

Basic information	
1998/0323(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	Procedure completed
Prevention, control and eradication of certain transmissible spongiform encephalopathies (TSEs) Amended by 2003/0046(COD) Amended by 2004/0270(COD) Amended by 2004/0270B(COD) Amended by 2008/0030(COD) Amended by 2013/0140(COD) Subject 3.10.08.05 Animal diseases 4.60.04.04 Food safety	

Key players			
European Parliament	Committee responsible		Rapporteur
	ENVI Environment, Public Health, Consumer Policy		ROTH-BEHRENDT Dagmar (PSE)
	Former committee responsible		Former rapporteur
	ENVI Environment, Public Health and Consumer Protection		ROTH-BEHRENDT Dagmar (PSE)
	Former committee for opinion		Former rapporteur for opinion
	AGRI Agriculture and Rural Development		BÖGE Reimer (PPE-DE)
Council of the European Union	Council configuration		Date
	Agriculture and Fisheries		2000-12-19
	Agriculture and Fisheries		2000-06-19
	Education, Youth, Culture and Sport		2001-02-12
European Commission	Commission DG		Commissioner
	Health and Food Safety		

Key events			
Date	Event	Reference	Summary
07/01/1999	Legislative proposal published	COM(1998)0623 	Summary
28/01/1999	Committee referral announced in Parliament, 1st reading		
18/04/2000	Vote in committee, 1st reading		Summary
18/04/2000	Committee report tabled for plenary, 1st reading	A5-0117/2000	
16/05/2000	Debate in Parliament		
17/05/2000	Decision by Parliament, 1st reading	T5-0219/2000	Summary
19/06/2000	Debate in Council		Summary
12/12/2000	Modified legislative proposal published	COM(2000)0824 	Summary
19/12/2000	Debate in Council		Summary
12/02/2001	Council position published	14780/1/2000	Summary
14/02/2001	Committee referral announced in Parliament, 2nd reading		
10/04/2001	Vote in committee, 2nd reading		Summary
10/04/2001	Committee recommendation tabled for plenary, 2nd reading	A5-0118/2001	
02/05/2001	Debate in Parliament		
03/05/2001	Decision by Parliament, 2nd reading	T5-0220/2001	Summary
22/05/2001	Final act signed		
22/05/2001	End of procedure in Parliament		
31/05/2001	Final act published in Official Journal		

Technical information	
Procedure reference	1998/0323(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
Amendments and repeals	Amended by 2003/0046(COD) Amended by 2004/0270(COD) Amended by 2004/0270B(COD) Amended by 2008/0030(COD) Amended by 2013/0140(COD)
Legal basis	EC Treaty (after Amsterdam) EC 152 Rules of Procedure EP 050
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/5/13393

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee report tabled for plenary, 1st reading/single reading		A5-0117/2000 OJ C 059 23.02.2001, p. 0004	18/04/2000	
Text adopted by Parliament, 1st reading/single reading		T5-0219/2000 OJ C 059 23.02.2001, p. 0070-0093	17/05/2000	Summary
Committee recommendation tabled for plenary, 2nd reading		A5-0118/2001	10/04/2001	
Text adopted by Parliament, 2nd reading		T5-0220/2001 OJ C 027 31.01.2002, p. 0019-0038 E	03/05/2001	Summary

Council of the EU

Document type	Reference	Date	Summary
Council position	14780/1/2000 OJ C 088 19.03.2001, p. 0001	12/02/2001	Summary

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(1998)0623 	07/01/1999	Summary
Modified legislative proposal	COM(2000)0824  OJ C 120 24.04.2001, p. 0089 E	12/12/2000	Summary
Commission communication on Council's position	SEC(2001)0241 	13/02/2001	Summary
Follow-up document	COM(2003)0546 	19/09/2003	Summary

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES0703/1999 OJ C 258 10.09.1999, p. 0019	07/07/1999	
EU	Implementing legislative act	32003R0260 OJ L 037 13.02.2003, p. 0007-0011	12/02/2003	Summary
EU	Implementing legislative act	32003R0650 OJ L 095 11.04.2003, p. 0015-0016	10/04/2003	Summary
EU	Implementing legislative act	32003R1053 OJ L 152 20.06.2003, p. 0008-0009	19/06/2003	Summary
		32003R1874		

