



Brussels, 5 March 2004  
SANCO/D/3/AS D(2004)

**M/352 EN**

**SUPPLEMENT N° 2 TO THE CEN's STANDARDISATION MANDATE  
CONCERNING METHODS OF ANALYSIS FOR MATERIALS AND ARTICLES  
INTENDED TO COME INTO CONTACT WITH FOODSTUFFS**

**1. INTRODUCTION**

At the 60th meeting of the 98/34 Committee on 5 May 1994, the Commission's services submitted, for advice the mandate M/052 (Doc.17/94) conferred on the CEN, which relates to methods of analysis in the field of materials and articles intended to come into contact with foodstuffs. On this occasion the Committee issued a favourable opinion regarding that mandate (see record, Document No 48/94 of 17.06.94). The mandate covers a certain number of analytical methods as listed in the table appended to it. It had been stated in paragraph II(b) that any other method of analysis in the area covered by Framework Directive 89/109/EEC - the latter to be added - would be covered by a future mandate after the Committee had been consulted.

The supplement M/291 to mandate M/052 introduces greater flexibility into the base mandate M/052 by making it open to other future specific requests in that area. The 98/34 Committee is only being informed of those requests (see item 3.b of the mandate M291 (document 55/99 submitted to the Committee at its meeting of 14 October 1999).

This supplement to mandate M/052 and M/291 covers the CEN's request that a method of analysis not provided for in 1994 should be devised.

**2. JUSTIFICATION**

The Directive 2002/72/EC on plastic materials intended to come into contact with foodstuffs, provides in Annex V for the general specification that plastic materials and articles manufactured by using aromatic isocyanates or colorants prepared by diazo-coupling, shall not release primary aromatic amines in a detectable quantity (DL 0.02 mg/kg food or food simulant, analytical tolerance included). Until now only a photometric screening method for primary aromatic amines is available (Official Method No. L00.00.6 under § 35 of the German Foods and Commodities Act LMBG). For a uniform implementation of this provision it is

necessary to lay down a method of analysis for the confirmation of the presence and identification of primary aromatic

**3. DESCRIPTION OF THE WORK**

The Commission invites the CEN to establish methods of analysis to confirm the identity and amount of migration into food simulants of the following substances:

1,3-Phenylendiamine

2,6-Toluenediamine

2,4-Toluenediamine

1,5-Diaminonaphthalene

Aniline

4,4'-Oxydianiline

4,4'-Diaminodiphenylmethane

3,3'-Dimethylbenzidine

2,2'-Diaminodiphenylmethane

2,4-Diaminodiphenylmethane

**4. BODIES TO BE ASSOCIATED**

See base mandate.

**5. IMPLEMENTATION OF THE MANDATE**

See base mandate.

**Annex:** Base mandate M/052 and supplement mandate M/291



Brussels, 30 July 1999  
DG III/E/1/LR D(99)

**M291 - EN**

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**1. INTRODUCTION**

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This supplement to mandate M/052 covers the CEN's request that a method of analysis not provided for in 1994 should be devised. Another aim of that supplement was to introduce greater flexibility into base mandate M/052 by making it open to other future specific requests in that area. The 98/34 Committee would then be informed of those requests.

**2. JUSTIFICATION**

2.1. The Standing Committee on Foods recently delivered a unanimous opinion in favour of a fifth amendment of Directive 90/128/EEC on plastic materials intended to come into contact with foodstuffs. That future Commission Directive, which is a specific Directive under Framework Directive 89/109/EEC, specifies a specific migration limit (SML) for the substance 2,2-bis (4-hydroxyphenyl)-propane-bis(2,3-epoxypropyl)ether (=BADGE) and for its conversion products, as referred to in Annex 5 to said Directive. It has therefore proved necessary and urgent that the Directive be implemented uniformly in order to lay down a method of analysis that has been validated at both Community and EFTA levels.

2.2. It is, moreover, probable that, against the future backdrop of the base mandate and of this supplement, other requests concerning methods of analysis relating to other substances referred to in said Directive or in other specific directives under

89/109/EEC will prove necessary. It is therefore requested that paragraph II(b) of base mandate M/052 be amended in order to make it more flexible to use and to make it more open to other specific future requests in this area.

### 3. **DESCRIPTION OF THE WORK**

The Commission invites the CEN to establish methods of analysis concerning the specific migration limits and/or, where appropriate, the residual quantity permitted in the final product that apply to the following substances:

- a) -BADGE(=2,2-bis(4-hydroxyphenyl)-propane-bis(2,3-epoxypropyl) ether)
  - BADGE.H<sub>2</sub>O
  - BADGE.HCl
  - BADGE.2HCl
  - BADGE.H<sub>2</sub>O.HCl
  - if necessary, potential BADGE substitutes, such as BFDGE ;
- b) any other substance referred to in the specific directives under Directive 89/109/EEC. The Commission will inform Committee 98/34 of the requests sent to the CEN on this matter.

