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FINAL CONSOLIDATED REPORT

TO THE TEMPORARY COMMITTEE OF THE EUROPEAN PARLIAMENT ON THE FOLLOW-UP OF RECOMMENDATIONS ON BSE

(presented by the Commission)

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AVANT-PROPOS

In February of this year the European Parliament put forward its recommendations on BSE. Since then a close and constructive co-operation has taken place between the European Parliament and the Commission. This has put consumer health and food safety at the centre of a major joint political effort.

Nevertheless, the shaken consumer confidence in food safety is not yet fully restored. In recent months, fraudulent trading in UK beef has checked the progress which had been made since the beginning of the year. The Commission is fully aware of the need to regain credibility in this field vis-à-vis public opinion and will continue its effort to reassure consumers as to the safety of their food.

The Commission is convinced that the European Parliament will continue to be a determined ally in this work. Confidence can only be restored if the three institutions (EP, Council, Commission) and the Member States work closely together based on a permanent commitment to the objective of protecting the health of consumers. It is obvious that all Member States will have to face up to their responsabilities, in particular concerning controls, if the fight against BSE is to be finally won.

Achievements

The foundations for this have been laid through a number of major achievements since February 1997. Several have a general bearing on food safety and consumer protection.

- A new political departure in the fields of scientific advice, risk analysis and control and inspection has been put forward by the Commission in its communication on consumer health and food safety. This approach is based on a separation of responsibilities for legislation on the one hand and for scientific advice and control and inspection on the other. It has been translated into a major reorganisation of Commission services which should ensure that the Commission is in a position to react appropriately to the challenges in the field of consumer health. Future action in the fields of scientific advice, risk analysis and control and inspection will be based on the principles of excellence, independence and transparency.

- A green paper on food law has been issued. Consultations have just ended, including a major contribution from consumer associations. A joint conference with the European Parliament will take place in early November. A proposal for a draft Directive on an extension of product liability to include primary agricultural products has been decided upon by the Commission .

- The Amsterdam Treaty has been signed. Article 129 provides a new legal basis for co-decision between the European Parliament and the Council on veterinary and phyto-sanitary matters directly related to public health protection. Consumer policy in general is strengthened by the revised Article 129a. Regrettably the Commission proposal for co-decision in the field of agricultural policy has been rejected by the Member States.

  The Agenda 2000 proposals contain major reforms of the CAP directed towards sustainable farming and the production of safe and healthy food.

Important developments focusing specifically on the fight against BSE have also taken place.

- The origin of the BSE crisis lies in the feeding of ruminants with meat and bone meal from ruminants. For this reason the Community has forbidden mammalian meat and bone meal to be fed to ruminants since 1994 but other important questions remain to be addressed. Therefore, together with the European Parliament, an important conference on the use of meat and bone meal was organised in July, involving many eminent international scientists. A large measure of agreement has been reached on the need for safe sourcing, the use of the best available production method and the continuation of the interdiction to feed ruminants with mammalian meat and bone meal. The proceedings of the conference will be published and its conclusions are being actively pursued.

- The Community has ear-marked about 50 million ECU for BSE research. The first financing decisions have been taken. The agreement on 23 September on the financial complement to the fourth framework programme freed the remaining 35 million ECU on which a project evaluation has already taken place in anticipation of this compromise between the European Parliament and the Council.

- The Commission has decided on a Community wide ban on the use of specific risk bovine material, in particular brain and spinal cord. This measure is an important part of the Commission action plan on BSE measures adopted on the 26 May 1997. It should also be recalled that the Commission had proposed this measure already in 1996.

- The Commission has acted strongly to ensure the respect of Community legislation in the field of BSE. The veterinary and fraud inspection services have contributed in a major way to act on fraudulent exports of UK beef.

- Concerning the implementation of Community rules for processing meat and bone meal the situation is unsatisfactory. As a result, infringement cases have been opened against a certain number of offending Member States.

- As regards the UK, the European Council in Florence agreed on five pre-conditions for the stepwise lifting of the ban. The UK has taken action to fulfil these conditions. The Commission receives fortnightly reports from the UK and has carried out a series of missions in order to inspect progress towards eradication and control. All these actions are designed to accelerate the eradication of BSE, protect public and animal health, and restore consumer confidence.

Missions have also been carried out in the UK to ascertain compliance of the UK with Community legislation and in particular the respect of the export ban. As a result, a pre-infringement letter was sent to the UK on 8 July 1997 in relation to the lack of clarity and transparency of UK legislation on the export ban, inadequate enforcement of rules and insufficient controls in abattoirs and other meat plants. In August 1997 the UK brought into force its new legislation providing clear and strengthened powers to act against attempts to breach the export ban. Taking into account recent veterinary inspection results it appears that the UK remains in breach of its obligations in respect of controls in abattoirs and meat plants. As a result the Commission opened an Article 169 procedure in respect of this aspect in September 1997.

The Commission is aware of some grievances which the European Parliament still has largely relating to the past. As to the future, the Commission, building on the conclusions of the committee of inquiry, has implemented major reorganisation measures which will ensure effective management.

On the issues of disciplinary measures, administrative proceedings against the United Kingdom and the non-appearance of the UK Minister of Agriculture, Fisheries and Food before the Enquiry Committee the Commission clearly sets out its point of view in the main report.

The Commission expresses its full sympathy with the victims of the new variant of the Creutzfeldt-Jacob Disease (nvCJD). Recent scientific findings published in "Nature" on 2 October 1997 found clear similarities of nvCJD in humans and BSE in animals. Requests for "a no-fault compensation scheme" have been addressed to the United Kingdom government by the families of the victims. In the spirit of solidarity, the Commission agrees with the European Parliament that financing could be provided through the Community budget in addition to means made available by Member States, under the condition that corresponding initiatives are taken by the latter.

For the Commission the most appropriate way of doing so would be through subventions to associations in the field (e.g. the nvCJD Families Association) to assist their development and operations. This would be in line with the Commission's proposal on rare diseases where a similar scheme for subventions has been foreseen.

Major issues

Major political issues have emerged in the process of cooperation with the European Parliament since February 1997 going beyond the concrete measures envisaged in the work programme.

Firstly, the European Union must take decisions in a global environment. As the world's largest trading block, the EU has a vital interest in ensuring that international trading rules are respected. It is important to ensure that legislation and procedures provide adequate reassurance for our trading partners and that our exports do not encounter unjustified restriction in gaining access to the world market. The Community must be able to set the level of protection for human health which it considers to be appropriate.

According to international rules safety measures must be based on scientific principles and may not be maintained without sufficient scientific evidence.

The Commission shares the opinion of the EP that transparency in the working methods and the decision-making procedures in the international organisations is of utmost importance and that improvements should be fostered. Concerning the SPS agreement, a review on its operation and its implementation shall be undertaken in 1998. The Commission is determined to use this opportunity to defend the Community's interests in food safety.

Secondly, for pharmaceutical products, the analysis of risk has also to take into account their beneficial effects. In this respect, there is a fundamental difference compared to the evaluation of risk, for example in relation to food. The Commission is sure that the European Parliament is also fully aware of this fundamental difference. Tallow derivatives and gelatine are ingredients in pharmaceuticals products and a number of very important, sometimes life-saving, medicines are derived from specific risk material. In view of the beneficial effects of medicinal products, there should therefore be no difference of opinion between the Commission and the European Parliament on the fact that, on the basis of scientific advice, a derogation should be envisaged for them in order to avoid any shortage in life-saving and essential medicines.

Tallow derivatives are not only important for pharmaceutical products but also for cosmetics. For this reason, the Scientific Committee for Cosmetology has been questioned on the safety of tallow derivatives. The Committee has concluded that tallow derivatives can be considered as safe when clearly specified production methods are applied. The inactivation of these processes is such that the exclusion of specific risk material does not appear necessary. Consequently, the Commission trusts that it will be supported by the European Parliament when it authorises the utilisation of tallow derivatives under the condition that the specific production methods are respected in a certified way. In this connection, the Commission will also have to address the issue of tallow which is used as raw material for producing tallow derivatives, taking into account the need to ensure proper control.

Thirdly, the actual control of the manner in which Community legislation is implemented is a responsibility of the Member States, with the Commission having the role essentially to check how Member States' authorities perform this duty. Each of the national authorities, in performing the tasks of control of Community veterinary and phyto-sanitary legislation, is acting to ensure the implementation of safety standards not only in respect of its own territory but also in respect of the entire EU territory. Therefore the system can work only if the Member States can guarantee an equivalent level in the manner in which they perform their control functions. Even if the organisation of control services is different in the Member States their operation should respect common standards in order to ensure equivalency. The Commission and the European Parliament seem to agree that the present situation where a different level of effort, resources and commitment is given by national administrations to the inspection and control services is not satisfactory.

The Commission has begun to implement its new approach to control and inspection through the Food and Veterinary Office based on controls over the whole food, animal and plant production chains, formal risk assessment procedures to identify control priorities and audit systems to monitor competent authorities' performances. Based on the audit of national control systems the Food and Veterinary Office will make recommendations for improvement. This will take some time and it would therefore be highly desirable if Member States now take a more common approach to procedures and manuals, organisation and operational criteria, education and training standards.

Fourthly, consumers are not easily convinced by scientific evidence and advice. On some occasions consumer concerns have led to a new risk assessment. There are three major reasons for this. Scientists might not agree on a subject. Moreover, in some circumstances, scientific advice might not be entirely free from specific interests. The third reason is that scientific knowledge evolves and matters that have been considered as safe at a certain time by scientists may be prove to be dangerous as new knowledge becomes available. In line with the concerns of the European Parliament in this matter, the Commission has taken the necessary action to counter the first two objections by making minority opinions known and by making sure that scientific advice is delivered in an independent way. The third objection is difficult to counter but a pro-active, forward looking role into potential sources of risk might provide some reassurance.

Transparency and openness are essential for convincing the European consumer that the scientific advice provided to the Commission is really geared to the objective of protecting their health. In addition to providing the scientific opinions in a timely and open manner, a permanent dialogue and in-depth discussion between consumer organisations, industry, producers and other socio-economic operators, scientific advisers and political decision-makers is of great importance.

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The Commission is fully aware that more needs to be done, building on the achievements since February 1997. Therefore, an ambitious work programme is put forward in this report, which is summarised in table A annexed to the report. It must also be stressed that the work programme does not depend on the Commission alone. The European Parliament and the Council, as co-legislators, will also have an important part to play.

In pursuing and monitoring this programme the Commission wishes to continue its close co-operation, following normal procedures, with the European Parliament and intends to report twice a year to the European Parliament and the Council on further progress.

1. Transparency of the action to combat BSE.

1.1 Comprehensive information policy to guarantee the widest possible dissemination of relevant research data and findings

In its communication on Consumer Health and Food Safety of 30.04.1997 (Com (97) 183 final) the Commission underlined its commitment to transparency with regard to risk assessment (including scientific advice), risk management and control. Risk communication is pointed out as an important element of transparency.

Efforts to improve transparency and accessibility of available research data and findings will continue. This includes the systematic use of all existing technical means of communication and data distribution to fully inform the general and specialised public.

1.1.1 Access for the specialists concerned

With regard to information on the *Scientific Committees* the widest possible access is guaranteed: Immediately after their adoption, the agenda, minutes and opinions of the Scientific Committees are systematically made available to the interested public, including the Member States, particularly the health authorities, the European Parliament, citizens, consumers and consumer associations, producers and their associations and other socio-economic operators. The preferred means are the Internet and press releases, but also publications, reports, letters etc. About 100 leading consumer associations receive these documents by rapid fax. However, commercial confidentiality will be respected. Efforts to present information in a form laymen can understand will be enforced. Appropriate staff has recently been recruited.

Research results which are relevant for consumer health and generated by EU-funded RTD projects are published through normal scientific channels such as publications, lectures or the Internet etc. The Commission requests special efforts from its contractors in this respect. It also regularly prepares catalogues etc. that summarise the RTD projects and their results.

A documentation of the TSE research projects financed under the FAIR programme is annexed. This includes a detailed description of projects approved under the current initiative, a description of research projects supported in the past and the main elements of projects which might be envisaged under a new call for proposals. Special information on TSE Research projects funded under the FAIR programme will be provided on Internet. Starting with the 1997 issue, the Annual Report on the Common Agricultural Policy will include a special chapter on TSE research.

With regard to the *public health action programmes*, the Programme Committee draft agendas, the results of votes and working documents for meetings are

passed on to the European Parliament. Detailed information on the implementation of each of these programmes is provided to the European Parliament and the Member States. This includes the use of the budget, the projects financed and an annual analysis of the development of the programmes.

The brochure "PREVENTION" for European policy makers, national institutions and organisations interested in public health sets out progress in implementing the public health programmes. It is published 3 or 4 times a year and distributed free of charge. For developments in relation to communicable diseases a monthly journal "EuroSurveillance" has been established by the surveillance authorities of the Member States and at the initiative of the Commission.

With regard to information specifically on developments in relation to communicable diseases, a new journal entitled "EuroSurveillance" has been established at the initiative of the Commission. This journal is produced monthly by the surveillance authorities of the Member States. In addition, a weekly Internet bulletin provides updated information and gives early warnings of problems. Both of these information facilities are funded by the Commission. Members of the European Parliament can access this information at the following Internet site: www.eurosurv.org

In addition, large amounts of information concerning the Community's public health activities are available to the public on the Commission's Internet site. This web site contains for example lists of financed projects. As it develops, it will present the main results of projects.
(http://europa.eu.int/en/comm/dg05/health/ph/main.htm).

In relation specifically to Creutzfeldt-Jakob disease, it should be emphasised that the greatest possible transparency is being assured, for example by replying in full to the questions which are received, and by distributing all new information on this disease, not least through the meetings of the (Health) Council to which working documents are regularly transmitted, with copies provided to the European Parliament, on Transmissible Spongiform Encephalopathies (TSEs). These documents contain the most up-to-date information on the epidemiology of CJD and its variants, and the measures taken by the Community and the Member States.

Finally, the Commission services publish, by all appropriate methods (the Official Journal and other publications), the information needed by organisations that wish to participate in Community programmes. The Commission will also organise regular presentations of consumer related issues for interested parties such as the European Parliament, Member States and consumers. Special information sessions shall be held with journalists.

1.1.2 Placing on the Internet of reports on the activities and findings of the Interdisciplinary Research Group and DG XXIV's Interservice Group and also the agendas, minutes and decisions of the Scientific Veterinary Committee and the Standing Veterinary Committee and the relevant legal texts adopted by the European institutions

The Internet site for the *Scientific committees* is fully operational since 10.6.97 (http://europa.eu.int/en/comm/spc/spc.html).

The Scientific Committees are just being reorganised. The agendas, opinions, (include possible minority opinions), and minutes adopted by the Multidisciplinary Scientific Committee/Scientific Steering Committee/(MDSC/SSC) and the Scientific Committees advising the Commission on Consumer Health issues (for food, veterinary public health, animal health and animal welfare, animal nutrition, pesticides, toxicology and ecotoxicology, and cosmetology) are systematically put on the Internet.

Once the new system is in place, the Mandates for the Scientific Steering Committee and the new and renewed Scientific Committees (Food, Animal Nutrition, Animal Health and Animal Welfare, Veterinary Public Health, Plants, Cosmetic Products and Non-Food Consumer Products, Medical Products and Medical Devices, Toxicology, Ecotoxicology and the Environment) will also be available on the Internet. The calls for expressions of interest which where separately published for the Scientific Steering Committee and the 8 Scientific Committees, were also put on Internet without delay.

Relevant parts of this information are published via different direct channels, including a large and growing mailing list (fax) which consists of more than 100 NGO consumer organisations at national or European level, 150-200 organisations representing the interests of industry or trade in the field of food, a list of interested individuals who wish to be kept informed, a list of MEP's, their assistants and relevant people in the secretariat of the European Parliament and the Permanent Representations. These lists are constantly completed and updated.

Related legal texts are on the CELEX Internet server. Access is available upon subscription.

Since December 1996, the Commission systematically informs the European Parliament about the agendas and the votes of these committees. The results of the Standing Veterinary Committee will be made more accessible for a wider public: The tape recordings of the Standing Veterinary Committee meetings will for example be kept for 5 years. A one page summary minute of the standing committees meetings will be published on the Commission's EUROPA server. In addition, the same information will be distributed to the EP and the interested public by automatic fax-mail.

1.2 Reform of the rules governing the work of the Advisory Scientific Committees

In its Communication on Consumer Health and Food Safety the Commission has outlined its intentions concerning the work of the Scientific Committees. It decided to establish the Scientific Steering Committee (OJ L 169/85 of 27.6.97) and the Scientific Committees(OJ L 237of 28.8.97) and profoundly overhauled their rules.

For the Scientific Steering Committee, the assessment was based on selection criteria published in annex to the Call for Expressions of Interest and followed the procedure outlined there (see below point 1.4.3.). The initial assessment was carried out by Commission representatives under the chairmanship of an independent external expert. The Commission nominated 8 members of the Scientific Steering Committee on 29.7.97.

The next step, namely the nomination of all the committee members on the basis of a transparent selection process and following a call for Expressions of Interest will be finished before the end of October. Up to 19 independent experts for each of the eight Scientific Committees are expected to be nominated on the basis of an assessment of more than 1100 Expressions of Interest received from over 800 experts all over the European Union.

The Committees themselves will adopt their own rules of procedure.

1.2.1 Guarantees concerning the independence of members by appointment solely on the basis of objective professional qualifications

The description of the selection process and the selection criteria for the selection of independent members of the Scientific Steering Committee and the Scientific Committees was published in the OJ (OJ C 187/6 of 19.6.97 and OJ C 233 of 1.8.97) together with the Calls for Expressions of Interest.

For the SSC the chairmanship was assured Prof. J.Schell, Max Planck Institute for Breeding Research. For the 8 Scientific Committees eight recently nominated members of the SSC will hold that function.

For each Scientific Committee the selection board will form an ad-hoc sub-group to assess the expressions of interest relating to the respective Scientific Committees. Each SSC-member will assume chairmanship of one of these sub-groups. One of these 8 SSC-members will act as Chairman of the overall selection board.

Observers from the European Parliament and the Council were invited to both selections. While the Council decided not to be present, the Parliament sent Mr. Augustin, secretary of the ad-hoc committee for the Temporary Committee on the follow-up of recommendations on BSE, as observer for the first selection

process and Mrs MAGNANO, member of the secretariat of the same ad-hoc committee for the second selection process.

1.2.2 Appointment of members by a neutral and interdisciplinary Science Council which will guarantee the impartial composition of Scientific Committees.

The Commission will nominate the members of the Scientific Committees following a call for expressions of interest and a pre-determined selection process, based on published criteria. (see above)

The eight independent members of the Scientific Steering Committee will advise the Commission in the selection of the members of the eight Scientific Committees. Each of them will chair one of the eight ad-hoc sub-groups of the selection jury. In case of disagreement, the chairmen of the sub-groups will have the deciding vote on the classification of each candidate. They will also advice the Commission on the treatment of those experts shortlisted for several Scientific Committees.

1.2.3 Presentation of minority views

If the members of the Scientific Committees and the Scientific Steering Committee cannot find an agreement, the minutes of the meeting and eventually adopted opinions will mention the minority view. Minority views shall be attributed to Committee members only at their request.

1.2.4 Provision of appropriate financial resources.

The Commission has submitted a supplementary and amending budget for 1997, which was discussed in the European Parliament and Council. This budget is essential to fulfil the new obligations. For 1998 sufficient resources are requested.

1.2.5 Changes in the administrative procedure for reimbursing expenses with the aim of making it easier for independent scientists to attend

The Commission will ensure that payment procedures will be accelerated. It has also decided to pay an indemnity to the members of the committees and to external experts providing scientific advice.

1.2.6 Involvement of doctors of human medicine when animal health matters are discussed in order to assess possible public health risks

Experts in human medicine are already included in the existing Scientific Veterinary Committee, section on veterinary public health. In connection with the nomination of the members to the reorganised scientific committees, the Commission will ensure that experts in human medicine are representated in the new formation of the Scientific Public health Committee. They are also invited to

express their interest to serve as a member of the animal health section of the Scientific Committee on "animal health and animal welfare".

1.2.7 Restriction of the committees to a purely advisory role of a non-political nature.

The Commission agrees with this principle. This is emphasised by the importance allocated to scientific excellence as a prime selection criteria for members of the SSC and the Scientific Committees.

1.3 Setting up of a joint Commission and European Parliament body with a fixed term of office to monitor the implementation of the measures set out in the BSE report and to submit an appropriate report to the European Parliament.

The Commission regards its cooperation with the temporary committee of the European Parliament on the follow-up of recommendations on BSE as such a joint effort. The experience has been very positive.

1.4 Ensuring transparency when publicising the results of the debates of the advisory Scientific Committees.

Concerning the advisory Scientific Committees, see also the responses to questions 1.1.1 and 1.1.2. in particular with regard to the handling of minority views. The Commission is willing to make background documentation available upon request, while respecting the needs of commercial confidentiality.

1.4.1 Extensive reporting on the meetings of the standing committees

There is a fundamental difference between those committees that are based on the Commission's autonomy as regards the exercise of its own competencies and those related to its implementing powers. They are governed by very different rules:

a) The standing committees belong to the committees created by the Council and the European Parliament . These committees are created by framework acts which confer implementing competencies to the Commission. The committees are composed of representatives of the Member States and chaired by arepresentative of the Commission. The Standing Veterinary Committee and the Standing Committee for Foodstuffs belong to this category of committees.

Since December 1996, the Commission systematically informs the European Parliament about the agendas and the votes of these committees. The results of the Standing Veterinary Committee will be made more accessible for a wider public: The tape recordings of the Standing Veterinary Committee meetings will for example be kept for 5 years. A one page summary minute of the standing committees meetings will be published on the Commission's EUROPA server.

In addition, the same information will be distributed to the EP and the interested public by automatic fax-mail.

b) Committees created by the Commission: These committees, including the Scientific Steering Committee and the Scientific Committees, advise the Commission in preparing legislative proposals or other initiatives. The Scientific Committees, for example, have to ensure that the scientific basis of Commission activities is correct. For their reporting system see the responses to questions 1.1.1., 1.1.2. and 1.4.

1.4.2 European Parliament to have access to this information

The European Parliament is a recipient of the information concerning the Scientific Advisory Committees and their work, as is the general public. The Commission will also give background material to the EP upon request, while respecting the confidentiality rules (also refer to point 1.4.5).

1.4.3 Ensuring that the public has access to the list of members of the Scientific Advisory Committees

The names and position of the newly nominated members of the SSC are on the Internet and were published in the OJ C 235/5 of 02.08.97. The decision on the Scientific Committees foresees the same procedure.

List of Members of the Scientific Steering Committee nominated by the Commission on 29/7/97 (alphabetical order).

