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

6916/21
COM(2021) 108 final

PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AMENDING REGULATION (EU) 2017/625 AS REGARDS OFFICIAL CONTROLS ON ANIMALS AND PRODUCTS OF ANIMAL ORIGIN EXPORTED FROM THIRD COUNTRIES TO THE UNION TO ENSURE COMPLIANCE WITH THE PROHIBITION OF CERTAIN USES OF ANTIMICROBIALS

Submitted by the Department for Environment, Food and Rural Affairs

_____**30**_____ March 2021

SUBJECT MATTER

1. European Union (EU) Regulation 2019/6[1] (on veterinary medicinal products) does not make provisions for official controls on compliance of imports from third countries into the EU with Article 118(1) of that Regulation. As there currently is no legal basis for such controls, the proposed Regulation is needed to enable appropriate implementation and enforcement of this Article.

2. Article 118(1) of EU Regulation 2019/6 sets out prohibitions for operators in third countries on the use of antimicrobial medicines in animals for the purpose of promoting growth or increasing yield, and on the use in animals of antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans, where this relates to animals and products of animal origin exported from those countries to the EU.

3. EU Regulation 2017/625[2] (on official controls on animals and products of animal origin, including those entering the EU from third countries) could ordinarily be used

[1] Regulation (EU) 2019/6 of the European Parliament and of the Council on veterinary medicinal products and repealing Directive 2001/82/EC
[2] Regulation (EU) 2017/625 of the European Parliament and of the Council 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)

to enable the official controls to legally take place, but in the present case official controls on compliance with EU Regulation 2019/6 are effectively excluded by Article 1(4)(c) of EU Regulation 2017/625. The proposed Regulation is a technical amendment to Article 1(4)(c) to include controls on compliance with EU Regulation 2019/6 Article 118(1) in the scope of EU Regulation 2017/625.

4. Implementing legislation specifying the particulars for official controls in relation to Article 118(1) is, as of yet, not publicly available and therefore details on those controls are not yet available.

5. The proposed Regulation would also correct a minor error in Article 47(1)(e) of EU Regulation 2017/625. This relates to an incorrect reference to an Article in EU Regulation 2016/429 (the EU's Animal Health Law) which applies from 21 April 2021.

SCRUTINY HISTORY

6. The Parliamentary scrutiny history relevant to this Explanatory Memorandum is contained in Annex A.

MINISTERIAL RESPONSIBILITY

7. Responsibility lies with the Secretary of State for Environment, Food and Rural Affairs.

8. Department for International Trade Ministers also have an interest in regard to standards and market access and exports.

INTEREST OF THE DEVOLVED ADMINISTRATIONS

9. Veterinary medicines are a reserved matter in Great Britain but generally devolved to Northern Ireland under the UK's devolution settlements. Policy on antimicrobial resistance is a devolved matter. Import controls on animals and animal products for the purposes of protecting human and animal health are devolved matters.

10. Devolved administrations have been consulted in the preparation of this Explanatory Memorandum.

11. Veterinary medicines are subject to the common framework Animal Health and Welfare: EU rules and standards that aim to maintain animal health and allow their movement, including policies covering: prevention of disease (entering UK), control of disease (endemic and exotic), surveillance (for exotic disease), movement of livestock, pet passports and veterinary medicines.

LEGAL AND PROCEDURAL ISSUES

12.

i. **Legal Base**

The legal bases of this proposed Regulation are Article 43(2), Article 114 and Article 168(4)(b) of the Treaty on the Functioning of the European Union.

ii. **Voting Procedure**

Qualified Majority Voting.

iii. **Timetable for adoption and implementation**

The proposed Regulation needs to be adopted before EU Regulation 2019/6 comes to apply, which is 28 January 2022, and also needs to be adopted in sufficient time for the preparation of necessary implementing acts before that date.

POLICY IMPLICATIONS

13. The EU legislation listed in Annex 2 of the Northern Ireland Protocol continues to apply in Northern Ireland. EU Regulation 2017/625 is listed in Annex 2. EU Regulation 2019/6 will directly apply in Northern Ireland from 28 January 2022. The proposed Regulation, if adopted, would be directly applicable in Northern Ireland. Neither EU Regulation 2019/6 nor the proposed Regulation will be applicable in Great Britain.

14. The appropriate authorities in Northern Ireland are obliged to apply and enforce the official controls set out in EU Regulation 2017/625. This includes the controls introduced into EU Regulation 2017/625 by this proposed technical amendment, which are to verify compliance with Article 118(1) of EU Regulation 2019/6 as regards animals and products of animal origin entering Northern Ireland/the EU from third countries.

15. As a third country, the UK were not involved in discussions on the proposed Regulation. The European Commission is working on legislation for import controls relating to the EU Regulations 2017/625 and 2019/6 (Article 118), but this is not yet published and therefore details on those controls are not yet available.

CONSULTATION

16. The European Commission has consulted on Article 118 in EU Regulation 2019/6, and the UK Parliament has previously scrutinised on the EU Regulation 2019/6, including Article 118 – see Parliamentary Scrutiny history in Annex A.

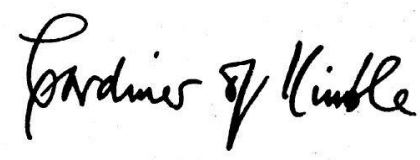
17. No consultation with external stakeholders has taken place or is planned by the Government on this proposal.

18. The European Commission is currently holding public consultation on the proposed Regulation; the feedback period is from 10 March 2021 to 05 May 2021: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12944-EU-rules-on-official-controls-update-to-allow-controls-of-imports-for-the-use-of-certain-antimicrobials-.

