COMMISSION DIRECTIVE 2001/61/EC

of 8 August 2001

on the use of certain epoxy derivatives in materials and articles intended to come into contact with foodstuffs

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/109/EEC of 21 December 1988 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs [1], and in particular Article 3 thereof,

After consulting the Scientific Committee on Food,

Whereas:

(1) The use and/or presence of 2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether ('BADGE'), bis(hydroxyphenyl)methane bis(2,3-epoxypropyl)ethers ('BFDGE') and novolac glycidyl ethers ('NOGE') in materials and articles intended to come into contact with foodstuffs has led to questions about their safety, mainly when they are used as an additive.

(2) Test results have shown significant levels of these substances and certain derivatives thereof in some foodstuffs.

(3) The Scientific Committee on Food has given an opinion that the specific migration limit for BADGE and some of its derivatives can be extended for another three years pending the submission of further toxicological data for evaluation.

(4) Acceptance of the use and/or presence of BADGE may therefore be provisionally extended.

(5) The Scientific Committee on Food has examined the data available on BFDGE, which are very similar to the corresponding data obtained for BADGE.

(6) Acceptance of the use and/or presence of BFDGE and some of its derivatives may therefore also be continued pending the submission and evaluation of further toxicological data, under certain conditions.

(7) The Scientific Committee on Food has stated that, in the absence of information about the potential exposure and toxicological profile of NOGE components with more than two aromatic rings and their derivatives, it is not in a position to evaluate the safety of use and/or the presence of corresponding products. The Committee is therefore of the opinion that at present, it is not appropriate to use NOGE as an additive in materials and articles intended to come into contact with foodstuffs due to its tendency to migrate in this application.

(8) The use and/or presence of NOGE components with more than two aromatic rings and their derivatives in plastic materials and articles, surface coatings and adhesives intended to come into contact with foodstuffs should be regulated through the establishment of a strict limit. That limit should, in practice, provisionally rule out their use as additives, pending the submission of adequate data for an appropriate risk assessment and the development of adequate methods for the determination of their levels in foodstuffs.

[1] OJ L 40, 11.2.1989, p. 38.

(9) The use and/or presence of NOGE and BFDGE as monomers and starting substances for the preparation of special coatings used to cover the surfaces of very big containers should provisionally be allowed to continue, pending the submission of further technical data. The large volume/surface area ratio of these containers, their repeated use over their long lifetime, which reduces migration and their contact with foodstuffs at ambient temperature in the majority of the applications suggest that it is not necessary to set a migration limit for NOGE and BFDGE in such containers.

(10) Member States which have not yet authorised the use and/or the presence of BADGE and/or BFDGE and/or NOGE in materials and articles intended to come into contact with foodstuffs may maintain their prohibition.

(11) The use of BADGE, BFDGE and NOGE and/or their presence in plastic materials and articles, surface coatings such as varnishes, lacquers and paints, as well as adhesives, should be regulated at Community level to avoid risks to human health and barriers to the free movement of goods.

(12) A transitional period should be provided for in respect of materials and articles intended to come into contact with foodstuffs or which are brought into contact with foodstuffs and which are manufactured before 1 December 2002.

(13) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive shall apply to the following materials and articles:

(a) materials and articles made of any type of plastics;

(b) materials and articles covered by surface coatings;

(c) adhesives;

which are manufactured with or contain one or more of the following substances:

— 2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether hereinafter called 'BADGE', and some of its derivatives,

— bis(-hydroxyphenyl)methane bis(2,3-epoxypropyl) ethers hereinafter called 'BFDGE', and some of their derivatives,

— other novolac glycidyl ethers hereinafter called 'NOGE', and some of their derivatives,

and which, in the finished product state, are intended to come into contact or are brought into contact with foodstuffs and are intended for that purpose.

2. This Directive shall not apply to containers or storage tanks having a capacity greater than 10 000 liters or to pipelines belonging to or connected with them, covered by special coatings called 'heavy-duty coatings'.

Article 2

The materials and articles referred to in Article 1(1) shall not release the substances listed in Annex I in a quantity exceeding the limit laid down in that Annex.

The use and/or presence of BADGE in the manufacture of those materials and articles may only be continued until 31 December 2004.