

Opinion of the Scientific Panel on Biological Hazards of the European Food Safety Authority on the BSE risk from cohort animals: bovine hides and skins for technical purposes¹

Question N° EFSA-Q-2005-292

Adopted on 18 May 2006

SUMMARY

The European Commission requested the European Food Safety Authority for an opinion on the TSE risk from use of hides and skins from cohort animals for technical purposes.

The major use of cattle hides is for the production of leather. However certain parts of these hides, unfit for leather production are used for manufacture of technical products and for the production of gelatine and collagen for human consumption. Allowing the hides of culled cohort cattle and those of UK cattle born before August 1996 to be used for leather production, both having a larger risk of being infected with (Bovine Spongiform Encephalopathy) BSE than the general cattle population, could result in an increased risk for consumers by accidental inclusion of such hides into the raw materials for gelatine and collagen.

Despite available results from studies on the presence of PrP^{Sc} and tissue infectivity of different type tissues and sensitive detection methods, so far infectivity has never been found in cattle hides. It is assumed that infectivity of cattle hides could only result from cross-contamination with nervous tissue during and after slaughtering. In this case cross-contamination would be very small, and different processes would have a certain capacity to inactivate Transmissible Spongiform Encephalopathy (TSE) agents. In addition to that and because of the regulations in place and all steps and processes are supervised by competent authorities and can be well controlled, it was concluded that if contamination is avoided, the production of leather made from the hides of cohort cattle presents a negligible risk.

Slaughtering cohort cattle applying the same conditions and precautions as in a slaughterhouse but under time separated conditions from normal slaughter or in dedicated premises, and removal of the hide immediately after slaughter will result in the smallest risk of cross-contamination. In addition, it was concluded that clear and immediate labeling of the hides of cohort cattle at the place of slaughter, direct transport of these hides from there to a tannery exclusively processing animal by-product (ABP) category 3 hides, and destruction of all untanned and tanned side products, will give the smallest risk of accidental inclusion of hide of cohort cattle in raw material for products intended for human consumption. Glue made from leather shaving from the hides of cohort cattle forms a higher risk than the other products if contamination can not be excluded. The hide of the head of cohort cattle presents

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the highest risk for cross-contamination by blood and brain spilled through the hole in the forehead contaminating the skin of the scalp.

A quantitative risk assessment (QRA) is not possible with the data, which are presently available, because no accurate data on the amount of cross contamination of skin with nervous tissue are known.

It is however recommended that measures should be taken to further minimise the risk of cross contamination and/or of accidental inclusion.

Keywords: TSE, BSE, hides, skin, cohort animals, leather, tanning, gelatine, collagen, animal by-products

BACKGROUND

Under Regulation (EC) No 999/2001 (“the TSE Regulation”, EC 2001), cohort animals must be killed and destroyed. No part of the animal may be used for any purpose. However, derogation was granted for the keeping of bulls for semen donation till the end of their productive life.

Under current animal by-products legislation, hides and skins from fallen stock are normally considered category 3 materials and as such are allowed to be used for technical purposes i.e. for leather production. However, fallen stock which are either suspected or confirmed TSE positive, as well as animals killed in the context of TSE eradication measures (i.e. cohorts) are category 1, and as such must be disposed of.

Different scientific opinions were issued related to the topic:

- The Scientific Steering Committee (SSC), in its fallen stock opinion 1999, considered that animals suspected or confirmed as having a TSE should not be used for any purpose.
- In the SSC opinion on BSE-related culling in cattle 14-15 September 2000, birth-cohort culling as recommended as the least measure to be taken, regardless of the epidemiological situation; culling assumed destruction and exclusion from food/feed.
- In the SSC opinion of 7-8 November 2002 on the TSE infectivity distribution in ruminant tissues, skin was categorised as tissues of confirmed BSE cases in which no infectivity was detected.
- In the SSC opinion of 6-7 March 2003 on the TSE risk from ruminant hides and skins used in the production of Gelatine, use of bovine hides did not present a risk with regard to TSE, provided contamination with potentially infected materials was avoided.
- Finally in the EFSA opinion on BSE related culling in cattle of 21 April 2004, the prevalence of BSE in birth cohort was reported as ten times higher than in the healthy population.

In addition, the OIE recommends that all cohort animals, when slaughtered or killed are completely destroyed at the end of their productive life. For trade, hides and skins from healthy slaughtered animals should not be subject to BSE-related conditions, provided that no other cattle tissues are contained.

In the meantime, however, certain Member States have raised serious concerns over the economic losses associated with the inability to use hides and skins of cohort animals, the difficulty in disposing of them and the disproportionate nature of the ban on their use for technical purposes.

TERMS OF REFERENCES (TOR)

The Commission would therefore like to request the Authority for an opinion on the TSE risk from use of hides and skins from cohort animals for technical purposes.

In particular, the EFSA is invited to answer the following questions:

1. Can hides and skins from cohort animals be considered, under certain conditions, safe for use of leather production?
2. If so, under what conditions might leather production from the hides and skins of BSE cohort bovine animals be considered safe?
3. Can the risk from accidental inclusion of hides and skins from cohort animals in the food or feed chains be assessed, quantitatively or semi-quantitatively, on the basis of scientific knowledge and BSE-prevalence data for the cohort?
4. If the risk from accidental inclusion of hides and skins from cohort animals in the food or feed chains cannot be assessed quantitatively, can a qualitative risk assessment be made?

ASSESSMENT

1. Introduction

The introduction provides an overview and summary on former opinions of the Scientific Steering Committee (SSC) and of the EFSA Scientific Panel on Biological Hazards related and relevant to this question.

