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.

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APPLICATION: from 24 September 2012.