CONSULTATION DOCUMENT

Proposed Novel Foods (England) Regulations 2017

CONSULTATION SUMMARY PAGE

Date launched:	31 MARCH 2017	Closing date:	26 MAY 2017

Who will this consultation be of most interest to?

Food businesses in England dealing in food/ food ingredients or processes that do not have a significant history of use within the European Union prior to 15 May 1997. In particular food innovators such as those developing engineered nanotechnology for use in food. This consultation will interest novel food and entomophagy (insects for human consumption) based businesses and importers dealing with fresh produce from third countries. It will also interest inland Enforcement Authorities and Port Health Authorities.

What is the subject of this consultation?

The proposed Novel Food (England) Regulations 2017 will repeal and replace in England the Novel Food and Novel Food Ingredients Regulations SI No. 1997/1335. The proposed Regulations will also repeal the Novel Foods and Novel Food Ingredients (Fees) Regulations SI No. 1997/1336. The proposed Regulations will enable the execution and enforcement in England of the Novel Food Regulation (EU) 2015/2283 (which amends Regulation (EU) No 1169/2011 and repeals Regulation (EC) No 258/97 and Commission Regulation (EC) No 1852/2001).

What is the purpose of this consultation?

To provide interested parties with the opportunity to comment on and express their views relating to the proposed Regulations; and share data that may contribute towards the associated impact assessment.

Responses to this consultation should be sent to:

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Impact Assessment included?	Yes ☒	No ☐ See Annex A for reason.

PROPOSED NOVEL FOOD (ENGLAND) REGULATIONS 2017

DETAIL OF CONSULTATION

1. We would welcome your comments on the proposed Novel Food (England) Regulations 2017 ('the proposed Regulations') provided at Annex B. The proposed Regulations will repeal and replace in England the Novel Food and Novel Food Ingredients Regulations SI No. 1997/1335 to provide for the enforcement and execution of the new Novel Food Regulation (EU) No 2015/2283. The proposed Regulations will also repeal the Novel Foods and Novel Food Ingredients (Fees) Regulations SI No. 1997/1336.

2. We would particularly welcome comments and supporting evidence in respect of any cost implications that may arise from these proposals as indicated in the draft Impact Assessment (IA) provided at Annex C.

3. The Novel Food Regulation (EU) No 2015/2283 is directly applicable in the UK, and was published in the Official Journal on 11 December 2015 and came into force on 31 December 2015. We are now within a two year transitional period before the EU Regulation becomes fully applicable on 1 January 2018. The EU Regulation amends Regulation (EU) No 1169/2011 of the European Parliament and of the Council; and repeals Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001.

4. Until any formal departure from the European Union, EU law continues to apply in the UK and we are required to ensure that we have an appropriate enforcement framework in place for these directly applicable EU requirements; failure to do so would carry the risk of infraction proceedings being brought against the UK. Whilst we cannot speculate on what will happen once we leave the EU, the UK will continue to follow a science-based and proportionate approach to regulation in this area.

5. A copy of the new EU Regulation is provided at Annex D and is available to download free of charge from the EUR-Lex website at:

http://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A32015R2283

6. This is an area of devolved competence and similar legislation will be consulted on in each of the devolved administrations of Scotland, Wales and Northern Ireland.

Background to New EU Regulation on Novel Foods

7. The new Novel Food Regulation (EU) No 2015/2283 provides revised legislative requirements for placing novel foods on the market and will become fully applicable in the UK on 1 January 2018. The EU requirements have been updated in line with technical and scientific progress and introduce:

- an updated definition of what constitutes a 'Novel food' (Chapter 1, Article 3);

- a clear duty on operators to verify whether the food they intend to place on the market falls within the scope of the legislation (Chapter I, Article 4). If unsure a food business operator should consult the Member State in which they first intend to market the product providing all necessary information to enable a determination of the novel food status to be made;

- a Union list of authorised novel foods, including any conditions of use that may apply (Chapter II, Article 6-9);

- a consistent, time-limited and streamlined authorisation process for food businesses (Chapter III, Section I);

- centralised risk assessments to be carried out by the European Food Safety Authority (Chapter III, Section I, Article 11);

- generic authorisations that will enable all operators to benefit from an authorisation unless any proprietary data protection provisions apply; this removes the need to demonstrate substantial equivalence with an already authorised novel food;

- a simpler notification procedure for traditional foods consumed to a significant degree in third countries but not in the EU prior to 1997, facilitating free trade (Chapter III, Section II); and

- a 5 year period (from the date of authorisation) of intellectual property protection for scientific evidence and data produced in support of applications (Chapter V, Article 26-27).

8. It is anticipated that these changes will help reduce burdens on EU and third country businesses seeking to place novel food products on the market and facilitate consumer access to new food innovations which have been risk assessed and whose proposed use is considered to be safe.

