Novel and Traditional Foods: Novel Food Regulation in the EU

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Abstract

The ongoing globalization, together with a continuing development of new technologies, has led to the emergence of novel foods seeking to enter the markets. These include exotic food from distant countries, biotechnologically gained products, edible microorganisms, or components containing new types of molecules or nanosized food components.

Safety regulations have been developed by many countries with the major aim to allow only safe novel food on the market.

In order to clearly exclude any known risks that may be associated with various nutrients and their ingredients or residues, and to avoid unknown risks that may potentially accompany novel technologies, the regulations became increasingly differentiated and complex.

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The present contribution briefly introduces regulations in different jurisdictions around the world, and analyzes the new European Novel Food Regulation (EU) 2015/2283 in greater detail.

It elucidates the historic evolution of the European regulation by comparing with the previous Regulation (EC) No 258/97 and presents central new aspects aiming of the new regulation to enhance the efficiency of the authorization process and reduce unnecessary trade barriers, while ensuring food safety. Along with the authorization process, the chapter elaborates the risk assessment process and, amongst others, the requirements concerning the assessment of compositional, toxicological, and allergological safety. Beyond this, the simplified notification procedure for traditional foods from third countries with a safe history of use is presented, including the respective requirements for the safety assessment.

Keywords

Novel Food Regulation · Regulation (EU) 2015/2283 · Authorization procedure for Novel Foods · Novel Food categories · Traditional foods from third countries · Safe history of use · Risk assessment · Exposure assessment · EFSA

Introduction

In general, food law does not impose any authorization or licensing requirements for the production, import, or marketing of food which is commonly consumed by the resident population. With respect to particular food, which are "new foods" on the market, great differences between the regulatory systems across the countries worldwide exist.

For example, "new foods" on the market in the **USA** are not specifically defined and do not require a premarket approval by governmental authorities. Basically, food business operators who want to bring "new foods" on the US market have a legal obligation to ensure that the foods they offer to consumers are safe under the conditions of use and in compliance with applicable legal requirements. In this so-called GRAS (generally recognized as safe) self-affirmation, the food business operator has the ability to self-affirm the safety of the Novel Food. If a food or ingredient is not very customary, its GRAS status can be affirmed by an independent panel of recognized experts. The pivotal studies used in the risk assessment must be generally available, e.g., through publication in the scientific literature. If the expert panel concludes the product is GRAS, the manufacturer may or may not consult the US Food and Drug Administration (FDA). Besides GRAS self-affirmation, the food business operator can voluntary notify the FDA of a conclusion that a substance is GRAS under the conditions of its intended use. In contrast, if a substance is used as food additive it needs approval by the FDA before retailing (details on FDA webpage (FDA (U.S. Food and Drug Administration) 2020)).

Novel foods in **Japan** are likewise not specifically defined. No premarket assessment and authorization is required for "new" food ingredients that are used as food, but compliance with the Food Sanitation Act has to be warranted. If the "new" food ingredient is a "new" food additive, a premarket assessment and authorization by the Ministry of Health, Labour, and Welfare (MHLW) is required (details on MHLW webpage (MHLW (Ministry of Health, Labour and Welfare) 2020)).

Comparable to the European Union, novel foods and novel food ingredients in **Australia and New Zealand** are specifically defined and regulated under the Food Standards Code (Standard 1.5.1). Novel foods are nontraditional foods that require premarket safety assessment by the statutory authority Food Standards Australia New Zealand (FSANZ) in order to determine their safety before they are offered to consumers. If the Novel Food passes this assessment, it is listed in the Standard and can be sold as food or used as food ingredient in Australia and New Zealand, as long as it complies with any specified conditions (details on FSANZ webpage (FSANZ (Food Standards Australia New Zealand) 2020)).

Novel foods in **Canada** are regulated under Division 28 of the Food and Drug Regulations (FDR) setting out the definition of a novel food, including foods derived from genetically modified organisms (GMOs) as well as premarket notification requirements. In the approval process the food business operator who wants to sell or advertise a novel food has to notify Health Canada, in particular the Food Directorate, and submit information regarding the product in question so that an assessment can be made by Health Canada with respect to the product's safety prior to sale (details on webpage of Government of Canada (2020)).

In the **European Union**, it is basically in the responsibility of the food business operator to ensure that food is safe when placed on the market and the requirements of food law based on Regulation (EC) No 178/2002 (2002) are met. With respect to particular food, for instance food additives, foods from genetically modified organisms (GMO), or new types of food, food ingredients or ways of producing food, specific regulations arose from the circumstances implementing premarket approval systems in the European Union. Contrary to food defined by Regulation (EC) No 178/2002, these particular foods are not considered as a priori safe. Therefore, authorization accompanied by assessment of the safety risk arising from consumption of those foods is regarded as mandatory to achive a high level of protection of human health and of consumers.

Hence, the regulation of novel foods and novel food ingredients evolved among others in response to applications of new technologies in the food sector (e.g., use of genetic modification in food) or exotic foods which may be traditional with a long history of use outside the EU as well as the continuous search for new sources of nutrients. On 15 May 1997, Regulation (EC) No 258/97 (1997), known as Novel Food Regulation, came into force to harmonize national procedures and to introduce a statutory approval system for Novel Foods across the European Union. The stated objective of the regulation was to ensure food safety and protection of human health related to new products or ingredients intended for human consumption on the European market. To enable integration of recent developments in Union law and technological progress and to simplify the current authorization procedures, the

Union's rules on Novel Foods initially established by Regulation (EC) No 258/97 of the European Parliament and of the Council and by Commission Regulation (EC) No 1852/2001 (2001) were replaced by the new Novel Food Regulation (EU) 2015/2283 (2015).

Regulation of Novel Foods in the European Union

Previous History: Situation Before 1 January 2018

Before 1 January 2018, novel foods were recently governed by the Regulation (EC) No 258/97 establishing a mandatory, decentralized premarket authorization system. The definition of Novel Food was based on two cumulative criteria that had to be fulfilled. The first defining criterion was that the food or ingredient was not used for human consumption to a significant degree within the European Union before the introduction of the legislation on 15 May 1997. The second defining criterion implied that the food had to fall within one of the defined food categories explicitly mentioned in Article 1 of Regulation (EC) No 258/97 (latest consolidated version from 07.08.2009).

Prior to placing a food or food ingredient falling under this regulation on the Community market an application in accordance with Commission Recommendation 97/618/EC (1997) concerning the scientific information and the safety assessment report was required. The risk assessment process involved an initial assessment by a Member State and if no objections were raised and no additional assessment was required, the novel food could be placed onto the market. In case of reasoned objections by another Member State or the European Commission to the initial assessment, the EC's Scientific Committee on Food (SCF)[1] or the European Food Safety Authority (EFSA) was consulted.

