

Novel foods, regulatory aspects EU

NOVEL FOODS, REGULATORY ASPECTS EU

Regulation (EU) 2015/2283 on novel foods (1 January 2018 is applicable). It repeals and replaces Regulation (EC) No 258/97.

The new Regulation **improves conditions so that food businesses can easily bring new and innovative foods to the EU market**, while **maintaining a high level of food safety** for European consumers.



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Scope Regulation 2015/2283:

Expanded categories of Novel Foods: The Novel Food definition describes the various situations of **foods originating from plants, animals, microorganisms, cell cultures, minerals, etc., specific categories of foods** (insects, vitamins, minerals, food supplements, etc.), **foods resulting from production processes and practices**, and state of the art technologies (e.g. intentionally modified or **new molecular structure, nanomaterials**), which were not produced or used before 1997 and thus may be considered to be as novel foods.

More details article 3 point 2.



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Scope Regulation 2015/2283:

Not apply in the following cases:

- **Food enzymes** within Regulation (EC) No 1332/2008.
- **Food additives** within Regulation (EC) No 1333/2008.
- **Flavourings** for use in foods within Regulation (EC) No 1334/2008.
- **Extraction solvents** used in the production of foods within Directive 2009/32/EC approximating EU countries' laws.
- **GMOs for food and feed**, covered by Regulation (EC) No 1829/2003.
- If foods and/or food ingredients were used exclusively in food supplements, new uses in other foods require an authorisation under the Novel Food Regulation e.g. food fortification requires an authorisation.



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News with Regulation 2015/2283:

Generic authorisations of Novel Foods. This means that any food business operator can place an authorised Novel Food on the European Union market, provided the authorised conditions of use, labelling requirements, and specifications are respected.

Establishment of a Union [list of authorised Novel Foods](#): This is a positive list containing all authorised novel foods (Commission Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods).

Novel Foods which will be authorised in the future will be added to the Union list by means of Commission Implementing Regulations.



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A simplified, centralised authorisation procedure managed by the European Commission using an online application submission system.

Centralised, safety evaluation of the Novel Foods will be carried out by the European Food Safety Authority (**EFSA**). The European Commission consults EFSA on the applications and bases its authorisation decisions on the outcome of the EFSA's evaluation.

Efficiency and transparency will be improved by establishing deadlines for the safety evaluation and authorisation procedure, thus reducing the overall time spent on approvals.

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Traditional foods

Foods with more than 25 years of safe consumption outside the EU now benefit from a simpler authorisation procedure. Examples include haskap berries ([COMMISSION IMPLEMENTING REGULATION \(EU\) 2018/1991](#)) and fonio seeds ([COMMISSION IMPLEMENTING REGULATION \(EU\) 2018/2016](#)), traditionally eaten in Japan and West Africa respectively. Food business operators providing evidence of historic consumption can access the EU market within five months under the new notification procedure.



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Edible whole insects

Regulations for consumption of insects are fragmented across the EU. Some member states allow it, whereas others consider whole insects as novel. The new legislation clarifies the situation.

In Europe, until the entrance of the new Regulation (EU) 2015/2283 on novel foods, some Member States of the European Union permitted the marketing of certain species of insects for human consumption.

For example, in Belgium up to 10 species of edible insects were marketed.

For example, in the UK, whole insects were not previously considered novel. So, the FSA has requested data demonstrating history of consumption for any insects being supplied in the UK.

[Spain situation](#)



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Steps to market a new food

Establishment of the status of novel food:

First, to place a “novel” food on the market in the European Union, the food business operator **must first confirm whether the product had a history of human consumption** in food in the European Union prior to 15 May 1997.

To determine novel food status for a specific food product, a consultation request must be submitted. Member States must confirm the validity of these applications. Therefore, it is necessary to establish rules for the verification process.

