

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)

January 2019

Endorsed by



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1. Aim of this guidance document

The new Novel Foods Regulation (EU) 2015/2008 (NFR) applies from the 1st of January 2018. This includes the application of the new definition of what foods are covered by its scope as laid down in Article 3.2.

Article 4.1 makes it a legal obligation for food business operators to verify whether or not the food which they intend to place on the market falls within the scope of the NFR. This is an important decision as it determines the difference between a pre-market authorisation of the food and direct market access.

Understanding the background and how to apply the new definition is therefore critical for food business operators to make this decision in the right way and avoid challenge of the product when marketed or, for certain foods, including food supplements, notified in accordance with applicable procedures.

Food Supplements Europe has elaborated this guidance document to help food business operators understand the scope of the new NFR and the principles to apply when verifying the status of their products. It focuses on all foods, including food supplements and ingredients thereof.

It is reminded that, in accordance with Article 4.2, if a food business operator is not sure whether or not the food it intends to place on the market within the European Union (EU) falls within the scope of the NFR, the food business operator is obliged to consult the Member State where it first intends to place the novel food on the market. This guidance document therefore can also help food business operators understand what information they should have available to help Member States take a decision.

2. Definitions

In this guidance document, the same legal definitions laid down in the General Food Law Regulation (EC) 178/2002 and NFR are used. In addition, the following terms are used:

Food, food ingredient, substance

Whenever reference is made to the term “food” it covers both foods as such and food ingredients or substances intended to be incorporated into a food. The context may make it more relevant to refer to a food as such, a food ingredient or a substance. However, all are foods in the legal sense.

Conventional

Where the word “conventional” is used, it is understood that this refers to elements that existed or were in use before 15 May 1997.

Original Regulation

Reference to the “Original Regulation” are references to Regulation (EC) 258/97. References to the “NFR” are references to Regulation (EU) 2015/2283.

History of safe food use

History of safe food use exclusively refers to the concept that is included in parts (iv) and (v) of the definition of novel food (Article 3.2 of the NFR).

3. Introduction

The original Novel Foods Regulation (EC) 258/1997 was established with the specific aim to submit foods that had never been consumed in the EU to a premarket authorisation process to ensure that their safety is evaluated and confirmed. This was a harmonisation of similar procedures that were already in place in a number of Member States (e.g. UK and NL) and aimed to avoid that authorisation for new foods would need to be obtained in each Member State individually.

Originally Genetically Modified Organisms (GMO) were the principal category of food that was targeted, although also other types of foods were included under the scope. In 2003 GMO were removed from the scope and included in a specific legislation, which only left the other categories as part of the Novel Food definition.

From 1997 to 2017 inclusive, decisions have been taken on 103 non-GMO novel food applications and about 77 were still in the process.¹ Novel foods were approved after assessment of the safety data by a national assessment body and in many cases a further assessment by the Scientific Committee on Food and since 2002, by its successor, the European Food Safety Authority (EFSA).

It is clear therefore that the scope of the novel foods legislation was rather limited and aimed at foods that have never been consumed before in the EU Member States and thus are genuinely new in the European diet either because they are newly synthesised, originate from source materials that have no history of use in the EU or are significantly different from existing counterparts used before 15 May 1997.

The cut-off date for deciding whether or not a food had been consumed to a significant degree in the EU was 15 May 1997, the date of entry into force of the Regulation.

One of the key principles of the new NFR is that in principle the scope should remain the same, as expressed in Recital 8. Therefore, also the new NFR is focused on foods that are genuinely new in the European diet, in particular consisting, isolated or produced from source materials that have no history of safe use in the EU or produced by processing techniques that have not been used for food production. The date of 15 May 1997 was retained as the cut-off point for novel food status also in the NFR.

It is important to acknowledge that the NFR therefore does not aim to impose a systematic pre-market authorisation procedure for all new foods that are developed and put on the market. The number of such new products is simply astounding. In most cases, when produced from source material with a history of use in the EU and using conventional food processing, there is no indication that safety could not be ensured by the application of the general food law framework already in place. Requiring approval for all new foods would not only be unfeasible, it would also be a very burdensome and resource consuming system with no added benefit for safety. In addition, it would have serious implications for the competitiveness of the EU food industry and for innovation. It would also not be a wise use of the resources of the Commission and EFSA.

1. https://ec.europa.eu/food/sites/food/files/safety/docs/novel-food_applications-status_en.pdf

As Recital 29 states: "New technologies and innovations in food production should be encouraged as they could reduce the environmental impact of food production, enhance food security and bring benefits to consumers as long as the high level of consumer protection is ensured."

Therefore, only genuinely novel foods should fall under the scope of the NFR. It is noted that a number of precisions are included in the new definition. These are intended to clarify the scope of the NFR where such clarification was not included in the original Regulation.

The original Regulation contained a simplified procedure applying in case substantial equivalence can be demonstrated between a certain novel food and an appropriate reference food. This procedure is removed in the NFR. Until the end of 2017 approximately 490 non-GMO novel food substantial equivalence notifications have been reported.² Most of these notifications concern substantial equivalence to already approved novel foods, such as phytosterols, chia seed, baobab and noni juice. This simplified procedure is no longer possible under the new NFR. The switch from applicant linked to generic authorisations is considered to make this procedure redundant. Still it is clear that new foods that can be demonstrated to be substantially equivalent to conventional foods with a history of safe use would present a low safety concern. Under the NFR the principles for demonstrating substantial equivalence can therefore be a good tool to help food business operators in the verification of the extent to which a new food differs from a comparator food in the context of a number of categories in the new definition.

It is now a legal obligation for food business operators to verify whether the new product they intend to place on the market falls within the scope of the NFR and to solicit the assistance of a national authority if they are unsure whether the product is covered by the NFR or not.

This guidance document therefore aims to help food business operators understand the scope of the new NFR and the elements that they would need to consider when performing such verification.

2. https://ec.europa.eu/food/sites/food/files/safety/docs/novel-food_notifications_en.pdf

Figure 1: The new Novel Foods Regulation in a nutshell

1. The scope should in principle be the same as with the previous Regulation (EC) 258/97
 - The date for determining if a food was used to a significant degree is 15 May 1997
 - The food should also fall into one of the 10 categories. These have been expanded to provide more clarity
 - Some foods are now specifically mentioned to be included (e.g. insects, foods from tissue cultures, engineered nanomaterials, etc)
 - For such foods, if lawfully marketed in the EU after 15 May 1997, a transition period applies: They can remain on the market if an application for authorisation is submitted before 1 January 2019 and the food is subsequently authorised
2. It is a legal obligation for the food business operator to consult a national authority in case he is unsure if his food falls within the scope of the NFR
 - Procedural steps and data requirements have been set in EC Implementing Regulation (EU) 2018/456
3. 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
 - The full procedure applies to all novel foods
 - There is no longer a simplified substantial equivalence notification procedure
 - Data requirements and procedural steps are specified in EC Implementing Regulation (EU) 2017/2469
 - EFSA also has published guidance as to the safety data required
 - Traditional foods from a third country can use a notification procedure and be authorised after 4 months, provided no reasoned safety objections are raised
 - This only covers foods from primary production, whether processed or not
 - Data requirements and procedural steps are specified in EC Implementing Regulation (EU) 2017/2468
 - EFSA published guidance on the data requirements to demonstrate tradition of use
4. 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.
 - The list of approved novel foods is published in EC Implementing Regulation (EU) 2017/2470
 - There is a possibility for 5-year exclusivity based on proprietary data protection

4. General principles

4.1. It is a legal obligation for the food business operator to verify whether its product falls within the scope of the NFR or not

Article 4.1 specifies that:

“Food business operators shall verify whether or not the food which they intend to place on the market within the Union falls within the scope of this Regulation.”

This is a legal obligation and thus requires a food business operator to verify the status of every new food it intends to market in the EU.

Since certain foods that were not covered under the original Regulation are now covered under the NFR because of the changed definition or added categories, the status of products already placed on the market since 15 May 1997 needs to be verified. It is recommended that food business operators keep written proof, documenting for each product that this check was carried out.

If a product already on the market would fall under the NFR the transitional measures of Article 35 apply, which means that such products may continue to be placed on the market until a decision is taken following an application for authorisation that needs to be submitted no later than 1 January 2019.

Since the NFR constitutes a pre-market authorisation procedure for foods falling within its scope, verification of the status must take place prior to the putting of the product on the EU market.

Where a food business operator has carried out a verification on a new food, it is recommended that the food business operator should prepare a written and reasoned record of this verification and retains this on file in case the status of the food is questioned. This record should contain the arguments justifying the decision that the food does not fall under the scope of the NFR.

The factors that need to be considered in the context of this evaluation are:

- The history of use of the food to assess if the food or its ingredients have been used to a significant degree for food consumption in the EU before 15 May 1997. 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 categories defined in the NFR.

It is noted that for carrying out this verification it is not sufficient to look only at the product's source material and composition. In line with the judgement of the Court of Justice of the European Union (CJEU) in case C-383/07 both the product's composition and production process need to be assessed. The fact that all the individual ingredients of a food product have a history of safe use before 15 May 1997 cannot be regarded as sufficient for the NFR not to apply. All the characteristics of the food product and of the production process need to be considered.

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

- The level of certain compounds in the food, except for those foods for which the category definition explicitly mentions that the extent to which changes in the composition or structure of the food affect its nutritional value, metabolism or level of undesirable substances (i.e. non-traditional plant propagation practices and production processes not used for food production within the EU).
- The conditions under which a food is used by consumers.
- 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.

When the food is an already authorised novel food, it must be used in accordance with the conditions that are specified in the authorisation. A new novel food authorisation will be required for other uses that are not already authorised (e.g. food categories, level of use, production process). Under the NFR, these conditions of use will be included in the Union List of authorised novel foods.

As example, such extensions have been authorised for a number of approved novel foods, including:

- Phytosterols (e.g. Decision 2006/59/EC, Decision 2004/334/EC))
- Chia seed (*Salvia hispanica L.*) (Decision 2013/50/EU)
- Lycopene Oleoresin from tomatoes (Decision 2009/355/EC)
- DHA (docosahexaenoic acid)-rich oil from micro-algae *Ullkenia* sp. (Decision 2009/777/EC)
- Noni (*Morinda citrifolia L.*) fruit puree and concentrate (Decision 2010/228/EU)
- Flavonoids from *Glycyrrhiza glabra L.* (Glavonoid) (Decision (EU) 2015/1213)

Figure 2: How to consult a Member State in case of uncertainty?

The principle:

A Food Business Operator must consult the Member State where he first intends to place a food on the market if he is unsure whether or not the food falls within the scope of the NFR.

The process:

1. Identify the Member State

The Member State of first marketing or if the food is marketed simultaneously in several Members 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)

4.2. It is a legal obligation to consult a Member State authority in case of uncertainty

Article 4.2 specifies that:

"Where they are unsure whether or not a food which they intend to place on the market within the Union falls within the scope of this Regulation, food business operators shall consult the Member State where they first intend to place the novel food. Food business operators shall provide the necessary information to the Member State to enable it to determine whether or not a food falls within the scope of this Regulation."

It is therefore a legal obligation to consult a Member State authority if, having tried to verify the status of a new food, the food business operator is uncertain whether it falls under the NFR or not. The food business operator therefore must make a formal judgement if its justification that a food falls under the scope of the NFR or not is sufficiently conclusive. If not, the Authority of the Member State of first marketing must be consulted.

This consultation is however not a systematic requirement. It should only apply where the food business operator is unsure whether the information it possesses is sufficient or not to justify its decision that the food does not fall under the scope of the NFR.

In such case, Commission Implementing Regulation (EU) 2018/456 specifies the procedure and data requirements for this process to be followed.