1.1 SSC Opinions on the safety with regard to TSE risks of hide (gelatine production)

- *Updated Opinion on the safety with regard to TSE risks of gelatine derived from ruminant bones or hides; adopted by the Scientific Steering Committee at its meeting of 12-13 September 2002 (SSC, 2002a).*

- *Updated Opinion on the safety with regard to TSE risks of gelatine derived from ruminant bones or hides; adopted by the Scientific Steering Committee at its meeting of 5-6 December 2002 (SSC, 2002b).*

- *Updated Opinion on the safety with regard to TSE risks of gelatine derived from ruminant bones or hides; adopted by the Scientific Steering Committee at its meeting of 6-7 March 2003 (SSC, 2003).*

The SSC concluded: “When ruminant hides are used for the production of gelatine, they are usually obtained from bovines. On the basis of current knowledge it can be considered that the parts of bovine hides used for the production of gelatine do not present a risk with regard to TSEs, provided contamination with potentially infected materials is avoided. The risk of contamination of the skin with TSE agent by contact with infected tissues is small if slaughter and skinning are appropriately performed. The SSC considers that - regardless of type of production process, but assuming that any gelatine from hide production process would have some TSE infectivity reduction capacity at least equivalent to a collagen production process - the respect of the recommendations on sourcing listed further on will result in a safe end-product.”

- *Updated Opinion on the safety with regard to TSE risks of gelatine derived from ruminant bones or hides from cattle, sheep or goats (including amendments to the Scientific Report attached to the Opinion of 21 January 2000); adopted by the Scientific Steering Committee at its meeting of 28-29 June 2001 (SSC, 2001a).*

The SSC concluded: “The conditions for raw material for food or feed-standard gelatine should apply or if the animals from which the raw material is derived are not fit for human consumption, the recommendations in the SSC opinion of 25 June 1999 on "Fallen stock" should be complied with. In addition, the specified risk materials (SRM) should be removed and the gelatine should be submitted to an appropriate production process, as discussed in the attached report of the TSE/BSE ad hoc Group. If the intended end use cannot be verified and controlled to exclude any human or animal consumption or use, or if no dedicated production lines exist for technical and other uses, then the conditions outlined for food-standard gelatine should apply.”

1.2 SSC Opinion on fallen stock animals

- *Scientific 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; adopted by the Scientific Steering Committee at its meeting of 24-25 June 1999 (SSC, 1999).*

The SSC considered that humans should not be exposed to hazardous agents via products recycled from fallen stock and condemned materials. If the reasons an animal died or was sacrificed was unknown or has been shown to involve a hazardous, chemical or biological agent, the fallen stock or suspect condemned material should be disposed of in such a way that any processing into human or animal consumption products is avoided. They might be suitable for certain industrial / technical uses provided their passage into food or feed and in medicinal products is excluded.

The SSC did not consider that it was currently practicable (although highly desirable) to expect a surveillance scheme in any member state which guarantees that only fallen stock and condemned material of proper quality are recycled in feed. It was also concerned about the potential for post slaughter infection or contamination of low risk material as a consequence of handling, transport and / or storage. The Committee therefore proposed that all material from dead animals of non specifiable causes should be considered as condemned.

The Committee further concluded that regarding the risks from TSEs and unconventional agents, according to current scientific knowledge, inter- and intraspecies transmission might occur across a range of animal species. The rendering standard of at least 133°/20 min/3 bars could not be considered as totally effective in inactivation TSE infectivity from infective materials. This would apply to all animal species with potential for TSE infectivity. Thus, additional protection measures ensuring absence of TSE infectivity were required.

1.3 SSC Opinion on TSE infectivity distribution in ruminant tissue

- *Update of the Opinion on TSE Infectivity distribution in ruminant tissues; adopted by the Scientific Steering Committee at its meeting of 10-11 January 2002 and amended on 7-8 November 2002 (SSC, 2002c).*

This Opinion summarizes several studies on the infectivity of various kinds of tissues from both naturally and experimentally BSE affected cattle. Bovine skin tissue was intracerebrally and intraperitoneally inoculated into the wild type mice RIII and C57BL (Kimberlin 1996; Wells et al., 1996, 1998, 1999 and unpublished data). Applying immunohistochemistry no evidence of PrP^{Sc} could be detected in the skin of the BSE affected cattle and the bioassays did not provide any positive result for infectivity of this tissue.

Infectivity was found in the hides of other species of the bovidae family, the greater Kudu, after inoculation into C57BL-J6 mice (Cunningham *et al* 2004). However, this is a different species from cattle and the pathogenesis and pathology is not considered to be representative for the cattle.

As the only potential source of infectivity the SSC considered that in the case of captive bolt stunning, blood containing brain material may spill through the hole in the forehead and contaminate the skin of the scalp.

1.4 Opinions on the BSE risk of cohort animals

- *SSC Opinion on the hypotheses on the origin and transmission of BSE Report adopted on 29-30 November 2001 (SSC, 2001b).*

- *Opinion on The six BARB BSE cases in the UK since 1 August 1996; adopted by the Scientific Steering Committee at its meeting of 29-30 November 2001 (SSC, 2001c).*

The higher risk of BSE in cohort animals compared to overall cattle population has been considered in depth in a number of former SSC Opinions.

On the basis of these opinions there is very clear and strong support from epidemiological studies, rendering studies and the effect of feed bans in all countries with BSE, for the hypothesis of infected mammalian protein in the form of MBM being the major vehicle for BSE transmission in cattle.

Maternal transmission was considered as another possible route of transmission. However, there is no evidence so far that this so called 'maternal transmission' occurs in the absence of a feed borne source and no plausible mechanism for the so-called maternal transmission has been identified. Nevertheless, it is not currently possible to eliminate maternal transmission completely as an occasional cause of BSE.

1.5 Opinions on the BSE-related culling

- *Opinion on BSE related culling in cattle; adopted by the Scientific Steering Committee at its meeting of 14-15 September 2000 (SSC, 2000).*

The SSC stated that in view of the limited data available the impact of the epidemiological situation in a country on the relative efficiency of practically possible culling schemes could not be fully assessed. It was, however, likely that birth cohort culling was in most cases more cost-efficient approach. The position was based on the definition of a birth cohort including, as suggested by the available data, all animals born and/raised in the same herd as the confirmed case within approximately 12 months before and after the date of birth of the index case. All animals from these cohorts should be traced, killed and destroyed, independent of their current localisation.

