

COMMISSION

COMMISSION DECISION

of 24 September 2009

concerning interim protection measures taken by France as regards the introduction onto its territory of milk and milk products coming from a holding where a classical scrapie case is confirmed

(notified under document C(2009) 3580)

(Only the French text is authentic)

(2009/726/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety⁽¹⁾, and in particular Article 54(2) thereof,

Whereas:

- (1) Regulation (EC) No 999/2001 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⁽²⁾ applies to the production and placing on the market of live animals and products of animal origin.
- (2) Annex VII to Regulation (EC) No 999/2001 lays down the measures to be taken in the event of suspicion or confirmation of a transmissible spongiform encephalopathy (TSE) in ovine or caprine animals in the Community. The rules for the placing on the market in the Community and for the importation into the Community of those animals and products thereof are laid down in Annexes VIII and IX thereto.
- (3) Regulation (EC) No 178/2002 lays down rules governing food and feed in general, and food and feed safety in particular, at Community and national level. Article 53 of

that Regulation provides that, where it is evident that food or feed originating in the Community or imported from a third country is likely to constitute a serious risk to human health, animal health or the environment, and that such risk cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned, the Commission is to immediately adopt certain measures which may include the suspension of the placing on the market or importation of the food of animal origin in question.

- (4) In addition, Article 54 of Regulation (EC) No 178/2002 provides that where a Member State officially informs the Commission of the need to take emergency measures, and where the Commission has not acted in accordance with Article 53 of that Regulation, the Member State may adopt interim protective measures and it is to immediately inform the other Member States and the Commission thereof. In that case, within 10 working days the Commission is to put the matter before the Standing Committee on the Food Chain and Animal Health (SCoFCAH) with a view to the extension, amendment or abrogation of the national interim protective measures. Pending the adoption of Community measures, the Member State may maintain its national interim protective measures.
- (5) On 8 March 2007, the European Food Safety Authority (EFSA) adopted an Opinion of the Scientific Panel on Biological Hazards on a request from the European Commission on certain aspects related to the risk of TSE in ovine and caprine animals⁽³⁾. In that opinion, EFSA concluded that: 'There is no evidence for an epidemiological or molecular link between classical and/or atypical scrapie and TSEs in humans. The BSE agent is the only TSE agent identified as zoonotic. However, in view of their diversity it is currently not possible to exclude transmissibility to humans of other animal TSE agents'⁽⁴⁾.

⁽¹⁾ OJ L 31, 1.2.2002, p. 1.

⁽²⁾ OJ L 147, 31.5.2001, p. 1.

⁽³⁾ *The EFSA Journal* (2007), 466, pp. 1-10.

⁽⁴⁾ See point 4 of the opinion.

- (6) Following that Opinion, Commission Regulation (EC) No 727/2007 of 26 June 2007 amending Annexes I, III, VII and X to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies⁽¹⁾ was adopted. Regulation (EC) No 727/2007 provided for the discontinuation of the obligation to cull the entire flock and provided for certain alternative measures to culling in the event of confirmation of an outbreak of TSE in a holding of ovine or caprine animals and where the presence of bovine spongiform encephalopathy (BSE) had been excluded. Following an action of annulment and demand for interim measures brought by France against certain provisions of this Regulation, by Order of 28 September 2007 of the Judge hearing the application for interim measures⁽²⁾, the Court suspended the application of the contested provisions pending delivery of a final judgment in the main action.
- (7) On 24 January 2008, following a request from the Commission, EFSA adopted a scientific and technical clarification in the interpretation of some facets of the conclusions of its Opinion of 8 March 2007 on certain aspects related to the risk of TSEs in ovine and caprine animals⁽³⁾, which had been considered at the time of the adoption of Regulation (EC) No 727/2007.
- (8) After considering that clarification in detail and after having examined the possible choices available to it in its role as risk manager, the Commission adopted Regulation (EC) No 746/2008 of 17 June 2008 amending Annex VII to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies⁽⁴⁾. Regulation (EC) No 746/2008, in essence, maintains the provisions already provided for in Regulation (EC) No 727/2007. Following new actions brought by France, by Order of 30 October 2008 of the President of the Court of First Instance⁽⁵⁾, the Court suspended the application of the relevant provisions pending delivery of a final judgment in which the legality of the risk management measures taken by the Commission by Regulation (EC) No 746/2008 will be fully assessed.
- (9) On 6 November 2008, EFSA published an Opinion of the Scientific Panel on Biological Hazards on a request from the European Commission on the human and animal exposure risk related to transmissible spongiform encephalopathies (TSEs) from milk and milk products derived from small ruminants⁽⁶⁾. In that Opinion, EFSA concluded that classical scrapie can be transmitted from ewe to lamb via milk or colostrums. EFSA also stated that the use of milk and milk products from a flock with classical scrapie may carry a TSE exposure risk for humans and animals. It also concluded that the breeding programmes for scrapie resistance in sheep can be expected to reduce human and animal exposure associated with small ruminants dairy products. As regards the atypical scrapie, it further concluded that the apparent restricted dissemination of the agent in the organism of affected individuals could limit the transmissibility through milk. As regards BSE, it noted that no information is available concerning the presence of infectivity or PrP^{Sc} in colostrum or milk from small ruminants affected with BSE. However, because of the early and progressive peripheral dissemination of the BSE agent in experimentally infected susceptible sheep, it concluded that the occurrence of infectivity in colostrum and milk of BSE infected susceptible small ruminants would be likely.
- (10) On 6 November 2008, the French Food Safety Agency (AFSSA) published an Opinion on the risk of classical scrapie spreading via the milk of small ruminant animals⁽⁷⁾ where it reached the same conclusions as regard the transmissibility of classical scrapie from ewe to lamb via milk or colostrums as the EFSA Opinion. With regard to the TSE exposure for humans, the AFSSA considered that consumption of milk or milk products from infected herds of small ruminants or those suspected of infection could result in excess consumer exposure and recommended 'that marketing of the milk and milk products from the herd be prohibited for human foods' in view of the high potential incidence of the disease in herds suffering from classical scrapie.
- (11) On 7 November 2008, based on the EFSA and AFSSA opinions, France adopted measures limited to the national market and banning the use of milk and milk products coming from scrapie infected flocks in France for food and feed purposes.⁽⁸⁾
- (12) On 11 and 26 November 2008, the consequences to be drawn from these new scientific elements have been examined in SCoFCAH.

