

**BUILDING A COMMON DATA BASE ON SCIENTIFIC RESEARCH AND  
PUBLIC DECISION ON TSES IN EUROPE – BASES**

**Concerted Action BMH4-CT98-6057 – Biomed programme, TSE joint call**

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**BSE and the Italy National Action System**

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## List of Abbreviations

AIDS	Acquired Immuno-Deficiency Syndrome
BSE	Bovine Spongiform Encephalopathy
CEA	Centro di Referenza Nazionale per le encefalopatie animali et neuropatologie comparate
CJD	Creutzfeldt-Jakob Disease
DOP	Denominazione di Origine Protetta
EC	European Community
ECC	European Communities Commission
ECMA	European Committee on Methods of Analysis
ICRF	Ispezione Centrale Repressione Frodi
IGP	Indicazione Geografica Protetta
MAFF	Ministry of Agriculture, Fisheries and Food (UK)
nvCJD	New variant Creutzfeldt-Jakob Disease
OFIVAL	Office National Interprofessionnel des Viandes de l'Elelevage et de l'Aviculture
OIE	Office International des Epizooties
SEAC	Spongiform Encephalopathy Advisory Committee (UK)
SBO	Specified Bovine Offal
SRM	Specified Risk Materials
TSE	Transmissible Spongiform Encephalopathy
UK	United Kingdom
HIV	Human Immuno-deficiency Virus
WHO	World Health Organization

## Introduction

In order to compare the ways in which the governments of several EC Member States responded to the problems of BSE in terms of collective risk management, we chose to do case studies in ten countries and to re-construct some of the BSE sagas using the same methodology. The BSE outbreak, started in the UK and became a European crisis to varying degrees at the political and economical level. Italy has been less affected by BSE in terms of diagnosed cases with only two confirmed cases of BSE in 1994 and no more after this date. According to the theoretical framework of the Sociology of Organized Action applied to risk analysis, we chose to use the concept of “Organized Action System” (Setbon, 1993), to study the management of the “BSE crisis” in Italy. As shown by the author, the analysis of an “Organised Action System” focused on risk is based on three assumptions.

- (i) The public authorities are at the centre of the admission of a situation to be a situation of risk. That is the institutional dimension of the risk management.
- (ii) A situation of risk is in relation to uncertainty implying the identification of risk factors. That is the cognitive dimension of the risk management.
- (iii) The identification of risk factors must be translated in devices and procedures. That is the organisational dimension of the risk management.

These three dimensions interact and in order to consider the BSE question as a problem of public health and of collective risk we shall identify, for each of the above dimensions, who the key actors are, their interests and their resources, and how they are involved in the construction of an “Organised Action System”.

Our analysis of the BSE crisis management in Italy is structured around three main themes.

- (i) The relations between science and public decision as responses towards the collective risk of a BSE epidemic and transmission of infection.
  - (ii) The building of regulations and the effect of these norms in terms of public management of TSE risks in regard to the European directives.
  - (iii) The reshaping by the “BSE crisis” of Public Action in terms of political and institutional changes.
- Our objective is to show, using the Italian “BSE saga” from 1986 to 1998, in which institutional system of health and how a new animal disease, which appeared in UK in 1985, became progressively a matter of concern for public health in Italy. To re-construct the “BSE saga”, we have chosen to underline:
- (i) the different status of BSE as a foreign animal disease to an issue of concern for public health.
  - (ii) the different methods of institutional mobilisation of organisational and scientific resources to identify the BSE risk factors and to contain the disease.
  - (iii) the influence of European Directives on the national regulatory activity
  - (iv) the main features of the public-decision making process concerning the management of the BSE crisis

With regard to this methodological process, in this report we show that the evolution of the BSE problem in Italy moved through five stages: up to 1990, scientific interest in the UK epidemic; organisational response to the risk of BSE based on existing scientific resources (1991-1992); formal organisation of animal TSE surveillance in Italy and the confirmation of the first cases of BSE (1993-1995); a situation of crisis after the announcement of the link between the BSE and the nvCJD (1996); a period of concerted collective risk management (1997-1998)

The “BSE saga” is in line with an institutional context in which the actors involved in the management of the BSE problem were the Italian System of Health. In Italy, for constitutional reasons, all animal and human health problems and food safety questions are the responsibility of the Ministry of Health, with the Ministry of Agriculture playing only a secondary role.

## The organisation of the institutional system of health in Italy

Italy is a parliamentary Republic. Parliament consists of the Chamber of Deputies and the Senate. The Deputies, numbering six hundred and thirty members, are elected by universal and direct suffrage. The Senate, composed of three hundred and fifteen members, is elected on a regional basis. Both assemblies are elected for a period of five years. The President of the Republic is elected by Parliament during a joint session of both chambers. Three delegates from every Region, elected by the Regional Councils, also take part in the election. The Republic is divided into twenty Regions<sup>1</sup>, Provinces and Districts. The Regions are constituted as autonomous territorial units with their own powers and functions. Each Region exercises its administrative functions through its own offices and delegates certain functions to the Provinces and Districts. A government

<sup>1</sup> Piemonte. Valle d’Aoste. Lombardia. Trentino. Alto Adige. Venetia. Friuli, Venetia Julia. Liguria. Emilia-Romagna. Toscana. Umbria. Marche. Latium. Abruzzi. Molise. Campania. Apulia. Basilicata. Calabria. Sicilia. Sardinia.

representative, residing in the capital of the Region, supervises the administrative functions exercised by central government and co-ordinates them with those of the Region.

In Italy, the system of healthcare, both for animals and humans, is under the supervision of the Ministry of Health which is the central organ of the public health policy. (See graph 1). The Ministry of Health is divided into five departments and six services. In its different tasks, it is assisted by a technical and consultative organ, the High Council of Health. In addition to this council, three Superior Institutes are also important actors in the Italian system of healthcare, as technical and scientific organs of the Ministry with functions of research, experimentation, information and training for safety and public health. One of them, the Superior Institute of Health, is particularly involved in the field of TSE .

The Superior Institute of Health was created in 1934 and since 1978 has been considered by the Ministry of Health to be an organ of permanent expertise and the seat of basic and applied research in human and animal health. The Institute comprises twenty research laboratories<sup>2</sup>. Three of them, Epidemiology and Biostatistics, Veterinarian Medicine and Virology, are directly involved in the BSE problem through research projects, co-ordination, training, consulting and assessment . In 1991, their human resources were increased by the hiring of new researchers. In addition to its internal members, the scientific committee of the Institute includes 14 experts appointed by the Ministry of Health and an expert from the Ministries of University and Research, of the Environment, of Industry and of Social Affairs. Since its creation, the Superior Institute of Health has developed scientific collaborations at an international level, welcoming to Rome several Nobel prizewinners, for instance Gajdusek, one of the specialists in TSE.

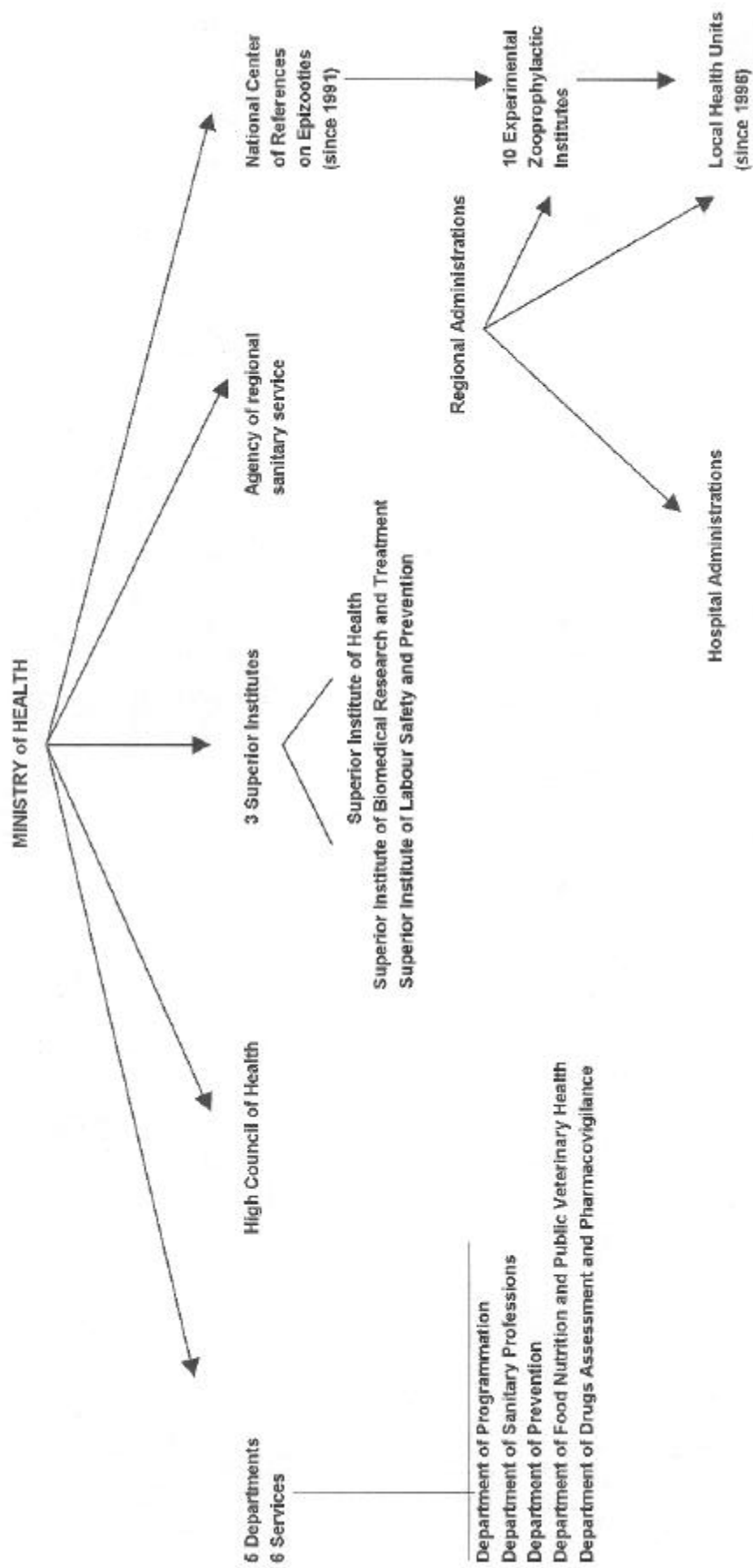
The regional administrations of the public health sector are supervised by the Regional Service Agency of the Ministry. In the field of the animal health, the most important regional actors are the ten Experimental Zooprophyllactic Institutes. Since the creation of the National Centre for Animal Encephalopathies (CEA) in 1991, they are formally structured in a network in order to collect data and to cooperate technically and scientifically with the CEA of Turin. (see table 1).