Based on the positive or negative opinion of this expert panel, an authorization decision had to be taken by the European Commission assisted by the Standing Committee on the Food Chain and Animal Health (SCFCAH) (previously known as the Standing Committee for Foodstuffs) consisting of Member States' representatives. According to experience, duration of the authorization process could take several years (e.g., decision on Chia seeds – 6 years (Commission Decision 2009/827/EC 2009); decision on Baobab dried fruit pulp – 2 years (Commission Decision 2008/575/EC 2008); and Decision on synthetic Zeaxanthin – 9 years (Commission Implementing Decision 2013/49/EU 2013)).

If novel foods or novel food ingredients were considered to be "substantially equivalent" to an existing food or food ingredient already available on the European market with regard to their composition, nutritional value, metabolism, intended use, and the level of undesirable substances, only a notification to the European Commission was required.

The New Novel Food Regulation (EU) 2015/2283: What Is Actually New?

Following Article 14 of the Regulation (EC) No 258/97, a revision was initiated after evaluation of the regulation which discussed issues that had emerged due to the practical implementation. Stakeholder consultations on a European Commission discussion document and a subsequent evaluation emphasized the need for an update and revision of the former provisions for Novel Food (EC (European Commission) 2008). To take into account the scientific and technological developments since 1997, it was necessary to specify and update the existing Novel Food categories, enhance the efficiency of the authorization process, and reduce unnecessary trade barriers, while ensuring food safety.

A final draft agreed upon by the EU institutions resulted in the preparation of the new Novel Food Regulation (EU) 2015/2283, which entered into force on 1 January 2018. The new Regulation centralized the authorization procedure at EU level with deadlines imposed on certain stages and the immediate involvement of EFSA in the risk assessment process. The applicant-based authorization was replaced by a generic authorization to avoid duplication of work and an Union list comprising all authorized novel foods was established. Furthermore, the definition and categories of Novel Foods were revised and a procedure for the determination of a Novel Food status was implemented. To simplify the authorization of traditional foods safely used in third countries a faster and structured notification process was introduced. For the sake of clarity and to facilitate understanding, all legislation and guidance documents concerning the new Novel Food Regulation (EU) 2015/2283 are listed in Table 1.

Revision of the Novel Food Categories

The Article 3 (2a) of the Regulation (EU) 2015/2283 contains the fundamental definition of Novel Food meaning " [. . .] any food that was not used for human consumption to a significant degree within the Union before 15 May 1997, irrespective of the dates of accession of Member States to the Union, and that falls under at least one of the following categories." The 15 May 1997 refers to the date of entry into force of the former Novel Food Regulation and was established in the new Novel Food Regulation to ensure continuity between both Regulations. The novel food categories covered by Regulation (EU) 2015/2283 comprise now ten categories of which four already existing categories have been revised, clarified, and updated, and whereas six further categories have been newly added (Table 2).

As under Regulation (EC) No 258/97, food enzymes (falling within the scope of Regulation (EC) No 1332/2008 (2008)), food additives (falling within the scope of Regulation (EC) No 1333/2008 (2008)), food flavorings (falling within the scope of Regulation (EC) No 1334/2008 (2008)), and extraction solvents used or intended to be used in the production of foodstuffs or food ingredients are excluded. However, some foods may be considered as novel foods if employed for a different intended use or manufactured in a different way. One example is Lycopene which is used for technical purposes as food additive (E160d) and falls within the scope of

Table 1 Overview over legislation and guidance documents related to the Novel Food Regulation (EU) 2015/2283

Regulation/Guidance	Title
Regulation (EU) 2015/2283	**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
Implementing Regulation (EU) 2018/456	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
Implementing Regulation (EU) 2017/2468	Commission Implementing Regulation (EU) 2017/2468 of 20 December 2017 laying down **administrative and scientific requirements concerning traditional foods from third countries** in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods
Implementing Regulation (EU) 2017/2469	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
Implementing Regulation (EU) 2017/2470	Commission Implementing 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
Implementing Regulation (EU) 2018/1023	Commission Implementing Regulation (EU) 2018/1023 of 23 July 2018 **correcting Implementing Regulation (EU) 2017/2470 establishing the Union list** of novel foods
EFSA guidance on applications for authorization	Guidance on the **preparation and presentation of an application for authorization** of a novel food in the context of Regulation (EU) 2015/2283 Administrative guidance on the **submission of applications for authorization of a novel food pursuant to Article 10** of Regulation (EU) 2015/2283
EFSA guidance on notifications and applications of traditional food	Guidance on the **preparation and presentation of the notification and application for authorization of traditional foods from third countries** in the context of Regulation (EU) 2015/2283
Information and guidance document	Guidance on human **consumption to a significant degree**

Table 2 Novel Food categories under the Regulation (EU) 2015/2283 and the former Regulation (EC) No 258/97 (Food categories newly added in Regulation (EU) 2015/2283) are given in red color)

Regulation (EU) 2015/2283		Regulation (EC) No 258/97 (2009)*
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	Foods and food ingredients with a new or intentionally **modified primary molecular structure**
ii	Food **consisting of, isolated from** or ***produced*** from microorganisms, fungi or algae	Foods and food ingredients **consisting of** or **isolated 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	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
v	Food **consisting** of, **isolated from** or ***produced from animals*** *or* ***their parts***, except for animals obtained by traditional breeding practices which have been used for food production within the Union before 15 May 1997 and the food from those animals has a history of safe food use within the Union	
vi	Food consisting of, isolated from or produced from **cell culture or tissue culture** derived from animals, plants, micro-organisms, fungi or algae	
vii	Food ***resulting from*** **a production process not used for food production within the Union** before 15 May 1997, which gives rise to significant changes in the composition or structure of a food, affecting its nutritional value, metabolism or level of undesirable substances	Foods and food ingredients to which has been applied a **production process not currently used**, 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.
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	

Regulation (EC) No 1333/2008, whereas any other food uses of this product have to be authorized pursuant to the Novel Food Regulation (e.g., purified lycopene from tomatoes [*Lycopersicon esculantum* L.]).

It is worth noting that two more categories (foods and food ingredients containing or consisting of genetically modified organisms within the meaning of Directive 90/220/EEC; foods and food ingredients produced from, but not containing, genetically modified organisms) existed in the original version of Regulation (EC) No 258/97 (version 14.2.97) but were deleted due to an amendment by Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. Thus food products containing, consisting, or produced from genetically modified organisms (GMOs) do not anymore fall within the scope of the Novel Food Regulation but are regulated under the separate, specific Regulation (EU) No 1829/2003 (2003) on genetically modified food and feed since 2003.

