the determination of the parent constituent and its hydrolysis products in the simulants.

2 PRINCIPLE

The test substance (monomer or additive) is dissolved in an appropriate solvent. An aliquot of the solution is transferred to the digestive fluid simulant, which is maintained at 37°C with continual agitation. After a specified time period the concentrations of both parent constituent and hydrolysis products are determined in the simulant, whereupon percentage hydrolysis is calculated.

3 REAGENTS

NOTE: All reagents should be of recognised analytical quality unless otherwise specified.

3.1 Chemicals

3.1.1 Water, distilled or deionised
3.1.2 Sodium bicarbonate ($NaHCO_3$)
3.1.3 Sodium chloride (NaCl)
3.1.4 Sodium taurocholate?
3.1.5 Potassium carbonate (K_2CO_3)
3.1.6 Sodium hydroxide standard solution, 0.2 M
3.1.7 Hydrochloric acid standard solutions, 2 M and 0.1 M
3.1.8 Potassium dihydrogen orthophosphate (KH_2PO_4)
3.1.9 Porcine pancreatin extract, activity equivalent to 8x SUP specification
3.1.10 Dispersing solvents, one of:

- acetonitrile
- N,N-dimethylacetamide
- 1,4-dioxane
- ethanol
- methanol
- propan-2-ol
- tetrahydrofuran
- water

3.2 Digestive fluid simulants

3.2.1 Saliva simulant:
Dissolve 4.2 g of sodium bicarbonate ($NaHCO_3$), 0.5 g of sodium chloride (NaCl) and 0.2 g of potassium carbonate (K_2C0_3) in 1 litre of water. The pH of the solution should be approximately 9.

3.2.2 Gastric-juice simulant:
Dilute 0.1 M hydrochloric acid standard solution to a concentration of 0.07 M. The pH of the solution should be 1.2 ± 0.1.

3.2.3 Intestinal-fluid simulant:
NOTE: Care should be taken to ensure that the simulant is prepared in the order given.

Dissolve 6.8 g of potassium dihydrogen orthophosphate (KH_2PO_4) in 250 ml of water, transfer to a 1 L volumetric flask and add 190 ml of 0.2 M sodium hydroxide (NaOH). Add 400 ml of water and shake briefly to mix. Weigh 10.0 g of pancreatin extract into a 250 ml beaker. Add a little water, and stir to make a stiff, homogenous paste. Gradually dilute the paste with small portions of water, stirring well after each dilution, to give approximately 150 ml of a lump-free solution. Transfer the solution to the volumetric flask, rinsing the beaker and funnel with water. Add 0.5 g of sodium taurocholate, gently

shake the flask and make the volume up to the neck of the flask. Adjust the pH of the solution to 7.5 ± 0.1 with 0.2 M sodium hydroxide (NaOH). Make the volume up to the mark with water and shake thoroughly to mix.

4 APPARATUS

NOTE: An instrument or item of apparatus is listed only where it is special, or made to a particular specification, usual laboratory equipment being assumed to be available.

4.1 Glass vials, 100 ml or 125 ml, with crimp-on type PTFE/silicone rubber septa.

4.2 Crimping and decapping pliers.

4.3 Device for mechanical agitation of the simulant, e.g. a flask shaker, or a magnetic stirrer bar for use with a stirrer plate, situated in a cabinet or water bath controlled to a temperature of 37 ± 1°C.

5 SAMPLES

NOTE: The test substance should be of similar purity as the substance used in food contact materials.

5.1 Preparation of stock solutions

Weigh out the required weight of the test substance to the nearest 0.1 mg into a 10 ml volumetric flask and dissolve in a suitable dispersing solvent such as one listed in section 3.1.10. Make the volume up to the mark, and shake the flask thoroughly to mix.

NOTE: The solvent selected must completely dissolve the test substance and must not chemically react with it.

The final concentration of solvent (other than water) in the digestive fluid simulant should not exceed 0.1% (v/v).

The concentration of the test substance in the digestive fluid simulant should be selected such as to enable determination of the substance down to 5% of the amount added to the simulant. Anyhow, that concentration should not be lower than the maximum likely human intake predicted from migration studies.

6 PROCEDURE

6.1 Hydrolysis equation

Set out the hydrolysis equation, using the following model expression:
PC => HP-1 + HP-2 (+ HP-3 +..... HP-N), in which:
PC = parent constituent
HP = hydrolysis product

6.2 Selection of simulants

Select simulants to be used in the test such that the analytical effort is kept to the minimum, e.g. a test with intestinal fluid simulant is often sufficient to demonstrate hydrolysis of esters. So, if the test substance is an ester, a test with intestinal fluid simulant should be carried out first. If complete hydrolysis is demonstrated, it is not necessary to perform tests with other simulants.

6.3 Performance of hydrolysis test

Transfer for each test 100 ml of the digestive fluid simulant to a glass vial using a measuring cylinder. Crimp-seal the vial with a PTFE-silicone rubber septum. Commence shaking the vial or stirring its contents and equilibrate the simulant at 37 ± 1°C.

NOTE: As for analytico-technical reasons each substance in the hydrolysis equation selected for determination has to be assessed in a separate hydrolysis test and each of the determinations has to be carried out in triplicate, the number of glass vials needed for the test amounts to thrice the number of combinations of substances (be it parent constituent or hydrolysis product) to be determined, specified time period and simulant.

Subsequently add a suitable aliquot of the stock solution (25 to 100 µl) to the simulant, using a 100 µl syringe. Inject the solution through the septum, below the surface of the simulant, and continue agitation or stirring for the duration of the test. Take the duration of the test from the following table:

-	saliva simulant	0.5 h
-	gastric-juice simulant	1, 2 and 4 h
-	intestinal-fluid simulant	1, 2 and 4 h

NOTE: If gastric-juice simulant or intestinal-fluid simulant is used for the test, a test for one hour should be performed first. If complete hydrolysis is demonstrated, it is not necessary to perform tests for two and four hours.

6.4 Analysis of hydrolysates

After termination of the hydrolysis test determine the hydrolysis products in the hydrolysate. Use an appropriate analytical method and calculate percentage hydrolysis from the results.

NOTE It is insufficient to only measure disappearance of the parent constituent. A case by case selection should be made about which hydrolysis products need be measured in order to permit a judgement about mass balance.

Suitability of the analytical methods should be demonstrated by performing tests with standard addition of the hydrolysis product(s) of interest set out in the CEN standard format, which can be found in the document "Commission Explanatory Guidance for Migration Testing") (see later).

7 TEST REPORT

The test report should conform to the CEN standard format set out in the document "Commission Explanatory Guidance for Migration Testing")

Annex 2 to Chapter III

POLYMERIC ADDITIVES

Components with a molecular mass above 1000 Dalton (D) are very unlikely to be absorbed by the gastro-intestinal tract and thus are not considered to present a toxicological risk. The value of 1000 D was chosen because it takes into account the effect of the shape of the molecule, which has an important influence on the likelihood of absorption of substances in the molecular mass range 600-1000 D. Below 600 D most substances are absorbed and the rate of absorption is determined by factors other than size and shape of the molecule.

Since only the fraction of the polymeric additive with molecular mass below 1000 D is regarded as toxicologically relevant a distinction has been made between polymeric additives with a weight averaged molecular mass (Mw) below 1000 D and those with Mw above 1000 D. For polymeric additives with Mw above 1000 D, the fraction with molecular mass below 1000 D will vary and a case-by-case consideration of the specification will determine whether further data are required.

The following data should be supplied:

I. Data according to "AFC-FCM-WG Explanatory Guidance to the SCF Guidelines for Food Contact Materials on:

- paragraph 1.4 "Identity"
- paragraph 2 "Properties"
- paragraph 3 "Use"
- paragraph 4 "Authorisation"

II. Genotoxicity data on the monomer(s) according to "SCF Guidelines", unless the monomer(s) are already in SCF lists 0-4.

IIIa. For those additives with Mw less than 1000 D: migration and toxicity data on the polymeric additive itself, according to "SCF Guidelines" with the exception that mutagenicity studies on the polymeric additive itself are not required.

IIIb. For those additives with Mw above 1000 D: data, including migration and toxicity, may be required on the polymeric additive itself once the AFC Panel has examined the specification; especially for those additives containing a significant fraction with molecular mass below 1000 D.

In deciding whether further data are needed, the AFC Panel will take into account both the size of the fraction with molecular weights below 1000 D and the proportion of the additive in the plastic.

N. B. As regards the migration, the level of the migrated fraction with molecular mass less than 1000 D should preferably be supplied. However, if the petitioner(s) is (are) unable to determine this or decides (decide) not to determine the migrated fraction with molecular mass less than 1000 D, the total migration of the polymeric additive will be attributed to the fraction with molecular mass less than 1000 D.

These guidelines apply to polymeric additives in general. The AFC Panel will however consider any scientific arguments put forward by applicants for deviation from the guidelines. For example, in cases of additives made using hydrogenation, or additives in which residual monomers have been removed from the final product, not all the data mentioned in the guidelines may be required.

If relevant toxicological data are available, they may be submitted because they may support evaluation.

Annex 3 to Chapter III

PEROXISOME PROLIFERATION STUDIES

These studies are no longer relevant to the evaluation of substances for Food Contact Materials. Pending an amendment of the SCF Guidelines the reader is kindly asked to consult the relevant statement adopted at the 12th meeting of the AFC Panel on 29 June 2005, which can be found on the EFSA website:
http://www.efsa.eu.int/science/afc/afc_documents/catindex_en.html

Annex 4 to Chapter III

ACCUMULATION IN MAN

This chapter focuses on accumulation in man and not on bioaccumulation in general. Many experts are familiar with the term 'bioaccumulation' as it relates to the fate of a chemical in the environment. It covers e.g. the behaviour in aquatic organisms and potential for accumulation through the food web.

In the case of food contact materials the interest centers on the potential for direct accumulation in mammalian tissues and not on biomagnification through the food chain. However, normally a log $k_{O/W}$ value below 3 would be considered sufficient evidence for the lack of accumulative potential in the mammalian body, unless special considerations, e.g. chemical structure, give cause for concern. On the other hand, a log $k_{O/W}$ of 3 and higher will not by itself be proof of accumulation as a substance may not be absorbed or be metabolised to substances with no accumulation potential. In these circumstances other evidence for the absence of accumulative potential is needed.

It is not possible to give definitive guidance as to the methods to be used, as different approaches must be followed for different substances according to their chemical structures and physical properties. If it can be shown by appropriate kinetic studies (absorption distribution, metabolism, excretion (ADME)) after oral exposure that the biological half-life excludes accumulation, this would be considered sufficient evidence. Furthermore, the use of appropriately radioactively labelled substances and autoradiography can demonstrate the existence/absence of an accumulative potential of a substance.

Guidelines describing in detail the procedures for such studies do not appear to exist, but some relevant information may be found in existing EU guidelines on veterinary drugs, additives in animal nutrition, and human drugs. Also IPCS (EHC70 and EHC57) as well as the FDA Red Book II could be useful sources on possible methodology.

In principle, accumulation is undesirable but not automatically associated with any toxic effects. In cases where accumulation potential has been demonstrated or its lack not demonstrated, it remains the responsibility of the applicant to provide evidence that any accumulation found will not be associated with toxic effects even after long-term exposure.

Annex 5 to Chapter III

DEFINITION OF THE SCF LISTS

The classification into a SCF_List is a tool used for tackling authorisation dossiers and do not prejudice the management decisions that will be taken on the basis of the scientific opinions of the AFC Panel and in the framework of the applicable legislation

List 0
Substances, e.g. foods, 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, e.g. food additives, for which an ADI (=Acceptable Daily Intake), a t-ADI (=temporary ADI), a MTDI (=Maximum Tolerable Daily Intake), a PMTDI (=Provisional Maximum Tolerable Daily Intake), a PTWI (=Provisional Tolerable Weekly Intake) or the classification "acceptable" has been established by this Committee or by JECFA.

List 2
Substances for which a TDI or a t-TDI has been established by this Committee.

List 3
Substances for which an ADI or a 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 or a specific limit of migration is stated. This is because the available toxicological data would give a TDI which allows that a specific limit of migration or a composition limit could be fixed at levels very much higher than the maximum likely intakes arising from present uses of the additive.

List 4 (for monomers)

Section 4A
Substances for which an ADI or TDI could not be established, but which could be used if the substance migrating into foods or in food simulants is not detectable by an agreed sensitive method.

Section 4B
Substances for which an ADI or TDI could not be established, but which could be used if the levels of monomer residues in materials and articles intended to come into contact with foodstuffs are reduced as much as possible.

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 foods or in food simulants is not detectable by an agreed sensitive method.

List 5
Substances which should not be used.

List 6
Substances for which there exist suspicions about their toxicity and for which data is lacking or is insufficient.
The allocation of substances to this list is mainly based upon similarity of structure with that of chemical substances already evaluated or known to have functional groups that indicate carcinogenic or other severe toxic properties.

Section 6A: Substances suspected to have carcinogenic properties. These substances should not be detectable in foods or in food simulants by an appropriate sensitive method for each substance.

Section 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 a TDI could not be established. The required additional information should be furnished.

List 8
Substances for which no or only scanty and inadequate data was available.

List 9
Substances and groups of substances which could not be evaluated due to lack of specifications (substances) or to lack of adequate description (groups of substances).
Groups of substances should be replaced, where possible, by individual substances actually in use.
Polymers for which the data on identity specified in "SCF Guidelines" are not available.

List W
"Waiting list". Substances not yet included in the EU lists, as they should be considered "new" substances, i.e. substances never approved at national level. These substances cannot be included in the EU lists, lacking the data requested by the Committee.

List W7
Substances for which some toxicological data exists, but for which an ADI or a TDI could not be established. The required additional information should be furnished.

List W8
Substances for which no or only scanty and inadequate data was available.

List W9
Substances and groups of substances which could not be evaluated due to lack of specifications (substances) or to lack of an adequate description (groups of substances).

Annex 6 to Chapter III

MODEL FOR A PETITIONER SUMMARY DATA SHEET ("P-SDS")

SUBSTANCE (1)…….....……

USE OF SUBSTANCE
(2).....…….....…….……

REF.N.(3).....…….....

