EXPLANATORY MEMORANDUM TO

THE FOOD AND FEED HYGIENE AND SAFETY (MISCELLANEOUS AMENDMENTS) (ENGLAND) REGULATIONS 2020

2020 No. 1410

1. Introduction

1.1 This explanatory memorandum has been prepared by the Food Standards Agency 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 This instrument amends various statutory instruments relating to food and feed hygiene and safety, to ensure an appropriate enforcement regime exists in respect of certain EU food and feed legislation. The instrument is being made under section 2(2) of the European Communities Act 1972, except in relation to some minor amendments to the Materials and Articles in Contact with Food (England) Regulations 2012 ("the 2012 Regulations") where domestic powers under the Food Safety Act 1990 are being relied on, to come into force after IP completion day.

2.2 This instrument amends the 2012 Regulations to provide the execution and enforcement, in England, of two EU Regulations: Regulation (EC) 282/2008 on recycled plastic processes and Regulation (EU) No. 2018/213 on bisphenol A. This instrument will also introduce the use of compliance notices for certain provisions of these EU Regulations, in addition to existing EU Regulations that are already executed and enforced under the 2012 Regulations. It will also remove the maximum penalty of a custodial sentence from nine specific offences in recognition that the penalty of a fine for these offences is now unlimited. The nature of these specific offences is unlikely to have a significant or widespread impact to public health, which justifies the approach taken. Overall, this will provide a graduated approach to enforcement that is both appropriate and proportionate. This instrument also makes minor amendments to the 2012 Regulations under the Food Safety Act 1990 which come into force immediately after IP completion day. These amendments are partly consequential on the provisions introduced by this instrument to ensure the 2012 Regulations (as amended by the Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 on IP completion day) operate correctly after IP completion date with the compliance notice regime introduced by this instrument, and partly to ensure minor errors contained in the amendments to the 2012 Regulations are corrected immediately after IP completion day.

2.3 This instrument amends the Animal Feed (Composition, Marketing and Use) (England) Regulations 2015 and the Animal Feed (Hygiene, Sampling etc. and Enforcement) (England) Regulations 2015 to provide for the execution and enforcement of Commission Regulation (EU) 2020/354 establishing a list of intended uses of feed intended for particular nutritional purposes and repealing Directive 2008/38/EC.

2.4 This instrument amends the Official Feed and Food Controls (England) Regulations 2009 and the Food Safety and Hygiene (England) Regulations 2013 to provide for the execution and enforcement, in England, of the food and feed elements of several pieces of tertiary legislation made under Regulation (EU) 2017/625 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products.

2.5 This instrument amends the Fishery Products (Official Controls Charges) (England) Regulations 2007 to correct an error identified by the Joint Committee on Statutory Instruments.

2.6 Whilst the UK had left the EU, this instrument proposes to execute and enforce the specified EU Regulations before the end of the transition period while the power under section 2(2) of the European Communities Act 1972 is available. EU law continues to apply in the UK during the transition period, including rules for food and feed. These EU Regulations will be retained in UK law at the end of the transition period and this had been accounted for in separate EU Exit related instruments. Outside the European Union, the UK will have greater flexibility to determine for itself the best approach to ensuring high food and feed standards, and suitable protection for consumers.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 Regulation 2 of this instrument amends the Fishery Products (Official Controls Charges) (England) Regulations 2007 to correct a minor error identified by the Joint Committee on Statutory Instruments (a definition in those Regulations was not in fact used in the body of those Regulations).

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 As this 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 England and Wales.

4.2 The territorial application of this instrument is England.

5. European Convention on Human Rights

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

6. Legislative Context

Materials and Articles in Contact with Food

6.1 European legislation regulates the safety of all materials and articles intended to come into contact with food as established in Regulation (EC) No. 1935/2004 ("the Framework Regulation"). The Framework Regulation includes provisions to allow for

specific measures to be adopted or amended for a given group of materials and articles such as plastics and ceramics.

6.2 Commission Regulation (EC) No. 282/2008 ("the Recycling Regulation") establishes the specific rules for food contact recycled plastic materials and articles. Food contact materials (FCMs) made from recycled plastics can only be placed on the market if they are obtained from an authorised recycling process, subject to the transitional requirements. This ensures that the recycled plastic material remains safe to use for FCM use.

6.3 Commission Regulation (EU) No. 2018/213 ("the BPA Regulation") sets out new requirements for bisphenol A (BPA). BPA is a chemical used to make plastics, including food storage containers and refillable drinks bottles. It is also used to make some protective coatings and linings for food and drinks cans. The BPA Regulation includes a specific migration limit, the maximum permitted amount of a given substance released from a material or article into food, in varnishes and coatings intended to come into contact with food. It also bans the use of BPA in varnishes and coatings for FCMs intended for infants and young children based on the European Food Safety Authority's (EFSA) precautionary principle.