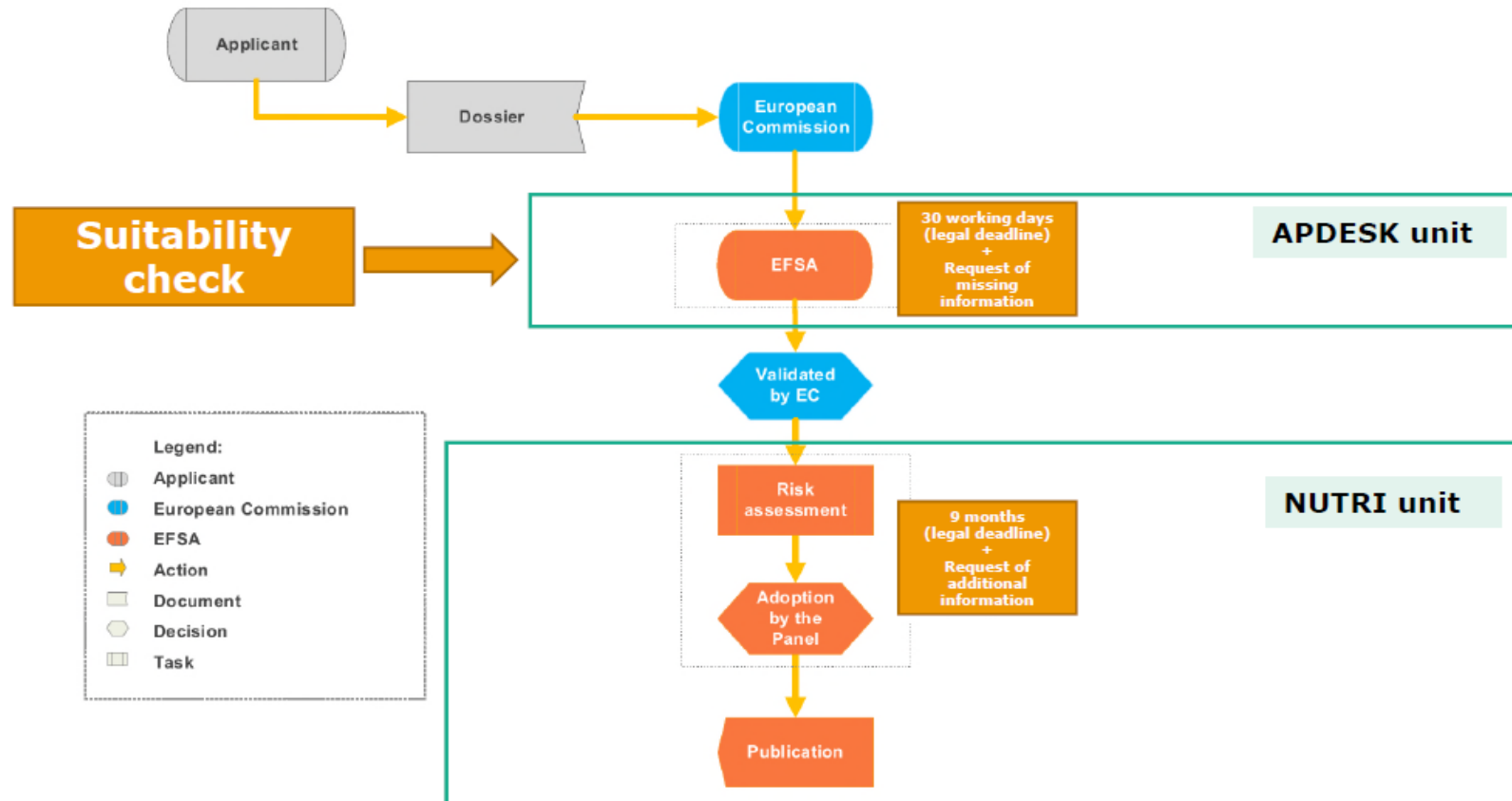


Steps to market a new food

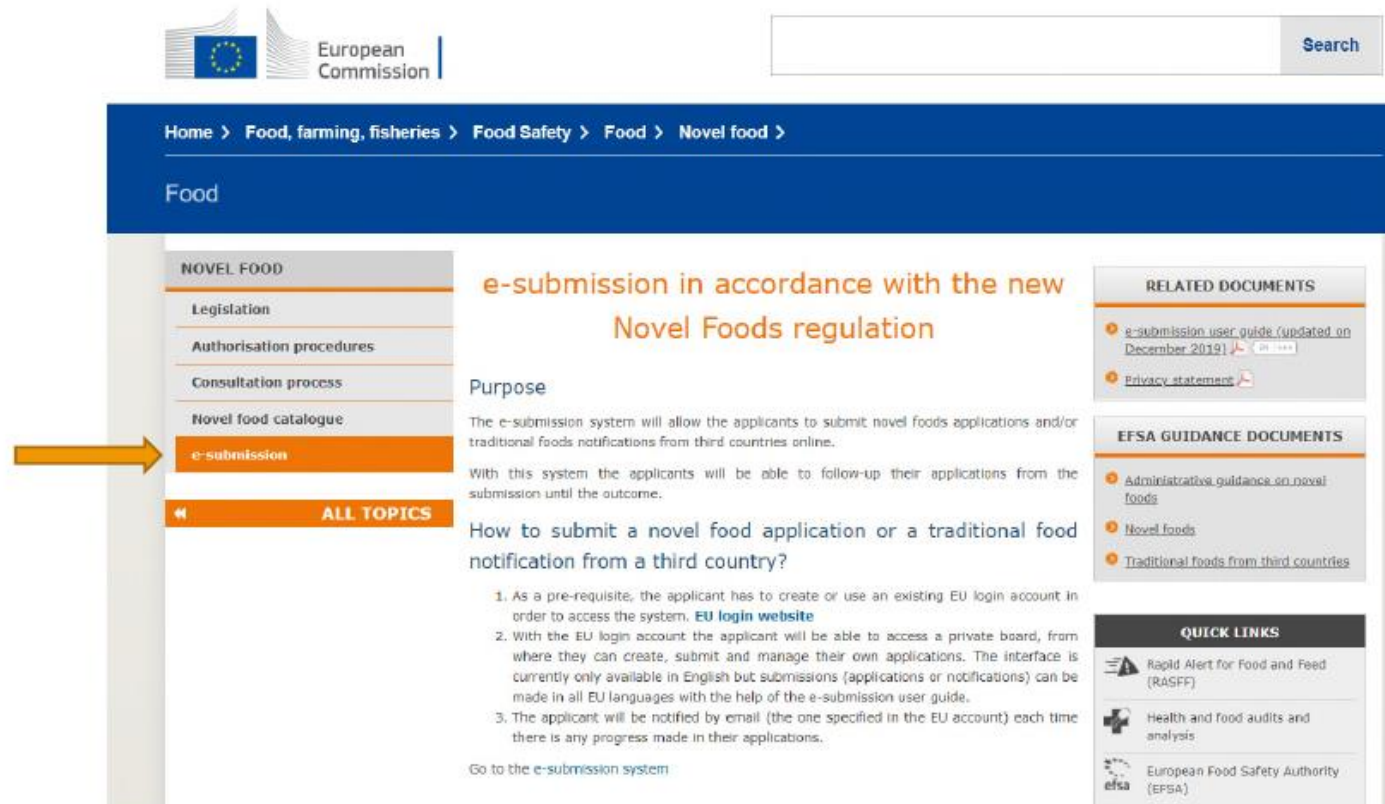
Demonstration of history of significant consumption: If no information is found after consulting the above information, the producer, importer or any other person responsible for the placing of a product in the corresponding EU market, shall provide the competent authorities with the information necessary to justify that the product does not fall under the scope of Regulation (EC) No 258/97, as the food operator has the primary responsibility for ensuring compliance with current food safety laws.

Applications workflow: Novel foods

Regulation EU 2015/2283



■ E-submission tool from EC



The screenshot shows the European Commission website interface. At the top, there is a search bar and the European Commission logo. Below the search bar, a breadcrumb trail reads: Home > Food, farming, fisheries > Food Safety > Food > Novel food >. A blue header bar contains the word "Food".

On the left side, there is a navigation menu under the heading "NOVEL FOOD". The menu items are: Legislation, Authorisation procedures, Consultation process, Novel food catalogue, e-submission (highlighted with an orange arrow), and ALL TOPICS. Below the menu is a search bar.

The main content area is titled "e-submission in accordance with the new Novel Foods regulation". It includes a "Purpose" section stating that the e-submission system allows applicants to submit novel foods applications and/or traditional foods notifications from third countries online. It also mentions that applicants can follow up on their applications until the outcome.

Below the purpose section is a heading "How to submit a novel food application or a traditional food notification from a third country?" followed by a numbered list of three steps:

1. As a pre-requisite, the applicant has to create or use an existing EU login account in order to access the system. [EU login website](#)
2. With the EU login account the applicant will be able to access a private board, from where they can create, submit and manage their own applications. The interface is currently only available in English but submissions (applications or notifications) can be made in all EU languages with the help of the e-submission user guide.
3. The applicant will be notified by email (the one specified in the EU account) each time there is any progress made in their applications.

At the bottom of the main content area, there is a link: "Go to the e-submission system".

On the right side, there are two sections: "RELATED DOCUMENTS" and "EFSA GUIDANCE DOCUMENTS".

RELATED DOCUMENTS

- [e-submission user guide \(updated on December 2019\)](#)
- [Privacy statement](#)

