# FOOD STANDARDS AGENCY IN NORTHERN IRELAND CONSULTATION

## Title: The Novel Foods Regulations (Northern Ireland) 2017

### CONSULTATION SUMMARY PAGE

| Date consultation launched: | Closing date for responses: |
|---|---|
| 4th April 2017 | 27th June 2017 |

**Who will this consultation be of most interest to?**

Food businesses in Northern Ireland 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 be of interest to district councils. The consultation may also be of interest to health professionals, consumer groups and others with an interest in food labelling legislation.

**What is the subject of this consultation?**

The Novel Foods Regulations (Northern Ireland) 2017 will repeal and replace the Novel Foods and Novel Food Ingredients Regulations (Northern Ireland) 2004 (S.R. 2004 No.33) and The Food Enzymes Regulations (Northern Ireland) 2009 (S.R. 2009 No.415). The proposed Regulations will enable the execution and enforcement in Northern Ireland 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 an opportunity to comment on the draft Northern Ireland Regulations. Parallel regulations will be produced in England, Scotland and Wales and consultations on these will be issued in due course.

**Responses to this consultation should be sent to:**


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**Division/Branch Finance, Business Support and Communications**
**FOOD STANDARDS AGENCY**
**Tel: 028 9041 7762**

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**Belfast**
**BT1 3BG**
**Email:** seth.chanas@foodstandards.gsi.gov.uk


| Is an Impact Assessment included with this consultation? | Yes ☒ Annex B | No ☐ |
|---|---|---|

**If you would prefer to receive future FSA consultations by e-mail, or** if you no longer wish to receive information on this subject please notify the named person in this consultation.

## The Novel Foods Regulations (Northern Ireland) 2017

## DETAIL OF CONSULTATION

1. We would welcome your comments on the proposed Novel Foods Regulations (Northern Ireland) 2017 ('the proposed Regulations') provided at Annex A. The proposed Regulations will repeal and replace the Novel Foods and Novel Food Ingredients Regulations (Northern Ireland) 2004 (S.R. 2004 No.33) and The Food Enzymes Regulations (Northern Ireland) 2009 (S.R. 2009 No.415) to provide for the enforcement and execution of the new Novel Food Regulation (EU) No 2015/2283.

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 B.

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 C 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. Similar legislation will be consulted on in Scotland, Wales and England.

### 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

**Proposal:**

- **To make The Novel Foods Regulations (Northern Ireland) 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. Statutory Rules (S.R.) are 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 Foods and Novel Food Ingredients Regulations (Northern Ireland) 2004 (S.R. 2004 No.33), which placed reliance on the Food Safety (Northern Ireland) Order 1991 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 draft Novel Foods Regulations (Northern Ireland) 2017 proposes enabling district councils in Northern Ireland to serve an improvement notice (IN) under Article 9 of the Food Safety (Northern Ireland) Order 1991 as applied and modified by these regulations in the event of non-compliance with the provisions of Regulation (EU) 2015/2283 specified in Schedule 1 to those Regulations. The INs would not impose criminal sanctions in themselves, but would require persons that fail to comply with the EU requirements to take specified steps in a limited time-period to remedy the situation. Failure to comply with an IN would be a criminal offence under Article 9(2) of the Food Safety (Northern Ireland) Order 1991 as applied and modified. The penalty is a fine not exceeding level 5 (£5000) on the standard scale. The regulations would also allow enforcement officers to bring a prosecution for an offence of non-compliance with Article 6(2) of Regulation (EU) No. 2015/2283. The penalty is a fine not exceeding level 5 (£5000) on the standard scale.

13. These Regulations also propose providing enforcement officers with the power to seize any novel foods that have been placed on the market in contravention of any of the specified Union provisions of Regulation (EU) 2015/2283 set out in Schedule 1 (except the first provision specified in the table “Article 4(1)”) of the draft Novel Foods Regulations (Northern Ireland) 2017.

**Proposals**
The options being considered are:

> **Option 1** – Do nothing. This means that the directly applicable European Regulation on novel foods could not be enforced in Northern Ireland, and risks incurring infraction proceedings. As an EU Member State, the UK remains obliged to provide for the enforcement of EU legislation. Failure to do so may lead to the UK being liable to infraction proceedings and consequent fines. The Department of Health remains under an obligation to comply with EU requirements in relation to Northern Ireland.
>
> **Option 2** – Introduce legislation to provide enforcement provisions in Northern Ireland for Regulation (EU) 2015/2283.

**Impact on businesses and Enforcement bodies**

14. 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.

15. 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.

16. 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**

17. 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.

18. 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

**Purpose of this Consultation**

19. 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 an 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.

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

21. 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 district council 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 B).**

**Q.7. One of the benefits to industry we have identified (paragraph 53-59 in the Impact Assessment, at Annex B) 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 district councils 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?**

**Q.9. Do you have any comments on our proposal to use Improvement Notices as the method for enforcement?**

**Q.10. Do you have any comments on our proposal for enforcement officers to have the power to seize novel foods that have been placed on the market?**

**Other Comments**

22. 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.

23. Following the consultation, we will review the responses received and consider whether any changes are required to the proposed domestic Regulations in Northern Ireland. 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**

24. 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

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

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

26. 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

27. 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

28. 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**

29. **Responses are required by close 27 June 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 Food Standards Agency in Northern Ireland for participating in this public consultation.

Yours

**Seth Chanas**
**Finance, Business Support and Communications**
**Food Standards Agency in Northern Ireland**

**Enclosed**

**Annex A: Draft Statutory Rules/The Proposed Regulations**

**Annex B: Impact Assessment**

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

**Annex D: Standard Consultation Information**

**Annex E: List of interested parties**

**Queries**

1. If you have any queries relating to this consultation please contact the person named on page 1, who will be able to respond to your questions.

## Publication of personal data and confidentiality of responses

2. In accordance with the FSA principle of openness our Information Centre at Aviation House will hold a copy of the completed consultation. Responses will be open to public access upon request. The FSA will also publish a summary of responses, which may include personal data, such as your full name and contact address details. 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/pdfs/dataprotection.pdf** 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 for alternative versions of the consultation documents in Braille, other languages or audiocassette.

7. Please let us know if you need paper copies of the consultation documents or of anything specified under '**Other relevant documents**'.

8. This consultation has been prepared in accordance with HM Government Code of Practice on Consultation, available at: **http://www.berr.gov.uk/files/file47158.pdf**

The Consultation Criteria are available at
**http://www.berr.gov.uk/whatwedo/bre/consultation-guidance/page44458.html**

9. Criterion 2 of HM Government Code of Practice on Consultation states *Consultations should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible*.

10. The Code of Practice states that an Impact Assessment should normally be published alongside a formal consultation. Please see the Impact Assessment at Annex B.

11. For details about the consultation process (not about the content of this consultation) please contact: Food Standards Agency Consultation Co-ordinator, Room 2C, Aviation House, 125 Kingsway, London, WC2B 6NH. Tel: 0207 276 8630.

## Comments on the consultation process itself

12. We are interested in what you thought of this consultation and would therefore welcome your general feedback on both the consultation package and overall consultation process. If you would like to help us improve the quality of future consultations, please feel free to share your thoughts with us by using the Consultation Feedback Questionnaire at
**http://www.food.gov.uk/multimedia/worddocs/consultfeedback.doc**

13. If you would like to be included on future Food Standards Agency consultations on other topics, please advise us of those subject areas that you might be specifically interested in by using the Consultation Feedback Questionnaire at
**http://www.food.gov.uk/multimedia/worddocs/consultfeedback.doc** The questionnaire can also be used to update us about your existing contact details.

STATUTORY RULES OF NORTHERN IRELAND

# 2017 No. 0000

# FOOD

# The Novel Foods Regulations (Northern Ireland) 2017

| | |
|---|---|
| *Made - - - -* | *0th Month 2018* |
| *Coming into operation -* | *1st January 2018* |

The Department of Health(**a**) makes the following Regulations in exercise of the powers conferred by Articles 15(1)(a), (e) and (f), 16(2), 17(1)(a), 25(1)(a) and (3), 26(3) and 47(2) of the Food Safety (Northern Ireland) Order 1991(**b**).

In accordance with Article 47(3A) of the Food Safety (Northern Ireland) Order 1991, the Department of Health has had regard to relevant advice given by the Food Standards Agency.

As required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(**c**), there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

**Citation and commencement**

**1.**.These Regulations may be cited as the Novel Foods Regulations (Northern Ireland) 2017 and. come into operation on 1st January 2018.

**Interpretation**

**2.**—(1) In these Regulations—

"the Order" means the Food Safety (Northern Ireland) Order 1991;

"Regulation (EU) 2015/2283" means Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001(**d**); and

(**a**) Formerly the Department of Health, Social Services and Public Safety; see 2016 c.5 (N.I.), section 1

(**b**) S.I. 1991/762 (N.I.7) as amended by S.I. 1996/1663 (N.I.12), paragraphs 26 to 42 of Schedule 5 and Schedule 6 to the Food Standards Act 1999 c.28 and S.R.2004 Nos.482 and 505

(**c**) OJ No. L 31, 1.2.2002, p.1 as last amended by Regulation (EU) No. 652/2014 of the European Parliament and of the Council of 15th May 2014 (OJ No. L 189, 27.6.2014, p.1)

(**d**) OJ L 327, 11.12.2015, p.1

"specified EU provision" means a provision of Regulation (EU) 2015/2283 specified in column 1 and described in column 2 of the table in Schedule 1.

(2) An expression used both in these Regulations and Regulation (EU) 2015/2283 has the meaning that it bears in Regulation (EU) 2015/2283 and any reference to a numbered article is a reference to the article so numbered in Regulation (EU) 2015/2283.

**Enforcement**

**3.** It is the duty of each district council within its district to enforce Regulation (EU) 2015/2283 and these Regulations.

**Offence and penalty**

**4.** A person who fails to comply with Article 6(2) as read with Articles 24 and 35(2) of Regulation (EU) 2015/2283 is guilty of an offence and liable on summary conviction to a fine not exceeding level 5 on the standard scale.

**Application and modification of provisions of the Order**

**5.**—(1) Article 9(1) and (2) of the Order (improvement notices) apply for the purposes of these Regulations with the modification (in the case of Article 9(1)) set out in Schedule 2, Part 1 for the purposes of-

(a) enabling an improvement notice to be served on a person requiring the person to comply with a specified EU provision; and

(b) making the failure to comply with a notice referred to in subparagraph (a) an offence.

(2) Article 8 of the Order (inspection and seizure of suspected food) applies for the purposes of these Regulations with the modifications set out in Part 2 of Schedule 2 for the purposes of enabling an authorised officer of a district council to either—

(a) give notice to the person in charge of the food that it is not to be used for human consumption, and is not to be removed or is not to be removed except to some place specified in the notice, or

(b) seize the food and remove it in order to have it dealt with by a justice of the peace.

(3) The provisions of the Order specified in column 1 of the table in Part 3 of Schedule 2 apply, with the modifications (if any) specified in column 2 of that table for the purpose of these Regulations.

(4) Paragraphs (1) to (3) are without prejudice to the application of the Order to these Regulations for purposes other than those specified in paragraph (1**)** and (2).

**Revocations**

**6.** The following regulations are revoked-

(a) The Novel Foods and Novel Food Ingredients Regulations (Northern Ireland) 2004(**a**); and

(b) The Food Enzymes Regulations (Northern Ireland) 2009(**b**).

Sealed with the Official Seal of the Department of Health on ***

(**a**) S.R. 2004 No.33
(**b**) S.R. 2009 No.415

L.S.

*Name*
A senior officer of the
Department of Health

# SCHEDULE 1

Regulation 2(1)

## Specified Union Provisions

| *1. Specified Union Provision* | *2. Subject matter* |
|---|---|
| Article 4(1) | Requirement that food business operators verify whether food they intend to place on the market is within scope of Regulation (EU) 2015/2283. |
| Article 6(2) as read with Article 24 and 35(2) | Requirement that only novel foods authorised and included in the Union list may be placed on the market or used in or on food and in accordance with the conditions of use and the labelling requirements specified therein, and with any post-market monitoring requirements. |
| Article 25 | Requirement that a food business operator who has placed a novel food on the market must immediately inform the Commission of any information of which it becomes aware concerning -<br>(a) any new scientific or technical information which might influence the evaluation of the safety of use of the novel food; or<br>(b) any prohibition or restriction imposed by a third country in which the novel food is placed on the market. |

# SCHEDULE 2

Regulation 5

## Application and modification of provisions of the Order

## PART 1

### Modification of Article 9(1)

**1.** For Article 9(1) of the Order (improvement notices) substitute—

"(1) If an authorised officer has reasonable grounds for believing that a person is failing to comply with any provision specified in Schedule 1 to the Novel Foods Regulations (Northern Ireland) 2017, the authorised officer may, by a notice served on that person (in this Order referred to as an "improvement notice") —

(a) state the officer's grounds for believing that the person is failing to comply with the relevant provision;

(b) specify the matters which constitute the person's failure so to comply;

(c) specify the measures which, in the officer's opinion, the person must take in order to secure compliance; and

(d) require the person to take those measures, or measures that are at least equivalent to them, within such period (not being less than 14 days) as may be specified in the notice.".

# PART 2

## Modification of Article 8

**1.** For Article 8 (inspection and seizure of suspected food) substitute—

"(1) An authorised officer may at all reasonable times inspect any food intended for human consumption which has been placed on the market and paragraphs (2) to (7) shall apply where, on such an inspection, it appears to the authorised officer that a provision specified in Schedule 1 to the Novel Foods Regulations (Northern Ireland) 2017 (except the first provision specified in the table in Schedule 1 "Article 4(1)") is being, or has been contravened in relation to any food which has been placed on the market.

(2) The authorised officer may either—

(a) give notice to the person in charge of the food that, until the notice is withdrawn, the food—

(i) is not to be used for human consumption; and

(ii) either is not to be removed or is not to be removed except to some place specified in the notice; or

(b) seize the food and remove it in order to have it dealt with by a justice of the peace;

and any person who knowingly contravenes the requirements of a notice under sub-paragraph (a) is guilty of an offence and liable on summary conviction to a fine not exceeding level 5 on the standard scale.

