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BOVINE SPONGIFORM ENCEPHALOPATHY (BSE)

Information for consumers

GUIDE

Second edition

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Summary

INTRODUCTION

(1) The announcement made by the United Kingdom authorities on 20 March 1996 that a link between bovine spongiform encephalopathy (BSE) and Creutzfeldt-Jacob Disease (CJD) could not be ruled out provoked **an unprecedented crisis of confidence** among European consumers with regard to beef and bovine products. Since then, a flood of contradictory and often incomplete information has merely amplified these concerns.

(2) It is appropriate, then, **to inform consumers** about the situation and the measures **to reinforce consumer safety** which have been taken or which are envisaged in the framework of the European Union and to try to outline the scientific uncertainties at the root of the crisis. This briefing, which incorporates, updates and supplements the guide of 28 May 1996[1], and which was prepared by the Interdepartmental Working Party established by the Commission on 27 March 1996, sets out to do just that.

A. WHAT IS BSE?

(3) Bovine spongiform encephalopathy (BSE) is a degenerative brain disease affecting cattle. This is a **new disease**, since the first case was officially recognised in the United Kingdom in 1986, 10 years ago. It belongs to the family of transmissible spongiform encephalopathies, which in animals include sheep and goat scrapie, mink spongiform encephalopathy and the encephalopathies of the cat and certain wild animals raised in captivity.

(4) The United Kingdom epizootic had affected 442 animals by the end of 1987, a figure which rose rapidly to a maximum annual incidence of over 37 000 cases in 1992[2]. With the introduction of control measures, the annual incidence has fallen by over 60% in three years to approximately 14 000 cases in 1995. This downward trend is continuing, the estimated incidence for 1996 being less than 8 500. The United Kingdom has had a total of almost **165 000 cases[2] affecting almost 34 000 farms**. In other countries, the total number of cases is approximately **500**, half of these being in Switzerland and the rest in other Member States[3] or in third countries which had imported animals or animal feed from the United Kingdom.

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1 Document GIS-BSE (96) 1.7.

2 36 681 cases in 1992, 14 076 cases in 1995, and a total of 163 071 cases in 33 657 farms at 6/9/1996 The estimated incidence for 1996 is 8 270 - see Annex IV.

3 CH (223), IRL (159), P (58), F (24), D (4), I (2), DK (1).

(5) The infectious agent responsible for BSE has not yet been identified. It is generally considered to be a protein known as a "**prion**". This prion possesses exceptional characteristics, such as resistance to heat, ultraviolet and ionising radiation and chemical disinfectants.

(6) According to the generally accepted scientific explanation, the BSE epidemic in the United Kingdom first originated in the recycling of contaminated bovine and ovine tissues processed into animal feed in the form of meat and bone meal, and in changes in the methods of producing these meals in the early eighties – specifically the reduction in the duration of treatment and treatment at lower temperatures.

These changes are thought to have been caused by the transmission of the sheep scrapie agent to bovine animals, or by the multiplication and propagation of a hitherto unidentified disease already present in bovine animals. Thus the feeding of ruminants with ruminant proteins was outlawed in the United Kingdom in 1988. Most of the Member States followed suit in the early nineties, and the official ban for the Community as a whole was declared in 1994.

(7) **Other possibilities of transmission**: so far there is no conclusive evidence that the disease can be transmitted either horizontally, i.e. from one animal to another, or vertically, from cow to calf. A large scale multi-year experiment has been launched in the United Kingdom to study the possibility of vertical transmission and research work is also being done into the possibilities of horizontal transmission. According to the results published in August 1996 concerning cows born to contaminated cows, there is a possibility of maternal transmission but it is very low. The results of these studies are currently being examined by the Scientific Veterinary Committee (SVC) and the Multi-disciplinary Scientific Committee (MSC).

(8) Transmissibility between different animal species: in the case of BSE, **crossing of the species barrier** is the subject of numerous evaluations. It has been possible to produce spongiform encephalopathies using contaminated bovine materials in the pig, the mink, the sheep and the monkey in a laboratory setting. However, it has never been demonstrated that such transmissibility is possible in the natural state, i.e. other than in experimental conditions.

(9) Infected organs: infectivity has been identified in a **limited number of organs**. In bovine animals: the brain, the spinal cord, the eyes and certain parts of the intestine. In sheep and goats, the spleen may also be infected. However, no trace of infectivity has been found in other organs or fluids, notably meat, milk and semen.

B. WHAT IS SCRAPIE?

(10) Scrapie is an animal spongiform encephalopathy which affects **ovine animals** and **goats**.

Known for almost three centuries[4], this epizootic differs from BSE in that one animal can transmit it to another (horizontal transmissibility) and the ewe can transmit it to its lamb (vertical transmissibility). It is found in several Member States and in most continents.

