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HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Scientific Opinions  
**C2 - Management of scientific committees; scientific co-operation and networks**

**Scientific Committee on Food**

**SCF/CS/PM/GEN/M95 Final**

**Opinion of the Scientific Committee on Food  
on the 23<sup>rd</sup> additional list of monomers and additives  
for food contact materials**

- p-Amino benzoic acid (PABA) and derivative
  - PM/REF No. 10180, p-(Acetylamino) benzoic acid, CAS no. 000556-08-1
  - PM/REF No. 12700, p-Amino-benzoic acid, CAS no. 000150-13-0
- Castor oil and some derivatives
  - PM/REF No. 14411 + 42880, Castor oil, CAS no. 008001-79-4
  - PM/REF No. 18900 + 61840, 12-Hydroxystearic acid, CAS no. 000106-14-9
  - PM/REF No. 24075 + 83700, Ricinoleic acid, CAS no. 000141-22-0
  - PM/REF No 24078 Ricinoleic acid, dehydrated, CAS no. - . -
  - PM/REF No. 43201, Castor oil, fatty acids, mono- and diglycerides, CAS no. - . -
  - PM/REF No. 56580, Glycerol, esters with ricinoleic acid, CAS no. - . -
- PM/REF No. 36640 Azodicarbonamide CAS no. 000123-77-3

(Opinion expressed on 4 April 2003)

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**Draft Opinion of the Scientific Committee on Food  
on the 23<sup>rd</sup> additional list of monomers and additives for food contact materials**

(expressed on 4 April 2003)

The Committee was made aware of that for some substances, the current classification, dated from many years ago, was not in line with the new SCF guidelines or not consistent. Therefore it has brought the evaluation up to date for p-amino benzoic acid and a derivative as well as for castor oil and some of its derivatives. For azodicarbonamide the Committee was made aware of publications showing a correlation between the use of this substance as a blowing agent in caps for beer bottles and the formation of ethyl carbamate. The Committee therefore re-evaluated this use of the substance. A definition of the classifications of the Committee is shown in Annex I.

Identification of substance/ compound	Assessment
<p><u>PM/REF No.:</u> 12700</p> <p><u>Name of the substance:</u> p-Amino-benzoic acid</p> <p><u>CAS number:</u> 000150-13-0 -----</p> <p><u>PM/REF No.:</u> 10180</p> <p><u>Name of the substance:</u> p-(Acetylamino) benzoic acid</p> <p><u>CAS number:</u> 000556-08-1</p>	<p><u>General information</u> Substances requested by Member States. No other information is available.</p> <p><u>Previous evaluations (by SCF)</u> p-Amino benzoic acid was evaluated in 1987 (SCF, 1989) and classified in SCF_List 7 with the following notation: "Needed: migration data and 28-day oral study". p-(Acetylamino) benzoic acid was evaluated in 1991 (SCF, 1992) and classified in SCF_List 7 with the following notation: "Needed: 28-day oral study, hydrolysis and migration data"</p> <p><u>Evaluation</u> The substances are now transferred to SCF-List 8 based on the absence of data in accordance with the new SCF Guidelines.</p> <p><u>Conclusion</u> SCF_List 8</p> <p><u>Needed data or information:</u> Data according to the new SCF-Guidelines.</p> <p><u>References:</u> SCF (1989). Second addendum to the first report of the Scientific Committee for Food on certain monomers and other substances to be used in the manufacturing of plastic materials intended to come into contact with foodstuffs. Opinion expressed on 10 December 1987, 20<sup>th</sup> series of reports of the SCF (Luxembourg 1989)  SCF (1992). Third addendum to the first report of the Scientific Committee for Food on certain monomers and other substances to be used in the manufacturing of plastic materials intended to come into contact with foodstuffs. Opinion expressed on 19 June 1991, 30<sup>th</sup> series of reports of the SCF (Luxembourg 1992)</p>
<p><u>PM/REF no.:</u> 14411//42880</p> <p><u>Name of the substance:</u> Castor oil</p> <p><u>CAS number:</u> 008001-79-4 -----</p> <p><u>PM/REF no.:</u> 18900//61840</p> <p><u>Name of the substance:</u> 12-Hydroxystearic acid</p> <p><u>CAS number:</u> 000106-14-9 -----</p> <p><u>PM/REF no.:</u> 24075//83700</p> <p><u>Name of the substance:</u> Ricinoleic acid</p> <p><u>CAS number:</u> 000141-22-0 -----</p>	<p style="text-align: right;">CS/PM/ 3938 rev. 5/September 2002</p> <p><u>General information</u> The SCF decided to re-evaluate castor oil and its constituents and derivatives mentioned in this opinion for the sake of consistency.</p> <p><u>Previous evaluations (by SCF)</u> Castor oil was evaluated in 1979 by JECFA (JECFA 1980). In its evaluation JECFA notes that castor oil in its unhydrolysed form has no laxative effect, but it is readily hydrolysed to ricinoleic acid in the GI tract. In larger doses only a fraction of this hydroxy acid is absorbed and exerts an irritative effect on the small intestine resulting in complete emptying of the guts within a few hours after ingestion of 15-30 g. Smaller doses are absorbed completely and can be stored and metabolised similar to dietary fatty acids. JECFA finally concluded that a dose of 4 g is absorbed completely and thus not exerting any laxative effect. This dose was selected as a NOEL and an unusual safety factor of 100 (when based on human data) was used because of the absence of toxicological studies. (4000 mg:60kg:100 ~ 0.7 mg/kg bw). The SCF endorsed the ADI of JECFA and allocated this substance in list 1 (SCF, 1992). As a consequence also ricinoleic acid, which is the main constituent of castor oil, and some derivatives were listed in list 2 and allocated with the same ADI. At the 52<sup>nd</sup> meeting of the SCF-WG "Food Contact Materials" in Nov. 1992, when fats and oils were discussed in general, it was decided that edible oils and fats should be listed in list 3 with the remark "food fats". It was also decided that castor oil, albeit not a food fat, should be included together with other castor oil derivatives, while ricinoleic acid and its derivatives stayed in list 2 with the ADI of 0.7 mg/kg bw. (SCF, 1999)</p>