9. An outline of transitional measures that will be put into place is provided in Article 35 of the EU Regulation. Further detailed requirements on certain provisions in the EU Regulation will be provided by means of delegated acts and implementing measures such as on creation of the Union list of authorised novel foods; these measures are being developed at present. Further information about the EU Regulation, including Question and Answer Guidance is available at:

https://ec.europa.eu/food/safety/novel_food/legislation_en

Key proposal:

- **To make the Novel Food (England) Regulations 2017, to provide for the execution and enforcement of the revised EU requirements introduced by Regulation (EU) No 2015/2283.**

Background to the proposed domestic Regulations on Novel Foods

10. A domestic Statutory Instrument (SI) is needed (as required by Chapter VI, Article 29 of Regulation (EU) No 2015/2283) to provide an effective and proportionate enforcement framework to facilitate compliance with the EU Novel Food Regulation

and effective functioning of the internal market; whilst providing a high level of protection of human health and consumer interests.

11. The enforcement approach taken in relation to 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 placed reliance on the Food Safety Act 1990 and related General Food Law (178/2002 EC) provisions for remedial action in relation to non-compliant novel food products. This has had the effect that non-compliant novel food products have remained on the market where a clear determination as to the risk posed to human health has not been reached.

12. The proposed Regulations will provide enhanced enforcement powers by providing for the use of compliance notices; stop notices; fixed monetary penalties (levels to be determined); and application of section 9 of Food Safety Act 1990 to enable the seizure and inspection of suspected food.

13. A criminal offence for non-compliance with the EU Regulation is contained in the existing legislation, the Novel Food and Novel Food Ingredients Regulations SI No. 1997/1335 (as amended). The FSA seek to maintain provision of a criminal offence where appropriate and necessary. These enhanced enforcement powers should help to ensure that harmonised requirements for placing novel foods on the market are complied with, and by this means provide necessary protection to human health.

14. A right of appeal to the First-tier Tribunal is also provided against fixed monetary penalties under Schedule 2 and against compliance notices and stop notices under Schedule 3 of the proposed Regulations. Specified grounds for appeal are provided and remedies may be awarded by the Tribunal as appropriate.

15. The FSA supports the need for a right of appeal mechanism however this should be delivered in an appropriate manner that provides value to the public purse. In considering whether provision of the right of appeal should be through the First-tier Tribunal it would be helpful to gather information from enforcement authorities about the number of prosecutions that each authority has taken forward under the current novel food legislation (the Novel Food and Novel Food Ingredients Regulations SI No. 1997/1335) in the past three years.

Impact on businesses and Enforcement bodies

16. There is likely to be a familiarisation cost associated with the proposed Regulations; this includes reading and disseminating information to key staff within the organisation.

17. The primary food business operators likely to be affected are those placing novel food products such as chia seeds on the market or those developing novel food ingredients/technologies for addition to/use in food products such as DHA rich oils. As the definition of what constitutes a novel food has been broadened in the new EU Regulation, operators placing other novel food products such as insects for human consumption on the market are also likely to be affected.

18. Transitional arrangements are outlined in Article 35 of the EU Regulation and further detailed rules are to follow in implementing acts as indicated in paragraph 9 above.

Engagement and Consultation on new EU Regulations

19. The new EU Regulation was based on objectives that were raised in public consultations on a 2008 proposal to update EU requirements on novel foods. The European Commission carried out a formal consultation on that proposal with stakeholders for the food industry, consumers, third countries and Member States and international organisations. Whilst the 2008 proposal lapsed, a further attempt in 2013 resulted in the new EU Regulation.

20. The Commission carried out an Impact Assessment in 2007; for each of the measures in the 2008 proposal, several options were considered in regards to their economic, social and environmental impact on the various stakeholders and Member States. The published Impact Assessment is available free of charge at:

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

21. During the course of negotiations with the Commission, the FSA has kept other government departments and Parliament informed of progress on the new EU Regulation; which cleared Parliamentary scrutiny on 18 March 2015.

Purpose of this Consultation

22. The FSA alerted stakeholders about the proposal to update EU requirements via its website and through direct engagement. The Advisory Committee on Novel Foods and Processes (ACNFP) is a , independent body of scientific experts that advises the FSA on any matters relating to novel foods and novel food processes. The ACNFP Open meeting on 4 February 2016 was attended by industry, consumers and other regulators. A presentation was given at that meeting to highlight the changes to the EU legislation and inform attendees of the FSA's intention to develop domestic Regulations that will provide for the execution and enforcement of the EU requirements.

23. The purpose of this eight week consultation is to provide interested parties with the opportunity to comment on and express their opinions on the proposed domestic Regulations, and the associated draft impact assessment. The FSA anticipate that the proposed Regulations will cause minimal impact to a fully compliant society and the main cost arising is likely to be familiarisation costs.

24. Interested parties are invited to respond to the following questions:

Questions asked in this consultation:

Q.1. Have we accurately captured the number of food businesses that are likely to need to familiarise themselves with the new EU Regulation and the proposed Regulations?

