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OPINION

of the French Food Safety Agency (Afssa)
on a draft order amending the Order of 21 August 2001 laying down the
technical and financial aspects of the animal health measures
for bluetongue

LA DIRECTRICE GENERALE

Terms of the referral

The Agence française de sécurité sanitaire des aliments (Afssa) [French Food Safety Agency] received a mandate on 12 September 2006 by fax from the Direction générale de l'alimentation [Directorate General for Food] for an opinion on a draft Order amending the Order of 21 August 2001 laying down the financial and technical aspects of the animal health measures for bluetongue, and on a draft protocol for the movement of week-old calves.

Opinion of the joint emergency expert group on "Bluetongue"

The joint emergency expert group on "Bluetongue", appointed in a decision dated 09 September 2006, met on 13 September 2006 using telematic facilities and has issued the following opinion:

"Context

- *The identification of a first case of bluetongue in the Netherlands in mid-August 2006 has resulted in the putting in place of surveillance and testing systems which have enabled the identification of infected animals (mostly cattle) in herds in the Netherlands, Germany and Belgium. In France, a reinforced surveillance programme has been in place since 22 August 2006.*
On 12 September 2006, four European Union Member States reported infected holdings: the Netherlands (41 holdings), Germany (67 holdings), Belgium (81 holdings) and France (4 holdings). Most of the infected holdings in the Netherlands, Belgium and Germany are located within a 100 km radius of the city of Maastricht.
- *In France, the testing and surveillance measures have involved:*
 1. *60 cattle herds (30 tests per herd) in Departments on the French frontier bordering the restriction zones defined by the EC. This has enabled the detection of two positive herds (ELISA competition serology), one herd in the Ardennes Department and another in the Nord Department, with both herds having only one positive animal among those tested;*
 2. *over thirty clinically suspect cases, in which the suspect animal has been subject to serological testing and PCR analysis, followed by serological testing of the herd in the event of a confirmation of positive status. This has led to the detection of two positive herds (both in the Ardennes): only the suspect animal was positive (out of 30 animals tested) in one of the herds; in the other, of the 22 animals tested, one serology test and three PCR analyses proved Positive.*
 3. *17 farms located around the two cases detected in (1) were the subject of further investigation: the 548 samples collected did not produce a single positive result (ELISA serology), neither did the 768 samples collected on 24 farms around an unconfirmed serologically suspect case.*

4. 2965 cattle and 4 sheep from the restriction zones defined by the European Commission in the three other affected Member States. Two cattle originating from Belgium were identified as positive (ELISA serology) in Seine-Maritime and slaughtered. In addition, 137 cattle from the restricted zones around the French outbreaks have been submitted to the same type of tests but with no positive results.
- The four herds of cattle in which positive animals were detected have not been submitted to the measures laid down by Article 13 of the Order of 21 August 2001 establishing the technical and financial aspects of the animal health measures for bluetongue (euthanasia of animals showing clinical signs of bluetongue, and immediate slaughter of all animals of susceptible species on the farm and not showing clinical signs of bluetongue). Moreover, Articles 1 and 2 of the Order of 28 August 2006 (JORF¹ of 29 August 2006) established in France restricted zones differentiated on the basis of the serotype of bluetongue involved, in accordance with Commission Decision 2005/393/EC of 23 May 2005. In Article 3, it amended Article 19 of the Order of 21 August 2001 as regards, in particular, the movements of animals of susceptible species, of their ova, sperm and embryos, firstly between the protection zone and the surveillance zone and secondly, from these zones to a bluetongue-free zone, in accordance with the derogations defined in Decision 2005/393/EC.

Questions

The referral of 12 September 2006 covered the following points:

- a draft Order amending Articles 13 and 19 of the Order of 21 August 2001 setting the technical and financial aspects of the animal health measures for bluetongue,
- a draft protocol for managing the movement of week-old calves in the French restricted areas (20 km zone) to fattening units inside the French protection zones (100 km zone),
- a wider series of questions with a view to other derogations which require examination (notably on the movement of grass-fed animals from the restricted zones) covering:
 - the practical vector control measures to be implemented in order to comply with the condition on protection against vectors laid down in Commission Decision 2005/393/EC, notably in Annex II, with a view to movements on a derogation basis;
 - the predictable period of inactivity of potential vectors for bluetongue in the Departments of north-eastern France currently under restriction ;
 - the tests to be prioritised for the animals with a view to movements on a derogation basis.

In view of the desired response time ("within 48 hours", reduced to 24 hours), only the first two questions will be addressed, since the third series of questions cannot be properly examined within the time available.

Method

The joint review exercise was conducted on the basis of a draft opinion produced by the emergency unit to support the joint emergency expert group on "bluetongue" which was discussed and validated by telematic means on 13 September 2006.