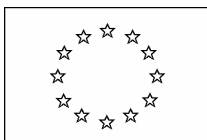
### 4. **BODIES TO BE ASSOCIATED**

See base mandate.

### 5. **IMPLEMENTATION OF THE MANDATE**

See base mandate.

**Annex:** Base mandate M/052



## EUROPEAN COMMISSION

DIRECTORATE GENERAL III  
INDUSTRY

Directorate B: legislation and standardization; telematics networks  
**Unit III/B-2: standardization**

**M/052**

### **STANDARDIZATION MANDATE TO CEN CONCERNING METHODS OF ANALYSIS FOR MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOODSTUFFS**

#### **I. MOTIVATION.**

1. Directive 89/109/EEC<sup>1</sup> lays down a general frame of reference for regulations on materials and articles intended to come into contact with foodstuffs. In particular, it establishes that the basic principle for the regulations on the subject must be that all materials and articles intended to come into contact with foodstuffs must be sufficiently inert that they do not transfer their constituents to foodstuffs in quantities which could endanger human health or bring about an unacceptable change in the composition of the foodstuffs or a deterioration in the organoleptic characteristics thereof (Article 2). It also provides for specific Commission directives on certain materials listed in its Annex (plastics, paper and board, ceramics, etc.) laying down more detailed rules to implement the abovementioned principle (Article 3). Inter alia, these directives may include lists of authorized substances ("positive lists") and quantitative limits on use of these substances, for which methods of analysis must be developed.
2. A number of specific directives have been adopted already. They cover ceramic articles (Directive 84/500/EEC)<sup>2</sup>, regenerated cellulose film (93/10/EEC)<sup>3</sup> and plastics (90/128/EEC<sup>4</sup> and others)<sup>5,6,7,8</sup>. Case by case, these directives lay down:
  - a) specific limits on the migration of substances which could endanger human health in certain concentrations;
  - b) limits on the content of certain substances in the final material;
  - c) in the case of plastics, an overall migration limit to avoid any unacceptable change in the composition of the foodstuffs in contact with the material.

Consequently, it has become necessary to study and develop validated methods of analysis to check compliance with these limits.

3. The abovementioned framework directive provided for the adoption of such methods of analysis by means of Commission directives (Article 3(i)). Methods for some

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1 OJ L 40, 11.2.1989.  
2 OJ L 277, 20.10.1984.  
3 OJ L 93, 17.4.1993.  
4 OJ L 75, 21.3.1990.  
5 OJ L 168, 23.6.1992.  
6 OJ L 90, 14.4.1993.  
7 OJ L 297, 23.10.1982.  
8 OJ L 372, 31.12.1985.

substances (vinyl chloride in plastic materials<sup>9,10</sup> and cadmium in ceramic articles<sup>2</sup>) have already been the subject of a directive. However, methods must still be developed or validated for a large number of other substances.

4. In a document discussed with the government officials responsible for inspections in the Member States, the Commission outlined the approach which it intended to follow on methods of analysis (Document III/3152/92). This approach can be summed up as follows:
  - a) if there is no method of analysis which could be validated and applied, at the request of DG III (Unit III/E/1 "Foodstuffs"), DG XII's testing and materials unit (formally the BCR) should provide for a research programme for the study or preparation of methods of analysis suitable for validation;
  - b) if there are one or more equivalent methods suitable for validation, the Commission should give a mandate to the CEN, subject to certain conditions (possibility of participation by the Commission, selection of the methods to be validated and involvement of laboratories designated by the Commission).

This approach was generally endorsed.

5. A joint working party of analysis experts from the national administrations and industry has sent the Commission proposals concerning the methods on which the CEN could start standardization work. The references of these methods are set out in the Annex to this draft order. Other methods are being considered by DG XII for possible inclusion in a further draft order expected in 1996.
6. Because of the health implications of the rules, the Commission requests the CEN to circulate the working papers to the Member States' administrations and to invite them to join in the standardization work. The Commission will send the CEN the list of officials responsible.
7. It must also be remembered that in 1989 the CEN set up, on its own initiative, Technical Committee 194 on "Utensils in contact with food" which has already drafted a series of European prestandards (ENV) and working papers in various stages of completion (see Column 4 in the Annex). These prestandards and working papers should be included in this order. The CEN is requested to continue its work with a view to upgrading them to European standards.
8. In this connection, the Commission approves TC 194's decision to draft European prestandards first and then, where necessary, use the period allowed for the public enquiry to conduct the interlaboratory tests to confirm the repeatability and reproducibility of the standardized methods. It should continue to apply this procedure when implementing this order.

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9 OJ L 213, 16.8.1980.