(11) Is this disease transmissible to humans? Given the relatively high incidence of this epizootic in many countries and the fact that it has affected herds for centuries, it is reasonable to assume that if it were transmissible to humans this feature would long have been scientifically established. Hence it may be considered that, on the basis of epidemiological data, classical scrapie **poses no danger to man**.

(12) However, research done in the United Kingdom in 1996 has shown that it is possible to transmit BSE to sheep through food consumption in an experimental setting. Some scientists think that the scrapie currently diagnosed in the United Kingdom may be a variant of BSE caused by the consumption of contaminated meal. One cannot rule out the possibility that sheep that have eaten infected meat and bone meal may have been infected by BSE. However, this is only a **hypothesis**, especially since it is relatively unusual for ovine animals to eat meal.

C. WHAT IS CJD?

(13) **Creutzfeldt-Jakob disease (CJD)** is an incurable and 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 twenties and is a worldwide phenomenon, with an incidence of the order of one case per million per year. There are two forms of the disease: classical CJD and a new variant, recently identified, known as V-CJD.

(14) **Classical CJD** can be divided into three categories: a sporadic form (about 85% of all CJD cases); forms associated with genetic predisposition (some 10% of cases); and iatrogenic transmission resulting from the transmission of infected human tissue, for example corneal grafts, or the practice during the early 1980s of using growth hormones obtained from human cadavers to treat growth deficiencies. The sporadic and genetic forms of CJD almost always affect elderly

[4] Scrapie was recognised for the first time in 1732 in the United Kingdom.

people (mean age of onset about 65). In general, patients die four to six months after the onset of the disease. Currently there is no scientific evidence of a link between the onset of classical CJD and the appearance of animal spongiform encephalopathies or dietary habits such as the eating of animal brains.

(15) In 1995 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**. These patients were all young (ranging from 19 to 41 years, with an average age of 29 years), the disease was of relatively long duration (13 months on average), it presented a clinical model differing from classical CJD, and distinctive pathological characteristics were observed at autopsy. The scientists studying these cases have found nothing in the patients' medical history, genetic analyses or other factors which could explain these cases. 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 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 SBO ban (i.e. prohibition of the use of certain specified bovine offals) in 1989". The British Advisory Committee's conclusion therefore reinforces concern about the transmissibility of the pathogenic BSE agent to man. Since then, one case of V-CJD has also been confirmed in France and four new cases in the United Kingdom, making a total of 15 cases to date. No case has been identified in any other country.

(16) On 2 and 3 April 1996, the **World Health Organisation (WHO)** called a meeting of experts on BSE and V-CJD. They confirmed that the most plausible hypothesis for the appearance of V-CJD was the United Kingdom population being exposed to BSE, but they stressed that no such link had so far been proved. These experts also concluded that "the risk, if there is one, of exposure to the BSE agent in other countries must be regarded as being lower than in the United Kingdom. Exposure to the BSE agent in the United Kingdom was likely to have been higher before the BSE regulations now in force". Studies conducted by the Imperial College of London and published in the 24 October 1996 issue of *Nature* seem to confirm that BSE can be transmitted from cattle to humans. These findings, which need to be corroborated by other tests, are currently being studied by the Commission's Multi-disciplinary Scientific Committee and Scientific Veterinary Committee.

D. MEASURES TAKEN TO CONTROL BSE

a. Measures taken before 20 March 1996

(17) The most important move to protect both human and animal health, introduced in the United Kingdom in 1988 and in other Member States in which BSE subsequently appeared, was **the slaughter and destruction of animals either infected or liable to be infected**[5]. Moreover, the United Kingdom banned the use of ruminant protein in ruminant feed and, in 1989, the use in human food of certain bovine tissues (specified bovine offals, including the brain and spinal cord) from bovine animals aged over six months. This action removed from the human and animal food chains the raw material most likely to present a danger of transmitting the disease.

(18) **Since 1988**, other measures have been implemented by the British Government and by the Community in order to prevent the spread of BSE and to minimise any risk to human health. These measures are summarised in the annexes. Principally, they involve withdrawing infected or potentially infected bovine tissue from the human food chain and stopping the epizootic from spreading to other Member States or third countries.

(19) Community measures to prevent the spread of BSE to other countries have been successful, since less than 0.50% of cases have occurred outside the United Kingdom. The measures taken within the United Kingdom to control the disease, notably the ban on feeding ruminants with infected feed, have also been relatively **effective**, because the incidence of BSE declined by over 60% from 1992 to 1995. However it is clear that this ban has not been fully observed because a significant number[6] of BSE cases have occurred in livestock born after the ban.

b. Measures following the 20 March 1996 announcement by the United Kingdom authorities

(20) Within a few days of the 20 March announcement, the other Member States adopted protective measures with regard to British cattle, beef and veal, and bovine products. Despite this sales of beef and veal in most Member States plummeted. In the wake of these national measures and after consulting the Scientific Veterinary Committee on 22 March, the Commission convened a meeting of the Standing Veterinary Committee on 25 and 26 March to elicit its opinion on the adoption of Community protective measures. The Commission then adopted **Decision 96/239/EC on 27 March**.