CAS.N.....…….…….……

SOCIETY(4) .....…….……...

PERSON RESPONSIBLE FOR THE TECHNICAL DOSSIER.....…….

ADDRESS OF THE RESPONSIBLE PERSON.....……..
.....…….
.....……..
PHONE.....FAX.....E_MAIL.....……..

Where the technical dossier does not contain all the requested data (see below) give reasons:
.....
.....
.....
.....
.....
.....
.....
.....
.....
.....
.....
.....

(1) Indicate first the most common chemical name of the substance or, in the case, of a substance included in the Directive 2002/72/EC the name given in this Directive.

(2) Specify whether it is monomer or additive.

(3) REF.N. = Substance Reference Number. Indicate this number if it has been given to the substance under examination.

(4) Company on behalf of which the dossier is submitted.

IMPORTANT NOTICE: Always give reference to the technical annex where the full information is included. For example:

1.2.8 molecular weight (Mw) and range:	
	Ref: Technical Annex x-

OR:

5.1 specific migration (SM)	
	Ref: Technical Annex y-

OR:

8.2.1 Subchronic (90d) oral toxicity:	
	Ref: Technical Annex z-

1. IDENTITY OF SUBSTANCE	**In this column the technical information will be provided in summary AS WELL AS THE REFERENCE TO THE TECHNICAL ANNEX where the information can be found in full.**
1.1 individual substance:	
1.1.1 chemical name:	
1.1.2 synonym(s):	
1.1.3 trade name(s):	
1.1.4 CAS Nr:	
1.1.5 molecular and structural formula:	
1.1.6 molecular weight:	
1.1.7 spectroscopic data:	
1.1.8 manufacturing details:	
1.1.9 purity (%):	
1.1.10 impurities (%):	
1.1.11 specifications:	
1.1.12 other information	
1.2 defined mixture:	
1.2.1 chemical name:	
1.2.2 synonym(s):	
1.2.3 trade name(s):	
1.2.4 CAS N°:	
1.2.5 constituents:	
1.2.6 proportions in the mixture:	
1.2.7 molecular and structural formula:	
1.2.8 molecular weight (Mw) and range:	
1.2.9 spectroscopic data:	
1.2.10 manufacturing details:	
1.2.11 purity (%):	
1.2.12 impurities (%):	
1.2.13 specifications	

1.2.14 other information:	
1.3 Non-defined mixture:	
1.3.1 chemical name:	
1.3.2 synonym(s):	
1.3.3 trade name(s):	
1.3.4 CAS N°:	
1.3.5 starting substances:	
1.3.6 manufacturing details:	
1.3.7 substances formed:	
1.3.8 purification by:	
1.3.9 by-products:	
1.3.10 molecular and structural formula:	
1.3.11 molecular weight (Mw) and range:	
1.3.12 purity (%):	
1.3.13 impurities (%):	
1.3.14 spectroscopic data:	
1.3.15 specifications	.
1.3.16 other information:	
1.4 polymer used as additive:	
1.4.1 chemical name:	
1.4.2 synonyms:	
1.4.3 trade name(s):	
1.4.4 CAS N°:	
1.4.5 starting substances:	
1.4.6 manufacturing details:	
1.4.7 additive(s):	
1.4.8 structure of polymer:	
1.4.9 weight averaged molecular mass:	
1.4.10 number averaged molecular mass:	
1.4.11 molecular mass range:	
1.4.12 constituents with molecular mass <1000 (%):	
1.4.13 viscosity, if available:	
1.4.14 melt flow index, if available:	
1.4.15 density (g/cm^3):	
1.4.16 spectroscopic data:	
1.4.17 residual monomers (mg/kg):	
1.4.18 purity (%):	
1.4.19 impurities (%):	
1.4.20 specifications	
1.4.21 other information:	
2. PHYSICAL AND CHEMICAL PROPERTIES OF SUBSTANCE	

2.1	**physical properties**	
2.1.1	**melting point (°C):**	
2.1.2	**boiling point (°C):**	
2.1.3	**decomposition temperature (°C):**	
2.1.4	**solubility (g/l):**	
2.1.5	**octanol/water partition (log Po/w):**	
2.1.6	**other information related to lipophilicity:**	
2.2	**chemical properties**	
2.2.1	**nature:**	
2.2.2	**reactivity:**	
2.2.3	**stability:**	
2.2.4	**hydrolysis:**	
2.2.5	**intentional decomposition/ transformation:**	
2.2.6	**unintentional decomposition/ transformation product(s):**	
2.2.7	**interaction with food substances:**	
2.2.8	**other information:**	
3.	**INTENDED APPLICATION OF SUBSTANCE**	
3.1	**food contact material:**	
3.2	**technological function:**	
3.3	**maximum process temperature (°C):**	
3.4	**maximum percentage in formulation:**	
3.5	**conditions of contact in practice:**	
3.5.1	**contact food:**	
3.5.2	**time and temperature:**	
3.5.3	**surface to volume ratio:**	
3.5.4	**other information:**	
3.6	**treatment of food contact material prior to use:**	
3.7	**other uses:**	
3.8	**other information:**	
4.	**AUTHORISATION OF SUBSTANCE**	
4.1	**EU countries**	
4.1.1	**in Member States:**	
4.1.2	**notified as “new substance” in the context of 6th Amendment of Directive 67/548/EEC**	
4.1.3	**other information:**	
4.2	**non-EU countries**	
4.2.1	**in USA:**	

4.2.2	**in Japan:**	
4.2.3	**in other countries:**	
4.2.4	**other information:**	
4.3	**other information:**	
5.	**DATA ON MIGRATION OF SUBSTANCE**	
5.1	**specific migration (SM)**	
5.1.1	**substance:**	
5.1.2	**test sample:**	
5.1.2.1	**chemical composition:**	
5.1.2.2	**physical composition:**	
5.1.2.3	**density, melt flow index of polymer:**	
5.1.2.4	**dimensions of test sample:**	
5.1.2.5	**dimensions of test specimen:**	
5.1.3	**treatment of test sample prior to testing:**	
5.1.4	**test food(s)/food simulant(s):**	
5.1.5	**contact mode:**	
5.1.6	**contact time and temperature:**	
5.1.7	**surface to volume ratio:**	
5.1.8	**analytical method:**	
5.1.9	**detection/ determination limit:**	
5.1.10	**precision of test method:**	
5.1.11	**recovery:**	
5.1.12	**other information:**	
5.1.13	**results:**	Give the results in a table appropriate to the specific case. An example of table recommended is indicated below.

Table

Simulants	**Time**	**Temperature (° C)**	**Results mg/dm²**	**Results* (mg/kg of food)**

* *Specify clearly the calculations made, mainly as regards the ratio S/V used.*

5.2	**overall migration (OM)**	
5.2.1	**test sample:**	
5.2.2	**treatment of sample prior to testing:**	
5.2.3	**food simulant(s):**	
5.2.4	**contact mode:**	

5.2.5	**contact time and temperature:**	
5.2.6	**surface to volume ratio:**	
5.2.7	**test method:**	
5.2.8	**other information:**	
5.2.9	**results:**	Give the results in a table appropriate to the specific case. An example of table recommended is indicated below.

Table

Simulants	Time	Temperature (° C)	Results mg/dm²	Results* (mg/kg of food)

**) Specify clearly the calculations made, mainly as regards the ratio S/V used.*

5.3	**Quantification and identification of migrating oligomers and reaction products derived from monomers, starting substances and additives:**	
5.3.1	**test sample:**	
5.3.1.1	**chemical composition:**	
5.3.1.2	**physical composition:**	
5.3.1.3	**density, melt flow index of polymer:**	
5.3.1.4	**dimensions of test sample:**	
5.3.1.5	**dimensions of test specimen:**	
5.3.2	**treatment of test sample prior to testing:**	
5.3.3	**test food(s)/food simulant(s) /extraction solvent(s):**	
5.3.4	**contact mode:**	
5.3.5	**contact time and temperature:**	
5.3.6	**surface to volume ratio in migration tests:**	
5.3.7	**analytical method:**	
5.3.8	**detection/ determination limit:**	
5.3.9	**recovery:**	
5.3.10	**other information:**	
5.3.11	**results:**	
6.	**DATA ON RESIDUAL CONTENT OF SUBSTANCE IN THE FOOD CONTACT MATERIAL**	
6.1	**actual content:**	

6.2	**substance**	
6.3	**test sample**	
6.3.1	**chemical composition:**	
6.3.2	**physical composition:**	
6.3.3	**density, melt flow index of polymer:**	
6.3.4	**dimensions of test sample:**	
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EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate D - Food Safety: production and distribution chain
D3 – Chemicals, contaminants and pesticides

CHAPTER IV

It has to be reviewed to take into account the addition of the new simulant 50% ethanol

III/5442/96 Rev. 1-EN

COMMISSION EXPLANATORY GUIDANCE

("**Commission Explanatory Guidance for Migration Testing**")

NOTA BENE
This annex, set out under EC responsibility, was prepared by a task force composed of some government, industrial, CEN and AFC experts. It should not be considered as an AFC Panel or AFC-FCM-WG "FCM" document. This document is strictly related to the Directive 97/48/EC (briefly called "2nd Amendment to Directive 82/711/EEC", which establishes the basic rules for migration testing).

1. Introduction

1.1 This document provides an explanation and guidance on the conducting of prescribed "migration tests" as well as the "substitute" and "alternative" tests. It is particularly aimed at the analysts who carry out testing to ensure compliance, e.g. enforcement authorities, industry, retailers and certification laboratories. It should also be used by the analysts preparing a technical dossier to be submitted to the National Competent Authorities. In principle, there is no relevant basic difference between the tests to be carried out to determine compliance with the EC Directives and the tests required by the AFC Panel to evaluate a substance to be authorised.

1.2 The Commission Services intend to periodically update this document to take account of developments in migration testing. The Commission Services recommend that these guidelines are strictly observed. It should be reminded that:

a) the EC Directives define the legal rules applicable at European level;

b) other EC documents, for example this document or the "SCF Guidelines", explain these rules and their application in practice;

c) the document "Methods of analysis" gives the references and/or the analytical procedures to determine overall migration as well the migration of the specific substances or groups of substances;

If there are discrepancies between CEN and EC documents, brought about for example by periodic updating at different times, then for compliance purposes the EC documents have precedence, unless a Commission document clearly states to the contrary.

2. Migration Testing

2.1 Migration into foodstuffs and into food simulants

Directive 82/711/EEC, as amendment by Directive 93/8/EEC and by Directive 97/48/EC provides for migration limits:

"Verification of compliance of migration into foodstuffs with the migration limits shall be carried out under the most extreme conditions of time and temperature foreseeable in actual use. Verification of compliance of migration into food simulants with the migration limits shall be carried out using conventional migration tests ....."

Therefore these Directives provide two options:

First option: to carry out the migration tests with foodstuffs themselves.

Second option: to carry out the migration tests using food simulants.

It is always possible to determine the migration, mainly the specific migration, directly in foodstuffs in the worst test conditions in order to a) ascertain compliance with the legislation or b) "provide sufficient information to permit estimation of the maximum daily intake of the substance and its impurities as well as its breakdown and reaction products" as prescribed by the "SCF Guidelines".

Alternatively, it is possible to determine the level of migration using the food simulants and the test conditions set out in the Directive 97/48/EC.

2.2 Food simulants

Directives 97/48/EC and 85/572/EEC provide the following four simulants[9]:

- distilled water or water of equivalent quality (simulant A).
- 3% acetic acid (w/v) in aqueous solution (simulant B).
- 10% ethanol (v/v) in aqueous solution (simulant C).
- rectified olive oil (simulant D).

9 The specifications of these food simulants can be found in the document "Methods of Analysis"

However, olive oil can be replaced by other equivalent non-volatile fatty food simulants (see point 2.3). These alternative fatty simulants are also indicated by the abbreviation "Simulant D". Therefore the abbreviation "simulant D" in Directive 97/48/EC refers not only to olive oil but also to each of the other equivalent non-volatile fatty food simulants (e.g. sunflower oil, synthetic mixture of triglycerides).

As simulant D is generally more aggressive than any solid or semi-solid fatty foods, and because of all the food simulants it is usually the most severe, reduction factors are introduced beside certain fatty foods to take into account this greater extraction power (see Directive 85/572/EEC). Therefore in order to establish in these cases whether the sample complies with the limits, the value obtained in the overall or specific migration tests shall be divided by the corresponding reduction factor in Directive 85/572/EEC to the fatty food under examination. If the material or article is intended to come into contact with more than one foodstuff or group(s) or foodstuffs having different reduction factors, various reduction factors shall be applied. If one or more results of such calculation, after consideration of the analytical tolerance, exceed the restriction, then the material is not suitable for that group(s) of foodstuff.

2.3 **Other equivalent non-volatile fatty food simulants (simulants D)**

Directive 97/48/EC, Chapter 1 states the following for olive oil (simulant D):

"However this reference simulant D may be replaced by a synthetic mixture of triglycerides or sunflower oil or corn oil with standardised specifications ("Other fatty food simulants", called "simulants D"). If, when using any of these other fatty food simulants, the migration limits are exceeded, for the judgement of non compliance a confirmation of the result by using olive oil is obligatory, when technically feasible. If this confirmation is not technically feasible and the material or article exceeds the migration limits it shall be deemed not in compliance with the Directive 90/128/EEC."

As clearly stated in the Directive, the use of other equivalent non-volatile fatty food simulants is authorised without any need to check "a priori" its equivalency or its greatest extraction power. In fact the available experimental data showed that the level of migration in these simulants is approximately of the same order or slightly greater than the level obtained with olive oil. Only in the case of legal prosecution due to overall or specific limits being exceeded is it recommended that the results are confirmed by testing with olive oil, provided this is technically feasible.

If the measurement is technically not feasible with olive oil (for valid reasons which should be documented), the values obtained with the alternative equivalent non-volatile fatty food simulant shall be taken as the correct value. A typical example of a valid reason for the use of other equivalent non-volatile fatty food simulants is the presence of an unacceptable amount of interfering components in the olive oil or in the test material. Otherwise the result with the alternative equivalent non volatile fatty simulant remains the only valid result.