(3) Where the authorised officer gives notice under paragraph (2)(a), the authorised officer shall, as soon as is reasonably practicable and in any event within 21 days from the date of the notice, determine whether or not they are satisfied that the food complies with the provision specified in Schedule 1 to the Novel Foods Regulations (Northern Ireland) 2017 and—

(a) if so satisfied, immediately withdraw the notice;

(b) if not so satisfied, seize the food and remove it in order to have it dealt with by a justice of the peace.

(4) Where an authorised officer seizes and removes food under paragraph (2)(b) or (3)(b), the authorised officer shall inform the person in charge of the food that it is to be dealt with by a justice of the peace and any person who might be liable to a prosecution in respect of the food shall, if attending before the justice of the peace by whom the food falls to be dealt with, be entitled to be heard and to call witnesses.

(5) If it appears to a justice of the peace, on the basis of such evidence as the justice of the peace considers appropriate in the circumstances, that any food falling to be dealt with under this Article fails to comply with the provision specified in Schedule 1 to the Novel Foods Regulations (Northern Ireland) 2017, the justice of the peace shall condemn the food and order—

(a) the food to be destroyed or to be disposed of as to prevent it from being used for human consumption; and

(b) any expenses reasonably incurred in connection with the destruction or disposal to be defrayed by the owner of the food.

(6) If a notice under paragraph (2)(a) is withdrawn, or the justice of the peace by whom any food falls to be dealt with under this Article refuses to condemn it, the district council shall compensate the owner of the food for any depreciation in its value resulting from the action taken by the authorised officer.

(7) Any disputed question as to the right to or the amount of any compensation payable under subparagraph (6) shall be determined by arbitration.".

# PART 3

## Application and modification of other provisions of the Order

| *Column 1*<br>*Provision of the Order* | *Column 2*<br>*Modifications* |
|---|---|
| Article 2(4) (extended meaning of "sale" etc.) | For "this Order" substitute "the Novel Foods Regulations (Northern Ireland) 2017," |
| Article 3 (application to food offered as prizes, etc.) | For "this Order" substitute "the Novel Foods Regulations (Northern Ireland) 2017,". |
| Article 4 (presumptions that food intended for human consumption) | For "this Order" substitute "the Novel Foods Regulations (Northern Ireland) 2017,". |
| Article 19 (offences due to fault of another person) | For "any of the preceding provisions of this Part" substitute "Article 9(2) as applied by regulation 5(1) of the Novel Foods Regulations (Northern Ireland) 2017 or regulation 4 of those regulations," |
| Article 20(1) and (5) (defence of due diligence) | In paragraph (1), for "any of the preceding provisions of this Part" substitute "Article 9(2), as applied by regulation 5(1) of the Novel Foods Regulations (Northern Ireland) 2017 or regulation 4 of those regulations,". |
| Article 30(8) (which relates to documentary evidence) | For "this Order" substitute " the Novel Foods Regulations (Northern Ireland) 2017," |
| Article 33 (power of entry) | In paragraph (1) for subparagraphs (a)-(c) substitute "(a) to enter any premises within the council's district for the purpose of ascertaining whether there is or has been on the premises any contravention of any of the provisions of Schedule 1 of the Novel Foods Regulations (Northern Ireland) 2017 (except the first provision specified in the table in Schedule 1 "Article 4(1)")." |
| Article 34 (obstruction etc. of officers) | In each place occurring in paragraph (1), for "this Order" substitute "the Novel Foods Regulations (Northern Ireland) 2017". |
| Article 37 (appeals) | For paragraph (1) substitute "(1) Any person who is aggrieved by a decision of an authorised officer to serve an improvement notice under Article 9(1) as applied and modified by regulation 5(1) and Schedule 2 of the Novel Foods Regulations (Northern Ireland) 2017 may appeal to a court of summary jurisdiction".<br>In paragraph (2A)(b) for "(1)(a)" substitute "(1) as applied by regulation 5(2) of the Novel Food Regulations (Northern Ireland) 2017 |
| Article 38 (appeals against improvement notices) | In both paragraphs (1) and (2) insert "as applied and modified by regulation 5(1) and Schedule 2 of the Novel Foods Regulations (Northern Ireland) 2017," after "improvement notice". |

## EXPLANATORY NOTE

*(This note is not part of the Order)*

To be completed after the consultation

| | |
|---|---|
| **Title:** NOVEL FOODS (ENGLAND) REGULATIONS 2017<br>**IA No: FOOD0158**<br>**RPC Reference No:**<br>**Lead department or agency:** FOOD STANDARDS AGENCY<br>**Other departments or agencies:** | **Impact Assessment (IA)**<br>**Date:** March 2017<br>**Stage:** Consultation<br>**Source of intervention:** EU<br>**Type of measure:** Secondary legislation<br>**Contact for enquiries:** Firth Piracha, Tel: 02072768126,Email:firth.piracha@foodstandards.gsi.gov.uk |

## Summary: Intervention and Options

**RPC Opinion:** RPC Opinion Status

| Cost of Preferred (or more likely) Option | | | | |
|---|---|---|---|---|
| **Total Net Present Value** | **Business Net Present Value** | **Net cost to business per year** (EANDCB in 2014 prices) | **One-In, Three-Out** | **Business Impact Target Status** |
| £m | £m | £m | Not in scope | Non-Qualifying provision |

**What is the problem under consideration? Why is government intervention necessary?**

The new directly applicable European Regulation (EU) 2015/2283 on novel foods will come into full effect in the UK on 1 January 2018 and takes account of operational experience; technological and scientific advancement; and changes in other areas of food law. UK Government intervention is necessary to provide an enforcement framework for the new requirements; and to incentivise food businesses to ensure novel foods are risk assessed prior to placement on the market, in this way protecting consumers through proportionate management of food safety risks. Protection against unauthorised Novel Foods prevents consumers consuming potentially harmful products (de-merit goods). An enhanced enforcement framework will provide a more proportionate and effective deterrent to operators from placing unauthorised and potentially harmful novel food products such as DMBA (1,3-dimethylbutylamine) on the market .

**What are the policy objectives and the intended effects?**

The new EU Regulation introduces a streamlined authorisation process for novel foods; centralised risk assessment by the European Food Safety Authority (EFSA); up to 5 years protection for new scientific evidence produced to support applications; and a simpler authorisation process for traditional foods consumed to a significant degree in third countries but not in the EU prior to 1997. These changes will help reduce burdens on EU and third country businesses seeking authorisation of novel foods and facilitate consumer access to new food innovations that are risk assessed and considered safe. The domestic Statutory Instrument (SI) is necessary to provide effective and proportionate enforcement by means of civil penalties and maintain a criminal offence for failure to comply with critical provisions of Regulation (EU) 2015/2283. The SI will revoke, in England, the Novel Foods and Novel Food Ingredients Regulations 1997; and the Novel Foods and Novel Food Ingredients (Fees) Regulations 1997.

**What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)**

The European Commission consulted on a range of options when it proposed to amend the pre-existing legislation, and published an Impact Assessment explaining the rationale for each major proposed change; options assessed in this IA:

**Option 1** – Do Nothing – do not make domestic Regulations to provide for the enforcement and execution of the new EU Regulation in England, N Ireland and Wales. This option will not prevent the new EU Regulation applying in the UK as it is already legally binding and applicable throughout the EU. However, enforcement authorities would not have the necessary powers to enforce the EU Regulations on novel foods; and so the UK would carry risk of infraction proceedings.

**Option 2** – Make appropriate domestic Regulations for the effective and proportionate enforcement of the new

**Will the policy be reviewed?** It will/will not be reviewed. **If applicable, set review date:** Month/Year

| | | | | |
|---|---|---|---|---|
| Does implementation go beyond minimum EU requirements? | | Yes / No / N/A | | |
| Are any of these organisations in scope? | **Micro** Yes/No | **Small** Yes/No | **Medium** Yes/No | **Large** Yes/No |
| What is the $CO_2$ equivalent change in greenhouse gas emissions? (Million tonnes $CO_2$ equivalent) | | **Traded:** | **Non-traded:** | |

***I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.***

Signed by the responsible SELECT SIGNATORY: ..... Date: .....

# Summary: Analysis & Evidence

Policy Option 1

**Description: Option 1 – Do Nothing: - do not make domestic Regulations to provide for the enforcement and execution of the new EU Regulation in England**

**FULL ECONOMIC ASSESSMENT**

| Price Base Year N/A | PV Base Year N/A | Time Period Years N/A | Net Benefit (Present Value (PV)) (£m) | | |
|---|---|---|---|---|---|
| | | | **Low:** Optional | **High:** Optional | **Best Estimate:** 0.0 |

| COSTS (£m) | Total Transition (Constant Price) | Years | Average Annual (excl. Transition) (Constant Price) | Total Cost (Present Value) |
|---|---|---|---|---|
| **Low** | Optional | | Optional | **Optional** |
| **High** | Optional | | Optional | **Optional** |
| **Best Estimate** | 0.0 | | 0.0 | **0.0** |

**Description and scale of key monetised costs by 'main affected groups'**

There are no costs or benefits associated with this option. This is the baseline against which all other options are appraised.

**Other key non-monetised costs by 'main affected groups'**

There are no costs or benefits associated with this option. This is the baseline against which all other options are appraised.

| BENEFITS (£m) | Total Transition (Constant Price) | Years | Average Annual (excl. Transition) (Constant Price) | Total Benefit (Present Value) |
|---|---|---|---|---|
| **Low** | Optional | | Optional | **Optional** |
| **High** | Optional | | Optional | **Optional** |
| **Best Estimate** | 0.0 | | 0.0 | **0.0** |

**Description and scale of key monetised benefits by 'main affected groups'**

There are no costs or benefits associated with this option. This is the baseline against which all other options are appraised.

**Other key non-monetised benefits by 'main affected groups'**

There are no costs or benefits associated with this option. This is the baseline against which all other options are appraised.

Key assumptions/sensitivities/risks — **Discount rate (%)** 3.5

There are no costs or benefits associated with this option. This is the baseline against which all other options are appraised.

**BUSINESS ASSESSMENT (Option 1)**

| Direct impact on business (Equivalent Annual) £m: | | | Score for Business Impact Target (qualifying provisions only) £m: 0.0 |
|---|---|---|---|
| **Costs:** 0.0 | **Benefits:** 0.0 | **Net: 0.0** | |

# Summary: Analysis & Evidence

Policy Option 2

**Description: Option 2 (Preferred) – make appropriate domestic Regulations for the execution and enforcement of the new EU Regulation on novel foods.**

**FULL ECONOMIC ASSESSMENT**

| Price Base Year 2016 | PV Base Year 2018 | Time Period Years 10 | Net Benefit (Present Value (PV)) (£m) | | |
|---|---|---|---|---|---|
| | | | **Low: 0.65** | **High: 1.73** | **Best Estimate:** 1.19 |

| COSTS (£m) | Total Transition (Constant Price) Years | Average Annual (excl. Transition) (Constant Price) | Total Cost (Present Value) |
|---|---|---|---|
| **Low** | 0.1 | 0.0 | **0.1** |
| **High** | 0.1 | 0.0 | **0.1** |
| **Best Estimate** | 0.1 | 0.0 | **0.1** |

**Description and scale of key monetised costs by 'main affected groups'**

**Industry:** One-off familiarisation cost: £92k

**Enforcement**: One-off familiarisation cost: £28k

**Other key non-monetised costs by 'main affected groups'**

Non-monetised costs were not identified

| BENEFITS (£m) | Total Transition (Constant Price) Years | Average Annual (excl. Transition) (Constant Price) | Total Benefit (Present Value) |
|---|---|---|---|
| **Low** | 0.0 | 0.1 | **0.8** |
| **High** | 0.0 | 0.2 | **1.9** |
| **Best Estimate** | 0.0 | 0.2 | **1.3** |

**Description and scale of key monetised benefits by 'main affected groups'**

**Industry:** Savings due to "Streamlined procedures for the assessment and authorisation of novel foods". (i) Administrative Costs: £0.78m (PV) (£91k (EAC)). (ii) Application Fees: £0.3m (PV) (£36k (EAC)

**Other key non-monetised benefits by 'main affected groups'**

**Industry:** (i) The Establishment of a Union list of Authorised Novel Foods**;** (ii) A simplified safety assessment procedure for traditional food from third countries

**Consumers:** (i) The Establishment of a Union list of Authorised Novel Food; (ii) A simplified safety assessment procedure for traditional food from third countries" and streamlined procedures for the assessment and authorisation of novel foods

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5

The administrative cost saving due to "Streamlined procedures for the assessment and authorisation of novel foods" per FBO ranges from £20k to £50k with a mid-point estimate of £35k.

It is assumed that the number of applications made over the last five years (using historical data) will reflect the number of applications over the next ten years.

**BUSINESS ASSESSMENT (Option 2)**

| Direct impact on business (Equivalent Annual) £m: | | | Score for Business Impact Target (qualifying provisions only) £m: - 0.5 |
|---|---|---|---|
| **Costs:** 0.0 | **Benefits:** 0.1 | **Net:** 0.1 | |

# Evidence Base (for summary sheets)

## Problem under Consideration

1. The current legislation, Commission Regulation (EC) No. 258/97[1] concerning novel foods and novel food ingredients has been in force since 1997 and applies to foods and food ingredients that do not have a significant history of consumption in the European Community before 15 May 1997. The Regulation includes a requirement for a review of its operation after 5 years in order to identify possible improvements. The review, however, has been delayed, to take account of other significant developments in EU food law, particularly:

    a) the adoption of General Food Law, Commission Regulation (EC) No. 178/2002[2], which provides an overall framework for food legislation and established the European Food Safety Authority;

    b) the adoption of Commission Regulation (EC) No. 1852/2001[3] laying down detailed rules for making certain information available to the public and for the protection of information submitted pursuant to Commission Regulation (EC) No. 258/97; and

    c) the adoption of Commission Regulation (EC) No 1829/2003[4] on genetically modified (GM) food and feed removed GM foods from the scope of the novel foods Regulation.

    Two Statutory Instruments, the Novel Foods and Novel Food Ingredients Regulations 1997 and the Novel Foods and Novel Food Ingredients (Fees) Regulations 1997, provide for the execution and enforcement of Regulation (EC) No. 258/1997 in relation to England. Equivalent national legislation is in place in the devolved administrations.

