Novel Foods in the EU Integrated Administrative Space: An Institutional Perspective

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Abstract Paying particular attention to the institutional dimension of the EU legal framework for the placing on the market of Novel Foods, this chapter examines the main elements of Regulation 2015/2283, including the definition of Novel Food, the objectives of the legislative measure, and the procedure for the authorisation of Novel Foods. The analysis focuses especially on the roles of the diverse actors involved, and on the Regulation's collocation in the broader context of EU food law and European integrated administration.

Keywords Novel foods · European Administration · Comitology · EFSA · Risk regulation

1 Introduction

The regulation of new technologies constitutes a daunting challenge for policymakers and regulators. The changes brought by innovation hold great potential to enhance prosperity and sustainability for society, but they may also entail significant risks and potential adverse effects for citizens.[1] Regulatory approaches in this context, thus, require a sensible balance between fostering innovation, protecting consumers, and addressing the potential unintended consequences of disruption. This balance is particularly delicate in the field of Novel Food technologies where a vast array of conflicting values, including scientific, economic, traditional, ethical and environmental instances, are inherently interlinked with cultural sensibilities and consumer perceptions on what is safe to be consumed.

Defining a regulatory framework which can unlock the potential of food technology and innovation while safeguarding high food safety standards may prove to be a complex legislative endeavour. Arguably, the success of the regulatory approach

[1] Neuwirth (2014), p. 44.

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requires not only the adoption of substantive provisions which enshrine a careful consideration of all the legitimate interests in question, but also procedural mechanisms able to include and reconcile divergent instances within the actual decision-making. Therefore, especially in the EU multi-layered institutional landscape, governance design and its articulation across different levels is of particular importance. It should accommodate and prevent the potential tensions between the EU institutions and the Member States, thus touching upon crucial issues of institutional balance in the EU legal system.[2] At the same time, a successful structure entails clear definition of the role of science and of expertise in the adoption of decisions which will have social, environmental and moral implications.

Paying particular attention to this institutional dimension of the regulatory framework, this chapter will describe the main elements of the regulation of Novel Foods in the EU, including the definition of Novel Food, the objective of the legislative measures (Sect. 2) and the procedure for the authorisation of Novel Foods (Sect. 3). The analysis will focus especially on the evolution of this procedure, reflecting on the role of the diverse actors involved and in its collocation in the broader context of the European space of integrated administration (Sect. 4). More substantive regulatory issues,[3] and in particular the specific issue of the authorisation of edible insects as Novel Foods,[4] will be addressed more in detail in other chapters of this volume.

2 Regulating Novel Foods in the Internal Market

2.1 The Definition of Novel Foods

The EU legislator has undertaken the challenge of regulating Novel Food technologies for the first time in the adoption of Regulation (EC) 258/97, which subjected the marketing of 'Novel Foods' in the EU territory to the granting of a specific authorisation by the competent authorities.[5] Novel Foods were defined as "foods and food ingredients which have not hitherto been used for human consumption to a significant degree within the Community" and which belonged to one of the ten categories listed in Article 1.[6] These categories included foods and food ingredients

[2] For a Member-State oriented understanding of institutional balance, see Vos (1997), p. 223. See also Gormley (2004), pp. 40–41.

[3] In particular, see *A Peculiar Category of Novel Foods: Traditional Foods Coming from Third Countries and the Regulatory Issues Involving Sustainability, Food Security, Food Safety, and the Free Circulation of Goods* by L. Scaffardi in this volume.

[4] See *Legislative and Judicial Challenges on Insects for Human Consumption: From Member States to the EU, Passing Through the Court of Justice of the EU* by G. Formici in this volume.

[5] Regulation (EC) 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients.

[6] The categories were specifically: (a) foods and food ingredients containing or consisting of genetically modified organisms within the meaning of Directive 90/220/EEC; (b) foods and food

containing or consisting of genetically modified organisms (GMOs), which were later regulated in a separate legislative act.[7] The two components of the definition were cumulative and were to be assessed by the Member States' authorities.[8] The wording of the definition, however, presented relevant ambiguities which gave rise to significant litigation before the Court of Justice of the EU (CJEU).[9] The interpretation of the concepts determining the scope of application and effects of the different procedures required several interventions by the CJEU, and not only. The rapid developments in food technologies[10] and international trade[11] soon called for the reform of a regulatory framework which increasingly appeared fragmented and outdated.[12]

After the failure in the adoption of the legislative proposal presented by the European Commission in 2008,[13] the EU legislator enacted Regulation (EU) 2015/2283 which represents the legislative framework currently in force.[14] This Regulation maintains a definition of Novel Food composed of two elements. On the one

ingredients produced from, but not containing, genetically modified organisms; (c) foods and food ingredients with a new or intentionally modified primary molecular structure; (d) foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae; (e) foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use; (f) foods and food ingredients to which a production process not currently used has been applied, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances.

[7] Regulation (EC) 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. Also, enzymes are now separately regulated Regulation (EC) 1332/2008 of the European Parliament and of the Council on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) 258/97.

[8] CJ Judgment (14 April 2011) Case C-327/09 *Mensch und Natur AG v. Freistaat Bayern*, para. 31. See also Klaus (2011), p. 190.

[9] For instance, on the notion of significant degree, see CJ Judgement (15 January 2009) Case C-383/07 *M-K Europa GmbH & Co. KG v. Stadt Regensburg*, para. 26; on substantial equivalence, CJ Judgement (9 September 2003) Case C-236/01 *Monsanto Agricoltura Italia SpA and Others v. Italy*, para.77; on the scope of the authorisation, CJ Judgment (14 April 2011) Case C-327/09 *Mensch und Natur AG v. Freistaat Bayern*.