**Table 1.** The Experimental Zooprophyllactic Institutes and the National Centre for Animal Encephalopathies

Location of the Experimental Zooprophyllactic Institutes	⇒ Brescia. Foggia. Portici. Padova. Palermo. Perugia. Roma. Sassari. Teramo. Torino.
Main tasks assigned to the Experimental Zooprophyllactic Institutes	⇒ Experimental research and diagnosis on domestic and wild animals diseases ⇒ Applied research on hygiene of breeding and zootechnics productions ⇒ Epidemiological surveillance on animal health ⇒ Microbiological and chemical analysis on foodstuff animal origin for human consumption and on animal feed stuff ⇒ Production of biologicals ⇒ Training of veterinarians and other operators skilled in zooprophyllactic activities
Missions of the Reference Centre for Animal Encephalopathies created in 1991 in Turin.	⇒ Diagnostic confirmation of animal TSE outbreaks ⇒ Diagnostic techniques (Immunohistochemistry, Western-Blot) for animal TSE ⇒ Epidemiological databases on animal TSE ⇒ National coordination of operative units and operators training

<sup>2</sup> Nutrition. Medical Bacteriology. Clinical Biochemistry. Cellular Biology. Drugs Chemistry. Hematology. Epidemiology and Biostatistics. Pharmacology. Physics. Physiopathology. Environmental Hygiene. Immunology. Biomedical Engineering. Veterinarian Medicine. Pathological Biochemistry. Parasitology. Applied Toxicology. Compared Toxicology. Ultrastructure. Virology.

Graph 1 . The formal Organisation of the health system in Italy



As shown in the table above, the system of animal health is very decentralised and the Experimental Zooprophyllactic Institutes are the best means for the CEA to collect data and to be kept up-to-date with local situations. As the BSE “ affair ” is destined to persist in Europe, and consequently in Italy, the CEA and the Superior Institute of Health have reinforced their cooperation in order to become ever more efficient at local and central level in the surveillance of TSE, through publications, TSE safety guidelines and diagnostic procedures.

## The Ministry of Agriculture : a peripheral actor in the BSE crisis management

The Ministry of Agriculture has not been involved in the management of the BSE problem. If we look into the past political status of Agriculture in the organisation of the Italian government, we can see that this sector has sometimes been a separate ministry and sometimes an integrated sector within a larger Ministry. From the middle of the nineteenth century to 1916, the administration of agriculture came under the Ministry of Agriculture, Industry and Trade. In 1916, a Ministry of Agriculture was created, essentially in response to the demands arising as a result of the First World War. Then, in 1923, Agriculture was again absorbed into the Ministry of National Economy. After the Second World War up to 1993, a Ministry of Agriculture and Forestry was again established with competencies of organisation of the production and modernisation of the sector.

Since the beginning of the nineties, the the Italian Ministry of Agriculture has suffered various setbacks, independent of the BSE crisis. From the end of the eighties, the Italian government has tried to reduce public expenditure and transfer responsibilities to Regions. In this context, maintenance of the Ministry of Agriculture was the most controversial. Following a referendum in 1993 which pointed to the necessity to reduce the number of ministries and their responsibilities in the Regions, the Ministry of Agriculture became the Ministry of Agricultural Research, Food and Forestry (law of 4/12/93, n° 491). Four years later, the Ministry yielded up even more competencies and its name was again changed to the Ministry of Agricultural Politics (decree of 4/6/97 n° 143). The responsibilities of this ministry are essentially concerned with technical control over sectors of products and representation of Italy at the European Ministry Councils. Because of this representation role it was not possible to do away with the ministry completely but the possibility has been often discussed as part of the decentralisation plan..

The present organisation of the Ministry reflects this new direction. It is composed of six central administrative bodies<sup>3</sup>, and within the framework of its technical competencies on the quality of products and implementation of the EC directive 2081/92, the Ministry of the Agricultural Politics, is involved in a process of certification involving labels concerning food quality, based on two criteria : “*Denominazione di Origine Protetta (DOP)*” and “*Indicazione Geografica Protetta (IGP)*”, and on a classification for five types of products : cheese, olive oil, fruit and cereals, meat and derived products, bread and cakes. This process is not directly aimed at providing a means for tracing the source of products but it can be considered as a first step in this direction. The “*Ispezione Centrale Repressione Frodi* ” (ICRF) of the Ministry has a global agreement of technical and scientific cooperation with the University for carrying out applied research on control methods to ensure food quality. In 1996, the ICRF developed an electron microscopic technique to control the risk of BSE infection and to check that the ban on MBM in ruminant feedstuffs was complete. In 1996-1997, under the coordination of the central services of the ICRF, the 21 local services of “*Repressione Frodi* ” have increased controls (25 891 in 96 and 27 400 in 97)<sup>4</sup> and sampling throughout the country in the food sector.

In Europe, Italy ranks second to France as a consumer of beef (26/kg/head/year, between 1990-1995)<sup>5</sup>. National production at around 66% of the total consumption of bovine meat is more important than imports. About 6% of imported bovine meat comes from the UK. In 1994, which was the year that saw the first two Italian cases of BSE, Italy imported from the European Economic Community 342,000 tonnes of bovine meat to augment a national production of 1,171,000 tonnes.

As for the risk of contamination from MBM, the fact that Italy imports very little bonemeal makes this risk very small. In 1993, the average production of meatbone meals in Italy was 355 thousands tonnes. It is the fourth largest producer in the EU (See table 2).

**Table 2.** Annual EEC production of Meat-Bone meals and animal fats<sup>6</sup>

<sup>3</sup> “ *Politiche Agricole Agroindustriali Nazionali. Politiche Comunitarie e Internazionali. Pesca e Acquacoltura. Risorse Forestali Montane e Idriche. Servizi Generali e del Personale. Ispezione Centrale Repressione Frodi* ”.

<sup>4</sup> data from Website of the Ministry. <http://www.politichagricole.it>

<sup>5</sup> Source : Eurostat. Animal production. Quaterly statistics, 2, 1998.

<sup>6</sup> Data from Revue de l'Alimentation Animale. N°467. 24 May 1993

Country	Meat-Bone Meals	Fats
France	520	240
Germany	470	220
UK	400	170
<b>Italy</b>	<b>355</b>	<b>160</b>
Netherlands	165	70
Spain	160	60
Denmark	155	60
Belgium. Luxembourg	150	70
Ireland	70	30
Portugal	30	13
Greece	5	1
Total EEC (12 countries)	2480	1094

(Annual average in thousands tonnes)

However, it is an economic issue for Italy to guarantee the safety of its animal derived products because a part of the production is exported for use in the cosmetic and pharmaceutical industries<sup>7</sup>. However, the implementation of safety measures concerning the production of meatbone meals is not easy in Italy, because the rendering industry is composed of heterogeneous actors : some large firms and many small and middle-sized firms (see table 3) with very different levels of equipment. The high cost of energy needed to achieve the necessary temperatures to inactivate the pathogen agents, is an added incentive for firms to contravene the law.

**Table 3.** European producers in rendering industry in 1990<sup>8</sup>

Country	Number of firms
ITALY	52
UK	46
FRANCE	20
IRELAND	6
DANMARK	3
NETHERLANDS	3
BELGIUM	2
<b>Total</b>	<b>132</b>

By 1994, the public authorities and the feedstuffs producers in Italy were becoming more and more aware of the economic and social stakes of food safety. Some of the researchers at the National Reference Centre for Animal Encephalopathies are members of a national committee composed of representatives of farmers associations, feedstuffs producers, officers and technical experts from the Ministry of Agriculture and the Ministry of Industry.

## The time of the UK epidemic signals : 1986-1990

As in many countries in Europe, during the years 1986-90, BSE was not considered to be a problem for public health by the political authorities in Italy.

## The BSE : an interesting scientific question for some researchers in Italy

When the first case of BSE in Europe was suspected in 1986 and officially diagnosed in the UK by the MAFF<sup>9</sup>'s Central Veterinary Laboratory of the UK<sup>10</sup>, it only aroused the attention of scientists working in the field of the animal and human TSE and members of two types of institutions : the University (Ministry of Research) and the Superior Institute of Health (Ministry of Health). One of their researchers<sup>11</sup> was the first to have made an anatomo-pathological examination of a case of scrapie in Italy in 1976 and since that time has concentrated its research and training in this area. A second researcher<sup>12</sup>, involved in research on the activation of mice experimental models to test tissues of scrapie, spent one year in 1985 at Edinburgh in the Neuropathogenesis Unit at the Institute of Animal Health where he worked with H. Fraser. Thanks to this

<sup>7</sup> Interview. Rome. 11/1/99.

<sup>8</sup> Data from European Renderers Association

<sup>9</sup> MAFF. Ministry of Agriculture, Fisheries and Food

<sup>10</sup> UK. United Kingdom

<sup>11</sup> F. Guarda, Pr of Veterinary Pathological Anatomy. University of Turin.

<sup>12</sup> G. Poli, Pr of Veterinary Microbiology and Immunology. University of Milan.

scientific collaboration he was able to return to Edinburgh in 1987 in order to observe the first case of BSE. At this time, for these Italian researchers, the problem of the British case of BSE was only of interest as a scientific question and discussion was confined to their scientific community, at the level of their laboratories and teams, through seminars and conferences.

Another researcher, M. Pocchiari, had worked as a neurologist since 1977 on CJD firstly at the University, where there were only a few researchers involved in this type of disease. In 1991, he left the University and joined the laboratory of Virology at the Superior Institute of Health. Another Italian neurologist, Pr Tagliavini, carries out clinical research on human TSE at the Neurological Hospital BESTA in Milan Both men have good scientific visibility at an international level, as shown by a scientometrics test on the MEDLINE database (See Annex 1). In 1988-1989, a scientific network, mainly composed of G. Macchi, M. Pocchiari, A. Ladogana and P. Casaccia, were working on the transmission of CJD and co-publishing papers which are identifiable in the Medline<sup>13</sup> database and show that Italy is scientifically present in this field.

