EXPLANATORY MEMORANDUM TO

THE MATERIALS AND ARTICLES IN CONTACT WITH FOOD (AMENDMENT) (EU EXIT) REGULATIONS 2019

2019 No. 704

1. Introduction

1.1 This explanatory memorandum has been prepared by the Food Standards Agency (FSA) and is laid before Parliament by Act.

2. Purpose of the instrument

2.1 The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 ("the instrument") are being made to fix inoperabilities in the retained EU Legislation on food contact material legislation; namely European Commission Regulation (EC) No. 1935/2004 ("the Framework Regulation") on materials and articles intended to come into contact with food, Regulation (EC) No. 450/2009, Regulation (EU) No. 10/2011, Regulation (EC) No. 282/2008, Regulation (EC) No. 2023/2006, Regulation (EC) No. 1895/2005 and Regulation (EU) No. 2018/213 that will arise as a consequence of the UK's exit from the European Union (EU).

2.2 This instrument is a legislative consequence of the UK's decision to leave the EU and will apply from Exit day in order to ensure the continued safety of materials and articles in contact with food.

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 food and feed (materials and articles in contact with food) policy and legislation.

Explanations

What did any relevant EU law do before exit day?

2.4 The EU measure providing overarching controls for all food contact materials and articles is European Council Regulation (EC) No. 1935/2004 which sets out the high-level principles and definitions relating to food contact material legislation across EU member states. It also lays down the framework of regulation of all such materials and articles intended to come into contact with food. Article 3 of that Regulation sets out the general requirements that all materials and articles expected, or likely to be in contact with food, shall be manufactured in compliance with 'good manufacturing practice' as defined in Commission Regulation (EC) No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food, so that under normal and foreseeable conditions of use they do not transfer their constituents to food in quantities which could:

- endanger human health; or
- bring about an unacceptable change in the composition of food; or
- bring about deterioration in the organoleptic characteristics of the food (i.e. texture, taste, aroma).

2.5 The Framework Regulation also provides for the general requirements for applying for the authorisation of substances not yet included in a specific measure. This will also include the modification, suspension or revocation of previously authorised substances. It also requires food contact material business operators to put in place systems and procedures to ensure the traceability of food contact materials they receive and supply, as well as demonstrating that the materials and articles for specific measures are compliant through the provisions of a Declaration of Compliance.

2.6 Substances covered by specific measures are outlined in separate regulations. Regulation (EU) No. 10/2011 provides the necessary legislative requirements for food contact plastics, including an authorised list of substances and setting rules on their use and amount in plastics to ensure they are safe. The authorised list of substances permitted for use in food contact plastics is generally updated several times a year.

2.7 Regulation (EC) No. 450/2009 provides the necessary legislative requirements for active and intelligent materials and articles intended to come into contact with food. Active food contact materials absorb or release substances to improve the quality of pre-packaged food or extend its shelf life. Intelligent food contact materials monitor the condition of packaged food or surrounding environment to provide information on the freshness of the food.

2.8 Regulation (EC) No. 282/2008 provides the necessary legislative requirements for recycled plastic materials and articles, ensuring that plastic packaging containing recycled plastic is safe.

2.9 Regulation (EC) No. 1895/2005 provides restrictions of use of certain epoxy derivatives in materials and articles intended to come into contact with food.

2.10 Regulation (EU) No. 2018/213 provides restrictions on the use of bisphenol A in varnishes and coatings intended to come into contact with food. It amends Regulation (EU) No. 10/2011 as regards the use of that substance in plastic food contact materials.

Why is it being changed?

2.11 The minor and technical amendments being made through this instrument will rectify deficiencies in the retained legislation that arise as a consequence of the UK's exit from the EU. These deficiencies relate to the conference of functions to EU institutions and processes to which the UK will no longer have access or place reliance on after exit.

2.12 Without this instrument, the current regulations would be inoperable because the powers under them would remain with the European Commission and the European Food Safety Authority. The retained EU law will need to be adapted in order for it to be operable in the UK after EU exit. All rules will remain the same. The changes introduced by the instrument will enable the retained EU law to work within the UK after exit day allowing for a smooth transition for businesses, the food contact materials sector and consumers.

2.13 Amendments introduced by this instrument will mean there will be no change in the high-level principles underpinning the day-to-day functioning of the food contact material legal framework. This will provide continuity for business, enforcers, and the voluntary sector and maintain public health protection for consumers.

What will it now do?

2.14 By broadly retaining the same approach, this instrument ensures that food safety is maintained in these areas as well as market stability immediately after exit. It will also continue to facilitate the trade of food contact materials and articles and uphold business and public confidence. Businesses will have the necessary legislative framework to adhere to.

2.15 This instrument removes from the retained EU legislation the tasks and roles assigned to the European Commission, its committees and the European Food Safety Authority as these will no longer be relevant. Where necessary, tasks and roles that need to be retained for the effective functioning of the UK legal framework have been assigned to appropriate UK entities and ensures the geographic scope of the Regulations remains consistent to ensure that the law remains operable and enforceable after EU exit.