(1) OJ L 165, 27.6.2007, p. 8.

(2) Case T-257/07 R, *France v Commission* [2007] ECR II-4153.

(3) Scientific Report of the Panel on Biological Hazards on a request from the European Commission on 'Scientific and technical clarification in the interpretation and consideration of some facets of the conclusions of its Opinion of 8 March 2007 on certain aspects related to the risk of transmissible spongiform encephalopathies (TSEs) in ovine and caprine animals'. *The EFSA Journal* (2008), 626, pp. 1-11.

(4) OJ L 202, 31.7.2008, p. 11.

(5) Case T-257/07 R II, *France v Commission* (O) C 327, 20.12.2008, p. 26).

(6) *The EFSA Journal* (2008) 849, pp. 1-37.

(7) AFSSA opinion of 8 October 2008 on the possible animal and public health consequences of new available scientific findings on the intra-species transmission of the classical scrapie agent by milk (<http://www.afssa.fr/Documents/ESST2008sa0115EN.pdf>).

(8) Arrêté du 7 novembre 2008 modifiant l'arrêté du 27 janvier 2003 fixant les mesures de police sanitaire relatives à la tremblante caprine (JORF, 8.11.2008, p. 17160).

- (13) During the SCoFCAH meeting of 11 November 2008, taking into account the new scientific evidence and in particular the proven transmissibility of classical scrapie through milk from ewe to lamb, a draft proposal for a Commission Regulation amending Annexes VII and IX to Regulation (EC) No 999/2001 in order to ban the use of milk and milk products from scrapie-infected flocks for feed purposes, to accelerate the eradication procedure in dairy flocks infected by classical scrapie and to restrict the use of milk and milk products for food purposes on the national market was presented. However, as that last element did not receive the support of a majority of the Member States, the proposal was not put to a vote.
- (14) On 26 November 2008, an amended proposal for a Commission Regulation amending Annexes VII and IX to Regulation (EC) No 999/2001 in order to ban the use of milk and milk products coming from holdings with a classical scrapie case for feed purposes, was presented and supported by qualified majority in SCoFCAH. In an official declaration, the French delegation welcomed the adoption of that proposal and invited the Commission to present another proposal for a Commission Regulation amending Regulation (EC) No 999/2001, in order to provide for similar measures for food. In reply to that request, the Commission confirmed that discussions would continue in that respect for food.
- (15) Subsequently, Commission Regulation (EC) No 103/2009 of 3 February 2009 amending Annexes VII and IX to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies ⁽¹⁾, was adopted. Regulation (EC) No 103/2009 provides for a number of amendments to be made to Annex VII to Regulation (EC) No 999/2001, including provision that in the case a confirmed TSE is classical scrapie, the milk and milk products derived from the animals to be destroyed on the holding cannot be used for the feeding of ruminants, except within that holding. In addition, the placing on the market of such products as feed for non-ruminants is to be limited to the territory of the Member State concerned. Finally, Regulation (EC) No 103/2009 provides for the acceleration of the eradication procedure in dairy flocks infected by classical scrapie in order to reduce the TSE exposure risk for humans.
- (16) On 18 December 2008, France requested the Commission to adopt emergency measures in accordance with Article 53(1) of Regulation (EC) No 178/2002, regarding the human exposure to the causal agents of classical scrapie. In addition, at the SCoFCAH meeting of 14 January 2009, France informed the delegations of the other Member States of that request.
- (17) On 20 January 2009, in line with the discussions following the presentation to the SCoFCAH on 26 November 2008 of a proposal for a Commission Regulation amending Annexes VII and IX to Regulation (EC) No 999/2001, the Commission pursued that discussion at working group level concerning the use for food purposes of milk and milk products from holdings with a classical scrapie case. It emerged from that discussion that the vast majority of Member States did not support the position adopted by France with regard to the necessity to take supplementary risk management measures restricting the use of such milk and milk products for food purposes.
- (18) By letter of 11 March 2009 addressed to France, the Commission confirmed that it did not intend to adopt any emergency measures regarding the use of milk and milk products for food purposes.
- (19) On 25 February 2009, France adopted a measure relating to the prohibition of import of milk and milk products for human consumption from ovine and caprine origin onto the French territory ⁽²⁾. On 9 March 2009, France notified those measures as interim protective measures to the Commission pursuant to Article 54(1) of Regulation (EC) No 178/2002. These measures provide that milk and milk products can be imported from another Member State onto the French territory if and only if they come from a holding which was not placed under an official movement restriction at the time of production and if and only if they do not come from animals which were to be destroyed or killed following the confirmation of a classical scrapie case.
- (20) Accordingly, the Commission has put the matter before the SCoFCAH at its meeting of 23 March 2009, with a view to the extension, amendment or abrogation of the national interim protective measures in accordance with Article 54(2) of Regulation (EC) No 178/2002.
- (21) As referred to in detail in the preamble to Regulation (EC) No 746/2008, and in particular recital 12 thereof, the EFSA acknowledges that there is no scientific evidence of any direct link between TSE in ovine and caprine animals, other than BSE, and TSE in humans even if the biodiversity of the disease agents in ovine and caprine animals is an important element which does not make it possible to exclude transmissibility to humans.

