



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 18.11.1998
COM(1998) 598 final

COMMUNICATION FROM THE COMMISSION

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

SECOND BI-ANNUAL BSE FOLLOW-UP REPORT

I.	PREFACE	4
II.	BSE FOLLOW-UP – ACTION UNDERTAKEN BY THE COMMISSION SINCE NOVEMBER 1997	6
1.	SCIENTIFIC RESEARCH AND ADVICE	6
1.1.	<i>Scientific committees</i>	6
	i) Nomination of members and payment procedures.....	6
	ii) Publicising the results.....	6
1.2.	<i>Scientific advice on BSE matters</i>	6
	i) Introduction.....	6
	ii) Evaluation of rapid diagnostic tests for BSE in bovines.....	6
	iii) Assessment of geographical risks.....	7
	iv) Risk of human exposure arising from consumption.....	8
	v) Risk of transmission via blood.....	9
	vi) Risk associated with the processing, use and disposal of dead animals and slaughter-offal.....	9
	vii) Risks associated with sheep and goats.....	9
	viii) Safety of products derived from ruminant materials.....	10
1.3.	<i>BSE related research</i>	11
	i) Follow-up on TSE research following the 17 March 1998 2 nd joint call for proposals.....	11
	ii) Organisation and completion of study of methods to establish quantity and quality of feed materials in compound feedstuffs.....	12
2.	INSPECTIONS AND CONTROL	13
2.1.	<i>Legal framework</i>	13
2.2.	<i>The Food and Veterinary Office</i>	14
	i) Development of internal Manual of Procedures by FVO.....	14
	ii) Receipt of, and response to, IGS report.....	14
	iii) Recruitment of staff.....	15
2.3.	<i>BSE inspections</i>	15
	i) Missions to the United Kingdom since the first bi-annual report.....	15
	ii) Missions to Portugal.....	16
	iii) Missions to other Member States.....	17
3.	IMPLEMENTATION OF COMMUNITY LAW	19
3.1.	<i>Community law obligations with regard to BSE and position in relation of illegal exports from the United Kingdom</i>	19
3.2.	<i>Other cases</i>	19
3.3.	<i>Conclusions</i>	20
4.	SITUATION WITH REGARD TO THE UK BEEF BAN	20
4.1.	<i>Export of gelatine and certain other products</i>	20
	i) Products covered.....	20
	ii) Traceability.....	21
4.2.	<i>The UK's Export Certified Herd Scheme (ECHS)</i>	21
4.3.	<i>The UK's Date-Based Export Scheme (DBES)</i>	21
5.	LEGISLATION	22
5.1.	<i>Co-decision procedure</i>	22
5.2.	<i>General legislative measures</i>	23
	i) Assessment of further changes to Directive 85/374/EEC (product liability).....	23
	ii) Food policy and the general principles of Food Law.....	23
	iii) Completion of simplification exercise on food hygiene legislation, including veterinary and phytosanitary legislation.....	23
	iv) Entry into force of Regulation EC/820/97 (beef labelling).....	24
5.3.	<i>Strengthening of controls in the European Union</i>	25
5.4.	<i>Prevention and control of TSE in animals</i>	26
	i) Commission Decision 98/272/EC on TSE surveillance.....	26
	ii) Commission Recommendation concerning the evaluation of the epidemiological status of countries.....	26
	iii) Draft Regulation concerning the effective surveillance of TSE in the Member States.....	26
5.5.	<i>Feedingstuff additives - Exclusion of risk material from the food and feed chain</i>	28
	i) Rendering standards, specified risk material and related matters.....	28
	ii) Labelling of compound feedingstuffs.....	29
	iii) Destruction of meat-and-bone meal.....	29
	iv) Feedingstuff additives.....	29

5.6.	<i>Update on the surveillance and control of communicable diseases and other health issues</i>	30
i)	Establishment of a Community network for the surveillance and control of communicable diseases and of an action programme on rare diseases	30
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	31
iii)	Blood products and CJD	31
6.	INTERNATIONAL ASPECTS	31
6.1.	<i>International standards with regard to TSEs</i>	31
i)	MBM safety standards and general standards in the IOE	31
ii)	Codex	32
6.2.	<i>Hormones</i>	32
7.	SITUATION WITH REGARD TO CJD AND nvCJD CASES AND ASSISTANCE TO nvCJD VICTIMS	33
7.1.	<i>Current situation regarding nvCJD cases in the European Union</i>	33
7.2.	<i>Assistance to nvCJD victims</i>	33
8.	FRAUDS AND FINANCIAL ASPECTS	33
8.1.	<i>Fraud: co-ordination</i>	33
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>	34
9.	CONSUMER'S GUIDE	35
III.	ANNEXES	36
	Annex 1	36
	TABLE A	36
	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	36
	Annex 2	40
	Acceleration of payment procedures for the members of the Scientific Committees	40
	Annex 3	41
	Scientific Opinions related to BSE, adopted by the Scientific Committees since November 1997 (status on 11.11.98)	41
	Annex 4	44
	General Conclusions of veterinary missions regarding BSE since 1996 to Member States (excluding the United Kingdom)	44
	Annex 5	49
	Action pursuant to Article 169 of the Treaty	49
	Annex 6	55
	Number of cases of BSE (at 5 November 1998)	55

I. PREFACE

On 20 October 1997, the Commission submitted to the European Parliament and the Council its "Final consolidated report to the temporary committee of the European Parliament on the follow-up of recommendations on BSE (COM(97)509 final)". The report describes the main progress made since February 1997 in the field of food safety and consumer protection and gives details of the principal developments in combating BSE.

In addition, the report sets out an ambitious work programme and states the Commission's intention to report every six months to the European Parliament and the Council on progress made in programme implementation. The Commission presented its first report in May 1998, which gave a broad overview of practical measures taken to combat BSE and to implement the new approach in the fields of scientific advice, risk analysis, risk management, control and inspection. The first report already gave details of completion of certain points in the Commission's work programme, e.g. checks under Community law on the reporting of cases of BSE. In other areas, the first six-monthly report described progress made to date.

As the present report, the second in the six-monthly series, explains, a large part of the work programme has now been completed, and a synopsis of this is set out in Annex 1 (Table A). There are just a few points where the desired progress has not been achieved, e.g. with the European Union becoming a full member of the WHO and the International Office of Epizootics. In general, the report reflects the priority that continues to be given to the BSE issue within the Commission.

However, despite the progress which has been made, it is clear that further effort is needed and future work must be guided by the following considerations.

1. With regard to BSE:

Despite all the Commission's efforts, the Council has not agreed to a common approach to removing "specific risk material" from the food and feed chain. As a consequence, recommendations issued by the scientific committees have not been properly taken into consideration. In this area, risk prevention on a Community base remains inadequate.

Progress has been made in implementing Community legislation, which was adopted to prevent the spreading of BSE, in particular the feed ban and the standards for treatment of meat and bone-meal. Concerns do, however, remain where Member States have been slow in implementing Community law concerning the control of BSE.

The Commission has been vigorously pushing ahead work on validating a post-mortem BSE test. In the first half of 1999 the validation results will show whether the European Union currently has a test that can reduce the consumer risk.

2. In relation to the Commission's new approach to consumer health protection

The implementation of new structures for the scientific committees and the checks carried out by the Food and Veterinary Office of the Commission have yielded important information on current working methods. This information will be properly evaluated to develop and optimise the existing structures.

Scientific recommendations and inspection visits require effective follow-up. The last year has shown how important it is to have good follow-up: deficiencies identified during inspection visits to third countries for fishery products and for milk products resulted in consequent Community

actions been taken, including import restrictions. Furthermore, recommendations of FVO inspectors have contributed to improvements of the hygiene situations in third countries, which enabled the Commission to allow imports of products from third countries under defined conditions.

The WTO-agreement on Sanitary and Phytosanitary Measures (SPS) lays down the guiding principles, which the European Union follows in an international context. These principles require further development. One particularly important issue is how to implement the precautionary principle within the context of a scientifically-based consumer protection policy. Furthermore, the judgement of equivalence is subject of an in-depth discussion on an international level in particular in the Codex alimentarius.

These issues of importance in the international context will be taken into consideration by the Commission in the draft negotiation mandate to be given by the Council for the forthcoming WTO-discussions on the SPS Agreement.

The Treaty infringement procedure is relatively time consuming and therefore of limited use in achieving immediate improvements in health standards in the Member States. The Commission has speeded up the procedures in order to improve its effectiveness. Experience shows clearly that in a reasonable number of cases the opening of infringement procedures has led the Member States to take action with a view to fully implement Community legislation.

The European Parliament's and the Commission's joint conference on food safety - Lessons to be learned from the BSE crisis - will provide an opportunity to take stock of past progress and future challenges from a variety of angles. As such, it will make an important contribution to future discussion.

Furthermore, the Commission will push ahead the work on its response to the debate on the Green Paper on the General Principles of Food Law in the European Union.

In addition, the Commission intends to take up a number of points set out in its 1999-2001 consumer protection action programme. Article 152 of the future Amsterdam Treaty gives more impact to the Community action in the field of health protection.

In this respect, lessons learnt from the BSE crisis will influence the Commission's consumer protection policy into the next century.

II. BSE FOLLOW-UP – ACTION UNDERTAKEN BY THE COMMISSION SINCE NOVEMBER 1997

1. Scientific Research and Advice

1.1. Scientific committees

i) Nomination of members and payment procedures

With Commission Decision of 4 November 1997, 132 members of the Scientific Committees have been nominated, following a selection process on which the European Parliament was kept fully informed. The payment procedures for the members of the Scientific Committees are described in Annex 2.

ii) Publicising the results

All opinions of the Scientific Committees are on the INTERNET and can be consulted by all interested parties. Normally they appear on the INTERNET two to three days after their final adoption by the responsible Scientific Committee. It is now foreseen to publish them regularly on CD-ROM but not any more in paper form.

1.2. Scientific advice on BSE matters

i) Introduction

In total 22 scientific opinions related to BSE have been adopted since the new structure for scientific advice became operational in November 1997. The complete list as well as the Scientific Committees involved are given in Annex 3.

These opinions cover, as main areas, Specified Risk Materials (SRM), BSE risk, criteria for the assessment of the geographical BSE status of countries, export of deboned meat and certain bovine products from the United Kingdom, pneumatic stunning as practice for slaughtering ruminants, the risk of infection of sheep and goats with the BSE-agent, the safety of products derived from ruminant materials such as tallow, gelatine, meat-and-bone meal, di-calcium phosphate, organic fertilisers and the equivalency of alternative products to intestines of animal origin for use as surgical sutures.

The opinions list appropriate measures to reduce the potential risk for humans and animals resulting from exposure to possibly infected materials and products therefrom. Where appropriate, they systematically refer to safe sourcing of the material, to the intended end-use of the final product, to the safe processing and to the exclusion of SRM as essential elements for risk reduction.

In the sections hereafter, emphasis is given to the scientific advice on BSE matters provided since the first bi-annual report of the Commission.

ii) Evaluation of rapid diagnostic tests for BSE in bovines

The Commission is conducting an exercise to evaluate rapid diagnostic tests for TSE in bovines. A public call for expression of interest to participate in an evaluation exercise was launched in May. Thirty initial expressions of interest from test developers were received, of which ten submitted full applications. Following expert assessment four tests were invited to participate.

The organisation of the evaluation exercise is now well underway. The evaluation will consist of an assessment of test sensitivity, specificity, detection limits and repeatability and is scheduled to be completed in spring 1999. As scientific developments on test research are continuing, the possibility of running a similar exercise in the future has been kept open.

The JRC Institute for Reference Materials and Measurements (IRMM) is providing support to the Commission in practical and scientific aspects of the test evaluation exercise, in particular as regards the handling and codification of samples, the critical assessment of results and the preparation of a final report.

The test evaluation protocol involves the provision of coded BSE positive and negative samples to the companies concerned according to their specifications. The Standing Veterinary Committee approved a proposal on 9 September amending Council Decision 98/256/EC (the UK export-ban) in order to allow BSE positive material to be exported from the UK for these trials. All samples will be coded prior to testing in order to guarantee an objective evaluation and comparison of the potential of each test. More than 10.000 individual samples have to be prepared to cover the needs for the project. Working with positive BSE tissue requires special authorisation and rigorous safety measures must be taken. The necessary authorisation has been obtained.

Following completion of the test evaluation exercise, it is intended that the results will be passed to the appropriate Scientific Committees for opinion.

iii) Assessment of geographical risks

The Scientific Steering Committee (SSC) issued an opinion on the geographical risk on 23 January 1998 and a slightly modified version on 20 February 1998. It defined three risk elements (incident risk, propagation risk and human exposure risk) 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 22 July 1998, the Commission adopted a recommendation inviting Member States and third countries to provide information in accordance with the data-set specified by the SSC in its opinion of 19 and 20 February 1998 with a view to assessing their epidemiological status with regard to TSEs. By 10 November 1998, the following countries had submitted a BSE status evaluation dossier as a result of the Commission's invitation of 30 July 1998 or as a reaction to the Scientific Steering Committee's opinion adopted on 19 February 1998 (on which the Recommendation is based): Argentina, Austria, Belgium, Chile, Czech Republik, Denmark, France, Germany, Italy, Luxembourg, Paraguay, New Zealand, Norway, Sweden and Spain. The United States of America, the United Kingdom and the Netherlands have announced that they will send their dossiers soon. In addition, a number of applications had already been addressed to the Commission prior to the 30th of July (the date of publication of the invitation): Australia, Canada, Finland, Switzerland and Namibia.

