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

(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’ is currently defined in Regulation (EU) No 1169/2011 of the European Parliament and of the Council[(11)]. 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[(12)] and Regulation (EC) No 1925/2006 of the European Parliament and of the Council[(13)] 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[(14)], 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.

(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[(15)] 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.

(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[16], 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[17], 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[(18)] 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.

(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:

(**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).

(**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).

Changes to legislation:
There are outstanding changes not yet made to Regulation (EU) 2015/2283 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to the whole legislation item and associated provisions

– Art. 32A(4)(d) words substituted by S.I. 2019/1013 reg. 101 (This amendment not applied to legislation.gov.uk. S.I. 2019/1013 revoked immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 21(e))