[10] See Salmon (2009), pp. 97–115; Van Der Meulen (2009), pp. 37–57.

[11] On the tension between Regulation 1997 and the WTO framework, see Marine (2013), p. 104; Downes (2013), p. 307; Streinz (1998), pp. 265–289; Bronckers and Soopramanien (2008), pp. 361–375.

[12] European Commission, Evaluation Report on the Novel Food Regulation 258/97 Concerning Novel Foods and Food Ingredients, 22 January 2004.

[13] Proposal for a Regulation of the European Parliament and of the Council on novel foods and amending Regulation (EC) No XXX/XXXX [common procedure], COM(2007) 872 final.

[14] 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) 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001.

hand, Novel Food is "any food that was not used for human consumption to a significant degree within the Union before 15 May 1997", thus keeping the day of the entry into force of Regulation (EC) 258/97 as a chronological reference in the new legislative framework.[15] On the other hand, the scope of the regime includes only those Novel Foods which fall into one of the ten updated categories.[16] They include not only products derived from the deployment of innovative food technologies, such as nanotechnologies, cell culture or tissue culture, but also products from animals obtained by non-traditional breeding practices. The latter comprises insects[17] and, in the absence of a specific regulation, cloned animals.[18]

[15] See CJ Judgement (9 June 2005) Joined Cases C-211/03, C-299/03, C-316/03, C-317/03 and C-318/03 *HLH Warenvertriebs GmbH et Orthica BV v. Bundesrepublik Deutschland*, para. 87.

[16] Art. 3 (2) of Regulation (EU) 2015/2283: "(i) food with a new or intentionally modified molecular structure, where that structure was not used as, or in, a food within the Union before 15 May 1997; (ii) food consisting of, isolated from or produced from microorganisms, fungi or algae; (iii) food consisting of, isolated from or produced from material of mineral origin; (iv) food consisting of, isolated from or produced from plants or their parts, except when the food has a history of safe food use within the Union and is consisting of, isolated from or produced from a plant or a variety of the same species obtained by: traditional propagating practices which have been used for food production within the Union before 15 May 1997; or non-traditional propagating practices which have not been used for food production within the Union before 15 May 1997, where those practices do not give rise to significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances; (v) food consisting of, isolated from or produced from animals or their parts, except for animals obtained by traditional breeding practices which have been used for food production within the Union before 15 May 1997 and the food from those animals has a history of safe food use within the Union; (vi) food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, microorganisms, fungi or algae; (vii) food resulting from a production process not used for food production within the Union before 15 May 1997, which gives rise to significant changes in the composition or structure of a food, affecting its nutritional value, metabolism or level of undesirable substances; (viii) food consisting of engineered nanomaterials as defined in point (f) of this paragraph; (ix) vitamins, minerals and other substances used in accordance with Directive 2002/46/EC, Regulation (EC) No 1925/2006 or Regulation (EU) No 609/2013, where: a production process not used for food production within the Union before 15 May 1997 has been applied as referred to in point (a) (vii) of this paragraph; or they contain or consist of engineered nanomaterials as defined in point (f) of this paragraph; (x) food used exclusively in food supplements within the Union before 15 May 1997, where it is intended to be used in foods other than food supplements as defined in point (a) of Article 2 of Directive 2002/46/EC". See also CJ Judgement (9 November 2016) Case C-448/14 *Davitas GmbH v. Stadt Aschaffenburg*.

[17] See, *inter alia*, Formici (2020) and Bonora (2016).

[18] In 2013, the European Commission presented two proposal on cloned animals: Proposal for a Directive of the European Parliament and of the Council on the cloning of animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purposes, COM/2013/0892 final, and Proposal for a Council Directive on the placing on the market of food from animal clones, COM (2013) 893. Both were withdrawn in 2020. See also Scaffardi (2020), pp. 59–63.

2.2 The Objectives of the Regulation of Novel Foods

Since 1997, the marketing of Novel Foods within the EU has been subject to specific rules established by the EU legislator to harmonise the differences between national laws relating to Novel Foods or food ingredients. These differences could hinder the free movement of foodstuffs and create conditions of unfair competition, thereby directly affecting the smooth functioning of the internal market.[19] At the same time, the rules adopted aimed to protect public health and safety, guaranteeing the "high level of protection" of human health required by its legal basis in primary law.[20] As effectively recognised by the CJEU in *Monsanto v Italy*, the objective of the Novel Food regime is thus twofold: on the one hand, "to ensure the functioning of the internal market in new foodstuffs" and, on the other hand, "to protect public health against the risks to which they may give rise".[21]

Strictly related to these objectives, Regulation (EU) 2015/2283 added the further dimension of consumer protection, thus aligning it to the fundamental objectives of EU general food law: guaranteeing the safety of food products which reach the table of the European consumer, while preserving their free movement within the EU internal market.[22] As has clearly emerged from the parliamentary debates during the approval of Regulation (EU) 2015/2283, however, concerns related to animal health and welfare, the environment, transparency and innovation within the agri-food industry are also relevant in relation to this regulatory framework.[23]

In line with these objectives, the placing on the market of new food products is subject to a specific authorisation. In particular, the marketing of Novel Food is allowed only where the food does not pose a safety risk to human health on the basis of the scientific evidence available.[24] The assessment of the safety of the Novel Food is clearly based on scientific grounds and, where scientific information is insufficient, inconclusive, or uncertain, the precautionary principle is applied.[25] Moreover, when the Novel Food is intended to replace another food and there is a significant change in the nutritional value, the Novel Food's intended use must not mislead the

[19] Regulation (EC) 258/97, esp. Recital 1.

