

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)

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<sup>(1)</sup>,

Acting in accordance with the ordinary legislative procedure<sup>(2)</sup>,

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<sup>(3)</sup> and by Commission Regulation (EC) No 1852/2001<sup>(4)</sup>. Those rules need to be updated to simplify the current authorisation

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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<sup>(5)</sup>, food enzymes falling within the scope of Regulation (EC) No 1332/2008 of the European Parliament and of the Council<sup>(6)</sup>, food used solely as additives falling within the scope of Regulation (EC) No 1333/2008 of the European Parliament and of the Council<sup>(7)</sup>, food flavourings falling within the scope of Regulation (EC) No 1334/2008 of the European Parliament and of the Council<sup>(8)</sup> and extraction solvents falling within the scope of Directive 2009/32/EC of the European Parliament and of the Council<sup>(9)</sup> 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<sup>(10)</sup>.
- (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.

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- (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' is currently defined in Regulation (EU) No 1169/2011 of the European Parliament and of the Council<sup>(11)</sup>. 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<sup>(12)</sup> and Regulation (EC) No 1925/2006 of the European Parliament and of the Council<sup>(13)</sup> 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<sup>(14)</sup>, 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

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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.
- (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<sup>(15)</sup> 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.

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- (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.
- (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

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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<sup>(16)</sup>, 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.
- (32) In accordance with Directive 2010/63/EU of the European Parliament and of the Council<sup>(17)</sup>, 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.

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- (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<sup>(18)</sup> 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.

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- (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.
- (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

#### *[<sup>F1</sup>Article 1*

#### **Subject matter and purpose**

1 This Regulation lays down rules for novel foods placed on the market within Great Britain.

2 The purpose of this Regulation is to ensure a high level of protection of human health and consumers' interests.]

#### **Textual Amendments**

**F1** Art. 1 substituted (31.12.2020) by [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, 6 (as amended by [S.I. 2020/1504](#), regs. 1(2), 15(2)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#))

#### *Article 2*

#### **Scope**

1 This Regulation applies to the placing of novel foods on the market within [<sup>F2</sup>Great Britain].

- 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.

#### Textual Amendments

- F2** Words in Art. 2(1) substituted (31.12.2020) by S.I. 2019/702, reg. 7 (as substituted by The Food and Feed Hygiene and Safety (Miscellaneous Amendments etc.) (EU Exit) Regulations 2020 (S.I. 2020/1504), regs. 1(2), 15(3))

### 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 [<sup>F3</sup>“novel food” means any food that was not used for human consumption to a significant degree within the EU or the United Kingdom before 15 May 1997, irrespective of the dates of accession of member States, 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 [<sup>F4</sup>EU or the United Kingdom] 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 [<sup>F4</sup>EU or the United Kingdom] 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 [<sup>F4</sup>EU or the United Kingdom] before 15 May 1997; or
  - non-traditional propagating practices which have not been used for food production within the [<sup>F4</sup>EU or the United Kingdom] 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 [<sup>F4</sup>EU or the United Kingdom] before 15 May 1997 and the food from those animals has a history of safe food use within the [<sup>F4</sup>EU or the United Kingdom];
- (vi) food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, micro-organisms, fungi or algae;

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- (vii) food resulting from a production process not used for food production within the [F4EU or the United Kingdom] 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 [F4EU or the United Kingdom] 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 [F4EU or the United Kingdom] 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;
- [F5d “the applicant” means the third country or the interested party;]
- 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.
- [F6g “third country” means any country or territory other than the British Islands;
- h “prescribe” means prescribe by regulations;
- i “appropriate authority” means—
- i in relation to England, the Secretary of State;
  - ii in relation to Wales, the Welsh Ministers;

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- iii in relation to Scotland, the Scottish Ministers;
- j “Food Safety Authority” means—
  - i as regards England and Wales, the Food Standards Agency;
  - ii as regards Scotland, Food Standards Scotland;
- k “list” means the list referred to in Article 6(1).]

