

## **Human and animal exposure risk related to Transmissible Spongiform Encephalopathies (TSEs) from milk and milk products derived from small ruminants Scientific opinion of the Panel on Biological Hazards**

**(Question No EFSA-Q-2008-310)**

**Adopted on 22 October 2008**

### **SUMMARY**

Following a request from the European Commission (EC), the Panel on Biological Hazards (BIOHAZ) was asked to deliver a scientific opinion on the Human and animal exposure risk related to Transmissible Spongiform Encephalopathies (TSEs) from milk and milk products derived from small ruminants.

In a recent scientific article from Konold *et al.*, published on 8 April 2008 in BMC Veterinary Research, on "Evidence of scrapie transmission via milk" it is concluded that: "...*there is a risk of the transmission of scrapie from ewe to lamb via milk or colostrum. Infection of lambs via milk may result in shedding of the infectious agent into the environment...*".

The BIOHAZ Panel was invited to provide an opinion on the conclusions from the article of Konold *et al.* (2008), and if considered necessary, based on any additional available scientific data, to update the current risk assessments on the human and animal exposure related to Transmissible Spongiform Encephalopathies (TSEs) from milk and milk products derived from small ruminants.

When approaching the mandate the BIOHAZ Panel did not consider the zoonotic potential of small ruminant TSE agents. This aspect is considered in detail in previous EFSA documents<sup>1,2</sup>. The TSE agents considered in the assessment were Classical scrapie, Atypical scrapie and BSE. Moreover, the assessment was performed employing mainly data from TSE in sheep, which were considered valid also for TSE in goats due to the lack of more specific data in that species.

The Panel considered valid the conclusion of the article of Konold *et al.* (2008). Expanding the article of Konold *et al.* (2008), another study from Lacroux *et al.* (2008) independently demonstrated that Classical scrapie can be transmitted from susceptible ewe to transgenic mice via colostrum and milk. It was emphasized that both studies were designed to achieve the highest possibility of transmission success and that this could differ from the field situation. The Panel noted that in both studies, milk from asymptomatic donor ewes transmitted disease, indicating that clinically healthy, Classical scrapie-incubating sheep may shed the causal agents of these TSEs in milk. Moreover, the level of prion infectivity in small ruminant milk

<sup>1</sup> Opinion of the Scientific Panel on Biological Hazards on certain aspects related to the risk of Transmissible Spongiform Encephalopathies (TSEs) in ovine and caprine animals. *The EFSA Journal* (2007) 466, 1-10

<sup>2</sup> Scientific and technical clarification in the interpretation and consideration of some facets of the conclusions of its Opinion of 8 March 2007 on certain aspects related to the risk of Transmissible Spongiform Encephalopathies (TSEs) in ovine and caprine animals. *The EFSA Journal* (2008) 626, 1-11

could become higher during the course of mastitis but the somatic cell count was considered as an unreliable indicator for presence or absence of TSE infectivity in small ruminant milk.

The Panel concluded that the use of milk and milk products from a flock with Classical scrapie may carry a TSE exposure risk for humans and animals. Furthermore, the use of milk and milk products from the general small ruminant population may carry a TSE exposure risk for humans and animals due to the presence of undetected affected flocks in that population. However, because of the difference in scrapie prevalence between affected flocks and the general small ruminant population, the risk of exposure for humans and animals associated with milk and milk products from the general small ruminant population will be lower than the risk from detected scrapie affected flocks.

The Panel also concluded that the exposure to a Classical scrapie agent via milk of an infected animal can be estimated to be 4 to 5  $\log_{10}$  lower than the infectivity found in the same weight of brainstem from a terminally affected animal, and 2 to 3  $\log_{10}$  lower than infectivity found in the same weight of lymphoid tissues from an animal incubating scrapie or from a clinically affected animal.

The BIOHAZ Panel further noted that no information is available concerning the presence of infectivity or PrP<sup>Sc</sup> in colostrum or milk from small ruminants affected by Atypical scrapie or BSE. However, the Panel emphasized that due to the early and progressive peripheral tissue dissemination of the BSE agent in experimentally infected susceptible sheep, the occurrence of infectivity in colostrum and milk of BSE infected susceptible small ruminants would be likely. On the other hand, the apparent restricted dissemination of the agent of Atypical scrapie in affected individuals could limit its transmissibility through milk.

As there is large variation between MS in prevalence of scrapie and production of small ruminant milk, the human and animal exposure associated with small ruminant dairy products varies greatly between MS.

The Panel further concluded that breeding of sheep for relative resistance to Classical scrapie according to the previous EFSA opinion<sup>3</sup> can be expected to reduce human and animal exposure associated with small ruminant dairy products.

The Panel recommended to perform research in order to characterise the exposure risk via milk especially in Atypical scrapie and BSE in small ruminants, to investigate on the stability of prion infectivity in milk during further processing, and to obtain more data to confirm and expand the preliminary information available on the quantitation of infectivity levels in small ruminant milk fractions.

**Key words:** TSE, milk, small ruminants, exposure risk

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<sup>3</sup> Opinion of the Scientific Panel on Biological Hazards on “the breeding programme for TSE resistance in sheep”, *The EFSA Journal* (2006), 382, 1-46  
[www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1178620775678.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620775678.htm)