EXPLANATORY MEMORANDUM TO

THE NOVEL FOODS (ENGLAND) REGULATIONS 2018

2018 No. 154

1. Introduction

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

2. Purpose of the instrument

2.1 Novel foods are foods or food ingredients that do not have a significant history of consumption within the European Union (EU) before 15 May 1997. Under EU law, in the interests of safeguarding public health, novel foods must undergo a safety assessment before they can be authorised for placing on the market. An example of a novel food that has recently been authorised is Chia seeds.

2.2 This instrument provides for the execution and enforcement, in England, of the directly applicable European Union Regulation (EU) 2015/2283 on Novel Foods which became fully applicable across the EU on 1 January 2018 repealing and replacing previous EU novel foods legislation.

2.3 The instrument also repeals the Novel Food and Novel Food Ingredients (England) Regulations 1997 (SI 1997 No. 1335) which provided for the enforcement of the previous EU legislation in England and repeals the Novel Foods and Novel Food Ingredients (Fees) Regulations 1997 (SI No. 1336/1997), made under section 56 of the Finance Act 1973, insofar as they extend to England and Northern Ireland. The latter regulations provided powers for the UK government to charge fees for initial assessments of novel food applications which is now undertaken at EU level, rendering those powers redundant.

Execution and Enforcement of the EU Regulation

2.4 In line with the Government's commitment to move away from unnecessary criminal offences and shift to civil sanctions in accordance with the Macrory principles on regulatory enforcement, the instrument introduces civil penalties for the enforcement of new EU legal requirements that apply to placing novel foods on the market.

2.5 In accordance with the hierarchy of enforcement set out in the statutory Food Law Code of Practice, authorised enforcement officers initially offer advice to food businesses on failures to comply with legal requirements that apply to novel foods. If that advice is not followed they will now be able to issue:

- compliance notices (e.g. if a novel food that had not been safety assessed and authorised under the regulation is being sold to consumers);
- stop notices, which might be used where immediate action is necessary to remove a product from sale (e.g. the removal from sale of an unauthorised novel food where there is reason to suspect it use be harmful to consumers);
- fixed monetary penalties, for other failures to comply with the EU Regulation (e.g. authorised novel food is being sold in additional food categories not covered by the authorisation).

2.6 The instrument applies Section 9 of the Food Safety Act 1990 ('Inspection and seizure of suspect food') to enable officers to seize and inspect suspected unauthorised novel foods.

2.7 The instrument will maintain a criminal offence for more serious and/or repeated non-compliance, where civil penalties are no longer appropriate. The penalty on conviction of this criminal offence will be an unlimited fine to be determined by a Magistrate in line with current sentencing guidelines.

Repeal of Domestic Regulations

2.8 This instrument repeals the Novel Food and Novel Food Ingredients (England) Regulations 1997 (SI 1997 No. 1335) which provided for the enforcement of the previous EU novel foods legislation.

2.9 With agreement from Her Majesty's Treasury, the instrument also repeals the Novel Foods and Novel Food Ingredients (Fees) Regulations 1997 (SI No. 1336/1997) made under section 56 of the Finance Act 1973, insofar as they extend to England and Northern Ireland.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 Novel foods is an area of devolved competence and the following similar, equivalent, instruments have been implemented in the devolved administrations:

- The Novel Foods (Scotland) Regulations 2017 (2017 No. 415);
- The Novel Foods (Wales) Regulations 2017 (2017 No. 1103 (W.279));
- The Novel Foods Regulations (Northern Ireland) (2017 No. 233).

Other matters of interest to the House of Commons

3.2 As this instrument is subject to the negative procedure and has not been prayed against, consideration as to whether there are other matters of interest to the House of Commons does not arise at this stage.

4. Legislative Context

4.1 In 2008, the European Commission put forward a proposal to replace Regulation (EC) No. 258/1997 on Novel foods and Novel food processes, with a view to updating the legislative framework which had been established ten years before. The original attempt to do so failed because of disagreement over certain technical aspects of the proposal and how of meat from cloned animals should be classified and labelled. Having agreed to maintain the status quo on meat from cloned animals until specific legislation is developed, a further attempt to update the legislation in 2013 was successfully concluded in line with the UK's negotiating objectives.

