

**EXPLANATORY MEMORANDUM TO**  
**THE REGULATED PRODUCTS (AMENDMENT) (NORTHERN IRELAND) (EU**  
**EXIT) REGULATIONS 2019**

**2019 No. 849**

**1. Introduction**

- 1.1 This explanatory memorandum has been prepared by the Department of Health and Social Care and is laid before Parliament by Command of Her Majesty.
- 1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

**2. Purpose of the Instrument**

- 2.1 The purpose of the Statutory Instrument (SI) is to ensure Northern Ireland legislation relating to regulated products listed below continues to operate effectively after the United Kingdom (UK) leaves the European Union (EU):
  - The Genetically Modified Food Regulations (Northern Ireland) 2004.
  - The Materials and Articles in Contact with Food Regulations (Northern Ireland) 2012.
  - The Food Additives, Flavourings, Enzymes and Extraction Solvents Regulations (Northern Ireland) 2013.
  - The Novel Foods Regulations (Northern Ireland) 2017.
- 2.2 The SI makes a number of minor and technical amendments to these regulations to deal with deficiencies arising from the withdrawal of the UK from the EU.
- 2.3 As a responsible government, we will continue to proportionately prepare to ensure readiness on exit day in all scenarios. The purpose of this instrument, therefore, is to ensure that there will continue to be a functioning statute book on exit day which maintains continuity in relation to regulated products legislation in Northern Ireland.

***Explanations***

***What did any relevant EU law do before exit day?***

- 2.4 The Genetically Modified Food Regulations (Northern Ireland) 2004 provide for the execution and enforcement of Regulation (EC) No. 1829/2003 in Northern Ireland. Regulation (EC) No. 1829/2003 makes provision for the authorisation, supervision and labelling of genetically modified food and feed.
- 2.5 The Materials and Articles in Contact with Food Regulations (Northern Ireland) 2012 provide for the implementation and enforcement of a number of European instruments in Northern Ireland:
  - Council Directive 84/500/EEC on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs.

- Commission Directive 2007/42/EC makes provision on materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs.
- Regulation (EC) No 1935/2004 makes provision on materials and articles intended to come into contact with food.
- Commission Regulation (EC) No 1895/2005 makes provision on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food.
- Commission Regulation (EC) No 2023/2006 makes provision for good manufacturing practice for materials and articles intended to come into contact with food.
- Commission Regulation (EC) No 450/2009 makes provision on active and intelligent materials and articles intended to come into contact with food.
- Commission Regulation (EU) No 10/2011 makes provision on plastic materials and articles intended to come into contact with food.
- Commission Regulation (EU) 2018/213 makes provision on the use of bisphenol A in varnishes and coatings intended to come into contact with food.

2.6 The Food Additives, Flavourings, Enzymes and Extraction Solvents Regulations (Northern Ireland) 2013 provide for the implementation and enforcement of a number of European instruments in Northern Ireland:

- Directive 2009/32 makes provision on the approximation of the laws of Member States on extraction solvents used in the production of foodstuffs and food ingredients.
- Regulation (EC) No. 2065/2003 makes provision on smoke flavourings used or intended for use in or on foods.
- Regulation (EC) No. 1332/2008 makes provision on food enzymes.
- Regulation (EC) No. 1333/2008 makes provision on food additives.
- Regulation (EC) No. 1334/2008 makes provision on flavourings and certain food ingredients with flavouring properties for use in and on foods.

2.7 The Novel Foods Regulations (Northern Ireland) 2017 provide for the execution and enforcement of Regulation (EU) No 2015/2283 in Northern Ireland. Regulation (EU) No. 2015/2283 makes provision for the placing of novel foods on the market within EU.

*Why is it being changed?*

2.8 A review of the Northern Ireland Regulations relating to regulated products identified a number of provisions which would not operate effectively or would be deficient (within the meaning of section 8 of the European Union (Withdrawal) Act 2018) arising from the UK's withdrawal from the EU. More information on the changes being made is provided at section 7. The instrument makes no substantive changes to the way the existing legislation operates. All changes make technical drafting fixes to maintain continuity of approach after exit day.

What will it now do?

- 2.9 The amended Regulations will operate effectively following the withdrawal of the UK from the EU. More information on the changes being made is provided at section 7.

