

BOVINE SPONGIFORM ENCEPHALOPATHY (BSE)

VADEMECUM

Information for consumers

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BSE Vademecum

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Preface

In this early part of autumn 1998, the Commission is still on the alert to ensure food safety for consumers and beat "mad cow disease". The structural reform of its departments begun in 1997 is almost completed. The Scientific Committees are continuing their work unrelentingly and, in the field, the new Food and Veterinary Office, established in Dublin, is gradually stepping up its checks and inspections. Research proposals have been adopted and the work started. Others will follow shortly.

Already, thanks to the measures taken, the epizootic is receding in the United Kingdom pending total eradication. The ban on cattle products in Northern Ireland has been partly lifted - under strict control - and there is every prospect of it being extended, with all the necessary guarantees, to the whole of the United Kingdom. Meat consumption has more or less returned to the levels reached in 1995, on the eve of the crisis.

For some, the crisis is now behind us and it ought to be possible to relax the pressure. This is not my point of view.

The findings from Portugal show in fact that non-observance of the measures prescribed may facilitate the spread of the epizootic to new areas. Without being as worrying, new cases are continuing to appear in other countries. Lastly, the scientific assessment of the risks calls for the utmost caution at all stages in the chain. The Commission therefore intends to continue with determination the action initiated in March 1996 and to explain it to as many people as possible.

That is why, just a few weeks away from the conference on food safety that the European Parliament and the Commission will be organising jointly at the end of November with a view to drawing lessons from the BSE affair, I have asked the Interdepartmental Working Party created at the very beginning of the crisis to update the BSE Vademecum in order to take stock of the situation and inform consumers directly about the progress made and the measures to be taken.

While, as I have often said, the "zero risk" does not exist as far as food is concerned, it is quite certain that serious information that is as full as possible will tend to reduce the risk and rekindle confidence. In 1996, in difficult circumstances, the BSE Vademecum already fulfilled this role. I have no doubt that this new version will also succeed in doing so.

Emma BONINO
Member of the Commission

Introduction

1. The announcement by the UK authorities on 20 March 1996 that ten people in that country had recently succumbed to a new variant of Creutzfeldt-Jakob disease and that a link between bovine spongiform encephalopathy (BSE) and

Creutzfeldt-Jakob disease (CJD) could not be ruled out triggered an **unprecedented crisis of confidence** among European consumers with regard to beef and bovine products. Since then, a flood of incomplete or even contradictory information has helped to increase and then maintain the level of concern.

2. In these circumstances, it seemed necessary to **inform consumers** about the situation, the state of scientific knowledge and the measures taken or planned in the European Union to enhance consumer safety. This is the aim of the BSE Vademecum.
3. The Vademecum has been prepared by the **Interdepartmental Working Party (IWP)** that the European Commission decided to create on 27 March 1996 to evaluate the consequences of the crisis for consumers and to improve the information supplied to them. It incorporates, updates and supplements two previous versions dated 28 May 1996¹ and 29 November 1996² respectively.
4. The Rapporteur of the European Parliament's Committee of Inquiry, ³ Mr Manuel MEDINA ORTEGA, wrote about this work: ... "The Commission should also be asked to step up the current activities of the Interdepartmental Working Party, created on the initiative of Mrs BONINO, and to ensure that its studies and activities are followed up as widely as possible; (...) the widest possible follow-up should also be given to the publications prepared by DG XXIV, such as the "Guide for consumers",⁴ in which the latter tries to provide answers and give guarantees in order to dispel the concern of consumers and of citizens in general ...".

Part I: What is BSE?

A. What is bovine spongiform encephalopathy?

5. Bovine spongiform encephalopathy (BSE) is a degenerative brain disease affecting cattle. It is a **new disease** since, having occurred for the first time in the United Kingdom in April 1985, it was officially recognised and described in November 1986.
6. BSE belongs to the family of **transmissible spongiform encephalopathies (TSE)**, which in animals includes scrapie of sheep and goats, spongiform encephalopathy of mink, encephalopathies of cats and certain wild animals raised

¹ Document GIS-BSE (96) 1.7.

² Document GIS-BSE (96) 7.5 : almost 3 000 copies distributed in the 11 languages of the Union.

³ Document FR/RR/319/319544en – EP220.544/def./A of 7/2/97, p. 41 § I.7.

⁴ i.e. the 2nd edition of the Vademecum.

⁵ Other term used in France: "transmissible subacute spongiform encephalopathies (TSSE)".

in captivity, and in humans Creutzfeldt-Jakob disease (CJD). Most TSEs seem to be **sporadic**.

7. **In the United Kingdom**, BSE spread like wildfire and quickly became an epidemic. Following its first occurrence in 1985, the number of animals affected by the disease amounted to around 400 cases in 1987, then increased rapidly to stand at **more than 37 000 cases in 1992**. Since then, thanks to the measures taken, this number **has been reduced by almost 90 % in five years**, standing at just over 4 300 cases in 1997.⁶ This downward trend ought to continue, with some 1 500 to 2 000 cases forecast in 1998.⁷ The United Kingdom has had a total of over **175 000 cases**,⁸ **affecting more than 34 000 farms**
8. **In the other countries** that have imported animals or animal feed from the United Kingdom, the total number of cases recorded is around **800**, which represents less than 0.5% of all recorded cases of BSE.⁹ In view of the low incidence¹⁰ of the epizootic in these countries, it is difficult to speak of a recession or spread of the disease except perhaps in Switzerland and Ireland, where, as a result of the measures taken, it seems to be receding, and in Portugal, where its spread in 1998 is a source of concern to the Commission.
9. The infective agent responsible for BSE has still not been identified. However, many things point to it being an abnormal form of protein called "**prion**". Prion has exceptional characteristics, such as resistance to heat, ultraviolet and ionising radiation and chemical disinfectants. The work carried out by Professor Stanley P. PRUSINER on this protein in the United States earned him the Nobel Prize for Medicine in 1997.
10. According to the generally accepted scientific explanation, the BSE epizootic in the United Kingdom has its roots in the recycling of contaminated cattle carcasses processed into animal feed in the form of **meat and bone meal**, and in changes made in 1981-82 in the technological processes used in the production of such meal (reduction of drying temperatures and discontinuation of solvent defatting in order to optimise the extraction of fats). These changes are suspected of leaving behind a degree of infectiousness and permitting the propagation of an

⁶ 37 280 cases in 1992, 4 334 cases in 1997, i.e. a fall of 88.4 % in 5 years.

⁷ 1.435 cases diagnosed up to 1.9.1998.

⁸ 175 239 cases on 34 473 farms were recorded in the United Kingdom as at 1/9/98. See Annex 4. According to Professor John WILESMITH, 60% of dairy cow herds and 15% of nursing cow herds had at least one case of BSE in the United Kingdom. Taking all herds together, this figure comes to just over 30%.

⁹ Around 75% of the cases diagnosed outside the United Kingdom have been in **Ireland** (312 cases as at 1/10/98) and **Switzerland** (275 cases). This percentage rises to over 90% if **Portugal** (151 cases) is included. See Annex 4.

¹⁰ The incidence is the ratio between the number of cases of BSE observed and the population of cattle aged over 2 years expressed in million head (see Annex 4).

unidentified but already present rare cattle disease. Another theory, which is losing ground nowadays, is that BSE was initially due to recycling of carcasses of sheep affected by scrapie and therefore to transmission of the scrapie agent from sheep to cattle and then to recycling of contaminated sheep and cattle carcasses.

However that may be, the responsibility of contaminated meat and bone meal put forward from the start of the epizootic is nowadays accepted by almost all scientists. The feeding of ruminants with ruminant proteins was therefore banned in the United Kingdom from **1988**. Some Member States followed suit at the beginning of the '90s, with the official ban for the Community as a whole being declared in 1994.¹¹

11. **Other possible ways of transmission:** to date, there is no formal proof that BSE can also be transmitted either horizontally, i.e. from one animal to another, or vertically, i.e. from cow to calf. Research was carried out over a number of years in the United Kingdom to study both possibilities. It showed that **horizontal transmission** is not very likely. If it existed at all, it could only occur at an extremely low rate; otherwise, the epidemic would not recede. The probability of **vertical transmission** is greater but likewise unconfirmed.¹² Under these circumstances, in order to explain the appearance of relatively many cases (over 20%) of BSE in the cattle born after the ban on using meat and bone meal¹³ for feeding ruminants, mention is made of difficulties in controlling such use and especially the theory that these cattle were contaminated either directly through absorption of feed containing unidentified contaminated meal or by "cross-contamination", i.e. through accidental contamination of their food by feed for pigs or poultry which itself might have contained contaminated meal.

Note: the theory of "sporadic" cases is also put forward by certain scientists to explain isolated cases of BSE, such as the first case occurring in Belgium, for example.

12. **Crossing of the species barrier:** in the case of BSE, transmissibility between different animal species is the subject of a great many studies. Indeed, it has been possible to transmit - in the laboratory - the disease intracerebrally and orally to

¹¹ Commission Decision 94/381/CE of 27 June 1994.

¹² On 8 September 1997, the Multidisciplinary Scientific Committee (MSC/SSC) stated that, taking the most recent - published and unpublished - scientific documentation on this issue into consideration, there was, in its opinion, a probability of an increase in the risks of maternal transmission. The overall order of magnitude of this increase was 5 to 15% (the confidence intervals being fixed at 95%), with, however, an increased risk during the months before and after the date of the clinical appearance of the disease in the mother. This effect was probably due to some form of direct maternal transmission, although differences in genetic predisposition could not be ruled out. The MSC/SSC also supported the theory that, in the absence of any infection via food and of any horizontal transmission, vertical transmission cannot by itself maintain the epidemic, even with a much higher rate than currently estimated.

¹³ In French, the "naifs" (nés après l'interdiction des farines); in English, the "babs" (born after ban): 37 122 cases in the United Kingdom as at 31/8/98. Diseased animals born after the ban on using meat-and-bone meal (18/7/88) account for 21.2% of the cases of BSE reported in that country.

mice and sheep in particular. In pigs it has been transmissible by intracerebral inoculation. On the other hand, it is very important to note that certain animals (cats, mink, monkeys and other zoo animals) seem to have contracted the disease in natural conditions by consuming contaminated bovine material (meal or, directly, bovine tissue).

B. What is scrapie?

13. Scrapie is an animal transmissible spongiform encephalopathy (TSE) affecting **sheep** and **goats**. Known for more than 250 years,¹⁴ this epizootic differs from BSE through its **contagiousness** from one sheep to another (horizontal transmissibility) and from ewe to lamb (vertical transmissibility). It is found in several Member States and in most continents. Scrapie has been a **notifiable** disease in the Member States since 1993.¹⁵
14. **Can this disease be transmitted to humans?** Given the relatively high incidence of this epizootic in many countries and the length of time it has been affecting flocks and herds, it may be thought that, if there were contagion of humans, it would have been recognised a long time ago. It can therefore be considered that, on the basis of epidemiological data, **classical scrapie is not dangerous to humans**.
15. As a result of work carried out in the United Kingdom it was established in 1996 that, experimentally, it was possible to transmit BSE to sheep via the food chain. Some scientists therefore put forward the theory that, in that country, the scrapie diagnosed nowadays might sometimes be a variant of the currently undetectable BSE caused by consumption of contaminated meal. The possibility cannot in fact be ruled out that ewes that had eaten infected meat and bone meal might be contaminated by BSE. However, this is only a **theory**, especially as sheep consume meal less frequently and in smaller quantities than cattle do.¹⁶
16. Some scientists are worried about the risk that this theory might represent for humans. They therefore recommend:
 - application of the obligation to notify cases of scrapie observed in flocks and destruction of the diseased animals;
 - eradication of scrapie;
 - extension to sheep and goats of the measures taken against BSE, especially as regards specified risk materials;

¹⁴ Scrapie was recognised for the first time in 1732 in the United Kingdom.

¹⁵ Council Directive 91/68/EEC of 28/1/91.

¹⁶ After being examined by the Scientific Steering Committee (SSC), this theory was confirmed in its opinion of 24-25 September 1998, given the lack of proof to the contrary.

- extension to non-Community countries of the measures taken within the European Union.
17. The non-Community countries and the Member States which consider themselves BSE-free dispute this theory and all the recommended measures arising from it.

C. What is Creutzfeldt-Jakob disease?

18. **Creutzfeldt-Jakob disease (CJD)** is a currently incurable fatal neurological disease affecting humans. It belongs to the family of human spongiform encephalopathies, which also includes kuru and two rare genetic diseases. It was first identified in the 1920s and has spread worldwide, with an incidence of around one case per million per year. It occurs in two forms: classical CJD and a recently identified new variant, known as nv-CJD.
19. **Classical CJD** can be divided into three categories: a "sporadic" form making up 90% of cases, "genetic" forms associated with genetic predisposition, and an "iatrogenic" form linked to a medical or surgical act, e.g. grafting of contaminated corneas or the use in the early '80s of hormones taken from human cadavers to treat growth deficiencies in children. The "sporadic" and "genetic" forms of CJD generally affect **persons aged over 60**. Patients usually die within 4 to 6 months of the onset of the disease. On the basis of the scientific data on classical CJD available so far, it is not possible to establish any links between the appearance of these animal spongiform encephalopathies and the existence of particular dietary habits, such as the consumption of animal brain.

A study was carried out on 405 patients and an equal number of controls in five Member States (D, F, I, NL, UK) from 1993 to 1995. The results published in the scientific journal *The Lancet* of 11 April 1998 confirm this lack of correlation.