## The BSE : a British problem of animal health

In 1988-89, Italy, like all the other European countries except the UK, was not very involved in either European or national debate over managing the risk of extension of BSE. Since 1989, M. Pocchiari had participated in some of the Brussels meetings as a member of the BSE sub-commission of the Scientific Veterinary Committee and a specialist in CJD, but he was not appointed to be the official representative expert of Italy at the European Permanent Veterinary Committee. At this time, the possibility of the transmissibility of BSE to humans was discussed in this sub-commission by a small group of scientists including M. Pocchiari, but these discussions did not receive any significant reaction from the political authorities at either in the EC or in Italy.”<sup>14</sup>.

At the end of 1989, Italian veterinarians began to be more interested in BSE because of its connection with scrapie and as a result of the Southwood report<sup>15</sup> which concluded that the BSE agent was probably derived from scrapie-affected material in feedstuffs. In 1990, the health services of most of the Italian Regions organised information dissemination meetings on BSE intended for veterinary practitioners. However, in general, opinion was that BSE was not a threat to Italian cattle but was only a problem with imported animals. The Southwood report concluded also that “ from present evidence, it is likely that cattle will prove to be a dead end host for the disease agent and most unlikely that BSE will have any implications for humans health ”<sup>16</sup>. This kind of conclusion meant that the minority assumption of the possible transmission of BSE to humans supported by some scientists, was given very little credence by the political authorities and the public administrations.

At the end of 1990, six Italian researchers<sup>17</sup> participated in a conference in the CEC Agricultural research programme held in Brussels on Sub-Acute Spongiform Encephalopathies<sup>18</sup>. The objectives of this international conference was to apprise the EEC, international organisations (WHO, OIE), other scientists and the administrators of all the significant findings on TSE and about all the major research projects in progress. Seventeen countries<sup>19</sup> were involved and the British scientists were, of course, the largest group (37/ 95).

## The first regulatory decisions

The first regulatory decisions taken by the Italian government were essentially the adoption of the European directives, (the ban on imported MBM from the (Ministerial circular n° 9076 of 5/11/89) had been put in place before the Directive). (See table 4 and table 5). Following the directive 89/469 of the European Commission to ban live cattle exports from the UK to member states of animals born before July 1988, the Italian government (Ministerial circular n° 6770 of 12/8/89) similarly banned such imports announcing the cut off date as 18/7/88. After the directive 90/200 of the European commission, the Italian government decided that all the animals displaying *ante mortem* clinical signals of BSE, must be slaughtered separately and must have their brains removed for analysis at the Zooprofylactic Institute of Turin (decree n° 2683 of 21/4/90).

<sup>13</sup> Medline is a database of INSERM. France.

<sup>14</sup> Interview in Rome. 11/1/98.

<sup>15</sup> The report, termed the 'Southwood report', after the chairman of the working group appointed to advise The British MAFF on the implications of BSE, was published in February 1989.

<sup>16</sup> MAFF. Department of Health. Report of the Working on Bovine Spongiform Encephalopathy. 3/2/89. § 9.2, p. 21.

<sup>17</sup> L. Amaducci . A. di Martino. P. Guarda. M. Pocchiari. G. Poli. F. Valenza.

<sup>18</sup> Bradley R., Savey M., Marchant (edited by) (1991). Sub-Acute Spongiform Encephalopathies. Proceedings of a seminar in the CEC Agricultural research programme. Brussels 12-14 November 1990. Kluwer Academic Publishers. Dordrecht/ Boston :London. For the Commission of the European Communities.

<sup>19</sup> Belgium. Slovakia. Denmark. France. Germany. Iceland. Ireland. Israel. Italy. Luxembourg. The Netherlands. Portugal. Spain. Switzerland. United Kingdom. USA. Yugoslavia.

Following the directive 90/261 of the European Commission which stated that bovine carcasses exported from the UK did not pose a threat, the Italian government decided to regulate all importation of cattle from the UK (decree n° 4207 of 13/6/90). One month later, the Italian government decided on a “ monitoring programme ” for the slaughter of the cattle (decree n° 4910 of 11/7/90)

**Table 4.** European directives. 1989-1990

Date	Directive N°	Content of European Directives
28/7/1989	89/469	Ban on live imports of cattle born before 18/7/88 for beef cattle or born after this date from dairy cows suspected of or confirmed with BSE. Amendments to the directive 64/432/EEC about the sanitary certificate concerning the intra-EEC trade of cattle.
7/2/1990	90/59	Following the advice of the Permanent Veterinary Committee, modification of the 89/469 directive Ban on live imports of cattle from UK of more than 6 months of age or the progeny of dairy cows suspected of or confirmed with BSE. The live imported UK cattle must be slaughtered before reaching 6 months
6/3/1990	90/134	Registration of Scrapie and BSE as infectious notifiable diseases (extension of the 82/894/EEC directive).
9/4/1990	90/200	Every animal suspected of having BSE at an <i>ante mortem</i> examination must be slaughtered separately and the brains analysed. In confirmed cases of BSE, carcasses and offal must be destroyed. Export ban on material from UK to other European member states : - tissues and organs (brains, spinal cord, thymus, tonsils, spleen, intestine) from cattle slaughtered after 6 months - bovine placenta, bovine cells culture, bovine foetus serum, lymphoid tissues, pancreas, ovaries, testicles, suprarenal glands, pituitary gland.
8/6/1990	90/261	Modification of 89/469 EEC directive. Live cattle imported from UK younger than 6 months must be tattooed in order to confirm they free of BSE. All bovine carcasses exported from UK must be free from BSE and must be accompanied by a microfiche identification .
26/6/1990 (European Council)	90/425	Veterinary and zootechnical controls must be carried out by each State Member on live animals on the farm and sanitary certificates must be issued by an authorised veterinarian . The State members importing live cattle must check the conformity of the papers (identification etc.) with the directives and isolate any animals that fail to comply with the rules.

**Table 5.** Italian regulatory measures in from 1989 to 1990

Date	References	Content of Italian measures
12/8/1989	Ministerial Circular N° 6770 –	Import ban on live cattle born before 18/7/88
5/11/1989	Ministerial Circular N° 9076	Import ban on meatbone meals from Ireland and the UK
21/4/1990	Ministerial Circular N° 2683	Surveillance norms of BSE on live animals, examination ante mortem and clinical diagnosis
13/6/1990	Ministerial Circular N° 4207	Limitations on bovine carcasses imported from UK
11/7/1990	Ministerial Circular N° 4910 –	Monitoring programme for slaughtering based on division between safe animals and those suspected of being infected with BSE. .

At the end of this period, we can observe that it was characterised by four main features

- ✓ BSE was not considered by the political authorities to be a public health problem in Italy
- ✓ BSE was seen to be a British animal health problem and, therefore, the most efficient public action was to protect the country from British cattle and British meatbone feedstuffs
- ✓ The Italian government in general modelled its regulatory action on the directives of the European Commission, except for the ban on MBM, which the Italian government had imposed earlier.
- ✓ The Ministry of Agriculture had no specific role during these two years in regard to the formal organisation of the Health system in Italy and the Ministry of Health dealt with all matters relating to human health as well as those of animal health.

### **The time of Alert towards risk management : 1991-1992**

During the years 1991-92 in Italy, BSE had become not just a UK problem and an interesting scientific question, but a problem of animal health requiring some institutional change.

## The year of transition :1991

Two main events indicate that the Italian government had begun to be concerned about the risks linked to BSE : the creation of the National Centre for Animal Encephalopathies (CEA) and the mobilisation of two laboratories of the Superior Institute of Health on TSE research.

The National Centre for Animal Encephalopathies was created in 1991 (decree 91A3704 of 3/8/91) in Turin by the Italian Health Ministry. It was charged with the diagnosis and confirmation of TSE outbreaks, the co-ordination of national operational units and the training of sanitary veterinarians. The choice of Turin was based on two factors : the proximity of the Faculty of Animal Pathology at the University of Turin and, more particularly, the laboratory of Pr Guarda ; and the human and technical resources of the Experimental Zooprophyllactic Institute of Piemonte-Liguria-Valle d' Aoste based in Turin which was of the required standard for such work. It was specified in the official remit of the new centre that it must work in co-operation with the Department of Animal Compared Pathology of the University of Turin (art. 2). A team of young researchers - most of whom had conducted their doctoral research under the supervision of Pr Guarda - were appointed to the center and Pr Guarda became the first Director of the National Center of References on Animal TSE.

The second event which must be mentioned was the mobilisation of scientists of the Superior Institute of Health and the collaborations on animal and human TSE, particularly between the laboratory of Veterinary Medicine, managed by Pr Macri, and the laboratory of Virology, managed by Pr Pocchiari. In addition, researchers from the Superior Institute of Health began to co-operate actively with their new colleagues at the National Center of References on Animal TSE in Turin, in terms of training and performing tests and protocols. At this time, there was no specific expert committee on TSE connected with the Ministry of Health. There was only an expert committee doing work on infectious diseases and mainly focusing on AIDS. With regard to the health risks linked to TSE, in 1991, Pr Pocchiari and Pr Agrimi from the Superior Institute of Health were put in charge of a working group focused on TSE with a two-fold mission : to provide the Ministry of Health with information and to elaborate a national research program on TSE. But the Ministry of Health did not really consult the working group, and the members met only twice<sup>20</sup>.

During the same period, several Italian researchers participated in the elaboration of a classification of specified risk tissues and organs at a WHO<sup>21</sup> Consultation meeting held in Geneva on the subject of “ Public Health Issues related to animal and human spongiform encephalopathies ”. In addition to the state of the knowledge on TSE (nature, occurrence, animal and human TSE, transmission, future research) three other important points were developed : tissue distribution of the TSE agents, prevention and control of BSE in cattle and “ minimising the risks to humans associated with the consumption of food, occupation and the use of medicinal and other products of bovine origin ”<sup>22</sup>. In order to define a formal framework for precautionary measures, one of the outcomes of this consultation was the adoption of a classification of BSE specified risk materials based on experimental results from research into scrapie conducted in 1980-82.<sup>23</sup> The norms adopted for scrapie were applied to BSE because they were considered to be sufficient.

