

# Guidance for food business operators on the verification of the status of a new food under the new Novel Foods Regulation (EU) 2015/2283 (NFR)

Summary

January 2019

Endorsed by





The new NFR applies from the 1st of January 2018. This guideline was developed to help food business operators understand the scope of the new NFR and the principles to apply when verifying the status of their products.

## Understanding the scope

The scope of the NFR is in principle the same as for Regulation 258/97. Although the definition of novel food has changed, it is not the intention of the new NFR to cover all foods that are produced from non-novel food ingredients, even if such foods are new in terms of composition. Only isolates and products that have no conventional counterpart are covered.

**A new food is only a novel food if it was not used on the EU market to a significant degree before 15 May 1997 for human consumption and falls into one of the 10 categories. Both conditions must be met.**

- Some foods are now explicitly included (e.g. insects, foods from tissue cultures, engineered nanomaterial, etc). Such foods, if lawfully marketed in the EU after 15 May 1997 can remain on the market if an application for authorisation is submitted before 1 January 2019 and the food is subsequently authorised.
- Although additives, food enzymes and flavourings are excluded from the scope of the NFR, when such substances are used as ingredients, but not for a technological function, they may still come under the scope of the NFR.
- Also, foods that do not meet the specifications or conditions of use specified in the Union List of authorised novel foods, require a new novel foods authorisation.
- Foods that have only been used in food supplements before 15 May 1997 and are now intended to be used in regular foods, require authorisation as novel food.

A detailed description of the principles to consider for each of the 10 categories is presented in this novel foods guidance. The decision tree below summarizes these elements.

# Legal obligations

## 1. Food business operators must verify for every new food or food ingredient whether it falls within the scope of the NFR before putting it on the market in the EU.

Because of the new definition, the status of products already placed on the market since 15 May 1997 needs to be verified.

it is recommended to keep a written and reasoned record of this verification and the fact that the judgment is conclusive.

Both the product's composition and production process need to be assessed

Factors that are useful to be considered in the context of this verification include:

- The history of use of the food. This can include a judgment of the extent to which the food is equivalent to an existing food that has a history of food use before 15 May 1997.
- The nature of the food to assess if it falls within one of the defined categories.

Factors that are not relevant in determining as such that a food is novel include:

- The level of certain compounds in the food, except for foods produced with non-traditional plant propagation practices and production processes not used for food production within the EU, for which it must be assessed whether the changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances, are significant.
- The conditions under which a food is used by consumers and the extent of the use of the food, including the various product matrices in which the food is or can be used, except for approved novel foods for which this is specified in the conditions of use of the authorisation, included in the Union List of Novel Foods.
- The mere possibility of a safety concern. It is at all times the responsibility of the food business operator to ensure that the food he puts on the market is safe and thus to put in place appropriate safety assurance measures.

Demonstrating significant consumption in the EU before 15 May 1997 is not easy, because often information is no longer available or missing indications on whether a product was marketed for food or other uses. The following elements can be considered when such proof needs to be developed.<sup>1</sup>

- The food must be sufficiently characterised to match it to the documentation.
- Demonstration of use should relate to the EU Member States.
- The best data is sales data, showing a period of food use before 15 May 1997.
- If such data are no longer available, other sources of data can be presented (e.g. invoices, recipes, cookbooks, catalogues etc) but should be sufficiently robust.
- Limited availability of the food (e.g. in pharmacies, health shops or restaurants) requires more information than wide availability in food stores and supermarkets.
- References in relevant national and EU legislation could also be good evidence.
- Evidence of continued market presence over a long period of time or traditional uses or practices can compensate evidence showing only local or regional use.
- Evidence should demonstrate food use (especially if other uses, e.g. in medicines, are known). Use as additive or flavouring is not acceptable evidence.
- In certain cases, the type of processing applied to the food is of relevance.

## 2. Food business operators must consult a national authority in case they are unsure if a food falls within the scope of the Novel Food Regulation.

This is a legal obligation but not a systematic requirement. The food business operator should make a formal judgement that the available information to support that a food falls under the scope of the NFR or not is sufficiently conclusive.