20. In 1996, the CJD Surveillance Unit in Edinburgh identified 10 cases of a form of CJD sufficiently distinct from classical CJD to be described as a **new variant**. The patients affected were all young adults whose average age was around 29 (between 19 and 41). Their disease was characterised by a relatively long development (13 months on average) and by clinical signs and lesions of the central nervous system observed on autopsy that were clearly different from the classical forms of CJD. The scientists who studied these cases were not able to find any predisposition (genetic or otherwise) in these patients' medical history that could provide an explanation. The **SEAC**,¹⁷ which is the United Kingdom's BSE advisory committee, examined these cases and concluded, **on 20 March 1996**, that "Although there is no direct evidence of a link on the basis of the current data and in the absence of any credible alternative, the most likely explanation at present is that these cases are linked to exposure to BSE before the introduction of the ban on specified bovine offals in 1989". The UK advisory committee's conclusion therefore created doubt about the transmissibility of the BSE pathogenic agent to humans.

¹⁷ Spongiform Encephalopathy Advisory Committee (SEAC).

Since then, 17 new cases of nv-CJD have been confirmed in the United Kingdom and 1 case in France, making a total of **28 cases to date**.¹⁸

A number of suspected cases have been mentioned by the press in Belgium (2), the Netherlands (1) and Poland (2), but have not been officially confirmed.

21. On 2 and 3 April 1996, the **World Health Organisation (WHO)** called a meeting of experts on BSE and nv-CJD. These experts confirmed that the most plausible theory regarding nv-CJD was the exposure of the UK population to BSE, but they stressed that no such link had been proved so far. They also concluded that "the risk, if there is one, of exposure to the BSE agent in other countries is considered lower than in the United Kingdom. Exposure to the BSE agent in the United Kingdom was likely to have been higher before the regulations on BSE now in force". The scientific work carried out since then has reinforced the probability of transmission of BSE from cattle to humans.

22. Is an epidemic of the new Creutzfeldt-Jakob disease conceivable?

In the absence of precise information on the disease, the most extreme declarations have been made. Whereas some declared in 1996 that nv-CJD would be the AIDS of the year 2000, others did not seem convinced of the existence of a link between BSE and nv-CJD.

23. On 16 September 1997, the **SEAC** came to the conclusion that recent research had provided fresh scientific evidence of the similarity between the causal agent of BSE and that of the new variant of CJD. Two days later (18.9.97), the UK Advisory Committee on Dangerous Pathogens (**ACDP**)¹⁹ concluded that the **BSE agent should henceforth be classified as a human pathogen**.
24. **Uncertainty** lingers, however, about the disease's possible development mechanisms. For example, a meeting of international experts on TSE held under the auspices of the CPMP²⁰ considered on 15 January 1998 that transmission of the disease by medical products derived from human blood or plasma was "very unlikely". For their part, a group of around 50 experts meeting from 11 to 13 February 1998 at the headquarters of the WHO in Geneva thought that a sizeable epidemic could not be ruled during the next 10 to 15 years. The new variant of CJD might in fact prove to be more infectious than classical CJD through the blood (**blood transfusion** in particular).

As regards the number of victims, it was stated at the International Conference on Emerging Diseases held in Atlanta in March 1998 that in the United Kingdom the number of persons affected by the new disease might be somewhere between a few

¹⁸ 27 cases were officially recorded in the United Kingdom by the Department of Health up to 1998, i.e. 3 cases in 1995, 10 cases in 1996, 10 cases in 1997 and 4 cases in 1998.

¹⁹ Advisory Committee on Dangerous Pathogens (ACDP).

²⁰ Committee for Proprietary Medicinal Products (CPMP).

hundred and 80 000 cases, depending on whether the incubation period was 10 or 25 years.

25. Conclusion : the absence of a diagnostic test and the lack of knowledge about the incubation period for nv-CJD place the scientific community in a situation of uncertainty that justifies the additional **cautionary and precautionary measures** taken or recommended and the efforts devoted to research by the European Commission.

Part II: Combating BSE: what measures have been taken?

26. As soon as the epizootic emerged in the United Kingdom in 1986, a whole host of measures were taken to counter its development until it could be eradicated. These measures were taken in the United Kingdom first of all, then in certain Member States and lastly throughout the European Union.

A. Measures taken up to 27 March 1996

27. The most important measure to protect both human and animal health, in the United Kingdom in 1988 and in the other Member States where cases of BSE appeared subsequently, was the **slaughter and destruction** of animals affected or liable to be affected.²¹ Moreover, in 1988 the United Kingdom banned the use for feeding ruminants of **meat and bone meal** (from ruminants) and in 1989 the use for human consumption of certain types of **offal**, such as the brain and spinal cord from cattle aged over 6 months. This involved therefore the withdrawal from the human and animal food chains of the materials most likely to present a risk of transmitting the disease.
28. **Since 1988**, other measures have been introduced by the British Government and by the Community in order to prevent the spread of BSE and minimise any risk to human health. These measures are listed in the Annexes.²² They relate mainly to the withdrawal of specified risk materials (SRM) from the human and animal food chains and to preventing the epizootic from spreading to the other Member States or to non-Community countries.²³
29. The Community measures to prevent the spread of BSE to other countries have been successful, since **less than 0.5 % of the cases have occurred outside the United Kingdom.**²⁴ The measures taken in the United Kingdom to control the

²¹ In the other countries (B, F, IRL, L, NL, P), the authorities go even further and slaughter all the herd in which a case is diagnosed.

²² See Annexes 2 and 3.

²³ Since March 1990, for example, the Member States have had to notify all cases of BSE to the Commission and the other Member States.

²⁴ 0.43%: see Annex 4.

disease - particularly the ban on feeding ruminants with infected meal - have likewise been **relatively effective**, since the annual incidence of BSE fell by 90% between 1992 and 1997 (see § 7). It seems clear, however, that this ban has not been fully observed, since more than 20% of the recorded cases of BSE²⁵ occurred in animals born after the ban. Although the scientific work being carried out reinforces the theory of vertical transmission of BSE, this theory alone does not seem able to explain the situation.

30. Within a few days of the announcement on **20 March**, the other Member States adopted safeguard measures against all British bovine products, especially beef. Despite that, the consumption of beef plummeted in most Member States. After consulting the Scientific Veterinary Committee (SVC) on 22 March, the Commission convened a meeting of the Standing Veterinary Committee (SVC) on 25 and 26 March in order to elicit its opinion on the adoption of Community safeguard measures. Following this consultation, the Commission adopted an **embargo decision on 27 March 1996**.²⁶

B. The ban of 27 March 1996

31. A large number of measures were taken at European Union level. They are listed in chronological order in the Annex.²⁷ The most "spectacular" measure was the embargo decision of 27 March. Pending an overall examination of the situation, it introduced a temporary **ban on exports from the United Kingdom** to the other Member States and non-Community countries of live cattle, their semen and embryos, meat and products derived from cattle slaughtered in the United Kingdom and intended for human and animal consumption, mammalian meat and bone meal and products intended for medical, cosmetic or pharmaceutical use. In addition, the United Kingdom was required to report to the Commission every two weeks on the application of national and Community measures to control BSE and asked to present further proposals for controlling BSE in that country.
32. With the exception of milk and milk products, and certain products such as leathers and skins, the United Kingdom could not export from its territory to the other Member States or to non-Community countries any product obtained from cattle slaughtered on its territory.

Contested by the British authorities, the embargo was the subject, in July 1997, of an action against the Commission before the European Court of Justice by the British trade union NFU.²⁸ The Court delivered its judgment on 5 May 1998, confirming the validity of the measure and considering that the Commission had acted in the interests of consumers, given the seriousness of the danger.

²⁵ Over 37 000 cases (see §11).

²⁶ Decision 96/239/EC of 27/3/96.

²⁷ See Annex 1.

²⁸ National Farmers Union (NFU).

33. **Milk and milk products** were not affected by the Decision of 27 March 1996. Indeed, so far, milk and milk products from animals infected with BSE have not shown any signs of **infectiousness**, and the data on other animal or human spongiform encephalopathies tend to prove that milk does not transmit these diseases. Milk and milk products are therefore considered to be safe, even in regions with a high incidence of BSE.

These are the conclusions set out in the WHO communiqué²⁹ of 3 April 1996, which the Commission has taken over. The Scientific Steering Committee (SSC) and the Scientific Veterinary Committee (SVC) have confirmed this position by classifying milk in category 4 ("no infectivity detected").³⁰

34. The same applied to products that do not enter the human or animal food chain, such as **leathers and skins** (category 4).
35. Similarly, the experiments have so far not revealed any infectiousness in **beef** and have not shown that such meat could play any sort of part in the transmission of BSE. Moreover, the measures taken since the emergence of BSE, and especially since 20 March 1996, have further increased the safety of meat and derived products for health. The national and Community authorities therefore consider that, in the United Kingdom as in the other Member States, the risks of consumers becoming contaminated through eating beef are virtually nil. For precautionary reasons, however, as long as all the guarantees have not been obtained, authorisation to export beef and products derived from animals slaughtered in Great Britain cannot be considered.³¹
36. In the case of **bovine semen**, the principle of lifting the ban was accepted in June 1996³² because no trace of infectivity has ever been detected in this product. The Scientific Veterinary Committee therefore considered that it was not a danger to animal health as regards transmission of BSE. Besides, in accordance with the provisions of Directive 88/407/EEC,³³ semen is taken only from bulls certified healthy.
37. **Gelatine** and **tallow** are used in the manufacture of or as ingredients in many industrial products, such as foodstuffs, medicines or cosmetics. It was therefore necessary to investigate whether such products can or could have been made from a raw material infected with the BSE agent, and to assess the possible risks of such situations.

²⁹ World Health Organisation (WHO).

³⁰ See Annex 10.

³¹ Except for meat from herds eligible for export from Northern Ireland (see §43).

³² Decision 96/362/EC of 11/6/96.

³³ Council Directive 88/407/EEC of 14/6/88.

In a WHO communiqué dated 3 April 1996, it was stated that "gelatine used in food is considered to be safe if it is obtained by a manufacturing process that has been shown to apply production conditions that make it possible to inactivate to a large extent any residual infectivity that might have existed in the source tissue. Tallow is also considered to be safe if effective processes for treating cadavers are used".

Two years later, in March 1998, the SSC adopted a more guarded opinion. When gelatine or tallow are to be used as ingredients in food ³⁴ or (in the case of gelatine) in pharmaceutical products, the Committee recommends in particular that the raw materials from which they have been made come from animals deemed fit for human consumption, that specified risk materials are excluded from the production chains in countries which are not BSE-free and that they have been produced under appropriate technological conditions. For the United Kingdom, the SSC recommends additional conditions.

38. By a Decision of 16 March 1998, the Council therefore lifted the export ban for a number of products, such as **tallow** and similar or derived products obtained from cattle slaughtered in the United Kingdom under the manufacturing conditions laid down by the Scientific Steering Committee. On the other hand, the Decision maintains the export ban for all the other products covered by the Decision of 27 March 1996 (including gelatine).
39. **Foodstuffs, cosmetics or pharmaceutical products** whose ingredients include gelatine, tallow or other similar or derived products are likewise considered safe provided the ingredients themselves are safe.
40. **Can the ban on the products covered by the Decision of 27 March 1996 be lifted?** The Commission has always considered that, in cases of doubt about the safety of a product, this doubt should be to the benefit of the consumer. Conversely, when scientifically a product is recognised as safe, the Commission considers that there is no reason to oppose its manufacture and distribution under the requisite conditions. At the **Florence summit** on 21 and 22 June 1996, the European Council confirmed this principle and envisaged the possibility of **a gradual relaxation of the restrictions** on the export of bovine products from the United Kingdom to the rest of the European Union and to non-Community countries. To this end, the 15 agreed on five conditions for gradual lifting of the ban, namely:
 - withdrawal of all meat and bone meal from farms or from establishments manufacturing animal feed;
 - stepping-up of checks in slaughterhouses;
 - introduction of a passport system for all cattle and setting-up of a computerised system for the identification and monitoring of animals;
 - removal of cattle aged more than 30 months from the human and animal food chains;
 - application of a selective culling programme.

³⁴ For humans or for animals.

41. The United Kingdom took measures to fulfil the conditions agreed on and since 1996 has been sending the Commission bi-monthly reports informing it of the measures taken and the results achieved. These show that in September 1998, taking all the eradication plans together, more than 4 million cattle had been slaughtered and destroyed in the United Kingdom.³⁵

In addition, more than 6 million³⁶ cattle passports have been issued.

42. The Commission has carried out a series of **inspections** in the United Kingdom in order to check the progress of the eradication and control measures. **Visits** are also made regularly to check compliance with Community legislation, especially as regards storage of meat and bone meal not yet destroyed and the export ban.
43. In February 1997, on the basis of the measures taken and results achieved, the United Kingdom presented an initial proposal aimed at lifting the restrictions on the export of cattle from herds certified as BSE-free. The Scientific Veterinary Committee made a large number of comments about this proposal, which prompted the United Kingdom to improve its arrangements in order to submit a fresh proposal in July.

Moreover, during summer 1997, the confirmation by the UCLAF³⁷ and the FVO³⁸ of large-scale fraud led the United Kingdom to step up the veterinary controls in order to prevent any export of British beef.

44. In the wake of all the measures taken by the United Kingdom and the agreement in principle of the "Scientific Committee for Veterinary Measures relating to Public Health" (ex-SVC) of the European Union, and after examination by the Standing Veterinary Committee (SVC), the Council of Agriculture Ministers finally gave its agreement³⁹, on 16 March 1998, to a **limited and conditional lifting of the ban on exports from Northern Ireland (Ulster)** of boneless beef from eligible herds, i.e. free of BSE for at least eight years.

This Decision came into effect on 1 June 1998⁴⁰, i.e. on the date set by the Commission on the basis of fresh inspections confirming the conformity of the measures taken by the UK authorities. Every three months, the Commission will have to revise the provisions adopted.

³⁵ The cattle population is estimated at under 12 million head in the United Kingdom - see Annex 12.

³⁶ As at 6/6/98, 5 215 960 passports, to which can be added 869 864 passports issued for calves slaughtered under the CPAS.

