OPINION OF THE SCIENTIFIC COMMITTEE ON COSMETIC PRODUCTS AND NON-FOOD PRODUCTS INTENDED FOR CONSUMERS

OPINION

CONCERNING

AMENDMENT TO ENTRY N° 419 OF ANNEX II TO DIRECTIVE 76/768/EEC ON COSMETIC PRODUCTS

adopted by the SCCNFP during the 19th Plenary Meeting
of 27 February 2002

1. Background

Entry n° 419 stipulating that "Bovine, ovine and caprine tissues and fluids from the encephalon, the spinal cord and the eyes, and ingredients derived therefrom" must not form part of the composition of cosmetic products, was first added to Annex II to Cosmetics Directive 76/768/EEC[1] by Commission Directive 97/1/EC[2] following an opinion of the Scientific Committee on Cosmetology.

Entry n° 419 was further amended by Commission Directives 98/16/EC[3], and 2000/6/EC[4] in order to align the list of prohibited animal materials to that contained in Commission Decisions defining Specified Risk Materials (SRM) as regards transmissible spongiform encephalopathies (TSEs).

At present Entry n° 419 reads as follows :

419. (a) the skull, including the brain and eyes, tonsils and spinal cord of :
- bovine animals aged 12 months
- ovine and caprine animals which are aged over 12 months or have a permanent incisor tooth erupted through the gum;

(b) the spleens of ovine and caprine animals and ingredients derived therefrom.

However, tallow derivatives may be used provided that the following methods have been used and strictly certified by the producer :

- transesterification or hydrolysis at at least 200°C at an appropriate corresponding pressure, for 20 minutes (glycerol, fatty acids and fatty acid esters);
- saponification with NaOH 12M (glycerol and soap) :

  - batch process: at 95°C for 3 hours

  or

  - continuous process: at 140°C, 2 bars (2000 hPa) for 8 minutes or equivalent conditions."

Based on the opinions of the SSC[5] and on Commission Decision 2001/2/EC[6] regulating the use of material presenting risks as regards TSEs, the SCCNFP adopted 2 further opinions on the amendment to entry n° 419 (SCCNFP/0451/01 of 12 June 2001 and SCCNFP/0521/01 of 25 September 2001).

[1] OJ L 262, 27.09.1976, p. 169
[2] OJ L 16, 18.01.1997, p. 85
[3] OJ L 77, 14.03.1998, p. 44
[4] OJ L 56, 1.03.2000, p. 42
[5] Opinion of the SSC on TSE infectivity distribution in ruminant tissues (state of knowledge December 2001), adopted 10-11 January 2002
[6] OJ L 001, 4.01.2001, p. 21

2. Terms of Reference

Recently Commission Decision 2001/2/EC was repealed by Commission Regulation (EC) n° 1326/2001/EC[7] of 29.6.2001 laying down transitional measures to permit the changeover to the Regulation (EC) No 999/2001[8] of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies.

The current definition for Specified Risk Material is found in Annex V of the latter legislative text and according to Article 3 1(g) does not include products containing or derived from those tissues unless indicated otherwise. There is also no exception made for tallow derivatives that may be used if defined methods have been used to prepare.

Because the designation of specified risk material is dynamic progress and in order to avoid the systematic consultation of the SCCNFP each time the designation of specified risk material is updated, the SCCNFP was asked to give advice on the following questions :

* Does the SCCNFP agree that the use in cosmetics of specified risk materials as defined in Regulation No. 999/2001 presents a health risk to consumers?

* Does the SCCNFP recommend that this list should be supplemented regarding ingredients derived from specified risk materials and should there be exceptions made for tallow derivatives provided that specific methods have been used to prepare them?

* Does the SCCNFP recommend any further restrictions with regard to specified risk materials to ensure consumer safety?

3. Opinion of the SCCNFP

Based on the information presented in the opinion adopted by the Scientific Steering Committee and in the respective EU legislative texts concerning specified risk material (SMR) and concerning certain transmissible spongiform encephalophathies, the SCCNPF is of the opinion that :

* the specified risk materials as defined in Regulation No. 999/2001 represent a health risk to consumers;

* this list should be supplemented by the ingredients derived therefrom. However, exceptions may be made regarding tallow derivatives provided that the following production methods have been used and strictly certified by the producer :

  - transesterification or hydrolysis at at least 200°C at an appropriate corresponding pressure, for 20 minutes (glycerol, fatty acids and fatty acid esters);
  - saponification with NaOH 12M (glycerol and soap) :

[7] OJ L 325, 8.12.2001, p. 35
[8] OJ L 147, 31.5.2001, p.1

- batch process: at 95°C for 3 hours

or

- continuous process: at 140°C, 2 bars (2000 hPa) for 8 minutes or equivalent conditions."

The SCCNFP recommend no further restrictions with regard to specified risk materials to ensure consumer safety.