Animal Feed for Particular Nutritional Purposes

6.4 The placing on the market and use of animal feed is regulated by Regulation (EC) 767/2009. In accordance with Article 9 of that Regulation, feed intended for particular nutritional purposes (dietetic feed) may only be marketed if its intended use is included in a list of intended uses established in accordance with Article 10 of Regulation (EC) 767/2009. The list of intended uses of feed intended for particular nutritional purposes is currently contained in Commission Directive 2008/38/EC which also established the general provisions for feed intended for particular nutritional purposes. This Directive is being repealed and the list is now included in Part B of the Annex of Regulation (EU) 2020/354. This will make it easier to keep the list up to date.

6.5 Feed intended for particular nutritional purposes which has been labelled before 25 March 2022 in accordance with the rules applicable before 25 March 2020 may continue to be placed on the market and used until the existing stocks are exhausted.

Official Controls

6.6 Regulation (EU) 2017/625 sets out a framework of requirements for the competent authorities in Member States which have responsibilities for organising and performing official controls and other official activities to verify compliance with agri-food chain legislation. Most of the provisions of Regulation (EU) 2017/625 and its empowered tertiary legislation clarify and simplify existing requirements and aim to introduce a more risk-based approach to controls. Therefore, existing enforcement arrangements in the UK are generally already in line with the new requirements.

7. Policy background

What is being done and why?

7.1 This instrument will amend various statutory instruments relating to food and feed safety and hygiene. These are outlined below.

Materials and Articles in Contact with Food

7.2 FCMs are used daily by everyone in the UK. These are made from a variety of materials such as plastic, paper, glass, ceramics, and rubber, and includes food packaging, kitchenware and tableware.

7.3 As the level of chemical transfer from FCMs to food cannot be determined by consumers, they are unable to assess any potential risks. This transfer of chemicals may be detrimental to the long-term health of consumers. Government intervention is necessary to reduce the chronic and acute health risks to consumers arising from chemical transfer.

7.4 Currently, all EU legislation relating to FCMs is implemented in England through the 2012 Regulations and the Plastic Kitchenware (Conditions on Import from China) (England) Regulations 2011.

7.5 The 2012 Regulations currently implement EU legislation relating to FCMs. The proposed amendments in the Food and Feed Hygiene and Safety (Miscellaneous Amendments) (England) Regulations 2020 relating to FCMs will provide for the execution and enforcement of the Recycling Regulation and the BPA Regulation, making appropriate domestic regulations and continue to provide a single point of reference for businesses and enforcement authorities.

7.6 It is proposed to update the existing offences and penalties in the 2012 Regulations by introducing the use of compliance notices to act as a first intervention for offences predominantly linked to failure of a business providing a declaration of compliance and/or relevant supporting documentation. Although compliance notices are being introduced, it is essential to introduce a criminal backstop for failure to adhere to compliance notices because of the risk involved and the vulnerable groups who may be at risk. The aim is to ensure that the sanctions are appropriate and proportionate.

7.7 For the BPA Regulation a criminal offence will relate to businesses failing to meet the revised migratory limit, and/or for failure to ensure that no migration occurs from varnishes or coatings applied to products intended to come into contact with food for consumption by infants or young children. It is important that these more stringent requirements of the BPA Regulation are met given that they are in line with the EFSA's recent evaluation on BPA and that one of these requirements relates to a high-risk group of the population. It is therefore proposed that penalties will be on conviction on indictment to a fine or a term of imprisonment not exceeding two years (or both), or on summary conviction to a fine or a term of imprisonment not exceeding 6 months (or both).

7.8 For the Recycling Regulation, a criminal offence has been introduced concerning placing recycled plastic materials and articles onto the market which have been manufactured with non-compliant source material. With an increased focus on single-use plastic and recycling, media and civil society interest in this area is rapidly increasing. Businesses will soon be under significant pressure to increase the percentage of recycled material in products, which without an appropriate deterrent, could lead to cutting corners and non-compliances that undermine consumer safety. It is proposed that the penalty for this criminal offence will, on summary conviction, be a fine.