EU	Implementing legislative act	OJ L 275 25.10.2003, p. 0012-0013	24/10/2003	
EU	Implementing legislative act	32003R2245 OJ L 333 20.12.2003, p. 0028-0033	19/12/2003	
EU	Implementing legislative act	32004R0836 OJ L 127 29.04.2004, p. 0048-0049	28/04/2004	Summary
EU	Implementing legislative act	32006R0546 OJ L 094 01.04.2006, p. 0028-0031	31/03/2006	Summary
EU	Implementing legislative act	32006R0657 OJ L 116 29.04.2006, p. 0009-0013	10/04/2006	Summary
EU	Implementing legislative act	32006R1041 OJ L 187 08.07.2006, p. 0010	07/07/2006	Summary

Additional information		
Source	Document	Date
European Commission	EUR-Lex	

Final act
Regulation 2001/0999 OJ L 147 31.05.2001, p. 0001 Summary

Prevention, control and eradication of certain transmissible spongiform encephalopathies (TSEs)

1998/0323(COD) - 19/09/2003 - Follow-up document

The Commission has presented its working document with regard to the state of play on the prohibitions to feed animal protein to farmed animals to prevent transmissible spongiform encephalopathies. In this document, the Commission recalls Council Decision 2000/766/EC of 4 December 2000 concerning certain protection measures with regard to transmissible spongiform encephalopathies (TSE) and the feeding of animal protein lays down the extended feed ban as a transitional measure for the implementation of Regulation 999/2001/EC of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (the TSE Regulation). The Council and the European Parliament have recently adopted a proposal to extend the TSE transitional measures until 30 June 2005, due to certain delays in the bovine spongiform encephalopathy (BSE) categorisation of countries. However, in order to clarify the legal situation as regards this ban, and because it is appropriate to maintain an extended feed ban regardless of the future BSE status of the Member States, a proposal to introduce the current measures into Annex IV of the TSE Regulation received a favourable opinion at the Standing Committee on the Food Chain and Animal Health of 17 June 2003 and is now in the process of adoption. It will apply from 1 September 2003. When appropriate, the specific provisions relating to the feed ban will be reconsidered, in particular regarding the use of fishmeal, in the light of new scientific developments, the availability of reliable tests, improved control measures in the Member States and, where appropriate, the outcome of a risk assessment.

Prevention, control and eradication of certain transmissible spongiform encephalopathies (TSEs)

1998/0323(COD) - 12/12/2000 - Modified legislative proposal

In this amended proposal for a Council Regulation laying down rules for the prevention and control of certain transmissible spongiform encephalopathies, the Commission accepted 40 of the European Parliament's 51 amendments in full, in part or after reformulation. Against this background, the main changes to the original proposal relate to the following: - comitology: the originally proposed use of the management procedure for adopting implementing measures has been replaced by the regulatory procedure in accordance with Council Decision 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission; - epidemio-surveillance and use of rapid tests for the detection of TSEs: one of the main issues raised by the European Parliament relates to a wider but responsible use of rapid post-mortem tests and this has been acknowledged in the amended proposal. The need to define all ruminant fallen stock (dead-on-farm animals) as BSE suspect animals, has been debated. The amended proposal extends the definition of suspect animals to include only those fallen and emergency slaughtered animals that have tested positive in the monitoring programme is seen as a balanced and justified public health measure. The definition of suspect animals requested by the Council is also clarified. Furthermore, a definition of the rapid diagnostic test has been introduced. However, the text has been slightly reformulated to create the possibility for delegating the evaluation, not the approval, of such tests to an external body if such a need would arise in future. A further important principle when laying down rules for the use of rapid tests, is their statutory approval for each distinct purpose by the Commission through a regulatory procedure. This condition following good legal practice has been introduced in all articles referring to rapid, diagnostic tests, rather than both its definition and the related articles as requested by the European Parliament. Finally, other amendments relate to the monitoring of TSEs providing for use of the rapid tests in the annual monitoring programmes, and of implementing rules reinforcing the protocol for confirming the disease by laboratory tests; - classification of countries according to BSE status: the amended proposal now more clearly recognises the relevance of the BSE criteria and risk factors recommended by the OIE. Moreover, a link has been established with the results of the annual monitoring programme by use of the rapid test and the possibility has been created to require statistically valid large-scale sampling in those circumstances where doubt exists on the BSE status of countries; - specified risk material (SRM): a review under a comitology procedure of the age limits for SRM (i.e the animal tissues being most at risk of harbouring the agent) removal in view of the statistical probability of the occurrence of BSE in the slaughter population has been introduced. However, the restraint of an annual review and the proposed deadline for the first review of 01.01.2001 has been changed into 'regular' reviews. The principles of granting derogations from the provisions on SRM removal in high risk areas and for taking account of an effective feed ban, is brought under co-decision; - feed ban: the extension of the feed ban has been brought under the comitology procedure but the text in the Annex has been reformulated to allow for extending the feed ban regardless of BSE status of the country concerned. Another amendment ensures that the feed ingredients banned for feeding are also not stored, dispatched or imported. Finally, it is proposed to derogate gelatine derived from hides and skins from the ban, but to extend the ban to feeding bovine blood products to ruminants; - disease eradication: a requirement has been added providing for an obligation for the Member States to inform the Commission of all TSE suspect cases on a regular basis. Furthermore, the European Parliament's amendments suggesting whole herd slaughter for BSE in cattle have been taken into account on condition that derogation is possible in those cases where the Commission under a Comitology procedure has approved equivalent measures; - conditions for marketing animals: the duration of the 'scrapie-free' period has been extended; - various: these amendments include an exception from the ban on certain slaughter techniques only granted in BSE free countries and finally, live animals for research have been excluded from the scope of the proposal.