[20] Art. 114 (3) and 168 (1) TFEU. See also Art. 35 EU Charter of fundamental rights.

[21] CJ Judgement (9 September 2003) Case C-236/01 *Monsanto Agricoltura Italia SpA and Others v. Italy*, para.74.

[22] See Art. 1 of 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.

[23] See European Parliament, Legislative Resolution of 25 March 2009 on the proposal for a regulation of the European Parliament and of the Council on novel foods, (COM(2007)0872—C6-0027/2008—2008/0002(COD)). Part of the amendments were retained in Recital 2 of Regulation 2015.

[24] Art. 7 (1) (a) Regulation (EU) 2015/2283. See also Art. 3 Regulation (EC) 258/97.

[25] See Recital 20 Regulation (EU) 2015/2283. On the notion and application of the precautionary principle, the literature is abundant. See, *inter alia*, de Sadeleer (2006), pp. 139–172; Scott (2005), pp. 50–74; Weimer (2019); Donati (2021); Zander (2010).

consumer nor differ from that other food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer.[26] Thus, consumers' interests are safeguarded.

3 The Procedure for the Authorisation of Novel Foods

3.1 The Historical Development of the Authorisation Procedure

While the requirements for safety and consumer protection and the first component of the definition of Novel Food have remained a constant in EU law, the procedure for their authorisation underwent a radical reform in 2015.[27] Regulation (EC) 258/97, which first introduced the authorisation procedures in the regulation of Novel Foods, distinguished between foods or food ingredients "substantially equivalent to existing foods or food ingredients",[28] whose placing on the EU market simply required a notification procedure to the European Commission,[29] and other Novel Foods, which were subject to a more articulated authorisation procedure.[30] The latter procedure (the so-called 'ordinary' procedure)[31] generally consisted in two phases situated at different levels of governance.[32] Pursuant to Article 4 of Regulation (EC) 258/97, the person responsible for placing on the EU market had to submit a request to the Member State in which the product was to be placed on the market for the first time, contextually forwarding a copy of the request to the Commission. Within 3 months, the competent authority of the Member State had to carry out an initial assessment, which was communicated to the European Commission and then forwarded to the other Member States in order to give them the possibility to object to the assessment.[33] Where an additional assessment was deemed necessary or an

[26] Article 7 (1) (b) and (c) Regulation 2015. See also Art. 3 Regulation 1997.

[27] Santini (2017), p. 640.

[28] Article 3 (4) Regulation (EC) 258/97. On the concept of "substantial equivalence", see Commission Recommendation of 29 July 1997 concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation (EC) No 258/97 of the European Parliament and of the Council, point 3.3.; CJ Judgement (9 September 2003) Case C-236/01 *Monsanto Agricoltura Italia SpA and Others v. Italy*, para.77.

[29] Art. 5 Regulation (EC) 258/97.

[30] Art. 4 Regulation (EC) 258/97.

[31] Scaffardi (2020), p. 48.

[32] Santini (2017), p. 641. *Contra* Scaffardi who identifies three procedures: the notification procedure, the authorisation procedure before the national authorities and the authorisation procedure before the European Commission, see Scaffardi (2020), p. 48.

[33] For a detailed analysis of the procedure, see *inter alia* Marine (2013), p. 99; Long and Cardonnel (1998), p. 14.

objection was raised, the procedure moved to the European level through the involvement of the Standing Committee for Foodstuffs and the final decision of the Commission.[34] As such, the initial procedure represented a typical example of composite administrative procedure[35] with remarkably decentralised characteristics.

The application of the regime established in Regulation (EC) 258/97 raised significant conceptual and practical issues.[36] Among these shortcomings, the authorisation procedure itself was considered inadequate - being too long, expensive, and non-transparent.[37] The financial burden of the application constituted an obstacle to the placing on the market of Novel Foods, especially for small- and medium-size enterprises which could not afford the (often unpredictable) costs of the procedure.[38] The procedure generally took more than 3 years[39]—a duration which discouraged companies from investing in research and innovation.[40] The reasons behind this situation were probably linked to the lack of binding deadlines for the competent authorities, especially at the European level, and to the multi-level structure of the procedure. In fact, it was often the case that in their initial assessments the national authorities were not able to reach a conclusion on the safety of the Novel Food, and an additional assessment by the European authorities was required.[41] Therefore, the assessment of the product was essentially conducted twice (at the national and then at the European level), consequently doubling the time for the decision.[42]

With a view to addressing these shortcomings and simplifying the authorisation procedure, as well as taking account of the significant developments in EU law and food technologies, Regulation (EU) 2015/2283 promoted a substantial overhaul of the legislative framework. In particular, it introduced a revised ordinary procedure, meant to be more "efficient, time-limited and transparent" than the previous one,[43] together with a new, simplified procedure for the recognition of traditional foods coming from third countries and having a history of safe food use.[44] Both procedures were put firmly in the hands of the European Commission and the European Food

[34] Art. 13 Regulation (EC) 258/97.

[35] On the concept of composite procedures, see *inter alia* Hofman (2009).

[36] For an overview of the difficulties in the application of the 1997 Regulation and the tortuous path towards the adoption of Regulation (EU) 2015/2283, see Volpato (2015).

[37] Marine (2013), p. 104.

[38] European Commission, Evaluation Report, p. 6.

[39] European Commission, Press memo: Commission Tables Proposals on Animal Cloning and Novel Food, 18/12/2013.

[40] Van Der Meulen (2009), p. 50.

[41] European Commission, Evaluation Report, p.16.

[42] Marine (2013), p. 105.

[43] Recital 22 Regulation (EU) 2015/2283.