<p><u>PM/REF no.:</u> 24078</p> <p><u>Name of the substance:</u> Ricinoleic acid, dehydrated</p> <p><u>CAS number:</u> - . -</p> <p>-----</p> <p><u>PM/REF no.:</u> 43201</p> <p><u>Name of the substance:</u> Castor oil, fatty acids, mono- and diglycerides</p> <p><u>CAS number:</u> - . -</p> <p>-----</p> <p><u>PM/REF no.:</u> 56580</p> <p><u>Name of the substance:</u> Glycerol, esters with ricinoleic acid</p> <p><u>CAS number:</u> - . -</p>	<p><u>Evaluation</u> The full hydrolysis of castor oil in the GI tract has been demonstrated for the small doses relevant in the applications of food contact materials and also allows the full absorption and metabolism similar to food fats. The Committee therefore sees no reason to allocate a numeric ADI, but finds castor oil acceptable for use in food contact materials.</p> <p>The same evaluation applies also to ricinoleic acid (24075/83700) and 12-hydroxystearic acid (18900/61840) and dehydrated ricinoleic acid (24078) and castor oil, fatty acids, mono- and diglycerides (43201) and glycerol, esters with ricinoleic acid (56580).</p> <p><u>Conclusion</u> Based on the above mentioned data these substances are classified: SCF_List: 3 Restriction: none. In small doses metabolised similarly to food fats</p> <p><u>References:</u> JECFA (1980), Evaluation of certain food additives. Twenty-third Report of the Joint FAO/WHO Expert Committee on Food Additives. Technical Report Series 648. WHO, Geneva 1980.</p> <p>SCF (1992). Third addendum to the first report of the Scientific Committee for Food on certain monomers and other starting substances to be used in the manufacturing of plastic materials intended to come into contact with foodstuffs. Opinion expressed on 19<sup>th</sup> June 1991. Reports of the Scientific Committee for Food 30<sup>th</sup> series. Directorate General for Industry 1992.</p> <p>SCF (1999). In "Compilation of the evaluations of the Scientific Committee for Food on certain monomers and additives used in the manufacture of plastic materials intended to come into contact with foodstuffs until the 21 March 1997". 42<sup>nd</sup> Series of Reports of the Scientific Committee for Food. Office of Official Publications of the European Communities, Luxembourg, 1999</p>
<p><u>PM/REF no.:</u> 36640</p> <p><u>Name of the substance:</u> Azodicarbonamide</p> <p><u>CAS number:</u> 123-77-3</p>	<p style="text-align: right;">CS/PM/3882/36640, 5 August 2001</p> <p><u>Introduction</u> Following the publication of articles showing a correlation between the use of azodicarbonamide as a blowing agent in caps for beer bottles and the formation of ethyl carbamate, there has been a request to the Commission to investigate whether this fact should be reflected in legislation.</p> <p><u>Background</u> Azodicarbonamide was evaluated for use in plastics as a blowing agent by the SCF in 1991 (SCF 1995) when it was listed in list 3 with the remark "Evaluated in the context of its use as blowing agent which on heating will break down." and with the restriction "only as a blowing agent". It was included in the directive with 5<sup>th</sup> amendment. In the evaluation it was taken into account that the substance had been accepted by JECFA at its 9<sup>th</sup> meeting in 1965 (JECFA, 1966) as a flour treatment agent at a treatment level of 45 mg/kg flour. SCF evaluated azodicarbonamide as a flour treatment agent on 19 October 1990 (SCF 1992) when it was concluded that there were not enough data to evaluate its safety in use.</p> <p>Azodicarbonamide, used as a blowing agent in closures for bottles, will decompose to gasses, primarily nitrogen and carbon monoxide together with some carbon dioxide and ammonia. Normally, it is claimed, the residues of non-volatiles are only small (biurea about 2% of added azodicarbonamide). However under certain conditions the residues of biurea could be as high as 34%. Other non-volatile reaction products from azodicarbonamide can be urazole, cyanuric acid, and cyamelide. (Hunter)</p> <p>Azodicarbonamide <i>per se</i> seems to be of little toxicological significance except its ability to induce asthmatic conditions in exposed workers (IPCS 1999), so the main potential problem is the formation of undesirable by-products.</p>