Prevention, control and eradication of certain transmissible spongiform encephalopathies (TSEs)

1998/0323(COD) - 10/04/2006 - Implementing legislative act

ACT: Commission Regulation 657/2006/EC amending Regulation 999/2001/EC of the European Parliament and of the Council as regards the United Kingdom and repealing Council Decision 98/256/EC and Decisions 98/351/EC and 1999/514/EC.

CONTENT: this Decision repeals Decision 98/256/EC, prohibiting the export, from the United Kingdom, of live cattle and products derived from cattle slaughtered in the United Kingdom, which are liable to enter the food or feed chain or which are destined for use in cosmetics or medical/pharmaceutical products.

The ban on the export of UK beef was issued in March 1996, due to the high incidence of BSE cases in the UK at the time. The provisions of this Decision state that the UK will be able to export live cattle born after 1 August 1996, and bovine meat and products produced after 15 June 2005, under the same terms as other Member States.

The export ban on UK cattle, their meat and products, has been in place since March 1996. In 1999, the ban was amended to allow de-boned beef and beef products from the UK produced under the Date-based Export Scheme (DBES) to be exported. Under the DBES, the UK could export beef and products from cattle born after 1 August 1996, subject to a series of strict and limited conditions. These included requirements that the animal was between 6 and 30 months old, had been clearly traced and identified throughout its lifetime, its mother did not develop BSE, and that beef from cattle older than 9 months was de-boned.

In proposing to end the ban, the Commission laid out very clear conditions which had to be met before the restrictions on UK beef exports could be lifted. Firstly, the UK would have to have a BSE incidence below 200 cases per million animals, and secondly, the EU Food and Veterinary Office (FVO) would have to deliver a favourable report on the enforcement of BSE controls in the UK and its compliance with EU legislation in this field.

The European Food Safety Authority (EFSA) issued an Opinion in May 2004, confirming that BSE incidence in the UK was below 200 cases per million, and therefore not anymore considered a high BSE risk country. In June 2005, an inspection carried out by the EU Food and Veterinary Office confirmed that BSE controls were being properly enforced in the UK, and that its compliance with EU legislation, particularly in relation to identification and registration of bovine animals and testing, was satisfactory.

In the interest of clarity and coherence the following Decisions have also been repealed: Commission Decision 98/351/EC setting the date on which dispatch from Northern Ireland of bovine products under the Export Certified Herds Scheme may commence; Council Decision 98/256/EC and Commission Decision 1999/514/EC setting the date on which dispatch from the United Kingdom of bovine products under the date-based export scheme may commence.

ENTRY INTO FORCE: 2 May 2006.

Prevention, control and eradication of certain transmissible spongiform encephalopathies (TSEs)

1998/0323(COD) - 19/06/2003 - Implementing legislative act

ACT: Commission Regulation 1053/2003/EC amending Regulation 999/2001/EC of the European Parliament and of the Council as regards rapid tests.