⁽¹⁾ OJ L 34, 4.2.2009, p. 11.

⁽²⁾ Arrêté du 25 février 2009 relatif à l'interdiction d'importation de laits, de produits laitiers et de produits contenant du lait d'origine ovine et caprine à risques au regard des encéphalopathies spongiformes transmissibles destinés à l'alimentation humaine (JORF, 5.3.2009, p. 4094).

- (22) The EFSA viewpoint that transmissibility to humans of TSE agents in ovine or caprine animals cannot be excluded is based on experimental studies on human species barrier and animal models (primates and mice). Those models, however, do not take into account genetic characteristics of humans which have a major influence on relative susceptibility to prion diseases. They also have limitations when extrapolating results to natural conditions, in particular regarding how well they represent the human species barrier and the uncertainty of how well the experimental inoculation route employed represents exposure under natural conditions. On that basis, it may be considered that although a risk of transmissibility to humans of TSE agents in ovine or caprine animals cannot be excluded, that risk would be extremely low, taking into account the fact that the evidence of transmissibility is based on experimental models which do not represent the natural conditions related to the real human species barrier and the real routes of infection.
- (23) A high level of protection of human life and health is assured in the pursuit of Community policies. Community measures governing food and feed must be based on an appropriate assessment of the possible risks for human and animal health and must, taking into account existing scientific evidence, maintain or, if scientifically justified, increase the level of protection of human and animal health. It is impossible, however, to consider the complete elimination of risk as a realistic objective for any risk management decision in matters regarding food safety, where the cost and benefits of risk-reducing measures have to be carefully weighed in order to ensure the measure's proportionality. It is the role and responsibility of the risk manager to decide the acceptable level of risk, taking into account all the elements present in a scientific risk assessment.
- (24) The Commission, in its role as risk manager at Community level, in close collaboration with the Member States, is responsible for establishing the acceptable level of risk and adopting measures that are the most appropriate for maintaining a high level of protection of public health. It has reviewed and assessed the most recent scientific information as regards the transmissibility of TSE to humans. It has assessed any risk that is present as being currently very low and acceptable. In addition to the rules related to feed and without taking disproportionate measures, the Commission has provided for the acceleration of the eradication procedure in dairy flocks infected by classical scrapie in its Regulation (EC) No 103/2009, which results in a further reduction of the TSE exposure for humans.
- (25) Therefore, based on the scientific evidence referred to in the scientific opinions available and also the consultations with the SCoFCAH, and pending the judgment of the Court of First Instance on the legality of the contested provisions of Regulation (EC) No 746/2008 which is pertinent also for the issue at stake in the notification made by France, the Commission, after having consulted the SCoFCAH, considers that the interim protective measures adopted by France go beyond what is necessary to avoid a serious risk to human health, even taking into account the precautionary principle.
- (26) Therefore, the Commission considers that the measures adopted by France on 25 February 2009 and notified to the Commission on 9 March 2009 should be suspended in accordance with Article 54(2) of Regulation (EC) No 178/2002 awaiting the delivery of a judgment in the case T-257/07 *France v Commission*.
- (27) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,
- HAS ADOPTED THIS DECISION:
- Article 1*
- France shall suspend the application of its measures prohibiting the introduction onto its territory of milk and milk products for food purposes from holdings where a case of classical scrapie has been confirmed, until the Court of First Instance has rendered its final judgment in the case T-257/07 *France v Commission*.
- Article 2*
- France shall take the necessary measures to comply with this Decision at the latest by 16 October 2009.
- France shall inform the Commission of those measures.
- Article 3*
- This Decision is addressed to the French Republic.
- Done at Brussels, 24 September 2009.
- For the Commission*
Androulla VASSILIOU
Member of the Commission