Prof. Michael J.Gibney:	Head of the Unit of Nutrition and Dietetics, Department of Clinical Medicine, Trinity College Medical School, Dublin
Prof. W. Philip James:	Director of the Rowett Research Institute, Aberdeen
Prof.Werner Klein:	Direktor des Fraunhofer Instituts für Umweltchemie und Ökotoxikologie, Schmallenberg
Prof. Robert Kroes:	Directeur van het Onderzoeksinstituut voor Toxicologie (RITOX), Universiteit Utrecht
Prof.Gérard Pascal:	Directeur du Centre National d'Etudes et de Recommandations sur la Nutrition et l'Alimentation (C.N.E.R.N.A.)
Prof.Vittorio Silano:	Direttore Generale del Servizio Farmaceutico, Ministerio della Sanità, Roma
Prof. Marcel Vanbelle:	Professeur à l'Université Catholique de Louvain
Prof. Per Jonas F.M. Wierup:	Head of the Swedish Animal Health Service, Stockholm

The names of participants, including ad hoc experts, will be included in the minutes of the committees' meetings.

1.4.4 Making public the criteria for the appointment of members and the allocation of their specific areas of responsibility

The selection criteria for the SSC (OJ C 187/6 19.6.97) and the Scientific Committees (OJ C 233 of 1/8/97) were published (see above). The appointment of members is based on these criteria, taking into account an overall balance in scientific expertise in the composition of the committees.

Being collegial bodies, the committees will nominate rapporteurs for specific tasks according to their expertise. The names of the rapporteurs will be mentioned in the minutes of the meetings. In their internal rules of procedure, the Committees may decide to allocate specific areas of responsibilities to their members. This shall be described in the minutes of the relevant meeting.

1.4.5 Guarantee that Parliament's rapporteurs have access to the advisory committee's data and documents.

The rapporteurs of the European Parliament can receive copies of committee documents, subject to the same confidentiality agreements as any of the experts in the committee.

The European Parliament will in this way get the widest possible access to the work of the Scientific Committees. This includes all the documentation, that is available for the members of the committees themselves, including confidential documents. In addition, the responsible persons in the Commission and the chairmen of the Scientific Committees will answer questions and be present for discussions whenever requested.

However, direct participation of European Parliament members in the committees will not be possible in order to ensure a clear division of competence between the Commission and the European Parliament. The European Parliament can be assured of the independence of the Scientific Committees.

1.5 Other transparency-related recommendations

1.5.1 Widest possible dissemination of the report of the committee of inquiry into BSE to the Community institutions and the governments of the Member States

The report was widely distributed within the Commission services under the code SEC(97)301.

1.5.2 Strengthening the work of the Interservice Group, set up on the initiative of Mrs Bonino, and the widest possible dissemination of its studies and findings

Following the proposal of the Commission on 27 March 1996, an interservice group on information for the consumers on BSE was set up on 2 April 1996. The Group participated actively in the spreading of information within the Commission and to consumers, notably by preparing and distributing the BSE guide "information for consumers" (Vademecum). This group continues its work under the new name "BSE Working Group".

On 26 February 1997, the Commission decided to create:

- a Commissioners' group "Consumer Health", chaired by President Santer,
- a steering group composed of the heads of cabinet of the Commissioners of the "Consumer Health" group, chaired by President Santer's Cabinet,
- an interservice group on consumer health, chaired by the Director General of DG XXIV.

The "BSE Working Group", a sub-group of the interservice group on consumer health, aims at ensuring consumers are kept informed, notably through a third revised and updated edition of the BSE guide "Information for Consumers". It also participated in the preparation of the international scientific conference on meat and bone meal which was held in Brussels on 1-2 July 1997.

1.5.3 Withdrawal of documents which have been contradicted by the work of the committee of inquiry, for example,

- the documentation for the press presented by the Commission's spokesman's office on 16 December 1996

The Commission's press release of 16 December 1996 was withdrawn from the Internet.

- DG XXIV publications (e.g. the "Consumer Information Guide")

This must be a misunderstanding because the DG XXIV guide "Information for Consumers" was welcomed in the original Medina report and is an important source of information for consumers.

2. Monitoring the action to combat BSE and protect public health and animal health.

2.1 Strengthening of Community monitoring and inspection mechanisms to ensure compliance with Community law and the protection of public and animal health in the internal market.

Proposals for amendments to the existing Community legislation on the performance of veterinary checks by the Commission's services in Member States and third countries were discussed in the Standing Veterinary Committee on 23 September 1997. The main changes proposed are as follows:

- to reduce the period of time allowed between the completion of the inspection mission and despatch of the report by the Commission to the national competent authorities from 2 months to 20 working days

- to reduce the period of time allowed between the receipt of the mission report by the national competent authorities and despatch of any comments to the Commission from 2 months to 20 working days

- to introduce a formal procedure for the handling of emergency reports where a significant risk to health or animal welfare has been identified. The Commission will inform the competent authorities of its findings as quickly as possible and, in any case, within 10 working days of the completion of the inspection mission. Similarly, the national competent authorities have a maximum of 10 working days in which to submit comments on the mission report. This procedure does not affect the Commission's powers to take immediate safeguard measures where this is necessary for the protection of health.

- to allow the findings of mission reports and the subsequent recommendations for action to be made available to the European Parliament and to the public, subject to the need to respect commercial confidentiality.

It is proposed to bring these proposals forward for a vote in the Standing Veterinary Committee at the end of October.

In addition to the changes to inspection procedures outlined in paragraph 2.1.1. below, which will serve to strengthen the operation of the FVO, the importance of an adequate follow-up to missions is fully recognised. This approach involves not only maintaining close contacts with Member States on the implementation of mission recommendations, but also the performance of follow-up missions to monitor developments on-the-spot.

The use of this approach is clearly seen in the action taken in respect of Decision 96/239/EC, and, in particular the "export ban" under Article 1(1) in the United Kingdom: Following earlier missions in April and July 1996 where serious deficiencies were found, a further follow-up mission was undertaken in September-October 1996 (Doc. VI/8056/96 and VI/1918/97) and following suspicions on frauds again in June 1997. The July mission revealed that no

portal surveillance system existed. Following this, the Commission put pressure on the British government to introduce such a system. As stated in the September-October mission report, a system of portal surveillance was in the process of being set up at the time of the mission to detect any movements to Member States in contravention of the requirements of article 1 (a). The June 1997 mission detected major deficiencies in the portal surveillance system which then led to a pre-infringement letter on 8 July 1997.

Equally, follow-up missions are being undertaken in respect of the earlier BSE missions in 1996 in all Member States (see point 6.3.).

2.1.1 Creation of suitable administrative structures in Member States and at EU level

The Commission's food, veterinary and plant health control and inspection services were re-established in the Food and Veterinary Office (FVO) with effect from 1 April 1997. A number of initial management changes have been introduced in order to improve the operational efficiency of the FVO. In particular, the division of responsibilities between the existing technical units has been modified to facilitate the introduction of team-based inspection teams and controls over the whole of the food production chains. A separate Unit with responsibilities for the administrative elements of the FVO's operation has been created. It must be appreciated, however, that the transfer to Ireland of the Office has led to transitional management problems.
The Commission communication (COM(97)183 final) on Consumer Health and Food Safety included proposals for a significant expansion and reorganisation of its food, veterinary and phytosanitary control and inspection services, based upon three principles:

- controls over the whole food, animal and plant production chain

The mission programme for the FVO for July - December 1997 makes extensive use of multi-disciplinary inspection teams, capable of monitoring the performance of the national competent authorities and the implementation of community health rules throughout the whole of the selected food production chain. This approach will be further developed, and will form the basis of the inspection and control activities of the Office in the future.

- risk assessment to allow prioritisation of missions

The selection of production sectors and countries in the FVO July - December 1997 mission programme was based upon an informal assessment of the health risks involved. An internal working group has been established within the FVO, including expertise from the risk analysis unit in DG XXIV, to formulate a more formal risk assessment procedure for the prioritisation of missions in the future. It is expected that the recommendations of this group will be available before the end of November. These will be used in the development of mission programmes from January 1998 onwards.

- expanded use of audit techniques, to monitor competent authority performance

Internal working groups have been established to develop standardised working and reporting techniques, and audit techniques suitable for use by the FVO in the future. It is proposed to set up a Quality Team within the FVO, with responsibility for continuing the development of the recommendations made by the working groups, and for the introduction of internal audit and quality assurance systems within the FVO. This is considered to be particularly important to ensure that the FVO works in a transparent, accountable, manner in the future.

An outline training programme for the staff to be recruited in 1997 and 1998, and for existing staff, is currently under development. Initially this will concentrate on training in audit techniques and in developing understanding of the new inspection approach.

2.1.2 Making available the necessary human and material resources

The Budget Council on 24 July did not discuss the Supplementary Amending Budget as had been expected, following the Parliament's first reading in plenary session in July. It is now understood that the SAB should be adopted at the end of October. This will make available to DG XXIV 35 category A posts. These will be allocated principally to the FVO and the secretariat of the Scientific Committees.

Whilst the posts foreseen in the SAB are the first step in the strengthening of the FVO as envisaged by the IGS audit, a further increase in staff numbers to the level foreseen in the audit will be needed in 1998 if the FVO is to be able to carry out the full range of its health inspection and control duties in an efficient and effective manner. The large number of outstanding missions identified in the third report to the Committee demonstrated the extent to which the FVO is unable to meet its obligations from its existing resources.

But there is also a need for reinforced ressources for the services involved in the legislative follow-up of the control and inspection results.

2.2 Setting up of a European Agency for Veterinary and Phytosanitary Inspection

The Commission has withdrawn the original proposal for an Agency.

The Inspectorate General Service (IGS) of the Commission has been carrying out an in-depth review of the structure, management and operation of control services in all Member States and selected third countries (USA, Canada, New Zealand). This study was designed to identify best practices world-wide, with a view to making use of them in developing the Commission's food, veterinary and phytosanitary control and inspection services in the future.

The IGS report will be finished in October 1997. A copy of the report will be made available to the Parliament. The Commission will examine the report's recommendations very carefully in considering the most effective operational structure for its control and inspection services in the future.

2.2.1 Setting up of the agency in close cooperation with the European Parliament

The Parliament will be kept fully informed of the outcome of any decisions on the future structure of the Commission's control services.

2.2.2 Provision in the EU and the Member States of inspection and control structures to guarantee food safety in line with international inspection standards (series EN 45000 ensuring the quality of inspection services)

The Commission is committed to an examination of the potential benefits of applying an externally audited quality control system to the management and operation of its control services. One of the principal tasks of the Quality Team referred to in paragraph 2.1.1. will be to examine the benefits to be gained from, and the action needed to establish, such a system.

2.2.3 Ensuring the closest possible coordination between the legislative authorities and the bodies responsible for monitoring and verifying the practical application or otherwise of the rules

The agreement reached on 4 July 1997 between Directorate Generals III, V, VI and XXIV in respect of inter-service cooperation procedures lays down detailed rules for the links between the Commission's legislative and control services. A copy of the manual (the modus operandi) detailing these procedures was passed to the Committee on 10 July under cover of "Notice to Members, No. 5".

This manual is the subject of continual review and procedures exist for its regular updating where experience with its operation indicates that this is necessary.

2.2.4 Areas of responsibility of the Agency: all phytosanitary, animal health, food hygiene and safety and food quality controls

See 2.2

2.2.5 Operation in accordance with the principles of the European standard EN 45004 on structures and procedures for inspection services.

See 2.2.2.

2.2.6 Guarantee that the public has access to the Agency's reports

The Commission wishes to apply this question to the situation in respect of the Food and Veterinary Office.

In its communication (COM(97) 183 final) on Consumer Health and Food Safety, and particularly in section 4.8, the Commission outlined the action that it would be taking to ensure that the public is kept informed of the activities of the control services. These included a number of initiatives intended to ensure that the Food and Veterinary Office operates in a transparent and accountable manner.

As indicated in paragraph 2.1., the Commission has submitted proposals to the Standing Veterinary Committee under which, inter alia, control and inspection mission findings and subsequent recommendations for action will be made available to the Parliament and consumers.

It is intended that extensive use will be made of the DG XXIV Internet home page site in publishing the mission programmes, mission findings and recommendations for action made by the FVO. In addition this information will be made freely available to outside inquirers upon request.

The Office will be presenting an annual report of its activities, which will be widely distributed and will be made readily available to outside inquirers.

2.3 Improved organisation and management of staff in certain units (objectives, communication, monitoring and penalties) in order to minimise the chances of deficient operation.

As indicated in paragraph 2.1.1, a number of changes have been made to the internal management of the FVO to ensure that it is better placed to perform its control and inspection activities. These new management systems will be kept under review and will be further developed where experience indicates that this is necessary.

The development of an internal manual of procedures, laying down clear rules for the manner in which the FVO will carry out its duties is being given a high priority through the activities of the internal methodology and audit working groups. This manual will provide a clear framework within which the FVO will operate, and will help to ensure that it acts in a transparent, independent and accountable manner at all times.

Following the transfer of the Food and Veterinary Office to Ireland on 1 September 1997, a liaison section has been established within Directorate General XXIV in Brussels to ensure that close working links are maintained with the Office.

The organisation of the unit DG VI-BII.2 , responsible for veterinary legislation, has been reviewed and a new Head of Unit has been appointed. Moreover, the objectives and responsibilities have been more clearly defined in this unit. To that end, sections have been created to deal with horizontal and international matters and animal welfare, animal health, veterinary public health, administrative procedures and disease eradication programmes.

3. Adoption of all relevant measures for the protection of public health.

3.1 Creation of appropriate legal bases

3.1.1 Proposal to the Intergovernmental Conference for the modification of Article 129 of the EC Treaty with the aim of providing a clear legal basis enabling the EU to exercise its powers in the field of public health

3.1,2 Restriction of Article 43 of the EC Treaty (consultation procedure) to day-to-day administration and management of the agricultural markets and common organisation of the markets

3.1.3 Joint action by the Commission and the European Parliament at the Intergovernmental Conference with the aim of the introduction of the co-decision procedure for all necessary agricultural legislation for which a qualified majority has been needed in the Council up to now

3.1.4 Use of Article 100a as the legal basis for all matters of animal health, health protection and food quality and safety

3.3 Commission proposals to the Intergovernmental Conference for improving the division of powers between EU institutions and Member States in the field of health protection and consumer protection and which define clearly the responsibility for the comprehensive monitoring of the performance of statutory tasks

(The following answer applies to questions 3.1. to 3.1.4 and to question 3.3).

1. On the matter of public health and appropriate legal bases, it is to be recalled that the position of the Commission was twofold :

   - that the present Treaty does not contain an adequate legal base which would meet present needs on public health at Community level;

   - that given the structure of Article 43, Parliament's role, in respect of the public health aspects of the common agricultural policy, is insufficient (simple consultation).

2. In order to remedy those two deficiencies, the Commission has undertaken the following actions:

   - The Commission submitted to the Conference a proposal on a revised version of Article 129 relating to health. That proposal sought to strengthen the coordination of Member States' actions in this field, but in particular it proposed that the following measures be adopted pursuant to co-decision:

     – harmonisation measures in the veterinary and phytosanitary fields that have as their object the protection of public health, and

– measures for the approximation of national provisions which have as their object the protection of human health.

Unfortunately the Amsterdam Treaty does not take on board textually the Commission's proposal, and in particular, that part which relates generally to the approximation of public health measures (2nd indent above). It is nevertheless clear that in the future, a situation such as that which has been the main concern of Parliament and which was the catalyst for the Committee of Enquiry would be completely covered under the new Article 129. The link between the veterinary/phytosanitary and public health fields has been inextricably made and made within the context of the co-decision procedure. In those fields, erstwhile governed by Article 43, the appropriate legal base will be Article 129 and the appropriate procedure for adoption will be co-decision. However, it is also clear that the Commission's proposal went further in other areas of public health, but this was not retained in the Treaty of Amsterdam.

- The Commission also submitted to the Conference a proposal for a new provision to be inserted into Article 129 a (consumer protection) to ensure that the Community would have competence:

  – to contribute to protecting the health, safety and economic interests of consumers as well as to promote their right to information, education and to organise themselves in order to defend their interests, and

  – to take into account consumer health protection requirements in the definition and implementation of other Community policies and activities.

  The new Article 129 a fulfils these ambitions, allowing an improved distribution of competencies.

- Pending the entry into force of the new Treaty, the Commission has already acted on its undertaking to ensure that for a proposal which has as its main object the protection of human health within the frame-work of the establishment and functioning of the internal market, the legal base of Article 100 A will be used, thereby ensuring the full participation of Parliament as co-legislator. Thus, the Commission modified its proposal for a Directive on the labelling of beef products and the identification of bovine animals by substituting Article 100 A as legal base instead of Article 43. The Council, however, adopted Regulation 820/97 on the basis of Article 43. As a consequence of that action, the Commission has taken the Council to Court, asking for the annulment of the Regulation.

  The Commission's contention is that the Regulation was adopted on the wrong legal base and that that act had, in particular, as a consequence, that Parliament was deprived of its role as co-legislator. The Commission has, in its pleadings to the Court, laid emphasis not only on this violation of Parliament's prerogatives but also on the fact that the main object of the Regulation is the protection of public health, within the internal market and not the establishment of a common agricultural policy, thus, necessitating the legal base of Article 100a. In this last

respect, the Commission underlined its view of the correlation between measures on public health within the internal market and the procedure of co-decision. The pleadings are, thus, in line with the Commission's proposals on public health to the Conference and, indeed, with the text of the Treaty of Amsterdam.

3.2. **Preparation of a framework directive on Community food law following wide-ranging consultations involving the different stages of the food chain and consumers' organisations with a view to improving environmental protection and human health; in the process Community legislation on product liability to be amended by September 1997 at the latest with the aim of including primary product liability and a proposal to be submitted for legislation regarding liability arising from the risk related to the activity.**

Liability for primary agricultural products: The Commission has just proposed to the European Parliament and Council, in the context of the follow-up to the EP's recommendations on BSE, to amend Council Directive 85/374/EEC of 25 July 1985, on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, by extending its scope to include primary agricultural products. (COM(97) 478 of 1.10.1997).

The confidence crisis in the safety of agricultural products sparked by BSE calls for a revision of directive 85/374/EEC, so as to extend, throughout the Community, the obligation for agricultural producers to compensate damages caused by their products. The inclusion of primary agricultural products within the scope of the directive constitutes an initial response to society's expectations for increased health protection and involves greater approximation of national rules on civil liability for producers of primary agricultural products. At present, only Greece, Luxembourg, Finland and Sweden include these products within the directive's scope, in accordance with the exemption of Article 15.

The proposed changes will not have retroactive effect and only concern primary agricultural products and game put on the market after implementation by the Member States of the changes or, at the latest, from the deadline for transposition fixed at 1 January 1999. The Commission would point out, however, that this rule does not prevent other rules of law on contractual or non-contractual liability from being applied to products put on the market before the date in question. This is consistent with Article 13 of the 85/374/EEC Directive, which preserves the rights of injured persons under other such rules.

The Commission continues to monitor the impact of the Directive on the well-functioning of the internal market and on consumer protection. In this context, consultation of all sectors involved will be launched to assess whether other aspects of the directive need to be reviewed (development risks, financial ceilings, statutory limits, etc.).

On 30 April 1997 the Commission adopted the Green Paper on the General Principles of Food Law in the European Union, which is designed to launch an intensive consultation of Member States and all interested groups, including consumer organisations, on the future development of Community food law. The

possibility of a general directive on food law is expressly considered in the Green Paper. In addition, the Green Paper discusses the possibility of the introduction into Community law of new obligations on producers and manufacturers to ensure that only safe and wholesome food is placed on the market.

The deadline for comments and reactions to the Green Paper was 19th September 1997 and the Commission is organising jointly with the European Parliament a special conference on 3 and 4 November with all interested parties. The Commission will consider the need for further measures once the consultation process launched by the Green Paper is complete.

In addition to this conference on Food Law, priority has been given to the ongoing simplification exercise of the veterinary hygiene legislation and the establishment of a single set of hygiene rules covering all foodstuffs. A major exercise has been undertaken with the help of the Advisory Veterinary Committee in establishing a guide over veterinary legislation contained in fourteen different Directives. This guide has been the subject of extensive consultations with interested parties, consumers, industry, producers, workers and transporters as well as the veterinary profession. On the basis of this consultation a revised document has been established with the attempt to consolidate, harmonise and simplify the requirements. All common provisions will go into horizontal requirements leaving the specific requirements for the individual products in different Annexes. A second round of consultation is now in process again with all interested parties. Once this process has been finalised and comments evaluated, the Commission will prepare a formal proposal for a legislative act providing a user friendly total overiew of veterinary requirements, which will be presented to the European Parliament and the Council in the first half of 1998.

3.4. Establishment of a Public Health Protection Unit

3.4.1 Status : Separate Directorate-General or operation under the umbrella of an existing Directorate-General (e.g. DG V or DG XXIV)

Without affecting the responsibilities of DG V in the area of public health, the Commission decided to give DG XXIV particular responsibility for consumer health protection as regards scientific advice, risk assessment and inspection, while confirming that responsibility for drafting legislation would remain with the services previously in charge of those aspects.
The Commission believes that a clear separation of responsibilities between scientific advice, legislation and control tasks is the most appropriate method for attaining the overall objective of consumer health protection.
Legislative responsibilities for cosmetics, toys and textile have accordingly been transferred from DG XXIV to DG III.

3.4.2 Provision of the necessary funding

Existing personnel dealing with advice and inspection within the Commission have been reallocated to DG XXIV on the basis of a report by the Inspectorate general for Services. This reallocation of staff being insufficient, however, in relation to the requisite strengthening of the functions in question, the Commission introduced as a first step a supplementary and amending budget proposal containing additional budgetary and staff resources (97 posts), in particular for the Food and Veterinary Office, as well as undertaking a further transfer of some 57 posts from other Commission services and from the 1997 and 1998 staff allocations. But there is also an urgent need for reinforced resources for the services involved in the preparation and the legislative follow-up of the scientific advice.
(Please refer also to point 2.1.2)

3.4.3 Task: accountable coordination of Community powers

The Commission's priority is to ensure that decisions are taken with full regard to the best available scientific advice. Preparation of legislation implies a close co-operation between the Commission departments. Operational guidelines which take account of the new structure of the services have been established between Directorate Generals III, V, VI and XXIV (please refer to point 2.2.3).

On public health, co-ordination between the Commission services involved takes place within a specific Inter-service Group which provides a forum to exchange information and discuss health-related issues among the Directorates-General, and coordinates the position of the services with respect to public health and other health-related matters that the Commission could subsequently consider, and with respect to the position of the Commission in meetings of the international organisations competent in the sphere of public health.

3.4.4 Additional task: assessment of Community policies with regard to the protection of public health, with the possibility of drawing up relevant legislative proposals or establishing priorities in work programmes

Beginning in 1995, the Commission has published an annual report on the integration of health protection requirements in Community policies. This is pursuant to the obligation in Article 129 of the Treaty to ensure that health protection requirements form part of other Community policies.

These reports provide a comprehensive overview of instruments, programmes and actions in the Community which have an impact on health. They help to increase awareness of the effects on health of Community policies in other areas, as well as stimulating in-depth impact and assessment studies.

3.4.5 Responsibility: measures relating to food law, food quality and hygiene, human and animal protection and consumer protection

Measures in the above mentioned fields are covered by DG III, V, VI, XII the Joint Research Center and XXIV, according to the assignment of responsibilities decided by the Commission and the subsequent inter-service cooperation procedures.