#### Textual Amendments

- F3** Words in Art. 3(2)(a) substituted (31.12.2020) by The Novel Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/702), regs. 1, **8(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F4** Words in Art. 3(2) substituted (31.12.2020) by The Novel Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/702), regs. 1, **8(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F5** Art. 3(2)(d) substituted (31.12.2020) by The Novel Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/702), regs. 1, **8(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F6** Art. 3(2)(g)-(k) inserted (31.12.2020) by The Novel Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/702), regs. 1, **8(a)(iii)** (as amended by S.I. 2020/1504, regs. 1(2), **15(4)**); 2020 c. 1, **Sch. 5 para. 1(1)**

### *I<sup>F7</sup>* Article 4

#### Procedure for determination of novel food status

1 Food business operators must verify whether or not the food which they intend to place on the market within Great Britain 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 Great Britain falls within the scope of this Regulation, food business operators must consult the Food Safety Authority. Food business operators must provide the necessary information to the Food Safety Authority to enable it to determine whether or not a food falls within the scope of this Regulation.]

#### Textual Amendments

- F7** Art. 4 substituted (31.12.2020) by The Novel Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/702), regs. 1, **9** (as amended by S.I. 2020/1504, regs. 1(2), **15(5)**); 2020 c. 1, **Sch. 5 para. 1(1)**

### *I<sup>F8</sup>* Article 5

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

The appropriate authority may prescribe that a particular food is a novel food within the meaning of this Regulation.]

#### Textual Amendments

- F8** Art. 5 substituted (31.12.2020) by The Novel Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/702), regs. 1, **10**; 2020 c. 1, Sch. 5 para. 1(1)

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## CHAPTER II

### REQUIREMENTS FOR PLACING NOVEL FOODS ON THE MARKET WITHIN [F<sup>9</sup>GREAT BRITAIN]

#### [F<sup>10</sup>Article 6

#### List of authorised novel foods

1 The appropriate authority must establish and update a list of novel foods authorised to be placed on the market within the constituent territory of Great Britain in accordance with Articles 7 and 9.

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

#### Textual Amendments

**F10** Art. 6 substituted (31.12.2020) by [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, **12** (as amended by [S.I. 2020/1504](#), regs. 1(2), **15(7)**); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

#### Article 7

#### General conditions for inclusion of novel foods in the F<sup>11</sup>..... list

The [F<sup>12</sup>appropriate authority must] only authorise and include a novel food in the F<sup>13</sup>... 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.

#### Textual Amendments

**F11** Word in [Art. 7](#) heading omitted (31.12.2020) by virtue of [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, **13(a)**; 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

**F12** Words in [Art. 7](#) substituted (31.12.2020) by [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, **13(b)**; 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

**F13** Word in [Art. 7](#) omitted (31.12.2020) by virtue of [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, **13(a)**; 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2015/2283 of the European Parliament and of the Council. (See end of Document for details)*

## <sup>F14</sup>Article 8

### Initial establishment of the Union list

#### Textual Amendments

- F14** Art. 8 omitted (31.12.2020) by virtue of [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, **14**; 2020 c. 1, Sch. 5 para. 1(1)

## Article 9

### Content and updating of the <sup>F15</sup>... list

- 1 The [<sup>F16</sup>appropriate authority must] authorise a novel food and update the <sup>F17</sup>... list in accordance with the rules laid down in:
- Articles 10, 11 and 12 and, where applicable, Article 27; or
  - Articles 14 to 19.
- 2 The authorisation of a novel food and updating of the <sup>F17</sup>... list provided for in paragraph 1 shall consist of one of the following:
- adding a novel food to the <sup>F17</sup>... list;
  - removing a novel food from the <sup>F17</sup>... list;
  - 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 <sup>F17</sup>... list.
- 3 The entry for a novel food in the <sup>F17</sup>... list provided for in paragraph 2 shall include the specification of the novel food and, where appropriate:
- 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;
  - 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;
  - post-market monitoring requirements in accordance with Article 24.

