



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

**SCIENTIFIC COMMITTEE ON EMERGING AND
NEWLY IDENTIFIED HEALTH RISKS
(SCENIHR)**

Opinion on

Chinese report on possible residual BSE risks in products derived from ruminant materials and used as cosmetics ingredients

Adopted by the SCENIHR
during the 12th plenary meeting of 20 June 2006

Chinese report on possible residual BSE risks in products derived from ruminant materials and used as cosmetics ingredients

TABLE OF CONTENTS

- 1. BACKGROUND..... 3
- 2. TERMS OF REFERENCE..... 3
- 3. ASSESSMENT 4
 - 3.1. Introduction 4
 - 3.1.1. Hearing Report 4
 - 3.1.2. Chinese Report 5
 - 3.2. Comments on the Chinese Report 5
 - 3.2.1. Introduction 5
 - 3.2.2. Risk classification / assessment..... 5
 - 3.3. Conclusion..... 6
 - 3.4. Recent data 6
- 4. COMMITTEE OPINION..... 6
- 5. REFERENCES..... 7
- 6. ACKNOWLEDGEMENTS 10

Chinese report on possible residual BSE risks in products derived from ruminant materials and used as cosmetics ingredients

1. BACKGROUND

In 2002, the Chinese administration responsible for the surveillance of imported cosmetic products (AQSIQ) introduced additional control measures because of their assessment of a possible risk of transmission of TSE through cosmetic products containing certain animal-derived ingredients.

The EU and China subsequently agreed to organize a joint hearing with scientists from both regions to assess the actual risk and to propose appropriate measures. Following this hearing, a report (hereafter referred to as the Hearing Report) was finalised and submitted to Chinese and EU authorities in May 2003.

In response to the above report, Chinese scientists have recently provided the Commission with a further report entitled “China’s risk evaluation of animal-origin TSE infectious factors in cosmetics” (hereafter referred to as the Chinese Report) which has been submitted to the SCENIHR for comments.

2. TERMS OF REFERENCE

The SCENIHR has been asked by the European Commission to evaluate whether the report “China’s risk evaluation of animal-origin TSE infectious factors in cosmetics” contains new scientific evidence for a risk of transmission of BSE and related diseases through cosmetic ingredients derived from ruminant material.

Chinese report on possible residual BSE risks in products derived from ruminant materials and used as cosmetics ingredients

3. ASSESSMENT

3.1. Introduction

The Committee welcomes the Chinese scientists' willingness to continue the cooperation on the safety evaluation of cosmetic materials in relation to bovine spongiform encephalopathy (BSE) risks.

3.1.1. Hearing Report

In the framework of technical co-operation between China and the EU, and in view of obtaining the maximum appropriate BSE-relevant information as a basis for a science based definition of ingredients allowed in cosmetics, a scientific hearing was organised in 2002-2003. Independent scientists from both China and the EU were involved. Following these hearings a report was produced in 2003¹.

This report identified that in terms of any risk from BSE five elements need to be considered:

- Appropriate sourcing of the animals. [Could the geographical source of animals possibly indicate a BSE risk?]
- Veterinary inspection assuring that the animal is healthy or fit for human consumption. [Does the animal itself possibly pose a BSE risk?]
- Appropriate sourcing, from a given animal, of the tissues. [Should certain tissues of the animal possibly be excluded for further use? Are there tissues likely to be infected?]
- Appropriate processing of the raw material, resulting in elimination or reduction below significant levels of agents that may still be present after the above steps. [Will the production process remove or destroy transmissible spongiform encephalopathy (TSE) infectivity?]
- Exclusion from certain (human, animal) uses of the product if a doubt remains about the safety of the end product (i.e., certain materials or products should be entirely disposed of or only find applications that exclude human or animal consumption such as certain technical uses.)

Algorithms for procedures were provided that, when properly followed, minimise any risk to users of cosmetics.

¹ Silano V, Wells GAH, Budka H, Vanbelle M, Somerville RA, Dormont D, White I. Clarifications on the scientific aspects of possible residual BSE risks if any in products derived from ruminant materials and used as a cosmetic, or as an ingredient of cosmetics (2003). Report prepared in the framework of an independent EU-China expert hearing composed of Dr. Bai Lu, Prof. H. Budka, Prof. Dong Xiaoping, Prof. D. Dormont, Prof. Ma Guiping, Prof. V. Silano, Dr. R. Somerville, Prof. M. Vanbelle, Prof. Wang Chao, Dr. G. Wells, Prof. I. White, Dr. Zhang Jinjing.