Furthermore, foods consisting of/isolated from/produced from plants or their parts are now listed separately from food consisting of/isolated from/produced from animals or their parts. While Regulation (EC) No 258/97 comprised a legal uncertainty for whole insects as the applicable food category was defined as "food ingredients isolated from animals," the situation regarding the authorization of insect-based products, whole insects, parts of insects, or food ingredients isolated from insects as Novel Foods, if no history of consumption is approved, is now clarified. Consequently, a number of applications under the new Novel Food Regulation are now dedicated to insects, e.g., the house cricket (*Acheta domesticus*), the larvae of the lesser mealworm (*Alphitobius diaperinus*), the larvae of the black soldier fly (*Hermetia illucens*), the male pupae of the honey bee (*Apis mellifera*), the tropical house cricket (*Gryllodes sigillatus*), the migratory locust (*Locusta migratoria*), or the larvae of the mealworm beetle (*Tenebrio molitor*).

Considering the expansion of nanotechnologies used in the food industry, food containing or consisting of engineered nanomaterials was also included as Novel Food along with a definition of engineered nanomaterial as "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."

Determination of Novel Food Status

Article 4 of the Novel Food Regulation (EU) 2015/2283 lays down basic principles on the procedure for the determination of the novel food status and requires food business operators to verify whether the food which they intend to place on the Union market falls within the scope of that Regulation or not.

Accordingly, the Novel Food catalog may serve as an indicative source of information on the history of use of the product. This nonexhaustive list maintained by the European Commission is based on information provided by the Member States and gives an orientation on whether a product of animal and plant origin or other substances will need an authorization under the Novel Food Regulation. Nevertheless, the food business operator should take into account specific national

regulations that may restrict the use of the product as food (e.g., considered as medicine), even in the case products have a history of use for human consumption in some Member States.

In case of uncertainties regarding the Novel Food status, the food business operator can consult the Member State, where the food is first intended to be marketed. This recipient Member State then determines, based on necessary information provided by the food business operator, whether or not a food was used for human consumption to a significant degree within the Union before 15 May 1997. In order to determine the Novel Food status the recipient Member state may also consult other Member States and the European Commission. Within 4 months after verifying the validity of the consultation request the recipient Member State concludes on the Novel Food status of the food and the outcome is made publicly available by the European Commission on the Commission's website.

More detailed guidance on the consultation process can be found in Commission Implementing Regulation (EU) 2018/456 (2018). In addition to determing the Novel Food status according to Article 4 of Regulation (EU) 2015/2283, Article 5 authorizes the European Commission to decide, on its own initiative or upon a request by a Member State, on the novel food status of a particular food.

A key element in the determination of a novel food status is the history of human consumption to a significant degree within the Union before 15 May 1997. To address the sometimes difficult question of "human consumption to a significant degree" an information and guidance document is available on the European Commission's webpage (EC (European Commission) 2020) laying down specific criteria that should be considered. In addition, the Novel Food Regulation (EU) 2015/2283 clarifies that the history of consumption of a food as food supplement before 15 May 1997 is not relevant for the evaluation of whether a food was used for human consumption to a significant degree within the Union before 15 May 1997. However, foods that were exclusively used as food supplements before 15 May 1997 are not considered to be novel if they are intended to be used as or in food supplements after this date.

More than 30 consultation requests under Article 4 have already been decided until now (March 2020), including among others an application for consultation to determine the Novel Food status of berries of *Aristotelia chilensis* (Maqui berries). Here, it was decided by the German Federal Office for Consumer Protection and Food Safety that Maqui berries are considered to be not novel for use as or in food supplements due to an authorization of Maqui berries as or in food supplements in Italy. Apart from that, Maqui berries have a history of being used for the coloring of wine in the EU. However, this was not approved to constitute a "consumption to a significant degree." As there were no evidences for the use of Maqui berries for nutritional purposes, it was decided that they have to be considered as Novel Food when used for food uses other than food supplements.

Traditional Foods from Third Countries

A further substantial specification was introduced by defining specific rules for novel foods with a history of safe food use in a third country. In order to be acknowledged as a "traditional food from a third country" the safety of the food has to be confirmed

with compositional data along with a history of safe consumption by a significant number of people in at least one-third country for at least 25 years. Furthermore, the food has to be derived from primary production as defined in Regulation (EC) No 178/2002. For example, a juice derived from an exotic fruit not consumed in the European Union before 15 May 1997, but having been part of a regular diet in a third country, would be considered as a "traditional food." If this is the case, a faster and simplified notification procedure is set out.

However, this applies only to novel foods belonging to the categories "microorganisms, fungi, or algae," "animals or their parts," "plants or their parts," and "cell or tissue cultures derived from animals, plants, microorganisms, fungi, or algae" (for detailed description see food categories ii, iv, v, and vi in Table 2). The Articles 14 to 20 of the Regulation (EU) 2015/2283 lay down the specific rules and requirements for this category of Novel Foods (see section "Notification and Application for Authorization of Traditional Foods from Third Countries").

Up to now (March 2020), nine notifications of traditional foods from countries outside the EU have been submitted. All of these notifications concern foods derived from plants. Three of the notified foods have already been authorized as traditional foods from third countries: berries of *Lonicera caerulea* L. (Commission Implementing Regulation (EU) 2018/1991 1991), decorticated grains of *Digitaria exilis* (Commission Implementing Regulation (EU) 2018/2016 2018), and syrup from *Sorghum bicolor* (L.) Moench (Commission Implementing Regulation (EU) 2018/2017 2018). Additionally, two notifications concerning the same traditional food, namely fruit pulp from the cocoa plant *Theobroma cacao* L. (Commission Implementing Regulation (EU) 2020/206 2020), have recently been authorized as well. Regarding the traditional foods leaf powder from *Moringa stenopetala* (EFSA (European Food Safety Authority) 2019a) and powder or juice concentrate of berries of *Aristotelia chilensis* (Maqui berries) (EFSA (European Food Safety Authority) 2019b), EFSA has raised safety objections to the placing on the market within the EU. In contrast, no safety objections were submitted by EFSA concerning an infusion from coffee leaves (*Coffea arabica* L. and/or *Coffea canephora* Pierre ex A. Froehner) as a traditional food from a third country (EFSA (European Food Safety Authority) 2020). For roasted sacha inchi seeds the notification process is still ongoing and the safety assessment by the EFSA is not yet published.

Union List of Generic Authorized Novel Foods

Once a food is authorized as a novel food, or a traditional food from a third country is successfully notified, it is included in the Union list of Novel Foods authorized to be placed on the market within the Union. According to Article 7 of the Novel Food Regulation (EU) 2015/2283, the European Commission only authorizes and includes a novel food in the Union list if it is in accordance 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.

The Union list contains the name of the authorized novel food, the specification, the specified conditions of use regarding food category and maximum levels, additional specific labeling requirements, and other requirements like post-market monitoring requirements which may be imposed by the European Commission for food safety reasons.