[44] The procedure for notifying the placing on the market within the Union of a traditional food from a third country is specifically regulated in Article 15 Regulation (EU) 2015/2283. For a detailed analysis of this procedure, see see *A Peculiar Category of Novel Foods: Traditional Foods Coming from Third Countries and the Regulatory Issues Involving Sustainability, Food Security, Food Safety, and the Free Circulation of Goods* by L. Scaffardi in this volume.

Safety Authority (EFSA), centralising the powers for assessment and decision on the new applications for Novel Food at the European level.

3.2 The Procedure for the Authorisation of Novel Foods: The Role of the Commission and EFSA

The new 'ordinary' authorisation procedure can be launched either on the Commission's initiative or following an application to the Commission by a Member State, a third country, or a natural or legal person who has an interest in placing a new item on the Novel Food market. The application shall contain the administrative and scientific information listed in Article 10 (2) of the Regulation, including scientific evidence demonstrating that the Novel Food does not pose a safety risk to human health.[45] The application is made available to the Member States without delay and a summary of it (containing in particular the name of the applicant, the name of the Novel Food and the abovementioned scientific evidence) is published on the Commission's website.[46] The transparency of the studies on the safety of Novel Foods was recently further enhanced by the specific guarantees established by Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain,[47] which applies also to this procedure as of 27 March 2021.

On receipt of the application, the Commission verifies whether the application falls within the scope of Regulation (EU) 2015/2283 and whether the application fulfils all the requirements.[48] In the positive case, it can request an opinion from the European Food Safety Authority (EFSA) within 1 month.[49] Established in 2002 and

[45] Further application requirements are specified in Commission Implementing Regulation (EU) 2017/2469 of 20 December 2017 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods.

[46] See European Commission (2022) Summary of applications and notifications. https://ec.europa.eu/food/safety/novel-food/authorisations/summary-applications-and-notifications_en, last accessed 15 February 2022.

[47] Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC.

[48] Art. 6 Commission Implementing Regulation (EU) 2017/2469.

[49] Art. 11 Regulation (EU) 2015/2283. For a detailed analysis of the role of EFSA in the procedure, see *inter alia* Martini *et al.* (2020); Canfora (2016). See also *Food (In)Security: The Role of Novel Foods on Sustainability* by S. Sforza, *Why "New" Foods Are Safe and How They Can Be Assessed* by C. Dall'Asta and *The Safety Assessment of Insects and Products Thereof as Novel Foods in the European Union* by G. Precup, E. Ververis, D. Azzollini, F. Rivero-Pino, P. Zakidou, A. Germini, all in this volume.

located in Parma,[50] EFSA is one of the most important EU decentralised agencies which support the EU institutions and Member States with the performance of highly specialised tasks of a scientific and technical nature.[51] Although the Commission has discretion on the decision to consult this agency, its involvement in the assessment of a Novel Food complies with the fundamental tenets of EU food policy which, since the White Paper on food safety of 2000, is based on scientific evidence and risk analysis.[52] According to these principles, the analysis of the risk posed by food products is divided in three phases: risk assessment, risk management, and risk communication.[53] While risk management and risk communication are mainly entrusted within the political institutions (*in primis*, the European Commission), the specialised activities related to risk assessment are generally carried out by EFSA and its scientific panels, whose technical and scientific expertise make them adequately equipped for dealing with these issues. The new procedure for the authorisation of Novel Food, hence, reflects more clearly this separation between risk assessment and risk regulation which characterises the fundamental architecture of food policy at the supranational level as it has developed in the last decades.[54]

EFSA shall adopt its opinion within 9 months, which can be extended where additional information is needed from the applicant.[55] The opinion is forwarded to the Commission, to the Member States and, where applicable, to the applicant. It provides an essential input for the decision of the Commission, which should be based on this opinion, on any relevant provision of Union law (including the precautionary principle), and on 'any other legitimate factors relevant to the application under consideration.'[56] The concept of 'other legitimate factors' is of particular interest. While irrational fears or other purely emotional reactions (such as the "yuck factor" or "the wisdom of repugnance")[57] cannot be considered legitimate factors since they lack the legitimacy generally associated with this notion,[58] certain non-scientific considerations may be relevant in the risk management phase of the decision. Other legitimate factors can include, for example, societal, economic, traditional, ethical and environmental factors.[59] Especially in situations where

[50] Regulation (EC) 178/2002.

[51] On EU agencies and the phenomenon of agentification of EU administration, see, *inter alia*, Everson et al. (2014), Chamon (2016), Chiti (2002), Tovo (2016) and Alberti (2018).

[52] See, *inter alia*, Recital 16 of Regulation (EC) 178/2002; Communication from the Commission on the precautionary principle, COM/2000/0001 final. See also Alemanno (2007); Santini (2017), p. 642.

[53] Art. 3 Regulation (EC) 178/2002.

[54] Santini (2017), p. 642. It is noteworthy that this separation is present also at the international level, see Codex Alimentarius.

[55] Art. 11 Regulation (EU) 2015/2283.

[56] Art. 12 (1) Regulation (EU) 2015/2283.

[57] Kass (1997), p. 217; Jasanoff (2011), p. 634.

[58] Petetin (2019), p. 246.

