EXPLANATORY MEMORANDUM TO

THE PESTICIDES (MAXIMUM RESIDUE LEVELS) (AMENDMENT ETC.) (EU EXIT) REGULATIONS 2019

2019 No. 557

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 Act.

2. Purpose of the instrument

2.1 This instrument is one of three that will make corrections to the converted EU plant protection product regulatory regime, so that it continues to operate effectively after the United Kingdom ('UK') leaves the European Union ('EU').

2.2 The instrument makes appropriate corrections to Regulation (EC) No 396/2005 to ensure that after EU Exit, effective arrangements and robust controls governing the level of residues permitted in food will continue to operate in the UK.

Explanations

What did any relevant EU law do before exit day?

2.3 Regulation (EC) No 396/2005 of the European Parliament and of the Council on maximum residue levels of pesticides in or on food and feed of plant and animal origin ('Regulation (EC) No 396/2005'), sets EU Maximum Residue Levels ('MRLs') for pesticides in food and feed and measures to ensure their compliance. This enables trade in treated produce by providing a basis for confirming whether pesticides have been used correctly, through the setting of MRLs for the relevant active substances that are approved to be included in the formulation of pesticides for use on food and feed.

Why is it being changed?

2.4 The changes made by this instrument are so that current MRLs for pesticides in food and feed continue to be effectively managed to enable trade to operate effectively after the UK has left the EU. This instrument addresses deficiencies in the converted Regulation (EC) No 396/2005 and other associated retained direct EU legislation relating to MRLs arising from EU Exit.

What will it now do?

2.5 This instrument will address deficiencies in the retained Regulation (EC) No 396/2005 and other associated retained direct EU legislation relating to MRLs arising from EU Exit and ensure that the existing protections and regulatory framework are maintained and continue to work in the same way once the UK has left the EU.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)

3.2 The territorial application of this instrument includes Scotland and Northern Ireland.

3.3 The powers under which this instrument is made in respect of Scotland and Northern Ireland cover the entire United Kingdom (see section 24(1) of the European Union (Withdrawal) Act 2018) and the territorial application of this instrument is not limited either by the Act or by the instrument.

4. Extent and Territorial Application

4.1 The territorial extent of this instrument is the United Kingdom.

4.2 The territorial application of this instrument is the United Kingdom.

5. European Convention on Human Rights

5.1 The Minister of State for Agriculture, Fisheries and Food, Robert Goodwill MP, has made the following statement regarding Human Rights:

"In my view the provisions of the Pesticides (Maximum Residue Levels) (Amendment etc.) (EU Exit) Regulations 2019 are compatible with the Convention rights".

6. Legislative Context

6.1 The European Union (Withdrawal) Act 2018 repeals the European Communities Act 1972 ('Withdrawal Act'), but section 2 saves EU-derived domestic legislation so that it continues to have effect in domestic law on and after "exit day". "Exit day" is defined by section 20 of the Withdrawal Act.

6.2 This instrument is made in exercise of powers conferred by section 8(1) of, and paragraph 21 of Schedule 7 to, the Withdrawal Act. Section 8(1) of the Withdrawal Act provides that a Minister of the Crown may by regulations make such provision as the Minister considers appropriate to prevent, remedy or mitigate any failure of retained EU law to operate effectively or any other deficiency in retained EU law arising from the withdrawal of the UK from the EU.

7. Policy background

What is being done and why?

7.1 Plant Protection Products ('PPPs') are 'pesticides' that are used to protect crops or desirable or useful plants, regulate plant growth or prevent growth of unwanted plants. They are primarily used in the agricultural sector but also in forestry, horticulture, amenity areas and in home gardens. For example, they play a fundamental role in UK farming and the provision of food, keeping the transport infrastructure clear of weeds, maintaining public spaces and controlling invasive species.

7.2 However, as PPPs contain chemicals that are designed to disrupt life processes, risks can be associated with their use. Regulation is required to ensure that PPPs do not harm human health or have unacceptable effects on the environment.

7.3 A key part of the process by which PPPs are approved/authorised is an assessment of the risks to consumers. There are robust controls which govern the level of residues that are permitted in food. MRLs are set on an EU-wide basis under Regulation (EC)

No 396/2005. Regulation (EC) No 396/2005 is directly applicable in UK law. It is supported by national enforcement legislation (the Pesticides (Maximum Residue Levels) (England and Wales) Regulations 2008; the Pesticides (Maximum Residue Levels) (Scotland) Regulations 2008, and the Pesticides (Maximum Residue Levels) Regulations (Northern Ireland) 2008) which creates the related enforcement provisions and criminal offences.