#### Ethyl carbamate (urethane)

Ethyl carbamate (NH<sub>2</sub>-COO-C<sub>2</sub>H<sub>5</sub>) is a well-known animal carcinogen (reviewed by Schlatter and Lutz (1990) and by Zimmerli and Schlatter (1991)).

SCF issued a statement on its 57<sup>th</sup> meeting on 28 Nov.1986 when it concluded that ethyl carbamate is a carcinogen and suggested an approach to reduce exposure “as low as possible” as it found it inappropriate to allocate a TDI. The SCF has not addressed this issue since.

The present opinion does not intend to update the risk assessment, but refers to the reviews mentioned above. It is assumed that the situation remains unchanged that any addition of ethyl carbamate, which could have been avoided, is unacceptable.

#### Formation of ethyl carbamate from the use of azodicarbonamide

Ethyl carbamate is found in most alcoholic beverages and is formed during the fermentation and after reaction of precursors with ethanol. The highest amounts are found in fruit brandies, but it is also a well-known fact that some beers, but not all, contain some ethyl carbamate.

Baxter (1992) found that canned beer contains more ethyl carbamate than draught beer, and bottled beer more than canned beer, and showed that part of this could be attributed to the use of azodicarbonamide as blowing agent, and that the problem could be minimised by changing the blowing technique.

Dennis et al. (1997b) confirmed the findings concerning the presence in various types of beers and also showed that the content of ethyl carbamate increased with the strength of the beer. They also showed that when liners from caps were refluxed with a 5% ethanol solution ethyl carbamate could be detected. A similar reaction was seen when azodicarbonamide was refluxed with 5% ethanol, but not when the cap liners were refluxed with dichloromethane. This led the authors to conclude that azodicarbonamide is the precursor for ethyl carbamate formation. However, as urea is a well-known precursor for ethyl carbamate formation (Zimmerli and Schlatter, 1991) it could be that biurea, which has been shown to be present in all treated bread and in some caps, might be considered as a possible candidate precursor.

#### Evaluation

Although it is clear that there is a direct association between the use of azodicarbonamide and the formation of ethyl carbamate when in contact with alcohol, it is not clear whether it is the substance as such or a degradation/reaction product, which acts as the direct precursor.

However, as any addition of ethyl carbamate to food from food contact materials must be considered unacceptable it is recommended that azodicarbonamide is not used in plastics intended for contact with alcoholic beverages.

#### Conclusion

Based on the above mentioned data this substance is classified:

SCF\_List 3

Restriction: Only as a blowing agent and not for materials intended for contact with alcoholic beverages.

#### References

Baxter, E.D. (1992). Food safety issues in relation to small packaged beers. *Ferment* **5**(1), 79-81.

Cañas, B.J., G.W. Diachenko and P.J. Nyman (1997), Ethyl carbamate levels resulting from azodicarbonamide use in bread. *Food Additives and Contaminants*, **14**(1), 89-94.

Dennis M.J., R.C. Massey, R. Ginn, I. Parker, C. Crews, B. Zimmerli, O. Zoller, P. Rhyn and B. Osborne (1997a), The effect of azodicarbonamide concentrations on ethyl carbamate concentrations in bread and toast. *Food Additives and Contaminants*, **14**(1), 95-100.