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5 In France, Ireland and Portugal the authorities are proceeding to slaughter all herds in which a case is diagnosed.

6 Approximately 27 000 cases.

(21) Pending an overall examination of the situation, Decision 96/239/EC imposed a temporary ban on United Kingdom exports to other Member States and third countries of live cattle, their semen and embryos, meat and meat products from cattle slaughtered in the United Kingdom and intended for human and animal consumption, together with medicinal, cosmetic or pharmaceutical[7] products and mammalian meat and bone meal. All Member States were required to modify the measures they had adopted, to bring them into line with this Decision, and to notify the Commission when they had done so. Moreover, the United Kingdom was required to report every two weeks to the Commission on the application of national and Community measures to control BSE and was invited to present supplementary proposals for the control of BSE within the United Kingdom.

(22) The **Council of the Ministers of Agriculture** that met in Luxembourg **on 1, 2 and 3 April** adopted a further series of measures:

- for the United Kingdom: various measures as part of the global plan to eradicate BSE in the United Kingdom adopted in Florence[8]

- for the Community as a whole:

  . the treatment of animal wastes in order to inactivate the scrapie and BSE agents,

  . the labelling of mammalian-derived meat and bone meal to exclude their use as feed for ruminants,

  . the introduction of a system of meat labelling to meet growing consumer concern with regard to the production methods and source of food products,

  . the intensification of research into BSE, the Commission being asked to submit a list of priorities before 1 July 1996.

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7 Commission Decision No 96/362/EC (see section 34) of 11 June 1996 specifies in regard to the latter that this concerns "materials obtained from bovine animals slaughtered in the United Kingdom, destined for use in cosmetic, medicinal or pharmaceutical products".

8 See sections 25 and 26 below.

(23) The **Agriculture Council of 29 and 30 April** confirmed the approach adopted earlier and reviewed developments. The ban on United Kingdom exports was upheld as a safeguard measure. The United Kingdom submitted a selective slaughter programme. Discussions are still continuing on this programme. At scientific level, the Council underlined the need to continue research into a possible link between BSE and CJD and called for the creation as soon as possible of a multidisciplinary scientific committee (human and veterinary medicine, public and animal health, toxicology and biology) in order to obtain scientific advice and recommendations on the various issues falling within the Community's jurisdiction.

(24) On 28 May the Commission also sent an **inspection team** to the United Kingdom to assess the measures taken there to tackle the crisis in accordance with the Community decisions. Other inspections followed in July and subsequently in September-October in the United Kingdom, but also in other Member States.

(25) Emphasising its approval of the framework for action presented by the Commission to eradicate BSE in the United Kingdom, the **Florence European Council of 21 and 22 June 1996** of the Heads of State and Government addressed the political difficulties associated with this issue. It was agreed that, once established, this framework for action would lead to a **gradual relaxation of the restrictions** currently governing the export of United Kingdom bovine products towards the rest of the European Union and third countries. To this end the Commission will submit appropriate decisions when it considers that the necessary conditions, based on scientific and technical opinions, are met. These decisions will be adopted uniquely and exclusively on the basis of public health criteria and objective scientific criteria.

(26) **The action plan envisages**:

- the mandatory selective slaughtering of animals and/or herds of birth cohorts born between 1989 and 1993 which have been identified as most liable to have been exposed to infected meat and bone meal. Approximately 140 000 bovine animals will be slaughtered.

- the introduction of an improved system of individual identification of bovine animals to ensure effective surveillance of their movements and their traceability (passport system),

- more stringent controls of firms that manufacture animal feed,

- a detailed veterinary study of each farm which is or has been affected by BSE, to identify the cohort animals to be slaughtered.

These measures are in addition to the measures already adopted by the Agriculture Council on 1, 2 and 3 April and 29 and 30 April in regard to the United Kingdom:

- destruction of bovine animals aged over 30 months,
- the elimination of specified offals[9] of bovine animals younger than 30 months,
- the tightening of veterinary controls,
- payment by the Community of 70% of the value of compulsorily slaughtered animals.

(27) The British requests for a review of the slaughtering plan following the experimental results obtained in September have been submitted to the Scientific Veterinary Committee and the Multi-disciplinary Scientific Committee for examination. In the meantime, as far as the Commission is concerned, **the plan remains fully applicable**.