**3. Matters of special interest to Parliament**

*Matters of special interest to the Joint Committee on Statutory Instruments.*

- 3.1 This instrument was laid for sifting by the Sifting Committees on the UK's exit from the EU, in accordance with the European Union (Withdrawal) Act 2018, on 11 February 2019. The Committees considered this instrument and recommended that the appropriate procedure is for it to be subject to annulment in pursuance of a resolution of either House of Parliament (i.e. the negative procedure).
- 3.2 This instrument is contingent on UK-wide legislation which the FSA is bringing forward to amend retained EU law on food and feed hygiene and safety. These FSA UK-wide SIs were originally scheduled with contingent PBL approval for laying in Parliament in Autumn 2018, but were delayed until mid-January 2019 due to additional Ministerial scrutiny. The FSA UK-wide legislation was subsequently laid in the weeks commencing 28th January 2019 and 4th February 2019 respectively. Although the majority of the FSA UK-wide SIs have now been made, The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 received an adverse report from the Joint Committee on Statutory Instruments (JSCI) on 15 March and was required to be re-laid before Parliament. As a consequence, this instrument will breach the 21-day protocol if exit day is within 21 days of the SI being laid, and will not breach the protocol should exit day fall outside of a 21 day period because the instrument cannot be made prior to all relevant FSA UK-wide legislation being made, to ensure the correct sequencing of the instrument in accordance with Government Legal Department guidance.
- 3.3 This instrument is required to come into force on exit day to ensure that the necessary operability changes to domestic Northern Ireland legislation on regulated products are in place so that the body of Northern Ireland Food Law will function properly once the UK leaves the EU. The enforceability of legislation on regulated products in Northern Ireland may be uncertain without this correcting instrument. It may be possible (in the short term) for food enforcement authorities to seek to continue to enforce the law represented by this instrument, for example, by prosecuting businesses who sell unsafe food to consumers. However, such prosecutions may be vulnerable to challenge in light of any existing deficiencies arising from this instrument not being in force on exit day. This could potentially compromise existing levels of public health protection and food/feed safety because the current legislative system to control regulated products would be inoperable. This would, in all likelihood, damage consumer, business and trading partner confidence in Northern Ireland.
- 3.4 Notwithstanding the risks of this instrument not being in force on exit day, contingency plans to mitigate the risks rely on the Food Safety (Northern Ireland) Order 1991 (as amended) and the retained EU Law, amended by FSA UK-wide legislation, which should continue to provide food safety protection for consumers. Guidance to NI food enforcement authorities will be issued if required.

*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)*

- 3.5 As the instrument is subject to negative resolution procedure, there are no matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business at this stage.

**4. Extent and Territorial Application**

- 4.1 The territorial extent of this instrument is limited to Northern Ireland.  
4.2 The territorial application of this instrument is limited to Northern Ireland.

**5. European Convention on Human Rights**

- 5.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

**6. Legislative Context**

- 6.1 The UK is leaving the European Union and the amendments made by The Regulated Products (Amendment) (Northern Ireland) (EU Exit) Regulations 2019 are needed to ensure the operability of the domestic legislation as referenced in section 2.2 once the UK has left the European Union. Section 8(1) of the European Union (Withdrawal) Act 2018 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. The instrument is made in exercise of these powers.

**7. Policy background**

*What is being done and why?*

- 7.1 This instrument applies to the Northern Ireland Regulations dealing with regulated products which is a transferred matter for Northern Ireland under the Northern Ireland Act 1998. Although the UK Government remains committed to restoring devolution in Northern Ireland, a functioning statute book is required across the UK, including in Northern Ireland, for exit day. UK Government Ministers have therefore decided that, in the interest of legal certainty in Northern Ireland, the UK Government will take through the necessary secondary legislation at Westminster for Northern Ireland, in close consultation with the Northern Ireland departments. This is one such instrument.
- 7.2 The amendments made by this instrument are being made to ensure the operability of the Northern Ireland Regulations once the UK has left the EU and can be broadly categorised as:
- Removing references to ‘Commission’, ‘Union’ and ‘territory of the EU’ to reflect the UK’s new status outside of the EU;
  - Removing definitions to redundant directives; and
  - Fixing references and copying out EU directives where necessary;

The following paragraphs (7.3-7.7) include some examples of these amendments.