2.4 Contact (t,T) conditions for migration tests

Directive 97/48/EC in addition to Annex 1 of Directive 2002/72/EC provides the test conditions (food simulants, contact times and temperatures, etc.) to be followed when conducting migration tests with food simulants. Details relating to the performance of migration experiments, the analytical procedures (apparatus, reagents, samples etc.) and the test methods to determine overall and specific migration levels into food simulants can be found in the CEN documents (see document "Methods of analysis"). As regards the recommendation of the Commission Services see the specific Section of "Practical Guide".

If there are any discrepancies between the CEN and EC documents (Directives or other publications) follow the recommendation of point 1.3 of the introduction of this document.

Other indications in the selection of the contact times and temperatures to be used in migration tests using the food simulants can be found, if considered appropriate, in the document "Explanatory note on the use of t-T Table in Directive 82/711/EEC as amended for selection of conditions in migration testing" included as annex in the document "Commission Explanatory Guidance on Migration Testing".

It should be recognised that all these references are sometimes insufficient to give guidance in the choice of test conditions in real cases. Therefore, the analyst should always carefully consider the potential uses of the material or article under examination and select from the times and temperatures specified in the Directive 97/48/EC and in the above mentioned references documents those which correspond to the worst foreseeable conditions of contact.

Some examples below illustrate the selection of test conditions from the time and temperature conditions occurring in real situations:

- A food contact material designed to be in contact with food during a sterilisation period of 20 minutes at 121ºC, followed by storage at room temperature for 6 months, shall be submitted to the test conditions of 30 minutes at 121ºC followed by 10 days at 40ºC.

- A food contact material that comes into contact with food for 9 seconds at 90ºC, and subsequent storage for 14 days in a refrigerator at temperatures of approximately 10ºC, shall be tested for 10 days at 20ºC. The period at 90ºC is much too short to be relevant and is therefore ignored. In fact in the case given, the rule following which the migration varies linearly with the square root of time and doubles with each 10ºC increase of test temperature can be applied, provided no change in the morphology of the plastic occurs. In so doing, the 9 seconds at 90ºC are equivalent to only about 20 minutes at 40ºC, which is negligible compared to 10 days.

- The packaging of a frozen ready meal which, according to the instructions, can be heated in the packaging in a conventional oven at 200ºC for 30 to 40 minutes shall be tested for 1 hour at 175ºC only. In this case the storage period before heating is not relevant as the test conditions of 1 hour at 175ºC are considered much more severe than the conditions (10 days at 5ºC) to simulate the storage period.

- Articles intended to be filled with hot food at a starting temperature of 85ºC and where the temperature decreases within 15 minutes to a temperature below 70ºC can be tested for 2 hours at 70ºC, if they are not intended to be used for storage, such as coffee cups. It is however also permitted to apply test conditions of 30 minutes at 100ºC as a more severe test.

- In case of hot fill, the temperature of the food after 15 minutes is still above 70ºC, the article shall be tested for 30 minutes at 100ºC.

- If the food in the above sample is subsequently stored for a long period at room temperature, then the material shall be submitted by a combination of test conditions of 30 minutes at 100ºC followed by 10 days at 40ºC.

2.5 Test conditions considered "more severe conditions"

Directive 97/48/EC provides at point 4 of the Annex the following general clause, applicable to all Chapters:

".... it is permissible:

a) to reduce the number of tests to be carried out to that or those which, in the specific case under examination, is (are) generally recognised to be the most severe on the basis of scientific evidence:

b) to omit the migration or the substitute or the alternative tests where there is conclusive proof that the migration limits cannot be exceeded in any foreseeable conditions of use of the material or article".

Further explanation is given in the subsequent paragraphs. In order to recognise the test conditions which should be considered “more severe conditions” the two main elements of these conditions are considered separately i.e. the simulants from one side and the time and temperature from the other side.

2.5.1 Simulants considered "more severe" or "less severe"

Directive 97/48/EC gives in Chapter 1 some examples of simulants considered more severe than others. For materials and articles intended for general purpose use with all four food types, the test with the water simulant is not necessary because water is considered less severe than 3% acetic acid or 10% ethanol simulants. Similarly, for materials and articles intended only for acidic and alcoholic foods the test with 3% acetic acid can be omitted because it is, in principle, considered less severe than the test with 10% ethanol.

It is generally recognised that ethanol 10% can be considered conventionally more severe than the test with water. Moreover, it is generally recognised that the test with acetic acid 3% can be omitted because it is considered less severe than the test with ethanol 10% if the sample does not contain organic and inorganic metals compounds, amines and other substances soluble in acetic acid.

Analysts can find other situations where it is evident that for specific plastics under examination, the test may be omitted, because it is "less severe" than another. A common example of this is the migration of a non-polar substance from a non-polar plastic which

is almost invariably higher into simulant D (olive oil and other fat simulants) than into the aqueous simulants A, B or C. If this is so then the three aqueous simulants may be omitted from testing for the migration of this substance. The only condition to be satisfied is that this omission can be justified "on the basis of scientific evidence".

2.5.2 **Test conditions (times and temperatures) considered "more severe"**

Directive 97/48/EC Chapter 2, point 2 already gives some examples of more severe test conditions. It is recognised in point 2.1 that for plastic materials and articles intended to come into contact with foodstuffs at any condition of time and temperature, the tests with simulants B and C for 4 hours at 100ºC or at reflux temperature and with simulant D for 2 hours at 175ºC should be considered more severe than any other to be selected in practice.

Other situations can easily occur in practice. For instance:

- to carry out a test at a higher temperature avoids testing the sample at a lower temperature if the contact time remains unchanged.

- A food contact material intended to be used in separate applications of contact time and temperature.

  1. long term storage at -20ºC.

  2. long term storage at room temperature.

  3. heating of food in boiling water ("au bain marie").

  should be respectively tested for:

  1. 10 days at 5ºC.

  2. 10 days at 40ºC.

  3. 2 hours at 100ºC or reflux temperature.

  to cover the individual contact conditions. However, the three individual tests may be replaced by one combined test of 2 hours at 100ºC followed by 10 days at 40ºC. That test will cover the three applications mentioned. Alternatively the tests for 10 days at 40ºC and the 2 hour at 100ºC can be performed separately. In that way also the condition of 10 days at 5ºC will be covered.

2.6 **Volatile migrants**

Directive 97/48/EC, Chapter 2, point 3, provides the following clause:

"When testing for the specific migration of volatile substances, the test(s) with simulant(s) shall be performed in a manner which recognises the loss of volatile migrants which may occur in the worst foreseeable conditions of use".

Testing in closed systems (i.e. by total immersion in gas-tight cells) gives more reproducible results and this method should preferably be used in the first instance. This represents a worst-case, however, as for most applications such as bottles, pouches,

containers etc., loss of the volatile substance will occur in actual use with the intended foodstuff. If results obtained in a closed system are within the specific migration limit then the plastic is acceptable for the application being considered. If the migration is above the limit then the plastic should not be rejected but should be re-tested using an exposure protocol more representative of actual use. It should be noted that if there still remains doubt about the validity of the exposure protocol, then for many volatile substances there are methods available to measure migration into the actual foodstuff itself.

2.7 Special cases

2.7.1 Directive 97/48/EC, Chapter 2, point 4.2, provides the following clause:

"If it is found that carrying out the tests under the contact conditions specified in table 3 causes physical or other changes in the test specimen which do not occur under worst foreseeable conditions of use of the material or article under examination, the migration tests shall be carried out under the worst foreseeable conditions of use in which these physical or other changes do not take place".

In some cases it is seen that a food contact material can be used under certain conditions of time and temperature in contact with specified foodstuffs, while the material cannot sustain the test conditions that should be applied in the migration experiments. In this respect the changes are mainly caused by the selection of "more severe" temperature conditions.

For example: take-away meals, such as fried rice with free fat on the surface, which are hot filled in a polystyrene or LDPE tray, will remain for more than 15 minutes at a temperature above 70ºC. In daily practice the tray will be capable of holding the food without any visible changes. As a consequence of the real contact conditions the tray has to be tested with olive oil for a period of 1 hour at 100ºC. It may appear that the tray deforms, or, even worse, deteriorates during contact with fat simulant at 100ºC. In such cases the selected test conditions may be adapted by taking a longer contact period at a lower temperature. As alternative conditions 2 hour 70ºC may be considered in this example. But also conditions of appropriate temperature which prevent the tray from deforming or melting with an adapted time may be selected. In those cases any written report should give notice of the deviations as well as arguments for that deviation.

Swelling of food contact materials during contact with food simulants is not considered to be a relevant change. Usually it will hardly be visible, most likely it will happen in daily use also. Even when using volatile fatty food simulants, swelling should not be considered a significant change of the food contact material.

2.7.2 Directive 97/48/EC, Chapter 2, point 4.4, provides the following clause:

"In those instances where the conventional conditions for migration testing are not adequately covered by the test contact conditions of the table 3 (for instance contact temperatures greater than 175º or contact time less than 5 minutes), other contact conditions may be used which are more appropriate to the case under examination, provided that the selected conditions may represent the worst foreseeable conditions of contact for the plastic materials or articles being studied".

Also in this case the general guideline which could be suggested is that the petitioner or the person responsible of the control give notice of the special conditions used and the reasons for their choice.

2.7.3 Another method for the determination of specific migration level

In principle Directive 2002/72/EC stipulates in annex 1, point 4 that the specific migration level should be determined by "analytical determination of ....the specific quantity of one or more substances... released by the sample ..... (to) the foodstuffs or simulant". It is normal practice to measure the concentration of the substance directly into the food simulant. It is possible in some cases, however, to measure the quantity of substance released by the difference in the concentration in the material or article before (QI) and after (QF) the migration test. This difference (DQIF, difference in quantity, initial minus final) when coupled with the mass of plastic and simulant employed, can be used to calculate the concentration of substance released into the simulant. To conduct this procedure the analyst must ensure that the method used to determine QI and QF has accuracy and precision characteristics sufficient to estimate the value DQIF reliably.

2.8 Substitute tests

2.8.1 Directive 97/48/EC, in point 2 of the Annex, provides the following clause:

"Substitute tests" which use the "test media" under the "conventional substitute test conditions" as set out in Chapter 3 shall be carried out if the migration test using the fatty food simulants (see Chapter 1) is not feasible for technical reasons connected with the method of analysis.

Various situations may occur which justify the use of substitute tests. However there are two main accepted reasons where the substitute tests should be applied, as set out in Chapter 3:

a) when the test with each of the possible simulants D is inapplicable for technical reasons connected with the test (e.g. interferences, incomplete extraction of oil, absence of stability of the weight of the plastic, excessive absorption of fat simulant, reaction of the component with the fat);

b) when the sensitivity of the analytical method in olive oil for specific substances is insufficient and obliges the petitioner to present additional toxicological data to that what reasonably could be expected to be requested by the AFC (e.g. migration not detectable with a detection limit greater than 0.05 mg/kg).

As the criteria under a) is too generic and because the use of substitute tests should be limited as much as possible, particularly in petitions, the analyst should give in the technical dossier the experimental or the theoretical elements which justify the departure from using simulants D. In general the elements requested are:

a) explanation for failure;

b) an outline of the experiments carried out;

c) some relevant data and visual proof, e.g. chromatograms;

d) additional data on the approximate solubility of the substance in the fat simulant as well as in the extraction media used in the substitute test and the stability or expected stability of the substance in olive oil should be provided to help the decision on accepting the extraction medium.

It should be stressed that if the technical difficulties in using olive oil (e.g. interference in the peak of oleic acid) can be avoided by using another simulant D (e.g. HB 307), this latter one should be used.

It should also be stressed that the substitute tests are conventionally deemed equivalent to the tests using simulants D, the reduction factors also apply to the extraction medium used in the substitute tests.

Below some typical examples of replacement or no replacement of simulant D are given.

- Expanded polystyrene samples with an open cell structure will usually absorb a large amount of the fat simulant. The analytical tolerance of 3 mg/dm² will be exceeded when more than approximately 400 mg of fat simulant is absorbed by 1 dm² of test material, taking into account a 1 to 4% analytical error in the determination of the amount of fat simulant. In such cases the determination of overall migration into the fat simulant is not possible unless a more accurate measurement of the amount of fat absorbed by the test sample is available.

- Moisture sensitive materials have to be conditioned to constant weight before and after contact with the fat simulant. It may appear that e.g. for thick polyamide samples constant weight can not be achieved by the prescribed methods given in relevant CEN methods. In such cases the fat test is not applicable and a substitute test should be performed.

- In the gas chromatogram of oil extracted from a test sample, an interference may be observed at the retention time of the prescribed internal standard. If this occurs an alternative internal standard should be used and therefore conducting of substitute tests is not acceptable.

- A polymer sample containing per dm² more than 2 mg of additive -which interferes in the GC determination at the retention time of oleic acid- should be tested using a fat simulant in which the oleic acid is not present. Fat simulants like HB 307 or Miglyol 812 are most appropriate in these circumstances. Substitute test may not be acceptable.

In the determination of the specific migration other difficulties may require the application of substitute tests, such as:

- Reaction of the migrant with the fat simulant. Amines such as hexamethylenediamine and ethylenediamine are known to react with oil constituents of the test material during the contact period with the oil. As a result migration can not be determined. Performance of substitute tests is required.

- Insufficient sensitivity of the analytical method. Typically with low specific migration limits, it may appear that no analytical method is available or can be developed to demonstrate migration to be less than the SML, even when taking a more favourable ratio of volume to contact area (conventionally 1 kg/6 dm²).

Assuming a reasonable effort has been made to develop a sensitive method, the use of a substitute test can be accepted. A typical example is an antioxidant, with a low SML, which cannot be isolated from the fat simulant to an acceptable level.

2.8.2 Directive 97/48/EC, Chapter 3, point 2, provides the following clause, which applies to overall and specific migration:

"By derogation…, it may be possible to omit one or two of the substitute tests … if these tests are generally recognised not appropriate for the sample under consideration on the basis of scientific evidence".