Figure 3: Data required for consulting a Member State authority on the status of a specific food

1. All foods other than extracts and foods resulting from a production process not used for food production within the Union before 15 May 1997

Description of the food

- Name of the food
- Detailed description of the food (including information whether the food consists of engineered nanomaterials)
- Proposed category of the novel food in accordance with Article 3 (2) (a) of Regulation (EU) 2015/2283

Further characterisation of the food and/or source of the food (where relevant)

For organisms (microorganisms, fungi, algae, plants, animals)

- Taxonomic name (full Latin name with author name)
- Synonyms, other names, where applicable
- Specification of which part of the organism the use for human consumption before 15 May 1997 within the Union refers to where applicable
- Specifications about purity/concentration

For chemical substances

- CAS number(s) (if this has been attributed)
- Chemical name(s) according to IUPAC nomenclature rules
- Synonyms, trade name, common name, where applicable
- Specifications about purity/concentration
- Molecular and structural formulae
- Specification about purity/concentration

Conditions of use

- How is the food intended to be used
- Type of product(s) in which the food is intended to be used
- Level/concentration (or range of levels) in the product(s) in which the food is intended to be used

Production process

- Detailed description of the production process. Include a flow process chart to describe the production process.

History of human consumption of the food within the Union before 15 May 1997

- To what extent was the food consumed to a significant degree throughout the Union.
- To what extent was the food consumed to a significant degree in one Member State.
- Was the food consumed only regionally/on a small local scale in the Union?
- Was the food available before 15 May 1997 in the Union as an ingredient designed for specific target population (e.g. food for a special medical purpose)?

Consultations on availability in the Union (Food business operators may consult other food business operators or food business operators federations to obtain sufficient information)

- Have other food business operators or food business operator federations been consulted?
- Is the food currently available on the market within the Union?

Additional information

- Is there any information that the product concerned is used within the Union as medicinal product in accordance with Directive 2001/83/EC?
- Is there any other information which would assist in determining the novel food status? Submit any information that is relevant even if not specifically requested

2. Extracts

- Any further details of the source material for the extract
- Specification of the extract
- If extracted from a food source, will the intake of any extract components in the new food be higher than the intake of these components from the original food source?

3. Foods resulting from a production process not used for food production within the Union before 15 May 1997

- Description, characterisation and conditions of use of the food (as above under 1)
- Detailed description of the production process, including a flow process chart to describe the production process
- Is the structure or composition of the food affecting its nutritional value, metabolism or level of undesirable substances because of the process by which the food has been prepared?
- Is the food produced from a source that in itself is not normally consumed as part of the diet?

4.3. Certain categories of food ingredients are explicitly excluded from the NFR

Article 2.2 clearly states which food ingredients are explicitly excluded from the NFR.

"This Regulation does not apply to:

- (a) genetically modified foods falling within the scope of Regulation (EC) 1829/2003*
- (b) foods when and in so far as they are used as:*
 - (i) food enzymes falling within the scope of Regulation (EC) 1332/2008;*
 - (ii) food additives falling within the scope of Regulation (EC) 1333/2008;*
 - (iii) food flavourings falling within the scope of Regulation (EC) 1334/2008;*
 - (iv) extraction solvents used or intended to be used in the production of foodstuffs or food ingredients and falling within the scope of Directive 2009/32/EC."*

These exclusions are justified because these categories of food ingredients are covered by their own specific regulations to ensure their safety.

Where an ingredient is used in compliance with the specific legislation listed above, it would not be subject to the obligations of the NFR even if it is covered by one of the defined Novel Food categories. However, this would only be the case when the ingredient is used specifically for the function that is within the scope of one or more of the legal texts listed in Article 2.2. When a food ingredient has an additive, flavouring, enzyme or extraction solvent function, but is not used in a food for any given technological function, it may then come under the scope of the NFR and be subject to an authorisation ((e.g. enzymes used for their digestive effect, bulking agents used for their fiber properties).

A clear example is the approval as novel food of guar gum by the French authorities for uses other than as food additive.

Another example is methyl cellulose, approved by the UK authorities as novel food.

It is noted that foods performing a technological function but falling out of the definition of an additive, such as foods with colouring properties, are considered as food and would fall under the scope of the NFR if they satisfy the definition of novel food.

4.4. The date of 15 May 1997 is determining for novel foods status

The new NFR defines novel food in Article 3.2.a as:

“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 new NFR therefore maintains the principle that a food is only novel when it meets both parts of the definition. It must be shown that the food was not used for human consumption to a significant degree in the EU before 15 May 1997 and that it belongs to one of the ten categories (i)-(x).

Foods that belong to one of the categories but have a history of significant use before 15 May 1997 cannot be considered as falling under the NFR. Conversely, foods that do not have a history of significant use before 15 May 1997 but do not belong to one of the categories listed can also not be considered to fall under the NFR. Both situations are possible for specific foods.

Demonstrating significant consumption in the EU before 15 May 1997 is not easy, given that it is a long time ago and information mostly has not been digitalised or retained. In addition, most information available does not provide information on whether a product was marketed for food or other uses. Guidance has been published by the Commission on what elements to consider when such proof needs to be developed.³

3. https://ec.europa.eu/food/sites/food/files/safety/docs/novel-food_guidance_human-consumption_en.pdf

The following elements should be considered when collecting data to show significant use:

- The food must be sufficiently characterised to be able to match it to the documentation presented.
- Demonstration of use should relate to the territory of the EU Member States (including those that were not members in 1997) and should demonstrate food use.
- The best source of information to present is sales data, showing sales for food use during a certain time before 15 May 1997.
- If such data are no longer available, other sources of data can be presented to build a convincing case. Information can come from all sorts of sources (e.g. invoices, recipes, cookbooks, catalogues etc) but should be sufficiently robust and referenced.
- The sales channel of the food could be a good indicator. Products with only limited availability (e.g. in pharmacies, health shops or specific restaurants) may need more information than foods that are widely available in food stores and supermarkets.
- References to the foods in relevant national and EU legislation could also provide good evidence.
- The more widely the use can be demonstrated the stronger the case. Information from one Member State may be sufficient. Evidence of continued presence on the market over a long period of time and/or traditional uses or practices can compensate evidence showing only local or regional use. Evidence from non-EU countries is obviously not acceptable for this purpose.
- The extent of the use should be demonstrated. Evidence should demonstrate food use, in particular when a food or food ingredient is also known to be used in medicines, cosmetics, or other products. Also use as additive or flavouring would not be acceptable to demonstrate significant use. Use of the food in food supplements is not acceptable as proof when the food is intended to be used in other food matrices.
- In certain cases, the type of processing applied to the food is of relevance. Especially in case of changes in the composition of the food or differences in the source material or the production process of the food that cannot be matched with the data presented, the data may not be sufficient.

This guidance remains applicable. The decision tree and questionnaire included in the EC guidance can be a helpful tool to assess the strength of the information available.

4.5. Not all new foods fall under the scope of the NFR

The new definition of Novel Food included in Article 3.2 is the result of the agreement between the European Parliament (EP) and the Council and reflects the principle that not all new food products but only foods that are genuinely novel would fall under the scope of the NFR. A too extensive application of this legislation to foods that do not present a safety risk would considerably affect the innovative potential of EU food business operators and create an impossible situation for small and medium sized food businesses, that constitute the vast majority of food producers.

The intention to limit the scope is clear from the fact that the co-legislators fundamentally amended the original scope proposed by the European Commission.

In its proposal (COM(2013) 894 final 2013/0435 (COD) of 18 December 2012), the Commission proposed the following definition:

“Novel food means all food that was not used for human consumption to a significant degree within the Union before 15 May 1997 [...] and includes in particular [a number of specific food categories]”

The words “and includes” mean that the food categories specified are to be considered as examples and that the scope was as broad as to encompass all foods that had not been used for human consumption before 15 May 1997.

This was thought to cover the spirit of the scope, meaning that if a food that has no conventional counterpart and had not been used before 15 May 1997, it should be subject to a pre-market authorisation to ensure the safety is established. However, legally speaking this would have meant that every new food, that had not been marketed before 15 May 1997 would fall under the scope of the NFR and require pre-market authorisation. This would also have covered any new food composition, even when using conventional non-novel food ingredients.

The EP and Council decided that this was not appropriate and amended this definition to explicitly specify categories of foods that are covered. This means that if a food does not belong to one of the categories it does not fall under the scope of the NFR, not even if it was not used for human consumption prior to 15 May 1997.

It is noted however that the categories included in the new NFR are likely to cover all possible types of novel foods, but would not cover foods that are simply composed of or produced from conventional non-novel food ingredients using conventional food processing.

This is also confirmed by Recital 17 that reads:

“Food produced exclusively from food ingredients that do not fall within the scope of this Regulation, in particular by changing the ingredients of the food or their amount, should not be considered to be a novel food. However, modifications to a food ingredient that has not yet been used for human consumption to a significant degree within the Union, should fall within the scope of this Regulation.”

Thus, it is not the intention of the new NFR to cover 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. New foods with a different composition because of changes in the recipe of the food, the use of alternative ingredients and variations in the amount or nature of the ingredients would not constitute a reason to consider the new food novel, even though this new food has not been marketed before 15 May 1997, if it is composed of non-novel ingredients and produced using conventional/known food processing methods.

This would not only apply to foods in which ingredients are incorporated as such (e.g. salami on a pizza or omega 3 fatty acids in a food supplement) but also to foods produced from non-novel ingredients, meaning that the ingredients are modified during the production of the food (e.g. a cake or pastry).

Also, only modifications to food ingredients that have not yet been used for human consumption to a significant degree within the EU, should fall within the scope of the NFR, but not modifications of non-novel foods using non-novel food processing techniques.

It is noted that the use of novel foods as ingredients of other foods would also not make the final product novel, unless the use of the novel food ingredient goes beyond the conditions of use it was approved for. A novel food, authorised for a number of specific food matrices, would still require a new novel food application for authorisation in other food matrices.

The NFR does not specify any moment at which an approved novel food would become conventional and thus be considered to have a history of safe use.

4.6. The quantity of the food consumed is not a criterion for novel food status

Foods are considered novel if they meet both parts of the definition. They must not have been used for human consumption to a significant degree within the EU before 15 May 1997 and fall under at least one of the specified categories.

Foods that have been consumed to a significant degree before 15 May 1997 and those that do not fall under one of the categories are not covered by the NFR.

The notion of quantity is not part of the definition or concept of novel food. A change in consumption pattern or quantity consumed would not bring a non-novel food within the scope of the NFR. This means that if a new food, not meeting the definition of novel food, would be used under conditions that result in increased intake of the food or one of its constituents, this is not sufficient to qualify the food as novel.

This is logic as EU Legislation already contains a procedure to deal with situations where a substance other than vitamins or minerals, or an ingredient containing a substance other than vitamins or minerals, is added to foods or used in the manufacture of foods under conditions that would result in the ingestion of amounts of this substance greatly exceeding those reasonably expected to be ingested under normal conditions of consumption of a balanced and varied diet and/or would otherwise represent a potential risk to consumers. This is covered by Article 8 of Regulation (EC) 1925/2006.

Also new uses of non-novel foods are not considered to trigger novel foods approval.

In this respect, there is one exception. When a non-novel ingredient was only used in food supplements and has no history of use in other food products, its use in other foods would trigger a novel food approval as indicated in part (x) of the definition. The use in food supplements would not be considered novel. This principle was adopted by the Member States in 2005 in that the use of foods and/or food ingredients in the EU exclusively as, or in, food supplements is not considered to be significant human consumption within the meaning of Regulation (EC) 258/97.⁴

If new uses would result in situations of increased intake that would present a potential risk to consumers, this can also be covered by the procedure of Article 8 of Regulation (EC) 1925/2006.

4. Standing Committee on the Food Chain and Animal Health. Section on Toxicological Safety & Section on General Food Law. Summary Record of the meeting of 14 February 2005. https://ec.europa.eu/food/sites/food/files/safety/docs/reg-com_gfl_summary14_en.pdf

4.7. Possibility of a safety concern is not a criterion for novel food status

The definition of novel food also does not contain any element that would make a food fall under it only on the basis of the possibility of safety concerns. This is logic as it is the aim of the whole of EU food law framework to manage inherent risks that are associated with food and ensure the safety of foods marketed in the EU.

