



OPINION ON
THE SAFETY OF TALLOW DERIVATIVES FROM CATTLE TALLOW

BACKGROUND AND MANDATE

On 24-25 June 1999 the Scientific Steering Committee (SSC) adopted its opinion on "*The risks of non conventional transmissible agents, conventional infectious agents or other hazards such as toxic substances entering the human food or animal feed chains via raw material from fallen stock and dead animals (including also: ruminants, pigs, poultry, fish, wild/exotic/zoo animals, fur animals, cats, laboratory animals and fish) or via condemned materials*".

In this opinion the SSC considers that "*Given the fact that animals and materials that carry an actual or suspected TSE risk should be disposed of (...), purified tallow derivatives which do not contain proteins or peptides, can be considered to be safe provided (a) the raw material is fit for human or animal consumption, or (b) provided the production process uses the appropriate, validated and scientifically most up-to-date methods in terms of inactivating the TSE agent.*"

Since June 1999 new data became available in relation to the evolution of the BSE epidemic and from TSE infectivity clearance experiments.

The SSC was asked whether:

"In the light of (1) this new data and (2) the fact that tallow itself is not infectious, would the SSC consider that tallow derivatives manufactured from raw tallow that is sourced from cattle from a GBR-C II country, i.e., where the presence of one or more cattle clinically or pre-clinically infected with the BSE agent in a region or country is unlikely but not excluded, are safe when they comply with the following two conditions:

- a) the raw tallow is sourced from ruminants that are fit for human consumption, i.e., fallen stock is excluded;

b) the raw tallow is then submitted to Hydrolysis at $> 200^{\circ}\text{C}$ for 2 hours and corresponding pressure, followed by either:

- To obtain glycerol and fatty acids and esters: transesterification or hydrolysis at at least 200°C and an appropriate corresponding pressure for 20 minutes, followed by a purification to remove (insoluble) impurities; or
- To obtain glycerol and soap: saponification with NaOH 12M :
 - batch process: at 95°C for 3 hours; or:
 - continuous process: at 140°C , 2 bars (2000 hPa) for 8 minutes or equivalent conditions,

followed by a purification to remove (insoluble) impurities.

If the combination of the above conditions results in a safe product, would only one of the above conditions also result in safe tallow derivatives? If so; which condition?"

OPINION

With regard to BSE risk, cattle tallow is being classified in the lowest category of infectivity; the SSC has not classified it as “not infectious”.

Given the pharmaceutical, cosmetic and food applications of tallow derivatives, the SSC considers it is justified to modulate the risk reduction according to the source of the tallow used for the production of the derivatives and the geographical BSE risk level:

- a) Tallow derivatives are safe with regard to BSE risk regardless of the production process if they are derived from food- or feed- grade tallow and if cross contamination is prevented. The criteria for food- and feed-grade tallow are detailed in the SSC opinion of 28-29 June 2001 on the safety of tallow obtained from ruminant slaughter by-products.
- b) Tallow derivatives are safe with regard to BSE risk regardless of the production process if they are derived cattle from GBR-C I countries¹ and fallen stock are excluded.

¹ GBR-C stays for “Geographical BSE risk in cattle”.

- c) For GBR-C II countries, tallow derivatives are safe if fallen stock are excluded, the animals from which the tallow is sourced are fit for human consumption, the raw tallow is produced according to the standards indicated in the SSC opinion of 28-29 June 2001 on the safety of tallow (including filtration), the processing conditions described in the mandate have been used and cross contamination is prevented.
- d) For GBR-C III and IV countries, tallow derivatives are safe if, in addition to the above (c), the specified risk materials have been removed and are not used for the production of tallow / tallow derivatives.

Notes:

- The SSC considers that the production of tallow derivatives is not a possible alternative method for the disposal / recycling of Category I animal by-products as defined in Regulation (EC) 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down the health rules concerning animal by-products not intended for human Consumption. Should this alternative be considered, a separate and specific risk assessment is required, along the lines specified in the *Framework for the assessment of the risk from different options for the safe disposal or use of animal by-products which might be contaminated with microbiological agents including TSE agent*, adopted by the SSC on 10-11 April 2003.
- The SSC, in its opinion on “Fallen Stock” of 24-25 June 1999 recommends excluding the recycling of fallen ruminant stock also in GBR-C I countries because it is in this class of risk animals that a TSE would most likely first occur if the agent had entered the cattle population.
- Experience has shown that in several of the countries originally classified as GBR-C II countries, BSE was eventually detected when the surveillance improved. Good BSE surveillance remains thus essential also in GBR-C II countries.