



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/EEC¹ 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)², regenerated cellulose film (93/10/EEC)³ and plastics (90/128/EEC⁴ and others)^{5,6,7,8}. Case by case, these directives lay down:

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.

- 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 substances (vinyl chloride in plastic materials^{9,10} and cadmium in ceramic articles²) 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.

⁹ OJ L 213, 16.8.1980.
¹⁰ OJ L 167, 24.6.1981.

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.

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.