Chinese report on possible residual BSE risks in products derived from ruminant materials and used as cosmetics ingredients

3.1.2. Chinese Report

The report which is the subject of this opinion was produced by Chinese scientists in late 2004². Several of the Chinese scientists involved in this report were also involved in the 2003 hearing. The report by the Chinese scientists comprises 3 parts:

- General Introduction and Background
- Risk classification / assessment
- Risk management measures consideration of which is outside of the remit of the SCENIHR.

It is noted that the Chinese Report does not contain any references to the published literature nor does it refer to the Hearing Report.

3.2. Comments on the Chinese Report

3.2.1. Introduction

The Committee notes that the Chinese Report is wide-ranging, covering BSE, TSEs and variant Creutzfeldt-Jakob disease (vCJD).

3.2.2. Risk classification / assessment

In spite of much recent research in the area, no additional scientific data that assists in the risk assessment is mentioned in the Chinese Report, compared to that in the Hearing Report. In terms of the risk classification, 85 substances are assigned to one of the 3 following categories:

- High fatalness
- Medium fatalness
- Low fatalness

The Committee has noted that, in general, the substances assigned to the above-mentioned three categories seem to correspond to the substances classified into three other categories in the Hearing Report i.e.: (i) not in use (especially Specified Risk Materials); (ii) not assessed because of time constraints; and (iii) case-by-case assessment. However, the criteria used in the two reports seem to be different. The criterion used in the Chinese Report is related to intrinsic infectivity properties, whereas that used in the Hearing Report relates to different approaches in

² Dong Xiaoping, Zhao Deming, Ma Guiping, Sun Youfu, Qin Juehui, Tian Haiyan, Chen Ying, Hu Yongqiang, Wang Lixia. China's risk evaluation of animal-origin TSE infectious factors in cosmetics (2004). Report submitted to the European Commission in December 2005.

Chinese report on possible residual BSE risks in products derived from ruminant materials and used as cosmetics ingredients

risk assessment. It is unclear whether this is an issue of translation³ or a fundamental difference in approach.

No list of scientific references or executive summary is included.

3.3. Conclusion

The report entitled “China’s risk evaluation of animal-origin TSE infectious factors in cosmetics” does not contain any new scientific evidence for a risk of transmission of BSE and related diseases through cosmetic ingredients derived from ruminant material as compared to the Hearing Report of 2003.

3.4. Recent data

Since the Chinese Report was finalized in 2004, significant advances in quantitative risk assessment of ruminant-derived materials and products have been achieved and applied indicating a significant reduction of the risk for a number of situations. For instance, the vCJD epidemic so far has turned out to be much smaller than predicted earlier and current predictions of future trends suggest that it is likely to be even smaller than previous forecasts (Andrews 2006, Clarke and Ghani 2005, Epstein 2005, Smith et al. 2004, Ward et al. 2006, Will 2005, SCENIHR 2006). Revised risk estimates have been published in various scientific opinions by EFSA and other scientific committees (see reference list).

4. COMMITTEE OPINION

There are no new scientific data or risk assessment approaches provided in the Chinese Report which were not considered in the Hearing Report. The Hearing Report was based on reasonable worst cases assumptions. The continuing decline in the BSE epidemic, continuing improvements in surveillance and developments in risk assessment methodology all show that the conclusions of the Hearing Report were rather conservative.

³ The version of the report provided to the European Commission is very difficult to interpret.

Chinese report on possible residual BSE risks in products derived from ruminant materials and used as cosmetics ingredients

5. REFERENCES

Andrews NJ. Incidence of variant Creutzfeldt-Jakob disease onsets and deaths in the UK. January 1994 - December 2005, Public Health Laboratory Service - Statistics Unit, 2006. <http://www.cjd.ed.ac.uk/vcjdqdec05.htm>.

Clarke P and Ghani AC. Projections of the future course of the primary vCJD epidemic in the UK: inclusion of subclinical infection and the possibility of wider genetic susceptibility. *J Roy Soc Interface* 2005, 2, 19-31.

EFSA Opinion of the Scientific Panel on Biological Hazards of the European Food Safety Authority on: "A quantitative assessment of risk posed to humans by tissues of small ruminants in case BSE is present in these animal populations". EFSA-Q-2004-170 Opinion adopted on 8 June 2005. *The EFSA Journal* 2005, 227, 1-11. (http://www.efsa.eu.int/science/biohaz/biohaz_opinions/990/biohaz_opinion_ej227_bse_goat_v2_en1.pdf)

EFSA. BSE-related culling in cattle. Opinion of the Scientific Panel on Biological Hazards on a request from the Commission on BSE-related Culling in Cattle Question N° EFSA-Q-2003-098. Adopted on 21 April 2004. *The EFSA Journal* 2004, 57, 1-8. (http://www.efsa.eu.int/science/biohaz/biohaz_opinions/420/opinion_biohaz_07_culling_en1.pdf)

