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OPINION*

of the French Food Safety Agency (Afssa) assessing the effectiveness of the measures taken in November 2000 to control the BSE epidemic

LA DIRECTRICE GÉNÉRALE

On 27/11/2006, the Agence française de sécurité sanitaire (French Food Safety Agency/Afssa) issued an internal request to assess the effectiveness of the measures taken in November 2000 to control the BSE epidemic, and tasked its Scientific Panel on TSEs for the purpose.

1 Context

- With the appearance of the BSE epidemic in Great Britain and demonstration of the central role played by meat and bone meal in the spread of the disease, control measures were put in place in France and Europe with the aim of preventing ruminant contamination and limiting the exposure of the human population.

- In France, the ban on meat and bone meal in cattle feed dates from 1990 and was extended to all ruminants in 1994. These measures were strengthened in 1996, in the wake of the first "mad cow" crisis associated with the demonstration of the first human cases of variant Creutzfeldt-Jakob disease (vCJD), at the same time as the regulations on the removal of specified risk materials (SRM) were put in place. Other measures, including restrictions on the use of animal fats and the putting in place of systematic testing, completed this provision. Nevertheless, a large number of cases of BSE were recorded in cattle born after August 1996 (over 100 cases born after the reinforced ban [BARB] have been recorded to date), with over 20 cases born after 1 January 1998, demonstrating that the system was not totally effective.

- At the end of the year 2000, following the second "mad cow" crisis, the ban on meat and bone meal was extended to all food-producing livestock and at the same time a system of systematic active surveillance was put in place at slaughterhouses for cattle aged over 30 months[1] and at rendering plants for cattle aged over 24 months. To date, no cases of BSE have been recorded in cattle born after 1 January 2001. Consequently, almost 6 years after these measures were put in place, there are now legitimate grounds for a quantitative re-assessment of their effectiveness and for an examination of the possibility of eradicating BSE from France. In several opinions issued in recent years the Scientific Panel on TSEs has stated that a report on this point would be necessary, though premature before the end of 2006[2].

As a result, on 27 November 2006, Afssa requested its Scientific Panel on TSEs and its epidemiology of animal TSEs working group to carry out a quantitative assessment of the effectiveness of the safety measures taken at the end of the year 2000 and to use this assessment as the basis for issuing recommendations on the measures to be taken to guarantee the future food safety of products or by-products from these animals.

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* this opinion integrates the modifications made by the erratum of the 1er juillet 2008 modifying the mention of the age threshold of screening at rendering plants: the age threshold of 30 months is replaced by 24 months on pages 4 and 1.

[1] Exhaustive screening was implemented in January 2001 for cattle aged over 30 months. This age limit was lowered to 24 months in July 2001 and raised again to 30 months in July 2004.

[2] Opinion of the CES ESST on surveillance of the BSE epidemic in France, dated 30 June 2004.

2 Method

The Scientific Panel on TSEs issued the following opinion on 18/06/2007.

"Current consumer exposure to BSE from the consumption of bovine tissue results firstly from the development of the epidemic of "classic" BSE, observed in Europe since the mid-80s, and secondly from the presence of cases of "atypical" BSE demonstrated recently[3]. In the expert assessment conducted by the TSE Scientific Panel, the first objective was to evaluate the development of the "classic" epidemic, for which a large quantity of data are available, in order to assess the incidence of this form of BSE in French livestock since 1 January 2001. This quantitative assessment was first carried out by the epidemiology working group whose report is attached in annex. The working group's conclusions were discussed at meetings of the Panel on 1 and 28 March 2007. In view of the scarcity of data available on atypical cases, their role was considered in a more empirical fashion in the follow-up to the analysis.
In a second phase, the Panel evaluated the consequences of this assessment and suggested some changes to the principal measures put in place in the early 1990s to guarantee consumer protection and control the BSE epidemic. These proposals relate firstly to a more flexible management system for SRM and secondly to a relaxation of active surveillance.

3- Assessment of the incidence of "classic" BSE in cohorts of cattle born after 1 January 2001. Consideration of cases of atypical BSE. The situation in France.

The working group based its assessment partly on the development of the BSE epidemic, insofar as it can be estimated from the data produced by active and passive surveillance, and partly on predictions produced by modelling the epidemic[4]. Its conclusions were as follows (see annex):