- *Opinion of the Scientific Panel on Biological Hazards on a request of the Commission on BSE-related Culling in Cattle Adopted on 21 April 2004 (EFSA, 2004).*

Based on results of testing of ruminants for TSE (2002-2003) it could be concluded that the prevalence of BSE in the birth cohorts of affected cattle was about ten times higher than the prevalence of BSE in the overall healthy animal population.

2. BSE risk of hides, skins from cohort animals for technical purposes

2.1 BSE prevalence in cohort animals

The Commission's Regulation 1492/2004 amending EC Regulation 999/2001, defines cohort animals: "Cohort means a group of bovine animals which include both (EC, 2004a):

- animals born in the same herd as the affected bovine animal and within 12 months preceding or following the date of birth of the affected bovine animal; and
- animals which at any time during the first year of their lives were reared together with the affected bovine animals during the first year of its life".

Because different member states applying different culling schemes (table 1) and several member states cull more animals than only cohort animals as defined by the legislation, the exact number of culled and positive tested cohort (in a strict sense) cattle is unknown. However figures on "animals culled under BSE eradication" are known (Annex A). These figures are forwarded by the member states to the EC and reported in the EC's annual report on the monitoring and testing of ruminants for the presence of transmissible spongiform encephalopathy (TSE) in the EU.

The EC's annual report defines "Animals culled under BSE eradication" as follows (EC, 2004b):

- birth cohorts (bovine cattle born in a herd within 1 year before or after the birth of a BSE case)
- rearing cohorts (bovine animals reared together with a BSE case during the first year of their life), offspring
- and any other bovine animals killed because of an epidemiological link to a BSE case.

It is important to note that this defined population in the EC's annual report covers all cohort animals according to legislation and in addition other animals depending on the different culling scheme applied in the member state. Therefore the absolute number of positive animals from this population "animals culled under BSE eradication" could be an overestimation when used for "positive cohort animals", but the relative number of positive animals, the prevalence, for cohort animals according to the definition of 999/2001 is likely to be greater. (E.g. in Ireland it is estimated that only around 10 percent of the animals culled under BSE eradication were true cohort animals.)

Table 1: Culling policy in member states (as communicated by DG Sanco, EC)

Member state	Culling policy
BE, DE, FL	cohort slaughter, and progeny, only
AU, DK, EL, FR, IRL, SW	cohorts and whole herd slaughter compulsory
ES, IT, LU, CY, CZ, EE, HU, LV, LT, MA, SL, SK	minimum cohorts, but additional culling schemes unknown
NL	minimum cohorts; farmer may choose to have herd slaughtered
PT, PO	All animals in the herd born before August 1996 must be culled, in addition to the cohorts. For cases in animals born after August 1996 only cohorts are culled
UK	Only the offspring is culled. Cohorts of cases born in 1996 or later are put under restrictions and are not allowed to be slaughtered for human consumption. Pre-1996 born animals not allowed into food or feed chains whether cohorts or not. Since March 2005, all cohort animals of BSE-positive cases born after July 1996 are identified and killed

The BSE prevalence in cattle culled under BSE eradication is considerably higher than in the average cattle population (Annex A). Over the period of 2001 until 2005 the BSE prevalence in culls under BSE eradication policy in 15 EU member states was 0.033 % compared to 0.0026 % in healthy cattle. While the BSE prevalence in healthy cattle has decreased in these member states from 0.0036 % in 2001 to 0.0012 % in 2005, in fallen stock from 0.0609 % in 2001 to 0.0196 % in 2005, the prevalence in cattle from cohort culls has increased from 0.028 % in 2001 to 0.078 % in 2005. However in terms of absolute figures, also the number of animals tested posted for BSE in the population of animals culled under BSE eradication, has decreased (from 16 in 2001 to 9 in 2005).

Because of the policy of the United Kingdom that cattle born before the August 1996 feed ban are not allowed to enter the food or feed chain approximately 700,000 cattle born before this ban are still alive in Great Britain (GB). In table 2 the healthy slaughter positives in the pre August 1996 birth cohorts for GB are given.