Both overall migration and specific migration are influenced by the physical properties of the polymer, the migrant and the simulant. Without being exhaustive, the following parameters will influence migration into simulants and also mass transfer into test media:

- physical properties and polarity of the polymer;
- diffusivity of the migrant in the polymer;
- Interaction of the simulant or the test medium with the polymer or with the migrants;
- time and temperature conditions of the test.

Penetration of the polymer by olive oil (or other non-volatile fatty simulants) can greatly accelerate the migration process. Therefore the interaction of substitute media with the material should be close or slightly greater than that of simulant D in the corresponding time and temperature conditions (Directive 97/48/EC, Table 4). However the determination of the interaction of the simulant or the test medium with the polymer may be complex. The affinity of a migrant with a food simulant can be reflected in some cases by its solubility in the simulant. In these cases mass transfer is expected to be low when the migrant is poorly soluble in the simulant or in the test medium. Therefore, comparison of the solubility (or solubility range) in simulant D and in test media in the corresponding time and temperature conditions (see Directive 97/48/EC, table 4) may be used as a first indication to help select the most suitable test medium.

For example: Ethanol 95% is a suitable test medium for non-polar polymers such as polyolefines and also for plastics of medium polarity like PVC and PET. However it is inappropriate for strong polar polymers (e.g. PA), for which iso-octane can be used if the limits are exceeded.

It is recommended that analysts maintain the comparison curves of simulant D and the test medium used in the alternative test. These curves should be requested by the national enforcement authorities as well as the Commission Services to verify the validity of the omission of a test medium. These comparison curves shall be always added in the petitions in order to have an EU agreement.

2.8.3 <u>Test media</u>

2.8.3.1 Iso-octane

The majority of published data demonstrate the suitability of iso-octane as a volatile test medium in the substitute fat test for the determination of overall migration. In EC

Research project No 33 revision 1 entitled "Migration testing with conventional and alternative fatty-food simulants" an overview is presented of all comparative data, available at that time (Feb. 1996), using a fat simulant or a volatile test medium. The compilation can be used to indicate suitability of the chosen volatile test medium.

However it should be noted that some special types of polyolefins may give migration values with iso-octane higher of those expected in the real use. Also polystyrene containing more than 6.5% of polybutadiene and/or mineral oil may give high results, while polyamides may give low results.

Data on specific migration into iso-octane are scarcer and use of iso-octane in specific migration testing should therefore be considered on a case by case basis.

As regards the analytical procedure consult the document "Methods of Analysis".

2.8.3.2 Ethanol 95%

The previously mentioned EC study (EC Research project No 33, revision 1) also contains useful data about the use of 95% ethanol as a volatile test medium in substitute tests. Also in that case mainly overall migration data are available.

Usually it is found that a good comparison is obtained between olive oil and 95% ethanol. It is found that 95% ethanol is more suitable for testing polystyrene/butadiene blends than iso-octane. However, it is also the case that values obtained with 95% ethanol tend to give slightly lower results compared to olive oil for most polyolefins.

Data on specific migration into 95% ethanol are relatively scarce and use of 95% ethanol in specific migration testing should therefore be considered on a case by case basis.

As regards the analytical procedure consult the document "Methods of Analysis".

2.8.3.3 Modified polyphenylene oxide (MPPO)

In order to circumvent a number of analytical difficulties caused by the overall migration determination with food simulant D at high temperatures, another test has been developed using MPPO as an absorption test medium. The draft Directive specifies the conditions to be fulfilled before applying this test i.e.:

a) the contact temperature in worst foreseeable use is higher than 70°C;

b) the results obtained in a "comparison test" are equal to or greater than those obtained in the test or with the abovementioned substitute tests or with representative foodstuffs;

c) the migration limits are not exceeded.

Comparative studies with ^{14}C-labelled HB307 have shown that, in experiments with a polypropylene and a polyetherimid tray at test conditions of 2 hours/100°C and 2 hours/175°C, respectively, the MPPO adsorbed amount is equivalent to overall migration in fat simulant D. In addition, further studies with a number of organic substances have

shown that MPPO provides stronger adsorption capacities than real foodstuffs such as pizza, pastry etc.

2.8.3.4 Other substitute media

The cases in which both substitute tests are recognised to be unfeasible for technical reasons connected with the method of analysis should be very rare. However in order to give legal guidance in every possible situation, the text offers the possibility to use other media e.g. MPPO or isopropanol (this last should be used at the same conditions of ethanol 95%).

2.9 Alternative tests

2.9.1 Directive 97/48/EC in Chapter 4, point 1, provides the following clause:

"It is permissible to use the result of alternative tests as specified in this Chapter provided that both the following conditions are fulfilled:

a) the results obtained in a "comparison test" show that the value are equal to or greater than those obtained in the test with simulant D;

b) the migration in alternative test does not exceed the migration limits, after application of appropriate reduction factors provided in Directive 85/572/EEC.

If either or both conditions are not fulfilled, then the migration tests must be performed."

Regarding tests with fatty food simulant, if certain specified conditions are satisfied, the Directive allows the possibility of replacing the tests described in Chapter 1, 2 and 3 either by alternative tests using volatile media, for example iso-octane or ethanol 95%, or by "extraction tests" which are tests with very aggressive volatile solvents used at high temperature.

The Directive does not specify how equivalency or greater severity of the alternative tests should be demonstrated in practice. In practice the frequency will depend on the particular situation under examination. If the alternative tests give the values of the released substances higher than those obtained by simulant D, it is not necessary to frequently repeat the comparison tests (check), provided the process of manufacture ensures a high probability that the reproducibility of the characteristics of the final article are constant. In this situation a check once each year could be sufficient. The check should be repeated more frequently if these conditions are not satisfied.

It should be emphasised that as the alternative tests are conventionally deemed equivalent to or giving higher values than the tests using simulants D, the reduction factors also apply to the alternative tests.

2.9.2 "Alternative test with volatile media"

The Directive does not specify the type of volatile test medium to be used as an alternative to the simulant D and the test conditions to be used. In fact it is impossible to establish a general relationship between the test conditions of simulant D and the alternative volatile test medium.

Therefore each analyst should select the appropriate alternative volatile medium taking into account the general considerations mentioned in point 2.8.2. and construct for each polymer the migration curves (migration against time for the different temperatures prescribed by the Directive according to rules of Chapter 2). From these curves, the test conditions to be used with the alternative test medium should be selected in order to obtain the same results or better, migration values higher than those obtained by simulant D. It is recommended that the choice of test conditions for the alternative volatile medium is such that there is a sufficient margin of the security between the values obtained with olive oil and those (higher) obtained with the volatile medium.

2.9.3 Extraction test

Directive 97/48/EC, Chapter 4, point 3.2, provides the following clause:

"Other tests, which use media having a very strong extraction power under very severe test conditions, may be used if it is generally recognised, on the basis of scientific evidence, that the results obtained using these tests ("extraction tests") are equal to or higher than those obtained in the test with simulant D."

On this basis, rapid extraction tests using appropriate solvents such as diethylether, iso-octane, ethanol 95% have been developed. A strong interaction with the polymer is achieved and, as a consequence, a rapid extraction test is obtained. This allows the amount of potential migrants to be determined which, in general, is higher than the migration into food simulants. These extraction tests are most suitable for the overall migration assessment of flexible packaging plastics with a thickness less than or equal to 300 µm. Appropriate test media were found it be iso-octane for non-polar plastics like polyolefines and 95% ethanol for more polar plastics such as polyamide. In case of doubt, both test media should be applied and the higher result used. Suitable test conditions were found to be 24 hours at 40°C. The method can also be applied to thicker materials provided the overall migration limit of 10 mg/dm² is not exceeded.

The method may also be suitable for specific migration assessment if it can be demonstrated that it achieves almost complete extraction from a polymer to calculate then the maximum possible migration under the assumption of total mass transfer.

Consult also the document "Methods of analysis".

3. Calculation of the maximum possible migration

Maximum possible migration can be calculated on the basis of residual or actual content of the migrant in the polymer sample. For that purpose the content of migrant in the polymer has to be determined by e.g. exhaustive extraction or dissolution of the polymer. This procedure has the advantage that the results can be easily extrapolated to any other food contact article made of the same polymer, with only one test having to be performed.

This calculation is made by applying the following formula:

$$M = \frac{Q \times A \times Lp \times D}{1000}$$

where:

M = is the maximum possible migration of the substance expressed in mg/kg foodstuff or mg/6 dm^2 of food contact material.

Q = is the quantity of the substance in the finished article in mg/kg polymer.

A = is area of the food contact material in cm^2, conventionally set at 600 cm^2.

Lp = is thickness of the food contact material in cm.

Maximum thickness can be set at 0.025 cm which conventionally is assumed to give maximum migration with the exception of plasticised polymers and of the migration of components with low diffusion coefficients (volatile components).

D = is density of the polymer in g/cm^3.

For example:

The residual content of migrant X in a polyethylene with a density of 0.95 (g/cm^3) has been determined to be 4.5 mg/kg polymer. The food contact material is used in a wide range of materials with a maximum thickness of 0.018 cm. Then M = the maximum migration may be:

$$M = \frac{4.5 \times 600 \times 0.018 \times 0.95}{1000} = 0.046 \text{ mg/kg foodstuff}$$

4. Exemptions from migration testing

Verification of compliance with the specific migration limits (SML) shall be ensured by one of the following ways :

a) migration testing according to paragraph 1 (« experimental value »)

b) determination of the quantity of a substance in the finished material or article (Q), *provided that* a relationship between Q and the value of the specific migration (M) of the substance has been established by an adequate experimentation (« estimated value »);

c) determination of the quantity of a substance in the finished material or article (Q), *provided that* a relationship between Q and the value of the specific migration (M) of the substance has been established by the application of generally recognised diffusion models based on scientific evidence.

To judge the non-compliance of a material or article, a confirmation of the estimated migration value by experimental testing is obligatory."[10]

10 An equivalent sentence exist in the 2nd Amendment of Directive 82/711/EEC when the migration limits are exceeded by the fatty simulants other than “Reference olive oil”.

Migration tests can be avoided, for example, in the following circumstances:

a) when the specific limit for the substances to be checked is higher than the overall migration level found in the experiments or by calculation (see Directive 2002/72/EC, article 8, point 2);

b) when assuming a 100% migration (see point 3) the limit(s) cannot be exceeded in any foreseeable conditions[11];

c) when a test may be considered less severe than another according to the criteria established in the EC Directives or in this document;

d) when it can be demonstrated by generally recognised diffusion models that the amount of substance in the material is such that the limit(s) cannot be exceeded in any foreseeable conditions.

e) when a relationship between the quantity of a substance in the finished material or article (Q) and the value of the specific migration (M) of the substance has been established by an adequate experimentation then the migration testing may be replaced by the determination of the substance in finished material or article;

5. Labelling related to the migration testing

Directive 97/48/EC, Chapter 1, point 2.2c, provides the obligation of an appropriate indication when a material or article is intended to be or not to be in contact with some foodstuffs or groups of foodstuffs. According to this rule

"This indication shall be expressed:

(i) at the marketing stages other than retail stage, by using the "reference number" or "description of foodstuffs" provided in the Table of the Directive 85/572/EEC;

(ii) at the retail stage using an indication which shall refer to only a few foods or groups of food, preferably with examples which are easy to understand."

It is known that some films are unable to comply with the migration limits in the fat test unless a reduction factor is applicable. Conventionally called "factor X film", a film which complies with the migration limits in the fat test after the reduction factor equal to X is applied. For instance a film having an overall migration in the fat test of 20 mg/dm² is in compliance with the overall migration limit at 10 only if the foodstuffs in contact have a reduction factor of 2. This film is called "Factor 2 film".

These films, which could be sold as such in supermarkets etc. should be labelled adequately in order to exclude the possibility that consumers might place the film in contact with food or groups of foods not having the appropriate reduction factor.

11 In this case the petitioner should provide an adequate method for the analysis of the substance in the finished product

Some examples of suitable labelling are suggested below:

5.1 Factor 2 films

"Suitable for contact with all foodstuffs except pure fats and oils, and food preserved in an oil medium."

5.2 Factor 3 films

"Suitable for contact with all foodstuffs except pure fats and oils, butter and margarine and food preserved in an oil medium."

5.3 Factor 4 films

“Suitable only for foodstuffs of which the following are examples:

Fresh meat and poultry

Processed meat products

Fried or roasted foods

Fruit and vegetables

Frozen foodstuffs

Bakers products and solid confectionery"

Annex 1 to Chapter IV

GUIDELINES FOR THE DESCRIPTION OF THE METHODS OF ANALYSIS

As stated in "AFC-FCM-WG Explanatory Guidance", a method of analysis must be included in the technical dossier. In order to help the applicant, some general indications are given below. However it is recommended to follow, as much as possible, the format recently adopted at CEN level, which is also reported later.

Methods should be capable of either quantification of the substance in the material or article itself or quantification in appropriate food simulants (or foods) respectively.

Method of analysis should comply with the following format (specimen examples may be seen in EN Methods for Food Contact Materials (See also the document "Methods of Analysis ")

1. Scope
2. Principle
3. Sampling
4. Reagents (Safety precautions)
5. Apparatus
6. Procedure
7. Confirmation
8. Precision
9. Test report

1. SCOPE

   Statement of types of materials and articles for which the method is applicable. Statement of food simulants (or foods) for which the method is suitable. Statement of the limit for which the method is capable of quantitative determination of the substance in the material and article or food simulant (or food).

2. PRINCIPLE

   Statement of the principle that is employed for the determination (for example headspace GC, extraction followed by HPLC, extraction followed by colorimetric determination).

3. REAGENTS

Statement of safety requirements and any special precautions in handling reagents. Statement of purity requirements of substance (obtainable from EC-JRC)[12], internal standard and any special requirements for solvent or reagent purity. Statement of primary and diluted calibrant solutions which should have a concentration range to span the QM or SML limit.

4. APPARATUS

Normal laboratory apparatus can be assumed but any instrument or special piece of apparatus or particular specification should be stated.

