

Safety of milk with regard to TSE: State of affairs

1. Summary

a. Because of the recent evidence of BSE being present in a number of countries where it had not been detected until recently, Commission services are frequently invited to express their opinion on the security status of ruminant milk as a possible source of TSE infectivity.

b. The experimental evidence so far of bovine milk being safe with regard to BSE risk has been questioned because these experiments were carried out on mice; it was considered ¹ that these tests may have underestimated any possible risk because of the species barrier from cows to mice. It is noted that milk had the potential to transmit prion diseases like BSE because it contains a significant component of leucocytes.

The Commission services therefore invited the Scientific Steering Committee (SSC) to prepare a state of affairs regarding the available knowledge and evidence on the safety of milk with regard to TSE risk.

On the basis of the discussion of a report prepared by the TSE/BSE *ad hoc* Group, the Scientific Steering Committee (SSC) considers that the conclusions of the Scientific Veterinary Committee (E.C., 1996), the Multidisciplinary Scientific Committee (E.C., 1997) and itself (E.C., 1999), remain valid and that the evidence available to date does not point at milk or colostrum representing a possible risk. The SSC also supports the recommendation that for precautionary reasons the milk, colostrum or milk products from suspect BSE cases should not be offered for consumption.

No final results of further experiments became recently available and the SSC confirms the recommendations for research made in each of the previously listed scientific opinions.

2. Report from the TSE/BSE ad hoc Group

The TSE/BSE *ad hoc* Group reviewed the information and evidence available to date. The state-of-affairs report prepared at its meeting of 15 March 2001 on the basis of contributions from various scientists (see section 3) is presented hereafter.

2.1 The Report of the Scientific Veterinary Committee of 1996 (E.C., 1997)

In its opinion of 1996, the Scientific Veterinary Committee, "having examined the considerable epidemiological and infectivity data pertaining to BSE, maternal transmission and milk, concludes that bovine milk from healthy cows and products derived therefrom which contain no animal-derived additives can be safely consumed in any form by any species. There is no evidence that milk transmits BSE and the Committee considers any risk from milk to be negligible".

"In regard to colostrum, [the Committee] regarded any risks to be negligible." It further recommended a "Prohibition on the use of milk (or colostrum) or any product derived from these commodities from any cow clinically suspected to have BSE for any nutritional or other purpose. An exception for the suspect's own calf can be made" (...).

2.2. The scientific opinion of the Multidisciplinary Scientific Committee of 1997 (Will, 1997, E.C., 1997b)

The evidence contained in the full report of the Scientific Veterinary Committee (E.C., 1996) was reviewed in 1997 by the Multidisciplinary Scientific Committee (Will, 1997; E.C., 1997) that concurred with the 1996 conclusions.

A maternal cohort study provided statistical evidence of a maternal risk enhancement (e.g., Donnelly *et al*, 1997 ^{a, b} ²), but did not provide evidence on the risk of transmission by milk as the calves in this study received only colostrum

from their dams and as other explanations than vertical transmission (for example peri-natal conditions) could not be excluded.

A serious hint that milk does not transmit the disease was the beef suckler study (Wilesmith and Ryan, 1997, 1998; Donnelly, 1998) where no cases were reported although all of them received colostrum and milk.

2.3. The SSC opinion on vertical transmission (1999)

In its opinion of 18-19 March 1999 on The possible vertical transmission of Bovine Spongiform Encephalopathy (BSE), the SSC referred as follows to the work of the UK Spongiform Encephalopathy Advisory Committee (SEAC):

"As regards the risks from bovine milk, the Scientific Steering Committee refers to the continuous review by the UK Spongiform Encephalopathy Advisory Committee (SEAC). SEAC has regularly discussed the safety of bovine milk in regard to BSE, the last time on 9 November 1998. The latest substantive SEAC view, expressed on 16 April 1997, was that the measures currently in place to protect the consumer were considered appropriate. (UK law states that milk derived from BSE affected cattle or cattle suspected to have BSE shall not be sold, supplied or used for human or animal consumption, with the exception that it may be fed to the cow's own calf.) SEAC concluded then (16/4/97) that no evidence had been found to suggest that milk from any species affected by transmissible spongiform encephalopathies was infectious. The Committee is keeping the possible risk infectivity in milk under review and stated most recently on 14 May 1998 that there was no reason to change their previous advice on the safety of milk. This advice may need to be updated as new data and information become available.

However, the Scientific Steering Committee notes that, in the absence of any infectivity studies on semen, embryos, fetal tissue, milk and colostrum by i/c inoculation of the homologous species in bovines, ovines and caprines, and in the absence of all the necessary experimental and epidemiological data as detailed in the report, precise estimates of these risks cannot be made."

2.4. Summary of presently available evidence (March 2001):

- a. To date, the infectious agent has not been detected by mice bioassay of milk from humans with kuru or CJD or from cattle with BSE ³ or sheep with scrapie.
- b. To date, no mother to child transmissions have occurred in any animal species used in experimental studies (including primates).
- c. One single case has been reported on in 1992 of a 38-year-old pregnant woman with sporadic CJD whose colostrum was found to be infected when injected i/c into mice (Tamai et al, 1992). However, following further morphological examination of fixed mouse brain by immunohistochemistry for PrP^{Sc}, the Japanese authorities concluded that the published results were invalid as no spongiform change or PrP^{Sc} was found on first passage from human colostrum to mice. The brain from the second passage (mouse to mouse) did show spongiform change and PrP^{Sc} but this was not attributed to transmission from the colostrum (Prof. K Yamanouchi, personal communication to R. Bradley February 1997, in: E.C., 1997)
- d. No mother to child CJD transmissions have occurred in kuru or CJD and neither epidemiological nor experimental studies have demonstrated the vertical transmission of CJD. (There are a handful of iatrogenic CJD cases in pregnant women who have delivered children who remain healthy years afterward - in one case 30 years).
- e. To date, no cow to calf disease transmissions has occurred in association with BSE infected suckler cows.
- f. No excess of BSE cases in the offspring of affected animals in the UK has been observed. Outside the UK, no BSE has been observed so far in the offspring of BSE cows

2.5. Research on milk

Experiments to test milk which can use enough volume of milk to be like the realistic situation are difficult to devise. Currently there seem not to exist plans to inoculate bovine milk i/c into cattle. However a PrP study of milk from experimentally infected cattle commissioned by the UK Food Standards Agency is planned and about to start. A small scale study is nevertheless presently running at the NPU (N.Hunter, personal communication, 14.03.01) with scrapie susceptible lambs removed from their mothers and hand reared. No results are yet available. EC FAIR Project N°CT98-7023 looking among other things to vertical transmission in scrapie. It is expected that it will also be foreseen to look at the colostrum and milk.

2.6. References:

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¹ See also the Prof.M.Ferguson-Smith, Cambridge University, reported on in the media of 16 January 2001.

² These and other studies are further reported and commented on in E.C., 1999.

³ There is no detectable infectivity in bovine milk or mammary gland collected from clinically-affected, natural cases of BSE following bioassay using the i/c route in susceptible mice (MAFF Progress Report 2000). Furthermore, there is no detectable infectivity in milk collected from clinically affected, natural cases of BSE at early, mid or late lactation following bioassay by the i/c or by the oral route in susceptible mice (Taylor et al 1995).