7.4 MRLs reflect the highest amount of residues expected in food when PPPs are applied correctly in accordance with authorised conditions of use. It is important to note that MRLs are not safety limits and are always set below, often far below, levels that would present a risk to consumers. MRLs apply to all foods placed on the EU market, irrespective of whether they have been produced inside or outside of the EU. They facilitate trade in treated produce by providing assurance to the regulator that PPPs have been used appropriately. As there is a high level of public interest in food safety, annual control and monitoring programmes provide additional reassurance to consumers to enable them to buy foodstuffs with confidence. Official monitoring is important to enable the regulator to check that food meets the required standards; that unauthorised pesticides have not been used, and that consumer safety is assured.

What is being done and why?

7.5 As with the assessment of active substances used in the formulation of PPPs (under Regulation (EC) No 1107/2009), decisions on setting MRLs are currently taken at EU level following Member State assessments. A rigorous assessment is made of the risks, which includes a full assessment of data on the level of residues resulting from their use and on the toxicology of the pesticide.

7.6 This instrument makes corrections to the existing Regulation (EC) No 396/2005 as it will be retained in domestic law applicable in the United Kingdom from exit day. These corrections are required to make it operable in a national context and do not make further substantive policy changes. This includes: measures applying to the evaluation and setting of MRLs; rules governing the marketing of goods to ensure compliance with MRLs; measures governing the review of MRLs; and measures governing national programmes for monitoring residues in foods placed on the market. Combined, these measures ensure that MRLs set for foods take account of the residues expected to arise from appropriate pesticide use practices ensuring the protection of the consumer, whilst also ensuring the control regime provides for consistency of control, continuity and stability in food production and supply.

7.7 There are a number of legislative deficiencies that arise due to EU Exit and we need to ensure that they are corrected so as to work sensibly in a national context. The most significant of these corrections in this instrument are as follows:

Repatriation of decision-making functions from the EU to national level

7.8 Various functions and subsidiary regulatory powers under the EU regulations can only be exercised at EU level. This includes decision making on setting MRLs.

7.9 EU-level decision making will no longer be relevant in a national context after EU Exit, and needs to be repatriated to a national level. In addition, EU bodies such as the European Food Safety Authority (EFSA) will no longer be available to support a national regime.

7.10 This instrument repatriates all decision making functions and powers under the EU regime, to national level using the powers in the European Union (Withdrawal) Act 2018, and in line with the government's approach to EU exit and devolution.

7.11 This instrument provides for UK-wide decision making and exercise of functions, subject to the consent of the Devolved Administrations. This instrument also allows for independent exercise of the powers by each part of the UK, should that be needed.

Establish a new national mechanism to give effect to national decisions

7.12 Currently, decisions on MRLs are given effect through EU tertiary legislation. There is an ongoing flow of regulatory decisions which need to be put into effect. To achieve this, the EU currently produces in the order of 50 additional Regulations per year.

7.13 EU mechanisms to give effect to decisions will no longer be operable after EU Exit. This instrument replaces the EU arrangements by establishing an administrative mechanism to give effect to national decisions on MRLs in an efficient and timely way, by means of a new statutory register, which will be published online.

Replace the EU components of the decision making processes

7.14 The EU regime sets out decision making processes in considerable detail, specifying that various functions will be carried out by Member States, EFSA, the Commission and decision making by committees of Member States, given effect through EU Regulations.

7.15 These EU processes will no longer be operable after EU Exit. Also, EU bodies such as EFSA will no longer be available to support a national regime. New national processes are therefore required with the EU-specific elements removed.

7.16 This instrument replaces the EU components of the decision making processes which remain relevant in a national context with new national processes, such as the evaluation as specified in the regulations and final decision making.

7.17 This enables decisions to be taken by national ministers (instead of the Commission and the committee of Member States) based on the assessment of the national regulator with all EU layers removed from the process.

7.18 The UK benefits from the considerable expertise of the national regulator, the Health and Safety Executive's Chemicals Regulation Division. This body already undertakes a significant share of the EU's risk assessment work under the EU regime, putting the UK in a strong position to be able to take its own decisions.