In order to increase the Community's scope of action (in the field of public health), the Commission proposed a modification of Article 129 of the Treaty in the framework of the Intergovernmental Conference.

On 30 April 1997, the Commission issued the Green Paper on the General Principles of Food Law in the European Union aimed at launching an in-depth debate with all interested parties on the future legislative approach on food. A special conference jointly organised by the European Parliament and the Commission, will be held on 3 and 4 November with all interested parties. The outcome of this conference will be evaluated by the Commission with a view to further action.

3.4.6 Bringing together of the Community's public health protection powers which are currently dispersed between DGs III, V, VI, XI and XXIV within the Public Health Protection Unit

As mentioned above, the Commission transferred scientific advice, risk assessment and food, veterinary and phytosanitary inspection to Directorate General XXIV, whereas responsibility for drafting legislation remains with the corresponding departments. This Commission decision is based on the belief that a clear separation between legislation on the one hand and scientific advice and inspection, on the other, would be the most appropriate strategy for attaining the overall objective of consumer health protection.

3.5 Action against Creutzfeldt-Jakob disease (CJD)

In the light of the announcement on 20 March 1996 of a possible link between BSE and CJD, the Commission convened on 10 April 1996 a joint meeting of the High-level Committee on Health, composed of senior Health Ministry officials, and the Chief Medical Officers of the Member States. The WHO Division on emerging diseases and other communicable diseases' surveillance and control was also represented. The aim of the meeting was to ensure proper co-ordination between the Member States and to achieve a consensus as to the best course of action in the field of public health.

On the basis of Commission staff working documents, the meeting agreed conclusions and recommendations concerning surveillance and response measures in relation to all types of CJD both at national and Community. The conclusions drew from the experience gained from the collaborative research

project on CJD surveillance involving five Member States and funded by the Commission.

Following this meeting, the Commission services established a mechanism for the reporting of CJD cases from all the Member States. The relevant data are compiled in a Commission staff working paper produced at regular intervals based upon a harmonised questionnaire sent to all Member States in order to allow review and comparison of developments. This also incorporates an overview of surveillance, laboratory analysis, and protective measures taken at the national and Community level.

Three such working papers have been produced so far. They were transmitted to the Council on 14 May 1996, 12 November 1996, and 5 June 1997 to assist the Health Ministers in their discussions of TSEs, and in particular CJD. Copies of the papers were sent to the European Parliament. The latest paper of 5 June presents the current epidemiological situation as regards all forms of CJD. The next paper is due to appear in mid-November 1997. Transmission of these documents will regularly take place in the future. Moreover, once the Community network for the surveillance and control of communicable diseases has been established (see below), this function, as well as a systematic and homogeneous surveillance of human TSEs will be set on a formal footing.

Update on new variant CJD cases

On the basis of the information provided by the reporting mechanism that has been established, the current situation (4 September 1997) is that there are 20 confirmed cases and 1 probable case in the United Kingdom, and 1 confirmed case in France.

Other actions and initiatives

I. Apart from the action being taken to monitor CJD, the Commission has launched a major initiative to counter the emergence or spread of a number of communicable diseases. Central to this is the proposal for a decision by the European Parliament and the Council, pursuant to Article 129, to set up a Community network for the surveillance and control of communicable diseases.

Significantly, this was submitted on 8 March 1996, before the announcement of a possible link between BSE and CJD, and provided for compulsory notification, alert, and other public health measures on a number of diseases, including CJD. The EP gave a favourable opinion on the proposal on 13 November 1996, as did ECOSOC on 25.9.96 and the CoR on 13.6.96. The Commission tabled an amended proposal, accepting most of the EP's amendments, on 5.2.97.

The proposal aims at securing a broad enabling measure (a decision), within which a series of further decisions by the Commission or the Council could be promulgated on specific topics. The areas covered were:

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

The Council adopted on 22 July 1997 a common position on this proposal. The Commission reserved its position, as, in its view, the text agreed by the Council represented a considerable watering down of its initial proposals, especially with regard to Community measures. It pointed out that the goal of the system proposed was the introduction of appropriate counter-measures both at the national and Community level, and thus exclusion or circumscription of the latter would deprive the system of much of its value.

The common position of the Council, as well as the Commission communication on this position, have been sent to the European Parliament for the second reading. Once the European Parliament's opinion on the Council's common position has been given, the Commission could submit a modified proposal to the Council for consideration with a view to reaching a joint decision by the Council and the European Parliament on this important measure.

II. A further important step was taken on 26 May 1997 in a related area when the Commission presented a communication and a proposal for a European Parliament and Council decision adopting a 5-year Community public health action programme on rare diseases (OJ C203, 3 July 1997,p.6). This would be in line with the Commission's proposal for a programme of action on rare diseases (COM (97) 225 final). This programme has been submitted to the Council and Parliament for co-decision within the framework for Community action in the field of public health. One of the objectives of the programme is to promote actions in favour of patient and family support groups who have been directly or indirectly affected by rare diseases, including neurodegenerative conditions.

The actions envisaged in pursuit of this objective include:

- promoting the establishment of groups of those persons with the same rare conditions or those professionally involved in order to disseminate their experience, to facilitate training and to coordinate their activities at national and Community level;

- promoting collaboration and networking between support groups and the setting-up of umbrella bodies, focusing particularly on efforts to encourage the continuity of work and cross-national cooperation.

The programme explicitly recognises that patient support groups can play a key role in relation to rare diseases as there is often a lack of information and health care facilities relating to such diseases. This, in turn, leads to particular difficulties for sufferers and their families. Patient support groups have proved instrumental in tackling these difficulties due to their wealth of knowledge and experience in dealing with rare diseases.

III. European Community legislation covers all work activities where there could be a risk of occupational exposure to TSEs whether or not the exposure was intentional (for example laboratory workers, abattoir workers, veterinarians, doctors, farmers and zoo-keepers). These activities are covered in particular by Council Directive 90/679/EEC, and its amendments Council Directive 93/88/EEC and Commission Directive 95/30/EEC, on the protection of workers from risks related to exposure to biological agents, which contain a series of measures designed to protect the workers concerned. The directives were adopted following proposals by the Commission pursuant to Art. 118A of the EC Treaty which confers specific powers on the Community for the protection of the health and safety of workers.

The 1993 Directive makes reference to "unconventional agents associated with CJD" and classifies them as hazardous biological agents which present a limited risk of infection for workers because they are not normally infectious by the air-borne route. Already in 1993, the provisions of the directives recommended containment level 2 (usual for agents which can cause human disease and might be a hazard to workers; they are unlikely to spread to the community; there is usually an effective prophylactic or treatment available) at least, as a precaution for laboratory work.

Since then, the directives have continuously been kept under review, and, having recently obtained a favourable opinion by the relevant Technical Progress Committee, the Commission intends to adopt a directive which recommends a stricter containment level for laboratory work which involves risk of exposure to the agent responsible for BSE.

The Commission is keeping these directives under review and will make any proposals that are required in the light of new scientific evidence relating to the risk of exposure to TSEs.

IV. As far as medicinal products are concerned, since 1991 the pharmaceutical industry has been applying guidelines adopted by the Committee for Proprietary Medicinal Products and published by the Commission with the aim to minimise the risk of transmission, via medicinal products, of the agents responsible for animal spongiform encephalopathies. These guidelines advocate, in order of priority, selecting materials first of all on the basis of the geographical origin of the animals

in question, taking only those from areas free of BSE, and then on the basis of the infectiousness potentials of the tissues used, and lastly to apply the recommended inactivation method to the materials finally selected.

The European Agency for the Evaluation of Medicinal Products (EMEA), upon request from the Commission, has undertaken in November 1995 a review of these guidelines which need to be adapted to new scientific data and to the new Community legal framework in particular in order to take into account the Commission Decision on the prohibition of the use of material presenting risks as regards transmissible spongiform encephalopathies.

In parallel, the Commission services have asked the EMEA (as far as medicinal products authorised by the Community are concerned) and the national competent authorities (for nationally approved products) to check which medicinal products could be affected by the above mentioned Commission Decision. The Commission will examine - in the light of the results of this evaluation - the need for introducing specific measures and/or derogation for medicinal products in order to avoid any shortage in life saving medicines in the Community.

V. In the field of cosmetics, a significant measure was already taken through the 20th adapting Commission Directive 97/1/EC to the original text of the Cosmetics Directive, 76/768/EEC. Directive 97/1/EC was published in the Official Journal on 18.01.97 (Reference number L 16). The Directive placed *Bovine, ovine and caprine tissues and fluids from the encephalon, the spinal cord and the eyes, and ingredients derived therefrom* into Annex II of the Cosmetics directive - *List of substances which must not form part of the composition of cosmetic products.* Member States have to comply with this Directive on 1st June 1997 at the latest, thereby excluding these materials from cosmetic products.

In the meantime the Scientific Committee on Cosmetology delivered an opinion on 24.6.1997 declaring that tallow derivatives could be regarded as safe if obtained by hydrolysis methodes (200°-240°C, 40 bars, 20 minutes). The Multidisciplinary Scientific Committee/Scientific Steering Committee gave an opinion at its meeting on 8.9.1997. On the basis of these opinions the Commission will propose to amend the Cosmetics Directive.

3.5.1 Creation of suitable structures and resources for the development of independent research programmes specifically for BSE and CJD

Since the announcement by the UK authorities on 20 March 1996 of the appearance of a new variant of the Creutzfeldt-Jakob Disease (nvCJD) the Commission has undertaken the following steps regarding the above mentioned issue:

April 1996: The Commission asked a group of scientists chaired by Prof. C. Weissmann to draw up an inventory of the state of knowledge and propose research priorities on BSE.

20 June 1996: The Commission made public its intention of proposing an action plan for research on CJD and BSE.

7 October 1996: The Commission set out this intention at the Research Council indicating that a supplementary funding would be needed. The Research Council invited the Commission to improve cooperation and coordination of research efforts and exchange of information in this field and to reinforce research efforts.

16 October 1996: The Weissmann report was presented to the Commission

13 November 1996: The Commission decided an action plan for research on transmissible spongiform encephalopathies (TSEs) which takes into account the recommendations of the Weissmann report and of the Multidisciplinary Scientific Committee, as well as ongoing national and Community research activities. The financial envelope for such an initiative was evaluated at 50.7 MECU of which 15.7 MECU from existing resources and 35 MECU from supplementary funding in the context of the financial supplement to the 4th Framework Programme subject to conciliation between Parliament and Council.

The action plan comprises two levels:

- the coordination of activities between the Member States, aimed at harmonisation of data collection and diagnostic criteria, essential for a proper comparability of data,
- specific calls for proposals, intended to stimulate research efforts at Community level.

5 December 1996: The Commission presented the action plan on TSEs to the Research Council, which reacted favourably to it and adopted a common position concerning the 4th Framework Programme financial complement with a financial envelope of 100 MECU of which 35 MECU to be devoted to research activities in the field of TSEs. This common position was formally adopted by Council on 27 January 1997.

15 December 1996: A specific call for proposals for RTD activities on TSEs was launched under the specific programme Agriculture and Fisheries (FAIR) covering the issues of BSE and animal health. Twenty four proposals were submitted before the deadline for the call, i.e. 14 February 1997.

13 March 1997: The European Parliament in its second reading proposed to increase the overall amount of the financial supplement to the 4th Framework Programme to 200 MECU, doubling the amount to be provided to different activities with the exception of TSEs, which remained with a potential budget of 35 MECU.

18 April 1997: In its second reading the Council confirmed its position concerning the 4th Framework Programme financial complement.

29 April 1997: The Commission launched, subject to agreement in the conciliation process between Parliament and Council on the financial supplement for final selection of projects, a Joint Call for proposals on TSEs which contained all the elements specified in the action plan. This call will be implemented within the Community research programmes Biomedicine and Health (BIOMED), Biotechnology (BIOTECH) and Agriculture and Fisheries (FAIR). The following six main research themes were included:

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

The deadline for submission of proposals was fixed for the 15th July 1997.

16 July 1997: The Commission decided to select for funding eight projects submitted to the 15th December 1996 call for proposals on BSE of the FAIR programme. These projects aim mainly at the development of methods for diagnosis and control of TSEs in cattle, goats and sheep. Contract negotiations with the participants in these projects are now in progress.

In annex you will find a detailed description of these projects.

23 September 1997: An agreement was reached at the second conciliation procedure meeting between the Parliament and the Council regarding the financial complement of the 4th Framework Programme. Out of the 115 MECU agreed, 35 MECU are to be devoted to TSE research. Formal adoption by the Commission of the projects to be selected following the 29th April 1997 Joint Call for proposals (the evaluation has now been completed) is pending the 3rd reading in Parliament and a Council meeting for Decision on the financial complement. Following the adoption of projects a detailed description of their content will be made available.

3.5.2 Launch of research programmes designed to identify the agent responsible for BSE and the new variants of the disease and the prospects for preventing and treating the new variant of CJD

Since 1990 and within the Community research programmes Biomedicine and Health Research (BIOMED 1 and 2, 1990-1994; 1994-1998), Biotechnology (BIOTECH, 1990-1994; 1994-1998) and Agriculture and Fisheries (AIR 1990-1994; FAIR 1994-1998) the Commission has been sponsoring research in this field.

As a result of these efforts 14 projects, with an overall Community contribution of 5.15 MECU, have been sponsored covering several areas, namely: identification of the agent, epidemiology and surveillance, neuropathology and diagnostic criteria, propagation and species barrier in transgenic animals and other models.

More specifically and as a result of the 2nd call for proposals within the BIOMED 2 programme, a project titled "CJD in the European Union - incidence and risk factors" was selected. The project is a continuation of a previous one, sponsored within the BIOMED 1 programme, which was the largest systematic survey of CJD ever carried out and at the basis of the discovery of the new variant of CJD ("Surveillance of CJD in the European Union"; Coordinator: Dr. R. Will, CJD Surveillance Unit, UK, 1992-1995).

This new project, started on May 1997 and also coordinated by the CJD Surveillance Unit in the UK, is mainly focused on the incidence of the new variant of CJD trying to assess potential risk factors. In addition, the project intends to continue ensuring surveillance of classical forms of CJD as well as provide material, including tissue samples for other research projects and develop educational material for relatives of patients and information to the general public. The project gathers partners from IT, FR, NL, DE, UK , ES, Switzerland, Australia and Canada.

Research efforts in this area are being further strengthened through the action plan on TSEs decided by the Commission on 13 November 1996. The financial requirements for full implementation of this plan have been evaluated at 50.7 MECU, of which 15.7 MECU from existing resources and 35 MECU from supplementary funding in the context of the financial supplement to the 4th Framework Programme subject to approval by Parliament and Council. Out of the 15.7 MECU from existing resources, 5.9 MECU will be used for TSEs research projects being or about to be financed as a result of call for proposals within the BIOMED and FAIR programmes and 8.8 MECU will be redeployed within the areas of the BIOTECH and FAIR programmes relevant for TSEs (i.e. specific call on BSE within the FAIR programme, closing date on 16 February 1997).

In addition, and as a part of the action plan on TSEs, the Commission launched on 29th April a Joint Call for proposals on TSEs which will be implemented within three research programmes BIOMED, BIOTECH and FAIR.

Several key actions proposed for the 5th framework programme would allow the continuation of this research for the periode 1998-2002.

3.5.3 Coordination of the Member States' research programmes with the corresponding EU programmes

On the initiative of the Commission, a meeting of Directors General for Research was held in Brussels on 5 June 1996. This meeting was aimed at exchanging information and views on research in the field of TSEs undertaken at national and Community level, the objective being to create a mechanism for strengthening cooperation and coordination in this field.

The Commission was requested to coordinate the collection of information on ongoing research in this field and to consider the launching of a specific call for proposals to encourage new ventures in this area.

As a follow up to this meeting and based on information provided by the Member States, the Commission has prepared an overview depicting the activities undertaken in this field at National level. The first issue was released on 1st February 1997 and sent to all interested parties in the different Member States. The 2nd issue was released on 1st July 1997.

In addition, the coordination of research activities between the Member States will be further implemented as part of the 29th April 1997 Joint Call for proposals on TSEs. The following coordination activities between the Member States are envisaged in this call:

- standardisation of case definitions for collection of data, of data analysis and of dissemination of information in order to ensure a proper surveillance
- harmonised procedures for early detection and diagnosis of the disease(s)
- continuous updating and dissemination of scientific knowledge in this field
- fluent and rapid dissemination of these data
- activation of an early warning system in case of crucial developments
- exchange and mobility activities including training of research staff
- a continuous inventory of the progress of national research programmes
- harmonisation and control of diagnostic methods for human and animal SEs

As indicated above (section 3.5.1), funding of the projects to be selected following this call is pending the 3rd reading in Parliament and a Council meeting for Decision on the financial complement of the 4th Framework Programme.

3.5.4 Encouragement of research in the United Kingdom into the new cases of Creutzfeldt-Jakob disease affecting young people

In the context of the Commission support of research work in the UK into the new variant of CJD and within the BIOMED 2 programme, a project titled: "CJD in the European Union - incidence and risk factors" is being sponsored.

The project, coordinated by the CJD Surveillance Unit in the UK (Edinburgh) intends to focus on the incidence of the new variant of CJD and try to assess potential risks. In addition, the project will continue ensuring the surveillance of classical forms of CJD as well as providing material, including tissue samples for other research projects, and will develop educational material for relatives of patients and information to the general public.

The project involves partners from IT, FR, NL, DE, UK, ES, Switzerland, Canada and Australia.

3.5.5 Increase in funding (in general)

On 13 November 1996 the Commission decided an action plan on research on TSEs (see section 3.5.1). This initiative includes an action plan comprising two levels:

- the coordination of activities between Member States,
- a specific call for proposals, intended to stimulate research efforts at Community level, which identifies 6 main research themes and 24 research topics.

The financial envelope for such an initiative was evaluated at 50.7 MECU of which 15.7 MECU from existing resources and 35 MECU from supplementary funding in the context of the financial supplement to the 4th Framework Programme subject to final approval by Parliament and Council.

These were minimum requirements both in terms of quantity of high priority research and overall cost and were based on the average costs of a high quality research project (around 1 MECU) and on the particularly expensive costs of the coordination activities envisaged (which include informatisation, databases creation and training programmes).

3.5.6 Reinforcement of budget allocation at national and Community level for the detection and elimination of the risks of transmission of Creutzfeldt-Jakob disease via medical, pharmaceutical and cosmetic products and the search for safe substitutes for at-risk human- or animal-derived products, use of these budget allocations for the detection and elimination of potential risks from transfusions, grafts and other surgical practices

In the context of its research activities, the Commission decided an action plan for research TSEs (see section 3.5.1), the following topics will allow to perform research on the above mentioned areas, namely:

1. "The process of identification of suspected cases and the sensitivity of the surveillance system". Within this topic the development of surveillance systems including heamovigilance could be foreseen.
2. "The mechanisms of propagation, transport and pathogenesis". Within this topic the possibility of further exploring potential blood transmission of this disease(s) could be pursued.
3. "The basis of species barrier limiting inter-and intraspecies transmission". This topic would allow to study the mechanisms involved in the potential blood transmission of this disease(s).
4. "Development of rapid and sensitive early diagnostic tests including surrogate markers, specially in living animals and humans". This topic would contribute to further the knowledge on the development of a diagnostic test of the disease(s) in blood.
5. "An evaluation of spongiform encephalopathies transmission modalities". Such a topic could allow to implement the knowledge on the risk of blood transmission for the disease(s).

Projects selected following the call for proposals of 16 December 1996 address some of these issues. Some other issues are addressed by proposals submitted to 29 April 1997 joint call for proposals.

3.5.7 Submission of a proposal for compensating nvCJD victims and their relatives and entry of the relevant appropriations of the preliminary draft 1998 budget

The Commission expresses its full sympathy with the victims of the new variant of the Creutzfeldt-Jacob Disease (nvCJD). Recent scientific findings published in "Nature" on 2 October 1997 found clear similarities of nvCJD in humans and BSE in animals. Requests for "a no-fault compensation scheme" have been addressed to the United Kingdom government by the families of the victims. In the spirit of solidarity, the Commission agrees with the European Parliament that financing could be provided through the Community budget in addition to means made available by Member States, under the condition that corresponding initiatives are taken by the latter.

For the Commission the most appropriate way of doing so would be through subventions to associations in this field (e.g. the nvCJD Families Association) to assist their development and operations. This would be in line with the Commission's proposal on rare diseases (see point 3.5 II) where a similiar scheme for subventions has been foreseen.

3.5.8 Submission to the budgetary authority of a proposal for transfer of appropriations with a view to releasing resources for BSE research at the earliest possible date

As mentioned in point 3.5.1 and 3.5.5 the Commission decided on 13 November 1996 an action plan on TSEs which was evaluated at 50.7 MECU. Out of these, 35 MECU are due from supplementary funding in the context of the financial supplement to the 4th Framework Programme agreed by conciliation procedure and only subject to final approval by Parliament and Council.

3.5.9 Creation of the maximum transparency, with regular information being provided to the Community institutions and the public

The Commission has decided to initiate the greatest possible transparency in respect of CJD and its new variant by replying openly to the questions which it receives and by distributing all new information on this disease, particularly through the meetings of the Health Council. The next edition of the BSE guide "information for consumers" (Vademecum) will contain an up-date on this question.

The guide is currently in preparation. It will be largely circulated both to Community institutions and public opinion and made available on the Internet.

3.6 Closer cooperation of the Community human and animal health services with the World Health Organisation and the International Office of Epizooties, on a basis of scientific rigour

When adopting its communication on Consumer Health and Food Safety, the Commission stressed the importance of an active participation in international fora with the objective that their recommendations, standards or guidelines have a scientific basis.

The organisation of joint seminars is considered to be an important tool towards fulfilling this objectif. The Conference on Food Law in November 1997 invites representatives of both the SPS and Codex. At present preparations are made to organise a big Conference on Eradication of Animal Diseases in the 21st century. Participation will be on invitation of the OIE.

The Commission shares the opinion of the European Parliament that transparency in the working methods and the decision making procedures in the international organisations is of utmost importance and that improvements should be fostered.

I. WHO

In the general area of work on communicable diseases, close collaboration with WHO has developed on several activities:

- The European Commission is actively involved in the process of revising the International Health Regulations (IHR). These regulations, adopted in 1969 by the World Health Assembly, need to be reviewed in the light of the major changes that have taken place in the evolution of communicable diseases since that time. The European Commission participates in this process at two levels:

- A Commission expert participates in and contributes to the small working group which is drafting the revised IHR;
  The European Commission will be formally consulted on the development of the work.

WHO has also been invited to take part in the work undertaken within the framework of the Task Force between the European Union and the United States on communicable diseases. The WHO Division on emerging diseases and other communicable diseases' surveillance and control is regularly consulted by the three working groups set up by this Task Force. In the context of the discussions within the Task Force, the division submitted a WHO Position Paper on Collaboration in Global Surveillance of Communicable Diseases and Response to Outbreaks.

Finally, WHO takes part as an observer in various communicable diseases surveillance projects funded by the Commission. One example is the European

field epidemiology project (EPIET) for which trainees come from WHO which pays for their participation. In parallel, the EPIET trainees are sent on international investigations co-ordinated by WHO.