Those countries whose dossiers are not considered to be in accordance with the Commission recommendation will be invited to submit additional data. Moreover, the Commission is proposing a legal base for the categorisation of countries in the framework of its proposal for an effective surveillance of TSEs based on Article 100A of the Treaty (see point 5.4.iii).

The SSC currently is working on a methodology for the assessment of the geographical BSE-risk. A handbook is under development that is meant to guide experts, asked to analyse the expected country dossiers, in order to ensure that each application is analysed by the same approach.

Together with other parameters, such as those listed by the International Office of Epizootics (IOE) in article 3.2.13.1 in the new version of the BSE-chapter, this risk assessment will form the basis for the categorisation of countries or regions with regard to their epidemiological BSE status. A preliminary version of the handbook was presented to the SSC at its September meeting. A final version is scheduled for adoption by the SSC in December 1998. The evaluation of country dossiers by external experts could then start in January 1999.

Up to now, no categories of BSE-status are proposed by the SSC. The work on this issue is executed in full awareness of the ongoing work at the IOE on the same subject. The results of the working group addressing the human exposure risk (see below) will likely also influence the final proposal of the SSC in this field.

iv) Risk of human exposure arising from consumption

In an attempt to establish a comprehensive analytical framework, one of the opinions of the SSC addressed the BSE-risk in general (March 1998). Three major issues were recognised, 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.

With regard to the human exposure risk the SSC came to the conclusion that the by far most important exposure would be via direct consumption. Even if the indirect consumption should not be ignored, in a first attempt the exposure of humans to BSE through the direct consumption of bovine and bovine products is going to be assessed. However, data on dietary consumption patterns are very difficult to obtain and/or require time to be assembled. Benefiting from nationally available work, the working group is making some progress.

As an exploratory effort the experts are asked to calculate some rough scenarios. These scenarios should estimate the number of humans exposed to the BSE-agent if one BSE-infected cattle would be slaughtered and "normally" processed. Assuming that the slaughtered animal would be sub-clinically infected, but the disease would be close to the outbreak, (i.e. the animal would carry the full load of the BSE-agent) the scenarios should be calculated for three situations:

- all SRM processed as "normal";
- all Central Nervous System (CNS) tissue and the Dorsal Root Ganglia (DRG) excluded from processing;
- the entire list of SRM, proposed by the SSC (excluding the lung, see opinion of 20 February 1998), would be excluded.

Preliminary results are expected for December 1998, but final figures will not be available before 1999. They will still lack the component of indirect consumption via derived intermediate products, such as gelatine or tallow.

On 22-23 October 1998, the Scientific Steering Committee adopted an opinion on *The safety of bones produced as by-product of the Date Based Export Scheme*. The main conclusion is that, under the strict conditions of the UK Date Based Export Scheme and given the risk analysis that was carried out as part of the elaboration of the DBES proposal, the risk born by bones remaining after the de-boning of meat from animals fulfilling the conditions of the DBES is considered to be remote. In order to address the remote risk that a clinically sound but BSE-infected animal would be slaughtered in the context of the DBES, or an equivalent scheme, the SSC recommended to exclude the skull (including the trigeminal ganglia) and the vertebral column (including the spinal

cord and the dorsal root ganglia) from further use. The other bones should be assumed to be at least as safe as bones from animals from geographical areas classified at lower-risk. When transformed into gelatine or other products, they would have to be treated as if coming from such a source. The SSC finally stressed that these conclusions were not extrapolable to the whole European cattle population, as age at slaughter, traceability of the animals and their dam may be different.

It should be stressed at this point that only deboned meat would be allowed for export under the DBES.

v) Risk of transmission via blood

Starting from the assumption that bovine blood could in principle behave as human blood, the SSC decided to postpone its opinion on this issue until a scientific opinion and the results of a risk assessment on the possibility of a transfer of CJD and nvCJD by human blood would be available from the Scientific Committee for Medicinal Products and Medical devices. This opinion was adopted on 21 October 1998 and immediately communicated to the SSC. It came to the conclusion that on the currently available scientific evidence the transfer of CJD via human blood can not be confirmed. For nvCJD the information available is too limited to allow any conclusion. Without further delay the SSC started working on the issue of bovine to bovine transfer via blood. However, it is therefore not expected to adopt an opinion on that issue before the end of this year.

vi) Risk associated with the processing, use and disposal of dead animals and slaughter-offal

The SSC has created a working group on these issues which reports to the TSE/BSE ad-hoc group. An opinion is expected for the December meeting of the SSC.

vii) Risks associated with sheep and goats

The SSC adopted at its plenary session of 24-25 September 1998 an opinion on the risk of BSE occurring in sheep and goats.

Although there is currently no evidence to suggest that BSE occurs naturally in sheep and goats under field conditions, it has been experimentally demonstrated with highly infective brain tissue that BSE can be orally transmitted to certain genotypes of small ruminants. In how far BSE-infected meat-and-bone meal would have the same effect as the high infective tissues fed during the experiments has not been tested yet.

On the basis of data on feeding practices, sheep and goats in many countries have probably been exposed to the BSE agent through MBM. The Scientific Steering Committee considers that, if BSE in sheep and goats exists, the most likely way of introduction has been through infected MBM. As a result, the previous or current geographical risks of exposure of sheep and goats to infection should be taken into account in any risk assessment. In this context it is noted that the feeding practices, e.g. the age and extent of MBM feeding of sheep and goats, are different from cattle. These will also vary depending on whether the animals are to be used for meat, wool or dairy purposes. Investigations under field conditions are needed.

There exist indications that the BSE agent behaves like scrapie in sheep and goats. Once and if introduced, it can therefore not be excluded that BSE may be maintained and spread in the sheep and goat population by means of horizontal (from animal to animal) and vertical (from ewe to lamb) transmission. This implies that the risk could persist, even after an effective implementation of a ruminant feed ban. No information is currently available but it is noted that study of maternal transmission of experimental BSE in sheep is in progress.

The risk of humans being exposed to the BSE agent would originate from animals in the pre-clinical and clinical stage of the disease. It can be reduced by effective measures reducing the exposure risk, in particular safe sourcing, exclusion of the potentially most highly infected tissues (age-specific specified risk materials) from processing, reducing the age at slaughter for human consumption and application of validated processing methods with a proven potential to reduce/eliminate any residual BSE-infectivity. These measures have been previously described by the SSC which considers that there is no scientific reason for a change in that advice.

The list of SRM should be regularly re-evaluated taking account of the results of ongoing epidemiological surveys on BSE in small ruminants and of new scientific data on BSE infectivity distributions in tissues of small ruminants, infectivity and transmission in small ruminants and whether in particular the lymphoreticular tissue should be considered more infective in sheep than they are in cattle.

The Scientific Steering Committee finally recommended that high priority should be given to the validation of tests for large scale testing for differential diagnosis of BSE and scrapie.

viii) **Safety of products derived from ruminant materials**

In addition to its earlier opinions on the safety of gelatine, meat-and-bone meal, tallow and tallow derivatives, the SSC has adopted opinions on the safety of di-calcium phosphate and of organic fertilisers. Regarding organic fertilisers, the scientists recommended that no organic fertiliser should be produced from animals from high risk areas. In low and negligible risk areas the safety standards of meat-and-bone meal should be met; if the animals come from a low risk country, ingestion by man and ruminants has to be prevented. Tissues which are not infected with the BSE agent (e.g. hooves, horns or hair) may be used as fertilisers.

The scientific bases of the Opinion on the safety of ruminant-derived meat-and-bone meal used as a feed for food-producing farm animals (adopted in March 1998) were amended. An assessment was made as to whether application of the direct treatment of raw material at 133°C/20'3 bars is equivalent to a process where the raw material is first treated at less than 133°C/20'3 bars and the meat-and-bone meal is only afterwards treated at 133°C/20'3 bars. Equivalency was confirmed provided that, during the second treatment, the material contains enough water and no air is in the sterilising chamber. Following this assessment, scientists adapted their definition of the appropriate standard for treatment of ruminant-derived meat-and-bone meal.

Finally, an assessment was carried out of the potential residual infectivity level in animal feedstuffs cross-contaminated with mammalian meat-and-bone meal. According to the scientists, no cross-contaminated feedstuffs, i.e. feed containing meat-and-bone meal, should be fed to ruminants. The level above which feedstuffs should be condemned should be the detection level, currently at about 0,5%.

On 22-23 October, the SSC adopted one opinion on *The safety of hydrolysed proteins produced from bovine hides* and one opinion on the *Evaluation of a new process for the production of gelatine regarding its equivalency with commonly used industrial gelatine production processes in terms of its capacity of inactivating/eliminating possible TSE infectivity in the raw material*.

Regarding hydrolysed proteins the SSC is of the opinion that they can be considered to be safe as long as the raw material ("fleshings" from hides, which are a material with no detectable infectivity) entering the hydrolysis process does not, for example through contamination, carry a high infective load and an appropriate transformation process is applied. Therefore, in order to prevent the risk of propagation of BSE, no material from animals suspected or known to carry the BSE agent, should be processed and the raw material should only be obtained from

healthy animals. In its opinion the SSC further specifies (severe) processing conditions according to the geographical source of the raw material (no risk, low risk or high risk countries or regions).

For what concerns the new process for the evaluation of gelatine, the SSC considered it impossible to evaluate at present the equivalency of the alternative production process in terms of the inactivation/elimination of TSE infectivity and invited the company to provide additional data and to carry out a study with spiked BSE infected raw material in order to estimate the infectivity reduction factor of the production process. Therefore, at present, the only preliminary conclusion can be that ruminant bones from animals certified fit for human consumption, to be used for production of gelatine with the alternative system, will have to come from BSE-free or BSE-negligible risk countries.

Concerning the equivalency of alternative products to intestines of animal origin for use as surgical sutures, the Scientific Committee on Medicinal Products and Medical Devices (SCMPMD) has given the opinion that there are sufficient synthetic alternative products to catgut suture that provide equal, or even better clinical performance than catgut and that there are no clinical indications for the preferred use of catgut.

With respect to any continued commercial supply of catgut sutures, the Committee is of the view that, in the light of the bovine and ovine origin of the material, and the classification of intestines as tissues of medium infectivity, special conditions have to be met in order to manage the risks related to TSE. Since there are no known inactivation processes that can be applied to catgut, risk management cannot be achieved by this method. The Committee is of the opinion that risk management could only be addressed through the sourcing of material from BSE-free areas, coupled with the use of processing methods that involve a controlled system of collection and handling in order to prevent cross contamination. Specifically, in the case of any continued production of catgut, the manufacturing process should be in conformity with the guidelines set forth in appropriate standards and guidance documents from the Commission.

1.3. BSE related research

i) Follow-up on TSE research following the 17 March 1998 2nd joint call for proposals

As part of the action plan on TSE research, a 2nd joint call for proposals was launched by the Commission on 17 March 1998, within the BIOMED, BIOTECH and FAIR research programmes. This call was aimed at strengthening efforts in specific areas of the action plan which were not fully covered following the implementation of the first joint call.

Based on expert's recommendations from the TSE risk assessment workshop, organised by the Commission on 28 January 1998, the call for proposals covered three main research themes:

- 1) Risk assessment of spongiform encephalopathies;
- 2) Treatment and prevention of spongiform encephalopathies;
- 3) Co-ordination of research activities between Member States.

The call, although very focused, attracted a wide response from the scientific community. 28 proposals (9 BIOMED, 2 BIOTECH, 17 Fair) involving 141 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, 13 proposals were considered to be of high quality and therefore proposed for funding.

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

Validation studies in performance

The JRC Institute for Health and Consumer Protection (IHCP) in Ispra (created in July 1998) in collaboration with the JRC Institute for Reference Materials and Measurements (IRMM) in Geel has started in 1998 the validation of two analytical methods within the frame of BSE funded by DG XXIV.

These studies are:

- Validation of a method for the detection of the appropriate heat treatment of animal meals.
- Detection of mammalian meals in feedingstuffs of plant origin by the so-called PCR method (polymerase chain reaction).

The validation studies will be finished in December 1998 and the final results will be reported to DG XXIV.

The following results have been achieved to-date for both methods of the validation studies:

- Standard operation procedures have been established containing the description of the analytical method;
- Videos being complementary to the written method and showing the critical items of the methods have been produced (copies are in production presently);
- Participating laboratories from EU Member States have been identified and invited to the collaborative trial study;
- The composition of typical feedingstuff mixtures (compound feed) in Europe was established;
- The test materials have been prepared for the trial studies (animal meal samples treated at various conditions) and are in production (feedingstuff);
- Workshops have been held with the participants of the trial studies planned in order to inform about critical steps of the methods (16 and 17 September 1998).

The validation of the method for detection of heat treatment has been started (20 September 1998) and the results are expected for 11 December 1998.

Further validation studies planned

The JRC has contacted Representatives of the Ministry of Agriculture, Fisheries and Food (MAFF), UK in order to discuss the validation of the UK ELISA method for the detection of mammalian meals in feedingstuff. It has been agreed that the JRC will examine in near future this method using the same samples which have been prepared for the study being based on PCR (actually in validation).

