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**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

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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.

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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.

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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.

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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.

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