EXPLANATORY MEMORANDUM FOR EUROPEAN UNION LEGISLATION WITHIN THE SCOPE OF THE UK/EU WITHDRAWAL AGREEMENT AND NORTHERN IRELAND PROTOCOL

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COMMISSION DELEGATED REGULATION (EU) …/... OF 28.11.2022 SUPPLEMENTING REGULATION (EU) 2016/429 OF THE EUROPEAN PARLIAMENT AND THE COUNCIL AS REGARDS RULES FOR THE USE OF CERTAIN VETERINARY MEDICINAL PRODUCTS FOR THE PURPOSE OF PREVENTION AND CONTROL OF CERTAIN LISTED DISEASES

Submitted by Department for Environment, Food and Rural Affairs

14 February 2023

SUBJECT MATTER

1. Regulation (EU) 2016/429 (the 'Animal Health Law') sets European Union (EU) rules for the prevention and control of animal diseases which are transmissible to animals or to humans. The delegated act of 28 November 2022 supplements the Animal Health Law. It sets detailed rules for the use of veterinary medicines to prevent and control certain animal diseases in the EU. These diseases include those that the EU defines as Category A and Category B. Category A diseases are those which do not normally occur in the EU and requiring immediate eradication measures. Examples include Rinderpest, Foot and Mouth Disease, Rift Valley Fever, Lumpy skin disease, Peste des petits ruminants, African horse sickness, Classical swine fever, Highly Pathogenic Avian Influenza and Newcastle disease virus. Category B diseases are those requiring control with the objective of eradication. Examples include bovine tuberculosis (TB) and brucellosis.

2. In general terms, the delegated act:

    - Restricts the use of certain veterinary medicines for prevention and control of category A and B diseases.
    - Imposes rules on the use of veterinary vaccines for prevention and control of category A diseases and certain category B diseases.
    - Sets out risk-mitigating measures to prevent the spread of category A diseases through vaccinated animals or their products.
    - Imposes rules for surveillance of category A diseases following the use of veterinary vaccines to prevent and control them.

3. Specifically, the delegated act:

    - Prohibits vaccination against Rinderpest and against bovine TB.

- Imposes conditions on the use of certain immunological veterinary medicines for the diagnosis of brucellosis and bovine TB.
- Sets detailed rules for vaccination of animals against Foot and Mouth Disease, Rift Valley Fever, Lumpy skin disease, Peste des petits ruminants, African horse sickness, Classical swine fever, Highly Pathogenic Avian Influenza and Newcastle disease virus.

4. The delegated act does not apply to the use of veterinary medicinal products for scientific studies or for product development and testing.

5. Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC sets out rules for the marketing, manufacturing, importing, exporting, supply, distribution, pharmacovigilance, control and use of veterinary medicines in the EU. The Regulation defines what a veterinary medicine is and sets out the conditions under which EU countries may exceptionally permit the use of immunological veterinary medicines which are not authorised in the EU. The delegated act supplements Regulation (EU) 2019/6 in setting out specific conditions relating to the use or the prohibition of veterinary medicines to prevent or control certain Category A and Category B diseases, irrespective of a veterinary medicine's origin, marketing authorisation or other characteristics.

6. Regulations (EU) 2019/4[1] and 2019/6 are not entirely covered by the Notice[2] the EU issued in December 2022 extending the grace period on veterinary medicine supplies to Northern Ireland until December 2025. However, as per the 'standstill' arrangement with the EU, all existing operational arrangements of the Northern Ireland Protocol will continue whilst discussions with the EU are ongoing. The interaction of the delegated act with the non-implementation of Regulations (EU) 2019/4 and 2019/6 is complex. Although the delegated act does not explicitly mention Article 110 of Regulation (EU) 2019/6, the delegated act has some limited interplay with the non-implementation of Regulation (EU) 2019/6, given Article 110 is one small part of the wider disease control mechanism. While this article is not implemented specifically, the use of vaccines is provided for where it is necessary.

SCRUTINY HISTORY

7. There is no Parliamentary scrutiny history relevant to this Explanatory Memorandum.

[1] Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC
[2] www.gov.uk/government/news/european-commission-announces-three-year-extension-to-the-grace-period-for-veterinary-medicines

MINISTERIAL RESPONSIBILITY

8. The Secretary of State for Environment, Food and Rural Affairs is responsible for animal health policy in England.

INTEREST OF THE DEVOLVED ADMINISTRATIONS

9. Animal health policy is a devolved matter. The devolved administrations are responsible for animal health policy in Scotland, Wales and Northern Ireland.

