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 22nd Plenary Meeting
of 17 December 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], 2000/6/EC[4] and 2003/1/EC[5] 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. From the date referred to in Article 22(1) of Regulation (EC) n° 999/2001[6] of the European Parliament and of the Council, the specified risk materials as designated in Annex V to that Regulation and ingredients derived therefrom.
Until that date, the specified risk materials as designated in Annex XI Part A to Regulation (EC) No 999/2001, 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, on Commission Decision 2001/2/EC[7] regulating the use of material presenting risks as regards TSEs and on Commission Regulation (EC) n° 1326/2001[8] of 29 June 2001 laying down transitional measures to permit the changeover to the Regulation of the European Parliament and of the Council (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies, and amending Annexes VII and XI to that Regulation, the SCCNFP adopted 3 further opinions on the amendment to entry n° 419 (SCCNFP/0451/01 of 12 June 2001, SCCNFP/0521/01 of 25 September 2001 and SCCNFP/0552/02 of 27 February 2002).

[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] OJ L5, 10.1.2003, p. 14
[6] OJ L 147, 31.5.2001, p.1
[7] OJ L 001, 4.01.2001, p. 21
[8] OJ L177, 30.06.2001, p. 60

2. Terms of Reference

It appeared, however, that the derogation for tallow derivatives, provided for in the current text of Entry n° 419, was possibly not in accordance with the opinions of the Scientific Steering Committee on :

- the safety of tallow obtained from ruminant slaughter by-products (opinion adopted on 28-29 June 2001);

- the risks of non-conventional transmissible agents, conventional infectious agents or other hazards such as toxic substances entering the human food or animal feed chains via raw material from fallen stock and dead animals (including also: ruminants, pigs, poultry, fish, wild/exotic/zoo animals, fur animals, cats, laboratory animals and fish) or via condemned materials of (opinion adopted on 24-25 June 1999 and re-edited during the meeting of 22-23 July 1999).

In order to clarify a possible discrepancy between the above mentioned opinions of the SSC and the opinion of the SCCNFP on the use of Specified Risk Materials in cosmetic products (entry 419 to Annex II), the SCCNFP was asked to answer the following questions :

* *Are exceptions made for tallow derivatives (provided that specific methods have been used to prepare them) scientifically consistent with the above mentioned scientific opinions of the SSC?*

* *If not, does the SCCNFP recommend that the list referred to in Regulation n° 999/2001 should be supplemented by the ingredients derived therefrom and no exceptions should be made regarding any of these ingredients?*

3. Opinion of the SCCNFP

Based on the information presented in the opinions adopted by the Scientific Steering Committee concerning (i) the safety of tallow obtained from ruminant slaughter by-products (opinion of 28-29 June 2001) and (ii) concerning the risks of non-conventional transmissible agents, conventional infectious agents or other hazards such as toxic substances entering the human food or animal feed chains via raw material from fallen stock and dead animals (including also: ruminants, pigs, poultry, fish, wild/exotic/zoo animals, fur animals, cats, laboratory animals and fish) or via condemned materials of (opinion adopted during the meeting of 24-25 June 1999 and re-edited during the meeting of 22-23 July 1999),

the SCCNPF is of the opinion that :

* the exceptions made for tallow derivatives in its latest opinion concerning the amendment to entry n° 419 of Annex II to Directive 76/768/EEC on cosmetic products (SCCNFP/0552/02 of 27 February 2002) are no longer scientifically consistent with the above mentioned scientific opinions of the SSC.

Consequently, the SCCNFP recommends that the list referred to in Regulation n° 999/2001 should be supplemented by the ingredients derived therefrom and that no exceptions should be made regarding tallow derivatives.