

Case No: 70950
Event No: 686405
Dec. No: 529/13/COL

EFTA SURVEILLANCE AUTHORITY DECISION

of 18 December 2013

to reject the Norwegian application for revision of the annual monitoring programme for
BSE

THE EFTA SURVEILLANCE AUTHORITY,

Having regard to Article 6(1b) of the Act referred to at point 12 of Part 7.1 of Chapter I of Annex I to the EEA Agreement,

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, as amended and adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I thereto

Having regard to the Act referred to at point 41b under the section *ACTS OF WHICH THE EFTA STATES AND THE EFTA SURVEILLANCE AUTHORITY SHALL TAKE DUE ACCOUNT* in Part 7.2 of Chapter I of Annex I to the EEA Agreement,

Commission Decision 2009/719/EC of 28 September 2009 authorising certain Member States to revise their annual BSE monitoring programmes, as amended

as adapted to the EEA Agreement by point 4(d) of Protocol 1 to the EEA Agreement and Articles 1(2) and 3 of Protocol 1 to the Surveillance and Court Agreement.

Whereas:

1 Introduction

By letter dated 30 November 2011 (your ref. 2011/187391, Event No 616752), Norway applied to the EFTA Surveillance Authority (“the Authority”) for a revision of its annual monitoring programme for *bovine spongiform encephalopathy* (“BSE”) similar to that granted to 25 of the EU Member States by Commission Decision 2009/719/EC.

By letter dated 14 December 2012 (your ref. S-2011/187391, Event No 656991), Norway amended its application to take into account recent amendments voted for in the Standing Committee on the Food Chain and Animal Health.¹

By the updated application, Norway seeks to amend its monitoring programme for BSE as follows:

- To stop testing bovine animals slaughtered normally for human consumption for BSE;
- For bovine animals sent for emergency slaughter or with observations at ante mortem inspection, or bovine animals which have died or been killed on the farm (fallen stock), to increase the age of animals to be tested for BSE to 48 months.

By letters of 26 April 2012 (Event No 630934) and 27 February 2013 (Event No 659734), the Authority requested scientific and technical assistance from the European Food Safety Authority (“EFSA”) pursuant to Article 31 of *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*² on the following matters:

1. Whether Norway’s continuous use of fishmeal in feed for ruminants until 1 May 2010 has had an impact of the overall risk of BSE in the country;
2. Whether the design of the proposed annual regime of 2 000 randomly selected samples in the subpopulation of healthy slaughtered animals over 72 months of age allows the detection of BSE with a yearly design prevalence of at least one case per 100 000 in the adult population at a confidence level of 95% in Norway;
3. If it is epidemiologically sound merging Norway with EU-25 as a unique epidemiological unit, and;
4. In case the latter can be done, whether the same conclusion of report on the minimum sample size to test should an annual BSE statistical testing regime be authorised in healthy slaughtered cattle³ would be true if one were to apply the model to the EU-25 plus Norway.

The request under point 2 was rendered moot by the amendments to the initial application submitted by Norway on 14 December 2012.

EFSA delivered its reports on 25 February 2013⁴ and 26 September 2013,⁵ respectively.

2 Relevant EEA law

Article 6(1) of Regulation (EC) No 999/2001 requires Member States to carry out an annual monitoring programme for *transmissible spongiform encephalopathies* (“TSEs”).

¹ Amendments adopted by *Commission Implementing Decision of 4 February 2013 amending Decision 2009/719/EC authorising certain Member States to revise their annual BSE monitoring programmes*, not yet incorporated in the EEA Agreement.

² Act referred to at point 13 of Part 7.1 of Chapter I of Annex I to the EEA Agreement.

³ Concerning a request from the European Commission, Question No EFSA-Q-2011-01175, approved on 8 October 2012. The final report was published in *EFSA Journal 2012;10(10):2913 [90 pp.]*.

⁴ *EFSA Journal 2013;11(2):3119 [46 pp.]*.

⁵ *EFSA Journal 2013;11(9):3380 [16 pp.]*.

For bovine animals, Article 6(1a) provides that:

“The annual monitoring programme referred to in paragraph 1 shall cover as a minimum the following subpopulations:

(a) all bovine animals above 24 months of age sent for emergency slaughter or with observations at ante mortem inspections;

(b) all bovine animals above 30 months of age slaughtered normally for human consumption;

(c) all bovine animals above 24 months of age not slaughtered for human consumption, which have died or been killed on the farm, during transport or in an abattoir (fallen stock).