These events show that 1991 saw the beginning of the construction of an institutional framework in Italy for the management of TSE risk, based on existing scientific resources and some recruitment of young researchers in the Centre in Turin.

## Regulatory measures in 1991-1992

Following the European Directives (see tables 6 and 7), the Italian Government at the beginning of the nineties defined an institutional framework on the surveillance of TSE with the creation of the National Centre of References on animal TSE in 1991 (see table 5). The Centre was put in charge of confirming diagnoses of animal TSE, national co-ordination of regional Zooprophyllactic Institutes, operator training and TSE epidemiosurveillance.

**Table 6.** European Directives.1991-1993

Date	Directive N°	Content of European Directives
5/2/1991	91/89	Following the recommendation of the Permanent Veterinary Committee, financial support by the EEC for a research programme to do a comparative study of scrapie strains coming from different member states

<sup>20</sup> Interview in Rome. 12/1/98.

<sup>21</sup> WHO World Health Organisation

<sup>22</sup> Report of a WHO consultation on “ Public Health Issues related to animal and human spongiform encephalopathies ”. Geneva 12-14 November 1991. WHO/CDS/VPH/92.104

<sup>23</sup> Hadlow W.J. Kennedy R.C., Race R.E., Eklund C.M. (1980) Veterinary Pathology, 17, pp.187-199

Hadlow W.J. Kennedy R.C., Race R.E., Eklund C.M. (1982) Journal of Infectious Diseases, 146, pp.657-664.

14/5/92	92/290	Ban on trade in bovine embryos from cows suspected of or confirmed with BSE between EEC member states. Ban on exports from UK of bovine embryos from cows born before 18/7/1988, or from cows suspected of or confirmed with BSE
30/7/1992	92/450	Following the recommendation of the Permanent Veterinary Committee, every case of BSE from 31.12.97 in the European Community must be registered

**Table 7. Italian regulatory measures**

Date	References	Contents of Italian measures
10/5/1991	Ministerial Order	Classification of Scrapie and BSE as infectious notifiable diseases
7/6/1991	Ministerial Decree	Measures of control on cosmetic and pharmaceutical products containing bovine tissues
3/8/1991	Ministerial Decree	Creation of the National Center of References
6/8/1991	Ministerial Order	Norms of protection concerning imported live animals and all animal derived products

In addition to the creation of a National Centre for Animal Encephalopathies, regulatory measures focused on the safety of cosmetic and pharmaceutical products containing bovine tissues. The Department of Drugs Assessment and Pharmacovigilance of the Ministry of Health and Pr Silano<sup>24</sup> played a central role in putting the necessary controls in place .

Three main results came out of this period. A formal framework for animal TSE control was elaborated in Italy with the creation of an institutional structure for the centralisation and the co-ordination of information. The sharing of responsibilities and roles among the Superior Institute of Health, the University and the National Center of References is not very clear. Vigilance with regard to public health was essentially concentrated on the cosmetic and pharmaceutical sectors with the food sector not really considered. As in France, it seems that the risk linked to cosmetics and pharmaceutical containing bovine derived products was perceived sooner than that linked to food.

## The formal organisation of the TSE surveillance in Italy and the first cases of BSE : 1993-1995

The 1993-95 period is characterised by two main events, the development of human and scientific resources of the recently established National Center of References and the first cases of BSE in Italy in 1994.

### First activities of the Reference Centre for Animal Encephalopathies

Under the direction of the Pr Guarda, the National Centre selected its technical and scientific team. Most of the young researchers were recruited from the laboratory of Pr Guarda. Amongst their organisational tasks, they began to coordinate the regional experimental zoophylactic Institutes into a national network.

In 1993, the Health Ministry launched a research programme co-ordinated by Dr Caramelli, a researcher from the Reference Centre for Animal Encephalopathies, and focused on the identification of an experimental animal model for research into the etiological agent of BSE in meat-bone meals produced in Italy . This programme was decided on in relation to the activity of the Permanent Veterinary Committee and the directives of the European Commission about safety technical norms in the rendering industry. (See Table 8).

**Table 8. European Directives. 1994-1995**

Date	Directive N°	Content of European Directives
27/6/1994	94/38	Following the recommendation of the Permanent Veterinary Committee, a ban on proteins derived from mammals for the feeding of ruminants
7/7/1994	94/381	Technical norms of conversion of ruminants produce into meals
27/7/1994	94/474	Repeal of 89/469 and 90/200 directives Ban on export of UK bovine meat except if younger than 6 months or born outside UK and import in UK after 1/1/91

<sup>24</sup> Pr V. Silano was nominated by the European Commission on July 1997 as a member of the Scientific Steering Committee by Commission decision n° 97/404/EC of 10/6/97.

14/12/1994	94/794	Modification of decision 94/474 ECC about bovine meat. Authorisation to export from UK, bovine meat coming from animals born after 1/1/92 or coming from farms BSE free for 6 years. Authorisation to export from UK, only bovine boned meat if one of the above conditions is fulfilled.
13/2/1995	95/29	Modification of 94/381 directive. About technical norms and accreditation of heating system for conversion of ruminants produce into meals and BSE agent inactivation
6/3/1995	95/60	.Modification of the 94/38 ECC directive, about safety concerning derived products (milk, gelatine, fatbone, blood products) and technical process of inactivation of pathogen agents
18/7/1995	95/287	Modification of decision 94/794 ECC about export bovine meat from UK. The sanitary certificate of exported bovine meat must notify : animals slaughtered before 2 ,5 years old and coming from farms free of BSE for 6 years ; or, if one of the above conditions is fulfilled, bovine boned meat stripped of nervous and lymphatic tissues

## Expertise and regulatory measures

In 1993 , Pr Pocchiarri and Pr Marabelli participate in the European Scientific Veterinary sub-committee on TSE with experts mainly from France, Germany and the UK. Most of them were neurologists and biochemists with some veterinarians However, the UK representation included several veterinarians who were very active in the debates at a very high scientific level. The nature of the BSE agent and how to inactivate it were the central themes of these debates. The probability of BSE transmission to humans was also discussed by the experts but such discussions produced no official recommendations, in spite of written notes sent to the ECC and to the national public authorities<sup>25</sup>.

During these two years the regulatory activity of the Ministry of Health was to confirm the European directives by implementing national measures, implementing ECC directives 94/381 and 94/474 extending the control on Specified Bovine Offals (SBO), prohibiting the use of mammalian protein in ruminants feedstuffs and prohibiting the export of SBO and protein derived from SBO except for research under licence. (See table 9) At the European level, 1994 was the year of the first directives about technical norms of conversion of ruminant products into meals (94/38 ECC, 94/381 ECC directives). Some researchers from the National Reference Centre for Animal Encephalopathies had been members of the ECMA since 1994 <sup>26</sup> (DG VI) where farmers and producers of feedstuffs participated in discussions with researchers and veterinarians.

**Table 9 . Regulatory measures 1994-1995**

Date	Reference	Contents of Italian measures
28/7/94	Ministerial Order	Ban on using proteins derived from mammals for the feeding of ruminants
29/8/94 9/9/94	Ministerial Circulars n°5706 n°5698	Control of meat exported from UK
20/1/95	Ministerial Circular n° 478	Adoption of decision 94/474 ECC (see table 5) about bovine meat imports to Italy
30/3/95	Ministerial Order	Modification of the ministerial ruling of the 28/7/94. Safety measures concerning derived products (milk, gelatine, fatbone, blood products) and technical process of inactivation of pathogen agents
15/9/95	Ministerial Circular n° 5561	Adoption of the modification to decision 94/794 ECC (see table 5) about bovine meat

## The first BSE cases in Italy

1994 was the first real alert with regard to public health being the year when the first cases of BSE were discovered in Italy. The two sick animals belonged to a group of fifty head of cattle that had been imported from the UK<sup>27</sup>. They were slaughtered under the supervision of experts such as Prs Guarda, Poli and Agrimi and BSE was confirmed by the histopathological examination of their brains. The farmers involved received financial compensation and a control of herds containing British imported animals was put in place.

<sup>25</sup> Interview in Rome. 11/1/99

<sup>26</sup> European Committee on Methods of Analysis

<sup>27</sup> The others were declared safe from infection by BSE. Interview in Turin. 10/11/98.

However, these two cases did not prompt any social mobilisation. Consumers did not seem concerned and the professional organisations of farmers kept fairly quiet about the event. As shown below (see table 7), the reinforcing of control measures on UK imported cattle and meat seemed to be sufficient to reassure consumers.

## The time of the “ Mad Cow Crisis ” : 1996

In March 1996, two events in UK turned the concern about BSE in Italy into a social economic and political crisis :

- (i) the information given by the CJD surveillance unit of UK to the SEAC<sup>28</sup> of 10 cases of what seems to be a new variant of the CJD ;
- (ii) the public announcement in parliament by the British Ministry of Health that the most probable explanation of these cases of nvCJD was exposure to the BSE agent before 1989.

### The social mobilisation

As in other European countries, the announcement of the likely contamination of humans by the BSE agent provoked real panic amongst consumers. In Italy at this time, consumers associations were not very well organised and were essentially perceived as trouble makers by the government rather than as acceptable negotiating partners. The media coverage of the announcement heightened the drama. Some programmes on primetime TV predicted an epidemic of even bigger proportions than HIV. They stressed that CJD was a fatal and rapid disease with a long incubation and nothing could be done to prevent or to cure it. Researchers were invited by the media, along with public veterinarians and farmers, to comment on these reports but they refused on the grounds that it was not possible to inform people and to have a clear debate under such conditions, specially on TV and radio. However, they did agree to give interviews to newspapers and to hold conferences for professional associations<sup>29</sup>.