[59] See, by analogy, Recital 19 of Regulation (EC) 178/2002.

scientific evidence is inconclusive, insufficient or uncertain,[60] this arguably creates "some real space for the incorporation into decision of values and concerns which go beyond technical and scientific reasons".[61]

In any event, within 7 months from the date of publication of the Authority's opinion, the Commission drafts an implementing act to be presented to the Standing Committee on Plants, Animals, Food and Feed (PAFF).[62] This draft implementing act contains the specification of the Novel Food and, where appropriate, the conditions under which the Novel Food may be used. It also includes any additional specific labelling requirements which may be imposed upon its sale in the EU market.[63]

3.3 *The Procedure for the Authorisation of Novel Foods: The Role of Comitology*

The Standing Committee on Plants, Animals, Food and Feed is part of a highly idiosyncratic system of committees (the so-called comitology system) established under EU law for the adoption of implementing acts according to Article 291 TFEU.[64] The committees are composed of representatives of Member States and are chaired by the Commission.[65] The powers and the functioning of the committees depend on the procedure they follow as established by Regulation 182/2011 in relation to the type and relevance of the act to be adopted.[66]

For the adoption of implementing acts concerning Novel Foods the most intrusive and complex procedure is applicable, namely, the examination procedure, which aims to ensure that these implementing acts cannot be adopted by the Commission if they are not in accordance with the opinion of the committee.[67] According to this procedure, the committee discusses the Commission's draft and delivers its vote by qualified majority, determined according to the ponderation set forth in the Treaties

[60] Szajkowska (2010), p. 191.

[61] Lee (2008), p. 83. See also Szajkowska (2012).

[62] This committee is established by Article 58(1) of Regulation (EC) No 178/2002. The competent section for the adoption of novel food authorisations is the Novel Food and Toxicological Safety section (Comitology register code: C20408).

[63] Art. 9 (3) Regulation (EU) 2015/2283.

[64] Article 291 TFEU. On the historical evolution of comitology, see, *inter alia*, Bergström (2005) and Bianchi (2012).

[65] The representative of the Commission, however, does not take part in the vote. See Regulation (EU) 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers.

[66] See Art. 2 Regulation (EU) 182/2011.

[67] Art. 12 (1) Regulation (EU) 2015/2283.

for the adoption of legislative acts by the Council.[68] The outcome of this vote determines the following steps in the procedure, depending on whether the committee delivers a positive opinion, a negative opinion, or a 'no opinion'. Where the outcome is a positive opinion, i.e., the qualified majority of Member States' representatives has approved the draft measure, the Commission is under an obligation to adopt it.[69] However, as specified in an interinstitutional statement on the adoption of the Comitology Regulation, "this provision does not preclude that the Commission may, as is the current practice, in very exceptional cases, take into consideration new circumstances that have arisen after the vote and decide not to adopt a draft implementing act, after having duly informed the committee and the legislator."[70] Therefore, although obliged to adopt the draft implementing act, the Commission exceptionally enjoys a certain margin of discretion where new circumstances arise after the vote.

Where the outcome is a negative opinion, i.e., the qualified majority of Member States' representatives has opposed the draft text, the Commission is precluded from adopting the implementing act.[71] In this case, the Commission is confronted with three alternatives: either to drop the act, to amend it, or to refer it to the Appeal committee. In the procedure for the authorisation of a Novel Food, where an applicant is expecting a decision on its application, the option of letting the draft implementing act simply drop is not viable. Therefore, in the procedure for the authorisation of a Novel Food the Commission can submit an amended version of the draft implementing act to the same committee within 2 months, hoping for a different outcome to overcome the veto. Otherwise, it can decide to submit the same draft implementing act to the Appeal committee within one month from the negative opinion.

When the outcome is 'no opinion', i.e., the committee did not reach a qualified majority either in favour or against the draft implementing measure, the Commission generally "may adopt the draft implementing act."[72] This outcome, hence, generally guarantees some discretion to the Commission. However, in the authorisation procedure for Novel Foods, the possibility to adopt the act is expressly precluded to the Commission by Article 30 (3) of Regulation (EU) 2015/2283. The Commission is thus left with the same options applicable in the case of a negative opinion: it can either submit an amended version of that act to the same committee within

[68] A qualified majority is attained where at least 55% of the members of the Council, comprising at least fifteen of them and representing Member States comprising at least 65% of the population of the Union are in favour. See Art. 16 (4) TEU, referred to in Art. 5(1) Regulation (EU) 182/2011.

[69] Art. 5(2) Regulation (EU) 182/2011.

[70] Statement by the European Parliament, the Council, and the Commission on the adoption of the Comitology Regulation, OJ L 55, 28.2.2011, 19.

[71] Art. 5(3) Regulation (EU) 182/2011.

[72] Art. 5(4) Regulation (EU) 182/2011.

2 months of the vote or submit the draft implementing act within 1 month of the vote to the Appeal committee for further deliberation.[73]

The submission to the Appeal committee initiates a new phase in the procedure, governed by specific rules. The Appeal committee, which actually represents one of the major innovations of the Regulation 182/2011,[74] is composed of Member States' representatives who meet "at the appropriate level" of representation.[75] The underlying idea is that the representatives in the Appeal committee should have "the necessary authority to decide on highly sensitive issues", taking a clear stance on the matter and not leaving discretion to the Commission to decide in case of disagreements in the first phase of the comitology procedure.[76] In the prevailing practice, the appeal committee is generally composed of members of the Permanent Representation,[77] who were initially the deputy permanent representatives (thus mirroring the composition of Coreper I) and, more recently, attachés at a lower level.[78]

The voting rules in the Appeal committee follow those established for the examination procedure.[79] Therefore, also in the case of the appeal committee, the possible outcomes of the vote are threefold, as are their consequences. Firstly, when the Appeal committee delivers a positive opinion, the Commission must adopt the draft implementing measure. Secondly, when the appeal committee delivers a negative opinion, the Commission cannot adopt the measure.[80] Thirdly, when no opinion is delivered, the Commission has discretion as to whether to adopt or not adopt the draft implementing measure.[81] Considering that the discretion of the Commission in this phase of the procedure is not limited by Article 30 of the Regulation (EU) 2015/2283,[82] in case of no opinion at the examination committee phase it may be strategically useful for the Commission to refer the matter to the Appeal committee when it expects the same outcome at the higher level.

