EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Scientific Opinions
C1 - Follow-up and dissemination of scientific opinions

OPINION ON

PEPTIDES FROM PIG MUCOSA: RISKS WITH RESPECT TO TSES

ADOPTED BY THE SCIENTIFIC STEERING COMMITTEE

AT ITS MEETING OF 21-22 FEBRUARY 2002

OPINION

In November 2001, the Company *BioIberica* submitted a dossier (BioIberica, 2001) describing the conditions under which it is producing peptides from porcine intestinal mucosa. The dossier provides information on the raw material and its origin, the production process, the composition of the end-product, quality control, etc. It includes also a risk assessment with respect to various risks such as cross-contamination, viral contamination, dioxins and BSE. The Scientific Steering Committee was invited to address the following question in an opinion:

"Can peptides produced from porcine intestinal mucosa according to the industrial conditions indicated in the dossier provided by *BioIberica*, be safely used for feed as far as TSE risks are concerned?"

On the basis of the attached report prepared by the TSE/BSE *ad hoc* Group, on the Scientific Steering Committee answers as follows to the question:

In the light of current knowledge and of the information provided in the *BioIberica* dossier, the SSC considers that peptides produced from porcine intestinal mucosa do not represent a TSE or BSE risk, provided the risk of contamination with a TSE agent from TSE-susceptible species from external sources can be excluded. Such sources are for example: contaminated animal feed given in the days prior to slaughter, cross-contamination with ruminant SRMs during slaughter, slaughter on non-dedicated lines in non-GBR I countries used also for slaughtering ruminants, or the inclusion of possibly TSE-infected animal material in the medium used for the growth of the micro-organisms from which the serine endopeptidase may have been isolated.

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REPORT ON:

PEPTIDES FROM PIG MUCOSA: RISKS WITH RESPECT TO TSEs

Report prepared by the TSE/BSE *ad hoc* Group

at its meeting of 7 February 2002.

Rapporteur: M.Vanbelle

I. MANDATE

The TSE/BSE *ad hoc* Group was invited to prepare a scientific report to serve as the basis for addressing the following question:

"Can peptides produced from porcine intestinal mucosa according to the industrial conditions indicated in the dossier provided by *BioIberica*, be safely used for feed as far as TSE risks are concerned?"

II. REPORT

II.1. TSEs in pigs

A detailed report and opinion on TSE risks in pigs, is currently being prepared by the TSE/BSE *ad hoc* Group of the SSC. Pending the outcome of this opinion, the current knowledge can be summarised as follows (Dawson *et al*, 1990; Hawkins *et al*, 1998; Ryder *et al*, 2000; EC, 1999a, 1999b, 2000c); Hawkins, 2001; Ryder, 2001):

There is no evidence of the natural occurrence of any form of TSE in the pig. Pigs are, nevertheless, susceptible to BSE infection by multiple parenteral challenge (combined i.c., peritoneal and intravenous routes inoculation). Prior to appropriate controls in the course of the BSE epidemic domestic pigs would have been exposed to ruminant derived meat and bone meal (MBM) and hence potentially or actually to the BSE agent via feedstuffs. However, pigs orally exposed at 8 weeks old to large amounts of brain from cattle clinically affected with BSE did not succumb to infection even after a 7 year observation period. Further research is ongoing.

Further research is needed to evaluate the susceptibility of pigs to BSE infection, including the possibility of BSE latent infection..

II.2 Possible TSE infectivity reduction by processing

The production process described in the BioIberica dossier has not been the object of an experimental verification of its TSE infectivity reduction / elimination capacity. The key-process is an enzymatic hydrolysis which is realised by a bacterial serine endopeptidase isolated from Bacillus licheniformis at 59°C ± 1°C at pH 7,6 during 11 hours

The BioIberica treatment[1] is not expected to destroy the proteinase K resistant PrP^{Sc}. It is also not expected that the various heat treatments have a significant TSE infectivity reduction activity should it be present. On the basis of current scientific literature it can be concluded that the reduction in TSE infectivity under the temperature conditions specified in the BioIberica dossier will not exceed 2 logs .-

[1] It may be noted that the production process described in BioIberica (2001) is different from the production processes from ruminant hides described in EC (2000a) and also from the process to produce amino acids from human hair hydrolysate described in EC (2000b).