In spite of the total embargo on all bovine products declared by the government (see table 13), the consumption of meat dropped in 1995 to 1996 and prices fell in April and June 1996. During the first six months of 1996, the consumption of bovine meat decreased by 7% in France, 14% in Italy, 16% in Germany, and 19% in the UK<sup>30</sup>. French farmers were particularly concerned because Italy was their main export market for beef cattle “ *Charolais* ”. It was in the South of Italy which imported most of the “ *Charolais* ” cattle that consumption fell the most.<sup>31</sup>

At the same time, there were tensions between the lobby of slaughterhouses who wanted to slaughter round the clock (24H/24h) and farmers who formally claimed “ the traceability of the meat from the farm to the dish ”. All the bovine sector was shaken by the crisis, all the more so because imports represented nearly half of Italy’s consumption of bovine meat. The President of COLDIRETTI, the main professional association of farmers in Italy, claimed in the media on 8/6/96 that the “ UK must pay the bill ”, considering that the UK was responsible for the disruption of the market<sup>32</sup> and he announced that COLDIRETTI intended to refer the case to the Law Courts of the EC.

### The institutional mobilisation

The “ mad cow crisis ” of 1996 was perceptible at the level of European regulatory activity. National plans for the eradication of BSE were required from all State Members. The recommendations of the Permanent Veterinary Committee became more concretely translated in terms of control measures. (See table 10).

<sup>28</sup> SEAC Spongiform Encephalopathy Advisory Committee

<sup>29</sup> Interviews . Rome. 11-12 /1/1999

<sup>30</sup> Data from OFIVAL, Conseil de direction, du 19 Septembre 1996.

<sup>31</sup> T. Baralon, F.Gary, Filière bovine : conséquences économiques de la "crise de la vache folle". Point Vétérinaire, 1996, 28 (179), 697-703.

<sup>32</sup> Mentionned in Agra Presse n° 2569 17/6/96

**Table 10 . European Directives. 1996.**

Date	Directive N°	Content of European Directives
27/3/1996	96/239	Following the recommendations of the Permanent Veterinary Committee, ban on imports from UK to State Members and other countries, of live cattle, cattle meat , bovine sperm and embryos, meat products from cattle and mammalian-derived meatbone meals. UK must report on the safety measures being taken against BSE to the Commission every two months.
11/6/1996	96/362	Modification of 96/239 directive. Ban on all bovine meat and bovine derived products coming from the UK, used in the animal and human food industry, in the cosmetics and pharmaceuticals sector
20/6/1996	96/381	Safety measures taken against BSE in Portugal
24/6/1996	96/385	Agreement on the UK's plan for BSE eradication presented in June 1996
18/7/1996	96/449	Extension of technical norms of inactivation of BSE non conventional transmissible agent
16/12/1996	97/18	Agreement on the French plan for BSE eradication presented in July 96

In Italy, the public authorities reacted to the panic by demonstrating their willingness to take efficient measures to control the risk BSE infection and to clarify the distribution of responsibilities and competencies between the Ministry of Health and the Ministry and the Universities and between the central and the local levels.

In spite of the regulatory measures taken at the beginning of the nineties in accordance with the European directives concerning the safety of the meatbone meals, the regulation was not really enforced in Italy until 1996<sup>33</sup>. After the British announcement of human contamination, the government decided to reinforce the controls on imported products and the manufacture of meatbone meals. The regional zooprophyllactic Institutes was given the remit of checking on the inspections made by the local sanitary services and informing the National Centre of References and the Ministry of Health. Judicial proceedings would follow the detection of cases of fraud. The Unit " Alimentazione Animale " of the Laboratory of Veterinarian Medicine of the Superior Institute of Health (Ministry of Health) was put in charge of developing analytical methods and guidelines to identify the risk factors linked to feedstuffs products and processes. In spite of this institutional activity, it was difficult to enforce safety procedures inside firms, an issue that was underlined by the European OAV audit of 6/10/97<sup>34</sup> which showed that the application of safety measures in the rendering industry was very poor in many cases (see table 11)

**Table 11. Main conclusions of the European OAV audit of 6/10/97 (DG XXIV)<sup>35</sup>**

No implementation of the directive n°96/449/CE , on the 1/4/97
Temporary suspension of accreditation for 32 factories
Some accreditation awarded without validation
Lack of transparency of administrative procedures
Necessity to improve the internal controls
Forecast of a national programme of inspection in order to have a global view of the situation

In May 1996, the Ministry of Health<sup>36</sup> decreed that a working group on TSE be appointed to focus specifically on the nvCJD, extending the competencies of the expert committee on emergent diseases and bringing together most of the Italian experts from The University and the Superior Institute of Health under the coordination of the Ministry of Health (See table 12).

**Table 12. Composition of the working group on nvCJD**

Names	Institutions
Dr R. Marabelli (Coordinator)	Ministry of Health. Department of Food Nutrition and Public Health
Pr L. Ortona (Coordinator)	Infectious Diseases Hospital – University " Sacro Cuore ", of Roma
Pr O. Bugiani	National Institute of Neurology " Besta " of Milan.
Dr V. Carreri	Public Health Services of Lombardia
Pr F. Dianzani	Lab. of Virology . University " La sapienza " of Rome
Dr G. Ferri	Ministry of Health. Department of Food Nutrition and Public Health
Pr F. Guarda	Lab of Veterinarian Pathology. University of Torino
Dr G. Ippolito	Aids References Center. Hospital " L. Spallanzani " of Roma

<sup>33</sup> Interview. Rome. 12/1/1999.

<sup>34</sup> DG XXIV. Consumer Health Protection. Veterinary inspection about BSE in member countries, in order to control the application of the EEC directive n°96/449/CE relating to the accreditation of the firms in the rendering industry.

<sup>35</sup> Reference : Special Report to the European Parliament about recommendations concerning BSE.

<sup>36</sup> Letter dated 11/5/96 from the AIDS Center of the Ministry of Health

Pr. G. Macchi	Clinical Lab. of Neurology. University " Sacro Cuore ",of Roma
Dr A. Macri	Lab. of Veterinarian Medicine. Superior Institute of Health. Ministry of Health
Pr Giorgio Poli	Lab. of Veterinarian Microbiology. University of Milano
Dr M. Pocchiari	Lab of Virology. Superior Institute of Health. Ministry of Health
Dr S. Squarcione	Department of Pharmacy. Ministry of Health

As demonstrated by the composition of the committee, the " panic period " had encouraged the public authorities to open a collective debate between institutions, the research sectors others involved in the controversial assumptions on the origin of the disease.

The government decided to provide fresh financial and human resources to the ten regional Experimental Zooprophyllactical Institutes to put in place histopathological laboratories that would be able to make a diagnosis in the case of suspected BSE, and organise a coordinated epidemiological observatory. In order to facilitate the collection of data and the control of safety norms, Local Health Units were created in 1996 in the Regions to provide on-the-spot contributions to the TSE epidemiosurveillance team.

The role of co-ordination of the Reference Centre for Animal Encephalopathies of Torino was backed by the Ministry of Health at three levels :

- (i) at the scientific and technical level with the mission of standardisation and diagnosis methods and development of BSE and other TSE diagnostic techniques ;
- (ii) at the networking level with the concept of centralised electronic databases on TSE co-ordinating the data collected by the regional Experimental Zooprophyllactical Institutes
- (iii) at the training level with the mission to improve the training of members of local sanitary inspection services and veterinarians, and official veterinarians (other than veterinarians and technicians of Ministry of Health and of Zooprophyllactical Institutes).

After some tensions between University and Ministry of Health and after a mission of the ECC in Italy, the Italian government decided to change the direction of the work of the National Centre of Turin in order to clarify its competencies and missions in relation to those of the University. Confirmation of BSE cases needed new methods of diagnosis, such as genetic and biochemical tests which were not carried out by the laboratory at the University of Turin. It was judged to be very important that the National Centre of References should handle such tests. The researchers at the National Centre, therefore, reoriented their scientific partnership towards the scientists of the Superior Institute of Health. At the end of 1996, they participated together with a poster in an International Symposium on TSE<sup>37</sup>.

## The sharp increase in regulatory activity

The Italian government confirmed by a national ruling the prohibition by the European Commission of all exports of live cattle, cattle meat , meat products from cattle and mammalian-derived meatbone meals from UK to anywhere in the world (96/239 ECC and 96/362 ECC directives). 1996 left its mark on the regulatory activity of the Italian government which did not content itself with only following the European measures but in addition added some specific national regulations to prove its intention to manage the BSE risk efficiently. (See table 13)

**Table 13.** Regulatory measures instituted in 1996

Date	References	Contents of Italian measures
29/3/96	Ministerial Circular n°2244	Prohibition of import from UK of live cattle, meat of cattle, meat products from cattle and mammalian-derived meatbone meals
16/4/1996	Ministerial Circular n°2666	Precautionary measures concerning cattle and meat imported from France
3/5/96 6/6/96 8/5/96 14/6/96	Ministerial Decrees	Technical norms of inactivation of BSE non conventional transmissible agent (WHO norms) Precautionary measures concerning cosmetics and drugs done with products of bovine origin Sanitary norms for production of gelatine intended for human consumption
25/6/96	Ministerial Circular n° 4566	Precautionary measures concerning cattle and meat imported from Switzerland
1/10/96	Ministerial Circular n° 2634	Monitoring programme for BSE and co-ordination of sanitary regional services and Ministry of health

<sup>37</sup> Valenza F., Caramelli M., Cantini-Cortellezi G., Guarda F., Castagnaro M., Casalone C., Capucchio M.T., Agrimi U., Cardone F., Pocchiari M. (1996) " Research on BSE in Italy : histological and immunohistochemical studies ". International Symposium on Spongiform Encephalopathies. Georgetown University, December 12-13 1996.

21/10/96	Law n° 532	Creation of Local Health Units
30/10/96	Ministerial circular n° 7511	Prohibition of import from Switzerland of live cattle, bovine embryos, meat of cattle, meat products from cattle and mammalian-derived meatbone meals, except for fresh meat without bones from farms that had been BSE free for 6 years
24/12/96	Ministerial circulars n° 8919 n° 8920	Prohibition of all bovine product imports from Switzerland, except for hides as long as they are not used in human dietary and feedstuffs Prohibition of all bovine products from Portugal, France, Ireland and UK

The regulatory activity of the Italian government during 1996 shows that it wanted to reassure the population that it was taking all possible measures to reduce the risk of BSE contamination. In addition, the TSE surveillance procedures were governed by efficient, national regulations.

