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

C (2022) 4400 FINAL + ANNEXES 1-7

COMMISSION DELEGATED REGULATION (EU) …/... OF 7.7.2022 SUPPLEMENTING REGULATION (EU) 2017/625 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL WITH SPECIFIC REQUIREMENTS FOR THE PERFORMANCE OF OFFICIAL CONTROLS ON THE USE OF PHARMACOLOGICALLY ACTIVE SUBSTANCES AUTHORISED AS VETERINARY MEDICINAL PRODUCTS OR AS FEED ADDITIVES AND OF PROHIBITED OR UNAUTHORISED PHARMACOLOGICALLY ACTIVE SUBSTANCES AND RESIDUES THEREOF

Submitted by the Department for Environment, Food and Rural Affairs

30 August 2022

SUBJECT MATTER

1. This Regulation ('C(2022)4400') outlines new requirements for Member States on the monitoring of residues of veterinary medicines and prohibited substances in products of animal origin (POAO).

2. These requirements will come into force on the 15 December 2022 and they are a technical iteration on existing residue monitoring requirements.

3. This legislation will sit under the existing EU Regulation 2017/625[1] on Official Controls on Food and Feed, termed the OCR. This draft legislation applies in Northern Ireland (NI) under the terms of the Protocol of Ireland/Northern Ireland Protocol (NIP). In NI the Department for Agriculture, Environment and Rural Affairs (DAERA) and the Food Standards Agency will be responsible for its operational implementation and delivery.

4. Prior to the publication of the OCR in 2017, the previous requirements for the monitoring of veterinary medicines and prohibited substances in POAO were outlined in Council Directive 96/23/EC[2]. This legislation was partly repealed by the OCR, with Annexes I-IV remaining live until the 14 December 2022 as per Article 150 of the OCR on transitional measures relating to 96/23/EC.

[1] Link
[2] Link

5. Annexes I-IV of 96/23/EC are critical as they outline the requirements for monitoring of residues in POAO, including the substances that must be monitored for and the sampling/testing frequencies required for each foodstuff. Without these Annexes remaining live there would be no clearly prescribed basis for monitoring by EU Member States.

6. Although this regulation will not apply directly in Great Britain (GB), the detail of 96/23/EC and any future residues regulations remain relevant in the UK post EU-Exit as the EC expects an equivalent level of POAO monitoring for non-EU trading partners as they do Member States. As a result, the existing requirements for POAO continue to be implemented in GB.

7. The requirement for non-EU trading partners to adhere to the existing requirements of 96/23/EC is captured in the DG Health & Food Safety's 'Guidance on EU Requirements for imports of POAO'[3], and this document also outlines the requirement for trading partners to submit their residue monitoring plans and results to the EC annually, by the 31 March each year.

8. This annual submission of residue plans and results, made by the Veterinary Medicines Directorate (VMD) with the sight of the UK Chief Veterinary Officer's Office, allows the United Kingdom (GB specifically, with NI out of scope under the terms of the NIP) to make exports of POAO into the EU, with the EU summarising the goods approved for EU import in Commission Decision 2011/163/EU[4]. Within this legislation GB are approved to export foodstuffs such as bovine meat, milk, fish, eggs and honey etc.

SCRUTINY HISTORY

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

MINISTERIAL RESPONSIBILITY

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

[3] Link
[4] Link

INTEREST OF THE DEVOLVED ADMINISTRATIONS

11. The control of residues of prohibited substances, veterinary medicines and contaminants is a devolved policy matter across England, Wales, Northern Ireland and Scotland, but in practice for most POAO these activities are coordinated by the VMD in GB, with some sampling undertaken by the Food Standards Agency, Food Standards Scotland or local authorities. The Department of Agriculture, Environment and Rural Affairs (DAERA) are the equivalent Competent Authority for residues in Northern Ireland and operate the monitoring and testing in accordance with EU legislation under the terms of the NIP in addition to sampling by the Food Standards Agency and local authorities.

12. Officials in DAERA have welcomed sight of this forthcoming legislation which is due to take effect from January 2023. DAERA note the requirements of the new legislation, specifically the creation of the three specific monitoring plans, with plans 1 and 2 being broadly similar to work already undertaken by DAERA regarding veterinary residues surveillance in Northern Ireland. The addition of the risk-based control plan for third country imports is a new requirement and will require further discussion to establish who will deliver this plan, as this has historically been within the remit of the Food Standards Agency (FSA). Input has been provided at official level and does not represent the views of NI Executive Ministers.

13. The Devolved Governments of Scotland and Wales were consulted in the preparation of this Explanatory Memorandum and although no concerns were raised by Scottish Government, the Welsh Government has raised ongoing concerns with the Northern Ireland Protocol.

LEGAL AND PROCEDURAL ISSUES

14.

i. Legal Base

The legal basis for the Delegated Regulation is Article 19(2)(a) of Regulation (EU) 2017/625.

ii. Voting Procedure

Not applicable - this is a Delegated Regulation to be made by the European Commission.

iii. Timetable for adoption and implementation

Under the terms of Article 150 of the OCR the European Commission will publish these new residue monitoring requirements by the 14 December 2022,

and it is described in this draft legislation that the new requirements will apply in Member States from 15 December 2022.

POLICY IMPLICATIONS

15. The policy implications of this new Regulation differ slightly for GB and NI, due to the nuances of NIP implementation and export listing, as detailed in the Subject Matter.

