



**COUNCIL OF
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PROPOSAL

from: European Commission
dated: 15 November 2010
Subject: Proposal for a Directive of the European Parliament and of the Council
amending Directive 2000/75/EC as regards vaccination against bluetongue

Delegations will find attached a proposal from the Commission, submitted under a covering letter from Mr Jordi AYET PUIGARNAU, Director, to Mr Pierre de BOISSIEU, Secretary-General of the Council of the European Union.

Following the meeting of COREPER (part 1) on 26 January 2011, the proposal is

- transmitted to the European Parliament with a view to the modification of its legal basis to Article 43(2) TFEU by the co-legislators under the ordinary legislative procedure; and
- forwarded to national Parliaments.

Encl.: COM(2010) 666 final



EUROPEAN COMMISSION

Brussels, 15.11.2010
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2010/0326 (NLE)

Proposal for a

COUNCIL DIRECTIVE

amending Directive 2000/75/EC as regards vaccination against bluetongue

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

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. This means that its occurrence and spread is largely influenced by environmental conditions and that the measures usually applied for the control of contagious animal diseases such as Foot-and-mouth disease are not appropriate for the control and eradication of bluetongue. When favourable environmental and climatic conditions exist, epidemic waves of disease may occur, in fully receptive (i.e. non-immune) ruminant populations in late summer-autumn, that are extremely difficult to control. In general, bluetongue control is based on a combination of vaccination, protection from vectors and restrictions on animal movements.

This disease was considered exotic to the EU until the late 1990s, as only sporadic incursions in the southern part of the EU had been reported at that time. However, the situation dramatically changed from the early 2000s: several epidemic waves of disease have occurred in many Member States, including in central and northern Europe, causing significant losses in terms of morbidity, mortality and disruption of trade in live animals. In the last few years the situation has significantly improved, as a result of massive vaccination campaigns largely co-financed by the Union (~150 MEUR in 2008, and allocation of ~120 MEUR in 2009 and ~100 MEUR in the years after), that have been based on new "inactivated vaccines", that have become available as from 2008. However, the disease has also shown a tendency to become endemic in some areas, and it is possible that from there further epidemic waves of disease may start in the future.

Council Directive 2000/75/EC of 20 November 2000 lays down specific provisions for the control and eradication of bluetongue, including rules on vaccination. These 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. However, in the last few years inactivated vaccines have been developed by a number of companies and largely used in the EU. These inactivated vaccines do not pose the risk of undesired vaccine virus circulation.

It is now widely agreed that vaccination with these vaccines is the preferred tool for bluetongue control and prevention of clinical disease in the EU. Their use is, however, limited by the current rules, that in particular foresee the use of vaccines only in areas where the disease occurred and which have therefore been subject to animal movement restrictions.

In order to ensure better control of bluetongue and reduce the burden on the agricultural sector posed by this disease, it is appropriate to update the current rules on vaccination to the recent technological developments in vaccine production. This proposal amends the rules on vaccination currently laid down in Directive 2000/75/EC to make them more flexible, taking into account the fact that inactivated vaccines are now available, which can also be successfully used outside areas subject

to animal movement restrictions. However, the use of live attenuated vaccines should not be excluded provided that appropriate precautionary measures are taken, 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.

2. PREFERRED OPTION AND ASSESSMENT OF ITS IMPACTS

2.1. Reasons for modification of EU legislative framework compared to other options

Under the current rules, the use of vaccines against bluetongue is prohibited outside "restricted zones". Consequently, Member States that wish to carry out preventive vaccination must either retain a restricted zone beyond the two years of absence of virus circulation, while other Member States decide to become part of a restriction zone although bluetongue has never occurred. This situation leads to unnecessary restrictions in the concerned areas with additional burdens for the farmers and the national authorities.

In the past three years modern inactivated vaccines against bluetongue have become available which could be safely used outside restricted zones. The provisions on vaccination against bluetongue should therefore be amended to allow the Member States to develop their national strategies on the prevention and control of the disease without the unnecessary intervention of the Union.

2.2. Economic and social impacts of the proposal

The proposal is expected to reduce the adverse economic and social impact, and the burden related to the implementation of certain veterinary restrictions as a result of bluetongue, by increasing the number of options available to control the disease. It is, however, difficult to quantify these benefits precisely, as they will vary dependent on the largely unpredictable nature of the evolution of the disease in Europe.