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 includes Scotland and Northern Ireland.

3.3 The powers under which this instrument is made cover the entire United Kingdom (see The European Union (Withdrawal) Act 2018 ('the Act').) The instrument is being enacted under powers afforded by section 8 of the Act to correct deficiencies in the retained legislation 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 covers the entire United Kingdom.

4.2 The territorial application of this instrument is the entirety of the United Kingdom for those aspects amending deficiencies in retained EU law. The elements of the instrument addressing deficiencies in the Materials and Articles in Contact with Food (England) Regulations 2012 apply only in England, and equivalent measures to amend the respective legislation in the devolved administrations will be made there.

5. European Convention on Human Rights

5.1 The Parliamentary Under Secretary of State for Public Health and Primary Care, Steve Brine, has made the following statement regarding Human Rights:

"In my view the provisions of the Materials and Articles in Contact with Food (Amendment) (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 on EU exit day. It maintains all domestic law and retains previously directly applicable European Union legislation provided it is in the English language. Section

8(1) and 8(2) of the Act enable UK Ministers to fix deficiencies in retained EU law enabling the retained legislation and the safeguards it provides to operate effectively following the UK's exit from the EU.

6.2 The EU legislation regulates the safety of all materials and articles (such as plastic bottles and containers, kitchen appliances, cutlery and crockery) intended to come into contact with food, collectively known as food contact materials. Regulation (EC) No. 1935/2004 provides the framework for this and includes provisions to enable further specific measures to be adopted for a given group of materials and articles. As chemicals can transfer from food contact materials into food, these Regulations apply strict migration limits on the amount of a given substance released from a material or article. This ensures that the user of the material is not exposed to a specific substance at a level that may cause harm. It is not expected for there to be any legal issues arising from this instrument.

6.3 The Framework Regulation also provides for specific measures for groups of materials and articles through regulations and these are:

- Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food;
- Regulation (EC) No. 282/2008 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No. 2023/2006;
- Regulation (EC) No. 1895/2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food;
- Regulation (EC) No. 450/2009 on active and intelligent materials and articles intended to come into contact with food;
- Regulation (EU) No. 2018/213 on the use of bisphenol A in varnishes and coatings intended to come into contact with food.

6.4 Article 9 of Regulation (EC) No. 178/2002 states that there will be open and transparent public consultation during the preparation, evaluation and revision of food law, except in urgent circumstances. Following EU Exit, this will continue to be the case with all future revisions of food law. Public consultation has been completed, as shown below, in accordance with this.

7. Policy background

What is being done and why?

7.1 No substantive changes are being introduced by this instrument; the policy objective is to maintain existing laws and fix the inoperabilities in retained direct EU legislation related to materials and articles in contact with food. This will include the following directly relevant regulations: Regulation (EC) No. 1935/2004 ("the Framework Regulation") on materials and articles intended to come into contact with food, Regulation (EC) No. 450/2009, Regulation (EU) No. 10/2011, Regulation (EC) No. 282/2008, Regulation (EC) No. 2023/2006, Regulation (EC) No. 1895/2005 and Regulation (EU) No. 2018/213. This will ensure that the retained EU law in the domestic Regulations continue to be operable following our exit from the European Union. Ultimately, it will continue to provide the necessary safety requirements to ensure businesses are producing safe food contact materials and articles for the end user.

7.2 The changes introduced in this instrument and listed below will ensure that the legislation remains operable.

- Functions currently undertaken by the European Commission in reviewing and making changes to legislation will in the future, be the responsibility of the 'appropriate authority'

  "appropriate authority" means –

  (a) in relation to England, the Secretary of the State;

  (b) in relation to Wales, the Welsh Ministers;

  (c) in relation to Scotland, the Scottish Ministers;

  (d) in relation to Northern Ireland, the Northern Ireland devolved authority.

- Under the retained EU law, the "Food Safety Authority" will have a role in providing food safety advice to the appropriate authority. The "Food Safety Authority" means

  (a) as regards England, Wales and Northern Ireland, the Food Standards Agency (FSA);

  (b) as regards Scotland, Food Standards Scotland.

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

8.1 This instrument is being made using the power in section 8 of 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 The instrument does not consolidate existing law, EU or UK.

10. Consultation outcome

10.1 A full public consultation was carried out from 4 September until 14 October 2018 on the FSA's proposed approach to retained EU law for food and feed safety and hygiene. This approach proposed making a number of corrections to the retained EU law which includes the Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019, using powers under the European Union Withdrawal Act. It was proposed in our approach that the corrections would be made by way of statutory instruments of which 15 had been prepared. Key corrections would provide a suitable replacement for the risk management function currently undertaken by the European Commission and for the risk assessment function currently undertaken by the European Food Safety Authority (EFSA), amongst other minor, non-controversial amendments. The corrections would not result in any material change in the level of protection to human or animal health, or to the high standard of domestic or imported food and feed which consumers expect. The statutory instruments which would make the corrections will be subject to review and approval by Parliament.