## The time of concerted collective risk management: 1997-1998

After the crisis of 1996, the Italian Government's attitude towards consumers associations changed and it decided to recognize them as social actors who should be listened to by allowing them in 1997 to be involved in regulatory activity. The year 1997 is also marked by the heavy involvement of the Reference Centre for Animal Encephalopathies in the TSE surveillance in Italy and the concentration on training of State veterinary officers, with the scientific and technical support of the laboratory of Veterinarian Medicine and the laboratory of Virology of the Superior Institute of Health (Ministry of Health). For example, during 1997 the National Centre ran eleven training sessions in the regional Zooprophyllactical Institutes. (See table 14)

**Table 14.** Training Activity of the Reference Centre for Animal Encephalopathies

Training Contents	Participants
TSE Etiopathogenesis	Zooprophylactical Institutes Veterinarians and Officers
TSE Epidemiology	Zooprophylactical Institutes technicians
TSE Clinics	Regional Health Ministry Officers
TSE Diagnostic procedures	
Histological and biochemical techniques	
TSE and risk to humans	
TSE safety guidelines	
National and European legislation	
High and low risk material	
Risk from meatbone meal imported from BSE infected countries	

The second important activity, managed by the National Centre of Torino in co-operation with the laboratories of the Superior Institute of Health of Roma, was the development of TSE diagnostic techniques (Antibodies, Western-Blot).

## TSE epidemiosurveillance Networks and research programmes

1997 was the year TSE epidemiosurveillance was properly organised and enforced in Italy. In July, a committee for the surveillance of TSE was officially appointed by the Ministry of Health with the objectives to design a TSE epidemiological research and surveillance network. It was composed of researchers and veterinarians from national and regional organisations, in order to facilitate the constitution of a network of actors co-ordinated throughout the country. This was necessary in order to get the same kind of information from farmers collected using homogeneous protocols. Three of the members of the committee also participated in the working group on the nVC-JD, two were researchers from the University and the third was the Director of the " *Dipartimento degli Alimenti e della Nutrizione e della Sanita Pubblica Veterinaria* " of the Ministry of Health. (See table 15)

**Table 15.** Composition of the working group on TSE surveillance

Names	Institutions	Participation in nVC-JD committee
Dr U. Agrimi	Superior Institute of Health	
Pr B. Biolatti	Faculty of Veterinarian Medicine of Padova	
Dr M. Caramelli	Reference Centre for Animal Encephalopathies	
Dr G. Guardo	Zooprophylactical Institute of Lazio and Toscana	
Dr. G. Ferrari		

Dr A. Ferraro	Department of Food Nutrition and Public Veterinary Health. (Ministry of Health)	
Dr L. Gemma	Zooprophylactical Institute of Lombardia	
Dr A. Giovannini	Zooprophylactical Institute of Abruzzo	
<b>Pr F. Guarda</b>	<b>Animal Pathology. University of Torino</b>	+
Dr C. Ligios	Zooprophylactical Institute of Sardegna	
Pr M. Pocchiari	Superior Institute of Health	
<b>Pr G. Poli</b>	<b>Veterinarian Medecine. University of Milano</b>	+
Dr G. Ru	Reference Centre for Animal Encephalopathies	
Dr G. Vecchi	Zooprophylactical Institute of Lombardia and Emilia Romagna	
<b>Dr R. Marabelli</b>	<b>Ministry of Health</b>	+

The Reference Centre for Animal Encephalopathies of Turin was the major actor in the TSE epidemiosurveillance exercise. A research and national surveillance Unit for scrapie and BSE had been established at Turin since January 1997 and it embarked on a biological sample bank of sheep and goat scrapie and collected data from the whole Italian diagnostic network of TSE surveillance.

In 1997 the first data<sup>38</sup> from the BSE epidemiosurveillance network were collected, 81 bovines with nervous symptoms were identified in the country but all tested negative for BSE and were shown to be affected by other diseases like listeriosis or meningo-encephalitis. The results were the same in 1998 : 91 neurological cases in bovine species were but diagnosed as BSE negative (See ; table16).

**Table 16.** Results of BSE epidemiosurveillance

	1997	1998
Bovine with nervous symptoms	81	91
of which were Bovines older than 24 months	6	12
Examination for BSE	81 negative	91 negative

These encouraging results might seem surprising but, as shown by the detailed data communicated by the Reference Centre for Animal Encephalopathies, each animal had a precise specified diagnosis.

What worried the research and national surveillance Unit of Turin much more was the epidemic of scrapie with a high incidence in 1997 (19 outbreaks) and a lower one in 1998 (8 outbreaks), which was perhaps linked to a iatrogenic origin (vaccination). After examination of a total of 434 sheep suspected of being infected with scrapie, 191 were histologically and immunohistochemically scrapie confirmed.

**Table 17.** Geographical distribution of Scrapie

Regions	Number of sheep
SARDEGNA	74
TOSCANA	106
SICILIA	1
Total	191

The epidemiological surveillance of scrapie is very important, because the main assumption for the research and the management of TSE risk for humans and animals, after the crossing of the species barrier (from scrapie to BSE to nvC-JD), is the eventuality of a specific bovine “ BSE ”. To develop research based on this assumption, the researchers of the National Centre of Turin are involved in three programmes .

(I) Since 1997 the ECC project “ Concerted action for the setting up of multicentric epidemiological databases and biological sample banks for small ruminant scrapie ” in which also teams from the Netherlands, Germany, Spain, Portugal and Switzerland are participating

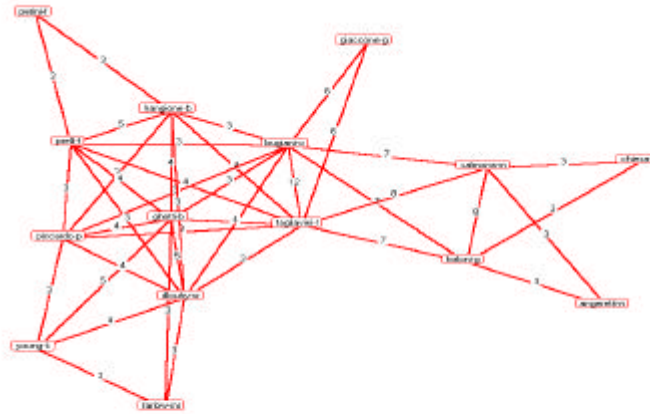
(II) A national programme started in 1998 by the Health Ministry on “ Risk Analysis applied on ruminant TSE ” in co-operation with the team of Prs Agrimi and Pocchiari of the Superior Institute of Health.

(III) The FAIR Project PL98/7021 on “Surveillance and Diagnosis of Ruminant TSE”

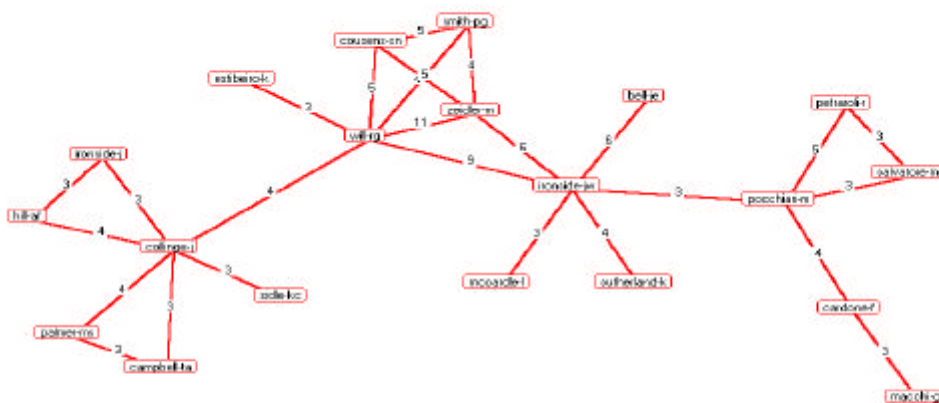
Results of a Scientometrics study show that in 1996-1997, the Italian scientific networks had grown at national and international levels. (see graphs 2 and 3)

## **Graph 2.** An Italian scientific network on CJD in 1996-1997

<sup>38</sup> All data mentioned in this part of the report were communicated to us by the Reference Centre for Animal Encephalopathies of Turin



**Graph 3.** Connection between an Italian network and an English one through publications in 1996-1997



In conclusion, it appears that efficient epidemiological surveillance of animal TSE is important both for public health reasons and for scientific reasons and both are interdependent. To achieve this goal of an efficient surveillance requires not only an institutional framework but also resources over a long term because of the great uncertainties characterising this kind of disease and the emergence of a field of research on a ovine BSE distinct from scrapie. However, government invests only 6 millions liras/year to be shared among many national projects, funding which is sometimes complemented by private funds<sup>39</sup> coming from the Italian “*Telethon*” on genetic diseases for projects on CJD.

### Regulatory activity

During 1997-98, the public authorities’ regulatory activities were in three directions : the formalisation of sanitary policies for scrapie and BSE, the creation of a national surveillance Unit for animal TSE at the

<sup>39</sup> Interviews. Rome. 11-12 /1/99

Reference Centre for Animal Encephalopathies and precautionary measures for food and drugs and for scientific experiments with specified risk materials (see table 18).

At the end of 1998, it could be said that Italy had a formal regulatory framework sufficient to manage the BSE risk, and two working groups of experts on TSE. There were, however, two ambiguities in the actions of the public authorities. Firstly, there seemed to be a gap between the decision-making on regulatory measures and the enforcement of their application in the field. Secondly, most of the time, the expert groups on TSE seem to carry on their work “without questions”<sup>40</sup> from the public authorities and the political decisions were often without consultation with the working groups.

**Table 18.** Regulatory measures

Date	References	Contents of Italian measures
29/1/97	Ministerial Decree	Creation of a national surveillance Unit for animal TSE at the Reference Centre for Animal Encephalopathies
29/1/97	Ministerial Decree	Precautionary measures against BSE risk in infant food
14/2/97	Ministerial Decree	Precautionary measures concerning the commercialisation and clinical experiments in containing products of bovine origin
30/4/97	Ministerial Order	Prohibition of all proteins derived from animal tissues in feedstuffs of ruminants
4/8/97	Ministerial Decree	Measures of the sanitary policy of scrapie and BSE
15/6/98	Ministerial Order	Precautionary measures for the elimination of specified risk materials from cattle, sheep and goats

### Formal regulatory activity and implementation in practice

In 1996, measures to improve safety in the rendering industry were taken at the European level (96/449 ECC Directive) and translated at the Italian level (Ministerial Decree of 6/6/96). However, the report of DG XXIV to the European Parliament, after veterinary inspections in the member state countries underlined a gap between the formal rules regarding safety and their enforcement. The final report of a veterinary inspection mission of EEC<sup>41</sup> to Italy gives an overview of the situation one year after the October 1997 mission. The mission was carried out by two Veterinary Inspectors accompanied by National Expert and Representatives of the Italian Ministry of Health.