JRC will investigate the possibility of the detection of an appropriate heat treatment of animal meals being added to feedingstuff where it is allowed.

Development of rapid screening methods

First experiments have been carried out in order to investigate the suitability of alternative (rapid) methods for the detection of mammalian meals in feedingstuff. These methods are based on the Fourier Transformed - Near Infrared Spectroscopy (FT-NIR) and the analysis of specific amino acids.

2. Inspections and control

2.1. Legal framework

At the time of the report of the Parliament's Temporary Committee of Inquiry into the BSE situation, guarantees were offered by the Commission as to the manner in which the reports from its control and inspection services would be handled. In particular, a fundamental commitment to transparency in the handling of the findings and recommendations of missions was given. This was intended to allow consumers to make informed choices, based upon independent, freely available, and timely information. The publication of the full texts of FVO reports, including the recommendations, is an essential part of this commitment.

In order to fulfil the guarantees, the Commission adopted two Decisions on performance of FVO inspections. Commission Decision 98/139/EC (Member State inspections) and Commission Decision 98/140/EC (third country inspections) came into effect in February 1998.

These Decisions 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 Member States, 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.

Veterinary on-the-spot missions carried out by the Food and Veterinary Office (FVO) are performed under these Decisions.

2.2. The Food and Veterinary Office

i) **Development of internal Manual of Procedures by FVO**

The Manual of Procedures has now been in use for nearly 12 months. Updating of its provisions in the light of experience, and the reorganisation of the FVO, as described below, is an on-going process. A major step forward has been the adaptation of the Manual in order to implement Commission Decisions 98/139/EC and 98/140/EC (see point 2.1. above). The Manual does now reflect these Decisions.

The Manual will be expanded in the near future to include additional guidelines on the organisation of missions and the presentation and distribution of mission findings. These will help to ensure a uniform approach by the FVO to the manner in which it carries out controls and inspections, and will make it easier for outside bodies to understand its mission findings.

Work has also been started on the establishment of written procedures to cover other aspects of the FVO's activities. Once completed, these will form a main part of the proposed Manual of Procedures, and will contribute significantly to achieving the undertakings given in the below Communications on the transparency of operations in the FVO. The development of guidelines for the performance of audits of competent authorities has also started.

ii) **Receipt of, and response to, IGS report**

Following a review of the structure and operation of the FVO, carried out in response to the IGS report, a number of changes to its internal organisation and operation came into effect on 1 October 1998. The main features are as follows:

The responsibilities of the existing inspection Units have been reorganised along thematic lines, to allow the full introduction of "plough to plate" controls over the whole of the food production chain, as follows:

Unit 1 Food of animal origin derived from mammals

Unit 2 Food of animal origin derived from birds

Plant health controls

Unit 3 Food of animal origin derived from aquatic animals

Food of non-animal origin

In addition, geographical contact points are being established within each Unit, to facilitate the handling of outside inquiries in relation to individual countries or regions.

A Quality and Planning Section has been established within the FVO, as foreseen in the Commission's earlier Communications (COM(97) 183final and COM(98) 32final) on its control services. This is responsible both for the planning and development activities necessary for the implementation of the new working practices described in the above Communications, and the establishment and operation of the internal audit systems which will ensure that these practices are being followed.

Reports of missions undertaken by the FVO, and copies of comments received from the competent authorities concerned, are now available on the DG XXIV internet site:

(http://europa.eu.int/comm/dg24/health/vi/reports/index_en.html).

iii) **Recruitment of staff**

The two competitions to establish reserve lists of veterinary, phytosanitary and other food experts have been completed since the first bi-annual report. Recruitment from these lists has begun and will accelerate during the autumn of 1998.

Office space in the FVO's present building in Blackrock, Dublin, is now fully used up. Until the new temporary building at Clonskeagh is ready next year, additional new inspectors and support staff will work temporarily in Brussels. They will be posted to Dublin as soon as the new building is available.

FVO staff on 1 October 1998 totalled 137. It is estimated that by March 1999 this number should increase to 160.

2.3. **BSE inspections**

i) **Missions to the United Kingdom since the first bi-annual report**

Council Decision 98/256/EC and supervision of meat plants

On 16 March 1998 the Council adopted Decision 98/256/EC concerning emergency measures to protect against bovine spongiform encephalopathy, amending Decision 94/474/EC and repealing Decision 96/239/EC. A mission was carried out by the FVO in the United Kingdom (Great Britain), from 15 to 19 June 1998. The scope of the mission included the implementation of Chapter III of Commission Decision 98/256/EC (material derived from bovine animals not slaughtered in the United Kingdom), the controls of the fresh meat establishments (focusing on the approval procedures, veterinary supervision and slaughter hygiene) and trade in fresh meat.

As regards the implementation of Chapter III of Commission Decision 98/256/EC, the findings of the mission team led to the conclusion that the United Kingdom's authorities took action to transpose and implement Chapter III of the above mentioned Decision and its provisions appeared to be properly implemented. Some recommendations were provided to the United Kingdom's authorities by the inspectors on different aspects such as traceability, certification and control of tallow.

With regard to supervision of meat plants, important improvements were noted. However, the requirements of Council Directive 64/433/EEC with regard to the level of supervision in meat-plants are not yet fully respected. The supervision and internal audits performed do not lead to correction of individual deficiencies. The actual application of the UK's Hygiene Assessment System (HAS) has not lead to acceptable hygiene standards in the plants visited. Even if culling and slaughter for human consumption is performed on different days, no sufficient guarantees exist that all hygienic requirements are fulfilled.

Some weaknesses in the system of traceability of the meat were observed. The major part of the resources of the official services is allocated to controls of SRM, the Over Thirty Months Scheme, calf-schemes and export of bovine products under Chapter III of Decision 98/256/EC. Other items are not inspected or supervised to the same level.

Date Based Export Scheme (DBES)

On 10 June 1998, the Commission agreed a Draft Commission Decision amending Council Decision 98/256/EC as regards certain emergency measures to protect against BSE, and including

rules for the DBES. Following discussion in the Standing Veterinary Committee (SVC), the United Kingdom's authorities agreed with the Commission services to have a mission carried out by the FVO in Great Britain on the matter. A list of issues to be covered by the mission was drafted by the FVO, discussed in the SVC on 7 July 1998 and finalised in light of Member States' comments received. The mission was carried out from 20 to 24 July 1998.

The scope of the mission was mainly concentrated in the assessment of following issues: epidemiology, feed ban, offspring cull, the rules in place for the future implementation of the DBES (eligibility of the animals and controls on eligible products). The findings of the mission led to the following recommendations:

- The United Kingdom's authorities should
 - try to clarify why the number of BSE suspects not confirmed by laboratory examination is decreasing relatively sharply
 - improve the controls on passports in particular with regard to the return of passports after death, the follow-up in case of non-compliance and on dairy farms. (Some of these improvements had already been planned).
- The Commission services should clarify
 - the appropriate requirement for the United Kingdom in order to verify the survival of the dam of eligible animals for 6 months;
 - which information would oblige the United Kingdom to cease issuing export certificates or to inform the competent authority of the place of destination if exports have already taken place;
 - the draft Decision with regard to the offspring cull in order to take into account the United Kingdoms' intention to directly incinerate the animals and to take into account the foreseeable fact that not all offspring (100%) will be traceable.

ii) Missions to Portugal

Two FVO missions were carried out in Portugal in 1998 on BSE related issues. The first mission took place from 11-15 May 1998. The outcome of this mission can be summarised as follows:

- Commission Decision 96/449/EC was implemented late (during 1998);
- There are administrative controls on the implementation of the ruminant feed ban; no laboratory examinations are carried out since the end of 1996;
- SRM are removed from the food chain since end January 1997; mammalian meat-and-bone meal containing SRM is entering into the feed chain;
- Doubts on the quality of the BSE surveillance were raised because the level of awareness seems not to be sufficient in some regions.

The Portuguese authorities announced a series of actions to address a number of recommendations made in the report of the mission.

A sharp increase in the BSE incidence during the summer motivated an emergency mission, which took place from 28 September to 2 October. This mission confirmed most of the findings

of the previous mission. The draft mission report has been sent to the Portuguese authorities for their comments on 16 October 1998. The report will be finalized in view of possible comments.

New data were provided on the results of BSE surveillance, which generally tend to be more satisfactory. However, the results of surveillance differ according to time and the geographical zone. Work remains to be done in that area. New information was also collected during the mission concerning the control on the processing of waste, the implementation of the feed ban and BSE surveillance and eradication.

The national incidence of BSE for the last 12 months up to the end of October 1998 is around 111 cases per million cattle over 24 months of age (on the basis of the dates of confirmation of cases notified to the Commission).

As a conclusion of the two missions, there is a considerable risk of recycling of the BSE-agent in Portugal. For legislative follow-up, please see Annex 5, point 1.1, Chapter on Portugal.

iii) Missions to other Member States

The following missions have been carried out from November 1997 up to October 1998. Most of the relevant reports have been provided to the Member States; in the light of the comments received from the Member States, they have now been finalised and some of them have been placed on the DG XXIV Internet site.

Member State	Dates	Scope
Sweden	24-28 November 1997	Decision 96/449/EC Follow-up regarding Directive 90/667/EEC, ruminant feed ban and BSE surveillance
Germany	24-28 November 1997	Decision 96/449/EC Follow-up regarding ruminant feed ban and BSE surveillance
France	8-12 December 1997	Decision 96/449/EC
Ireland	12-23 January 1998	Decision 97/735/EC; 97/312/EC (SRM only); Follow-up on Decision 96/449/EC
Belgium	16-20 February 1998	Decision 97/735/EC; <u>National</u> rules for SRM
Denmark	23-26 February 1998	Decision 97/735/EC Follow-up regarding Decision 96/449/EC
Finland	30 March-2 April 1998	Decision 97/735/EC
Netherlands	11-15 May 1998	Decision 97/735/EC; <u>National</u> rules for SRM
France	6-11 July 1998	Decision 97/735/EC; <u>National</u> rules on SRM Follow-up on Decision 96/449/EC
Sweden	24-25 August 1998	Decision 97/735/EC, Decision 98/272/EC Follow-up on Directive 90/667/EEC and Decision 96/449/EC
Italy	14-18 September 1998	Decision 97/735/EC Follow-up on Decision 96/449/EC and BSE Surveillance

Spain	28 September to 2 October 1998	Decision 97/735/EC Follow-up on Decision 96/449/EC and BSE Surveillance
Austria	27-30 October 1998	Decision 97/735/EC, Decision 98/272/EC Follow-up on Decision 96/449/EC
Germany	26 - 30 October 1998	Decision 97/735/EC Follow-up on Decision 96/449/EC

General conclusions of the series of missions carried out since March 1996, including the missions of 1998, are given in Annex 4.

3. **Implementation of Community law**

3.1. **Community law obligations with regard to BSE and position in relation of illegal exports from the United Kingdom**

On 26 June 1997, the Commission decided to open an infringement procedure against ten Member States for failing to apply certain aspects of Community law with regard to BSE. This first set of procedures was concerned essentially with the inadequate implementation of Commission Decision 96/449/EC (133°C/20'3 bars heat treatment system for processing animal waste) and inadequate controls regarding Commission Decision 94/381/EC banning the use of mammalian tissue-derived proteins in ruminant feeds.

In the light of further FVO inspections carried out in the second half of 1997, relating mainly to the application of Decision 96/449/EC, new infringement procedures were initiated on 25 March 1998 against two other Member States (see Annex 5).

Following the detection of illegal beef exports from the United Kingdom, the Commission opened on 22 September 1997 an infringement procedure against the United Kingdom because of violation of Council Directives 64/433/EEC and 89/662/EEC, and because of the export ban imposed under Decision 96/239/EC.

In the same context a letter of formal notice was sent to the German authorities for failure to operate controls in conformity with Directives 64/433/EEC and 89/662/EEC.

A detailed description on the current state of affairs with regard to all these infringement procedures is given in Annex 5.

3.2. **Other cases**

As far as France is concerned, checks have now been completed concerning the ban on the use of fish meal in animal feeds and restrictive measures on the import of pet food from certain third countries (particularly the USA and Canada). Two letters of formal notice in respect of fish meal and pet food were dispatched on 4 August 1998.

In each case, the reply period is two months.

The Italian restrictions on fish meal (similar to the French restrictions) were the subject of an Article 169 letter dated 9 September 1998.

3.3. Conclusions

The initiation of infringement procedures following FVO inspection missions to the Member States has achieved considerable progress in bringing Member States' national laws into line with Community law, and in achieving the practical application of Community rules and regulations.

Where shortcomings persist, the Commission will persevere with these procedures. It also intends to open new procedures wherever inspection visits bring to light new situations which are in violation of Community law. In other situations where the strengthening of Community regulations would appear to be the sounder legal approach, the Commission will make the appropriate legislative proposals. Such is the case, in particular, concerning the requisite level of controls to be carried out by Member States in application of Decisions 94/381/EC and 96/449/EC (see point 5.3).

The Commission would point out that it is making full use of the reforms decided in July 1996 for applying Article 169 procedures: cases of infringement qualifying for a decision, especially BSE cases, are now dealt with on a two-monthly rather than a six-monthly basis; this increases the pressure on the Member States. Additionally, deadlines within which the Member States have to respond to formal letters of notice or reasoned opinions have been cut drastically (to just 15 days, rather than the 60 days before).