Procedural steps and data requirements for this consultation process have been published in Regulation (EU) 2018/456.<sup>2</sup>

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1. [https://ec.europa.eu/food/sites/food/files/safety/docs/novel-food\\_guidance\\_human-consumption\\_en.pdf](https://ec.europa.eu/food/sites/food/files/safety/docs/novel-food_guidance_human-consumption_en.pdf)

2. Regulation (EU) 2018/456. Official Journal of the European Union L 77/6, 20 March 2018

## How to consult a Member State in case of uncertainty?

### 1. Identify the Member State:

The Member State of first marketing or if the food is marketed simultaneously in several Member States, one of these

### 2. Submit a consultation request to one Member State

Electronically and containing the following information:

- a cover letter -> template included in Regulation (EU) 2018/456
- a technical dossier -> template included in Regulation (EU) 2018/456
- supporting documentation;
- an explanatory note clarifying the purpose and relevance of the submitted documentation.

### 3. Member State will confirm without delay (validity check)

Member State may request further information to be provided within a certain time frame.

### 4. Member State will reach a conclusion within 4 months (extendable once with 4 months)

Information will include:

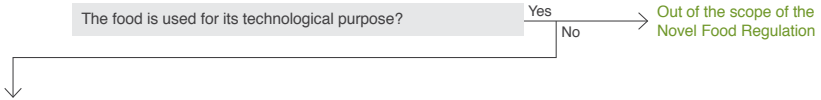
- the name and description of the food concerned;
- a statement indicating whether the food concerned is novel, not novel or not novel only in food supplements;
- reasons justifying the statement referred to above;
- where the food is a novel food, the most appropriate food category under which it falls in accordance with Article 3(2) of Regulation (EU) 2015/2283.

### 5. Commission to publish the outcome on the website

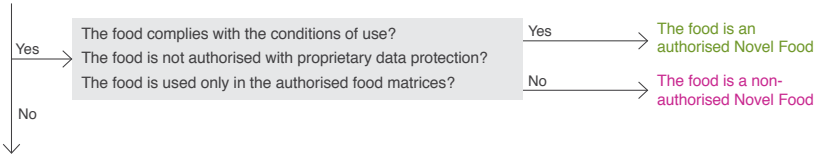
([https://ec.europa.eu/food/safety/novel\\_food/consultation-process\\_en](https://ec.europa.eu/food/safety/novel_food/consultation-process_en))

## Decision tree for determining the status of a new food

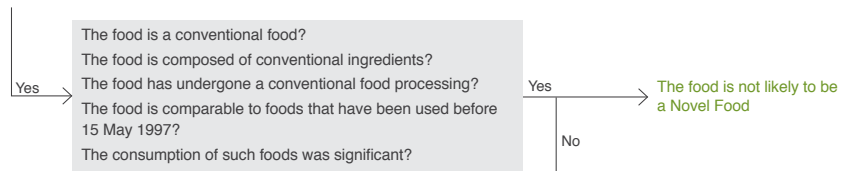
1: The food is a food additive, food flavouring, food enzyme or extraction solvent?



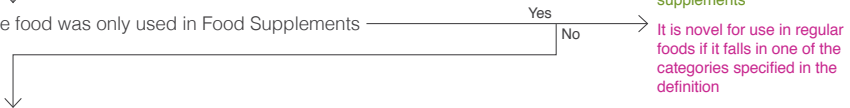
2: The food is an authorised Novel Food listed in the Union List? .....> Verify the Union list



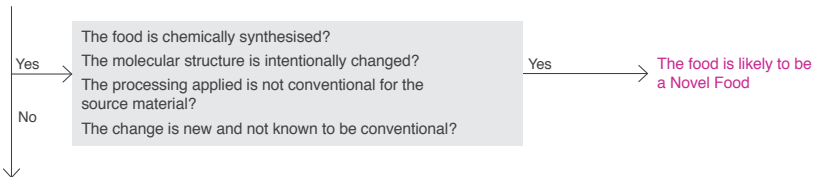
3: The food was used as food in the EU to a significant degree before 15 May 1997? .....> Collect data on the food



The food was only used in Food Supplements .....> It is novel for use in regular foods if it falls in one of the categories specified in the definition

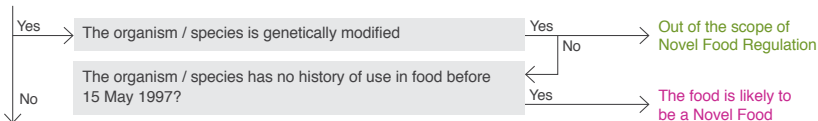


4: The food has a new or intentionally modified molecular structure? .....> Assess the nature of the food



5: The food is consisting of, isolated from or produced from microorganisms, fungi or algae? .....> Assess the nature of the food

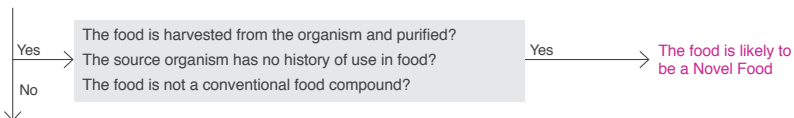
5.1: The food consists of microorganisms, fungi or algae?