#### Textual Amendments

- F15** Word in Art. 9 heading omitted (31.12.2020) by virtue of [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, **15(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F16** Words in Art. 9(1) substituted (31.12.2020) by [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, **15(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F17** Word in Art. 9 omitted (31.12.2020) by virtue of [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, **15(a)**; 2020 c. 1, Sch. 5 para. 1(1)

*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2015/2283 of the European Parliament and of the Council. (See end of Document for details)*

#### Textual Amendments

- F9** Words in **Ch. 2** title substituted (31.12.2020) by **The Novel Food (Amendment) (EU Exit) Regulations 2019** (S.I. 2019/702), regs. 1, **11** (as substituted by S.I. 2020/1504, regs. 1(2), **15(6)**); 2020 c. 1, **Sch. 5 para. 1(1)**

## CHAPTER III

### AUTHORISATION PROCEDURES FOR A NOVEL FOOD

#### SECTION I

#### General rules

#### <sup>F18</sup> Article 10

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

1 The procedure for authorising the placing on the market within Great Britain of a novel food and updating the list provided for in Article 9 must start either on the initiative of the appropriate authority or following an application to the appropriate authority by an applicant. The appropriate authority must 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 must include—

- the name and address of the applicant;
- the name and description of the novel food;
- the description of the production process;
- the detailed composition of the novel food;
- scientific evidence demonstrating that the novel food does not pose a safety risk to human health;
- where appropriate, the analysis method;
- 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 appropriate authority, the Food Safety Authority must 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 must 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 Great Britain of a novel food and updating the list as provided for in Article 9 ends when the appropriate authority prescribes an update of the list in respect of that novel food in accordance with Article 12.

*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2015/2283 of the European Parliament and of the Council. (See end of Document for details)*

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

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

#### Textual Amendments

**F18** Art. 10 substituted (31.12.2020) by The Novel Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/702), regs. 1, 16 (as amended by S.I. 2020/1504, regs. 1(2), 15(5)); 2020 c. 1, Sch. 5 para. 1(1)

### *[<sup>F19</sup>Article 11*

#### **Opinion of the Food Safety Authority**

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

2 In assessing the safety of novel foods, the Food Safety Authority must, 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 Great Britain;
- b the composition of the novel food and the conditions of its use do not pose a safety risk to human health in Great Britain;
- 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 Food Safety Authority must forward its opinion to the appropriate authority and, where applicable, to the applicant.

4 In duly justified cases, where the Food Safety Authority requests additional information from the applicant, the nine month period provided for in paragraph 1 may be extended. After consulting the applicant, the Food Safety Authority must specify a period within which that additional information is to be provided.

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

6 Where an applicant submits additional information on its own initiative, it must send that information to the Food Safety Authority. In such cases, the Food Safety Authority must give its opinion within the nine month period provided for in paragraph 1.

7 The Food Safety Authority must make the additional information provided in accordance with paragraphs 4 and 6 available to the appropriate authority.]

*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2015/2283 of the European Parliament and of the Council. (See end of Document for details)*

#### Textual Amendments

**F19** Art. 11 substituted (31.12.2020) by [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/702), regs. 1, **17** (as amended by S.I. 2020/1504, regs. 1(2), **15(5)**); 2020 c. 1, **Sch. 5 para. 1(1)**

### <sup>F20</sup> Article 12

#### Authorisation of a novel food and updates of the list

1 Within seven months from the date of publication of the Food Safety Authority's opinion, the appropriate authority must, by prescribing an update of the list, authorise the placing on the market within Great Britain of a novel food, 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 retained direct EU legislation, including the precautionary principle as referred to in Article 7 of Regulation [\(EC\) No. 178/2002](#);
- c the Food Safety Authority's opinion;
- d any other legitimate factors relevant to the application under consideration.

2 Where the appropriate authority has not requested an opinion from the Food Safety Authority in accordance with Article 10(3), the seven month period provided for in paragraph 1 of this Article starts from the date on which the valid application is received by the appropriate authority in accordance with Article 10(1).]

#### Textual Amendments

**F20** Art. 12 substituted (31.12.2020) by [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/702), regs. 1, **18** (as amended by S.I. 2020/1504, regs. 1(2), **15(5)**); 2020 c. 1, **Sch. 5 para. 1(1)**

### Article 13

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

F21

#### Textual Amendments

**F21** Art. 13 omitted (31.12.2020) by virtue of [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/702), regs. 1, **19**; 2020 c. 1, Sch. 5 para. 1(1)



*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2015/2283 of the European Parliament and of the Council. (See end of Document for details)*

## 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 [<sup>F22</sup>Great Britain] a traditional food from a third country, may opt to submit a notification of that intention to the [<sup>F23</sup>appropriate authority].