7.9 Due to the frequency of amendments to the annexes in Commission Regulation (EU) 10/2011 ("the Plastics Regulation") (fifteen since coming into force in 2011), these are introduced via ambulatory references. The addition of substances benefits industry

as it provides a wider number of substances with which to manufacture plastics enabling improvements in technical performance. The amendment or introduction of specific migration limits is done after consideration of new scientific evidence and an evaluation. This improves the safety of food, in contact with plastics, to consumers. In this amendment, the main changes are new migration limits for aluminium and zinc, updates to definitions and assigning appropriate testing conditions for carrying out more effective chemical migration tests to determine the safety of an FCM. These are outlined in paragraph 25 and 26 of the Impact Assessment.

7.10 The Post Implementation Review of the 2012 Regulations didn't examine the use of sanctions, however, in line with the Government's commitment to reduce reliance on criminal offences and penalties, the 2012 Regulations also removes the maximum penalty of a custodial sentence from nine specific offences, retaining the maximum penalty on summary conviction to a fine.

7.11 Overall, the proposal is considered to be a proportionate regime. The introduction of the new criminal sanctions in relation to the BPA Regulation and the Recycling Regulation, in addition to the amendments to existing criminal sanctions, will ensure that they apply to serious contraventions that have the potential to impact on public safety. The introduction of civil sanctions in the form of compliance notices replaces seven criminal offences and provides business operators with the opportunity to make prompt improvements to record keeping, which is unlikely to have an immediate impact to public health. It aims to ensure that these sanctions are appropriate and proportionate. More broadly the FSA will continue to review offences under food and feed law with the intention of reducing reliance on criminal offences and sanctions and make greater use of civil sanctions to drive regulatory compliance.

7.12 If the 2012 Regulations are not amended to implement the two EU Regulations, they would still be applicable in England. However, enforcement authorities in England wouldn't have the powers to enforce certain provisions, potentially having adverse impacts on public health. Non-compliance with the requirements of the legislation couldn't be prevented nor penalties imposed. There would be a lack of deterrence for businesses not abiding by these Regulations, potentially leading to instances of harm to consumers.

Animal Feed for Particular Nutritional Purposes

7.13 Feed intended for particular nutritional purposes, also known as dietetic feed, is feed that can satisfy a particular nutritional purpose because of its composition or its manufacturing process, which clearly distinguishes it from ordinary feed.

7.14 The list of intended uses of feed for particular nutritional purposes is currently contained in Commission Directive 2008/38/EC which also established the general provisions for feed intended for particular nutritional purposes. This Directive is being repealed and the list included in Regulation (EU) 2020/354. This will make it easier to keep the list up to date.

7.15 Articles 11 to 17 of Regulation (EC) No 767/2009 established new principles and rules for the placing on the market of animal feed, including labelling. As a consequence, several entries in the list of intended uses of feed for particular nutritional purposes contained in Directive 2008/38/EC became outdated, partially because of poor and overly general descriptions in the column 'Essential nutritional characteristics'. For such entries, it has been very difficult for the control authorities to verify compliance with the provisions of Regulation (EC) 767/2009, including

whether the specific composition of the feed concerned fulfils the respective particular intended nutritional purpose. Establishing compliance with the provisions should be simpler under Regulation (EU) 2020/354.

Official Controls

7.16 In the area of official controls, this Statutory Instrument amends two existing SIs in England: the Official Feed and Food Controls (England) Regulations 2009 and the Food Safety and Hygiene (England) Regulations 2013.

7.17 The principal purpose of these changes is to amend references and to give effect to the relevant elements of EU Tertiary Regulations made under Regulation (EC) 2017/625 since Commission Implementing Regulation (EU) 2019/1873. This ensures that the competent authorities continue to have the powers to undertake checks required by this legislation.

7.18 This instrument also amends the Fishery Products (Official Controls Charges) (England) Regulations 2007 to correct an error identified by the Joint Committee on Statutory Instruments. The error occurred because a definition in the instrument was not in fact used in the body of the instrument.

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

8.1 This instrument does not relate to withdrawal from the European Union.

9. Consolidation

9.1 This instrument does not consolidate any legislation.

10. Consultation outcome

10.1 Separate, targeted consultations were conducted by the FSA in relation to specific proposed amendments contained within this instrument. They are outlined separately below.

Materials and Articles in Contact with Food

10.2 For the amendment to the 2012 Regulations, the FSA conducted a formal public consultation from 9 April to 4 June 2018, seeking comments on the draft instrument. Due to a previous public consultation held in 2017 on the draft BPA Regulations by the EU Commission, and directly informing UK stakeholders of the introduction of the BPA regulation in February 2018, it was felt that eight weeks would be sufficient in length for industry and enforcement authorities to respond. This consultation was conducted during the time when the BPA Regulation was expected to come into force.