For Northern Ireland:

- These requirements will need to be implemented by the 15 December 2022, and failure to do so may result in the European Commission (EC) deeming NI residue controls to not meet the legal obligations in assuring compliance with food safety controls – this could result in issues for export of POAO on a commodity basis e.g. for milk, pork, beef etc.

- The costs of administering residue controls in NI and GB are recovered from the agricultural sectors, and the mechanism for doing so is outlined in NI and GB legislation. The cost of the existing veterinary medicine residues controls in Northern Irish POAO costs £1.8m per annum. Any additional costs that may arise as a result of potential regulatory divergence cannot be quantified as they will depend on the nature of any future divergence. As is also the case with the GB programme, the Government would seek to recover any new/additional costs from the livestock industry, and consultation with the respective agricultural sectors on any additional fees will be a key part of any legislative (fee) changes required in future

- However, it should be highlighted that these new monitoring requirements are already largely met in NI via existing vet residue controls, and as such the risk of failing to meet new requirements is low. The draft requirements are less prescriptive than 96/23/EC in terms of specific sampling and testing requirements, and in some cases the testing rates are lower than the current ones, but there are new requirements which will need to be implemented in NI – the two significant schemes involve testing of imported goods, and implementation of a small-scale additional sampling programme to meet EU requirements.

- These two aspects will require significant logistical planning to implement, and work continues to ensure delivery. DAERA will also need to fund the Agri-Food Biosciences Institute of Northern Ireland (AFBI NI) or their designated EU National Reference Laboratory (NRL) to validate laboratory test methods for several substance groups as outlined in the legislation.

We recognise the impact the Northern Ireland Protocol is having on the ground. The UK Government has been clear for some time that the Protocol has been causing serious problems. We will continue to talk with the EU and our preference is - and has always been - to reach a negotiated outcome with EU, while in parallel moving forward with our solution to protect peace in Northern Ireland. We remain open to continuing talks with the EU, while these continue, we will take steps to stabilise the situation in Northern Ireland and bring parity to everyone living the UK.

For Great Britain:

- GB is not legislatively bound to implement the additional sampling schemes as required of NI, but we will seek to have equivalent domestic controls with the new requirements for existing domestic controls – as is the case presently, the legislation is quite clear that the EC expects non-EU trading partners to have equivalent vet residue controls in place. In the context of these controls, ensuring equivalence means adhering to the same technical requirements on sampling frequencies, testing levels and Maximum Residue Limits (MRLs).

- On MRLs, the legislation is clear that POAO exported from GB to the EU and NI should meet EU MRLs for veterinary medicines. Whilst this is not an issue at present due to lack of divergence between GB and EU veterinary MRLs, close scrutiny of any changes to domestic MRLs will be required for the future to ensure harmonisation.

- Unfettered Market Access will continue from NI to GB. We consider these amendments low risk for NI-GB trade.

CONSULTATION

16. A communication[5] published on the 07 July 2022 confirms that the EC consulted and agreed these new legislative requirements ('C(2022) 744 final') with Member State experts in the EU Official Controls Expert Group on the 10 June 2022.

17. No impact assessment was carried out by the EC in January 2022 as the Delegated Regulation is not expected to have any significant impact on MS - and likewise NI colleagues have not had sight of these drafts or discussions until now.

[5] Link

FINANCIAL IMPLICATIONS

18. There will likely be no economic or financial impacts if the requirements of this proposal are adopted and implemented in NI, outside of the costs of setting up additional sampling, testing, and test method validation. Though these requirements are unlikely to be met, failure to bring existing monitoring in line with these new requirements could lead to rejection of NI exports of POAO to the EU – and this would have significant financial impacts for exporters in NI, as well as the wider agricultural sector.

THE RT HON LORD BENYON
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:

COMMISSION DELEGATED REGULATION (EU) …/... OF 7.7.2022 SUPPLEMENTING REGULATION (EU) 2017/625 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL WITH SPECIFIC REQUIREMENTS FOR THE PERFORMANCE OF OFFICIAL CONTROLS ON THE USE OF PHARMACOLOGICALLY ACTIVE SUBSTANCES AUTHORISED AS VETERINARY MEDICINAL PRODUCTS OR AS FEED ADDITIVES AND OF PROHIBITED OR UNAUTHORISED PHARMACOLOGICALLY ACTIVE SUBSTANCES AND RESIDUES THEREOF

7536/22+ ADD 1, C(2022) 744 FINAL+ ANNEXES 1 TO 2: COMMISSION DELEGATED REGULATION (EU) …/...OF 23.3.2022 SUPPLEMENTING REGULATION (EU) 2017/625 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL BY LAYING DOWN RULES FOR THE PERFORMANCE OF OFFICIAL CONTROLS AS REGARDS CONTAMINANTS IN FOOD

DATE EM SIGNED: 24/05/2022

SCRUTINY COMMITTEES' RECOMMENDATIONS:

COMMONS	LORDS
SCRUTINY COMPLETED (OUTCOME AGENDA NO 4 08/06/22)	DRAWN TO THE ATTENTION OF THE PROTOCOL ON IRELAND/NORTHERN IRELAND SUB-COMMITTEE (AT CHAIR'S SIFT NO 20; 14/06/22)

FSA 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 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**