



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 06.05.1998  
COM(1998) 282 final

COMMUNICATION FROM THE COMMISSION

TO THE COUNCIL, THE EUROPEAN PARLIAMENT,  
THE ECONOMIC AND SOCIAL COMMITTEE  
AND THE COMMITTEE OF THE REGIONS

**FIRST BI-ANNUAL BSE FOLLOW-UP REPORT**

## TABLE OF CONTENTS

|      |  |    |
|------|--|----|
| I.   | AVANT-PROPOS.....  | 6  |
| II.  | ACTION UNDERTAKEN BY THE COMMISSION CONCERNING BSE/TSE SINCE<br>NOVEMBER 1997 .....  | 7  |
| 1.   | SCIENTIFIC ASPECTS .....   | 7  |
| 1.1. | <i>Scientific committees : procedures</i> .....  | 7  |
| i)   | Nomination of Scientific Committee members.....  | 7  |
| ii)  | Publicising the results of the scientific committees .....   | 7  |
| iii) | Acceleration of payment procedures for the members of the Scientific Committees – Payment<br>of indemnity of SC members.....                               | 7  |
| 1.2. | <i>Scientific advice</i> .....   | 8  |
| i)   | Scientific Steering Committee to discuss list of Specified Risk Material (SRM) and abolition<br>of age limits on exclusion of younger animals.....         | 8  |
| ii)  | Meat and Bone Meal (MBM): Safety of inactivation processes .....   | 9  |
| iii) | Destruction of MBM.....  | 9  |
| iv)  | Post mortem BSE tests.....   | 9  |
| 1.3. | <i>Research activities</i> .....   | 10 |
| i)   | Adoption by the Commission of projects on TSE research following the 29 <sup>th</sup> April 1997 joint<br>call for proposals .....                         | 10 |
| ii)  | Organisation and completion of study of methods to establish quantity and quality of feed<br>materials in compound feedstuffs.....                         | 12 |
| 2.   | INSPECTIONS .....  | 14 |
| 2.1. | <i>Legal framework</i> .....   | 14 |
| i)   | Replacement of two Commission Decisions relating to performance of on-the-spot checks.....   | 14 |
| ii)  | Co-operation with Member States (Directive 89/608/EEC).....  | 15 |
| 2.2. | <i>The Food and Veterinary Office (FVO)</i> .....  | 16 |
| i)   | Receipt of, and response to, IGS report.....   | 16 |
| ii)  | Recruitment of staff under the Supplementary and Amending Budget (SAB) 1997 –<br>Additional increase in staff numbers in FVO .....                         | 16 |
| iii) | Development of internal manual of procedures by FVO .....  | 17 |
| 2.3. | <i>BSE inspections</i> .....   | 17 |
| i)   | Further follow-up missions concerning the reporting of all BSE cases<br>(Germany, Italy and Sweden).....   | 17 |
| ii)  | Over Thirty Months Scheme (OTMS inspection (9 – 11 February '98)).....   | 17 |
| 3.   | IMPLEMENTATION OF COMMUNITY LAW .....  | 17 |
| 3.1. | <i>Taking appropriate action pursuant to Article 169 of the Treaty, where the UK<br/>failed to apply Decision 96/239/EC and Directive 64/433/EEC</i> ..... | 17 |
| 3.2. | <i>Implementation of Community law/inspections/infringements with regard to BSE:<br/>overall situation</i> .....   | 18 |
| 3.3. | <i>New information obtained by the FVO inspectors with regard to implementation<br/>of Decision 96/449/EC</i> .....  | 24 |
| 4.   | SITUATION WITH REGARD TO THE UK BEEF BAN .....   | 25 |

|      |   |    |
|------|---|----|
| 4.1. | <i>Submission to the European Parliament of the report of the mission to the UK 9 – 13.6.97</i> .....   | 25 |
| 4.2. | <i>Appropriate action on the basis of scientific advice on the UK's Export Certified Herd Scheme (ECHS)</i> .....   | 25 |
| 4.3. | <i>The UK proposal on a Date-Based Export Scheme (DBES)</i> .....   | 26 |
| 4.4. | <i>Introduction of a legal requirement for traceability of gelatine and certain other products made in the UK from non-UK material / Reinforcement of veterinary checks with regard to Decision 96/239/EC</i> ..... | 26 |
| 5.   | <b>LEGISLATION</b> .....  | 27 |
| 5.1. | <i>Co-decision procedure</i> .....  | 27 |
| 5.2. | <i>General legislative measures</i> .....   | 28 |
|      | i) Assessment of further changes to Directive 85/374/EEC.....   | 28 |
|      | ii) Food policy and the general principles of Food Law .....  | 29 |
|      | iii) Completion of simplification exercise on food hygiene legislation, including veterinary and phytosanitary legislation.....   | 29 |
|      | iv) Entry into force of regulation EC/820/97 (beef labelling) .....   | 29 |
| 5.3. | <i>Reinforcement of controls in the European Union</i> .....  | 30 |
| 5.4. | <i>Surveillance and control of communicable diseases and other health issues</i> .....  | 32 |
|      | i) Establishment of a Community network for the surveillance and control of communicable diseases and of an action programme on rare diseases .....   | 32 |
|      | ii) Reinforcement of the protection of the health and safety of workers from risks related to exposure to BSE and TSE agents at work by the adoption of Directive 97/65/EC .....                                    | 34 |
|      | iii) Proposal on effective surveillance of TSEs in animals in the Member States .....   | 35 |
| 5.5. | <i>Exclusion of risk material from the food and feed chain</i> .....  | 35 |
|      | i) Commission consultation paper on exclusion of high risk material from the feed chain and on a ban on feeding animal protein to ruminants.....  | 35 |
|      | ii) Adoption of a feed ban on MBM not produced in accordance with the standards of Decision 96/449/EC and restriction on use .....  | 36 |
|      | iii) SRM: Proposal to exclude specific hazardous materials from the human or animal food chain .....  | 36 |
|      | iv) Labelling of compound feedingstuffs .....   | 37 |
|      | v) Destruction of MBM / Landfill .....  | 37 |
| 6.   | <b>INTERNATIONAL ASPECTS</b> .....  | 38 |
| 6.1. | <i>Participation, collaboration and membership of the Commission in international organisations</i> .....   | 38 |
| 6.2. | <i>MBM safety standards + general standards in the OIE</i> .....  | 38 |
| 6.3. | <i>Hormones, feedingstuffs additives</i> .....  | 39 |
| 7.   | <b>nvCJD VICTIMS: CURRENT SITUATION AND ASSISTANCE TO nvCJD VICTIMS ORGANISATIONS</b> .....   | 41 |
| 7.1. | <i>Current situation regarding CJD and nvCJD cases in the EU</i> .....  | 41 |
| 7.2. | <i>Assistance to nvCJD victims organisations</i> .....  | 43 |
| 8.   | <b>FRAUDS AND FINANCIAL ASPECTS</b> .....   | 43 |
| 8.1. | <i>Fraud: co-ordination</i> .....   | 43 |

|   |           |
|---|-----------|
| 8.2. <i>Financial consequences from findings on the Over Thirty Months Scheme (OTMS) and the selective cull scheme, should there be justifications of failures by the UK authorities to respect Community Regulations</i> ..... | 44        |
| <b>III. ANNEXES</b> .....   | <b>46</b> |
| ANNEX 1A: JOINT CALL FOR PROPOSALS ON TSE .....   | 46        |
| ANNEX 1B: RESEARCH THEMES .....   | 49        |
| ANNEX 2A: SUMMARY AND CONCLUSIONS OF MISSIONS TO ALL MEMBER STATES IN 1997 REGARDING DECISION 96/449/EC .....   | 51        |
| ANNEX 2B: ANIMAL WASTE LEGISLATION – WORKING PROGRAMME 1998 .....   | 56        |
| ANNEX 3: CURRENT SITUATION REGARDING CJD AND NVCJD CASES IN THE EU.....   | 57        |
| ANNEX 4: LIST OF THEMES COVERED BY THE PRESENT REPORT IN THE LIGHT OF THE “BÖGE REPORT” OF THE EUROPEAN PARLIAMENT, IN ADDITION TO THE ACTION PROMISED IN DOCUMENT COM(97) 509 FINAL .....                                      | 64        |

## I. AVANT-PROPOS

On 20 October 1997, the Commission presented its final consolidated report to the Temporary Committee of the European Parliament on the Follow-up of Recommendations on BSE (COM(97) 509 final) to the European Parliament and to the Council. The report described major achievements realised in the field of food safety and consumer protection and important developments in the fight against BSE since February 1997.

The Commission was however fully aware of the need for further action in addition to the initiatives taken between February and October 1997. By presenting its final consolidated report, the Commission consequently announced an ambitious work programme and indicated that further progress would be reported twice a year to the European Parliament and the Council. Furthermore, a common conference will be organised before the end of 1998 by the Commission and the European Parliament with a view to taking stock of the situation in a future-oriented perspective.

The present first bi-annual BSE follow-up report informs the European Parliament and the Council of the state of implementation of this work programme. In addition, the report describes developments concerning questions which are of particular concern for the European Parliament, as reflected in the report presented by Mr Böge, which the European Parliament adopted during its plenary session of 19 November 1997<sup>1</sup>. In this context, the Commission confirms that it shares the European Parliament's view that the improvement of food safety and the restoration of major consumer confidence must be a major target of the reform of the Common Agricultural Policy as recently presented in the Agenda 2000 proposals, in addition to the measures described in the present communication.

As already underlined in the October 1997 report, the Commission believes that consumer confidence can only be restored through a close co-operation between the European Parliament, the Council and the Commission and the Member States on the basis of a permanent commitment to the objective of protecting the consumers' health.

By adopting a declaration on food safety at its meeting of 12-13 December 1997 in Luxembourg, the European Council underlined that "food safety is more than ever a matter of major concern for the public, and everything must be done to restore public confidence severely shaken by the BSE crisis" and "welcomed the Commission's undertaking to submit twice-yearly reports on BSE to the European Parliament and the Council".

The Commission invites the European Parliament and the Council to take note of the present report.

---

<sup>1</sup> In parallel to the present report, a BSE vademecum for consumers is being prepared for the general public. Before its finalisation, clarifications were awaited on the following questions :

- the scientific evaluation of the safety of certain products (tallow, gelatine, ...);
- the lifting of the embargo with regard to the Export Certified Herds Scheme in Northern Ireland;
- the definition of the measures to be taken with respect to SRM.

Work has now been accelerated with a view to publishing the Vademecum before the end of July 1998.

## **II. ACTION UNDERTAKEN BY THE COMMISSION CONCERNING BSE/TSE SINCE NOVEMBER 1997<sup>1</sup>**

### **I. SCIENTIFIC ASPECTS**

#### **1.1. Scientific committees : procedures**

##### **i) Nomination of Scientific Committee members**

With Commission Decision of 5 November 1997, 132 members of the Scientific Committees (SC) have been nominated, following a selection process on which the EP was kept fully informed.

##### **ii) Publicising the results of the scientific committees**

All scientific opinions and minutes of the meetings of the scientific committees and the scientific steering committee are published on the INTERNET as soon as the responsible committee adopts them as final. The Scientific Steering Committee (SSC) has recently published some preliminary opinions by this way, inviting comments which then had been taken into account before finally adopting the opinions. A brochure presenting the 9 committees is in preparation. It is planned to publish the available opinions in form of a series of booklets.

##### **iii) Acceleration of payment procedures for the members of the Scientific Committees – Payment of indemnity of SC members**

A serious problem remains concerning the payment system. Thus there is still a large backlog of reimbursement of the travel and subsistence expenses of members of the scientific committees.

Nevertheless, in April 1998 an important specific effort has been made to clear the backlog and there is a commitment that a significant acceleration of the reimbursements will take place. The aim is to ensure that reimbursements arrive on the accounts of the experts no later than 2 months after the meeting.

As regards the indemnity payment, the Commission has decided in agreement with the scientific committees to make this by 3 payments per year, covering

---

<sup>1</sup> The present report describes the action promised by the Commission's final consolidated report to the Temporary Committee of the European Parliament on the follow-up of recommendations on BSE (COM(97) 509final) and additional questions covered in the light of the "Böge report" of the European Parliament (see also annex 4 of the present report). A special report concerning recommendations on BSE was presented by the Commission to the European Parliament and the Council by the end of January 1998.

meetings held in the period November to February, March to June, and July to October. The payments for the first period are now underway.

## **1.2. Scientific advice**

### **i) Scientific Steering Committee to discuss list of Specified Risk Material (SRM) and abolition of age limits on exclusion of younger animals**

The SSC was requested to continue the work started by the Multidisciplinary Scientific Committee (MDSC) and adopted on 9 December 1997 an opinion on SRMs in which it proposed a list of tissues that should be classified as SRM. In establishing this list, the SSC took account of the relative infectivity of the respective tissues in infected animals but also took into account the species and age of animals. In further opinions of 26-27 March 1998, the SSC concluded that this list may be modulated on the basis of a risk assessment which takes into account the geographical origin of the animals, their species and their ages.

On 23 January 1998 the SSC issued an opinion on that geographical risk. It defined three risk elements and concluded that it should be possible to assess the geographical risk if sufficient data were available. It also specified an ideal set of data and undertook to carry out a regional risk assessment as soon as appropriate data would be available.

On 20 February 1998 the SSC issued several preliminary opinions which were open for comments by any interested party until 16 March 1998. In its final opinions adopted on 26 March 1998, the SSC took account of the comments received..

In an attempt to establish a comprehensive analytical framework, one of these opinions addressed the BSE-risk in general. The SSC recognised three major issues, namely the risk for humans from direct and indirect consumption of potentially infective bovine material and the risk of propagating the disease by recycling the infective agent via the animal feed chain.

As SRMs are identified as key factors in assessing these risks, the SSC presented a table of the relative infectivity of suggested SRMs from an infected bovine (data provided by SEAC, Feb. 1998). This table shows that the brain and the spinal cord of an infective bovine together represent 89.6% of the total infective load of such an animal. The trigeminal and dorsal root ganglia represent 6.4% and the ileum another 3.3%. Excluding these six tissues would reduce the infective load entering the food and feed chains when such an animal is slaughtered by 99.3%. The SSC also confirmed its list of SRM presented on 9 December 1997 but added that lungs should not be regarded as SRM if suitable slaughtering procedures are in place. The SSC also clarified that it would not be necessary to exclude the entire intestine if separation of the ileum from the rest proves to be practical.

The SSC re-affirmed that the presence of BSE in sheep and goats is possible but not confirmed. It nevertheless insisted that certain parts of these animals should be classified as SRM (head, spinal cord of animals older than 1 year and spleen and distal ileum at all ages).

Concerning the age limit, the SSC did state in its opinion of December 1997 that animals under 12 months of age do not carry any SRM other than the intestine (now reduced to the ileum) and the spleen (only ovine and caprine). The reason being that the infective load seems not to be likely to reach a critical level before that age, even if infection would have taken place at birth.

**ii) Meat and Bone Meal (MBM): Safety of inactivation processes**

The SSC has been working on an opinion on the safety of MBM since October 1997. Intensive discussions took place between Prof. Taylor and other experimental researchers in this field and Prof. Riedinger, who based his arguments on an analysis of available literature data and an extrapolation from microbiological infections to BSE.

The debate can be summarised as follows: The experimental data seem to indicate an efficiency of the inactivation process of  $10^{-2}$  to  $10^{-3}$ . The calculation of Riedinger seems to indicate that a reduction by  $10^{-6}$  is realistic (even up to  $10^{-9}$ ). However, the latter values are only possible if clearly defined conditions are perfectly respected.

The SSC came therefore to the conclusion that in high risk countries no MBM should be produced from ruminants with the aim to feed it to any mammalian animal.

In countries with a lower risk, safety of MBM could be reached by respecting the necessary process conditions and suppressing SRMs.