Safety concerns are inherent in most foods and food source materials. These can be of various nature (microbiological, toxicological, etc). Legal provisions are in place and appropriate processing and control measures are implemented by food business operators in accordance with EU law to ensure that potential safety concerns are adequately dealt with, so the food is safe for consumption. If any food that is marketed would present a safety concern, this could also be addressed under the procedure of Article 8 of Regulation (EC) 1925/2006 and/or by appropriate enforcement action. It is not the intention of the NFR to assess such safety concerns for foods that do not fall within its definition.

Still in accordance with Regulation (EC) 178/2002, it is a food business operator's responsibility to ensure at all times the safety of all foods put on the market.

In a number of categories in the new definition of Novel Food, certain foods are only covered if the process applied to these foods gives rise to significant changes in the composition or structure of the food, affecting its nutritional value, metabolism or level of undesirable substances (e.g. categories (iv) and (vii)).

Assessing this is the responsibility of the food business operator as part of the decision process to verify whether or not the food falls under the scope of the NFR. It is not the intention that this assessment is part of a novel food submission. A novel food submission may however result as a consequence of this assessment when a food business operator concludes that the process indeed gives rise to significant changes in the composition or structure of the food, affecting its nutritional value, metabolism or level of undesirable substances.

5. Differences between the old and new definition of novel food

Recital 8 states that:

“The scope of this Regulation should, in principle, remain the same as the scope of Regulation (EC) 258/97.”

This was the principle that the EP and Council agreed when they decided to amend the definition proposed by the Commission and reinstate the categories to define what are novel foods.

It is not anticipated therefore that the decision on what foods are considered novel will be fundamentally different than in the past.

Recital 8 however recognises that “on the basis of scientific and technological developments that have occurred since 1997, it is appropriate to review, clarify and update the categories of food which constitute novel foods.” A number of products that should be considered novel while this was not clearly the case in the previous legislation are specifically listed:

- Whole insects and their parts
- Food with a new or intentionally modified molecular structure
- Food from cell culture or tissue culture derived from animals, plants, microorganisms, fungi or algae
- Food from microorganisms, fungi or algae
- Food from material of mineral origin
- Food from plants obtained by non-traditional propagating practices where those practices give rise to significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances
- Food consisting of certain micelles or liposomes
- Food resulting from a production process not used for food production within the EU 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.

Some of these foods are already covered by the original Regulation, but others might not be. The explicit mention of these categories shows that it is the intention that such foods are considered novel under the new NFR.

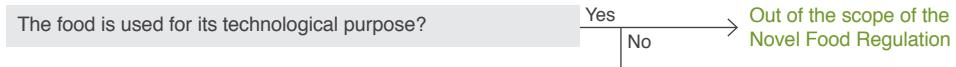
The differences between the old definition and categories and those defined in the new NFR are described below.

Figure 4: The 10 categories of novel foods

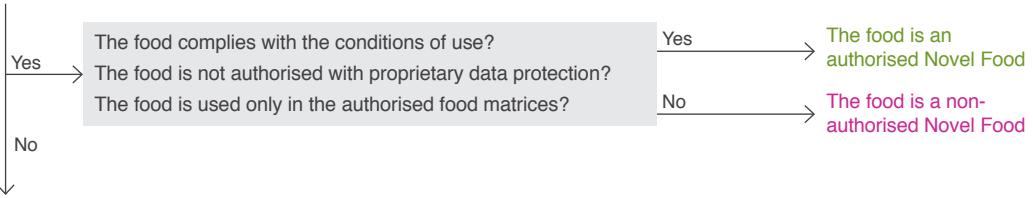
1. Food with a new or intentionally modified molecular structure, where that structure was not used as, or in, a food within the Union before 15 May 1997
2. Food consisting of, isolated from or produced from microorganisms, fungi or algae
3. Food consisting of, isolated from or produced from material of mineral origin
4. 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
5. 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
6. Food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, micro-organisms, fungi or algae
7. 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
8. Food consisting of engineered nanomaterials as defined in point (f) of the NFR
9. Vitamins, minerals and other substances used in accordance with Directive 2002/46/EC, Regulation (EC) 1925/2006 or Regulation (EU) 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 7; or
 - they contain or consist of engineered nanomaterials as defined in point (f) of the NFR
10. 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

Figure 5: Decision tree for determining the status of a new food

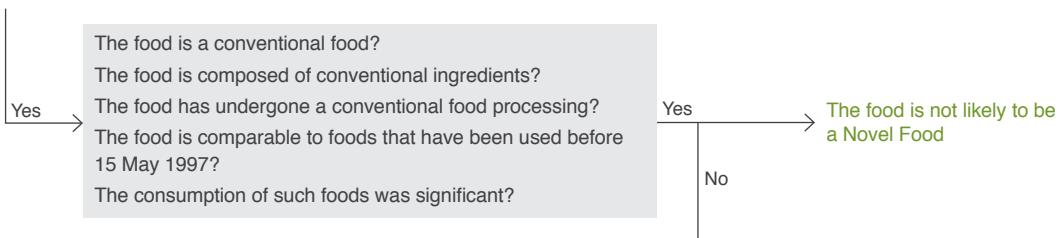
1: The food is a food additive, food flavouring, food enzyme or extraction solvent?



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



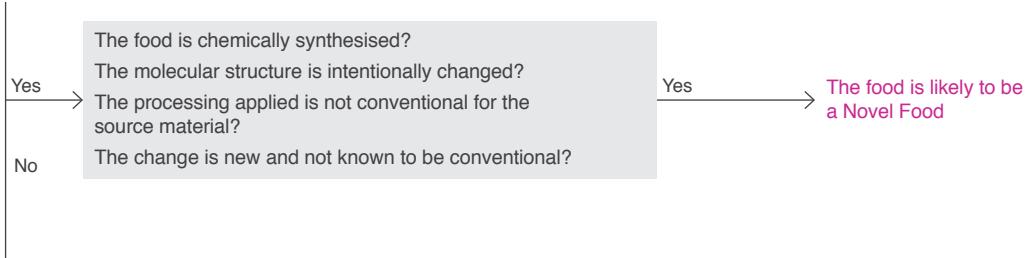
3: The food was used as food in the EU to a significant degree before 15 May 1997? -----> Collect data on the food

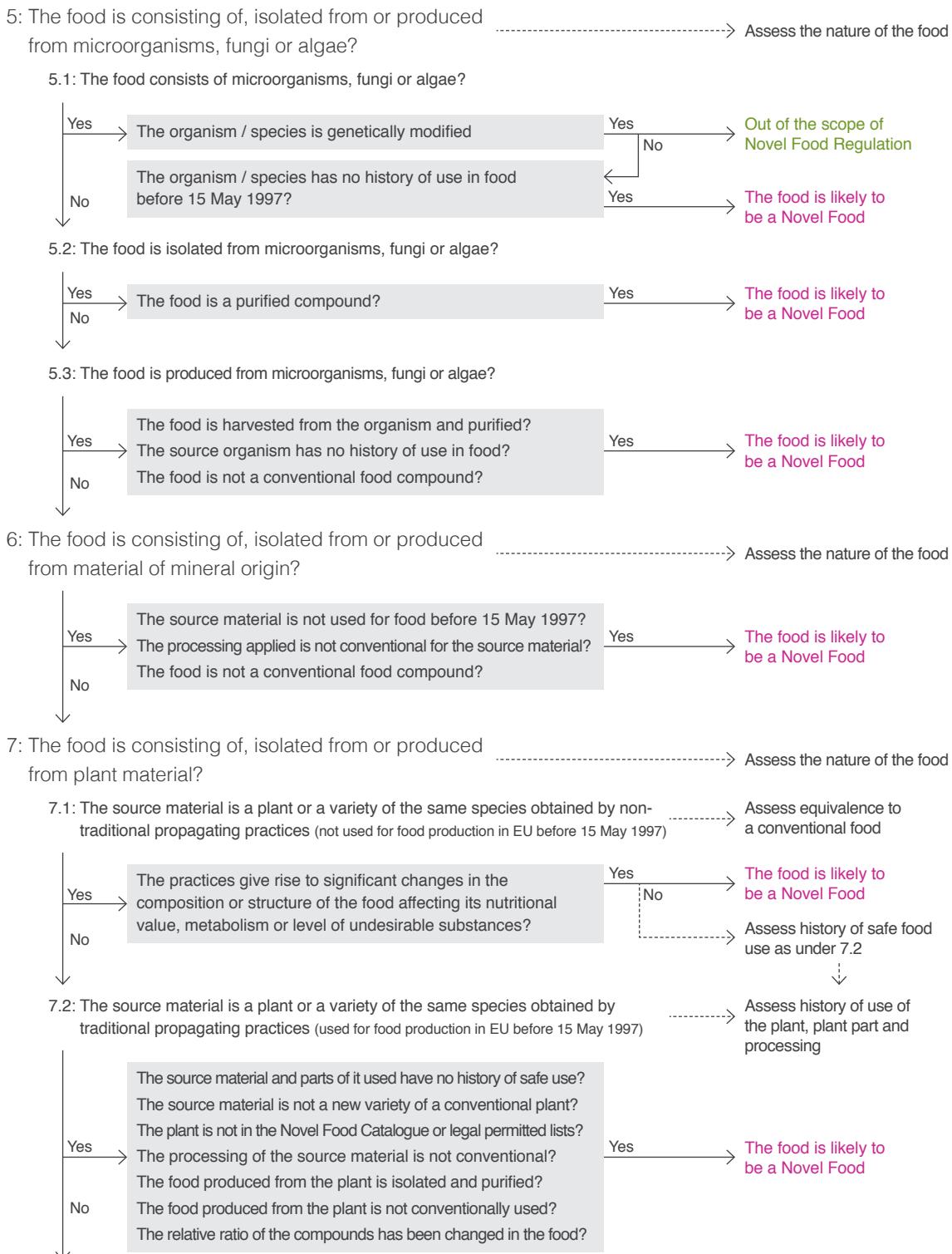


The food was only used in Food Supplements -----> The food is not a Novel Food for use in food supplements