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.

#### **Textual Amendments**

- F22** Words in Art. 14 substituted (31.12.2020) by [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, **20(a)** (as substituted by [S.I. 2020/1504](#), regs. 1(2), **15(8)**); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F23** Words in Art. 14 substituted (31.12.2020) by [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, **20(b)**; 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

#### <sup>F24</sup>Article 15

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

1 The appropriate authority must forward the valid notification provided for in Article 14 without delay, and not later than one month after having verified its validity, to the Food Safety Authority.

2 Within four months from the date on which a valid notification under Article 14 is received by the appropriate authority, the Food Safety Authority may issue to the appropriate authority duly reasoned safety objections to the placing on the market within Great Britain of the traditional food concerned.

3 The appropriate authority must inform the applicant of any duly reasoned safety objection as soon as it is issued.

*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2015/2283 of the European Parliament and of the Council. (See end of Document for details)*

4 Where no duly reasoned safety objections have been issued in accordance with paragraph 2 within the time limit laid down in that paragraph, the appropriate authority must authorise the placing on the market within Great Britain of the traditional food concerned by prescribing an update to the list without delay. The entry in the list must 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 may be specified.

5 Where duly reasoned safety objections have been issued in accordance with paragraph 2, the appropriate authority must not authorise the placing on the market within Great Britain of the traditional food concerned or update the list. In that case, the applicant may submit an application to the appropriate authority in accordance with Article 16].

#### Textual Amendments

**F24** Art. 15 substituted (31.12.2020) by [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, **21** (as amended by [S.I. 2020/1504](#), regs. 1(2), **15(5)**); 2020 c. 1, **Sch. 5 para. 1(1)**

### *f<sup>F25</sup> Article 16*

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

Where the appropriate authority does not authorise the placing on the market within Great Britain of a traditional food from a third country, 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 issued in accordance with Article 15(2). The appropriate authority must, without delay, forward the valid application to the Food Safety Authority.]

#### Textual Amendments

**F25** Art. 16 substituted (31.12.2020) by [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, **22** (as amended by [S.I. 2020/1504](#), regs. 1(2), **15(5)**); 2020 c. 1, **Sch. 5 para. 1(1)**

### *f<sup>F26</sup> Article 17*

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

1 The Food Safety Authority must 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 Food Safety Authority must 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 Great Britain;
- 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.

*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2015/2283 of the European Parliament and of the Council. (See end of Document for details)*

3 The Food Safety Authority must forward its opinion to the appropriate authority and the applicant.

4 In duly justified cases, where the Food Safety Authority requests additional information from the applicant, the six month period provided for in paragraph 1 may be extended. After consulting the applicant, the Food Safety Authority must specify a period within which that additional information is to be provided and the six month period provided for in paragraph 1 is extended by that additional period.

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

6 Where an applicant submits additional information on its own initiative, it must send that information to the Food Safety Authority. In such cases, the Food Safety Authority must give its opinion within the six month period provided for in paragraph 1.

7 The Food Safety Authority must make the additional information provided in accordance with paragraphs 4 and 6 available to the appropriate authority.]

#### Textual Amendments

**F26** Art. 17 substituted (31.12.2020) by [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, **23** (as amended by [S.I. 2020/1504](#), regs. 1(2), **15(5)**); 2020 c. 1, **Sch. 5 para. 1(I)**

### *f<sup>F27</sup> Article 18*

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

1 Within three months of the date of publication of the Food Safety Authority's opinion, the appropriate authority must authorise the placing on the market within Great Britain of the traditional food from a third country by prescribing an update of the 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 law, including the precautionary principle as referred to in Article 7 of Regulation [\(EC\) No. 178/2002](#);
- c the Food Safety Authority's opinion;
- d any other legitimate factors relevant to the application under consideration.

2 By way of derogation from paragraph 1, the appropriate authority may, having taken account of the Food Safety Authority's opinion and any other legitimate factors relevant to the update under consideration, terminate the procedure at any stage and decide not to proceed with an update of the list where it considers that such an update is not justified. The appropriate authority must inform the applicant 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.]