E. CAN THE BAN ON CERTAIN PRODUCTS COVERED BY THE DECISION OF 27 MARCH BE LIFTED?

(28) Traditionally the Commission has always considered that consumers should have the benefit of the doubt in the case of misgivings as to a product's safety. On the other hand, when a product is believed to be safe the Commission considers that there can be no grounds for challenging its manufacture and distribution under the appropriate conditions. At the Florence Summit of 21 and 22 June 1996, the European Council[10] confirmed this principle and envisaged the possibility of a **gradual relaxation of the restrictions** currently governing the export of United Kingdom bovine products towards the rest of the European Union and third countries. In this connection the Commission will take into account the recommendations submitted to it by the **competent scientific committees** which it has created and whose scientific status and total independence are assured. Hence the Commission was invited to consider a partial lifting of the ban on semen, gelatine, tallow and derived or similar products.

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9 The specified offals of bovine animals include the brain, spinal cord, thymus, tonsils, spleen and the intestines.

10 See section 25.

(29) These assessments were carried out at Community level as soon as the crisis arose. The relevant experts in the Member States for the various types of product met in the BSE-related committees under the aegis of the Commission (see annex). With the utmost caution and even though there is no proof that BSE can be transmitted to humans, they have consistently recommended that all measures taken should help to reduce the risk of human exposure to the infective agent, acting on the assumption that transmission is possible.

(30) As regards **bovine semen**, it was decided to lift the ban because no trace of infectivity has ever been found. The Scientific Veterinary Committee therefore concluded that this product is not a danger to animal health as regards the transmission of BSE. In compliance with the provisions of Directive 88/407/EEC, semen will be taken only from bulls certified as healthy.

(31) **Gelatine** and **tallow** are used in the manufacture of or as ingredients in many industrial products, including a large number of foodstuffs, drugs and cosmetic products. It was therefore necessary to investigate whether such products can or could have contained a raw material infected with the BSE agent and then to assess the associated risks.

(32) On 26 April the Scientific Veterinary Committee (SVC) concluded that if a bovine material of appropriate origin is used and minimum standards of treatment are applied which have been proved to be genuinely effective in inactivating the BSE agent, these products can be considered as safe for use in food or cosmetics.

Previously, in a WHO communication dated 3 April 1996, it was stated that gelatine used in food is considered to be safe if obtained using a manufacturing procedure shown to implement production conditions that definitively inactivate any residual infectivity which may have existed in the source tissue. The WHO communication goes on to say that tallow is also considered to be safe if effective procedures are used to treat the cadavers.

(33) **Foodstuffs, cosmetics and pharmaceutical products** which include gelatine, tallow or other similar or derived products are also considered to be safe provided the ingredients are themselves safe.

(34) This is why the Commission has adopted a new decision amending that of 27 March 1996 and authorising a conditional and partial lifting of the ban. This decision[11] was taken on **11 June 1996** and published in the Official Journal of the European Communities the next day[12].

Pursuant to this decision, all British bovine products covered by the decision of 27 March remained banned **with the exception of**:

- bovine semen

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11 Commission Decision 96/362/EC of 11 June 1996

12 OJ EC No L 139, 12 June 1996.

- gelatine, tallow and similar or derived products[13] obtained using the specified manufacturing processes
- products of which they are an ingredient.

Hence this a **partial, conditional and strictly limited lifting** of the ban on exports of British bovine products.

(35) It is also specified that, in the manufacture of gelatine, tallow and similar or derived products, the following may not be used as **raw materials** in the United Kingdom:

- bovine animals over 30 months of age
- tissues[14] susceptible of infectivity from bovine animals aged less than 30 months
- bovine animals suffering from BSE or suspected of having BSE.

Finally, the **manufacturing conditions**, i.e. pH, temperature, pressure, duration of treatment, specified in the Annex to the Decision, must also be such as to ensure the products' safety.

(36) However the ban has not yet effectively been lifted. Not enough scientific work has been done to validate the effectiveness of the method. Therefore further studies will be conducted and the dossier will be forwarded to the Scientific Veterinary Committee and the Multi-disciplinary Scientific Committee for evaluation.

Hence the ban on exports of gelatine and derived products will not be effectively lifted until the situation has been clarified and a safe method of gelatine manufacture clearly defined.

(37) When this condition is met, the ban will be lifted in **five stages**.

1. the United Kingdom must have ensured:
   - control of the production units,
   - an appropriate labelling system;
2. the United Kingdom must have notified the Commission and must forward to the Commission and the Member States the list of establishments under veterinary control which can meet the manufacturing conditions;

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13 Gelatine and di-calcium phosphate, amino acids and peptides produced from hides and skins; tallow and tallow products and certain foods additives and products used in the manufacture of medicines.

14 Skull, vertebral column, brain, spinal cord, eye, tonsil, thymus, intestine, spleen.

3. the Commission must have carried out Community inspections to verify that the manufacturing and control systems have been established in the United Kingdom. Member State experts will participate in these inspections;
4. the Standing Veterinary Committee must have been consulted;
5. the Commission must have laid down on a case by case basis, i.e. for each individual product and establishment, the date on which dispatch of the product is to recommence.

