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HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Scientific Opinions

C2 - Management of scientific committees II; scientific co-operation and networks

Scientific Committee on Food

SCF/CS/ADD/CONS/53 Final

2 April 2003

Statement of the Scientific Committee on Food

on the Parabens

(expressed on 4 April 2003)

Statement on *p*-hydroxybenzoic acid alkyl esters and their sodium salts (Parabens)

Parabens have been used as preservatives in food for over 50 years. Under EU Directive 95/2/EC, Annex III, the parabens (E214-219) are conditionally permitted for use in a limited number of foods in combination with either sorbates or sorbates and benzoates, i.e. in jelly coatings of meat products, surface treatment of dried meat products, cereal- or potato-based snacks and coated nuts, confectionery (excluding chocolate), and liquid dietary food supplements. They are not permitted for use as the sole preservative in any foods.

Following a review of the published literature, the SCF expressed an opinion on the parabens in 1994 in which it concluded that the available data showed some inadequacies and uncertainties (Reports of the Scientific Committee for Food, Thirty-fifth series). A temporary ADI of 0-10 mg/kg bw was allocated for the sum of methyl, ethyl and propyl *p*-hydroxybenzoic acid and their sodium salts. Further studies in the rat to investigate cell proliferation in the forestomach and developmental toxicity were requested.

The situation was reviewed again in 2000 when the Committee reiterated its wish to review the safety of both benzoates and the parabens (Minutes of the 123rd Plenary Meeting of the Scientific Committee on Food, October 2000). Subsequently, data were submitted by industry in support of the benzoates and a favourable opinion allocating a group ADI for the benzoates was adopted (Minutes of the 134th Plenary Meeting of the Scientific Committee on Food, September 2002). No data have been submitted in support of the parabens.

It is unclear whether the lack of support for the parabens indicates that they are no longer used in food sold in the EU. The Committee recommends that the Commission take steps to ascertain whether or not the parabens are still used in food before any further scientific advice is sought. In the event that the parabens are still used in food, the Committee draws attention to its statement of October 2000, that the temporary ADI should be withdrawn if no further data are submitted.