



Brussels, 6.12.2017
COM(2017) 742 final

2017/0329 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
amending Council Directive 92/66/EEC introducing Community measures for the
control of Newcastle disease

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. LEGAL CONTEXT OF THIS DIRECTIVE

Council Directive 92/66/EEC lays down measures to be applied in the event of an outbreak of Newcastle disease in poultry and in certain birds. Among other things, the Directive confers on the Council, acting by qualified majority on a proposal from the Commission, the power to amend the Directive's Annexes. Inter alia, the Council has therefore the power to amend, Annexes V, VI and VII which cover the designation of an EU Reference Laboratory (EURL) for Newcastle disease, the template to be used by Member States to report to the Commission on the situation of the disease, and the control measures applied, as well as the criteria for Member States to draw up contingency plans to be implemented in the event of a disease outbreak.

Those empowerments conferred on the Council are at odds with the new system of legislation and executive rule-making introduced by the Treaty on the Functioning of the European Union (TFEU), more specifically with Article 291. Furthermore, in relation to the designation of EURLs, the current provisions for amending Annex V of Council Directive 92/66/EEC are inconsistent with the new designation regime for EURLs introduced by Regulation (EU) 2017/625 on Official Controls ('OCR'). This Regulation requires the Commission to designate EURLs by means of implementing acts.

The objective of this Proposal is to amend Council Directive 92/66/EEC to be aligned with the TFEU and new official control provisions in order to ensure legal coherence and certainty to enable the necessary simplification of procedures.

The current European Reference Laboratory (EURL) for Newcastle disease is located in the United Kingdom. Hence, it needs to be replaced by an EURL located in one of the other 27 Member States in view of the United Kingdom exiting the EU. The current procedure for designating an EURL for Newcastle disease is via a Council Directive. Therefore, an aligned and simplified decision procedure is urgently needed to enable the new EURL to be properly functioning by the date when the United Kingdom will exit the EU. This technical revision of the Directive will enable the use of the required implementing procedure to designate a new EURL for Newcastle disease within the tight deadlines related to BREXIT.

Whilst the main objective is to align the Directive in question with the TFEU and EU rules on the designation of EURLs, the measures proposed will also provide greater legal consistency and more streamlined implementing procedures.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THIS DIRECTIVE

The revision of Directive 92/66/EEC concerns purely necessary technical changes. Those changes are needed to ensure consistency with the TFEU and Regulation (EU) 2017/625 on official controls. Stakeholders were widely consulted on both the Treaty and the Regulation.

In addition, considering the purely technical/procedural nature of the intended changes, a full public consultation strategy is not considered necessary in this specific case. The 4-week feedback mechanism on the Roadmap will apply.

3. LEGAL BASIS OF THIS DIRECTIVE

The legal basis is Article 43(2) TFEU.

4. BUDGETARY IMPLICATION

The proposal does not imply incurring any expenditure which is not already foreseen in the financial statement of the common financial framework. No additional human resources are envisaged either.

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(Text with EEA relevance)

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 Committee¹,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) Council Directive 92/66/EEC² lays down the Union control measures to be taken in the event of an outbreak of Newcastle disease in poultry, racing pigeons and other birds kept in captivity.
- (2) Article 15 of Directive 92/66/EEC provides that the European Union reference laboratory for Newcastle disease is referred to in Annex V to that Directive. Annex V to that Directive duly refers to that laboratory and lists its functions and duties.
- (3) Article 19 of Directive 92/66/EEC lays down control measures to be taken by the Member States in the event that carrier pigeons or birds kept in captivity are suspected of being infected with Newcastle disease. It provides that to the extent required for the proper application of those control measures, the Member States are to furnish the Commission with information on the disease situation and the control measures applied in accordance with the model form set out in Annex VI to that Directive.
- (4) Article 21 of Directive 92/66/EEC provides that Member States are to draw up contingency plans, specifying the national measures to be implemented in the event of an outbreak of Newcastle disease. It provides that the criteria to be applied for drawing up those plans are set out in Annex VII to that Directive.
- (5) Article 24 of Directive 92/66/EEC provides that the Annexes thereto are to be amended, as and when required, by the Council acting by a qualified majority on a proposal from the Commission, in particular to take into account developments in research and in diagnostic procedures.

¹ OJ C [...], [...], p. [...].

² Council Directive 92/66/EEC of 14 July 1992 introducing Community measures for the control of Newcastle disease (OJ L 260, 5.9.1992, p. 1).