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





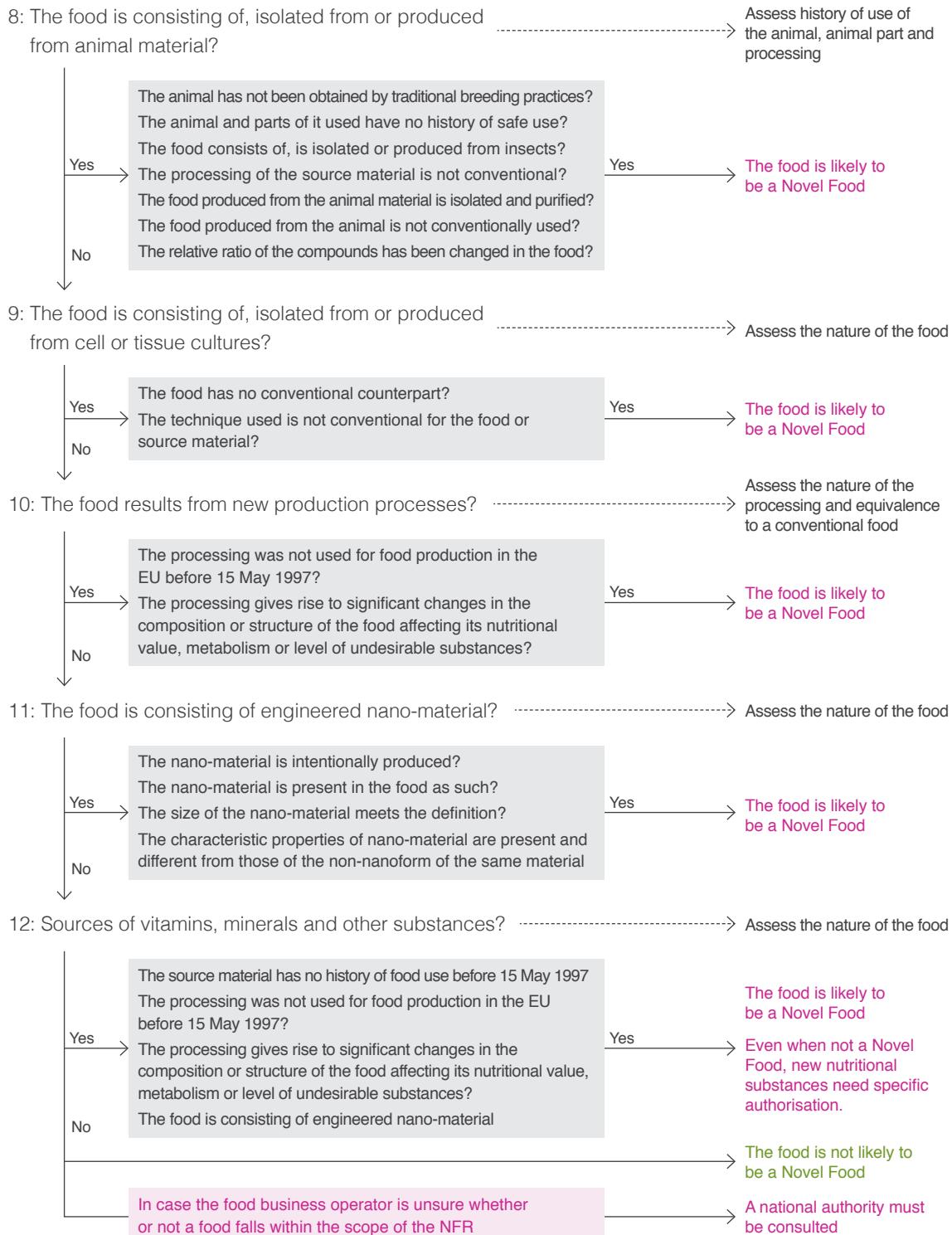


Figure 6: Update of the Union List

Commission initiative or Application for authorisation



Figure 7: Difference between the old and new procedure

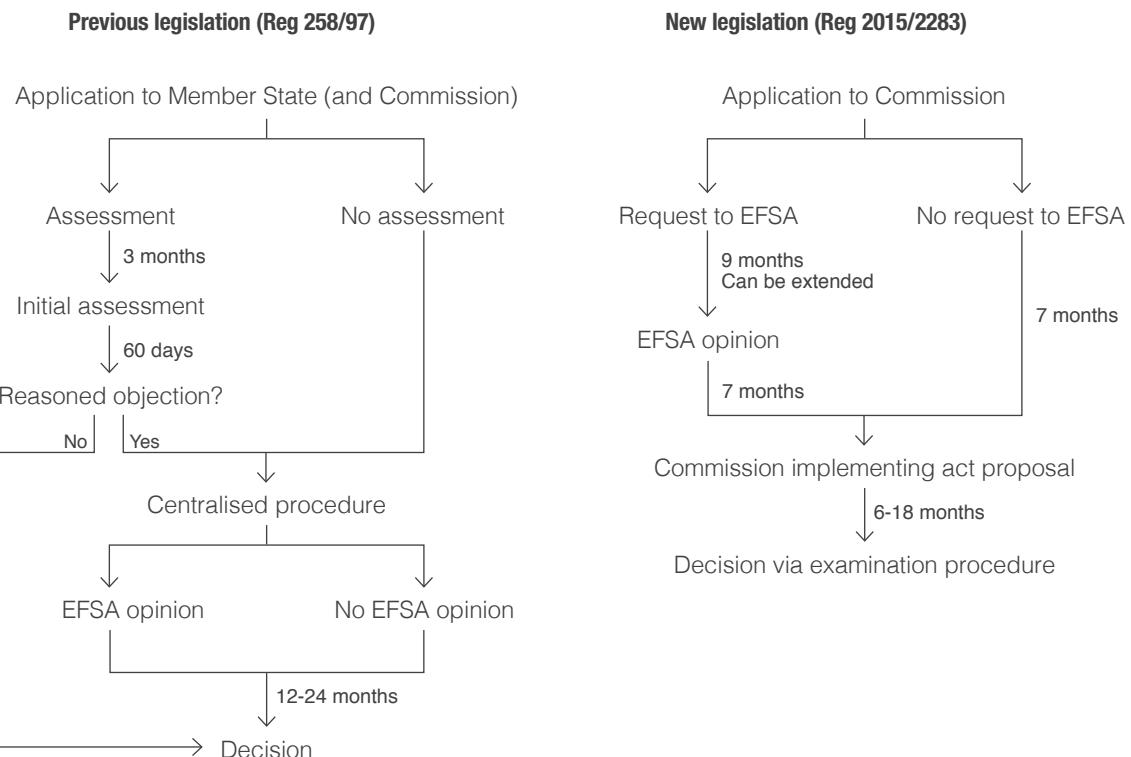


Figure 8: Proprietary data protection: conditions

The applicant may request protection for new scientific data under the following conditions:

The newly developed scientific evidence or scientific data was designated as proprietary by the applicant at the time the first application was made

→ so the request must be made in the application

The applicant had exclusive right of reference to the proprietary scientific evidence or scientific data at the time the first application was made

**→ so the applicant must demonstrate ownership of the data
(irrespective of whether the data are in the public domain or not)**

The novel food could not have been assessed by EFSA and authorised without the submission of the proprietary scientific evidence or scientific data by the applicant

→ so the data must be necessary as evidence

Proprietary data protection will be granted for a period of 5 years.

The applicant may agree that the data can be used by a subsequent applicant.

Note: proprietary data protection has no bearing to confidentiality of data.

It should be noted that protection of proprietary data only covers the data, and not the product. Any other applicant can still submit and obtain authorisation for the same food, provided he has rights to use the same data or has access to other data that would be sufficient to substantiate his application. Data protection is also not a patent.

Data that are protected are not automatically confidential. This is a separate concept. Parts of the application that an applicant wants to keep confidential need to be highlighted throughout the application. The revision of the EU transparency rules currently underway may in future significantly change the nature of the data for which confidentiality can be requested.

5.1. Category (i): Foods with a new or intentionally modified molecular structure

Article 3.2.a.(i) specifies the first category of foods to be considered novel:

“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.”

This corresponds to category (c) of the original Regulation:

“Foods and food ingredients with a new or intentionally modified primary molecular structure.”

The word “primary” is no longer part of the definition. No reason is given for this change. However, in order to be able to judge if a molecular structure has been modified, the food must have a defined molecular structure in the first place. This means that complex foods that consist of different compounds would not fall under this part of the definition but rather under the other parts. In that sense, it is therefore not anticipated that the deletion of the word “primary” is of much relevance in deciding what products fall under this category.

The legislation does not specify examples of foods that would fall under this category. However, the following foods are likely to be considered as covered:

- Substances that are chemically synthesised and thus do not originate from animal, plant or mineral material. These substances can be identical to naturally occurring substances or have a completely new structure.
- Substances of which the molecular structure is intentionally modified by specific chemical or enzymatic conversions.

Examples of such novel foods include:

- Synthetic Zeaxanthin (Decision 2013/49/EU)	- Methyl Vinyl Ether-Maleic Anhydride Copolymer (Decision 2014/905/EU)
- Synthetic Lycopene (Decision 2009/348/EC, Decision 2009/362/EC)	- Synthetic dihydrocapsiate (Decision 2012/726/EU)
- Synthetic Trans-resveratrol (Decision 2016/1190/EU)	- Synthetic Lacto-N-neotetraose (Decision 2016/375/EU)
- Synthetic L-ergothioneine (Decision 2017/1281/EU)	- Synthetic 2'-O-fucosyllactose (Decision 2016/376/EU)
- Synthetic novel chewing gum base (Decision 2011/882/EU)	- Synthetic lactitol (Decision 2017/1576/EU)

One question is to what extent processing as such that result in changes of molecular structure of ingredients are covered. Heat treatment invariably changes the molecular structure of food ingredients and in many cases, this is intentional (e.g. for the creation of flavours during cooking and frying). Also, physical forces, such as friction or freezing can change the molecular structure. It is obvious that non-novel foods that are subject to conventional/recognised food production processes that result in changes in molecular structure should not be considered novel in the sense of this definition.

Congruent with the examples of novel foods authorised so far, it is clear that many foods have a changed structure after processing but such changes would not be considered a “modification” in the sense of this part of the definition. Such foods could still be considered novel when they would fall under one of the other categories of the definition.

However, when the modification of the molecular structure is an intentional objective, an assessment will need to be carried out to assess the extent to which the modified molecular structure was not used as or in food in the EU before 15 May 1997.

If the outcome of this assessment is that it concerns a modification of the molecular structure of a food that is not known to conventionally undergo the kind of processing applied, then the food may still be considered to fall under this part of the definition.

If the source material is not novel and is subject to a non-novel food production process, the resulting food is likely not to be considered novel, even if the food has been subject to compositional or structural changes. Other aspects of food safety law would apply however in this case.

As an example: hydrolysis and re-esterification are conventional processing techniques applied to fats. Provided the fat is not from a novel source, such products should not normally be considered as novel. Where however, because of the processing the (primary) structure of the food is changed in a way that it has no conventional counterpart, the food would be considered novel food.

An example of a novel food that was produced by re-esterification and authorised as novel foods is salatrim, which are a group of reduced calorie triacylglycerides. These fats were not considered conventional because of their reduced calorie content which has no conventional counterpart food. (Decision 2003/867/EC).

This would also apply to hydrolysis. By hydrolysis, either through chemical, physical or enzymatic processes, the molecular structure of a protein, fat or carbohydrate is split. However, hydrolysis has a long history of use in food processing and has been applied to many conventional food ingredients (e.g. to dairy protein fractions, fats and starches). It has also been applied to proteins to reduce allergenicity and such hydrolysates are extensively used in specific infant formulas. It is a particularly useful technique to produce derivatives with specific properties. Under the original novel foods definition, food the composition of which has changed by the application of hydrolysis has not been considered as novel and did not require novel foods authorisation under this part of the definition. This situation is not intended to be changed with the new NFR.

Still, foods that undergo hydrolysis can fall under other parts of the definition and still require novel foods authorisation. This is particularly the case if hydrolysis is applied to foods to which it has not been conventionally applied and results in foods that have no conventional counterpart.

If hydrolysis is applied to a novel food, the hydrolysed form of the novel food would be subject to a new authorisation if not included already within the conditions of approval for that novel food.

It is noted that the source material and the processing that is applied often lead to changes of the composition or structure of a food that are not necessarily considered as modifications of the molecular structure. Therefore, products that have a changed structure because of the specific source material used or processing applied would not necessarily fit under this part of the definition, but rather under categories (iv) or (v) (foods produced from plant or animal material) or category (vii) (food resulting from a production process not used for food production in the EU before 15 May 1997). These categories do cover the aspect that these changes may alter the nutritional value or the way in which the food is metabolised, which is not a criterion under category (i), that only refers to a modified molecular structure.

Therefore, to avoid that the other categories of the definition would serve no purpose, only genuine modifications of the molecular structure of a food should be covered by this part of the definition and not mere changes created by the use of specific source materials or specific processing.

An example is diacylglycerol oil. While the source material can be any edible oil, the specific processing results in a composition that is selectively enriched in diacyl glycerols (at least 80%), which has no conventional counterpart (Decision 2006/720/EC). The processing as such (enzymatic esterification of edible oils) would not result in the food having a modified molecular structure that has not been used as or in food in the EU before 15 May 1997.

Phosphated distarch phosphate is an example of a food that was approved as food additive (E1413) and required novel food approval for use in food in general because it is structurally modified to make it resistant to digestion and such substances had not been used as food ingredients before 15 May 1997 in the EU. In addition, the specific raw material used was high amylose maize instead of the usual low amylose maize varieties. Therefore, these two elements resulted in the food requiring novel food authorisation and not the processing applied, which is conventionally used for the manufacturing of modified starches and also not the changes to the structure of the starch are known to be conventional for modified starches. (Decision 2011/494/EU).