> *"*Overall, current data on the cohorts predating the 2001 cohort and the absence of cases born after 1 January 2001 provide strong grounds for estimating that the number of animals infected in past years was less than one hundred per year, since only some (15 to 30%) of these animals can be or were detected, due to culling and death. Once more time has elapsed, and if the number of cases detected in animals born after 2000 remains low, this estimate could gradually be refined, probably down to an annual number of infections of less than twenty.
>
> Nevertheless, another major element to be taken into account is that one cannot currently rely on the number of positive animals being nil. Each year, a minimum of one to three cases of atypical BSE are discovered, which could be the result of another determining factor. To these can be added a few cases of classic BSE, which, while they are being observed, could be the result of very low levels of the disease with an indeterminate aetiology.
>
> Finally, based on the detection capacities of the current system (exhaustivity of tests at rendering plants and slaughterhouses on cattle aged over 24 and 30 months respectively[5] and the detection capacity of the rapid tests on the brain stem approved for use at the present time), the characteristics of the disease (age at infection and incubation period) and the demographic structure of the cattle population, the absence of cases detected in a given birth cohort is compatible with twenty infected animals in that cohort (with 95% probability).
>
> The result of these three additional pieces of information is that if no cases of BSE have been detected, when considering subsequent years one can work on the basis of around twenty as the maximum number of infected cattle per year in France. A review of any changes to the infection control measures and of how the risk to humans is managed can be carried out on that basis.*"*

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[3] Biacabe AG, Laplanche JL, Ryder S, Baron T. Distinct molecular phenotypes in bovine prion diseases. EMBO Rep. 2004 Jan;5(1):110-5.
[4] Supervie V, Costagliola D. The unrecognised French BSE epidemic Vet Res. 2004 May-Jun;35(3):349-62.
[5] It should be noted that this capacity would not be altered by raising the minimum age for screening at the abattoir, cf. Opinion of the Scientific Panel of 21 November 2005, in reply to Request No. 2005-SA-0291.

It should be noted that the Working Group report did not really enable a specific assessment of the effectiveness of the 2000 measures insofar as the incidence of BSE in the cohorts prior to 2001 (1999 and 2000) was already very low. It is also important to state that even under the current, very strict conditions of active surveillance (exhaustive post-mortem tests carried out at rendering plants and on animals over 30 months slaughtered for human consumption), an absence of detected cases does not mean that there are no infected animals. This analysis also highlights the fact that in the absence of tests capable of detecting BSE early, it would be very difficult to conclude that it had been eradicated.

The TSE Scientific Panel examined these conclusions at its meeting on 1 March 2007 and validated the working group's analysis.

For the next stage of its expert assessment, the Panel used the following information:

- *the apparent or predictable development of the BSE epidemic supports the assumption that, in the cohorts born after 1 January 2001, the absence of detected cases is compatible with a number of cattle infected annually of around twenty at most;*
- *the presence in France of a maximum of around twenty animals a year infected with BSE, of which more than two-thirds are slaughtered before reaching a detectable stage, represents a low health risk in view of the physiopathological particularities of "classic" BSE in cattle (almost total absence of peripheral infectious tissue, with the exception of the ileum and the tonsils) prior to the detectable stage.*
- *to take account of the time period required to implement the measures decided at the end of 2000, any changes to the measures recommended following the expert assessment will only apply to animals born after 1 July 2001.*
- *despite the favourable developments in the epidemic of "classic" BSE, account must be taken of the possible presence of a low number of "atypical" or "classic" cases of an indeterminate aetiology.*

Consequently, the Panel considers that the risk of human exposure to the different forms of BSE from the cohorts of cattle born in France after 1 July 2001 is extremely low compared with the period 1980-2000, perhaps even lower than the risk prior to the epidemic of "classic" BSE[6] *and that it therefore seems possible that consumer protection measures could be relaxed without reducing their level of protection. However, the Committee considers that the main elements of the measures to prevent the spread of the disease in ruminants should be kept in place. Indeed, the possibility that the epidemic could recur cannot be excluded despite the very low numbers of animals infected annually.*

4- Possible changes to consumer protection measures

Based on the preceding conclusions, the Panel considered what level of relaxation could be made to the measures designed to protect consumers from the BSE risk. This analysis focussed firstly on management of SRM and then on changes to active surveillance. In view of the complexity of the regulations (French and European) put in place to control the BSE epidemic and its consequences, there is no question, in this document, of entering into the detail of any amendments to regulations which could be made, rather the intention is simply to set out the broad outlines of a possible change.

4.1- Changes to the management of specified risk materials

In view of the very low incidence expected in the cohorts born since 1 July 2001, the Panel considers that the list of SRM could be restricted to the tissues in which the highest levels of infectivity have been demonstrated (reduced list of SRM):

- removal of the brain, eyes and spinal cord from animals over 24 months with demedullation prior to splitting for animals over 24 months[7]*; removal of the tonsils and the ileum*

[6] It is not impossible that cases of atypical BSE already existed at that time since no management measures were in force (such as SRM removal), as TSEs were unknown in cattle.