- (6) Annexes V, VI and VII to Directive 92/66/EEC set out respectively (i) the indication of the European Union reference laboratory for Newcastle disease as well as its functions and duties, (ii) the model form to be used by Member States in order to report on the disease situation and the control measures applied; and (iii) the criteria to be applied by Member States for drawing up contingency plans specifying the national measures to be implemented in the event of an outbreak of Newcastle disease.
- (7) In order to simplify and streamline the procedures regarding the control of Newcastle disease, in particular taking into account the new rules in relation to the designation of European Union reference laboratories provided for by Article 93 of Regulation (EU) 2017/625 of the European Parliament and of the Council³, and also the new system of implementing acts provided for in Article 291 of the Treaty on the Functioning of the European Union, and to ensure uniform conditions for the implementation of Directive 92/66/EEC, Annexes V, VI and VII to Directive 92/66/EEC should be deleted and implementing powers in the fields covered by those Annexes should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council⁴.
- (8) For reasons of clarity, the functions and duties of the European Union reference laboratory for Newcastle disease should be laid down in Article 15 of Directive 92/66/EEC, and the criteria for the contingency plans should be laid down in Article 21 of that Directive.
- (9) For reasons of consistency and efficiency, Member States should ensure timely transposition of the provisions of this Directive.
- (10) Directive 92/66/EEC should therefore be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

Article 1
Amendments to Directive 92/66/EEC

Directive 92/66/EEC is amended as follows:

- (1) Article 15 is replaced by the following:

‘Article 15

1. The Commission shall, by means of implementing acts, designate a European Union reference laboratory for Newcastle disease. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 25.

³ Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

⁴ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

2. The functions and duties of the European Union reference laboratory for Newcastle disease shall be the following:
- (a) to coordinate, in consultation with the Commission, the methods employed in the Member States for diagnosing Newcastle disease, specifically by:
 - (i) typing, storing and supplying strains of the Newcastle disease virus for serological tests and the preparation of antisera;
 - (ii) supplying standard sera and other reference reagents to the national reference laboratories in order to standardise the tests and reagents used in the Member States;
 - (iii) building up and retaining a collection of Newcastle disease virus strains and isolates;
 - (iv) organising periodical comparative tests of diagnostic procedures at Union level;
 - (v) collecting and collating data and information on the methods of diagnosis used and the results of tests carried out in the Union;
 - (vi) characterising isolates of Newcastle disease viruses by the most up-to-date methods available to promote a greater understanding of the epidemiology of Newcastle disease;
 - (vii) keeping abreast of developments in Newcastle disease surveillance, epidemiology and prevention throughout the world;
 - (viii) retaining expertise on Newcastle disease virus and other pertinent viruses to enable a rapid differential diagnosis;
 - (ix) acquiring a thorough knowledge of the preparation and use of the products of veterinary immunology used to eradicate and control Newcastle disease;
 - (b) to actively assist in the diagnosis of outbreaks of Newcastle disease in Member States by receiving virus isolates for confirmatory diagnosis, characterisation and epidemiology studies;
 - (c) to facilitate the training or retraining of experts in laboratory diagnosis with a view to the harmonisation of techniques throughout the Union.’;

(2) Article 19 is amended as follows:

- (a) paragraph 5 is replaced by the following:

‘5. To the extent that it is required for the proper application of the measures laid down in this Article, the Member States shall submit to the Commission, within the framework of the Standing Committee on Plants, Animals, Food and Feed, information on the disease situation and the control measures applied.’;
- (b) the following paragraph 6 is added:

6. The Commission may, by means of implementing acts, lay down rules regarding the information to be submitted by the Member States to the Commission as provided for in paragraph 5. Those implementing acts

shall be adopted in accordance with the examination procedure referred to in Article 25.’

- (3) Article 21 is replaced by the following:

‘Article 21

1. Each Member State shall draw up a contingency plan, specifying the national measures to be implemented in the event of an outbreak of Newcastle disease. The contingency plan shall be updated, as appropriate, to take account of developments in the situation.

The contingency plan must allow access to facilities, equipment, personnel and all other appropriate materials necessary for the rapid and efficient eradication of the outbreak of Newcastle disease. It must give a precise indication of the vaccine requirements which each Member State deems necessary for emergency vaccination.

2. The contingency plans and any updates thereto shall be submitted to the Commission.
3. The Commission shall examine the contingency plans and any updates thereto in order to determine whether they permit the desired objective to be attained and shall suggest to the Member State concerned any amendments required in particular to ensure that they are compatible with those of the other Member States.

The Commission shall approve the contingency plans and any updates thereto, if necessary amended, in accordance with the examination procedure referred to in Article 25.

4. The Commission may, by means of implementing acts, lay down criteria to be applied by Member States for drawing up the contingency plans. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 25.’

- (4) Article 25 is replaced by the following:

‘Article 25

1. The Commission shall be assisted by the Standing Committee on Plants, Animals, Food and Feed established by Article 58(1) of Regulation (EC) No 178/2002 of the European Parliament and of the Council^(*). That committee shall be a committee within the meaning of Regulation (EU) No 182/2011 of the European Parliament and of the Council^(**).
2. Where reference is made to this Article, Article 5 of Regulation (EU) No 182/2011 shall apply.

(*) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

(**) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission’s exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).’;

(5) Annexes V, VI and VII are deleted.

Article 2

Transposition

By 30 June 2018, Member States shall adopt and publish the measures necessary to comply with this Directive. They shall immediately inform the Commission thereof.

They shall apply those measures from 1 January 2019.

When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

Article 3

Transitional provision

The designation of the Community reference laboratory for Newcastle disease referred to in Annex V to Directive 92/66/EEC, before the amendments made by this Directive, shall remain effective until a European Union reference laboratory for Newcastle disease has been duly designated in accordance with Article 15 of Directive 92/66/EEC, as amended by this Directive.

Article 4

Entry into force

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

Article 5

Addressees

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President