The minimum performance of chromatographic methods should be stated in terms of the resolution of the substance to be determined from internal standard, solvent or other components. Examples of columns found to be suitable should be given.

5. SAMPLES

Statement of requirements for taking of representative samples of materials and articles for analysis. For testing with simulants the guide to the selection of conditions and methods of test is stipulated in an EN Method (see the document "Methods of analysis").

6. PROCEDURE

Statement in sufficient detail of how to carry out procedure which should include the manner of preparation of calibration curves, evaluation of data, and final determination graphically or by calculation.

As quantitative extraction from materials and articles can never be fully demonstrated the method of standard addition should always be employed for calibration. For determinations of substances in food simulants an internal standard should always be employed for chromatographic procedures and calibration should be against blank food simulant fortified with the substance in question.

7. CONFIRMATION

The method of analysis must include details for confirmation of test results to be used in cases where the measured QM or SML values have been found to exceed the limits specified in Directive 2002/72/EC and subsequent amendments.

The principle behind the confirmation step is that the technique used is sufficiently different from that first used, that it confers additional assurance of identity and level of putative substance. Thus for example:

12 See "EU and National Authorities"

For volatile substances where GC is employed then confirmation by GV/MS (scanning or selected ion monitoring) is appropriate polarity or derivative formation. For non-volatile substances using HPLC, confirmation can be carried out by GC/MS after formation of a suitable volatile derivative or by using at least one other HPLC column with differing separation characteristics and a different solvent system, and/or stopped-flow scanning UV or fluorescence studies.

8. PRECISION

Statement of the detection limit of the method of analysis and the limit of quantification. The analytical tolerance that will be applied to QM or SML limits will depend on the performance of the method and the calculation of a critical difference value that can only be obtained by inter-laboratory collaborative trial. However, the method should include a statement of the within-laboratory "repeatability" of the method obtained by the proposer of the method or similar laboratory.

9. TEST REPORT

The test report should give the relevant information on the method used.

(extract from CEN document, final version - 18 March 1992)

STANDARD FORMAT FOR DRAFTING OF CEN METHODS FOR DETERMINATION OF PLASTICS CONSTITUENTS IN FOODSTUFFS, FOOD SIMULANTS AND MATERIALS AND ARTICLES

PART 0. EXPLANATORY NOTE

This Standard Format has been prepared by Task Group 4 of Working Group 5 of CEN TC194 'Utensils in contact with food' as a template for drafting analytical methods of test for plastics materials and articles destined to come into contact with foodstuffs.

The analytical methods of test are concerned with the determination of specific migration of plastics constituents into foodstuffs and food simulants and with the determination of residual constituents in plastics materials and articles.

The Standard Format consists of two parts:
Part 1. STANDARD FORMAT sets out the minimum requirement of items to be covered in the description of an analytical method of test. The items are given in a very general way only.

Part 2. GUIDELINE FOR COMPLETION OF STANDARD FORMAT sets out in what way the items in Part 1. can be elaborated in a particular case in order to obtain the full description of the method.

Therefore Part 1 should be read in direct conjunction with Part 2 .

1. **STANDARD FORMAT**

TC194/[PM/REF-Y] [ISSUED]

MATERIALS AND ARTICLES IN CONTACT WITH FOODSTUFFS

PLASTICS

PART [X]. DETERMINATION OF [ANALYTE] IN [MATRIX]

WARNING: [SET OUT]

Contents

Foreword
0 Introduction
1 Scope
2 Principle
3 Reagents
4 Apparatus
5 Samples
6 Procedure
7 Confirmation
8 Precision
9 Test report
[ANNEX]

FOREWORD

This part of European Standard EN [XXX] has been prepared by Working Group 5 of TC194 'Utensils in contact with food' as one of a series of analytical methods of test for plastics materials and articles intended to come into contact with foodstuffs.

The methods of test are concerned with the determination of overall and specific migration of plastics constituents into foodstuffs or food simulants and with the determination of residual content of plastics constituents in the finished plastics product.

[ANNEX]

This part should be read in conjunction with PART 1 of EN [XXX].

0. INTRODUCTION

ANALYTE, FORM], [PM/REF] is a [CONSTITUENT] used in the manufacture of certain plastics materials and articles intended to come into contact with foodstuffs.
After the manufacture residual [ANALYTE] can remain in the finished product and may migrate into foodstuffs coming into contact with that product.

The method described in this European standard allows of the determination of [ANALYTE] in [MATRIX]. The method is to be used in conjunction with Part 1 of EN [XXX] which describes the procedures required prior to the determination of [ANALYTE] in [MATRIX].

The method has been validated by collaborative trial using [MATRIX] (see 8).

1. SCOPE

This part of EN [XXX] describes a method for the determination of [ANALYTE] in [MATRIX].

The method is appropriate for the quantitative determination of [ANALYTE] in approximate analyte concentration range of [RANGE] [MASS]/kg [MATRIX].

2. PRINCIPLE

The level of [ANALYTE] in [MATRIX] is determined by [TECHNIQUE]. Quantification is achieved using [STANDARD].

[CONFIRM].

3. REAGENTS

Reagents and solvents shall be of analytical quality.

3.1 [ANALYTE ST, FORM]
(PURITY)

3.2 [STANDARD, FORM]
(PURITY)

3.3 [REAGENTS]
(PURITY)

3.4 [SOLUTIONS]
(INSTRUCTIONS)
(CONDITIONS)

4. APPARATUS

NOTE An instrument or item of apparatus is listed only where it is special or made to a particular specification, usual laboratory glassware and equipment being assumed to be available.

4.1 [SPECIAL]

5. SAMPLES

The laboratory samples of [MATRIX] to be analysed are obtained as described in PART 1 of EN [XXX]. Analyte-free samples of [MATRIX] of the same type as those to be analysed are also required for use for calibration purposes.

(CONDITIONS)

5.1 Test sample preparation

(DESCRIPTION)

5.2 Calibration sample preparation

(DESCRIPTION)

5.3 Blank sample preparation

(DESCRIPTION)

6. PROCEDURE

6.1 [TECHNIQUE] parameters

(DESCRIPTION)

6.2 Optimisation of instrumentation

(DESCRIPTION)

6.3 Calibration

(DESCRIPTION)

6.4 Execution of determination

(DESCRIPTION)

6.5 Evaluation of data

NOTE The following calculations assume that for all measurements exactly the same weight or volume of [MATRIX] has been used and, for the internal standard, that invariably the same volume of internal standard solution has been added.

6.5.1 [TECHNIQUE] interferences

(DESCRIPTION)

6.5.2 Calculation of analyte level

(DESCRIPTION)

7. CONFIRMATION

In cases where [SML or QM] of [ANALYTE], calculated according to the procedure given in Part 1 of EN [XXX] from the analyte level calculated according to Section 6.5 exceeds the restriction criterion set in Commission Directive 2002/72/EC (SML or QM),

the result of the determination shall be confirmed. The confirmation is qualitative in the sense that it should demonstrate the correct identity of the measured analyte and the absence of interferences. For the purposes of quantitation the result as calculated according to Section 6.5 shall be taken as the true value.

(DESCRIPTION)

8. PRECISION

Method performance has been evaluated by carrying out a precision experiment according to ISO 5725-1990 'Accuracy (Trueness and Precision) of Measurement Methods and Results', Parts 1-6.

8.1 Validation *(N.B. For the applicant this item may be omitted).*

For validation of this method a precision experiment was conducted in [YEAR], involving [NUMBER] laboratories. Each participant in this experiment obtained [NUMBER] samples of [ANALYTE]-free [MATRIX] together with sets of [NUMBER] samples of [MATRIX] fortified with [ANALYTE] at levels of approx. [LEVEL] [MASS]/kg respectively.

Calibration solutions were prepared with comparable concentrations so that the calibration samples could be corrected.

8.2 Repeatability and reproducibility

Evaluation of the results of the precision experiment at a concentration of [LEVEL] [MASS] [ANALYTE]/kg [MATRIX] for the 95% probability level yielded the following performance characteristics:

Repeatability: r = [LEVEL][MASS][ANALYTE]/kg

Reproducibility:R=[LEVEL][MASS][ANALYTE]/kg *(N.B. For the applicant this item may be omitted).*

There was no influence of the calibration method using [STANDARD] on the numerical values of r and R.

8.3 [LIMIT]

The [LIMIT] of [ANALYTE] - measured as equal to the mean content of representative [BLANK] (n _ 20) plus three times the standard deviation of the mean - was found to be in the range of [RANGE] [MASS] [ANALYTE]/kg [MATRIX].
Thus the method is capable of quantitative determination of [ANALYTE] at a minimum level of [LEVEL] [MASS]/kg [MATRIX].

8.4 Critical [ANALYTE] level

The question whether there is a significant difference for the 95% probability level between the restriction for [ANALYTE] - i.e. [RESTRICTION] - and [SML or QM], calculated from the analyte concentration in [MATRIX] determined by this method, can be decided by means of the critical difference CrD95.

If the determined [ANALYTE] level in [MATRIX] exceeds the limit value calculated from the [RESTRICTION] by more than CrD95, [SML or QM] of [ANALYTE] must be considered to exceed the [RESTRICTION].

So, if analyte level and CrD_{95} are expressed in mg/kg [MATRIX]:

Critical [ANALYTE] level = [RESTRICTION] + CrD_{95} mg/kg [MATRIX].

Evaluation of the results obtained in a precision experiment involving [NUMBER] laboratories resulted in:

CrD_{95} = [LEVEL] [MASS]/kg [MATRIX].

9. TEST REPORT

The test report shall contain, as a minimum, the following:

- an identification
- name of laboratory
- name of person responsible for analysis
- date of report
- date of analysis
- analyte
- a reference to this method
- performance characteristics of the method
- sample details, such as:
    - type of food/food simulant/material/article
    - origin and denotation of the sample
    - date and method of obtaining the laboratory sample
    - storage conditions
- results expressed in [MASS] [ANALYTE]/kg [MATRIX]. Results should be reported as the average value from two or more determinations satisfying the repeatability criterion of Section 8.2
- details of confirmation procedure, if any
- reasons for modifications introduced into the test method, if any.

2. GUIDELINE FOR COMPLETION OF STANDARD FORMAT

Expressions between brackets in PART 1. STANDARD FORMAT should be completed as follows:

Method No.:

[PM/REF-Y] = set out EEC PM/REF No. of analyte and Y = version no. of method.

Date of issue:

[ISSUED]= set out month (abbreviated) and year of issue, e.g. 'Feb. 1993'.

PART No.:

[X] = set out part no. of method in European Standard [XXX].

PAGE No.:

[page p of q] = set out p = sequential number of page and q = total number of pages of method description.

Throughout PART 1. STANDARD FORMAT:

[XXX] = number of European Standard
[ANALYTE] = set out food contact material constituent to be determined
[MATRIX] = set out foods and/or food simulants in which food contact material constituent can be determined by this method.

WARNING:

[SET OUT] = set out whether analyte or any other chemical involved in the procedure is hazardous or harmful to health and what precautions must be taken before or during application of the method.

Contents:

[ANNEX] = set out annexes, if any

FOREWORD:

[ANNEX], if any = set out 'Annex to this standard is normative, where applicable'.

0. INTRODUCTION:

[ANALYTE, FORM] = set out analyte to be determined, bruto formula inclusive
[PM/REF] = set out EEC PM/REF No. of analyte

[CONSTITUENT] = set out 'monomer' or 'additive' or 'aid to polymerisation'.

1. SCOPE:

[RANGE] = set out numerical values of analyte concentration range
[MASS] = set out 'µg' or 'mg'.

2. PRINCIPLE:

[TECHNIQUE] = set out principle of method used to determine analyte in matrix, e.g. 'headspace gas chromatography' or 'solvent extraction, then gas chromatography' or 'high performance liquid chromatography', etc.

[STANDARD] = set out whether an internal standard or an external standard is used or whether standard addition is applied.

Note 1: An internal standard should be used whenever possible and an explanation should be offered for not using one.

[CONFIRM] = set out what confirmation procedure is used.

3. REAGENTS:

3.1 [ANALYTE ST, FORM] = set out analyte standard used for calibration, bruto formula inclusive

(PURITY) = set out purity requirements, if any, of analyte standard.

3.2 [STANDARD, FORM] = set out internal or external standard, bruto formula inclusive

(PURITY) = set out purity requirements, if any, of internal standard, if any.

Note 2: In general the internal standard should contain no impurity at > 1% by peak area or peak height which will elute at the same retention time as that of the analyte.

3.3 [REAGENTS] = set out chemicals, other than anal yte standard and internal standard or external standard and solvents involved in the procedure

(PURITY)= set out purity requirements, if any, of reagents and solvents, or set out 'all reagents shall be of analytical quality'.

3.4 [SOLUTIONS]= set out solutions, concentration inclusive, involved in the procedure, such as:

- primary solution of analyte standard
- dilute solution(s) of analyte standard
- solution(s) of internal or external standard
- mobile phase
- reagent solutions
- etc.

(INSTRUCTIONS) = set out detailed instructions for preparation of solutions.

Note 3: Two primary solutions of analyte standard should be prepared and checked against one another with one dilution only. If there is agreement within 5% then further dilute standards are made from only one of the primary standards.

Note 4: Avoid weights of analyte and internal standard larger than 150 mg and also avoid volumes of solvent greater than 100 ml.

(CONDITIONS) = set out conditions of storage and maximum storage time for solutions, as obtained from stability tests.

4. APPARATUS:

4.1 [SPECIAL] = set out special equipment e.g.:

- gas chromatograph, equipped with:
  - automatic headspace sampler
  - alkali flame-ionisation detector
- chromatographic column
- etc.

Note 5: set out column requirements, such as:

- the column must exhibit reasonable peak shape with respect to half-width and asymmetry and must permit the separation of analyte and internal standard
- the column must exhibit minimum overlap of peaks of analyte and internal standard and other substances. A check should be specifically carried out on interference with the internal standard.
- etc.

Note 6: set out examples of columns that have been found suitable for analyte determination - include details of type, dimensions, column flow, temperature etc.