³⁷ Anti-fraud coordination unit of the European Commission.

³⁸ Food and Veterinary Office (FVO) of DG XXIV, established in Dublin since 1997.

³⁹ Council Decision 98/256/EC of 16/3/98.

⁴⁰ Commission Decision 98/351/EC.

45. Given the number, scale and effectiveness of the measures taken by the European Union and the United Kingdom against BSE, it is possible to envisage, in the medium term, a partial and conditional lifting of the ban that has been affecting meat exports from Great Britain for more than two years. To this end, the programme proposed by the UK authorities (date based export scheme) will have to be approved by the Commission, which will then have to submit to the Standing Veterinary Committee (SVC) and subsequently to the Council of Agriculture Ministers a proposal to this effect for final approval by the latter. However, this is hardly likely to happen before the end of 1998.

C. Specified-risk materials (SRM)

46. **Importance of this issue:** scientists very soon realised that certain tissues were more likely than others to carry the infectious agent and transmit BSE. By acting on these tissues, it seems that it is possible to reduce the risk of transmission appreciably.
47. From 1989, the UK authorities have banned the use of specified bovine offal in human food and then, since 1990, in animal feed.⁴¹
48. In April 1996, a group of experts convened by the World Health Organisation (WHO) recommended that no product or part of any animal whatsoever that had shown signs of transmissible spongiform encephalopathy (TSE) be introduced into the food chains (human or animal), and that no country allow **tissues liable to contain the BSE agent** to enter these chains.
49. On 21 October 1996, the Scientific Veterinary Committee (SVC) of the European Union drafted an opinion stating that the presence of scrapie could not be ruled out in any Member State. Subsequently, while the risk linked to BSE was much lower in the Member States other than the United Kingdom, it was nevertheless not zero. It therefore recommended that these tissues, termed "**specified risk materials**" (SRM), be withdrawn from all the food chains (human or animal) in the countries or regions where a potential risk had been identified and that, in the case of cattle, sheep and goats found dead, the SRM be withdrawn so that they could not enter the human or animal food chain or, better still, that the whole carcase be destroyed. In the case of cattle, sheep and goats aged over 12 months, these tissues comprised mainly at that time the brain, spinal cord and eyes, as well as the spleen of sheep and goats.
50. On the basis of these recommendations and opinion, the Commission drew up a proposal for a decision aimed at banning the use of SRM from cattle, sheep or goats in the manufacture of foodstuffs and animal feed. The proposed measures were to be applied in all the Member States without prejudice to the stricter measures already applied in the United Kingdom. On the other hand, provision was made for derogations to be granted to non-Community countries.

⁴¹ See Annex 3.

When it was examined by the Agriculture Council on 16 and 17 December 1996, only five delegations (F – IRL – L – S – UK) were in favour of the proposal, while the other ten voted against it. The decision was therefore rejected.

51. **Decision 97/534/EC of 30/7/97:** in the following July, the Commission presented a new proposal for a decision aimed at prohibiting all use of SRM in the human and animal food chains and for the manufacture of medical, pharmaceutical and cosmetic products. Although divided to the point of not taking a decision, the Council was not against the Commission doing so itself, which it did on 30 July 1997.⁴²

This Decision prohibited, from 1 January 1998, all use of SRM and introduced measures to ban imports of products derived from or containing these tissues from non-Community countries.

52. In the following months, it emerged that **problems** might arise with the supply of essential pharmaceutical products that could be manufactured from these tissues only. Moreover, Article 2 of the Decision ("all use of SRM shall be prohibited") could be interpreted too widely. Accordingly, the placing on the Community market of all products in which SRM are used, including car tyres, electrical components, silicones, etc., could have been prohibited. The Commission therefore proposed to amend the Decision by adapting it in the light of the scientific opinions adopted in the meantime.

In order to enable the Commission to present a new proposal, it was decided to put back the date for implementation of the Decision from 1 January to 1 April 1998.

53. On 17 and 31 March 1998, two new proposals for Decisions presented by the Commission were rejected in turn by the Agriculture Council, which decided to **extend to 1 January 1999** the Decision of 30 July 1997, while asking the Commission to **present a new proposal** after the general session of the International Office of Epizootics (IOE) in May 1998.
54. The question of SRM illustrates the difficulties sometimes facing the European Union, the Member States and the international community.
55. On the one hand, a certainty shared by practically everybody: the dangerousness of specified risk materials (SRM). Moreover, certain Member States, particularly those most directly concerned (UK, IRL, F, P, B, L, NL), have already taken precautionary measures to protect their consumers from all risks of contamination. For example, the United Kingdom banned the use of SRM in human (1989) and animal (1990) food, as did France (1996), the Netherlands (August 1997) and Belgium (March 1998). These countries approve the measures recommended by the Commission and would like them to be applied not only by all the Member States but also by non-Community countries not recognised as BSE-free.

⁴² Decision 97/534/EC of 30/7/97.

On the other hand, opposition to the measures recommended by the Commission. In actual fact, the Member States which consider themselves free of BSE or even TSE approve the measures recommended by the Commission, provided that such measures take account of the status of each country and, therefore, are not applied to themselves.

56. As for non-Community countries, with the exception of Switzerland, they claim to be BSE-free and refuse to see the slightest Community constraint applied to their exports. However, apart perhaps from Australia and New Zealand, all sheep-rearing countries are affected by scrapie.
57. Given the economic interests at stake and the scientific uncertainties about the dangerousness and geographical spread of BSE, as well as the Commission's determination to give consumers in the Union the greatest possible guarantee, the debate on the measures to be taken is likely to divide the Member States for quite some time yet. For their part, the Scientific Steering Committee and the IOE are continuing their investigations on this subject.⁴³

D. Animal meal

58. Very shortly after the appearance of BSE, British scientists suspected the consumption of meat and bone meal (MBM) by cattle of being responsible for the epizootic. That was why, as long ago as July 1988, the United Kingdom, then certain Member States and lastly, in June 1994, the European Union (EU) **banned the use of mammalian meal for feeding ruminants** Moreover, the EU laid down compulsory manufacturing standards in all the Member States in order to improve the safety of meal for other animals (pigs, poultry, fish, etc.). These standards have been tightened since 1 April 1997.⁴⁴
59. At the same time, certain consumer organisations came out against meat and bone meal in feed for herbivores. Other organisations went even further. Following the transmission of BSE to carnivorous animals, they called for **a ban on the consumption of animal proteins in the form of meal for all animals of any species whatsoever**. However, while the measures taken in this area have had beneficial effects as far as BSE is concerned, going further towards a ban on meat and bone meal might have far-reaching ecological and economic or even health consequences in certain countries. Before any decisions were taken in this area, it was therefore necessary to measure the potential risks of such meal for animal and, ultimately, human health.
60. That was why the European Parliament and the Commission decided to organise jointly an **International Scientific Conference on Animal Meal** on 1 and 2 July 1997 in Brussels. Under the aegis of the EU's Scientific Steering Committee (SSC), the Conference's aim was to review the situation with regard to animal

⁴³ See Annex 10.

⁴⁴ Decision 94/449/EC of 18/7/96: minimum parameters for the processing of animal waste from mammals, excluding fats : Ø < 50 mm, d° > 133° C, t: 20', p: 3 bar.

meal in order to provide the Commission and the Parliament with as much information as possible.

The Conference enabled the issue of animal meal to be tackled with the best scientific specialists on the subject while fostering a **wide-ranging debate** with all the parties concerned in both the Community and non-member countries.

A **broad consensus** was obtained on:

- the maintenance of the ban on feeding ruminants with meat and bone meal derived from mammals;
- the need for a healthy supply of raw materials;
- the use of the best available rendering and production methods.

The **Conference proceedings** were published in the form of a report and placed on the Internet. This report is available from the Commission.⁴⁵

61. Before deciding on the legislative measures to be proposed, the Commission initiated in November 1997 a **wide-ranging consultation** on two fundamental questions:

- (1) for the manufacture of meal for animal consumption, should the cadavers of fallen animals and all materials impounded on health grounds be excluded, using only the materials deemed fit for human consumption but which, for commercial or technical reasons, are not used for this purpose?
- (2) should all use of animal proteins for feeding herbivores be banned?

Launched in November 1997, the consultation finished at the end of February 1998.

The Standing Veterinary Committee was informed of the findings on 5 May and the Consumer Committee on 26 May. The latter forwarded a resolution to the Commission⁴⁶ on 17 June 1998.

The Commission is now going to decide what amendments might have to be made to the current legislation.

62. In the light of the results of the Conference of 1-2 July 1997, the **SSC** adopted on 26-27 March 1998 an **opinion on meat and bone meal** derived from mammals and intended for feeding non-ruminants (the feeding of ruminants with MBM being banned in any event).⁴⁷ The Committee recommends *inter alia* that the animals from which the raw materials are derived be fit for human consumption, that the specified risk materials be removed if the origin of the animals is not certified as being in a BSE-free country, and that appropriate production processes be used, particularly the minimum standard of 133 C/20 minutes/3 bar,

⁴⁵ Report on the International Scientific Conference on Animal Meal – Brussels, 1 and 2 July 1997.

⁴⁶ See Annex 8.

⁴⁷ See Annex 10.

or an approved equivalent. For the United Kingdom, the SSC recommends a total ban on the use of MBM derived from ruminants as feed for any mammal.

63. In its final report to the Temporary Committee of the European Parliament on the follow-up of recommendations on BSE (COM(97)509), the Commission proposed that the Joint Research Centre (JRC) carry out studies on the validation of tests to identify meat and bone meal in feedingstuffs.

The JRC has started work on validating two methods of analysis, at an international level with the participation of all the EU Member States:

1. the first method is used to establish whether animal meal has undergone correct heat treatment (20' at 133°C);
2. the second method is used to detect the presence of mitochondrial bovine DNA in feedingstuffs containing less than 0.125% of MBM of bovine origin.

For both methods, the JRC is also going to prepare reference documents.

E. Traceability from the farm to the table

64. The BSE crisis revealed a whole series of shortcomings in the monitoring of animals, meat and derived products. It became clear, for example, that the **labelling of beef** and derived products had to be improved in order to reassure consumers about their quality and hygiene in particular.
65. One of the main objectives of Council Directive 92/102/EEC on the identification and registration of animals⁴⁸ was to give the inspection services the means of going back to the animal's farm of origin and tracing its movements within the Member States. To this end, it had introduced a **system of identification and registration** of bovine animals.⁴⁹ Experience showed that the implementation of this Directive had not been satisfactory and that the system had to be improved. The main weaknesses detected were, on the one hand, the impossibility of tracing animals owing to the lack of recording of movements in a centralised database and, on the other, the shortcomings of the accompanying documents.
66. A new Regulation⁵⁰ was therefore drawn up to consolidate the provisions of Directive 92/102/EEC, through a **new system of identification and registration**. It provides for **earmarks** to identify bovines individually, a central computerised **database**, a **passport** for each animal and **registers** of animals on each farm. In order to achieve effective and rapid traceability of animals, the data on all farms situated on the Member State's territory will be recorded in the computerised database along with the animals' identity and movements.

⁴⁸ OJ No L 355, 5.12.1992, p. 32.

⁴⁹ But also sheep, goats and pigs.

⁵⁰ Council Regulation (EC) No 820/97 of 21 April 1997.

67. As regards the **labelling of beef** and derived products, the new Regulation consolidates the existing provisions in order to make them more effective. It stipulates that every operator or organisation in the beef sector must submit a specification indicating the information to appear on the label and the measure to be taken to guarantee its accuracy. The specification must also describe the control system to be applied and the measures to be taken with regard to operators who do not comply with its provisions.

The specification has to establish the link between the identification of the carcass, cuts of meat or meat-based products and the identification of the animal from which they come.

The Regulation also mentions the information that may appear on the label. It relates to the animal itself, especially its fattening method and its feed as well as the country or countries where it was born, lived and was slaughtered. It is applicable compulsorily from **1 January 2000**, but the Member States have the **option of applying it in their own country without waiting for this date**.

A number have already done this (B, D, F, UK) or are on the point of doing so.

F. Research

68. Since 1990, research on BSE has received financial support from the European Union under the research and technological development programmes in particular. This effort has been bolstered by the financing of 16 research projects dealing with questions relating to CJD surveillance, the harmonisation of neuropathological diagnostic criteria and the use of animal models to identify the nature of the agent and the effectiveness of the species barrier.
69. On 3 and 30 April 1996, the Council of Agriculture Ministers highlighted the need to **intensify research** on the outstanding questions concerning BSE and welcomed the creation by the Commission of a group of scientific experts, chaired by Professor **Charles Weissmann** of the University of Zurich, and the decision to create a multidisciplinary scientific committee as soon as possible.
70. Similarly, the Council of Health Ministers and the Council of Research Ministers, which had met on 14 May and 5 December 1996 respectively, stressed the need **to improve cooperation and the coordination** of research efforts in this area, covering fundamental and applied biology, human and animal health, and problems of diagnosis. This ought to result mainly in coordination of research activities between the Member States and in calls for proposals for specific research.
71. The Weissmann Group was set up in April 1996 and submitted its report to the Commission on 7 October 1996. The **Multidisciplinary Scientific Committee**, chaired by Professor **Fritz Kemper**, was set up on 18 June 1996.

Lastly, in 1997, the Commission decided to **reform its scientific research committees**, to reinforce their independence and increase the transparency of their work, and to create a **Scientific Steering Committee (SSC)** to coordinate their work. Started in April 1997, the reform was to result by November of the same year in the recruitment of 132 eminent scientists and the constitution of eight committees and the Scientific Steering Committee.⁵¹

72. In this context, taking account of the recommendations of the Weissmann Committee and after analysing the national and Community research activities under way, the Commission launched on 13 November 1996 a **European initiative on TSE** (transmissible spongiform encephalopathies). This action plan has two strands: coordination of activities between the Member States and a call for proposals on **six specific research topics** clinical and epidemiological research on human spongiform encephalopathies (SE), the infective agent and its transmission mechanisms, diagnosis of SE, evaluation of the risk from SE, treatment and prevention of SE, and coordination of research activities between the Member States.
73. A **call for proposals** relating to TSE was launched under the FAIR programme in December 1996. Covering the field of BSE and animal health, it provided funding for **8 projects** relating to the development of methods for diagnosis and control of animal TSEs.