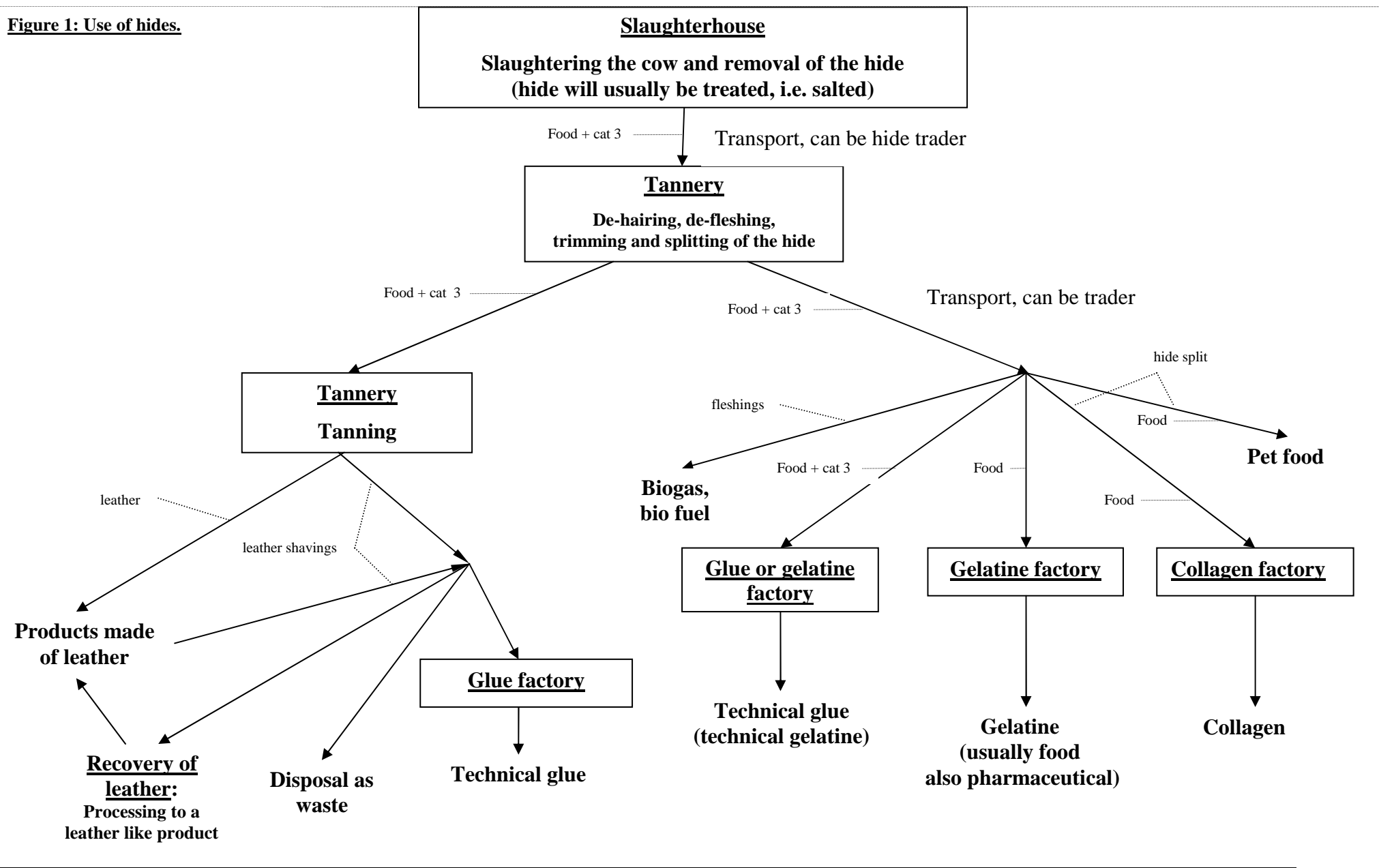
Table 2: Healthy slaughter BSE positives in GB pre August 1996 birth cohorts (personal communication by Dr. Mark Arnold, 2006)

Year	Number of cattle tested	Number of BSE positives found
2001	650	0
2002	10086	9
2003	10742	9
2004	10015	6
2005	8401	6

2.2 The processing and use of hides as raw material for the leather production, for other technical purposes and for gelatine and collagen

Figure 1 provides an overview on the processing and use of hides as raw material for leather production, for other technical purposes and for gelatine and collagen.

Figure 1: Use of hides.



2.2.1 Collection of hides

The hide is removed (skinned) as one of the first steps in the slaughtering process. The hide is then numbered by the slaughterhouse and stored in a collection centre. This will usually be the collection centre of a hide-trader, but can also be the collection centre of the slaughterhouse. Here the hide is stored until the results of post-mortem testing, including a BSE test, are known. If the result of the BSE test is negative, then the hides are sorted into hides from cattle intended for human consumption and category 3. Hides from BSE positive are collected as category 1 animal waste. After post mortem sorting the labels are removed from the hides and the hides are sorted into lots, which are clearly labelled. Collection centres/hide storages must provide separate storage of the different categories: before post mortem examination of the animal including the BSE test, hides from cattle intended for human consumption, category 3. Slaughterhouses with an own collection centre may deliver directly to the tanneries or to hide-traders. The hide trader(s) deliver the hides to the tanneries.

As the majority of hides are from animals fit for human consumption a large portion of these are sold as category 3 hides.

2.2.2 Tanning of the hides

Tanneries may process hides from cattle fit for human consumption and category 3 hides. The different categories must be processed separately, or on dedicated production lines or separated in time on the same production line. To prevent the (logistical) problems involved with two categories, many tanneries are exclusively processing hides of only one category. The tanning process consists of several consecutive steps. Often the hides are washed first to remove the salt used for conserving the hide and any remaining blood. Then the hides are de-haired with a solution/emulsion of calcium hydroxide and sodium sulphite. To this, sodium hydroxide may also be added. Hereafter the hide undergoes several treatments: washing to remove hair and alkali, treatments with enzymes and treatment with an acid salt solution to remove the remaining alkali and to prepare the hides for the tanning step, while also the fleshings and the parts less fit for leather are removed, and the hide is split into the grain layer for leather production and the dermal layer. These parts can be removed at several points in between these steps, but can also be left on the hide and removed after tanning of the hide. In that case the resulting fleshings, hide cuts and splits can only be used for technical products.

Fleshings may also already have been removed at the slaughterhouse and disposed of.

Presently tanning is mainly done with chromium salts (chromium sulphate or similar material) the so-called wet blue tanning, but several other methods can be used like the wet white method (glutaraldehyde), which because of environmental reasons is now often used instead of the wet blue method, tanning with organic products; i.e. vegetable tanning like the old method using oak bark and leaves, tanning with fat and/or oil, with aliphatic aldehydes etc. The tanned hides next undergo several finishing steps, one of these is a process in which material is removed from the tanned hide, the so called leather shavings. During the processing of the leather into final products there will be also leather waste.

2.2.3 Application of leather and by-products of the tannery

The main product of the tanneries is the leather, which is processed into different products made from leather. A large part of this production will take place in low cost third countries, after which the final product will be imported into the EU again. The different by-products go to different industries or to other streams (see figure 1):

Gelatine and collagen for human consumption must be manufactured from material from cattle fit for human consumption. Therefore, these manufacturers can only buy their raw material at tanneries processing this kind of hides. Technical glue and gelatine may be manufactured from category 3 raw material. However, in the EU almost all producers of technical glue and technical gelatine also manufacture food gelatine. Therefore, because of the EC legislation, these manufacturers must also use raw material from animals fit for human consumption for these technical products.