It is only then that the ban will be lifted for these products.

F. THE SITUATION AS REGARDS OTHER BOVINE PRODUCTS

(38) Except for milk and dairy products and products which do not enter the food chain such as leathers and skins, the United Kingdom may not dispatch from its territory to the other Member States or third countries any bovine product obtained from cattle slaughtered on its territory. This is required by **Commission Decision 96/239/EC** of 27 March 1996 and is still **fully applicable today**.

(39) Milk and dairy products are not covered by the decision of 27 March 1996. Milk and dairy products from animals infected with BSE have shown no signs of being infected and the data on other animal and human spongiform encephalopathies indicate that milk does not pass on these diseases. Milk and dairy products are therefore considered to be safe even in countries with a high incidence of BSE. These are the conclusions of the WHO communique of 3 April 1996.

(40) The same applies to products that do not enter the human or animal food chain such as **leathers and skins**.

(41) In all the Member States, including the United Kingdom, ongoing experiments have not shown any infectivity of **beef** and provide no evidence that meat can transmit BSE. Moreover the measures taken since the appearance of BSE and notably since 20 March have further enhanced the safety of meat and derived products. The national and Community authorities reckon that the risks of contamination from the consumption of beef are practically zero. However for precautionary reasons, and until every safeguard has been obtained, there can be no question of authorising the exportation of beef or beef products from the United Kingdom.

(42) Since 1989 in the United Kingdom, **specified bovine offals** and specifically the brain, spinal cord, thymus, tonsils, spleen and the intestines have been banned for human consumption. These offals must be carefully removed from the carcasses of bovine animals intended for consumption and then destroyed. As a precautionary measure the Commission in July 1996 discussed at the Council of Agriculture Ministers the banning of bovine offals as well as offals of sheep and goats in all the Member States. This question is currently being examined by the Scientific Veterinary Committee and the Multi-disciplinary Scientific Committee.

G WHAT SUPPLEMENTARY MEASURES MAY BE ENVISAGED?

a. In the agricultural sector

(43) As indicated in Sections 22 and 23, on 3 and 30 April 1996 the Agriculture Council adopted the framework for all the necessary measures, including both immediate and longer term ones. It emphasised in particular the need to improve the **tagging** and **traceability** of bovine animals and bovine products in order to develop a genuine **passport** and to introduce a **labelling system** for beef and beef products to accommodate consumers' concerns with regard to food production methods and sources. Voluntary measures will be encouraged in this domain. Two proposals for regulations[15] were thus adopted by the Commission on 2 October and presented to the Council (COM(96) 460 final).

(44) The Council has also stressed the need to intensify research work in order to answer many of the outstanding questions concerning BSE. It welcomed the measures taken by the Commission relating to the remit of the Working Party chaired by Professor **Charles Weissmann** from the University of Zurich and to the earliest possible establishment of a multi-disciplinary scientific committee. The Weissmann Working Party was created in April 1996 and submitted its report to the Commission on 7 October. The **Multi-disciplinary Scientific Committee**, which was created on the basis of a decision taken on 18 June, will have met five times in 1996. It is chaired by Dr **F. H. Kemper** from the University of Muenster.

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15 Proposals for Council Regulations:
- establishing a system for the identification and registration of bovine animals
- regarding the labelling of beef and beef products

(45) The Council is currently examining a proposal for a regulation[16] on the creation of a **European Agency for Veterinary and Phytosanitary Inspection**. The main task of this agency will be to carry out inspections in the Community to ensure the uniform application of Community animal and plant health legislation.

b. In the health sector

(46) The Council of Health Ministers addressed the question of TSEs (transmissible spongiform encephalopathies) on 13 December 1993 and 30 April 1994 in response to German public health concerns; they focused on epidemiological surveillance and the need for scientific research.

(47) The Council of Health Ministers of 14 May 1996 welcomed the fact that the question of TSEs, which is a public health problem deserving the utmost priority, had again been drawn to its attention by a Commission document with an eye to discussing appropriate measures.

(48) In its conclusions the Council recommends in particular the following:

- implement measures to monitor the **scientific** evidence relating to the causes and transmission of CJD so that appropriate public health protection measures can be determined in a timely manner;
- extend the epidemiological surveillance of CJD to all the Member States using the same methods as have been applied in five Member States;
- encourage exchanges between Member States, of experience and expertise in the areas of control and diagnosis of cases;
- conduct further additional studies and research into TSEs, including CJD.

(49) The Council also decided **to follow up this question on a permanent basis**. Hence the dossier will be re-examined by the Health Ministers at the next Health Council meeting on 12 November 1996, with particular attention to the epidemiology of the Creutzfeldt-Jakob Disease in the Member States of the European Union.

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16 Proposal for a Council regulation presented by the Commission on 11 July 1996, published in OJEC No C 239 of 17/8/96.