Moreover, WHO also provide scientific advice in some networks of communicable diseases surveillance, particularly when these networks cover Central and Eastern European countries (such as the AIDS and HIV surveillance network and the tuberculosis surveillance network).

With regard in particular to scientific information on transmissible spongiform encephalopathies , Commission officials have maintained close liaison with the World Health Organisation (WHO), including the WHO representative with the EU in Brussels, and have participated in BSE meetings as observers.

To underline the close collaboration with WHO, at the 50th World Health Assembly (Geneva, May 1997), the Commission representative stressed that the safeguard measures taken in the EC have been based on scientific advice which took into account and was coherent with the advice produced by the WHO expert meetings, in which a number of experts serving on the European Commission Scientific Committees had participated.

For its part, the WHO indicated in its report that there had been close collaboration with the Commission on scientific issues relating to BSE. At the recent meeting of the WHO Regional Committee for Europe (Istanbul, 15-19 September 1997), the importance of continued cooperation between the European Commission and the WHO was again emphasised.

II. OFFICE INTERNATIONAL DES EPIZOOTIES (O.I.E.)

Commission officials have maintained close liaison with the Office International des Epizooties (OIE) and have participated in meetings as observers. However, the Community does not have the status of member of this organisation. Changes in the basic statutes of OIE are necessary for this to happen. Meanwhile the Commission will continue to play its full role in ensuring scientific development and coordination in this and other health fields, in its current capacity as observer.

The OIE *is* an organisation made up of states in which, despite the fact that it is only an observer, the Community plays an increasing role. So as to improve transparency of the OIE workings, the Commission undertakes to make available to the European Parliament the opinions and information it receives from the OIE. Furthermore, the Commission will endeavour to ensure that minority opinions will be recorded in the minutes of the OIE meetings.

Its organisation

The Central Office has its seat in Paris (Rue de Prony) and is composed of about twenty persons: administrative and financial service, scientific and technical service, information and international trade service and publication service.

1) Statute:

Created in 1921 by an "arrangement international", it comprises currently 143 Member Countries. It is the only veterinary international organisation in the field of animal health. The statutes of the OIE can only be modified by unanimity of the Member Countries. There is no international organisation member of the OIE.

2) A regulatory role

The OIE establishes in particular international recommendations as regards animal health (animal health code) applicable in trade of animals and animal products (see S.P.S.).

3) A role of information and of monitoring of world animal health

a) The Member Countries of the OIE have to inform it of any change in their health statute in particular for the list A diseases. The OIE distributes immediately these information to all Member Countries.

b) The OIE each year makes an assessment of the world health status and recognises world reference laboratories

Its operation

The OIE is composed of Countries, represented at the plenary sessions by their directors / heads of the veterinary services.

Decision-making process under the animal health Code:

- The animal health Code Commission is one of the Commissions of the OIE. It prepares the work relating to the animal health Code.
- The Members of the animal health Code Commission are designated at the general Session.
- The Working groups of the animal health Code Commission prepare the draft amendments of the Code and are designated:

  by the OIE on the basis of their lists of persons working in the world reference laboratories.

  by the animal health Code Commission.

- The draft amendments are submitted to the animal health Code Commission. They are sent to all the Member Countries for written comments (December / January).
- The text is amended by the animal health Code Commission on the basis of the various comments received from the Member Countries. It is then transmitted to the

Member Countries (April) for the general Session (May). Member Countries make, before the general Session, their written comments on the new proposals.

- The texts distributed in April are discussed and submitted for vote (possibly modified following the discussion) during the general Session: vote by a simple majority but in practice spirit of consensus.

The Commission is only observer but plays an ever increasing role

The Commission plays only a role of observer:

the role of observer is very limited because statutes do not even specify that the Commission can speak

The Commission plays an increasing role

1) reasons for the Commission to increase its role:

in the veterinary field, legislations are harmonised and the Commission has international negotiation competence (SPS); it is therefore logical that it co-ordinates the action of the Member States within the only international organisation as regards animal health.

- by adopting a joint position Member States increase their weight in the decision-making process.

2) since 1995, the Commission has been playing an increasing role:

- under the proposals of the animal health code Commission:

- the Commission receives the proposals of the animal health Code Commission of the OIE. It prepares (DGVI in close association with DG XXIV and possibly after consultation with other DGs) a joint draft position which is submitted to the Council. The Community position is approved by the COREPER following working groups. This position is then transmitted in writing to the OIE by the Commission and by the Council. It is defended at the general Session by the Presidency of the Council.

- within the framework of the regional Commission for Europe.

3) this co-ordination made it possible to obtain successes:

- BSE: following the last meeting of May 1997, on initiative from the Commission, the OIE adopted more restrictive and more precise rules for the definition of the Member Countries free from BSE.

- thanks to a co-ordinated action of the Community, representatives of the Union were appointed to key position in the OIE.

Membership

The Community is not a Member of the OIE but will once again put the question of full membership in the OIE on the agenda of the Council. The Community will continue to seek to become Member of OIE or if this appears to be impossible, the Commission will investigate all possibilities, in order to change the rules of procedure to allow it to intervene on behalf of the Community.

During several debates on the subject of Membership of the Commission in the Council, Member States marked their reservations and did not agree to such a Membership.

Up to now, the Commission undertakes successfully a role of co-ordinator of the Community positions in particular under the animal health Code Commission and regional Commission for Europe.

Steps have now been taken within the Commission Services to initiate the application for the membership of the OIE.

The changes made during the General Session of the International Committee are also indicated.

The Zoosanitary Code has the status of recommendations only, although the SPS Agreement - as mentioned under the description of the SPS Agreement - gives particular prominence to the OIE standards with regard to animal health. The recommendations are not always followed by the European Community, which normally acts on the specific advice of the Scientific Veterinary Committee. This advice is usually requested to address a particular situation in the European Union and is more detailed than the general OIE codes. The translation of this advice into legislation may at times result in a diversion from the OIE code. The Community has taken measures which go beyond OIE recommendations.

III CODEX ALIMENTARIUS

The Codex Alimentarius is responsible for the implementation of the Joint FAO/WHO Food Standards Programme, the purpose of which is protecting the health of consumers and ensuring fair practices in the food trade. The Codex works through the preparation of international food standards. At the present time, some 170 countries are members of Codex Alimentarius. Membership of Codex is open to any member of the WHO or the FAO.

At the present time, the Community is not a member of Codex, but has the status of an observer. By virtue of its membership of FAO, the Community is entitled to become a member of Codex. The Council has agreed a mandate for negotiation in view of Community accession to Codex, and the Commission has formally written to the Director General of FAO to notify him of the Community's intention to become a member. However, some sensitive issues have arisen concerning the division of competencies between Member States and

the Community on Codex matters and the role of Parliament in the preparation of Community positions for Codex.

At the head of the Codex structure is the Codex Alimentarius Commission, which meets every two years. The work of the Commission is prepared by a series of Committees which normally meet once a year, or once every two years. The list of these Committees provides a useful indication of the range of issues tackled by Codex.

Horizontal Committees	Sectoral Committees	Regional Committees
General principles	Cocoa and chocolate	Africa
Additives and contaminants	Sugars	Asia
Food hygiene	Processed fruit and vegetables	Europe
Food labelling	Fats and oils	Latin America + Caribbean
Methods of analysis and sampling	Meat Meat hygiene	N. America + S.W. Pacific
Pesticide residues	Processed meat and poultry products	
Veterinary Drug Residues	Fish and fisheries products	
Import/Export Inspection and Certification Systems	Edible ices Cereals, pulses and legumes	
Nutrition and Foods for Special dietary uses	Vegetable Protein Fresh fruit and vegetables	
	Milk and milk products	
	Natural mineral waters	

Preparation of Codex Standards

Codex standards are elaborated through a uniform step procedure:

- Steps 1-3, a first draft is prepared and circulated to members and observers for comments.
- Step 4, the draft is discussed by the relevant Codex Committee
- Step 5, the draft standard is discussed by the Codex Alimentarius Commission, or the Executive Committee with a view to its adoption as a draft standard

- Step 6, the draft standard is circulated to members and observers for comment
- Step 7, the draft standard is again discussed by the relevant Codex Committee
- Step 8, the draft standard is submitted to the Codex Alimentarius Commission for final adoption.

In urgent, or non-controversial cases, steps 6 and 7 can be omitted. This means that the minimum time needed for adoption of a Codex standard is about 2 years. In practice, the average is closer to 4 years, but may be substantially longer in difficult or controversial cases. Following the adoption of a standard, there is a formal procedure for notification of its acceptance to Codex.

For acceptance of a Codex standard, a proposal must be prepared for consideration by the competent institution in accordance with the Community's normal internal legislative procedures.

Some concerns, {1) the number of votes required to adopt standards, 2) confidential nature of industry data, and, 3) selection of experts to serve in scientific Committees of Codex,} have been expressed at the lack of transparency in the work of Codex Alimentarius, in particular as regards consumer involvement. This issue was considered at the 22nd Session of the Codex Alimentarius Commission which took place in Geneva from 23-27 June 1997. For its part, the Commission is committed to the greatest possible transparency in Codex work. At this session Consumer International asked for more transparency during preparatory work, notably concerning scientific work. Consumer International asked that NGO's, like themselves, be consulted by the Codex on documents under examination. This request was firmly supported by numerous delegations, including the Commission.

Status of Codex standards

Following the entry into force of the Agreement on Sanitary and Phyto-Sanitary Measures (SPS) the work of Codex is given particular prominence. For food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives , veterinary drug and pesticide residues, contaminants, methods of analysis and sampling and codes and guidelines of hygienic practice are considered to be international standards, guidelines and recommendations.

In accordance with Article 3(2) of the SPS Agreement, sanitary and phytosanitary measures which conform to international standards, guidelines and recommendations are deemed to be necessary to protect human, animal or plant health or life, and presumed to be consistent with the SPS.

However, in accordance with Article 3(3), Members may introduce or maintain sanitary or phyto-sanitary measures which result in a higher level of protection than would be achieved through measures based on the relevant international

standards, if there is a scientific justification or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate.

At present, the correct interpretation of these provisions is subject to dispute (in the hormone-treated meat panels). Nevertheless, it is already becoming clear that SPS is leading to major changes in the working practices of Codex with draft standards being subject to far greater scrutiny than in the past.

The role of the Community in Codex

As noted above, the Community is not a member of Codex, but has the status of an observer. Nevertheless, the Community plays an active role at meetings of the Codex Alimentarius Commission and its subsidiary Committees.

Coordination takes place before Codex meeting within the Council "Codex Alimentarius Group" on the basis of a staff paper prepared by the services of the Commission. This paper will define a Community position on each Agenda item of Community interest. Before preparing the paper, the Commission's services will, whenever possible, consult with interested parties. However, in practical terms the possibilities for effective consultation are restricted by the fact that many Codex documents are circulated only shortly before the relevant meetings. Both the Commission and Member States have emphasised the importance of timely circulation of documents in order to allow for proper consultation.

For questions governed by existing Community legislation, where the Community is competent, the agreed Community position will be presented by the representative of the Commission. In other areas, the agreed position will be presented by the Council Presidency or by the Commission representative, as considered appropriate. Further coordination meetings will take place, as necessary, on the margin of the Codex meeting concerned to adjust the agreed position to developments which may arise during discussions.

In addition to preparing for formal meetings of Codex committees, the Commission uses its best endeavours to ensure that the Community interest is properly represented in informal Codex drafting groups which may be established from time to time to prepare early drafts of Codex standards, through the participation of Community officials, or failing this of national officials.

Codex standards relating to food additives and contaminants, residues of veterinary drugs and pesticide residues are usually prepared following scientific assessments which are undertaken by the Joint Expert Committee on Food Additives (JECFA) which also covers contaminants and veterinary drugs, and the Joint Meeting on Pesticide Residues (JMPR). These advisory committees are formally independent of Codex, and their members are appointed by WHO and FAO on a temporary basis to provide independent scientific advice. Without in any way seeking to influence the scientific advice given, the Commission seeks to ensure that recognised independent Community scientists, in particular members of the Community's own scientific advisory committees, participate actively in their work. The Commission has also been pressing for improvements

in the transparency of the work of these bodies. But more work needs to be done in order to improve effectively the independence, impartiality and quality of the scientists serving the Codex Committees. Likewise, the Commission encourages the participation of Community scientists in ad hoc scientific consultations on food safety issues which may be convened from time to time by FAO or WHO, and which may ultimately serve as a basis for the elaboration of Codex standards.

Substantial efforts have been undertaken in recent years to improve the presentation of Community positions at Codex, and within the institutional limitations imposed, the current arrangements are in general working reasonably well in the case of non-controversial dossiers. However, these arrangements remain rather fragile and much depends on the good will of the representatives of the Member States, Codex officials and the Chairmen of Codex Committees. From time to time, situations have arisen where individual Member States have not followed the agreed Community position, or where third countries have sought to exploit the uncertainty surrounding the Community's status in Codex.

For these reasons, the Commission considers it essential that the Community should become a full member of Codex Alimentarius as soon as possible.

The 22nd Session of the Codex Alimentarius was held in Geneva on 23-28 June 1997.

During this meeting, the point of view of the European Community, represented by the Commission, and its Member States, represented by the Council Presidency was followed on several occasions. On conflictual topics, such as the use of BST (bovine somatotropin), standards for natural mineral water and the evaluation and acceptation of food inspection systems, the Codex Commission had to proceed with a formal vote. On these issues, the proposals of the European Community obtained a majority vote.

IV. WTO AND THE SPS AGREEMENT: factual report and activities

The purpose of the WTO Agreement on the application of Sanitary and Phytosanitary Measures is to ensure that measures necessary to protect human animal or plant life or health shall not represent a disguised restriction on international trade or arbitrary or unjustifiable discrimination between Members. The Agreement concerns the application of food safety and animal and plant health regulations, which may directly or indirectly affect international trade.

The Agreement recognises Government's rights too take sanitary and phytosanitary measures but stipulates that they must be based on science, should be applied only to the extent necessary to protect human, animal and plant life or health and, as indicated above, should not be used as a disguised restriction on trade and should not discriminate between Members where identical or similar conditions prevail.

Members are encouraged to base their measures on international standards, guidelines or recommendations established by the relevant bodies such as Codex, and the OIE, where they exist. However, Members may maintain or introduce measures which results in a higher level of protection, than would be achieved by

measures based on relevant international standards, guidelines or recommendations, if there is a scientific justification or as a consequence of the level of sanitary and phytosanitary protection that Members determine to be appropriate, provided that the measures otherwise are consistent with the provisions of the Agreement. The exact meaning and practical consequences of these provisions is somewhat unclear and currently subject to WTO dispute settlement proceedings in the hormone-free meat panels.

Members should accept sanitary and phytosanitary measures of others as equivalent if the exporting country objectively demonstrates to the importing country that its measures achieve the importing country's appropriate level of health protection.

The Agreement requires that Governments must provide advance notice of new or changed sanitary and phytosanitary regulations. In particular for those cases in which a Member does not apply an international standard, guideline or recommendation as a condition for import, the Member shall provide an indication of the reason thereof.

The Committee on Sanitary and Phytosanitary Measures provides a forum for monitoring the implementation of commitments and for consultations and discussions on matters with potential trade impact.

The intention is that the SPS Agreement will be reviewed during 1998. The review should be considered in the light of the practical experience gained and the outcome of the relevant disputes.

Summary of the Activities carried out by the EC SPS Enquiry Point:

Each member of the SPS Agreement has to notify to the SPS secretariat in Geneva and to the other members the "Enquiry Point" which is in charge of communicating the introduction of new or changes of existing sanitary and phytosanitary measures. The Enquiry Point gives copies of the legal texts for the intended measures and provides upon request information or explanation of the proposed measure. A comment period of minimum 60 days should be respected before the entry into force of the measure. In case of urgency (safeguard measure) the measures may be notified after the entry into force. The Enquiry Point also comments on measures by other members. The Commission (DG VI) is the Enquiry Point for the EC.

(a) Notifications

A total amount of 192 Third Country and EC notifications has been dealt with, during 1996.

Any notification implies a number of notes to be prepared in order to circulate the notification and to obtain the relevant text by the notifying authorities.

In managing the overall procedure, approximately 370 notes have been sent throughout the year.

In case of comments received or made on any of the above draft, the EC Enquiry Point is responsible for the coordination with the relevant Commission Services, for

seeking the agreement of the different General Directorates and of the EU Member States on the final draft, in the appropriate committees if necessary.

(b) Meetings

Three meetings of the SPS Committee are held annually in Geneva. The Enquiry Point is responsible for the interservice coordination and the coordination with Member States on any relevant issue to be discussed in Geneva. In order to attain the above, interservice meetings and coordination meetings with representatives of Member States are held.

In addition, information on the activities of the SPS Enquiry Point and the SPS Committee is given to Member States on a monthly basis during the DG VI Standing Committees of Animal Health, Public Health and Plant Health.

N.B. : The annexes had been transmitted to the EP as part of the Commission's Second Progress Report.

3.7 Matters concerning animal feedingstuffs, and especially meat-and-bone meal

3.7.1 (together with the European Parliament) Immediate convening of a scientific conference to look into the problems of using animal proteins in animal feedingstuffs to serve as the basis for a future Commission proposal to the Council, with a view to recommending its prohibition in future, if this is considered advisable

The International Scientific Conference on meat and bone meal has been organised 1 and 2 July 1997 by the European Parliament and Commission, in Brussels.

25 speakers have presented the scientific, regulatory, control, ecological and economic aspects for the animal meals and afterwards the consumer perspectives on the question to approximately 350 participants directly concerned : scientists, consumers, manufacturers, traders, farmers, ecologists.

A consultation paper is in preparation in order to consider the different options, as did the Meat and Bone Meal Conference, with regard to the economic, scientific, environmental, ethical, trade and possibly other consequences of the exclusion of fallen animals and slaughter condemned material ("high risk material") from the feed chain and of the introduction of a ban on feeding animal protein to ruminants.

This paper will be ready by October 1997. In order to guarantee its wider diffusion, it will be put on the Internet.

Furthermore, the Commission will review of the Community legislation dealing with the production of meat and bone meal, in addition to the measures already adopted or in the course of being adopted (removal of specified risk material from the feed and food chain, labelling of feedingstuffs and rules on trade of MBM).

In addition, the Commission will ensure that before the end of the year the controversy on the safety of MBM inactivation procedures will be dealt with in the appropriate Scientific Committee.

The Joint Research Center studies the developments and considers possible validation of tests methods to monitor compliance with processing standards and to identify meat and bone meal in feedingstuff.

3.7.2 Submission forthwith of proposals for regulations governing the questions of animal food and dealing with the following:

Proposals requested by the Parliament have been made, and legislation adopted, as follows:

3.7.2.1 Confirmation of the general ban on the feeding of meat-and-bone meal to ruminants

The use of mammalian protein for feeding to ruminants was prohibited by Commission Decision 94/381/EC which was adopted on 27 June 1994 and came into force within 30 days of notification. A derogation was possible for Member States which enforce a system which makes it possible to distinguish between ruminant and non-ruminant species, to permit the feeding of protein from species other than ruminants to ruminants, under a procedure laid down in the Decision. However, no Member State was given this derogation by the Commission. Derogations are also possible for certain products particularly milk, gelatine, amino acids, di-calcium phosphate and blood and blood products.

3.7.2.2 Ban on the feeding of carcasses or offal of sick animals to all animals

A ban on use of fallen stock (ie animals which die on the farms) and on the use of detained material from the abattoir for use in meat and bone meal for animal feeding has ecological and health implications and such a measure cannot be introduced without making other arrangements for safe disposal.

In the consultation paper mentioned in point 3.7.1 the economic, scientific, environmental, ethical, trade and possibly other consequences of the exclusion of fallen animals and slaughter condemned material ("high risk material") from the feed chain and of the introduction of a ban on feeding animal protein to ruminants will be addressed. In the beginning of next year the Commission will put forward concrete proposals in the light of the results of the consultation.

Point 3.7.2.2 and 3.7.2.3; Proposal to exclude specified risk material from human and animal food chain (SRM proposal)

The Commission Decision on the banning of specified risk materials from the human and animal food chains (SRM-proposal) is based on the opinion of the Scientific Veterinary Committee of October 1996 and harmonises at the highest level of protection for public and animal health. The draft proposal was explained to the Temporary Committee on BSE Follow-up on 23 June 1997 by

the Commission. This same draft proposal was discussed for the first time with the Member States in a Standing Veterinary Committee meeting on 20 June 1997. The proposal has been received with reservation by several Member States. Mainly because they feel that the risk of TSEs is absent on their territories, and hence they should not be subject to the same stringent rules. The proposal was presented for a vote in the meeting of the Standing Veterinary Committee on 10 July 1997. On 23 July it was presented to the Council where it was nor accepted by qualified majority, nor rejected by simple majority. A simple majority of Member States voted in favour of the measure. It was finally adopted by the Commission on 30 July 1997 as the Commission Decision on the prohibition of the use of material presenting risks as regards TSE and published on the Official Journal (Decision 97/534/EC, OJ L 216, 8.8.97, p. 95 Annex).

The decision bans the use for any purpose, be it for the production of edible as well as for any non-edible product, of specified risk materials. The following are defined as specified risk materials; the skull, including the brain and eyes, tonsils and spinal cord of cattle, sheep and goats aged over 12 months, and the spleens of sheep and goats of any age. In addition the production of mechanically recovered meat from the vertebral column is prohibited. Specified risk materials shall be stained when removed and subsequently destroyed by incineration or burial. In exceptional circumstances specified risk materials may be burned or buried without prior staining. Exemptions are foreseen for teaching, research and fur animal feed. Products of animal origin and medical, pharmaceutical and cosmetical products or their precursors when imported into the Community shall be accompanied by a certificate completed by a declaration of the competent authority that the products do not contain nor are derived from specified risk materials.

A provision to comply with the EC's obligations of international agreements (by way of the SPS agreement) is in the Decision. Any application for a derogation for TSE free areas will have to be scientifically reviewed before consideration by the Standing Veterinary Committee. A minimum period of active surveillance for six years is necessary to demonstrate freedom.

Regionalisation within the EU as regards the SRM ban is not foreseen because no Member state can under the present circumstances as the inspection reports have shown, demonstrate freedom from TSE's because of a number of unquantifiable risk factors: Inadequate surveillance of TSE's - particular scrapie and BSE, inadequate rendering systems, late introduction of mammalian protein ban to ruminants, inadequate enforcement of the ban with potential cross contamination at the level of farm and feed mills, inadequate enforcement of national import bans against UK meat-and bone meal, export of live animals from the UK before the introduction of the EC export ban in 1989, Commission Decision 89/469/EC.

The decision was notified to the WTO in the framework of the SPS procedure. Considerable comments can be expected to be made at international level as highlighted by diplomatic demarches undertaken by several third countries following the Commission decision.

The Multidisciplinary Scientific Committee/Scientific Steering Committee will meet again on 16.10.1997, where a number of issues will be discussed;

I. List of SRMs

II. Should be age limit be abolished as regards exclusion of younger animals (under 12 month)

If necessary, the decision will be amended in light of new Scientific advice.