Hide cuts and hide splits from category 3 hides, which are not used for technical glue and gelatine, have to be disposed as animal waste, or exported as raw material for technical glue/gelatine to third countries.

In the EU no gelatine or glue is manufactured anymore from chrome leather shavings or leather waste, however in certain third countries it is. Because much of the leather tanned in the EU is exported to low cost third countries for the manufacture of leather products, shavings and leather waste from these hides may be used there for the production of technical glue.

2.2.4 Gelatine and glue

When hides splits and trimmings are used to manufacture gelatine, these are after arrival at the gelatine plant first cut to smaller pieces and often first washed with water. Then, or directly after cutting when the washing step is omitted, the pieces are subjected to treatment with a saturated lime solution of pH 12.5 for at least 3 weeks, usually 4 to 8 weeks, or to a treatment with lime and NaOH for a shorter period of time. Then the hide pieces are washed to remove most alkali and neutralised and conditioned with dilute H₂SO₄ followed by washing with water to remove excess acid. Sometimes the washing water is made slightly alkaline with NaOH. Next gelatine is extracted from the limed hide pieces with hot water. The obtained gelatine extract is purified by filtration with diatomaceous earth and often the extract is ion-exchanged to remove residual salts. Next the gelatine solution is concentrated by vacuum evaporation of most of the water, or by ultra filtration followed by vacuum evaporation. Finally the gelatine solution is UHT sterilised at 138 to 140°C for at least 4 seconds, cooled to a gel, which is extruded, finely divided, and dried by a stream of warm air.

Technical glue can be made from fleshings, hide trimmings and splits. It can be manufactured by the above alkaline (limed hide) process, usually with a shorter liming time, or by a process in which the starting material after cutting is only subjected to a treatment with dilute acid for several days. Glue is usually less thoroughly purified than gelatine; i.e. instead of diatomaceous earth filtration other means are used to remove drifting particles, like filtration through cloth or precipitation. Technical glue also will not be sterilised, and usually preservatives are added to it.

2.2.5 Collagen

Collagen from hides is exclusively made from hide splits. Unlike to gelatine manufacture there is no single manufacturing process for collagen and different manufacturers use different processes. Collagen manufacturing processes differ from the gelatine manufacturing process. The reason is the nature of the final material; gelatine is made by partial hydrolysis of collagen such that a mixture of soluble proteins is obtained. In collagen manufacture the collagen must remain intact. Collagen is not or very poorly soluble in water.

Common treatments in all collagen manufacturing processes are treatment with alkaline (calcium hydroxide eventually with added NaOH) and Na₂S. This is almost always done at the tannery but can be repeated at the collagen plant. The other common treatment is washing with water which will be done several times in the process. Many processes also contain a treatment with alkali, usually a solution of Ca(OH)₂, of which the pH may be between 10 and 12.5, and of which step the duration may vary. A treatment with HCl in the pH range of 0.5 to 3 is also very often used. Other treatments, which can be used are treatment with NaOH + Ca(OH)₂ at pH 12 to 13, treatment with proteolytic enzymes to break down non-collagen protein, enzymatic degreasing, and treatment with dilute alkaline H₂O₂.

The duration of these steps may vary in the range between a few hours and 3 weeks; a few hours is most common

2.2.6 Regulations and commercial document

The entire process from the slaughterhouse until manufacture of gelatine and collagen is strictly regulated. All participants, slaughterhouses, hide collection centres, traders, tanneries, gelatine manufacturers and collagen manufacturers must be registered and are supervised by the veterinary authorities or their equivalents. Hides or batches of hides must be labelled and accompanied by veterinary or commercial documents, containing information to identify the batch, the contents and category of the batch and the name and registration number of the supplier. All participants must have a quality system, and have to keep documentation for at least 2 years. All participants are regularly inspected by the competent authorities.

At the collection centre the fresh hides from the slaughterhouse of which the carcass is awaiting post mortem BSE testing, are kept separate, and the hides are labelled individually or batch wise. When test results are known the hides are sorted into hides from cattle fit for human consumption and category 3 hides. Hides of BSE positives are disposed of for destruction. The slaughterhouse labels are removed, and batches of sorted hides are labelled according the system used by the collection centre, which is approved by the authorities.

When hides are transported from the collection centre to tanneries the hides are accompanied by the above mentioned commercial document which states the category of the hides. When delivered to a tannery which processes hides from cattle fit for human consumption the category of the batch must correspond with that, and this category must be on the commercial document. When delivered to a tannery which processes category 3 hides, the category of these hides may be category 3 or fit for human consumption downgraded to category 3. Tanneries which process both categories must take care for separation of starting material of both categories, for separate processing, or at dedicated lines, or separated in time, must also take care for separate storage of the by products, and for correct labelling, documenting and delivery of material of both categories.

When by-products of the tannery (fleshings, hide cuts, hide splits) are delivered at a company which processes these, they must be of the correct category and accompanied by the earlier mentioned commercial document stating this category. In case of EU gelatine manufacturers and collagen manufacturers the category must be from cattle fit for human consumption. In case of manufacturers of technical products or disposal, it can be category 3 or fit for human consumption downgraded to category 3.

Delivery will not always be directly from collection centre to tannery, and from tannery to processors of tannery by-products, but will also take place through traders. Traders only can act as intermediates, or can store the products themselves. These traders must also be registered, and are also supervised by the authorities.

When the processes of handling, labelling, storage, transportation, delivery and receipt are done correctly no material of the wrong category will be used for the different final products. This depends on the quality systems of the companies, their organisation, and on the supervision on it both by the companies themselves, and by the authorities. Important is that all these companies must be officially registered, for which they have to comply with the demands of the competent authority, and that they are supervised by that authority.

Accidental exchanging of categories can occur at the collection centres, at the storage of traders, and at tanneries, which process hides from cattle fit for human consumption and category 3 hides. Accepting material of the wrong category during delivery is very improbable as long as the category on the documentation is indeed the category of the delivered batch; identification of material fit for human consumption and/or category 3 is only by the commercial document, which states the category.