4. Situation with regard to the UK beef ban

4.1. Export of gelatine and certain other products

i) Products covered

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-bone meal from the United Kingdom. Commission Decision 96/362/EC of 11 June 1996 allowed the resumption, subject to 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 within the United Kingdom and products derived from bovine animals slaughtered inside or outside the UK.

Decision No 98/256/EC of 16 March 1998 gave the go-ahead for exports of certain products such as tallow, tallow-based products and derived products, and 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 bovine animals slaughtered in the United Kingdom, thereby excluding their use in the human food or animal feed chains or in the manufacture of cosmetics or medical or pharmaceutical products.

The Council also asked the Commission to review, in the light of scientific opinions adopted by the SSC, measures concerning certain products of animal origin such as tallow and gelatine. Against this background, the Commission submitted to the Standing Veterinary Committee on 12 and 18 June 1998 a proposal to amend the conditions for the resumption of dispatches of tallow and gelatine derived from materials from animals slaughtered in the United Kingdom. This proposal took account of the recommendations made by the SSC on 26 and 27 March 1998. At those meetings, most of the Member States said that they wanted to leave the working group set up by the Commission, parallel to this discussion, to complete their appraisal of harmonising the

rules for production of these products at Community level and to resume discussion subsequently by reference to the special case of the United Kingdom. The United Kingdom has since gone on record as not having any intention of dispatching to the other Member States gelatine produced from materials covered by the draft decision.

ii) **Traceability**

The new Decision introduces a legal obligation concerning the traceability of gelatine and other products manufactured in the United Kingdom from materials not originating in the United Kingdom and eligible for export, by strengthening the labelling, marking and certification conditions. These products also have to be handled separately from ineligible products in terms of time or space.

4.2. **The UK's Export Certified Herd Scheme (ECHS)**

Council Decision 98/256/EC of 16 March 1998 concerning emergency measures to protect against BSE repeals Commission Decision 96/239/EC of 27 March 1996. In this Decision, it was decided to resume – in a conditional and limited fashion – dispatches from Northern Ireland of de-boned bovine meat from animals belonging to “eligible” herds, i.e. herds clear of BSE for at least eight years.

This first step towards lifting the ban on beef exports from the United Kingdom was possible because of the computerised cattle traceability system in Northern Ireland. Rigorous controls on the eligibility of animals for slaughter under the scheme and on the separation and traceability of products were laid down following an inspection visit undertaken by the Food and Veterinary Office in November 1997 to evaluate the proposed procedures and controls for the Export Certified Herd Scheme (ECHS).

As provided for in Article 6(5) of the Council Decision, a further inspection visit took place on 20-22 April 1998, with a view to evaluating the veterinary controls system in the light of Articles 6 and 7 of the Council Decision. The outcome was that the authorities in Northern Ireland have clearly taken all necessary action to apply the ECHS in accordance with Council Decision 98/256/EC. Only one slaughterhouse and only one cutting plant have applied for approval and have received it. Following presentation of the mission report to the Standing Veterinary Committee, the Commission decided, by Decision 98/351/EC, to allow dispatches to commence as from 1 June 1998.

4.3. **The UK's Date-Based Export Scheme (DBES)**

The UK scheme concerns the export of meat and meat products from bovine animals of more than six months, but less than 30 months, either born or imported after 1 August 1996 and raised in the United Kingdom. Following a positive opinion from the SSC and various contacts between Commission services and United Kingdom authorities, a draft proposal was approved by the Commission on 10 June 1998 and submitted for discussion at two successive meetings of the Standing Veterinary Committee on 12 and 18 June 1998.

Most Member States shared concerns about the applicability of the system at a time when new cases of BSE are still being confirmed at an elevated rate in comparison to other regions. It was agreed to discuss the DBES again after completion of a mission by the FVO on the applicability of the system (see point 2.3).

This mission took place from 20 to 24 July 1998 (see point 2.3.) and led to a broadly satisfactory outcome. On 9 September the FVO reported on the mission in the SVC.

Following the mission, the United Kingdom has forwarded information on how it intends to implement and improve the controls. In addition, the Commission services have introduced legal clarifications in line with the recommendations of the mission report in the draft proposal.

The amended draft Decision has been discussed at the SVC meeting held on 6 and 7 October 1998. The draft proposal has been voted in the SVC on 4 November and has received a favourable vote of a majority of Member States. However, as a qualified majority was not achieved, the Commission decided on 11 November to submit a proposal to the Council for discussion on 23-24 November 1998.

5. Legislation

5.1. Co-decision procedure

The Commission's operational approach is that action related to the production or marketing of agricultural products, especially in the veterinary and phytosanitary fields, must be based on Article 100a of the EC Treaty insofar as the aim of such action is to protect public health. It follows that legislation in this field must be adopted under the co-decision procedure.

The Commission defends this approach in Case C-269/97 (*Commission v Council*, an action for having Regulation No 820/97 declared null and void), in which Parliament has given its backing to the Commission's conclusions.

The new provisions in the Future Amsterdam Treaty concerning public health serve to extend the scope and effectiveness of Community powers in this field. More especially, the new Article 152 establishes a link between veterinary and phytosanitary measures and public health within the framework of the co-decision procedure. Clearly, this innovation will mean that Parliament is fully involved in any new measures taken in this field.

The Commission firmly believes that the new Article 152 will make it possible to deal effectively at Community level with crisis situations like BSE.

In the current context, the following dossiers are worthy of note:

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

The Council adopted its Decision unanimously, contrary to the Commission's opinion and contrary to the opinion of Parliament. The Commission is currently contesting this decision at the European Court of Justice (Case C296/97 of 22 July 1997). The Court is not expected to pass judgement before 1999.

- A proposal for a Council Regulation on measures to promote and market quality beef and veal and on information measure 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 Parliament's amendment concerning the inclusion of Article 129 as a legal basis for consumer information measures. This amendment was not accepted by the Council which instead, unanimously, adopted a regulation restricted to information measures concerning labelling and using the initial legal basis. The Commission has protested at the lack of consultation of Parliament by the Council.

Preparation of a "horizontal" TSE regulation based on Article 100a.

The Commission is submitting to Council and the European Parliament a proposal for a global and long-term surveillance system for transmissible spongiform encephalopathies, based on Article 100a (see point 5.4 iii).

5.2. General legislative measures

i) **Assessment of further changes to Directive 85/374/EEC (product liability)**

On 1 October 1997, the Commission adopted its proposal to extend the 1985 Product Liability Directive to primary agricultural products¹. The proposal gives full effect to the EP's recommendation contained in the report of February 1997 (by the Temporary Committee of inquiry into BSE) which called for a legislative proposal on primary product liability.

The proposal was supported by most delegations in the Council² and welcomed by the economic sector, in particular consumers, food processors, distributors and retailers. The European Parliament held its first reading on 4-5 November 1998. It approved the Commission's proposal to extend Product Liability to the agricultural sector. It also recommended to substantially modify a number of points of the 1985 Product Liability Directive (period and financial limits of liability).

A common position could be reached before the end of the Austrian Presidency. In this case, the directive could be finally adopted by next year.

Once the proposal is adopted by the European Parliament and Council, the Commission intends to assess whether any other initiative is needed in a context broader than the follow-up of the BSE inquiry. This assessment will be made through proper consultation (which could take the form of a Green Paper) with all parties concerned by product liability legislation (consumers, producers, distributors, legal professions, insurance sector, public administrations). This exercise would be launched before January 2000.

As required by Article 21 of the 1985 Product Liability Directive, the Commission will report by 2000 on the application of the Directive. If the Commission concludes in this report that, in the light of the findings drawn from the consultation, the Directive needs to be modified, it will submit further proposals.

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

The Commission response to the debate on the Green Paper on « The General Principles of Food Law in the European Union » is being actively prepared, but will take more time than previously anticipated.

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

The simplification of the existing 13 Veterinary Directives and the General Hygiene Directive is progressing steadily. The work requires significant re-alignment of detailed texts and is scheduled to be finished by the end of 1999.

¹ COM(97)478, OJ N° C 337, of 7.11.97

² Internal Market Council of 18.5.98.

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

The Commission has adopted regulations for applying Council Regulation (EC) 820/97 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products.

As far as identification and registration are concerned, these are:

- transitional arrangements for the start-up period (Regulation (EC) No 2628/97, as amended by Regulation (EC) No 2105/98);
- eartags, holding registers and passports (Regulation (EC) No 2629/97 as amended by Regulation (EC) No 1177/98);
- 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).

The application on the spot of Council Regulation (EC) 820/97 and of implementing regulations adopted by the Commission raises problems for different national administrations. In this context, the setting up of a fully operational database constitutes a major task for many Member States. Under Article 5 of Regulation (EC) No 820/97, all computerised databases in the Member States must be operational by 31 December 1999. Pursuant to the first subparagraph of Article 6(3) of this Regulation, the Commission is authorised to decide what is "fully operational". The Commission has therefore sent the Member States a questionnaire, drawn up with the assistance of national experts, to obtain the necessary details. As soon as the Commission has received the completed questionnaires, it will examine them according to the set procedure.

As far as labelling is concerned, they are:

- mutual recognition (Article 1 of Regulation (EC) No 1141/97);
- the minimum requirements for specifications (Article 2 of Regulation (EC) No 1141/97);
- checks (Article 3 of Regulation (EC) No 1141/97);
- sanctions (Article 4 of Regulation (EC) No 1141/97);
- third-country approvals (Regulation (EC) No 2406/97).

Where the production of beef takes place, in full or in part, in a third country, operators and organisations shall be entitled to label beef according to this Regulation if they have obtained approval of their specifications by the competent authority designated for that purpose by each third country concerned.

The validity within the Community of any approval granted by a third country shall be subject to prior notification of the approval procedure of the third country concerned to the Commission. The Commission shall examine that notifications received from third countries are complete in order to ensure that the labelling arrangements relating to imported beef are of equivalent reliability to those applicable to Community beef. Up to date the Commission services have received 12 notifications from third countries, of which 11 are complete.

On 18 February 1998, the Commission submitted to the European Parliament and the Council a proposal for a Directive based on Article 100a and amending Directive 64/432/EEC on health

problems affecting intra-Community trade in cattle and swine (OJ C100 of 2 April 1998) with a view to enabling the Commission to adopt, where necessary, practical arrangements concerning databases so as to ensure data flow between the different national databases and to guarantee their operational nature.

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

Finally, a report drawn up pursuant to Article 10 of Council Directive 92/102/EEC on the identification and registration of animals was presented to the Council (COM (1998) 207).

5.3. Strengthening of controls in the European Union

Harmonisation of control programmes

Commission Decision 98/470/EC implementing Council Directive 89/662/EEC as regards information on veterinary checks was adopted and published in OJ L208 of 24 July 1998. It provides for the computerised forwarding to the Commission, according to a harmonised model, of the essential information on checks carried out at the point of origin and on arrival at destination. The requisite information mainly concerns the number of establishments subject to checks, the quantities checked, the type of controls carried out, the results of these checks and the staff deployed to carry them out. Under Article 16 of Directive 89/662/EEC, the information will be examined by the Commission in the form of the Standing Veterinary Committee.

Strengthening of sanctions

For the purposes of Regulation (EC) No 97/820 (beef labelling), rules have been laid down for the application of minimum administrative sanctions in Regulation (EC) No 98/494 (see point 5.2.iv).

Strengthening of routine controls in the animal feed sector

- Article 22 of Directive 95/53/EC fixing the principles governing the organisation of official inspections in the field of animal nutrition requires Member States to draw up, by 1 October 1998 at the latest, programmes laying down the nature and frequency of regular inspection arrangements. In the light of shortcomings found in the Member States, the Commission has adopted on 3 November 1998 a proposal based on Article 100A amending the rules with a view to making the Member States' inspection arrangements more effective so as to comply with Decision 94/381/EC banning the use of mammalian-derived proteins in animal feeds. The proposal could be discussed in the Council on 14 – 15 December 1998.
- The Commission is proposing to amend Article 22 to give it the opportunity to draw up specific control programmes at Union level, more especially laying down the frequency of inspections, alongside the general national programmes provided for in this article.
- The Commission has adopted on 13 November 1998 a Directive establishing guidelines for the microscopic identification and estimation of constituents of animal origin for the official control of feedingstuffs. This directive provides that microscopic examination with a view to official controls of the identification and estimation of constituents of animal origin in feedingstuffs are carried out using the guidelines. According to the progress of scientific and technological knowledge, this directive does not exclude the use of methods of analysis, other than microscopic examination, which have been scientifically proved to be valid for the identification and estimation of the constituents of animal origin.

- The SSC recommends avoiding cross-contamination between raw materials from different animal species and between final products for consumption by different species. The Community legislation will include measures designed to prevent the contamination of animal feeds by mammalian-derived proteins during production and transport. The Community legislation will also lay down inspection arrangements based, if possible, on a single analytical method, as soon as such a method becomes available and has been validated.