As announced by the Italian Administration, the guidelines for validation of the processing parameters had not yet been finalised but a first draft was planned to be presented by the Central Veterinary Services and discussed with representatives of the regions with a view to it being finalised at the end of 1998. With regard to controls in the plants, during the period April-August 1998 only eight plants operating pressure systems were visited by the central services of the Ministry of Health, because of the shortage of staff resources at central level to deal with issues related to animal waste. In two of these inspected plants deficiencies relating to safety devices were reported.

The European Veterinary Mission of 1998 visited one rendering plant in Lombardy, two in Emilia Romagna and one in the Lazio Region. The plant in the Lombardy Region had been authorised to process high risk material since July 1998, following the installation of new pressurised equipment in compliance with the requirements of the Directive. One of the authorisations for the two plants in Emilia Romagna had been withdrawn in December 1997. The plant management declared that improperly processed MBM stored in the plant (6000 tonnes) had been completely reprocessed. The plant in Lazio was equipped with a continuous system not appropriate to fulfil the processing requirements of decision 96/449/EC and was authorised only to process raw material other than That designated to be processed under the pressure standard. During the visit, the mission team observed that??? it was unavoidable that certain waste present in the in-take would be mammalian waste. The mission noted that, with the exception of one of the plants visited, the hygienic conditions were satisfactory, including, as far as possible, separate access and appropriate storage of the products.

If we compare the conclusions of the two missions, it can be seen that the implementation of the 96/449/EC was in progress. There is more transparency in administrative procedures and more co-ordination between the Central Administration and the Local Services.

<sup>40</sup> Interviews. Rome. 11-12 /1/99

<sup>41</sup> Final report with regard to certain protective measures against BSE implementation of Commission Decision 97/735/EC ; follow-up of previous mission on Commission Decision 96/449/EC and BSE surveillance ; National rules for SRM (14-18 september 1998).

## Conclusion. Lessons from the “ BSE saga ” in Italy

At the beginning of the BSE problem in the UK in 1987, the only people in Italy who were interested in the topic of BSE were the scientific actors based at the University or those doing clinical research who were interested, but no one was really worried about the potential risk to animal and human health. BSE was a new and interesting topic of discussion in relation to their research on human TSE or Scrapie. In 1989, they begin to discuss of BSE in term of a health risk to humans but discussions were only inside their scientific community and at the BSE sub-commission of the European Scientific Veterinary Committee. As in France, non of these researchers represented the majority point of view. Each of them tried to alert the public authorities as well as the European Commission to the risk of human infection, but the large uncertainty about the nature of the BSE agent added to the cumbersome administrative process meant that these warnings had no influence on the agenda setting of the public decisionmakers until the middle of 1989. The first regulatory measures taken by the Italian Government demonstrate that for the government the right answer to the BSE threat was to protect Italian cattle from contamination by British cattle and British feedstuffs. The year 1991, with the creation of a Reference Centre for Animal Encephalopathies, can be considered as the beginning of a constructive formal framework for the management of BSE, but the main preoccupation of the Public Authorities was still Scrapie rather than BSE.

In fact, until the scare following the two first cases of BSE in Italy in 1994 and the shock of the British announcement concerning nvC-JD in 1996, the action of the public decision was focused on the formal translation of European Directives into national measures, except for the ban on MBM in ruminant feedstuffs taken in 1989 in Italy and not until 1994 by the ECC (94/381/EC directive). The speed insertion of the European Directives into national regulations shows the trend in the public decision making process but at more of a formal level than a concrete one with regard to enforcement as was shown up by the European Veterinary missions on MBM. It was only in 1996 that a group of experts was officially appointed to work on nvC-J, but this working group was an extension of the expert committee on emergent diseases. In Italy, there is no specific independent expert committee on TSE.

The BSE crisis did not change the traditional relationships between Science and Politics in Italy. The Ministry of Health had its permanent organ of expertise within the Superior Institute of Health, but regulatory activity seems to have been disconnected with the activities of these experts. This did not mean that the experts worked completely independently of the public authorities and the committees were chaired by a member of the Ministry. The Central Administrations did not have the “ right ” information to make the “ right ” decision, especially in the case of infectious diseases. This statement of fact is somewhat balanced by the fact that the Superior Institute of Health is not only a technical consulting structure for the Ministry of Health but also a place of basic research open to other national and international centres of research.

The main institutional effect of the BSE crisis was an organisational innovation with the creation of a Reference Centre for Animal Encephalopathies and an organisational innovation that allowed the co-ordination of the regional Zooprophyllactical Institutes into a network of scrapie and BSE surveillance. However, it seems that the Surveillance Unit of the National Centre did not have sufficient resources to perform the tasks required by the Ministry of Health. The public management of the TSE risk, through these institutional and organisational answers, heightened the awareness of the central Administration to the necessity to increase the resources for training, surveillance and research on TSE. However, with the resources available to the research programmes on TSE the effective organisation of BSE and Scrapie epidemiosurveillance only began in 1997 and a national program on TSE risk analysis started only in 1998. However, as shown by a Scientometrics study in Italy, there have been researchers in the field of TSE with a good international visibility from 1986 and some of whom have connections with the Collinge Network in UK.

In Italy, the main institutional actor in the management of the BSE problem was the Ministry of Health due to the fact that the animal and human health sectors fell under the same Ministry. Thus, in Italy, researchers in human health and researchers in animal health cooperate more readily than in France, for example.

Veterinarians and physicians belong to the same professional organisation and researchers in human health play a central role in helping epidemiologists and veterinarians to manage the surveillance of TSE. Their research work and their international collaborations give them credibility as well as scientific as technical expertise and the co-operation between the professions has been easy at both the national and European levels.

Unlike the situation in France, in Italy the Ministry of Agriculture did not have a part to play during the BSE crisis. It dealt purely with agricultural products. The fact that human health, animal health and food safety come under the authority of one Ministry makes the co-ordination between actors more efficient, especially with regard to the debate over the management of BSE threat and TSE epidemiosurveillance. Even if the BSE crisis did not radically change the system of public decisionmaking with regard to the organisation of research and in matter of utilising available expertise, it provided the opportunity for more cooperation between central

administration and the local services in a country that historically has resisted centralised control for a long time.

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### Web sites

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- <http://www.Ceses.org/eurosurv/el-6.htm> - Eurosurveillance
- <http://www.europa.eu.int/eur.lex> - Journal officiel des Communautés Européennes
- <http://europa.eu.int/comm/dg24/health/sc> :
- <http://www.ital.com:italy/constitu/>
- <http://www.sanita.interbusiness.it/sanita/organizz.htm>
- <http://www.politiche agricole.it> – Ministero per le Politiche Agricole
- <http://www.sanita.it/> - Ministero della Sanita
- <http://ministero.izs.it>
- <http://to.izs.it>
- <http://www.iss.it/> - Istituto Superiore di Sanita
- <http://www.iss.it/> - Laboratorio di Epidemiologia e biostatistica
- <http://www.iss.it/> - Laboratorio di Medicina veterinaria
- <http://www.iss.it/> - Laboratorio di Virologia

**Appendix 1. Scientometrics test on Medline data base 1986-1997****Numbers of publications by researcher on TSE**

242	PRUSINER-SB
119	BROWN-P
115	GAJDUSEK-DC
86	TATEISHI-J
81	LIBERSKI-PP
79	KITAMOTO-T
71	DEARMOND-SJ
58	COLLINGE-J
57	HOPE-J
52	GIBBS-CJ JR
50	CARP-RI
47	FRASER-H
45	WELLS-GA
42	GOLDFARB-LG
42	POCCHIARI-M
42	WILL-RG
41	TAYLOR-DM
39	IRONSIDE-JW
39	WILESMITH-JW
38	CAUGHEY-B
38	DORMONT-D
36	AGUZZI-A
36	GROTH-DF
36	KRETZSCHMAR-HA
34	COHEN-FE
32	DIRINGER-H
32	HUNTER-N
32	RUBENSTEIN-R
32	TAGLIAVINI-F
32	WEISSMANN-C
31	WISNIEWSKI-HM

## **Appendix 2. BSE Investigation in Italy**

### **I - Guideline for the interviews in Italy**

#### 1. Identity of the interviewee

- Trajectory and function of the interviewee
- Position and role in relation to the management of the BSE crisis in Italy (scientist, expert, decision-maker, etc.)
- Other actors, organisations, or institutions with whom there is cooperation in relation BSE, and what they do?

#### 2. General organisation of human and animal health in Italy

- Main actors
- Legal context
- Interactions between central level and local level

#### 3. The unfolding of the BSE crisis

- Facts (N. of BSE cases, quantitative data about imported meatbone meal/national production and imported cattle)
- Government actors, Expert committees, researchers involved in the management of the crisis
- Scientific production (shared knowledge and controversial issues)
- Laws, decrees, administrative measures
- Epidemiosurveillance
- Social mobilisation (professional associations, environmental organisations, consumers associations, etc.)
- Media coverage

#### 4. Consequences of the BSE crisis

- European-wide decisions and national decisions
- Institutional changes in the animal and human health sector
- Legal production, laws, decrees
- Main political sanitary/health measures
- New research programmes
- Scientific cooperations (interorganisms, interdisciplines, intercountries)
- Epidemiological networks

## **II - Interviews**

- Pr G. Poli

- Dr P. Dall'Ara

Istituto de microbiologia e immunologia veterinaria. Universita degli Studi di Milano

- Pr F. Guarda

Centro di Patologia Comparata. Dipartimento di Patologie animale. Universita da Torino

- Dr M. Caramelli

- Dr E. Bozzetta

- Dr G. Ru

Centro di Referenza Nazionale per le encefalopatie animali et neuropatologie comparate. (CEA) Torino

- Dr U. Agrimi

- Dr G. Brambilla

Laboratorio di Medicina veterinaria . Istituto Superiore di Sanita. Roma

- Pr M. Pocchiari.