2.2.1. Economic impacts

A. *Effects on co-financed animal disease control programmes*

The proposal does not have an effect on the control measures, including vaccination programmes that take place within areas that are affected by bluetongue disease. Therefore, the proposal will not have a direct impact on the EU annual and multi annual programmes for the eradication, control and monitoring of certain animal diseases.

B. *Effects on agricultural sector*

By allowing the wide use of vaccination in the Union, this proposal has the potential to reduce the negative economic impact of bluetongue caused by both direct and indirect losses (morbidity and mortality, disruption of trade in live ruminants) caused by this

disease. In addition, a positive effect can be expected on the burden on farmers due to disease control measures and restrictions on trade currently applied in areas where vaccination is applied and that are therefore currently included in restricted zones (see 2.1).

C. Effects on other types of operators

The proposal will allow a wider use of vaccination and therefore a potential increased market for the pharmaceutical companies who produce the inactivated vaccines against bluetongue.

D. Effects on administrative costs

It is not expected that the wider and more flexible use of inactivated vaccines against bluetongue will have any effect on the administrative burden for Member States. No additional registration or procedures are required, except for the information Member States must provide to the Commission of their intention to put in place a vaccination programme.

2.2.2. Social impacts

Apart from a certain positive effect that arises from the flexibility that will be allowed for Member States, farmers and other animal keepers in the decision making on bluetongue control strategy, it is expected that the proposal will have no significant social impact.

2.3. Conclusion

The Commission considers that the amendment of the legislation is necessary to reflect the technological progress in the field of vaccine development. The current obstacles for preventive vaccination outside areas subjected to animal movement restrictions are not necessary when modern safe "inactivated vaccines" are used. The proposed amendment will facilitate decision making on bluetongue control strategies on the basis of the specific situation within the Member States without unnecessary intervention by the Union.

This approach is expected to address the demands of several Member States and receive the support of stakeholders. It is also estimated that the potential economic and social benefits of this proposal are likely to outweigh potential disadvantages. The expected impacts are not considered significant enough to merit a full format impact assessment.

3. LEGAL ELEMENTS OF THE PROPOSAL

The legal basis of Directive 2000/75/EC is the second indent of Article 15 of 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 (the "basic act"), which provides that the Council may adopt specific provisions relating to the control and eradication measures for any of the animal diseases listed in Annex I to the Directive, acting on a qualified majority on a

proposal from the Commission. Since the basic act providing for this legal basis is still in force, the legality of the powers vested in the Council in this act are not affected by the entry into force of the Lisbon Treaty and these powers remain solely with the Council.

4. RELATION TO OTHER EU INITIATIVES

This proposal is in line with the Animal Health Strategy (2007-2013) "Prevention is better than cure", as it moves towards a more flexible approach to vaccination, as well as improving current measures to control major animal diseases.

Proposal for a

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THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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 disease¹, and in particular the second indent of Article 15 thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) Council Directive 2000/75/EC of 20 November 2000 laying down specific provisions for the control and eradication of bluetongue² 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, after the adoption of Directive 2000/75/EC, and particularly after 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 of becoming 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" that were the only vaccines available when that Directive was adopted. The use of those vaccines may lead to an undesired local circulation of the vaccine virus also in unvaccinated animals.
- (4) In recent years, as a result of new technology, "inactivated vaccines" against bluetongue have become available, which do not pose that risk 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 bluetongue control and the prevention of clinical disease in the Union.

¹ OJ L 62, 15.3.1993, p. 69.

² OJ L 327, 22.12.2000, p. 74.

- (5) In order to ensure the better control of the spread of the bluetongue virus and 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) 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 are now available, which can also be successfully used outside areas subjected to animal movement restrictions.
- (7) In addition, the use of live attenuated vaccines should not be excluded provided that appropriate precautionary measures are taken, 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.
- (8) Directive 2000/75/EC should therefore be amended accordingly.

HAS ADOPTED THIS DIRECTIVE:

Article 1

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

- (1) In Article 2, the following point (j) 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 shall be replaced by the following:

'Article 5

1. The competent authority of a Member State may 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) shall be 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) shall be 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 twelve months.'
- (5) In Article 10, paragraph 2 shall be 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 30 April 2011 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions from 1 May 2011.

When Member States adopt those provisions, they shall contain a reference to this Directive or 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 twentieth 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 Brussels,

For the Council
The President