The smaller the number of steps and the number of organisations that handle both categories, the smaller the risk of accidental exchange of categories; when hides of cattle fit for human consumption will go directly from a hide collection centre to a tannery, which exclusively processes hides from cattle fit for human consumption, and which directly delivers the by-products to gelatine manufacturers and collagen manufacturers, accidental exchange of categories can only occur at the collection centre.

Not only the hides of cattle slaughtered at slaughterhouses are used for leather production, but also the hides of fallen stock. These animals are usually skinned at the rendering facility and are exclusively category 3.

2.3 Risk from accidental inclusions of hides and skins into the food and feed chain

2.3.1 Human exposure risk

Human infection with vCJD by BSE agent on hides probably could only occur from the final products.

The route of infection by remaining infectivity of leather would be directly through the skin, but this risk is considered as extremely unlikely. There are very limited data available on the protection the human skin will give against BSE infection, but on the other hand butchers regularly have been in direct contact with BSE infected brain and spinal cord and no link

between this kind of exposure and vCJD has been found. Further the level of infectivity of leather would be extremely low if at all existing.

A potential route of infection by gelatine and collagen is the oral route, though infection through implantable medical devices containing gelatine or collagen is also a possibility.

2.3.2 Possibilities of cross-contamination and accidental inclusion into the food and feed chain.

The possibility that hides or parts of hides of cattle culled in the frame of BSE eradication in EU25 and of the UK pre-August 1996 cattle will be accidentally included in the food or feed chain depends on the circuit in which these hides will be handled. When we assume that these hides will be handled in the same circuit as hides originating from slaughtered cattle and from fallen stock a number of risks of accidental inclusion in the food and feed chain can be identified. In it is assumed that cohort cattle will not be slaughtered at a slaughterhouse where cattle is slaughtered for meat production, but at a dedicated place.

There is a risk of accidental inclusion of these hides or of parts of these on all places where also hides or parts of hides of cattle fit for human consumption and category 3 hides are handled, these are:

- In the slaughterhouse cattle are usually killed with a captive bolt which penetrates the brain. This could potentially result in cross-contamination of the hide by two different ways: by blood and brain directly coming from the wound as small drops and aerosols which could fall on the hair of the slaughtered animal and also on carcasses. Most of the spilled material would be on the head near the wound, but some may also be on the hair of the body hide. The second is that some brain may get into the blood stream and be transported in the blood vessels in the hide.
- Cattle culled in the frame of BSE eradication in EU25 and of the UK pre-August 1996 cattle would be killed in one place and the cadavers would be transported to a second place where the hides would be removed, allowing heavy cross-contamination by blood and brain from the wounds in the skulls on the hides of all cadavers. Culling under slaughter house conditions could reduce this risk of cross-contamination.
- The rendering facility when the hides are removed there, instead of the place where the cattle are killed. The hides accidentally could be exchanged with category 3 hides of fallen stock, and could be exchanged accidentally again further on in the circuit with hides of cattle fit for human consumption, or be exported to a third country and parts of it used in the production of edible gelatine or collagen.
- The storage facility of a hide trader where also hides from cattle fit for human consumption are stored. In the case of accidental exchange with category 3 material at the storage facility of a trader there are the same risks as above on a consecutive second exchange with hides form cattle fit for human consumption and the risk of export to third countries.
- At a tannery which also processes hides from cattle fit for human consumption, in their storage of hides and when they also store splits etc. as batches in their storage of these materials. The risk during the processing of hides will be small, as this should be done separately, but when separated in time there is a risk when changing categories. There is

also a risk at removal of fleshings, hide cuts and hide splits, when these would not be handled in strictly separated circuits.

- At a tannery which processes category 3 hides there would be the risk of exchange with category 3 material, which will need a second exchange with food grade material, which would not be very probable. This risk of a second exchange could be somewhat larger when the tannery would also process hides from cattle fit for human consumption.
- When the leather manufactured from the hides of cohort cattle would not be allowed to be exported to third countries, accidental exchange could still occur in the leather storage of a tannery.

It should however be noted that, as has been described above, the circuit of traders with storage, and of tanneries is strictly regulated and supervised by the competent authorities. Though the risk of exchange in this circuit cannot be excluded it most probably will not be very large.

When the hides of cattle culled in the frame of BSE eradication in EU25 and of the UK pre-August 1996 cattle would be allowed to be exported, there is a risk, because of the large trade in hides, that these same hides could be imported again in the EU. How large this risk is, is difficult to estimate. That these hides would be re-imported in the EU as hides from cattle fit for human consumption is improbable. When exported, hide cuts and splits could be used for gelatine manufacture because regulations on gelatine differ in different countries. This gelatine, or products containing it, might be imported into the EU.

The hide of the head is not used in the EU for manufacture of gelatine. Most head hide is exported to third countries and can be used for this purpose. When the head hide of cattle culled in the frame of BSE eradication in EU25 and of the UK pre-August 1996 cattle would be allowed to be exported, it might also be used for that purpose. This gelatine or products containing it could be imported into the EU.

Much of the leather tanned in the EU is exported as half product to low wage third countries to be processed into various end products like shoes and leather cloths etc. In some third countries shavings and cuttings of wet blue leather are processed into technical glue. However, that some of this glue will be used for edible purposes cannot be completely excluded. In the EU leather shavings and cuttings are disposed of, or are used for the manufacture of recovered leather.

There is in the EU still a limited production of technical glue in dedicated factories. Such factories can use category 3 raw material. It cannot be excluded completely that a small amount of this glue will finally (accidentally or illegally) enter the food circuit. When the fleshings, hide cuts and splits of the hides of cattle culled in the frame of BSE eradication in EU25 and of the UK pre-August 1996 cattle would be allowed for the manufacture of technical glue, some might finally enter the food circuit.