In addition to the authorized Novel Foods under Regulation (EU) 2015/2283, the Union list also contains all Novel Foods authorized and notified under the former Novel Food Regulation (EC) No 258/97. These novel foods were included in the Union list established through Implementing Regulation (EU) 2017/2470 (2017). On 23 July 2018, the Union list was corrected by replacing the Annex to Implementing Regulation (EU) 2017/2470 with the Annex to Implementing Regulation (EU) 2018/1023 (2018) due to the inclusion of newly authorized novel foods and the correction of a number of errors and omissions regarding existing entries of already authorized novel foods.

Once a novel food is included in the Union list, the authorization is generic meaning any food business operator can directly market their products following the conditions and specifications set out in Implementing Regulation (EU) 2018/1023. If that is not the case, food business operators may request a so-called extension of a Novel Food authorization, and therefore have to submit a new application to the European Commission for adding, removing, or changing the conditions, specifications, or requirements set out in the Union list.

The Union list will be updated regularly by the European Commission when a novel food is added or removed from the list, or when the conditions of commercialization have changed.

The concept of generic authorizations replaces the previously valid principle of the former Regulation (EC) No 258/97 that foods being substantially equivalent to existing foods were not subject to authorization. To protect the applicant's investment and to promote research, development, and innovation within the agri-food sector, applicants that submit newly developed scientific evidence and proprietary data can request data protection for 5 years. Subsequent applicants cannot benefit from the application during this period unless they obtain authorization for the novel food without reference to the protected data or with the agreement of the initial applicant. Where data protection is granted, the Union list specifies it, and indicates that during the period of data protection the novel food is authorized for placing on the market within the Union only by the initial applicant.

Transitional Measures

Foods which were lawfully placed on the market prior to 1 January 2018 and did not fall within the scope of the former Regulation (EC) No 258/97, but are subject to the new Novel Food Regulation (EU) 2015/2283, are covered by transitional provisions laid down in Article 35 of this Regulation. Provided that an application for authorization of a Novel Food or a notification of a traditional food from a third country has been submitted by 1 January 2019, these foods can continue to be placed on the market until an outcome of the authorization procedure has been decided. In addition, the transitional measures also regulate that applications for placing a novel food on the market under the former Novel Food Regulation (EC) No 258/97 not finally decided by 1 January 2018 are treated as applications under the new Regulation (EU) 2015/2283.

Authorization Procedure in the EU

Food business operators, who intend to introduce a "new food" into the EU market, have to determine in advance whether their food is subject to the Novel Food Regulation (EU) 2015/2283. This means they have to check if the food falls under the definition of Novel Food and into one of the specified novel food categories as presented in section "Revision of the Novel Food Categories." The novel food catalog (section "Determination of Novel Food Status") may serve as an orientation in addressing the question of whether a food has to be regarded as a novel food or not. Food business operators may also submit a formal request to a Member State according to Article 4 to clarify the status of the food. If the "new food" is indeed regarded as a novel food, it will need an authorization under Regulation (EU) 2015/2283, either as an authorization of a novel food or as a notification of a traditonal food from a third country.

Authorization Procedure for Novel Foods

To ensure an EU-wide harmonized authorization and safety assessment of novel foods the new Novel Food Regulation introduced a centralized autorization procedure managed by the European Commission. The different steps of the authorization procedure are laid down in chapter III of Regulation (EU) 2015/2283 in Articles 10 to 13.

Before placing a novel food on the market within the European Union for the first time, the applicant, as defined in Article 3 (2a) of Regulation (EU) 2015/2283, has to directly submit an application for authorization to the European Commission in line with the requirements of Article 10 of the Regulation using the "e-submission"-system (Fig. 1). The application dossier should be in accordance with Commission Implementing Regulation (EU) 2017/2469 (2017) which lays down specific

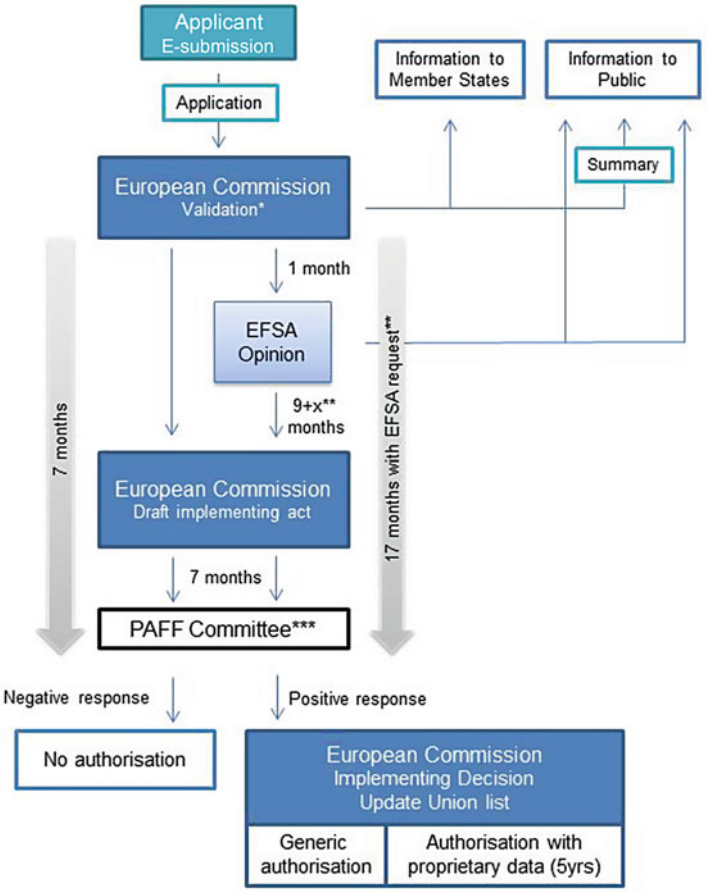

Fig. 1 Authorization procedure according to Novel Food Regulation (EU) 2015/2282. * Verification of validity + possible consultation with EFSA; ** Time period may be extended when EFSA requests additional information from the applicant; *** Standing Committee on Plants, Animals, Food and Feed

rules for the implementation regarding the administrative and scientific requirements for applications as well as the transitional measures.

Having received the application, the European Commission verifies the validity of the application dossier. If the European Commission requests the opinion of the European Food Safety Authority (EFSA) it forwards the valid application without delay and within 1 month of verifying the validity of the application to EFSA which carries out a scientific assessment of the safety of the proposed novel food within 9 months from the date of receipt of the valid application. If EFSA requests additional information from the applicant, the 9-month period may be extended. After EFSA has forwarded its opinion to the European Commission, to the Member States and, where applicable, to the applicant, the Commission submits a draft implementing act for the authorization of the novel food and updating of the Union list to the Standing

Committee on Plants, Animals, Food and Feed (PAFF Committee), composed of representatives of the Member States, within 7 months from the date of the publication of the EFSA opinion. In case the European Commission has not requested an opinion from EFSA, the 7-month period starts from the date on which a valid application is received by the Commission. Once the implementing act receives a positive response from the PAFF Committee and is adopted and published by the European Commission, the authorized novel food can be placed on the market within the European Union and the Union list is updated (see section "Union List of Generic Authorized Novel Foods").