Dennis M.J., R.C. Massey, R. Ginn, P. Willetts, C. Crews and I. Parker (1997b): The contribution of azodicarbonamide to ethyl carbamate formation in bread and beer, *Food Additives and Contaminants*, **14**(1), 101-108.

Schlatter, J. and W.K. Lutz (1990). The carcinogenic potential of ethyl carbamate (urethane): Risk assessment at human dietary exposure levels. *Fd. Chem. Toxic.* **28** (3), 205-211 (=CS/PM/3868/36640).

	<p>Zimmerli, B. and J. Schlatter (1991). Ethyl carbamate; analytical methodology, occurrence, formation, biological activity and risk assessment. <i>Mutation Research</i> <b>259</b>, 325-350.</p> <p>Hunter, B.A. Chemical Foaming Agents Chemistry and Decomposition Mechanisms (<a href="http://www.uniroyalchemical.com/celocad.htm">http://www.uniroyalchemical.com/celocad.htm</a>).</p> <p>SCF (1992): Second series of food additives of various technological functions (opinion expressed on 19 October 1990). Reports of the Scientific Committee for Food 26<sup>th</sup> Series. Directorate-General for Internal Market and Industrial Affairs, 1992</p> <p>SCF (1995), First report of the Scientific Committee for Food on certain additives used in the manufacture of plastic materials intended to come into contact with foodstuffs (Opinions expressed until 3 May 1992). Reports of the Scientific Committee for Food 33<sup>rd</sup> series. Directorate-General for Industry. 1995</p> <p>JECFA (1966): WHO Food Additive Series 67.29 (from 9<sup>th</sup> and 10<sup>th</sup> meeting).</p> <p>IPCS (1999). Azodicarbonamide. Concise International Chemical Assessment Document 16. World Health Organization, Geneva, 1999.</p>
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## **APPENDIX 1**

### **DEFINITION OF THE SCF LISTS**

#### **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 this Committee has established a TDI or a t-TDI.

#### **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 that should not be used.

#### **List 6**

Substances for which there exist suspicions about their toxicity and for which data are lacking or are 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 were 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 Community lists, as they should be considered "new" substances, i.e. substances never approved at national level. These substances cannot be included in the Community lists, lacking the data requested by the Committee.

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## APPENDIX 2

### **Previous opinions adopted by the SCF in the area of Food Contact Materials (status up to April 2003)**

#### 1) Evaluations of individual substances

The 42<sup>nd</sup> Series of Reports of the SCF contains the compilation of the SCF opinions on Food Contact Materials for the period 1974 (the beginning of the existence of the Committee) to May 1997. ("Compilation of the evaluations of the Scientific Committee for Food on certain monomers and additives used in the manufacture of plastics materials intended to come into contact with foodstuffs expressed until 21st March 1997, Office of Official Publications of the European Communities, Luxembourg 1999" [http://europa.eu.int/comm/food/fs/sc/scf/reports\\_en.html](http://europa.eu.int/comm/food/fs/sc/scf/reports_en.html))

Following this compilation, the Committee has evaluated or re-evaluated a number of substances. All these opinions have been published on the Internet (at the webpages of the Committee, in the Europa server, [http://europa.eu.int/comm/food/fs/sc/scf/outcome\\_en.html](http://europa.eu.int/comm/food/fs/sc/scf/outcome_en.html) )

- Opinion on the 22<sup>nd</sup> additional list of monomers and additives for food contact materials (expressed on 4 April 2002)
- Opinion on the 21<sup>st</sup> additional list of monomers and additives for food contact materials (expressed on 5 March 2002)
- Opinion of the Scientific Committee on Food on Potential risks from organotin compounds used as catalysts in silicone-coated baking papers (expressed on 5 March 2002)
- Statement on the re-allocation of some substances for consistency with new SCF guidelines for food contact materials (expressed on 4 December 2002)
- Statement of the Scientific Committee on Food on 1,6-Diamino-2,2,4-trimethylhexane (PM/REF.N. 15370), 1,6-Diamino-2,4,4- trimethylhexane (PM/REF.N 15400) and on their mixture of (40% w/w) 1,6- diamino-2,2,4-trimethylhexane and (60% w/w)1,6-diamino-2,4,4-trimethylhexane (PM/REF. N. 22331, previously mentioned as PM/REF.N. 15355) (expressed on 4 December 2002)
- Statement of the Scientific Committee on Food on 1,6-Diamino-2,2,4-trimethylhexane (PM/REF.N. 15370), 1,6-Diamino-2,4,4- trimethylhexane (PM/REF.N 15400) and on their mixture of (40% w/w) 1,6- diamino-2,2,4-trimethylhexane and (60% w/w)1,6-diamino-2,4,4-trimethylhexane (PM/REF. N. 22331, previously mentioned as PM/REF.N. 15355) (expressed on 4 December 2002)
- Opinion on the introduction of a Fat (Consumption) Reduction Factor (FRF) in the estimation of the exposure to a migrant from food contact materials (expressed on 4 December 2002)
- Statement on Bisphenol A diglycidyl ether (BADGE) (expressed on 4 December 2002)
- Opinion on the 20th additional list of monomers and additives for food contact materials (expressed on 25 September 2002)
- Opinion on the 19th additional list of monomers and additives for food contact materials (expressed on 25 September 2002)
- Opinion on the 18th additional list of monomers and additives for food contact materials (expressed on 24 September 2002)