7.19 Elements of EFSA's current role will be repatriated to the national competent authority in the post-exit UK regime where they remain relevant (for example, producing the MRL evaluation report and reasoned opinion as one process, analysing reports of pesticide residues). Other elements of EFSA's role which are specifically related to the EU context will no longer be required to operate a national regime, for example, the additional layer of process to review Member States' risk assessment conclusions to ensure harmonisation across all Member States.

7.20 We greatly value the role of transparency and independent expert advice in decision making and therefore wish to continue to have access to a source of independent expert scientific advice to provide assurance on national decisions and input to development of national policies. This instrument will include provisions enabling

national decision makers to take independent expert scientific advice at national level to replace that element of the role of EFSA.

Reviews of MRLs

7.21 Under Regulation (EC) No 396/2005, there is a requirement to review MRLs within 12 months following active substance decision requirements under Regulation (EC) No 1107/2009. This is intended to ensure that MRL assessments continue to meet modern standards and that account is taken of current uses, current knowledge and decisions from the active substance review. In addition to such routine reviews under the scheduled programme, the Regulation also allows for emergency MRL reviews to be carried out if specific and immediate safety concerns arise.

7.22 This instrument converts this requirement for MRL reviews into a requirement for reviews at national level.

7.23 In doing so, there is a need to reconsider the timelines to undertake reviews. Currently, Regulation (EC) No 396/2005 requires that following a decision on an active substance approval under Regulation (EC) No 1107/2009, EFSA should submit a reasoned opinion on any changes to relevant MRLs within 12 months of an active substance approval decision being given effect under the relevant EU tertiary legislation. In practice, EFSA is supported by all 28 Member States in this review work to ensure that workloads are shared across the EU community.

7.24 Even with the workload shared across EU Member States, this 12 month deadline has routinely not been achieved. Ongoing internal EU discussions and working practices acknowledge this reality and the much longer timeframes needed to complete this work.

7.25 In converting the EU provisions into national requirements, it is necessary to ensure it is practicable and realistic for the UK, acting alone, to deliver. In order to make the overall timeline for this work more realistic in a national context and aligned to actual EU current practice, the deadline for MRL reviews following an active substance approval has been set at 36 months. This may be extended further where the competent authority considers it necessary, such as when time is required to obtain and assess the necessary data. This is more in line with actual EU practice. We will continue to prioritise reviews to maintain effective consumer protection; reducing timelines where public health concerns exist. This relates to reviews of extant MRLs and so these remain in place while a review is carried out, meaning this does not have any impact on external stakeholders.

Residue Monitoring Programme

7.26 Regulation (EC) No 396/2005 requires Member States to undertake national pesticide residue testing programmes, and also to take part in a Community Control programme which sets out particular requirements for each Member State.

7.27 This instrument replaces the current residue monitoring programme at EU level with an equivalent national power to put in place a national monitoring programme. This will ensure that the same standards of protection are maintained after EU Exit. Requirements placed upon the UK via Commission Implementing Regulation (EU) 2018/555 for the three year period from 2019 to 2021 will be retained. The provision to report information to the Commission for analysis and development of an EU report is replaced with a requirement to publish an equivalent national report online.

Transitional Measures

7.28 Transitional measures are required to enable continuity and avoid any significant impacts at the point of EU Exit and to ensure that the changeover from an EU to a national regime is smooth. Some of these transitional measures are provided by Schedule 8 to the Withdrawal Act, but others are included as part of the proposed corrections.

7.29 This instrument ensures that all MRLs in place at the point of the UK's exit from the EU under Regulation (EC) No 396/2005 will remain valid in the UK after EU Exit.

8. European Union (Withdrawal) Act 2018/Withdrawal of the United Kingdom from the European Union

8.1 This instrument is being made using the power in section 8(1) of, and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018 in order to address failures of retained EU law to operate effectively or other deficiencies arising from the withdrawal of the United Kingdom from the European Union. In accordance with the requirements of that Act the Minister has made the relevant statements as detailed in Part 2 of the Annex to this Explanatory Memorandum.

9. Consolidation

9.1 Not applicable.

10. Consultation outcome

10.1 The Scottish, Welsh and Northern Irish devolved administrations have been consulted about the amendments in this instrument.