Risk Assessment Process

The risk assessment of novel foods aims to ensure that the requested Novel Food does not pose a safety risk to human health. In order to enable a comprehensive risk assessment of the novel food in question, the applicant should, according to Article 10 of the Novel Food Regulation (EU) 2015/2283, provide information on the name and description of the novel food, the production processes, the composition of the novel food, scientific evidence demonstrating that the novel food does not pose a safety risk to human health, the analysis methods (where appropriate), and a proposal for the conditions of intended use as well as a proposal for specific labeling requirements which do not mislead the consumer.

Upon request by the European Commission, the EFSA assesses the safety of the novel food under the proposed conditions of use. EFSA carries out its scientific risk assessment based on the dossier provided by the applicant and considers the following aspects (see EFSA guidance document 2016 (EFSA NDA Panel (European Food Safety Authority Panel on Dietetic Products, Nutrition and Allergies) 2016a)):

1. Whether the novel food concerned is as safe as food from a comparable food category already existing on the market within the Union.
2. Whether the composition of the novel food and the conditions of its use do not pose a safety risk to human health in the Union.
3. 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.

EFSA has developed two guidance documents (EFSA NDA Panel (European Food Safety Authority Panel on Dietetic Products, Nutrition and Allergies) 2016a; EFSA (European Food Safety Authority) 2018a) which provide scientific information and data needed for the safety assessment of novel foods and present a common format for the organization of the requested data. The guidance documents are intended to support applicants in the preparation of comprehensive applications and to facilitate an effective and consistent evaluation by EFSA in order to ensure a harmonized scientific assessment of novel foods. Apart from administrative data the application should contain technical and scientific data specific to the novel food which are of relevance for the risk assessment and provided in more detail in the following sections.

Introduction and Identity of the Novel Food

The novel food should be briefly introduced by describing the source, the principle of the production process, typical compositional features as well as the purpose and the intended use. For novel foods referring to chemical substances, polymers, or food consisting of, isolated from, or produced from material of mineral origin information on the identity of the novel food should comprise the chemical name, CAS number, or other identification numbers, synonyms, trade names and abbreviations, molecular and structural formulae, stereochemistry, molecular weigth as well as particle size, shape, crystal form, and distribution. For novel foods consisting of, isolated from, or produced from microorganisms, fungi, algae, plants/plant parts, animals/animal parts, or cell/tissue culture derived from animals/plants/fungi/algae, the identity should be substantiated by providing the scientific name, synonyms, common names, verification of the identity of plants, algae, and fungi according to internationally recognized databases and methodology, organ and tissue or parts used of the source organism, geographical origin, and laboratory or culture collection used as source. The characterization and identification of food consisting of engineered nanomaterials calls for a broader range of parameters. The required information regarding engineered nanomaterials are elaborated in detail in the EFSA guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain (EFSA SC (European Food Safety Authority Scientific Committee) 2018).

Production Process

To ensure that no safety concerns arise from the production process of the novel food, a comprehensive description of all information relevant to the production and processing of the novel food needs to be provided. This includes the detailed description of the processes involved in the production of the novel food. Information regarding the handling of sources, post-harvest handling of unprocessed foods, raw materials, and/or chemical substances used, processes employed to convert the raw materials into the product, specification of reaction conditions, purification methods, and identification of potential by-products, impurities, and contaminants should be provided. Furthermore, a description of operational limits and key parameters of the production process, measures concerning production control as well as quality and safety assurance, production flow charts indicating quality and safety control checks, and standardization criteria should be included.

One category of novel foods in the Novel Food Regulation (EU) 2015/2283 explicitly concerns the novelty of the employed production processes and refers to food resulting from a production process not used for food production within the Union before 15 May 1997. As the Regulation, in this regard, confines the term novel to production processes that do not significantly change the composition or structure of a food and do not affect the nutritional value, the metabolism or the level of undesirable substances, it is essential that all novel aspects of the production process as well as its effects on the bioavailibility, nutritional value and safety of the Novel Food in question are characterized in detail by the applicant.

Compositional Data

The composition of the novel food should be demonstrated by qualitative and quantitative data and should include information on physicochemical, biochemical, and microbiological characteristics. The data should contain the identification and quantification of substances of toxicological concern, impurities, by-products, residues, and contaminants. The analytical methods used should be validated and the provided data should include a description of the methods, the limit of detection and quantification as well as information on the accreditation of laboratories. To represent a certain range of variability, at least five representative and independently produced batches of the novel food should be analyzed. If the Novel Food refers to a single compound or fully chemically characterized mixtures thereof, compositional data should contain information on the identity and relative ratios of all components, the mass balance, identity tests used for the analyses, physicochemical properties as well as minimum purity. In contrast, complex mixtures or whole foods cannot be fully chemically characterized. Here, the qualitative and quantitative analysis should focus on the main constituents, proximate analyses, nutritionally relevant components, substances posing a possible concern to human health, and naturally or chemically derived components typically characteristic for the novel food. Analytical data on the composition of the novel food should be compared with data from literature.

Safety concerns may also arise from the storage and transport of the Novel Food. Therefore, the physicochemical, biochemical, and microbiological stability have to be tested and evaluated preferably on at least five representative and independently produced batches of the novel food.

Specification

The specification shall ensure that the product intended to be placed on the EU market complies with the analyzed and evaluated Novel Food. It should appropriately characterize the novel food by setting physicochemical, biochemical, and microbiological key parameters including the contents of nutritionally or biologically active compounds, contents of major groups of food constituents, purity, limits for impurities, and degradation products as well as maximum levels for chemical and microbiological contaminants.

History of the Novel Food and/or of Its Source

Information on the experience gained with a Novel Food regarding the previous exposure and use of a novel food outside the EU is of high relevance for the risk assesment. This includes data on the use of the Novel Food outside the EU as well as for nonfood purposes. Relevant aspects to assess the history of use are the extent of use, the characterization of the population groups which have consumed the Novel Food, the role of the novel food in the diet of these population groups, specific information regarding the handling and preparation of the food as well as precautions regarding its preparation and use. Furthermore, information on human studies about relevant safety aspects of the novel food in question resulting from a thorough and comprehensive literature review should be provided by the applicant. In general,

data concerning the history of use of a novel food should not be limited to the novel food itself but, in addition, should also include information on the composition, production, and experience from use of other products derived from the same source (e.g., a certain plant) as the novel food.

