

POSITION (EU) No 5/2012 OF THE COUNCIL AT FIRST READING

with a view to the adoption of a Directive of the European Parliament and of the Council amending Directive 2000/75/EC as regards vaccination against bluetongue

Adopted by the Council on 15 December 2011

(2012/C 46 E/02)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 43(2) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee ⁽¹⁾,

Acting in accordance with the ordinary legislative procedure ⁽²⁾,

Whereas:

(1) Council Directive 2000/75/EC of 20 November 2000 laying down specific provisions for the control and eradication of bluetongue ⁽³⁾ lays down control rules and measures to combat and eradicate bluetongue, including rules on the establishment of protection and surveillance zones and the use of vaccines against bluetongue.

(2) In the past, only sporadic incursions of certain serotypes of the bluetongue virus were recorded in the Union. Those incursions mainly occurred in the southern parts of the Union. However, since the adoption of Directive 2000/75/EC, and particularly since the introduction into the Union of bluetongue virus serotypes 1 and 8 in the years 2006 and 2007, the bluetongue virus has become more widespread in the Union, with the potential to become endemic in certain areas. It has therefore become difficult to control the spread of that virus.

(3) The rules on vaccination against bluetongue laid down in Directive 2000/75/EC are based on experience of the use of so-called 'modified live vaccines', or 'live attenuated

vaccines', which were the only vaccines available when that Directive was adopted. The use of those vaccines may also lead to an undesired local circulation of the vaccine virus in unvaccinated animals.

(4) In recent years, as a result of new technology, 'inactivated vaccines' against bluetongue have become available which do not pose the risk of undesired local circulation of the vaccine virus to unvaccinated animals. The extensive use of such vaccines during the vaccination campaign in the years 2008 and 2009 has led to a significant improvement in the disease situation. It is now widely accepted that vaccination with inactivated vaccines is the preferred tool for the control of bluetongue and for the prevention of clinical disease in the Union.

(5) In order to ensure better control of the spread of the bluetongue virus and to reduce the burden on the agricultural sector posed by that disease, it is appropriate to amend the current rules on vaccination laid down in Directive 2000/75/EC in order to take account of the recent technological developments in vaccine production.

(6) In order to enable the vaccination season 2012 to benefit from the new rules, this Directive should enter into force on the day following that of its publication in the *Official Journal of the European Union*.

(7) The amendments provided for in this Directive should make the rules on vaccination more flexible and also take into account the fact that inactivated vaccines that can also be successfully used outside areas subject to animal movement restrictions are now available.

(8) In addition, and provided that appropriate precautionary measures are taken, the use of live attenuated vaccines should not be excluded, as their use might still be necessary under certain circumstances, such as following the introduction of a new bluetongue virus serotype against which inactivated vaccines may not be available.

(9) Directive 2000/75/EC should therefore be amended accordingly,

⁽¹⁾ OJ C 132, 3.5.2011, p. 92.

⁽²⁾ Position of the European Parliament of 7 April 2011 (not yet published in the Official Journal).

⁽³⁾ OJ L 327, 22.12.2000, p. 74.

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 2000/75/EC is hereby amended as follows:

(1) In Article 2, the following point is added:

‘(j) “live attenuated vaccines”: vaccines which are produced by adapting bluetongue virus field isolates through serial passages in tissue culture or in embryonated hens’ eggs.’.

(2) Article 5 is replaced by the following:

Article 5

1. The competent authority of a Member State may decide to allow the use of vaccines against bluetongue provided that:

- (a) such decision is based on the result of a specific risk assessment carried out by the competent authority;
- (b) the Commission is informed before such vaccination is carried out.

2. Whenever live attenuated vaccines are used, Member States shall ensure that the competent authority demarcates:

- (a) a protection zone, consisting of at least the vaccination area;
- (b) a surveillance zone, consisting of a part of the Union territory with a depth of at least 50 kilometres extending beyond the limits of the protection zone.’.

(3) In Article 6(1), point (d) is replaced by the following:

‘(d) implement the measures adopted in accordance with the procedure laid down in Article 20(2), in particular with regard to the introduction of any vaccination programme or other alternative measures;’.