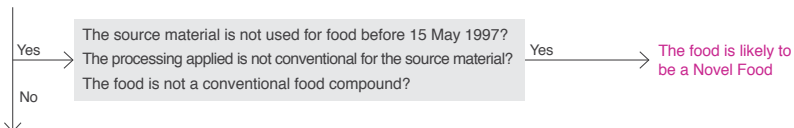
5.2: The food is isolated from microorganisms, fungi or algae?



5.3: The food is produced from microorganisms, fungi or algae?

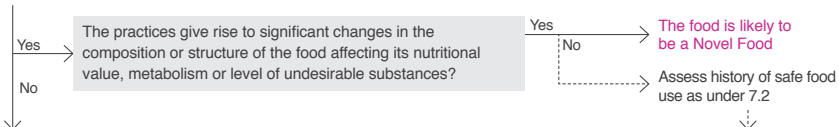


6: The food is consisting of, isolated from or produced from material of mineral origin? .....> Assess the nature of the food

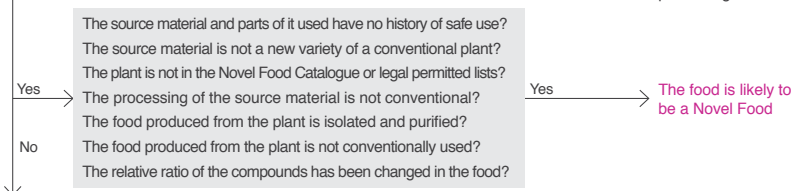


7: The food is consisting of, isolated from or produced from plant material? .....> Assess the nature of the food

7.1: The source material is a plant or a variety of the same species obtained by non-traditional propagating practices (not used for food production in EU before 15 May 1997) .....> Assess equivalence to a conventional food

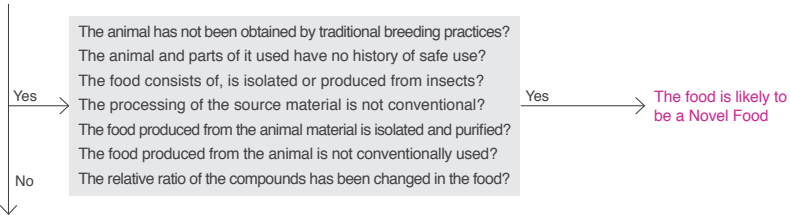


7.2: The source material is a plant or a variety of the same species obtained by traditional propagating practices (used for food production in EU before 15 May 1997) .....> Assess history of use of the plant, plant part and processing

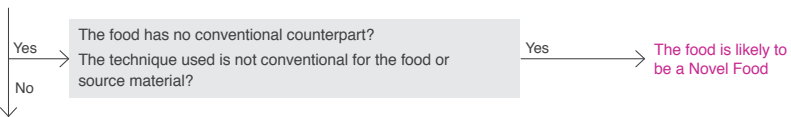




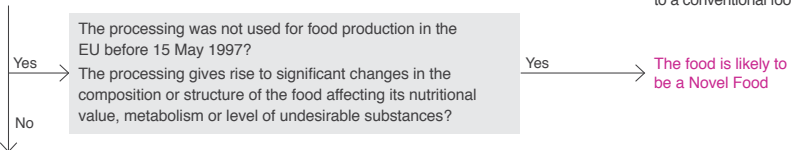
8: The food is consisting of, isolated from or produced from animal material? .....> Assess history of use of the animal, animal part and processing



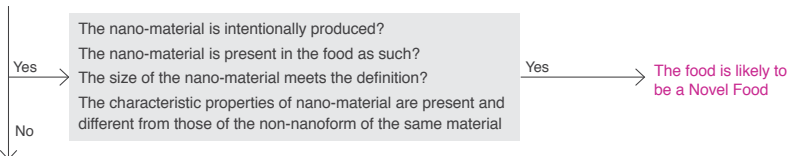
9: The food is consisting of, isolated from or produced from cell or tissue cultures? .....> Assess the nature of the food