The Commission is reviewing the implications of its SRM Decision for medicinal products and medical devices and will come up with a proposal to modify the SRM decision in order to ensure adequate availability of necessary medicines.

3.7.2.3 Only the offal of animals which have been released for human consumption may, after it has been adequately sterilized (at 133°C, 3 bar for 20 minutes), be fed to non-ruminants such as pigs, poultry and fish

The Commission will review its position on this matter in the light of the outcome of the conference on animal meal.

See also point 5.4.

3.7.3 Assurance to the European Parliament that Decision 96/449/EC is implemented throughout the Community by 1 April 1997 as regard the standards applicable to the processing of meat-and-bone meal and that Member States will not be granted extensions

The standards governing meat and bone meal are set out in Commission Decision 96/449/EC (heat treatment system for processing animal waste), and those concerning the use of mammalian tissue in ruminant feed are set out in Commission Decision 94/381/EC.

The Commission considers that the strict enforcement of these texts is essential for the eradication of BSE and for avoiding potential risks to animal and human health pending eradication. To reinforce the applicable standards, the Commission decided on 26 June 1997 to initiate the first stage of the infringement procedure provided for in Article 169 of the EC Treaty against ten Member States which have not fully applied or enforced certain aspects of Community BSE legislation (see also point 5.4).

The Commission is currently examining a number of complaints against Member States charged with infringing the Single Market rules by taking unilateral national measures going beyond the measures introduced at Community level.

See points 3.8 and 5.4.

3.8 (together with the Council by 1 September 1997)
Measures to ensure uniform respect of maximum guarantees for the elimination of suspect meat-and-bone meal and dangerous or possibly dangerous animal waste, together with a ban on exports of these products to third countries

A draft for a Commission Decision concerning protection measures with regard to trade of meat and bone meal was discussed at the Standing Veterinary Committee of 9-10 September. A revised draft will be submitted for a vote on the Standing Veterinary Committee of 7-8 October 1997.

This draft establishes that mammalian meat an bone meal not produced to the new standards cannot be *marketed* within the European Union and cannot be sent to third countries.

In addition, this proposal clarifies that any meat and bone meal not produced in accordance to the new standards cannot be fed to animals. Member States must immediately send a report to the Commission on the application of the measures taken to this regard.

Furthermore, in line with the conclusion of the Conference on Meat and bone meal of 1-2 July, the proposal lays down a model of commercial document which must accompany all consignments of meat and bone meal intended to be traded. In addition to this document, a model of an official declaration certifying that the meat and bone meal was produced in accordance with the new rendering standard is also laid down. These measures will ensure the traceability of meat and bone meal from production to feeding.

3.9 Amendment of the legislation on animal nutrition with inclusion in labelling of a mandatory explicit declaration for feedingstuffs by their manufacturers which should facilitate the clear identification of components and of the origin of ingredients and on user instructions

Since the European Parliament issued its recommendations on BSE, the Commission has passed new legislation concerning the feed ban of mammalian protein to ruminants and labelling of ingredients in compound feedingstuffs

a) Directive 97/47/EC, which amends the labelling provisions of Directives 77/101/EEC and 79/373/EEC on the marketing of straight and compound feedingstuffs for animals to prevent the users of feedingstuffs containing protein derived from certain mammalian tissue from feeding them to ruminants by warning them against this through appropriate labelling ; this Directive also deletes the category "Land animal products" from Directive 91/357/EEC laying down the categories of ingredients which may be used for the purpose of labelling compound feedingstuffs for animals so that livestock farmers are fully informed about whether or not the compound feedinstuffs they are using contain protein derived from mammalian tissue and, if so, are aware that they may not feed those feedingstuffs to ruminants.

b) Decision 97/582/EEC which, to ensure legal consistency, integrates a ban on feeding mammalian derived protein to ruminants (laid down by Decision 94/381/EC of 27 June 1994 concerning certain protection measures with regard to bovine spongiform encephalopathy and the feeding of mammalian derived protein) into Decision 91/516/EEC establishing a list of ingredients whose use is prohibited in compound feedingstuffs.

Drafts of both pieces of legislation were communicated to Parliament.

Further Developments concerning the labelling of animal products in the context of measures to combat BSE

The Commission plans following measures for the future.

Measures planned for the future:

1) Consumers and inspection authorities should be able to identify the source of feedingstuffs immediately and without difficulty and to establish that the rules on the handling of meat and bone meal to guarantee health safety have been complied with. The Commission is preparing a proposal for a Council and Parliament Directive to this end.
It is foreseen that in future the following should be included in the information which it is compulsory to provide concerning the ingredients of feedingstuffs:
The name or business name and the address of the registered place of business of the producing establishment, the approval number where the establishment must be approved, and the reference number of the lot and any other statement which ensures that the feed material can be traced.
This proposal will be presented to Parliament and the Council before the end of the year.

2) The Commission has undertaken to examine the possibility of including in the legislation on feedingstuffs a rule requiring the percentages of feed materials in compound feedingstuffs to be indicated. For this rule to be enforceable, the authorities need to have the means to check the information provided by the producer. The existing rules require the manufacturers of compound feedingstuffs to declare the nature of the ingredients (eg fish meal, meat meal, corn gluten feed, etc) listed in a descending order by weight in the feedingstuffs. But manufactuers are not obliged to indicate for each ingredient the quantity present in the feedingstuff, which would be of interest provided there were adequate analysis methods in existence.

The Commission services are therefore going to organise an informal study to gain an overview of the ways in which it is currently possible to establish the quality and quantity of feed materials - in particular meat and bone meal - present in a compound feedingstuff, using microscopy and possibly other methods. All official laboratories with experience of analysing feedingstuffs using microscopy, as well as a few private ones, will be included in the study.

Experts from the Member States will be consulted at the 88th meeting of the Committee of Experts on legislation concerning feedingstuffs (Sub-Group on Methods of Analysis) The intention is to establish the parameters for the study as

soon as possible so that it can begin not later than 1 January 1998 and be completed around the middle of that year.

At the Expert Committee meeting mentioned earlier, the possibility of Community-wide rules on methods of analysis was also discussed.

If the result of the researching studies lead to the conclusion that it is possible to control the quantitative declaration of ingredients, the Commission will propose an amendement of the current labeling legislation in order to prescribe the quantitative declaration of ingredients.

3) In relation with the declaration of the origin of proteins present in compound feedingstuffs, the Commission is prepared to study the possibility of controlling such an information.

Until now, legislation has only required the declaration of crude protein in the feedingstuffs regardless of its origin; actually, a lot of different origins are possible, having regard to the great number of ingredients present in a compound feedingstuff (more or less 15).

In the past, the Commission tried to introduce the declaration of the "digestible protein"; the Commission considers that this provides the farmer the most important information.The idea was nonetheless abandoned, because no reliable analysis method was available at that moment.

4) **Adoptation of measures to restore the smooth functioning of the markets.**

- **Reinforcement of the veterinary checks system**

A pre-condition for the smooth functioning of the beef market is a reliable system of controls throughout the Community. It is clear from the investigations by UCLAF and FVO that there are deficiencies in the official control of meat production in the UK and other Member States and that the present Community control regime needs reinforcement. The Commission will take measures to strengthen the veterinary checks system in order to better prevent fraud. An ad-hoc inter-service groupe (DG VI, DG XXIV and UCLAF) has been set up to give urgent consideration to the action which must be taken as a result of these findings. The following lines of action have been identified:

– ***Reinforcing controls in the United Kingdom***

Transport through the UK

The following measures could be envisaged. To avoid fraud related to potential transit through the UK, provisions for official sealing of means of transport should be foreseen. The de-sealing of the means of transport should be done by an official. The consignments should be accompanied by veterinary certificates. In the case of intra-Community trade the consignment should be announced by the competent authority issuing the veterinary certificate to the competent

authority at the place of destination by a computerised message (ANIMO-system) or by fax.

Processing of meat derived from bovines slaughtered outside the UK

With regard to the dispatch of meat and meat products derived from cattle slaughtered outside the UK (as foreseen under Article 1(a) of Decision 96/239/EC), the following measures could be envisaged :

- only originals of veterinary certificates, or in case of meat from third countries certificates issued by the EC inspection post, should be accepted for meat used under Article 1(a);
- the veterinary certificates for dispatch from the UK should include reference to all establishments where the meat was stored and handled;
- all premises storing, handling or processing meat under Article 1(a) in the UK should be approved;
- storing and handling of meat under Article 1(a) should take place separated in time or space from any meat which is not eligible;
- meat under Article 1(a) should be stored in specified locked chambers which are sealed when the supervising official is not present;
- cross-checks of amounts of incoming and outgoing materials used under Article 1(a) to ensure traceability should be applied;
- an official should control any handling of meat under Article 1(a);
- health marks must not be removed from meat intentionally except where unavoidable in the cutting process;
- the health labels and the special labels to indicate production under Article 1(a) should bear serial numbers and should be handed out by the supervising official for the production of each day;
- dispatch of products under Article 1(a) to in and from the UK should take place in officially sealed means of transport;
- in case of dispatch of products under Article 1(a) to other Member States the competent authority issuing the veterinary certificate should announce the consignments to the competent authority at the place of destination by a computerised message (ANIMO-system) or by fax.

– ***Reinforcing controls in the European Community***

On the more general question of strengthening the Community control regime, a number of initiatives are being discussed. They include:

Harmonisation of control plans and improvement of collaboration within the Union

- application of Article 16 of Directive 89/662, requiring the Member States to communicate their control plans to the Commission, with the possibility for the Commission to recommend changes;

- application of the Directive on Mutual Assistance (89/608/EEC), and where necessary amendments to provide for the designation of contact points in all Member States and mandatory involvement of the Commission in view of public and animal health as well as fraud problems;

Reinforcing controls when emergency measures apply

- certain movements of products of animal origin, i.e. movements into, through and out of areas which are restricted for the protection of animal or public health, to be announced via the computer system ANIMO;

- increased veterinary surveillance, in establishments, particularly in cutting plants and cold stores, going beyond the requirements under routine circumstances;

- Member States are requested to increase and strengthen their physical checks on the export of beef meat in the framework of Regulation (EC) No 2221/95, laying down detailed rules for the application of Council Regulation (EEC) No 386/90 as regards physical checks carried out at the time of export of agricultural products qualifying for refunds;

Reinforcing sanctions

- effectively deterring measures of sanctions must be foreseen and harmonised;

Reinforcing routine controls

- increased veterinary surveillance, in establishments, particularly in cutting plants and cold stores;

- increased powers to official services, including placing all health marking instruments, labels etc. under the direct control of the official veterinarian;

- serial numbering of health labels, with the official service maintaining a register of numbers and the numbers mentioned on health certificates or commercial documents;

- health marks must not be removed from meat intentionally, except, when unavoidable in the cutting process.

4.1. Efforts to achieve all possible cooperation with the UK authorities with a view to ending the crisis as soon as possible.

The Commission's position paper on the stepwise lifting of the ban was welcomed in the June 1996 European Council in Florence. The five preconditions in this paper are:

A. implementation of the selective slaughter programme,

B. improved methods for removal of specified bovine materials,

C. introduction of a cattle passport system for animals born after 1 July 1996,

D. measures for the removal of meat and bone meal from feed mills and farms, from 1 August 1996,

E. effective implementation of the over 30 month rule (OTM scheme).

The UK has taken action to fulfill these conditions. The Commission receives fortnightly reports from the UK and has carried out a series of missions in order to inspect progress towards eradication and control. These actions are designed to accelerate the eradication of BSE, protect public and animal health, and restore consumer confidence.

- **The UK programme for the eradication of BSE**

The UK programme for the eradication of BSE was adopted by the Commission on 24 June 1996. The principle elements of the plan are:

- selective compulsory slaughter of animals,
- improved system of identification of cattle (animal passport system),
- intensified control of feed manufacturing industry,
- detailed investigation into animals which may have been exposed to contaminated meat and bone meal.

The implementation of the selective slaughter programme was delayed by the UK. However, after review, the UK did go ahead with the selective slaughter in January 1997.

The Spongiform Encephalopathy Advisory Committee of the UK has concluded that maternal transmission could occur in approximately 7% of cases. In the light of this information, the Commission has asked the UK to review its slaughter programme. Other measures have been introduced, co-funded by the Community, in order to improve the protection of public health and restore consumer confidence. In particular, the Commission draws the attention of Parliament to the "Over Thirty Months Scheme" in which all animals over 30 months of age are removed from the food and feed chains (OTM scheme).

- **Mission findings on the Florence preconditions:**

A mission has taken place to the United Kingdom to study the implementation of the measures to meet the preconditions of the conclusions of the Florence Summit, on 9-13 June 1997, (see below). The draft mission report was sent to the UK in July. The final report will be forwarded Member States and to Parliament.

– *Selective slaughter program*

Progress has been much faster in Northern Ireland than in Great Britain. In general it can be concluded that this conditions of the Florence Agreement has been fulfilled for NI but not for GB.

The United Kingdom has proposed several changes of this program to the Commission and has been asked to submit a formal amendment of the programme already adopted by the Commission including their reaction to maternal transmission.

– *Animal identification and movement recording*

In GB, since 1 July 1996, all cattle which move must have an officially issued passport recording all premises through which the animal has passed. In addition movement records have to be kept by the owners. There is no central cattle movement database yet.

In Northern Ireland all movements are recorded in a central computer database. No passports are issued.

– *Legislation for the removal of mammalian meat and bone meal from feedmills and farms*

A series of legislation has been introduced, the latest being a ban on the possession or holding of mammalian meat and bone meal on feedmills and farms with livestock, effective on 1 August 1996. Samples have been taken for testing; and there have been no positives in ruminant feed since August 1996.

– *Over Thirty Months Scheme*

Under the OTM Scheme animals aged 30 months or over are required to be killed in specially designated slaughterhouses, and the carcasses and all parts of the carcasses stained, processed and destroyed. Because of limited incineration capacity the carcasses are rendered into Meat and Bone Meal which is stored under official control pending final destruction. All cold stores

in Great Britain are now clear of frozen OTMS materials and it is estimated Northern Ireland will be clear by the end of the year. Deliveries of meat and bone meal (MBM) for destruction in a high temperature industrial incinerator continue to be made; roughly 4,200 tonnes have been processed to date.

Several inspection missions have taken place, involving veterinary and financial checks. Initially, problems were identified, but most have been resolved. However, in *UK* there is still an undercapacity for incineration of the rendered material. In June 1997, the mission team was informed that there are ongoing discussions with power plants and there are contacts with operators concerning the incineration of carcasses. However, no definitive solution has been found.

More than 250,000 tons of MBM are currently stored. The current incineration capacity stands at 15,000 tons per year. The report on the mission of 9-13.06.1997 states that "This poses a serious problem in terms of the final destruction of the animals, as foreseen in Regulation 716/96, as amended". (p. 18). The report concludes : "In terms of the fulfilment of this precondition, the main problem rests with the stipulation that it includes "destruction". Even though the final destruction may be ensured, the very limited current incineration capacity implies that this destruction cannot be actually achieved in the short term."

However, the removal of all contaminated material from the food and animal feed chain goes substantially towards fulfilling the objective of guaranteeing food safety as aimed at by the Florence European Council. For this, the storage of contaminated material under secure conditions must be guaranteed.

– *Improved methods for removing specified bovine materials from carcases*

The mission stated that there had been a substantial improvement in the level of compliance, due to improvements in the procedures and controls, but that no new methods had been introduced. It is clear that there have been significant improvements which will result in a real reduction of the risk of exposure of the human and animal population from this source.

- **Submissions by the United Kingdom**

– *Export Certified Herd Scheme*

The United Kingdom have presented a revised paper on the ECHS, taking into account some of the comments of the opinion of the Scientific Veterinary Committee of 11 June 1997, and answering others where the suggestions have not been incorporated into the new Scheme.

The revised conditions would exclude animals which do not come directly from the natal herd, unless they are recorded throughout their life on an official central database. At present, the second condition is applicable only in NI. Only meat prepared to the specifications for deboning and removal of

specified tissues as laid down in Commission Decision 94/474/EC would be eligible for export.

The revised plan was discussed and adopted by the Scientific Veterinary Committee on 17 September 1997. The Committee stated that adjustments to the United Kingdom program in line with the smaller recommendations would not need further examination and approval by the Scientific Committee.

The opinion of the Veterinary Scientific Committee on the revised Export Certified Herds Scheme looks promising with regard to parial lifting of the ban for areas where a computerized identification system exists. However, careful consideration is needed, both of the scientific aspects, as well as of the control aspects. In fact, the Committee stated that "small modifications could be made to minor aspects of the programme at the request of the inspection or legislative services in order to comply with certification or control requirements". As a follow-up further contacts will have to be taken between the Commission and the UK.

- *Date-based Export Scheme (DBES)*

This Scheme has been submitted officially to the Commission on 2 October 1997.

The basis of this approach is that animals born after the effective date of the feed ban should be considered to be safe from the risk of food-borne exposure. This date is considered to be 1 August 1996.

In accordance with the Florence Conclusions, this proposal will be submitted to the appropriate scientific committees for their opinion as soon as possible.

- **Further proposals from the United Kingdom**

The United Kingdom informed the Commission on possible further proposals dealing with two aspects:

- Amendments to the already approved selective cull, to take account of some operational problems,

- A proposal to slaughter progeny born after 1 August 1996 of all cases of BSE, in response to the recent report on maternal transmission.

In accordance with the conclusions of the Florence Summit, when the United Kingdom presents official working documents on the above mentioned aspects, these will be sent to the appropriate scientific committees for an opinion. The Commission will act as appropriate on the basis of the scientific advice.

- **FEOGA financing for restoring market balance**

The list of the measures taken to restore the market balance and the normal functioning of the markets is given in annex.

The most important measures taken are measures listed under points 1, 2, 3 and 4 in annex. The biggest impact is coming from the OTM scheme under which, 1.700.000 animals are already killed,

The payment for these animals is now fixed at
- 0,8 ecu/kg liveweight for cows
- 0,9 ecu/kg liveweight for animals other than cows.

The FEOGA cofinancement covers 291 ecu per cow and 328 ecu for the others, once the animal is destroyed (based on a cofinancement rate of 70%). However FEOGA pays an advance of 80% to UK after rendering in order to take account of the big backlog for the incineration.

On request from UK, and in order not to create a situation where it is profitable to extra fatten animals just before their killing, a maximum weight for any payment of 560kg was introduced.

From the start of BSE subsidy measures in the UK, the Commission Services in a clearance of accounts context have sought to assist the UK authorities in the setting up of an adequate management and control system. The assistance has mainly consisted of a number of missions made to ensure that proper administrative and control measures were taken in the application of the over thirty month scheme and the selective cull scheme. In relation to the over thirty month scheme five missions were made between April 1996 and April 1997, three of which involved the veterinary service of the Commission. One of these missions (April 1997) also examined the selective cull procedures and the problems observed were followed up in a subsequent mission in July 1997. Subsequently observation letters have been sent to the UK authorities with recommendations for improvements to be made to the procedures applied to safeguard Community funds and ensure that animals slaughtered under the schemes were not diverted. Meetings have been held in Brussels where further clarification was necessary.

4.2 The following considerations should be seen as fundamental elements in future changes to the rules of the CAP

On 15 July 1997, the Commission adopted its Agenda 2000, "For a stronger and wider Union". On 16 July, President Santer presented it to the Parliament. The package includes major reform proposals for the CAP, which are based on the following objectives:

- increasing competitiveness internally and externally in order to ensure that EU producers take advantage of positive world market developments;

- ensuring food safety and food quality which are both a fundamental obligation towards consumers and an important element of competitiveness;
- ensuring a fair standard of living for the agricultural community and contributing to the stability of farm incomes;
- integrating environmental goals;
- creating alternative job and income opportunities for farmers and their families;
- contributing to economic cohesion within the Union;
- simplifying EU legislation.

Food safety and food quality have therefore been recognised by the Commission as an integral part of the reform package of the CAP which the Commission proposes.

4.2.1 Priority for the market interests of the COMs is only a short-sighted policy option for the CAP

In the agricultural chapter of Agenda 2000, the Commission sets out policy objectives for the CAP (see above). In particular, food safety and food quality are recognized as being a top priority. The Commission then develops concrete proposals regarding mainly the common market organizations and rural accompanying measures, which form the basis of the CAP. However, the CAP instruments cannot address all the problems related to food safety and food quality. Other policies are also concerned. In particular, the Commission has continuously been active on establishing norms for food safety. The same holds for veterinary standards. The actions related to BSE are the subject of the present progress report.

As regards quality improvement, a legal framework aiming to guarantee the high quality of agricultural produce of a specific character and geographical denomination of agricultural produce has been established since 1992. Moreover, specific aid for marketing of such produce, including those from organic production, is an important option for EU co-financing and will remain so in the future.

4.2.2 Restoration of consumer confidence through appropriate guarantees for public health protection is the only way to ensure a viable agricultural policy which satisfies both consumers and producers

The image of European products on domestic and international markets depends upon complete reliability from the point of view of food safety and from continuous efforts to improve quality. The most important way of restoring and increasing consumer confidence in food is by ensuring its safety. The necessary structures must then be put in place to prove this to the consumer.

As regards beef, the Commission is already acting along the lines of the present progress report. In particular, two important measures proposed by the Commission (cattle identification and registration and beef labelling) were agreed by the Council in April 1997.

4.3 Submission without delay of a proposal for a harmonised system of certification for meat in order to restore consumer confidence in this sector

4.3.1. Animal identification and beef labelling

In order to restore consumers' confidence in beef one has to give sufficient guarantees as to the safety and the quality of the beef. A conditio sine qua non therefore is to lift the beef out of the anonymity of a mass product, to individualise it and to provide for an efficient traceability system. This means one needs a reliable system for the identification and registration of bovine animals.

Regulation (EC) No 820/97 puts into place

- a bovine animal identification and registration system which reinforces the old directive 92/102 mainly by.
- replacing the directive by a regulation which has direct application in all Member States,
- reinforcing the registration element of the system by obliging every Member State to create a central data base with all bovine animals and their movements,
- ameliorating the animal identification (two eartags, european definition and coding for the eartag)
- a beef labelling system which is:

  from now until 31.12.99 voluntary, but Member States having already now a good animal identification and registration system can start as from now with an obligatory system for meat coming from animals born, raised and slaughtered on their territory. The Commission asked Member States about their plans for making use of this scheme. Until now only France seems interested in this and has announced that it will start on 1.10.97 but did not yet introduce its working plan to the Commission. A apriori approval by the Commission is however needed;

  from 1.1.2000 onwards obligatory, but Member States may decide that it remains voluntary for meat traded on their territory. The detailed application rules for such an obligatory system still have to be proposed and adopted (Council and Parliament).

The Commission as well as the Parliament insisted on defining already now in more details the obligatory system applicable from 1.1.2000 onwards, based on the codecision procedure as provided for in article 100A of the Treaty. The decision of the Council was taken by unanimity, against the Commission and against the advice given by Parliament. The Commission is challenging this decision before the European Court of Justice (case C 269/97 lodged on 22.7.97). The Commission will continue its attempts to induce Member States to advance the deadline as far as possible. In the Commission's view, the presentation of a new proposal based on Article 100A would have no chance of advancing matters in view of the decision-making delays and the pending Court case.