4.2 Regulation (EU) No. 2015/2283 sets down legal requirements that apply to novel foods placed on the market in the EU. It streamlines the authorisation process and updates legal requirements in line with technical and scientific progress. It is anticipated that the changes will help reduce burdens on businesses wishing to place novel foods on the market and facilitate consumer access to new food innovations which have been assessed and are considered to be safe. The EU Regulation repealed

earlier EU novel foods legislation and became fully applicable across the EU on 1 January 2018.

4.3 This instrument is required to provide for the execution and effective enforcement of Regulation (EU) 2015/2283 in England.

5. Extent and Territorial Application

5.1 The instrument extends to England only with respect to the provisions for the execution and enforcement of Regulation (EU) 2015/2283 and the repeal of the Novel Food and Novel Food Ingredients (England) Regulations 1997 (SI 1997 No. 1335) and extends to England and Northern Ireland with respect to the repeal of the Novel Foods and Novel Food Ingredients (Fees) Regulations 1997 (SI No. 1336/1997). The similar, equivalent, instruments in Scotland and Wales repealed the latter regulations insofar as they as they extended to those parts of the UK.

5.2 The instrument applies to England only with respect to the provisions for the execution and enforcement of Regulation (EU) 2015/2283 and the repeal of the Novel Food and Novel Food Ingredients (England) Regulations 1997 (SI 1997 No. 1335) and applies to England and Northern Ireland with respect to the repeal of the Novel Foods and Novel Food Ingredients (Fees) Regulations 1997 (SI No. 1336/1997). The similar, equivalent, instruments in Scotland and Wales repealed the latter regulations insofar as they as they applied to those parts of the UK.

6. European Convention on Human Rights

6.1 As the instrument is subject to the negative resolution procedure and does not amend primary legislation, a statement is not required.

7. Policy background

What is being done and why

Previous EU legislation on novel foods

7.1 The previous EU novel foods legislation, Regulation (EC) No. 258/1997, required novel foods to undergo a safety assessment before they could be authorised for placing on the market. Businesses were required apply for authorisation with a supporting dossier of scientific evidence and data. Applications could be either:

- a full application where a novel food and its proposed uses, was being considered for authorisation for the first time in the EU. If authorised, only the authorisation holder could place that novel food on the market;
- a 'substantial equivalence' ('me too') application, may be made by others wanting to supply the same authorised novel food or where a product is very similar to one already on the market. These applications need to demonstrate that the product is substantially equivalent in terms of nutritional composition, safety etc. to the food already on the market.

7.2 In the UK, applications were submitted to the FSA for safety assessment which was undertaken by an independent panel of scientists, the Advisory Committee on Novel Foods and Processes (ACNFP). A report of the ACNFP's assessment was sent to the European Commission and other Member States and there was a facility for the Commission to request an additional assessment by the European Food Safety

Authority (EFSA). Once fully assessed, the European Commission would then grant, or refuse, the novel food authorisation, advising the applicant accordingly.

7.3 This approach often resulted in applications being safety assessed twice, once by the ACNFP and then EFSA. Businesses needed to put greater administrative effort into getting through the authorisation process and as such it inevitably took longer to come to a point where a decision could be made on whether or not to grant an authorisation.

New EU novel foods legislation

7.4 The new legislation, Regulation (EU) 2015/2283, maintains the safety-based positive authorisation approach of the earlier legislation, but streamlines it by:

- providing a consistent, time-limited authorisation procedure, harmonising the application process so that a single safety assessment is carried out by EFSA rather than Member States;
- introducing generic authorisations, removing the need for 'me too' substantial equivalence applications;
- establishing a Union list of authorised novel foods, with any conditions of use;
- placing a clear duty on food businesses to check whether the food they intend to place on the market falls within the scope of the legislation and providing that businesses can seek help from Member States if they are unsure;
- providing a new simpler notification procedure for traditional foods consumed to a significant degree in countries outside the EU, but not in the EU, prior to 1997; and
- providing intellectual property confidentiality safeguards for scientific evidence and data produced in support of certain applications for a maximum 5-year period from the date of authorisation.

Changes to the Enforcement Approach introduced by this Instrument

7.5 The enforcement approach on novel foods has been amended in the light of operational experience of the Novel Food and Novel Food Ingredients Regulations (1997 SI No. 1335), which relied on provisions of the Food Safety Act 1990 and related EU General Food law provisions in Regulation (EC) No 178/2002 to take action in relation to non-compliant novel foods. That reliance made it necessary to carry out a safety assessment to clearly demonstrate a risk to human health before action could be taken. However, this can be difficult where there is insufficient information or little scientific data on the suspected novel food; such safety assessments are costly, resource intensive and take time, which has deterred authorised officers from proactively carrying out enforcement action.