CONTENT: the purpose of this implementing legislative act is three-fold. Firstly, to change the reference to the Greek "national reference laboratory" for the monitoring and carrying out of tests on transmissible spongiform encephalopathy (TSE's). Secondly, one of the companies authorised to test for TSE's under the terms of Regulation 999/2001, has informed the Commission of its intention to market its test under a new trade name. Thirdly, the Scientific Steering Committee has recommended the inclusion of two new tests for monitoring bovine spongiform encephalopathy (BSE). The producers of both tests have provided enough data to conclude that their tests may also be used for the monitoring of TSE in sheep. In order to ensure a high level of performance after approval of a test, a new procedure has been laid down for possible modifications to the test or the test protocol.

Bearing the above in mind, the Commission has amended Annex X of Regulation 999/2001. The amended Annex now includes new reference details for the authorised Greek national laboratory. Further, Chapter C on "Rapid Tests" has been modified so as to include the new testing methods. As far as the new procedure is concerned the following shall apply.

The producer of the rapid tests must have a quality assurance system in place agreed by the Community reference laboratory which ensures that the test performance does not change. The producer must provide the test protocol to the Community reference laboratory. Modifications to the rapid test or to the test protocol may only be made following advance notification to the Community reference laboratory and provided that the Community reference laboratory finds that the modification does not reduce the sensitivity, specificity or reliability of the rapid test. The findings shall be communicated to the Commission and to the national reference laboratories.

ENTRY INTO FORCE: 10 July 2003.

Prevention, control and eradication of certain transmissible spongiform encephalopathies (TSEs)

1998/0323(COD) - 13/02/2001 - Commission communication on Council's position

The Commission supports the common position by the Council, which has been adopted by unanimity by the Council. The Commission notes that the common position accepts a large majority of the amendments adopted by the European Parliament and includes in its amended proposal. One of the amendments not respected fully concerns the scrapie trade provisions on which the Council is divided. The Commission accepted in its first reading to reinforce the scrapie trade rules as requested by the European Parliament. But the Presidency text contains a compromise presenting only a slight reinforcement from the current rules (3 instead of a 2-year statutory scrapie freedom for flocks or origin) together with recognition of national eradication programmes. The absence of either scientific or international guidance on scrapie prevention renders this compromise an acceptable temporary solution. Future adoption of implementing rules on scrapie on the basis of this Regulation will assure quick implementation of new scientific advice or the draft OIE scrapie Code to be presented for adoption in May 2001. The Commission can accept the Presidency compromise in view of the importance of having the legal base created enabling speedy future action on scrapie.

Prevention, control and eradication of certain transmissible spongiform encephalopathies (TSEs)

1998/0323(COD) - 12/02/2001 - Council position

Whilst sharing the approach and objectives proposed by the Commission and endorsed by the European Parliament, the Council found it necessary in drawing up its common position to make certain changes, to both the substance and the form of the proposal for a Regulation. In making these changes, the Council wished in particular to : - make the wording more precise and more consistent, and thus improve the legal clarity of the text; - introduce provisions aimed at managing intra-Community trade and imports, and if necessary exports, which would comply with the OIE's recommendations, so as to honour the Community's WTO commitments; - update the texts containing the measures decided on under the safeguard clause; - specify the scope of certain provisions adopted in the context of the said measures. The main amendments made to the Commission proposal concern : - the inclusion of all the provisions currently in force as safeguard measures (particularly the elimination of specified risk material) and the main recommendations adopted in May 2000 by the OIE, especially the country classification criteria (5 categories) in terms of the incidence of BSE. The Council also provided for transitional measures enabling the application of measures laid down in the new regulation to be modulated. Finally, the Council integrated into the text all the provisions to be applied with regard to scrapie. With regard to the Council's position on the European Parliament's amendments, it endorsed virtually all of the amendments accepted by the Commission. Furthermore, the Council responded to the demands of public health and consumer policy by making provision for a compulsory test on all bovine animals aged over 30 months and by amending the inspection provisions applicable. On the other hand, the amendments not incorporated into the common position relate to rapid diagnostic testing, a country or region presenting "no" risk is hard to envisage, therefore the Council has retained the reference to the "lowest risk". Also, the an extension of

the period required for confirming a case of scrapie from 2 to 6 years was not justified. Pending a review of this period by the OIE, the Council extended the period to 3 years. Lastly, the Council considers that its common position, which includes the amendments set out above, takes extensive account of the European Parliament's opinion at first reading and represents a balanced solution which responds to the expectations of operators and consumers and which aims to allow for more satisfactory implementation by the national authorities, particularly as regards controls. It should be allowed for better management of the BSE crisis in the Union and restore consumer confidence.

