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Dear Finlay

THE PLANT PROTECTION PRODUCTS (MISCELLANEOUS AMENDMENTS) REGULATIONS 2023

I am writing in response to the Committee's correspondence of 19 September 2023 concerning the notification of Scottish Ministers' intention to consent to the Plant Protection Products (Miscellaneous Amendments) Regulations 2023. Your email requested further information on points relating to seeds treated with plant protection products (PPPs) and parallel trade of PPPs. I have responded to the points raised in Annex A below. For ease of reference, the answers are provided alongside the text of the relevant point from the Committee.

It has been brought to my attention that there was an inaccuracy in the original notification sent to you on 4 September. In summarising the proposals of the statutory instrument (SI), the notification suggested that the issue relating to seeds treated with PPPs had arisen partly due to a lack of capacity within the Health and Safety Executive (HSE) to process applications for GB authorisation of relevant PPPs. In fact, HSE have been working with the industry on this matter and has provided advice on submitting new applications in anticipation of the end of the transitional period.

Please accept my apologies for providing inaccurate information. A revised notification is enclosed at Annex B.

I note that the Committee will discuss the SI on 4 October. I look forward to hearing from you.

I am copying this letter to the Convener of the Delegated Powers and Law Reform Committee and the Convener of the Net Zero, Energy and Transport Committee.

Kind regards

A handwritten signature in cursive script that reads "Lorna Slater". The ink is dark and the signature is fluid and connected.

LORNA SLATER

Further information requested by the Committee following notification of the intention to consent to the Plant Protection Products (Miscellaneous Amendments) Regulations 2023.

Regarding seeds:

- **whether this approach to seeds was inherited from when the UK was a member of the EU, or whether it was a transitional approach developed for EU exit;**

Within the EU and EEA, seeds treated with plant protection products (PPPs) authorised for use in at least one Member State can legally be placed on the market and used in any other Member State. The UK had access to these arrangements while it was a Member State. In preparing for EU Exit, arrangements were established to enable seeds treated with PPPs authorised in an EU Member State before the end of the transition period to continue to be imported, marketed and used in GB up until 31 December 2023.

- **the reasons why the seed treatments are not authorised in GB, particularly whether there are concerns with the treatments;**

For a product to be authorised in GB it must pass through our regulatory system, which is operated by the HSE as the UK and GB independent regulator. HSE has worked closely with pesticide manufacturers and the seed treatment industry since the transitional arrangements began to prepare them for the change and encourage the submission of applications for authorisation. Since the beginning of the transitional arrangements, only one application has reached the assessment stage for a maize seed treatment. This is currently undergoing assessment. During this further extension, we expect more applications for GB authorisations to be submitted.

- **whether a longer-term solution is anticipated**

Provisions in the Plant Protection Products (Miscellaneous Amendments) Regulations 2023 are temporary. They are designed to provide sufficient time for growers to find alternative solutions to crop protection, and for manufacturers to both submit applications for full GB authorisations of existing products, and develop and submit applications for alternatives.

Regarding parallel trade:

- **whether these PPPs are not currently permitted to be sold, given that it is after 30 June 2023;**
It is correct that these PPPs are not currently permitted to be sold. PPPs that have already been purchased can be used until 30 June 2024.
- **the meaning of a ‘non-parallel pesticide product’, and a clarification of the final paragraph of the notification;**
‘Non-parallel pesticides products’ are also known as the ‘reference products’. Parallel trade products being imported from the EU or EEA that are not authorised in GB, must be identical to a GB-authorized product (the “reference product”).
Manufacturers and distributors of ‘GB reference products’ may face increased competition and lose profit from sales of products that would be substituted by parallel imports.
For parallel trade permit applicants, the fee associated with applying will be waived. UK Government will incur the cost of the processing of parallel trade permits which would usually have been covered by application fees paid to HSE.
- **the date from which a permit will be issued for a further two years;**
An application for the reinstatement of the original parallel trade permit must be made no later than 1st April 2024. Where a parallel trade permit is granted, HSE will specify the date on which the permit has effect. It will be valid for 2 years (or until the GB reference product authorisation expires).
- **whether a longer-term solution is anticipated.**
In the long term we want to work together with industry to increase the supply of new and innovative products authorised for use in GB. In this way, we will bolster the choice and competitiveness of the market for all PPP users.