[73] Art. 5 (4) third subparagraph Regulation (EU) 182/2011.

[74] Christiansen and Dobbels (2013), p. 48.

[75] Recital 7 and Art. 3 (7) last subparagraph Regulation (EU) 182/2011.

[76] Corona (2014), p. 100.

[77] European Commission, Report to the European Parliament and the Council on the Implementation of Regulation (EU) 182/2011, COM(2016) 92 final, p. 5.

[78] Christiansen and Dobbels (2013), p. 49.

[79] Art. 6 Regulation (EU) 182/2011.

[80] This provision is considered problematic since, differently from the previous regime, it entails a definitive stop of the procedure without a clear decision on the matter. See Blumann (2011), p. 18; Bianchi (2013), p. 204.

[81] Art. 6 (3) Regulation (EU) 182/2011.

[82] The only derogation to the flexibility of this article is the prohibition against adopting the implementing act when definitive multilateral safeguard measures are at stake, see Art. 6-(4) Regulation (EU) 182/2011.

3.4 The Union List of Authorised Novel Foods and Data Protection

Once approved through the comitology procedures, the implementing act is adopted by the European Commission and published in the Official Journal. The placing on the EU market of the Novel Food is thus authorised under the specifications, conditions of use, additional specific labelling requirements, or post-market monitoring requirements associated with the authorisation.[83] Different from the previous practice, the authorisation is not in the form of a decision with an individual addressee, namely the applicant, but it has general effects. It consists in the inclusion of the relevant Novel Food in the Union List of Authorised Novel Foods.[84] This list, established by the Commission on 30 December 2017,[85] contains the 125 Novel Foods authorised under the previous Regulation and the new entries added through the implementing acts resulting from the described procedure.[86]

The establishment of the Union List and the demise of individual authorisations represented an important shift in the regulation of Novel Foods, paving the way for a less burdensome and more extensive production of these products.[87] Aiming at the simplification and transparency of the system, this major change is intended to favour in particular the small- and medium-sized enterprises since it reduces the unnecessary administrative expenditure and avoids superfluous studies and experiments.[88] At the same time, however, this system risks penalising the applicant which invested in the development of new food technologies by allowing an undue exploitation of the results by other producers and competitors.[89] Therefore, in order to stimulate research and development, and consequently innovation within the agri-food industry, Regulation (EU) 2015/2283 sets forth a balanced form of protection of the investment made by the applicants in gathering the information and data provided in support of an application for a Novel Food.[90]

According to Articles 26 and 27, the applicant can request the protection of newly developed scientific evidence and proprietary data provided in support of an application under certain conditions. Where granted, these data cannot be used for the

[83] Art. 9 Regulation (EU) 2015/2283.

[84] Art. 9 Regulation (EU) 2015/2283.

[85] Commission Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods, OJ L 351, 30.12.2017, p. 72–201. The initial list has been repeatedly corrected, most recently by Commission Implementing Regulation (EU) 2022/202 of 14 February 2022 correcting Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods.

[86] For a detailed analysis of the Union List, see Haber and Aurich (2018), p. 404.

[87] *Ibidem*.

[88] Especially animal testing, see Recital 32 of Regulation (EU) 2015/2283.

[89] Santini (2017), p. 645.

[90] Recital 30 Regulation (EU) 2015/2283.

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.[91] Although on paper this represents a reasonable compromise between the individual protection of the applicant's investment and the general promotion of Novel Foods at larger scale, the current application of these provisions has been strongly criticised as *de facto* impeding effective competition in the market for a significant period of time.[92]

4 The Centralisation of the Procedure and the Role of the Member States

4.1 Novel Food Governance in the European Space of Integrated Administration

From an institutional perspective, the evolution of the legal framework for Novel Foods authorisation—with the described shift from a decentralised to a centralised procedure and with the systematic involvement of EFSA—epitomises significant trends which can be recognised in the overall development of the governance structure of EU law implementation in the last decades. At the same time, it puts into sharp relief the tensions underlying the regulation of controversial policy areas such as those related to risk regulation, where scientific complexities, value judgments, and consumer sensibilities need to be accommodated in the design of the decision-making procedure.

With regard to the centralisation of the procedure, it is important to recognise that its evolution reflects the broader trend towards the progressive emergence of a European space of integrated administration.[93] While the EU original governance model was essentially based on the harmonisation of divergent national legislation through the adoption of directives and regulations whose implementation was essentially demanded from national authorities separately (the so-called indirect administration),[94] the EU integration process led to the increasing development of forms of horizontal recognition of transnational acts, and of mutual cooperation

[91] Art. 26 (1) Regulation (EU) 2015/2283.

[92] See, *inter alia*, La Porta (2021), esp. p. 47. See also Holle (2014), pp. 280–284. But also, with specific reference to insects-as-food, *Legislative and Judicial Challenges on Insects for Human Consumption: From Member States to the EU, Passing Through the Court of Justice of the EU* by G. Formici in this volume.

[93] *Inter alia*, Hofmann (2009), pp. 24–38; Hofmann *et al.* (2011), pp. 5–11.