Subsequently, a **joint call** under the BIOMED, BIOTECH and FAIR programmes was issued in April 1997. It covered the six areas mentioned in the action plan on TSE. 22 projects were selected for funding.

74. The projects selected complement the research in progress at European and national level in the field of TSE and constitute a coordinated effort aimed at increasing knowledge in such important areas as:
- identification of the agent responsible for the disease;
 - development of diagnostic methods, using tools such as magnetic resonance imaging, electro-encephalography or specific antibodies;
 - establishment of harmonised procedures for epidemiological surveillance of human and animal TSE.
75. A second joint call for proposals in the field of TSE was issued on 17 March 1998. Like the previous one, it comes under the BIOMED, BIOTECH and FAIR Community research programmes and covers three areas of research:
- evaluation of the risks of SE;
 - treatment of SE;

⁵¹ See Annex 6.

- coordination of national research activities between the Member States.

The closing date for submission of applications was 17 June 1998.

Twelve projects were subjected to scientific evaluation. Final selection of the projects is now under way.

76. **Funding:** On 10 November 1997, the community allocated over **50 MECU**⁵² to research on BSE.

One of the research topics to which the Commission attaches particular importance is that of tests for post-mortem BSE diagnosis.

77. The Commission has launched a project for the evaluation of a number of available methods of post-mortem BSE diagnosis. The **Joint Research Centre (JRC)** is collaborating here, particularly as regards the handling and coding of samples, the critical evaluation of the findings and the preparation of the final report. It is also working on a project for electronic identification of animals aimed at facilitating surveillance of their progression from birth to slaughter and thereby giving consumers an additional guarantee about the origin of the animal (March 1998).

G. Health and safety of products placed on the market

78. **The Council of Health Ministers** looked at the question of transmissible spongiform encephalopathies (TSE) on 13 December 1993, 30 April 1994 and 14 May 1996 in order to consider Germany's concerns regarding public health; they then focused their attention on the questions of epidemiological surveillance and the needs of scientific research.

In its conclusions, the Council recommended in particular:

- setting up mechanisms for following up scientific evidence relating to the causes and transmission of CJD in order to be able to determine in good time the appropriate action to be taken to protect public health;
- extending epidemiological surveillance of CJD to all the Member States on the basis of the methods used by five Member States;
- encouraging the exchange, between all Member States, of their experience as regards control and diagnosis;
- carrying out further studies and research on TSE, including CJD.

The Council also decided to **monitor this matter on a permanent basis**

⁵² 50.7 million ecus (MECU), comprising 15.7 million from resources available under the Community programmes and 35 million from the supplementary finance for the 4th framework programme.

79. In this context, the reference made to the protection of public health in the Order of the **Court of Justice** of the European Communities of 12 July 1996 on the "Summary procedure Agriculture-Health policy-Emergency measures against BSE" is particularly important. According to the Court, "the circumstances show that the Commission had, above all, regard for the protection of public health in the context of the internal market, as moreover it is obliged to do in application of Directives 90/425 and 89/662. It should be stressed on this point that the EC Treaty stipulates, among the objectives of the Community, that it "shall help to **ensure a high level of protection of human health**"⁵³ and also that "the requirements in the area of health protection shall be a component of the other Community policies".⁵⁴
80. **In the case of pharmaceutical products**, the risk analysis is specific. There is a fundamental difference here from the risk assessment for foodstuffs. For example, products derived from tallow and gelatine are used in the composition of many pharmaceutical products, and a number of very important medicinal products are derived from specific risk materials (SRM). Given the beneficial effects of these medicinal products, a derogation based on a scientific opinion may therefore be envisaged in order to avoid any shortage of essential and vital medicines.
81. With regard to **cosmetic products**, the Scientific Committee on Cosmetology was consulted about the safety of products derived from **tallow**. The Committee concluded that tallow products can be considered safe when clearly specified production methods are used. The inactivation afforded by these treatment processes is such that the exclusion of specified risk materials (SRM) does not seem necessary.
82. Transparency in the working methods and decision-making procedures of the **international organisations** is of the utmost importance. Improvements should be sought. In the case of the agreement on health and phytosanitary measures, an examination of its results and implementation will be carried out in 1998. The Commission is determined to take advantage of this opportunity to uphold the Community's interests in the field of **food safety**.
83. **Conference:** in view of the importance and topicality of the issue, the European Parliament and the European Commission have decided to organise in Brussels on 30 November and 1 December 1998 a Conference on the subject of "**The European Union and food safety: the lessons from BSE**" along the same lines as the July 1997 Conference on Animal Meal (see § 59).

H. Impact of the measures taken on trade with non-Community countries

84. The European Union is the **world's leading trade power**. It therefore has a vital interest in ensuring that the rules of international trade are complied with.

⁵³ Article 129 (1) subparagraph 3.

⁵⁴ Article 129 (1) subparagraph 1.

Accordingly, it must make sure that the legislation and procedures provide adequate assurances to our trade partners and that our exports do not come up against unjustified restrictions in access to the world market. That being so, the Community must also be capable of setting the level of human health protection that it considers appropriate. In accordance with the international rules, safety measures must be based on scientific principles and must be backed up by sufficient scientific evidence.

Part III: The partners: what do they want? what are they proposing?

A. Consumers

85. Consumers' **confidence** in the safety of foodstuffs, especially meat, which was badly shaken on 20 March 1996, is not yet fully restored, particularly as **fraudulent trading** of beef in Britain and the threat of having to consume "hormonal" meat imported from the United States have jeopardised the progress that had been made since the beginning of 1997 in this area. The Commission is still aware, however, of the need to restore the confidence of public opinion and is determined to continue its efforts to reassure consumers about the safety of their food. To this end, a large-scale advertising campaign throughout the Union has been decided by the Commission, with total funding of 33 MECU.
86. Since 20 March 1996, the European Commission has organised quarterly meetings of the **Consumer Committee**⁵⁵ and, practically every time, included the question of BSE on the agenda in order to inform its members about the measures taken and, in return, to get to know consumers' fears and wishes. On 9 October 1996, for example, the Committee submitted to the Commission the Resolution to be found in the Annex.⁵⁶ As can be seen from the Vademecum, several of the proposals in this Resolution have already been approved by the Commission and have started to be implemented.
87. Similarly, at the **International Scientific Conference on Animal Meal** held in Brussels on 1 and 2 July 1997 and the consultation which followed it,⁵⁷ consumers were able to make their wishes on this matter widely known. Moreover, the Consumer Committee sent the Commission, on 17 June 1998, a document setting out its position on this question⁵⁸. The Commission took note of their point of view and that of all interested parties, with the aim of making the necessary amendments to European legislation.

⁵⁵ See Annex 14.

⁵⁶ See Annex 7.

⁵⁷ See § 60 *et seq.*

⁵⁸ See Annex 8.

88. It is in fact difficult to reassure consumers. Apart from "mad cow disease", they are very worried about food and feel themselves somehow caught in the trap of having to consume products which, rightly or wrongly, they fear (genetically modified organisms, hormonal meat, chocolate with modified composition, ionised products, residues of fertilisers, pesticides, antibiotics, etc.). In an attempt to resolve this difficulty, the Commission decided to stake everything on **transparency in scientific knowledge and information** and to step up contacts with consumer organisations in the field in order to listen to their point of view and react to their demands.
89. Consumers are not easily swayed, even by scientific opinions. They need hard-and-fast proof. In keeping with the European Parliament's concerns on this point, the Commission took the necessary steps to obtain the best scientific opinions possible and to inform consumers by publishing all the opinions, including the minority ones, and ensuring that such opinions are issued independently.
90. But **how can the consumer's degree of confidence or distrust** in a product be judged? The best criterion is probably that of consumption. Thus, the day after the statement of 20 March 1996 in the House of Commons (see § 1), the sharp fall in meat consumption in most of the Member States made it possible to gauge the impact of the crisis that had been triggered off. This fall, which in some cases reached 15 to 20% of normal monthly consumption, lasted for several months, with variations from one Member State to another, before starting to turn around from autumn 1996. In 1998, it can be estimated that, *mutatis mutandi*, consumption has returned to its 1995 level.

Is the crisis over for all that? Only the future will tell.

B. Researchers

91. Very little is known about bovine spongiform encephalopathy (BSE) and, in general, transmissible spongiform encephalopathies (TSE), including Creutzfeldt-Jakob disease and its new variant, despite the many years of scientific research devoted to them. While waiting for their work to bear fruit, scientists are therefore forced to put forward hypotheses and, as far as recommendations are concerned, to abide by the precautionary principle, thereby putting the Community and national authorities in a very embarrassing position.
92. Aware of this situation, the research centres have got together to coordinate their work, while the national and Community authorities have increased their budgetary resources. There is no doubt that this effort will bring results, but also that it will be many months or even several years before the main uncertainties surrounding this matter are dispelled.

C. Cattle-sector operators

93. The economic consequences of the BSE crisis have been and still are quite considerable for all cattle-sector operators. Although meat consumption has now gone up again to its 1995 level, it is still vulnerable and extremely sensitive to any further upheavals in the sector.

94. Not only for the cattle sector but also for the agri-food industry in general, this crisis has clearly highlighted all the connections that may exist between the food sector and certain areas of health, as well as in all probability the lack of consultation structures for assessing the risks associated with technological developments. It has also shown the sector's chronic shortcomings in terms of communication and information.
95. The cattle-sector operators are prepared to do everything they can to guarantee the safety of their products. For them too, the priority is still of course consumers' health. Already, the requirements of traceability from the farm to the table are at the heart of their concerns in order to enhance the present arrangements and provide the information sought by the consumer. However, in order to continue along the right path, they need clear guidance not only from the Community or national authorities and scientists but also from consumers, who through their purchases make it possible for the operators to continue or redirect the efforts already made.

Conclusion

Towards a new approach to consumer policy

96. The Commission had a hard time during the mad cow crisis. Apart from the criticisms and even accusations levelled at the institution, it transpired that some of its methods were unsuitable for the situation. Through its President, Mr Jacques SANTER, addressing the European Parliament on 18 February 1997, the Commission acknowledged the situation and announced **reforms** to make its policy and structures more suitable for handling the BSE crisis and above all to try to avoid a repetition of such a crisis in the future.
97. **With regard to consumers**, the Commission decided to pay even more heed than in the past to their expectations, particularly in the field of food safety, by stepping up research initiatives upstream and inspection and control activities downstream. Through its action and even more extensive dialogue with consumers and their organisations, and thanks to improved transparency of its research procedures and activities, it intends to establish a **new climate of confidence**.
98. As far as scientific research, risk analysis and assessment, and control and inspection are concerned, the Commission presented its **new policy approach**⁵⁹ in April 1997. This approach is based on a **separation of responsibilities** between the legislative function on the one hand and scientific evaluation, control and inspection on the other. It has resulted in a major reorganisation of the Commission's departments.⁶⁰

⁵⁹ Communication from the Commission on consumer health and food safety (Doc. COM(97) 183 final of 30/4/97).

⁶⁰ See the new organisation chart of DG XXIV in Annex 5.

The Commission also sets out here its intentions regarding the reorganisation and operation of all the Scientific Committees. Action in the **scientific** field will henceforth be based on the **principles of excellence, independence and transparency**.

99. In the wake of this Communication, the Commission established on 10 June 1997 a **Scientific Steering Committee**⁶¹ and created or reorganised on 23 July **eight Scientific Committees**⁶² for which Directorate XXIV.B provides the secretariat. The 132 members of these new committees were nominated by a Commission Decision of 5 November 1997⁶³ following a selection procedure including a call for expressions of interest in which more than 800 experts took part.
100. The responsibility for applying **Community legislation** lies with the Member States. The Commission's role is basically to check how the Member States discharge this obligation. The system cannot work therefore unless an equivalent level of control is guaranteed in all the Member States. Even if the inspection services are organised differently from one Member State to another, they ought to operate according to common standards in order to guarantee this equivalence. In this regard, the Commission considers that the present situation is not yet entirely satisfactory.
101. In order to improve the situation, the Commission started to apply, in 1997, a new approach to **control and inspection** through the **Food and Veterinary Office (FVO)**,⁶⁴ relying on:
- checks covering all food, animal and crop production chains;
 - formal risk-assessment procedures aimed at identifying inspection priorities;
 - systems for auditing the national inspection systems with a view to monitoring the performance of the competent authorities and formulating the necessary recommendations.

This task will take some time, and the Member States will be asked to adopt a common approach from now on as regards procedures and handbooks, organisation and operating criteria, and education and training standards.

102. Aware that **there is still a lot to be done**, the Commission intends to continue along the lines of the progress achieved since March 1996, and especially since February 1997, in order to carry out its work programme. It must be stressed,

⁶¹ OJ L169/85, 27/6/97.

⁶² OJ L237, 28/8/97.

⁶³ See Annex 6.

⁶⁴ The FVO has replaced the Veterinary and Phytosanitary Office (VPO), which was previously attached to the Directorate-General for Agriculture (DG VI) and established in Brussels. Having been established in Dublin since 1 September 1997, the FVO is currently being installed in Grange (Ireland). See Annex 5.

however, that this ambitious programme does not depend on the Commission alone. As co-legislators, the European Parliament⁶⁵ and the Council too will have an important part to play.