2. Following a range of stakeholder consultation activities 2002-2007 the Commission attempted to revise the legislation on novel foods in 2008 to take account to scientific and technological advances that have taken place since the legislation was first put in place. The consultations highlighted the following areas for improvement:

    - operator specific authorisations mean that other operators need to demonstrate substantial equivalence of their product to the one authorised so that they too can place their product on the market;
    - most products are often risk assessed twice, once by the Member State (MS) competent authority and again by EFSA;
    - traditional foods from third countries (such as baobab fruit) without a demonstrable history of significant consumption within the EU are required to go through the full authorisation and risk assessment process; this was considered by stakeholders to be an unjustified barrier to trade;
    - considerable delays (occasionally several years) are associated with the authorisation process;
    - overlap with other European Community legislation results in unnecessary duplication in assessments and authorisations;
    - further clarity is required in the legal text; and to bring it in line with developments in EU food law (outlined above) and scientific/technical developments.

    However, that attempt failed because of disagreement over how to regulate products from cloned animals and their offspring and the definition of nanomaterials. A further attempt to revise the Regulation was initiated in 2013. With effective intervention and influence provided by the UK on a number of areas, that attempt culminated in the successful adoption of the new Novel Food Regulation in 2015.

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[1] Ref OJ L 43, 14.2.97, p.g. 1

[2] Ref OJ L 31, 1.2.2002, p.g. 1, Full title: Regulation (EC) No. 178/2002 of the European Parliament and of the Council, laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

[3] Ref OJ L 251, 21.9.2001, p.g. 17, Full title: Commission Regulation (EC) No. 1852/2001, laying down detailed rules for making certain information available to the public and for the protection of information submitted pursuant to European Parliament and Council Regulation (EC) No. 258/97

[4] Ref OJ L261, 18.10.2003, p.g. 1-23, Full title: Commission Regulation (EC) No. 1829/2003, on genetically modified food and feed.

## Rationale for Intervention

3. National intervention is necessary to ensure that those placing novel foods on the market within the European Union (EU) are fully compliant with the requirements of Commission Regulation (EU). 2015/2283, and facilitate the effective functioning of the internal market, whilst providing a high level of protection of human health and consumer interests.

4. The new European Regulation, Commission Regulation (EU) 2015/2283[5] of the European Parliament and of the Council on novel foods ("the new EU Regulation") was published in the Official Journal (OJ) of the European Communities on 11 December 2015 and is directly applicable throughout the EU. The new EU Regulation came into force on 30 December 2015 with a two year transition period to the new provisions. The new rules will be fully applicable from 1 January 2018 subject to a number of provisions (as discussed further in this Impact Assessment). Government intervention is required to make national Regulations that provide for the effective and proportionate enforcement of the new EU Regulation in England, Wales and Northern Ireland so that food businesses are incentivised to ensure novel foods are risk assessed prior to placement on the market, in this way protecting consumers through proportionate management of food safety risks.

5. The new EU Regulation delivers:

   a) an updated definition of what constitutes a 'Novel food' based on technological and scientific advancements;

   b) centralised risk assessments to be carried out by the European Food Safety Authority within 9 months (time may be stopped if further information is required);

   c) the establishment of a Union list of authorised novel foods (newly authorised food to be added within 6 months);

   d) generic novel food authorisations which remove the need for a separate application seeking to demonstrate substantial equivalence to an authorised novel food;

   e) a maximum 5 year period (from the date of authorisation) of intellectual property protection for new scientific evidence and data produced in support of applications; and

   f) a simpler notification procedure for traditional foods from third countries, facilitating free trade.

   This new streamlined, time restricted approach to novel food authorisations should deliver consistency for food businesses and encourage innovation whilst ensuring that a high level of food safety is maintained.

6. On the definition of engineered nanomaterials, the current definition from the Food Information for Consumers Regulation (EU) 1169/2011[6] has been retained and moved to the new Novel Food Regulation, with scope to amend the definition through the use of delegated acts to allow for technological and scientific advancements. The text also places emphasis on ensuring that methods used to assess the safety of engineered nanomaterials are appropriate and up to date. These changes should help to ensure that legislative requirements keep pace with scientific progress.

7. Agreement was reached on the use of delegated acts and implementing acts to update the Regulation. Implementing acts will be used for updates to the Union list of authorised novel foods. Cloning was a key issue discussed in the negotiation of the new EU Regulation; which retains the status quo of the 1997 legislation where the products of cloned animals, but not their descendants, will be subject to pre-market risk assessment under the Novel Food Regulations until such time as any changes are agreed as part of separate legislation on food from animal clones which is currently under discussion in the EU.

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[5] Ref OJ L 327, 11.12.2015, p.g. 1 - Regulation (EU) 2015/2283 of the European Parliament and of the Council, on novel foods, amending Regulation (EC) no. 1169/2015 of the European Parliament and of the Council and repealing Regulation (EC) No.258/97 of the European Parliament and of the Council and Commission Regulation (EC) No. 1852

[6] Ref OJ L304, 22.11.2011, p.g. 18-63 – Regulation (EU) 1169/2011 of the European Parliament and of the Council, on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004.

**Proposed Regulations**

8. The purpose of the proposed Novel Foods (England) Regulations 2017 ("the proposed Regulations") is to:

   - Ensure that those placing novel foods on the market within the UK and wider European Union (EU) are fully compliant with the new legislative requirements. This supports consumers accessing safe food innovation and facilitates trade in new foods by UK businesses, whilst providing a high level of protection of human health and consumer interests;
   - Provide for the effective and proportionate enforcement of the new EU Regulation on novel foods through the use of improved enforcement tools that may be employed to deal with suspected non-compliances with the EU Regulation and a range of civil penalties;
   - Maintain access to a back stop criminal offence and provide for defences against prosecution and establish a right of appeal for committing an offence in particular circumstances;
   - Specify penalties that the Courts may impose upon conviction and enable the award of compensation where enforcement authorities are found not to have taken appropriate action; and
   - Revoke the Novel Foods and Novel Food Ingredients Regulations 1997/1335 (as amended) and the Novel Foods and Novel Food Ingredients (Fees) Regulations 1997 in relation to England.

9. The penalties referred to above reflect the requirement in the new EU Regulation to ensure that penalties are dissuasive as well as being effective and proportionate. MS are required to notify the provisions to the Commission by 1st January 2018.

**Civil Sanctions; Compliance notices, Stop notices, fixed monetary penalties and powers**

10. The Novel Food and Novel Food Ingredients Regulations 1997 (SI No. 1997/1335) provides for the execution and enforcement in England of certain specified provisions of Regulation (EC) No 258/97. The current enforcement provisions provide a criminal offence for non-compliance but do not have specific provisions to remove products from sale. Reliance is placed on the Food Safety Act 1990 and related General Food Law (178/2002 EC) provisions for the seizure and/or detention of unauthorised novel foods or products containing unauthorised novel food ingredients; this approach requires a risk assessment to determine if the ingredient is unsafe. In the absence of evidence of harm it is difficult to remove unauthorised products from the market despite the safety of the products in question not having been verified. Any other avenues of enforcement related to labelling or health claims are unlikely to result in the removal of non-compliant products from the market.

11. In the light of this operational experience, the proposed Regulations introduce the use of compliance notices, stop notices, and fixed monetary penalties (level to be determined) for minor contraventions. Use of civil sanctions will help to ensure that any minor non-compliances can be remedied quickly and that if sanctions are applied these are appropriate and proportionate. Consequently it will become possible for remedial enforcement action seeking to improve compliance and maintain high levels of public protection to take place without the need to prove that a non-compliant product is categorically unsafe. This will also mean that minor regulatory breaches may be addressed by authorised officers without recourse to the courts, by this means reducing the inherent cost, resource and time needed to carry forward prosecutions and reduce burdens on business at the same time.

12. It is also deemed necessary for authorised officers/justices of the peace to be empowered to seize, detain and/or require the destruction of non-compliant novel food products where any alternative remedy is not or cannot be applied within a reasonable period to render products compliant with the EU Regulation. A modification of section 9 of the Food Safety Act 1990 (as amended) has been provided in the proposed Regulations in this regard.

13. The offences to arise as a result of the new EU Regulation on novel foods will be of strict liability. The proposed Regulations provide a mechanism for appeal of the fixed monetary penalties under Schedule 2 and of the compliance notices and stop notices under Schedule 3 of the proposed Regulation. The right to appeal is to the First-tier Tribunal and provision has been made for possible remedies such as the award of compensation in respect of stop notices and completion certificates.

14. The legislative response is designed to overcome the market's failure to ensure that food products placed on the market comply with the regulatory requirements for novel foods. Ingredients such as DMBA (1,3-dimethylbutylamine) have been found added to sports and weight loss supplements as a 'fat burner'. The US Food & Drink Administration first issued warnings about DMBA being used as a replacement for DMAA (1,3-dimethylamylamine) because it is an easily synthesised analogue. DMAA was banned by the UK Medicines & Healthcare Products Regulatory Agency in 2012, and it also appears on the World Anti-Doping Agency Prohibited list. Consumption of DMAA has been linked to symptoms such as high blood pressure, nausea, cerebral haemorrhage, stroke and death. Due to its structural similarity to DMAA it is considered that consumption of DMBA could also possibly lead to similar effects. This is an example of inefficient market response to food safety.

15. In this case, government intervention is necessary to provide enhanced enforcement powers that will help to ensure that minor non-compliances can be remedied quickly and efficiently through the use of compliance notices, stop notices and fixed monetary penalties. Whilst the provision of powers of entry, seizure and detention of non-compliant novel food products will help to ensure that where corrective action is not possible or appropriate, non-compliant products can be removed from the market. These preventative measures are taken to ensure protection of public health and consumer interests and prevent negative impacts on public health being realised.

**Background to EU Regulatory changes**

16. The current EU legislation, Commission Regulation (EC) No. 258/97 concerning novel foods and novel food ingredients has been in force since 1997 and applies to foods and food ingredients that do not have a significant history of consumption in the European Union (EU) before 1997. That Regulation included a requirement for a review of its operation in order to identify possible improvements. In practice however, the review was delayed, to take account of other significant developments in EU food law particularly with the adoption of General Food Law[7], which provides an overall framework for food legislation and established the European Food Safety Authority (EFSA). The adoption of Commission Regulation (EC) No. 1829/2003, removed genetically modified foods (GM) from the scope of Regulation (EC) No. 258/97.

17. The scope of the new EU Regulation broadly remains the same as Regulation (EC) No. 258/97 and maintains the requirement for novel foods to undergo a safety assessment before they can be marketed. The criteria for authorisation are essentially unchanged and it is therefore, not expected that the new EU Regulation will impose new ongoing costs on applicants, food operators or enforcement bodies. All businesses placing novel foods on the market are likely to be affected by the new EU Regulation. Micro-enterprises were not excluded from the scope of the EU Regulations; as it was felt that such an exemption would be incompatible with the overall objective of ensuring the safety of novel foods placed on the market in the EU.

18. The new EU Regulation repeals Commission Regulation (EC) No. 258/97 and Regulation (EC) No. 1852/2001 as from 1 January 2018. However, transitional measures in Article 35 of Regulation (EU) No. 2015/2283 allow that:

    i. Where an application for placing a novel food on the market within the EU is submitted in accordance with Article 4 of Regulation (EC) No. 258/97 but for which a final decision has not been reached by the date of entry into force of the new EU Regulation (i.e. 1 January 2018), shall be considered as an application made under the new EU Regulation.

    ii. Article 11 (requiring a scientific opinion from the European Food safety Authority) will not be applied by the Commission, where a risk assessment has already been provided by the MS

[7] Ref OJ L 31, 1.2.2002, p.g. 1: Regulation (EC) No. 178/2002of the European Parliament and of the Council, laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

on the basis of Regulation (EC) No. 258/97 and no other MS has raised any reasoned objection to that assessment.

iii. Foods not falling within the scope of Regulation (EC) No 258/97, which are lawfully placed on the market by 1 January 2018 and which fall within the scope of the new EU Regulation may continue to be placed on the market until a decision is taken in accordance with Articles 10 to 12 or Articles 14 to 19 of the new EU Regulation following an application for authorisation of a novel food or a notification of a traditional food from a third country submitted by the date specified in the implementing rules adopted in accordance with Article 13 or 20 of the new EU Regulation respectively, but no later than 2 January 2020.

iv. The Commission may, by means of implementing acts, adopt measures concerning the requirements referred to in Articles 13 and 20 necessary for the application of paragraphs 1 and 2 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(3).

19. The new EU Regulation also amends Regulation (EU) No. 1169/2011, adding in Article 2(1) the following:

    - (h) the definition of 'engineered nanomaterials' as established by point (f) of Article 3(2) of Regulation (EU) No. 2015/2283 of the European Parliament and of the Council (*)

**Clarification of definitions and scope of the new EU Regulation**

20. The new EU Regulation has a broader scope than the current legislation; the definition of a 'novel food' has been updated (as mentioned at paragraph 5a above) to include:

- whole insects;
- engineered nanomaterials (the definition is taken from the Food Information for Consumers Regulation (EU) No. 1169/2011 and may be updated via delegated acts in light of technical progress);
- food with an intentionally modified molecular structure;
- food from cell/tissue culture derived from plants, animals, microorganisms, fungi or algae;
- food from microorganisms, fungi, algae, or material of mineral origin;
- food consisting of certain micelles or liposomes; and
- food from plants obtained by non-traditional propagating techniques where those practices give rise to significant changes in the composition or structure of the food affecting its nutritional value, metabolism, or level of undesirable substances.

21. Clarifying the definition of a novel food will help reduce uncertainty on whether some new technologies with an impact on food fall within the scope of the legislation. This will in turn help to protect consumers by ensuring that the effect of the new technology on food is evaluated prior to use on food entering the market. . The current provisions have, on occasions, been found to be ambiguous in this regard. The new EU Regulation aims to provide a clearer definition than at present.

22. The new EU Regulation places a duty on food businesses to verify whether the food they intend to place on the market falls within the scope of the legislation. Whilst the establishment of the Union list of authorised novel foods will help in this regard, if unsure food businesses should consult and provide all necessary information to the MS in which they first intend to market the product to enable a determination to be made. MS may consult each other to make such determinations within specified timescales. The wording has also been amended to reflect the introduction of general EU food law, Commission Regulation (EC) No. 178/2002, providing improved clarity.

23. The new EU Regulation intends to provide greater clarity and certainty for food operators who may otherwise be unsure whether a food they intend to market falls within the scope of the EU Regulation on novel foods and therefore, requires authorisation.