EFSA. Opinion of the European Food Safety Authority on BSE risk from dissemination of brain particles in blood and carcass following stunning. Question N° EFSA-Q-2003-122 Adopted on 21 October 2004. *The EFSA Journal* 2004, 123, 1- 4. (http://www.efsa.eu.int/science/biohaz/biohaz_opinions/731/finalbiohaz_stunningopinion1.pdf)

EFSA. Opinion of the European Food Safety Authority on safety of collagen and a processing method for the production of collagen Question N° EFSA-Q-2004-085 Adopted on 26 January 2005. *The EFSA Journal* 2005, 174, 1-9. (http://www.efsa.eu.int/science/biohaz/biohaz_opinions/849/opinion_safety_collagen2.pdf)

EFSA. Opinion of the Scientific Panel on Biological Hazards of the European Food Safety Authority on the "Quantitative assessment of the residual BSE risk posed by di-calcium phosphate (DCP) and tri-calcium phosphate (TCP) from bovine bones used as an animal feed additive or as fertiliser" (Question N° EFSA-Q-2003-099) Adopted on 16 March 2006. *The EFSA Journal* 2006, 339, 1-25. (http://www.efsa.eu.int/science/biohaz/biohaz_opinions/1440/biohaz_op_ej339_qra_dcp_tcp_en1.pdf)

EFSA. Opinion of the Scientific Panel on Biological Hazards of the European Food Safety Authority on the "Quantitative assessment of the human BSE risk posed by gelatine with respect to residual BSE risk" (Question N° EFSA-Q-2003-099) Adopted on 18 January 2006. *The EFSA Journal* 2006, 312, 1-29. (http://www.efsa.eu.int/science/biohaz/biohaz_opinions/1333/biohaz_op_ej312_qra_gelatine_vf_feb06_en1.pdf)

EFSA. Opinion of the Scientific Panel on Biological Hazards of the European Food Safety Authority on the usefulness of somatic cell counts for safety of milk and milk derived products from goats. Question N° EFSA-Q-2005-074 Adopted on 14 December 2005. *The EFSA Journal* 2005, 305, 1-19. (http://www.efsa.eu.int/science/biohaz/biohaz_opinions/1273/biohaz_op_ej305_tse_safety_goatmilk_en1.pdf)

EFSA. Opinion of the Scientific Panel on Biological Hazards of the European Food Safety Authority on the "Quantitative risk assessment of the animal BSE risk posed by meat and bone meal with respect to the

Chinese report on possible residual BSE risks in products derived from ruminant materials and used as cosmetics ingredients

residual BSE risk". (Question N° EFSA-Q-2003-099) Adopted on 12-13 July 2005. *The EFSA Journal* 2005, 257, 1-30.

(http://www.efsa.eu.int/science/biohaz/biohaz_opinions/1148/biohaz_op_ej257_qra_mbm_en_cor31.pdf)

EFSA. Opinion of the Scientific Panel on Biological Hazards of the European Food Safety Authority on the "Assessment of the human and animal BSE risk posed by tallow with respect to residual BSE risk". (Question N° EFSA-Q-2003-099) Adopted on 27-28 April 2005. *The EFSA Journal* 2005, 221, 1-47.

(http://www.efsa.eu.int/science/biohaz/biohaz_opinions/1110/biohaz_op_ej221_qra_tallow_en2.pdf)

EFSA. Opinion of the Scientific Panel on Biological Hazards of the European Food Safety Authority on the application of the United Kingdom for Moderate Risk BSE status (Question N° EFSA-Q-2003-013) Adopted on 21 April 2004. *The EFSA Journal* 2004, 55, 1-3.

(http://www.efsa.eu.int/science/biohaz/biohaz_opinions/426/opinion_biohaz_09_georisk_ef55_v3_en1.pdf)

EFSA. Opinion of the Scientific Panel on Biological Hazards of the European Food Safety Authority on the scientific justification for proposing amendments to the United Kingdom Date Based Export Scheme (DBES) and to the Over Thirty Months (OTM) rule. (Question N° EFSA-Q-2003-13) Adopted on 21 April 2004. *The EFSA Journal* 2004, 56, 1-4.

(http://www.efsa.eu.int/science/biohaz/biohaz_opinions/429/opinion_biohaz_10_dbesotm_ef56_v2en1.pdf)

EFSA. Opinion of the Scientific Panel on Biological Hazards of the European Food Safety Authority on the application of the United Kingdom for Moderate Risk BSE status (Question N° EFSA-Q-2003-013) Adopted on 21 April 2004. *The EFSA Journal* 2004, 55, 1-3.