10.2 Defra undertook informal stakeholder engagement in relation to PPPs. In July 2018, a series of four stakeholder workshops on the 'no deal' legislative proposals were held. The purpose was to increase awareness of our day 1 contingency planning to enable businesses to make their own plans and to support our own day 1 readiness work, through acquiring practical feedback and views on our proposed approach to operational fixes.

10.3 Representatives from all sectors with an interest in the PPP regime attended including from industry, consultancies, farming and growers' organisations, and environmental Non-Government Organisations. They were advised on the proposed legislative modifications as a result of EU Exit.

10.4 Stakeholders posed a number of questions, but there were no strong objections to the proposals, with a general acceptance that the approach was sensible and proportionate, and would be necessary in the overall context of a no deal scenario.

11. Guidance

11.1 There is no associated guidance.

12. Impact

12.1 Defra has produced an assessment of the impacts which is published alongside these Regulations and the Explanatory Memorandum on the legislation.gov.uk website. This document considers the collective impact of the set of three Statutory Instruments which have been prepared as part of contingency planning to ensure that an operable

national plant protection product regulatory regime is put in place from March 2019 should it be required at that point.

12.2 It is concluded that there would be large benefits associated with introducing the instrument compared to the 'do nothing' option, as the instrument offsets the negative impacts on the UK's ability to manage risks to health and the environment, and impacts on business that would arise as a result of an inoperable regime after EU Exit. There is no significant, impact on business, charities or voluntary bodies.

12.3 The impact on the public sector is from additional costs incurred by Government to operate a national regime. This includes work to build national capacity to run decision making bodies, review legislation, guidance and process around the approvals of active substances and their maximum residue levels. To do this, the government will require extra resources to manage these processes, as well as funding for additional expert advice and research. The principal part of this cost will be the additional staff required for policy making and regulation.

12.4 A full Impact Assessment has not been prepared for this instrument because no significant impact on business, charities or voluntary bodies is foreseen, with any costs or benefits falling below £5 million in any one year. This instrument only amends deficiencies arising from the UK's withdrawal from the EU.

13. Regulating small business

13.1 The legislation applies to activities that are undertaken by small businesses.

13.2 The effect of these Regulations is to maintain the status quo, therefore no specific action to minimise the impact on small businesses is required.

14. Monitoring & review

14.1 The approach to monitoring of this legislation is no specific monitoring arrangements are needed.

14.2 As this instrument is made under the EU Withdrawal Act 2018, no review clause is required.

15. Contact

15.1 Duncan Williams at the Department for Environment, Food and Rural Affairs (Defra), Telephone: 020 8026 6659 or email: Duncan.Williams@defra.gov.uk can be contacted with any queries regarding the instrument.

15.2 Gabrielle Edwards at the Department for Environment, Food and Rural Affairs can confirm that this Explanatory Memorandum meets the required standard.

15.3 The Minister of State for Agriculture, Fisheries and Food, Robert Goodwill MP, at the Department for Environment, Food and Rural Affairs can confirm that this Explanatory Memorandum meets the required standard.

Annex

Statements under the European Union (Withdrawal) Act 2018

Part 1

Table of Statements under the 2018 Act

This table sets out the statements that may be required under the 2018 Act.

Statement	Where the requirement sits	To whom it applies	What it requires
Sifting	Paragraphs 3(3), 3(7) and 17(3) and 17(7) of Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) to make a Negative SI.	Explain why the instrument should be subject to the negative procedure and, if applicable, why they disagree with the recommendation(s) of the SLSC/Sifting Committees.
Appropriate-ness	Sub-paragraph (2) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2.	A statement that the SI does no more than is appropriate.
Good Reasons	Sub-paragraph (3) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2.	Explain the good reasons for making the instrument and that what is being done is a reasonable course of action.
Equalities	Sub-paragraphs (4) and (5) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2.	Explain what, if any, amendment, repeals or revocations are being made to the Equalities Acts 2006 and 2010 and legislation made under them. State that the Minister has had due regard to the need to eliminate discrimination and other conduct prohibited under the Equality Act 2010.
Explanations	Sub-paragraph (6) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2 In addition to the statutory obligation the Government has made a political commitment to include these statements alongside all EUWA 2018 SIs.	Explain the instrument, identify the relevant law before exit day, explain the instrument's effect on retained EU law and give information about the purpose of the instrument, e.g., whether minor or technical changes only are intended to the EU retained law.