*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2015/2283 of the European Parliament and of the Council. (See end of Document for details)*

#### Textual Amendments

**F27** Art. 18 substituted (31.12.2020) by [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, **24** (as amended by [S.I. 2020/1504](#), regs. 1(2), **15(5)**); 2020 c. 1, **Sch. 5 para. 1(1)**)

#### Article 19

#### Updates to the <sup>F28</sup>... 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 <sup>F29</sup>... 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 <sup>F29</sup>... list.

#### Textual Amendments

**F28** Word in Art. 19 heading omitted (31.12.2020) by virtue of [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, **25**; 2020 c. 1, Sch. 5 para. 1(1)

**F29** Word in Art. 19 omitted (31.12.2020) by virtue of [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, **25**; 2020 c. 1, Sch. 5 para. 1(1)

#### <sup>F30</sup>Article 20

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

#### Textual Amendments

**F30** Art. 20 omitted (31.12.2020) by virtue of [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, **26**; 2020 c. 1, Sch. 5 para. 1(1)

### CHAPTER IV

## ADDITIONAL PROCEDURAL RULES AND OTHER REQUIREMENTS

#### <sup>F31</sup>Article 21

#### Additional information concerning risk management

1 Where the appropriate authority requests from an applicant additional information on matters concerning risk management, the appropriate authority must 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.

*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2015/2283 of the European Parliament and of the Council. (See end of Document for details)*

2 Where the additional information referred to in paragraph 1 is not received within the additional period referred to in that paragraph, the appropriate authority must act on the basis of the available information.]

#### Textual Amendments

**F31** Art. 21 substituted (31.12.2020) by [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, **27**; 2020 c. 1, Sch. 5 para. 1(1)

### *l<sup>F32</sup> Article 22*

#### Extension of time periods

In exceptional circumstances, the appropriate authority 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 Food Safety Authority's request, where the nature of the matter in question justifies an appropriate extension.]

#### Textual Amendments

**F32** Art. 22 substituted (31.12.2020) by [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, **28**; 2020 c. 1, Sch. 5 para. 1(1)

### *l<sup>F33</sup> Article 23*

#### Confidentiality of applications for updates of the 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 must 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 must be given in such cases.

3 After being informed of the appropriate authority's position on the request, applicants may withdraw their application within three weeks, during which the confidentiality of the information provided must 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 appropriate authority must decide which parts of the information are to remain confidential and notify the applicant accordingly. However, the following information is not confidential—

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

*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2015/2283 of the European Parliament and of the Council. (See end of Document for details)*

5 The appropriate authority and the Food Safety Authority must 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 appropriate authority and the Food Safety Authority must not disclose confidential information, including the information whose confidentiality is the subject of disagreement between the appropriate authority and the applicant.

7 The application of paragraphs 1 to 6 does not restrict the exchange of information concerning the application between the appropriate authority and the Food Safety Authority.

8 The appropriate authority may prescribe rules for the implementation of paragraphs 1 to 6.]

#### Textual Amendments

**F33** Art. 23 substituted (31.12.2020) by [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, **29**; 2020 c. 1, Sch. 5 para. 1(1)

### Article 24

#### Post-market monitoring requirements

The [<sup>F34</sup>appropriate authority] 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.

#### Textual Amendments

**F34** Words in Art. 24 substituted (31.12.2020) by [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, **30**; 2020 c. 1, Sch. 5 para. 1(1)

### <sup>F35</sup> Article 25

#### Additional information requirements

Any food business operator which has placed a novel food on the market must immediately inform the Food Safety Authority 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.]

**Textual Amendments**

- F35** Art. 25 substituted (31.12.2020) by [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, **31**; 2020 c. 1, Sch. 5 para. 1(1)

## 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 [<sup>F36</sup>appropriate authority] 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 [<sup>F37</sup>Great Britain] of traditional foods from third countries.