5.4. Prevention and control of TSE in animals

i) Commission Decision 98/272/EC on TSE surveillance

Following the advice of the Standing Veterinary Committee meeting on 3 and 4 March 1998, the Commission adopted a decision on the epidemiological surveillance of TSE and amending Decision 94/474/EC with a view to enabling a harmonised approach in the Member States and imposing an obligation to notify details of TSE cases to the Commission and to the other Member States (Decision 98/272/EC, OJ L122 of 24 April 1998).

An overview on the current situation with regard to BSE in the Member States is given in Annex 6.

ii) Commission Recommendation concerning the evaluation of the epidemiological status of countries

On 22 July 1998, the Commission adopted a recommendation on information required to underpin requests for evaluation of the epidemiological status of Member States and of third countries with regard to TSE (see also point 1.2.iii).

iii) Draft Regulation concerning the effective surveillance of TSE in the Member States

• Introduction

The Commission has adopted on 18 November 1998 a proposal that fulfils the commitment taken by the Commission on 20 October 1997, in its final consolidated report to the Temporary Committee of the European Parliament on the Follow up of the Recommendations on BSE, to present a proposal for an effective surveillance of TSEs based on Article 100A to the European Parliament and the Council.

The proposal represents a large range of measures addressing all human and animal health aspects of food and feed production relating to risks of exposure to all TSEs. The specific risk assessment and management needed for cosmetic, medicinal or pharmaceutical products and medical devices justify the exclusion of these products from its scope.

• Creation of the legal base

The main objective of the proposal is to create the legal base for the control and prevention of all animal TSEs and for all products, including those not covered by Annex II of the Treaty. Implementing rules are foreseen where future action can be expected.

• International standards, scientific advice

The provisions are based on the IOE recommendations on BSE and on the various Community scientific opinions available in order to ensure a very high level of protection. In addition to the amendments to the Code adopted by the IOE in May 1998, the amendments proposed in

September 1998 by the IOE Code Commission have been taken into account. These latter amendments follow the recommendations of the scientific Ad hoc Group on the epidemiology of BSE; which met in June.

Where international standards or scientific advice are absent, for example for the eradication of BSE, current Community standards are proposed.

- Scope

In principle the prevention and control of all animal TSEs with respect to food and feed is covered.

Industrial, cosmetic and pharmaceutical products and medical devices and products destined for research, exhibitions or teaching are not included, because there is either no inherent risk for human or animal health or the provisions are covered by sectorial legislation. A general provision to ensure that those products can not enter the food and feed chains provides the necessary protection during the production process.

An important exception to the above is the exclusion of the animal waste legislation, despite the fact that the predominant motivation for this legislation is protection against TSEs. For technical reasons it was considered beneficial to keep the animal waste legislation separate as a coherent independent set of legislation. The elements of this legislation such as waste processing standards, validation of processes, approval of establishments, placing on the market of rendered products, etc. are strongly interdependent and form a coherent entity. Moreover, they are primarily based on general hygiene standards.

Another exception of lesser importance is the maintenance of general, though TSE related, standards for the production of products such as gelatine and tallow in specific legislation. An example is the suggested purification of tallow, which is proposed to apply generally regardless of the TSE status of the country.

- Placing on the market

It is proposed to treat national trade, intra-community trade, import and export in an equivalent manner. As a consequence, Community rules for export are introduced and the dual standard for consumers in high-risk areas, i.e. the United Kingdom, is abolished. This approach is consistent with international obligations under the SPS Agreement.

- Scrapie and BSE in sheep

The successful experimental infection of sheep by feeding them BSE contaminated material, and the ensuing clinical expression of the disease which is indistinguishable from scrapie, the fact that exposure to contaminated feed of sheep in the field can not be excluded and, finally, the hypothesis that in the past scrapie could have evolved into BSE and caused the BSE epidemic, lay at the root of the policy of the Commission to address all TSEs and all ruminants in its preventive measures to protect against TSEs. The feed ban prohibits the use of mammalian protein in all ruminant rations. The SRM ban requires removal and incineration of SRMs from bovine, ovine and caprine animals. The TSE surveillance addresses all TSEs and in particular BSE and scrapie.

This policy is continued in the current proposal. All existing Community rules on TSEs are incorporated in the proposal, hence including the preventive measures mentioned above.

A new aspect is the creation of the legal base for eradication of all TSEs, including scrapie and BSE in sheep, and for trade requirements preventing the spread of BSE by movements of live bovine, ovine and caprine animals. In the absence of scientific advice and international standards on the eradication of scrapie, or on trade rules to prevent the spread of BSE through sheep, no detailed rules are proposed in these areas. Scientific advice and international standards on the eradication of BSE in sheep are also lacking but following the precautionary principle, detailed rules for BSE eradication in sheep are proposed nevertheless.

Community rules for the movement of live breeding sheep and goats related to scrapie do exist. These have been transposed to this proposal, with the exception of the current option for Member States to demand additional guarantees on the basis of a Community approved scrapie control programme. In the past a policy decision was taken not to proceed with the approval of national programmes and the subsequent granting of additional guarantees beyond the limited list of diseases for which programmes had already been approved. It was felt that the accumulation of national programmes and additional guarantees would constitute an unjustified barrier to trade and disrupt the internal market. The aforementioned list does not include scrapie. Since the proposal at hand has as its objective to harmonise all trade rules relating to TSEs, including scrapie, and offers the legal base for eradication of scrapie there is no longer a need for national programmes for scrapie control.

5.5. Feedingstuff additives - Exclusion of risk material from the food and feed chain

i) Rendering standards, specified risk material and related matters

With a view to minimising the risk of re-cycling BSE through animal feed, the Commission adopted Decision 96/449/EC which imposes from 1 April 1997 minimum heat treatment conditions for processing animal waste to meat and bone meal, namely a temperature of 133°C, a pressure of 3 bars, a heating time of 20', which have been demonstrated as being effective for the inactivation of the agents of scrapie and BSE. The following legislative measures were initiated since adoption of Decision 96/449/EC:

a) Adoption of a ban in animal feeds on meat-and-bone meal not produced in accordance with Decision 96/449/EC and restrictions 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 mammal waste; this includes a feed ban for material not treated in accordance with Decision 96/449/EC.

b) Draft Commission Decision concerning certain protection measures with regard to transmissible spongiform encephalopathies and repealing Commission Decision 96/449/EC and amending Commission Decision 97/735/EC

As part of the programme of work mentioned in point II.3.3, an amendment to Decision 96/449/EC is now under discussion in the Standing Veterinary Committee with a view to

- clarifying problems of legal interpretation raised during infringement procedures and in connection with inspection missions conducted by the Community in the Member States, particularly with regard to:
 - the definitions in Article 1 (low-risk material, animal waste etc.);
 - the derogation's set out in Article 1(2) ("bones for human consumption", fertilisers etc.);

- introducing health protection criteria for tallow production, in accordance with the new SSC recommendation of 26 and 27 March 1998;
- taking account of a number of technical comments made by the FVO in its document on the general conclusions (see first paragraph of point 3.3): validation of rendering plants, post-sterilisation treatment etc.

The Scientific Veterinary Committee will also be asked to review its document on the validation procedure for rendering plants in the light of the standards imposed by Decision 96/449/EC.

Decision 97/735/EC will be amended also to be in line with the new provisions.

The Commission will also be submitting to the Council, as quickly as possible, an amendment to Decision 97/534/EC, the entry into force of which is currently scheduled for 1 January 1999, anticipating measures which the Commission intends to propose on the basis of Article 100A (see point 5.4.iii), the point being to defer the entry into force of the current decision to coincide with the entry into force of the amended decision.

ii) Labelling of compound feedingstuffs

Any proposal relating to the quantitative and qualitative labelling of animal feed should imply that the competent authorities are able to verify, using "fit for purpose methods", to confirm the accordance of the real composition of feed with the declaration of the ingredients provided by the manufacturers. A co-operative study has been organised to check the current possibilities for the determination i.e. qualitatively and semi-quantitatively, by microscopical analysis of the ingredients of compound feedingstuffs and in particular to detect the presence, the origin and the quantity of meat and bone meal. Twenty-five laboratories (23 official and 2 private laboratories) of 12 Member States (and Norway) participated to the co-operative study. The final report of the study is available since end of September and has been transmitted to the participating laboratories, the competent authorities and the European Parliament. The results of the study are in discussion in the Expert Committee "Methods of Analysis"; the conclusions and further follow-up will be submitted in December to the competent authorities of the Member States in the Standing Committee for Feedingstuffs (see also point 1.3.ii).

iii) Destruction of meat-and-bone meal

The stockpile of MBM resulting from the Over Thirty Months Scheme stood, in August 1998, at 350 000 tonnes, and only some 1 300 tonnes have been disposed of in a household refuse incinerator. The United Kingdom gave notice to the Commission, in a letter dated 6 October 1998, of the conclusion of a contract between the UK authorities and a commercial firm for the large-scale incineration of 255 000 tonnes over a minimum period of three years. Work could get under way in the first quarter of 1999 provided the necessary permits can be obtained quickly.

iv) Feedingstuff additives

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.

Different safeguard clauses applied by the Member States have been examined by the Scientific Committee on animal nutrition, in particular tylosine, spiramycine, virginiamycine, carbadox and olaquinox. Dimetridazole is still under examination.

The Commission has presented a draft proposal withdrawing the authorisation of four antibiotics in feedingstuffs, in order to reserve their use or the use of antibiotics belonging at the same family, to the human medical use.

Furthermore, as regards antibiotics, and in addition to the specific molecule by molecule examination carried out by the Scientific Committee on animal nutrition, an across-the-board examination is under way into the growing problem of resistance to anti-microbial agents. An ad hoc working party was set up to this effect in April 1998 by the Steering Committee. The group is now looking into the phenomena of resistance caused by the use of antibiotics in human medicine, in veterinary medicine, as feedingstuff additives or for other purposes (e.g. plant-health products), their development and dissemination, and is looking into what corrective measures, if any, should be taken. An interim assessment is expected to be available by the end of 1998, followed by a final report in April 1999.

The World Health Organisation conference held in Berlin in October 1997, the Economic and Social Committee of the European Union, the International Office of Epizootics and the conference on antibiotic resistance held in Copenhagen in September 1998 concluded that antibiotic resistance must henceforth be regarded as a major, complex problem of international dimensions, and that the problem of resistance encountered not only in hospitals but also in the general population should be addressed. In the light of these conclusions, by consideration of the opinion expressed by the Scientific Committee on Animal Nutrition and by taking into account additional data supplied by Member States the Commission took the view that there are in the meantime sufficient scientific grounds in particular as regards the possibility of transfer of resistance and the development of cross-resistance for a ban on certain antibiotics authorised in feedingstuffs. On this background a draft Regulation was presented to the Member States withdrawing the authorisation of four antibiotics in feedingstuffs, in order to reserve their use or the use of antibiotics belonging to the same family, to human medical use.

5.6. Update on the 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.

Referring to the first bi-annual BSE follow-up report the following has developed:

- Following the conciliation procedure in May 1998 the European Parliament and the Council jointly approved the setting up of a Community network for the surveillance and control of communicable diseases in the Community. The network is to be used for:
 - the epidemiological surveillance of selected diseases including CJD; and
 - an early warning and response system for the prevention and control of these diseases.

The network will enter into force three months after publication in the Official Journal in October 1998 (Decision n° 98/2119/EC; OJ of 3 October 1998, L268).

The network is intended to respond effectively and in a co-ordinated way to epidemics or outbreaks of communicable diseases in the Community and to set up a system for effective co-

ordination and consultation between the Member States which will address both routine and emergency situations.

Work on implementing the network has already started and many of the surveillance projects under the 1996 – 2000 Community public health action programme on AIDS and communicable diseases (Decision N° 96/647/EC of the European Parliament and the Council) will be integrated into this network.

- Further to the Commission Communication and proposal for a programme of Community action 1999 to 2003 on rare diseases within the framework for action in the field of public health (OJ C 203, 3 July 1997, p.6), the Council has adopted on 30 April 1998 a common position for a European Parliament and Council decision pursuant to Article 129 EC (OJ C 227, 20 July 1998, p.1).

One of the objectives of this programme is to promote cross-border collaboration between groups of persons directly or indirectly affected by rare diseases, including neurodegenerative conditions.

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**

Commission Directive 97/65/EC strengthens the existing provisions under Directive 90/679/EEC on the protection of workers from the 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 abattoir workers, farmers, veterinarians, doctors, zoo-keepers and laboratory workers.

Directive 97/65/EC came into force on 1 July 1998. On 30 October 1998, its transposition into national law had been communicated to the Commission by 9 out of 15 Member States.

iii) **Blood products and CJD**

In June 1998, the Council adopted a Recommendation on the suitability of blood and plasma donors and the screening of donated blood in the European Community (98/463/EC). This Recommendation includes permanent deferral criteria for blood and plasma donors for the protection of recipients of blood and blood products. These criteria include individuals who have or have a history of TSEs (or a history thereof in the genetic family), cornea/dura mater transplantation, or pituitary hormone of human origin (e.g. human growth hormone).

The Commission has also sought the opinion of the Scientific Committee on Medicinal Products and Medical Devices on risk quantification for CJD transmission via substances of human origin. This opinion was adopted on 21 October 1998 (see point 1.2.v)).

