



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL
Directorate C - Public Health and Risk Assessment
C7 - Risk assessment

SCIENTIFIC COMMITTEE ON CONSUMER PRODUCTS

SCCP

Opinion on

Risk of ingredients deriving from category 1-material and category 2-material as defined in Regulation 1774/2002 in cosmetic products

Adopted by the SCCP during the 5th plenary meeting
of 20 September 2005

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1. BACKGROUND

Regulation (EC) 1774/02 laying down health rules concerning animal by-products not intended for human consumption (“**ABP-Regulation**”) has an important regulatory impact on the manufacturing of a cosmetic product within the Community: The ABP-Regulation provides for sourcing restrictions by classifying animal by-products in three categories. Only category-3 material (= material from animals fit for human consumption) may enter the production chain towards a cosmetic product. Category-1 and category-2 material is prohibited for the use in cosmetics. Category 1-material includes *inter alia* specific risk material. Category 2-material includes *inter alia* ‘fallen stock’. It is important to note that all animal by-products not listed as category 3-material are by definition category 2-material and are therefore excluded for the production of cosmetic ingredients.

However, according to the scope of application of the ABP-Regulation, these restrictions do not apply to imported finished cosmetic products but only to the manufacturing of cosmetic products within the Community.

In order to be coherent with Community-legislation on the safety of animal by-products, the Commission, in agreement with Member States, intends to list ‘category 1-material’ and ‘category 2-material’ and ingredients deriving therefrom in annex II to the Cosmetics Directive 76/768.

2. TERMS OF REFERENCE

Does the SCCP agree that the use of ingredients deriving from category 1 and 2 material (as defined in Regulation 1774/02) in cosmetic products raises concerns in terms of biological risk for human health?

3. OPINION

Based on the opinions adopted by the Scientific Steering Committee 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” (adopted during the meeting of 24-25 June 1999 and re-edited at the meeting of 22-23 July 1999).¹

¹ http://www.europa.eu.int/comm/food/fs/sc/ssc/out53_en.pdf

- the safety of tallow obtained from ruminant slaughter by-products (revised opinion and report adopted during the meeting of 28-29 June 2001 and editorial clarifications introduced during the meeting of 6-7 September 2001).²

and referring to the opinions adopted by the SCCNFP on:

- the use of specified risk material in cosmetics, clarification for tallow derivatives, adopted on 30 July 2003;
- the amendments to entry 419 of Annex II to Directive 76/768/EEC on Cosmetic Products, adopted on 12 June 2001, 25 September 2001, 27 February 2002 and on 17 December 2002,

the SCCP is of the opinion that ingredients derived from category 1 and 2 material (as defined in Regulation 1774/02) raise concern in terms of biological risk for human health and therefore must not be present in cosmetic products.

4. ANNEX

CATEGORY -1, -2, -3 MATERIAL ACCORDING TO THE ABP-REGULATION

1. CATEGORY 1 MATERIAL (= NOT TO BE USED FOR THE PRODUCTION OF COSMETIC INGREDIENTS)

Animal by-products of the following description, or any material containing such by-products:

(a) all body parts, including hides and skins, of the following animals:

- (i) animals suspected of being infected by a TSE in accordance with Regulation (EC) No 999/2001 or in which the presence of a TSE has been officially confirmed,
- (ii) animals killed in the context of TSE eradication measures,
- (iii) animals other than farmed animals and wild animals, including in particular pet animals, zoo animals and circus animals,
- (iv) experimental animals as defined by Article 2 of Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes, and
- (v) wild animals, when suspected of being infected with diseases communicable to humans or animals;

² http://europa.eu.int/comm/food/fs/sc/ssc/out228_en.pdf

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<p>(b) (i) specified risk material³, and</p> <p>(ii) where, at the time of disposal, specified risk material has not been removed, entire bodies of dead animals containing specified risk material;</p>
<p>(c) products derived from animals to which substances prohibited under Directive 96/22/EC⁴ have been administered and products of animal origin containing residues of environmental contaminants and other substances listed in Group B(3) of Annex I to Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC⁵, if such residues exceed the permitted level laid down by Community legislation or, in the absence thereof, by national legislation;</p>
<p>(d) all animal material collected when treating waste water from Category 1 processing plants and other premises in which specified risk material is removed, including screenings, materials from desanding, grease and oil mixtures, sludge and materials removed from drains from those premises, unless such material contains no specified risk material or parts of such material;</p>
<p>(e) catering waste from means of transport operating internationally;</p>
<p>(f) mixtures of Category 1 material with either Category 2 material or Category 3 material or both, including any material destined for processing in a Category 1 processing plant.</p>

2. CATEGORY 2 MATERIAL (= NOT TO BE USED FOR THE PRODUCTION OF COSMETIC INGREDIENTS)

Animal by-products of the following description, or any material containing such by-products:

(a) manure and digestive tract content;

³ Specified risk material is defined in the ABP-Regulation as “material referred to in Annex V to Regulation (EC) No 999/2001 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.” (Art. 2 (1) (o)).