Prevention, control and eradication of certain transmissible spongiform encephalopathies (TSEs)

1998/0323(COD) - 19/12/2000

On 4 December 2000, the Council stated its determination to reach agreement (with a view to a common position) before the end of the year on the draft overall Regulation on TSE which would incorporate all the measures already adopted at Community level to combat BSE. Today, the Council took a favourable political stance on the texts: - laying down rules for the prevention and control of certain transmissible spongiform encephalopathies and - amending Directive 91/68/EEC as regards scrapie. Furthermore, it instructed the Council General Secretariat to finalise the texts, in accordance with the relevant procedure, so that its meeting in January 2001, it could adopt a common position for forwarding to the European Parliament.

Prevention, control and eradication of certain transmissible spongiform encephalopathies (TSEs)

1998/0323(COD) - 31/03/2006 - Implementing legislative act

ACT: Commission Regulation 546/2006/EC implementing Regulation 999/2001/EC of the European Parliament and of the Council as regards national scrapie control programmes and additional guarantees and derogating from certain requirements of Decision 2003/100/EC and repealing Regulation 1874/2003.

CONTENT: Regulation 999/2001 provides for the approval of "national scrapie control programmes" in cases where a Member State is likely to have a low prevalence, or indeed absence of scrapies on its territory. In addition, those Member States whose national scrapie programmes have been approved may derogate from Commission Decision 2003/100/EC. This Decision lays down minimum requirements for the establishment of breeding programmes for resistance to transmissible spongiform encephalopathies in sheep.

In 2003, the Commission approved the national scrapie control programmes for Denmark, Sweden and Finland on the basis that they can all prove a low prevalence of, or indeed absence of, scrapies on their territories. On the basis of this approval the Commission also granted Denmark, Sweden and Finland permission to derogate from the breeding programme established in Decision 2003/100/EC. Further, provisions on additional guarantees relating to holdings, official movement restrictions and derogations from the requirement to establish a breeding programme, have also been spelt out in implementing Regulation 1874/2003.

In November 2005, the Commission approved a similar "national scrapie control programme" for Austria based on the fact that it too can prove a low prevalence or absence of scrapies on its territory. Similarly, on the basis of that national scrapie control programme Austria has been granted a derogation from the breeding programme provided for in Commission Decision 2003/100/EC. Accordingly, trade guarantees required by Annex VIII, Chapter A and Annex IX, Chapter E of Regulation 999/2001/EC have been amended.

However, for practical reasons and in the interest of clarity, the Commission has decided to repeal Commission Regulation 1874/2004 and replace it by the present Regulation. Effectively, the new Regulation states that the national scrapie control programmes of Denmark, Sweden, Finland and Austria have been approved. Additional provisions relating to:

- the actual approval of national scrapie control programmes,
- additional guarantees relating to holdings,
- official movement restrictions and
- derogations from the requirement to establish a breeding programme,

have been included in this Regulation.

ENTRY INTO FORCE: 21 April 2006.

Prevention, control and eradication of certain transmissible spongiform encephalopathies (TSEs)

1998/0323(COD) - 10/04/2003 - Implementing legislative act

ACT: Commission Regulation 650/2003/EC amending Regulation 999/2001/EC of the European Parliament and of the Council as regards the import of live ovine and caprine animals.

CONTENT: this implementing act has been introduced following the introduction of new Community rules for the eradication of scrapies following confirmed cases in a small ruminant holding. To recall, the Commission changed the rules for intra-Community trade in breeding sheep in order to remove scrapie-related restrictions from trade in sheep of the ARR/ARR prion protein genotype. Similarly, rules for the import of live ovine and caprine animals were amended in Annexes VII, VIII and XI.

