Basic information

2010/0326(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Directive	Procedure completed
Animal diseases: vaccination against bluetongue **Subject** 3.10.08 Animal health requirements, veterinary legislation and pharmacy 3.10.08.05 Animal diseases	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
AGRI Agriculture and Rural Development	WOJCIECHOWSKI Janusz (ECR)	26/01/2011

Former committee responsible	Former rapporteur	Appointed
AGRI Agriculture and Rural Development	WOJCIECHOWSKI Janusz (ECR)	26/01/2011

Former committee for opinion on the legal basis	Former rapporteur for opinion	Appointed
JURI Legal Affairs	GERINGER DE OEDENBERG Lidia Joanna (S&D)	16/02/2011

Council of the European Union

Council configuration	Meetings	Date
Agriculture and Fisheries	3137	2011-12-15

European Commission

Commission DG	Commissioner
Health and Food Safety	DALLI John

Key events

Date	Event	Reference	Summary
26/01/2011	Legislative proposal published	05499/2011	Summary
03/02/2011	Committee referral announced in Parliament, 1st reading		

04/04/2011	Vote in committee, 1st reading		Summary
05/04/2011	Committee report tabled for plenary, 1st reading	A7-0121/2011	
07/04/2011	Decision by Parliament, 1st reading	T7-0147/2011	Summary
07/04/2011	Results of vote in Parliament		
07/04/2011	Debate in Parliament		
15/12/2011	Council position published	16696/1/2011	Summary
19/01/2012	Committee referral announced in Parliament, 2nd reading		
06/02/2012	Vote in committee, 2nd reading		
08/02/2012	Committee recommendation tabled for plenary, 2nd reading	A7-0031/2012	
14/02/2012	Decision by Parliament, 2nd reading	T7-0036/2012	Summary
14/03/2012	Final act signed		
14/03/2012	End of procedure in Parliament		
21/03/2012	Final act published in Official Journal		

Technical information

Procedure reference	2010/0326(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Directive
Legal basis	Treaty on the Functioning of the European Union TFEU 043-p2
Other legal basis	Rules of Procedure EP 165
Stage reached in procedure	Procedure completed
Committee dossier	AGRI/7/08145

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE458.532	23/02/2011	
Specific opinion	JURI	PE460.661	01/03/2011	
Amendments tabled in committee		PE460.809	17/03/2011	
Committee report tabled for plenary, 1st reading/single reading		A7-0121/2011	05/04/2011	
Text adopted by Parliament, 1st reading/single reading		T7-0147/2011	07/04/2011	Summary
Committee draft report		PE480.564	18/01/2012	
Committee recommendation tabled for plenary, 2nd reading		A7-0031/2012	08/02/2012	
Text adopted by Parliament, 2nd reading		T7-0036/2012	14/02/2012	Summary

Council of the EU

Document type	Reference	Date	Summary
Legislative proposal	05499/2011	26/01/2011	Summary
Council position	16696/1/2011	15/12/2011	Summary
Draft final act	00009/2012/LEX	14/03/2012	

European Commission

Document type	Reference	Date	Summary
Commission response to text adopted in plenary	SP(2011)4619	25/05/2011	
Commission communication on Council's position	COM(2011)0943	06/01/2012	Summary

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES0538/2011	15/03/2011	

Additional information

Source	Document	Date
National parliaments	IPEX	
European Commission	EUR-Lex	

Final act

Directive 2012/0005
OJ L 081 21.03.2012, p. 0001 Summary

Animal diseases: vaccination against bluetongue

2010/0326(COD) - 07/04/2011 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 587 votes to 1, with 19 abstentions, a legislative resolution on the proposal for a directive of the European Parliament and of the Council amending Directive 2000/75/EC as regards vaccination against bluetongue.

