EXPLANATORY MEMORANDUM TO

THE PLANT PROTECTION PRODUCTS (MISCELLANEOUS AMENDMENTS) REGULATIONS 2023

2023 No. 1321

1. Introduction

1.1 This explanatory memorandum has been prepared by the Department for Environment, Food and Rural Affairs ("Defra") and is laid before Parliament by Command of His Majesty.

2. Purpose of the instrument

- 2.1 The purpose of this instrument is to ensure continued access to important plant protection products ("PPPs", often referred to simply as pesticides) imported from the EU or EEA, for the control of pests, weeds and diseases. This is important for both the farming and amenity sectors, the latter includes transport infrastructure, sports facilities and areas managed by local authorities.
- 2.2 This instrument will allow seeds treated with PPPs authorised for that use in at least one EU or EEA Member State before the end of the implementation period (IP), to be imported, marketed and used in GB for an additional 3.5 years, up to 1 July 2027 ("treated seed imports") as long as they remain authorised in at least one EU or EEA Member State.
- 2.3 It will also allow those who held a valid Parallel Trade Permit (PTP) on 31 December 2022, to apply for it be reinstated for a maximum of 2 years ("parallel imports"). Prior to EU Exit, PTPs could be issued for products authorised in an EEA or EU Member State, if the Health and Safety Executive (HSE) was satisfied that there was an identical product authorised in the UK (the "reference product"). Post EU Exit arrangements allowed a PTP granted prior to the end of the IP to continue to be valid for up to 2 years. Existing stocks could be sold until the end of June 2023 and can be used until the end of June 2024.
- 2.4 The provisions of this instrument are temporary and address potential significant impacts on crop yield and output. The timing is designed to ensure farmers and growers have access to these products for the 2024 growing season, while allowing manufacturers sufficient time to submit new applications for product authorisations, and PPP users to source alternative solutions to pest management.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

4. Extent and Territorial Application

- 4.1 The extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law of) is the United Kingdom.
- 4.2 The territorial application of this instrument (that is, where the instrument produces a practical effect) is England and Wales, and Scotland.

4.3 Under the terms of the Withdrawal Agreement and Windsor Framework, EU PPP legislation continues to apply in full to Northern Ireland (NI).

5. European Convention on Human Rights

- 5.1 The Minister for Food, Farming and Fisheries, Mark Spencer, has made the following statement regarding Human Rights:
- 5.2 "In my view the provisions of the Plant Protection Products (Miscellaneous Amendments) Regulations 2023 are compatible with the Convention rights."

6. Legislative Context

- 6.1 Regulation (EC) No 1107/2009, concerning the placing of plant protection products on the market ("the PPP Regulation"), lays down rules for the marketing, sale and use of PPPs in Great Britain (GB). It is supplemented by the Plant Protection Products Regulations 2011 ("the 2011 Regulations"), which lays down enforcement powers and penalties for infringements of the PPP Regulation. This instrument revokes and replaces certain provisions of the PPP Regulation and makes consequential amendments to the 2011 Regulations.
- 6.2 Article 49 of the PPP Regulation makes provision in relation to the placing on the market and use of seeds treated with a PPP. It is modified by Part 4 of Schedule 1 to the Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019, to allow seeds treated with a PPP authorised for that use in at least one EEA or EU Member state before the end of the IP to be placed on the market and used in GB until 31 December 2023. This instrument extends the period during which these seeds may be placed on the market and used in GB by 3.5 years to 1 July 2027.
- 6.3 Article 52 of the PPP Regulation made provision for the continued use of PTPs granted by HSE for the import of parallel products prior to the end of the transitional period, for a maximum period of 2 years ending on 1 January 2023. This instrument revokes Article 52 and replaces it with the new article 52A, which allows the original permit holders to apply for their permits to be reinstated for up to 2 years, if certain conditions are met.

7. Policy background

Import of treated seeds

What is being done and why?

- 7.1 Seed treatments are used to protect delicate seeds and young seedlings from disease, virus transmission and predation in order to support good crop establishment. Within the EU and EEA, seeds treated with PPPs authorised for use in at least one Member State can be legally placed on the market and used in any other Member State.
- 7.2 Post EU Exit, transitional arrangements were put in place to allow seeds treated with a PPP authorised for that use in any EU or EEA Member State, before the end of the IP, to be placed on the market and used in GB for 3 years until 31 December 2023. Under current arrangements, once this date has passed, only seed treatments authorised in GB can be marketed and used. Since EU Exit no new seed treatments for maize have been authorised in GB.
- 7.3 Without GB authorisations for these seed treatments, or similar alternatives, we expect the end of these provisions to have a severe impact on certain key agricultural sectors.

For example, 99% of all maize seeds are treated with at least one of three PPPs that do not currently have GB authorisation for use as seed treatments. Maize is a vital crop for cattle feed, as well as energy generation through anaerobic digestion.

Explanations

7.4 This instrument will extend the provisions, which allow the import, sale and use of seeds treated with a PPP which was authorised in at least one EU or EEA Member State prior to IP completion day, and which remains authorised in at least one of those countries, until 1 July 2027. This timing is designed to provide growers with sufficient time to find alternative solutions to crop protection (including through integrated pest management techniques), and manufacturers sufficient time to both submit applications for GB authorisations of existing products and develop and submit applications for new alternative products.

Parallel imports

What is being done and why?