The specific purpose of this act is to amend Annex IX of Regulation 999/2001 to allow this Annex to become compatible with the new rules. More specifically speaking, Regulation 999/2001 and Chapter E of Annex IX on the "Import of ovine and caprine animals" now states that: as from 1 October 2003 the import of ovine and caprine animals into the Community will be subject to the presentation of an animal health certificate. This certificate must certify that animals were born in and continuously reared on holdings in which a case of scrapie has never been diagnosed. In the case of ovine and caprine animals for breeding they must now satisfy certain specific requirements stated elsewhere in the Annexes. Alternatively, the certificate must certify that the sheep being imported are of the ARR/ARR prion protein genotype and come from a holding where no case of scrapie has been reported in the last six months.

ENTRY INTO FORCE: 1 May 2003. It applies as from 1 October 2003.

Prevention, control and eradication of certain transmissible spongiform encephalopathies (TSEs)

1998/0323(COD) - 07/07/2006 - Implementing legislative act

ACT : Commission Regulation 1041/2006/EC amending Annex III to Regulation 999/2001/EC of the European Parliament and of the Council as regards monitoring of transmissible spongiform encephalopathies in ovine animals.

CONTENT : Regulation 999/2001/EC lays down rules for the monitoring of transmissible spongiform encephalopathies (TSE) in ovine animals.

On 8 March 2006, a panel of experts on TSEs in small ruminants, chaired by the Community Reference Laboratory for TSEs (CRL), confirmed that bovine spongiform encephalopathy (BSE) in those animals cannot be excluded following the results of the second stage of discriminatory testing of brain samples of two sheep from France and one sheep from Cyprus. Further testing is required in order to exclude the presence of BSE in such animals.

In April 2002, the former Scientific Steering Committee of the European Commission (SSC) adopted an opinion on safe sourcing of small ruminant materials should BSE become likely in small ruminants. In its opinion of November 2003, the Scientific Panel on Biological Hazards of the European Food Safety Authority (EFSA) endorsed the recommendations of the SSC opinion with regard to the TSE-related safety of certain small ruminant products.

The significance of those TSE cases in France and Cyprus, where the presence of BSE cannot be excluded should be assessed. In order to do so, the results of an increased monitoring of TSEs in sheep is essential. Therefore, and in line with the SSC and EFSA opinions, the monitoring of sheep should be extended in order to improve the Community eradication programmes. Those programmes also increase the level of consumer protection, in addition to the safe sourcing of sheep products assured by the current measures, in particular the provisions on the removal of specified risk materials, in Regulation 999/2001/EC.

The extended monitoring should be based on a statistically valid survey in order to determine the likely prevalence of BSE in sheep as soon as possible and to improve knowledge of the geographical distribution of the disease.

In view of the high level of TSEs in the ovine and caprine population in Cyprus the extended monitoring of ovine animals can be limited to non-infected flocks.

The monitoring programme in ovine animals should be reviewed after at least six months of effective monitoring.

Regulation 999/2001/EC should therefore be amended accordingly. This is the aim of this Regulation.

Lastly, in order to ensure the highest possible level of consumer protection by assessing the possible prevalence of BSE in ovine animals, the amendments made by this Regulation should enter into force without delay.

ENTRY INTO FORCE : 09/07/2006.

Prevention, control and eradication of certain transmissible spongiform encephalopathies (TSEs)

1998/0323(COD) - 19/06/2000

Following an exchange of views, the President noted that there was neither a qualified majority in support of the Commission's proposal, nor a simple majority against it, and that the Council would not return to this subject before the two-week deadline had expired. That being so, the Commission would be able to adopt the proposed measures before 30 June 2000.

Prevention, control and eradication of certain transmissible spongiform encephalopathies (TSEs)

1998/0323(COD) - 17/05/2000 - Text adopted by Parliament, 1st reading/single reading

The European Parliament, in its first reading, adopted the report drafted by Dagmar ROTH-BEHRENDT (PES, Germany) on Transmissible spongiform encephalopathies (TSE), and made a number of amendments to the Commission's proposal. Some of these amendments ensure that the Parliament remains fully involved in TSE prevention. The other main amendments include: -rapid diagnostic tests for TSEs. Testing methods should include these as far as possible. The test procedures to be used as rapid diagnostic tests within the meaning of the regulation is laid down in amendment to Annex X. -the definition of "animals suspected of being infected" is amended. -the BSE status of a Member State or third country or region will be determined by reference to criteria set out in the Regulation and the outcome of a risk analysis on the basis of all potential factors for the appearance of BSE. The risk analysis must include a conclusive statistical survey on the basis of rapid diagnostic tests. -When a post-slaughter test gives a positive result, all bovine, ovine or caprine material produced in the same batch shall be destroyed. -geographical areas will be defined by analogy with the concept of "health intervention areas" in the existing Animal Disease Notification System (ADNS). -the management procedure is changed to a committee procedure.