**Detailed provisions of the new EU Regulation**

24. The new EU Regulation does not apply to:
    a) Genetically modified foods falling within the scope of Regulation (EC) No. 1829/2003;
    b) Foods when and insofar as they are used as:
        (i) Food enzymes falling within the scope of Regulation (EC) No. 1332/2008;
        (ii) Food flavourings falling within the scope of Regulation (EC) No. 1334/2008;
        (iii) Food used solely as additives falling within the scope of Regulation (EC) No. 1333/2008; and
        (iv) Extraction solvents used or intended to be used in the production of foodstuffs or food ingredients falling within the scope of Directive 2009/32/EC;
25. Article 3 of the new EU Regulation provides for the applicable definitions and updates the definition of 'novel foods' based on technological and scientific advancements.

Union List

26. The new EU Regulation requires that the Commission shall establish and update a Union list of novel foods authorised to be placed on the market within the Union in accordance with Articles 7, 8 and 9 ("the Union list") (Articles 6-12). Only novel foods authorised and included in the Union list may be placed on the market within the Union, or used in or on foods, in accordance with conditions of use and the applicable labelling requirements. In order for novel foods to be included in the Union list they are required to meet the specific conditions: a) the food does not, on the basis of scientific evidence available pose a safety risk to human health; b) the food's intended use does not mislead the consumer, especially if the food is intended to replace another food and there is significant change in the nutritional value; c) where food is intended to replace another food, it does not differ from that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer.

27. The Union list will be established by 1 January 2018, through an implementing act by the Commission, and will include novel foods that are already authorised or notified under Article 4, 5 or 7 of Regulation (EC) No 258/97, including any existing authorisation conditions and requirements.

Centralised Risk assessment

28. Centralising the authorisation procedure for novel foods; the European Food Safety Authority (EFSA) will carry out an initial assessment on novel foods. The current system requires MS to carry out an initial assessment, which is then shared with all other MS for comment – a process that takes a significant period of time, particularly as most dossiers are later referred to EFSA for advice on outstanding concerns raised by MS. Once EFSA's opinion is available, there is a further delay while the Commission prepares a formal authorisation decision which is voted on by MS. The new streamlined, time restricted centralised approach to novel food authorisations should deliver consistency for food businesses and encourage innovation whilst ensuring that a high level of food safety is maintained.

Generic Authorisations

29. Introducing generic novel food authorisations as in other areas of food law such as food additives, the new EU Regulation has removed the need for a separate application from a food business wishing to supply an already authorised novel food. Whilst in most cases this was considered under a simplified procedure based on demonstrating that both products are substantially equivalent; this has created unnecessary administrative burdens on applicants and competent national authorities. Where data protection provisions do not apply food businesses wishing to supply already authorised novel foods will be able to proceed directly to market.

Simplified Notifications for traditional food from third countries

30. Introducing a simplified safety assessment procedure for traditional food from third countries will enable traditional foods to gain authorisation relatively quickly if applicant companies are able to demonstrate a history of safe use outside the EU. At present, foods made from plants, microorganisms, fungi, algae and animals (e.g. chia seeds or baobab fruit) that are widely consumed elsewhere in the world have to undergo the same detailed lengthy assessment procedures as completely innovative products. Under this new notification procedure applicants need to present evidence of safe use of the traditional food in at least one country outside of the EU for a period of at least 25 years. EFSA and MS will assess the evidence in parallel procedures and a decision will be taken on whether a product should be allowed on the market. This simplified process should help facilitate free trade in traditional foods and broaden consumer choice whilst ensuring that high levels of food safety are maintained.

Data Protection

31. Where applicants request confidentiality for certain information submitted for updates to the Union list under the new EU Regulation, which may harm their competitive position, applicants are required to indicate which parts of the information should be treated as confidential, and to provide the necessary details to substantiate their request. Verifiable justification will be required in such cases.

32. The new EU Regulation also introduces a maximum 5 year period (from the date of authorisation) of intellectual property protection for new scientific evidence and data produced in support of applications. Applicants who have invested in new data to demonstrate suitability of their product can seek a limited period of data protection; if authorisation is granted, it would give the applicant the sole right to market the product during this period, using this safety data. Other operators could also apply for authorisation but they would have to provide their own safety data.

Post market monitoring

33. For food safety reasons and taking into account the EFSA opinion, the Commission may impose post-market monitoring requirements, which may include on a case by case basis the identification of the relevant FBOs.

**Consultation on the new EU Regulation**

34. Prior to the adoption of the new EU Regulation the European Commission carried out a formal consultation; this included stakeholders for the food industry, consumers, third countries and MS and international organisations. Commission representatives also participated in several meetings/seminars organised by stakeholders committed to specific issues (e.g. traditional food from third countries, assessment and authorisation procedure, nanotechnologies) and bilateral meetings with interested groups. Stakeholders also had the opportunity to express their positions during the first and second reading and the Conciliation procedure on the 2008 legislative proposal.

35. Furthermore, 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 MS. The published Impact Assessment is available at:

http://ec.europa.eu/food/food/biotechnology/novelfood/initiatives_en.htm.

36. Whilst the 2008 proposal lapsed, the stakeholder consultations conducted in relation to it had identified a number of areas for improvement in the existing Regulation and the Commission used this exercise to identify the following objectives:

- avoid delays that are associated with the current authorisation procedure for novel foods;

- remove any unjustified barriers to the introduction of traditional foods from non-EU countries that have a history of safe food use in those countries;
- avoid unnecessary duplication due to the current requirements for different manufacturers to submit applications for the same product;
- remove the overlap with other EU food law, which currently leads to unnecessary duplication in assessments and authorisations; and
- update the legal text in order to improve its clarity and to bring it in line with developments in EU food law.

A further proposal was brought forward in 2013 based upon the objectives previously identified by the Commission; the final compromise text was adopted on 16 November 2015 resulting in Regulation (EU) No. 2015/2283.

**Simplification**

37. The new EU Regulation provides for simplification of the legislation and administrative procedure for public authorities and businesses compared to the existing legislation:
    - there is only one centralised procedure for the assessment and authorisation of novel foods; the wording of the EU Regulation has been updated and now provides further clarity;
    - national administrative procedures and duplication of work have been removed;
    - the authorisation procedure is streamlined, increasing its efficiency and reducing the administrative burden in particular, for businesses;
    - A simplified procedure for the placing on the market of the traditional foods from third countries is introduced reducing barriers to trade.

**Policy Options Considered**

**Option 1 – Do Nothing – do not make domestic Regulations to provide for the enforcement and execution of the new EU Regulation in England; Wales; and Northern Ireland.**

38. This option will not prevent the new EU Regulation applying in England; Wales; and Northern Ireland as it is already legally binding and applicable throughout the EU. However, enforcement authorities would not have the necessary powers to enable them to enforce it.

**Option 2 – Make appropriate domestic Regulations for the execution and enforcement of the new EU Regulation on novel foods.**

39. This option will provide enforcement authorities with the necessary powers to enforce the new EU Regulation, and remove the risk of the UK incurring infraction proceedings.

40. This is the preferred option.

**Option Appraisal**

**Costs and Benefits**

**Option 1: Do Nothing – do not make national Regulations to provide for the enforcement and execution of the new EU Regulation in England; Wales; and Northern Ireland.**

41. There are no costs or benefits associated with this option. This is the baseline against which the policy option is appraised.

**Option 2: Make appropriate domestic Regulations for the execution and enforcement of the new EU Regulation on novel foods.**

42. There will be some cost to industry and enforcement in ensuring compliance with the new EU Regulation as identified below.

**Option 2 - One-off Costs to Industry**

***One –off familiarisation cost***

43. This figure is calculated by firstly taking the 2016 Provisional ONS ASHE (Annual Survey of Hours and Earnings)[8] figure 'Production managers and directors' £25.54 and uprating it by 20%, according to the Standard Cost model[9], to account for overheads, giving a mean[10] hourly wage rate of £30.65. It is estimated that the reading and understanding of the EU Regulations and the proposed Regulations and will take one and half hours with a further one and a half hours more for dissemination to key staff within each firm (a total of three hours). Given the number of enquiries, the FSA receives annually from companies concerning this area of legislation, it is estimated that approximately 1,000 companies[11] will need to invest in understanding the new legislation. Thus yielding an approximate one-off familiarisation cost to firms of £92k.

44. In order for 'one-off' familiarisation costs to be compared on an equivalent basis across policies spanning different time periods, it is necessary to 'equivalently annualise' costs (EAC) using a standard formula.[12] In line with Her Majesty's Treasury (HMT) Green book guidance a discount rate of 3.5% is used. Annualising the total one off familiarisation of £92k (see previous paragraph) yields an EAC of £11k in the England, Wales and Northern Ireland over 10 years.

**Option 2 – Benefits to Industry**

**Generic Novel Food Authorisations**

45. Under current regulatory requirements operators wishing to place novel foods on the market may either submit:
    - a full novel food application (with accompanying scientific dossier) for authorisation; or
    - an application seeking to demonstrate the substantial equivalence (SE) of their novel food product to one that is already authorised.

46. Under the current system novel food authorisations are issued specifically to the company that submitted the application, consequently any other company wishing to market the same novel food product must submit a separate application. In most cases this can be done via a simplified procedure that is based on demonstrating to one of the national Competent Authorities that the two products are substantially equivalent. This has led to a large number of SE applications, creating unnecessary administrative burdens on applicants and national Competent Authorities.

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[8] https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/occupation4digitsoc2010ashetable14

[9] SCM methodology http://www.berr.gov.uk/files/file44503.pdf

[10] The median figure would have been used but only the 'mean' figure was available at the time.

[11] The FSA has made the reasonable assumption that approximately 1,000 food business operators are active in considering placing novel foods on the market based on the number of enquiries we receive; these enquiries generally concern whether a product is novel; procedures for seeking authorisation of a novel food; and how to demonstrate that a product has a history of consumption in the EU.

[12] EACB = PVCB/$a_{tr}$, Where $a_{tr}$ is the annuity rate given by:

$$a_{t,r} = \sum_{j=0}^{t-1} \prod_{i=0}^{j} \left( \frac{1}{1+r_i} \right)$$

PVCB is the present value of costs, r is the social discount rate and t is the time period over which the policy is being appraised.

47. By way of illustration, Company A wishes to place chia seeds on the market, and submits a full novel food application seeking authorisation. Company A's application is successful and is duly authorised to place their chia seeds on the market. Company B also wishes to place chia seeds on the market. Company B can submit a SE application, which should show how the novel food or novel food ingredient may be substantially equivalent to the existing authorised food as regards to its:

    - composition (such as the source organism and preparation method);
    - nutritional value;
    - metabolism;
    - intended use (such as a food ingredient or supplement); and the
    - level of undesirable substances (such as contaminants, mycotoxins and allergens).

48. The new EU Regulation has introduced a move from applicant specific authorisations to generic authorisations (as mentioned at paragraph 5d). Once a novel food is authorised any operator could benefit from that authorisation subject to any proprietary data protection restrictions that may apply (see paragraph 5e above). This move to generic authorisations has removed the need for SE applications.

49. Informal enquiries amongst industry sources in the UK suggest the administrative cost of preparing an SE application and taking it through the existing process may be in the order of £5k-£25k; this is a saving for industry. It is expected that this will benefit small and medium sized businesses in particular as it means they too could place an authorised novel food on the market even if they did not submit the initial application for authorisation.

**Streamlined procedures for the assessment and authorisation of novel foods**

50. The time taken for decisions to be made by the Commission on applications submitted under the current EU Regulation has varied between 6 months to more than 4 years. The Commission has calculated that authorisations have, on average, been issued 39 months after the application was submitted. This might be reduced to 18 months under the new EU Regulation if the authorisation process runs smoothly. Based on valid applications being forwarded for safety assessment within 1 month; 9 months for EFSA to carry-out the safety assessment and deliver its opinion; and 3 months thereafter to present a possible draft implementing decision for a vote by MS.

51. The cost to an applicant of making a novel application will vary from case by case; depending on the complexity of the case and the need to generate new data to demonstrate the acceptability of the product. Unilever estimated that the total cost of obtaining authorisation for their Phytosterol ingredient (used in spreads and other products under the brand name 'Flora Pro-activ' range) was €25 million[13] (£19.8m), although this figure does not differentiate between costs which would have been incurred in the absence of the current Regulation (e.g. work required to satisfy general obligations under EU food law, to meet the company's own level of corporate safety assurance or to obtain authorisation in other regions of the world).

52. There are no data on which an estimate of the financial benefits of enabling a new product to be brought to the market in a shorter time after the dossier is submitted.

**On-going (annual) benefit of savings due to lower 'Administrative Costs'**

53. Informal enquiries amongst industry sources in the UK suggest that the administrative cost of preparing a full novel food application dossier and taking it through the existing process may be in the order of £20k-£50k. If the applicant does not already have the data to undertake a formal risk assessment, the cost of the individual studies could range from £5k-£12k (for a detailed analysis of

[13] This figure was provided in 200. To convert it to sterling the Bank of England annual average Spot exchange rate, Euro into Sterling (code: XUAAERS) was used. This resulted in a figure of £19,860,184.

the composition of the product) to a possible £250k (for a full Organisation for Economic Co-operation and Development 90-day feeding study in laboratory rats).

54. The current authorisation procedure is based on assessments carried out by the relevant authorities in one of the 28 EU MS, which are then scrutinised by the others. In some cases, there are outstanding questions and concerns which, if they cannot be satisfied by further information from the applicant, are referred to EFSA. The new EU Regulation will replace this with a single centralised assessment by EFSA (as mentioned at paragraph 5b above), in line with the approach used in other areas of EU food law, such as food additives. It is anticipated that whilst this will speed up the authorisation process, the financial cost of assembling data and preparing the initial dossiers would be substantially the same as at present. The centralised approach under the new EU Regulation is more supportive of a consortium of applicants than previously, providing opportunities for businesses to share the cost of preparing an application.

55. Reliance on a single, centralised safety assessment should not detract from the rigour of the safety assessment and it would be essential to ensure that assessments are carried out to a high standard and with the maximum degree of transparency.

56. Having centralised safety assessment will, however, remove some of the burden placed on National Competent Authorities; with this being transferred to EFSA. However, the ongoing need for expert advice on novel foods to support the effective functioning of the new EU Regulation is not yet clear, in particular in relation to assessment of traditional foods from third countries. No allowance has therefore, been made for financial savings resulting from the transfer of the safety assessment from national level to EFSA.