10. Scottish Government Ministers, Welsh Government Ministers and Northern Ireland have an interest. The devolved administrations have been consulted in the preparation of this Explanatory Memorandum and have no comments.

11. The delegated act applies in Northern Ireland in accordance with article 5.4 and annex 2 of the Northern Ireland Protocol.

LEGAL AND PROCEDURAL ISSUES

12.

i. Legal Base

Article 47(1) of Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law').

ii. Voting Procedure

Qualified majority voting.

iii. Timetable for adoption and implementation

The European Commission adopted the delegated act on 28 November 2022. Once the European Commission adopts a delegated act, the European Parliament and the European Council have two months to scrutinise it. However, there is some flexibility around this timeframe. If neither object to the delegated act within the scrutiny period, it enters into force.

POLICY IMPLICATIONS

13. The delegated act applies in Northern Ireland under the Northern Ireland Protocol but does not affect existing animal disease control measures applied UK-wide. It should have no impact on the movement of goods between Great Britain and Northern Ireland as it relates to animal disease prevention and control measures. Regarding Northern Ireland, the Protocol is causing significant problems. It is our preference to find a solution and resolve these problems through talks, and the

Government is engaging in constructive dialogue with the EU to find solutions to these problems. However, the Northern Ireland Protocol Bill aims to fix the practical problems the Protocol has created in Northern Ireland if a solution cannot be found with the EU.

14. With regards to prohibition on vaccines, Rinderpest has been eradicated worldwide and the World Organisation for Animal Health (WOAH) advises that the only potential bovine TB vaccine for cattle is Bacille Calmette-Guèrin (BCG). BCG may sensitise animals to bovine TB tests which underpin international trade. Hence, vaccination of cattle against TB is prohibited in many countries. The EU already has an implicit ban on vaccinating cattle in the EU against bovine TB because BCG is not compatible with EU-approved tests for bovine TB eradication and trade in live cattle. The European Commission's rationale for prohibiting vaccination of cattle against bovine TB reflects its long-standing position. In 2013, the relevant commissioner wrote to the then Secretary of State for Environment, Food and Rural Affairs that '*vaccination against bTB is explicitly forbidden in the EU legislation on disease control (Council Directive 78/52/EEC) and implicitly also in intra-Union trade legislation, as vaccination is not compatible with the provisions for testing and herd qualification (Council Directive 64/432/EEC). EU legislation is fully in line with OIE* [now WOAH] *standards on international trade'*. The Animal Health Law repealed these directives in 2021.

15. There is no authorised bovine TB vaccine for cattle in the UK and vaccination of cattle against bovine TB without Ministerial consent is prohibited under national legislation. The Government (on behalf of the Welsh Government and Scottish Government) is funding research and development, which aims to secure national marketing authorisations and international recognitions for a bovine TB vaccine for cattle and a new DIVA test to detect infected among vaccinated animals. UK field trials of the candidate vaccine and DIVA test are ongoing and securing the necessary marketing authorisations and international recognitions remains some years away. In the meantime, the Government is considering future bovine TB vaccine deployment options in anticipation. This includes a consideration of potential trade implications and how best to mitigate them. For example, under the UK-EU Trade and Cooperation Agreement, we will need to notify the EU if there are changes to preventive policy, including vaccination policy. There are hypothetical risks of future policy divergence if one or more administrations in Great Britain permits vaccination of cattle against bovine TB with a UK-authorised vaccine while the EU prohibition remains. The EU prohibition will also deter EU countries from seeking their own national marketing authorisations. This may impact on potential commercial opportunities for the Government to supply relevant data to support that process. Securing WOAH recognition of the new DIVA test will be crucial in gaining EU and wider international acceptance of bovine TB vaccination and trade in vaccinated cattle and mitigating the above risks. The

Government continues to monitor and mitigate the impact of policy developments that have created or have the potential to create regulatory divergence.

CONSULTATION

16. The Government has not consulted external stakeholders, other than the devolved administrations, about the delegated act and has no plans to do so.

FINANCIAL IMPLICATIONS

17. No financial implications have been identified as the delegated act does not affect existing UK animal disease control measures.

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