5. SAMPLES:

(CONDITIONS) = set out conditions of storage of samples

Note 7: Analytical determinations should be carried out on duplicate samples, these being duplicate portions of [MATRIX], with at least duplicate measurements (injections) of the final extract.

5.1 Test sample preparation:

(DESCRIPTION) = set out test sample preparation.

5.2 Calibration sample preparation:

(DESCRIPTION) = set out calibration sample preparation.

5.3 Blank sample preparation:

(DESCRIPTION) = set out blank sample preparation.

6. PROCEDURE:

6.1 [TECHNIQUE] parameters:

[TECHNIQUE] = set out 'GC' or 'HSGC' or 'HPLC', etc.

(DESCRIPTION) = set out established parameters or guidance parameters, e.g. injector/column/detector tempera-ture, carrier gas and flow rate, etc.

6.2 Optimisation of instrumentation:

(DESCRIPTION) = set out optimisation of instrumentation.

Note 8: For methods involving GC or HPLC, optimisation will be required in terms of demonstrating adequate specificity and sensitivity. The satisfactory choice of column should be demonstrated, and optimum instrumental parameters should be established, such as:

- injector temperature
- column temperature
- detector voltage/wavelength
- detector temperature
- detector gas flow rate(s)
- carrier gas/elution solvent
- carrier gas flow rate/elution solvent flow rate
- etc.

Some indication should be given of the minimum requirement in terms of detector performance, e.g.: should be able to detect 20 pg on-column of analyte at a signal to noise ratio of 5:1.

6.3 Calibration:

(DESCRIPTION) = set out in what way calibration is achieved.

i. By calibration graph using an internal or external standard:

- the calibration graph shall be constructed from at least five measurements
- concentration range of analyte calibration solutions shall span from x 0.1 specific migration limit (SML) or x 0.1 residual content limit (QM) to x 2.0 SML or x 2.0 QM
- the calibration graph shall be rectilinear
- the correlation coefficient shall be 0.996 or better.

Set out construction of calibration graph.

ii. By calibration graph employing standard addition:

- the sample with no addition of analyte standard solution shall be analysed in triplicate
- addition of analyte standard shall be at three levels, i.e. at sample level, at double and at thrice the sample level
- analyses shall be carried out with at least duplicate measurements (injections) of the final extracts
- the standard addition graph shall be rectilinear
- the standard error on the intercept shall not exceed a coefficient of variation of 10% of the mean value.

Set out construction of calibration graph.

iii. Where recovery experiments are appropriate (e.g. with methods involving extraction, without standardisation and not using standard addition) they shall be carried out in duplicate, using at least three different analyte concentrations. Where correction for recovery is appropriate recovery shall be 70% or better.

Set out recovery experiments.

6.4 Execution of determination:

(DESCRIPTION) = set out execution of the determination.

6.5 Evaluation of data:

6.5.1 [TECHNIQUE] interferences:

[TECHNIQUE] = set out 'GC' or 'HSGC' or 'HPLC', etc.
(DESCRIPTION) = set out possible interferences and set out instructions to solve the problems.

6.5.2 Calculation of analyte level:

(DESCRIPTION) = set out in what manner analyte level in the matrix is calculated.

Note 9: Either a mathematical or a graphical method may be applied to calculate analyte level in the matrix.

7. CONFIRMATION:

[SM or QM] = set out 'specific migration' or 'residual content'

(DESCRIPTION) = set out in what way confirmation is achieved, e.g.:

i. For volatile substances, determined before by a GC-procedure:

i.1 Using gas chromatography/mass spectrometry (GC/MS):

Note 10: If the SML or QM for the analyte and the method allow for more than 20 ng analyte/injection then full mass scanning should be carried out for the supposed analyte peak, looking for a correspondence in the analyte spectrum and in the spectrum of the analyte standard, in terms of presence and correspondence of relative intensities of specified characteristic ions.

If the analyte mass is estimated to be less than 20 ng/injection then the selected ion monitoring (SIM) mode should be used. Confirmation is now achieved by observance of the presence of two characteristic ions - one of those for preference being the molecular ion - at the retention time of the analyte, which in relative abundances agree to ± 10%.

NOTA BENE: SIM conditions could also be stated for quantitative confirmation.

Set out in what way confirmation of determination is carried out.

i.2 Using at least one other column with a different polarity:

Note 11: A peak must be found at the correct retention time for analyte ± 3%, and when measured the quantitative result for the two columns must agree to within ± 10%, or - if within less than 10% - within ± the critical difference CrD95 for the method.

Set out in what way confirmation of determination is carried out.

ii. For non-volatile substances, determined before by an HPLC-procedure:

ii.1 By formation of a volatile derivative:

Note 12: qualitative confirmation may be obtained by formation of a volatile derivative which subsequently is examined by GC/MS as described in Section i.1.

Set out in what way confirmation of determination is carried out.

ii.2 By formation of a non-volatile derivative:

Note 13: Qualitative confirmation may be obtained by formation of a non-volatile derivative which subsequently is subjected to HPLC examination. The shift in retention time as compared to that of the analyte must be found to correspond to within ± 3% with the shift in retention time obtained for the analyte standard.

Set out in what way confirmation of determination is carried out.

ii.3 Using at least one other column with differing separation characteristics and a different solvent system:

Note 14: A peak must be found at the correct retention time for analyte ± 3%, and when measured the quantitative result for the two columns must agree to within ± 10%, or - if within less than 10% - to within ± the critical difference CrD_{95} of the determination.

Set out in what way confirmation of determination is carried out.

ii.4 Using a UV or diode array detector:

Note 15: When using a UV detector, absorbance values for analyte at three separate wavelenghts should agree to within ± 3% with that of the analyte standard. When using a diode array detector, correspondence of spectra of analyte and analyte standard should be obtained.

Set out in what way confirmation of determination is carried out.

8. PRECISION:

8.1 Validation *(N.B. For the applicant this item may be omitted).*

[YEAR]	=	set out year in which precision experiment was performed
[NUMBER]	=	set out number of laboratories or number of samples

[LEVEL]	=	set out numerical values of levels of analyte
[MASS]	=	set out 'µg' or 'mg'.

8.2 Repeatability and reproducibility (N.B. For the applicant the reprodicibility may be omitted):

[LEVEL]	=	set out numerical value of level of analyte
[MASS]	=	set out 'µg' or 'mg
[STANDARD]	=	set out 'internal standard' or 'external standard' or 'standard addition'.

8.3 [LIMIT]:

[LIMIT]	=	set out 'detection limit' or 'determination limit'
[BLANK]	=	set out 'matrix blanks' or 'matrix blanks fortified with analyte at the level of x 0.1 SML' or 'matrix blanks fortified with analyte at the level of x 0.1 QM'
[RANGE]	=	set out numerical values of analyte concentration range
[MASS]	=	set out 'µg' or 'mg'
[LEVEL]	=	set out numerical value of level of analyte.

8.4 Critical [ANALYTE] level:

[RESTRICTION]	=	set out 'SML' or 'QM' or a value derived from one of either of those
[SM or Q]	=	set out 'specific migration' or 'residual content'.
[LEVEL]	=	set out numerical value of level of analyte.
[MASS]	=	set out 'µg' or 'mg'.

9. TEST REPORT:

[MASS]	=	set out 'µg' or 'mg'.

Annex 2 to Chapter IV

EXPLANATORY NOTE" ON THE USE OF t-T TABLE IN DIRECTIVE 82/711/EEC AS AMENDED FOR SELECTION OF CONDITIONS IN MIGRATION TESTING

(called briefly "Guidelines for Selection of Test Conditions")

NOTA BENE: This appendix was prepared by TNO under EC contract.

Introduction

It has already become evident that the text of Chapter II of Directive 93/8/EEC needs some elucidation in order to make interested parties better understand how to select conditions in migration testing (simulant, time and temperature) that would match conditions of contact between foodstuffs and food contact materials in practice.

In order to meet this need an inventory was drawn up in the first place by the Commission Services of conditions of contact between foods and food contact materials practised in the food industry in preparing and storage of packed foods.
Subsequently the data collected was entered into a table which is similar to the one in Directive 85/572/EEC for the classification of foodstuffs.
The contact time in actual use, as presented in the table, are assumed to represent maximum contact time.

In the table conditions for testing such as food simulant, time and temperature are proposed that match the conditions of contact in practice of food and food contact material.

In case of multi-layer materials the contact material is mentioned first (e.g. paper/alufilm). In many cases the packaging consists of various parts that all are in contact with the food (e.g. plastic film/plastic tray). In that case each part should be subject to migration testing.
For the sake of completeness, packaging materials, like glass or coated board, are included which are not yet covered by an EC Directive. These materials are not yet subject to migration testing.

It goes without saying that the list of packed foods in the table is not complete. Interested parties are invited to provide the Commission Services with additional information which would allow the table to be corrected where necessary and to enlarge the number of examples. Cooperation of several experts in food industry as well as of retail store managers in drafting the guidelines is gratefully acknowledged.

Explanation of expressions and abbreviations

dfr	deep-freezer
h	hour
lam	laminate
m	month
mw	microwave
past	pasteurised
pl	plastic
ref	refrigerator (3 - 10°C)
ster	sterilised

Ref.no.	Description of foodstuffs	Food contact material	Simulants to be used A	B	C	D	Contact conditions in actual use (time-temperature)	Test conditions (time-temperature)
01.	**Beverages**							
01.01	non-alcoholic beverages or alcoholic beverages of an alcoholic strength lower than 5 % vol.:							
	beer, various	can		X			0.5h -past (<70°C) + 6m ambient storage	0.5h-70°C + 10d-40°C 1)
	fruit juice, various	coated board					0.5 h past. max (70-100°C) + 1y-ambient	0.5h-100°C + 10d-40°C
	fruit juice, various	can		X			0.5h past (70-100°C) + 1y -ambient	0.5h-100°C+10d-40°C
	lemon juice	pl bottle/pl closure		X			>1y-ambient	10d-40°C
	lemonade syrup	pl bottle/pl closure		X			1y -ambient	10d-40°C
	mineral water	glass bottle/pl closure	X				1y -ambient	10d-40°C
	mineral water	coated board	X				1m -ambient	10d-40°C
	soft drinks, various	can		X			1y -ambient	10d-40°C
	soft drinks, various	pl bottle/pl closure		X			1y -ambient	10d-40°C
01.02	alcoholic drinks of an alcoholic strenght equal to or exceeding 5% vol.:							
	beer, various	glass bottle/pl closure		X	X		0.5h past (<70°C) + 6m ambient	0.5h-70°C + 10d-40°C 1)
	alcoholic drinks	glass bottle/pl closure		X 2)	X 3)		>1y-ambient	10d-40°C
	egg-and-brandy liqueur	glass bottle/pl closure			X 3)		>1y-ambient	10d-40°C
01.03	miscellaneous: non-denatured ethanol							
02.	**cereals, cereal products, pastry, biscuits, cakes and other baker's ware**							
02.01	Starch							
02.02	cereals, unprocessed, puffed and in flakes, including popcorn, corn flakes and the like							
	Muesli	pl sachet					6m -ambient	-
	Popcorn	pl bag					1y -ambient	-
	Rice	pl bag					>1y-ambient	-
02.03	cereal flour and meal							
02.04	pasta (macaroni, spaghetti, vermicelli, etc.)							
	spaghetti, macaroni, etc.	pl bag					1y -ambient	-
02.05	pastry, biscuits, cake and other dry baker's ware							
	A. with fatty substances on the surface							
	biscuits, various	pl tray/pl film				X/5	1y -ambient	10d-40° C
	Cake	pl tray/pl film				X/5	3m -ambient	10d-40°C
	cake base	pl tray/pl film				X/5	6m -ambient	10d-40°C

Ref.no.	Description of foodstuffs	Food contact material	Simulants to be used A	B	C	D	Contact conditions in actual use (time-temperature)	Test conditions (time-temperature)
	cheese crackers	pl film				X/5	1y -ambient	10d-40°C
	fancy cakes	pl tray/pl film				X/5	3m -ambient	10d-40°C
	pastry	pl film				X/5	1m -ambient	10d-40°C
	pastry, various	pl film/pl tray				X/5	1m -ambient	10d-40°C
	salty biscuits, various	pl film				X/5	6m -ambient	10d-40° C
	sand cakes	pl tray/pl film				X/5	6m -ambient	10d-40°C
	spicy biscuits	pe/paper lam				X/5	1m -ambient	10d-40°C
	treacle wafers	pl film				X/5	3m -ambient	10d-40°C
	B. other							
	biscuits, various	pl film					6m -ambient	-
	cocos bread	pl film	X				6m -ambient	10d-40°C
	instant bread	pl bag					3m -ambient	-
	reform biscuits	pl tray/pl film					6m -ambient	-
	rusk	paper + pl film					6m -ambient	-
02.06	pastry, cake and other fresh baker's ware							
	A. with fatty substances on the surface							
	bread, various	pl bag				X/5	1w -ambient	10d-40°C
	buns	pl film				X/5	1w -ambient	10d-40°C
	coffee rolls	pl bag				X/5	1m -ambient	10d-40°C
	fancy pastries, various	pl film/pl tray				X/5	1w -ref	10d-20°C
	B. other							
	flans, various	pl film/pl tray	X				1w -ref	10d-20°C
	gingerbread	pl film	X				3m -ambient	10d-40°C
	pastry, various	pl tray/pl film	X				1m -ambient	10d-40°C
	puffs	pl tray	X				1w -ref	10d-20°C
	sugar bread	pl bag	X				1m -ambient	10d-40°C
03.	**chocolate, sugar and products thereof, confectionery**							
03.01	chocolate, chocolate-coated products, substitutes and products coated with substi-tutes							
	chocolate bars, various	paper/alufilm				X/5	6m -ambient	2d-20°C 4)
	chocolate granules	pl sachet				X/5	1y -ambient	10d-40°C
	pralines	pl tray				X/5	6m -ambient	10d-40°C
03.02	confectionery							
	A. in solid form							
	I. with fatty substances on the surface							
	II. other							
	marsh mellows	pl bag					1y -ambient	-
	sugared caraway seeds	pl sachet					1y -ambient	-

