EXPLANATORY MEMORANDUM FOR EUROPEAN UNION LEGISLATION WITHIN THE SCOPE OF THE UK/EU WITHDRAWAL AGREEMENT AND WINDSOR FRAMEWORK

C(2024) 661 FINAL

COMMISSION DELEGATED REGULATION (EU) 2024/1159 OF 7.2.2024 SUPPLEMENTING REGULATION (EU) 2019/6 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL BY LAYING DOWN RULES ON APPROPRIATE MEASURES TO ENSURE THE EFFECTIVE AND SAFE USE OF VETERINARY MEDICINAL PRODUCTS AUTHORISED AND PRESCRIBED FOR ORAL ADMINISTRATION VIA ROUTES OTHER THAN MEDICATED FEED AND ADMINISTERED BY THE ANIMAL KEEPER TO FOOD PRODUCING ANIMALS
Delegated regulation - EU - 2024/1159 - EN - EUR-Lex (europa.eu)

Submitted by Department for Environment, Food and Rural Affairs
16 May 2024

SUBJECT MATTER

1. The purpose of this delegated regulation is to establish rules on appropriate measures to ensure the effective and safe use of veterinary medicinal products administered via drinking water or milk. This delegated regulation falls under the Windsor Framework as it supplements 2019/6, which is included in Annex 2, as it replaced 2001/82/EC.

2. Veterinary medicines can be administered orally via drinking water and milk. The delegated regulation states this type of administration may be associated with risks to public and animal health and to the environment. This is due to inappropriate administration or dosing leading to possible reduction of product effectiveness, development of antimicrobial or antiparasitic resistance, unintended administration to non-target animals and risks for the target animals, environment and for consumers. The purpose of the regulation is to address this risk.

SCRUTINY HISTORY

3. The Parliamentary scrutiny history relevant to this Explanatory Memorandum is contained in the attached Annex A.

MINISTERIAL RESPONSIBILITY

4. The Secretary of State for Environment, Food and Rural Affairs is responsible for this policy.

INTEREST OF THE DEVOLVED ADMINISTRATIONS

5. The draft EM was shared with the Scottish and Welsh Governments, and also with the Northern Irish Executive, no comments were received.

LEGAL AND PROCEDURAL ISSUES

6.

i. Legal Base

This is a delegated Regulation supplementing EU Regulation 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC.

ii. Voting Procedure

In accordance with Article 147(5) of Regulation (EU) 2019/6, the Commission has carried out substantial consultation with Member States' experts on veterinary medicines.

This draft Delegated Regulation was also made available to the European Parliament and the Council.

There were no comments received from the Council.

There were no comments received from the European Parliament.

In addition, stakeholders' comments on the draft Delegated Regulation were collected in the context of the Better Regulation feedback mechanism during the period between 13 December 2023 and 10 January 2024

iii. Timetable for adoption and implementation

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

It shall apply from 18 months after the date of entry into force of this Regulation.

This Regulation shall be binding in its entirety and directly applicable in all Member States.
Done at Brussels, 7.2.2024

POLICY AND LEGAL IMPLICATIONS

7. The delegated regulation describes various measures to ensure:
    a. Responsible prescribing and use
    b. Effective dosing
    c. Prevention of cross contamination

d. Maintenance/cleaning of dosing equipment

e. Use of these veterinary medicines in accordance with the product information

8. Under the Windsor Framework this Delegated Regulation will apply in Northern Ireland, subject to the democratic scrutiny mechanism in place. The newly introduced legislation is similar to existing GB legislation. In both pieces of legislation, all medicines administered via drinking water or milk are prescription medicines and therefore cannot be used without oversight and guidance of a prescribing vet. GB legislation also states that no person may administer a veterinary medicine to an animal unless its administration is in accordance with its marketing authorisation (MA) (with two exemptions).

9. The Delegated Regulation sets out rules around prescribing decisions, including for antimicrobial and antiparasitic veterinary medicines, simultaneous use of veterinary medicines and other categories of products such as biocidals or feed additives, and the information that needs to be provided by the vet to the animal keeper on the disposal of the product. It also introduces specific rules for the handling and use of these medicines by animal keepers and the equipment. Finally, the Regulation sets out what needs to be included in the product information of the medicines covered by it.