10.3 79 stakeholders, including select enforcement authority representatives, were consulted directly on these proposals, however some of these were industry bodies therefore the expectation is that the consultation was disseminated more widely. Data analytics of the consultation webpage over the consultation period supports this assertion. The analytics show that the webpage was visited on 704 occasions and the consultation PDF downloaded 242 times.

10.4 The FSA received two responses to the consultation. One from an industry trade body (Industry) and the other from a Trading Standards Association (TSA). Comments

were mainly focussed on the costs to their respective industry and the inclusion of compliance notices within the draft instrument.

10.5 Stakeholders were specifically asked to comment on the introduction of compliance notices to act as a first intervention, whether they would provide adequate protection for consumers, and whether they should have an associated 'backstop' criminal offence for compliance. The Industry and TSA welcomed the introduction of compliance notices. The TSA saw them as a "cost-effective and timely addition to the toolbox" and viewed a backstop criminal offence for compliance notices as essential to deal with persistent and wilful non-compliance.

10.6 Comments received from industry on familiarisation costs highlighted that the Impact Assessment does not account for time spent by industry to discuss declarations of compliance with their suppliers. The FSA's response to this is that the potential discussions involving declarations of compliance could be construed as normal practice given that a declaration of compliance is already required for certain types of food contact materials.

10.7 In response to the FSA's consultation question, the TSA didn't completely agree that the additional burden as a result of these changes on enforcement authorities would be minimal, due to the additional training required for all food officers; implementation of new internal policies and procedures; and the redrafting of business information leaflets. This has also been noted in paragraph 12.2. The FSA's response is that several food policy areas have, or are, in the process of introducing compliance notices as a first line of intervention, therefore there will be a standard template in which enforcement officers can use and they should be familiar with the process, particularly given the delay in updating these enforcement provisions. The FSA is happy to support individual enforcement authorities with any initial concerns. The TSA's additional concerns about auditing of recycled plastic processes is no longer relevant as the FSA is looking to obtain a third party to carry out these audits. Therefore, additional training will not be required in this area. Although out of scope of the original question, they raised an audit point from FVO Mission Report ref. DG(SANCO)/2009-8170-MR which stated that staff of local authorities are kept up to date in their area of competence, particularly regarding the declaration of compliance for FCMs.

10.8 The TSA welcomed the consolidation of the different Regulations and do not believe there will be a significant impact on small and micro businesses because of the legislation. More generally, the TSA raised the issue of improving information exchange between the involved parties and suggested further training for enforcers.

10.9 Comments received in response to the consultation have been reflected, in the Impact Assessment attached to this memorandum. Full details of the consultation and the Government's response will be published on the FSA's website.

10.10 The FSA conducted a further consultation from 4 to 18 November 2020, in relation to further proposed changes limited to the criminal offences within the regulations. The delay between the original and further consultation was primarily related to the Government commitments to reduce reliance on criminal sanctions. Following further consideration, it was decided to additionally amend some minor provisions within the original proposals. The updated proposals included removing the maximum penalty of a custodial sentence from nine specific criminal offences, including on conviction on indictment to a fine, retaining the maximum penalty on summary conviction to a fine.

This will now also be applicable to the Recycling Regulation. The devolved administrations were consulted and regularly informed of the updated proposals.

10.11 The FSA received five responses to the further consultation. We had asked specifically for comments on the updated proposals in relation to offences within the regulations. There were no objections to the latest proposed amendments. One response indicated that restricting the maximum penalty for the nine offences, to an unlimited fine rather than a custodial sentence, appeared proportionate and a deterrent. One response was also in agreement with the proposed changes. The remaining three responses acknowledged the proposals but did not provide any additional comments in relation to the consultation.

Animal Feed for Particular Nutritional Purposes

10.12 For the implementation of regulations establishing a list of intended uses of animal feed for particular nutritional purposes (PARNUTS) in England, the FSA conducted a formal public consultation from 2 October to 13 November 2020, seeking comments on draft regulations. As the measures were considered a mechanical change it was felt that six weeks would be sufficient for industry and enforcement authorities to respond.

10.13 46 stakeholders were consulted directly on this proposal, however some of these were industry and enforcement authority representatives therefore the expectation is that the consultation was disseminated more widely. This assertion is supported by data analytics of the consultation webpage. Data over the consultation period showed that the webpage was visited on 633 occasions and the consultation PDF downloaded 145 times.

