

**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 18th Plenary Meeting
of 25 September 2001

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 by Commission Directive 97/1/EC following an opinion of the Scientific Committee on Cosmetology.

Entry n° 419 was further amended by Commission Directives 98/16/EC, and 2000/6/EC 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).

In the light of recent development of the BSE situation in the Community, the SSC was requested to give opinion on the scientific validity of some management measures related to BSE risks.

In its opinion of 27/28 November 2000 the SSC particularly addressed questions concerning additional SRM. It was observed that histological analyses of casings made from intestines have found neural and lymphoid cells also in parts of the gut other than the ileum. Therefore it was concluded that the entire intestine should be regarded as SRM, independent of the age of the animal, whenever it is not highly unlikely that the slaughtered animals are infected.

In the light of information presented in the opinion of the SSC and of the Commission Decision 2001/2/EC regulating the use of material presenting risks as regards TSEs, the SCCNFP adopted during the 17th Plenary meeting of 12 June an opinion to amend entry n° 419 of Annex II as follows :

- 419. (a) the skull, including the brain and eyes, tonsils and spinal cord of bovine animals aged over 12 months, the intestines from the duodenum to the rectum of bovine animals of all ages, and ingredients derived therefrom;
- (b) the skull, including the brain and eyes, tonsils and spinal cord of ovine and caprine animals aged over 12 months or that have a permanent incisor tooth erupted through the gum, the spleens of ovine and caprine animals of all ages, 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.”

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.”

2. Terms of Reference

Commission Decision 2001/233/EC of 14 March 2001, amending Decision 2000/418/EC regulating the use of material presenting risks as regards transmissible spongiform encephalopathies, updates the list of tissues designated as Specified Risk Materials (SRMs) on the basis of the opinion of the Scientific Steering Committee of 27/28 November 2000. Materials defined as SRM must be removed and deconstructed.

Although these Commission Decisions do not apply to cosmetic products, the Cosmetics Directive 76/768/EEC should comply with their provisions.

The SCCNFP is asked to give advice on the following questions :

- Does the present Entry n° 419 of Annex II of the Cosmetics Directive cover the latest scientific evidence on the use of risk material contaminated with BSE/TSE?
- Does the SCCNFP propose an amendment of the present entry n° 419 of the Annex II of the Cosmetics Directive 76/768/EEC?

3. Opinion of the SCCNFP

In the light of information presented in the opinion of the SSC and of the Commission Decision 2001/233/EC regulating the use of material presenting risks as regards TSEs, the SCCNFP is of the opinion that entry n° 419 of Annex II should be amended as follows :

419. (a) the skull including the brain and eyes, the tonsils, the vertebral column excluding the vertebrae of the tail, but including dorsal root ganglia and spinal cord of bovine

animals aged over 12 months, and the intestines from the duodenum to the rectum of bovine animals of all ages, and ingredients derived therefrom;

- (b) the skull including the brain and eyes, the tonsils and the spinal cord of ovine and caprine animals aged over 12 months or that have a permanent incisor tooth erupted through the gum, and the spleens of ovine and caprine animals of all ages, and ingredients derived therefrom.
- (c) In addition to the specified risk material listed in points (a) and (b), the following tissues shall be designated as specified risk material in the United Kingdom and in Portugal with the exception of the Autonomous Region of the Azores :
 - the entire head excluding the tongue, including the brains, eyes, trigeminal ganglia and tonsils; the thymus; the spleen and spinal cord of bovine animals aged over six months.

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.”