⁴ Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC

⁵ Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC

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(b) all animal materials collected when treating waste water from slaughterhouses other than slaughterhouses covered by Article 4(1)(d) or from Category 2 processing plants, including screenings, materials from desanding, grease and oil mixtures, sludge and materials removed from drains from those premises;
(c) products of animal origin containing residues of veterinary drugs and contaminants listed in Group B(1) and (2) of Annex I to Directive 96/23/EC ⁶ , if such residues exceed the permitted level laid down by Community legislation;
(d) products of animal origin, other than Category 1 material, that are imported from non-member countries and, in the course of the inspections provided for in Community legislation, fail to comply with the veterinary requirements for their importation into the Community, unless they are returned or their importation is accepted under restrictions laid down under Community legislation;
(e) animals and parts of animals, other than those referred to in Article 4, that die other than by being slaughtered for human consumption, including animals killed to eradicate an epizootic disease;
(f) mixtures of Category 2 material with Category 3 material, including any material destined for processing in a Category 2 processing plant; and
(g) animal by-products other than Category 1 material or Category 3 material.

3. Category 3- material (admissible for the production of cosmetic ingredients, fit for human consumption)

Animal by-products of the following description, or any material containing such by-products:

(a) parts of slaughtered animals, which are fit for human consumption in accordance with Community legislation, but are not intended for human consumption for commercial reasons;
(b) parts of slaughtered animals, which are rejected as unfit for human consumption but are not affected by any signs of diseases communicable to humans or animals and derive from carcasses that are fit for human consumption in accordance with Community legislation;
(c) hides and skins, hooves and horns, pig bristles and feathers originating from animals that are slaughtered in a slaughterhouse, after undergoing ante-mortem inspection, and were fit, as a result of such inspection, for slaughter for human consumption in accordance with Community legislation;

⁶ Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC

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(d) blood obtained from animals other than ruminants that are slaughtered in a slaughterhouse, after undergoing ante-mortem inspection, and were fit, as a result of such inspection, for slaughter for human consumption in accordance with Community legislation;
(e) animal by-products derived from the production of products intended for human consumption, including degreased bones and greaves;
(f) former foodstuffs of animal origin, or former foodstuffs containing products of animal origin, other than catering waste, which are no longer intended for human consumption for commercial reasons or Due to problems of manufacturing or packaging defects or other defects which do not present any risk to humans or animals;
(g) raw milk originating from animals that do not show clinical signs of any disease communicable through that product to humans or animals;
(h) fish or other sea animals, except sea mammals, caught in the open sea for the purposes of fishmeal production;
(i) fresh by-products from fish from plants manufacturing fish products for human consumption;
(j) shells, hatchery by-products and cracked egg by-products originating from animals which did not show clinical signs of any disease communicable through that product to humans or animals;
(k) blood, hides and skins, hooves, feathers, wool, horns, hair and fur originating from animals that did not show clinical signs of any disease communicable through that product to humans or animals;
(l) catering waste other than as referred to in Article 4(1)(e).

5. MINORITY OPINION

Not applicable

6. SUPPORTING DOCUMENTS

1. Scientific Steering Committee: "Scientific Opinion on 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" (adopted by the SSC at its meeting of 24-25 June 1999 and re-edited at its meeting of 22-23

July 1999).⁷ Please note that the term ‘technical use’ used in this opinion does not cover the use as a cosmetic product (cf. p. 10, footnote no. 7).

2. Scientific Steering Committee: Revised opinion and report on: “The safety of tallow obtained from ruminant slaughter by-products.” Adopted by the scientific steering committee at its meeting of 28-29 June 2001 (editorial clarifications introduced at the SSC meeting of 6-7 September 2001).⁸ This document contains a list of scientific and technical material used by the working group (cf. page 20).

7. ACKNOWLEDGEMENTS

Not applicable

⁷ http://www.europa.eu.int/comm/food/fs/sc/ssc/out53_en.pdf

⁸ http://europa.eu.int/comm/food/fs/sc/ssc/out228_en.pdf