10.2 The consultation covered the proposed approach used for all of the FSA's Statutory Instruments in relation to EU Exit. It received 50 responses of which 82% supported or did not disagree with the proposed approach being outlined by the Food Standards Agency. 16% of replies contain mixed comments. The main concerns regarding the FSA approach in general were related to the communication of change and ensuring sufficient lead time is given. A more detailed analysis of the responses can be seen at the published link below.

10.3 One respondent raised concerns around the timeframe for delivering the legislation needed for day one readiness.

10.4 The consultation and its responses can be viewed at:

https://www.food.gov.uk/news-alerts/consultations/proposed-approach-to-retained-eu-law-for-food-and-feed-safety-and-hygiene

11. Guidance

11.1 It is considered that guidance is not required for this instrument as it does not introduce any substantive policy changes.

12. Impact

12.1 The impact on business, charities or voluntary bodies is minimal. According to the ONS Inter Departmental Business Register (IDBR) there were 214,175 businesses active in the agri-food sector in 2017. The FSA envisages minimal one-off familiarisation costs to businesses, charities and voluntary bodies; where we estimate that it will take each organisation less than 60 minutes[1] to read and understand the proposed regulations and then disseminate the information to key staff within their organisation. However, it is unlikely that the envisaged changes will present any other impact on businesses', charities or voluntary bodies' day to day operations as the rules are not changing as a result of this instrument. The associated direct cost for businesses has been calculated by applying the 2017 median annual wage for "production managers and directors" of £22.05 and uprating it by 20% to account for overheads[2]. Multiplying this wage rate with the expected familiarisation time gives an estimated total one-off cost to businesses of £5.7m. After adjusting for inflation and applying a discount rate of 3.5% as per HMT Green Book guidance, this translates to an Equivalent Annual Net Direct Cost to Business (EANDCB) of approximately £600,000.

12.2 In terms of the impact on the public sector, there are approximately 419 Local Authorities (LAs) and 35 Port Health Authorities (PHAs) in the UK, which enforce existing food and feed law and will continue to enforce the retained EU law after the UK's EU Exit. The FSA envisages minimal one-off familiarisation time costs to LAs and PHAs; where we estimated that it will take authorities less than 60 minutes to read and familiarise themselves with the EU Regulations and then disseminate to staff and key stakeholders. It is estimated that one officer in each of these authorities (one Food/Feed Officer from each local authority; and one 'Port Health Officer' from each PHA) will need to undertake this task. The instrument is not considered to add additional or new burdens on enforcement bodies, other than those identified here.

[1] Please note the familiarisation time has been amended from less than 30 to less than 60 minutes following consultation feedback.

[2] Wage rate taken from the ONS' 2017 Annual Survey of Hours and Earnings (ASHE), table 14.6a.

12.3 An impact assessment has not been produced for these Regulations which the FSA has certified as being below the *de minimis* threshold of +/- £5m equivalent annual net direct cost to business. The Regulations are designed only to fix the inoperability of retained EU legislation (detailed in Section 6) and ensure the continued safety of food and feed after the UK exits the EU. The Regulations provide continuity for stakeholders and the FSA has not identified any significant impact on stakeholders other than in relation to a negligible one-off familiarisation cost from the legislative change.

13. Regulating small business

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

13.2 Over 90% of the UK food industry sector comprises small and micro businesses and EU legislation generally applies to food and feed businesses regardless of size, as requirements are intended to be risk based to reflect the activities undertaken by business. Due to the high ratio of small and micro food businesses in the UK, it is often not feasible to exempt smaller businesses from new food measures, as this would fail to achieve the intended effect of reducing risks to public health. The FSA makes every effort to identify the impacts and minimise burdens on small and micro businesses where possible.

13.3 The changes made to the legislation will provide continuity for business and should not impact on the day-to-day workload of small and micro businesses as all food and feed safety standards and legal definitions are maintained.

14. Monitoring & review

14.1 The approach to monitoring of this legislation is dependent on what deal is reached between the United Kingdom and the European Union.

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

15. Contact

15.1 Tim Chandler at the Food Standards Agency, Telephone: 020 7276 8127 or email: Tim.Chandler@food.gov.uk, can be contacted with any queries regarding the instrument.

15.2 Michael Wight, Director for Food Policy, at the Food Standards Agency can confirm that this Explanatory Memorandum meets the required standard.

15.3 Steve Brine, Parliamentary Under Secretary of State for Public Health and Primary Care, at the Department for Health and Social 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. Appropriateness statement

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 the Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 does no more than is appropriate".

1.2 This is the case because: the instrument only fixes the inoperabilities detailed in section 2 of this Explanatory Memorandum and adds no additional legislative measures.

2. Good reasons

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

2.2 These are: because the legislation will maintain the high-level principles underpinning the day-to-day functioning of the food contact material legal framework. This will provide continuity for business, enforcers, and the voluntary sector and maintain public health protection for consumers.

3. Equalities

3.1 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."

3.2 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."

4. Explanations

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