(50) In this context the reference to the protection of public health in the order of the **European Court of Justice** of 12 July 1996 on "Application for interim relief - Agriculture - Animal Health - Emergency measures against bovine spongiform encephalopathy" is of the essence. According to the Court the circumstances show that the Commission's primary concern is to protect public health in the framework of the single market, as is its duty under Directives 90/425 and 89/662. Here it should be noted that the EC Treaty[17] includes among the Community's objectives that of contributing to the attainment of a high level of health protection, that it states that "the Community shall contribute to assuring a high level of human health protection"[18], and that health protection requirements form a constituent part of the Community's other policies[19].

c. In the research sector

(51) **At national level**, research in the field of spongiform encephalopathy has been addressed at two levels:

1. clinical research and surveillance of human spongiform encephalopathy thanks to the creation of **national reference centres** to record and evaluate all possible cases of the disease. Hence the new variant of CJD was made was identified at the British national reference centre, which also coordinates the CJD surveillance project at European level.

2. Basic research on human and animal spongiform encephalopathy addressing questions such as the structure and function of the prion protein, the mechanisms of the disease's transmission, the development of transgenic models which can be used as models for human prion diseases, and the search for diagnostic tools.

(52) **At Community level** these efforts have been underpinned by the creation of six research centres which, since 1992, have been addressing 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 inter-species barrier.

This Community action has improved the system for monitoring CJD and related diseases in the countries concerned, has made it possible to draw comparisons between countries and to develop harmonised procedures for identifying and characterising the disease. Hence such a structure can be used as a basis for developing standard procedures for the identification and surveillance of the disease at the level of all the Member States.

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17 Article 3(o) of the EC Treaty.

18 Article 129(1), subparagraph 1.

19 Article 129(1), subparagraph 3.

(53) **A meeting of the Directors-General of Research in the Member States** was held on 5 June. The meeting focused on the pooling of information and viewpoints concerning ongoing research at national and European level, the objective being to create a mechanism to strengthen cooperation and coordination in this domain. On this occasion the Commission was requested to make arrangements to coordinate the collection of information on ongoing research and to create a rapidly as possible an information system on research problems. The Member States also proposed that the Commission provide additional resources and consider launching a special call for proposals designed to encourage new ventures in this domain.

(54) In this context the Commission has prepared an action plan geared primarily to enhancing the coordination of research work in the Member States, notably with a view to improving the surveillance, early detection and diagnosis of CJD. This action plan is to be examined by the "Research" Council on 5 December 1996.

d. In the cosmetic products sector

(55) The Commission is currently preparing a proposal for a Directive pursuant to which Member States must take the necessary measures to ensure that as of 1 July 1997 cosmetic products containing tissues or fluids from the encephalon, the spinal cord or the eyes of bovine animals, ovine animals or goats and derived ingredients may no longer be placed on the market. The measure will be adopted on a precautionary basis for a period of two years, with the possibility of renewal.

The Scientific Committee on Cosmetology was consulted on 2 October 1996 and concluded that risks linked to the utilisation of these products cannot be excluded and delivered a favourable opinion on the measures proposed by the Commission based on the precautionary principle and justified on grounds of public health.

H CONCLUSIONS

(56) The fact that cattle and the parts most likely to be contaminated did in the past enter the food chain, particularly in the United Kingdom, gives rise to legitimate concern about past exposure.

(57) The studies have only shown that infective properties are limited to the brain, spinal cord, retina and part of the intestine. This is why these products have been banned from human food in the United Kingdom since 1989. Other parts or products of bovine origin, particularly meat and milk, have not been found to be infective.

(58) Research work on the possibilities of transmission is being continued. The Commission's Interdepartmental Working Party is monitoring scientific progress so as to keep consumers abreast of events and to issue appropriate recommendations as soon as possible.

(59) Since 20 March 1996 the European Commission has convened the **Consumer Committee** on three occasions and has entered the BSE question on the agenda of each meeting with an eye to informing the consumer representatives of the measures taken and to eliciting information as to the measures consumers want. The Committee has proposed to the Commission the annexed resolution[20]. As can be seen from the Guide, several proposals in this resolution have already been approved by the Commission and some of them are being implemented right now (a reply will be given to the Committee at a forthcoming meeting).

(60) In conclusion, the Interdepartmental Working Party would impress on consumers the Commission's determination:

- to do its utmost to answer the questions raised by BSE and in particular:

– to involve in its efforts to protect consumer health all the appropriate authorities, including organisations representing consumers;
– to intensify scientific research and to take such measures as appear justified in the light of the findings;
– to inform consumers as fully, accurately and clearly as possible.

Lastly the Interdepartmental Working Party reaffirms that the Commission's primary objective is to safeguard public health and to keep consumers properly informed.

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20 See Annex III "Resolution of the Consumer Committee".