[94] With the exception of certain specific policies, such as competition law, which was already attributed at the European level by the Treaty of Rome. Indirect administration is still the rule, see Article 291 (1) TFEU.

between national authorities.[95] With the deepening of the internal market, and the consolidation of EU policies towards "an ever closer Union",[96] cooperation mechanisms were established not only horizontally between Member States, but also vertically between the European Commission and national authorities, often in the form of procedural linkages between diverse actors and across different levels.[97] The decentralised composite procedure of Regulation (EC) 258/97 was thus the expression of this particular phase of the EU integration process, characterised by multi-level procedural cooperation among the different actors.

This model of governance has, however, been increasingly dismissed in cases in which the application of EU legislation by national authorities led to persistent inconsistencies and divergences,[98] also in light of the unsolved issues of effective judicial protection that composite procedures may raise.[99] As in the case of Novel Foods, the tendency is hence towards the centralisation of the implementing tasks, resulting in forms of direct administration by the European Commission and/or EU agencies.[100] Only recently has this trend perhaps slowed down its pace, with the re-nationalisation of the implementation of certain polices in the name of a more 'active subsidiarity'.[101]

With specific regard to the Novel Food authorisation procedure, it was argued that such centralisation of the governance model resulted in the expansion of the powers of EU institutions which, hence, manage to maximise their competences to the detriment of the national authorities.[102] Regulation (EU) 2015/2283 has certainly affected the role of the national authorities which were previously responsible for the assessment of the safety of Novel Foods. The demise of their role and the consequent loss of the expertise acquired in the two decades in which the decentralised procedure was in place was indeed an object of debate during the approval of the Regulation.[103]

Against this backdrop, Article 4 of the Regulation provides for a specific procedure for determination of Novel Food status before the national authorities. Any business operator who is unsure whether or not a food which they intend to place on the market falls within the scope of this Regulation can consult the competent authorities of the Member State where they first intend to place the Novel Food, providing the necessary information for this assessment.[104] The decision on the

[95] Hofmann (2017), p. 6; De Lucia (2016), p. 245. See also Weiler (1991).

[96] Art. 1 TEU. See also Petetin (2019), p. 236.

[97] Hofmann (2017), p. 15.

[98] De Lucia (2016), pp. 104–105.

[99] Eliantonio (2015) and Brito Bastos (2018).

[100] De Lucia (2016), pp. 90–114.

[101] See, for instance, European Commission, Communication—The Principles of subsidiarity and proportionality: Strengthening their role in EU policymaking, COM(2018) 703 final.

[102] Petetin (2019), p. 236. See also Randour et al. (2014).

[103] ENVI Committee, First exchange of views on novel foods, 19 March 2014, http://www.europarl.europa.eu/ep-live/fr/committees/video, last accessed 20 June 2014.

[104] Art. 4 Regulation (EU) 2015/2283.

Novel Food status of a food is taken by the Member State and communicated to the business, the other Member States, and the Commission.[105] The Commission then makes the information on the Novel Food status publicly available on the Commission's website.[106] Forms of cooperation and information sharing across different levels are thus retained in the new legal framework, blurring the lines of a strict distinction between direct and indirect administration.[107]

4.2 The (Lack of) Tensions Within the Comitology System

A significant role is maintained by the Member States also within the described comitology procedure which allows them, by qualified majority voting, to oppose the adoption of the Commission's decision. In such a system of intensive interaction between national and supranational representatives, the complex operational rules described ensure the control of the Member States over the exercise of the implementing powers by the Commission, while providing the Commission with the expertise and technical information of experts and national officials working in this field in the Member States.[108]

Interestingly, in the approval of Novel Foods Member States have never made use of their veto power against the Commission: all 392 relevant votes of the Standing Committee on Plants, Animals, Food and Feed have resulted in a positive opinion.[109] This is in line with the practice of most comitology committees where positive opinions represent the most common outcome of the procedure, confirming that the comitology system is, also in the field of Novel Foods, a highly consensual

[105] Commission Implementing Regulation (EU) 2018/456 of 19 March 2018 on the procedural steps of the consultation process for determination of novel food status in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods.

[106] *Ibidem*, Art. 7 (2).

[107] See, *inter alia*, Cassese (2004), pp. 21–36; Della Cananea (2004), pp. 197–218.

[108] In the EU political science literature, there are actually two opposite views of comitology. On the one hand, the idea of "interinstitutional bargaining" according to which comitology is a mechanism of Member State control over the Commission and Member States negotiate in an intergovernmental manner (see, *inter alia*, Steunenberg *et al.* (1994), pp. 329–344; Pollack (2003); Franchino (2000), pp. 155–181; Ballmann et al. (2002), pp. 551–574). On the other hand, the idea of "deliberative supranationalism" according to which committees have evolved into forums of discussion among experts, based on persuasion and dialogue (see, *inter alia*, Joerges and Neyer (1997), pp. 273–299; Dehousse (2003), pp. 798–813). See Blom-Hansen and Brandsma (2009), pp. 719–740.

[109] Voting sheet data on the Standing Committee on Plants, Animals, Food and Feed - Novel Food and Toxicological Safety section (Comitology register code: C20408) retrieved from the Comitology Register. https://ec.europa.eu/transparency/comitology-register/screen/datasets?lang=en, last accessed 18 February 2022.

exercise.[110] However, these data contrast sharply with the ones available on the procedure for authorising a GMO for food or feed, where similar economic, scientific, and societal issues are at stake.