6. **International aspects**

6.1. **International standards with regard to TSEs**

i) **MBM safety standards and general standards in the IOE**

The question of the harmonisation of international standards for the production of meat-and-bone meal was not addressed at the last General Session of the International Office of Epizootics at the end of May 1998. The current IOE code on the inactivation of transmissible spongiform encephalopathy agents during the production of meat-and-bone meal is less restrictive than the present Community legislation and not fully in line with the recent scientific opinions of the

Scientific Steering Committee. In its staff working paper on the position to be taken by the Community, the Commission proposes taking 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.

ii) **Codex**

Codex Alimentarius which is the FAO/WHO joint programme for international food standards is now examining the implications of regional differences in the prevalence of foodborne pathogens in the management of microbiological hazards for foods in international trade.

It is generally accepted that differences in the prevalence of various foodborne pathogens in the food chain do exist between regions. These differences may be linked to the environment or may be a result of active and extensive control programmes. Examples are given including brucellosis, tuberculosis, BSE, trichinosis, salmonellosis which have been eradicated or the prevalence of which is significantly different in some countries.

Food safety objectives in general and more specifically sampling plans, criteria etc. cannot always be considered universally common, but should reflect these relevant and significant differences. The existence of regional differences in the prevalence of foodborne pathogens in the food chain should be taken into account in the elaboration of relevant Codex documents, such as risk management procedures, inspection and certification of foodstuffs in international trade. Discussions on these implications have been initiated during the meeting of the Codex Committee on food hygiene (Orlando, USA, 26 – 30 October 1998).

6.2. **Hormones**

The WTO Appellate Body (AB) has, following an appeal by the European Commission, revised the ruling handed down by the Panel on a number of important points. In its report, which was adopted on 13 February 1998, the AB found that the prohibition on the use of the hormones for growth promotion in meat production was not based on a sufficiently specific risk assessment to show the existence of residues constituting a risk to the consumer.

On 13 March 1998 the EC announced that it intended to carry out a complementary risk assessment focusing specifically on the potential health risks from hormone residues in meat and meat products. This risk assessment will include the evaluation of existing data in the EC's possession, those provided by other interested parties and the results of new studies.

On the basis of the results of the risk assessment the EC will draw the appropriate conclusions and amend Community legislation where necessary.

According to the rules and procedures governing the settlement of WTO disputes, a Member shall have a reasonable period of time to implement the recommendations and rulings of the AB. If the parties concerned are unable to find a mutual agreement, the reasonable period of implementation is determined through binding arbitration. Fifteen months are given as a guideline for the arbitrator in such cases, which can be shorter or longer, depending upon the particular circumstances.

In the course of the negotiations with the US and Canada, it became evident that it was not possible to reach a mutual agreement on the reasonable period of time. Hence an arbitrator was appointed.

The Commission pleaded for a much longer implementation period pointing to the fact, that 15 month would be insufficient both to complete a risk assessment focused specifically at potential adverse human health effects of hormone residues and their metabolites in meat and to implement the possible legislative measures.

Nevertheless the arbitrator followed the guideline of the dispute settlement provisions and awarded the EC 15 months to implement the AB ruling. This period will expire on 13 May 1999.

Taking note of the decision by the arbitrator, the EC continues the complementary risk assessment of the potential adverse human health effects of hormone-treated meat. To assist with the risk assessment the Commission has decided to call on its independent Scientific Committee on Veterinary Measures related to Public Health (SCVPH) which will evaluate the scientific knowledge and evidence on the hormones in question.

7. Situation with regard to CJD and nvCJD cases and assistance to nvCJD victims

7.1. Current situation regarding nvCJD cases in the European Union

The total incidence of definite and probable new variant CJD cases identified by specific neuropathology to date is 30 in the United Kingdom and 1 in France.

7.2. Assistance to nvCJD victims

Since the first bi-annual report, the Commission has made an internal transfer of resources (30.000 Ecus) to the new budgetary line (B3-4308) entitled "Support for Associations seeking to help victims of Creutzfeldt-Jacob disease".

Following contacts with the Human BSE Foundation in the United Kingdom, a grant of 30.000 Ecus has been awarded to that association to assist in its operations.

8. Frauds and financial aspects

8.1. Fraud: co-ordination

With regard to the illegal traffic in beef of United Kingdom's origin discovered in the Netherlands the Dutch magistrate has transmitted the first part of the Dutch judicial file to the Belgian examining judge in Brugge.

The judicial authorities in Belgium dealing with the investigations against the Belgian companies involved have ordered house searches of the persons suspected to be involved in this affair. Three arrests were made on 10 September 1998 but two persons were released after interrogation. The detention of one of them has been confirmed by the competent judicial authorities in Brugge and the person concerned did not lodge an appeal against this.

The enquiries in France are still ongoing. The French magistrate has sent rogatory commissions to different Member States and has also issued an international warrant of arrest against two persons of Belgian nationality involved in the United Kingdom's beef case.

The German judicial authorities which carried out proceedings against three German exporters have closed the cases. The reason being that there was no proof against the exporters of knowingly having exported beef of United Kingdom's origin. The option remains, however, of reopening the proceedings should further evidence be obtained.

Criminal proceedings have been instituted by the United Kingdom's Ministry of Agriculture, Fisheries and Food against three defendants in respect of an investigation into allegations of the export of meat products in breach of European Union's Regulations. Further information will be available as soon as notice of the proceedings has been served upon the defendants. It should be noted that under United Kingdom's law there are restrictions on what can be reported whilst criminal proceedings are in progress which limits the amount of information which can be released at this stage.

At the end of July 1998, the Belgian veterinary authorities discovered in a coldstore, non-approved for the storage of meat, a consignment of 50 t of beef. The outside of the cartons was marked with health labels allegedly issued for two Dutch establishments, but the labels turned out to be false. Moreover, health labels of the two Belgian establishments which were used last year to identify the illegal consignments including UK beef, were also found. A physical inspection of the beef revealed that veterinary stamps were mostly cut out, but in some cases UK stamps could still be identified. According to transport documentation, the beef was loaded in Belgium and in the Netherlands and subsequently stored for the account of a Belgian company involved in the case. This affair is still under investigation by the competent Belgian and Dutch authorities and is included in the judicial proceedings in Belgium.

UCLAF will maintain contact with the competent authorities in the Member States concerned.

The Council Regulation (EC) No 97/515 of 13 March 1997, concerning the mutual assistance between the administrative authorities of the Member States and the collaboration of these authorities and the Commission in order to insure the appropriate application of the customs and agriculture legislation, is in force since 13 March 1998. Title V of this Regulation set up the legal framework laying down a centralised database on customs information (CIS) with the objective of assisting the prevention, detection and follow-up operations contravening the customs and agriculture legislation by means of a faster transmission of information and more effective co-operation and control procedures on the part of competent authorities.

Commission Regulation (EC) No 98/696 of 27 March 1998, based on Regulation (EC) No 97/515, establishes those agriculture operations that could be targeted by the CIS in cases where a similar system is not provided elsewhere. During the preparation of this Regulation, the Commission took particular account of fraud cases related to BSE which could be covered by the information provided, in the near future, into CIS database.

Information provided by CIS will allow suspected goods to be linked to such movements, both at intra-Community and extra-Community level, in order to trace them back to source.

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

The Commission services have decided to propose financial consequences as regards expenditure declared in financial year 1996 and 1997 in view of the problems established by the Clearance of Accounts Unit, in particular as regards accounting, the control over scheme material, and the lack of decisive plans for destruction of the majority of the scheme material still held in storage.

The UK authorities have appealed to the conciliation body in accordance with Art. 2(4) of Commission Decision 94/442/EC.

The Commission continues to monitor the implementation of the BSE measures in the UK and has reserved its opinion as regards future financial corrections for expenditure incurred in relation to these measures.

9. **Consumer's guide**

Following the publication of two versions of the "Guide to BSE" ("Vademecum") designed to address consumer concerns, the Commission's interdepartmental working party has continued its work and produced a third version. Distribution of this guide commenced in October 1998 and will, like the previous version¹, be available in the 11 official languages.

¹ Doc GIS-BSE (96) 7.5: almost 3 000 copies distributed in the 11 official languages of the EU.

III. ANNEXES

Annex 1

TABLE A

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

This table gives an overview of the state of achievement of the work programme included in document COM(97) 509final of 20 October 1997

<i>Ref. N°</i>	<i>Action promised</i>	<i>Indicative timing</i>	<i>Time of delivery</i>
1.2	Nomination of Scientific Committee (SC) members	October 1997	November 1997
1.2.5	Acceleration of payment procedures for SC members Payment of indemnity to SC members	As from 1.1.1998, DG24 responsible For new committees: as from their first meeting	May 1998 (ongoing) November 1997 (ongoing)
2.1	Replacement of two Commission decisions relating to performance of on-the-spot checks	Standing Veterinary Committee (SCV) vote Oct. 1997, Decision coming into effect Nov. 1997	February 1998
2.1.2	Recruitment of staff under SAB 1997 Additional increase in staff numbers in FVO	Before end of the year In 1998	End 1997 Ongoing
2.2	Receipt of, and response to, IGS report.	October 1997	January 1998
2.3	Development of internal manual procedures by FVO	Beginning 1998	November 1997
3.2	Consultation procedures on other amendments to Directive 85/375/EEC	Consultation for beginning of 1998	1 st Semester 1998

	Consideration of Green Paper on Food Law responses (1) and organisation of Food Law conference (2)	November 1997	(1) Ongoing (2) November 1997
	Completion of simplification exercise on veterinary hygiene legislation	1998 / 1999	Ongoing
3.5	Establishment of a Community network for the surveillance and control of communicable diseases	1998	Entry into force 3 months after publication (October 1998)
	Adoption of amendment to Directive 93/88/EC re. stricter containment levels for BSE laboratory work 1998	Beginning 1998	November 1997
3.5.1	Adoption by the Commission of projects on TSE research following the 29th April 1997 joint call for proposals	December 1997	February 1998
3.5.9	Production and distribution of BSE vademecum information for consumer	Before end 1997	October 1998
3.6	Develop full membership of WHO and OIE by Commission	Timing uncertain	Ongoing
3.7.1	Commission consultation paper on exclusion of high risk material from the feed chain and on ban on feeding animal protein to ruminants	Oct/Nov 1997	November 1997
3.7.2.3	MDSC/SSC to discuss list of SRMs and abolition of age limits on exclusion of younger animals	16.10.1997	Opinion December 1997
3.8	Vote in SVC on proposed ban on MBM not produced to new standards and restriction on use	SVC vote Oct. 1997, Decision coming into effect Nov. 1997	Adoption October 1997
3.9	Organisation and completion of study of methods to establish	1998	Ongoing ; final results expected

	quantity and quality of feed materials in compound feedstuffs		December 1998
4	Introduction of a legal requirement for traceability of gelatine and certain other products made in the UK from non-UK material	Before end of 1997	Adoption March 1998
	Reinforcement of veterinary checks with regard to Decision 96/239/EC	Before end of 1997	Adoption March 1998
	Reinforcement of veterinary controls in the European Union:		
	<ul style="list-style-type: none"> • Harmonisation of control plans 	Beginning of 1998	Publication of Commission Decision July 1998
	<ul style="list-style-type: none"> • Application of Directive 89/608/EEC 	October 1997, ongoing	Ongoing
	<ul style="list-style-type: none"> • Amendment of Directive 89/608/EEC, where necessary 	1998 / 1999	Not pursued
	<ul style="list-style-type: none"> • Reinforcing controls when emergency measures apply 	October 1997, ongoing	Ongoing
	<ul style="list-style-type: none"> • Reinforcing sanctions 	1998 / 1999	For beef labelling : Regulation 1141/97 of 23 June 1997, Article 4
	<ul style="list-style-type: none"> • Reinforcing routine controls 	1998 / 1999 (at least partly to be based on Article 100A)	Outstanding
4.1	Appropriate action on the basis of scientific advice on the UK's Export Certified Herd Scheme	Revised UK proposal expected	Adoption March 1998

	Submission of the report of the mission to the UK 9-13.6.1997 to EP	October 1997	October 1997
	Submission of UK's proposal on a date-based export scheme to the appropriate scientific committees for their opinion	Official UK proposal of 2 October to be examined in November	Opinion February 1998
5.3	Taking appropriate action pursuant to Article 169 of the Treaty, where the UK failed to apply Decision 96/239/EC	Ongoing	Ongoing
	Financial consequences from findings on the over thirty months scheme and the selective cull scheme, should there be justifications of failures by the UK authorities to respect Community Regulations	Ongoing (clearance of account procedure)	Ongoing (end 1998/beginning 1999)
5.4	New information obtained by the FVO inspectors with regard to implementation of Decision 96/449/EC will be submitted to the Commission services responsible for infraction procedures	Oct.-Dec. 1997	October 1997 – February 1998
6.3	Further follow-up missions concerning the reporting of all BSE cases will be undertaken to Germany, Italy and Sweden	October – December 1997	October – December 1997
	Proposal for a Council Regulation on effective TSE surveillance in the Member States	Before end 1997	18 November 1998

Acceleration of payment procedures for the members of the Scientific Committees

In October 1997, an analysis of the payment system was carried out and consequently improvements were introduced. However, a serious backlog of reimbursements existed until May 1998 but, since then, significant improvement has been achieved. Under normal conditions, i.e. when there are no specific problems with a claim, reimbursements are credited to the accounts of the experts no later than 2 months (60 days) after a meeting.