(4) In Article 8(2), point (b) is replaced by the following:

‘(b) The surveillance zone shall consist of a part of the Union territory with a depth of at least 50 kilometres extending beyond the limits of the protection zone and in which no vaccination against bluetongue with live attenuated vaccines has been carried out during the previous 12 months.’.

(5) In Article 10, point 2 is replaced by the following:

‘2. any vaccination against bluetongue using live attenuated vaccines is prohibited in the surveillance zone.’.

Article 2

1. Member States shall adopt and publish, by ... (*) at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall communicate immediately to the Commission the text of those provisions.

They shall apply those provisions from ... (**) at the latest.

When Member States adopt those provisions, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at

For the European Parliament
The President

...

For the Council
The President

...

(*) Six months after the entry into force of this Directive.

(**) Six months and one day after the entry into force of this Directive.

STATEMENT OF THE COUNCIL'S REASONS

I. INTRODUCTION

On 15 November 2010, the Commission submitted to the Council a proposal for a Council Directive, based on Article 15 of Council Directive 92/119/EEC ⁽¹⁾. Upon advice of the Council Legal Service, the derived legal basis of the Commission proposal was replaced by Article 43(2) of TFEU, which involves the ordinary legislative procedure ⁽²⁾.

The European Parliament delivered its opinion on 7 April 2011 ⁽³⁾.

The Economic and Social Committee adopted its opinion on 15 March 2011 ⁽⁴⁾.

In accordance with Article 294 of the Treaty, the Council adopted its position in first reading on 15 December 2011.

II. OBJECTIVES

The draft Directive aims to update the current rules on vaccination against bluetongue set out in Directive 2000/75/EC by making them more flexible. Bluetongue is a disease affecting ruminants (such as cattle, sheep and goats) and is transmitted by insect vectors that spread the virus from one animal to another. Vaccination is the preferred tool for bluetongue control and prevention of clinical disease in the EU. The use of vaccines is, however, limited by the current rules set out in Directive 2000/75/EC, that foresee the use of vaccines only in areas where the disease occurred and which have therefore been subject to animal movement restrictions. Those rules are based on experiences with the so-called 'modified live vaccines', or 'live attenuated vaccines' that were the only vaccines available when the Directive was adopted a decade ago. Those vaccines may lead to undesired circulation of the vaccine virus in unvaccinated animals in the areas where the vaccine has been used. The new flexible rules introduced by the draft Directive are based on the fact that inactivated vaccines are now available, which can also be successfully used outside areas subject to animal movement restrictions.

III. ANALYSIS OF THE COUNCIL'S POSITION

The Council's position confirms the objectives proposed by the Commission and incorporates the quasi-totality of the European Parliament's first-reading amendments.

In particular, the Council shares the European Parliament's view that Article 43(2) of TFEU is the correct legal basis for this Directive. This line was confirmed by Coreper (Part I), which, following the advice of the Council Legal Service against the use of a derived legal basis for this proposal, decided at its meeting on 26 January 2011 to propose to the European Parliament such modification of the legal basis by the co-legislators, as the Commission services were unable to commit to rapid re-submission of the proposal with this modified legal basis ⁽⁵⁾.

The Council's position introduces changes to the European Parliament's first-reading opinion only in two areas:

1. While all other proposed requirements related to the communication of national provisions to the Commission are maintained in the Council's position, the specific obligation to use correlation tables is deleted. The Council considers this to be in line with the conclusion reached in horizontal negotiations between the Institutions on the issue of correlation tables and takes note of the Commission representative's confirmation that his Institution would not deem such specific requirement justified for the present Directive.
2. The other change concerns the deadline for the national transposition of the Directive.

⁽¹⁾ Council Directive 92/119/EEC of 17 December 1992 introducing general Community measures for the control of certain animal diseases and specific measures relating to swine vesicular disease (OJ L 62, 15.3.1993, p. 69).

⁽²⁾ Doc. 5498/11.

⁽³⁾ P7_TA-PROV(2011)0147.

⁽⁴⁾ NAT/512 - CESE 538/11.

⁽⁵⁾ Docs 5498/11 and 5499/11.