(http://www.efsa.eu.int/science/biohaz/biohaz_opinions/426/opinion_biohaz_09_georisk_ef55_v3_en1.pdf)

EFSA. Opinion of the Scientific Panel on Biological Hazards of the European Food Safety Authority on BSE risk from bovine tonsil and consumption of bovine tongue (Question N° EFSA-Q-2003-095) Adopted on 4 March 2004. *The EFSA Journal* 2004, 41, 1-4.

(http://www.efsa.eu.int/science/biohaz/biohaz_opinions/243/opinion_biohaz_06_en1.pdf)

EFSA. Opinion of the Scientific Panel on Biological Hazards of the European food safety on the interpretation of results of EU surveillance of transmissible spongiform encephalopathies (TSEs) in ovine and caprine animals, culling strategies for TSEs in small ruminants and the TSE-related safety of certain small ruminant products (Question N° EFSA-Q-2003-029) adopted on 26 November 2003. *The EFSA Journal* 2003, 12, 1-6.

(http://www.efsa.eu.int/science/biohaz/biohaz_opinions/231/opinion_biohaz_02_en1.pdf)

EFSA. Opinion of the Scientific Panel on Biological Hazards of the European Food Safety Authority on the safety vis-à-vis biological risk including TSEs of the application on pastureland of organic fertilisers and soil improvers. (Question N° EFSA-Q-2003-090) Adopted on 3 March 2004. *The EFSA Journal* 2004, 40, 1-10.

(http://www.efsa.eu.int/science/biohaz/biohaz_opinions/228/opinion_biohaz_05_en1.pdf)

EFSA. Opinion of the Scientific Panel on Biological Hazards on the assessment of the age limit in cattle for the removal of certain Specified Risk Materials (SRM). Question N° EFSA-Q-2004-146 Adopted on 28 April 2005. *The EFSA Journal* 2005, 220, 1-7.

(http://www.efsa.eu.int/science/biohaz/biohaz_opinions/938/biohaz_opinion_ej220_srmremove_en1.pdf)

Epstein HA. Risk assessment of variant Creutzfeldt-Jakob disease in cosmetics. *Skinmed* 2005, 4, 377-378.

Chinese report on possible residual BSE risks in products derived from ruminant materials and used as cosmetics ingredients

SCCNFP. Opinion on the Use of specified risk material in cosmetics - Clarification for tallow derivatives. Adopted on 30 July 2003.

(http://ec.europa.eu/comm/health/ph_risk/committees/sccp/documents/out229_en.pdf)

SCCP. Opinion on Amino Acids obtained by Hydrolysis of Human Hair. Adopted on 21 June 2005.

(http://ec.europa.eu/comm/health/ph_risk/committees/04_sccp/docs/sccp_o_005.pdf)

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.

(http://ec.europa.eu/comm/health/ph_risk/committees/04_sccp/docs/sccp_o_00k.pdf)

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 on 20 September 2005.

(http://ec.europa.eu/comm/health/ph_risk/committees/04_sccp/docs/sccp_o_00k.pdf)

SCENIHR. Opinion on “The Safety of Human-derived Products with regard to Variant Creutzfeldt-Jakob Disease”. Adopted on 11/12 May 2006.

(http://ec.europa.eu/comm/health/ph_risk/committees/04_scenihhr/docs/scenihhr_o_004.pdf)

Smith PG, Cousens SN, d' Huillard Aignaux JN, Ward HJ and Will RG. The epidemiology of variant Creutzfeldt-Jakob disease. *Curr Top Microbiol Immunol* 2004, 284, 161-191.

Ward HJT, Everington D, Cousens SN, Smith-Bathgate B, Leitch M, Cooper S, Heath C, Knight RSG, Smith PG and Will RG. Risk factors for variant Creutzfeldt-Jakob disease: A case-control study. *Annals of Neurology* 2006, 59, 111-120.

Will RG. Commentary: The risk of variant Creutzfeldt-Jakob Disease: reassurance and uncertainty. *Int J Epidemiol* 2005, 34, 52-53.

Further information on TSE assessments:

(http://www.efsa.eu.int/science/tse_assessments/catindex_en.html)

Chinese report on possible residual BSE risks in products derived from ruminant materials and used as cosmetics ingredients

6. ACKNOWLEDGEMENTS

Members of the working group are acknowledged for their valuable contribution to this opinion. The members of the working group are:

SCENIHR members:

Prof. Jim Bridges (*Chair and Rapporteur*)

SCENIHR associate members:

Prof. Vittorio Silano, EFSA Scientific Committee

External experts:

Prof. Herbert Budka, EFSA BIOHAZ Panel

Dr. Robert Somerville, Institute for Animal Health, United Kingdom

Marcel Vanbelle, Retired Professor, Université Catholique de Louvain-La-Neuve, Belgique

Prof. Gerald Wells, Filmer Consulting Limited, United Kingdom

Prof. Ian White, SCCP