ANNEX I

Bovine spongiform encephalopathy: an overview of measures taken by the Commission and the Council to protect consumers

Since bovine spongiform encephalopathy appeared in the United Kingdom in 1986, and as scientific knowledge has advanced, the Commission and the Council have taken a wide range of measures to protect consumer health and to eradicate the epidemic.

Here, in chronological order, are the main Commission Decisions involved.

- The Decision of 28 July 1989[21] banning the export of live cattle born prior to 18 July 1988 or born to cows suspected of having BSE. Subsequent Decisions modifying or providing for more detailed implementation of this measure culminated in the Decision of 27 March 1996[22], which ordered the provisional cessation of all exports of live cattle, beef, veal and beef-derived products from the United Kingdom to other Member States and third countries.

- The Decision of 9 April 1990[23] 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 the carcass and offal. The Decision also regulated the export from the United Kingdom to other Member States of other tissues and organs from cattle aged over six months at slaughter.

- The Decision of 8 June 1990[24], in particular requiring the United Kingdom to make full use of computer records to guarantee identification of animals.

- The Decision of 27 June 1994[25] banning, with effect from 27 July 1994, the use in any Member State of animal feed containing protein derived from ruminant tissue. Where identification of the tissue was difficult, the ban was extended to tissue from any mammal.

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21 Decision 89/469/EEC (OJ No L 225, 3.8.1989, p. 51)

22 Decision 96/239/EEC (OJ No L 78, 28.3.1996, p. 47).

23 Decision 90/200/EEC (OJ No L 105, 25.4.1990, p. 24).

24 Decision 90/261/EEC (OJ No L 105, 25.4.1990, p. 24).

25 Decision 90/381/EEC (OJ No L 146, 9.6.1990, p. 29).

- The Decision of 27 June 1994[26] setting out minimum conditions for the processing of ruminant wastes so as to inactivate the BSE agents;

- The Decision of 27 July 1994[27] requiring the United Kingdom to destroy specified bovine offals (brain, spinal cord, thymus, tonsils, spleen, intestines) of cattle aged over six months.

At the same time, in order to take the fullest possible account of the opinions of scientists and experts, meetings of the Commission **committees** involved in BSE were held as often as was helpful. The committees primarily involved since 20 March 1996 are:

- the Consumer Committee,
- the Scientific Committee on Cosmetology,
- the Scientific Committee for Food,
- the Scientific Committees of the European Medicines Evaluation Agency: Committee for Proprietary Medicinal Products and Committee for Veterinary Medicinal Products,
- the Scientific Veterinary Committee,
- the Scientific Committee for Animal Nutrition,
- the Group of Government Scientific Experts on the Protection of Workers from the Risks related to Exposure to Biological Agents at Work,
- the Working Party on Cosmetic Products,
- the "General Product Safety" Emergencies Committee
- the High Level Committee on Public Health
- the Pharmaceutical Committee,
- the Standing Veterinary Committee,
- the Management Committee for Beef and Veal.
- the Standing Committee for Foodstuffs.

In addition to these committees there is the Scientific Multi-disciplinary Committee created on 18 June 1996 and the Working Party of scientific experts chaired by Professor Charles Weissmann.

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26 Decision 94/382/EEC (OJ No L 172, 7.7.1994, p. 25).

27 Decision 94/474/EEC.

ANNEX II

MEASURES TAKEN BY THE BRITISH GOVERNMENT

1988 BSE made a notifiable disease, with slaughter and destruction of suspect and confirmed cases.
Ban on feeding ruminant protein to ruminants.

1989 Ban on the use of specified bovine offals in human food.

1990 New requirements for livestock breeding and movement records to be kept by farmers.

1995 Tighter controls on the keeping and presentation of records
Ban on removal of brains or eyes (whole skull becomes an SBO).
Ban on mechanical recovery of meat from vertebral column.

1996 Ban on marketing of meat from cattle aged over 30 months.
Ban on use of mammalian meat-and-bone meal in feed for all farm animals.

As a result of public concern about the safety of UK meat, the UK government has decided to exclude meat from animals slaughtered in the UK over the age of 30 months from the human and animal food chains as well as from cosmetics or pharmaceutical use. Meat and carcases from such animals must be destroyed. This decision, when correctly and effectively implemented, will help, in accordance with the Scientific Veterinary Committee's recommendations, to significantly reduce the likelihood of human exposure to any infectious agent which might be present in such bovine tissues. Effectively, this means that only animals born after 1 October 1993 may enter the food chain in the UK. This date will move forward with time, thus further reducing the likelihood of such animals ever having been exposed to infected meat and bonemeal, as the ban on meat and bonemeal in ruminant feed takes ever greater effect.

Furthermore, the United Kingdom has expanded the ban on the consumption of certain tissues from cattle over the age of six months with the result that, in addition to the above-mentioned tissues, the whole skull of the animal should now be destroyed.