57. The centralised authorisation procedure might reduce the administrative burden on the applicant as they would have to liaise with a single body rather than with individual MS. However, it is anticipated that applicants may still wish to seek advice from competent authorities in the transitional period until understanding of the new regulatory framework is fully embedded. For the purpose of this Impact Assessment, it has been assumed the current administrative costs of preparing a dossier and taking it through the authorisation process is £20k - £50k (see above, para.46) and that 50% of this might be saved on full applications and 100% on SE applications. Sensitivity analysis has been used by taking an upper bound of £50k, a lower bound of £20k and best estimate of £35k, which is the mid-point of the two bounds. Calculations have been made on the basis of 5.2 full applications and 2.4 applications seeking an opinion on substantial equivalence per year in the UK (the novel food applications that were made during 2011-2016 were 26 full applications and 12 applications seeking to demonstrate substantial equivalence). For full applications, the best estimate of annual savings in England, Wales and Northern Ireland is £91k, with a total cost savings over 10 years of £783k (present value); with an upper bound estimate of £1.1m and a lower bound estimate of £448k (also present value figures). For opinions on substantial equivalence, the best estimate of annual savings is £36k, with a total cost savings over 10 years of £310k (present value; with an upper bound estimate of £516k and a lower bound estimate of £103k (also present value figures).

58. No calculation could be made for UK businesses seeking authorisation through other MS as the number of business affected are unknown.

**On-going (annual) benefit savings due to 'Removal of application fees'**

59. In addition to the potential administrative costs that operators might save, the proposed Regulations provide for the removal of fees through revocation of the Novel Foods and Novel Food Ingredients (Fees) Regulations 1997; this Regulation empowers the FSA to charge:

    - £4,000 in respect of a full novel food applications; and
    - £1,725 in respect of an opinion on substantial equivalence.

60. Calculations have been made on the basis of 5.2 full applications and 2.4 applications seeking an opinion on substantial equivalence per year. For full applications, the administrative cost saving of

£4k per application leads to a total annual saving of £20.8k, leading to a total saving of £179k (present value) in England, Wales and Northern Ireland over ten years. For opinions on substantial equivalence, the administrative cost saving of £1.7k per application leads to a total annual cost saving of £4.1k, leading to a total annual saving of £36k (present value) over ten years.

**Non-monetised benefit to industry of "the Establishment of a Union list of Authorised Novel Foods"**

61. The establishment of a Union list of authorised novel foods (as mentioned at paragraph 5c above) and any applicable conditions of use will benefit industry by providing greater clarity as to the novel foods that may legally be placed on the market. This will assist operators in the delivery of the obligation placed on them by Chapter I, Article 4 of Regulation (EU) No 2015/2283 which requires operators to verify whether the food they intend to place on the market falls within the scope of the legislation**.**

**Non-monetised benefit to industry of "A simplified safety assessment procedure for traditional food from third countries"**

62. There is increasing interest in the introduction of exotic fruits and vegetables coming into the EU market from non-EU countries, which have not previously been exported to Europe. For example, a group of Andean countries (Columbia, Ecuador, and Peru) have estimated that there are about 60 plant species that are traditionally consumed in their regions that could in future be exported to the EU.

63. Whilst the existing Novel Foods Regulation does not prevent trade in traditional foods, such products need to go through the full authorisation procedure that applies to other novel food; but few applications have been received, possibly because the requirements for authorisation are seen by exporters as unduly onerous and burdensome.

64. The simplified traditional food from third countries notification procedure (as mentioned at paragraph 5f above) set out in the new EU Regulation requires the submission of a dossier demonstrating the safety of a traditional food. EFSA has developed a scientific and technical guidance document intended to support applicants in providing the type and quality of information needed by EU MS and EFSA to consider whether there are reasoned safety objections to the placing on the market within the Union of the traditional food with the proposed conditions of use.

65. Dossiers should contain specifications on the traditional food; reliable data on the composition of the food; information about the experience of continued use in a third country; and its proposed conditions of use. In addition to this, normal consumption of the traditional food should not be nutritionally disadvantageous for consumers. If the procedure were to operate smoothly (a valid dossier being forwarded to MS and EFSA for consideration within 1 month of receipt by the Commission and the specified 4 month period permitted for MS and EFSA to raise any reasoned safety objections) the notified traditional food could be added to the authorised Union list within 6 months.

66. This simplified procedure should help facilitate trade by enabling traditional foods to proceed swiftly to the market, unless a MS, or EFSA, lodges a reasoned objection to the claim that the product has a history of safe use in a non-EU country.

**<u>Option 2 – Benefits to Consumers</u>**

**Non-monetised benefit to consumers of "the Establishment of a Union list of Authorised Novel Foods"**

67. The establishment of a Union list of authorised novel foods is expected to benefit consumers by providing clarity on what novel foods have been risk assessed and are considered not to present a

risk to human health. The Union list will also provide any applicable conditions of use that should be observed in relation use of the novel food.

**Non-monetised benefit to consumers of "A simplified safety assessment procedure for traditional food from third countries" and streamlined procedures for the assessment and authorisation of novel foods**

68. It is expected that the simplified process for traditional food from third countries and streamlined procedures for the assessment and authorisation of novel foods is likely to result in an increase in the choice of foods available to consumers. It is also expected that consumers will benefit from products proceeding to market more swiftly and potentially at a lower cost as the commensurate costs to industry of authorisation are reduced.

**Option 2 - Costs to Enforcement**

***One –off familiarisation cost***

69. There are approximately 386 local authorities and 36 Port Health Authorities in England, Wales and Northern Ireland. It is estimated that one officer in each of these authorities (one / Health Officer from each local authority'; and one 'Inspector of Standards' from each Port Health Authority) is expected to read and familiarise themselves with the EU Regulations and the proposed Regulations and that it may takes them one and a half hours to do so. In addition, we have estimated that a further hour and a half is required to disseminate to key staff within the organisation (three hours in total).

70. An estimate of the cost with respect to the time taken by enforcement officers at local authorities to familiarise themselves is £18.97. This figure taken from the 2016 Provisional ONS ASHE (Annual Survey of Hours and Earnings)[14], figures for an Environmental Health Officer £18.97 per hour (median value), which, in line with the Standard Cost Model, is then up-rated by 20% to account for overheads, which gives an hourly wage rate of £22.76. With 386 local authorities, this gives a total cost of £26k. An estimate of the cost with respect to the time taken by 'Inspectors of standards' at Port Health Authorities, to familiarise themselves is £17.83. This figure taken from the 2016 Provisional ONS ASHE (Annual Survey of Hours and Earnings), figures for an 'Inspector of standards' £15 per hour (median value), which, in line with the Standard Cost Model, is then up-rated by 20% to account for overheads. With 36 Port Health Authorities, this gives a total cost of £2k. This result in a total approximate one-off cost for enforcement bodies of £28k.

71. Compared with the current system, there would be no additional or new burden on enforcement bodies, other than those identified in the costs and benefits above.

**Data Protection**

72. As mentioned earlier, under the new EU Regulation, authorisations will be issued on a generic basis, as they are in other areas of EU food law, such as food additives.

73. However, as the original applicant may have made a substantial investment in general new or proprietary data. In order to protect this investment and to promote innovation, the new EU Regulation provides a data protection system that could be applied in appropriate cases (as mentioned at paragraph 5e above). In qualifying cases, only the original applicant would be able to benefit from the authorisation. Other operators could also apply for authorisation, but they would have to provide their own data or seek permission from the original applicant to use that applicants data. This part of the new EU Regulation was modelled on Regulation (EC) No. 1924/2006 (as amended) on nutrition and health claims.

[14] https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/occupation4digitsoc2010ashetable14

74. This change may provide benefits for the original applicant in cases where they are unable to rely on other systems that provide protection for intellectual property e.g. patents.

75. Where the data protection system does not apply, generic authorisation would benefit other operators who currently would have to notify their equivalent products under the simplified procedure, since generic authorisations will allow them to proceed directly to market.

**Novel Food Market**

76. No data are available on the size of the current or future EU market for novel foods. As in the EU impact assessment for the 2008 proposal it is very difficult to produce data on the size and extent of the novel food market in the UK, because it is not a single uniform market covering a broad range of different products. As such it would difficult to try and extrapolate an overall picture of the UK market for novel food products. So whilst there is potential for innovative food technologies and products, supporting data is not readily available. Overall, novel foods play only a minor role in the diet.

77. Phytosterols are probably the most successful of the products authorised under the 1997 EU Regulation, being widely available in a range of products aimed at people who wish to reduce their cholesterol levels. More recently the authorisation of chia seeds has seen successful commercialisation of this novel food product which is widely available to consumers in a range of food products. Other authorised novel foods are less widely available on the market, being found; for example, in a limited number of food supplements or more specialised products. In some cases, the products may not yet be introduced onto the market for commercial reasons unrelated to the Novel Food Regulation.

**Competition Assessment**

78. The present system is regarded by many food businesses as a barrier to innovation and any improvements to the efficiency and clarity of the procedures (including allowing reasonable returns on investments by means of data protection) are expected to lead to increased innovation and potentially competition. Especially, if the time-to-market of new novel food products/ingredients is reduced.

**Small and Micro Business Assessment (SMBA)**

79. The UK food industry sector is comprised of mainly small and micro businesses and therefore the greatest impact from changes in from the new EU Regulation introduced in the UK will, in the vast majority of cases, be on small and micro businesses. For this reason the FSA assesses the impact on small and micro businesses as standard when undertaking impact assessments.

80. EU legislation generally applies to food businesses regardless of size, as requirements are intended to be risk based to reflect the activities undertaken. 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 consumer health. That said, the FSA makes every effort to minimise burdens on small and micro businesses and pays particular attention to impacts on them. In considering the likely impact on SMBAs the FSA believe the changes at EU level will help to simplify and increase efficiency of the regulatory procedures that apply to novel foods. This should in turn increase the ability of small firms to bring novel foods to the EU market.

**Sustainable development**

81. There are two possible impacts, related to the introduction of novel foods derived from natural sources:

a). ingredients could be derived by harvesting scarce natural resources. While, trade in products obtained from recognised endangered species would be illegal, a sudden increase in demand could

significantly reduce the numbers of a given species if the ingredients obtained from plant or animals taken from the wild.

b). the authorisation of traditional foods from countries outside the EU could increase the innovation of wild species through horticulture and provide a valuable source of income for farmers developing countries.

**Race/gender equality issues**

82. The proposed Regulation does not impose any restrictive compliance to any person from a particular race, gender or with disability.

I

*(Legislative acts)*

# REGULATIONS

## REGULATION (EU) 2015/2283 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

**of 25 November 2015**

**on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001**

**(Text with EEA relevance)**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee ([1]),

Acting in accordance with the ordinary legislative procedure ([2]),

Whereas:

(1) The free movement of safe and wholesome food is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, and to their social and economic interests. Differences between national laws concerning the safety assessment and authorisation of novel foods may hinder the free movement of such food, thereby creating legal uncertainty and unfair conditions of competition.

(2) A high level of protection of human health and of consumers' interests and the effective functioning of the internal market needs to be assured in the pursuit of Union food policies, whilst ensuring transparency. A high level of protection and improvement of the quality of the environment are among the objectives of the Union as established in the Treaty on European Union (TEU). It is important that all relevant Union legislation, including this Regulation, take those objectives into account.

(3) Union legislation applicable to food is also applicable to novel foods placed on the market within the Union, including novel foods imported from third countries.

(4) The Union's rules on novel foods were established by Regulation (EC) No 258/97 of the European Parliament and of the Council ([3]) and by Commission Regulation (EC) No 1852/2001 ([4]). Those rules need to be updated

([1]) OJ C 311, 12.9.2014, p. 73.
([2]) Position of the European Parliament of 28 October 2015 (not yet published in the Official Journal) and decision of the Council of 16 November 2015.
([3]) Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1).
([4]) Commission Regulation (EC) No 1852/2001 of 20 September 2001 laying down detailed rules for making certain information available to the public and for the protection of information submitted pursuant to European Parliament and Council Regulation (EC) No 258/97 (OJ L 253, 21.9.2001, p. 17).

to simplify the current authorisation procedures and to take account of recent developments in Union law and technological progress. Regulations (EC) No 258/97 and (EC) No 1852/2001 should be repealed and replaced by this Regulation.

(5) Food intended to be used for technological purposes and genetically modified food which is already covered by other Union acts should not fall within the scope of this Regulation. Therefore, genetically modified food falling within the scope of Regulation (EC) No 1829/2003 of the European Parliament and of the Council ([1]), food enzymes falling within the scope of Regulation (EC) No 1332/2008 of the European Parliament and of the Council ([2]), food used solely as additives falling within the scope of Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([3]), food flavourings falling within the scope of Regulation (EC) No 1334/2008 of the European Parliament and of the Council ([4]) and extraction solvents falling within the scope of Directive 2009/32/EC of the European Parliament and of the Council ([5]) should be excluded from the scope of this Regulation.

(6) The existing definition of novel food in Regulation (EC) No 258/97 should be clarified and updated with a reference to the general definition of food provided for in Regulation (EC) No 178/2002 of the European Parliament and of the Council ([6]).

(7) In order to ensure continuity with the rules laid down in Regulation (EC) No 258/97, one of the criteria for food to be considered a novel food should continue to be the absence of use for human consumption to a significant degree within the Union before the date of entry into force of that Regulation, namely 15 May 1997. Use within the Union should also refer to a use in the Member States irrespective of the dates of their accession.

(8) The scope of this Regulation should, in principle, remain the same as the scope of Regulation (EC) No 258/97. However, on the basis of scientific and technological developments that have occurred since 1997, it is appropriate to review, clarify and update the categories of food which constitute novel foods. Those categories should cover whole insects and their parts. There should be, inter alia, categories for food with a new or intentionally modified molecular structure, as well as for food from cell culture or tissue culture derived from animals, plants, microorganisms, fungi or algae, for food from microorganisms, fungi or algae and for food from material of mineral origin. There should also be a category covering food from plants obtained by non-traditional propagating practices where those practices give rise to significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances. The definition of novel food may also cover food consisting of certain micelles or liposomes.

