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

OPINION

CONCERNING

USE OF SPECIFIED RISK MATERIAL IN COSMETICS CLARIFICATION FOR TALLOW DERIVATIVES

adopted by the SCCNFP on 30 July 2003
by means of the written procedure

1. Background

1. Entry n° 419 stipulates 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.

2. 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).

3. Entry n° 419 stipulates that "From the date referred to in Article 22 of Regulation (EC) No 999/2001 (8) 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 least: 200 °C, 40 bars (40,000 hPa) for 20 minutes (glycerol and fatty acids and esters),

   – saponification with NaOH 12M (glycerol and soap) :

     batch process: at 95 °C for 3 hours

     or

     continuous process: at 140 °C, 2 bars (2 000 hPa) for 8 minutes or equivalent conditions.

4. 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).

5. Consequently, the SCCNFP recommended 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.

[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

6. In its opinion adopted by the SCCNFP during the 22nd Plenary Meeting of 17 December 2002 the SCCNFP (SCCNFP/0612/02) stated 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 scientific opinions of the Scientific Steering Committee on the safety of tallow.*

7. Recently the SSC adopted on its last meeting on 10 - 11 April 2003 an opinion on the safety of tallow derivatives from cattle tallow based on an updated report by the "European Oleochemicals and Allied Products Group" (APAG) on "The safety of tallow derivatives with respect to Bovine Spongiform Encephalopathy"

8. Due to the cosmetic applications of tallow derivatives the SSC stated that it is justified to modulate the risk reduction according to the source of the tallow used for the production of the derivatives and the geographical BSE risk level.

2. Terms of Reference

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:

1. *Are tallow derivatives safe for use in cosmetic products with regard to BSE risk regardless of the production process if they are derived from food- or feed- grade tallow and if cross contamination is prevented?*

2. *Are tallow derivatives safe for use in cosmetic products with regard to BSE risk regardless of the production process if they are derived cattle from GBR-C I countries[9] and fallen stock are excluded?*

3. *For GBR-C II countries, are tallow derivatives safe for use in cosmetic products if fallen stock are excluded, the animals from which the tallow is sourced are fit for human*

[7] OJ L 177, 30.6.2001, p. 60
[8] OJ L 147, 31.5.2001, p.1
[9] GBR-C stays for "Geographical BSE risk in cattle".

consumption, the raw tallow is produced according to the standards indicated in the SSC opinion of 28-29 June 2001 on the safety of tallow (including filtration), and the following processing conditions have been used:

to obtain glycerol and fatty acids and esters: transesterification or hydrolysis at at least 200°C and an appropriate corresponding pressure for 20 minutes, followed by a purification to remove (insoluble) impurities;

to obtain glycerol and soap: saponification with NaOH 12M : batch process: at 95°C for 3 hours; or: continuous process: at 140°C, 2 bars (2000 hPa) for 8 minutes or equivalent conditions, followed by a purification to remove (insoluble) impurities;
and cross contamination is prevented?

4. *For GBR-C III and IV countries, are tallow derivatives safe for use in cosmetic products if, in addition to the conditions described under (3), the specified risk materials have been removed and are not used for the production of tallow / tallow derivatives?*

3. Opinion of the SCCNFP

Based on the information presented in the last 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 SCCNFP is of the opinion that tallow derivatives are safe for use as ingredients in cosmetic products.

It is justified to modulate the risk reduction according to the source of the tallow used for the production of the derivatives and the geographical BSE risk level.

1. Tallow derivatives are safe with regard to BSE risk regardless of the production process if they are derived from food- or feed- grade tallow and if cross contamination is prevented. The criteria for food- and feed- grade tallow are detailed in the SSC opinion of 28-29 June 2001 on the safety of tallow obtained from ruminant slaughter by products.

2. Tallow derivatives are safe with regard to BSE risk regardless of the production process if they are derived from cattle from GBR-C I countries and fallen stock are excluded.

3. For GBR-C II countries, tallow derivatives are safe if fallen stock are excluded, the animals from which the tallow is sourced are fit for human consumption, the raw tallow is produced according to the standards indicated in the SSC opinion of 28-29 June 2001 on the safety tallow (including filtration), the processing conditions described in the mandate have been used and cross contamination is preserved.

4. For GBR-C III and IV countries, tallow derivatives are safe if, in addition to the above (3), the specific risk materials have been removed and are not used for the production of tallow/tallow derivatives.