In the authorisation of GMO food and feed, a significant number of comitology procedures result in a 'no opinion' scenario before the examination committee and, subsequently, before the Appeal committee.[111] In fact, the majority of cases tackled by the Appeal committee relate to this controversial area or to the authorisation of plant protection products.[112] In these areas, the discretion granted to the Commission in case of a 'no opinion' scenario at appeal level is increasingly perceived as problematic since it pushes the Commission to act on politically sensitive matters which have a direct impact on citizens and business, and where the public opinion is strongly polarised, without clear backing from the Member States.[113] Arguably, in recent years the Member States appear to have used this mechanism strategically to abstain from assuming responsibility for controversial decisions before the electorate. For these reasons, in 2017 significant amendments to the comitology system were proposed by the Commission to tackle this issue.[114] Should these amendments be adopted by the Parliament and the Council, the rules applicable in the case of no opinion and the correlated balance between the Commission and the Member States would be altered significantly.[115]

It is thus remarkable that, while in relation to GMO the adoption of decisions through a centralised procedure was perceived to be so controversial that unprecedented amendments to the comitology system were proposed,[116] the approval of

[110] European Commission, Report to the European Parliament and the Council on the Implementation of Regulation (EU) 182/2011, COM(2016) 92 final, p. 2.

[111] See Comitology Register, available at https://ec.europa.eu/transparency/comitology-register/screen/datasets?lang=en, last accessed on 18 February 2022.

[112] European Commission, Report to the European Parliament and the Council on the Implementation of Regulation (EU) 182/2011, COM(2016) 92 final, p. 6.

[113] Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) No. 182/2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers, COM (2017) 85, p. 3.

[114] See Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) No. 182/2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers, COM (2017) 85. In relation to GMO, see also Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No. 1829/2003 as regards the possibility for the Member States to restrict or prohibit the use of genetically modified food and feed on their territory, COM (2015) 177; Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Reviewing the decision-making process on genetically modified organisms (GMOs), COM(2015) 176 final.

[115] For a discussion of the possible implications of the reform, see Volpato (2022), pp. 186–187.

[116] In relation to GMO cultivation, the trend towards decentralisation is even more clear, as it can be recognised in the introduction of 'opt out' clauses by Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC regarding the possibility for Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory. See Petetin (2019), p. 242.

Novel Foods did not raise similar tensions between levels of governance. On the one hand, this may be partially explained by the authority enjoyed by EFSA's opinion in the authorisation procedure which, different from the case of plant protection products for instance, has never been called into question.[117] In fact, decisions on Novel Food authorisations are systematically aligned to the outcome of the risk assessment, leaving limited room for debate on the non-scientific legitimate factors in risk management.[118] On the other hand, the Novel Foods authorised so far have not polarised the public debate to the same extent as GMOs or plant protection products (especially, glyphosate), thus shielding the representatives of the Member States from the pressure of national politics. From the *travaux préparatoires* of the Regulation it could be expected that strong opposition may be raised in relation to edible insects and cloned animals.[119] Although Regulation 2015/2283 entered into force in 2018, the first authorisations for edible insects were issued only starting from summer 2021. Apart from this and the authorisation of *stevia*,[120] it is arguable that the institutional design of the centralised authorisation procedure has thus not yet been put to the test of a significant tension between different governance levels.

5 Conclusions

The regulation of Novel Foods in the internal market inevitably touches a vast array of delicate and conflicting issues, such as innovation and safety in the agri-food sector, sustainability concerns and ethical values, as well as cultural sensibilities and consumer perceptions.[121] Certainly, the growing global population and the consequent food needs urgently require new sustainable solutions for the future of food production, which innovative food technologies and non-traditional breeding techniques may provide. Nevertheless, food safety concerns and societal values need to be taken into account to guarantee a high level of consumer protection and to endow the regulatory approach with legitimacy and transparency. A careful weighing of the divergent interests and values is, therefore, crucial in the design of the substantive and procedural rules applicable in this field.

The EU legislator strove to find this delicate balance, initially with the Regulation (EC) 258/97 which laid down detailed provisions on the definition and the placing into the EU market of Novel Foods, and subsequently with Regulation (EU) 2015/

[117] On the glyphosate saga, see *inter alia* Morvillo (2020) and Leonelli (2018).

[118] Petetin (2019), pp. 246–249.

[119] *Inter alia*, European Parliament, Report on the proposal for a regulation of the European Parliament and of the Council on novel foods (COM(2013)0894 - C7-0487/2013 - 2013/0435 (COD)).

[120] As reported by Marine (2013), p. 108.

[121] On this point see *Consumer Perceptions and Acceptance of Insects as Feed and Food: Current Findings and Future Outlook*, by G. Sogari, H. Dagevos, M. Amato, D. Taufik in this volume.

2283 which updated, strengthened and simplified the applicable regulatory framework. This legislative reform purposefully maintained continuity in the main elements of the definition of Novel Food, the regulatory objectives, and the level of food safety to be guaranteed to European consumers. Conversely, it realised a paradigm shift in the structure of the authorisation procedure and in the legal effects of this authorisation, centralising decision-making powers in the hands of the European Commission and establishing the Union list.

While this change from a form of decentralised composite procedure to a clearer expression of direct administration is in line with the general development of EU food law and of the European space of integrated administration, the reform of the procedure entailed a fundamental re-shaping of the reciprocal roles, both of the Member States and their national authorities, and of the European Commission and EFSA. Despite these changes, the practice of Novel Foods authorisation has proven to be less problematic and controversial than what one could have expected in light of the tensions underlying the field, and given the reality of the parallel system of GMO authorisations. This may show that the new procedure has successfully accommodated the tensions between scientific and non-scientific factors (through the clearer distinction between risk assessment and risk management), and between national and European levels. It is, however, undeniable that the new procedure has yet to be tested against truly controversial matters. Considering the importance of the interests at stake for the future of food and feed in Europe, and for the future of our planet, it remains to be seen whether the institutional structure and the governance model adopted in Regulation (EU) 2015/2283 will manage to reconcile differing values and uphold the fundamental tenets of EU food policy.

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