2.3.3 Use of hides under the “Over Thirty Month” (OTM) scheme in the UK.

From April 1996 until 23 January 2006 in the UK all cattle over 30 months of age was not allowed for human consumption and had to be destroyed. For this purpose these animals were slaughtered at dedicated slaughterhouses. The hides of these cattle were recovered and marked with a stain that was indelible until processed. The hides were kept physically

separate from other hides. Fleshings were removed at the slaughterhouse and destroyed with the rest of the carcass. The hides were processed under official control, at approved tanneries. The hides were processed in the UK to make sure that they were properly controlled, and that all untanned by-products were controlled and destroyed.

The Over Thirty Month scheme was replaced by the “Older Cattle Disposal Scheme” in January 2006.

2.3.4 BSE risk of products manufactured from hide

To compare the risk of different products made from hides of cattle culled in the frame of BSE eradication in EU25 and of the UK pre-August 1996 cattle an estimate of the residual infectivity would have to be made. A full QRA is not possible with the data, which are presently available, because no accurate data on the amount of cross contamination of skin with nervous tissue are known.

An assumption could be made that the cross contamination of a hide with brain will be at least 10 times less than of bone with nervous based on former SSC opinion on gelatine (SSC 2002a, SSC 2002b).

It should be noted that if regulations would be complied with, glue from leather shavings can only accidentally get into the food chain. It should further be noted that gelatine and collagen for human consumption can only be manufactured from tissues of animals fit for human consumption. According to current legislation, hides from cattle culled in the frame of BSE eradication in EU25 and of the UK pre-August 1996 cattle should not enter the food and feed chain.

2.4 Can hides and skins from cohort animals be considered, under certain conditions, safe for use of leather production? (ToR, Question 1)

No infectivity has been detected in hides in the pathogenesis study, and infectivity most probably could only result from cross contamination. When properly slaughtered, skinned and handled the cross-contamination on a hide will be minimal, while the tanning process also will reduce part of the infectivity. An infection by remaining infectivity of leather through the intact skin is considered as extremely unlikely. There are very limited data available on the protection the intact human skin will give against BSE infection, but on the other hand butchers regularly have been in direct contact with BSE infected brain and spinal cord and no link between this kind of exposure and vCJD has been found. Further the level of infectivity of leather would be extremely low.

Compared with healthy slaughtered cattle population, the BSE incidence in cattle culled in the frame of BSE eradication culling is higher. When it is assumed that BSE infectivity due to eventual cross contamination will remain mainly on the hide of the infected bovine, and those slaughtered immediately before and/or after it, the likelihood that leather from cattle culled in the frame of BSE eradication in EU25 and of the UK pre-August 1996 cattle could carry residual BSE infectivity due to cross contamination is larger than with the average population.

Altogether if contamination is avoided, the production of leather made from the hides of cattle culled in the frame of BSE eradication in EU25 and of the UK pre-August 1996 cattle presents a negligible risk.

The SSC Report on the UK Date Based Export Scheme and the UK proposal on Compulsory Slaughter of the Offspring of BSE Cases emphasised that measures to avoid cross-contamination should include issues concerning time and space separations should be in compliance with previous recommendations from the committee on the UK Export Certified Herds Scheme (SSC, 1998). The same could be applied in this context of culling cohort animals to minimize risk.

2.5 Under what conditions might leather production from the hides and skins of BSE cohort bovine animals be considered safe? (ToR, Question 2)

Safe conditions were used in the UK where all cattle over 30 months of age were not allowed to enter the food and feed chain according to the UK “Over Thirty Month” rule. When such animals were slaughtered the entire carcass had to be destroyed except for the hide. For this purpose these animals were slaughtered at dedicated slaughterhouses. The hides of these cattle were recovered and marked with a stain that was indelible until processed. The hides were kept physically separate from other hides from normal slaughter. Fleshings were removed at the slaughterhouse and destroyed with the rest of the carcass. The hides were processed under official control, at approved tanneries. The hides were processed in the UK to make sure that they were properly controlled, and that all untanned by-products were controlled and destroyed.

Testing of the cattle culled under BSE eradication schemes and of UK pre-August 1996 cattle, of which the hides will be used for leather production, on BSE could further reduce the risk.

The smaller the number of intermediate steps between slaughtering and tanning; storage and transport of the hides, different owners of the hides, the smaller is the risk of accidental exchange with hides of a different category and/or inclusion in a batch of hides of a different category. Ideally these hides, after removal, would be immediately and clearly labeled and transported directly from the place of removal to the tannery; without intermediate storage.

2.6 Can the risk from accidental inclusion of hides and skins from cohort animals in the food or feed chains be assessed, quantitatively or semi-quantitatively, on the basis of scientific knowledge and BSE-prevalence data for the cohort? If the risk from accidental inclusion of hides and skins from cohort animals in the food or feed chains cannot be assessed quantitatively, can a qualitative risk assessment be made? (ToR, Question 3+4)

A full QRA is not possible for products manufactured from hides with the data which are presently available, because no accurate data on cross contamination of skin with brain are known.

An estimate however could be made for the residual infectivity, calculated from the total infective load of hides from cattle culled in the frame of BSE eradication in EU25 and from UK pre-August 1996, using the assumption that the cross-contamination of a hide with brain will be at least 10 times less than of bone with nervous tissue.

The residual levels of BSE infectivity in gelatine and collagen, when these would be made from hide of cohort cattle slaughtered under slaughterhouse conditions, would be in a comparable range as to that of bovine bone gelatine.

Consequently, due to estimated low level of residual infectivity in these products, a slight accidental inclusion of hide from cohort cattle in the raw material for gelatine and collagen, manufactured from hides from cattle fit for human consumption will keep the level of infectivity negligible.

When cohort cattle would be slaughtered, and the cadavers then transported to a place where the hides are removed, such that blood and brain from the head wounds would liberally run over all cadavers, such that an infected animal in the truckload probably would contaminate all hides, while also the amount of infectivity would be very large. Accidental inclusion of hide from these animals in the raw materials for gelatine and collagen would increase the residual level of infectivity in these products considerably. Accidental contamination of gelatine with technical glue made from these hides or glue made from leather shavings from these hides would have the same result.