Ref.no.	Description of foodstuffs	Food contact material	Simulants to be used A	B	C	D	Contact conditions in actual use (time-temperature)	Test conditions (time-temperature)
	sweets, various	pl sachet					1y -ambient	-
	B. in paste form: I. with fatty substances on the surface							
	II. moist							
03.03	sugar and sugar-based products							
	A. in solid form							
	moist sugar	pl bag	X				>1y-ambient	10d-40°C
	sugar	paper					1y -ambient	-
	B. honey and the like							
	honey	glass pot/pl closure	X				1y -ambient	10d-40°C
	C. molasses and sugar syrup							
04.	**fruit, vegetables and products thereof**							
04.01	whole fruit, fresh or chilled							
	apples	pl bag					1w -ambient	-
	citrus fruit	pl bag					1w -ambient	-
	citrus fruit	pl net					1w -ambient	-
	cucumber	pl film					1w -ambient	-
	grapes	pl bag					1w -ambient	-
	passion fruit	pl box					1w -ambient	-
	strawberries	pl box					1w -ambient	-
04.02	processed fruit							
	A. dried or dehydrated fruit, whole or in the form of flour or powder							
	fruit snacks	can					>1y-ambient	-
	subtropical fruit	pl sachet					1y -ambient	-
	sultanas, various	pl sachet					1y -ambient	-
	B. fruit in the form of chunks, purée or paste							
	apple sauce	glass pot/twist-off cap		X			1h -ster (100-125°C) + >1y-ambient	1h-121°C + 10d-40°C
	apple sauce	can		X			1h -ster (100-125°C) + >1y-ambient	1h-121°C + 10d-40°C
	C. fruit preserves (jams and similar products - whole fruit or fruit chunks, flour or powder, preserved in a liquid medium):							
	I. in an aqueous medium							

Ref.no.	Description of foodstuffs	Food contact material	Simulants to be used A	B	C	D	Contact conditions in actual use (time-temperature)	Test conditions (time-temperature)
	jams, various	glass pot/twist-off cap	X(a)	X(a)			hot fill (<15 min, 70-100°C) + >1y-ambient	0.5h-100°C + 10d-40°C 5)
							hot fill (>15min, 70-100°C) + >1y-ambient	0.5h-100°C + 10d-40°C
	olives	pl sachet	X				>1y-ambient	10d-40°C
	II. in an oily medium							
	III. in an alcoholic medium (≥ 5% vol.)							
04.03	nuts (peanuts, chestnuts, almonds, hazelnuts, walnuts, pine kernels and other):							
	A. shelled and dried							
	nut chips, various	pl sachet					1y -ambient	-
	B. shelled and roasted							
	nuts, various	pl sachet				X/5 6)	6m -ambient	10d-40°C
	C. in the form of paste of cream							
	hazelnut cream	glass pot/pl closure	X			X/5	1y -ambient	10d-40°C
	peanut butter	glass pot/pl closure				X/3	1y -ambient	10d-40°C
04.04	whole vegetables and potatoes, fresh or chilled							
	aubergines	pl film					1w -ambient	-
	beetroot	pl film					1w -ref	-
	broccoli	pl film					1w -ambient	-
	cabbage, various	pl film					1w -ambient	-
	cabbage, various	pl film					1w -ref	-
	carrot	pl film					1w -ambient	-
	carrots	pl bag					1w -ref	-
	celery	pl bag					1w -ambient	-
	endive	pl film					1w -ref	-
	haricots verts	pl box					1w -ambient	-
	icicles	pl bag					1w -ambient	-
	lettuce	pl film					1w -ref	-
	maize-ear	pl film					1w -ambient	-
	mushrooms	pl box					1w -ref	-
	onions	pl net					1w -ambient	-
	paprikas	pl film					1w -ambient	-
	potatoes	pl bag					1w -ambient	-
	red peppers	pl bag					1w -ambient	-
	tomatoes	pl box					1w -ambient	-
04.05	processed vegetables:							
	A. dried of dehydrated vegetables, whole or in the form of flour of powder							
	cabbage, various	alufoil					<1y -ambient	-

Ref.no.	Description of foodstuffs	Food contact material	Simulants to be used A	B	C	D	Contact conditions in actual use (time-temperature)	Test conditions (time-temperature)
	B. vegetables, cut or in the form of purée							
	potato, cut	pl bag	X				1d -ref	10d-20°C
	rhubarb, cut	pl bag		X			1w ref	10d-20°C
	selected vegetables for bami	pl tray/pl film	X				1w -ref	10d-20°C
	tomato-puree	coated board		X			>1y-ambient	10d-40°C
	tomato-puree	can		X			0.5h -ster (100-125°C) +>1y -ambient	0.5h-121°C + 10d-40°C
	instant potatoes	pl bag					1w -dfr	-
	C. preserved vegetables:							
	sauerkraut	pl bag		X			3m -ambient	10d-40°C
	I. in an aqueous medium							
	beans, various	glass pot/twist-off cap	X				1h -ster (100-125°C) + >1y-ambient	1h-121°C + 10d-40°C
	celery salade	glass pot/twist-off cap	X				1h -past (70-100°C) + >1y-ambient	1h-100°C + 10d-40°C
	cocktail mix	glass pot/twist-off cap	X				1h -past (70-100°C) + >1y-ambient	1h-100°C + 10d-40°C
	gherkin	glass pot/twist-off cap		X			1h -past (70-100°C) + >1y-ambient	1h-100°C + 10d-40°C
	green peas	glass pot/twist-off cap	X				1h -ster (100-125°C) + >1y-ambient	1h-121°C + 10d-40°C
	marrowfat pea	can	X				1h -ster (100-125°C) + >1y-ambient	1h-121°C + 10d-40°C
	olives, filled	glass pot/twist-off cap	X				0.5h -past (70-100°C) + >1y-ambient	0.5h-100°C + 10d-40°C
	piccalilli	glass pot/twist-off cap		X			0.5h -past (70-100°C) + >1y-ambient	0.5h-100°C + 10d-40°C
	red cabbage	glass pot/twist-off cap	X				1h -ster (100-125°C) + >1y-ambient	1h-121°C + 10d-40°C
	silver onions	glass pot/twist-off cap		X			0.5h -past (70-100°C) + >1y-ambient	0.5h-100°C + 10d-40°C
	vegetables in pickle	glass pot/twist-off cap		X			0.5h -past (70-100°C) + >1y-ambient	0.5h-100°C + 10d-40°C
	vegetables preserves, various	can	X(a)	X(a)			1h -ster (100-125°C) + >1y-ambient	1h-121°C + 10d-40°C
	vegetables salad	glass pot/twist-off cap	X				0.5h -past (70-100°C) + >1y-ambient	0.5h-100°C + 10d-40°C
	wine-sauerkraut	glass pot/twist-off cap		X			0.5h -past (70-100°C) + >1y-ambient	0.5h-100°C + 10d-40°C
	II. in an oily medium							
	III. in an alcoholic medium (≥ 5% vol.)							
05.	**fats and oils**							
05.01	animal and vegetable fat, whether natural or treated (including cocoa butter, lard, resolidified butter)							
	cooking fat	paper				X	1y -ambient	2d-20°C 4)
	corn oil	pl bottle/pl closure				X	>1y-ambient	10d-40°C
	frying fat	paper				X	6m -ambient	2d-20°C 4)
	sunflower oil	pl bottle/pl closure				X	>1y-ambient	10d-40°C
05.02	margarine, butter and other fats and oils made from water-in-oil emulsions							
	butter	paper/al lam				X/2	3m -ref	10d-20°C
	halvarine	pl tub				X/2	3m -ref	10d-20°C
	margarine	paper				X/2	3m -ref	1d-20°C 4)
06.	**animal products and eggs**							

Ref.no.	Description of foodstuffs	Food contact material	Simulants to be used A	B	C	D	Contact conditions in actual use (time-temperature)	Test conditions (time-temperature)
06.01	fish:							
	A. fresh, chilled, salted, smoked							
	eel	pl sachet	X			X/3	2w -ref	10d-20°C
	mackerel, smoked	pl sachet	X			X/3	3m -ambient	10d-40°C
	salmon	pl vacupack	X			X/3	2w -ambient	10d-40°C
	B. in the form of paste							
06.02	crustaceans and molluscs (including oysters, mussels, snails) not naturally protected by their shells							
06.03	meat of all zoological species (including poultry and game):							
	A. fresh, chilled, salted, smoked							
	beef heart	pl tray/pl film	X			X/4	1w -ref	10d-20°C
	beefsteak	pl tray/pl film	X			X/4	1w -ref	10d-20°C
	beef, slices	pl tray/pl film	X			X/4	1w -ref	10d-20°C
	chicken chops	pl tray/pl film	X			X/4	1w -ref	10d-20°C
	chicken filet	pl tray/pl film	X			X/4	1w -ref	10d-20°C
	chicken, pieces	pl tray/pl film	X			X/4	1w -ref	10d-20°C
	hamburger	pl tray/pl film	X			X/4	1w -ref	10d-20°C
	liver	pl tray/pl film	X			X/4	1w -ref	10d-20°C
	pork chop	pl tray/pl film	X			X/4	1w -ref	10d-20°C
	rib of beef	pl tray/pl film	X			X/4	1w -ref	10d-20°C
	steak	pl tray/pl film	X			X/4	1w -ref	10d-20°C
	turkey schnitzel	pl tray/pl film	X			X/4	1w -ref	10d-20°C
	turkey, pieces	pl tray/pl film	X			X/4	1w -ref	10d-20°C
	turkey, sausages	pl tray/pl film	X			X/4	1w -ref	10d-20°C
	B. in the form of paste or cream							
	beef rolls	pl tray/pl film	X			X/4	1w -ref	10d-20°C
	beef, minced	pl tray/pl film	X			X/4	1w -ref	10d-20°C
	brawn	pl tray		X		X/4	1m -ref	10d-20°C
	liver pie	can	X			X/4	0.5h -ster (100-125°C) + >1y-ambient	0.5h-121°C + 10d-40°C
	minced meat, mixed	pl tray/pl film	X			X/4	1w -ref	10d-20°C
	pate ardennois	pl tray	X			X/4	1w -ref	10d-20°C
	pate spread	pl tray	X			X/4	1m -ref	10d-20°C
	pork rolls	pl tray/pl film	X			X/4	1w -ref	10d-20°C
06.04	processed meat products (ham, salami, bacon and other)							
	bacon, sliced	pl sachet	X			X/4	1w -ref	10d-20°C
	cooked sausage, sliced	pl sachet	X			X/4	1w -ref	10d-20°C
	corned beef	can	X			X/4	0.5h -ster (100-125°C) + >1y-ambient	0.5h-121°C + 10d-40°C
	corned beef, sliced	pl sachet	X			X/4	1w -ref	10d-20°C
	ham	can	X			X/4	1h -ster (100-125°C) + >1y-ambient	1h-121°C + 10d-40°C

Ref.no.	Description of foodstuffs	Food contact material	Simulants to be used A	B	C	D	Contact conditions in actual use (time-temperature)	Test conditions (time-temperature)
	ham, sliced	pl sachet	X			X/4	1w -ref	10d-20°C
	liver sausage, sliced	pl sachet	X			X/4	1w -ref	10d-20°C
	liver sausage	casing	X			X/4	1h -cook + 1m -ambient	1h-100°C + 10d-40°C
	luncheon meat	can	X			X/4	0.5h -ster (100-125°C) + >1y-ambient	0.5h-121°C + 10d-40°C
	minced-meat ball	pl vacupack	X			X/4	1m -ref	10d-20°C
	salami	casing	X			X/4	1w -ambient	10d-40°C
	sausage	pl bag	X			X/4	3m -ambient + 1,5min-mw	10d-40°C + 0.5h-130°C 7)
	sausages, various	pl sachet	X			X/4	1y -ambient	10d-40°C
	sausage, sliced	pl sachet	X			X/4	3m -ref	10d-20°C
	saveloy, sliced	pl sachet	X			X/4	3m -ref	10d-20°C
	smoked sausage	pl bag	X			X/4	1m -ambient + 2,5min-mw or 1m -ambient + 15 min au bain marie	10d-40°C + 0.5h-130°C 7) 10d-40°C + 0.5h-100°C
06.05	preserved and partly preserved meat and fish:							
	A. in an aqueous medium							
	bismarck herring	glass pot/twist-off cap		X			0.5h past (<70°C) + 3m -ambient	0.5h-70°C + 10d-40°C 1)
	herring filets in tomato sauce	can		X			0.5h -ster (100-125°C) + >1y-ambient	0.5h-121°C + 10d-40°C
	crab	can	X				0.5h -ster (100-125°C) + >1y-ambient	0.5h-121°C + 10d-40°C
	minced-meat balls	can	X				0.5h -ster (100-125°C) + >1y-ambient	0.5h-121° C + 10d-40°C
	minced-meat soup balls	can	X				0.5h -ster (100-125°C) + >1y-ambient	0.5h-121°C + 10d-40 °C
	mussels	can	X				0.5h -ster (100-125°C) + >1y-ambient	0.5h-121°C + 10d-40° C
	mussels in pickle	glass pot/twist-off cap		X			0.5h -past (>70°C) + 1y -ambient	0.5h-100°C + 10d-40°C
	Frankfurter	can	X				0.5h -ster (100-125°C) + >1y-ambient	0.5h-121°C + 10d-40°C
	sausages	glass pot/twist-off cap	X				0.5h -ster (100-125°C) + >1y-ambient	0.5h-121°C + 10d-40°C
	sausages	can	X				0.5h -ster (100-125°C) + >1y-ambient	0.5h-121°C + 10d-40°C
	shrimps	can	X				0.5h -ster (100-125°C) + >1y-ambient	0.5h-121°C + 10d-40°C
	B. in an oily medium							
	anchovy	can				X	0.5h -ster (100-125°C) + >1y-ambient	0.5h-121 °C + 10d-40°C
	fish in oil, various	can				X	0.5h -ster (100-125°C) + >1y-ambient	0.5h-121°C + 10d-40°C
	salmon	can				X	0.5h -ster (100-125°C) + >1y-ambient	0.5h-121°C + 10d-40°C
	sardines	can				X	0.5h -ster (100-125°C) + >1y-ambient	0.5h-121°C + 10d-40°C
	tuna fish	can				X	0.5h -ster (100-125°C) + >1y-ambient	0.5h-121°C + 10d-40°C
06.06	eggs not in shell:							
	A. powdered or dried							
	eggs, whole, powdered	can					>1y -ambient	-
	B. other							
06.07	egg yolk							
	A. in liquid form							
	B. frozen or powdered							
06.08	dried white of egg							
07.	**dairy products**							