In countries without a BSE risk or where the risk is considered negligible, MBM could be safely produced by any method. However, as a precautionary measure the SSC recommends also in these cases certain actions to eliminate the remote risk that spontaneous cases might occur.

**iii) Destruction of MBM**

This question is included into a more general one currently addressed by the SSC concerning the safe disposal of animals and animal tissues assumed to carry a risk of being infected with BSE (SRM). An opinion is envisaged for June or July.

**iv) Post mortem BSE tests**

A group of experts from inside and outside the Commission Services visited two companies, which claimed early in 1998 to have a BSE-test. They reported positively on the perspectives but added that there could be no guarantee that either of these tests could finally be developed up to an extent that it could be used for official purposes. As a result the Commission has launched a procedure to validate such tests. Any provider of a test is invited to participate in that validation procedure. First results are hoped for end 1998. It is worth noting that in the meantime the Commission has become aware of other tests approaching applicability, which have not been validated either.



In this context the Joint Research Center (JRC) has an important role to play as it can provide support to the Commission in some important tasks related to the possible validation of the two available post-mortem BSE diagnostics methods, in particular as regards the handling and codification of samples, the critical assessment of results and the preparation of a final report. The JRC will work closely with other Commission services such as DG XXIV, DG XII, DG VI and DG III to ensure an appropriate planning and co-ordination of logistic aspects.

Within the Community research programmes BIOMED, BIOTECH and FAIR the Commission is funding or in the process to fund 9 projects on diagnostic issues for human and animal TSE. These projects intend to evaluate the effectiveness of different markers (cerebrospinal fluid, specific antibodies, specific proteins) or methods (use of transgenic animals, magnetic resonance, cultured cells) as potential diagnostic tools for in vivo and in vitro diagnosis.

### **1.3. Research activities**

#### **i) Adoption by the Commission of projects on TSE research following the 29<sup>th</sup> April 1997 joint call for proposals**

- *First joint call for proposals in the field of transmissible spongiform encephalopathies*

The 1st Joint Call for proposals on research in the field of transmissible spongiform encephalopathies (TSE) was launched by the Commission on 29 April 1997 in the framework of its three Community research programmes on Life Sciences and Technologies (BIOMED, BIOTECH and FAIR) as part of the Action plan for Research on TSE.

The call included six main research themes:

1. clinical, social and epidemiological research on human spongiform encephalopathies (SEs);
2. the infectious agent and its transmission mechanisms;
3. diagnosis of SEs;
4. risk assessment of SEs;
5. treatment and prevention of SEs;
6. co-ordination of research activities between Member States.

This call attracted a wide response from the scientific community and an excellent mobilisation of expertise from most Member States. Altogether, 66 proposals (39 in BIOMED, 15 in BIOTECH and 12 in FAIR) involving 308 laboratories were received.

Following an evaluation of the scientific and technical quality of the projects as well as their impact on ethical terms, carried out by the Commission assisted by independent experts, 22 proposals were considered to be of excellent quality and therefore worthwhile to deserve funding. The distribution of proposals among the three research programmes was 12 in BIOMED, 7 in BIOTECH and 3 in FAIR.

Following the unanimous positive opinion of the three programme committees concerned, the Commission adopted on the 16 February 1998, 22 projects for a total amount of 21.9 Million ECU. A detailed description of the projects is shown in Annex 1A.

These projects will be financed as a result of the decision taken by the European Parliament and the Council of Ministers on 1 December 1997 on the financial complement to the 4th Framework programme which raised by 115 million ECU the total budget for European Union research programmes including 35 million ECU for TSE research.

A particularly attractive characteristic of these projects is their combination of widely separate but nevertheless complementary skills (e.g. structure of proteins, tissue culture, epidemiology, etc) through the joint development of specialised teams some of which have had no prior involvement in the TSE field, maximising the chances of achieving results.

The adopted projects strengthen and complement the ongoing research in this field within these programmes and will also allow the development of a comprehensive research effort on issues which can be considered as a pre-requisite for a proper risk assessment, namely:

- European epidemiology, aimed at ensuring, on a harmonised scale, the identification, comparison and epidemiological surveillance of TSEs both in humans and in animals;
- identification of the agent(s) responsible for TSEs, with a view to determining its principal characteristics and transmission mechanisms;
- development of diagnostic tools, using techniques such as magnetic resonance, electroencephalography and use of specific antibodies;
- risk assessment, notably with regard to risks associated with the consumption of livestock products and with blood transfusions;
- therapeutic and preventive strategies, the examination of the properties of certain families of substances with a view to determining their suitability as therapeutic agents;
- co-ordination of the research activities of the Member States, with the development of the first network comprising 11 Member States for the epidemiological surveillance of scrapie and the establishment of a common scientific database on scientific research and public decision making on TSE.

- Specific call for proposals for the FAIR programme

This call for proposals was implemented by means of an internal redeployment within the FAIR programme, freeing ECU 8.8 million. The contracts corresponding to the eight projects selected last year have been drawn up. Five have already been signed, and the other three are about to be. This research work, announced in the previous report in autumn 1997, is therefore now under way.

Full information on these projects, and on all other research projects administered by DG VI in the area of TSE under the FAIR, AIR and CAMAR programmes, can be accessed on the DG VI Internet server (address: <http://europa.eu.int/en/comm/dg06>).

- Launching of the 2nd joint call for proposals in the field of TSE research

On 28 January 1998, the Commission organised a workshop in the area of TSE risk assessment with a view to the launching of a 2nd joint call for proposals in the field of TSE research which would tackle in a more focused way further issues in this area.

This workshop, attended by leading independent experts in the field, aimed at reviewing the existing knowledge and at identifying research priorities in this area.

The 2nd joint call for proposals within the research programmes BIOMED, BIOTECH and FAIR was launched on 17 March 1998 and will include 3 main research themes based on the experts' recommendations:

1. risk assessment of SEs;
2. treatment and prevention of SEs;
3. co-ordination of research activities between Member States.

The deadline for submission of proposals is 17 June 1998. A detailed description of the research themes is shown in Annex 1B.

**ii) Organisation and completion of study of methods to establish quantity and quality of feed materials in compound feedstuffs**

A validation study on two analytical methods concerning BSE is being carried out by the JRC-Environment Institute (also with the participation of the Institute for Reference Materials and Measurements) with funding from DG XXIV. The following two validation methods will be investigated:

- *Validation of a method for the detection of the appropriate heat treatment of animal meals*

The detection of an appropriate heat treatment of animal meals (20 minutes at 133°C at 3 bars) in the context of the Decision 96/449/EC will be investigated. An appropriate heat treatment is not always guaranteed because of the different technical installations for heat treatment that are in use in the Member States. There is, therefore, a need for a suitable method able to detect compliance with requirements in the above mentioned Decision, and to allow to determine clearly whether or not animal meals have been thermally treated according to the Decision.

A recently developed method based on an ELISA (Enzyme Linked Immunosorbent Assay) technique will be validated on an international level by JRC in order to demonstrate the general suitability of the method (a negative result of the ELISA test indicates a properly heat treated animal meal).

The delivery of results of the validation is foreseen for the end of 1998. In addition, "reference" animal meal samples (heat treated under various conditions) will be produced and will be made available to the public after the validation study.

- *Detection of mammalian meals in feedingstuff of plant origin*

The detection of mammalian meals in feedingstuff of plant origin will be investigated. In the context of BSE, the source of mammalian feedingstuff should be known and labelled correctly. Therefore validated methods are needed in order to prove the absence or presence of mammalian meals in feedingstuff. The method to be validated by JRC is the one based on mitochondrial DNA determination.

The delivery of results of this validation is foreseen for the end of 1998/beginning of 1999. In addition, JRC will prepare the reference material samples of relevant feedingstuff.

These detection methods could be extended to investigate the presence of meal from other animal species.

*Method based on DNA analysis*

The presence of mammalian meals in feedingstuffs of plant origin can be detected by determination of animal DNA. The method of choice should allow to detect bovine material in meals even at a level of about 0.1 % in feedingstuff. However, when the mammalian meals added to the feedingstuff have been heat treated according to the Decision 96/449/EC there is most probably only a small chance that the mammalian DNA is still detectable. Therefore, other methods based on microscopy, immunoassay or spectroscopies should be also investigated and validated by JRC in the future.

The JRC intends to carry out the following three studies, after the validation of the above mentioned two methods are completed:

*Methods based on microscopy*

At least two microscopic method approaches are already available in the European Union. The JRC will propose to validate both microscopic methods.

*Method based on ELISA technique*

This ELISA test for the detection of ruminant and porcine heat stable proteins in compound animal feedingstuff has been already validated within the United Kingdom. Contacts have already been taken between the JRC and those responsible for the UK validation study, in order to collaborate on a validation study on a European level.

*Development of rapid screening methods*

The JRC wishes to start research on the possibility to use the Fourier Transform - Near Infrared (FT-NIR) spectroscopic method and the Differential Scanning Calorimetry (DSC) technique as rapid methods for the detection of animal proteins in compound feedingstuff. The experimental work could be initiated in 1998.

The Commission will take account of these results with the aim of drawing up a draft amendment to Council Directive 70/373/EEC on the introduction of Community methods of sampling and analysis for the official control of feedingstuffs.

## 2. INSPECTIONS

### 2.1. Legal framework

#### i) **Replacement of two Commission Decisions relating to performance of on-the-spot checks**

The following Commission Decisions were published in Official Journal L 38, of 12 February 1998:

- Commission Decision 98/139/EC of 4 February 1998 laying down certain detailed rules concerning on-the-spot checks carried out in the veterinary field by Commission experts in the Member States.
- Commission Decision 98/140/EC of 4 February 1998 laying down certain detailed rules concerning on-the-spot checks carried out in the veterinary field by Commission experts in third countries.

These Decisions replace existing Community legislation in this field, and have the following main effects:

- a reduction in the time allowed to the Commission to despatch its mission findings to the country concerned from 2 months to 20 working days;
- a reduction in the time allowed to Member States to respond to mission findings from 2 months to 25 working days. The same provision will be applied administratively to third countries;
- where an emergency health risk has been identified, the above exchanges must take place as quickly as possible. A maximum period of 10 working days is allowed for the Commission to despatch its report, and the same period for the Member State to respond;
- the findings of inspections and any recommendations for action will be made available to the European Parliament and to the public, subject to the need to respect the provisions of Article 214 of the Treaty of the European Community;
- account is taken of the potential impact on the organisation and performance of control missions in the context of agreements between the European Community and third countries on sanitary measures applicable to trade.

**ii) Co-operation with Member States (Directive 89/608/EEC)**

- Application of Directive 89/608/EEC

In application of article 9 (2) of Directive 89/608/EEC the Commission's services (DG XXIV) on 3 April 98 informed the veterinary authorities of all Member States about severe irregularities which were revealed during FVO inspections to Member States. The practices observed were undermining the traceability of meat. Basic principles of meat trade in the Community were disregarded and thereby fraudulent international trade facilitated.

The veterinary services were asked to give priority to the official controls on identification of fresh meat, documentation of trade and the performance of self controls by the industry, as foreseen by Community legislation. In accordance with article 11 of Directive 89/608/EEC further discussions of the issue with Member States will take place in the Standing Veterinary Committee when the reports of the above mentioned missions will be presented.

- Amendment of Directive 89/608/EEC, where necessary, and reinforcing controls when emergency measures apply

These questions were dealt with in the special report to the European Parliament concerning recommendations on BSE.

## **2.2. The Food and Veterinary Office (FVO)**

### **i) Receipt of, and response to, IGS report**

The Commission communication to the European Parliament and the Council on food, veterinary and plant health control and inspection (COM (1998) 32final) provided the response to the IGS report.

The Commission fully endorsed the recommendations made in this report. In particular, it has decided that its control and inspection responsibilities will continue to be undertaken by the FVO, under the overall responsibility of the Commission, rather than being assumed by an external Agency.

The IGS report fully supported the introduction of the new working procedures, originally described in the earlier Commission communication on consumer health and food safety (COM(97) 183final). The action necessary to introduce these changes is in hand within the FVO.

It should be noted that following the conclusions of the European Council of October 1993, the Commission has moved the Food and Veterinary Office to Ireland on 1 September 1997. Experience has begun to indicate that the establishment of the Office in Ireland poses certain operational and financial difficulties.

### **ii) Recruitment of staff under the Supplementary and Amending Budget (SAB) 1997 – Additional increase in staff numbers in FVO**

As indicated in the Commission communication to the European Parliament and the Council on food, veterinary and plant health control and inspection (COM(1998) 32 final), the Commission is taking action to fill the 166 extra posts identified by the IGS report (SEC(97) 482/3) of 11 March 1997 as being necessary for its control services to meet their commitments.

35 additional posts were made available under the SAB 1997. All of these have now been filled. 99 posts and credits for 12 auxiliaries have been allocated in the 1997 and 1998 allocation procedures both through redeployment (66) and by allocating new posts (33).

Altogether, 146 of the 166 necessary extra posts identified in the IGS Report have thus been made available and will be filled in 1998. The remainder (around 20 posts) will be made available in the 1999 allocation of resources.

Several selections for the recruitment of temporary agents have been organised and completed. The remaining candidates on existing competition reserve lists have been recruited to the maximum extent possible. Of the two competitions launched last summer for veterinary, phytosanitary and other food experts, one (at the A5/A4 level) is completed and recruitments are beginning from the reserve list; while the other (at the A7/A6 level) will be completed in June 1998. For the last 20 posts for 1999, it is also intended to begin the recruitment procedures in 1998.

The recruitment exercise has made major training efforts necessary. These have been initiated in particular with regard to audit procedures.

**iii) Development of internal manual of procedures by FVO**

An initial manual of operations has been prepared, and is now in use by the FVO. In particular this covers the planning, performance and reporting procedures for control and inspection missions. It allows a standardised approach to be adopted to the manner in which these activities are undertaken. This document represents an important first step towards the final adoption of the complete manual of procedures, which will also include standardised formats for reports and other documents, as well as detailed rules for the performance of audits.

**2.3. BSE inspections**

**i) Further follow-up missions concerning the reporting of all BSE cases (Germany, Italy and Sweden)**

The results of these missions were summarised in the Special Report to the European Parliament concerning recommendations on BSE.

**ii) Over Thirty Months Scheme (OTMS inspection (9 – 11 February '98))**

A joint mission to inspect the implementation of the scheme for slaughter and destruction of bovines over thirty months of age was undertaken by inspectors of the Clearance of Accounts Unit of DG VI and the FVO from 9 to 11 February 1998. Priorities of the mission were measures to avoid material from these animals to enter the food and feed chains. Improvements have been noticed since the previous missions. However, some further improvement is still required in the context of slaughtering bovines under the rules of the OTMS.

The draft report has been sent to the UK authorities for comments. The final report will be submitted to the European Parliament and to the Standing Veterinary Committee.

**3. IMPLEMENTATION OF COMMUNITY LAW**

**3.1. Taking appropriate action pursuant to Article 169 of the Treaty, where the UK failed to apply Decision 96/239/EC and Directive 64/433/EEC**

Following intervention from the Commission the United Kingdom adopted during August and September 1997 new national rules to better provide for the imposition and enforcement of the export ban imposed by Commission Decision 96/239/EC as amended. Administrative circulars governing the enforcement of the new legislation have also been supplied. The competent



Commission services concluded on 29 October 1997 that the legislative measures were now generally adequate. Need for improvement with regard to the practical enforcement at some ports has been identified in the report of the FVO mission from 29 September to 3 October 1997.

- In respect of insufficient controls at meat plants involving alleged breaches not only of General Community Veterinary and Public Health Legislation under Council Directives 64/433/EEC and 89/662/EEC but also the BSE export ban imposed by Decision 96/239/EC the Commission opened an Article 169 procedure by letter dated 22 September 1997.

As the United Kingdom reply of 20 October 1997 was not considered to constitute a legal justification for the inadequacies noted in the FVO report the Commission decided to send the Reasoned Opinion.