Prevention, control and eradication of certain transmissible spongiform encephalopathies (TSEs)

1998/0323(COD) - 07/01/1999 - Legislative proposal

PURPOSE: to lay down rules regarding the effective surveillance of transmissible spongiform encephalopathies (TSEs) based on Article 100A. CONTENT: The main objective of the proposal is to create the legal base for the control and prevention of all animal TSEs and for all products, including those not covered by Annex II of the Treaty. The articles of the proposal provide the necessary instruments to reach this goal and in the Annexes the details are worked out as far as possible according to current knowledge. Implementing rules are foreseen where future action can be expected. The provisions are based on the OIE recommendations on BSE and the various scientific opinions available in order to ensure a very high level of protection. In principle, the prevention and control of all animal TSEs with respect to food and feed is covered. Industrial, cosmetic and medicinal products, medical devices and products destined for research, exhibitions and teaching are not included, because there is either no inherent risk for human or animal health or the provisions are covered by sectoral legislation. A general provision to ensure that those products, which are not covered by the Regulation, cannot enter the food and feed chains provides the necessary protection during the production process. An important exception to the above is the exclusion of the animal waste legislation despite the fact that the predominant motivation for this legislation is protection against TSEs. For technical reasons, it was considered beneficial to keep the animal waste legislation separate as a coherent independent set of legislation. The elements of this legislation, such as waste processing standards, validation of processes, approval of establishments, placing on the market of rendered product, etc. are strongly interdependent and form a coherent entity. Moreover they are primarily based on general hygiene standards. It is proposed to treat national trade, intra-Community trade, import and export in an equivalent manner. All existing Community rules on TSEs are incorporated in the proposal including preventive measures e.g. feed and SRM bans. A legal base is created for eradication of all TSEs, including scrapie and BSE in sheep, and for trade requirements preventing the spread of BSE by movements of live bovine, ovine and caprine animals. In the absence of scientific advice and international standards on the eradication of scrapie, or on trade rules to prevent the spread of BSE through sheep, no detailed rules are proposed in these areas. The same would apply to eradication of BSE in sheep but following the precautionary principle and the serious consequences of the possible establishment of a BSE reservoir in sheep, detailed rules for BSE eradication in sheep are proposed nevertheless. Community rules for the movement of live breeding sheep and goats related to scrapie already exist. These have been transposed to this proposal, with the exception of the current option for Member States to demand additional guarantees on the basis of a Community approved scrapie control programme. In the past, a policy decision was taken not to proceed with the approval of national programmes and the subsequent granting of additional guarantees beyond the limited list of diseases for which programmes had already been approved. It was felt that the accumulation of national programmes and additional guarantees would constitute an unjustified barrier to trade and disrupt the internal market. The aforementioned list does not include scrapie. Since the proposal at hand has as its objective to harmonise all trade rules relating to TSEs, including scrapie, and offers the legal base for eradication of scrapie, there is no longer a need for national programmes for scrapie control. For implementing rules, the management procedure is proposed; for new rules, and amendment of the Annexes, the Regulatory procedure is proposed. This is considered appropriate to give the Commission the necessary tools to 'manage' the BSE crisis.

Prevention, control and eradication of certain transmissible spongiform encephalopathies (TSEs)

1998/0323(COD) - 03/05/2001 - Text adopted by Parliament, 2nd reading

The European Parliament endorsed, without amendment, the report by Mrs Dagmar ROTH-BEHRENDT (PES, D) on the Council's common position on Commission proposals for rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies. (Please refer to the previous document).

Prevention, control and eradication of certain transmissible spongiform encephalopathies (TSEs)

1998/0323(COD) - 12/02/2003 - Implementing legislative act

ACT: Commission Regulation 260/2003/EC amending Regulation 999/2001/EC of the European Parliament and of the Council as regards the eradication of transmissible spongiform encephalopathies in ovine and caprine animals and rules for the trade in live ovine and caprine animals and bovine embryos.