ANNEX 1

Bovine spongiform encephalopathy

CHRONOLOGY OF THE MOST SIGNIFICANT EVENTS

I. FROM 1985 TO 1995

- Sept. 1985: First identification of BSE in a cow from Pitsham, Midhurst, Sussex, at the Central Veterinary Laboratory in Weybridge (UK)
- Nov. 1986: Formal identification of the BSE disease in a number of herds in England. It is thought that the first cases occurred in April 1985
- June 1987: Ministries officially notified by the Weybridge laboratory (UK)
- July 1988: Ban on feeding ruminants with meat and bone meal in the United Kingdom
- 1989: First cases of "mad cow disease" identified in Ireland
- Dec. 1989: Ban on specified bovine offal for human consumption in the United Kingdom
- 1990: First cases of "mad cow disease" in Portugal
- May 1990: After Germany, the USSR and Austria, France in turn bans imports of British beef. The Commission demands that Germany and France, with the support of Italy, Luxembourg and Portugal, reverse their decision
- June 1990: The bans are lifted against a promise to step up health measures
- July 1990: Experimental transmission of BSE to pigs in the laboratory. *The Lancet* puts forward the theory of possible transmission to humans
- Nov. 1990: Seminar organised by the European Commission: "Sub-Acute Spongiform Encephalopathies"
- Mar. 1991: First case of "mad cow disease" in France
- 1992: Peak of the epizootic in the United Kingdom: 37 280 cases officially recorded that year

⁶⁵ The Commission wishes to maintain its close cooperation with the European Parliament and report to it twice a year on the progress made.

May 1995: Death of Stephen CHURCHILL at the age of 19. He is the first victim of the new variant of Creutzfeld-Jakob disease

II. 1996

- 20/3/96 Announcement by the British Secretary of State for Health, Stephen DORREL, of a possible link between BSE and CJD
- 27/3/96 Community ban on British exports of beef and derived products; setting-up at the Commission of an Interdepartmental Working Party on BSE; presentation of the situation to the Consumer Committee
- 28/3/96 Creation of a special group of experts on BSE, chaired by Prof. Weissmann from Zurich
- 2-3/4/96 Consultation of experts on BSE and nv-CJD by the WHO
- 22/5/96 Decision by the United Kingdom to obstruct the working of the European institutions in order to get the ban lifted
- 28/5/96 First edition of the BSE Vademecum by the Commission
- 18/6/96 Creation of the Multidisciplinary Scientific Committee by the Commission
- 21/6/96 European Council in Florence: the United Kingdom decided to end its policy of obstruction adopted on 22/5/96; adoption by the Council of a plan for gradual lifting of the ban
- 30/6/96 Beginning of a press campaign against the Commission in France and then in Europe following an article published by the *Journal du Dimanche*
- 5/7/96 First meeting in Brussels of the Multidisciplinary Scientific Committee created by the Commission on 18 June
- 17/7/96 Setting-up by the European Parliament of a Committee of Inquiry on the handling of the “mad cow” crisis by the Commission
- 9/10/96 Conclusions of the Weissmann report: confirmation of the theory of contamination of cattle through feed. Transmission of the disease from livestock to humans is not proven so far. There is no evidence that milk is a risk factor. Research is to be continued on these matters
- 24/10/96 Publication in the journal *Nature* of research findings providing an initial scientific pointer to the transmissibility of BSE to humans
- 18/11/96 Agriculture Council: formal adoption of the plan for funding exceptional aid to breeders suffering from the crisis on the beef market caused by BSE

- 29/11/96 Second edition of the BSE Vademecum by the Commission
- Dec. 1996 Beginning of selective culling of cattle at risk in the United Kingdom
- 3-12/12/96 Committee of Inquiry: hearing of a number of personalities, particularly Mrs Bonino, Mr Fischler, Mr Flynn and Mr Van Miert, Members of the Commission. Mr J. Santer is himself heard on 15/1/97 in Strasbourg

III. 1997

- 17/1/97 Publication in the journal *Science* of the findings of a study by Prof. Dormont's team questioning the theory of transmissibility by prion
- 18/2/97 Speech by Mr Jacques SANTER, President of the Commission, to the European Parliament in Strasbourg
- 19-20/2/97 Strasbourg: the European Parliament adopts the report of the Committee of Inquiry and a resolution underlining the Commission's responsibilities in the management of the BSE crisis and calling on it to do certain things; rejection of a motion of censure against the Commission
- 26/2/97 Creation of the Group of Commissioners responsible for consumers' health, under the chairmanship of President Jacques Santer, to ensure that the recommendations of the Parliamentary Committee of Inquiry on BSE are followed up
- 11/3/97 Adoption by the Scientific Veterinary Committee of a report concluding that there is no risk of transmission of the disease via milk or milk products
- 1/4/97 Reorganisation of certain Commission departments concerned with BSE. DG XXIV becomes the Directorate-General for "Consumer policy and consumer health protection"
- Implementation of Commission Decision 96/449/EC on the minimum parameters for the processing of animal waste of mammalian origin
- 21/4/97 Traceability: the Agriculture Council adopts Regulation (EC) No 820/97 establishing a system of identification and registration of cattle and regarding the labelling of beef and beef products
- 24/4/97 Creation by the European Parliament of the Temporary Committee on the follow-up of recommendations on BSE presented in February by the Committee of Inquiry on the "mad cow" crisis
- 1-2/7/97 International Scientific Conference on Animal Meal organised jointly by the Commission and the European Parliament under the aegis of the EU's new Scientific Steering Committee in Brussels

- 30/7/97 Adoption by the Commission of Decision 97/534/EC defining specified risk materials and prohibiting their use as from 1 January 1998
- 30/9/97 Confirmation by the Commission of the existence of exports of beef from the United Kingdom to Europe and non-member countries
- 4/11/97 Identification of the first case of “mad cow disease” in Belgium
- 6/11/97 Adoption by the European Parliament of the conclusions and recommendations of the Temporary Committee on the follow-up of the “mad cow” crisis by 427 votes for, 33 against and 45 abstentions
- Nov. 1997 Setting-up of the Commission's new Scientific Committees
- 2/12/97 Identification of the first case of “mad cow disease” in Luxembourg
- 9/12/97 Postponement from 1/1/98 to 1/4/98 of the date of application of the Decision of 30/7/97 on specified-risk material
- 16/12/97 Entry into force of the ban on consumption of beef-on-the-bone in the United Kingdom
- 23/12/97 United Kingdom: opening of an inquiry on the relevance of the measures taken in the United Kingdom against BSE

IV. 1998

- 16/3/98 Decision of the Agriculture Council lifting the ban on exports of boneless beef from Northern Ireland herds free of BSE for 8 years
- 31/3/98 Postponement from 1/4/98 to 1/1/99 of the date of application of the Decision of 30/7/97 on specified risk materials (SRM)
- 26/5/98 Presentation by the Commission of the first six-monthly follow-up report on BSE to the European Parliament
- 29/5/98 Commission Decision to lift the ban on exports of boneless meat from Northern Ireland herds free of BSE
- 10/6/98 Commission proposal to lift the ban on exports of boneless meat obtained from BSE-free cattle slaughtered in the United Kingdom. The draft proposal will be submitted to the Standing Veterinary Committee.
- 22/7/98 Commission Recommendation to the Member States and third countries with a view to evaluation of their epidemiological status with respect to TSEs
- 25/9/98 Spain bans the entry of cattle and beef from Portugal onto its territory

(to be continued!)

ANNEX 2

BSE : main measures taken by the Commission and the Council

Since bovine spongiform encephalopathy first appeared in the United Kingdom, the Commission and the Council have taken a wide range of measures to protect consumer health and eradicate the epizootic in the light of advances in scientific knowledge. Below is a list of the **Commission Decisions** in chronological order:

- 89/469/EEC of 28 July 1989⁶⁶ banning the **export of live cattle** born before 18/7/88 or born to cows suspected of having BSE from the United Kingdom to the other Member States. Subsequent Decisions amended or clarified this measure until Decision 96/239/EC of 27 March 1996⁶⁷ ordered the provisional cessation of all exports of live cattle, beef and derived products from the United Kingdom to the other Member States and non-Community countries;
- 90/134/EEC of 6 March 1990⁶⁸ on compulsory **notification** of any source of BSE;
- 90/200/EEC of 9 April 1990⁶⁹ requiring in particular the separate retention and slaughtering of all **cattle suspected of having BSE**, an examination of their brain tissue to determine whether BSE was present and, on confirmation of the disease, the destruction of their carcass and offal. The Decision also prohibited the **export to the other Member States of certain tissues and organs** of bovine animals aged over 6 months born in the United Kingdom;
- 90/261/EEC of 8 June 1990⁷⁰, in particular requiring the United Kingdom to make full use of computer records to guarantee **identification of animals**;
- 91/89/EEC of 5 February 1991⁷¹ making financial provision for a project relating to the inactivation of the agents of scrapie and BSE in the United Kingdom;

⁶⁶ Decision 89/469/EEC (OJ No L225, 03.08.1989).

⁶⁷ Decision 96/239/EC (OJ No L78, 28.03.1996).

⁶⁸ Decision 90/134/EEC (OJ No L76/23, 22.03.90) repealed by Decision 92/450/EEC of 30.07.92 (OJ No L248, 28.08.92).

⁶⁹ Decision 90/200/EEC (OJ No L105, 25.04.1990).

⁷⁰ Decision 90/261/EEC (OJ No L146, 09.06.1990).

⁷¹ Decision 91/89/EEC (OJ No L49, 22.02.91).

- 94/381/EC of 27 June 1994⁷² banning, with effect from 27 July 1994, in all the Member States the use of proteins derived from ruminant tissue or - in the event of difficulty of identification - from any mammalian tissue for **feeding ruminants**;
- 94/382/EC of 27 June 1994⁷³ setting out the minimum conditions for the processing of **ruminant wastes** so as to inactivate the BSE agents;
- 94/474/EC of 27 July 1994⁷⁴ regulating **exports** from the United Kingdom to the other Member States of certain beef products and in particular requiring the United Kingdom to destroy **specified offals** (brain, spinal cord, thymus, tonsils, spleen, intestines) from cattle aged over 6 months, amended by Decision 95/287/EC of 18 July 1995;
- 96/239/EC of 27 March 1996⁷⁵ **banning** most British beef products;
- 96/362/EC of 11 June 1996⁷⁶ amending Decision 96/239/EC banning certain categories of beef products;
- 96/385/EC of 24 June 1996⁷⁷ approving the **plan for the control and eradication** of BSE in the United Kingdom;
- 96/449/EC of 18 July 1996⁷⁸ on the approval of alternative heat treatment systems for **processing animal waste** with a view to the inactivation of spongiform encephalopathy agents;
- Directive 97/1/EC of 10 January 1997⁷⁹ relating to **cosmetic products**;
- Council Regulation 820/97 of 21 April 1997⁸⁰ establishing a system for the **identification and registration** of bovine animals and regarding the **labelling** of beef and beef products;

⁷² Decision 94/381/EC (OJ No L172, 07.07.1994) amended by Decision 95/60/EC of 6.03.95 (OJ No L55, 11.03.95).

⁷³ Decision 94/382/EC (OJ No L172, 07.07.1994) amended by Decision 95/29/EC of 18.02.95 (OJ No L38, 18.02.95).

⁷⁴ Decision 94/474/EC (OJ No L194, 29.07.1994).

⁷⁵ Decision 96/239/EC (OJ No L78, 23.03.96).

⁷⁶ Decision 96/362/EC (OJ No L139, 12.06.1996).

⁷⁷ Decision 96/385/EC (OJ No L151, 26.06.1996).

⁷⁸ Decision 96/449/EC (OJ No L184, 24.07.1996).

⁷⁹ Directive 97/1/EC (OJ No L16, 18.01.97).

- 97/404/EC of 10 June 1997⁸¹ setting up a **Scientific Steering Committee**;
- 97/579/EC of 23 July 1997⁸² setting up **Scientific Committees** in the field of consumer health and food safety;
- 97/534/EC of 30 July 1997⁸³ on the prohibition of the use of **materials presenting risks** as regards transmissible spongiform encephalopathies;
- 97/582/EC of 28 August 1997⁸⁴ establishing a **list of ingredients** whose use is prohibited in compound feeding stuffs;
- 97/735/EC of 21 October 1997⁸⁵ concerning certain protection measures with regard to trade in certain types of mammalian animal waste;
- Commission Directive 97/65/EC of 26 November 1997⁸⁶ adapting, for the third time, to technical progress Council Directive 90/679/EEC on the protection of workers from risks related to exposure to biological agents at work;
- 98/139/EC of 4 February 1998⁸⁷ concerning **veterinary controls** by the Commission;
- 98/256/EC of the Council of 16 March 1998⁸⁸ lifting the ban on exports of certain British beef products and certain categories of meat from cattle born and bred in **Northern Ireland**;
- 98/248/EC of the Council of 31 March 1998⁸⁹ postponing to 1/1/99 the date of application of Decision 97/534/EC of 30/7/97 on specified risk materials;
- 98/272/EC of 23 April 1998 on epidemio-surveillance for TSE;

⁸⁰ Council Regulation 820/97 (OJ No L117, 07.05.1997) supplemented by Commission Regulations (EC) 114/97 and (EC) 2406/97.

⁸¹ Decision 97/404/EC (OJ No L169, 27.06.97).

⁸² Decision 97/579/EC (OJ No L237, 28.08.97).

⁸³ Decision 97/534/EC (OJ No L216, 08.08.1997).

⁸⁴ Decision 97/582/EC (OJ No L237, 28.08.97).

⁸⁵ Decision 97/735/EC (OJ No L294, 28.10.1997).

⁸⁶ Directive 97/65/EC (OJ No L335, 6.12.97).

⁸⁷ Decision 98/139/EC (OJ No L38, 12.02.98).

⁸⁸ Council Decision 98/256/EC (OJ No L113, 15.4.98).

⁸⁹ Council Decision 98/248/EC (OJ No L102, 2.4.98).