An example of a food to which hydrolysis has been used despite the fact that the source organisms has a long history of food use is Sardine Peptide Product, which is produced from alkaline protease-catalysed hydrolysis of sardine (*Sardinops sagax*) muscle. In this case the food was considered novel, not by the fact that it was hydrolysed but because it was a clear isolate that had not been used before 15 May 1997 (Decision 2011/80/EU).

Another example is rooster comb extract, produced by enzymatic hydrolysis, followed by filtration, concentration and precipitation steps. Also in this case the source material and nature of the food was the decisive factor, not the fact that hydrolysis was part of the processing (Decision 2013/705/EU).

5.2. Category (ii): Food consisting of, isolated from or produced from microorganisms, fungi or algae

Article 3.2.a.(ii) specifies the second category of foods to be considered novel:

“Food consisting of, isolated from or produced from microorganisms, fungi or algae.”

This corresponds to category (d) of the original Regulation:

“Foods and food ingredients consisting of or isolated from microorganisms, fungi or algae.”

Foods consisting of microorganisms, fungi or algae

As under the original Regulation, new micro-organisms that are used as or in foods were considered novel. This primarily covers species that have not been used for human consumption before.

One question is to what extent new strains of species that have a conventional food use can be considered as not covered by the NFR. Under the original Regulation new strains of organisms which had a known history of use in the European Union before 1997 were not considered novel food. In particular, new strains of micro-organisms that have been assigned QPS status by EFSA are generally not considered novel food. QPS or “Qualified Presumption of Safety” is a concept developed by EFSA. In essence, this means that a safety assessment of a defined taxonomic group (e.g. genus or group of related species) could be made based on four pillars (establishing identity, body of knowledge, possible pathogenicity and end use). If the taxonomic group does not raise safety concerns or, if safety concerns exist, but could be defined and excluded (the qualification) the grouping could be granted QPS status. Thereafter, any strain of microorganism the identity of which could be unambiguously established and assigned to a QPS group would be freed from the need for further safety assessment other than satisfying any qualifications specified (like virulence factors or antimicrobial resistance abnormal for the species). Microorganisms not considered suitable for QPS would remain subject to a full safety assessment.⁵

Therefore, this principle could be applied to new strains of conventional micro-organisms that have QPS status and to conventional micro-organisms that do not have QPS status but have a long history of use in food. The food business operator should have verifiable information available to justify that in this specific case QPS as established by EFSA can be applied to the new strain or, in case of a non-QPS organism, that the strain has been assessed as being safe.

In other words, for microorganisms listed in the QPS list with a history of food consumption for the genus or the species, no strain specific history of consumption or other additional safety information is necessary unless there is evidence suggesting that the particular strain has characteristics that may impact its safety profile. The history of food consumption of the genus or species before 15 May 1997, however, needs to be documented. The fact that the genus or species is listed in the QPS list is not in itself sufficient to be excluded from the scope of the NFR. It must also be confirmed that the microorganism has been used as or in food, and not only for non-food applications (e.g. feed).

EFSA has published over time a list with those biological agents intentionally added to food and feed that have been granted QPS and keeps this list up to date.⁶

It is also noted that to date the QPS approach is only valid for microorganisms and not for other biological entities (e.g. algae, botanicals, etc).

5. Opinion of the Scientific Committee on a request from EFSA on the introduction of a Qualified Presumption of Safety (QPS) approach for assessment of selected microorganisms referred to EFSA. The EFSA Journal (2007) 587, 1-16

6. Scientific Opinions of the Panel on Biological Hazards on a request from EFSA on the maintenance of the QPS list of microorganisms intentionally added to food or feed. EFSA Journal (2008) 923, 1-48 ; EFSA Journal 2009; 7(12):1431 ; EFSA Journal 2010;8(12):1944 ; EFSA Journal 2011;9(12):2497 ; EFSA Journal 2012;10(12):3020 ; EFSA Journal 2013;11(11):3449

It is important to stress that QPS is not a criterion to decide on novel food status per se. Given that the QPS assessment by EFSA is not a systematic process, microorganisms for which EFSA has not assessed the QPS status, may not necessarily be considered novel. In these situations, the history of food use before 15 May 1997 is the criterion to consider. Lists of microorganisms that have traditionally been used in food, many of which not having been assessed as QPS, have been published for reference.⁷

One example of a microorganism that was authorised as novel food is *Clostridium butyricum* (CBM 588). *C. butyricum* was considered by EFSA's BIOHAZ Panel in its 2011 update to the QPS list. EFSA concluded that "the safety of *C. butyricum* is a strain-related property, therefore *C. butyricum* should not be recommended for the QPS list." This conclusion was based on the observation that a minority of strains contain a gene coding for botulinum neurotoxin type E and there is only limited knowledge of human and animal exposure to this species. Since the microorganism did not have a history of consumption before 15 May 1997 and safety is strain-specific, precluding general listing of the microorganism in the QPS list, it was required to undergo a full novel food assessment (Decision 2014/907/EU).

Another example is heat-treated milk products fermented with *Bacteroides xylanisolvans* DSM 23964. *B. xylanisolvans* was not assessed under the QPS scheme at the time when this novel food was submitted. The application triggered a QPS assessment by EFSA. The conclusion was that although no safety concerns have been observed (as only a β -lactamase resistance gene (*cepA*) has been identified in the genomic DNA, which is unlikely to be transferable), the studies published on *B. xylanisolvans* are not sufficient for the inclusion of this species in the QPS list. Therefore, a full novel foods application was required (Decision 2015/1291/EU).

Foods isolated from microorganisms, fungi or algae

Also, foods that are isolated from microorganisms are under the scope of the new NFR, as long as they are not explicitly excluded (e.g. additives, enzymes, flavours).

The concept of "isolated from" has not been defined, but in line with its general meaning, it is understood that a compound is isolated from something when it is harvested from the source material and purified to a significant degree to yield a compound that can be characterised and meets set specifications.

The microorganism itself that is used for the production of a novel food would not fall under the NFR if it is not part of the novel food and thus not ingested. The safety of the microorganism in the context of the manufacturing process of the novel food will obviously be considered during the risk assessment of the novel food. If the micro-organism is ingested however, it needs to be verified if it is novel and if so, it will need an assessment under the NFR.

Genetically modified microorganisms (GMM) are explicitly excluded from the scope of the NFR. A genetically modified organism (GMO) is defined in Article 2.2. of Dir 2001/18 as "an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination."

Thus, when used for the production of a food, the microorganism needs to respect the specific legislation relating to GMM and not be evaluated under the NFR. The contained use of GMM is covered by Directive 2009/41.

7. Mogensen G. et al. Inventory of microorganisms with a documented history of use in food. Bull. Int. Dairy Fed. 2002;377:10–19; IDF. Safety demonstration of microbial food cultures (MFC) in fermented food products. Bull. Int. Dairy Fed. 2012;455:1–62;

Also, a food that consists of, contains or is produced from these GMOs is excluded from the scope of the NFR as other specific legislation is applicable (Regulation (EC) 1829/2003).

Foods produced with the aid of GMMs however are excluded from the scope of Regulation (EC) 1829/2003. If such foods have no history of safe use before 15 May 1997 and belong to one of the categories of the definition, they would fall under the NFR.

Foods produced from microorganisms, fungi or algae

Since the extent of purification of compounds isolated from microorganisms, fungi or algae may differ and leaves room for discussion, the words "produced from" have been added to the new NFR definition. This means that in principle every food that is produced from a microorganism, fungus or alga would also fall under the NFR, irrespective of its degree of purity, provided of course that the food has not been used for human consumption to a significant degree already before 15 May 1997.

One question is to what extent products that are produced by bacterial fermentation are covered by this provision. Fermentation is a conventional food processing technique with multiple applications in the food area. Many microorganisms are used for that purpose. There is a distinct difference between a food that is produced from a microorganism (by which the microorganism or its enzymes synthesise the compound and the compound is harvested and purified) and the process of fermentation of a food by which the microorganism synthesises compounds that provide flavour or acidity in the food. Most conventional fermentation processes using microorganisms with a history of use for such purpose would not be covered by the NFR.

This is also the case when microorganisms are used in a food to produce specific compounds that are among the natural metabolites conventionally known to be produced by the microorganism in that food and which have been consumed in the human diet as part of that food.

If however, the specific compound is harvested, concentrated or further purified, the NFR may apply. In assessing whether such a compound falls under the scope of the NFR, a food business operator will need to address the following elements:

- The nature, type and history of use of the microorganism (QPS, GMM, ...), fungus or alga before 15 May 1997.
- The nature and history of use of the food before 15 May 1997.
- Presence of the microorganism in the food.
- Extent of purification of the food.

Foods produced with the aid of enzymes, not involving the microorganism, would not be considered to fall under this part of the definition. In such cases, it is the product resulting from the enzymatic activity that needs to be considered for assessment of novel food status. The enzyme itself needs to be authorised under the provisions of Regulation (EC) 1332/2008 and is excluded from the scope of the NFR.

One question is if the use of an authorised enzyme would automatically lead to the resulting food not to be considered as novel. Although the list of authorised food enzymes is not yet established, the intended use of the enzyme will be part of the risk assessment. The fact that an authorised enzyme is used in accordance with its intended use would therefore as a general rule not make the resulting food a novel food. However, such use would also not in all cases automatically preclude that the resulting food is novel.

This will depend on the substrate, the processing parameters and if the enzyme is used in a mix together with other enzymes. In such cases, it will need to be assessed if the enzyme is used in accordance with the conditions of use specified and if this processing would not give rise to significant changes in the composition or structure of the food, affecting its nutritional value, metabolism or level of undesirable substances, as required under part (vii) of the definition of novel food.

Below are examples of authorised novel foods that are isolated or produced from microorganisms, fungi or algae, including:

Specific fats and oils:

- Oil rich in DHA (docosahexaenoic acid) from the micro-algae *Schizochytrium sp.* (Decision 2003/427/EC) (Alga).
- Arachidonic rich oil from *Mortierella alpina* (Decision 2008/968/EC) (Fungus).

Specific carbohydrates:

- Trehalose produced by fermentation from sucrose (Decision 2001/721/EC) (Microorganism).
- Dextran preparations produced by *Leuconostoc mesenteroides* (Decision 2001/722/EC) (Microorganism).
- Isomaltulose (Decision 2005/457/EU) (Microorganism).
- Alpha-cyclodextrin (Decision 2008/413/EC) (Microorganism).
- Gamma Cyclodextrin (Decision 2012/288/EU) (Microorganism).
- Chitin-Glucan (Decision 2011/76/EU) (Fungus).
- Beta-glucan rich extract from *Lentinus edodes* (Decision 2011/73/EU) (Fungus).
- Yeast beta-glucans from *Saccharomyces cerevisiae* (Decision 2011/762/EC) (Microorganism).

Specific Proteins:

- Ice Structuring Protein type III HPLC 12 (Decision 2009/344/EC) (Microorganism).

Other substances:

- Lycopene from *Blakeslea trispora* (Decision 2006/721/EC) (Fungus).
- Citicoline (choline cytidine 5"-pyrophosphate) (Decision 2014/423/EU) (Microorganism).

In all the above examples the food that is isolated or produced by the microorganism (or enzymes that are derived from microorganisms), the fungus or alga did not have a history of use in the EU before 15 May 1997 and thus was considered novel.

Also, foods that have been fermented with microorganisms have been covered by novel foods authorisations.

One example is fermented black bean extract or Touchi extract, which is a protein-rich powder obtained by water extraction of small soybeans (*Glycine max*) fermented with *Aspergillus oryzae*. This extract is rich in protein (over 55 %). It is typically produced from small soybean grown in the Sichuan province of China. *A. oryzae* is a well-established microorganism employed in the production of soy sauce, sake and miso. The processing uses conventional processing techniques. So, in this case, it was not the source material and the fermentation, but the specific food being significantly different from existing foods, which was not used in the EU before 15 May 1997, that triggered novel food status, despite many other fermented black bean products having a history of food use in the EU. (Decision 2011/497/EU).