- Opinion on the 17th additional list of monomers and additives for food contact materials (expressed on 27 February 2002)
- Opinion on the 17th additional list of monomers and additives for food contact materials (expressed on 27 February 2002)
- Opinion on the 16th additional list of monomers and additives for food contact materials (expressed on 13th December 2001)
- Opinion on the 15th additional list of monomers and additives for food contact materials (expressed on 13th December 2001)
- Statement on a recent report on primary aromatic amines in food and packaging samples in a Danish magazine (expressed on 26 September 2001)
- Opinion on the 14th additional list of monomers and additives for food contact materials (expressed on 30th May 2001)
- Opinion on the 13th additional list of monomers and additives for food contact materials (expressed on 30th May 2001)
- Opinion on the 12th additional list of monomers and additives for food contact materials (expressed on 28th February 2001)
- Opinion on the 11th additional list of monomers and additives for food contact materials (expressed on 19 October 2000)
- Opinion on the 10th additional list of monomers and additives for food contact materials (expressed on 22 June 2000)
- Opinion on the 9th additional list of monomers and additives for food contact materials (expressed on 22 June 2000)
- Opinion on an additional list of monomers and additives intended to be used for food contact materials (10 compounds) (expressed on 2 December 1999)
- Statement on the use of Novolac glycidyl ethers (NOGE) as additives in food contact materials. Minutes of the 119<sup>th</sup> meeting of the SCF (1st/2nd December 1999)
- Statements on a recent survey on Bisphenol A diglycidyl ether (BADGE) and Bisphenol F diglycidyl ether (BFDGE) in canned food. Minutes of the 119<sup>th</sup> meeting of the SCF (1st/2nd December 1999)
- Opinion on an additional list of monomers and additives intended to be used for food contact materials (9 compounds) (expressed on 23 September 1999)
- Opinion on an additional list of monomers and additives intended to be used for food contact materials (11 compounds) (expressed on 17 June 1999)
- Opinion on an additional list of monomers and additives intended to be used for food contact materials (6 compounds) (expressed on 24 March 1999)
- Opinion on Bisphenol A diglycidyl ether (expressed on 24 March 1999)
- Opinion on an additional list of monomers and additives intended to be used for food contact materials (23 compounds) (expressed on 10 December 98)
- Opinion on an additional list of monomers and additives intended to be used for food contact materials (13 compounds) (expressed on 17 September 1998)
- Opinion on an additional list of monomers and additives intended to be used for food contact materials (37 compounds) (expressed on 19 March 1998)
- Additional list of monomers and additives evaluated by the WG "Food Contact Materials" of the SCF during the 69th-70th meetings. (16 compounds) (adopted during the SCF meeting of 12 and 13 June 1997). Also appearing in the Forty-third series of Reports of the Scientific Committee for Food, ISBN 92-828-5887-1)

## 2) Guidelines

The Committee has adopted also "**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**". These guidelines have been modified for the last time on 13 December 2001. (Document SCF/CS/PLEN/GEN/100 Final: [http://europa.eu.int/comm/food/fs/sc/scf/out82\\_en.pdf](http://europa.eu.int/comm/food/fs/sc/scf/out82_en.pdf)).

### **Extract of the Guidelines:**

These guidelines establish the general requirements of data to be submitted. As a general principle, the greater the exposure through migration, the more toxicological information will be required. In case of high migration (i.e. 5 - 60 mg/kg/food) an extensive data set is needed to establish the safety. In case of migration between 0.05 – 5 mg/kg food a reduced data set may suffice. If the data are appropriate, a restriction of 5 mg/kg of food is attributed to the substance. In case of low migration (i.e. <0.05 mg/kg food) only a limited data set is needed. If the data are appropriate, also in this case a restriction of 0.05 mg/kg of food is attributed to the substance. The full text of the guidelines provides a more detailed explanation. The guidelines are available at the web pages of the Committee.