Proposed Use and Use Levels and Anticipated Intake

An essential part of risk characterization is the exposure assessment. To estimate the intake of the novel food in question, information on the use levels of the novel food and data on the food consumption are needed. The use and use levels are proposed by the applicant. This requires to specify the target population, the form of uses, the food categories in which the Novel Food is intended to be used, the proposed maximum use levels, and concentrations in the final product intended to be consumed and the proposed daily intakes. It also needs to be clarified whether the novel food is meant to replace another food. Food consumption data should be retrieved from representative databases like the EFSA Comprehensive European Food Consumption Database (EFSA (European Food Safety Authority) 2011a) or national dietary surveys. Based on these information the anticipated mean and high daily intakes are estimated taking into account different population groups, combined comsumption of all the food categories the Novel Food is proposed to be used in, and different consumption scenarios. Additionally, it might occur that a novel food also has other dietary sources like being a natural constituent in food. In this case, the combined exposure from the novel food and the background diet must be taken into consideration and the extent of the additional intake of the novel food in relation to the overall intake should be assessed. Even nondietary sources like cosmetics or pharmaceuticals might be relevant and considered in the overall exposure assessment. As the compositional analysis of the novel food might also reveal undesirable compounds present in the novel food, the intake assessment must also comprise such constituents. Based on the exposure assessment and all available data concerning the safety of the novel food, relevant precautions and restrictions regarding the use of the novel food should be specified.

Absorption, Distribution, Metabolism, and Excretion (ADME)

A comprehensive assessment of all relevant toxicological and nutritional aspects of the Novel Food also requires toxicokinetic information. Data on absorption, distribution, metabolism, and excretion should be preferably provided for all toxicologically and nutritionally relevant constituents of the Novel Food according to the principles outlined in the EFSA guidance for the evaluation of food additives (EFSA ANS PANEL (European Food Safety Authority Panel on Food Additives and Nutrient Sources added to Food) 2012). These principles describe a tiered approach to toxicokinetic testing. Tier 1 assesses whether the Novel Food or its breakdown products are absorbed. If it can be demonstrated that the absorption is negliable, omitting higher tiered toxicological studies may be scientifically justified. Tier 2 requires in vivo assessment of absorption, distribution, metabolism, and excretion as well as basic single dose toxicokinetic parameters after systemic exposure to a single dose. If indications for bioaccumulation like limited or slow excretion are observed,

tier 3 toxicokinetic testing is necessary to define toxicokinetic parameters following repeated administration. Requirements regarding ADME studies for Novel Foods consisting of engineered nanomaterials are specified in the EFSA guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain (EFSA SC (European Food Safety Authority Scientific Committee) 2018).

Nutritional Information

According to Article 7 of the Novel Food Regulation (EU) 2015/2283, a novel food that 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. The applicant has to demonstrate that the consumption of the novel food in question does not lead to nutritional disadvantages under the proposed conditions of use. To assess the novel food's impact on nutrient intake, comprehensive information about the nutritional composition regarding macro- and micronutrients and the bioavailability of the novel food are required. This also includes information regarding the presence of antinutritional constituents and any possible effects and interactions with nutrients. Furthermore, the proposed use levels and estimated exposure for nutritional and antinutritional factors should be considered and assessed in relation to available dietary intakes, tolerable upper intake levels, and relevant health-based guidance values. If the target population includes sensitive subpopulations with particular physiological or metabolic characteristics (e.g., infants, young children, pregnant, or lactating women), these population groups should be specifically considered in the nutritional evaluation.

Toxicological Information

As the safety of the novel food is assessed, the toxicological information should be derived from toxicological studies analysing the novel food in the form as it is intended to be placed on the market. Information on compounds having a structure similar to the Novel Food are suitable to assist in the safety assessment of the novel food in question. In general, the toxicological testing should follow international guidelines and principles of good laboratory practice. Similar to the evaluation of ADME data, toxicological testing should be carried out according to EFSA's tiered toxicity testing approach described for food additives (EFSA ANS PANEL (European Food Safety Authority Panel on Food Additives and Nutrient Sources added to Food) 2012). It adresses genotoxicity, subchronic toxicity, chronic toxicity, and carcinogenicity as well as reproductive and developmental toxicity.

Assessing the genotoxic and mutagenic potential in a chemical risk assessment aims for the identification of substances capable of causing heritable damage in humans, the prediction of potential genotoxic carcinogens when no carcinogenicity data are available, and elucidation of the specific mechanism of actions of chemical carcinogens. Following a stepwise approach a series of in vitro assays (bacterial reverse mutation assay (OECD (Organisation for Economic Co-Operation and Development) 1997), in vitro mammalian cell micronucleus test (OECD (Organisation for Economic Co-Operation and Development) 2016a)) are initially

recommended to evaluate the induction of gene mutation and chromosomal abberations (clastogenicity/aneuploidy). In the case of positive results, further approaches are recommended including substitution and completion of in vitro assays with other appropriate in vitro and in vivo assays (e.g., in vivo micronucleus test (OECD (Organisation for Economic Co-Operation and Development) 2016b), in vivo Comet assay (OECD (Organisation for Economic Co-Operation and Development) 2016c), and transgenic rodent assay (OECD (Organisation for Economic Co-Operation and Development) 2013)). The evaluation of test results and the selection of follow-up assays should always consider all available relevant data of the substance including chemical reactivity, bioavailability, metabolism, toxicokinetics, target organ specificity, and endpoints. For novel foods representing complex mixtures or whole foods which naturally encompass a multitude of different compounds, it is recommended to focus on toxicologically relevant constituents of the Novel Food.

In addition to genotoxicity, the safety assessment of a Novel Food requires the evaluation of subchronic toxicity. Subchronic toxicity studies aim to provide information on the affected target organs and tissues, the type, extent, and severity of any effects as well as on dose-response relationships including the determination of reference points/points of departure like the relevant benchmark dose lower confidence limit (BMDL) or the no observed adverse effect level (NOAEL). Furthermore, they should assist in estimating appropriate dose levels for chronic toxicity studies and provide information regarding the need for additional in-depth investigation of particular effects and endpoints, e.g., neurotoxic effects, immunological effects, reproductive organ effects, or endocrine-mediated effects. Subchronic toxicity data should be derived from a repeated dose 90-day oral toxicity study in rodents (OECD (Organisation for Economic Co-Operation and Development) 2018a) modified to include additional parameters to assess endocrine activity as described for repeated dose 28-day oral toxicity studies in rodents (OECD (Organisation for Economic Co-Operation and Development) 2008). In absence of systemic availability, analyses should focus on pathological and physiological effects in the gastrointestinal tract.

Critical findings resulting from preceding genotoxicity tests and subchronic toxicity studies may raise the need for conducting a chronic toxicity (OECD (Organisation for Economic Co-Operation and Development) 2018b) and a carcinogenicity study (OECD (Organisation for Economic Co-Operation and Development) 2018c). Both studies are preferably performed in rats for a duration of 12 months (chronic tocxicity) or 24 months (carcinogenicity). Alternatively to conducting two seperate studies, it is also possible to perform a more time and cost-effective combined chronic toxicity/carcinogenicity study (OECD (Organisation for Economic Co-Operation and Development) 2018d).