On 2 April 1998 the UK submitted a document outlining improvements in the level of supervision in meat plants in Great Britain and initiatives to move towards compliance with EC rules. Commission services have considered the technical and legal implications of this document.

- Another issue considered in this context is the notification sent to the Commission by the Dutch authorities concerning the presence on the Dutch market of beef consommé and similar products seized in the Netherlands.

In the framework of the Rapid alert system, the Commission services recently forwarded this notification to all Member States. These foodstuffs fall undoubtedly under Article 1 of Decision 96/239/EC. The UK authorities are still investigating this. However it is still unclear whether these products were prepared from bovines slaughtered outside the United Kingdom. The same products were also withdrawn from the Canadian Market.

### **3.2. Implementation of Community law/inspections/infringements with regard to BSE: overall situation**

#### **a) Community law obligations with regard to BSE**

The respect by the Member States of their Community law obligations with regard to BSE has been subject to strict monitoring by the Commission services. New results of inspections in Member States have been carefully examined in respect to possible infringements of Community law.

In cases where it has been established that national law and administrative practices within a Member State did not reflect that Member State's obligations or that the Member State concerned failed to enforce the applicable

legislation within its territory the Commission has intervened with the Member State in order to ensure compliance.

In cases where early voluntary compliance by a Member State has not followed the Commission's intervention, infringement proceedings under Article 169 of the EC Treaty have been opened.

Thus, on 26 June 1997 the Commission decided to open infringement proceedings against ten Member States in respect of their apparent failure to enforce some aspect of Community legislation concerning BSE. The subject matter of these initial proceedings concerned principally inadequate implementation of Commission Decision 96/449/EC (heat treatment system for processing animal waste) and failure to sufficiently control the respect of Commission decision 94/381/EC prohibiting the use of mammalian tissues in feeding stuffs destined for ruminants.

In addition, in the light of the results of the new FVO inspections carried out in the second half of 1997, relating primarily to the application of Decision 96/449/EC, new infringement proceedings were launched on 25 March 1998 against two other Member States.

The Commission regards the meticulous implementation of both these texts as vital if BSE is to be eradicated and the possible risks to human health pending eradication are avoided. In this respect, it should be noted that the Commission is now making full use of the internal reforms decided in July 1996 to speed up the Article 169 procedures: infringement cases ready for a decision, in particular those concerning BSE, are now handled on a bi-monthly basis, which leads to increased interventions with the Member States. In addition, time limits granted to Member States for replying to the letters of formal notice or the reasoned opinions have been sharply reduced (to 15 days only).

b) The Member States concerned by the infringement procedures mentioned above are as follows:

1. France

France failed to implement Decision 96/449/EC on the grounds that it disputed the efficacy of the technical parameters for processing animal waste imposed by the decision and questions the legal basis on which the text was adopted.

The Commission decided on 26 June 1997 to open an infringement procedure. Following the dispatch by the Commission of a letter of formal notice on 7 July 1997 and a Reasoned Opinion on 22 December 1997 the French Government communicated on 9 March 1998 the text of an arrêté ministériel of 6 February 1998 providing for obligatory treatment of animal waste in accordance with Commission Decision 96/449/EC.

2. Belgium

The OAV inspection visit in November 1996 brought to light shortcomings in the system for monitoring the application of Decision 94/381/EC (feed ban), particularly the lack of sampling for microscopic analysis of ruminant feed at various stages of the process (production, marketing, use).

On 26 June 1997, the Commission decided to commence infringement proceedings. Following the sending of a letter of formal notice on 7 July 1997 and subsequent correspondence, the Belgian authorities agreed to supplement their programme of administrative and accounting controls with microscopic analyses of samples of ruminant feed taken at different stages of the process (107 analyses in 1997)<sup>1</sup>.

In addition, following the finding during the FVO visit on 18 September 1997 of defects in the system for monitoring the application of Decision 96/449/EC in Belgium, the Commission has decided to commence new infringement proceedings.

### 3. Luxembourg

The infringement procedure against Luxembourg begun on 26 June 1997 was targeted initially at the shortcomings in the system for monitoring the application of Decision 94/381/EC highlighted by the FVO inspection visit on 23 November 1996, in particular the lack of sampling for microscopic analysis of animal feed at different stages of the process, and secondly at integrating Decision 94/381/EC into Luxembourg national legislation.

In response to the letter of formal notice of 7 July 1997, the Luxembourg authorities established a programme for taking 40 samples per year of ruminant feed for analyses relating to the entire process (see (1)).

In addition, the Luxembourg authorities have transposed Decision 94/381/EC into national law.

### 4. Netherlands

A veterinary inspection mission took place in December 1996. Failure to complete approval of all plants processing animal waste and failure to provide a list of all plants concerned and also incomplete implementation of Decision 96/449/EC motivated the Decision on 26 June 1997 by the Commission to open an infringement procedure and the dispatch of a formal notice on 7 July 1997. At present the only remaining problem concerns the approval of 6 low-risk establishments which do not meet certain housing requirements laid down in the relevant EC rules.

### 5. Germany

Following a veterinary mission in November 1996, a decision to open an infringement procedure was taken on 26 June 1997 and a formal notice was sent on 7 July 1997 for the following reasons:  
failure to implement Decision 96/449/EC as far as particle size parameter is concerned;

---

<sup>1</sup> The Commission services are looking into this programme and also exploring the manner in which to adopt a legal instrument providing for a control system to properly enforce Decision 94/381/EC (see under point 5.3: reinforcing routine controls in animal feed).

also national exemption from the requirements of processing under Decision 96/449/EC of certain by-products used for animal feed of processing material fit for human consumption.

With regard to the first complaint, the German authorities have complied by amending the Regulations concerning rendering plants. With regard to the interpretation of the derogations set out in Article 1(2) of Decision 96/449/EC, Germany maintained its original position. In the light of this situation, the Commission has decided to propose to the Standing Veterinary Committee a clarification of the texts of Decision 96/449/EC in question.

## 6. Spain

An infringement procedure was decided on 26 June 1997 and a letter of formal notice was issued on 7 July 1997, based on a FVO mission in October 1996, for the following reasons:

Risk material considered as low risk processed into animal feed without being treated in accordance with the parameters of Decision 96/449/EC;

Enforcement of feed ban imposed by Decision 94/381/EC is inadequate, because no official analysis of feed to detect mammalian Meat and Bone meal is made;

Spain failed also to ensure that a waste processing plant had its processing procedures validated as required by Community Legislation.

A Reasoned opinion has been issued on 3 February 1998. As a result of a further inspection in October 1997, it appeared that the Spanish authorities changed their position on the first point and consider that Decision 96/449/EC does apply to low risk material within the meaning of Council Directive 90/667/EEC. With regard to the problem of the enforcement of the feed ban, the Spanish authorities stated in their reply to the Reasoned opinion, that they are improving their programme of control, which is under analysis by the Commission services (see footnote (1)). Concerning point 3, the Commission considers that further examinations will be required to ensure the complete conformity of the Spanish plants with the validation process.

## 7. Sweden

A veterinary inspection mission in November 1996 established that Sweden failed to transpose Article 3(2) of Directive 90/667/EC by the due date and also to officially approve rendering plants as required by Article 4(1) of Directive 90/667/EEC.

Commission's interpretation of Decision 96/449/EC as far as processing of bones fit for human consumption into animal feed is disputed by Sweden.

Sweden's enforcement of the ban under Decision 94/381/EC of incorporating mammalian material in ruminant feed is considered inadequate in so far as the Swedish control regime only envisages annual analysis of 100 samples.

A letter of formal notice was issued by the Commission on 7 July 1997 after the Commission decided to open an infringement procedure on 26 June 1997.

A veterinary inspection mission carried out in Sweden from 24 to 28 November 1997 confirmed regularisation of the first two previous grounds.

The Commission intends to modify Decision 96/449/EC in such a way that it clearly reflects the Commission's construction thereof.

The Commission services have been supplied with information to the effect that the Swedish administration foresees to take 200 samples in the course of 1998 (see footnote (1)).

#### 8. Finland

The Commission took the decision on 26 June 1997 to open an infringement procedure and issued a letter of formal notice was issued by the Commission on 7 July 1997, after a FVO mission on October 1996, for the following reasons:

Carcasses of dead ruminants used as food for certain wild animals contrary to Directive 90/667/EEC and Decision 96/449/EC.

Inadequate enforcement of feed ban under Decision 94/381/EC as inadequate controls imposed to detect mammalian protein in ruminant feed (notably no microscopic tests). A Finnish reply to this allegation is being currently examined by the Commission services.

#### 9. Italy

Based on the results of a visit by Commission veterinary inspectors between 25 and 29 November 1996 and subsequent discussion of the results, the Commission began infringement proceedings on 26 June 1996 with regard to the application of Decision 94/381/EC, and in particular to the insufficient number of specific controls concerning the accidental or fraudulent inclusion of mammalian meat- or bonemeal in ruminant feed.

The Italian reply to the letter of formal notice sent on 7 July 1997 provided indications as to the number of controls carried out, their type (documentary and microscopic analysis), the detection rate of suspect samples and the follow-up in such cases (760 controls carried out between May 1996 and May 1997, 155 of them microscopic; eight own-initiative cases) (see footnote (1)).

#### 10. Portugal

A letter of formal notice, based on the decision of 26 June 1997 by the Commission to open an infringement procedure, was issued by the Commission on 10 July 1997 for the following failure to co-operate with Commission in answering its written requests for information, which is a breach of Article 5 of the EC Treaty.

In addition to the breach of its obligations mentioned above, the veterinary inspection mission to Portugal which took place between 15-21 June 1997 recorded infringements of Directive 90/667/EEC and Decision 96/449/EC and a complementary letter of formal notice was sent on 3 December 1997. No reply has been received. Therefore the Commission decided to dispatch a Reasoned Opinion on 7 April 1998.

#### 11. Denmark

A veterinary inspection mission in July 1997 showed that two plants were not operating in full conformity with the requirements of Decision 96/449/CE and some mammalian meat and bone meal which had not been processed as required had been sold in Denmark or exported to third countries.

Furthermore the control of mammalian meat and bone meal during the transport from one plant to another in order to complete the process laid down in the decision, appeared not to be sufficient. Therefore the Commission decided on 25 March 1998 to open an infringement proceeding.

#### 12. Greece

In the light of the finding by the FVO, during the inspection visit carried out between 29 September and 3 October 1997, of significant shortcomings in the implementation of Decisions 94/381/EC and 96/449/EC, the Greek authorities have provided information on specific measures adopted in order to comply strictly with the requirements of Decision 96/449/EC. However, there have been no indications concerning the implementation of Decision 94/381/EC. The Commission therefore decided on 25 March 1998 to send a letter of formal notice demanding that samples be taken and analysed with a view to establishing that proteins derived from mammalian tissues are not being used in ruminant feed.

#### c) Position in relation to Member States - handling illegal UK exports

In relation to the illegal beef exports the Commission is also continuing its examination on whether those Member States where the illegal beef was handled after it left the United Kingdom also failed to control adequately the respect of Community legislation. In this connection correspondence has been exchanged with the Belgian and German authorities. The FVO inspection carried out between 8-12 September 1997 brought to light failures in the keeping of records to allow the monitoring of the entry and exit of meat into and out of packing plants and cold storage depots, resulting from shortcomings in German regulations. As the reply from the German authorities was considered unsatisfactory, the Commission decided to begin infringement proceedings. In the case of Belgium, new Royal Decrees and circulars have stepped up the system of checks on premises.

#### d) Other cases

In relation to France the prohibition of use of fishmeal in animal feed and requirements on import of petfood from certain 3rd countries (notably the USA and Canada) are currently being examined.

Italian restrictions on fish meal similar to those of France are also being examined.

e) Conclusions

In conclusion, the commencement of infringement proceedings following FVO inspection visits in the Member States has brought about considerable progress in the bringing into line of the national regulations of the Member States concerned, and in actual compliance with the Community regulations under examination. Where shortcomings persist, the Commission will continue with the proceedings already begun. Similarly, the Commission will commence new proceedings as and when new inspections establish the existence of new infringements. In other situations, where reinforcing Community regulations appears to be a more legally certain approach, the Commission will make the appropriate legislative proposals. This is particularly the case with the level of checks required in Member States in connection with the application of Decisions 94/381/EC and 96/449/EC.

With regard to the recommendation made to the Commission to carry out follow-up inspections on principle, prior to any infringement proceedings, to verify whether shortcomings uncovered and pointed out during previous inspections have actually been rectified, the Commission points out that the principle of on-the-spot verification of the fulfilling of commitments made following the veterinary inspection has already been applied on several occasions in the infringement dossiers. In the context of the BSE dossiers, the Commission has systematically set out in a pre-infringement letter the deficiencies noted during inspection visits and, on the basis of comments by the Member States, commenced infringement proceedings where those infringements apparently persisted. Follow-up visits are very useful in highlighting the persistence of infringement situations, especially where practices are concerned, and for moving on to the following stages of the infringement proceedings (reasoned opinion or reference to the courts).

However, it would not be normal practice to delay the initiation of infringement proceedings until follow-up missions have been undertaken, as this might lead to further delay in any necessary action being taken.

**3.3. New information obtained by the FVO inspectors with regard to implementation of Decision 96/449/EC**

As indicated in the Special Report to the European Parliament of January 1998 all intended missions concerning implementation of Decision 96/449/EC were carried out. All draft reports were submitted to the Member States and the Commission services responsible for infringement procedures. The results were summarised in the Special Report to the European Parliament. A document describing the general conclusions of the inspectors on the basis of the results was finalised and was discussed with Member States in April 1998. This document is annexed to the present report (see annex 2A). Follow-up missions are currently being undertaken.

In order to follow up points raised by the inspection service and to reconsider legislation, taking into account the latest scientific advice, a working programme has been established (cf. annex 2B).

As part of this working programme an amendment of Decision 96/449 EC is in preparation in order to:

- Clarify problems of legal interpretation raised in the framework of the infringement procedures and during the Community inspection missions in Member States, and in particular the following:
  - definition in article 1 (high-low risk, catering waste etc.)
  - derogations laid down in article 1(2) ('bones fit for human consumption', fertilisers etc.);
- introduce health requirements for the production of tallow and MBM in line with the new advice of 26-27 March 1998 of the Scientific Steering Committee;
- take into account some technical remarks made by the FVO in its document describing the general conclusions (see: 1<sup>st</sup> paragraph of point 3.3.) validation of rendering plants, post-sterilisation treatment, etc.) .

Furthermore, the Scientific Veterinary Committee will be asked to reconsider its document on the validation procedure for rendering plants, in view of the standards imposed by Decision 96/449/EC.

#### **4. SITUATION WITH REGARD TO THE UK BEEF BAN**

##### **4.1. Submission to the European Parliament of the report of the mission to the UK 9 - 13.6.97**

The report of the FVO mission to the UK from 9 to 13 June 1997 with regard to the pre-conditions of the Florence Agreement (Doc. XXIV/1525a/97-EN) was submitted to the European Parliament in October 1997.

##### **4.2. Appropriate action on the basis of scientific advice on the UK's Export Certified Herd Scheme (ECHS)**

In the Council Decision on emergency measures to protect against BSE, repealing Commission Decision 96/239/EC and amending Commission Decision 94/474/EC, it was decided to lift the ban on exports from Northern Ireland for herds authorised for export.

This first step to lift the UK beef export ban could be taken because a computerised traceability system for bovines is in place in Northern Ireland. Strict controls on the eligibility of the animals to be slaughtered under the scheme and on the separation and traceability of the products have been laid down following a mission undertaken by the FVO in November 1997 to assess



the proposed procedures and controls concerning the Export Certified Herd Scheme (ECHS).

As foreseen by the Council Decision (see Article 6(5)) a further mission has been carried out to inspect the implementation of the ECHS. Following this mission, Northern Irish authorities have taken all necessary action to implement the ECHS rules as laid down in Council Decision 98/256/EC. The implementation phase is well managed and national legislation including the rules of the ECHS is planned to come into effect in the beginning of May, 1998. Only one slaughterhouse and one cutting plant asked for approval and are foreseen to receive it. The mission report will be presented to the Standing Veterinary Committee in due time in order to inform the Member States on the outcome of the mission. Subsequently the Commission shall set the date on which dispatch may commence.