**Textual Amendments**

- F36** Words in Art. 26(2) substituted (31.12.2020) by [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, **32(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F37** Words in Art. 26(3) substituted (31.12.2020) by [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, **32(b)** (as substituted by S.I. 2020/1504, regs. 1(2), **15(9)**); 2020 c. 1, **Sch. 5 para. 1(1)**

*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2015/2283 of the European Parliament and of the Council. (See end of Document for details)*

## <sup>F38</sup> Article 27

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

1 Where a novel food is authorised and included in the 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 list must indicate, in addition to the information referred to in Article 9(3)—

- a the date of inclusion of the novel food in the 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 Great Britain 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 is not to be granted renewed protection.]

#### **Textual Amendments**

**F38** Art. 27 substituted (31.12.2020) by [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, 33 (as amended by [S.I. 2020/1504](#), regs. 1(2), 15(5)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#))

## Article 28

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

1 The [<sup>F39</sup>appropriate authority must], 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 [<sup>F40</sup>Food Safety Authority] in accordance with Article 11.

2 The [<sup>F39</sup>appropriate authority must] 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).



*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2015/2283 of the European Parliament and of the Council. (See end of Document for details)*

4 The authorisation procedure shall resume when [<sup>F41</sup>the opinion has been received] on the health claim pursuant to Regulation (EC) No 1924/2006.

The [<sup>F39</sup>appropriate authority must] 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.

#### Textual Amendments

- F39** Words in Art. 28 substituted (31.12.2020) by [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, **34(a)** (as substituted by S.I. 2020/1504, regs. 1(2), **15(10)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F40** Words in Art. 28(1) substituted (31.12.2020) by [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, **34(b)** (as substituted by S.I. 2020/1504, regs. 1(2), **15(10)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F41** Words in Art. 28(4) substituted (31.12.2020) by [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, **reg. 34(c)** (as substituted by S.I. 2020/1504, regs. 1(2), **15(10)**); 2020 c. 1, **Sch. 5 para. 1(1)**

## CHAPTER VI

### PENALTIES AND GENERAL PROVISIONS

#### <sup>F42</sup>Article 29

##### Penalties

#### Textual Amendments

- F42** Art. 29 omitted (31.12.2020) by virtue of [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, **35**; 2020 c. 1, Sch. 5 para. 1(1)

#### <sup>F43</sup>Article 30

##### Committee procedure

*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2015/2283 of the European Parliament and of the Council. (See end of Document for details)*

#### Textual Amendments

**F43** Art. 30 omitted (31.12.2020) by virtue of [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/702), regs. 1, **35**; 2020 c. 1, Sch. 5 para. 1(1)

### *[<sup>F44</sup> Article 31*

#### **Engineered nanomaterials**

For the purposes of achieving the objectives of this Regulation, the appropriate authority may prescribe changes to the definition of engineered nanomaterials referred to in point (f) of Article 3(2) to reflect technical and scientific progress or definitions agreed at international level.]

#### Textual Amendments

**F44** Art. 31 substituted (31.12.2020) by [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/702), regs. 1, **36**; 2020 c. 1, Sch. 5 para. 1(1)

### *<sup>F45</sup> Article 32*

#### **Exercise of the delegation**

#### Textual Amendments

**F45** Art. 32 omitted (31.12.2020) by virtue of [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/702), regs. 1, **37**; 2020 c. 1, **Sch. 5 para. 1(1)**

### *[<sup>F46</sup> Article 32A*

#### **Regulations and devolved powers**

- 1 Any power to make regulations under this Regulation—
  - (a) so far as exercisable by a Minister of the Crown, is exercisable by statutory instrument;
  - (b) so far as exercisable by the Welsh Ministers, is exercisable by statutory instrument.
- 2 For regulations made under this Regulation by the Scottish Ministers, see also section 27 of the Interpretation and Legislative Reform (Scotland) Act 2010 (Scottish statutory instruments).
- 3 Any power to make regulations under this Regulation includes power—
  - (a) to make different provision in relation to different cases or classes of case (including different provision for different areas or different classes of business); and
  - (b) to provide for such exceptions, limitations and conditions, and to make such supplementary, incidental, consequential or transitional provisions, as the appropriate authority considers necessary or expedient.

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*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2015/2283 of the European Parliament and of the Council. (See end of Document for details)*

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4 Any statutory instrument or Scottish statutory instrument containing regulations made under this Regulation is subject to annulment in pursuance of a resolution—

- (a) in the case of England, of either House of Parliament;
- (b) in the case of Wales, of Senedd Cymru;
- (c) in the case of Scotland, of the Scottish Parliament.