As regards the indemnity payments, the Commission has decided, in agreement with the members of the Scientific Committees, to make these payments 3 times per year. The first series of payments under this system was initiated in March and completed by May. A second batch was sent out in July. The final payments in 1998 will be in November.

Annex 3

Scientific Opinions related to BSE, adopted by the Scientific Committees since November 1997 (status on 11.11.98)

Scientific Committee	Date of adoption	Title of opinion adopted
1. Scientific Committee on Veterinary Measures relating to Public Health	17 February 1998	Safety of slaughter practices and methods: risk of spread of BSE infectivity through cross contamination of different tissues by using pneumatic stunning during the slaughter process of ruminants
2. Scientific Committee Cosmetic Products and Non Food Products	23 September 1998	Opinion on tallow derivatives
3. Scientific Committee on Medicinal Products and Medical Devices	16 September 1998	Opinion and report on the equivalency of alternative products to intestines of animal origin for use as surgical sutures.
4. Scientific Committee on Medicinal Products and Medical Devices	21 October 1998	Opinion on the risk quantification for CJD transmission via substances of human origin.
5. Scientific Steering Committee	9 December 1997	Listing of Specified Risk Materials: a scheme for assessing relative risks to man
6. Scientific Steering Committee	9 December 1997	Report on the UK Date Based Export Scheme and the UK proposal on Compulsory Slaughter of the Offspring of BSE Cases
7. Scientific Steering Committee	22-23 January 1998	Opinion of the Scientific Steering Committee defining the BSE risk for specified geographical areas
8. Scientific Steering Committee	19-20 February 1998	Opinion on the revised version of the UK Date Based Export Scheme and the UK proposal on compulsory slaughter of the offspring of BSE-cases, submitted on 27.01.98 by the UK Government to the European Commission
9. Scientific Steering Committee	19-20 February 1998	Final Opinion on the contents of a "Complete dossier of the

		epidemiological status with respect to TSEs”.
10. Scientific Steering Committee	26-27 March 1998	Opinion on BSE risk
11. Scientific Steering Committee	26-27 March 1998	Opinion on the Safety of Gelatine
12. Scientific Steering Committee	26-27 March 1998	Opinion on the Safety of Tallow
13. Scientific Steering Committee	26-27 March 1998	Opinion on the Safety of Meat and Bone Meal
14. Scientific Steering Committee	25-26 June 1998	The safety of dicalcium phosphate precipitated from ruminant bones and used as an animal feed.
15. Scientific Steering Committee	25-26 June 1998	Possible links between BSE and organophosphates used as pesticides against ecto- and endoparasites in cattle.
16. Scientific Steering Committee	24-25 September 1998	Opinion on the risk of infection of sheep and goats with Bovine Spongiform Encephalopathy agent.
17. Scientific Steering Committee	24-25 September 1998	Report and Opinion on mammalian derived meat and bone meal forming a cross-contaminant of animal feedstuffs.
18. Scientific Steering Committee	24-25 September 1998	Scientific Opinion on the safety of organic fertilisers derived from mammalian.
19. Scientific Steering Committee	24-25 September 1998	Updated Scientific Report presented on 24-25 September to the Scientific Steering Committee on the safety of meat and bone meal derived from mammalian animals fed to non-ruminant food-producing farm animals,
20. Scientific Steering Committee	22-23 October 1998	The safety of hydrolysed proteins produced from bovine hides.
21. Scientific Steering Committee	22-23 October 1998	The safety of bones produced as by-product of the Date Based Export Scheme.
22. Scientific Steering Committee	22-23 October 1998	Evaluation of the <i>ELLCO-FOOD</i> process for the production of gelatine regarding its equivalency with commonly used industrial gelatine production processes in terms of its capacity of inactivating/eliminating possible TSE infectivity in the raw

General Conclusions of veterinary missions regarding BSE since 1996 to Member States (excluding the United Kingdom)

1. Rendering standards

A first round of inspections to Member States (except the United Kingdom, subject to specific missions) took place from October to December 1996, to assess the presence and management of main risk factors and surveillance procedures with regard to BSE. The assessment was founded in particular on IOE criteria (supporting document of the IOE International Health Code on BSE, up-dated May 1996).

Part of the assessment covered the systems of commercial rendering and other methods of animal waste disposal. At this time, Commission 96/449/EC on alternative heat treatment for mammalian waste (so-called « pressure standard ») was not fully applicable yet.

The following main findings were made:

- Certain Member States had not fully implemented Community legislation (Directive 90/667/EEC, Decision 92/562/EEC, Decision 94/382/EC) with regard to the approval/registration of plants and their processing requirements. Some Member States did not even have a full knowledge of all plants and their processing parameters.
- A few Member States produced mammalian Meat and Bone Meal only or almost only by pressure standard.
- There were deficiencies in the official controls over the processing requirements in the rendering plants in most of the Member States visited and cases of non-compliance with the processing requirements were identified during the missions.
- Certain Member States ensured incineration of bovines which had been diagnosed to have BSE, whereas in others, suspect cases might entered the normal rendering chain or be buried.

General conclusions and a number of recommendations were drawn up following these inspections and provided to the Commission and Member States.

The second round of inspections was targeted in particular at assessing the implementation of 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), but also at following-up on the previous missions.

None of the Member States, except one, had fully implemented the Decision, even the degree of non-compliance varied largely. In a number of cases, improperly processed mammalian protein (not treated with the pressure standard) entered the feed chain.

It must be recognised that, considering the relatively short time available and the extent of the required adaptation, major efforts were developed by a large part of the industry in the Community under monitoring by Member States authorities, to implement the pressure standard.

The major reasons for incomplete implementation varied: decision from the Member State not to apply or not to fully apply the decision, sometimes due to an interpretation different from the one of the Commission concerning the high number of plants which needed to install a new equipment; deficiencies or delays in the administrative action, in particular by not applying the appropriate authorisation procedures or not adequately controlling storage and movement of improperly processed material.

However, it shall be noted that the second set of missions usually revealed a relative improvement in the implementation of Community legislation in the area of animal waste handling and certain deficiencies were corrected.

The main remaining deficiencies were:

- The situation in certain Member States still has to be clarified in respect of the implementation of the pressure standard at all relevant plants ;
- There are still deficiencies in the self-controls and official controls over the processing requirements. A certain lack of training and knowledge amongst the officials responsible is still noted.
- There is also a need to apply specific control procedures at national level to ensure that improperly processed material sent to a re-processing plant is adequately traceable and effectively re-processed.
- Deficiencies with regard to implementation of Directive 90/667/EEC are still observed in certain Member States, mainly with regard to registration of plants, microbiological controls, quality of the incoming material and general hygiene in the plants.

Certain deficiencies identified during the missions were explained by the perceived inadequacy of the legislation, the interpretation of this legislation or local situations.

General conclusions and a number of recommendations were made following these inspections. An amendment to Decision 96/449/EC taking on board certain recommendations from the FVO has already been drafted.

The missions currently carried out during the third round of inspections to Member States follow-up on these issues as far as possible. Preliminary results show a certain improvement of the situation.

2. Traceability of processed animal protein

Traceability of processed animal protein is of major importance in order to demonstrate and verify compliance with the legislative requirements, in particular regarding the rendering standards and the feed ban.

The first round of inspections in 1996 revealed that there were significant problems with tracing the movements of processed animal protein, notably mammalian MBM, imported from the UK in particular.

After this first round of inspections already, the FVO had made a recommendation to introduce appropriate rules and controls to guarantee traceability from production to feeding, and to lay down models of accompanying documents.

Commission Decision 97/735/EC concerning certain protection measures with regard to trade in certain types of mammalian animal waste, entered into force in October 1997.

This Decision established models of documents for trade in processed animal protein with a view to ensuring traceability. It laid down additional strict requirements for trade in improperly processed mammalian protein destined either for re-processing or for destruction in another Member State.

The current round of inspections to Member States concerning Decision 97/735/EC showed that implementation varied largely in the Member States visited. Transposition and /or application was delayed or incomplete.

Processed mammalian protein was not always accompanied by the relevant documents and Member States did not note that certain parts of the decision (model of commercial document) did apply also to non mammalian protein. The question of the applicability of the decision to feed containing processed animal protein was raised and none of the Member States visited so far implemented the decision for feed at the time of the mission.

As far as trade in improperly processed mammalian protein is concerned, this part of the decision was not always fully implemented, although traceability was usually ensured.

Certain Member States took additional measures to ensure a certain traceability of the processed material on their territory. In particular they required to accompany the consignments by documents providing certain details. This is of particular importance where flows of different categories of properly/improperly/derogated processed mammalian protein exists.

3. Feed ban

- **Ruminants**

After feed containing processed ruminant waste contaminated by the infective agent was identified as the primary source of BSE, a Community wide ban on feeding protein derived from mammalian tissues to ruminants (with the exception of certain products) was established in mid-1994 by Decision 94/381/EC. An assessment of this issue in the Member States (except UK which was assessed earlier) was included in the scope of the first round of inspections to Member States in 1996.

It showed in particular that such a ban was implemented between 1990 and 1996 in all Member States except one, which implemented it in early 1997. The UK had implemented certain earlier rules, due to the specific disease situation.

The competent authorities carried out documentary and visual checks in the feed industry in all Member States visited. However, official laboratory examinations for the illegal presence of mammalian protein were carried out only in certain Member States.

The tests used were essentially microscopic examination, but also ELISA.

The results of official surveillance, in particular via microscopic tests, revealed a relatively high number of cases of presence of MBM (of mammalian origin or not in feed labelled as not containing MBM in certain Member States

In a number of cases, « residual » presence attributed to cross-contamination was not exceptional.

Certain Member States introduced legal provisions to avoid cross-contamination within the feed-mills. In other member States, the feed industry took voluntary measures on the basis of Good Manufacturing Practices in particular.

After the round of inspections in 1996, recommendations were made by the FVO to introduce appropriate rules.

It shall be noted that since the missions were carried out, a number of Member States have introduced laboratory examinations, apparently mainly in the feedingstuff industry, more than at on-farm mixers.

- **Ban on feeding improperly processed mammalian protein to livestock**

This was part of the inspections in 1997, pursuant to Decision 96/449/EC and the current round of inspections further includes the issue, in the framework of Decision 97/735/EC.

4. TSE Surveillance

TSE surveillance was included into the scope of the first round of missions carried out by the FVO in Autumn 1996. BSE was the most developed part, but scrapie, as a risk factor for BSE, also was covered.

At this time there was hardly any EC legislation concerning TSE surveillance.

All Member States visited made BSE notifiable at the latest in 1990.

The extent to which surveillance was applied varied widely between Member States. However, in some Member States, examples and elements of well-structured networks for BSE surveillance with a clear designation of responsibilities and a high level of technical qualification were observed.

The missions revealed weak points in a number of Member States visited, like:

- Lack of written guidance from the veterinary authorities on symptomatology, epidemiology, sampling etc;
- Unclear criteria on which BSE could be suspected and reasons leading to BSE testing (with particular reference to emergency slaughtering);
- Insufficient co-ordination of surveillance;
- Lack of BSE examinations;
- Inadequate practices for collecting samples, laboratory testing, keeping of records.

After this first round of inspections, the FVO made certain recommendations in order to improve the surveillance.

During the second round of inspections to Member States in 1997, a follow-up on BSE surveillance was made where considered appropriate. Improvements were generally observed, although not all Member States could provide a fully satisfactory view on the situation.

On 1 May 1998, Commission Decision 98/272/EC on epidemio-surveillance for TSE entered into force, providing an EC legislative basis and certain detailed requirements for TSE surveillance within the Community. From August 1998, the FVO started to assess the implementation of this decision in the Member States.

5. Specified Risk Material and geographical risks

Implementation of Commission Decision 97/534/EC on the prohibition of the use of material presenting risks as regards TSE was postponed until 1 January 1999.

In the meantime, the Commission urged the Member States having national measures in place on Specified Risk Material to keep a status quo.

In that framework, the FVO included in the scope of the round of missions in 1998 an initial assessment on the measures in the relevant Member States (other than the United Kingdom for which the situation was assessed already).

It should be noted that serious efforts were developed by the relevant countries, which generally based their attitude on the content of the above decision. Certain areas for improvement were identified and suggestions were made to the countries visited.

Action pursuant to Article 169 of the Treaty

The Member States concerned by the infringement procedures are as follows:

1. United Kingdom

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 a reasoned opinion. A subsequent communication from the UK authorities dated 20 April 1998 was not considered to have shown adequately that the situation had been regularised, and the reasoned opinion was consequently dispatched on 26 May 1998.

In its reply to the reasoned opinion dated 24 July 1998 the United Kingdom accepted that its current level of veterinary supervision in approved slaughterhouses, cutting plants and cold stores or approved packing centres does not meet the requirements of Directive 64/433/EEC. The United Kingdom indicated, however, that it is working to correct this situation and has produced a programme of changes designed over time to bring all supervision fully in line with European Union's requirements. Full details of the measures taken or to be taken were supplied by the United Kingdom notably in respect of the recruitment of additional veterinarians.

The United Kingdom however contested that its admitted deficiencies in general official veterinary supervision also resulted in a failure to properly enforce Commission Decision 96/239/EC notably because of the particular supervision and enforcement measures taken in respect of plants currently processing non UK meat for export.