Reproductive toxicity studies aim to reveal effects on male and female fertility, on the female's ability to carry pregnancy to term and on maternal lactation and care of the young. Regarding effects on the offspring, they provide information on the prenatal and postnatal survival, growth, functional and behavioral development, and reproductive capacity. Additionally, the studies enable the histological identification of important target organs for toxicity in parents and offspring. Prenatal

developmental toxicity studies provide information on lethal, teratogenic, or other toxic effects on the embryo and fetus. The need for reproductive and developmental toxicity studies has to be evaluated based on available toxicokinetic and toxicity information. In the case of proven or suspected systemic availability of a substance or if the repeated dose 90-day oral toxicity study indicates any effects on reproductiove organs or parameters, reproductive and developmental toxicity testing is required. Recommended testing studies are a prenatal developmental toxicity study in the rabbit (OECD (Organisation for Economic Co-Operation and Development) 2018e) and an extended one-generation reproduction toxicity study in the rat (OECD (Organisation for Economic Co-Operation and Development) 2018f).

Furthermore, relevant information regarding the safety of a novel food can be derived from availiable human studies. Such studies may assist in evaluating potential adverse effects and in demonstrating the safety of the novel food under the proposed conditions of use.

There is an increasing interest in the consumption of insects as novel foods. The production and consumption of insects as food and feed may be associated with specific microbiological, chemical, and environmental hazards. These insect-related risks have been comprehensively identified and evaluated by EFSA and should be carefully considered in the safety assessment of insects as novel food (EFSA SC (European Food Safety Authority Scientific Committee) 2015).

Novel Foods may also be composed of, isolated from, or produced from microorganisms. Thus, ensuring that the novel food in question does not pose a risk to human health requires a microbiological safety assessment. This includes taxonomic classification at the species level and strain characterization at the genomic sequence level for the detection of potential virulence-related genes, antibiotic resistances, and their potential horizontal transfer. Additional potentially adverse genotypic and phenotypic characeteristics and features should be evaluated as well. If a microorganism has a history of safe use and is assigned to a group of microorganism with a qualified presumption of safety (QPS) status, the requirements for the safety evaluation are reduced to complying with the criteria and qualifications specified in the QPS list (EFSA (European Food Safety Authority) 2008) and the risk assessment of antimicrobial resistance (EFSA FEEDAP Panel (European Food Safety Authority Panel on Additives and Products or Substances used in Animal Feed) 2012). A QPS status is granted for taxonomic groups posing no safety risk or where safety concerns can be defined and excluded.

Regarding the toxicological safety assessment of novel foods consisting of engineered nanomaterials, the specific data requirements and principles are outlined in the EFSA guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain (EFSA SC (European Food Safety Authority Scientific Committee) 2018).

Allergenicity

To ensure the safety of a novel food, the allergenic potential of the novel food needs to be evaluated. As most food allergens are protein-based, all novel foods containing proteins are assumed to potentially elicit allergic reactions. To assess the allergenic

potential information regarding sensitization, studies on allergenicity and case reports concerning allergic reactions are needed. Investigation of allergenicity may include data on structural aspects of the proteins or peptides, detection of cross-reactive IgE antibodies, skin prick testing, or double-blind placebo-controlled oral food challenges. Evidence for potential allergenic reactions of a novel food requires risk management measures like restriction and labeling of the novel food to protect potentially affected consumers.

Notification and Application for Authorization of Traditional Foods from Third Countries

The new Novel Food Regulation (EU) 2015/2283 introduces a faster and more appropriate notification procedure for traditional foods from non-EU countries with a demonstrated safe history of use of at least 25 years. The specific requirements applying to traditional foods from third countries are set out in Article 14 to 20.

Before placing the food on the market within the European Union as traditional food, the applicant has to directly submit an online notification for authorization to the European Commission (Fig. 2) which has to be in accordance with the requirements in Article 14 of the Regulation (EU) 2015/2283 and Commission Implementing Regulation (EU) 2017/2468 (2017) setting out administrative and scientific requirements for applications for authorizations of traditional foods from third countries. Within 1 month after verifying the validity of the notification, the European Commission forwards the notification to the Member States and EFSA. If EFSA and Member States do not raise duly reasoned safety concerns regarding the placing on the market within the Union of the traditional food within a period of 4 months, the traditional food is authorized by the European Commission and the Union list is updated. However, in case of duly reasoned safety objections submitted by EFSA or Member States, the European Commission neither authorizes the traditional food concerned nor updates the Union list. Instead, the applicant may submit an application for the authorization of traditional foods from third countries to the European Commission following the requirements of Article 16 of Regulation (EU) 2015/2283. Here, in addition to the information already requested for the notification procedure for traditional foods from third countries according to Article 14, the applicant is also required to provide specific data related to the duly reasoned safety objections raised by EFSA or Member States.

The application for the authorization of traditional foods from third countries is forwarded without delay to EFSA and made available to the Member States by the European Commission. EFSA is requested by the European Commission to review the application and assess the safety of the traditional food from a third country within 6 months. The 6-month period may be extended if EFSA requests additional information from the applicant. After receiving EFSA's opinion on the application within 3 months the European Commission submits to the PAFF Committee a draft implementing act authorizing the placing on the market within the Union of the traditional food from a third country. When the authorization is granted, the Union

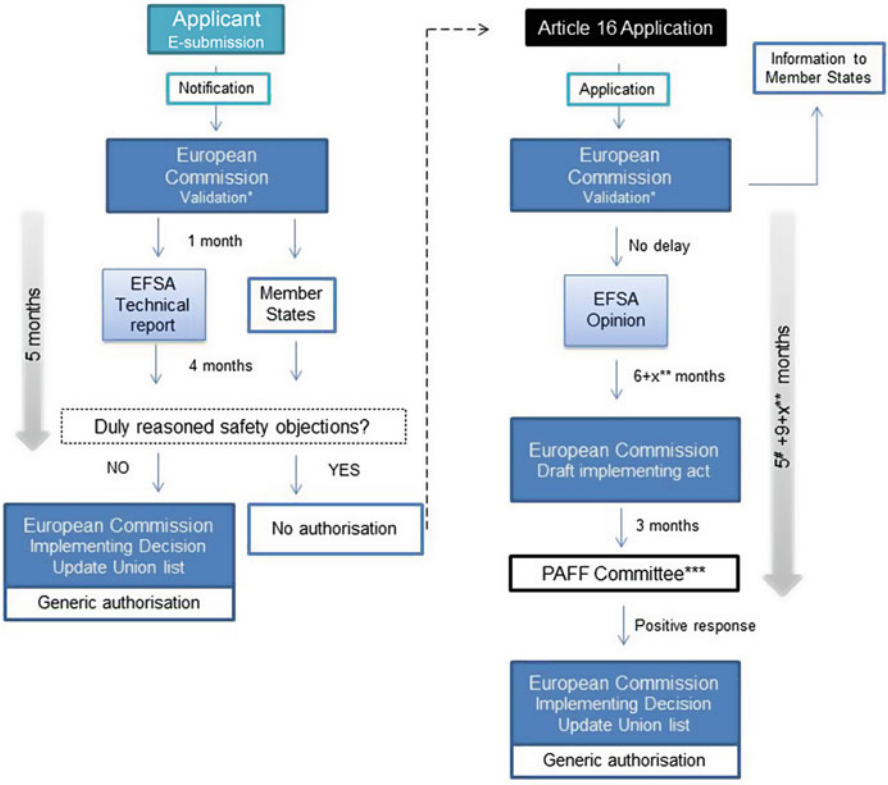

Fig. 2 Notification procedure and application for authorization of traditional foods from third countries according to Novel Food Regulation (EU) 2015/2282. * Verification of validity + possible consultation with EFSA; ** Time period may be extended when EFSA requests additional information from the applicant; *** Standing Committee on Plants, Animals, Food and Feed; # Time period due to notification procedure