- 7.5 While the UK was an EU Member State, PPP suppliers could apply for a PTP to import a PPP from the EU or EEA that was not authorised in the UK, as long as it was identical to a UK-authorised product (the "reference product"). This was facilitated by an information-sharing arrangement between regulators in Member States.
- 7.6 When the UK left the EU, transitional arrangements were put in place so that PTPs granted before 31 December 2020 could be used to import products until December 2022. Existing stocks could be sold until the end of June 2023 and can be used until the end of June 2024.
- 7.7 Parallel imports helped to reduce costs to PPP users and may have helped manage supply shortages. As the scheme ends, this could increase financial burdens on farmers and growers, which may have a downstream impact on UK food security.

Explanations

- 7.8 This instrument will give the competent authority the power to reinstate PTPs for 2 years (or until the GB reference product authorisation expires).
- 7.9 These permits will replicate those previously issued and valid at the end of 2022. Only those who held valid PTPs at the end of the previous scheme will be able to apply to have their permit reinstated. Applicants will be asked to submit a declaration confirming that the information included in the application for the original permit, and subsequent amendments, remains valid. Applicants will also be required to submit new photos of the source product label to show that the product remains authorised and available on the market in the EU or EEA Member State from which it is being imported.
- 7.10 Only PPPs in line with our robust regulatory system should be used in GB. Any parallel product must be identical to a reference product authorised in GB, which has been subject to a scientific risk assessment that concludes all human health and environmental safety requirements are met.
- 7.11 We will continue to use both intelligence-led investigation and a broad range of controls, including the annual formulation survey as a way of monitoring and identifying any products that do not meet regulatory standards. This is in line with current enforcement practice.

8. European Union Withdrawal, Future Relationship, and REUL Reform

- 8.1 This instrument does not relate to withdrawal from the European Union / trigger the statement requirements under the European Union (Withdrawal) Act 2018.
- 8.2 This instrument does however relate to the reform of REUL under section 14 of the Retained EU Law (Revocation and Reform) Act 2023 because it revokes and replaces certain provisions of the PPP Regulation, which is secondary retained EU law, as explained above.

9. Consolidation

9.1 Defra does not intend to consolidate the relevant legislation at this time.

10. Consultation outcome

- 10.1 We have not carried out a public consultation as this instrument does not represent a significant change to current policy.
- 10.2 Defra officials have worked collaboratively with Scottish and Welsh Devolved Governments to develop this instrument, and the policy has been agreed across all three nations.

11. Guidance

- 11.1 Guidance will be provided on HSE's website for both treated seeds and parallel imports by the time this SI comes into force. Existing or former guidance will be updated in line with the new timelines, and in the case of parallel imports, with the new requirements.
- 11.2 The guidance will be accessed here: (https://www.hse.gov.uk/pesticides/pesticides-registration/applicant-guide/treated-seed.htm) for the import of treated seeds and here: (www. www.hse.gov.uk/pesticides/pesticides-registration/applicant-guide/parallel-trade-permits.htm) for parallel imports.

12. Impact

- 12.1 There is no impact from this instrument on charities and voluntary bodies. The impact on businesses varies depending on sector. For farmers and growers, we expect there to be a positive impact, as access to PPPs through parallel imports and treated seeds imports will likely reduce their input costs and increase their margins. Cattle farmers and anaerobic digestion companies are likely to benefit in terms of productive efficiency and therefore profit margins. We expect the reinstatement of certain PTPs to have a positive impact on the amenity sector, as it will likely reduce input costs. For distributors, we expect the impact to be varied; for those that source and sell a significant proportion of parallel imports and imported seed treatments, these measures are likely to be positive. However, there may be some negative impacts for manufacturers producing and marketing the reference products for which parallel imports are likely to be granted due to increased competition and reduced prices.
- 12.2 There may be a positive benefit to the public sector. Local authorities and other public bodies are responsible for managing certain public areas where PPPs may be used, including streets, parks and transport infrastructure. The temporary reinstatement of certain PTPs may reduce their costs.

12.3 We have produced a full Impact Assessment (IA) which has received final Regulatory Policy Committee clearance. It has been published alongside the Statutory Instrument.

13. Regulating small business

- 13.1 The legislation may apply to activities that are undertaken by small businesses in the agriculture, distribution and anaerobic digestion sectors.
- 13.2 The impact is likely to largely be positive in relation to product availability and price, therefore no specific action is proposed to minimise regulatory burdens on small businesses.

14. Monitoring and review

- 14.1 As this instrument is made under the Retained EU Law (Revocation and Reform) Act 2023, no review clause is required.
- 14.2 We will, however, internally review the extent to which the policy objectives have been met by the end of the extension periods. This will include analysis of key indicators such as PPP prices and dairy farm profits. The primary intention of this assessment will be to inform future policy development particularly regarding long-term solutions to the issues the proposals aim to address. This will not be published.

15. Contact

- 15.1 Sabina Shahaney at the Department for Environment, Food and Rural Affairs. Telephone: 07780 224005 or email: sabina.shahaney@defra.gov.uk can be contacted with any queries regarding the instrument.
- 15.2 Rachel Irving, Deputy Director for Chemicals, Pesticides and Hazardous Waste at the Department for Environment, Food and Rural Affairs can confirm that this Explanatory Memorandum meets the required standard.
- 15.3 Mark Spencer, Minister for Food, Farming and Fisheries at the Department for Environment, Food and Rural Affairs can confirm that this Explanatory Memorandum meets the required standard.