7.6 Consequently, unauthorised novel foods have on occasion remained on the market due to the lack of conclusive evidence that they pose a risk to human health with authorised officers only able to encourage food business operators to withdraw the products from the market rather than compel them to do so. This undermines the established legal requirement that novel foods must undergo a safety assessment before they can be authorised for placing on the market. The instrument therefore applies Section 9 of the Food Safety Act 1990 ('Inspection and seizure of suspect food') to enable officers to seize and inspect suspected unauthorised novel foods.

7.7 This instrument provides a graduated approach to enforcement that ensures public health and safety is maintained by making certain that potentially harmful novel foods

placed on the market are removed from sale and that enforcement powers keep pace with the emerging food trends and rapid industry evolution and innovation in this area. It should also incentivise industry to ensure their products comply with novel food requirements and improve public health protection against potentially harmful products whilst enabling the enforcement community to encourage greater compliance. The enhanced enforcement powers and civil penalties provided by this instrument will enable Local Authorities in England to enforce the new legal requirements in line with the UK's statutory obligation to provide equivalent and effective enforcement of this directly applicable EU Regulation.

EU Exit Considerations

7.8 On 23 June 2016, the EU referendum took place and the people of the United Kingdom voted to leave the European Union. The Government respected the result and triggered Article 50 of the Treaty on European Union on 29th March 2017 to begin the process of exit. Until exit negotiations are concluded, the UK remains a full member of the European Union and all the rights and obligations of EU membership remain in force. During this period, the Government will continue to negotiate, implement and apply EU legislation. This instrument provides for the execution and enforcement, in England, of the directly applicable EU Regulation (EU) 2015/2283 on Novel Foods

8. Consultation

8.1 The FSA consulted with external organisations during the negotiations on the European Commission proposal which became EU Regulation (EU) 2015/2283, holding ad hoc meetings with key organisations to help inform the UK negotiating position. Since the EU Regulation was published, the FSA has been advising stakeholders mainly from industry, consumer organisations and food enforcement bodies, about the changes it brings and proposals for the changes to the domestic enforcement framework for novel foods to provide for the enforcement and execution of the EU Regulation. This commitment was first made at the February 2016 Open meeting of the Advisory Committee on Novel Foods and Processes, which was attended by a range of stakeholders.

8.2 The FSA consulted the Local Authority Food Standards and Labelling and Food Hygiene Focus Groups on the adequacy of current enforcement provisions and the proposed introduction of civil sanctions; a power of seizure; and maintaining use of a criminal offence. Both groups are made up of trading standards and environmental health officers responsible for enforcing food legislation in England, Wales and Northern Ireland. The approach was welcomed by both groups as well as the Council for Responsible Nutrition when it responded to the public consultation on this instrument.

8.3 The public consultation was conducted from 31 March to 26 May 2017, seeking comments on a draft of this instrument and, in particular:

- the changes introduced to the enforcement framework for novel foods;
- the provisions in this instrument; and
- whether the FSA's assumptions were a fair reflection of the costs, benefits and wider impacts on stakeholders.

The public consultation and summaries of the responses are published on the FSA's website at:

https://www.food.gov.uk/news-updates/consultations/2017/novel-food-regs-2017

8.4 Four responses were received. Two responses expressed dissatisfaction with the need for authorisation of foods that are new to the EU; these relate to the EU Regulation and not the draft instrument which was the focus of the consultation. The FSA believe it is necessary to carry-out an assessment of foods that are new to the EU population so that any implications of the novel food for human nutrition; toxicological concerns or allergenic potential can be identified.

8.5 Other comments related to the estimated reduction in administrative costs (mostly consisting of consultant fees) that arise in supporting an application through the authorisation process. As detailed at paragraph 7.4 above, the new authorisation process means that applicants only need to liaise with a single body of safety assessors so an administrative saving should arise from this change. The FSA estimated this might be a 50% reduction in administrative costs to support a full application. However, none of the responses provided any factual data that could be used to revise the estimate in the final impact assessment.

8.6 A local authority suggested that the time taken to familiarise themselves with the new legislation may be greater but without any factual data provided by the respondent it was not possible to revise the familiarisation cost. The authority also suggested it would be more efficient if this Instrument recognised officers were authorised to act on novel foods if they were already authorised to act under General food law. The draft Instrument was amended to reflect this change.