#### **4.3. The UK proposal on a Date-Based Export Scheme (DBES)**

The UK draft relates to the export of meat and meat products from bovine animals aged between six and 30 months born after 1 August 1996, to a cow which was still alive six months after the animal's birth, or imported after that date and raised in the UK.

The UK's proposal of a date-based export scheme was submitted to the SSC on 2 October 1997 and it issued opinions on the proposal at its meetings of 8/9 December 1997 and 22/23 January 1998. On 27 January 1998, a revised version of the proposal was received on which the SSC commented at its meeting of 19/20 February 1998. The SSC is largely in agreement with the proposal, insofar as it would ensure a sufficient degree of safety of de-boned meat.

The Commission services have held a number of meetings with the UK authorities to discuss the possibilities for a date-based export scheme, in the light of the opinions of the SSC.

The Commission intends to put forward the appropriate legislative proposal shortly.

#### **4.4. Introduction of a legal requirement for traceability of gelatine and certain other products made in the UK from non-UK material / Reinforcement of veterinary checks with regard to Decision 96/239/EC**

The Council, meeting on 16 and 17 March 1998, adopted Decision 98/256/EC on emergency measures to protect against BSE, repealing Commission Decision 96/239/EC and amending Commission Decision 94/474/EC.

It is worthwhile recalling that Commission Decision 96/239/EC of 27 March 1996 imposed an absolute ban on the export of live bovine animals, their meat and meat products, tallow and gelatine, and mammalian derived meat- and bonemeal from the United Kingdom. Commission Decision 96/362/EC of 11 June 1996 permitted the resumption under certain conditions of exports from the United Kingdom of meat, meat products, meat

preparations for human consumption, food for domestic carnivores obtained from bovine animals which were not slaughtered in the United Kingdom and products obtained from bovine animals slaughtered outside or within the United Kingdom.

The new Decision of 17 March 1998 restricts to technical purposes the export of gelatine, di-calcium phosphate, collagen, tallow, tallow products and products derived from tallow produced in the United Kingdom from animals slaughtered in the United Kingdom, thus excluding their use in the human and animal food chain or in the manufacture of cosmetic, medical or pharmaceutical products.

In addition, the Council Decision on emergency measures to protect against BSE, repealing Commission Decision 96/239/EEC and amending Commission Decision 94/474/EEC introduces a legal obligation for the traceability of gelatine and other products manufactured in the United Kingdom from material not originating in the United Kingdom and eligible for export, strengthening in particular the conditions governing labelling, marking and certification. Furthermore, processing of these products must be carried out in a different place or at a different time from non-eligible products.

Finally, it steps up the controls to be carried out by official veterinarians in authorised establishments. FVO inspections are also intended to verify application of the provisions and implementation of official controls.

These control elements were elaborated by an inter-service expert group and had been described in the Final consolidated Report on the follow-up of recommendations on BSE (COM(97) 509 final).

Furthermore following new control provisions, which have been included in the Council Decision, transit of beef through the United Kingdom has now to take place in sealed trucks and to be covered by veterinary certification.

## **5. LEGISLATION**

### **5.1. Co-decision procedure**

The Commission would, first of all, recall that it has defined and implemented a policy, whereby it has proposed the use of a legal base, which implies the appropriate involvement of Parliament: this policy will continue in line with the Commission's undertaking thereon to Parliament. Indeed, as the Parliament rightly points out, the Commission has introduced proceedings in the Court of Justice against the Council, because that institution did not accept the legal base proposed by the Commission.

The Commission also notes with satisfaction Parliament's support for its commitment to the creation of an adequate legal base which would meet present and future needs on public health at Community level. The new provisions of the Amsterdam Treaty regarding public health serve to broaden the scope and effectiveness of the Community's competence in the domain. In particular, the new Article 152 effectively makes the link between veterinary

and phytosanitary measures and public health and it makes that link within the context of the co-decision procedure. This last innovation will, of course, ensure the full participation of Parliament in any future measures in the field.

The Commission is strongly of the view that the new Article 152 creates a more precise legislative apparatus which would ensure a situation, such as the BSE crisis, be effectively covered at Community level.

In the current context, it is worthwhile highlighting the following dossiers:

- Proposal for a Council Regulation on measures to promote and market quality beef and veal and on information measures concerning the labelling of beef and veal, repealing Regulation (EEC) No 2067/92.

The Commission has amended the initial legal basis (Article 43 only) and accepted the European Parliament's amendment concerning the inclusion of Article 129 as the legal basis for consumer information measures. This amendment has not been accepted by the Council, but it has been unable to obtain unanimity in order to amend it. As a result, the former Regulation remains in force;

- Council Regulation (EC) No 820/97 of 21 April 1997 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products.

The Council adopted its decision unanimously, contrary to the opinions of the Commission and the Parliament. The Commission is currently contesting this decision before the European Court of Justice (Case C296/97 of 22 July 1997). The Court's judgement will not be announced until 1999;

- Preparation of a TSE regulation based on Article 100a.

As soon as possible, the Commission will submit to the Council and the European Parliament a proposal for a global, long-term system for the surveillance of transmissible spongiform encephalopathies on the basis of Article 100a.

## **5.2. General legislative measures**

### **i) Assessment of further changes to Directive 85/374/EEC**

By adopting proposal for a Directive COM(97) 478 of 1 October 1997, the Commission followed the EP's recommendation in 1997 to extend Directive 85/374/EEC to primary agricultural products. The current proposal should meet the European Parliament's concerns in the context of BSE.

However, the Commission must report every five years on the application of the 1985 Directive (Article 21 of Directive 85/374/EEC). In the context of this periodical monitoring, the Commission may present further proposals to modify the Directive.

Once the current proposal is adopted by the European Parliament and Council, consultation will take place to assess whether any other initiative is needed in a context broader than the follow-up of the BSE enquiry.

In its Opinion of 29 January 1998, the ECOSOC supports this approach.

**ii) Food policy and the general principles of Food Law**

The Commission published in May 1997 a Green Paper on the General Principles of Food Law in the European Union. In response to this consultation document, the Commission has received some 150 comments, which are at present being analysed by the responsible services. The Commission intends to give its reply to these comments in the form of a communication to the Council and the European Parliament to be published before the summer this year. This communication will outline the principles on which the Commission will base its future actions as regards food legislation and wherever possible, a timetable for legislative proposals.

Furthermore the Commission has organised together with the European Parliament in November 1997 a Conference on Food Policy and Food Law and published a conference report in December. The information gathered during this conference will also be taken into account in the preparation of the above-mentioned communication.

**iii) Completion of simplification exercise on food hygiene legislation, including veterinary and phytosanitary legislation**

The Commission is currently involved in simplifying the legislation on veterinary hygiene (13 Directives on food hygiene and three on animal health) and the Directive on the hygiene of foodstuffs (Directive 93/43/EC). This work should be completed by the end of 1998. The new legislation will be based on a general application of the Hazard Analysis and Critical Control Points (HACCP) principles, extended to cover the entire production chain.

**iv) Entry into force of regulation EC/820/97 (beef labelling)**

The Commission's implementing regulations relating to Council Regulation (EC) No 820/97 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products have been adopted.

With regard to identification and registration, they relate to:

- transitional provisions for the start-up period of the system for the identification and registration of bovine animals (Regulation (EC) No 2628/97);
- eartags, holding registers and passports (Regulation (EC) 2629/97);

- the minimum level of controls to be carried out (Regulation (EC) No 2630/97);
- the application of minimum administrative sanctions (Regulation (EC) No 494/98).

With regard to labelling, they relate to:

- mutual recognition (Regulation (EC) No 1141/97, Article 1);
- minimum requirements for the specification (Regulation (EC) No 1141/97, Article 2);
- checks (Regulation (EC) No 1141/97, Article 3);
- sanctions (Regulation (EC) No 1141/97, Article 4).
- approvals granted by third countries (Regulations (EC) Nos 2406/97 and 824/98 amending Regulation (EC) No 1141/97).

In addition, the Commission will submit to the European Parliament and the Council during the first half of the year a draft Directive based on Article 100a and amending Directive 64/432/EEC on animal health problems affecting intra-Community trade in bovine animals and swine, to enable the Commission, if necessary, to adopt implementing procedures relating to databases in order both to ensure exchanges of data between the different national bases and to guarantee their operational nature.

The Commission also launched the IDEA pilot project at the beginning of 1998 on the electronic identification of bovine animals.

Finally, a report in accordance with Article 10 of Council Directive 92/102/EEC on the identification and registration of animals has been drawn up and will be presented to the Council.

In its proposal for a Council Regulation on measures to promote and market quality beef and veal and on information measures concerning the labelling of beef and veal repealing Regulation (EEC) No 2067/92, the Commission included a measure intended to inform consumers of the guarantees offered by the labelling system. Provision has been made for funding this measure.

However, the Council has not adopted this proposal.

### 5.3. Reinforcement of controls in the European Union

- Harmonisation of control plans

In May 1998, the Commission is to submit to the Standing Veterinary Committee a draft Commission Decision laying down the procedures concerning essential information relating to the veterinary checks carried out under the terms of Directive 89/662/EEC. The draft provides for the

computerised forwarding to the Commission, in accordance with a harmonised model, of essential information relating to checks carried out at the point of origin and on arrival at destination. In particular, this information relates to the number of establishments subject to checks, the quantities checked, the checks carried out, the results of those checks and the staff deployed to carry them out.

In accordance with Article 16 of Directive 89/662/CEE, the information will be examined by the Commission within the framework of the Standing Veterinary Committee.

- Reinforcing sanctions

With regard to Regulation EC/820/97 (beef labelling) rules on the application of minimal levels of administrative sanctions have been laid down by Regulation EC/494/98 (see point 5.2. iv).

- Reinforcing routine controls

- in meat production plants

Following inspections carried out in the Member States, which highlighted fraudulent practices in contravention of Community regulations governing BSE, the Commission is to submit to the Council a draft Council Directive amending Directive 64/433/EEC on health problems affecting intra-Community trade in fresh meat with a view to stepping up health measures. It is planned to step up official checks on the production process, health marking and certification procedures, and to introduce a requirement for meat production plants to keep records of their animal feed production.

- in animal feed

Article 22 of Directive 95/53/CE fixing the principles governing the organisation of official inspections in the field of animal nutrition obliges the Member States to draw up, by 1 October 1998 at the latest, programmes setting out the number and frequency of inspections, which must be performed regularly. In the light of the shortcomings noted in the Member States, the Commission is currently assessing the regulations with a view to stepping up the effectiveness of the checks carried out by Member States to ensure compliance with Decision 94/381/CE prohibiting the use of mammalian derived protein in ruminant feed.

Thus, with regard to the sampling method, a draft amendment to Directive 76/371/CEE is being studied. In addition, the Commission will take into account the results of the study of microscopic methods of analysing the composition of animal feed, and will submit a draft amendment to Directive 70/373/CEE (see also item 1.3.ii).

Finally, the Commission intends to amend Article 22 of Directive 95/53/CE in order to give itself the possibility of drawing up specific programmes of checks at Union level, laying down in particular their frequency, alongside the general national programmes provided for in that Article.

The SSC recommends to avoid cross-contamination between raw material from different animal species and between the final products to be consumed by different species. The Commission will propose the necessary EC legislation to include measures to avoid contamination of ruminant feed with mammalian protein during production and transport. Furthermore, the Commission will propose the necessary EC legislation to lay down details concerning controls based, if possible, on a uniform analytical method, as soon as such a method will be available and validated.

#### **5.4. Surveillance and control of communicable diseases and other health issues**

##### **i) Establishment of a Community network for the surveillance and control of communicable diseases and of an action programme on rare diseases**

The surveillance and control of communicable diseases is one of the major strands of action in the field of public health. The strategy that the Commission has developed in this area encompasses the following closely - co-ordinated activities:

- Setting up and building on co-operative networks on specific diseases involving the surveillance authorities and competent institutes of the Member States; initiating and developing the most important field epidemiologist training action outside the US, the production and dissemination to the surveillance and control constituencies of monthly survey publications and a weekly electronic bulletin, and the establishment of methods and protocols for collecting and sharing surveillance data; and facilitating regular contacts and co-operative efforts of the surveillance institutes of the Member States, all in the context of the 5-year (1996-2000) Community programme of action on AIDS and certain other communicable diseases.
- Creating, as part of the Community's IDA programme, the appropriate technical infrastructure for the timely and accurate exchange of data between the administrations in charge of the surveillance, prevention, and control of communicable diseases in order to enable them to take the requisite measures as soon as outbreaks occur.
- Undertaking a major co-operative effort with the US in the context of the New Transatlantic Agreement (NTA), and in collaboration with the WHO, to set up a global effective early warning system and response network for communicable diseases.
- Convening expert groups on specific topics of communicable disease surveillance and control (such as Ebola, avian influenza, blood safety, etc.) and providing for the regular mutual consultation and rendering of regulatory advice among key national experts from the Member States.
- Collecting and collating epidemiological data on CJD from focal points designated by the Member States, on the basis of protocols developed in

the context of the 4th Community R&TD Programme and forwarding this information to the Council and the European Parliament, at 6-month intervals, following the express request of the former to assist Health Ministers in their deliberations concerning that disease and its implications for public health action.

- Launching a major initiative to equip the Community with an instrument to counter the emergence or spread of communicable diseases, by tabling a proposal for a decision by the European Parliament and the Council, pursuant to Article 129, to set up a Community network for the surveillance and control of communicable diseases with express obligations on the Member States for detecting and responding to communicable disease outbreaks.

The proposal was presented on 8 March 1996, before the announcement of a possible link between BSE and CJD, and envisaged the compulsory notification, alert, and other public health measures on a number of diseases, including CJD. It aims at securing a broad enabling measure (the decision by the European Parliament and the Council), within which a series of further decisions by the Commission or the Council could be promulgated on specific topics. The areas covered were:

- the creation of a network for the sharing of validated information derived from the surveillance of selected diseases including CJD;
- the establishment of requirements for the epidemiological and microbiological surveillance methods used, including case definitions and the format of data to be transmitted;
- the use of the network for rapid alert in the case of outbreaks/emergencies occurring both within and outside the Community relating to specific diseases;
- the use of the network to provide information to the Member States on control measures applied and the results of special investigations into outbreaks;
- provision for the consultation and co-ordination of the Member States concerning protective measures;
- provision for Community protective measures.

The EP gave a favourable opinion on the proposal on 13 November 1996, as did ECOSOC on 25 September 1996 and the CoR on 13 June 1996. The Commission tabled an amended proposal, accepting most of the EP's amendments, on 5 February 1997.

The Council adopted on 22 July 1997 a common position on this proposal. The Commission reserved its position on the Council's common position, as, in its view, the text agreed by the Council represented a considerable watering down of its initial proposals, especially with regard to the possibility of taking measures at the level of the Community. It pointed out that the goal of the



system proposed was the introduction of appropriate counter-measures both at the national and Community level, and thus exclusion or circumscription of the latter would deprive the system of much of its value.

On 14 January 1998 the European Parliament adopted 22 amendments to the common position. The Commission accepted wholly or partially 17 of these amendments and forwarded to the Council an amended proposal on 13 February 1998. The Council noted that it could not accept all of the Parliament's amendments, and preparatory work is now in hand with a view to the launching of the conciliation procedure once trilogue deliberations have reached the appropriate point.

- A further important step in respect of action on CJD was taken on 26 May 1997 when the Commission presented a communication and a proposal for a European Parliament and Council decision adopting a 5-year Community public health action programme on rare diseases pursuant to Article 129 of the EC Treaty (OJ C203, 3 July 1997, p.6). One of the objectives of the programme is to promote actions in favour of patient and family support groups who have been directly or indirectly affected by rare diseases, including neurodegenerative conditions.