10 OJ L 167, 24.6.1981.

## **II. DESCRIPTION OF THE MANDATED WORK.**

The Commission requests the CEN to lay down, following the procedure set out in paragraph 4.3 below, standards for:

- a) The methods of analysis listed in the table in the Annex. Column 4 of the table indicates the stage reached by the work already done by the CEN on its own initiative on some of these methods. Column 5 indicates the directives which set quantitative limits that must be checked by the methods of analysis covered by this order.
- b) Any other methods of analysis in the field of governed by Directive 89/109/CEE, if this is added to the table annexed to a future mandate by the Commission, after consultation of the Member States within the Standards and Technical Regulations Committee.

## **III. BODIES TO BE ASSOCIATED.**

The standards should be prepared in cooperation with the main industrial associations concerned and representatives of European consumers. In the case of plastics and varnishes in particular, the APME, CEFIC, EUPC, CIIA and CEPE should be invited to participate. The Commission will send the CEN the list of bodies to invite depending on the work ordered. The CEN will also invite the Commission to participate in the standardization work covered by this order.

## **IV. EXECUTION OF THE MANDATE.**

1. The CEN will submit to the Commission the English, French and German versions of the EN European standards adopted to implement this order, together with the titles in the other Community languages, by the date specified in column 3 of the table in the annex.
2. The EN standards adopted will be incorporated into the national standards and any divergent national standards will be withdrawn from the catalogues of the national standardization bodies within six months of adoption of the EN standards.
3. Acceptance of this order by the CEN starts the standstill period referred to in Article 7 of Council Directive 83/189/EEC.
4. To improve transparency, the CEN will inform the Commission of any new programme of activities, not covered by this order, planned on materials intended to come into contact with foodstuffs.  
The programme will indicate the field covered by the standard, the link with the ongoing activities and the timetable for adoption.
5. The CEN will keep the Commission informed of the measures taken to execute this order and of any difficulties which arise in the process. By 30 November each year, the CEN will submit a progress report on the activities of the various working parties concerned by this order and will indicate the persons and bodies participating in the working parties' meetings and activities. In this context, the CEN will also indicate whether the standards adopted need to be adapted to technical progress.
6. This mandate covers the revision of adopted standards in accordance with this mandate, according to the internal rules of the CEN.

**ANNEXE**

**METHODES PRÊTES A ETRE MANDATEES**

N.	Title	Deadlines for EN	Stade at CEN level	EEC Directive
(1)	(2)	(3)	(4)	(5)
1	Guide to the selection of conditions and test methods for overall migration	1997	ENV1186	90/128
2	Determination of overall migration into olive oil by total immersion	1997	ENV1186	90/128
3	Determination of overall migration into aqueous food simulants by total immersion	1997	ENV1186	90/128
4	Determination of overall migration into olive oil by cell	1997	ENV1186	90/128
5	Determination of overall migration into aqueous food simulants by Tice Cell	1997	ENV1186	90/128
6	Determination of overall migration into olive oil using a pouch	1997	ENV1186	90/128
7	Determination of overall migration into aqueous food simulants using a pouch	1997	ENV1186	90/128
8	Determination of overall migration into olive oil by article filling	1997	ENV1186	90/128
9	Determination of overall migration into aqueous food simulants by article filling	1997	ENV1186	90/128
10	Determination of overall migration into olive oil (modified method for use in cases where incomplete extraction of olive oil occurs)	1997	ENV1186	90/120
11	Determination of overall migration at low temperature	1998	ENV1186	90/128
12	Determination of overall migration from plastics at high temperature	1998	in preparation	90/128
13	Guide to the selection of conditions and determination of specific migration and residual monomer for plastics	1997	in preparation	90/128
14	Determination of acrylonitrile	1997	in preparation	90/128
15	Determination of 1,3-butadiene	1997	in preparation	90/128
16	Determination of residual isocyanate in finished product	1998	in preparation	90/128



17	Determination of monoethylene glycol	1997	in preparation	90/128
18	Determination of diethyethylene glycol	1997	in preparation	90/128
19	Determination of terephthalic acid	1997	in preparation	90/128
20	Determination of vinylidene chloride	1997	in preparation	90/128
21	Determination of residual vinylidene in finished product	1997	in preparation	90/128
22	Determination of the release of N-nitrosamines and N-nitrosatable substances from elastomers or rubber teats and tetines	1998	in preparation	93/11
23	Determination of the release of lead and cadmium from silicate surfaces	1997	ENV	84/500
24	Determination of the overall migration from polymeric coatings on metal substrates	1998	in preparation	future Directive
25	Determination of the overall migration from polymeric coatings on cellulosic substrates	1998	To start in 1994	future Directive
26	Determination of the free fat on surface of food	1998	To start in 1994	85/572
27	Determination of the temperature at the interface between the plastic and the food	1998	To start in 1994	93/8
28	Determination of the molecular weight of polymer additives	1997	To start in 1994	future Directive