Note: Some media used for bacterial growth contain material from bovine origin. A medium obtained from an animal that represents a BSE risk could represent a risk itself. The inclusion of possibly TSE-infected animal material in the medium used for the growth of the bacteria *Bacillus licheniformis* from which the bacterial serine endopeptidase may have been isolated, could thus potentially constitute a risk.

According to the data submitted, the BioIberica production process does not use material of animal origin for this purpose.

II.3. Other sources of possible risk

From what precedes and from the SSC opinion on intra-species recycling of 17 September 1999 (EC, 1999a) it may be concluded that pig mucosa, processed as indicated in the BioIberica dossier, could only constitute a possible BSE risk if:

(1) the pig intestine mucosa would be accidentally contaminated by BSE infectivity present in risk materials from ruminant animals slaughtered at the same premises, or if

(2) during the days prior to slaughter, the animals had been fed BSE contaminated feed possibly resulting in residual infectivity in the intestine (see: EC, 1999a).

III. CONCLUSION

The TSE/BSE *ad hoc* Group concludes that in the light of current knowledge, peptides produced from porcine intestinal mucosa do not represent a TSE or BSE risk, provided the risk of contamination with a TSE agent from TSE-susceptible species from external sources can be excluded. Such sources are for example: contaminated animal feed given in the days prior to slaughter, cross-contamination with ruminant SRMs during slaughter, slaughter on non-dedicated lines in non-GBR I countries used also for slaughtering ruminants, or the inclusion of possibly TSE-infected animal material in the medium used for the growth of the bacteria *Bacillus licheniformis* from which the bacterial serine endopeptidase may have been isolated.

LITTERATURE LIST

BioIberica (2001). Dossier on Peptides produced from porcine intestinal mucosa, submitted to Commission Services in November 2001. 4 Volumes.

BioIberica (2002). Letter of 12 February 2002 to to Commission Services, including a certificate on the non-use of animal materials for the production of Alcalase 3.0T and Alcalase 2.5 L DX enzymes.

Dawson *et al* (1990). Primary parenteral transmission of BSE to the pig. Vet. Record, 327, 338.

EC (European Commission) (1999a). The risk born by recycling animal by-products as feed with regard to propagating TSE in non-ruminant farmed animals. Opinion adopted by the Scientific Steering Committee at its meeting 17 September 1999.

EC (European Commission) (1999b). The risk born by recycling animal by-products as feed with regard to propagating TSE in non-ruminant farmed animals. Report from the TSE/BSE ad hoc Group prepared for the Scientific Steering Committee for the preparation of an opinion on the same subject.

EC (European Commission) (2000a). the safety of hydrolysed proteins produced from bovine hides. Initially adopted by the Scientific Steering Committee at its meeting of 22-23 October 1998 and updated at its meeting of 25-26 May 2000

EC (European Commission) (2000b). Considerations on the safety of amino acids from human hair hydrolysate used in cosmetic products for topical application, with regard to Transmissible Spongiform Encephalopathy risks. Adopted by the Scientific Steering Committee at its meeting of 25-26 May 2000.

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EC (European Commission) (2001). Opinion on the questions submitted by EC services following a request of 4 December 2000 by the EU Council of Agricultural Ministers regarding the safety with regard to BSE of certain bovine tissues and certain animal-derived products. Adopted by the Scientific Steering Committee at its meeting of 12 January 2001.

Hawkins S. (2001). Transmissibility of BSE and scrapie by oral exposure to brain homogenate. FSA, TSE Research Seminar 22-23 November 2001.

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Ryder S. (2001). Further studies on the transmission of BSE to pigs MO 3010. FSA Research Seminar 22-23 November 2001.

Rohwer ,R.G., 1984. Virus-like sensitivity of the scrapie agent to heat inactivation. *Science* **223**, 600-602

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