CONTENT: in April 2002, the Scientific Steering Committee (SSC) recommended the culling of entire flocks in cases where scrapies has been diagnosed on a small ruminant holding. At the same time, however, the SSC noted that culling sheep of the ARR/ARR prion protein genotype would be of little "risk-reduced" benefit. In a bid to safeguard breeds which may have a low level of resistance it has been agreed to introduce a gradual approach to culling. Such a measure has the additional advantage of helping to prevent farmers from hiding suspected cases. In adopting this act the rules for intra-Community trade in breeding sheep have been amended in order to remove scrapie-related restrictions from trade in sheep of the ARR/ARR genotype.

In a further amendment, based on advice from the SSC and OIE, it has been agreed to delete all trade conditions related to bovine embryos and ova. BSE related trade conditions for bovine embryos and ova in Regulation 999/2001 have therefore been deleted. Commission Decision 92/290/EEC, concerning certain protection measures relating to bovine spongiform encephalopathy (BSE) in the United Kingdom, as amended by the Act of Accession of Austria, Finland and Sweden has been repealed.

In order to enact the above provisions, Annexes VII, VIII and XI of Regulation 999/2001/EC have been amended.

ENTRY INTO FORCE: 5 March 2003.

Prevention, control and eradication of certain transmissible spongiform encephalopathies (TSEs)

1998/0323(COD) - 28/04/2004 - Implementing legislative act

LEGISLATIVE ACT : Commission Regulation 836/2004/EC laying down the transitional measures to be applied by Cyprus with regard to scrapie. CONTENT : Regulation 999/2001 includes provisions regarding the eradication of scrapie in ovine and caprine animals and diagnostic techniques to be used for the confirmation of the disease. Cyprus has been granted transitional measures in relation to eradication measures in scrapie-infected holdings. These measures are necessary in view of the high level of scrapie in the ovine and caprine population, the low level of genetically determined resistance in the ovine population, and the nature of farming in Cyprus. The application also requests transitional measures regarding diagnostic techniques for scrapie, in view of limited laboratory capacity. This Regulation provides that the competent authority in Cyprus shall implement the provisions of Regulation 999/2001/EC in accordance with the provision of this Decision, until the 30 April 2007 at the latest. Cyprus has undertaken to furnish an action plan to address the shortage of breeding ovine animals of a suitable genotype, to increase the level of resistance in the ovine population and to provide replacement animals in infected holdings. This plan will be submitted by 1 June 2004 as part of its application for Community financing for specific veterinary measures under the provisions of Council Decision 90/424/EEC on expenditure in the veterinary field. During the period of application of these transitional measures, and taking control requirements into account, the export of products derived from ovine and caprine animals to other Member States and to third countries is prohibited. ENTRY INTO FORCE : 02/05/04. The Regulation shall apply until 30 April 2007.

Prevention, control and eradication of certain transmissible spongiform encephalopathies (TSEs)

1998/0323(COD) - 22/05/2001 - Final act

PURPOSE : to lay down rules on the effective surveillance of transmissible spongiform encephalopathies. COMMUNITY MEASURE : Regulation 999/2001/EC of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (TSE). CONTENT : these rules apply to the production and placing on the market of live animals and products of animal origin, with certain exceptions such as cosmetic products. There are the following provisions: - safeguard measures to be taken by the Commission in cases where a risk from TSE has not been adequately addressed by the competent authority of a Member State or third country. - a procedure to establish the BSE status of a Member State, a third country and of one of their regions - education programmes for those involved in the prevention and control of TSE. - each Member State is to carry out an annual programme for monitoring BSE and scrapie, which includes a screening process using rapid tests. - the feeding to ruminants of proteins derived from mammals is prohibited. - Some ruminant tissues classed as specified risk material which is more fully defined in the regulation, must be removed and destroyed in accordance with its provisions. - Member States must ensure that any animal suspected of being infected by a TSE is notified immediately to the competent authorities. - the regulation lays down certain measures which must be taken with regard to suspect animals. They are to be placed under an official movement restriction until the results of tests are known, or killed for laboratory examination under official control. - there are measures laid down following confirmation of the presence of a TSE. - Member states have to establish contingency plans specifying national measures to be implemented in case of TSE. - there are further provisions on live animals, their semen, embryos and ova, and placing on the market of products of animal origin. - Experts from the commission may make on the spot checks in cooperation with the competent authorities of the Member States. DATE OF ENTRY INTO FORCE : 1 July 2001.