The actions envisaged in pursuit of this objective include:

- promoting the establishment of groups of those persons with the same rare conditions or those professionally involved in order to disseminate their experience, to facilitate training and to co-ordinate their activities at national and Community level;
- promoting collaboration and networking between support groups and the setting-up of umbrella bodies, focusing particularly on efforts to encourage the continuity of work and cross-national co-operation.

The programme explicitly recognises that patient support groups (including sufferers and their families) can play a key role in relation to rare diseases as there is often a lack of information and health care facilities relating to such diseases. Patient support groups have a wealth of knowledge and experience in dealing with rare diseases.

Following the adoption of a favourable opinion by the European Parliament at its March 1998 session, the Commission has forwarded an amended proposal to Council, with a view to the adoption of a common position by the latter at its meeting on 30 April 1998.

**ii) Reinforcement of the protection of the health and safety of workers from risks related to exposure to BSE and TSE agents at work by the adoption of Directive 97/65/EC**

In application of Council Directive 90/679/EEC as amended by Council Directive 93/88/EEC, employers are obliged to carry out a risk assessment for all activities in which workers may be exposed, either inadvertently or

intentionally, to biological agents at the workplace, and to apply any necessary protective measures which result.

On November 1997 the Commission adopted Directive 97/65/EC to be transposed into national law by Member States by 30 June 1998, strengthening the existing provisions under Directive 90/679/EEC on the protection of workers from risks related to exposure to biological agents at work, to cover situations arising from exposure to agents responsible for BSE and other related TSEs, and thus reinforcing the protection of workers, including farmers, abattoir workers, veterinarians, doctors, zoo-keepers and laboratory workers.

Commission Directive 97/65/EC makes technical amendments to the provisions of Directive 90/679/EEC by replacing in particular the existing recommendation by an obligation for the application of containment level 3(\*\*) measures to be applied for all workers exposed to the agents responsible for BSE and other related animal TSEs which will now be classified in the same hazard group as the agent responsible for CJD, including the new variant CJD, under the Community classification of biological agents.

**iii) Proposal on effective surveillance of TSEs in animals in the Member States**

After receiving the opinion of the Standing Veterinary Committee, meeting on 3-4 March 1998, the Commission adopted a Decision concerning epidemiological TSE surveillance and amending Decision 94/474/EC, enabling a harmonised approach in the Member States and imposing a duty to notify detected cases of TSE to the Commission and to the other Member States (Decision 98/272/CE, OJ L 122, 24 April 1998).

As soon as possible, the Commission will submit to the Council and the European Parliament a proposal for a global, long-term system for the surveillance of transmissible spongiform encephalopathies on the basis of Article 100a.

**5.5. Exclusion of risk material from the food and feed chain**

**i) Commission consultation paper on exclusion of high risk material from the feed chain and on a ban on feeding animal protein to ruminants**

The Commission consultation paper was published on the Internet from 14 November 1997.

In addition the Consultation Paper was directly addressed to a number of professional associations, organisations, federations and other bodies, and was presented to the following Committees: the Standing Veterinary Committee, the Standing Committee of Animal Nutrition, the Waste Management Committee and the Veterinary Advisory Committee.

Until the end of February 1998, the Commission received 75 comments on this consultation, from a wide variety of organisations, including farmers, renderers, feed manufactures, meat producers, consumers and professional organisations, as well as from governments of Member States and Third countries, and individual citizens.

All of these comments were accepted by the Commission and are currently being collated and assessed. The relevant document titled "Summary of the Comments Received on the Consultation Paper on Meat and Bone Meal" is available.

This should lead to an amendment to Council Directive 90/667/EEC laying down the veterinary rules for the disposal and processing of animal waste, for its placing on the market and for the prevention of pathogens in feedstuffs of animal or fish origin and amending Directive 90/425/EEC.

**ii) Adoption of a feed ban on MBM not produced in accordance with the standards of Decision 96/449/EC and restriction on use**

On 21 October 1997, the Commission adopted Decision 97/735/EC concerning certain protection measures with regard to trade in certain types of mammalian animal waste.

Following article 1 (2) of this Decision Member States shall ensure that mammalian animal waste falling within the scope of Decision 96/449/EC which has not been processed in accordance with the parameters laid down in that Decision cannot enter the feed chain.

This Decision restricts trade in wastes processed in accordance with the parameters laid down in Decision 96/449/EC to well-defined purposes such as incineration or use as fuel. The Member State of destination must have been informed by the Member State of origin and must have authorised the receipt of the material. The material must be accompanied by an official certificate clearly indicating its use and the fact that it is not for animal consumption.

**iii) SRM: Proposal to exclude specific hazardous materials from the human or animal food chain**

Noting the existence of a simple majority in the Council against the new Commission proposal on the prohibition of the use of material presenting risks as regards transmissible spongiform encephalopathies and repealing Decision 97/534/EC of 30 July 1997, the Commission proposed repealing Decision 97/534/EC. The Council, in contrast, decided unanimously at its meeting on 31 March 1998 to postpone once again, to 1 January 1999, the date of entry into force of the Decision of July 1997 (Council Decision 98/248/EC).

In the light of this decision, the Commission issued a statement saying that it was astonished at this attitude, even though, throughout recent months, the Council had hampered all efforts by the Commission towards the adoption of a

Decision amended in the light of the latest scientific data and aimed at ensuring a Community level of health protection for consumers. Decision 97/534/EC is based on the safeguard clauses of the Directives on veterinary checks on live animals and animal products deriving from Article 9 of Council Directive 89/662/EEC concerning veterinary checks in intra-Community trade with a view to the completion of the internal market and Article 10 of Directive 90/425/EEC concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market.

With regard to the proposal for a global, long-term system of surveillance for transmissible spongiform encephalopathies based on Article 100a, the reader is referred to item 5.3.iii above.

**iv) Labelling of compound feedingstuffs**

Any proposal relating to the quantitative and qualitative labelling of animal feed should permit reliable monitoring of the data and be based on recognised analytical methods. Additional studies of analysis methods are under way (see item 1.3.ii).

**v) Destruction of MBM / Landfill**

• Destruction of MBM

The stockpile of MBM resulting from the Over Thirty Months Scheme (OTMS) stands at present (20 March 1998) at 313.000 tonnes. Concerns have been expressed that this stockpile should be completely destroyed as quickly as possible. The Commission has asked the United Kingdom to provide a plan and a timetable for disposing of animal meal. In a letter dated 2 April 1998, the UK Government said it is pressing forward with negotiations to increase disposals by incineration. First contracts are expected to be concluded in April/May 1998. Provided that any environmental or planning consents can be obtained quickly, the scale of burning will increase substantially in the latter part of 1998. If timescale can be met, the backlog of stored product would be burned over the next 2-3 years.

• Landfill

Question had been raised about whether material had been landfilled. During 1996 the UK authorities took national measures, notified as State aids to the Commission and approved as such in May and June 1996, to provide assistance to slaughterhouses to remove an estimated 40.000 tons of unsalable beef and beef products on the UK market (Beef Stock Transfer Scheme) and a service for the disposal of unsold beef products resulting from the legal measures taken on BSE at Community and UK level (Beef and Beef products Disposal Scheme. According to Commission's information material from these schemes has been landfilled. However the Commission has received no information nor found any evidence of landfill of MBM from EAGGF-funded

schemes (Over Thirty Month Scheme, Selective Cull Scheme, Pre-1996 intervention beef-Reg.1757/96) having taken place.

A set of studies have been carried out to assess the risks from various aspects of disposal of material arising from the BSE situation, including BSE carcasses in landfills. These studies were prepared by a private consultant on behalf of the Environmental Agency of the UK. In November 1997, a national scientific evaluation of these studies was asked. So far, scientific evaluation has not started.

## 6. INTERNATIONAL ASPECTS

### 6.1. Participation, collaboration and membership of the Commission in international organisations

Within the framework of the World Trade Organisation, and in carrying out the re-examination for the SPS (Sanitary and Phytosanitary Measures) Agreement, the Commission is currently assessing whether to propose extending the agreement to include aspects relating to consumer concerns, particularly the well-being of animals.

The Commission, as observer, has continued to participate actively in the meetings of both the World Health Assembly and the Executive Board of WHO. It has been invited and took an active part in the various expert meetings convened by WHO on the topic of both BSE and CJD.

With regard to the IOE, the Commission is to transmit to the Council and the European Parliament a draft Decision formalising the co-ordination procedure between the Member States and the Commission in preparation for the European Community's accession as a full member. The main problem in this respect is the fact that the non-member countries are not prepared to accept the Commission as a full member and speaking on behalf of the Community unless the votes of the 15 Member States are replaced by a single vote for the Community. In addition, the Commission's admission is dependent upon an amendment to the IOE statutes.

As an observer, the Commission plays an active part in the various committees of the Codex Alimentarius. The current situation should be rectified as soon as possible by allowing the Community full member status. A proposal to this effect has been presented to the Council, which has given the Commission a mandate, and negotiations with the Codex Secretariat have begun. The Commission intends to speed up the dossier. It is shortly to present a proposal to the Member States, and hopes that the Community will be a member of the Codex with effect from 1999.

### 6.2. MBM safety standards + general standards in the OIE

With respect to the harmonisation of international standards for the production of meat-and-bone meal the next General Session of the World Organisation for

Animal Health (OIE – Paris) at the end of May is of importance. The present OIE Code on inactivation of transmissible spongiform encephalopathy agents during the production of meat-and-bone meal is less restrictive than our present Community legislation and not fully in line with the recent scientific opinion of the Scientific Steering Committee. The Commission, in its Commission Staff Working Paper on the position to be taken by the Community, proposes to take the recent opinions of the Scientific Steering Committee of 26 March 1998 on gelatine, tallow and meat-and-bone meal into consideration when examining the proposed chapter on bovine spongiform encephalopathy.

### **6.3. Hormones, feedingstuffs additives**

The SPS Agreement covers measures intended:

- to protect animal or plant life or health from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease causing organisms;
- to protect human or animal life or health from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;
- to protect human life or health from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests;
- and to prevent or limit other damage from the entry, establishment or spread of pests.

The SPS allows Members to require imported animals, plants and products to meet their SPS standards (or equivalent provisions).

The hormones case is likely to set the standard for interpretation of the SPS Agreement in future cases, thanks also to the very thorough analysis conducted by the Appellate Body as a result of the EC's appeal of the original panel report.

The original panel report misinterpreted the SPS Agreement and gave a very unbalanced view of WTO Members' obligations under the SPS Agreement. Some interpretations were seen as effectively undermining Members' right to set the level of protection they deemed appropriate, such as:

- the panel's interpretation of international standards as binding norms from which deviation due to a higher level of protection was considered not as an autonomous right, but rather as an exception,
- the panel's finding that the burden of proving that sanitary measure is compatible with the SPS Agreement rested on the country adopting the SPS measure rather than on the country bringing the case to establish the inconsistency of the measure,

- an interpretation of the obligation of “consistency” which equated the mere existence of different levels of protection with a disguised restriction on trade.

The panel’s interpretation of the concept of risk assessment consisted of a purely scientific analysis, without the possibility of taking into account other factors such as control, and without the possibility of taking into account minority scientific views when adopting the SPS measure.

The Appellate Body has corrected such erroneous interpretations. It has correctly shifted the burden of proving that a measure is SPS-inconsistent on the complaining country. It has furthermore clarified that the provisions on harmonisation of sanitary measures on the basis of international standards cannot be taken to mean that Members have an obligation to make their measures conform to international standards. It is sufficient that the measure is reasonably supported by the risk assessment performed. As regards consistency, the Appellate Body made clear that the existence of different levels of protection for different substances or products is not enough; the complaining party must also demonstrate that such difference results in a disguised restriction on international trade.

The Appellate Body’s most important corrections were on the concept of risk assessment. The Appellate Body has confirmed the characteristics of risk assessment that the EC had always thought were incorporated in the SPS, that is the possibility to take into account risks arising from other factors such as control, testing, conditions of use; the possibility for responsible governments to take into account minority scientific view; the absence of the requirement to fix a minimum level of risk, and other factors which have a potential for adverse effects on human health in the real world.

The Appellate body has in fact made a serious step into the direction of restoring the SPS Agreement to its original meaning as always interpreted by the EC. Distorted views of the application of the SPS Agreement from future panels now seems less probable.

However, the Appellate Body has confirmed that the ban on the use of six growth hormones in meat production is not based on a sufficiently specific risk assessment to show the existence of residues constituting a risk to the consumer. The Community has undertaken to abide by the Appellate Body’s conclusions on this point, and to then amend Community legislation where necessary in line with the results of a supplementary risk assessment.

In this context, the Commission has started work on generating the scientific data required for a risk assessment linked more specifically to the residues from these six hormones and their metabolites in meat.

The Commission has freed financial resources for the scientific studies required to produce the missing data. It has also asked the USA, Canada, New Zealand and Australia to forward the scientific and risk assessment data they have used in granting legal authorisation for the use of these hormones, as set out in the SPS agreement.

The Scientific Steering Committee has appointed the Scientific Committee on Veterinary Measures relating to Public Health to study the new data to be obtained, and the risk assessment to be carried out by a group of experts, and to give its opinion to the Commission.

Meanwhile, Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC remains in force.

On the basis of a report from the Scientific Committee on Animal Nutrition, the Commission has adopted a Directive amending Directive 70/524/EEC, which bans the use of ronidazole as an additive in feedingstuffs.

The Committee is currently assessing certain aspects of carbadox, olaquinox and dimetridazole as additives in feedingstuffs. This examination follows the application of a safeguard clause by some Member States. In addition, within the framework of Directive 70/524/EEC as amended by Directive 96/51/EC, antibiotic, coccidiostatic and other medicinal additives, as well as growth promoting substances, authorised prior to 1 January 1988, will be systematically reassessed for a final decision before 1 October 2003 as to whether to retain or prohibit them as additives.

On a wider scale, the Scientific Steering Committee has had put before it the question of the increasing resistance noted to anti-microbial agents, underlined both by individual scientists and international organisations such as the WHO. The Committee has been invited to examine this question within a multidisciplinary framework covering all areas of use of these products.

## **7. *nvCJD VICTIMS: CURRENT SITUATION AND ASSISTANCE TO nvCJD VICTIMS ORGANISATIONS***

### **7.1. *Current situation regarding CJD and nvCJD cases in the EU***

#### *UPDATE ON EPIDEMIOLOGICAL DATA*

- *Questionnaire*

In order to collect and compile the latest epidemiological data on transmissible spongiform encephalopathies (TSEs), an updated questionnaire was sent in January 1998 to the specialised centres designated by the Member States for the diagnosis of CJD. Additional questions related to the risk management of blood and blood products in relation to human TSEs were introduced.

- *Notification requirements*

With Sweden's decision in April 1998 to make CJD a notifiable disease, the number of Member States having such a requirement rose to 9 (see annex 3, table 1). The criteria as to what is to be notified, however, have not yet been standardised: the majority of Member States include all suspected cases of CJD while two require confirmed cases (Austria and Ireland). The situation regarding



familial CJD cases is not clear. France includes Gerstmann-Sträussler-Scheinker syndrome (GSS) and Fatal Familial Insomnia (FFI) in the criteria of a notifiable disease, while Germany explicitly excludes GSS. The criteria for Sweden are at present unknown.

- *Case referrals*

The number of cases referred to the CJD diagnostic centres for assessment (see annex 3, table 2) increased between 1996 and 1997 in all Member States, except Spain, Germany and the Netherlands. This increase included persons both younger and older than 50 years. In France, the dramatic increase (nearly 350% since 1995) can be attributed in part to a change in the database records, which now include all referred cases rather than only those diagnosed as CJD prior to 1996, and to a policy of 14.3.3 protein and enolase examinations in patients for whom CJD diagnosis is very unlikely. Another explanation for this increase in many Member States is selection bias, as increased awareness among physicians of this problem results in more referrals of patients with neurological disorders for CJD diagnosis. Of importance is the fact that responses from many Member States on consecutive questionnaires show different referral data, indicating corrections over previous years and the absence of a uniform way to define a 'referral'. Clarification as to what is meant by 'referral' in each Member State is required.