Another example is soybean extract, fermented with a selected strain of *Bacillus subtilis* var. *natto*. Also in this case both the source material and the microorganism have a history of food use, but the food itself has not been used to a significant degree before 15 May 1997 (Decision (EU) 2017/115).

5.3. Category (iii): Food consisting of, isolated from or produced from material of mineral origin

Article 3.2.a.(iii) specifies the third category of foods to be considered novel:

“Food consisting of, isolated from or produced from material of mineral origin.”

This category has no match in the original Regulation. However, the CJEU in Case C-448/14 already confirmed that material of mineral origin was covered by part (c) of the original definition, by ruling that the expression “new primary molecular structure” relates to foods or food ingredients which were not used for human consumption in the territory of the EU before 15 May 1997.

Therefore, under the original Regulation a new molecular structure was also judged to cover molecules that have not been modified but had not been used as foods for human consumption before 15 May 1997.

Food business operators intending to market new products originating from material of mineral origin will therefore need to assess:

- The source material and if that source material as such has been consumed as food before 15 May 1997.
- Whether the food that is isolated or produced from that source material is a non-novel food.

It is noted that such products may have been marketed between 15 May 1997 and 1 January 2018. In that case the transition period specified in article 35.2 of the NFR applies (see chapter 6).

5.4. Category (iv): food consisting of, isolated from or produced from plant material

Article 3.2.a.(iv) specifies the fourth category of foods to be considered novel:

"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."*

This definition corresponds to part e of the original novel foods definition:

"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."

It is anticipated that most novel food products fall under this category given that the vast majority of food is of vegetable origin. Understanding the scope of this definition is therefore important to assess the extent to which a food falls under the scope of the NFR and needs pre-market approval.

Recital 8 clarifies the nature of the change of this definition:

"There should also be a category covering food from plants obtained by non-traditional propagating practices where those practices give rise to significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances."

So, in principle not all new foods that consist of, are isolated or produced from plants are covered by this definition. The new NFR clearly targets foods derived from plants that are not conventional, by either focusing on plants obtained by non-traditional propagation methods or plants that have no history of safe use. It is clear from the exemption included in this part of the definition that foods with a history of safe food use should not in general be covered.

To assess whether the food under consideration falls in this exemption, two elements are important to assess:

- The food must have a history of safe use in the EU, AND
- The food must be produced from plants that are obtained by traditional propagating practices or from plants obtained by non-traditional propagating practices but with no significant changes in structure, nutritional value, metabolism or level of undesirable substances.

This means that the following foods will fall under the scope of the NFR:

- Foods with a history of safe food use but obtained from non-traditional propagating practices giving rise to significant changes in the composition or structure of a food, affecting its nutritional value, metabolism or level of undesirable substances.
- Food with no history of safe food use, irrespective of what plants they are obtained from.

Foods with a history of safe food use consisting of or isolated or produced from plants obtained by non-traditional propagating practices

A food is not covered by the NFR when it consists of, is isolated or produced from a plant or a variety of the same species that is obtained from traditional propagating practices which have been used for food production within the EU before 15 May 1997 and has a safe history of food use.

“Traditional propagating practices” is not defined. Plain traditional propagating practices include both sexual (growing plants from seeds) and various techniques of a-sexual propagation (e.g. propagation by means of layering, division, grafting, micropropagation, stolons or runners, storage organs such as bulbs, corms, tubers and rhizomes, striking or cuttings, twin-scaling, offsets, etc).

The term is often used as opposite for (intentional) genetic modification. Annex 1A of Dir 2001/18 specifies a number of techniques that constitute genetic modification and thus are clearly not traditional propagating practices. This Annex also specifies a number of techniques that are not considered as genetic modification, including:

- in vitro fertilisation,
- natural processes such as: conjugation, transduction, transformation,
- polyploidy induction.

on condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms.

In addition, and on the same conditions, Annex 1B lists a number of techniques that are also excluded for the Directive on genetically modified organisms, including:

- mutagenesis,
- cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods.

A recent ruling by the CJEU (Case C-528/16) clarifies however that this exemption only applies to organisms obtained by means of techniques/methods of mutagenesis which have conventionally been used in a number of applications and have a long safety record. New forms of mutagenesis, that have been developed since the Directive came into force alter the genetic material in a way that does not occur naturally and thus can have the same effect as the introduction of foreign genetic material and are therefore covered under the requirements for GMO.

These elements need to be considered for judging if the source material (plant) is obtained by traditional propagating methods or not.

A food is also not covered by the NFR when it consists of, is isolated or produced from a plant or a variety of the same species that is obtained from 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 and has a safe history of food use.

So, foods consisting of, isolated or produced from plants that are obtained by non-traditional propagating practices are not even covered if verifiable evidence exists that shows that the practices have not given rise to significant changes in the composition or structure of the food that affects its nutritional value, metabolism or level of undesirable substances. It is not defined what is "significant". This is left to a case-by-case assessment.

Although the concept of "substantial equivalence" has not been retained in the new NFR, it can be a good tool to judge the significance of such changes. This presupposes of course that there is an appropriate reference food with a history of safe food use to compare the food with. Such reference food must be a relevant counterpart for the food under consideration and be a genuine basis for comparison (see chapter 7).

In assessing the extent of the changes to the composition, both nutritional and non-nutritional composition should be covered, as well as effects caused by the specific processing.

Therefore, for assessing these aspects the following elements need to be taken into account:

- The changes to the composition of the food and the extent to which these changes no longer result in it being substantially equivalent to the food it is compared to.
- The changes to the structure of the food and the extent to which these changes no longer result in it being substantially equivalent to the food it is compared to.
- The extent to which these changes affect the nutritional value, metabolism or level of undesirable substances.

A food with a history of safe food use is therefore only covered by the NFR if it is obtained from non-traditional propagating practices that give rise to significant changes in the composition or structure of a food, affecting its nutritional value, metabolism or level of undesirable substances.

Examples of plants and plant parts that have been authorised (or refused) under the novel foods Regulation because they were considered to have a history of use or not before 15 May 1997 include:

- Noni Juice (Decision 2003/426/EC)
- Nangai nuts (Decision 2001/17/EC)
- *Stevia rebaudiana* (Decision 2000/196/EC)
- *Morinda citrifolia* Leaf (2008/985/EC)
- Baobab (*Adansonia digitata*) dried fruit pulp (2008/575/EC)

Food with no history of safe food use

This is a difficult criterion to address.

"History of safe use" is not defined as such in the NFR. The concept of "History of safe food use in a third country" is defined as meaning "that the safety of the food in question has 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, prior to a notification referred to in Article 14."

However, this definition is applicable as criterion to judge if or not the simplified notification procedure for traditional foods from a third country can be applied. The concept is further explained and the data required laid down in Commission Implementing act 2017/2468.

In the original NFR, the history of safe food use of the food was not an explicit condition in that part of the definition, but was inherent in the requirement that foods are not novel if they have been consumed to a significant degree prior to 15 May 1997. In the context of foods that have been used in the EU, the cut-off date of 15 May 1997 therefore applies in all cases as a criterion to judge whether or not the NFR is applicable. Therefore, the notion of "safe food use" of the food must be different from determination if the food was used to a significant degree before 15 May 1997. If it were the same, the inclusion in the definition would simply serve no purpose. Since this notion of "safe food use" is the first element of the exemption and the source materials are the second, demonstration of safe food use should therefore apply to a food, irrespective of the source material. In other words, it is the compound or ingredient or food as such that should be shown to have a history of safe use.

As an example, Lutein has a history of use in the EU as a substance used in foods and food supplements. It is listed as non-novel in the novel food catalogue. Therefore, lutein can be considered as a food with a history of safe use. Only lutein that would be derived from either a plant that has not been used in food to a significant degree before 15 May 1997 or from plants that are obtained from non-traditional propagating practices would be covered under the NFR.

It is noted that the processing applied is a separate factor to consider and may also result in a food falling within the scope of the NFR even though the above would apply.

To assess history of safe food use in this context, the date of 15 May 1997 is not a cut-off date. Still significant use before 15 May 1997 can be considered as history of safe food use in this context. Safe history of food use however does not explicitly require use before 15 May 1997 since it would otherwise not make sense to have it as part of this category definition.

It is obvious that no new food has a history of use in the EU before 1997 as such as it is new. Also interpreting that history of use of each new food must be demonstrated before 15 May 1997 would lead to most new foods ending up in the NFR, which was not the intention. Recital 8 confirms that the scope of the NFR should, in principle, remain the same as the scope of by Regulation (EC) 258/97 and foods derived from plants obtained from traditional propagating practices are not among the categories mentioned as requiring update or clarification.

Therefore, the justification of the history of safe food use of a new food derived from plant material will need to be assessed in the light of the application of the current NFR to avoid that all new plant-derived foods would be covered. This is a case-by-case assessment. In accordance with article 4, if a company is unsure whether or not a new food falls within the scope of the NFR, a national authority must be consulted and the data laid down in Commission Implementing Regulation (EU) 2018/456 be presented.

The assessment of whether a new food can be considered as having a safe history of use will need to consider the following elements

- History of safe use of the plant or plant variety
- History of safe use of the processing
- Nature of the food

a. History of safe food use of the plant or plant variety

The first important determinant to consider is the plant or plant part that is the source material of the food.

If the plant that is the source material of the food was used to a significant degree before 15 May 1997, it falls out of the scope of the NFR. This can be used as an important indication for the history of safe use of the food. Foods have a high likelihood of being considered to have a history of safe use if they are derived from the plant parts that have been used as food before that date and obtained by recognised food processing techniques.

It is important to understand that the concepts of “plants” and “their parts” are two distinct elements that need to be considered separately, as both can be considered novel and both should have a history of safe food use for being excluded. This means that while a plant can have a history of safe food use this would only apply to the parts of the plant that are usually consumed and not to parts that do not have such history of use.

Plants or parts of plants that have not been used before 15 May 1997 to a significant degree will require novel food approval, as well as any product that is derived thereof.

An example is oils expressed from the seeds of the Allanblackia tree (*A. floribunda* and *A. stuhlmannii*), an African plant with no history of use in the EU. The resulting oil therefore is considered novel (Decision 2008/5589/EU).

Another example of an oil extracted from a species of plants with no history of use in the EU before 15 May 1997 is oil obtained from the seeds of *Buglossoides arvensis* (L.) I. M. Johnston (Decision 2015/1290/EU).

Also, oil from *Argania spinosa* L. (Argan) was considered novel, but demonstrated to be substantially equivalent to other edible oils.

To identify if a plant has been used before 15 May 1997, information can come from various sources. Plants legally allowed for the production of certain foods (e.g. fruit juice, herbal tea, food supplements) before that date should in general be considered as non-novel. Also, the EU novel food catalogue contains information on the status of many plants.

One question is if new varieties of plants that are obtained by traditional propagating processes after that date would have to be considered novel food as they obviously do not have this history of safe use. There is no specific mention of this in the new NFR itself. However, this is believed not to be the case. In its 2002 discussion document on novel foods, it was mentioned that 2000-3000 new varieties of plants are included in the EU's common catalogue each year.⁸ The EC already indicated that the inclusion of such new varieties does not appear to be feasible. Given that the EP and Council opted for a limited scope of the NFR, it does not seem the intention that new varieties are to be considered novel foods.

In addition, Article 3.2.a.(iv) refers to "a variety of the same species", indicating that it is the plant species that is of relevance for the determination of whether the plant falls under the scope of the NFR and that all varieties of a specific species are considered in the same way.

This is confirmed by the application of the original Regulation, where the same definition applied and where no single new variety of a plant obtained by traditional propagation processed has been challenged for being novel. New varieties of plants obtained by traditional propagating methods would therefore not be considered novel under the NFR.