Annex III to Regulation (EC) No 999/2001 contains further provisions on TSE monitoring systems.

Point 2.2 of Part I of Chapter A to Annex III specifies that

“All bovine animals over 30 months of age:

- subject to normal slaughter for human consumption, or*
- slaughtered in the context of a disease eradication campaign [...] but showing no clinical signs of disease,*

shall be tested for BSE.”

Under point 12 of Part 7.1 of Chapter I of Annex I to the EEA Agreement, the following adaptation is inserted in Part I of Chapter A of Annex III to the Regulation:

“By way of derogation from point 2.2, and with regard to bovine animals born, reared and slaughtered on its territory, Norway may decide to examine only a random sample. The sample shall comprise at least 10 000 animals per year.”

Article 6(1b) of Regulation (EC) No 999/2001 provides that:

“At the request of a Member State which can demonstrate the improvement of the epidemiological situation of the country [...] the annual monitoring programmes for that particular Member State may be revised.

[...] In particular the Member State shall demonstrate:

[...]

(c) that it has implemented and enforced for at least six years Community legislation on total feed ban for farmed animals.

Point 7 of Part I of Chapter A of Annex III contains further provisions on revisions of the annual monitoring programmes concerning BSE.

Article 7(1) of Regulation (EC) No 999/2001 prohibits “*the feeding of ruminants of protein derived from animals*” (“total feed ban”).

3 The Authority’s assessment

Article 6(1b) of Regulation (EC) No 999/2001 sets as a condition for revision of a Member State’s BSE monitoring programme that the total feed ban has been implemented for at least six years.

The time limit for the EEA EFTA States to make *Regulation (EC) No 1292/2005 amending Annex IV to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards animal nutrition*, which amended Regulation (EC) No 999/2001 as regards the total feed ban, part of their legal order expired on 23 September 2006. However, the Regulation was initially only partially incorporated in Norway. The Authority delivered a reasoned opinion to Norway in this regard on 15 October 2009 (Event No 533793). Following this, the Regulation was made part of the Norwegian legal order in full with effect from 1 May 2010 (Form 1 - Event No 555890).

However, the Authority has noted that the production of ruminant feed may in Norway take place in facilities not physically separate from facilities that also produce feed for non-ruminant species containing fishmeal, as long as the different productions are separated in time. Moreover, a contamination of the ruminant feed of up to 0,15% of fishmeal is allowed. Accordingly, the total feed ban is currently not fully implemented in Norway. The Authority sent a letter of formal notice in this regard to Norway on 12 December 2012 (Event No 642928) concluding that Norway was in breach of Article 7 of Regulation (EC) No 999/2001.

The Authority points out that one of the conditions for revision of the annual monitoring programme for BSE is that the total feed ban has been implemented and enforced for at least six years.

It follows from the above that the total feed ban has not been implemented and enforced for at least six years in Norway. Accordingly, the Authority considers that the conditions for revising the Norwegian annual monitoring programme for BSE are not met.

Moreover, the Authority notes that, in its report of 26 September 2013, EFSA stated that:

“A physical separation of feed production lines is recommended to gain further confidence in the Norwegian measures to prevent the spread of BSE and other TSEs.”

The Authority further notes that *Commission Decision 2009/177/EC* did not derogate from the condition that a Member State seeking revision of its BSE monitoring programme has implemented and enforced for at least six years the total feed ban.

On the basis of the above, the application from Norway for revision of its annual monitoring programme for BSE must be rejected.

In its report of 26 September 2013, EFSA also stated that:

“From a cattle BSE epidemiological point of view, Norway and EU25 can be considered as a unique epidemiological unit. Based on C-TSEMM estimates, when EU25 and Norway are considered as a unique epidemiological unit, and the systematic testing of at-risk animals above 48 months of age is maintained, then healthy slaughtered animals would not need to be tested in order to meet a yearly design prevalence of one detectable case in 100 000 adult cattle at a confidence level of 95%”

However, it follows from the above that this is not sufficient to alter the conclusion that the application from Norway must be rejected.

HAS ADOPTED THIS DECISION:

The EFTA Surveillance Authority rejects the application from Norway for revision of its annual monitoring programme for BSE.

Done at Brussels, 18 December 2013

For the EFTA Surveillance Authority



Signed version!

Oda Helen Sletnes
President

Sverrir Haukur Gunnlaugsson
College Member