[7] Buschman, and Groschup (2005) J. Infect. Dis. 192, 934-942; Espinosa et al. (2007) J. Gen. Virol., 88, 1379-1383; Hopffmann et al. (2007), J; Gen. Virol., 88, 1048-1055. EFSA report EFSA-Q-2006-002, The EFSA journal (2007), 476, 1-47.

whatever the age. All these tissues contain more than 99% of the infectivity potentially present in cattle at the clinical stages of BSE[8]

- no more distinction between the fat removed before and after splitting, all are authorised for human consumption;

- no more removal of the vertebral column up to the age of 48 months; if demedullation has been carried out correctly, the vertebral column could be used for the preparation of gelatine for human consumption [9]*;*

- removal of the vertebral column, in the same conditions as currently for animals over 48 months.

4.2 Changes to active surveillance

For cattle born since 1 July 2001:

- continue exhaustive screening at rendering plants for animals over 24 months in order to maintain a system capable of revealing a possible recurrence of the epidemic;

- discontinue tests at abattoirs. In practice, once these measures are in place this would mean testing only animals over 78 months (6.5 years) slaughtered for human consumption, assuming measures are in place by 1 January 2008.

- with the aim of retaining epidemiological surveillance systems for atypical BSE and ensuring consumers are protected from this potential risk, animals over 7 years old will be systematically tested in the slaughterhouse. In these conditions, very soon after these measures are put in place, only animals over 7 years old will be tested.

5- Possible changes to the measures designed to prevent recirculation of the agents responsible for BSE and a recurrence of the epidemic

The Panel considers that it would be inappropriate to amend the measures designed to prevent the recirculation of the agent(s) responsible for the different forms of BSE, notably the ban on using meat and bone meal in feed used for food-producing animals.

6- Conclusions

For cattle born in France after 1 July 2001, reared and slaughtered in France:

- the list of SRM is restricted to the brain, eyes and spinal cord for animals over 24 months, and to the tonsils and ileum whatever the age. All other bovine tissue, including the vertebral column (up to the age of 48 months) and the fat removing after splitting, are permitted for human consumption;

- this reduced list of SRM, and the rest of the intestines (except the ileum) and the vertebral column (for animals aged over 24 months) and their derived products remain banned from feed used for food-producing animals as well as all meat and bone meal prepared from mammal tissue;

- the fat removed after the splitting of cattle carcasses may be used in feed used for food-producing animals, including ruminants[10]*;*

- only animals born between 1 January and 1 July 2001 and animals aged over 7 years slaughtered for human consumption will be subject to a post-mortem rapid test for BSE, however, testing at rendering plants will be continued at the current level of exhaustiveness.

7- Conditions for implementing the proposed relaxation of the measures

Since the analysis conducted by the Panel is based on French epidemiological data, the proposed relaxation of the measures will only apply to animals born, reared and slaughtered in France.

Continuation of these measures will be conditioned by the data supplied from active surveillance and any change to the state of knowledge on the different forms of BSE. If these indicate a recurrence of the BSE epidemic or the existence of risks not taken into consideration in this Opinion, the measures may be reconsidered".

[8] Quantitative assessment of the residual BSE risk in bovine derived products. EFSA QRA report 2004, The EFSA journal (2005), 307, 1-135.

[9] At this stage of the review, the Panel does not wish to express and opinion on the possibility of producing mechanically recovered meat from material which could contain vertebral column.

[10] The grounds for this measure are given in the response to mandate No. 2007-SA-0084

8 Opinion of the Agence française de sécurité sanitaire des aliments

These are the points of analysis which the Agency is in a position to provide at the present time and which should assist the Health Authorities with clarifying the options for relaxing the measures in place without increasing consumer risk.

In addition, as regards bovine derived products likely to be re-authorised for human and animal consumption subject to their coming from cohorts of cattle born in France after 1 July 2001, reared and slaughtered in France (see table below), the Agency would like to emphasise the importance of not amending the measures designed to prevent the recirculation of the agents responsible for BSE and a recurrence of the epidemic[11]. This is the reason why the re-authorisations for human consumption envisaged in this opinion cannot be transposed to feed for food-producing animals, and, more generally, the use of processed animal proteins should be banned in feed for food-producing species.

Bovine products likely to be re-authorised for human and animal consumption, but only if they are from cohorts of cattle born in France after 1 July 2001 and reared and slaughtered in France.	
For human consumption	For animal consumption (food-producing species)
- the brain and spinal cord from cattle aged under 24 months - the vertebral column from cattle aged under 48 months - the intestines (except the ileum) - the fats removed after the carcass is split	- the fats removed after the carcass is split, collected in slaughterhouses and cutting plants[12].

Key words: TSE, cattle, meat and bone meal, BSE, SRM, surveillance.

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[11] In effect, if the regulations are not in place, the re-authorisation of these products (other than fats removed after splitting) from ruminants and intended for ruminants constitutes a risk factor for the recycling of agents for TSEs. Moreover, the re-authorisation of these same products for monogastric species raises the issue of cross-contamination.

[12] See Afssa opinion on three draft orders regarding the re-authorisation of fats removed after the splitting of ruminant carcasses for human and animal consumption dated 13 July 2007.