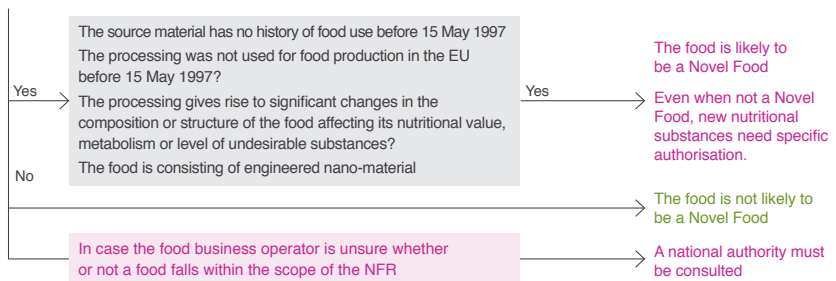
10: The food results from new production processes? .....> Assess the nature of the processing and equivalence to a conventional food



11: The food is consisting of engineered nano-material? .....> Assess the nature of the food



12: Sources of vitamins, minerals and other substances? .....> Assess the nature of the food



## The value of the principles of substantial equivalence

In the NFR it is no longer possible to obtain novel foods approval by using the substantial equivalence notification process. Still, many new foods, while not being identical still are substantially equivalent to a conventional counterpart that was on the market before 15 May 2017 and therefore would not require a novel food assessment. In some of the categories of the new NFR it is specified that a food would only be covered under its scope if there would be significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances. For deciding on what changes are significant, the demonstration of substantial equivalence can be a helpful tool in the verification process of the status of the food.

To judge if a food is substantially equivalent, the following aspects are important:

- The reference food must have a history of significant food use in the EU before 15 May 1997.

The composition of both the food and the reference food must be well characterised and in sufficient detail to enable a comparison of all aspects that are relevant for safety. The closer the reference food is to the new food, the higher the chance of having a meaningful outcome.

This does not only apply to the analytical composition but also to the source material and the way it is processed.

Both foods should have similar conditions of use or pattern of consumption.

- Analytical data should be available to the same level of detail for both the food and its reference counterpart. Both the nutritional and non-nutritional composition should be covered on a sufficiently wide range of batches to cover variability. Sufficient information should be available on the content of all contaminants, residues and other inherently present substances that are known or expected to be present and can have an effect on safety, such as environmental contaminants, mycotoxins, allergens, naturally occurring toxins and anti-nutrients, and undesirable microorganisms. This should be based on a detailed literature search to identify any undesirable substances that could be associated with the food and its source material.
- If the composition of the food does not differ from the reference counterpart, it is unlikely that there will be significant differences in its metabolism and its nutritional and physiological effects.

# Procedure for authorisation

The procedure for authorisation is centralised. An application for authorisation is submitted to the European Commission and assessed by EFSA. A decision is taken by the Commission.

Data requirements and procedural steps are specified.<sup>3</sup> EFSA also has published guidance as to the safety data required.<sup>4</sup>

## Commission initiative or Application for authorisation

Electronic EC portal



Full application available to the Member States



Summary of the application published



May ask EFSA for a scientific assessment

9 months but extendable



Proposal to the Standing Committee

7 months



Standing Committee vote

? months



Implementing act published

Applicant can withdraw application at any time during the process

However, any opinion adopted by EFSA will be published irrespectively

Also the Commission may terminate the procedure at any stage

The authorisation is generic except when data protection is granted



3. Regulation (EU) 2017/2469. Official Journal of the European Union L 351/64, 30 December 2017

4. EFSA. Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283. EFSA Journal 2016;14(11):4594. <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2016.4594/epdf>

## The Novel Food Catalogue

The Novel Food Catalogue was established by the European Commission to provide clarity on the status of a food or food ingredient based on information provided by the EU Member States. It serves as orientation on whether a product would need an authorisation under the NFR. It also indicates those foods that are not novel when used in food supplements but would require an application for authorisation for an extension of their use to other foods.

When assessing the status of a new food or food ingredient, the Novel Food Catalogue should be consulted. The catalogue has no legal and many foods are not included. Their status will nevertheless need to be verified by food business operators intending to use them in their products.

The Novel Food Catalogue can be consulted on the European Commission website ([https://ec.europa.eu/food/safety/novel\\_food/catalogue\\_en](https://ec.europa.eu/food/safety/novel_food/catalogue_en)).

## The Union List of authorised novel foods

The Union List of authorised novel foods is the official legal instrument authorising novel foods. It contains a table identifying the novel foods with associated conditions of use and a table with specifications for each authorised novel food.

Any food that is included in the Union List can be used by any food operator in accordance with the conditions of use specified, except in case of accepted proprietary data protection.

Each food operator that places a novel food on the EU market (as is or as ingredient in a food product), is legally responsible for ensuring compliance with the compositional and any other relevant criteria specified.