FINANCIAL IMPLICATIONS

19. The proposed Regulation would allow for the controls to fall under the framework of EU Regulation 2017/625 and the European Commission states that this therefore will not introduce any significant burden on economic operators and on EU Member States.

20. However, there may be a cost to the appropriate authorities in Northern Ireland to put in place the infrastructure to perform the controls.



LORD GARDINER OF KIMBLE
PARLIAMENTARY UNDER SECRETARY OF STATE (MINISTER FOR RURAL AFFAIRS AND BIOSECURITY)
DEPARTMENT FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS

ANNEX A

PARLIAMENTARY SCRUTINY HISTORY RELEVANT TO A:

PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AMENDING REGULATION (EU) 2017/625 AS REGARDS OFFICIAL CONTROLS ON ANIMALS AND PRODUCTS OF ANIMAL ORIGIN EXPORTED FROM THIRD COUNTRIES TO THE UNION TO ENSURE COMPLIANCE WITH THE PROHIBITION OF CERTAIN USES OF ANTIMICROBIALS

EM 8280/20: COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS A FARM TO FORK STRATEGY FOR A FAIR, HEALTHY AND ENVIRONMENTALLY-FRIENDLY FOOD SYSTEM

8280/20 ADD 1: ANNEX TO THE COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS A FARM TO FORK STRATEGY FOR A FAIR, HEALTHY AND ENVIRONMENTALLY-FRIENDLY FOOD SYSTEM

DATE DEFRA EM SIGNED: 26/06/2020 SEM 15/7/2020

SCRUTINY COMMITTEES' RECOMMENDATIONS:

COMMONS	LORDS
SCRUTINY COMPLETE (ESC OUTCOME AGENDA 24) 21/10/2020	DRAWN TO THE ATTENTION OF (EU ENVIRONMENT SUB COMMITTEE) AT CHAIR'S SIFT 23 23/7/2020

EUROPEAN COURT OF AUDITORS: SPECIAL REPORT NO 21/2019. ADDRESSING ANTIMICROBIAL RESISTANCE: PROGRESS IN THE ANIMAL SECTOR, BUT THIS HEALTH THREAT REMAINS A CHALLENGE FOR THE EU

DATE DEFRA EM SIGNED: 20/12/2019

SCRUTINY COMMITTEES' RECOMMENDATIONS:

COMMONS	LORDS
CLEARED AS NOT IMPORTANT (ESC OUTCOME AGENDA 30/4/2020)	CLEARED (ENERGY AND ENVIRONMENT) AT CHAIRMAN'S SIFT 1760 - 16/1/2020

EM 11128/17: COMMUNICATION FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN PARLIAMENT A EUROPEAN ONE HEALTH ACTION PLAN AGAINST ANTIMICROBIAL RESISTANCE (AMR)

ADD1: COMMISSION STAFF WORKING DOCUMENT SYNOPSIS REPORT ACCOMPANYING THE DOCUMENT

DATE DHSC EM SIGNED: 02/08/2017

SCRUTINY COMMITTEES' RECOMMENDATIONS:

COMMONS	LORDS
REPORTED AS POLITICALLY IMPORTANT IN REPORT 3 & 13, 17/19 AND NOT CLEARED	CLEARED AT SIFT 1664 ON 06/09/2017

EM 13240/14: PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AMENDING REGULATION (EC) NO 726/2004 LAYING DOWN COMMUNITY PROCEDURES FOR THE AUTHORISATION AND SUPERVISION OF MEDICINAL PRODUCTS FOR HUMAN AND VETERINARY USE AND ESTABLISHING A EUROPEAN MEDICINES AGENCY

EM 13289/14: PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON VETERINARY MEDICINAL PRODUCTS

13289/14 ADD 1: ANNEXES TO THE PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON VETERINARY MEDICINAL PRODUCTS

13289/14 ADD 2: COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT ACCOMPANYING THE DOCUMENT PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON VETERINARY MEDICINAL PRODUCTS

13289/14 ADD 3: COMMISSION STAFF WORKING DOCUMENT EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT ACCOMPANYING THE DOCUMENT PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON VETERINARY MEDICINAL PRODUCTS

DATE DEFRA EM SIGNED: 26/09/2014

SCRUTINY COMMITTEES' RECOMMENDATIONS:

COMMONS	LORDS
13240-14 CLEARED AS POLITICALLY IMPORTANT, (AGENDA FOR REPORT NO 21; 21/3/2018 13289-14 POLITICALLY IMPORTANT CLEARED, FURTHER INFORMATION REQUIRED (AGENDA FOR REPORT NO 32; 20/6/2018)	CLEARED BY HOUSE OF LORDS LETTER DATED 11/10/2017

EM 9464/13, COM (2013) 265 FINAL: DRAFT INSTRUMENT CONCERNING A PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL 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, PLANT REPRODUCTIVE MATERIAL AND PLANT PROTECTION PRODUCTS

DATE FSA EM SIGNED: 03/06/2013

SCRUTINY COMMITTEES' RECOMMENDATIONS:

COMMONS	LORDS
REPORT NO: 09 DATED: 10/07/2013: RECOMMEND: LPINC REPORT NO: 39 DATED: 24/03/2015: RECOMMEND: LPINC REPORT NO: 07: DATED: 28/10/2015: RECOMMEND: LPIC	SIFT NO: 1508: DATED: 11/06/2013 FINAL CLEARED ON 14/11/2016