Commission services are launching a pilot project called IDEA. This project includes electronic individual identification of about one million animals, as well as a global reporting system. It should last 3 years and involve 7 Members States.

4.3.2. Financement for the the labelling of beef

For the moment, there is no direct cofinancement of label activities. However:
- All prepacked beef which benefits from our promotion cofinancement sheme for quality beef has to be labelled in conformity with our new labelling system (R 820/97) guaranteeing full tracebility to the individual animal or the group of animals concerned.
- In the proposal for a regulation on beef promotion which is for the moment discussed in Council and in Parliament, the Commission proposed to include in the beef promotion financement sheme publicity measures intended to inform the consumer of the guarantees offered by the EC labelling system introduced by regulation (EC) n° 20/97.

During the debate in EP September Plenary Session on this proposal for a regulation, the Commission accepted an amendment by the European Parliament changing the legal base from Article 43 to Articles 43 and 129a.

5. Measures corresponding to the responsibilities identified by the committee of inquiry

5.1 Submission of legislative proposals with a view to making the authorities which have allowed the disease to appear and spread responsible for the financial costs of BSE

BSE-related costs may include those arising, directly or indirectly, from :

- Commission Regulation (EC) No 716/96 adopting exceptional support measures for the beef market in the United Kingdom.[1]

- Commission regulations adopting exceptional support measures in other Member States.[2]

- Commission Decision 96/385/EC approving the plan to eradicate BSE in the United Kingdom.[3]

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1 OJ 1996 L 99, p. 14, as last amended by Regulation (EC) No 2423/96 (OJ 1996 L 329, p. 43).

2 For example, Commission Regulation (EC) No 717/96 (OJ 1996 L 99, p. 16) (Belgium, France and the Netherlands).

3 OJ 1996 L 151, p. 39.

- Commission decisions approving the plans to eradicate BSE in other Member States.[4]

- Intervention : Community purchases of beef,[5] and Community aid for the private storage of veal.[6]

- The early processing and early marketing premia.[7]

- Temporary income support for farmers affected by the outbreak of BSE.[8]

A preliminary question is to determine the real nature of these measures. In the view of the Commission (and probably of the Council) these are not measures intended to compensate for specific damage, but measures of solidarity, similar to those adopted on many occasions in the past pursuant to the Common Agricultural Policy.

Furthermore, if the "damage compensation" rather than the "solidarity" approach were pursued, a second problem would be to identify those considered responsible for the damage. Would it be the United Kingdom ? Judicial action against the United Kingdom is considered below at point 5.3. Would it be those involved in feeding such products to ruminants (i.e. the farmers)? It would appear difficult to reconcile such action with the Community's continuing efforts to support beef producers. A third possibility might be those involved in the production of mammalian derived meat-and-bone meal for ruminants. It should be noted that there is no suggestion that such producers have at any time committed breaches of Community law.

It is highly doubtful that the Community has the competence to impose such costs on those considered responsible by legislation, in the absence of any judicial remedy. It is also highly doubtful that such an approach would be accepted by the Council. A further formidable legal obstacle to such legislation would be the Community law principle of non-retroactivity. It would not be possible to adopt Community legislation with retroactive effect.

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4 For example, Commission Decision 97/18/EC (OJ 1997 L 6, p. 43) (France).

5 See, by way of example only, Commission Regulation (EC) No 1358/96 (OJ 1996 L 175, p. 12) and Commission Regulation (EC) No 1124/96 (OJ 1996 L 149, p. 23).

6 Commission Regulation (EC) No 830/96 (OJ 1996 L 112, p. 7).

7 As provided for in Council Regulation (EEC) 805/68 (OJ 1968 L 148, p. 24) , as last amended by Regulation (EC) No 2222/96 (OJ 1996 L 296, p. 50), Article 4i.

8 Council Regulation (EC) No 1357/96 (OJ 1996 L 175, p. 9).

Furthermore, it is highly doubtful that the Community has the power to impose a general tax or charge on the current commercial activities of such operators with a view to raising revenue intended to compensate for BSE-related costs, particularly if it were proposed that such a charge be imposed only on operators in the United Kingdom. It is also highly doubtful that such an approach would be accepted by the Council.

5.2 Adoption of the necessary personnel and disciplinary measures with regard to the incorrect behaviour of Commission officials

The Commission would point out first of all, in general terms, that like any other administration which attracts criticism, it has to look into whether the cause of the difficulties in question are of a structural nature or have to do with individual failings.

On the BSE issue, the Commission followed up the committee of inquiry's report by taking a very close look at the possible causes of the events which attracted criticism from the committee. In its administrative reorganisation, the Commission also took account of the recommendations made in the report from the Inspectorate General of January 1996, which was produced in the wake of problems encountered in dealing with other veterinary matters.

- The Commission felt that the BSE crisis had revealed shortcomings in its organisation. In consequence, it took the necessary administrative measures, both in reorganising its administrative structures, as described in this report, and in transferring certain of its officials. These measures were taken with a view to creating a new management structure and re-establishing administrative efficiency. A number of management posts which are still vacant will be filled shortly. Overall, the operation has been completed, and the Commission is convinced that past failings have been remedied and that a solid basis has been built for the future.

- As regards the behaviour of certain officials referred to in the aforementioned report, the Commission has examined whether such behaviour could be attributed to deliberate neglect or negligence in observing the obligations to which the officials were bound under the Staff Regulations (Article 11 *et seq* - Title II), such failings being an indispensable premise for any disciplinary measures. Any such failings must be properly identified in relation to the relevant provisions of the Staff Regulations and the case-law of the Court of Justice of the European Communities. As regards the officials whose names were cited by the committee at the hearing on 17 September 1997, the Commission - as Commissioner Liikanen pointed out - has found no compelling reasons which would justify initiating disciplinary proceedings against them, including in the case which was still under investigation at the time of the hearing.

5.3 If the Commission denies responsibility, as was suggested by the Commission President on 15 January 1997 when speaking before the committee of inquiry, immediate bringing of administrative proceedings against the United Kingdom for repayment of all sums allocated in previous years for the purposes of eradicating BSE

The objective of such judicial action would be recovery from the United Kingdom of costs relating to the eradication of BSE.

The following could be considered, at least in part, as giving rise to costs relating to the eradication of BSE:

- Commission Regulation (EC) No 716/96 adopting exceptional support measures for the beef market in the United Kingdom (slaughter of animals over 30 months).[9]

- Commission regulations adopting exceptional support measures in other Member States (slaughter of animals from the United Kingdom).[10]

- Commission Decision 96/385/EC approving the plan to eradicate BSE in the United Kingdom.[11]

- Commission decisions approving the plans to eradicate BSE in other Member States.[12]

There are serious legal obstacles to the recovery of such costs from the United Kingdom :

- Subject to clearance of accounts (see below) there are no procedures in Community law which would permit a judicial action against the United Kingdom for repayment of moneys paid by the Community to the United Kingdom, in lieu of payments made by the United Kingdom to farmers pursuant to Community legislation such as Commission Regulation (EC) N° 716/96.

- The only remaining possibility would be an action for damages against the United Kingdom. Such an action is not provided for in the Treaties. The question remains whether or not it would be possible to envisage such an action against the United Kingdom in the English jurisdiction.

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9 OJ 1996 L 99, p. 14, as last amended by Regulation (EC) No 2423/96 (OJ 1996 L 329, p. 43).

10 For example, Commission Regulation (EC) No 717/96 (OJ 1996 L 99, p. 16) (Belgium, France and the Netherlands).

11 OJ 1996 L 151, p. 39.

12 For example, Commission Decision 97/18/EC (OJ 1997 L 6, p. 43) (France).

Action for damages

With regard to legal responsibilities, in deciding whether or not to bring an action before any court, the Commission must consider what are its prospects of success. Such consideration includes an autonomous assessment of the facts and law. It is for this reason that the Commission is bound, when considering what legal action to take, to consider where, from a purely legal perspective, responsibility may lie. That is, to identify those legally responsible. The Commission cannot proceed in legal matters only on the basis of the political responsibilities identified by the committee of inquiry. Neither would that be a course of action that would maximise the Commission's prospects of success in a given legal forum. Not every human action actually or potentially, wholly or partly, directly or indirectly, prejudicial to others will give rise to the possibility of legal action. There are a series of legal tests or obstacles that a would-be litigant has to satisfy. In other words, the scope for legal attribution of responsibility is narrower than the scope for political attribution of responsibility. This exercise of identifying where legal responsibility may lie is entirely without prejudice to the findings of the committee of inquiry as to where political responsibility may lie. In some cases, the prospects of success are so remote, even non-existent, that the bringing of an legal action would be pointless, and even counter-productive. That is the Commission's conclusion with regard to an action for damages against the United Kingdom. That is why the Commission does not consider that this would be an appropriate course of action.

English law concerning non-contractual liability is highly technical and complicated, and constantly evolving. The jurisprudence is casuistic, and not amenable to summary. Naturally, complexity is no bar to action.

To succeed in an action against the United Kingdom for the "tort of negligence", it would be necessary to show that, in the matter in question, the United Kingdom owed the Community a "duty of care", and that the "standard of care" imposed on the United Kingdom was breached. These notions cannot be summarised in a general and abstract fashion. They are a function of the particular facts of individual cases.

In the present case, any action would have to be based on the assertion that there was a "breach of statutory duty" (that is, failure by, for example, a Minister to respect a duty or obligation imposed on him by statute), and that damage was sustained as a result of administrative action or inaction.

A first serious difficulty is that the Commission has not identified any basis for action for breach of statutory duty.

However, even if a breach of a statutory obligation could be identified, the Commission is of the opinion that this would not give rise to a right on the part of the Community to recover damages. Breaches of statutory duty only give rise to a right to damages where the courts find that the intention of the legislation

was to confer such a right in addition to the normal administrative law remedies such as declarations annulling unlawful acts. The test is a strict one. There is no general remedy. The act being violated must explicitly grant a right to obtain damages or implicitly be considered to do so. The Commission is of the opinion that the *Francovich* jurisprudence does not help. It cannot be extended to allow the Community itself to recover damages against a Member State. The Treaties set out the rights of the institutions and the Member States and provide a framework for the resolution of disputes between them, notably through the use of Article 169. The Commission has been advised that, for these reasons, the English courts would find that no action for damages for breach of statutory duty would lie in favour of the Community against the United Kingdom, the intention of the Treaties being that disputes be resolved through the mechanisms provided thereby.

This grave difficulty would be compounded, in the Commission's view, by two further difficulties: the difficulty of establishing causality and recoverable damage.

With regard to the question of alleged "damage". The Commission would refer to the Community legislation listed above. The characterisation of expenditure pursuant to these measures as damages in the context of rules governing non-contractual liability would be highly problematic. The expenditure has been incurred not as the inexorable consequence of any alleged breaches of the relevant rules, but as a result of policy decisions made pursuant to the common agricultural policy.

On the question of causality, even on the assumption that the expenditure in question could be characterised as damages, as indicated above, the fact remains that the expenditure was made pursuant to acts adopted by the Community institutions, and was not incurred as an inevitable consequence of any alleged breaches of the relevant rules.

The Commission's conclusion is that such an action would stand no chance of success. No purpose would therefore be served by attempting to bring such an action, which could, indeed, be counter-productive. The possibility of a counter-claim against the Community, however far-fetched that might appear, could not be ruled out.

With regard to exports of beef from the United Kingdom in contravention of Commission Decision 96/239. These were illegal acts committed by private individuals, who will be subject to the sanctions provided for under United Kingdom law. Where, in applying Decision 96/239, the United Kingdom has failed to comply with Community law, the Commission is taking and will take the appropriate action pursuant to Article 169 of the Treaty. If it transpires that the exported beef benefited from the arrangements introduced by Regulation 716/96, then it would follow that the terms of that Regulation (which require the destruction of beef which benefits under it) would not have been

complied with. It would follow that an appropriate correction would be made in the context of the clearance of accounts procedure.

Clearance of accounts

The Commission is currently legally not in a position to recover the entire expenditure relating to BSE-measures which the UK authorities have charged to the EAGGF since the outbreak of the BSE-crisis in March 1996, in so far as the UK authorities respect the Community regulations authorising the expenditure and its charging to the Community Budget.

However, it must be stressed that the Commission services, in the context of the clearance of accounts procedures, have conducted vigorous controls of the over thirty month scheme and the selective cull scheme, and have made numerous recommendations for improvements of the control measures. The Commission will not hesitate to draw financial consequences from its findings on these BSE-eradication measures as it does for all other schemes, should this be justified by any failures by the UK Authorities to respect the Community Regulations. Any financial corrections can be made before paying the remaining sums due to the UK. They must however concern expenditure actually incurred. Failures to make expenditure, for example when implementation of the selective cull scheme was delayed, cannot be sanctioned through the clearance procedure.

Expenditure incurred by Member States during 1996 is in the process of being cleared. Two decisions have so far been adopted:

Commission decision 97/316/EC of 5 May 1997 on the clearance of the accounts of Member States' expenditure financed by the European Agricultural Guidance and Guarantee Fund (EAGGF), Guarantee Section, for the 1996 financial year (OJ 1997 L 138, p. 24).

Commission decision 97/609/EC of 30 July 1997 on the clearance of the accounts of certain Member States' expenditure financed by the European Agricultural Guidance and Guarantee Fund (EAGGF), Guarantee Section, for the 1996 financial year (OJ 1997 L 245, p. 25).

These decisions, adopted on the basis of accounting information, do not prejudge decisions to be taken subsequently by the Commission excluding from Community financing expenditure not effected in accordance with Community rules.

Council Regulation (EC) No 1469/95 on measures to be taken with regard to certain beneficiaries of operations financed by the Guarantee Section of the EAGGF (so called "black list" regulation) and Commission Regulation (EC) No 745/96 laying down detailed rules for the application of Regulation 1469/95, contain provisions that allow Member States to identify operators who have, deliberately or as a result of serious negligence, committed an irregularity

prejudicial to the Community Budget or who are suspected on solid grounds of having done so.

In application of these measures the Member States are responsible for the identification of individual operators and notification. The procedure is started by the Member State in which the risk of the operator's "non reliability" has been established. In this respect, persons who, within the meaning of Article 7 of Regulation (EC/ Euratom) n° 2988/95, have participated in committing an irregularity or who are under a duty to take responsibility for an irregularity or to ensure that it is not committed, should be identified and notified under the "black list" procedure.

The Commission services are responsible for the management of these regulations including the communications system used for the transmission of all information between the Member States.

On 11.09.1997 the Commission sent a communication to all Member States in order to remind them of their obligations as provided for in the "black list" regulations. Though the regulations do not provide for the possibility for the Commission services to identify and notify companies on its own initiative, a further letter was sent by the Commission to Member States on 29.09.1997, enclosing a list of operators which according to the knowledge of the Commission services have been involved in the illegal traffic of UK beef and which could be regarded as "operators presenting a risk of non-reliability" as defined in the above regulations. The Commission services are awaiting replies from the Member States.

The Commission Services have taken contact with certains third countries in order to envisage an "early warning system" for consignments which could be subject to fraud and might also concern public and animal health.

5.4 Application of the procedure under Article 169 of the Treaty to those Member States which have not fulfilled their obligations under the Treaty

I. General remarks - consolidated summary of previous three reports

The respect by the Member States of their Community law obligations with regard to BSE has been subject to strict monitoring by the Commission's services. Any new results of inspections in Member States will be carefully examined in respect to possible infringements of Community law.

In cases where it has been established that national law and administrative practices within a Member State did not reflect that Member State's obligations or that the Member State concerned failed to enforce the applicable legislation within its territory the Commission has intervened with the Member State in order to ensure compliance.

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

Thus, on 26 June 1997 the Commission decided to open infringement proceedings against 10 Member States in respect of their apparent failure to enforce some aspect of Community legislation concerning BSE. The subject matter of these initial proceedings concerned principally inadequate implementation of Commission Decision 96/449/EC (heat treatment system for processing animal waste) and failure to sufficiently control the respect of Commission decision 94/481/EC prohibiting the use of mammalian tissues in feeding stuffs destined for ruminants.

The Commission regards the meticulous implementation of both these texts as vital if BSE is to be eradicated and the possible risks to human health pending eradication are avoided.

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

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

2. and 3. Belgium & Luxembourg

Inadequate measures adopted to enforce Decision 94/381/EC.

4.Netherlands failure to complete approval of all plants processing animal waste and failure to provide list of all plants concerned. Also incomplete implementation of Decision 96/449/EC.

5. Germany Failure to implement Decision 96/449/EC as far as particle size parameter is concerned. Also national exemption from the requirements of processing under Decision 96/449/EC of certain by-products used for animal feed of processing material fit for human consumption.

6. Spain Spain maintains that low risk material processed into animal feed need not be treated in accordance with the parameters of Directive 96/449/EC.
Inadequate enforcement of feed ban imposed by Decision 94/381/EC because no official analysis of feed to detect mammalian meat and bone meal is made.
Failure to ensure that a waste processing plant had its processing procedures validated as required by Community Legislation.

7. Sweden Failure to transpose Article 3(2) of Directive 90/667/EC by the due date.
Failure to officially approve rendering plants as required by Article 4(1) of Directive 90/667/EEC,

Commission's interpretation of Decision 96/449/EC as far as processing of bones fit for human consumption into animal feed is disputed by Sweden.
Sweden's enforcement of the ban under Decision 94/381/EC of incorporating mammalian material in ruminant feed is considered inadequate in so far as the Swedish control regime only envisages annual analysis of 100 samples.

8. Finland carcasses of dead ruminants used as food for certain wild animals contrary to Directive 90/667/EEC and Decision 96/449/EC,
Inadequate enforcement of feed ban under Decision 94/381/EC as inadequate controls imposed to detect mammalian protein in ruminant feed (notably no microscopic tests).

9. Italy Control of the respect of the ban on feeding mammalian material to ruminants (the implementation of Decision 94/381/EC is inadequate).

10. Portugal Failure to co-operate with Commission in answering its written requests for information-breach of Article 5 of the EC Treaty.
In addition to the breach of its obligations mentioned above, the veterinary inspection mission to Portugal which took place between 15-21 June 1997 recorded infringements of Directive 90/667/EEC and Decision 96/449/EC. A pre-infringement letter was sent to the Portuguese Government on 20 August 1997. No reply has been received and opening of the Article 169 procedure will be proposed.

II. Position as at the date of publication of the present (4th) progress report concerning Member states except united Kingdom

1. Position in relation to the 10 Member States initially concerned

The state of play of the infringement proceedings taken against 10 Member States and referred to in paragraph 1 is also set out in the table.

The Commission intends to take such further action as is necessary in respect of the Member States which have not regularized their position.

2. Position in relation to Member States - handling illegal UK exports

In relation to the illegal beef exports the Commission is also continuing an examination of whether those Member States where the illegal beef was handled after it left the United Kingdom, also failed to control adequately the respect of Community legislation. In this connection correspondence has been exchanged with the Belgian and German authorities.

3. Position in relation to further Portuguese infringements.

In relation to Portugal the examination of the report of the Food and Veterinary Office mission which took place between 15-21 June 1997 revealed infringements of Directive 90/667/EEC and Decision 96/449/EC. A pre-infringement letter was sent to the Portuguese Governement on 20 August 1997. No reply has been received and the opening of the article 169 procedure will be proposed.

4. Position in relation to Member States applying stricter measures than required by Community law

The Commission continues to examine the cases where Member States are alleged that single market obligations have been infringed by applying stricter measures than required by Community legislation governing BSE. No infringement procedures have yet been opened in this connection.

Member State	Date of Article 169 letter	Date of reply	Remarks
Belgium	7.7.1997	17.8.1997	Incomplete reply the Commission will seek further information
Finland	7.7.1997	none received	Infringement procedure should continue for non reply
France	7.7.1997	3.9.1997	France maintains position continuation of procedure should be proposed
Germany	7.7.1997	23.9.1997	Germany has accepted to regularise one of the two grounds of the infringement. Maintains its position on processing bones fit for human consumption - Infringement procedure should continue on this latter aspect
Italy	7.7.1997	22.8.1997	Reply still in the course of examination
Luxembourg	7.7.1997	20.8.1997	Partial reply only. Commission will seek further information
Netherlands	7.7.1997	29.8.1997	The reply indicated compliance with most of the Commission's requirements.
Portugal	10.7.1997	None received	Infringement procedure should continue for non reply
Spain	7.7.1997	None received 6.8.1997	Infringement procedure should continue for non reply
Sweden	7.7.1997		The reply indicates compliance with two of the grounds for infringement, willingness to meet the Commission's concerns in respect of the third and maintenance of its position in respect of the fourth (processing of bones fit for human consumption) It appears necessary to continue with infringement proceedings in respect of this latter issue.
United Kingdom	22.9.1997	Time granted 1 month from date of Article 169 letter	Last date for reply not yet reached.

III. Position as at the date of publication of the present (4th) progress report concerning the United Kingdom

The Commission has recently obtained evidence of fraudulent exports of United Kingdom beef to other Member States and third countries. United Kingdom legislation as communicated to the Commission by the United Kingdom authorities and explained by them prohibits the export of beef of animals slaughtered in the United Kingdom, and other products subject to Decision 96/239/EC as amended.

Taking account of the possibility that a certain lack of clarity and transparency of United Kingdom legislation and administrative measures concerning the beef export ban together with inadequate enforcement of these rules and of the Community rules applicable in abattoirs and meat plants may have facilitated the illegal exportations which have come to light the Commission dispatched a pre-infringement letter to the United Kingdom on 8 July 1997.

The United Kingdom Minister of Agriculture Fisheries and Food after receipt of the letter undertook to take urgent action to meet the Commission's concerns. Thus on 1 August 1997 new legislation re-enforcing and extending existing powers in relation to the export ban, came into force in Great Britain to be followed a few days later by corresponding Northern Irish legislation.

Given the action taken by the United Kingdom the Commision postponed consideration of the opening of infringement proceedings until September 1997. United Kingdom legislation on portal controls now appears to contain all the powers necessary to provide for enforcement of the export ban. Practical application of the rules has been subject to a further Commission inspections from 29 September to 3 October 1997. The mission team noted that an enhanced and more flexible system of portal controls has been implemented. These controls are useful but their effect is limited because of the very small proportion of trucks which undergo a physical check of the goods.

However, taking into account recent veterinary inspection reports, it still appeared that the United Kingdom remained in breach of its Community obligations in respect of controls at meat plants. The Commission therefore opened by formal notice dated 22.9.1997 the Article 169 procedure in respect of this aspect.

IV. Inspections with regard to Decision 96/449/EC

The following Member States were visited by the Food and Veterinary Office to inspect 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": Austria, Belgium, Denmark, Finland, The Netherlands, Portugal, the United Kingdom and Greece.

The other Member States (except Luxembourg) will be visited by the end of the year.

The inspection reports will also be finalized by the end of the year. The following points will be dealt with by the reports :

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

Furthermore, as a follow-up of missions carried out in 1996, points of criticism with regard to the processing of animal waste mentioned in previous reports are subject of the current round of inspections.

The preliminary results of the missions carried out up to now reveal the following points of concerns :

- New evidence was found that in some Member States the national legislation and administrative procedures do not provide the framework for implementation of Decision 96/449/EC. Provisions are not always in place to ensure that the relevant rendering plants process their raw material to the standards laid down in the Decision or that improper treated proteinaceous material is destroyed as foreseen by Article 2(5) of the Decision.