(9) Emerging technologies in food production processes may have an impact on food and thereby on food safety. Therefore, this Regulation should further specify that a food should be considered a novel food where it results from a production process not used for food production within the Union before 15 May 1997, which gives rise to significant changes in the composition or structure of a food affecting its nutritional value, metabolism or level of undesirable substances.

(10) To ensure a high level of protection of human health and consumers' interests, food consisting of engineered nanomaterials should also be considered a novel food under this Regulation. The term 'engineered nanomaterial'

([1]) Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1).
([2]) Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 (OJ L 354, 31.12.2008, p. 7).
([3]) Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16).
([4]) Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34).
([5]) Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (OJ L 141, 6.6.2009, p. 3).
([6]) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

is currently defined in Regulation (EU) No 1169/2011 of the European Parliament and of the Council ([1]). For consistency and coherence purposes, it is important to ensure a single definition of engineered nanomaterial in the area of food law. The appropriate legislative framework for including such a definition is this Regulation. Accordingly, the definition of engineered nanomaterial, along with the related conferral of delegated powers to the Commission, should be deleted from Regulation (EU) No 1169/2011 and replaced by a reference to the definition set out in this Regulation. Furthermore, this Regulation should provide that the Commission should, by means of delegated acts, adjust and adapt the definition of engineered nanomaterial set out in this Regulation to technical and scientific progress or to definitions agreed at international level.

(11) Vitamins, minerals and other substances intended to be used in food supplements in accordance with Directive 2002/46/EC of the European Parliament and of the Council ([2]) and Regulation (EC) No 1925/2006 of the European Parliament and of the Council ([3]) or in infant formula and follow-on formulae, processed cereal-based food and baby food for infants and young children, food for special medical purposes, and total diet replacement for weight control in accordance with Regulation (EU) No 609/2013 of the European Parliament and of the Council ([4]), should also be assessed in accordance with the rules laid down in this Regulation when they fall within the definition of novel food set out therein.

(12) Where vitamins, minerals or other substances used in accordance with Directive 2002/46/EC, Regulation (EC) No 1925/2006 or Regulation (EU) No 609/2013 result from a production process not used for food production within the Union before 15 May 1997, which gives rise to significant changes in the composition or structure of a food, affecting its nutritional value, metabolism or level of undesirable substances, or where those vitamins, minerals or other substances contain or consist of engineered nanomaterials, they should also be considered novel foods under this Regulation and should be re-assessed first in accordance with this Regulation and subsequently in accordance with the relevant specific legislation.

(13) A food used before 15 May 1997 exclusively as, or in, a food supplement, as defined in Directive 2002/46/EC, should be permitted to be placed on the market within the Union after that date for the same use, as it should not be considered to be a novel food for the purposes of this Regulation. However, that use as, or in, a food supplement should not be taken into account for the assessment of whether the food was used for human consumption to a significant degree within the Union before 15 May 1997. Therefore, uses of the food concerned other than as, or in, a food supplement should be subject to this Regulation.

(14) Food from animal clones has been regulated under Regulation (EC) No 258/97. It is crucial that no legal ambiguity should emerge as regards the placing on the market of food from animal clones during the transitional period after the end of the application of Regulation (EC) No 258/97. Therefore, until specific legislation on food from animal clones enters into force, food from animal clones should fall under the scope of this Regulation as food from animals obtained by non-traditional breeding practices and should be appropriately labelled for the final consumer in accordance with the Union legislation in force.

(15) The placing on the market within the Union of traditional foods from third countries should be facilitated where the history of safe food use in a third country has been demonstrated. Those foods should have been consumed in at least one third country for at least 25 years as a part of the customary diet of a significant number of people. The history of safe food use should not include non-food uses or uses not related to normal diets.

([1]) Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).

([2]) Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).

([3]) Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 404, 30.12.2006, p. 26).

([4]) Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35).

(16) Foods from third countries which are regarded as novel foods in the Union should only be considered as traditional foods from third countries when they are derived from primary production as defined in Regulation (EC) No 178/2002, regardless of whether or not they are processed or unprocessed foods.

(17) Food produced exclusively from food ingredients that do not fall within the scope of this Regulation, in particular by changing the ingredients of the food or their amount, should not be considered to be a novel food. However, modifications to a food ingredient that has not yet been used for human consumption to a significant degree within the Union, should fall within the scope of this Regulation.

(18) Directive 2001/83/EC of the European Parliament and of the Council ([1]) applies in cases where a product, taking into account all its characteristics, may fall both within the definition of 'medicinal product' as laid down in that Directive and within the definition of a product covered by this Regulation. In that respect, where a Member State establishes in accordance with Directive 2001/83/EC that a product is a medicinal product, it may restrict the placing on the market of that product in accordance with Union law. Moreover, medicinal products are excluded from the definition of food as laid down in Regulation (EC) No 178/2002 and should therefore not fall within the scope of this Regulation.

(19) The determination of whether a food was used for human consumption to a significant degree within the Union before 15 May 1997 should be based on information submitted by food business operators and, where appropriate, supported by other information available in Member States. Food business operators should consult Member States if they are unsure of the status of the food which they intend to place on the market. Where there is no information on human consumption before 15 May 1997 or the information available is insufficient, a simple and transparent procedure, involving the Commission, the Member States and food business operators, should be established for collecting such information.

(20) Novel foods should be authorised and used only if they fulfil the criteria laid down in this Regulation. Novel foods should be safe and if their safety cannot be assessed and scientific uncertainty persists, the precautionary principle may be applied. Their use should not mislead the consumer. Therefore, where a novel food is intended to replace another food, it should not differ from that food in a way that would be nutritionally less advantageous for the consumer.

(21) Novel foods should not be placed on the market or used in food for human consumption unless they are included in a Union list of novel foods authorised to be placed on the market within the Union ('the Union list'). Therefore, it is appropriate to establish, by means of an implementing act, the Union list by including in that list the novel foods already authorised or notified in accordance with Regulation (EC) No 258/97, including any existing authorisation conditions. That list should be transparent and easily accessible.

(22) It is appropriate to authorise a novel food by updating the Union list subject to the criteria and procedures laid down in this Regulation. A procedure that is efficient, time-limited and transparent should be put in place. As regards traditional foods from third countries having a history of safe food use, the applicants should be able to opt for a faster and simplified procedure to update the Union list if no duly reasoned safety objections are expressed.

(23) Criteria for the assessment of the safety risks arising from novel foods should also be clearly defined and laid down. In order to ensure the harmonised scientific assessment of novel foods, such assessments should be carried out by the European Food Safety Authority ('the Authority'). Under the procedure for authorising a novel food and updating the Union list, the Authority should be requested to give its opinion if the update is liable to have an effect on human health. In its opinion, the Authority should assess, inter alia, all the characteristics of the novel food that may pose a safety risk to human health and consider possible effects on vulnerable groups of the population. In particular, the Authority should verify that, where a novel food consists of engineered nanomaterials, the most up-to-date test methods are used to assess their safety.

([1]) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

(24) The Commission and the Authority should be subject to deadlines to guarantee a smooth processing of applications. However, in certain cases, the Commission and the Authority should have the right to extend those deadlines.

(25) The applicant may be requested by the Authority or by the Commission to provide additional information for the purposes of risk assessment or risk management respectively. In case the applicant fails to provide the additional information, as required, within the period set by the Authority or by the Commission after consulting the applicant, lack of such information may have consequences for the opinion of the Authority or for a possible authorisation and update of the Union list.

(26) As regards the possible use of nanomaterials for food use, the Authority considered in its opinion of 6 April 2011 on Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain that limited information is available in relation to aspects of nanotoxicokinetics and toxicology of engineered nanomaterials and that existing toxicity testing methods may need methodological modifications. The Organisation for Economic Cooperation and Development Council Recommendation of 19 September 2013 on the Safety Testing and Assessment of Manufactured Nanomaterials concluded that the approaches for the testing and assessment of traditional chemicals are, in general, appropriate for assessing the safety of nanomaterials, but may have to be adapted to the specificities of nanomaterials. In order to better assess the safety of nanomaterials for food use and in order to address the current gaps in toxicological knowledge and measurement methodologies, test methods, including non-animal tests, which take into account specific characteristics of engineered nanomaterials may be needed.

(27) When test methods are applied to nanomaterials, an explanation should be provided by the applicant of their scientific appropriateness for nanomaterials and, where applicable, of the technical adaptations and adjustments that have been made in order to respond to the specific characteristics of those materials.

(28) When a novel food is authorised and included in the Union list, the Commission should have the power to introduce post-market monitoring requirements to monitor the use of the authorised novel food to ensure that the use is within safe limits as established in the risk assessment by the Authority. Post-market monitoring requirements may therefore be justified by the necessity to gather information on the actual marketing of the food. In any event, food business operators should inform the Commission of any new relevant information regarding the safety of the food they have placed on the market.

(29) New technologies and innovations in food production should be encouraged as they could reduce the environmental impact of food production, enhance food security and bring benefits to consumers as long as the high level of consumer protection is ensured.

(30) Under specific circumstances, in order to stimulate research and development within the agri-food industry, and thus innovation, it is appropriate to protect the investment made by the applicants in gathering the information and data provided in support of an application for a novel food made in accordance with this Regulation. The newly developed scientific evidence and proprietary data provided in support of an application for inclusion of a novel food in the Union list should be protected. Those data and information should, for a limited period of time, not be used to the benefit of a subsequent applicant, without the agreement of the initial applicant. The protection of scientific data provided by an applicant should not prevent other applicants from seeking the inclusion of a novel food in the Union list on the basis of their own scientific data or by referring to the protected data with the agreement of the initial applicant. However, the overall five-year period of data protection which has been granted to the initial applicant should not be extended due to the granting of data protection to subsequent applicants.

(31) In cases where an applicant requests the protection of scientific data relating to the same food in accordance with this Regulation and with Regulation (EC) No 1924/2006 of the European Parliament and of the Council [1], it should be possible for the respective data protection periods to run concurrently. Therefore, provision should be made for staying, on request by the applicant, the authorisation procedure for a novel food.

[1] Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods (OJ L 404, 30.12.2006, p. 9).

(32) In accordance with Directive 2010/63/EU of the European Parliament and of the Council ([1]), tests on animals should be replaced, reduced or refined. Therefore, within the scope of this Regulation, duplication of animal testing should be avoided, where possible. Pursuing this goal could reduce possible animal welfare and ethical concerns with regard to novel food applications.

(33) Novel foods are subject to the general labelling requirements laid down in Regulation (EU) No 1169/2011 and other relevant labelling requirements in Union food law. In certain cases it may be necessary to provide for additional labelling information, in particular regarding the description of the food, its source, its composition or its conditions of intended use to ensure that consumers are sufficiently informed of the nature and safety of the novel food, particularly with regard to vulnerable groups of the population.

(34) Materials and articles intended to come into contact with novel foods are subject to Regulation (EC) No 1935/2004 of the European Parliament and of the Council ([2]) and the specific measures adopted thereunder.

(35) In line with the Commission's better regulation policy, the Commission should carry out an *ex-post* evaluation of the implementation of this Regulation, addressing in particular the new procedures on traditional foods from third countries.

(36) For those applications which have been submitted under Regulation (EC) No 258/97 and for which a final decision has not been taken before the date of application of this Regulation risk assessment and authorisation procedures should be concluded in accordance with this Regulation. Furthermore, a food not falling within the scope of Regulation (EC) No 258/97, which was lawfully placed on the market before the date of application of this Regulation and which falls under the scope of this Regulation, should in principle be allowed to continue to be placed on the market until the risk assessment and authorisation procedures under this Regulation have been concluded. Therefore, transitional provisions should be laid down to ensure a smooth transition to the rules of this Regulation.

(37) This Regulation respects the fundamental rights and observes the principles recognised, in particular, by the Charter of Fundamental Rights of the European Union.

(38) The Member States should lay down rules on penalties applicable to infringements of this Regulation and should take all measures necessary to ensure that they are implemented. Those penalties should be effective, proportionate and dissuasive.

(39) In order to achieve the objectives of this Regulation, the power to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of the adjustment and adaptation of the definition of engineered nanomaterial to technical and scientific progress or to definitions agreed at international level. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

(40) In order to ensure uniform conditions for the implementation of this Regulation with regard to updating the Union list concerning the adding of a traditional food from a third country where no reasoned safety objections have been expressed, implementing powers should be conferred on the Commission.

(41) The advisory procedure should be used for the adoption of the implementing act establishing the initial Union list given that it will concern only novel foods that have already been assessed for their safety, have been legally produced and marketed in the Union and have not given rise to health concerns in the past. The examination procedure should be used for the adoption of implementing acts in all other cases.

([1]) Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).

([2]) Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).

(42) Since the objectives of this Regulation, in particular the laying down of rules for the placing of novel foods on the market within the Union, cannot be sufficiently achieved by the Member States but can rather be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 TEU. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

**SUBJECT MATTER, SCOPE AND DEFINITIONS**

*Article 1*

**Subject matter and purpose**

1. This Regulation lays down rules for the placing of novel foods on the market within the Union.

2. The purpose of this Regulation is to ensure the effective functioning of the internal market while providing a high level of protection of human health and consumers' interests.

*Article 2*

**Scope**

1. This Regulation applies to the placing of novel foods on the market within the Union.

2. This Regulation does not apply to:

(a) genetically modified foods falling within the scope of Regulation (EC) No 1829/2003;

(b) foods when and in so far as they are used as:

(i) food enzymes falling within the scope of Regulation (EC) No 1332/2008;

(ii) food additives falling within the scope of Regulation (EC) No 1333/2008;

(iii) food flavourings falling within the scope of Regulation (EC) No 1334/2008;

(iv) extraction solvents used or intended to be used in the production of foodstuffs or food ingredients and falling within the scope of Directive 2009/32/EC.

*Article 3*

**Definitions**

1. For the purposes of this Regulation, the definitions laid down in Articles 2 and 3 of Regulation (EC) No 178/2002 apply.