- 98/351/EC of 29 May 1998 setting the date on which dispatch from Northern Ireland may commence;
- Commission Recommendation 98/477/EC of 22 July 1998 to the Member States and third countries with a view to evaluation of their epidemiological status with respect to TSEs.

ANNEX 3

BSE: main measures taken by the British Government

- 1988 BSE made a notifiable disease; suspected and confirmed cases have to be culled and destroyed (21 June)
- Ban on feeding ruminant protein to ruminants in Great Britain (18 July) and Northern Ireland (28 November)
- Compulsory slaughtering of suspected cattle, with compensation in Great Britain (8 August) and in Northern Ireland (28 November)
- 1989 Ban on the use of specified bovine offals in human food in England and Wales (30 December), then in Scotland and Northern Ireland (30 January 1990)
- 1990 Ban on the use of specified bovine offals extended to all animal feed, including vis-à-vis the other Member States (25 September)
- New requirements for livestock breeding and movement records to be kept by farmers in Great Britain (15 October) and Northern Ireland (1 February 1991)
- 1991 Ban on the use as fertiliser of meat and bone meal produced from specified bovine offals in Great Britain (6 November) and Northern Ireland (8 June 1992)
- 1995 Tighter controls on the keeping and presentation of records
- Ban on removal of brains or eyes (the whole of the skull becomes specified offal)
- Ban on mechanical recovery of meat from the vertebral column
- 1996 Ban on marketing of meat from cattle aged over 30 months (March)
- Ban on the use of mammalian meat and bone meal in feed for all farm animals
- 1997 Obligation to bone all indigenous or imported meat obtained from cattle aged over 6 months before it is sold to the consumer (16 December)

1998 Public inquiry on BSE announced by the Minister of Agriculture in the House of Commons (22/12/97) for 31 December 1998

Reinforcement of measures concerning the use of meat and bone meal in the preparation of fertilisers

Compulsory slaughter of sheep and goats suspected of being affected by TSE (scrapie) and compensation of breeders.

ANNEX 4

Annual trends in BSE in the United Kingdom and worldwide

- 1) Table of confirmed cases
- 2) Graph

ANNEX 4

Confirmed cases of BSE situation at 1/10/1998

Country	Up to 1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998 (2)	Total (1)	%
UK	446	2514	7228	14407	25359	37280	35091	24434	14560	8151	4334	1435	175239 (2)	99.54
B	-	-	-	-	-	-	-	-	-	-	1	5	6	-
DK	-	-	-	-	-	1*	-	-	-	-	-	-	1*	-
D	-	-	-	-	-	1*	-	3*	-	-	2	-	6*	-
F	-	-	-	-	5	-	1	4	3	12	6	12	43	0.02
IRL	-	-	15**	14**	17**	18**	16	19**	16**	73	78	46	312	0.18
I	-	-	-	-	-	-	-	2*	-	-	-	-	2*	-
L	-	-	-	-	-	-	-	-	-	-	1	-	1	-
NL	-	-	-	-	-	-	-	-	-	-	2	1	3	-
P	-	-	-	1*	1*	1*	3*	12	14	29	30	60	151	0.09
EU excl. UK	-	-	15	15	23	21	20	40	33	114	120	124	525	0.30
CH	-	-	-	2	8	15	29	64	68	45	37	7	275	0.16
Others (3)	-	-	3*	-	-	-	1*	-	-	-	-	1	5	-
Total excl. UK	-	-	18	17	31	36	50	104	101	159	157	132	805	0.46
World total	446	2514	7246	14424	25390	37316	35141	24538	14661	8310	4491	1567	176044	100%

* imported animals

** IRL: figures including imported animals (5 in 1989, 1 in 1990, 2 in 1991 and 1992, 1 in 1994 and 1995)

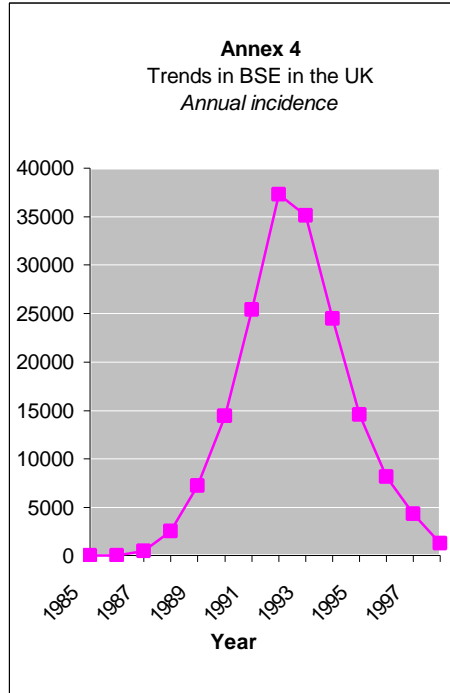
(1) Statistical sources: International Office of Epizootics (IOE) and European Commission: the cumulative figures are more or less identical up to 1997: for EC (173 804), IOE (173 862) and MAFF (173 848)

(2) Provisional figures as at 12/10/1998

(3) 1989 (Falkland Islands: 1 case, Oman: 2) - 1993 (Canada: 1) - 1998 (Liechtenstein: 1)

Annual incidence: this criterion is more significant than the number of observed cases for the purpose of assessing the scale of the epizootic. It represents the quotient of the number of cases of BSE observed and the cattle population aged over 2 years in million head. In the United Kingdom, the annual incidence was estimated at 6 904 in 1992 and 816 in 1997. In the other countries, it was estimated in 1997 at 41.9 in Switzerland, 41.2 in Portugal, 22.4 in Ireland and 0.5 in France.

Graph



ANNEX 5

DG XXIV

Director-General : Horst REICHENBACH

Adviser : Jean-Jacques RATEAU

Assistants to the Director-General : Martin TERBERGER, Viviane HOFFMANN

Unit "Evaluation of health risks" : Arpad SOMOGYI

Directorate A - Consumer Policy

Director : Marina MANFREDI

Adviser dealing with Information society : Kenneth ROBERTS

Unit A1 - Policy development : Agne PANTELOURI

Unit A2 - Consumers' economic interests : Dieter HOFFMANN

Unit A3 - Agriculture, food products and health : Patricia BRUNKO (f.f.)

Unit A4 - Consumer safety and environment : Bernardo DELOGU

Unit A5 - Financial services : Thierry VISSOL

Directorate B - Scientific Health Opinions

Director : Bertrand CARSIN

Adviser : Walter DE KLERCK

Unit B1 - Monitoring and dissemination of scientific opinions : Walter SCHULLER

Unit B2 - Management of scientific committees I : Mercedes DE SOLA DOMINGO

Unit B3 - Management of scientific committees II : Peter WAGSTAFFE

Directorate C - Coordination of Horizontal Questions

Director : Theodius LENNON

Adviser dealing with integration of consumer policy in relation with non-member countries, excluding PHARE) : Antoine VAN DER HAEGEN

Unit C1 - Resources and coordination : Gerard RIJSSENBECK

Unit C2 - Legal matters : Mario-Paulo TENREIRO

Unit C3 - Development of consumer information, education and representation : Jens NYMAND-CHRISTENSEN

Unit C4 - Relations with the EP, the Council and the other institutions; liaison with the Food and Veterinary Office (Dublin) : Jean-Marie COURTOIS

Food and Veterinary Office (Ireland)

Director : Peter PRENDERGAST

Adviser (Brussels) : Jacques GENNATAS

Quality and Planning Section : Stephen HUTCHINS

Unit 1 - Food of animal origin - Mammals : Carlo BERLINGIERI

Unit 2 - Food of animal origin - Birds and Plant Health : Saara REINIUS

Unit 3 - Food of animal origin - Fish - Food of non-animal origin : Willem PENNING

ANNEX 6

Scientific Committees of the Commission

The Scientific Committees in the field of consumer health and food safety were set up by Commission Decision in 1997.

The Commission consults them in the cases provided for by Community legislation. It may also consult them also on other questions of special relevance to consumer health and food safety.

At the request of the Commission, the Scientific Committees issue scientific opinions on questions relating to consumer health and food safety. It may also ask them to carry out a critical examination of the risk assessment, devise new risk-assessment procedures, draw up scientific opinions and evaluate the scientific principles.

The agendas, minutes and opinions adopted by the Scientific Committees are made public and put on the Internet.

1. The Scientific Steering Committee (SSC)⁹⁰

Chairman: Prof. Gérard PASCAL, Director of the Centre National d'Etudes et de Recommandations sur la Nutrition et l'Alimentation (CNERNA) (F)

Vice-Chairmen: - Dr Vittorio SILANO, Director-General of the Pharmaceuticals Division, Ministry of Health, Rome (I)
- Prof. Marcel VANBELLE, Université Catholique de Louvain (B)

Direct members

Prof. Michael GIBNEY, Trinity College, Dublin (IRL)

Dr Philip JAMES, Rowett Research Institute, Aberdeen (UK)

⁹⁰ Commission Decision 97/404/EC of 10/6/97.

Prof. Werner KLEIN, Schmalleberg (D)
Prof. Robert KROES, University of Utrecht (NL)
Dr Martin WIERUP, Animal Health Service, Stockholm (S)

Chairmen of the eight Scientific Committees (below)
Ing. Georges BORIES, INRA, Toulouse (F)
Prof. James W. BRIDGES, University of Surrey (UK)
Dr Fulgencio GARRIDO-ABELLAN, Santa Fe (E)
Dr Keith M. JONES, Medical Control Agency, London (UK)
Prof. Fritz KEMPER, University of Münster (D)
Dr Ib KNUDSEN, Institute of Toxicology, Soborg (DK)
Prof. Albert OSTERHAUS, Erasmus Universiteit, Rotterdam (NL)
Prof. Antonio SILVA FERNANDES, Instituto Superior de Agronomia, Lisbon (P)

2. The eight **Scientific Committees**⁹¹

- Scientific Committee on Food (Dr Ib KNUDSEN),
- Scientific Committee on Animal Nutrition (Ing. Georges BORIES),
- Scientific Committee on Animal Health and Animal Welfare (Dr Fulgencio GARRIDO-ABELLAN),
- Scientific Committee on Veterinary Measures relating to Public Health (Prof. Albert OSTERHAUS),
- Scientific Committee on Plants (Prof. Antonio SILVA FERNANDES),
- Scientific Committee on Cosmetic Products and Non-Food Products (Prof. Fritz KEMPER),
- Scientific Committee on Medicinal Products and Medical Devices (Dr Keith M. JONES),
- Scientific Committee on Toxicity, Ecotoxicity and the Environment (Prof. James W. BRIDGES)

3. **Ad hoc Group TSE/BSE**

- Herbert BUDKA, Neurologisches Institut, Vienna (A)
- Dominique DORMONT, Commissariat à l'Energie Atomique (F)
- Michael GIBNEY, Trinity College, Dublin (IRL)
- Philip JAMES, Rowett Research Institute, Aberdeen (UK)
- Hans KRETZSCHMAR, Universität Göttingen (D)
- MALMFORS, Malmfors Consulting AB, Stockholm (S)
- Albert OSTERHAUS, Erasmus Universiteit, Rotterdam (NL)
- Gianfranco PIVA, Ist. di Scienze degli Alimenti e della Nutrizione, Piacenza (I)
- Josef SCHLATTER, Swiss Federal Office of Public Health, Univ. Zürich (CH)
- Marcel VANBELLE, Université Catholique de Louvain (B)
- Emmanuel VANOPDENBOSCH, VAR, Brussels (B)
- Philippe VERGER, CNERNA, Paris (F)
- Preben WILLEBERG, Veterinary and Agricultural Univ., Frederiksberg (DK)

⁹¹ Commission Decision 97/579/EC of 23/7/97.

4. For information: this report also mentions the **Multidisciplinary Scientific Committee** (MSC), which was created in June 1996 and operated until November 1997.

Chairman: Fritz KEMPER, University of Münster (D)

Members: Dominique DORMONT, Commissariat à l'énergie atomique (F)
Gérard PASCAL, CNERNA (F)
Maurizio POCCHIARI, University of Rome (I)
Giuseppe VICARI, University of Rome (I)
Robert WILL, National CJD Surveillance Unit, Edinburgh (UK)
Preben WILLEBERG, University of Copenhagen (DK)

DG XXIV provides the secretariat for the Scientific Committees mentioned in the previous paragraphs.

5. **Other committees:** there are other Scientific Committees whose secretariat is provided by other DGs, such as:

DG III:

- Scientific Committees of the European Agency for the Evaluation of Medicinal Products:
- Committee for Proprietary Medicinal Products and
 - Committee for Veterinary Medicinal Products

DG V:

- Group of government scientific experts on the protection of health from risks relating to biological agents at work

DG VI:

- Standing Committee on Agricultural Research
- Scientific Committee on designations of origin, geographical ascriptions and certificates of specificity
- Scientific and Technical Committee of the Community Fund for tobacco research and information

DG XII:

- Scientific and Technical Committee

ANNEX 7

Consumer Committee Resolution on BSE (9 October 1996)

1. The Consumer Committee welcomes the Commission's efforts to improve consumer information about the background and the current situation regarding the BSE issue. The members of the Consumer Committee took note of the Vademecum on bovine spongiform encephalopathy (BSE).
2. For consumer organisations public health and food safety issues must be the top priority.
3. Consumer organisations have argued from the beginning of the crisis in the late 1980s for a precautionary approach to the consumer health and safety issues involved.

Enforcement and inspection

Consumer organisations stress the importance of the enforcement of all the rules and controls **on slaughterhouses and farms**. The safety of beef depends on the implementation of these controls.

Resources and levels of inspection by national meat hygiene services must be adjusted to current requirements and, if necessary, increased with regard to BSE and the potential risk to human health.

National control systems of procedures in slaughterhouses and meat-processing industries must be subject to **monitoring at EU level**, with publication of the results of the monitoring exercises.

There should be more random inspections by **EU appointed vets** of standards in slaughterhouses throughout the EU.