If not, please provide us with information on the number of food businesses affected, their location and ideally firm size in terms of the number of employees.

Q.2. It is our assumption that it will take one person per food business and enforcement authorities one and a half hours to read through the new EU Regulation and proposed Regulations and a further hour and a half to disseminate the information within their respective organisation.

Is this a reasonable assumption?

If not, please provide us with evidence to support your view on the amount of time required for familiarisation.

Q.3. Is our estimation of the familiarisation costs for industry reasonable?

If you agree or disagree with this assessment please provide evidence to support your view on the cost per business for familiarisation.

Q.4. Is our estimation of the familiarisation costs for enforcement authorities reasonable?

If not, please provide us with evidence to support your view on the amount of time required per authority for familiarisation.

Q.5. We invite all interested parties to comment on whether we have accurately captured all costs and benefits that arise from the proposed Regulations in this impact assessment.

If you believe these have not been accurately captured please provide us with evidence to support your view.

Q.6. We invite all interested parties to provide any data on the potential financial benefits that may arise from enabling a new product to be brought to the market in a shorter time (see paragraph 52 in the Impact Assessment, at Annex C).

Q.7. One of the benefits to industry we have identified (paragraph 53-59 in the Impact Assessment, at Annex C) is a potential lowering of administrative costs for food businesses seeking authorisation of a novel food.

Do you agree with the assumptions made?

If not, please provide us with evidence to support your view.

Q.8. It would be very helpful if enforcement authorities could provide the FSA with information about the number of prosecutions that they have taken forward on the basis of the Novel Foods legislation.

a) How many prosecutions have been initiated in the last three years?

b) How many ended in successful prosecution?

Other Comments

25. Any comments that interested parties wish to provide in relation to the proposed Regulations would be gratefully received. We are particularly keen to hear from small and micro food businesses on the likely impact of the proposed Regulations.

26. Following the consultation, we will review the responses received and consider whether any changes are required to the proposed domestic Regulations in England. A summary of all comments received and the FSA's response to each will be published on the FSA's website within 3 months following the end of the consultation period.

Other relevant documents

27. The new Novel Food Regulation (EU) No 2015/2283 is available to download free of charge from the EUR-Lex website at:

http://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A32015R2283

28. Further information about the EU Regulation, including Question and Answer Guidance is available at:

https://ec.europa.eu/food/safety/novel_food/legislation_en

29. The published Impact Assessment for the 2008 proposal is available free of charge at:

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

30. Regulation (EC) No 258/1997 is available to download free of charge from the EUR-Lex website at:

http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A31997R0258

31. Regulation (EU) No 1169/2011is available to download free of charge from the EUR-Lex website at:

http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1490270370124&uri=CELEX:32011R1169

Responses

32. **Responses are required by close 26 May 2017**. Please state, in your response, whether you are responding as a private individual or on behalf of an organisation/company (including details of any stakeholders your organisation represents).

Thank you on behalf of the Food Standards Agency for participating in this public consultation.

Yours,

Olujuwon Adetokunbo
Regulatory Officer
Corporate Support Unit

Enclosed

Annex A: Standard Consultation Information

Annex B: Draft Statutory Instrument/The Proposed Regulations

Annex C: Draft Impact Assessment

Annex D: Regulation (EU) 2015/2283 on novel foods

Annex E: List of interested parties

Publication of personal data and confidentiality of responses

1. In accordance with the FSA principle of openness we shall keep a copy of the completed consultation and responses, to be made available to the public on receipt of a request to the FSA Consultation Coordinator (020 7276 8308). The FSA will publish a summary of responses, which may include your full name. Disclosure of any other personal data would be made only upon request for the full consultation responses. If you do not want this information to be released, please complete and return the Publication of Personal Data form, which is on the website at **http://www.food.gov.uk/multimedia/worddocs/dataprotection.doc** Return of this form does not mean that we will treat your response to the consultation as confidential, just your personal data.

3. In accordance with the provisions of Freedom of Information Act 2000/Environmental Information Regulations 2004, all information contained in your response may be subject to publication or disclosure. If you consider that some of the information provided in your response should not be disclosed, you should indicate the information concerned, request that it is not disclosed and explain what harm you consider would result from disclosure. The final decision on whether the information should be withheld rests with the FSA. However, we will take into account your views when making this decision.

4. Any automatic confidentiality disclaimer generated by your IT system will not be considered as such a request unless you specifically include a request, with an explanation, in the main text of your response.

Further information

5. A list of interested parties to whom this letter is being sent appears in Annex E. Please feel free to pass this document to any other interested parties, or send us their full contact details and we will arrange for a copy to be sent to them direct.

6. Please contact us if you require this consultation in an alternative format such as Braille or large print.

7. This consultation has been prepared in accordance with HM Government consultation principles[1].

[1] http://www.bis.gov.uk/policies/bre/consultation-guidance