- New evidence of deficits of validation and controls were observed. Even if the competent authorities provide for regular frequent visits of a veterinarian and the plant is equipped with appropriate equipement the appropriate validation, control and processing in conformity with the Decision was not ensured in all cases.

The new information gathered by the inspectors is being made available in due time to the services of the Commission responsible for infraction procedures.

5.5 **(After being called upon to do so by the European Parliament): Institution of proceedings against the UK government in the European Court of Justice on the basis of Article 3(2) of the joint decision of Parliament, the Council and the Commission of 19 April 1995 and Article 169 of the Treaty on account of the failure of Mr Hogg, the UK Minister of Agriculture, to appear before the committee**

Proceedings under Article 169 of the Treaty must be based on a breach of an obligation under Community law. The key question is whether the United

Kingdom was obliged to send a Minister to appear before the Committee of Enquiry.

Article 3 of the Interinstitutional Decision of 19 April 1995 on the rules governing committees of enquiry sets out the elements in terms of witnesses and documentation which are necessary to allow the Committee to accomplish its functions. The Decision envisages two distinct regimes in respect of the appearance of witnesses, depending upon whether those witnesses are ministers or officials.

In relation to ministers, the text of the second paragraph of Article 3 of the Decision states that

"the temporary committee of enquiry may invite...the Government of a Member State to designate one of its members to take part in its proceedings".

This text is not drafted in such terms as to place an obligation on the invited government to act. An invitation is not per se an act of a compulsory nature. This drafting is to be contrasted with that of paragraph 3 relating to officials.

The third paragraph of Article 3 states

"on a reasoned request from the temporary committee of inquiry, the Member States concerned...shall designate the official or servant whom they authorise to appear before the temporary committee of enquiry".

This text is in mandatory terms and, thus, the Member State under paragraph 3 is required to designate an official. In this respect, it must be remembered that the Government did send a high level official to attend the Committee.

The wording of paragraph 2, therefore, does not support a finding of a legal obligation on the Member State to respond to the invitation by designating a Minister. Thus, Article 169 proceedings based on a breach of Article 3 of the Decision would not be legally appropriate.

The question has been raised as to a breach by the United Kingdom of its general duty under Article 5 of the Treaty to "facilitate the achievement of the Community's tasks". It is clear that it is inherent in the very nature of a committee of enquiry process that Member States should do all that is necessary to facilitate the task of the Committee. Indeed, this assertion is set out in the second recital of the Decision. It is also true that the fact that the UK Minister for Agriculture, Fisheries and Food did not appear before the Committee of Enquiry was not helpful from the point of view of interinstitutional cooperation but that fact is not per se sufficient to mount an infringement proceeding based on a breach of Article 5 of the Treaty. The wording of Article 5 requires that the Member State shall facilitate the achievement of the Community's tasks. In other words, in the context at hand, it must, thus, be demonstrated that the indicted behaviour was, in law and in fact, not such as to facilitate the achievement of the Committee of Enquiry's tasks.

If Article 138 C of the Treaty sets out the tasks of a Committee of Enquiry, it is contended that the Decision of April 1995 serves to set up the modalities of how a Committee of Enquiry should function and what are the necessary powers and concomitant obligations for that functioning. Indeed, the second recital of the Decision supports this interpretation[13]. Thus, as regards obligations, Article 3 sets outs the parameters of the cooperation to be expected from Member State governments as regards the appearance of witnesses. Thus, the fact that paragraph 2 of Article 3 of the Decision does not place an obligation on a Minister to attend can be interpreted as meaning that it was considered that a Committee could accomplish its tasks without the appearance of a Minister. In this context, it is relevant that the UK sent a senior official, which is entirely consistent with the obligatory nature of paragraph 3 of Article 3 and, thus, with the fact that such attendance is considered necessary to facilitate the Committee's task.

Even if the Commission could admit that the Decision of 1995 is not exhaustive in its list of the means necessary for a Committee of Enquiry to carry out its duties and that, thus, additional means not therein enumerated could well, within the evolution of a specific enquiry, become necessary and be invoked, this would not, however, entail that matters already enumerated in the Decision could be unilaterally modified so as to, for example, change a "means" not drafted as mandatory into an obligation.

In the light of the experiences of this case, the Commission considers that the representation of Member States before a Committee of Enquiry of the European Parliament should be discussed at the review of the joint decision of the European Parliament, the Council and the Commission of 19 April 1995, in order to ensure a satisfactory and institutionnally balanced political representation before a Committee of Enquiry of the European Parliament.

6. Other recommendations

6.1 Proposals to the Intergovernmental Conference for an amendment of the Treaty enabling a motion of censure to be tabled against individual members of the Commission (Article 144 to be carried by the same majority as is required in the case of a motion of censure against the Commission as a whole)

The question of the individual motion of censure of Members of the Commission was the subject of discussions within the IGC in the context of the composition, organisation and functioning of the institution, but such discussions did not lead to any Treaty amendment.

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[13] "Whereas temporary committees of inquiry must have the means necessary to perform their duties; whereas, to that end, it is essential that the Member States and the institutions and bodies of the European Communities take all steps to facilitate the performance of those duties."

As far as the Commission is concerned, it considers that the individual motion of censure of Members of the institution is hardly compatible with the principle of collegiality; such a principle contributes, in the view of the Commission, in a decisive way to the efficient and independent performance of its duties in the general interest of the Community.

6.2 Submission of proposals by the Commissioner for Agriculture for the restructuring of the current CAP, to cover :

Agenda 2000 includes major reform proposals for the CAP. They are based on the policy objectives mentioned under 4.2 and can be summarized as follow:

- closing the gap between EU and world prices;
- further shifting from price support to direct payments to farmers;
- developing a coherent rural policy to accompany this process;
- simplifying EU legislation and decentralising policy implementation.

The main sectors concerned by reform proposals are the crop sector (cereals, oilseeds and protein crops), beef and dairy. In addition, the Commission already tabled its reports on tobacco and olive oil (currently under consideration within the other EC institutions) and announces a new proposal on wine.

In Agenda 2000, the Commission proposes to gradually reduce the effective market support of beef by 30%, from 2 780 ECU/ton to 1 950 ECU/t, over the period 2000-2002. Such a substantial reduction will help develop new export outlets of high quality beef without subsidies, in particular to Asian countries. As a consequence of this proposal, the reliance on high export subsidies would be greatly diminished, which would considerably reduce the risk of fraud related to this instrument.

6.2.1 Promotion of extensive farming practices

In addition to the points already made in the Second Progress Report, the Commission wishes to draw the attention to the following points which are contained in the Agenda 2000 proposals:

- excluding silage cereals, which are linked to intensive livestock farming, from the support regime of cereals, oilseeds and protein crops;
- in relation to the stocking density factor, increasing the importance of beef premia (headage payments): this will induce producers to increase their forage area;
- strengthening and improving the effectiveness of the different incentives to extensify production, in particular the "extensification scheme";
- gradually transforming the support scheme regarding Less Favoured Areas (LFAs) into a basic instrument to maintain and promote low-input farming systems;

- enabling Member States to make direct payments conditional on the respect of environmental provisions;
- reinforcing targeted agri-environmental measures (Regulation No 2078/92) through increased budgetary resources and, where necessary, higher co-financing rates; extensification is a central aim of these measures.

The Commission will present a report on the application and experience gained from the existing programmes under the agri-environmental measures (Regulation N° 2078/92) to the European Parliament and the Council in November of this year.

6.2.2 Increasing the amount of land under cultivation

This question is linked to the previous one (6.2.1), as extensification tends to increase land under "cultivation". In addition to the proposals already mentioned above, the Commission also proposes to set the reference rate for compulsory set-aside at 0 %, instead of 17.5 %. This, linked to price cut for cereals, is expected to contribute to cultivating more land, in a more extensive way.

6.2.3 Ban on all practices which could be harmful for animal health and human health

a) Animal feedingstuffs

Various measures were taken in the framework of the legislation concerning animal feedingstuffs in order to protect better the health of the animals.

As regards use of additives in animal feedingstuffs, the Commission has since 1970 prohibited15 antibiotics which, according to it, had to be reserved for veterinary or medical use,. At the number of the prohibited substances appeared in particular all the tetracyclines, penicillin, streptomycin. Recently, avoparcin was also prohibited as a precautionary measure.

In addition, the Commission, has set up a monitoring programme of the microbial resistance to the antibiotics which should be operational at the beginning of 1998.

The adoption of the directive 74/63/EEC and its regular update also made it possible to reduce appreciably the contamination of animal feed by heavy metals (lead, mercury ...), mycotoxins (aflatoxins), alkaloids, etc ...

The Commission has fixed a list of ingredients of which the use is prohibited in compound feedingstuffs. This list is updated according to the development of scientific and technical knowledge.

b) Overview on farm animal welfare legislation in the EC

The Commission attaches a high priority to issues related to animal welfare legislation. Responsibilities in this area fall into the following three broad categories: farming practices; the transport of animals and slaughter of animals. In all of these areas Community legislation exists and is in the process of being

refined and amended to take account of changes and advances in scientific knowledge.

1. The aspects related to the welfare of laying hens in battery cages have been in application since 1988. (Council Directive 88/166/EEC, the so-called "Battery Hens Directive"). At present, the Commission is engaged in a review of the welfare of hens under various rearing systems starting with a request to the Scientific Veterinary Committee to review and update the 1992 report. Consultations have been held with industry, consumers and welfare organisations and the Commission will in the near future table the appropriate legislative proposals to the Council and the European Parliament.

2. A revision of Council Directive 91/629/EEC laying down minimum standards for the protection of calves was recently adopted by the Council and will enter into force by January 1998. The conditions under which calves can be kept are now strengthened and provisions on feeding and tethering of animals are fixed.

3. The Community has had rules on the protection of animals during transport since 1977. These rules were up dated to take account of the establishment of the Single Market, in 1992 (Council Directive 91/628/EEC). In June 1995, the Council adopted more comprehensive standards for livestock transport which Member States are required to transpose into their national legislation and fully apply by 1 January 1997.

4. The Commission has presented a proposal to the Council under which the payment of export refunds would be subject to compliance with the provisions on the protection of animals during transport. The Commission's services are at the moment preparing a Commission Regulation with detailed rules on the matter.

5. As regards the welfare of animals at the time of slaughter or killing, the European Union has had legislation in force since 1974. Since 1 January 1995, a new Directive on the protection of animals at the time of slaughter or killing replaces the old legislation (Council Directive 93/119/EC). The new Directive updates killing/slaughtering methods and regulates certain specific problems which have arisen in the application of the former Directive (killing of animals for disease control purposes, killing of fur animals and killing of day old chicks).

6.3 Strict vigilance concerning the reporting of all BSE cases throughout the European Union as there is reason to believe that there have been instances of underreporting.

BSE has been a notifiable disease in all Member States since, at the latest, 1990. This means that any suspect cases must be notified to the relevant competent authorities for further investigation. Confirmed cases must be notified by these authorities to the European Commission without delay.

A key incentive for notification is the provision of adequate compensation to encourage farmers to report disease.

The missions undertaken by the Commission inspectors during 1996 to examine the controls in place in respect of BSE in Member States have raised questions in some instances as to the effectiveness of the notification procedures for suspect cases and of the diagnostic techniques employed. As a result, it was not possible to exclude the possibility of under-reporting of the disease. Since the first Commission report to the Temporary Committee of the European Parliament on the Follow-Up of Recommendations on BSE in June, the final reports on the missions and the discussions with the Member States concerning the notification procedures for suspect cases, as well as the relevant diagnostic techniques, have been discussed by the Standing Veterinary Committee (SVC) in June and July. In addition, during control missions, further checks were carried out (Holland, Portugal) or will be undertaken in the near future (Germany, Italy, Sweden).

The sub-group the Scientific Veterinary Committee, to advise the Commission on measures for the surveillance and monitoring of transmissible spongiform encephalopathies (TSEs) in the Community and in third countries from which imports are allowed, has presented its report, which was adopted by the Scientific Veterinary Committee (SciVC) on 11 June 1997. This report also established the TSE status of New Zealand. On 17 September 1997 the Scientific Veterinary Committee adopted the reports on "The TSE Status of Australia and the USA" and "The Scrapie Eradication Programme in Norway". Therefore, the Commission is now proceeding to examine its future course of action in this area. Account will be taken of the results of the International Office of Epizootics General Session meeting in May 1997, where general guidelines for BSE surveillance and disease freedom criteria were agreed at an international level.

The Scientific Veterinary Committee indicated that both active and passive surveillance for BSE and scrapie should be adopted. It furthermore recommended with regard to scrapie that the programme should lead to a distinction in flocks with and without scrapie, and for countries with scrapie to an estimate of the prevalence. Both sheep and goats should be monitored. Passive surveillance should be by declaration of suspect cases by the farmers, veterinarians and others. Active surveillance should be under control of the competent authority and generally targeted on those flocks where epidemiological evidence suggests a risk of exposure to TSE agents. With regard to BSE recommendations as to the sampling methods and size were made. It was stressed that offspring of BSE cases, where not slaughtered, should be included in the survey. In Commission Decision 97/534/EC on the exclusion from human food and animal feed of risk material as regards Transmissible Spongiform Encephalopathies, the Commission stated that it will make proposals to set up an effective TSE Surveillance in the Member States. In preparing the proposals for a regulation, the Commission will base its work on the advise of the Scientific Committees.

The possible sampling of clinically healthy animals at routine slaughter has been considered as a means of surveillance, but the Scientific Veterinary Committee felt that this would be ineffective, because the disease incidence is probably too

low to be detected with the currently available sampling methods and tests. This option will be kept under review, in the event of a cheap, reliable, and sensitive test in live animals becoming available. However, the Committee also pointed out the importance of the availability of diagnostic tests to facilitate more accurate surveillance. Fully validated tests in live animals are not yet available. Development of diagnostic tests and related methods to identify the disease are therefore important elements of the FAIR program in the area of animal health evaluated according to Community approved procedures.

A blue print for future legislation concerning surveillance, control and eradication has been prepared. A first version for a proposal for a Council Regulation on TSE surveillance is being finalised. The proposal follows the recommendations from the OIE on BSE surveillance.

6.4 Review of the Florence decision of 11 June 1996 (96/362) to lift the import ban on gelatine derived from cattle

This Decision laid down a series of conditions and procedures which would have permitted the export of gelatine made from raw materials of UK origin to take place. In the light of later information that inactivation of the BSE agent could not be guaranteed in the production process, the implementation was effectively suspended. On 14 May 1997, the Commission adopted a communication concerning further measures with regard to BSE. It confirmed, i.a., that action must be taken to amend article 1 paragraph 2 of Commission decision 96/362 in respect of gelatine made from UK material pending new scientific evidence. At the same time, the Commission will introduce a legal requirement for traceability of gelatine made in the UK from non-UK material. This traceability system will also apply to certain other related by-products produced in the UK.

The Multidisciplinary Scientific Committee/Scientific Steering Committee in its meeting of 8.9.1997 has adopted :

- an opinion on tallow and tallow derivatives and sperm and embryos
- and is reviewing the situation concerning certain products listed in Annex 1 to the Commission Decision 96/362/EC (Di-calcium phosphate and amino acids and peptides).

On semen and embryos, the opinion states that "trade in semen and embryos cannot be recommended if assurance as to freedom of disease (BSE) of sire or dam cannot be provided". The follow-up on this opinion needs careful examination. On tallow, the opinion requires tallow to be produced from animals fit for human consumption, after removal of SRMs and processing according to the '133°C, 20 minutes, 3 bar' standard. It is not clear to what potential uses and to what geographical areas these standards apply. Pending clarification from the scientists, amendment of the currently required treatment processes for tallow which may be exempted of the UK ban, is foreseen.

A proposal to amend the Decision on the UK ban (96/239/EC) to (re)introduce gelatine into the ban and to clarify its scope, in particular in relation to petfood, was prepared and ready to be presented to the Standing Veterinary Committee of early September.

However, in light of the opinions of the Scientific Steering Committee of 8 September 1997 and of the Scientific Veterinary committee of 17 September 1997 and the extent of illegal trade in UK-beef coming to light recently, further amendments are required. By consequence the above proposal was withdrawn from the agenda of the Standing Veterinary Committee of 10 September.

6.5 Cooperation with the Member States so that the public is kept systematically and fully informed about all aspects of nutrition that are important for public health

A number of activities relating to nutrition and health are being carried out within the context of the public health action programmes. Under the programme on cancer, the largest ever investigation on cancer and nutrition is being undertaken with the support of the Commission, as well as studies on the prevention of adenoma and on the prevention potential, sustainability , and transferability of the Mediterranean diet. In the context of the health promotion programme, actions are funded on nutrition in schools and other educational establishments, the development of public health strategies on nutrition targeted at specific groups but also the general public, as well as the creation of a pan-European database on consumer attitudes to nutrition.

En ce qui concerne l'ESB, la Commission élabore actuellement la 3e édition du "Vademecum ESB - Informations à destination des consommateurs". La diffusion du Vademecum est prévue pour la fin de l'année 1997.

Dans l'avant-projet de budget 1998, la Commission a proposé une campagne d'information sur la sécurité de l'alimentation au titre de la ligne budgétaire B5-103. 5,3 millions d'écus sont prévus pour cette campagne. Dans la mesure du possible, la Commission exécutera cette campagne en coopération étroite avec les Etats membres et le Parlement européen.

Furthermore a number of activities relating to nutrition and health are being carried out within the context of the public health action programmes on cancer and on health promotion, information, education and training.

6.6 Changes to the CAP so as to create a framework which makes possible and reinforces the responsibility of agricultural holdings for the production of healthy food using sustainable farming methods

See proposals on Agenda 2000 in particular under point 6.2.1 and extended producer liability under point 3.2.

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

Ref. N°	Action promised	Indicative timing
1.2	Nomination of Scientific Committee (SC) members	October 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
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
2.1.2	Recruitment of staff under SAB 1997 Additional increase in staff numbers in FVO	Before end of the year In 1998
2.2	Receipt of, and response to, IGS report.	October 1997
2.3	Development of internal manual procedures by FVO	Beginning 1998
3.2	Consultation procedures on other amendments to Directive 85/375/EEC Consideration of Green Paper on Food Law responses and organisation of Food Law conference Completion of simplification exercise on veterinary hygiene legislation	Consultation for beginning of 1998 Nov. 1997 1998/1999
3.5	Establishment of a Community network for the surveillance and control of communicable diseases Adoption of amendment to Directive 93/88/EC re. stricter containment levels for BSE laboratory work	1998 Beginning 1998

Ref. N°	Action promised	Indicative timing
3.5.1	Adoption by the Commission of projects on TSE research following the 29th April 1997 joint call for proposals	December 1997
3.5.9	Production and distribution of BSE vade mecum information for consumer	Before end 1997
3.6	Develop full membership of WHO and OIE by Commission	Timing uncertain
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
3.7.2.3	MDSC/SSC to discuss list of SRMs and abolition of age limits on exclusion of younger animals	16.10.1997
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
3.9	Organisation and completion of study of methods to establish quantity and quality of feed materials in compound feedstuffs	1998
4	Introduction of a legal requirement for traceability of gelatine and certain other products made in the UK from non-UK material Reinforcement of veterinary checks with regard to Decision 96/239/EC Reinforcement of veterinary controls in the European Union: • Harmonisation of control plans • Application of Directive 89/608/EEC • Amendment of Directive 89/608/EEC, where necessary • Reinforcing controls when emergency measures apply • Reinforcing sanctions • Reinforcing routine controls	Before end of 1997 Before end of 1997 Beginning of 1998 Oct. 1997, ongoing 1998/1999 Oct. 1997, ongoing 1998/1999 1998/1999 (at least partly to be based on Art. 100A)
4.1	Appropriate action on the basis of scientific advice on the UK's Export Certified Herd Scheme Submission of the report of the mission to the UK 9-13.6.1997 to EP Submission of UK's proposal on a data-based export scheme to the appropriate scientific committees for their opinion	Revised UK proposal expected Oct. 1997 Official UK proposal of 2 October to be examined in November

5.3	Taking appropriate action pursuant to Article 169 of the Treaty, where the UK failed to apply Decision 96/239/EC 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 Ongoing (clearance of account procedure)
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
6.3	Further follow-up missions concerning the reporting of all BSE cases will be undertaken to Germany, Italy and Sweden Proposal for a Council Regulation on effective TSE surveillance in the Member States	Oct. - Dec. 1997 Before end 1997

CONFIRMED CASES OF BSE IN MEMBER STATES AND SWITZERLAND

. 1986 - 1997

30 September 1997

	1985 1989	1990	1991	1992	1993	1994	1995	1996	1997[14]
DE	0	0	0	1	0	3	0	0	2
FR	0	0	5	0	1	4	3	12	2
NL	0	0	0	0	0	0	0	0	2
IT	0	0	0	0	0	2	0	0	0
UK	10.188	14.407	25.359	37.280	35.091	24.434	14.560	8.151	3.819
IR	15	14	17	18	16	19	16	73	54
DK	0	0	0	1	0	0	0	0	0
PO	0	1	1	0	3	12	14	29	19
	10.203	14.422	25.382	37.300	35.121	24.474	14.593	8.265	
CH[15]	0	2	8	15	29	64	68	45	29
	9.336	14.424	25.390	37.315	35.150	24.538	14.661	8.310	

[14] Source; for all countries until 1997 OIE - BSE, for Member States during 1997 ADNS (Animal Disease Notification System)

[15] Source; until 1997 OIE - BSE, for 1997 personal information from Swiss authorities

Annex to point 3.5 Action against Creutzfeld-Jakob Disease (CJD)

FAIR SPECIFIC CALL FOR PROPOSALS ON TSE

Project N°	Title	Participants	Comments
PL973311	Analysis of molecular factors affecting variability in BSE and scrapie susceptibility	UK, I, N	Study of genetic factors on the susceptibility of cattle to BSE and of sheep to scrapie. Systematic study of the PrP locus in both species, including non-coding regions, eventual role of other loci in the genome affecting outcome of challenge with the infectious agent. The study will reveal all polymorphisms in the population and the possible association of polymorphism with disease. Will complete basic molecular information required to study the disease.
PL973314	Relationship between conformation of PrP, infectivity and pathogenicity of bovine spongiform encephalopathy (BSE) as a basis for diagnostic	D, UK, F,	Development of diagnostic tests through the study of basic features of BSE and prion diseases in general. Will provide valuable information on the molecular and cellular biology of PrP. Particular emphasis on strain characteristics of BSE agent. Contribution to elucidate the prion hypothesis.
PL973304	Generation of bovine and ovine PrP transgenic mice for the development of improved bioassays for BSE and scrapie agent detection	D UK F	Generation of bovine and ovine transgenic mice. The new approach foreseen should provide tools for highly sensitive detection of infectivity and to study the function of PrP. Increase knowledge on pathogenesis.