2. The following definitions also apply:

(a) 'novel food' means any food that was not used for human consumption to a significant degree within the Union before 15 May 1997, irrespective of the dates of accession of Member States to the Union, and that falls under at least one of the following categories:

(i) food with a new or intentionally modified molecular structure, where that structure was not used as, or in, a food within the Union before 15 May 1997;

(ii) food consisting of, isolated from or produced from microorganisms, fungi or algae;

(iii) food consisting of, isolated from or produced from material of mineral origin;

(iv) food consisting of, isolated from or produced from plants or their parts, except when the food has a history of safe food use within the Union and is consisting of, isolated from or produced from a plant or a variety of the same species obtained by:

— traditional propagating practices which have been used for food production within the Union before 15 May 1997; or

— non-traditional propagating practices which have not been used for food production within the Union before 15 May 1997, where those practices do not give rise to significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances;

(v) food consisting of, isolated from or produced from animals or their parts, except for animals obtained by traditional breeding practices which have been used for food production within the Union before 15 May 1997 and the food from those animals has a history of safe food use within the Union;

(vi) food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, micro-organisms, fungi or algae;

(vii) food resulting from a production process not used for food production within the Union before 15 May 1997, which gives rise to significant changes in the composition or structure of a food, affecting its nutritional value, metabolism or level of undesirable substances;

(viii) food consisting of engineered nanomaterials as defined in point (f) of this paragraph;

(ix) vitamins, minerals and other substances used in accordance with Directive 2002/46/EC, Regulation (EC) No 1925/2006 or Regulation (EU) No 609/2013, where:

— a production process not used for food production within the Union before 15 May 1997 has been applied as referred to in point (a) (vii) of this paragraph; or

— they contain or consist of engineered nanomaterials as defined in point (f) of this paragraph;

(x) food used exclusively in food supplements within the Union before 15 May 1997, where it is intended to be used in foods other than food supplements as defined in point (a) of Article 2 of Directive 2002/46/EC;

(b) 'history of safe food use in a third country' means that the safety of the food in question has been confirmed with compositional data and from experience of continued use for at least 25 years in the customary diet of a significant number of people in at least one third country, prior to a notification referred to in Article 14;

(c) 'traditional food from a third country' means novel food as defined in point (a) of this paragraph, other than novel food as referred to in points (a) (i), (iii), (vii), (viii), (ix) and (x) thereof which is derived from primary production as defined in point 17 of Article 3 of Regulation (EC) No 178/2002 with a history of safe food use in a third country;

(d) 'the applicant' means the Member State, the third country or the interested party, which may represent several interested parties and has submitted to the Commission an application in accordance with Article 10 or 16 or a notification in accordance with Article 14;

(e) 'valid' in respect to an application or a notification means an application or a notification which falls within the scope of this Regulation and contains the information required for risk assessment and authorisation procedure;

(f) 'engineered nanomaterial' means any intentionally produced material that has one or more dimensions of the order of 100 nm or less or that is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic of the nanoscale.

Properties that are characteristic of the nanoscale include:

(i) those related to the large specific surface area of the materials considered; and/or

(ii) specific physico-chemical properties that are different from those of the non-nanoform of the same material.

*Article 4*

**Procedure for determination of novel food status**

1. Food business operators shall verify whether or not the food which they intend to place on the market within the Union falls within the scope of this Regulation.

2. Where they are unsure whether or not a food which they intend to place on the market within the Union falls within the scope of this Regulation, food business operators shall consult the Member State where they first intend to place the novel food. Food business operators shall provide the necessary information to the Member State to enable it to determine whether or not a food falls within the scope of this Regulation.

3. In order to determine whether or not a food falls within the scope of this Regulation, Member States may consult the other Member States and the Commission.

4. The Commission shall, by means of implementing acts, specify the procedural steps of the consultation process provided for in paragraphs 2 and 3 of this Article, including deadlines and the means to make the status publicly available. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(3).

*Article 5*

**Implementing power concerning the definition of novel food**

The Commission may decide, on its own initiative or upon a request by a Member State, by means of implementing acts, whether or not a particular food falls within the definition of novel food, as laid down in point (a) of Article 3(2). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(3).

CHAPTER II

**REQUIREMENTS FOR PLACING NOVEL FOODS ON THE MARKET WITHIN THE UNION**

*Article 6*

**Union list of authorised novel foods**

1. The Commission shall establish and update a Union list of novel foods authorised to be placed on the market within the Union in accordance with Articles 7, 8 and 9 ('the Union list').

2. Only novel foods authorised and included in the Union list may be placed on the market within the Union as such, or used in or on foods, in accordance with the conditions of use and the labelling requirements specified therein.

*Article 7*

**General conditions for inclusion of novel foods in the Union list**

The Commission shall only authorise and include a novel food in the Union list if it complies with the following conditions:

(a) the food does not, on the basis of the scientific evidence available, pose a safety risk to human health;

(b) the food's intended use does not mislead the consumer, especially when the food is intended to replace another food and there is a significant change in the nutritional value;

(c) where the food is intended to replace another food, it does not differ from that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer.

*Article 8*

**Initial establishment of the Union list**

By 1 January 2018 the Commission shall, by means of an implementing act, establish the Union list by including in it the novel foods authorised or notified under Article 4, 5 or 7 of Regulation (EC) No 258/97, including any existing authorisation conditions.

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 30(2).

*Article 9*

**Content and updating of the Union list**

1. The Commission shall authorise a novel food and update the Union list in accordance with the rules laid down in:

(a) Articles 10, 11 and 12 and, where applicable, Article 27; or

(b) Articles 14 to 19.

2. The authorisation of a novel food and updating of the Union list provided for in paragraph 1 shall consist of one of the following:

(a) adding a novel food to the Union list;

(b) removing a novel food from the Union list;

(c) adding, removing or changing the specifications, conditions of use, additional specific labelling requirements or post-market monitoring requirements associated with the inclusion of a novel food in the Union list.

3. The entry for a novel food in the Union list provided for in paragraph 2 shall include the specification of the novel food and, where appropriate:

(a) the conditions under which the novel food may be used, including in particular any requirements necessary to avoid possible adverse effects on particular groups of the population, the exceeding of maximum intake levels and risks in case of excessive consumption;

(b) additional specific labelling requirements to inform the final consumer of any specific characteristic or food property, such as the composition, nutritional value or nutritional effects and intended use of the food, which renders a novel food no longer equivalent to an existing food or of implications for the health of specific groups of the population;

(c) post-market monitoring requirements in accordance with Article 24.

CHAPTER III

## AUTHORISATION PROCEDURES FOR A NOVEL FOOD

*SECTION I*

### *General rules*

*Article 10*

### Procedure for authorising the placing on the market within the Union of a novel food and updating the Union list

1. The procedure for authorising the placing on the market within the Union of a novel food and updating of the Union list provided for in Article 9 shall start either on the Commission's initiative or following an application to the Commission by an applicant. The Commission shall make the application available to the Member States without delay. The Commission shall make the summary of the application, based on the information referred to in points (a), (b) and (e) of paragraph 2 of this Article, publicly available.

2. The application for an authorisation shall include:

(a) the name and address of the applicant;

(b) the name and description of the novel food;

(c) the description of the production process(es);

(d) the detailed composition of the novel food;

(e) scientific evidence demonstrating that the novel food does not pose a safety risk to human health;

(f) where appropriate, the analysis method(s);

(g) a proposal for the conditions of intended use and for specific labelling requirements which do not mislead the consumer or a verifiable justification why those elements are not necessary.

3. Upon request by the Commission, the European Food Safety Authority ('the Authority') shall give its opinion as to whether the update is liable to have an effect on human health.

4. When test methods are applied to engineered nanomaterials as referred to in points (a) (viii) and (ix) of Article 3(2), an explanation shall be provided by the applicants of their scientific appropriateness for nanomaterials and, where applicable, of the technical adaptations or adjustments that have been made in order to respond to the specific characteristics of those materials.

5. The procedure for authorising the placing on the market within the Union of a novel food and updating the Union list as provided for in Article 9 shall end with the adoption of an implementing act in accordance with Article 12.

6. By way of derogation from paragraph 5, the Commission may terminate the procedure at any stage, and decide not to proceed with an update, where it considers that such an update is not justified.

In such cases, where applicable, the Commission shall take account of the views of Member States, the Authority's opinion and any other legitimate factors relevant to the update under consideration.

The Commission shall inform the applicant and all Member States directly of the reasons for not considering the update to be justified. The Commission shall make the list of such applications publicly available.

7. The applicant may withdraw its application at any time, thereby terminating the procedure.

*Article 11*

**Opinion of the Authority**

1. Where the Commission requests an opinion from the Authority, it shall forward the valid application to the Authority without delay, and not later than one month after having verified its validity. The Authority shall adopt its opinion within nine months from the date of receipt of a valid application.

2. In assessing the safety of novel foods, the Authority shall, where appropriate, consider whether:

(a) the novel food concerned is as safe as food from a comparable food category already placed on the market within the Union;

(b) the composition of the novel food and the conditions of its use do not pose a safety risk to human health in the Union;

(c) a novel food, which is intended to replace another food, does not differ from that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer.

3. The Authority shall forward its opinion to the Commission, to the Member States and, where applicable, to the applicant.

4. In duly justified cases, where the Authority requests additional information from the applicant, the nine-month period provided for in paragraph 1 may be extended.

After consulting the applicant, the Authority shall specify a period within which that additional information is to be provided and shall inform the Commission thereof.

Where the Commission does not object to the extension within eight working days of being informed by the Authority, the nine-month period provided for in paragraph 1 shall be automatically extended by that additional period. The Commission shall inform the Member States of that extension.

5. Where the additional information referred to in paragraph 4 is not provided to the Authority within the additional period referred to in that paragraph, the Authority shall draw up its opinion on the basis of the available information.

6. Where an applicant submits additional information on its own initiative, it shall send that information to the Authority.

In such cases, the Authority shall give its opinion within the nine-month period provided for in paragraph 1.

7. The Authority shall make the additional information provided in accordance with paragraphs 4 and 6 available to the Commission and to the Member States.

*Article 12*

**Authorisation of a novel food and updates of the Union list**

1. Within seven months from the date of publication of the Authority's opinion, the Commission shall submit to the committee referred to in Article 30(1) a draft implementing act authorising the placing on the market within the Union of a novel food and updating the Union list, taking into account the following:

(a) the conditions provided for in points (a) and (b) of Article 7 and, where applicable, in point (c) of that Article;

(b) any relevant provision of Union law, including the precautionary principle as referred to in Article 7 of Regulation (EC) No 178/2002;

(c) the Authority's opinion;

(d) any other legitimate factors relevant to the application under consideration.

That implementing act shall be adopted in accordance with the examination procedure referred to in Article 30(3).

2. Where the Commission has not requested an opinion from the Authority in accordance with Article 10(3), the seven-month period provided for in paragraph 1 of this Article shall start from the date on which a valid application is received by the Commission in accordance with Article 10(1).

*Article 13*

**Implementing acts laying down administrative and scientific requirements for applications**

By 1 January 2018, the Commission shall adopt implementing acts concerning:

(a) the content, drafting and presentation of the application referred to in Article 10(1);

(b) the arrangements for verifying the validity, without delay, of those applications;

(c) the type of information to be included in the opinion of the Authority referred to in Article 11.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(3).

*SECTION II*

***Specific rules for traditional foods from third countries***

*Article 14*

**Notification of a traditional food from a third country**

Instead of following the procedure referred to in Article 10, an applicant, who intends to place on the market within the Union a traditional food from a third country, may opt to submit a notification of that intention to the Commission.

The notification shall include the following information:

(a) the name and address of the applicant;

(b) the name and description of the traditional food;

(c) the detailed composition of the traditional food;

(d) the country or countries of origin of the traditional food;

(e) documented data demonstrating the history of safe food use in a third country;

(f) a proposal for the conditions of intended use and for specific labelling requirements, which do not mislead the consumer, or a verifiable justification why those elements are not necessary.

*Article 15*

**Procedure for notifying the placing on the market within the Union of a traditional food from a third country**

1. The Commission shall forward the valid notification provided for in Article 14 without delay, and not later than one month after having verified its validity, to the Member States and to the Authority.

2. Within four months from the date on which a valid notification is forwarded by the Commission in accordance with paragraph 1, a Member State or the Authority may submit to the Commission duly reasoned safety objections to the placing on the market within the Union of the traditional food concerned.

3. The Commission shall inform the applicant of any duly reasoned safety objection as soon as it is submitted. The Member States, the Authority and the applicant shall be informed of the outcome of the procedure referred to in paragraph 2.

4. Where no duly reasoned safety objections have been submitted in accordance with paragraph 2 within the time-limit laid down in that paragraph, the Commission shall authorise the placing on the market within the Union of the traditional food concerned and update the Union list without delay.

The entry in the Union list shall specify that it concerns a traditional food from a third country.

Where applicable, certain conditions for use, specific labelling requirements, or post-market monitoring requirements shall be specified.

5. Where duly reasoned safety objections have been submitted to the Commission in accordance with paragraph 2, the Commission shall not authorise the placing on the market within the Union of the traditional food concerned or update the Union list.

In that case, the applicant may submit an application to the Commission in accordance with Article 16.

*Article 16*

**Application for the authorisation of a traditional food from a third country**

Where the Commission, acting in accordance with Article 15(5), does not authorise the placing on the market within the Union of a traditional food from a third country or update the Union list, the applicant may submit an application including, in addition to the information already provided in accordance with Article 14, documented data relating to the duly reasoned safety objections submitted in accordance with Article 15(2).

The Commission shall, without delay, forward the valid application to the Authority and make it available to Member States.

*Article 17*

**Opinion of the Authority on a traditional food from a third country**

1. The Authority shall adopt its opinion within six months from the date of receipt of a valid application.

2. In assessing the safety of a traditional food from a third country, the Authority shall consider the following matters:

(a) whether the history of safe food use in a third country is substantiated by reliable data submitted by the applicant in accordance with Articles 14 and 16;

(b) whether the composition of the food and the conditions of its use do not pose a safety risk to human health in the Union;

(c) where the traditional food from the third country is intended to replace another food, whether it does not differ from that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer.

3. The Authority shall forward its opinion to the Commission, the Member States and the applicant.

4. In duly justified cases, where the Authority requests additional information from the applicant, the six-month period provided for in paragraph 1 may be extended.

After consulting the applicant, the Authority shall specify a period within which that additional information is to be provided and shall inform the Commission thereof.

Where the Commission does not object to the extension within eight working days of being informed by the Authority, the six-month period provided for in paragraph 1 shall be automatically extended by that additional period. The Commission shall inform the Member States of that extension.

5. Where the additional information referred to in paragraph 4 is not provided to the Authority within the additional period referred to in that paragraph, the Authority shall draw up its opinion on the basis of the available information.

6. Where an applicant submits additional information on its own initiative, it shall send that information to the Authority.