- *Probable and definite cases of sporadic CJD*

The survey questionnaire sought data on the probable and definite cases of sporadic CJD in 1995, 1996 and 1997. The resulting data (see annex 3, figure 1) must be interpreted with caution, since a long delay exists between the onset of the disease and diagnosis by a specialised centre. Data from the United Kingdom are based on deaths, whereas those of the other Member States are based on cases. Two thirds of these cases were recorded as 'definite' for 1995 (65%) and 1996 (67%) and only 54% in 1997. Important variations still exist between Member States: for instance in 1997, 100% of cases were 'definite' in Sweden and Finland, 90% in UK but only 13% in the Netherlands. Sometimes variations exist within one Member State (for example, 'definite' cases in the Netherlands represent 73% and 13% of total cases in 1996 and 1997 respectively).

- *Cases of nvCJD*

Regarding new variant CJD, the total number of definite and probable cases to date is 25 in the United Kingdom and 1 in France. A problem exists, however, regarding the date of notification. For instance, in France, the nv-CJD case was indicated in the previous survey as a 1996 case, according to the date of diagnosis. In this survey, the case is now classified as being from 1994 - when the first symptoms appeared.

- *Blood products and CJD*

With regard to the safety of blood products, no differentiation was made in the survey between the labile components used for transfusion and the industrially manufactured medicinal products derived from blood and plasma. The approach taken towards the safety of blood products is summarised in table 3. With respect to determining donor suitability, most Member States have introduced specific

permanent deferral criteria that are generally the same in all Member States. WHO exclusion criteria are cited by two Member States (Austria, Italy) while Finland follows the Council of Europe recommendations. The approach taken with regard to medicinal products derived from blood and plasma that may be considered to be contaminated is mainly to follow the advice issued by the Committee for Proprietary Medicinal Products (CPMP). Requirements in some Member States, however, appears to be stricter such as in France, where the withdrawal of products covers all TSE cases; Germany, where all products except plasma are withdrawn for familial or sporadic cases; and Ireland, where the policy of the Food and Drug Administration of the United States (FDA) is followed. Recommendations on the processing blood products are not homogeneous. As the introduction of leucodepletion is currently being contemplated in many Member States, consideration should be given to laying the foundation for a common European Community position regarding the efficacy and efficiency of this process, based on sound scientific evidence, with a precise description of the methodology. Finally, the approach that is taken by Member States with regard to informing recipients of potentially contaminated blood products differs. Some Member States do not provide any information, one provides it to the attending, one considers this on a case by case basis and in others this subject is under discussion.

## **7.2. Assistance to nvCJD victims organisations**

Following the creation of a new budgetary line (B3/4308) entitled 'Support for Associations seeking to help victims of Creutzfeldt-Jacob disease', the Commission services have had contacts with the Human BSE Foundation and the UK authorities.

The Commission services have written to the Human BSE Foundation asking for further information in order to prepare a proposal for a budgetary transfer. The Commission intends to submit the transfer proposal as quickly as possible.

## **8. FRAUDS AND FINANCIAL ASPECTS**

### **8.1. Fraud: co-ordination**

A lack of co-ordination between the police and customs services of the Member States was not a major issue in this affair. However, due to a certain lack of co-operation between national customs and veterinary services, UCLAF considered it necessary to remind the competent authorities appointed by the Member States to act as correspondents for the application of Regulation (EEC) N° 1468/81 and Regulation (EEC) N° 595/91 of the need to notify the Commission of irregularities suspected or established by the veterinary services.

UCLAF did make use on two occasions of its powers under the new Regulation (EC) N° 2185/96 on on-the-spot checks.

The importance of future relations between UCLAF and EUROPOL has been emphasised in the Commission's "fight against fraud" work programme 1997/1998<sup>1</sup> (point 1.9). A continuing process of consultation has been established in the context of Recommendation 10 of the Action Plan approved by the European Council of Amsterdam in June 1997 with regard to organised crime<sup>2</sup>.

However, the EUROPOL convention has not yet been ratified by all Member States. Moreover, this convention would not by itself provide a proper legal basis for action in this area in the form of a fully co-ordinated criminal investigation among the Member States involved.

Judicial enquiries in Belgium, the Netherlands, France and Germany are still ongoing. Rogatory requests from Germany, the Netherlands and Belgium have been sent to the Northern-Ireland authorities. The Commission has been informed by the Dutch magistrate dealing with this matter of the intention to transmit, in due course, the Dutch judicial file to the Belgian examining judge in Brugge who is in charge of the relevant investigations against one company.

The enquiries undertaken by the British Ministry of Agriculture, Fisheries and Food have made considerable progress and a final report of the investigations is expected soon. An independent legal Counsel will then decide on the breaches of national and EU legislation.

Recovery actions regarding refunds unduly paid for exports to third countries of beef of UK origin are being undertaken in France, the Netherlands and Germany.

In the framework of the "black-list"-regulations, to date only Germany has reported the name of the companies involved in these cases. No such reports have been received from Belgium, France or the UK.

**8.2. Financial consequences from findings on the Over Thirty Months Scheme (OTMS) and the selective cull scheme, should there be justifications of failures by the UK authorities to respect Community Regulations**

An interim report on the work undertaken by the Clearance of Accounts Unit in relation to the BSE measures to 31 December 1998 (Doc. No. VI/633/98 of 5 February 1998) was forwarded to the Budgetary Control Committee by letter No. 06344 of 9 February 1998.

The report stated that in relation to the OTMS, numerous observations and subsequent recommendations have arisen from the control missions made. The 3 main problem areas established by the Clearance of Accounts Unit concern accounting, the control of storage, and the lack of plans for destruction of the majority of the scheme material still held in storage.

---

<sup>1</sup> COM (97) 199 final of 06.05.1997  
<sup>2</sup> OJ N° C 251 of 15.08.1997, page 1

Although no final position on all financial consequences can be reached at this stage by the Clearance of Accounts as regards the BSE measures, since only an 80% advance has been paid of the EAGGF financial contribution to the OTMS, the procedure in accordance with Art. 8 of Reg. No. 1663/95 has already been launched concerning the weaknesses in control procedures, particularly in the first months of the scheme, and accounting. The first bilateral meeting was held in Brussels on 05 December 1997. The formal notice of the results of these bilateral discussions including the requests for further information were forwarded to the UK authorities on 15 December 1997. A UK reply was received on 18 February 1998.

If the Commission services decide to propose financial consequences after an in-depth examination of the reply, which is currently being undertaken, and taking into account the fact that only advances have as yet been paid, the formal conclusions must be notified to the UK authorities, which will then have 30 working days to appeal to the conciliation body. Should this be the case the conciliation body then in accordance with art. 2(4) of Commission Decision 94/442/EC has 4 months to review the case. Only when the Conciliation body has finished its work can a final proposal for an ad hoc decision be submitted for consultation of the EAGGF Committee and subsequently for decision by the Commission. It is expected that after completion of internal procedures a Commission decision will be adopted in December 1998.

A correction in relation to the pre-1996 ,UK intervention beef, Reg. N° 1757/96 is also currently under consideration in light of weight differences and some control deficiencies established. This correction will be subject to the same conciliation procedures as the eventual OTMS correction.

\* \*  
\*

### III. ANNEXES

#### Annex 1A: Joint call for proposals on TSE

| <b>JOINT CALL FOR PROPOSALS ON TSE</b> |  |
|--|--|
| <b>PL 976003</b>                       | <p><b>“Transgenic mice expressing human prion protein. Use for characterisation of human encephalopathies and sensitivity for detection of infectivity”.</b> Co-ordinator: <b>Professor HAUW (FR).</b></p> <p>The project intends to assess the susceptibility of a transgenic mouse carrying the human prion protein to classical forms and new variant of Creutzfeldt-Jakob-Disease. The project will also validate a sensitive tool for the assessment of human-derived tissues and biological products.</p>  |
| <b>PL 976006</b>                       | <p><b>“Investigation of putative signal transduction processes of normal prion protein and their role in spongiform encephalopathy pathogenesis”.</b> Co-ordinator: <b>Professor ANDERTON (UK).</b></p> <p>The project intends to investigate the role of prion protein on signal transduction and explore the possibility of prion protein influencing intracellular calcium concentrations.</p>  |
| <b>PL 976011</b>                       | <p><b>“In vitro investigation of PrP-induced neurodegeneration: development of a system for testing potential therapeutic agents”.</b></p> <p>Co-ordinator: <b>Professor WILLIAMS (UK).</b></p> <p>The project will develop an in vitro system of cultured cells in order to investigate the effects of prion protein neurotoxicity as well as the ability of selected compounds to reduce or abolish these effects of the prion protein.</p>  |
| <b>PL 976013</b>                       | <p><b>“PrPsc distribution and kinetics in lymphoid tissues of sheep with natural scrapie: effects on sheep PrP genotype and scrapie strains”.</b> Co-ordinator: <b>Professor VAN KEULEN (NL).</b></p> <p>To study distribution and kinetics in lymphoid tissues in sheep with natural scrapie using a recent developed technique based on the detection of PrPsc in tonsil biopsies.</p> <p>Identification of scrapie-infected sheep with a possible carrier status.</p> <p>Differences between scrapies strain endemic in the EU.</p> <p>Development of a pre-clinical diagnostic test for scrapie using easily accessible tissues.</p> |
| <b>PL 976015</b>                       | <p><b>“European centralised facility for human transmissible spongiform encephalopathies (prion diseases)”.</b> Co-ordinator: <b>Professor BUDKA (AT).</b></p> <p>The project is aimed at establishing a centralised facility for the harmonisation and quality control of clinico-epidemiological and neuropathological criteria for the diagnosis of human prion diseases.</p>   |
| <b>PL 976016</b>                       | <p><b>“Analysis and function of 14-3-3 isoforms. Early diagnosis of CJD”.</b> Co-ordinator: <b>Professor AITKEN (UK).</b></p> <p>The project intends to establish a role for protein 14-3-3 in prion diseases and develop immunoassay tests as a tool for diagnosis of human prion diseases</p>  |

|           |  |
|-----------|--|
| PL 976022 | <p><b>“Role of PrP in prion spread and establishment of central nervous system infection”. Co-ordinator: Dr DORMONT (FR).</b></p> <p>To study prion spread and replication: passage of prion through the intestinal barrier; identification of the cell types supporting transmucosal transport and primary replication of prions after oral administration.</p> <p>Passage of prion through the skin; role of dendritic cells in prion spread.</p> <p>Nature of the neuro-immune interface; transfer of prion from lymphoid tissue to nerve cells.</p> <p>Replication in the central nervous system and the species barrier requirements.</p> <p>Replication in the centre nervous system and PrP expression and timing</p> |
| PL 976027 | <p><b>“The role of plasma membrane structure and oxidative stress in prion propagation, transport and pathogenesis”. Co-ordinator: Professor KRISTENSSON (SE).</b></p> <p>The project intends to assess the role of oxidative stress in the development of prion diseases. In addition, the transmission of the prion infection from cell to cell will also be studied.</p>  |
| PL 976029 | <p><b>“Risk assessment in primates of TSE transmission to humans through food and blood products”. Co-ordinator: Professor HUNSMANN (DE).</b></p> <p>The project intends to evaluate the possibility of risk transmission of BSE to humans through consumption of contaminated food. The minimal dose of infectious agent needed to produce infection will be assess. In addition, the project intends to evaluate the risk for blood transmission of the disease.</p>   |
| PL 976030 | <p><b>“TSE spiking experiments for process validations: evaluation of different sources of infectivity and spiking approaches”. Co-ordinator: Dr REICHL (AT).</b></p> <p>This proposal aims at evaluating different sources of infectivity and spiking approaches. The proposal also intends to evaluate existing and emerging in vitro assays by comparing them with in vivo assays.</p>  |
| PL 976040 | <p><b>“Prion diseases: mechanisms of transmission and identification of targets for potential therapeutics.” Co-ordinator: Dr COLLINGE (UK).</b></p> <p>This project will aim at attempting to modify the expression and availability of the abnormal prion protein and try to develop peptides as a potential therapeutic strategy.</p>   |
| PL 976045 | <p><b>“Maintenance and transmission of yeast prions: a model system”.</b></p> <p><b>Co-ordinator: Dr TUIE (UK).</b></p> <p>The proposal is using yeast prion as a model system to identify the key cellular factors responsible for the maintenance and transmission of prion proteins.</p>  |
| PL 976046 | <p><b>“Diagnosis of transmissible spongiform encephalopathies using PrPSc/PrPc specific antibodies”. Co-ordinator: Professor KRETZSCHMAR (DE).</b></p> <p>The proposal aims at developing diagnostic methods for human and bovine TSEs using PrP/PrPsc specific antibodies.</p>  |
| PL 976048 | <p><b>“Quantitative analysis of MR scans in CJD”. Co-ordinator: Professor COLCHESTER (UK).</b></p> <p>The objective of this project is to assess the ability of magnetic resonance as a diagnostic tool for the identification in vivo of Creutzfeldt-Jakob-Disease and compare it with the existing diagnostic procedures (clinical diagnosis and autopsy). The potential impact of such a project is very high.</p>  |
| PL 976050 | <p><b>“The bovine prion protein: from structure analysis to the molecular mechanism of conformational transitions”. Co-ordinator: Professor SORGATO (IT).</b></p> <p>The project is aimed at the identification of the structure of the prion protein and its conformational changes. This could lead to a better understanding of the mechanism of plaque formation and may provide further insight into further programmes to design therapeutic or diagnostic agents.</p>   |

|           |  |
|-----------|--|
| PL 976051 | <p><b>“Structure, function and interactions of prion proteins and prion protein domains”. Co-ordinator: Professor KRETZSCHMAR (DE).</b><br/> This project studies the structural and functional features of the different domains of the prion protein, their interactions and the conditions by which the normal protein becomes abnormal.</p>  |
| PL 976054 | <p><b>“Development of TSE therapies based on prion protein-binding oligosaccharides”. Co-ordinator: Professor GABIZON (Israel).</b><br/> The project is aimed at identifying chemical compounds which interact with the prion protein and then determine whether they influence TSE infection in tissue culture and in TSE animal models.</p>  |
| PL 976055 | <p><b>“Trafficking pathways of normal and pathologic isoforms of the prion protein”. Co-ordinator: Professor LEHMANN (FR).</b><br/> The proposal aims to understand how PrPc converts to PrPsc. To approach this issue the proposers will elucidate the trafficking of PrP and the molecular interactions that control it.</p>   |
| PL 976056 | <p><b>“Concerted action for the setting up of multicentric epidemiological databases and biological samples banks for small ruminants scrapie”. Co-ordinator: Dr LANTIER (FR).</b><br/> To create a network on the standardisation of methods for biological sampling procedures, diagnostic techniques and the collection of clinical and epidemiological data.<br/> Setting up of infected biological materials banks and multicentre epidemiologies and data bases.</p> |
| PL 976057 | <p><b>“Building a common database on scientific research and public decision on TSE in Europe”. Co-ordinator: Dr JOLY (FR).</b><br/> The project is aimed at creating a database which will include, chronologically, information on the emergence of scientific information on BSE and related disorders and the response to those developments in the form of research projects and programmes and in the form of expert and official regulations .</p>                  |
| PL 976060 | <p><b>“Cerebellar networks alterations in prion diseases”. Co-ordinator: Professor AXELRAD (FR).</b><br/> The proposal deals with the mechanisms of prion induced pathogenesis in TSE's as well as the role of normal PrPc. The proposal will address whether it is the loss of PrPc or the accumulation of PrPsc which triggers the physiopathological events in prion diseases.</p>  |
| PL 976064 | <p><b>“Development of cell culture models of infectious forms of TSE.”</b><br/> <b>Co-ordinator: Professor LAUDE (FR).</b><br/> The objective of this proposal is to develop cell culture models for the study of PrP. These cell lines can be used in transfection studies and in trafficking studies and replace animal studies.</p>   |
| PL 976065 | <p><b>“Inactivation of the causative agents of transmissible spongiform encephalopathies by thermophilic and hyperthermophilic proteases”. Co-ordinator: Professor RAVEN (UK).</b><br/> The aim of this proposal is to attain inactivation of the infective agent of TSE's by the action of highly thermostable proteolytic enzymes.</p>   |