It adopted its position at first reading under the ordinary legislative procedure. The amendments adopted in plenary are the result of a compromise negotiated between the European Parliament and the Council. They amend the proposal as follows:

- the proposal should be adopted under the ordinary legislative procedure pursuant to Article 43(2) of the Treaty on the Functioning of the European Union;

- the date of transposition of the Directive is set at 30 June 2011 and its provisions shall apply from 1 July 2011 at the latest;

- in order to enable the vaccination season 2011 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.

Animal diseases: vaccination against bluetongue

2010/0326(COD) - 26/01/2011 - Legislative proposal

PURPOSE: to amend the European Union’s legislative framework 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.

PROPOSED ACT: Council Directive.

BACKGROUND: Council Directive 2000/75/EC of 20 November 2000 lays down specific provisions for the control and eradication of bluetongue, including rules on vaccination. 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.

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.

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. 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. Under the current rules, the use of vaccines against bluetongue is prohibited outside "restricted zones" where the disease has appeared and where animal movement has been restricted.

PREFERRED OPTION AND ASSESSMENT OF ITS IMPACTS: 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.

LEGAL BASIS: 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. This article 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.

CONTENT: 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.

The proposed amendments 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.

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.

BUDGETARY IMPLICATION: the proposal has no implication for the European Union’s budget.

Animal diseases: vaccination against bluetongue

2010/0326(COD) - 06/01/2012 - Commission communication on Council's position

The Commission welcomes the Council position at first reading, which paves the way for an early second reading agreement.

The European Parliament proposed amendments to the proposal, essentially modifying the legal base to **Article 43(2)**, and introducing new implementation dates to ensure enforcement in time for the vaccination season. None of those amendments were controversial.

However the interinstitutional discussions on the question of **correlation tables** blocked any progress on the proposal. With regard to the request for a correlation table for the present proposal, the Council is opposed to it.

Given the delays in the adoption of the proposal due to the inter-institutional debate on the issue of correlation tables, the Council intends to postpone the proposed dates of adoption and publication of the national laws, regulations and administrative provisions necessary to comply with this Directive and of application of those provisions. The Commission accepts this postponement which stays compatible with the next vaccination season.

In light of the limited number of amendments proposed to an existing Directive transposed in national law since a decade, and the resulting easy check on their transposition, the Commission can accept that no provision on correlation tables is inserted in this Directive.

Animal diseases: vaccination against bluetongue

2010/0326(COD) - 15/12/2011 - Council position

The Council adopted its position at first reading with a view to the adoption of the Directive of the European Parliament and of the Council amending Directive 2000/75/EC as regards vaccination against bluetongue.

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

Legal basis: 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.

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

- 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 other **change concerns the deadline** for the national transposition of the Directive.

Animal diseases: vaccination against bluetongue

2010/0326(COD) - 14/02/2012 - Text adopted by Parliament, 2nd reading

The European Parliament adopted a legislative resolution on the Council position 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.

Parliament approved, without amendment, the Council’s position at first reading.

Animal diseases: vaccination against bluetongue

2010/0326(COD) - 14/03/2012 - Final act

PURPOSE: to amend the European Union's legislative framework 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.

LEGISLATIVE ACT: Directive 2012/5/EU of the European Parliament and of the Council

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

CONTENT: following early agreement at second reading to allow the entry into force of the new rules in time for the vaccination campaigns of 2012, the Council and European Parliament adopted this Directive amending Directive 2000/75/EC as regards vaccination against bluetongue.

The Directive is **aimed at updating 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.

Council Directive 2000/75/EC 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. In the past, only sporadic incursions of certain serotypes of the bluetongue virus were recorded mainly 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.

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 lead to an undesired local circulation of the vaccine virus in unvaccinated animals.

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.

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, this Directive **amends the rules on vaccination laid down in Directive 2000/75/EC in order to take account of the recent technological developments in**

vaccine production. 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.

In addition, and provided that appropriate precautionary measures are taken, **the use of live attenuated vaccines is not 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.

ENTRY INTO FORCE: 22 March 2012.

TRANSPOSITION: 23 September 2012.

APPLICATION: from 24 September 2012.