



EUROPEAN COMMISSION
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/Add/MsAd/218 Final
30 April 2002

**Addendum to the
Opinion of the Scientific Committee on Food
on carnauba wax of 11 July 2001**

(expressed on 17 April 2002)

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Terms of reference

The Scientific Committee on Food is requested to advise the Commission on whether the requested use levels of 500 mg/kg in confectionery (hard and soft sugar coated centers) and 1200 mg/kg in chewing gum for carnauba wax as a glazing agent are acceptable in terms of safe intake in the framework of its earlier opinion of 11 July 2001.

Background

On 11 July 2001, the Scientific Committee on Food (SCF) adopted an opinion on carnauba wax (SCF, 2001). In that opinion, following the submission of studies that it had requested before, the Committee withdrew its previous temporary acceptance of the use of carnauba wax (SCF, 1990,1994), and concluded that the use of carnauba wax as a glazing agent was acceptable, in the context of information provided earlier by industry of a maximum use level of 200 mg/kg of food.

The Commission has subsequently received a request from the Association of Chocolate, Biscuit and Confectionery Industries of the European Union and European Association of Chewing Gum Industries (CAOBISCO and EAGGI) to permit the use of carnauba wax in confectionery and chewing gum at higher levels than those stated in the SCF opinion of 11 July 2001. The request indicates that there is a technological need for 500 mg/kg in confectionery (hard and soft sugar-coated centres) and 1200 mg/kg in chewing gum.

Evaluation

The Committee has considered the request for higher use levels of carnauba wax as a glazing agent, up to 1200 mg/kg of food, in the light of its earlier opinion (SCF, 2001). In that opinion, the available toxicology studies were described, including sub-acute studies in rats and dogs, a 90-day dietary study in rats, a 6-month dietary study in dogs, reproduction and developmental toxicity studies in rats, and *in vitro* mutagenicity studies. No adverse effects were observed in any of these studies.

In view of the absence of toxicity in these studies, which included dietary levels of carnauba wax up to 1% or 10%, the Committee has no objection to the use of carnauba wax as a glazing agent at higher levels in products requiring it.

The Committee notes that its previous worst-case calculation of intake, assuming use at 200 mg/kg of food, was 8 mg/person/day (SCF, 2001). A use level of 1200 mg/kg of food would yield a worst-case intake estimate of 48 mg/person/day. This equates to 4.8 mg/kg bw/day for a 10 kg child, or less for an adult, and is within the Acceptable Daily Intake of 0-7 mg/kg bw set by the Joint FAO/WHO Expert Committee on Food Additives (JECFA, 1993).

References

JECFA (1993). Toxicological Evaluation of Certain Food Additives and Naturally Occurring Toxicants. WHO Food Additive Series 30. World Health Organization, Geneva.

Letters from CAOBISCO (Association of Chocolate, Biscuit and Confectionery Industries of the European Union) and EAGCI (European Association of the Chewing Gum Industry) to the Commission dated 1 February 2002.

SCF (1990). Report on a second series of food additives of various technological functions (opinion expressed on 19th October 1990). Food-Science and Techniques. Reports of the Scientific Committee for Food (26th series). EUR 13913 EN. Office of Official Publications of the European Communities, Luxembourg, 1992.

SCF (1994). Opinion of carnauba wax (expressed on 16 December 1994). Food-Science and Techniques. Reports of the Scientific Committee for Food (36th series). Office for Official Publications of the European Communities, Luxembourg, 1997. (Also in Minutes of the 95th plenary meeting held on 15/16 December 1994. Document III/5488/94-EN).

SCF (2001). Opinion of the Scientific Committee on Food on carnauba wax (expressed on 11 July 2001). http://europa.eu.int/comm/food/fs/sc/scf/out94_en.pdf