Taken together, all these measures should have effectively reduced the risk of human exposure to the infectious agent through the consumption of food.

ANNEXE III

BSE

CONSUMER COMMITTEE RESOLUTION (9 October 1996)

1. The CC welcomes the Commission's efforts to improve consumer information about the background and the current situation regarding the BSE issue. The members of the CC took note of the Vademecum on 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 as 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 frontier.

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

- There should be an EU wide training programme to 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 of 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. lambs 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 Reconstituted 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

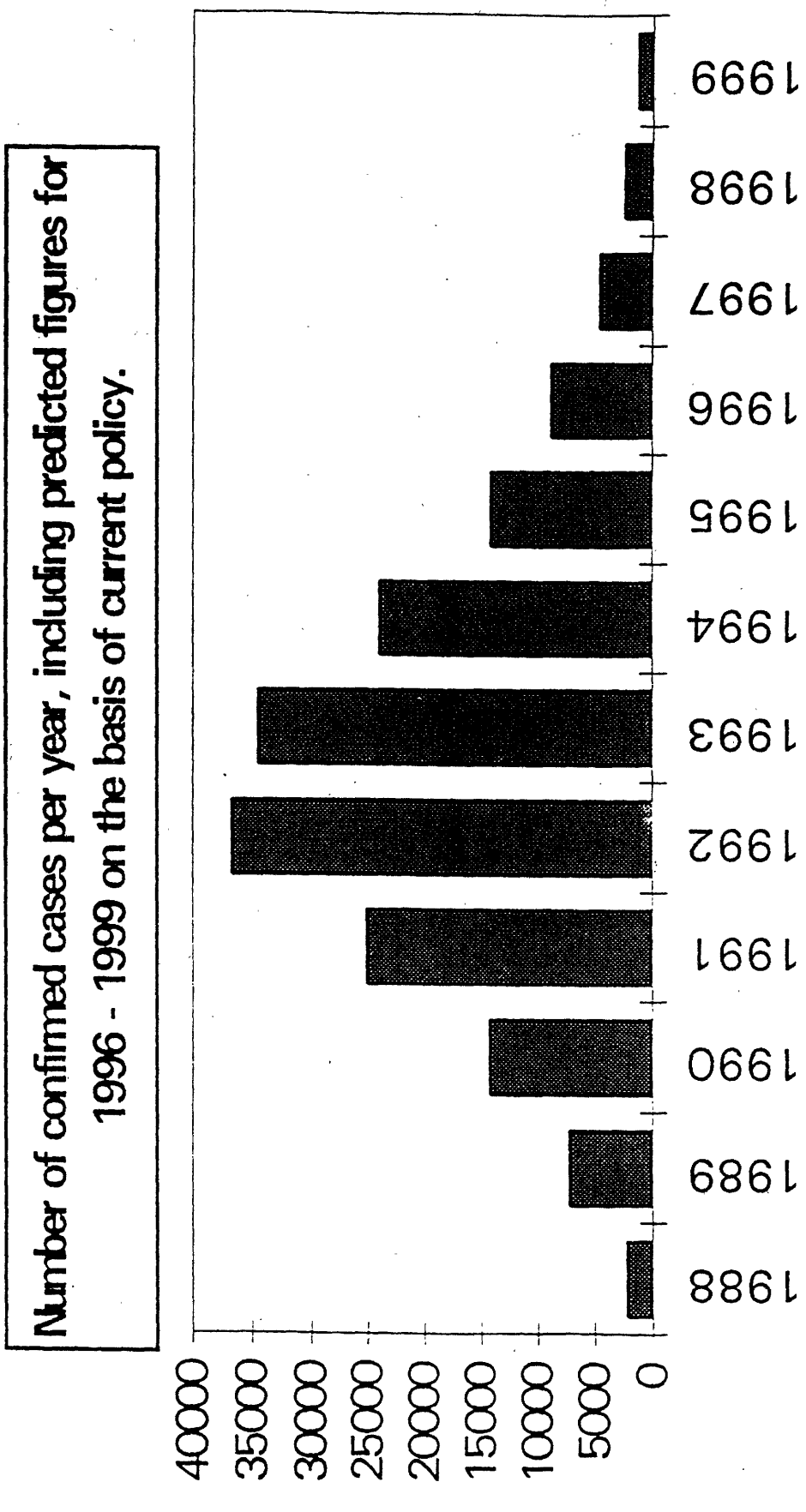
- Consumers ask the Commission to promote consumer representation on all scientific and consultative committees at EU level.

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 particularly 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.


Number of confirmed cases per year, including predicted figures for 1996 - 1999 on the basis of current policy.
40000
35000
30000
25000
20000
15000
10000
5000
0
1988
1989
1990
1991
1992
1993
1994
1995
1996
1997
1998
1999