NOTIFICATION TO THE SCOTTISH PARLIAMENT

Name of the SI

The Plant Protection Products (Miscellaneous Amendments) Regulations 2023

Is the notification Type 1 or Type 2

Type 1

A brief overview of the SI

The Plant Protection Products (Miscellaneous Amendments) Regulations 2023 (“the 2023 Regulations”) will extend, for a short period, EU Exit transition arrangements in two different areas related to plant protection products (PPPs), namely the importation of seeds treated with PPPs and parallel trade of PPPs. With regards to EU Alignment, the 2023 Regulations will continue the status quo in these areas.

The main purpose of the 2023 Regulations is to: (a) allow treated seeds to be placed on the market and used in GB as long as the PPP used to treat them was authorised for that use in at least one EU or EEA Member State immediately before IP completion date for a further 3.5 years and; (b) allow permits to be issued, by the GB regulator, for any PPP for a further 2 years if there was a valid Parallel Trade Permit (PTP) in place on 31 December 2022 provided that the GB reference product is still authorised. The reference product is defined as “the plant protection product which was already authorised in the United Kingdom prior to the application for the original parallel trade permit, and to which the product to which that permit related is identical in composition”.

This action would provide certainty for growers, producers and suppliers who have not had sufficient time to prepare for the end of the transition period. It would allow the market and industry to adjust and provide the additional time needed for any GB authorisations to be applied for and assessed.

The 2023 Regulations will be made under section 14 of the Retained EU Law (Revocation and Reform) Act 2023. They will revoke and replace Article 52 of EU Regulation 1107/2009 in relation to parallel trade permits and the relevant words in the Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 in relation to treated seeds.

Details of the provisions that Scottish Ministers are being asked to consent to

The 2023 Regulations revoke and replace Article 52 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (“the 2009 Regulation”) and modify paragraph 14(4)(b) of Part 4 of Schedule 1 to the Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (“the 2019 Regulations”). The 2009 Regulation and the 2019 Regulations are secondary retained EU law within the meaning of section 11(2) of the Retained EU Law (Revocation and Reform) Act 2023.

The 2023 Regulations also amend the Plant Protection Products Regulations 2011 in consequence of the replacement of Article 52 of the 2009 Regulation and make saving provision in respect of Article 52 of that Regulation to ensure the proper operation of Article 52A.

The 2023 Regulations amend the 2019 Regulations to extend the maximum period during which treated seeds not authorised for use in Great Britain, but authorised in another EU or EEA state immediately before IP completion day, may be placed on the market and used to 1st July 2027.

Article 52 of the 2009 Regulation made provision for the continued use of parallel trade permits for a maximum period of two years ending on 1st January 2023. The 2023 Regulations revoke Article 52 and make new provision under Article 52A for the reinstatement of parallel trade permits which had ceased to be valid under the Article 52 arrangements. Only the original permit holders may apply for the reinstatement of their permits. Applications must be submitted no later than 1st April 2024 and must be accompanied by evidence demonstrating that the plant protection product concerned remains substantively the same, subject to any changes made to ensure that the product has remained identical to the reference product. The reinstated permit is to be valid for two years from the date of issue, provided the authorisation of the reference product does not expire in the meantime.

Article 28 of the 2009 Regulation is amended to refer to new Article 52A of that Regulation. An equivalent consequential amendment is made to regulation 11 of the Plant Protection Products Regulations 2011, which makes it an offence to place on the market or use a plant protection product in contravention of Article 52A; and regulation 20 of those Regulations is amended to make it an offence to provide false information in connection with an application for a parallel trade permit under Article 52A.

Summary of the proposals

Seed Treatments

Post EU-exit transitional arrangements enable seeds treated with products authorised for use in at least one EU member state to continue to be imported, marketed and used in GB up until 31 December 2023. When these arrangements end, several seed treatments currently relied upon by GB growers will be unavailable as they do not have GB product authorisations. This will impact their ability to control certain pests and diseases during crop establishment, in turn causing poor germination and in some cases low yield.