8.7 In addition to the public consultation, the FSA issued a further exploratory request to the Food Standards and Labelling Focus Group and the Food Hygiene Focus Group on the number of appeals against a compliance, improvement or emergency protection notice in relation to other areas of food law. This found that in the last two years only two appeals had arisen. Consequently, the FSA considered that the right of appeal provided in this Instrument should be via the Magistrates Courts as this would provide greater value for the public purse, because the First Tier Tribunal requires an initial set-up cost of approx. £36,000 and a yearly maintenance fee of approx. £7000. The draft Instrument was amended to route appeals through the Magistrates Courts.

9. Guidance

9.1 The FSA will provide guidance for authorised officers via the Focus Groups and in the statutory Food Law Code of Practice when it is next revised.

9.2 EFSA has produced guidance on novel food applications and the submission of scientific dossiers. This is available on the European Union website at http://www.efsa.europa.eu/en/supporting/pub/en-1109. It is not felt that domestic guidance for business is required in addition to this.

10. Impact

10.1 An Impact Assessment has been prepared for this instrument. It was published for comment in the public consultation on this Instrument, details of which can be found in Paragraph 8 of this Explanatory Memorandum.

10.2 The European Commission prepared an impact assessment for its original proposal to update the EU novel foods legislation in 2008 which did not ultimately progress. The Impact Assessment remained relevant in respect of the revised proposal presented by the Commission in late 2013 which became Regulation (EU) 2015/2283. As such, a further impact assessment was not necessary. The Impact Assessment is available on the European Union website at:

https://ec.europa.eu/food/sites/food/files/safety/docs/novel-food_impactassessment_en.pdf

10.3 Impact on the public sector will be limited to familiarisation with the new enforcement powers and sanctions made available through this Instrument. The FSA will work with the local authority focus groups to help develop an understanding of when fixed penalty notices should be used and has developed a template notice for the use of authorised officers to help ensure consistency. There is no particular impact on charities or voluntary bodies, rural areas or on members of the ethnic communities of any particular racial group that can be identified. The fixed monetary penalties themselves do not count as burdens, as they only penalise non-compliant businesses, consequently any impact arising from these has not been considered.

10.4 Regulation (EU) 2015/2283 requires applications for the authorisation of novel foods to be directed to the European Commission rather than via Member States and removes the need the requirement for 'me too' substantial equivalence applications seeking to demonstrate substantial equivalence to an already authorised novel food. Potential savings on administrative costs for full applications could amount to £783,000 (at present value) over 10 years. Removing the requirement for 'me too' applications results in a 100% saving on administrative costs amounting to £310,000 (at present value) over 10 years.

10.5 Under the Novel Foods and Novel Food Ingredients (Fees) Regulations 1997 (SI No. 1336/1997) businesses applying for authorisation of novel foods or making 'me too' substantial equivalence applications via the UK were charged fees as follows:

- £4,000 per full application; or
- £1,725 per substantial equivalence application.

10.6 The changes to EU novel foods legislation described in paragraph 7.4 above render the 1997 Fees Regulations redundant and lead to a total saving in respect of full applications (based on the recent numbers of applications) of £179,000 (at present value) in England, Wales and Northern Ireland over ten years. In respect of 'me too' substantial equivalence applications, based on the administrative cost per application the changes lead to a total annual saving of £36k (present value) over ten years. The revocation, by this instrument, of the 1997 Fees Regulations insofar as they extend to England and Northern Ireland removes these redundant regulations from the Statute Book.

11. Regulating small business

11.1 The instrument will apply to all businesses, small and large.

11.2 Small and medium sized businesses are not expected to be adversely affected by the proposed measures. Fixed monetary penalties will only be used where there is a breach of the law and informal advice from authorised officers is not followed. As for fines on conviction of a criminal offence by a Magistrates' Court, the current

sentencing guidelines require fines to be in line with both the seriousness of the offence and the financial turnover of the business.

12. Monitoring & review

12.1 The FSA is required to carry out a review of this instrument every five years. The review period begins when this instrument comes into force. In carrying out the review, the FSA is required to produce a report that sets out the objectives of this instrument, the extent to which they have been achieved and whether they could be achieved by means that impose less regulation.

13. Contact

13.1 Colin Clifford at the Food Standards Agency, Tel: 020 7276 8584, E-mail: colin.clifford@food.gov.uk, can answer any queries regarding the instrument.