Because small accidental inclusion of hide of cohort cattle slaughtered under slaughterhouse conditions in the raw material for gelatine and collagen will not increase the residual level of BSE infectivity will remain negligible, and small accidental contamination of gelatine with technical glue made from this hide will also not, there is from this point of view also no objection to use the hides of this cattle for leather production. Measures should however be taken to, such that the risk of accidental inclusion would be as small as possible.

The risk of inclusion of hides or parts from cohort animals into raw materials for the production of gelatine and collagen for human consumption would be smallest, when the hides are labelled immediately after removal, are transported directly from the place of removal to a tannery exclusively processing category 3 hides, and when untanned and tanned side products would be destroyed.

Measures should also take in account the much increased risk when cadavers of cohort cattle would be transported to a place where the hides would be removed, and that technical glue made from leather shaving from these hides forms a higher risk than the other products.

CONCLUSIONS

- 1) If contamination is avoided, the production of leather made from the hides of cohort cattle presents a negligible risk.
- 2) Slaughtering cohort cattle applying the same conditions and precautions as in a slaughterhouse but under time separated conditions from normal slaughter or in dedicated premises, and removal of the hide immediately after slaughter will result in the smallest risk of cross-contamination.
- 3) Clear and immediate labeling of the hides of cohort cattle at the place of slaughter, direct transport of these hides from there to a tannery exclusively processing ABP category 3 hides, and destruction of all untanned and tanned side products, will give the smallest risk of accidental inclusion of hide of cohort cattle in raw material for products intended for human consumption.
- 4) Glue made from leather shaving from the hides of cohort cattle forms a higher risk than the other products if contamination can not be excluded.
- 5) The hide of the head of cohort cattle presents the highest risk for cross-contamination by blood and brain spilled through the hole in the forehead contaminating the skin of the scalp.
- 6) A QRA is not possible with the data, which are presently available, because no accurate data on the amount of cross contamination of skin with nervous tissue are known.

RECOMMENDATIONS

- 1) Measures should be taken to minimise the risk of contamination and of accidental inclusion of hides from BSE positive cohort animals into the food and feed chain. Therefore cohort animals intended for leather production should be subject to BSE testing.
- 2) It is recommended to slaughter cohort cattle, from which the hides will be used for leather production, only under slaughterhouse conditions separated in time from normal slaughter or in dedicated premises followed by appropriate decontamination.
- 3) The following measures should be taken into account with respect to:
 - clear labelling immediately after slaughter,
 - limiting the number of intermediate steps (storage, transport, owners) between slaughtering and tanning by direct transport of these hides from there to a tannery exclusively processing category 3 hides,
 - destruction of all untanned and tanned side products.

- 4) Measures should take into account that glue made from leather shavings from the hides of cohort cattle forms a higher risk.
- 5) Measures should take into account that the hides of the head of cohort cattle are at highest risk for contamination.

DOCUMENTS PROVIDED TO EFSA

1, Letter with the ref. D(2005)SD/khk/421135 from the European Commission – Health et Consumer Protection Directorate-General, requesting EFSA for an opinion the BSE risk from cohort animals: bovine hides and skins for technical purposes.

2, Dossier provided from COTANCE (Confederation of National Associations of Tanners and Dressers of the European Community), European Leather Association, including:

- European Guidance Note on the Safe handling of Raw Hides and Skins throughout the whole value chain in the Community, prepared by GME, COTANCE, UECEBV, Collagen Industry, December 2005.
- European Committee for Standardization (CEN); Leather – raw hides and skins; Cattle and Calf – Definitions, Presentation, Classification and Preservation, Marketing; CEN/TC 289 WG 5 N013.
- Information on the tanning process and tannery wastes.

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Annex A: Statistics BSE cases found in testing healthy cattle, culled animals under BSE eradication and fallen stock

Year	EU15										
	Healthy Slaughter			Culled Animals under BSE Eradication				Fallen Stock			
	Tested	Positives	% (X)	Tested	Positives	% (Y)	Diff (Y/X)	Tested	Positives	% (Z)	Diff (Z/X)
2001	7.655.822	279	0,0036%	56.464	16	0,028%	7,78	651.501	397	0,0609%	16,72
2002	9.124.887	286	0,0031%	57.720	16	0,028%	8,84	985.973	606	0,0615%	19,61
2003	8.716.481	265	0,0030%	24.966	10	0,040%	13,17	1.031.458	425	0,0412%	13,55
2004	8.542.869	140	0,0016%	15.712	4	0,025%	15,53	1.042.124	305	0,0293%	17,86
2005*	7.291.850	90	0,0012%	11.500	9	0,078%	63,41	978.577	192	0,0196%	15,90
2001-2005	41.331.909	1.060	0,0026%	166.362	55	0,033%	12,89	4.689.633	1.925	0,04%	16,01
Year	New MS										
	Healthy Slaughter			Cohort Cull				Fallen Stock			
	Tested	Positives	% (X)	Cull tested	Positives	%	Diff (Y/X)	Tested	Positives	%	Diff (Z/X)
2004	862.816	15	0,0017%	1.333	0	0,000%	0,00	107.194	7	0,01%	0,00
2005*	855.751,00	18,00	0,00	1.334,00	2,00	0,00	71,28	107.078	7	0,01%	3,11
Year	Total EU25										
	Healthy Slaughter			Culled Animals under BSE Eradication				Fallen Stock			
	Tested	Positives	% (X)	Tested	Positives	Ratio	Diff (Y/X)	Tested	Positives	%	Diff (Z/X)
2004	9.405.685	155	0,0016%	17.045	4	0,023%	14,24	1.149.318	312	0,03%	16,47
2005*	8.147.601	108	0,0013%	12.834	11,00	0,086%	64,66	1.085.655	199	0,02%	13,83
total	17.553.286	263	0,0015%	29.879	15,00	0,050%	33,51	2.234.973	511	0,023%	15,26
* Provisional											