The food must meet the specifications listed. Where a reference is made to the method of production, only this production method is covered by the novel food authorisation. If the food, its origin or method of production differ, it must be ascertained if it needs to be authorised as a different novel food following an application for authorisation.

In a number of cases, novel foods have been authorised that apparently are very close to foods having a history of use in the EU. Similar foods that do not meet the set specifications would not necessarily need to comply with the specifications of the novel food or be approved as novel food in case of protection of proprietary data, if it can be shown that these foods were used to a significant degree in the EU before 15 May 1997 or fall out of the scope of the categories of novel foods, in accordance with the principles of these guideline.

The Union List of Authorised Novel Foods was initially published on 30 December 2017 and is constantly updated. A non-legal consolidated version of this legislation can be retrieved via [www.eur-lex.europa.eu](http://www.eur-lex.europa.eu)<sup>5</sup>

## Authorisations and proprietary protection

Authorisations are generic, which means that once authorised a novel food can be used by any food business operator provided the conditions of use and specifications are met and proprietary data are not protected.

A 5-year exclusivity based on proprietary data protection is possible, provided that:

- The newly developed scientific evidence or scientific data was designated as proprietary by the applicant at the time the first application was made.
- The applicant had exclusive right of reference to the proprietary scientific evidence or scientific data at the time the first application was made irrespective of whether the data are in the public domain or not.
- The novel food could not have been assessed and authorised without the applicant's proprietary scientific evidence or data.

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5. Regulation (EU) 2017/2470. Official Journal of the European Union L 351/72, 30 December 2017

## Traditional foods from a third country

Traditional foods from a third country can use a notification procedure and be authorised after 4 months, provided no reasoned safety objections are raised. Data requirements and procedural steps are specified.<sup>6</sup> EFSA published guidance on the data requirements to demonstrate tradition of use.<sup>7</sup>

Conditions for the acceptance of a traditional foods from a third country notification:

- The food should not fall under points (a) (i), (iii), (vii), (viii), (ix) and (x) of the novel foods definition.
- The safety of the food should have been confirmed with compositional data and from experience of continued use for at least 25 years in the customary diet of a significant number of people in at least one third country.
- The history of safe food use should not include non-food uses or uses not related to the customary diet.
- The food should be derived from primary production but may be processed. Traditional food processing techniques can be applied.

Extracts or preparation should retain the essential characteristic properties of the source material (e.g. the nutritive value, the flavour, the colour, the characteristic other substances contained, etc.). Also, the ratio between the constituents should not be significantly different from that present in the source material. In other words, the primary material should still be recognisable.

A product would however no longer be considered as derived from primary production if it is incorporated in a food or mixed with other ingredients or concerns compounds that are isolated, such as specific component proteins, carbohydrates or fats or other compounds.

It is however possible that a product derived from primary production is not consumed as such in the customary diet, but traditionally prepared or only used as ingredient in specific foods or combined with other foods. In such case, it would be possible to apply the notification procedure to the ingredient as it is traditionally used.

If a food business operator is not certain the product would be accepted under this procedure, it is best to consult a Member State authority.

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6. Regulation (EU) 2017/2468. Official Journal of the European Union L 351/55, 30 December 2017

7. EFSA. Guidance on the preparation and presentation of the notification and application for authorisation of traditional foods from third countries in the context of Regulation (EU) 2015/2283. EFSA Journal 2016;14(11):4590. <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2016.4590/epdf>

## Notification by an applicant

Electronic Commission portal



Validity check by Commission .....→ 1 month



Notification to Members States and EFSA .....→ 4 months



→ In case of no duly reasoned safety objection:



↳ Commission authorises food



→ In case of duly reasoned safety objections:



↳ Food not authorised



Application required

Addressing the reasoned safety objections

- EFSA scientific assessment .....→ 6 months but extendable
- Proposal to the Standing Committee .....→ 3 months
- Standing Committee vote .....→ ? months
- Implementing act published



The application should contain data relating to the objection

Applicant can withdraw application at any time during the process

However, any opinion adopted by EFSA will be published irrespectively

Also the Commission may terminate the procedure at any stage

The authorisation is generic with no possibility for data protection



The European food supplement sector brings together many of the most innovative and dynamic companies in the food area, making a substantial contribution to Europe's public health goals.

Food Supplements Europe combines the unique expertise of associations and companies committed to building partnership with regulatory, scientific and consumer bodies to help shape the future regulatory and policy framework in this area and to ensure that consumers can benefit from safe and high quality products.



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