- 7.3 The Genetically Modified Food Regulations (Northern Ireland) 2004 are amended to substitute the reference to ‘Commission’ with ‘Food Safety Authority’.
- 7.4 The Materials and Articles in Contact with Food Regulations (Northern Ireland) 2012 are amended to replace cross references to Council Directive 84/500/EEC relating to ceramic articles intended to come into contact with foodstuffs. The content of this Directive has been copied out and inserted into these regulations.
- 7.5 The Food Additives, Flavourings, Enzymes and Extraction Solvents Regulations (Northern Ireland) 2013 are amended to remove and replace references to ‘Commission’ with ‘Authority’, ‘Union’ with ‘domestic’ and ‘European Union’ with ‘United Kingdom’. Schedule 1 is amended to ensure food additive labelling is in English or English and Welsh.
- 7.6 The Novel Foods Regulations (Northern Ireland) 2017 are amended to remove and replace references to ‘Commission’ with ‘Food Safety Authority’.
- 7.7 These drafting fixes are the extent of this instrument’s purpose; the intention is to ensure the operability of the Northern Ireland Regulations once the UK has left the EU. As a result, there are not expected to be any significant impacts arising from this SI.
- 8. European Union (Withdrawal) Act/Withdrawal of the United Kingdom from the European Union**
- 8.1 The SI is being made using the power in section 8(1) of the European Union (Withdrawal) Act 2018 to prevent, remedy or mitigate any failure of retained EU law to operate effectively, or other deficiency in retained EU law, arising from the withdrawal of the UK from the EU. 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 The SI does not involve consolidation and there are no plans to consolidate the relevant legislation at this time.
- 10. Consultation outcome**
- 10.1 The policy areas covered and the changes within this SI were the subject of a four-week public consultation conducted in Northern Ireland, which closed on 20 December 2018. The consultation was published at the following link: <https://www.food.gov.uk/news-alerts/consultations/proposed-approach-for-the-amendment-of-domestic-legislation-in-northern-ireland> .
- 10.2 The consultation sought comments on the proposed approach to the amendment of Northern Ireland domestic legislation relating to food and feed safety and hygiene, food compositional standards and food labelling.
- 10.3 Two responses were received in relation to food labelling and did not concern the proposed changes being made in this SI.

## **11. Guidance**

- 11.1 Contingencies have been considered to mitigate the risks if this instrument is not in force on exit day, and guidance to NI food enforcement authorities will be issued if required.

## **12. Impact**

- 12.1 There is no, or no significant, impact on business, charities or voluntary bodies.
- 12.2 There is no, or no significant, impact on the public sector.
- 12.3 An Impact Assessment has not been prepared for this instrument because no, or no significant, impact on the private or voluntary sector is foreseen.

## **13. Regulating small business**

- 13.1 The legislation is not expected to disproportionately affect the activities undertaken by small businesses, so no specific action is proposed.

## **14. Monitoring & review**

- 14.1 As this instrument is made under the European Union (Withdrawal) Act 2018, no review clause is required.

## **15. Contact**

- 15.1 Esther Chartres at the Food Standards Agency can be contacted with any queries regarding the instrument: Telephone: 02890417737 or email: [esther.chartres@food.gov.uk](mailto:esther.chartres@food.gov.uk) .
- 15.2 Kirsten Dunbar, Head of EU Exit & Legal, at the Food Standards Agency can confirm that this explanatory memorandum meets the required standard.
- 15.3 Seema Kennedy MP, Parliamentary Under Secretary of State for Public Health and Primary Care, 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 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	Set out the 'good reasons' for creating a criminal offence, and the penalty attached.

		23(1) or jointly exercising powers in Schedule 2 to create a criminal offence	
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 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	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 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	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. Sifting statement(s)**

- 1.1 The Parliamentary Under Secretary of State for Public Health and Primary Care Steve Brine has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

“In my view Regulated Products (Amendment) (Northern Ireland) (EU Exit) Regulations 2019 should be subject to annulment in pursuance of a resolution of either House of Parliament (i.e. the negative procedure).”

- 1.2 This is the case because this statutory instrument does not make provision falling within paragraph 1(2) of Schedule 7 to the European Union (Withdrawal) Act 2018, addresses only technical deficiencies in the relevant Northern Ireland legislation that will arise from withdrawal of the UK from the EU and will not introduce any new policy.

#### **2. Appropriateness statement**

- 2.1 The Parliamentary Under Secretary of State for Public Health and Primary Care Steve Brine has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

“In my view the Regulated Products (Amendment) (Northern Ireland) (EU Exit) Regulations 2019 does no more than is appropriate.”

- 2.2 This is the case because this statutory instrument addresses only technical deficiencies in the relevant Northern Ireland legislation that will arise from withdrawal of the UK from the EU and will not introduce any new policy. Further details, including examples of all the changes included in the instrument, are detailed in Section 7 of the main body of this explanatory memorandum.

#### **3. Good reasons**

- 3.1 The Parliamentary Under Secretary of State for Public Health and Primary Care Steve Brine 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.”

- 3.2 These are that failure to progress this legislation would result in Northern Ireland legislation relating to regulated products failing to operate effectively after the UK leaves the EU. Further details, including examples of all the changes included in the instrument, are detailed in Section 7 of the main body of this explanatory memorandum.

#### **4. Equalities**

- 4.1 The Parliamentary Under Secretary of State for Public Health and Primary Care Steve Brine has made the following statement(s):

“The draft instrument 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.”

- 4.2 The Parliamentary Under Secretary of State for Public Health and Primary Care Steve Brine has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

“In relation to the draft instrument, I, Steve Brine, 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. This Act does not extend to Northern Ireland. The Regulated Products (Amendment) (Northern Ireland) (EU Exit) Regulations 2019 extend only to Northern Ireland, I have given equivalent due regard to the implications for equality of opportunity in Northern Ireland.”

## **5. Explanations**

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