5 In this Regulation, any power—

- (a) of the Secretary of State to make regulations is limited to regulations which apply in relation to England only;
- (b) of the Welsh Ministers to make regulations is limited to regulations which apply in relation to Wales only;
- (c) of the Scottish Ministers to make regulations is limited to regulations which apply in relation to Scotland only.]

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**Textual Amendments**

**F46** Art. 32A inserted (31.12.2020) by [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, **38** (as amended by [S.I. 2020/1504](#), regs. 1(2), **15(11)**); 2020 c. 1, [Sch. 5 para. 1\(1\)](#))

## 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<sup>(19)</sup>..
- (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.

*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2015/2283 of the European Parliament and of the Council. (See end of Document for details)*

## Article 35

### Transitional measures

F47<sup>1</sup> .....

[<sup>F48</sup>2 A novel food, which is the subject of an application for authorisation submitted in accordance with Article 10, and which is received by the appropriate authority on or before 31 December 2023, may remain on the market in Great Britain until the application concludes, if—

- a it did not fall within scope of Regulation (EC) No 258/97 before that Regulation was repealed;
- b it was lawfully placed on the market in the European Union or the United Kingdom before 1 January 2018; and
- c it was the subject of an application for authorisation or notification of a traditional food from a third country received by the European Commission on or before 1 January 2019.

2A. For the purpose of paragraph 2, an application concludes when—

- a the appropriate authority informs the applicant, in accordance with Article 6(5) of Commission Implementing Regulation (EU) 2017/2469, that the application is not considered valid;
- b the appropriate authority terminates the procedure in accordance with Article 10(6);
- c the applicant withdraws the application; or
- d the list established in Commission Implementing Regulation (EU) 2017/2470 is updated to authorise the novel food in accordance with Article 12(1) of this Regulation.]

F49<sup>3</sup> .....

#### Textual Amendments

- F47** Art. 35(1) omitted (31.12.2022) by virtue of [The Food and Feed \(Miscellaneous Amendments\) Regulations 2022 \(S.I. 2022/1351\)](#), regs. 1(1), **20(a)**
- F48** Art. 35(2)(2A) substituted for Art. 35(2) (31.12.2022) by [The Food and Feed \(Miscellaneous Amendments\) Regulations 2022 \(S.I. 2022/1351\)](#), regs. 1(1), **20(b)**
- F49** Art. 35(3) omitted (31.12.2022) by virtue of [The Food and Feed \(Miscellaneous Amendments\) Regulations 2022 \(S.I. 2022/1351\)](#), regs. 1(1), **20(c)**

## 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);

*Status: Point in time view as at 31/12/2022.*

**Changes to legislation:** *There are currently no known outstanding effects for the Regulation (EU) 2015/2283 of the European Parliament and of the Council. (See end of Document for details)*

- (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.

F50  
...

Done at Strasbourg, 25 November 2015.

*For the European Parliament*

*The President*

M. SCHULZ

*For the Council*

*The President*

N. SCHMIT

#### **Textual Amendments**

**F50** Words in [Signature](#) omitted (31.12.2020) by virtue of [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, [39](#); 2020 c. 1, Sch. 5 para. 1(1)

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*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2015/2283 of the European Parliament and of the Council. (See end of Document for details)*

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- (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.](#))
- (5) 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.](#))
- (6) 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.](#))
- (7) 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.](#))
- (8) 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.](#))
- (9) 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.](#))
- (10) 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.](#))
- (11) 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.](#))
- (12) 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.](#))
- (13) 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.](#))
- (14) 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.](#))
- (15) 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.](#))
- (16) 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.](#))
- (17) 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.](#))

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**Status:** Point in time view as at 31/12/2022.

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EU) 2015/2283 of the European Parliament and of the Council. (See end of Document for details)

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- (18) 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](#)).
- (19) 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](#)).

**Status:**

Point in time view as at 31/12/2022.

**Changes to legislation:**

There are currently no known outstanding effects for the Regulation (EU) 2015/2283 of the European Parliament and of the Council.