*Annex 1B: Research themes*

| RESEARCH THEMES <sup>1</sup>  | SPECIFIC PROGRAMMES CONCERNED              |
|---|--|
| <p><b>4. Risk Assessment of SE's</b></p> <p>Proposals with a multidisciplinary approach, including basic research, mathematical modelling, as well as other aspects of risk analysis, leading to quantitative risk assessment, will be encouraged.</p>  |  |
| <p><b>4.1. Evaluation of SE's transmission modalities (including oral transmission) from cattle to man and other food animals, environmental vectors</b></p> <ul style="list-style-type: none"> <li>- possible transmission through animal derived products e.g. gelatine, tallow; and rendering;</li> <li>- transmission studies in food animals;</li> <li>- pathogenesis of BSE in sheep, across a range of European genotypes;</li> <li>- feeding of meat and bone meal;</li> <li>- search of possible factors (genetic factors) and cofactors (nematode infection, mites, etc.).</li> </ul>   | <p>BIOMED (*)<br/>and<br/>FAIR (***)</p>   |
| <p><b>4.2. Extended surveillance programme on BSE and related diseases</b></p> <p>Establishment of a European network for the epidemiological surveillance of BSE and related diseases aiming at assessing: e.g.</p> <ul style="list-style-type: none"> <li>- standardisation and harmonisation of the process and criteria (neuropathological, clinical and biological diagnosis) of identification of suspected cases;</li> <li>- the incidence, geographical distribution and role of specific risk factors (genotype, feeding regime, exposure, environmental, etc.);</li> <li>- assessment of the surveillance system and development of quality control procedures;</li> <li>- comparison of scrapie strains with BSE.</li> </ul> | <p>FAIR (***)</p>                          |
| <p><b>4.3. Determine incidence of covert disease in cattle</b></p> <ul style="list-style-type: none"> <li>- BSE: Pre-clinical disease and latent infection in cattle, sheep and other species (ruminants and non-ruminants);</li> <li>- Scrapie: Pre-clinical disease and latent infection in sheep.</li> </ul>   | <p>FAIR (***)</p>                          |
| <p><b>4.4. Determine infectivity titre of cattle tissues and cattle derived products entering the human food chain or used in pharmaceutical and cosmetic products.</b></p> <p>It will also include:</p> <ul style="list-style-type: none"> <li>- determination of infectivity levels in human blood;</li> <li>- effect of different processing methods of blood and blood products on infectivity level;</li> <li>- sheep and sheep derived products.</li> </ul>   | <p>BIOTECH (**)<br/>and<br/>FAIR (***)</p> |
| <p><b>4.5. The potential exposure of human population</b></p> <p>Environmental contamination:</p> <ul style="list-style-type: none"> <li>- survival of the agent in the environment e.g. dust, soil, rats, mice;</li> <li>- safe disposal of specific risk material;</li> <li>- safe handling of meat and bone meal;</li> <li>- methods of disposal: incineration, composting, rendering, biogas;</li> <li>- methods of validation for effectiveness of inactivation and handling procedures;</li> </ul>  | <p>BIOMED (*)</p>                          |

<sup>1</sup>

Referring to the communication from the Commission on "A European initiative on transmissible spongiform encephalopathies" COM(96)582 final of 13.11.1996.



|   |  |
|---|--|
| <ul style="list-style-type: none"> <li>- effluents;</li> <li>- safety of workers;</li> <li>- disinfection;</li> <li>- risk perception of the population in relation to exposure.</li> </ul>   |  |
| <p><b>4.6. Determine contamination level of meat with brain/spinal cord after standard butchering procedures</b></p> <ul style="list-style-type: none"> <li>- risk assessment of current diversity of slaughtering, butchering and meat recovery procedures in Europe;</li> <li>- safety of abattoir workers.</li> </ul>  | FAIR (***)   |
| <p><b>4.7. Determination of oral feeding and intracerebral dose responses to BSE agent and whether multiple doses is cumulative</b></p>   | FAIR (***)   |
| <p><b>4.8. Investigation of possible biological mechanisms of maternal transmission of BSE</b></p>  | FAIR (***)   |
| <p><b>5. Treatment and prevention of SE's</b></p> <p>5.1. Assessment and development of inactivation procedures currently used in industry (food, pharmaceuticals, cosmetics). Development of alternative procedures will also be considered.</p>   | BIOTECH (**)<br>and FAIR (***)   |
| <p><b>6. Co-ordination of research activities between the Member States</b></p> <p>6.1. Standardisation of case definitions for collection of data, of data analysis and of dissemination of information in order to ensure a proper surveillance.</p> <p>6.2. Harmonised procedures for early detection and diagnosis of the disease(s).</p> <p>6.3. Continuous updating and dissemination of scientific knowledge in this field.</p> <p>6.4. Fluent and rapid dissemination of these data.</p> <p>6.5. Activation of an early warning system in case of crucial developments.</p> <p>6.6. Exchange and mobility activities including training of research staff. In areas such as diagnosis:</p> <ul style="list-style-type: none"> <li>- creation of network of laboratories with the aim of exchanging staff for shorter periods, 1-3 months.</li> </ul> <p>6.7. A continuous inventory of the progress of national research programmes.</p> <ul style="list-style-type: none"> <li>- creation of a European network of national information centres.</li> </ul> <p>6.8. Harmonisation and control of diagnostic methods for human and animal SE's.</p> | <p>BIOMED (*) and FAIR (***)</p> <p>BIOMED (*) and FAIR (***)</p> <p>BIOMED (*) and FAIR (***)</p> <p>BIOMED (*) and FAIR (***)</p> <p>BIOMED (*) and FAIR (***)</p> <p>BIOMED (*) and FAIR (***)</p> <p>BIOMED (*) and FAIR (***)</p> <p>BIOMED (*) and FAIR (***)</p> <p>BIOMED (*) and FAIR (***)</p> |

\* Specific programme of research and technological development, including demonstration, in the field of Biomedicine and Health (1994-1998).

\*\* Specific programme of research and technological development, including demonstration, in the field of Biotechnology (1994-1998).

\*\*\* Specific programme of research and technological development, including demonstration, in the field of Agriculture and Fisheries (including agro-industry, food technologies, forestry, aquaculture and rural development).

**Annex 2A: Summary and Conclusions of Missions to all Member States in 1997  
regarding Decision 96/449/EC**

**1. Introduction**

On 1 April 1997 "Commission Decision 96/449/EC on the approval of alternative heat treatment systems for processing animal waste with a view to the inactivation of spongiform encephalopathy agents" came into effect. This Decision caused the major change ever required from the animal waste industry, which had to comply with the requirements in the Decision within 8 months.

Missions to all Member States (except Luxembourg which has no rendering industry,) were carried out from June to December 1997. The following issues were covered by the missions:

- National legislation to ensure compliance with the Decision.
- Processing requirements used by the rendering industry.
- Use of derogations as foreseen by Article 1(2) and Article 2(5) of the Decision.
- System of official authorisation, control and validation as foreseen in Article 2(1), (2) and (3) of the Decision.
- Verification on-the-spot.

To guarantee a harmonised inspection approach the responsible inspectors developed guidelines for the plant visits taking into account the report of the Scientific Veterinary Committee on procedures for the validation of rendering procedures (Doc. VI/8490/94 Rev.1).

The draft reports have been sent to the Member States concerned and will be finalised in light of the comments received from national authorities<sup>1</sup>.

This note gives an overview on the situation with regard to implementation of Decision 96/449/EC in the European Union as a whole. Reasons and consequences for cases of incomplete implementation are described. Furthermore, remarks on other aspects of implementation of EU legislation in the field of animal waste processing are given. Recommendations for improvements based on the mission results are made.

---

<sup>1</sup> A summary of the findings of each mission was included in the Commission's special report concerning recommendations on BSE, January 1998.

The points have been discussed with the Member States.

In reference to points 5 and 6 action has been initiated by the Commission in order to follow up points raised by the inspection service and to reconsider legislation, taking into account the latest scientific advice, a working programme has been established.

## **2. Results of missions**

### **2.1. State of implementation of Decision 96/449/EC:**

None of the Member States, except Finland, had fully implemented the Decision, even the degree of non-compliance varied. The shortcomings were severe in certain cases.

However, it must be recognised that major efforts were developed by a large part of the industry in the Community. As regards Finland, it should be noted that a specific derogation was laid down in Commission Decision 96/449/EC for the fur animal industry, which eased the implementation of the Decision.

### **2.2. Reasons of incomplete implementation:**

There are three major reasons:

- The decision of certain Member States not to apply or not to fully apply the Decision.

In particular Article 1(2) of the Decision is interpreted in a way, which differs from the interpretation of the Commission. Infringement procedures were already opened before the missions in these cases.

- The high number of rendering plants in certain Member States, which do not yet comply with the new legal standards and have to install new equipment. It was declared that difficulties were faced by the industry to be supplied with adequate equipment in a relatively short implementation period.
- Deficiencies in the administrative action.

Administrative guidance by central authorities was insufficient or delayed in some cases. In other cases the field veterinary services were deficient by not following the appropriate authorisation procedures, in particular by not performing proper validation or by not inspecting the processing parameters or the storage and movement of improperly processed meat- and bone-meal in a reliable manner.

## **3. Consequences of incomplete implementation**

It was observed that improperly treated meat- and bone-meal entered the animal feed chain.

Some of the material was treated according to the parameters in place before Decision 96/449/EC came into effect (see Decision 94/382/EC). These treatment standards lead to a reduction of the potential level of TSE agents present.

Other material, in particular in cases where Member States considered it to be covered by the derogations of Article 1(2) of Decision 96/449/EC, was not treated in accordance with any standard. The latter material should be considered

as not having undergone any treatment reducing the potential level of TSE agents present.

Furthermore, intra-Community trade and export to third countries of improperly treated material was observed. No specific EC rules for this trade were in place until Commission Decision 97/735/EC entered into force in October 1997. In some cases no structures were in place to ensure further processing or final destruction of this material at the point of destination. Where this material originated in Member States with cases of BSE this practice is a reason of particular concern. Improperly processed material entering the feed chain following national or international trade creates serious health risks and has a negative impact on the TSE status of the Community as a whole.

#### **4. Other shortcomings**

Shortcomings of a general nature identified during inspections carried out in 1996 have been described in a working document presented to the Standing Veterinary Committee in May 1997 (Doc. VI/2001/97). Part of these deficiencies had not been corrected. The following shortcomings were observed in the second half of 1997:

Traceability of meat- and bone-meal was not ensured at the time of the mission. (It was too early to assess possible effects of Commission Decision 97/735/EC on this subject).

- In some Member States there is insufficient precaution in avoiding suspect BSE cases to enter the feed chain. (This observation was already included in the above-mentioned working document (see no.1.3.7) and confirmed by events in Germany, Belgium and Luxembourg).
- There are deficiencies in the self-controls and official controls over the processing requirements of the rendering industry. There is a lack of training and knowledge amongst the officials responsible.

In particular, the validation and calibration of the equipment and precautionary safety devices create difficulties (see no. 1.3.6 of the above-mentioned working document). The validation procedures defined by the Scientific Veterinary Committee (see Article 2(2) of Decision 96/449/EC) are not helpful to the services as they were not drafted specifically for plants working under the standards of Decision 96/449/EC and as they give questionable advice on certain control aspects, in particular concerning the particle size.

- Deficiencies with regard to implementation of Directive 90/667/EC were still observed in some Member States, mainly with regard to registration of plants, microbiological controls (bacteria to be tested, products to be tested, definition of a batch) and general hygiene in approved plants.

#### **5. Points which need further consideration**

The following issues were identified where no satisfactory answer could be given to technical or legal questions arising during the missions:

- a) In some rendering plants interruption of the 20 minutes heat-treatment of single batches was observed. Does Decision 96/449/EC require uninterrupted treatment for 20 minutes?
- b) Improperly treated meat- and bone-meal, derived from high risk material within the meaning of Directive 90/667/EEC could be included in pet-food. Would this practice be in conformity with Article 1(2) of Decision 96/449/EC?
- c) Article 4(1)b of Decision 97/735/EC sets the 31.3.1998 as the final date for intra-Community trade in improperly treated material designated for reprocessing in the Member State of destination. Is it consistent and appropriate to accept reprocessing as a national option?
- d) Is fertiliser containing relevant mammalian animal waste, a product covered by the derogations of Article 1(2)b of Decision 96/449/EC (“products derived from mammalian animal waste, which can be assured, will not enter any food or feed chain”)? If the answer is no, this would require the fertiliser to be treated with the pressure standard.
- e) Is the exemption for catering waste from the requirements of Decision 96/449/EC justified (catering waste is not covered by the definition of animal waste laid down in Council Directive 90/667/EEC)?
- f) The different status of rendering plants approved under Directive 90/667/EEC which may or may not be authorised under Article 2(2) of Decision 96/449/EC, are not reflected by the approval numbers of most Member States. Would it be advisable to introduce an approval numbering system allowing differentiation of the status of the plants?

## **6. Follow-up / recommendations**

- 6.1. All efforts should be made to achieve full implementation of Decision 96/449/EC.
- 6.2. Some infraction procedures had been opened due to lack of implementation of Decision 96/449/EC already before the inspection started. On the basis of the inspection results further infraction procedures are considered by the responsible Commission Service (DG VI).

One of the reasons for opening such a procedure was the interpretation of some Member States that bone rendering is excluded from the provisions of Article 2(1) (“pressure cooking”) if the bones were derived from animals fit for human consumption. In light of the risks relating to the ongoing practice of bone rendering without pressure cooking in these Member States and the long duration of the infraction procedures, it is recommended to the Commission to clarify the scope of the derogations of Article 1(2)a of the Decision.

- 6.3. The issues raised in n° 5 above should be clarified.

- 6.4. If reprocessing of improperly treated material is accepted as a long-term solution, Member States should be obliged to introduce appropriate controls to avoid leakage into the feed chain.
- 6.5. The Scientific Veterinary Committee should review its document on validation procedures under the following aspects:
- the document should concentrate on the standards of Decision 96/449/EC;
  - details concerning the day-to-day control activities should not be fixed in this document;
  - recommendations on the calibration of measuring equipment should be considered;
  - the guidelines should be reconsidered with regard to the frequency and the tolerance for controls of the particle size.
- 6.6. Certain aspects of Directive 90/667/EEC should urgently be reassessed in light of developments with regard to BSE. In particular the destruction of improperly treated material for further processing or incineration puts in question the need of microbiological testing of this material required by this Directive. Furthermore, the different hygienic and control requirements for high risk and low risk processing plants are questionable. In particular the limitation of the requirement to keep records and accompanying documents to high risk material within the meaning of Directive 90/667/EEC is critical (see Annex I n° 3 of that Directive).
- 6.7. Guidelines for official controls of the rendering industry should be developed and implemented in all Member States. Training should be provided to responsible staff to enable them to control the industry effectively.
- 6.8. The FVO should undertake follow-up inspections. The scope of inspections should be enlarged to take into account the basic Council Directive 90/667/EEC and EC legislation concerning international trade of raw material and products. (A further round of inspections, in particular concerning Commission Decision 97/735/EC and to follow-up deficiencies with regard to Decision 96/449/EC has been started in early 1998).

***Annex 2B: Animal waste legislation – Working programme 1998***

The following legislative working programme on animal waste legislation for 1998 was presented and discussed at a working group meeting of 16 April 1998.