PL973306	New approaches to the diagnosis and control of transmissible Spongiform Encephalopathies	IR E UK SE	Development of diagnostic tests to detect animals incubating the disease suitable for live animals and for tissues of animal carcasses. New methods for the production of specific antibodies to distinguish between the normal PrP and the abnormal PrPsc isoforms. Search already described markers of the disease in different fluids and tissues. Screening for new markers. Development of bovine and porcine transgenic mice. Study transmission of BSE to pigs and between pigs.
PL973301	Measures to reduce contamination of meat and environment with CNS tissue during slaughter and processing of cattle and sheep	UK F IR	Methods to reduce or eliminate the risk of contamination of meat with CNS material. Results useful for policy decision at national and Community level concerning the elimination of brain/ spinal cord in butchering procedures.
PL973305	Improving prospects for scrapie control in sheep and goats by study of host genotypes, TSE isolates and their in vivo and in vitro interaction	F, UK, NL, D, IS GR, IR N, CY	European network to study genetic factors on scrapie susceptibility of major European sheep and goat breeds and their interaction with the scrapie isolates. Impact on breeding strategies.
PL973315	Development of a novel diagnostic to assist quality assurance procedures in European meat production	D, UK IL SE	Several approaches for the development of blood tests for diagnosis of TSE in vivo and in tissues of slaughtered animals.
PL973308	Separation, identification and characterisation of the normal and abnormal isoform of prion protein from normal and experimentally infected fish	I, F, E,	Isolation and characterisation of normal PrP in fish. Assess possibility of transmission of scrapie and BSE to fish. Important phylogenic information.

Projects adopted following the FAIR specific call for proposals on TSEs

PL973311 : Analysis of molecular factors affecting variability in BSE and scrapie susceptibility

Coordinator: J. Williams, Roslin Institute (Edinburgh), Division of Molecular Biology (UK)
Participants :
- L. Ferretti, Consiglio Nazionale delle Ricerche, Istituto per la Difesa e la Valorizzazione del Germoplasma Animale (IT)
- I. Olsaker, Norwegian College of Veterinary Medicine Department of Morphology, Genetics and Aquatic Biology (NO)
- P. Kitchin, Rosgen Ltd., Limited Company registered in Scotland (UK)

This project will examine the genetic factors involved in the susceptibility of sheep to scrapie and whether there are genetic factors involved in the susceptibility of cattle to BSE.
Much work has been carried out in sheep on the relationship between particular forms of the PrP gene and prevalence of natural scrapie, with particular forms in defined breeds being associated with high disease incidence (Hoinville et al Vet Rec 136 312). Studies so far have focused on variations in regions of the gene which code for the protein , and in particular on a specific part of the gene - the octapeptide repeat region. No information is available regarding the way the different forms of the gene affect susceptibility to disease or on regions of the gene which regulate its'expression. In addition although breeding experiments have pointed to PrP as the major factor governing progression of scrapie in sheep, there has been no work to formally exclude the involvement of other genes.
In cattle despite the seriousness and extent of the BSE epidemic in the UK, little work has been done to examine the genetics of infection and progression of the disease. The coding region of PrP has been sequenced twice and three polymorphisms have been found (Goldmann et al 1991 J. Gen. Virol. 72 201). The study of the effect of the different forms of PrP on BSE susceptibility has proved inconclusive (Neiburgs et al Anim Genet 25 313) while examination of incidence of disease in calves of BSE affected and unaffected cows, is suggestive of a genetic variation in susceptibility to disease (Hoinville et al 1995 Vet. Rec. 136 312).

The work that will be undertaken in this project will add to the knowledge of genetic factors involved in the development of scrapie in sheep and will test whether there are genetic factors affecting the susceptibility of cattle to BSE. The study will focus at several levels:
1) The complete PrP gene including flanking regulatory regions will be sequenced from both sheep and cattle. This information will be used to identify the majority of polymorphisms in the gene for both species. The frequencies of the polymorphisms found will be measured accross different breeds and populations. Selected

polymorphisms, focusing on regulatory and conserved elements of the gene, will then be tested for a role in the development of disease in sheep and cattle by linkage analysis.
2) The expression levels of the PrP gene in affected vs unaffected individuals will be examined to see whether the level of PrP expression is associated with pre-disposition to disease.
3 The chromosomal region neighborouring the PrP gene will be examined for other genes that may be involved in disease. This search will initially use of genetic markers, selected from genetic maps, which will be tested for involvement in disease by segregation analysis. In addition novel expressed sequences near to the PrP gene, which may confer differing susceptibility to disease, will be sought through exon trapping using large fragment yeast artificial chromosome (YAC) clones covering the chromosomal region containing the PrP gene. The putative role of the expressed sequences identified in development of scrapie will be tested by examining expression levels in affected vs healthy sheep.
4) Finally the whole genome will be examined for additional loci that are involved in development of BSE in cattle. Using microsatellite markers selected to cover the whole genome at roughly 20 cM intervals (1/150th of the genome) the inheritance of chromosomal regions will be tracted from selected sires into affected and unaffected progeny. Distorted segregation of markers between affected and unaffected progeny will reveal loci that may be involved in the disease.

This work will complete the basic molecular information required for studying the disease.

Annex 3.5 continued

PL973314 : Relationship between conformation of PrP, infectivity and pathogenicity of bovine spongiform encephalopathy (BSE) as a basis for diagnosis.

Coordinator : D. Riesnev, Heinrich-Heine - Universitaet Duesseldorf, Institut für Physikalische Biologie (DE)

Participants :

- R. Jackman, Veterinary Laboratory Agency, Central Veterinary Laboratory (CVL) Addlestone (UK)
- S. Weiss, Ludwig-Maximilians-Universitat Munchen, Institut fur Biochemie - Genzentrum der LMU München (DE)
- D. Dormont, Commissariat à l'Energie Atomique, Direction des Sciences du Vivant Département de Recherche Médicale, Service de Neurovirologie (FR)
- H. Kretzschmar, Georg-August-Universtität, Institut für Neuropathologie (DE)
- J. Rossier, Centre National de la Recherche Scientifique, Ile de France - Secteur Paris B, Unité de Recherche Associée 2054, Neurobiologie de la Diversité Cellulaire (FR)
- C. Reiter, Connex Gesellschaft zur Optimierung von Forschung und Entwicklung Mbh, Connex Gmbh (DE)

According to the prion-model, BSE is transmitted by a proteinaceous infectious agent (prion); the major component is a host protein, the so-called prion-protein, which is present in the cellular form, PrP^{c} and after infection in an abnormal form PrP^{BSE}. The abnormal isoform of PrP triggers the transformation of the cellular into the abnormal form thereby multiplying the agent. The knowledge of the basic biological, biochemical, and biophysical features of PrP^{BSE} is regarded as a prerequisite to develop new techniques for diagnosis.

The molecular properties of PrP^{c}, PrP^{BSE} and PrP-peptides of the bovine system will be determined and compared with those of scrapie and CJD to differentiate between general principals of prion diseases and particular BSE-features like the so-called BSE-strain of the prion agent. Methods from molecular biology, biochemistry and biophysics will be applied. As an alternative way of a fast and reliable diagnosis of BSE, a cell culture susceptible to BSE infection will be established by transfection of the bovine PrP. Specified antibodies and other PrP-interacting ligands will be studied systematically to differentiate between PrP^{c} and PrP^{BSE}. The mechanism of neurodegeneration and the appearance of early markers after BSE infection will be studied in neuronal cell cultures. With the progress of the project the partners will study the relation between BSE infection, PrP accumulation, PrP conformation, interacting ligands, appearance of early markers and develop an optimal concept for a sensitive diagnosis.

Annex 3.5 continued

PL973304: Generation of bovine and ovine PrP transgenic mice for the development of improved bioassays for BSE and scrapie agent detection.

Coordinator: M.H. Groschup, Federal Research for Virus Diseases of Animals , Institute for Vaccines, Federal Research Centre for Virus Diseases of Animals (DE)

Participants :

- M. Dawson, Veterinary Laboratories Agency, Virology Department, Research and Development Division, Addleston (UK)
- J.L. Vilotte, Institut National de la Recherche Agronomique - Bâtiment des Biotechnologies (FR)

The need for more sensitive and cost efficient bioassay models for BSE and scrapie infectivity than currently exist is evident. The aim of this project is to generate transgenic mice which highly overexpress bovine and ovine prion protein. All transgenic mice will be analyzed immunochemically with respect to PrP^c expression, tissue specificity of expression and histopathologically for spontaneous neuro- and myodegeneration in aged animals. According to the prion theory similarity in the amino acid sequence of the prion proteins of a donor in comparison to the receptor species largely determines the efficiency of transmission of an infectious agent. Accordingly transgenic mice expressing ruminant prion proteins should be more susceptible to BSE or scrapie than conventional mice and therefore useful for the development of highly sensitive bioassays for agent detection. Bovine and ovine prion protein transgenic mice will therefore be test inoculated with brain homogenates of BSE and scrapie diseased animals in order to determine their susceptibility. If animals come down with disease they will be analyzed using histopathology, immunocytochemestry and immunoblot for detection of spongiform brain lesions and accumulation of pathological prion protein. Transgenic mice will eventually be challenged with BSE brain homogenates, of which the inherent infectivity has already been determined by cattle inoculation experiments.

Annex 3.5 continued

PL973306 : New approaches to the diagnosis and control of transmissible spongiform encephalopathies.

Coordinator: M. Rogers, University College Dublin, University Dept. of Zoology and Biotechnology Centre (IE)

Partipicants :

-J.M. Sánchez-Vizcaíno, Instituto Nacional de Investigación y Tecnología Agraria y Alimentaria, Centro de Investigación en Sanidad Animal (CISA) (ES)

- B. Adair, The Queen's University of Belfast, Department of Veterinary Sciences (UK)
- T. Linne, Swedish University of Agricultural Sciences, Department of Veterinary Microbiology, Section of Virology - Unit of Molecular Virology (SE)
- M. Merza, Svanova Biotech (SE)

This project takes a comprehensive approach to the development of diagnostic tests for BSE and other TSEs. Specifically, the proposal seeks:

-to develop diagnostic tests for BSE and other TSEs that can be used to detect animals incubating the disease but which do not display clinical symptoms both in a live (field) test and in the tissues of animal carcasses, in an abattoir test. A preclinical test for BSE will either identify PrP^{sc} or some other disease specific marker. Initially, the best candidate marker is PrP^{sc} though this protein is poorly immunogenic and no antibodies are available which can discriminate between the normal and disease specific isoforms. The proposal sets out novel methods that will allow the isolation of PrP^{sc} monoclonal antibodies. Once appropiate antibodies against PrP^{sc} or other marker proteins have been identified, assays using these reagents will be developed and optimised.

-to develop transgenic mice expressing PrP constructs from bovine and porcine species that provide rapid methods for assessing the levels of infectious agent in animal tissues or their products. Such animals should provide sensitive and reasonably rapid tests for BSE in different tissues and fluids derived from potentially infected animals.

-to determine the relative efficiencies of transmission of BSE to and between pigs by the oral and intracerebral routes as part of the more general investigation into TSEs. Part of this work will also utilise a transgenic mouse model expressing the porcine PrP gene analogous to the bovine model described above.

In conclusion, this project presents a comprehensive and complete approach to the development of diagnostic tests for BSE and as part of their development and validation, provides sensitive animal models for the relatively rapid testing of beef and beef products for BSE.

Annex 3.5 continued

PL973301 Measures to reduce contamination of meat and environment with CNS tissue during slaughter and processing of cattle and sheep.

Coordinator : D. Harbour, Department of Clinical Veterinary Science, Division of Molecular and Cellular Biology, University of Bristol (UK)

Participants :

- J.P. Frencia, Association pour le Dévelopment de l'Institut de la Viande, Clermont Ferrand(FR)
- J. Sheridan, Teagasc, the National Food Centre, Dublin (IE)
- D. Tinker, Silsoe Research Institute, Company Ltd, Bedford (UK)
- M. Owen, Meat and Livestock Commission, Public Corporation, Milton Keynes (UK).

Innovative techniques to assess, directly or indirectly, the level of cross-contamination with CNS material during conventional slaughter, dressing and butchery of cattle and sheep, will be developed. For direct measurement, nucleic acid-based (RT-PCR) and protein antigen-based (ELISA) assays will be developed to detect CNS-specific mRNA and proteins respectively. Furthermore, an innovative technique to detect prion protein (PrP), based on the affinity of PrP for molecular chaperone proteins, will be developed. For indirect measurement of cross-contamination, the use of tracer dyes and *Escherichia coli* K12 injected into the CNS will be assessed.

These direct and indirect assays will be used to monitor cross-contamination of carcasses, equipment and abattoir environment (including atmospheric) with CNS material during conventional slaughter, dressing and butchery of cattle and sheep, in order to identify critical practices. Based on the results of these studies, changes to conventional methods will be devised, and tested under experimental conditions to ascertain wether cross-contamination can be reduced. Concurrently, innovative equipment (particularly saws and vacuum devices) for the safe removal of CNS material will be developed and tested for their ability to reduce or eliminate cross-contamination. Practices or equipment that do decrease the risks under experimental conditions will be assessed under commercial conditions for economic and practical viability.

New practices or equipment will be assessed and demonstrated to industry. A set of guidelines for avoidance of CNS cross-contamination in the meat industry will be drafted for presentation to the EC.

Annex 3.5 continued

PL973305 Improving prospects for scrapie control in sheep and goats by study of host genotypes, TSE isolates and their in vivo and in vitro interaction.

Coordinator: J.M Elsen, Institut National de la Recherche Agronomique, Station d'Amélioration Génétique des Animaux, Auzeville (FR)

Participants :

- M. Dawson, Veterinary Laboratories Agency, Virology Department, Research and Development Division, Addlestone (UK)
- N. Hunter, Institute for Animal Health, BBSRC and MRC Neuropathogenesis Unit, Edinburgh (UK)
- M.A. Smits, DLO Institute for Animal Science and Health, Lelystad (NL)
- M. Groschup, Federal Research Centre for Virus Diseases of Animals, Institute for Vaccines at the Federal Research Centre for Virus Diseases of Animals,Tübingen(DE)
- A. Palsdottir, Institute of Experimental Pathology, University of Iceland, Keldur (IS)
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- J. Roche, University College Dublin, Department of Animal Husbandry and Production (IE)
-J. Jarp, Department of Epidemiology, National Veterinary Institute,Oslo (NO)
-T. Baron, Laboratoire de Pathologie Bovine, Centre National d'Etudes Vétérinaires et Alimentaires, Lyon (FR)
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Differences in sheep PrP amino acid 136, 154 and 171 codons are clearly associated with susceptibility to scrapie in most outbreaks and this has opened the opportunity to breed for resistance to scrapie. However, scrapie has been described in few animals of genotypes expected to be resistant and, on the other hand , animals expected to be highly susceptible have remained healthy. It is thus important to understand why these cases occur in order to effectively control disease outbreaks and avoid any chance of scrapie appearing in flocks bred for resistance. Previous studies of experimental scrapie have suggested that there may be different strains of scrapie which target different PrP genotypes and the same may be true for natural scrapie. Strain differences can be revealed by transmission to mice and by the biochemical characteristics of PrP^{sc} extracted from affected animals.

The objectives are firstly to create a network of sheep PrP geneticists throughout Europe and to carry out genotyping at the three most important codons in sheep from different countries and breeds to those which have been tested previously. In order to underpin this effort, improved genotyping techniques will be developed. Strain typing transmission studies (to mice) will be set up from selected outbreaks of scrapie in different countries and comparisons made with previous transmissions using scrapie and BSE. In addition PrP^{sc} biochemical strain typing methods will be improved and differences in brain areas damaged by disease will be assessed. The potential for sheep to act as carriers of infection will be investigated using similar techniques. Sheep

deviating from the expected response to scrapie will be investigated for any influence of other PrP gene polymorphic variants and genes other than the PrP gene in disease incidence.

Annex 3.5 continued

PL973315 Development of a novel diagnostic to assist quality assurance procedures in European meat production (DIAQAM).

Coordinator: H. Schroeder, Institut fuer Physiologische Chemie, Johannes Gutenberg-Universitaet Mainz (DE)

Participants:
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-S.J. Holmes, ADGEN Diagnostic Systems,Auchincruive (UK)
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The objectives of the project are: (1) Development of a blood test for detecting pre-clinical BSE in live cattle. (2) Development of a test using tonsils or eyes and associated nervous tissue for detecting preclinical BSE in newly slaughtered cattle. (3) Provision of a kit for further testing throughout Europe.
Diagnoses of TSEs, including scrapie of sheep and BSE are currently confirmed posthumously either by histological examination to reveal the presence of spongiform areas of the brain or by immunohistochemical detection of the abnormal prion protein PrP^{sc}, a conformational isomer of the normal PrP^{c}. Conformational change renders it insoluble and partially resistant to degradation by proteinase K. Since the two isoforms cannot be distinguished serologically, discrimination depends on treatment of brain tissue with proteinase K, and subsequent recognition of the residual Pr27-30 fragment with a specific antibody.
Recent experiments with sheep, however, have indicated that scrapie may be detected preclinically by identifying PrP^{sc} in tonsils biopsies instead of brain. Tonsillar tissue may also prove to be of diagnostic value in cattle, but obtaining samples from live animals is less convenient than obtaining blood, and the best solution would be to sample tonsils from newly slaughtered animals. instead of tonsils, which might prove to be free of PrP^{sc} in cattle, the eyes and associated nervous tissue may be used for a test on carcasses. It may also be possible to diagnose BSE from the presence of PrP^{sc} or some new marker in blood.
The peptide conformation may have an important role in determining prion toxicity. The increased β-sheet structure was found to correlate with enhanced neurotoxic activity. Neurotoxicity of the prion proteins, extracted from biological samples from sick and suspected animals, on the neural cell culture may be an additional diagnostic tool for detectionof PrP^{sc} in BSE. Identification of the regions on the prion molecules where pathological conformational changes occur may facilitate the design and preparation of antibodies or small compounds that might prevent such transition and may delay or prevent the disease.
The consortium consists of six partners(1 DE, 3 GB, 1 IL, 1 SE). The inclusion of two SMEs gives the capability of producing prototype kits which may be used to diagnose BSE throughout Europe.

Annex 3.5 continued

PL973308: Separation, identification and characterization of the normal and abnormal isoforms of prion protein from normal and experimentally infected fish.

Coordinator: C.G. Bolis, Institute of Pharmacological Sciences, Faculty of Pharmacy, University of Milan (IT)

Participants:

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It was recently described the presence of PrP normal isoform in the brain of salmon. This is phylogenetically very important since it was the first time identified in aquatic vertebrate.

This finding will be important to contribute to the better understanding of the functions of PrP normal isoform proteins and the interspecies relationship.

The presence of normal isoform was very well described including molecular characterization in several species of terrestrial vertebrates. It was, in addition, described in *Drosophila* (the fruit fly).

The main purpose of the study is to separate, to identify and to perform the molecular characterization of the normal isoform of prion protein from normal and experimentally infected fish.

ANNNEX to POINT 4.0

Market measures taken in order to restore the smooth functioning of the markets

1. The financement of the destruction of the "over thirty months" (OTM) animals in UK.
   Starting on 29.4.96, until now 1 700 000 animals are killed.

2. The financement of the destruction of the selective culling in several Member States.

3. The financement of the destruction of calves in Belgium, France and the Netherlands, originating from UK.

4. Destruction of the old UK intervention stock.

5. A private storage operation for veal in order to stop the price reductions on the veal market.

6. More flexible rules applicable to public intervention (higher max. weight, more categories and qualities, etc.). For 1996, the ceiling was increased from 400 000 to 550 000 . For 1997, the ceiling was increased from 350 000 to 500 000.

7. Direct income support was given to the beef producers, totalling

   - in July 96: 850 mio ecu
   - in December 96: 500 mio ecu

8. In November 96, the Council agreed on a global package of measures in view of rebalancing the beef market:

   - stop 2nd premium payment for young bulls (with a temporary exemption for a limited extensive production);
   - reduction of the ceiling for the number of special premia paid to male animals by 20% (which corresponds in average to a reduction of 5% on the number of applications introduced in 94 or 95);
   - every Member State is obliged to introduce on its territory at least one of following measures:
     - the calf processing premium.
     - the early marketing premium paid to calves slaughtered for veal at a weight which is 15% lower than the historical weight for the Member State concerned.

ANNEX to POINT 4.0

EXPORT REFUNDS IN THE BEEF SECTOR

The tables hereafter show the following:

1. The first table gives the EU prices for young bulls and cows, the amount of refund and the FOB export price.
   This kind of calculation is done on a very regular basis by the Commission Services, together with the follow-up of the quantity for which licences are applied for compared to the available WTO quantity (twice a week).
   The table shows the drop in prices needed to sustain our market by exports at the start of the BSE crisis and the return to a normal situation in less than 9 months afterwards.
2. Table 2 shows the percentage refunds represented over the EU value of the carcass. In 4 years, this percentage came down by one third for male carcasses and nearly by half for female carcasses.
3. Table 3 is comparing the refunds with the amounts fixed at the start of '93. It shows the very considerable drop that took place (and which is normal because of the price reductions decided in the '92 reform plus the more strict following of our export performance and the competition created as a consequence of the introduction of the WTO export ceiling).
4. Finally, the last table is showing the relationship between the refund fixed for live animals and the one fixed for carcasses.

ANNEX TO POINT 4.0

1. **Evolution of prices and refunds in the beef sector** ([16])

	14.1.93	27.1.94	26.1.95	11.1.96	3.5.96([17])	30.1.97	5.9.97
prices young bulls	3268	3292	3144	2965	2685	2843	2766
refund	2072	1782	1691	1320	1550	1395	1165
Fob prices	1196	1510	1453	1645	1135	1448	1601
prices cows	2510	2517	2469	2171	2197	1929	2236
refund	1528	1310	1244	970	1140	1025	770
Fob prices	1196	1207	1225	1201	1057	904	1466

2. **Evolution of the percentage of refund over the value of a carcas in E.U.**

	14.1.93	27.1.94	26.1.95	11.1.96	3.5.96	30.1.97	5.9.97
male	63%	54%	54%	45%	58%	49%	42%
female	61%	52%	50%	45%	52%	53%	34%

[16] - ecu/ton

- the amounts before 1.2.95 have been converted in new ecus by way of the coefficient 1,20795

- refund for Africa, Middle East, Russia

[17] increase of the refund after the start of the BSE crisis

ANNEX TO POINT 4.0

3. **Evolution of the refund compared to the one fixed in 1993.**

	14.1.93	27.1.94	26.1.95	11.1.96	3.5.96	30.1.97	5.9.97
male	100%	86%	82%	64%	75%	67%	56%
female	100%	86%	81%	63%	75%	67%	50%

Since the increase done at the start of the BSE crisis, refunds have been reduced at several occasions, adding up to 25% for carcasses of male animals and 32% for other carcasses

4. **Evolution of the relationship between refunds for live animals and those for carcasses**

	male live	carcas	relation	female live	carcas	relation
Jan. 93	1347	2072	0,65	1033	1528	0,68
Jan. 94	1051	1782	0,59	767	1310	0,59
Jan. 95	1087	1691	0,64	695	1244	0,56
Jan. 96	620	1320	0,47	505	970	0,52
Jan. 97	655	1395	0,47	490	1025	0,48
5.9.97	545	1165	0,47	365	770	0,47

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