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Statement

of the Scientific Committee on Food

on Bisphenol A diglycidyl ether (BADGE)

(expressed on 4 December 2002)

B-1049 Bruxelles/Brussel - Belgium
Telephone: exchange (+32-2) 299.11.11. Fax: (+32-2) 299.48.91
Telex: COMEU B 21877. Telegraphic address: COMEUR Brussels

http://europa.eu.int/comm/food/fs/sc/scf/index_en.html

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on Bisphenol A diglycidyl ether (BADGE)**

(expressed on 4 December 2002)

Terms of reference

The Commission services asked the SCF to examine a) the new mutagenicity data available on BADGE.2HCl and b) to estimate the exposure of the consumer to BADGE and its derivatives regulated by Directive 2002/16/EC.

Background

In its opinion of 24 March 1999 (1), the Scientific Committee on Food asked industry to provide within 3 years, detailed studies on BADGE and its chlorinated derivatives.

In July 2002 the Commission services and the SCF were informed that for BADGE the industry intends to transmit in February 2004 the results of a two-year gavage chronic toxicity/carcinogenicity study in the Fisher 344 rat. An intermediate report of this study describing the results obtained after the first 12 months is available.

The EC Commission services also received from the industry association in July 2002 (2) three mutagenicity studies on BADGE.2HCl, as requested previously by the Committee.

Evaluation

The Committee examined the three mutagenicity studies on BADGE.2HCl supplied by the industry association along with two published reports and concluded as follows: *"The negative results obtained with BADGE.2HCl in the Ames test and a forward mutation assay in mammalian cells in vitro, indicate that BADGE.2HCl is unable to induce gene mutations in vitro. Negative results were also obtained in a well-conducted assay for structural chromosomal aberrations in vitro, indicating absence of clastogenic activity. Therefore, the positive response elicited by BADGE.2HCl in the in vitro micronucleus assay suggests that BADGE.2HCl might affect chromosome segregation, e.g. by interference with spindle organisation or function. This aspect should be further investigated, e.g. by testing BADGE.2HCl in the standard in vivo micronucleus test in the mouse (in bone marrow or peripheral blood erythrocytes)".*

The Committee carried out an assessment of exposure to BADGE and its derivatives regulated by Directive 2002/16/EC. The assessment was based on new surveys in the EU countries (3, 4, 5, 6, 7, 8) which found that migration levels into foods are considerably lower than in the past and are now well below the migration limit set in Directive 2002/16/EC (9). The Committee concluded that exposure of consumers (both average consumers and high consumers of food products expected to be in contact with can coatings that may contain BADGE) is low.

Taking into account the available toxicological database and the low exposure of consumers, and awaiting the results of the new mutagenicity test and of the ongoing two-year chronic toxicity/carcinogenicity study, the Committee can accept an extension to the deadline of its request for the detailed studies on BADGE and its chlorinated derivatives, until February 2004.

References

- (1) SCF (Scientific Committee on Food), 1999. Opinion on Bisphenol A diglycidyl ether (BADGE), expressed on 24 March 1999. SCF/CS/PM 3243 Final. Available at http://europa.eu.int/comm/food/fs/sc/scf/out28_en.pdf
- (2) Dossier submitted by APME (Association of Plastics Manufacturers in Europe).
- (3) JRC (Joint Research Centre), IHCP (Institute of Health and Consumer Protection, Ispra. Personal communication.
- (4) TNO Nutrition and Food Research. Personal communication.
- (5) Central Science Laboratory (UK). Personal communication.
- (6) Official Food Control Authority, Zurich. Personal communication
- (7) GEMS/FOOD Regional Diets, Regional Per Capita Consumption of Raw and Semi-processed Agricultural Commodities, WHO/FSF/FOS/98.3, WHO, Geneva, 1998.
- (8) SECODIP: Enquête Nationale sur les achats des ménages, Paris, 1997.
- (9) Directive 2002/16/EC on the use of certain epoxy derivatives in materials and articles intended to come into contact with foodstuffs, OJ L51, 22.02.2002 p.27-31