Animal feedstuffs and ruminant material

Consumers believe that it is fundamental for the eradication of BSE that all animal waste of mammalian origin in the Community should be processed by a method that has been demonstrated as being de facto effective for the inactivation of the agents of scrapie. This requirement is laid down in Commission **Directive 96/449/EC** of 18 July 1996, which shall apply from 1 April 1997. We urge the Commission to provide guarantees regarding compliance with this Decision from that date.

In addition to the existing EU ban on the feeding of meat and bone meal derived from mammalian tissues to ruminant species, consumers request that **no ruminant should be fed with feed containing animal protein**.

The EU should take steps to recall **residual stocks** of feed that might contain meat and bone meal originating from BSE-infected animals, both within the EU and from third countries. Stocks should be destroyed in such a way that they cannot re-enter the food chain.

There should be EU legislation to oblige feed manufacturers to **declare all the ingredients** of animal feeds.

Levels and detection of tracing

Consumers request the full implementation of Directive 92/102 on the **identification and registration** of animals, and assurance of the traceability of any **movement of individual cattle** both nationally and across frontiers.

Systems assuring that **meat is traceable** "from the table" to the slaughterhouse should be introduced.

There should be an EU-wide **training** programme enable veterinarians and farmers to recognise the symptoms of BSE.

Research

Funds allocated to independent research, concerning the underlying causes of BSE, the possibility of transmission to other animals and to humans and the process of transmission, should be increased.

The top research priority must be to develop a **test** for BSE which can be carried out on live animals. If and when a live test is developed, an extensive EU-wide test programme should be put into operation as soon as possible.

Part of the funds could also be allocated to the development of a reliable system of **epidemiological monitoring** of BSE and to the collection of reliable statistical data of cases.

Labelling

There should be a system of labelling for meat and meat products which makes clear what **type of meat** and from what type of animal is present in foods (e.g. lamb's liver). Such a system should also allow for **country of origin** labelling for beef and beef products marketed to consumers.

Manufacturers should be required to declare the use of any **mechanically recovered meat (MRM)**, even below 25% of the product.

EU-wide definitions of both meat and MRM are needed to prevent consumers from being misled.

Product liability

The 1985 EU product liability Directive excludes liability for **primary agricultural produce**. It should be amended to cover primary agricultural produce in order to raise standards.

Lack of public information

We consider that the growth of panic on the European beef market and the loss of consumer confidence are largely due to a lack of information, or

partial or contradictory information. This is why consumers should be assured of the **publication of the results of research** and of a **complete transparency** with regard to the scientific elements on which the Community bases its decisions.

We believe that consumers should be given correct, complete and transparent information to enable them **to make an informed choice**.

One possibility could be the creation at EU level of an **information office** responsible for circulating data forwarded by the national sanitary authorities.

Risk assessment

As long as there are no definitive scientific results, the precautionary principle should apply. This means that measures to cope with a risk must be based not only on solid scientific evidence but also on the existence of valid scientific questions that have not yet been definitively answered. Measures for the protection of human health must be designed to achieve the highest possible **level of protection**.

Consumer representation

Consumers ask the Commission to promote consumer representation **on all scientific and advisory committees at EU level**

EU food policy and production methods

The BSE crisis stresses the consequences of an economic policy the objective of which is intensive **productivity**.

One contributing factor to the current crisis has been a lack of regard for consumers' preferences, expectations and emotions in relation to food. Policy-makers have tended to dismiss these preferences and expectations unless they can be proved to be fully rational and based on scientific evidence. Issues such as origin, production methods, processing and previous history of food can influence consumer attitudes, yet current EU food policy tends to ignore the legitimacy of **consumer concerns** on these issues.

We call therefore for an urgent review of food policy (and in particular of food production and distribution) in order to meet more closely the **expectations and preferences of consumers** On 29/30 April 1996, the Agriculture Council agreed that a long-term solution (to the current crisis) requires, inter alia, "production techniques which correspond to the legitimate expectations of consumers...". This conclusion should be followed up immediately with practical action.

ANNEX 8

Consumer Committee Resolution on meat-and-bone meal (17 June 1998)

The Consumer Committee welcomes the Commission's consultation paper on meat and bone meal and is happy to answer the following questions.

1. Exclusion of fallen animals and all condemned meat from the feed chain

The Consumer Committee supports the exclusion of fallen animals and all condemned material from the feed chain.

The Consumer Committee considers that this exclusion would further reduce the risk of:

- disease transmission;
- contamination of pasture land and water which might arise from dumping animal waste in land-fill sites;
- unacceptably high levels of residues within animal feed.

It would also answer many ethical concerns and objections to feeding animals on cadavers.

The Consumer Committee considers that more research is needed into the health risks attached to the various alternative disposal options to rendering. There must be effective monitoring and inspection of whatever method is chosen. This must be backed up by random inspections carried out by EU veterinary, medical and environmental officials.

2. Ban on the use of all animal protein in the feeding of ruminants

The Consumer Committee supports the EU ban on the use of all animal protein in the feeding of ruminants as a precautionary measure of consumer safety.

However, considering the need to have high-protein feed in certain production systems, particularly where it is needed for animal welfare reasons, the Consumer Committee calls for urgent research to be undertaken to find alternatives.

Once the ban is in place, there must be a European-wide compulsory recall of residual stocks of feed containing animal protein, followed by their destruction so that stocks cannot re-enter the food chain.

ANNEX 9

**European Parliament Resolution on the report of the Temporary Committee
instructed to follow up the recommendations on BSE⁹²**

The European Parliament,

- having regard to the report of the Temporary Committee of Inquiry into BSE of 7 February 1997 (A4-0020/97),
 - having regard to the mandate given to the Temporary Committee instructed to follow up the recommendations on BSE on 23 April 1997,⁹³
 - having regard to the report of the Temporary Committee instructed to follow up the recommendations on BSE (A4-0362/97),
 - having regard to the Council and Commission answers given on 18 November 1997 to the oral questions on this subject,
- (1) Endorses the conclusions and recommendations of the Temporary Committee instructed to follow up the recommendations on BSE, especially as regards the implementation of its recommendations by the Commission, as well as the shortcomings and non-implementation which still exist;
 - (2) Instructs its standing committees to monitor, according to their respective competences, the future implementation of the recommendations of the Temporary Committee of Inquiry into BSE by the Commission, based on the half-yearly progress reports the Commission has promised to present;
 - (3) Notes with satisfaction that the work of the Temporary Committee of Inquiry into BSE and the Temporary Committee instructed to follow up the recommendations on BSE has given a new quality to its institutional position with respect to the Commission, thereby facilitating effective control of the executive branch, and expects that the Commission will continue with the collaboration it has provided in the field of BSE and will extend it to other areas of its activities;
 - (4) Welcomes the fact that the report of the Committee of Inquiry into BSE and the setting up of the Temporary Committee instructed to follow up the recommendations on BSE have led to the Commission taking considerable steps toward making the action to combat BSE transparent through information measures, both as regards the inspection reports and the transparency of the work of the scientific committees;

⁹² Text adopted at the plenary sitting on Wednesday 19/11/1997.

⁹³ OJ C 150, 19.5.1997, p. 9.

- (5) Expects the Commission in future consistently to exploit any leeway for interpretation with regard to application of the appropriate legal basis in favour of the greatest possible involvement of Parliament and requests the Commission to insist together with Parliament, during the next Intergovernmental Conference, on full co-decision power for all sectors of the common agricultural policy;
- (6) Asks the Commission and the Member States concerned, in the light of the recent results of scientific research proving the close link between BSE and nv-CJD, to provide rapidly and in a non-bureaucratic way the financial means to demonstrate solidarity with the families of nv-CJD victims;
- (7) Criticises the Commission for having refused to take any disciplinary measures in the context of the handling of the BSE crisis by Commission departments and insists that the promise made by the President of the Commission to change the Staff Regulations before 1999 in order to allow more flexible use of disciplinary measures should be fulfilled;
- (8) Is in favour of organising a joint conference with the Commission at the end of 1998 in order to check those recommendations not implemented by then and to evaluate the consequences of the BSE crisis as regards Community legislation and full legislative control over agricultural policy, veterinary inspections and food safety, on the basis of the requests of its Temporary Committee of Inquiry;
- (9) Requests the Council to make a binding declaration to the effect that Article 3 (2) of the Decision of the European Parliament, the Council and the Commission of 19 April 1995 on the detailed provisions governing the exercise of the European Parliament's right of inquiry⁹⁴ will in future be interpreted by all members of the Council in such a way that a Member State's government is required to send one of its members to appear before a committee of inquiry of the European Parliament at the committee's request;
- (10) Instructs its President to forward this Resolution to the Council, the Commission and the governments and parliaments of the Member States.

Resolution passed by the European Parliament at the plenary sitting on 19/11/97
by:

427 votes for
33 votes against
45 abstentions.

⁹⁴ OJ L 113, 19.5.1995, p. 2.

ANNEX 10

Specified risk materials (SRM)

Opinion of the SSC on the risk of BSE, adopted by the Scientific Steering Committee (SSC) at its plenary meeting on 26-27 March 1998

After public consultation on the preliminary opinion adopted on 19-20 February 1998

In its study of the risk of BSE, the SSC identified three main points:

1. the risk of human exposure due to direct consumption of potentially infectious materials;
2. the risk to humans arising from ingestion of processed potentially infectious materials (tallow or gelatine, for example) or from exposure to such materials, and
3. the risk of propagation of the infection by recycling of the infectious material in animal feed (meat and bone meal).

A key factor in the study of these three risks is the relative infectivity of the tissues of an infected animal. By excluding the most infectious tissues from the processing cycle, it is possible to reduce the risk of transmission of BSE considerably. This position is confirmed by recent data which make it possible to quantify the contribution of the most infectious tissues to the total infectious burden of an infected animal (see Table 1).

Table 1: Relative infectivity of specified risk materials from an infected animal (data supplied by the SEAC, February 1998)

Tissue	Density of infectivity (CoID ₅₀ /g) ₁	Weight (kg) per animal of 537 kg	ID ₅₀ per animal	% of total infectious burden per animal
Brain	10	0.5	5000	64.0
Spinal cord	10	0.2	2000	25.6
Trigeminal lymph glands	10	0.02	200	2.6
Spinal lymph glands	10	0.03	300	3.8
Ileum	3.2*10 ⁻²	0.8	256	3.3
Vertebral column	3.2*10 ⁻³	5.0	16	0.2
Spleen	3.2*10 ⁻³	0.8	3	0.04

Eyes and rest of head	3.2×10^{-3}	11.6	37	0.5
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¹ CoID₅₀ = Cattle oral Infectious Dose 50%

The SSC confirmed the list of SRM which it presented on 9 December 1997 on the basis of infectivity, but stated that, with appropriate slaughtering procedures, the lungs are not contaminated and can therefore be excluded from this list. Similarly, the SSC is convinced that it is possible to define practical slaughterhouse procedures for separating the ileum from the other parts of the intestine. If such procedures are guaranteed, only the ileum is to be regarded as infectious.

As regards the importance of the animal species, the SSC reaffirmed its conclusions to the effect that it is impossible to estimate the risk of BSE in sheep and goats, although no case of TSE caused by the BSE agent has been detected in small ruminants, other than in experiments. It therefore reiterates its conclusion of 9 December 1997 that the head and spinal cord of sheep and goats have to be removed for animals aged over 1 year and the ileum and spleen have to be discarded whatever the age of the animal. However, in order to confirm this conclusion, the risk of the probability of the presence of BSE in sheep and goats should be assessed. This requires data which the SSC does not have at present.

1. Human exposure through direct consumption

With regard to human exposure through direct consumption, the SSC acknowledged that a list of SRM must take account of their specific infectivity and the total weight of the various tissues (see Table 1).

On the basis of quantitative data, the SSC declared that the brain, spinal cord, spinal lymph glands and trigeminal lymph glands represent the main risks for direct consumption by humans. They might make up as much as 96% of the infective burden from an infected animal, entering the food chain during the last nine months before the clinical manifestation of the disease (youngest animal ever found: 20 months). The animal's age therefore affects the risk of infectivity too. That is why the SSC reaffirms its opinion of 9 December 1997, according to which the SRM have to be eliminated in animals aged over 12 months in countries which are not BSE-free or where the risk is not negligible.

Mechanically recovered meat too may constitute a risk material, since it may contain spinal lymph glands.

2. Human exposure via processed products (tallow and gelatine)

With regard to the risk presented by tallow and gelatine, the SSC has issued two opinions on the safety of these two products. It stresses that these opinions are based on an assessment of the risks aimed at achieving the lowest possible risk. It will supplement these opinions with a quantitative risk assessment once it has the necessary data.

3. Propagation of the disease via the food chain

On the subject of the risks presented by meat and bone meal, the SSC has adopted an opinion on the safety of such meal. It stresses that this opinion is based on an assessment of the risks aimed at achieving the lowest possible risk. It will supplement this opinion with a quantitative risk assessment once it has the necessary data.

4. Origin of the animals

The geographical origin of the animals has been studied very closely at three different levels:

- the risk of an infectious animal entering the food chain (risk of incidence);
- the risk of an infectious animal propagating the disease by entering the food chain (risk of propagation), and
- the risk for humans of exposure to an infectious dose of BSE (risk of human exposure).

Examination of the dossiers already sent by some countries shows clearly that the data currently available are not enough to classify these countries with any certainty. With a view to obtaining the necessary data, the SSC approves the list of requisite data presented in its final opinion on the content of a "request for recognition of epidemiological status with respect to TSE", adopted on 20 February 1998.

At this stage, the SSC is not able to issue a definitive opinion on the geographical categories. It will re-examine this point and will also devise a methodology for evaluating the data sent by the countries on this subject.