Ref.no.	Description of foodstuffs	Food contact material	Simulants to be used A	B	C	D	Contact conditions in actual use (time-temperature)	Test conditions (time-temperature)
07.01	milk:							
	A. whole milk							
	cocoa milk	pl bottle/pl closure	X				6m -ambient	10d-40°C
	cocoa milk	coated board	X				6m -ambient	10d-40°C
	milk	coated board	X				1w -ref	10d-20° C
	milk	coated board	X				6m -ambient	10d-40°C
	milk	pl bottle/pl closure	X				6m -ambient	10d-40°C
	B. partly dehydrated							
	coffee creamer	coated board	X				6m -ambient	10d-40°C
	coffee creamer	al cup	X				6m -ambient	10d-40°C
	milk, condensed	can	X				0.5h -ster (100-125°C) + >1y-ambient	0.5h-121°C + 10d-40°C
	C. skimmed or partly skimmed							
	curdled milk	pl tub	X				1w -ref	10d-20°C
	D. dried							
07.02	fermented milk products like yoghurt and buttermilk and mixtures thereof with fruit or fruit products							
	buttermilk	coated board		X			1w -ref	10d-20°C
	dressing (yoghurt), fresh	pl pot		X			3m -ref	10d-20°C
	yoghurt	coated board		X			1w -ref	10d-20°C
	yoghurt	pl pot		X			3m -ref	10d-20°C
	yoghurt drink	coated board		X			6m -ambient	10d-40°C
07.03	cream and sour cream							
	cream	pl pot	X				1w -ref	10d-20°C
07.04	cheese:							
	A. whole and with rind							
	cheese, various a	rind					1w -ref	-
	B. processed							
	cheese, various	pl tub/pl film	X			X/3	1w -ref	10d-20°C
	C. other							
	brie soft cheese	pl film	X			X/3	2w -ref	10d-20°C
	cheese spread	al cup	X			X/3	1y -ref	10d-20°C
1122	cheese, grinded	pl sachet	X			X/3	1m -ref	10d-20°C
	cheese, sliced	pl box	X			X/3	3m -ref	10d-20°C
	cheese, various	pl film/p tub	X			X/3	3m -ref	10d-20°C
	cottage cheese	pl pot	X				1w -ref	10d-20°C
	feta	pl tray		X			3m -ref	10d-20°C

Ref.no.	Description of foodstuffs	Food contact material	Simulants to be used A	B	C	D	Contact conditions in actual use (time-temperature)	Test conditions (time-temperature)
	monchou soft cheese	paper/al lam	X			X/3	3m -ref	10d-20°C 8)
	paturain soft cheese	pl tub/pl closure	X			X/3	1m -ref	10d-20°C
	stmoret soft cheese	pl tray/pl closure	X			X/3	3m -ref	10d-20°C
07.05	rennet:							
	A. in liquid or semi-liquid form							
	B. powdered or dried							
07.06	milk products, processed							
	custard, various	coated board	X				6m -ambient	10d-40°C
	custards, various	coated board	X				1w -ref	10d-40°C
	pudding	pl pot	X				3m -ref	10d-20°C
08.	**miscellaneous products**							
08.01	vinegar							
	vinegar	pl bottle/pl closure		X			>1y-ambient	10d-40°C
08.02	fried or roasted foods:							
	A. fried potatoes, fritters and the like							
	chips, various	pl bag				X/5	6m -ambient	10d-40° C
	instant patates frites	pl bag				X/5	>1y-dfr	-
	kroepoek	pl bag				X/5	3m -ambient	10d-40°C
	B. of animal origin							
	beefburger	alufoil pack				X/4	1y -ambient + 0.5h- au bain marie	10d-40°C + 0.5h-100°C
	hamburger	alufoil pack				X/4	1y -ambient + 0.5h- au bain marie	10d-40°C + 0.5h-100°C
	hot dog, prep	coated board				X/4	1y -dfr + 30sec-mw	1h-60°C 4)
08.03	preparations for soups or broth, in liquid or powder form, extracts and concentrates, prepared dishes, homogenised composite food preparations:							
	A. powdered or dried							
	I. with fatty substance on the surface							
	dishes, various	pl pot				X/5	3m -ambient	10d-40°C
	meat juice, powdered	pl sachet				X/5	>1y-ambient	10d-40°C
	sauce powder, various	pl sachet				X/5	1y -ambient	10d-40°C
	soup powder, various	alufilm				X/5	>1y-ambient	10d-40°C
	II. other							
	B. liquid or paste:							
	I. with fatty substance on the surface							
	babi pangang, prep	alutray	X			X/3	1y -dfr + 10min-mw, or 1y -dfr + 0.5h -oven (>150°C)	0.5h reflux(sim A) / 0.5h-130°C(sim D) 0.5h reflux(sim A) / 0.5h-130°C(sim D)

Ref.no.	Description of foodstuffs	Food contact material	Simulants to be used A	B	C	D	Contact conditions in actual use (time-temperature)	Test conditions (time-temperature)
	babi sateh, prep	alutray	X			X/3	1y -dfr + 10min-mw, or 1y -dfr + 0.5h -oven (>150°C)	0.5h reflux(sim A) / 0.5h-130°C(sim D)
	baked rice, prep	coated board	X			X/3	2w -ref	10d-20°C 8)
	beef salade	pl tray	X	X		X/3	1m -ref	10d-20°C
	cannelloni, prep	coated board	X			X/3	1y -dfr + 10min-mw, or 1y -dfr + 0.5h -oven (>150°C)	0.5h-100°C (sim A) / 0.5h-130°C (sim D) 9)
	chicken curry, prep	coated board	X			X/3	1y -dfr + 10min-mw, or 1y -dfr + 0.5h -oven (>150°C)	0.5h-100°C (sim A)/ 0.5h-130°C (sim D) 9)
	lasagna, prep	alu tray	X			X/3	1y -dfr + 10min-mw, or 1y -dfr + 0.5h -oven (>150°C)	0.5h-100°C (sim A)/ 0.5h-130°C (sim D)
	macaroni dish	can	X			X/3	0.5h -ster (100-125°C) + >1y-ambient	0.5h-121°C + 10d-40° C
	meat extract	glass pot/twist-off cap	X			X/3	0.5h -ster (100-125°C) + 1y -ambient	0.5h-121°C + 10d-40°C
	mihoun with chicken, prep	alu tray	X			X/3	1y -dfr + 10min-mw, or 1y -dfr + 0.5h -oven (>150°C)	0.5h-100°C (sim A)/ 0.5h-130°C (sim D)
	paella, prep	coated board	X			X/3	1y -dfr + 10min-mw, or 1y -dfr + 0.5h-oven (>150°C)	0.5h-100°C (sim A)/ 0.5h-130°C (sim D) 9)
	quiche, prep	coated board	X			X/3	2w -coolcab	10d-5°C 10)
	ragout	can	X			X/3	0.5h -ster (100-125°C) + >1y-ambient	0.5h-121°C + 10d-40°C
	salads, various	PL tray		X		X/3	1w -reef	10d-20°C
	salmon with herbs, prep	coated board	X			X/3	1w -reef + 4min-mw	0.5h-100°C (Siam A)/ 0.5h-130°C (Siam D) 9)
	spaghetti, prep	salutary/alveoli	X			X/3	1y -ambient + 0.5h-au ban Marie	10d-40°C + 0.5h-100°C
	vegetarian hamburger	PL tray/PL film	X			X/3	1w -reef	10d-20°C
	vegetarian kebab	PL tray/PL film	X			X/3	1w -reef	10d-20°C
	vegetarian schnitzel	PL tray/PL film	X			X/3	1w -reef	10d-20°C
	II. other							
	potato/endive, prep	salutary/alveoli	X				1w -ambient + 0.5h-au ban Marie	10d-40°C + 0.5h-100°C
	tomato soup, prep	PL pot/PL closure		X			2w -reef + 3min-mw	10d-20°C + 0.5h-100°C
08.04	yeast and raising agents:							
	A. in the form of paste							
	B. dried							
08.05	table salt							
08.06	sauces:							
	A. no fatty substance on the surface							
	ketchup	PL bottle/PL closure		X			1y -ambient	10d-40°C
	ketchup	glass bottle/pl closure		X			1y -ambient	10d-40°C
	salade dressing, light	glass bottle/pl closure	X	X			>1y-ambient	10d-40°C
	sauces, various	glass bottle/pl closure		X			6m -ambient	10d-40°C
	soy-bean sauce	pl bottle/pl closure	X				1y -ambient	10d-40°C
	B. mayonnaise, sauces derived from mayonnaise, salad dressings and other oil-in-water emulsions							

Ref.no.	Description of foodstuffs	Food contact material	Simulants to be used A	B	C	D	Contact conditions in actual use (time-temperature)	Test conditions (time-temperature)
	fried potato sauce	pl pot/pl closure		X		X/3	6m -ambient	10d-40°C
	mayonnaise	glass pot/twist-off cap		X		X/3	>1y-ambient	10d-40°C
	mayonnaise	al tube/pl closure		X		X/3	6m -ambient	10d-40°C
	salade cream	glass bottle/pl closure		X		X/3	6m -ambient	10d-40°C
	salade dressing	glass bottle/pl closure		X		X/3	6m -ambient	10d-40°C
	sandwich spread	glass pot/twist-off cap		X		X/3	0.5h -past (70-100°C) + 1y -ambient	0.5h-100°C + 10d-40°C
	sauces, various	glass pot/twist-off cap	X(a)	X(a)		X/3	0.5h -past (70-100°C) + >1y-ambient	0.5h-100°C + 10d-40°C
	sauces, various	glass bottle/pl closure	X(a)	X(a)		X/3	(0.5h past (70-100°C) + 6m -ambient	0.5h-100°C + 10d-40°C
	C. containing oil and water in distinct layers							
08.07	mustard (except powdered mustard as under heading 08.17)							
	mustard	glass pot/pl closure		X		X/3	>1y-ambient	10d-40°C
08.08	sandwiches, toasted bread and the like containing any kind of foodstuff:							
	A. with fatty substance on the surface							
	sandwiches	pl bag				X/5	1d -ambient	24h-40°C
	B. other							
08.09	ice cream							
	ice-cream	pl box	X				>1y-dfr10d-5°C	
	ice-cream, magnum	paper					1y -dfr	-
	ice-cream, snickers	paper					1y -dfr	-
	ice-lolly	paper					>1y-dfr	-
08.10	dried foods:							
	A. with fatty substance on the surface							
	B. other							
08.11	frozen or deep-frozen foods							
	bavarois pudding	coated board					1y -dfr	-
	beans	coated board					1y -dfr	-
	cod filet	coated board					1y -dfr	-
	croquettes	coated board					1y -dfr	-
	cuttle-fish	coated board					1y -dfr	-
	green cod	coated board					1y -dfr	-
	green peas	coated board					1y -dfr	-
	hamburgers	coated board					1y -dfr	-
	herring	coated board					1y -dfr	-
	loempias	coated board					1y -dfr	-
	minced-meat balls	coated board					1y -dfr	-

Ref.no.	Description of foodstuffs	Food contact material	Simulants to be used A	B	C	D	Contact conditions in actual use (time-temperature)	Test conditions (time-temperature)
	minced-meat balls	pl box					1y -dfr	-
	minced-meatb balls	pl bag					1y -dfr	-
	pastries, various	coated board					3m -dfr	-
	pizza	coated board					>1y-dfr	-
	potato croquettes	pl bag					>1y-dfr	-
	prepared dishes, various	coated board					1y -dfr	-
	rolled chicken	coated board					1y -dfr	-
	shrimps	coated board					1y -dfr	-
	spiced loempias	coated board					1y -dfr	-
	vegetable dish	coated board					1y -dfr	-
	vegetables, cut	coated board					1y -dfr	-
08.12	concentrated alcoholic extracts of an alcoholic strength equal to or exceeding 5% vol.							
08.13	cocoa:							
	A. powder							
	B. paste							
	cocoa paste	pl pot/pl closure				X/3	1m -ambient	10d-40°C
08.14	coffee, whether or not roasted, decaffeinated of solubilized, coffee substitutes, granulated or powdered							
	coffee, powdered	alufoil					1m -ambient	-
	coffee, powdered	can					>1y-ambient	-
08.15	liquid coffee extract							
08.16	aromatic herbs and other herbs (camomile, mallow, mint, tea, lime blossom, etc.):							
08.17	spices and seasonings in the natural state (cinnamon, cloves, powdered mustard, pepper, vanilla, saffron, etc.):							
	spices, various	paper/al sachet					>1y-ambient	-
	spices, various	pl sachet					>1y-ambient	-

REFERENCES

1) According to Directive 93/8/EEC only a test at 40°C for 10 days is required.

2) This test shall be carried out only in cases where the pH is 4.5 or less.

3) This test may be carried out in the case of liquids or beverages of an alcoholic strength exceeding 15% vol. with aqueous solutions of ethanol of a similar strength.

4) Test to be carried out with iso-octane

5) or 2 h - 70°C and 10 days at 40°C separately, according to Directive 93/8 EEC.

6) If it can be demonstrated by means of an appropriate test that there is no 'fatty contact' with the plastic, the test with simulant D may be dispended with

7) Simulant A: 10 d - 40°C + 0.5 h - 100°C

8) Simulant D may be replaced with iso-octane using test conditions of 1 d - 20°C

9) Simulant D may be replaced with iso-octane using test conditions of 1 h - 60°C

10) Simulant D may be replaced with iso-octane using test conditions of 1 d - 5°C

THE END