It is noted that nutri-fortification of plants produced using non-traditional propagating techniques would normally result in the food falling under the NFR when the composition of the food is such that it falls significantly outside the normal range of conventional counterparts of the foods derived from the plant.

b. History of safe food use of the processing

The second factor is the processing the food has undergone.

This is also covered under part (vii) of the definition of novel food. If a food is produced from a source material with a history of safe use, by a production process not used for food production within the EU before 15 May 1997, this is highly indicative that such food would not have a history of safe use.

This could for instance be the case when extraction solvents are used that have not been used for the food under consideration before.

In line with part (vii) of the definition however, such a food would only fall under the scope if the processing applied gives rise to significant changes in the composition or structure of the food, affecting its nutritional value, metabolism or level of undesirable substances.

c. Nature of the food

The third element is the nature of the food. In case the source material (plant or plant part) and the processing are both non-novel, still, the resulting product should also have a history of safe use, since part (iv) of the definition of novel food not only covers foods that consist of plants and their parts, but also foods that are isolated or produced from these. How to demonstrate the history of safe food use of every new product produced from a non-novel plant using a non-novel processing is obviously a case-by-case assessment.

8. Discussion Paper: Implementation of Regulation (EC) 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients. July 2002

Foods that are isolated from plants and their parts

As with the original Regulation, the concept of isolated covers plant extracts and preparations in which a compound is selectively isolated and purified. Such isolates usually are further refined to obtain a more or less pure compound that is then used for incorporation into other foods. Such compounds are covered by the NFR if there is no history of safe use before 15 May 1997 in the EU and require pre-market approval.

This will be particularly the case when the plants or plant parts these compounds are derived of are novel and do not have a history of safe use. In such cases it is the food and not the source material that is subject of the novel food application. The safety of the source material will obviously be considered in the risk assessment of the data.

In case plants and plant parts with a history of safe food use are the source material, the history of safe use of the food as such also needs to be justified. For foods that are isolated, it is the history of safe use of the isolated compound from the specific source material that needs to be demonstrated.

The clearest example of a compound that is isolated from a plant with history of use in the EU is obviously phytosterols from soy. In this case, although the source material clearly has a history of safe food use, the phytosterols as such are still considered to be novel since they are isolated and have not been consumed as such or added to foods (there only was a history of use of phytosterols in food supplements prior to 15 May 1997) (Decision 2000/500/EC). It is noted that plant stanol esters, although they have been derived from pine trees, have not been subject of a novel food authorisation because they had been marketed prior to 15 May 1997. However, the extension of their use in other food categories was subject to subsequent novel foods authorisations.

Another example is the novel foods authorisation of coagulated potato protein and hydrolysates thereof that was considered to fall under the Novel Foods Regulation because although protein has been extracted from a number of plants to be used in foods, potato protein had not been on the market in the EU prior to 15 May 1997 and therefore, potato protein required authorisation. (Decision 2002/150/EC).

Also oils and fats are usually considered to be isolates and require novel food approval if the oil from a particular plant source has no safe history of food use.

One example is echium oil, extracted from *Echium plantagineum*. Although the plant was known to be used in food supplements, the oil had no history of use and thus required novel foods authorisation (Decision 2008/558/EC)

Other examples of concentrates isolated from plants that had no history of use in the EU include:

- Alfalfa protein concentrate as food isolated from Lucerne (*Medicago sativa*) (Decision 2009/826/EC)
- Coriander seed oil from *Coriandrum sativum* L (Decision 2014/155/EU).
- Phosphatidylserine from soya phospholipids (Decision 2011/513/EU)
- Rapeseed protein isolate from *Brassica napus* L. and *Brassica rapa* L. (Decision 2014/424/EU)

If another non-novel source material is used it should be assessed if this change is of a nature to affect the history of safe use of the compound. If a new novel source material is used, a new application for authorisation is required.

As an example, the oil of chia seed (*Salvia hispanica*) was subject to a novel food authorisation. Chia seed as such was already approved as novel food. Still, this isolate required a separate novel foods authorisation. (Decision 2014/89/EU).

The specific processing applied is a separate factor that needs to be considered in this respect (see section 5.7). It is however the nature of the product that is the first element to consider and not its processing.

As an example, rapeseed oil high in unsaponifiable matter was authorised as novel food. (Decision 2006/722/EC). In this case rapeseed is a conventional source material (although it is not consumed as such) and rapeseed oil a conventional food ingredient and also the processing applied (involving molecular distillation (i.e. evaporation under high-vacuum)) is conventionally used in fat processing. Still the nature of the rapeseed oil having a very specific composition in which the content of triglycerides in the final product is reduced from 99 to 91%, whereas the “unsaponifiable matter” increases from 1% to 9%, is so specific that no conventional counterpart exists.

The same applied to maize oil high in unsaponifiable matter (Decision 2006/723/EC).

One question is to what extent essential oils are covered by the NFR. In this respect, there is no difference between an essential oil and other oils. If they have not been marketed to a significant degree before 15 May 1997, they would be covered by the NFR as any other food complying with part (iv) of the definition. For essential oils used in food supplements, obviously demonstrating use in food supplements should be sufficient to ascertain significant use for use in food supplements. Certain Member States have established data requirements for essential oils that are not novel to be submitted at the moment of notification.⁹

When use in regular foods is envisaged history of use in food supplements only would not be sufficient and the essential oil would require novel foods authorisation.

It is noted that an essential oil used as a flavouring falls under the flavouring Regulation (EC) 1334/2008 and would be excluded from the scope of the NFR.

Foods that are produced from plants and their parts

The concept of produced from was added to the definition in the new NFR. No explanation is provided. In theory, this is so broad that it covers all foods that are produced from plant material, which is the vast majority of foods and food ingredients in the EU. It is clearly not the intention to cover all new foods, but mainly products derived from plants that have not been marketed before.

It is noted that under the original Regulation, very few foods produced from (and thus not isolated from) plants and their parts have entered the novel foods authorisation process. Most extracts used for use in food, particularly food supplements are accepted to fall out of the scope when they were produced

9. <https://www.health.belgium.be/fr/data-sheet-essential-oils-and-concretes>

from plants with a history of use before 15 May 1997. Also, the novel food catalogue in most cases only addresses the status of the plant species and not of all the products that are produced from these plants. This is not likely to change.

However, foods that are produced from plants or plant parts that are not really isolated but are still significantly different from the original plant as such, e.g. specific preparations or highly selective extracts may be covered by the NFR, as before.

Again, as with isolates, when plants or plant parts that do not have a history of safe use before 15 May 1997 are the source material for the production of the food, a food produced from such a plant or plant part falls under the NFR.

When plants or plant parts with a history of safe use are the source material, the likelihood of the food being considered as having a history of safe use is higher. The specific processing applied is a separate factor that needs to be considered in this respect (see section 5.7).

Still the question remains how history of safe food use should be demonstrated in such cases. A number of elements can help food business operators to confirm that the product would not fall under the scope of the novel foods definition:

a. History in the market

The new NFR retains the date of 15 May 1997 as cut-off date for the decision of significant use. Because of the inclusion of the term “produced from” in the new definition, the scope could potentially cover thousands of foods that are produced from plants or plant parts put on the market between 15 May 1997 and 1 January 2018. The nature of what is intended to be covered and what not is not explained. However, foods produced from plants and their parts are not mentioned in the recitals as a category that needs updating or clarifying. Nor has it been evident in any communication from the Commission and the legislators that this should be the case.

Therefore, products that are currently lawfully on the market should as a general rule not be challenged retrospectively. This is in particular the case for products that have been notified to national authorities in accordance with EU and national provisions, are on the market for a long period and have not been challenged as novel food as part of official controls before.

It should be kept in mind however, that the notification under Article 10 of Directive 2002/46/EC is not an approval of legality of a product and does not automatically confirm non-novel food status of the product or its ingredients.

b. Nature of the product

Many foods undergo processing and depending on the type of processing and processing parameters differ more or less substantially from the source material.

The closer a new food is to a source material or a food produced from the same source material with a history of safe food use, the more likely the chances that the history of safe use will also be valid for the new food produced from the same non-novel plant or plant part. An important criterion is therefore the extent to which the characteristics of the source material are retained in the food that is produced from it. Foods that are isolated, as described in the point above, retain little of these characteristics. Other preparations and extracts however may.

If the product as such can be demonstrated to have been on the market before 15 May 1997, this would be the best proof justifying its history of safe food use. Also demonstrating that the product is similar to products that have been marketed before 15 May 1997 can be acceptable. Proof of such marketing can come from a variety of sources. In particular for botanical preparations and extracts, knowledge of the traditional preparation of the plant material is helpful to justify the history of safe food use of the specific preparations. Such information can come from a variety of sources, including monographs, recognised text books, in house documentation, etc. However, in most cases collecting such proof is difficult as available information from before 1997 is limited and does not always indicate that the use at that moment was intended as or in products regulated as foods. Still, as indicated before, demonstration of history of safe food use is not identical to demonstration of significant use before 15 May 1997 and the value of the data available will need to be assessed in this context.

To determine significant use, use in or as food supplement is sufficient in case the food is only used in food supplements.

Conversely the more a product differs from its source material, from a food produced from it that has a history of safe food use or from the way the source material is usually processed, the more difficult the justification of history of safe food use becomes for products that were not marketed before 15 May 1997 in that form.

For assessing the extent of the difference between the food and a counterpart with a history of safe food use, the concept of substantial equivalence can be a useful tool (See chapter 7).

One question is to what extent a new plant preparation or extract would fall under the NFR. In particular the status of selective extracts is of importance.

Recital 17 of the NFR states that:

"food produced exclusively from food ingredients that do not fall within the scope of this Regulation, in particular by changing the ingredients of the food or their amount, should not be considered to be a novel food. However, modifications to a food ingredient that has not yet been used for human consumption to a significant degree within the Union, should fall within the scope of this Regulation."

The definition of the NFR has been developed to reflect this and under category (iv), with the inclusion of the words "produced from", this would cover new extracts. This part of the definition was, however, subject to much debate between the Council and the EP to ensure that only those products that genuinely need to be assessed before marketing are covered and not all plant derived products. In that sense, it is important to consider that in its original proposal, as indicated in Recital 13, the Commission envisaged including modifications of a food ingredient, such as selective extracts under the scope. However, the proposed definition has been fundamentally modified by the EP and the Council and this reference to selective extracts was removed. Therefore, it is not the intention to cover all new extracts under the NFR, but only those that are modified from ingredients with no history of safe use in the EU.

This is congruent with the application of the original Regulation so far, which shows that most novel foods relate to isolated and purified compounds and that plants extracts have entered the novel food approval process only when they are substantially modified from the source material. Judging from the applications that have been assessed to date, preparations and extracts produced from non-novel plants or plant parts have not often been considered novel under the original Regulation.

However, the criterion that the food should have a history of safe use remains and this should be considered based on the two elements listed above: the history of marketing and the nature of the product. While every extract is in a way selective, there are extracts with a known history of use and those that are completely new.

When certain compounds are selectively enriched in an extract, not by simple drying or concentration but by selective extraction, strong justification of the history of use of these extracts or processes will need to be provided.

As long as the typical characteristics of the source material is preserved in the resulting preparation, the safety of the source material can be argued to apply to that specific preparation. However, in many extracts, especially those used in food supplements, it is not possible to judge on whether the characteristic properties are retained by organoleptic means. In such cases analysis of the extract will need to be performed. As a general rule of thumb, as long as the relative ratio between the components that are naturally present in the source material is not significantly affected, the extract is not considered as selective.

Also, depending on the extraction solvent used, the extract can only contain those compounds that are soluble in the specific solvent. If the relative ratio between all the compounds extracted is maintained as in the source material, the extract is also not considered selective.

In both cases, the history of safe use of the source material could be justified to be valid also for the resulting preparation.

For determining that the ratio of compounds is maintained, the normal range of variation in composition should be taken into consideration. The range of variation will depend on the variety of the plant used and on other factors, such as seasonal and geographical influences. The establishment of such values for the source material can come from generally recognised literature.