list will be updated. Overall, the time frame for the EFSA opinion and the European Commission decision are somewhat shorter for an application for the authorization of a traditional food from a third country compared to the regular authorization procedure of Novel Foods, though the process is still complex and time-consuming for the applicant.

Safety Assessment Procedure for Traditional Foods from Third Countries

Before a traditional food from a third country pursuant to Regulation (EU) 2015/2283 and Commission Implementing Regulation (EU) 2017/2468 (2017) can be placed on the market within the EU, it must be subjected to a premarket safety assessment based on a history of safe food use. Notifications according to Article 14 of Regulation (EU) 2015/2283 should contain sufficient information and scientific

documentation for the European Commission to verify the validity and enable Member States and EFSA to evaluate the history of safe use of the traditional food in at least one country outside of the EU for a period of at least 25 years. These information should include the name, description, and composition of the traditional food, the country/countries of origin, documented data demonstrating the history of safe food use in a third country as well as a proposal for the conditions of intended use and for specific labeling requirements not misleading the consumer.

In order to support applicants in providing the entire type and quality of information relevant to conclude whether there are reasoned safety objections, EFSA provided a scientific and technical guidance document for the preparation and presentation of the notification dossier (EFSA NDA Panel (European Food Safety Authority Panel on Dietetic Products, Nutrition and Allergies) 2016b). As indicated in this guidance document, it is the duty of the applicant to provide all the available and reliable data that are pertinent to the safety of the traditional food.

Consistent with application dossiers of novel foods according to Article 10 of Regulation (EU) 2015/2283, the notification dossier needs to contain information on the identity of the traditional food and reliable data on the respective production process, the composition and specifications of the traditional food as described in sections "Introduction and Identity of the Novel Food," "Production Process," "Compositional Data," and "Specification." In addition, the applicant has to demonstrate the experience of continued use of the traditional food and has to propose conditions of use for the EU market. In contrast to the evaluation of novel foods, the applicant is not specifically requested to provide specific information or perform specific studies on toxicokinetic, toxicological, nutritional, and allergenic properties of the traditional food (see Table 3). However, if such data are available they should be provided to ensure a comprehensive risk assessment of the traditional food covering all relevant safety aspects.

Data from the Experience of Continued Food Use in the Third Country

A central point in the safety assessment of a traditional food is the experience of continued use of the traditional food for at least 25 years in the third country. Data should cover a description of the extent of use including data on production (e.g., place, volume per year) and geographical areas along with information on intake levels and intake estimates. For example, in the case of notifying the placing on the market of berries of *Lonicera caerulea* L. (Haskap berries) as a traditional food from a third country, the applicant provided amongst others references to document the annually average consumption per person over the past 30 years in Hokkaido (Japan) (EFSA (European Food Safety Authority) 2018b).

In addressing the continued food use, information on the specific population group(s) of consumers (e.g., general population or subpopulations defined by specific criteria like age and ethnic background) along with the group size should be provided by the applicant. The role of the traditional food in the diet should also be documented including consumption pattern and frequency (e.g., consumed in the form of beverages or as food ingredient in processed foods). It may be conducive to supply data on how the intake of the traditional food contributes to the total intake of

Table 3 Data requirements of the application/notification dossier for risk assessment of novel foods and traditional foods from third countries (EFSA NDA Panel (European Food Safety Authority Panel on Dietetic Products, Nutrition and Allergies) 2016a, b)

Application for authorization of novel foods	Notification for authorization of traditional foods from third countries
Identity of the novel food	Identity of the traditional food
Production process	Production process
Compositional data	Compositional data
Specifications	Specifications
History of use of the novel food and/or of its source	Data from experience of continued use
Proposed uses and use levels and anticipated intake	Proposed conditions of use for the EU market
Absorption, distribution, metabolism, and excretion	
Nutritional information	
Toxicological information	
Allergenicity	

macro- and micronutrients of the population. Additionally, the traditional manufacture, preparation, preservation, packaging, or storage should be described.

Precautions regarding preparation and handling of the food as well as restrictions of use (e.g., for specific subpopulations like children) should be provided along with any kind of treatments or methods leading to the reduction of toxicological relevant and antinutritional substances or improving the digestibility of the food. Furthermore, any available human data related to the safety of the traditional food should be reported including clinical trails, observational studies, and information from case and surveillance reports. Additionally, data on specific and typical components of the traditional food or on similar foods from related sources as well as other important data (e.g., animal toxicity studies and nonfood use in medicine) should be adressed to support a conclusion on the history of safe use of the notified traditional food.

Proposed Conditions of Use for the EU Market

In order to place on the market within the EU a traditional food from a third country, the notification should clearly and specifically define the target population intended to consume the traditional food. It is particularly important to provide specific information about the proposed uses und use levels to evaluate whether the traditional food may pose a risk for human consumption. This includes the form of uses and clearly defined food categories (preferentially by following the EFSA food classification system (EFSA (European Food Safety Authority) 2011b)). It needs to be clarified whether the traditional food is supposed to replace another food and that the consumption of the traditional food is not nutritionally disadvantageous for the consumer. The proposed maximum use levels and concentrations in the final

product as well as the proposed daily intake levels for different subgroups classified by age and gender should, if applicable, also be indicated.

Regarding restrictions of use of the traditional food the (sub)groups of the population which should avoid the consumption should be defined and any other restrictions and precautions related to the handling, preparation, and consumption should be described along with any effects of potential overconsumption on population or subgroups of population.

Cross-References

- ▶ Exposure Scenarios in Toxicology
- ▶ Microbiome Product Toxicology: Regulatory View on Translational Challenges
- ▶ Risk Assessment of Food Additives
- ▶ Risk Assessment of Novel Food and Genetically Modified Food and Feed

Notes

1. When the General Food Law Regulation (Regulation (EC) No 178/2002) entered into force in 2002 the tasks of the SCF were taken over by the EFSA.

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