**A. Commission Decision amending Decision 96/449/EC to take into account:**

- Problems of legal interpretation raised during the infringements procedures;
- Results of EC inspection missions;
- New scientific advice on tallow and Meat-and-Bone meal.

A draft proposal will be discussed at the ad hoc working group on 20 May 1998.

**B. Commission Decision amending chapter 9 (lard and rendered fats) Directive 92/118/EC (trade and imports) to take into account:**

- New scientific advice on tallow

A draft proposal will be discussed at the ad hoc working group on 20 May 1998.

**C. Commission Decision laying down the animal health requirements and the veterinary certification for the importation of lard and rendered fats from third countries**

A draft proposal will be discussed at the ad hoc working group on 20 May 1998.

**D. Commission Decision laying down specific health conditions for the preparation of gelatine intended for human consumption**

A draft proposal will be discussed at the ad hoc working group on 4 May 1998.

**E. Commission Decision laying down the health requirements and the veterinary certification for the importation of gelatine from third countries**

A draft proposal will be finalised on the basis of the outcome of the ad hoc working group meeting on 4 May 1998.

**F. Council Directive amending Directive 90/667/EEC to take into account:**

- New scientific advice on Meat-and-Bone Meal;
- Future expected scientific advice on fallen stock, risk assessment on means of disposal of animal waste, safety of fertilisers etc.;
- Outcome of the Consultation Paper on Meat-and-Bone Meal

A draft proposal will be finalised as soon as the above scientific advice will be available.

**Annex 3: Current situation regarding CJD and nvCJD cases in the EU**

**Table 1: Situation regarding CJD as a notifiable disease**

| Member State    | CJD notifiable | date of onset | definition   |
|-----------------|----------------|---------------|--|
| Belgium         | N              |               | intended   |
| Denmark         | Y              | 05/1997       | all suspected cases of CJD   |
| Germany         | Y              | 07/1994       | probable and confirmed cases of sporadic CJD + HSE not linked with familiar or hereditary history (GSS excluded) |
| Greece          | Y              | 09/1996       | all suspected cases of CJD   |
| Spain           | N              |               |  |
| France          | Y              | 09/1996       | all suspected cases of CJD + other Human Spongiform Encephalopathies (GSS, FFI)                                  |
| Ireland         | Y              | 12/1996       | confirmed cases of all CJD   |
| Italy           | N              |               | possibility to include CJD in the 3rd class of the reporting system  |
| Luxembourg      | Y              | 06/1997       | all suspected cases of CJD   |
| The Netherlands | N              |               |  |
| Austria         | Y              | 04/1996       | confirmed cases of all CJD   |
| Portugal        | Y              | 06/1996       | all suspected cases of CJD   |
| Finland         | N              |               |  |
| Sweden          | Y              | 04/1998       | Criteria not yet known   |
| United Kingdom  | N              |               |  |



**Table 2: Number of cases referred to the diagnostic Centre for CJD assessment  
Total number (<50 years)**

|                        | 1990  | 1991  | 1992  | 1993   | 1994    | 1995    | 1996    | 1997     |
|------------------------|-------|-------|-------|--------|---------|---------|---------|----------|
| <b>Belgium</b>         | 4(0)  | 3(0)  | 3(0)  | 5(0)   | 5(0)    | 6(1)    | 6(1)    | 7(1)     |
| <b>Denmark</b>         |       |       |       |        | 4(0)    | 5(0)    | 5(0)    | 13(4)    |
| <b>Germany</b>         |       |       |       | 36(0)  | 148(17) | 142(15) | 192(29) | 181 (14) |
| <b>Greece</b>          |       |       |       |        |         |         | 3(1)    | 4 (0)    |
| <b>Spain</b>           |       |       |       | 19(4)  | 21(1))  | 25(1)   | 29(3)   | 27(1)    |
| <b>France</b>          |       |       | 59(6) | 55(3)  | 85(12)  | 104(14) | 196(34) | 347(94)  |
| <b>Ireland</b>         |       |       |       |        |         | 3(2)    | 6(0)    | 12(1)    |
| <b>Italy</b>           |       |       |       | 51(7)  | 62(11)  | 52(6)   | 77(13)  | 138(22)  |
| <b>Luxembourg</b>      |       |       |       |        | 1(0)    | 1(1)    | 1(0)    |          |
| <b>The Netherlands</b> |       |       |       | 13(3)  | 15(1)   | 6(0)    | 22(4)   | 16(2)    |
| <b>Austria</b>         |       |       |       |        |         |         | 9(0)**  | 38(4)    |
| <b>Portugal</b>        | 5(0)  | 2(0)  | 3(0)  | 2(0)   | 2(0)    | 1(0)    | 2(0)    | 8(0)     |
| <b>/Finland</b>        |       |       |       |        |         |         |         | 10(4)    |
| <b>Sweden</b>          | 15(1) | 8(0)  | 6(0)  | 12(0)  | 12(1)   | 14(0)   | 10(1)   | 18(2)    |
| <b>United Kingdom</b>  | 53(6) | 75(4) | 96(9) | 78(11) | 116(12) | 86(16)  | 133(44) | 151(46)  |

\*\* since July 1, 1996 only

**Table 3: Approach towards the safety of blood products**

| <u>Member State</u> | <u>Selection of Donors</u>   |
|---------------------|--|
| Belgium             | Exclusion of: <ul style="list-style-type: none"> <li>- familial history of CJD</li> <li>- past record of neurosurgery</li> <li>- history of growth hormone or dura mater transplant</li> </ul>   |
| Denmark             | The danish blood donor system is a passive one. The blood donors are volunteers. The donors are asked about their personal and family anamnesis in relation to diseases and about risk behaviour.  |
| Germany             | 3 criteria for exclusion: <ul style="list-style-type: none"> <li>- history of growth hormone treatment</li> <li>- familial history of CJD</li> <li>- dura mater or cornea transplant</li> </ul>  |
| Greece              | Legally binding criteria for exclusion: <ul style="list-style-type: none"> <li>- persons treated with human pituitary glands or products (November 1994)</li> <li>- persons who received cornea or duramater transplantation (October 1997)</li> <li>- persons with a history of familial TSEs (October 1997)</li> </ul>   |
| Spain               | By law (7/02/1996), exclusion of: <ul style="list-style-type: none"> <li>- persons treated with human pituitary hormones or dura mater products;</li> <li>- familial history of CJD</li> </ul>   |
| France              | Exclusion of: <ul style="list-style-type: none"> <li>- persons having received non secured biological products</li> <li>- past treatment with human growth hormones or other comparable products</li> <li>- history of neurosurgery</li> <li>- history of familial TSEs</li> </ul>   |
| Ireland             | Donor questionnaire with questions related to : <ul style="list-style-type: none"> <li>- medical procedures undergone within the previous 12 months</li> <li>- neurosurgery undergone at any stage</li> <li>- family history of CJD</li> <li>- treatment with human pituitary growth hormones or comparable products</li> <li>- corneal transplants</li> </ul>   |
| Italy               | WHO exclusion criteria   |
| Luxembourg          | Criteria defined for selection of donors: <ul style="list-style-type: none"> <li>- persons with CJD or GSS</li> <li>- persons with familial history (1st degree) of CJD or GSS</li> <li>- persons with duramater or cornea transplantation</li> <li>- persons treated with human pituitary growth hormones or comparable products</li> </ul>   |
| The Netherlands     | Exclude subjects with a positive family history  |
| Austria             | WHO exclusion criteria   |
| Portugal            | General rules for selection of donors, plus exclusion of recipients of dura mater transplantation  |
| Finland             | Follows the Council of Europe recommendations  |
| Sweden              | History of CJD in family is asked  |
| United Kingdom      | Exclusion of: <ul style="list-style-type: none"> <li>- persons with diseases of the central nervous system</li> <li>- persons treated with human growth pituitary hormone</li> <li>- recipients of human gonadotrophin of pituitary origin</li> <li>- persons injected with human pituitary extract before 1985</li> <li>- persons with a family history of CJD (direct blood-line relatives)</li> </ul> |

**Member State****Approach regarding contaminated products**

---

|                 |   |
|-----------------|---|
| Belgium         | Follows the EMEA policy   |
| Denmark         | Possibly contaminated products will be drawn back. Any precaution which apply for the whole blood will apply as well as for any later processed and/or secured product. |
| Germany         | Follows the EMEA policy. In case of a suspicion of nvCJD, all products are withdrawn. For familial or sporadic CJD, same rules except for plasma products               |
| Greece          | Measures to be introduced by the National Medicines Organisation  |
| Spain           | No withdrawing of classical CJD contaminated products; withdrawal of nv-CJD contaminated products   |
| France          | Withdrawal and destruction of all products coming from an at-risk donor.<br>Withdrawal of medicinal products derived from material coming from TSE cases                |
| Ireland         | Follows the policy adopted by FDA   |
| Italy           | Details still to be supplied  |
| Luxembourg      | Withdrawal of possibly contaminated products  |
| The Netherlands | Withdrawal of possibly contaminated products  |
| Austria         | Details still to be supplied  |
| Portugal        | Details still to be supplied  |
| Finland         | Follows the guideline of CPMP for possibly contaminated products  |
| Sweden          | Details still to be supplied  |
| United Kingdom  | Follows the guideline of CPMP for possibly contaminated products  |

**Member State****Recommendations on processing of blood products**

---

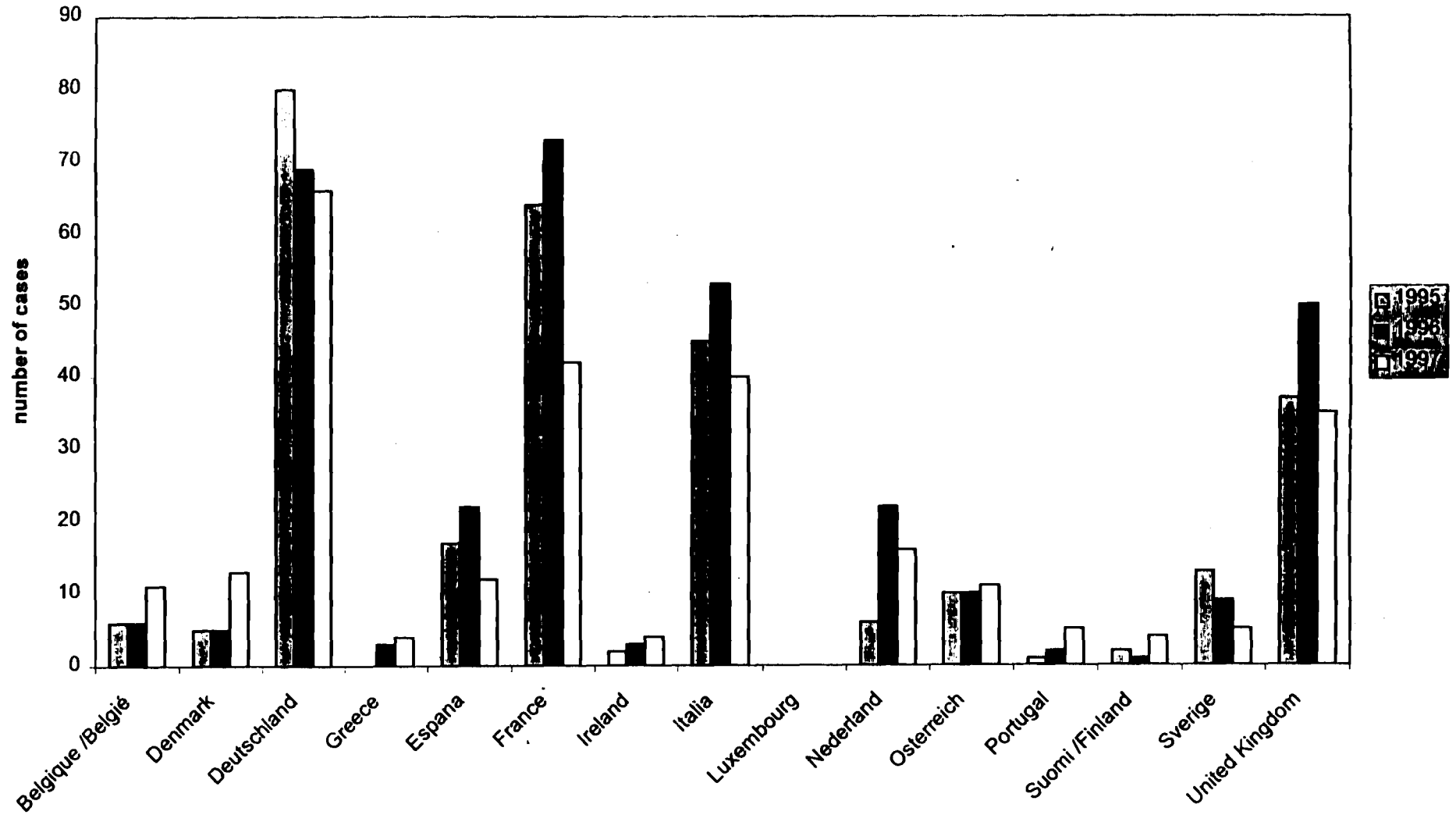
|                 |   |
|-----------------|---|
| Belgium         | Follows the blood products safety rules   |
| Denmark         | Possibly contaminated products will be drawn back. Any precaution which apply for the whole blood will apply as well as for any later processed and/or secured product. |
| Germany         | Leucocyte filtration under discussion   |
| Greece          | Follows the EC blood product safety rules   |
| Spain           | Follows the CPMP recommendations:<br>- no use of plasma or derived products coming from an area where nv-CJD cases have been identified                                 |
| France          | Leucocyte filtration for blood products will be implemented in April 98   |
| Ireland         | Implementation of universal leucodepletion of blood and blood components under study  |
| Italy           | Possibly contaminated products are withdrawn  |
| Luxembourg      | Question still under examination  |
| The Netherlands | No advice   |
| Austria         | No answer (to be checked)   |
| Portugal        | Filtration of blood recommendation  |
| Finland         | Possibly contaminated products are withdrawn  |
| Sweden          | To be withdrawn   |
| United Kingdom  | Standard safety precautions applied. Leucodepletion is under consideration.   |

**Member State****Information to possibly contaminated persons**

---

|                 |   |
|-----------------|---|
| Belgium         | Under discussion  |
| France          | No direct information, but traceability ensured by an indication in the patient's 'dossier'   |
| Denmark         | If a bloodproduct is found to be positive for Hiv, Hepatitis B and/or C a look-back investigation will be performed, and an eventually individual information will be given by the bloodbanks at the hospitals. If information is not given, it must be extremely unlikely that there are any risk for the recipient. |
| Germany         | Under discussion  |
| Greece          | Considered case by case.  |
| Spain           | No direct information   |
| Ireland         | Currently no notification of recipients of possibly contaminated products   |
| Italy           | No information, because it is devoid of any practical usefulness  |
| Luxembourg      | No direct information, but traceability ensured by an indication in the patient's "dossier"   |
| The Netherlands | No information unless transmission has been shown in the past   |
| Austria         | Information still to be supplied  |
| Portugal        | No information  |
| Finland         | Considered case by case   |
| Sweden          | Follow up of patients. Information to the attending physician   |
| United Kingdom  | Only epidemiological study is undertaken for such cases   |

Figure 1 : total of Definite and probable CJD cases ; years 1995, 1996, 1997



68

**Annex 4: List of themes covered by the present report in the light of the "Böge report" of the European Parliament, in addition to the action promised in document COM(97) 509 final**

Publicising the results of the Scientific Committees

SRM

MBM: safety of inactivation processes

Destruction of MBM

Post mortem BSE tests

OTMS inspection (9-11 February '98)

Implementation of Community law/inspections/infringements

Co-decision procedure

Labelling of compound feedingstuffs

Landfill

Entry into force of Regulation EC/820/97 (beef labelling)

MBM safety standards + general standards in the OIE

Hormones, feedingstuffs additives

Assistance to nvCJD victims organisations

Frauds: co-ordination