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Scientific Committee on Food

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**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)

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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 ¹.

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.

¹ 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).

- (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.

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"².

1. IDENTITY OF THE SUBSTANCE

The name and all relevant information were 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. MICROBIOLOGICAL PROPERTIES OF THE SUBSTANCE

All relevant information on microbiological properties of substance

² This document is available on line on the Internet at the site of the European Commission's Joint Research Centre - Food Contact Materials Resource Centre, at: <http://cpf.jrc.it/webpack/>.

5. AUTHORISATION OF THE SUBSTANCE

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

6. 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

7. 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.

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 tk 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 7.2
- 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 7.2.

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, 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.

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 programme 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 (M_w) below 1000 D and those with M_w above 1000 D. For those polymeric additives with a $M_w > 1000$ 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 Biocides

Biocides, 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.