10.14 The FSA received three responses to the consultation. Responses supported the changes and the proposal that the list would be easier to use and that the changes were necessary and appropriate. Stakeholders recognised that feed and food safety standards are devolved matters in the UK, in the interests of animal health and welfare and ensuring product availability, stakeholders suggested that a harmonised approach to enforcement of the regulations should be taken. One feed business raised concerns as their product would require labelling changes as a result of the new regulation. To mitigate this a lengthy transition period is provided for in the new legislation and this is intended to minimise the risk of products not compliant with the new regulation having to be removed from sale. Feed intended for particular nutritional purposes which has been labelled before 25 March 2022 in accordance with the rules applicable before 25 March 2020 may continue to be placed on the market and used until the existing stocks are exhausted.

Official Controls

10.15 The FSA held a six-week consultation on the implementation in England of Regulation (EU) 2017/625 and its empowered tertiary legislation between 28 August to 11 October 2019. The consultation response document was published on the FSA's website in January 2020. 37 consultation responses were received in England (7 from businesses and associations, 25 from individuals or consumer groups, 5 from public bodies). Most respondents acknowledged the need for government intervention. As this instrument makes only minor technical amendments in line with the approach outlined in that consultation, further consultation was not considered necessary for the

later EU implementation of these changes as the proposals were identified in the 2019 consultation.

11. Guidance

11.1 The legislation largely affects the authorities responsible for enforcing the various food and feed law contained within this instrument. The FSA routinely updates its local authority (LA) delivery partners on a monthly basis and this will serve as appropriate guidance on the food and feed areas covered by this instrument.

12. Impact

Materials and Articles in Contact with Food

12.1 For the amendment to the 2012 Regulations, the impact on business, charities or voluntary bodies is £104,150. This is through one-off familiarisation costs to businesses. This will affect manufacturers of coatings, cans and food canners, along with plastic manufacturers. Plastic recyclers face low familiarisation costs as they will already be aware of the Regulations. They will however face future costs due to the auditing requirements of (EC) No. 282/2008 expected to come into force in early 2021.

12.2 The impact on the public sector is £15,673 as one-off familiarisation costs. There are 403 public-sector services affected by the new regulations which are local authorities, port health authorities and official control laboratories. In response to the TSA's comments in paragraph 10.7 of this explanatory memorandum, the FSA notes their concerns regarding additional burden on enforcement authorities and these have been addressed in the same paragraph. Overall, the FSA considers this to be a short-term burden and is addressed in the Impact Assessment.

12.3 A full Impact Assessment is submitted and published alongside this memorandum on the legislation.gov.uk website.

Animal Feed for Particular Nutritional Purposes

12.4 Whilst the legislation has changed from an EU Directive to an EU Regulation, the FSA identified no significant change to the requirements for business, or in the regulatory approach undertaken and therefore the measure is considered to be mechanical in nature. Transitional measures are provided for which will allow product labelled before 25 March 2022 under the present rules to be used up. The FSA therefore anticipate that the proposed regulations will introduce no significant impacts other than a small familiarisation cost. A full regulatory Impact Assessment was not considered necessary for this mechanical change.

Official Controls

12.5 An Impact Assessment was consulted on as part the package to introduce domestic enforcement legislation when Regulation 2017/625 came into effect on 14 December 2019 which also noted the impact of the tertiary legislation. The tertiary legislation brings clarity to the changes already introduced by the main Regulation, so a further Impact Assessment was not deemed necessary.

13. Regulating small business

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

13.2 No specific action is proposed to minimise regulatory burdens on small businesses.

14. Monitoring & review

14.1 Statutory review clauses are contained in the 2012 Regulations, the Food Safety and Hygiene (England) Regulations 2013, the Animal Feed (Composition, Marketing and Use) (England) Regulations 2015 and the Animal Feed (Hygiene, Sampling etc. and Enforcement) (England) Regulations 2015. The approach to monitoring of these instruments is that reviews will be conducted at least every 5 years. Outside the European Union, the UK will have greater flexibility to determine for itself the best approach to regulatory provisions.

14.2 It is not considered necessary to include a review clause for the minor corrective amendments made to the Fishery Products (Official Controls Charges) (England) Regulations 2006, and a statutory review clause is included in respect of the amendments to the Official Feed and Food Controls (England) Regulations 2009.

15. Contact

15.1 Timothy Chandler at the Food Standards Agency Telephone: 020 7276 8127 or email: tim.chandler@food.gov.uk can be contacted with any queries.

15.2 Michael Wight, Deputy Director for the Food Policy Division, at the Food Standards Agency can confirm that this explanatory memorandum meets the required standard.

15.3 Edward Argar MP, Minster for Health at the Department of Health and Social Care can confirm that this explanatory memorandum meets the required standard.