Laboratorio di Virologia. Istituto Superiore di Sanita. Roma

- Dr A. Ferrara.

Ministero della Sanita. Dipartimento degli Alimenti e della Nutrizione et della Sanita Publica Veterinaria.  
Ufficio VI. Roma.

## **III – Other data collected**

- The Italian and the European regulatory production on TSE from 1986 to 1998

- Scientometrics study conducted by M. A de Looze

- Epidemiological data given by the Reference Centre for Animal Encephalopathies of Turin.

### Appendix 3. BSE European Directives 1989 - 1998

#### 1989-1990

Date	Directive N°	Content of European Directives
28/7/1989	89/469	Ban on live imported cattle born before 18/7/88 or born after this date of dairy cows suspected of or confirmed with BSE. Amendments to the directive 64/432/EEC about the sanitary certificate concerning intra-EEC trade of cattle .
7/2/1990	90/59	Following the advice of the Permanent Veterinary Committee, modification to the 89/469 directive Ban on live imported cattle from the UK older than 6 months or born dairy cows suspected of or confirmed with BSE. Cattle imported from UK must be slaughtered before 6 months of age
6/3/1990	90/134	Registration of Scrapie and BSE as a notifiable infectious disease (extension of the 82/894/EEC directive).
9/4/1990	90/200	Every head of cattle suspected of BSE during the examination <i>ante mortem</i> must be slaughtered separately and the brains analysed. In case BSE is confirmed , carcasses and offal must be destroyed. Ban of exports, from UK to other European states members of: - tissues and organs (brains, spinal cord, thymus, tonsils, spleen, intestine) from cattle slaughtered after 6 months - bovine placenta, bovine cells culture, bovine foetus serum, lymphoid tissues, pancreas, ovaries, testicles, suprarenal glands, pituitary gland.
8/6/1990	90/261	Modification to 89/469 EEC directive. Live imported cattle from UK younger than 6 months must be tattooed in order to confirm they are free of BSE. All bovine carcasses exported from the UK must be free from BSE and have a microfiche identification .
26/6/1990 (European Council)	90/425	Veterinary and zootechnical controls must be enforced in each State Member country on live animals at the farm and the appropriate sanitary certificates must be issued by a veterinarian appointed by the competent authorities. The State members importing live cattle must check the conformity of the papers (identification etc..) with the directives and isolate any animals that do not comply with the rules.

#### 1991-1993

Date	Directive N°	Content of European Directives
5/2/1991	91/89	Following the recommendation of the Permanent Veterinary Committee, financial support of the EEC for a research programme to make a comparative study of scrapie strains coming from different State Members
14/5/1992	92/290	Ban on trade in bovine embryos coming from cows suspected of or confirmed with BSE between EEC State Members. Ban on exports of UK bovine embryos from cows born before 18/7/1988., or from cows suspected or confirmed of BSE
30/7/1992	92/450	Following the recommendation of the Permanent Veterinary Committee, every BSE outbreak from 31.12.87???in the European Community must be registered

#### 1994-1995

Date	Directive N°	Content of European Directives
27/6/1994	94/38	Following the recommendation of the Permanent Veterinary Committee, ban of using proteins derived from mammals for the feeding of ruminants
7/7/1994	94/381	Technical norms of conversion of ruminants produce into meals
27/7/1994	94/474	Repeal of 89/469 and 90/200 directives Ban of export from UK bovine meat except if younger than 6 months or born outside UK and import in UK after 1/1/91
14/12/1994	94/794	Modification of decision 94/474 ECC about bovine meat. Authorisation to export from UK, bovine meat coming from animals born after 1/1/92 or coming from farms without BSE since 6 years. Authorisation to export from UK, only bovine boned meat if one above condition is fulfilled.
13/2/1995	95/29	Modification of 94/381 directive. About technical norms and accreditation of heating system for conversion of ruminants produce into meals and BSE agent inactivation
6/3/1995	95/60	.Modification of the 94/38 ECC directive, about safety concerning derived products (milk, gelatine, fatbone, blood products) and technical process of inactivation of pathogen agents

18/7/1995	95/287	Modification of decision 94/794 ECC about export bovine meat from UK. The sanitary certificate of exported bovine meat must notify : animals slaughtered before 2 ,5 years old and coming from farms without BSE since 6 years ; or, if one above condition is fulfilled, bovine boned meat without nervous and lymphatic tissues
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**1996**

Date	Directive N°	Content of European Directives
27/3/1996	96/239	Following the recommendation of the Permanent veterinary Committee, ban of import ,from UK to State Members and other countries, of live cattle, meat of cattle, bovine sperm and embryos, meat products from cattle and mammalian-derived meatbone meals. UK must send each two months a report to the Commission about the safety measures taken against BSE
11/6/1996	96/362	Modification of 96/239 directive. Ban of all bovine meat and bovine derived produce coming from UK , used in animal and human food industry, in cosmetic and pharmaceutical sector
20/6/1996	96/381	Safety measures against BSE in Portugal
24/6/1996	96/385	Agreement of the UK plan of BSE eradication presented in June 1996
18/7/1996	96/449	Extension of technical norms of inactivation of BSE non conventional transmissible agent
16/12/1996	97/18	Agreement of the French plan of BSE eradication presented in July 96

**1997-1998**

Date	Directive N°	Content of European Directives
12/5/1997	97/312	Agreement of the Irish plan of BSE eradication presented in May 97
16/12/1997	97/870	Modification of 96/385 directive. Scrapped animals after 1/2/97 are covered by the UK BSE eradication plan.
15/12/1997	98/12	Repeal of 92/450 directive. Each BSE outbreak in the European Community must be registered until 31/12/2002
16/3/98 (European Council)	98/256	Modification of 94/474 directive and repeal of 96/239 directive. Urgent safety measures against BSE concerning technical process and using of all bovine produce coming from animals slaughtered in and out UK
22/7/1998	98/477	Recommendations about information having to be sent to the Commission by each State Member about :structure of bovine, ovine and caprine population ; animals trade ; feedstuffs ; ban of meat-bone meals ; ban of bovine specified offals and specified risk materials ; ESST Epidemiosurveillance ; Rendering industry ; Slaughtering in relation with scrapie and BSE
7/10/1998	98/564	Modification of 98/256 directive. Following the advice of the Permanent Veterinary Committee. Authorization for the Veterinary Laboratory Agency of Weybridge to send samples of BSE bovine tissues to other certified laboratories outside UK in order to do reseach , experimentations and diagnosis tests.
18/11/1998	98/653	Urgent safety measures against BSE in Portugal

**Appendix 4 . Italian regulatory measures 1989 - 1998**

Date	References	Content of Italian measures
12/8/1989	Ministerial Circular N° 6770 –	Ban of lived imported cattle born before 18/7/88
5/11/1989	Ministerial Circular N° 9076	Ban of imported meatbone meals from Ireland and the UK
21/4/1990	Ministerial Circular N° 2683	Surveillance norms of BSE on live animals, examination ante mortem and clinical diagnosis
13/6/1990	Ministerial Circular N° 4207	Limitation of bovine carcasses imported from UK
11/7/1990	Ministerial Circular N° 4910 –	Monitoring programm for slaughtering based on division between safe and BSE suspected animals.

Date	References	Contents of Italian measures
10/5/1991	Ministerial Order	Inscription of Scrapie and BSE as infectious disease and as obligatory notification
7/6/1991	Ministerial Decree	Measures of control of cosmetical and pharmaceutical products containing bovine tissues
3/8/1991	Ministerial Decree	Creation of the National Center of References
6/8/1991	Ministerial Order	Norms of protection concerning imported live animals and all derived products made from animals.

Date	Reference	Contents of Italian measures
28/7/94	Ministerial Order	Ban of using proteins derived from mammals for the feeding of ruminants
29/8/94 9/9/94	Ministerial Circulars n°5706 n°5698	Control of meat exported from UK
20/1/95	Ministerial Circular n° 478	Adoption of decision 94/474 ECC (see table 5) about bovine meat imported in Italy
30/3/95	Ministerial Order	Modification of the ministerial ruling of the 28/7/94. Safety measures concerning derived products (milk, gelatine, fatbone, blood products) and technical process of inactivation of pathogen agents
15/9/95	Ministerial Circular n° 5561	Adoption of the modification of decision 94/794 ECC (see table 5) about bovine meat

Date	References	Contents of Italian measures
29/3/96	Ministerial Circular n°2244	Prohibition of import from UK of live cattle, meat of cattle, meat products from cattle and mammalian-derived meatbone meals
16/4/1996	Ministerial Circular n°2666	Precautional measures concerning cattle and meat imported from France
3/5/96 6/6/96 8/5/96 14/6/96	Ministerial Decrees	Technical norms of inactivation of BSE non conventional transmissible agent (WHO norms) Precautional measures concerning cosmetics and drugs done with products of bovine origin Sanitary norms for the gelatine production intended to the human consumption
25/6/96	Ministerial Circular n° 4566	Precautional measures concerning cattle and meat imported from Switzerland
1/10/96	Ministerial Circular n° 2634	Monitoring program BSE and co-ordination sanitary regional services and Ministry of health
21/10/96	Law n° 532	Creation of Local Health Units
30/10/96	Ministerial circular n° 7511	Prohibition of import from Switzerland of live cattle, bovine embryos, meat of cattle, meat products from cattle and mammalian-derived meatbone meals, except for fresh meat without bones coming from farms without BSE since 6 years ago
24/12/96	Ministerial circulars n° 8919 n° 8920	Prohibition of all bovine products import from Switzerland, except for hides if they are not used in human dietary and feedstuffs Prohibition of all bovine products coming from Portugal, France, Ireland and UK

Date	References	Contents of Italian measures
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29/1/97	Ministerial Decree	Creation of a national surveillance Unit for animal TSE at the Reference Centre for Animal Encephalopathies
29/1/97	Ministerial Decree	Precautional measures against BSE risk in infant food
14/2/97	Ministerial Decree	Precautional measures concerning the commercialisation and clinical experiments of drugs containing products of bovine origin
30/4/97	Ministerial Order	Prohibition of all proteins derived from animal tissues in feedstuffs of ruminants
4/8/97	Ministerial Decree	Measures of the sanitary policy of scrapie and BSE
15/6/98	Ministerial Order	Precautional measures for elimination of specified risk materials from cattle, sheep and goats