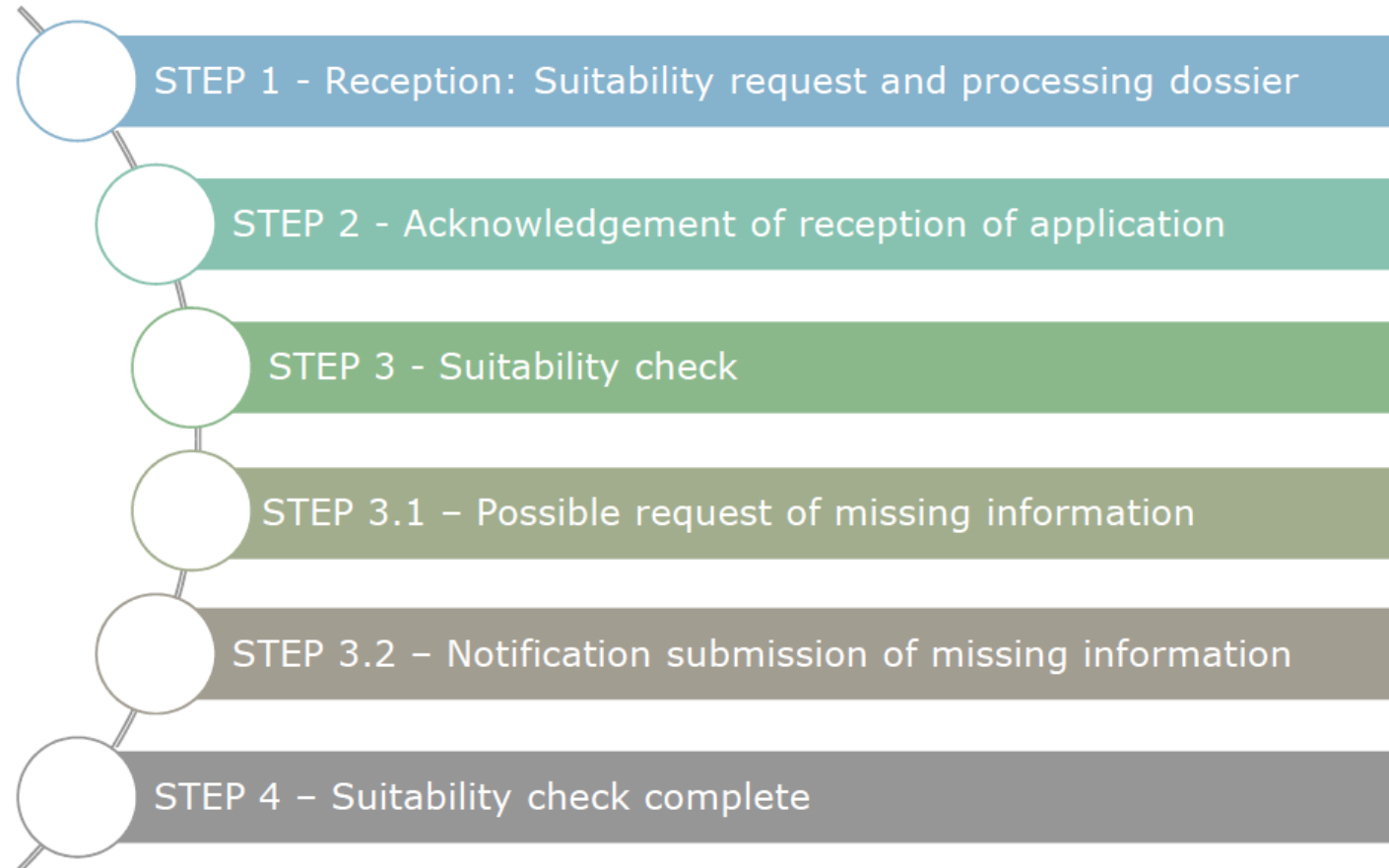
EFSA GUIDANCE DOCUMENTS

- [Administrative guidance on novel foods](#)
- [Novel foods](#)
- [Traditional foods from third countries](#)

At the bottom right, there is a "QUICK LINKS" section:

- [Rapid Alert for Food and Feed \(RASFF\)](#)
- [Health and food audits and analysis](#)
- [European Food Safety Authority \(EFSA\)](#)

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Information sources Novel Foods

SCIENTIFIC OPINION



ADOPTED: 21 September 2016

doi: 10.2903/j.efsa.2016.4594

Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283

TECHNICAL REPORT

European Food Safety Authority
Supporting Publications

APPROVED: 07 February 2018

doi:10.2903/sp.efsa.2018.EN-1381

Administrative guidance on the submission of applications for authorisation of a novel food pursuant to Article 10 of Regulation (EU) 2015/2283



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Information sources Novel Foods

EFSA

<https://www.efsa.europa.eu/en/topics/topic/novel-food>

EUROPEAN COMMISSION

https://ec.europa.eu/food/safety/novel_food_en

AESAN

http://www.aecosan.msssi.gob.es/en/AECOSAN/web/seguridad_alimentaria/sub_detalle/comercializar_nuevo_alimento.htm



Thank you very much for your attention

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<http://comunidad.ainia.es/web/ainiacomunidad/blogs/legislacion-alimentaria>

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