In such cases, the Authority shall give its opinion within the six-month period provided for in paragraph 1.

7. The Authority shall make the additional information provided in accordance with paragraphs 4 and 6 available to the Commission and to Member States.

*Article 18*

**Authorisation of a traditional food from a third country and updates of the Union list**

1. Within three months of the date of publication of the Authority's opinion, the Commission shall submit to the committee referred to in Article 30(1) a draft implementing act authorising the placing on the market within the Union of the traditional food from a third country and updating the Union list, taking into account the following:

(a) the conditions provided for in points (a) and (b) of Article 7 and, where applicable, point (c) of that Article;

(b) any relevant provision of Union law, including the precautionary principle as referred to in Article 7 of Regulation (EC) No 178/2002;

(c) the Authority's opinion;

(d) any other legitimate factors relevant to the application under consideration.

That implementing act shall be adopted in accordance with the examination procedure referred to in Article 30(3).

2. By way of derogation from paragraph 1, the Commission may terminate the procedure at any stage and decide not to proceed with an update where it considers that such an update is not justified.

In such case, where applicable, the Commission shall take account of the views of Member States, the Authority's opinion and any other legitimate factors relevant to the update under consideration.

The Commission shall inform the applicant and all Member States directly of the reasons for not considering the update to be justified.

3. The applicant may withdraw its application referred to in Article 16 at any time, thereby terminating the procedure.

*Article 19*

**Updates to the Union list as regards authorised traditional foods from third countries**

Articles 10 to 13 apply to removing a traditional food from a third country from the Union list or to adding, removing or changing specifications, conditions of use, additional specific labelling requirements or post-market monitoring requirements associated with the inclusion of a traditional food from a third country on the Union list.

*Article 20*

**Implementing acts laying down administrative and scientific requirements concerning traditional foods from third countries**

By 1 January 2018 the Commission shall adopt implementing acts concerning:

(a) the content, drafting and presentation of the notifications referred to in Article 14 and of applications referred to in Article 16;

(b) the arrangements for verifying the validity, without delay, of those notifications and applications;

(c) the arrangements for the exchange of information with the Member States and with the Authority for submitting duly reasoned safety objections as referred to in Article 15(2);

(d) the type of information to be included in the opinion of the Authority referred to in Article 17.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(3).

CHAPTER IV

**ADDITIONAL PROCEDURAL RULES AND OTHER REQUIREMENTS**

*Article 21*

**Additional information concerning risk management**

1. Where the Commission requests from an applicant additional information on matters concerning risk management, it shall determine, together with the applicant, the period within which that information is to be provided.

In such cases, the period provided for in Article 12(1) or (2) or in Article 18(1) may be extended accordingly. The Commission shall inform the Member States of that extension and shall make the additional information available to Member States once it has been received.

2. Where the additional information referred to in paragraph 1 is not received within the additional period referred to in that paragraph, the Commission shall act on the basis of the available information.

*Article 22*

**Ad hoc extension of time periods**

In exceptional circumstances, the Commission may extend the time periods provided for in Articles 11(1), 12(1) or (2), 17(1) and 18(1) on its own initiative or, where applicable, at the Authority's request, where the nature of the matter in question justifies an appropriate extension.

The Commission shall inform the applicant and the Member States of the extension and the reasons therefor.

*Article 23*

**Confidentiality of applications for updates of the Union list**

1. Applicants may request confidential treatment of certain information submitted under this Regulation where disclosure of such information may harm their competitive position.

2. For the purposes of paragraph 1, applicants shall indicate which parts of the information provided they wish to be treated as confidential and provide all the necessary details to substantiate their request for confidentiality. Verifiable justification shall be given in such cases.

3. After being informed of the Commission's position on the request, applicants may withdraw their application within three weeks, during which the confidentiality of the information provided shall be observed.

4. After expiry of the period referred to in paragraph 3, if an applicant has not withdrawn the application and in case of disagreement the Commission shall decide which parts of the information are to remain confidential and, in case a decision has been taken, notify the Member States and the applicant accordingly.

However, confidentiality shall not apply to the following information:

(a) the name and address of the applicant;

(b) the name and description of the novel food;

(c) the proposed conditions of use of the novel food;

(d) a summary of the studies submitted by the applicant;

(e) the results of the studies carried out to demonstrate the safety of the food;

(f) where appropriate, the analysis method(s);

(g) any prohibition or restriction imposed in respect of the food by a third country.

5. The Commission, the Member States and the Authority shall take necessary measures to ensure appropriate confidentiality of the information as referred to in paragraph 4 and received by them under this Regulation, except for information which is required to be made public in order to protect human health.

6. Where an applicant withdraws, or has withdrawn, its application, the Commission, the Member States and the Authority shall not disclose confidential information, including the information whose confidentiality is the subject of disagreement between the Commission and the applicant.

7. The application of paragraphs 1 to 6 shall not affect the exchange of information concerning the application between the Commission, the Member States and the Authority.

8. The Commission may, by means of implementing acts, adopt detailed rules on the implementation of paragraphs 1 to 6.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(3).

*Article 24*

**Post-market monitoring requirements**

The Commission may, for food safety reasons and taking into account the opinion of the Authority, impose post-market monitoring requirements. Such requirements may include, on a case-by-case basis, the identification of the relevant food business operators.

*Article 25*

**Additional information requirements**

Any food business operator which has placed a novel food on the market shall immediately inform the Commission of any information of which it has become aware concerning:

(a) any new scientific or technical information which might influence the evaluation of the safety of use of the novel food;

(b) any prohibition or restriction imposed by a third country in which the novel food is placed on the market.

The Commission shall make that information available to the Member States.

CHAPTER V

**DATA PROTECTION**

*Article 26*

**Authorisation procedure in case of data protection**

1. On request by the applicant, and where supported by appropriate and verifiable information included in the application provided for in Article 10(1), newly developed scientific evidence or scientific data supporting the application shall not be used for the benefit of a subsequent application during a period of five years from the date of the authorisation of the novel food without the agreement of the initial applicant.

2. The data protection shall be granted by the Commission under Article 27(1) where the following conditions are met:

(a) the newly developed scientific evidence or scientific data was designated as proprietary by the initial applicant at the time the first application was made;

(b) the initial applicant had exclusive right of reference to the proprietary scientific evidence or scientific data at the time the first application was made; and

(c) the novel food could not have been assessed by the Authority and authorised without the submission of the proprietary scientific evidence or scientific data by the initial applicant.

However, the initial applicant may agree with a subsequent applicant that such scientific evidence and scientific data may be used.

3. Paragraphs 1 and 2 shall not apply to notifications and applications concerning the placing on the market within the Union of traditional foods from third countries.

*Article 27*

**Authorisation of a novel food and inclusion in the Union list based on protected proprietary scientific evidence or scientific data**

1. Where a novel food is authorised and included in the Union list pursuant to Articles 10 to 12 based on proprietary scientific evidence or scientific data that are granted data protection as provided for in Article 26(1), the entry of that novel food in the Union list shall indicate, in addition to the information referred to in Article 9(3):

(a) the date of inclusion of the novel food in the Union list;

(b) the fact that that inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26;

(c) the name and address of the applicant;

(d) the fact that during the period of data protection the novel food is authorised for placing on the market within the Union only by the applicant specified in point (c) of this paragraph, unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 or with the agreement of the initial applicant;

(e) the end date of the data protection provided for in Article 26.

2. Scientific evidence or scientific data protected in accordance with Article 26 or for which the protection period under that Article has expired shall not be granted renewed protection.

*Article 28*

**Authorisation procedure in case of a parallel application for the authorisation of a health claim**

1. The Commission shall, on request by the applicant, stay an authorisation procedure for a novel food started following an application, where the applicant has submitted:

(a) a request for data protection in accordance with Article 26; and

(b) an application for the authorisation of a health claim on the same novel food in accordance with Article 15 or 18 of Regulation (EC) No 1924/2006, in conjunction with a request for data protection in accordance with Article 21 of that Regulation.

The stay of the authorisation procedure shall be without prejudice to the assessment of the food by the Authority in accordance with Article 11.

2. The Commission shall inform the applicant about the date of effect of the stay.

3. While the authorisation procedure is stayed, time shall cease to run for the purposes of the time-limit laid down in Article 12(1).

4. The authorisation procedure shall resume when the Commission has received the opinion of the Authority on the health claim pursuant to Regulation (EC) No 1924/2006.

The Commission shall inform the applicant about the date of resumption of the authorisation procedure. From the date of resumption, time shall begin to run afresh from the beginning for the purposes of the time-limit laid down in Article 12(1) of this Regulation.

5. In the cases referred to in paragraph 1 of this Article, where data protection has been granted in accordance with Article 21 of Regulation (EC) No 1924/2006, the period of data protection granted in accordance with Article 26 of this Regulation shall not exceed the period of data protection granted in accordance with Article 21 of Regulation (EC) No 1924/2006.

6. The applicant may withdraw at any time the request for staying the authorisation procedure submitted in accordance with paragraph 1. In that case, the authorisation procedure shall resume and paragraph 5 shall not apply.

CHAPTER VI

**PENALTIES AND GENERAL PROVISIONS**

*Article 29*

**Penalties**

Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by 1 January 2018 and shall notify it without delay of any subsequent amendment affecting them.

*Article 30*

**Committee procedure**

1. The Commission shall be assisted by the Standing Committee on Plants, Animals, Food and Feed established by Article 58(1) of Regulation (EC) No 178/2002. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011 of the European Parliament and of the Council ([1]).

([1]) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

Where the opinion of the committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the committee so decides or a simple majority of committee members so request.

3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the opinion of the committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the committee so decides or a simple majority of committee members so request.

Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.

*Article 31*

**Delegated acts**

For the purposes of achieving the objectives of this Regulation, the Commission shall, by means of delegated acts adopted in accordance with Article 32, adjust and adapt the definition of engineered nanomaterials referred to in point (f) of Article 3(2) to technical and scientific progress or to definitions agreed at international level.

*Article 32*

**Exercise of the delegation**

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. It is of particular importance that the Commission follow its usual practice and carry out consultations with experts, including Member States' experts, before adopting those delegated acts.

3. The power to adopt delegated acts referred to in Article 31 shall be conferred on the Commission for a period of five years from 31 December 2015. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

4. The delegation of power referred to in Article 31 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or on a later date specified therein. It shall not affect the validity of any delegated acts already in force.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 31 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and to the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

CHAPTER VII

**TRANSITIONAL MEASURES AND FINAL PROVISIONS**

*Article 33*

**Amendments to Regulation (EU) No 1169/2011**

Regulation (EU) No 1169/2011 is amended as follows:

(1) In Article 2(1) the following point is added:

'(h) the definition of "engineered nanomaterials" as established by point (f) of Article 3(2) of Regulation (EU) 2015/2283 of the European Parliament and of the Council (*).

(*) Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1).'.

(2) Point (t) of Article 2(2) is deleted.

References to the deleted point (t) of Article 2(2) of Regulation (EU) No 1169/2011 shall be construed as references to point (f) of Article 3(2) of this Regulation.

(3) In Article 18, paragraph 5 is deleted.

*Article 34*

**Repeal**

Regulation (EC) No 258/97 and Regulation (EC) No 1852/2001 are hereby repealed from 1 January 2018. References to Regulation (EC) No 258/97 shall be construed as references to this Regulation.

*Article 35*

**Transitional measures**

1. Any request for placing a novel food on the market within the Union submitted to a Member State in accordance with Article 4 of Regulation (EC) No 258/97 and for which the final decision has not been taken before 1 January 2018 shall be treated as an application under this Regulation.

The Commission shall not apply Article 11 of this Regulation, where a risk assessment has already been provided by a Member State on the basis of Regulation (EC) No 258/97 and no other Member State has raised any reasoned objection to that assessment.

2. Foods not falling within the scope of Regulation (EC) No 258/97, which are lawfully placed on the market by 1 January 2018 and which fall within the scope of this Regulation may continue to be placed on the market until a decision is taken in accordance with Articles 10 to 12 or Articles 14 to 19 of this Regulation following an application for authorisation of a novel food or a notification of a traditional food from a third country submitted by the date specified in the implementing rules adopted in accordance with Article 13 or 20 of this Regulation respectively, but no later than 2 January 2020.

3. The Commission may, by means of implementing acts, adopt measures concerning the requirements referred to in Articles 13 and 20 necessary for the application of paragraphs 1 and 2 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(3).

*Article 36*

**Entry into force**

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2018, except for the following provisions:

(a) Article 4(4), Articles 8, 13 and 20, Article 23(8), Article 30 and Article 35(3) shall apply from 31 December 2015;

(b) Article 4(2) and (3) shall apply from the date of application of the implementing acts referred to in Article 4(4);

(c) Article 5 shall apply from 31 December 2015. However, implementing acts adopted under Article 5 shall not apply before 1 January 2018;

(d) Articles 31 and 32 shall apply from 31 December 2015. However, delegated acts adopted under those Articles shall not apply before 1 January 2018.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 25 November 2015.

| *For the European Parliament* | *For the Council* |
|---|---|
| *The President* | *The President* |
| M. SCHULZ | N. SCHMIT |

**Annex E**

**List of Interested Parties**

Antrim and Newtownabbey Borough Council
Ards and North Down Borough Council
Armagh Banbridge and Craigavon Council
Asda
Asia Supermarket
Azora
Belfast City Council
Belfast Port Health
Camseng Oriental Food Suppliers
Causeway Coast & Glens Borough Council
Consumer Council
Co-operative
Costcutter
Curleys Supermarkets Ltd
Derry and Strabane Council
Dunnes Stores
Fermanagh and Omagh District Council
First Health
Forest Feast
Framar Health
Gilfresh
Golden Glen Catering
Hao Clinic
Henderson Group
Invest NI
James A. S. Finlay (Holdings) Ltd
Lidl
Linwoods
Lisburn and Castlereagh Council
Lynas Foodservice Ltd
Marks and Spencer
Mid & East Antrim Borough Council
Mid Ulster Council
Natural Health Products
Nature Trail
Newry Mourne and Down Council
NI Food and Drink Association
NI Supplements
Northern Ireland Retail Consortium
O'Kane Food Services
PASS
PatentNav Ireland Ltd
Pitman Berryhill
Quince Grove Fine Foods Ltd
Sawers
Scrabo Health Products
Skinny Malinky's
Tesco

**Annex E**

That Protein
The Real Health Store
Zest