Criminal offences	Sub-paragraphs (3) and (7) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9, and 23(1) or jointly exercising powers in Schedule 2 to create a criminal offence.	Set out the 'good reasons' for creating a criminal offence, and the penalty attached.
Sub-delegation	Paragraph 30, Schedule 7	Ministers of the Crown exercising sections 10(1), 12 and part 1 of Schedule 4 to create a legislative power exercisable not by a Minister of the Crown or a Devolved Authority by Statutory Instrument.	State why it is appropriate to create such a sub-delegated power.
Urgency	Paragraph 34, Schedule 7	Ministers of the Crown using the urgent procedure in paragraphs 4 or 14, Schedule 7.	Statement of the reasons for the Minister's opinion that the SI is urgent.
Explanations where amending regulations under s. 2(2) ECA 1972	Paragraph 13, Schedule 8	Anybody making an SI after exit day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s. 2(2) ECA 1972.	Statement explaining the good reasons for modifying the instrument made under s. 2(2) ECA, identifying the relevant law before exit day, and explaining the instrument's effect on retained EU law.
Scrutiny statement where amending regulations under s. 2(2) ECA 1972	Paragraph 16, Schedule 8	Anybody making an SI after exit day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s. 2(2) ECA 1972.	Statement setting out: a) the steps which the relevant authority has taken to make the draft instrument published in accordance with paragraph 16(2), Schedule 8 available to each House of Parliament, b) containing information about the relevant authority's response to— (i) any recommendations made by a committee of either House of Parliament about the published draft instrument, and (ii) any other representations made to the relevant authority about the published draft instrument, and c) containing any other information that the relevant authority considers appropriate in relation to the scrutiny of the instrument or draft instrument which is to be laid.

Part 2

Statements required when using enabling powers under the European Union (Withdrawal) 2018 Act

1. Appropriateness statement

1.1 The Minister of State for Agriculture, Fisheries and Food, Robert Goodwill MP, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view the Pesticides (Maximum Residue Levels) (Amendment etc.) (EU Exit) Regulations 2019 does no more than is appropriate".

1.2 This is the case because it does no more than prevent, remedy or mitigate deficiencies in retained EU law arising from the withdrawal of the UK from the EU examples of which are mentioned in section 7 in the main body of this explanatory memorandum.

2. Good reasons

2.1 The Minister of State for Agriculture, Fisheries and Food, Robert Goodwill MP, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view there are good reasons for the provisions in this instrument, and I have concluded they are a reasonable course of action".

2.2 These Regulations correct deficiencies in pesticides regulatory framework to ensure that it can continue to operate from exit day. This instrument does not impose any new liabilities or obligations on any relevant persons.

3. Equalities

3.1 The Minister of State for Agriculture, Fisheries and Food, Robert Goodwill MP, has made the following statement:

"The Pesticides (Maximum Residue Levels) (Amendment etc.) (EU Exit) Regulations 2019 does not amend, repeal or revoke a provision or provisions in the Equality Act 2006 or the Equality Act 2010 or subordinate legislation made under those Acts".

3.2 The Minister of State for Agriculture, Fisheries and Food, Robert Goodwill MP, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In relation to the instrument, I, Robert Goodwill, have had due regard to the need to eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010".

4. Explanations

4.1 The explanations statement has been made in section 2 of the main body of this explanatory memorandum.

5. Legislative sub-delegation

5.1 The Minister of State for Agriculture, Fisheries and Food, Robert Goodwill MP, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view it is appropriate to create a relevant sub-delegated power in the Pesticides (Maximum Residue Levels) (Amendment etc.) (EU Exit) Regulations 2019."

5.2 This is appropriate because: the provisions to which this applies are provisions which the Commission currently exercises through implementing or delegated acts, but which it is more appropriate, in the domestic context, to exercise administratively. These provisions are very minor in scope as they are intended as supplementary measures covering technical or non-essential elements of the Regulation.

5.3 It would be disproportionately inefficient to use statutory instruments to implement or revise these non-essential elements due to the time and administrative effort involved. This would act as an administrative barrier and could make them unlikely to be exercised at all or only infrequently, impacting on securing effective outcomes.

5.4 For these minor powers, this instrument converts them into a power to act administratively, specifically to set an administrative mechanism to give effect to national decisions on MRLs in an efficient and timely way, by means of a new statutory register, which will be published online and to allow for administrative publication of the monitoring control programme.