The review was conducted based on the following documents:

- the draft opinion for review;

¹ Journal Officiel de la République Française [Official Gazette of the French Republic]

- the draft protocol for review on the management of movements of week-old calves;
- the Order of 21 August 2006 laying down the technical and financial aspects of the animal health measures for bluetongue, amended by the Order of 28 August 2006;
- Commission Decision 2005/393/EC of 23 May 2005 on protection and surveillance zones in relation to bluetongue and conditions applying to movements from or through these zones;
- the available data on the epidemiological situation in the Netherlands, Belgium, Germany and France as at 11 September 2006;
- OIE alerts up to 12 September 2006.

Examination of the issues

1. Article 1 of the draft order:

- The first two paragraphs of Article 1 of the draft order amend Article 13 of the Order of 21 August 2001. They replace the compulsory euthanasia or slaughter of animals of susceptible species on holdings where a bluetongue infection has been confirmed with a simple option of implementing non-compulsory measures based on the local situation and any changes in the overall risk.

This change is based on the new context marked by the presence, in part of France (zone B), of a serotype (8) whose pathogenicity and epidemiological impact (itself probably linked to the vectoral competence, not yet estimated, of one or more *culicoides*), based on the assessment conducted prior to 13 September 2006, are manifestly different from those of the vector/serotype pairing identified in Corsica in Autumn 2000.

In view of the current uncertainty on the future development of bluetongue in northern France and in the other reported infected Member States, this proposal, already implemented operationally, elicits the specific observation that it is generating a profound change to the policy for controlling bluetongue outbreaks.

This can be explained by the highly specific situation in northern France. It gives the risk manager greater latitude in his action. The choice between the different measures proposed (and their combinations) would need to be adapted to the precise epidemiological situation. It also implies the provision of management measures for the infected animals remaining in the outbreak zone.

- The third paragraph of Article 1 goes back to the notion, already developed in Article 13 of the Order of 21 August 2001, of the option of vaccinating the animals of susceptible species found on the holding if they are showing no clinical signs of bluetongue. In order not to impose the use of the vaccination, if this option is selected, on all the animals and all the susceptible species, a change to the wording is proposed: "vaccination against bluetongue of animals of susceptible species found on the holding."

2. Article 2 of the draft order:

Close examination of the proposal identified an ambiguity in the wording which was only resolved following direct questioning of the requester. This revealed that the experts should have been given certain essential elements of additional information. Once these elements have been obtained and the request clarified, a further examination of this article will be possible.

3. Draft protocol on the movement of week-old calves in the French restricted zone (20 km zone) to fattening units within the French protection zone (100 km zone).

The protocol on the movement of week-old calves between restricted zones and protection zones within France involves young animals (less than a month old) of a receptive species habitually not very ~~sensitive~~ susceptible (cattle). This issue in fact involves the ability to transfer, within a restricted zone with a 100 km radius, animals from the exit ban zone (20 km radius) to special units (fattening units) where their lifespan prior to slaughter will be less than six months.

In view of the current epidemiological situation in northern France, very different and probably more favourable than that identified in the epicentre of the outbreak (Maastricht area), the probability of a calf being born infected or becoming infected during its first two weeks of life

is estimated by the joint emergency expert group as "nil to negligible". Any change in the epidemiological situation would require a re-assessment of this level of risk. Moreover, the measures as proposed in the protocol submitted to expert examination, enable the level of risk to be reduced even more. However, the effectiveness of these measures, in particular the disinsectisation of the animals, would need to be assessed in the actual context (vectors, species affected, zones affected ...).

Conclusions and recommendations

The joint emergency expert group on "Bluetongue" which met on 13 September 2006 using telematic facilities, was only able to examine within the required response time, firstly Article 1 of the draft order, on which it expressed a favourable opinion and suggested an amendment to the third paragraph; secondly, the protocol for managing movements of week-old calves within the French protection zone, which, in the current epidemiological situation, received its approval for the next few weeks in northern France.

The group would like to emphasise the many uncertainties concerning the conditions of the emergence and development of this episode and the difficulty of predicting its evolution in time and space.

Future proposals and assessments must take into account these uncertainties, which can only be lessened by a better understanding of the actual development of the situation on the ground, both in France and in the other Member States.

Key words: bluetongue, cattle, sheep, regulations

Opinion of the Agence française de sécurité sanitaire des aliments

These are the points of analysis which Afssa is in a position to provide in response to the request from the Direction générale de l'alimentation regarding a draft order amending the Order of 21 August 2001 laying down the technical and financial aspects of the animal health measures for bluetongue, and on a draft protocol for the movement of week-old calves.

Afssa wishes to note the uncertainties regarding:

1. the lack of retrospective information on the pathogenicity and epidemiological impact of the serotype 8 currently identified in zone B (French part of the F zone following decision 2005/393/EC) in France;
2. the limited amount of data on the role of local vectors in the dissemination of the virus;
3. the lack of precise information on the origin of the infection of four Member States with this hitherto exotic serotype.

Afssa recommends that the proposed measures, submitted for its opinion now and in the future, should form part of an overall animal health strategy as regards this exotic serotype with, if possible, clearly expressed objectives and management options.

The Director General of the Agence française
de sécurité sanitaire des aliments

Pascale BRIAND