Category	Organs
1. High degree of infectivity	a) Brain of bovines, eyes, spinal cord and spinal lymph glands of bovines, dura mater ^{1,2} , pituitary gland ^{1,2} , skull ^{2,3} and vertebral column of bovines ² , lungs ⁵ b) Brain of sheep/goats, eyes and spinal cord, spinal lymph glands and vertebral column ² , spleen of sheep and goats ⁴ ,lungs ⁵
2. Medium degree of infectivity	a) Whole intestine, from the duodenum to the rectum ⁶ , tonsils b) Spleen of bovines, placenta, uterus, foetal tissue ⁷ , adrenals, cerebro-spinal fluid, lymph glands
3. Low degree of infectivity	Liver, pancreas, thymus, bone marrow, other bones ⁸ , nasal mucosa, peripheral nerves
4. No infectivity detected⁹	Skeletal muscle, heart, kidneys, colostrum, milk, separated adipose tissues ¹⁰ , salivary gland, saliva, thyroid, mammary gland, ovaries, testicles, seminal gland, other bones, cartilage tissues, connective tissue, skin, hair, blood clot ¹¹ , serum ¹¹ , urine, bile, faeces

Notes

When the species is not stated, the tissues mentioned are those from cattle, sheep and goats.

1. These tissues are included because the human iatrogenic form of CJD has been associated with human tissues or extracts contaminated by the CJD agent.

2. These tissues have been placed in one, two or three higher categories on account of the risk of contamination by tissues with a higher degree of infectivity during slaughtering and the fact that they contain spinal lymph glands. The spinal cord of sheep and goats, the spinal lymph glands and the spinal column have been classified in this subdivision because they might be infected or contaminated whenever sheep or goats might have been infected by the BSE agent through ingesting infectious bovine products introduced into their feed.
3. Definition of the skull: the whole of the head apart from the tongue.
4. The spleen of sheep is included on account of the discovery of the BSE agent in the spleen of sheep contaminated experimentally by large doses of BSE. The degree of infectivity by the BSE agent has not been tested in goats, but infectivity from scrapie has been observed in these animals. The spleen of cattle has been tested, and no infectivity was observed in the test carried out on mice.
5. The lungs should be included in this category if the methods of stunning or neck stabbing used during slaughter involve a transfer of brain into the lungs via the blood.
6. Concerns only cattle, unless sheep and goats are deemed infected by the BSE agent. If so, the lymph glands and the thymus should also be removed.
7. It would be best to include them in the same category as the placenta on account of the high probability of contamination during the removal of the placenta on slaughter.
8. In view of the possible presence of spinal cord in the long bones and taking account of a potential infectivity of older animals, these bones should be classified in the same category as the spinal cord.
9. All the substances listed in category 4 were tested in mice with samples corresponding to 0.01- 0.1 g of the initial infectious tissue. In these samples, a degree of infectivity 1 000 times lower than in the brain is undetectable by this method. The sensitivity of this method ought to be further improved, which may entail a revision of the above table of relative infectivity.
10. This new term is used to describe the reserves of fat that can be easily removed during slaughter in slaughterhouses or cutting shops. It does not apply to the lipids extracted from mechanically recovered meat or from many other tissues or, subsequently, during the production process. It involves removal of the associated lymph glands.
11. Non-conclusive evidence suggests that the mononuclear globules of the peripheral circulation might transmit nv-CJD.

Extract from the opinion of the SSC on meat and bone meal

Synoptic table: criteria to be met to ensure a sufficient degree of safety of meat and bone meal produced from mammals and enable it to be introduced into the feed of non-ruminants

Geographical origin of the animals	Criteria to be met
NON-EXISTENT OR NEGLIGIBLE RISK OF BSE	<ul style="list-style-type: none"> – Material whose origin in regions where the risk of BSE is considered non-existent or negligible is certified. – Animals certified fit for human consumption. – Production processes complying with the standards laid down (133°C/20/3 bar) or equivalent conditions for the inactivation/elimination of the BSE or scrapie

	<p>agent.</p> <ul style="list-style-type: none"> - Regarding continuous or discontinuous processes: see section 3.1.
LOW RISK	<ul style="list-style-type: none"> - Certified fit for human consumption.¹ - Exclusion of specified-risk materials.² - Production processes complying with the standards laid down (133°C/20/3 bar) or equivalent conditions for the inactivation/elimination of the BSE or scrapie agent. - Measures designed to prevent cross-contamination.
HIGH RISK	<ul style="list-style-type: none"> - No meat and bone meal intended for feeding mammals should be produced from ruminants.
STATUS UNKNOWN	<p>To be evaluated; if it is not possible to give an opinion on the basis of the available evidence or owing to the lack of information: to be regarded as high-risk.³</p>

1 Fit for consumption means here that the animal must satisfy all the provisions of the appropriate and relevant national and European legislation.

2 The term "SRM or specified risk materials" applies to all the tissues on the list given in the opinion of the Scientific Steering Committee (SSC) adopted on 9 December 1997 and amended on 19 and 20 February 1998. However, the SSC intends to examine the possibility of selecting specified risk materials on the basis of the results of the risk assessment, taking account of the animals' geographical origin, species and age.

3 This statement does not prejudge the SSC's opinion on the TSE/BSE status of any country.

ANNEX 11

Estimate of the budget costs for Chapter 21 «Beef and veal» arising from the BSE crisis

Market measures linked to BSE	1996(1)	1997	1998	1999	1996-1999	
	actual Mio Ecu	Actual Mio Ecu	estimate Mio Ecu	estimate Mio Ecu	total cost	Actual mid-March '98 tonnes/animals
Direct measures						
<i>Intervention /Storage</i> Aid to private storage for veal (NL, I, ...)	9	9			18	12.000 T
Additional costs of intervention	315	272	106		693	693 000 t bought since March 96, of which 2/3 due to BSE
<i>Slaughtering measures</i> Processing premium, newborn male calves	24	122	115	24	285	1 630 000
Premium for early slaughtering of calves		56	105	37	198	2 100 000
Programme of voluntary slaughtering in UK	224	300	197	331	1 052	2 200 000
Compulsory selective slaughtering in UK, P, F, IRL, D	27	12	76	10	125	95 000
Destruction of fattening calves of UK origin (in F and NL)	52				52	120 000
<i>Support for the sector /losses of income</i>	815	495			1 310	
Cost of direct measures	1 466	1 266	599	402	3 733	
Improvement of certain premium systems						
Modification special system « male cattle » (single premium)			53	49	102	
Prolongation deseasonalisation premium in IRL and Northern IRL		37	38	36	111	
Intensification premium (reinforced incentive)			144	166	310	
Cost of improvement of certain premium systems		37	235	251	523	
TOTAL BUDGET COSTS	1 466	1 303	839	653	4 246	

(1) Including expenditure on deferred appropriations

ANNEX 12

SLAUGHTERING PROGRAMMES IN THE UNITED KINGDOM

Programme	Dates (1)	Number (2)
OTMS (3)	from 29/4/97 to 13/9/98	2 512 512
CPAS (4)	from 22/4/96 to 11/9/98	1 413 936
SC (5)	from 22/2/97 to 13/9/98	73 956
Total	At 11-13/9/98	4 000 404

The animals slaughtered under these three programmes did not enter the human or animal food chain. Their carcasses were in fact destroyed.

Source: BSE Enforcement Bulletin No 26 (Sept. 1998) of the MAFF

- (1) dates of implementation of the programmes
- (2) number of cattle slaughtered
- (3) over thirty month slaughter scheme (OTMS)
- (4) calf processing aid scheme (CPAS)
- (5) selection cull

ANNEX 13

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Vademecum 2nd edition (29/11/96)

Speech by President Jacques SANTER to the European Parliament (18/2/97)

Communication from the Commission of 30/4/97 on consumer health and food safety (Doc. COM(97)183 final)

Proceedings of the International Scientific Conference on Animal Meal (Brussels, 1-2/7/97)

Final consolidated report to the Temporary Committee of the European Parliament instructed to follow up the recommendations on BSE (October 1997) COM(97)509

Speaking note for Commissioner Emma Bonino - Temporary Committee instructed to follow up the recommendations on BSE – European Parliament – (15/10/97)

Proceedings of the Conference "Food Law and Food Policy" (Brussels, 3-4/11/97)

Report to the Conference of Presidents on the follow-up by the European Commission to the recommendations of the Committee of Inquiry into BSE (7/11/97)

Speech by President Jacques SANTER to the European Parliament (18/11/97)

Special report to the European Parliament on the Recommendations on BSE (29/1/98)

First half-yearly report of the European Commission on BSE follow-up (6/5/98)

Second half-yearly report of the European Commission on BSE follow-up (October 1998)

Consultation paper on meat and bone meal (Doc. VI/4842/98)

ANNEX 14

CONSUMER COMMITTEE OF THE EUROPEAN COMMISSION

List of members (20)

GERMANY	Herr Dirk KLASSEN Arbeitsgemeinschaft der Verbraucherverbände e.V.
AUSTRIA	Herr Hannes SPITALSKY Verein für Konsumenteninformation
BELGIUM	Monsieur S. MAUCQ Test-Achats
DENMARK	Hr. Peter NEDERGAARD Forbrugerrådet Danish Consumer Council
SPAIN	D. Francisco Javier ANGELINA Vice-Presidente Consejo de Consumidores y Usuarios
FINLAND	Mrs Sinikka TURUNEN The Finnish Consumers' Association
FRANCE	M. Gérard MONTANT INDECOSA-CGT (Association pour l'Information et la Défense des Consommateurs Salariés)
GREECE	Mr Sotirios PASCHALIDIS KEPKA
IRELAND	Mr Peter DARGAN Irish Countrywomen's Association
ITALY	Sig. Vincenzo DONA Unione Nazionale Consumatori
LUXEMBOURG	M. Aloyse SCHMITZ Union Luxembourgeoise des Consommateurs
NETHERLANDS	Mr Koos ANDERSON Consumentenbond
PORTUGAL	Dra. Elisa RAMOS DAMIÃO União Geral de Consumidores

UNITED KINGDOM Mrs Anne DALTROP

SWEDEN Mrs Maicen EKMAN
Swedish Consumer Council

The following five organisations are also members of the Consumer Committee:

EBCU – European Bureau of Consumers' Unions

Director: Mr Jim MURRAY

IEIC – European Interregional Institute for Consumer Affairs

Director: Mme Mireille LEROY

COFACE – Confédération des organisations familiales de la Communauté européenne

Director of Studies: M. Noël MOLISSE

CES – "Euro-C" – ETUC

Trade Union Confederation

Ms Anna CIAPERONI

EURO-COOP – European Community of Consumer Cooperatives

General Secretary: Mme Caroline NAETT

ANNEX 15

Scientific opinions on BSE adopted by the Commission's Scientific Committees since November 1997 (status: 1.10.98)

Internet address: http://europa.eu.int/comm/dg24/health/sc/index_en.html

Scientific Committee	Date of adoption	Title of opinion adopted
1. Scientific Steering Committee	9 December 1997	Listing of Specified Risk Materials: a scheme for assessing relative risks to man
2. "	"	Report on the UK Date Based Export Scheme and the UK proposal on Compulsory Slaughter of the Offspring of BSE Cases
3. "	22-23 January 1998	Defining the BSE risk for specified geographical areas
4. Scientific Committee on Veterinary Measures relating to Public Health	17 February 1998	Safety of slaughter practices and methods: risk of spread of BSE infectivity through cross contamination of different tissues by using pneumatic stunning during the slaughter process of ruminants
5. Scientific Steering Committee	19-20 February 1998	Opinion on the revised version of the UK Date Based Export Scheme and the UK proposal on compulsory slaughter of the

		offspring of BSE cases, submitted on 27.01.98 by the UK Government to the European Commission
6.	"	Final opinion on the contents of a "Complete dossier of the epidemiological status with respect to TSEs"
7.	"	26-27 March 1998 BSE risk
8.	"	Safety of Gelatine
9.	"	Safety of Tallow
10.	"	Safety of Meat and Bone Meal
11.	"	25-26 June 1998 The safety of dicalcium phosphate precipitated from ruminant bones and used as an animal feed
12.	"	Possible links between BSE and organophosphates used as pesticides against ecto- and endoparasites in cattle
13. Scientific Committee on Medicinal Products and Medical Devices	16 September 1998	Equivalency of alternative products to intestines of animal origin for use as surgical sutures
14. Scientific Committee on Cosmetic Products and Non-Food Products	23 September 1998	Updating of the opinion on the safety of tallow derivatives
15. Scientific Steering Committee	24-25 September 1998	Risk of infection of sheep and goats with BSE agent
16.	"	Mammalian derived meat and bone meal forming a cross-contaminant of animal feedstuffs
17.	"	Safety of organic fertilisers derived from mammalian animals
18.	"	Updated Scientific Report on the safety of meat and bone meal derived from mammalian animals fed to non-ruminant food-producing farm animals, prepared by the Working Group

ANNEX 16

LIST OF ABBREVIATIONS USED

Abbreviation	Meaning
ACDP	Advisory Committee for Dangerous Pathogens
BABS	(Animals) born after the ban

BSE	Bovine spongiform encephalopathy
CJD	Creutzfeldt-Jakob disease
CPMP	Committee for Proprietary Medical Products
DBES	Date Based Export Scheme
DNA	Desoxyribonucleic acid
FVO	Food and Veterinary Office
IOE	International Office of Epizootics
JRC	Joint Research Centre
MAFF	Ministry of Agriculture, Fisheries and Food
MBM	Meat and bone meal
MECU	ECU million
MRM	Mechanically recovered meat
NFU	National Farmers Union
SEAC	Spongiform Encephalopathy Advisory Committee
SRM	Specified risk materials
SSC	Scientific Steering Committee
SVC	Scientific Veterinary Committee
SVC	Standing Veterinary Committee
TSE	Transmissible spongiform encephalopathy
WHO	World Health Organisation

ANNEX 17

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- BSE in Switzerland: § 7
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