The issue being addressed is the lack of GB product authorisations for some seed treatments that are currently imported from the EU and used by farmers and growers in GB. The issue has arisen due to a lack of alternative methods to control pests targeted by these seed treatments. This issue therefore needs time to be resolved through a long-term solution.

Parallel Trade

The issue being addressed is the end of the parallel trade permit scheme PPPs in GB, which may lead to shortages and higher prices of some PPPs. The parallel trade permit scheme allowed PPP suppliers to import PPPs that were not authorised in GB, but were identical to GB-authorised products, from other EU countries.

This scheme was possible when the UK was an EU Member State, and it helped to keep costs down and deal with shortages of some PPPs. However, after the UK left the EU, the scheme came to an end as of December 2022 in GB. When the permits expired, the Health and Safety Executive (HSE) put grace periods in place which allowed existing stocks to be sold until 30 June 2023 and used until 30 June 2024. Parallel trade coming to an end may create problems for PPP users who rely on these products for profitable operation of their agricultural activities.

Does the SI relate to a common framework or other scheme?

Yes. The 2023 Regulations are within the scope of the provisional Chemicals and Pesticides Common Framework.

Summary of stakeholder engagement/consultation

Defra held an industry roundtable to discuss the issues and potential solutions.

A note of other impact assessments

A full impact assessment of the effect that this instrument will have on the costs to business, the voluntary sector and the public sector will be published alongside the regulations.

Summary of reasons for Scottish Ministers' proposing to consent to UK Ministers legislation

Scottish Ministers consider that consenting to the 2023 Regulations is the most effective and transparent way to make these amendments as they will operate consistently across GB in line with the common framework. Officials have worked with Defra to ensure the drafting delivers for Scottish interests and respects devolved competence in Scotland, and so Scottish Ministers propose to agree to a GB-wide approach. The Scottish Government is satisfied this is the most appropriate legislative approach to making the necessary legislative changes.

Notification of the 2019 Regulations, which initially established EU-Exit transitional arrangements in these areas, and which the Scottish Government consented to, is included at the following link for information: [20180111SINotificationREC2.pdf \(parliament.scot\)](#).

Intended laying date of the instrument

The 2023 Regulations are due to be laid on 16 October 2023.

If the Scottish Parliament does not have 28 days to scrutinise Scottish Minister's proposal to consent, why not?

The Scottish Parliament has 28 days to scrutinise this proposal.

Information about any time dependency associated with the proposal

The 2023 Regulations are required to be implemented by the end of 2023 to ensure continuity of the current arrangements, and mitigation of potential impacts on crop production in the 2024 growing season.

Are there any broader governance issues in relation to this proposal and how will these be regulated and monitored post-withdrawal?

There is a risk from reintroducing parallel trade permits that PPPs could come into the GB market that contain contaminants, impurities or incorrect active concentrations relative to the formulation of the reference product.

The GB regulator (HSE) has previously used two different routes to check compliance which will remain in operation for new permits granted. The first is chemical checks on formulations through the 'annual formulation survey'. The products are selected on the basis of the actives they contain. A small proportion of parallel trade products are captured through this survey. Parallel trade products will continue to be in scope for being selected for the annual formulation survey for the duration of the permits (and subsequent use of associated parallel products in potential grace periods). The second is reactive enforcement (where there are reports - often via intelligence from manufacturers - that products are not identical to the GB reference product).

Any significant financial implications?

As regards the use of treated seeds, it is expected that growers and users of maize will benefit from more profitable crop production and better productivity from use of maize. For parallel imports, importers and distributors of parallel products will likely gain profits from being able to sell parallel products into the market and pesticide users (mainly farmers and amenity users) will gain from lower prices for the small portion of the market served by parallel imports.

Manufacturers and distributors of non-parallel pesticide products would be the main business group negatively affected by the proposals. It is estimated that they will lose profit equal to what would have been sold in the absence of parallel trade. The GB regulator would also incur a small cost associated with the processing of parallel permits which would be underwritten by the Defra.