The competent services are still considering whether to propose bringing this case before the Court of Justice.

The problem regarding the seizure in the Netherlands in February 1998 of beef consommé and similar products manufactured in the United Kingdom, which undoubtedly fall within the scope of Article 1 of Decision 96/239/EC, has been looked into with the UK authorities, which maintain that the beef content of the product was from non-UK sources. However, the United Kingdom manufacturer is under police investigation in the United Kingdom.

2. France

Faced with the consistent failure of the French authorities to apply Decision 96/449/EC, 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 submitted, on 9 March 1998, the text of a ministerial decree of 6 February 1998 providing for obligatory treatment of animal waste in accordance with Commission Decision 96/449/EC. Further information on the new legislation was provided by France on 22 April

1998. The problem of non-transposition has therefore been regularised, and the way the decision is being applied on the ground will be examined at a subsequent inspection visit.

3. Belgium

The FVO inspection visit from 8 to 11 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 and use).

On 26 June 1997, the Commission decided to open an infringement procedure. 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).

In addition, following the discovery during the FVO visit on 18 September of defects in the system for monitoring the application of Decision 96/449/EC in Belgium, the Commission decided, on 25 March 1998, to open a further infringement procedure. The letter of formal notice was sent on 6 August 1998. The Belgian authorities' reply of 9 September 1998, in which they took the view that they had already done everything possible to tackle the BSE problem, is currently being looked at from a technical angle so as to judge the control measures in force in Belgium. From a legal standpoint, Decision 96/449/EC has still not been incorporated into the body of law in the Walloon region and in the Brussels-Capital region. However, according to the Belgian authorities, the decision is being applied in practice in the Walloon region, while the Brussels-Capital region has no plant which is affected by the decision.

4. Luxembourg

The infringement procedure against Luxembourg was opened on 26 June 1997 and 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 process¹.

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

5. Netherlands

A veterinary inspection mission took place from 9 to 12 December 1996. Failure to complete approval of all plants processing animal waste and failure to provide a list of all plants concerned, as well as incomplete implementation of Decision 96/449/EC led the Commission, on 26 June 1997, to open an infringement procedure and to send a letter of formal notice on 7 July 1997. In the meantime, the situation has been largely regularised, and the only remaining problem at present concerns the approval of six low-risk establishments which do not meet certain housing infrastructure requirements laid down in the relevant EC rules (Article 11 of Directive 90/667/EEC). The Commission is awaiting further information from the Dutch authorities.

¹ The Commission is looking into this programme and is considering ways of adopting a legal instrument providing for a control system to properly enforce Decision 94/381/EC (see point 5.3: reinforcing routine controls in animal feed).

6. Germany

a) Following a veterinary inspection mission from 18 to 21 November 1996, the decision to open an infringement procedure was taken on 26 June 1997, and a letter of formal notice was sent on 7 July 1997 on the following grounds:

failure to implement Decision 96/449/EC as far as the particle size parameter is concerned;

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 derogation's set out in Article 1(2) of Decision 96/449/EC, the Commission has proposed a clarification of this provision to the Standing Veterinary Committee.

b) As regard illegal exports of beef, the FVO inspection mission of 8 to 12 September 1997 revealed that the shortcomings in the keeping of registers for checking on meat entering and leaving cutting plants and cold stores was the result of inadequacies in the German regulations.

Having held the German authorities' reply to be unsatisfactory, the Commission decided to open an infringement procedure. A letter of formal notice was sent on 19 May 1998 for failure to operate controls in conformity with Directives 64/433/EEC and 86/662/EEC. In their answer dated 16 July 1998, the German authorities admitted that the control scheme had to be improved by the adoption of mandatory rules. A draft of these texts has been sent to the Commission, which is keeping a close eye on this matter.

7. Spain

It was decided on 26 June 1997 to open an infringement procedure, and a letter of formal notice was issued on 7 July 1997, based on an FVO inspection mission from 14 to 18 October 1996, the grounds being as follows:

low-risk material had been processed into animal feed without being treated in accordance with the parameters set out in Decision 96/449/EC;

inadequate enforcement of the feed ban imposed by Decision 94/381/EC: no official analysis had been made to detect mammalian meat-and-bone meal.

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

A reasoned opinion was issued on 3 February 1998. As a result of a further inspection between 26 and 31 October 1997, the Spanish authorities would seem to have changed their position on the first point and now 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 enforcement of the feed ban, the Spanish authorities stated in their reply to the reasoned opinion that they were improving their programme of controls, which is currently being examined by the Commission (see footnote (1) in Annex 5). Concerning point 3, the Commission believes that more detailed checks will be needed to ensure that the Spanish plants are fully in line with the validation process.

8. Sweden

A veterinary inspection mission from 11 to 15 November 1996 established that Sweden had failed to transpose Article(3) of Directive 90/667/EC by the due date and had also failed to officially approve rendering plants as required by Article 4(1) of the same Directive.

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

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

A letter of formal notice was issued by the Commission on 7 July 1997 after the Commission had 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 that the first two grounds had been regularised.

The Commission's services met a Swedish representative on 24 March 1998. The Commission representative explained that the Commission intended to ensure that Decision 96/449 was amended so as to clearly reflect the current Commission position. The Swedish representative indicated his willingness to abide by the Decision as modified.

As regards enforcement of the feed ban, the Commission is taking appropriate steps for an EC control scheme to be adopted (see footnote (1) in Annex 5).

9. Finland

On 26 June 1997, the Commission decided to open an infringement procedure, and a letter of formal notice was issued on 7 July 1997 following a FVO inspection mission from 21 to 25 October 1996, on the following grounds:

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

inadequate enforcement of the feed ban under Decision 94/381/EC; inadequate checks to detect mammalian protein in ruminant feed (in particular, no microscopic tests).

The reply from the authorities of Finland to the letter of formal notice is, in essence, as follows:

- a) the feeding of wild animals is to be considered as equivalent to that of zoo circus or fur animals which is covered by the derogation's set out in Article 7 of Directive 90/667/EEC.
- b) Finland is entitled to control enforcement of decision 94/381/EC by measures other than microscopic tests (a register for approval of raw materials in feed mixtures is kept, labelling and packing controls are operated). Nevertheless, it has started microscopic testing.

The Commission is satisfied with the Finnish stance in respect of paragraph 1. The particulars supplied by Finland as regards the controls operated were considered inadequate. A letter requesting further information was sent on 16 January 1998, the Finnish authorities replied supplying a detailed description of the controls operated in Finland to ensure enforcement of the feed ban. The Commission is currently in the process of having an adequate European Community's control system adopted (see footnote (1) in Annex 5).

10. 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 1997 with regard to the application of Decision 94/381/EC, and in particular the insufficient number of specific controls concerning the accidental or fraudulent inclusion of mammalian meat-and-bone meal in ruminant feed.

The Italian reply to the letter of formal notice 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 checks carried out between May 1996 and May 1997, 155 of them microscopic; eight own-initiative cases) (see footnote (1) in Annex 5).

11. Portugal

An infringement procedure was opened on 10 July 1997 by way of a letter of formal notice alleging lack of co-operation with the Commission. In addition, the veterinary inspection visit to Portugal from 15 to 21 June 1997 brought to light infringements of Directive 90/667/EEC and Decision 96/449/EC. A complementary letter of formal notice was sent to the Portuguese Government. No reply has been received either to this letter or to the letter sent on 3 December 1997 pursuant to Article 169. Consequently, the Commission dispatched a reasoned opinion on 26 May 1998.

The Portuguese authorities replied to the Commission's reasoned opinion by letters dated 19 and 23 June 1998, in which they mentioned the progress made and their readiness to make good any shortcomings.

In the meantime, another FVO inspection visit was made to Portugal from 11 to 15 May 1998. The report of this mission noted significant progress, but also confirmed the shortcomings in applying the BSE rules. The report recommends that the Portuguese authorities enact rules banning the generalised use of mammalian-derived meat-and-bone meal.

On 2 September 1998, the Commission sent the Portuguese authorities a copy of this report in Portuguese, asking for their comments. An official reply was sent to the Commission on 25 September 1998.

The epidemiological situation in Portugal is also worrying. An considerable increase in the number of cases of BSE in Portugal was officially notified to the Commission's veterinary services in mid-July. A meeting between the Commission and the Portuguese authorities was held in Brussels on 11 September, and confirmed the seriousness of the situation.

A further FVO inspection visit took place from 28 September to 2 October 1998 and confirmed the facts established by the May mission concerning the ban on the use of mammalian-derived meat-and-bone meal in ruminant feeds, the treatment of mammalian waste, SRM measures and the epidemiological aspects.

After assessing the risks for human and animal health, the Commission has concluded that there is a considerable risk of an autonomous recycling process of the BSE agent in the Portuguese cattle population. Following a positive vote by the SVC in its meeting of 30 October 1998, the Commission adopted a decision on 18 November 1998 to ban any exports from Portugal of live bovine animals and MMBM and, until 1 August 1999, bovine meat and products. Furthermore, Portugal shall apply a series of national measures including an overall ban on the use of MMBM in animal feed (see also point 2.3.ii).

12. Denmark

A veterinary inspection mission from 28 to 30 July 1997 showed that two plants were not operating in full conformity with the requirements of Decision 96/449/EC, and that 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 controls on mammalian meat-and-bone meal during transport from one plant to another in order to complete the process laid down in the Decision was insufficient. In their reply to the letter of formal notice dispatched on 7 May 1998, the Danish authorities have informed that trade of improperly processed mammalian meat-and-bone meal was stopped from 10 May 1997 and that the transport between the different plants was regularised from 10 July 1997. A new inspection will be carried out by FVO in order to verify the situation.

13. Greece

In the light of the discovery by the FVO, during the inspection visit carried out between 29 September 1997 and 3 October 1997, of significant shortcomings in the implementation of Decisions 94/381/EC and 96/449/EC, the Greek authorities provided information on specific measures adopted in order to comply strictly with the requirements of Decision 96/449/EC. However, no information was provided on the implementation of Decision 94/381/EC. Consequently, the Commission sent the Greek authorities a letter of formal notice dated 19 May 1998. In their reply of 18 June 1998, the Greek authorities explained that drastic measures had been taken to deal with the shortcomings established at the previous inspection visit in terms of sampling and analysis with a view to establishing that proteins derived from mammalian tissue were not being used in ruminant feed. The Greek authorities have invited the Commission to check these measures on the spot, and the FVO will be carrying out a follow-up inspection.

**Number of cases
of BSE
(at 5 November 1998)**

Country	Until 1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	Total
Germany	0	0	0	0	0	1 ^(a)	0	3 ^(a)	0	0	2 ^(a)	0	6 ^(a)
Ireland	0	0	0	0	0	0	0	0	0	0	1	5	6
United Kingdom	0	0	0	0	0	1 ^(a)	0	0	0	0	0	0	1 ^(a)
France	0	0	0	0	5	0	1	4	3	12	6	12	43
Italy	0	0	15 ^(b)	14 ^(b)	17 ^(b)	18 ^(b)	16	19 ^(b)	16 ^(b)	73	78	57	323
Spain	0	0	0	0	0	0	0	2 ^(a)	0	0	0	0	2 ^(a)
Portugal	0	0	0	0	0	0	0	0	0	0	1	0	1
Netherlands	0	0	0	0	0	0	0	0	0	0	2	2	4
Other countries	0	0	0	1 ^(a)	1 ^(a)	1 ^(a)	3 ^(a)	12	14	29	30	75	166

Total including the UK	0	0	15	15	23	21	20	40	33	114	120	151	552
-------------------------------	----------	----------	-----------	-----------	-----------	-----------	-----------	-----------	-----------	------------	------------	------------	------------

Population	446	2514	7228	14407	25359	37280	35091	24434	14560	8151	4334	1619	175423
------------	-----	------	------	-------	-------	-------	-------	-------	-------	------	------	------	--------

Total EU	446	2514	7243	14422	25382	37301	35111	24474	14593	8265	4454	1770	175975
-----------------	------------	-------------	-------------	--------------	--------------	--------------	--------------	--------------	--------------	-------------	-------------	-------------	---------------

Denmark	0	0	0	2	8	15	29	64	68	45	38	12	281
Austria	0	0	0	0	0	0	0	0	0	0	0	2	1
Sweden	0	0	3	0	0	0	1	0	0	0	0	0	4

World-wide total	446	2514	7246	14424	25390	37316	35141	24538	14661	8310	4492	1784	176262
-------------------------	------------	-------------	-------------	--------------	--------------	--------------	--------------	--------------	--------------	-------------	-------------	-------------	---------------

Sources: up to and including 1996: IOE for all countries
after 1996: European system for the notification of animal diseases
for the Member States (November 1998), supplemented by the UK's monthly BSE report (September 1998);
IOE for the other countries

- (a) Imported cases
(b) Including imported cases:
5 in 1989, 1 in 1990, 2 in 1991 and 1992, 1 in 1994 and 1995
(c) Imported cases recorded in 1989 (Falkland Islands: 1, Oman: 2) and 1993 (Canada: 1)

ISSN 0254-1475

COM(98) 598 final

DOCUMENTS

EN

03 05 15 17

Catalogue number : CB-CO-98-679-EN-C

Office for Official Publications of the European Communities

L-2985 Luxembourg