10. The Delegated Regulation introduces some further detail in law around practical measures (in relation to the areas set out in the list above) than currently exists in GB law, but these are already considered good practice within the UK. There is therefore no practical divergence on how products will be used on farms.

11. The appropriate use of these veterinary medicines is linked to managing antimicrobial and antiparasitic resistance. More targeted administration of antibiotics reduces the risk of development and spread of antimicrobial resistance (AMR). In water use can allow for more targeted antibiotic administration than in-feed, reducing AMR risk. This is therefore in accordance with the Veterinary Medicines Directorate (VMD)'s ambitions (as the relevant government authority in this area) to reduce the unnecessary use of antibiotics in animal production in line with the One Health approach, and in compliance with the Global Action Plan on AMR.

12. It is also in accordance with the VMDs objective to ensure the safe and efficacious use of all veterinary medicines.

CONSULTATION

13. There is no planned consultation on this Regulation.

FINANCIAL IMPLICATIONS

14. There are no financial implications for the UK.

LORD DOUGLAS-MILLER
PARLIAMENTARY UNDER SECRETARY OF STATE (MINISTER FOR BIOSECURITY, ANIMAL HEALTH & WELFARE)
DEPARTMENT FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS

ANNEX A

PARLIAMENTARY SCRUTINY HISTORY RELEVANT TO:

COMMISSION DELEGATED REGULATION (EU) 2024/1159 OF 7.2.2024 SUPPLEMENTING REGULATION (EU) 2019/6 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL BY LAYING DOWN RULES ON APPROPRIATE MEASURES TO ENSURE THE EFFECTIVE AND SAFE USE OF VETERINARY MEDICINAL PRODUCTS AUTHORISED AND PRESCRIBED FOR ORAL ADMINISTRATION VIA ROUTES OTHER THAN MEDICATED FEED AND ADMINISTERED BY THE ANIMAL KEEPER TO FOOD PRODUCING ANIMALS

C(2023)1272 FINAL;COMMISSION DELEGATED REGULATION (EU) …/... OF 27.2.2023 SUPPLEMENTING REGULATION (EU) 2019/6 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AS REGARDS THE APPLICATION OF THE PROHIBITION OF USE OF CERTAIN ANTIMICROBIAL MEDICINAL PRODUCTS IN ANIMALS OR PRODUCTS OF ANIMAL ORIGIN EXPORTED FROM THIRD COUNTRIES INTO THE UNION

DATE DEFRA EM SIGNED: 19/05/2023

SCRUTINY COMMITTEES' RECOMMENDATIONS:

COMMONS	LORDS
CLEARED FROM SCRUTINY (OUTCOME AGENDA 39, 12/7/23)	CLEARED FROM SCRUTINY (OUTCOME AGENDA 39, 12/7/23)

EM 9216/21, C (2021) 3552 FINAL: COMMISSION DELEGATED REGULATION (EU) …/... OF 26.5.2021 SUPPLEMENTING REGULATION (EU) 2019/6 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL BY ESTABLISHING THE CRITERIA FOR THE DESIGNATION OF ANTIMICROBIALS TO BE RESERVED FOR THE TREATMENT OF CERTAIN INFECTIONS IN HUMANS

DEFRA SUBMITTED AN EM DATED 09/12/2021

SCRUTINY COMMITTEES' RECOMMENDATIONS:

COMMONS	LORDS
SCRUTINY COMPLETED (OUTCOME AGENDA NO 26 26/1/22)	DRAWN TO THE ATTENTION OF THE PROTOCOL ON IRELAND/NORTHERN IRELAND SUB-COMMITTEE (AT CHAIR'S SIFT NO 12; 16/12/21)

EM 6916/21, 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

DATE DEFRA EM SIGNED: 30/03/2021

SCRUTINY COMMITTEES' RECOMMENDATIONS:

COMMONS	LORDS
SCRUTINY COMPLETED (OUTCOME AGENDA NO 1 12/5/21)	SIFTED FOR EXAMINATION TO THE PROTOCOL ON IRELAND/NORTHERN IRELAND SUB-COMMITTEE (AT CHAIR'S SIFT 1 22/4/2021)

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