The relative ratio of the product composition should be determined by means of the analytical values from independent accredited laboratories to justify that the relative ratio of compounds is not significantly changed.

This is also the case for demonstrating that the processing is not resulting in significant changes in the composition or structure of the food, affecting its nutritional value, metabolism or level of undesirable substances, whenever this is applicable.

One example of a selective extract that was authorised under the novel foods legislation and was derived from a plant with known food use is Glavonoid®, which is an extract rich in polyphenolic type substances, derived from the root or rootstock of *Glycyrrhiza glabra L.* (liquorice root) by extraction with ethanol followed by further extraction of this ethanolic extract with medium-chain triglycerides (MCT). The resulting extract contains 30 % ethanolic extract from liquorice roots and 70 % MCT. The content of polyphenolic type substances was reported to be 24 %. This process changes the profile of the plant considerably as it concentrates the hydrophobic polyphenolic-type substances and removes the characteristic glycyrrhizinic acid to a level below 0.005 % (w.w) (Decision 2011/761/EU).

The relative ratio is the factor to consider. The absolute content of certain compounds in the extract or preparation is not a relevant parameter as extracts and preparations can be used at varying levels in the final products. The levels in a final product is governed by general EU or national legislation and if not existing, by the general principle that a food should be safe. In case the food would undergo a novel foods assessment, the proposed levels in the various food matrices will need to be part of the application and will be specified in the authorisation.

Extraction solvents used or intended for use in the production of foodstuffs or food ingredients should comply with the rules laid down in Directive 2009/32. Extraction solvents not listed, are not allowed for food production. An application for authorisation of the extraction solvent would be required. For extracts that are produced with extraction solvents that are not known to be used for the specific plant or plant part the provisions of part (vii) of the definition apply and the extent to which the process gives rise to significant changes in the composition or structure of the food, affecting its nutritional value, metabolism or level of undesirable substances will need to be assessed.

Also in cases that during production the compounds that are naturally present in the source material are modified, the application of part (vii) of the definition of novel food should be considered.

5.5. Category (v): Food consisting of, isolated from or produced from animal material

Article 3.2.a.(v) specifies the fifth category of foods to be considered novel:

“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.”

This definition also corresponds to part e of the original novel foods definition:

“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.”

As with foods of plant origin the focus here is clearly on animals obtained by non-traditional breeding practices or products thereof that have no history of safe use in the EU before 15 May 1997. This is clear from the exception that explicitly excludes from the scope foods that consist, are isolated or produced from animals and their parts obtained by traditional breeding practices which have been used for food production within the EU before 15 May 1997, the food of which has a history of safe food use in the EU.

The same principles as for food that consist of or are isolated or produced from plants and their parts apply in relation to demonstration of history of safe food use.

The concept of “animal” and “their parts” are to be considered separately, meaning that even if the animal and most of the foods produced from it have a history of safe food use, parts that have not been used before and thus have no history of safe food use, can still make a food be subject to the NFR.

An example of an animal part that does not have a history of safe food use is deer horn powder, which clearly is a part of animal that had no history of food use before 15 May 1997. This novel food was refused in the initial assessment carried out by the French authorities.

There is no definition of what constitutes traditional breeding practices. It is however logic to consider that this covers forms of sexual reproduction, including in vitro fertilisation.

One technique that is clearly not considered traditional is cloning. “Cloning” is defined (in Commission proposal COM(2013) 892) as meaning “asexual reproduction of animals with a technique whereby the nucleus of a cell of an individual animal is transferred into an oocyte from which the nucleus has been removed to create genetically identical individual embryos (“embryo clones”), that can subsequently be implanted into surrogate mothers in order to produce populations of genetically identical animals (“animal clone”).”

As Recital 14 confirms, food from animal clones already was covered under the definition of the original Regulation. The whole animals were not however.

During the discussions on the scope of the NFR, the topic of cloned animals was the subject of a political discussion between the Commission, EP and Council. In the end, it was agreed that legislation on cloned animals would be established. Recital 14 clearly explains that until such specific legislation on food from animal clones enters into force, food from animal clones should fall under the scope of the NFR as food from animals obtained by non-traditional breeding practices and should be appropriately labelled for the final consumer in accordance with EU legislation in force.

One question is if foods produced from descendants of cloned animals are also covered by the NFR. Legally speaking the answer is no as the descendants are obtained by traditional breeding practices and are indistinguishable from normal animals. Such animals are also imported into the EU and EFSA has concluded that there is no indication that differences exist in terms of food safety between food products from healthy cattle and pig clones and their progeny, compared with those from healthy conventionally-bred animals.¹⁰ It is the intention of the European Commission to ban the cloning of animals for food production altogether in the EU. However, the discussions on the imports of descendants of cloned animals is still holding up the two Commission proposals. Until these enter into force, cloned animals and products produced from these remain under the scope of the NFR.

Foods consisting of animals or their parts

This provision covers animals and parts of animals that have not been used in the EU for food production and thus have no history of safe use. It is noted that this is different from the original Regulation in which whole animals were not covered.

One example of a food that was not covered under the original Regulation is whole insects. These now fall plainly within the scope of the new NFR as confirmed by Recital 8. Since the date of 15 May 1997 is retained, products that have been lawfully marketed since that date, would need to comply with the transition measure of Article 35.2 and be subject of an application for authorisation (see chapter 6).

It is noted that nutri-fortification of animals would normally result in the food falling under the NFR when the composition of the food is such that it falls significantly outside the normal range of conventional counterparts of the foods derived from the animals.

One example of such a food is iodine enriched wild-type eggs, in which the inherent iodine content had been increased and as such therefore this is not covered by food fortification legislation (Regulation (EC) 1924/2006) and had not been consumed before 15 May 1997. The placing on the market was refused in the initial assessment by the Belgian authorities.

10. Scientific Opinion of the Scientific Committee on a request from the European Commission on Food Safety, Animal Health and Welfare and Environmental Impact of Animals derived from Cloning by Somatic Cell Nucleus Transfer (SCNT) and their Offspring and Products Obtained from those Animals. The EFSA Journal (2008) 767, 1-49

Foods that are isolated from animals and their parts

As with the original Regulation, the concept of isolated covers animal extracts and preparations in which a compound is selectively concentrated. Such isolates usually are further refined to obtain a more or less pure compound that is then used for incorporation into other foods. Such compounds are covered by the NFR and require pre-market approval.

It is to be reminded that foods that are isolated from animals and their parts only fall under the NFR if they originate from animals that are obtained by non-traditional breeding practices or have no history of safe use.

Still, the processing of the food is an independent factor that needs to be considered and may still result in a new food being novel under part (vii) of the definition.

A good example is phospholipids from egg yolk that was authorised as novel food. Despite the food having originated from a source material that has been consumed to a significant degree before 15 May 1997, the food was still considered novel, because it was purified and concentrated using a new process. (Decision 2000/195/EC)

Another example of an isolate from animal material that has been authorised as novel food is lipid extract from *Euphausia superba* (which are small crustaceans, also called krill). (Decision 2009/752/EC)

Also, lactoferrin, isolated from bovine milk is an example of such a compound authorised under the novel food rules (Decision 2012/727/EU)

Foods that are produced from animals and their parts

The concept of “produced from” has no counterpart in the original Regulation. The aim of introducing this is not explained in the NFR. It is likely that this is introduced to cover foods produced from animals or their parts that are not really isolated but are still significantly different from the original animal material as such.

Still, all animal products we eat are produced from animals and not all new products should be covered by the NFR. Therefore, also in this case, such foods do only fall under the NFR if they are produced from animals that are obtained by non-traditional breeding practices or have no history of safe use.

The same considerations as in the previous section on plants and plant parts apply.

5.6. Category (vi): Food from cell culture or tissue culture

Article 3.2.a.(vi) specifies the sixth category of foods to be considered novel:

“Food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, micro-organisms, fungi or algae.”

This definition has no counterpart in the original Regulation. Nevertheless, it can be argued that such products already were covered by parts d and e of the original definition, corresponding to parts (ii) and (v) of the new NFR.

As such it is quite clear what is meant by cell cultures or tissue cultures. This category was explicitly included after announcements of 'cultured' meat produced in the lab. Such technology is new and the technology has no history of use, so such products could also fall under category (vii).

5.7. Category (vii): Food resulting from new production processes

Article 3.2.a.(vii) specifies the seventh category of foods to be considered novel:

“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.”

This definition corresponds to part f of the original novel foods definition:

“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.”

Despite the different wording the concept remains the same, the aim being to cover production processes not used for food production before.

It is not defined in the NFR what constitutes a production process that is not used for food production. The number of processes that are used in food processing are multifold. One overview of food processing techniques can be found in Regulation (EC) 1334/2008, listing in annex II the traditional processes permitted for the manufacturing of natural flavouring preparations:

“chopping, coating, heating, cooking, baking, frying (up to 240 °C at atmospheric pressure) and pressure cooking (up to 120 °C), cooling, cutting, distillation/rectification, drying, emulsification, evaporation, extraction, incl. solvent extraction in accordance with Directive 88/344/EEC, fermentation, filtration, grinding, infusion, maceration, microbiological processes, mixing, peeling, percolation, pressing, refrigeration / freezing, roasting / grilling, squeezing, steeping”.

This list gives a useful indication and it is defendable that any processing mentioned should not require further proof of conventional food processing. But this list is by far not listing all processes that are applied in food processing, as it only covers the processes that are considered suitable for the production of natural flavourings. Therefore, any food processing techniques that can be demonstrated to have been used before 15 May 1997 would be acceptable as not being covered under the NFR. Such proof can come from a variety of data, including documentation on equipment and machinery.

One example of a food to which was applied a new food processing technique that was authorised as novel food is fruit preparations pasteurised using a high-pressure treatment process. (Decision 2001/424/EC).

Another example is bread to which a treatment with UV radiation is applied after baking in order to convert ergosterol, which is present in bread as a result of yeast fermentation, to vitamin D2 (ergocalciferol) (Decision 2014/396/EU).

Also, milk treated with UV-C light resulting in elevated concentrations of vitamin D3 by conversion of 7-dehydrocholesterol present in milk to vitamin D3 has been authorised as novel food undergoing a novel food processing (Decision (EU) 2016/1189).

One question is if a food that is produced using a process that is used for food production but has not yet been applied to that specific food would fall under the NFR.

The definition does not indicate this and thus it is not a systematic requirement to provide proof that every method of food production has been used for every specific new food. This would be difficult to demonstrate anyway because food business operators are mostly not aware of processing that is applied on specific foods for reason of intellectual property protection confidentiality.

In addition, not all foods that undergo a processing technique that has not been used before 15 May 1997 for food production need to be submitted to the pre-market authorisation procedure. This is only the case if the process would give rise to significant changes in the composition or structure of the food, affecting its nutritional value, metabolism or level of undesirable substances.

Therefore, when a food business operator is intending to apply a processing technology not used for food production in the EU before 15 May 1997, it needs to be assessed whether this processing will give rise to significant changes in the composition or structure of the food, affecting its nutritional value, metabolism or level of undesirable substances.

As described before, demonstrating substantial equivalence can be a helpful tool to judge if the changes to the composition or structure of the food are significant (Chapter 7).

It is noted that it is not the manufacturing process that will be approved, but the food resulting from it. Therefore, approval of the use of the process for a certain specific food does not automatically exempt the use on other food matrices from the requirement to submit an application for authorisation as novel food. If a food business operator wants to have the technology applied to various types of foods, it should include the relevant data to cover all different uses in its application.

Finally, it is important to note that hygiene legislation should be complied with for any production process to ensure that the produced food is safe.

5.8. Category (viii): Food consisting of engineered nanomaterials

Article 3.2.a.(viii) specifies the eighth category of foods to be considered novel:

"Food consisting of engineered nanomaterials as defined in point (f) of this paragraph."

This definition has no counterpart in the original Regulation. Still, it was argued that such products were covered by the existing definition, and more particularly by part f.

Engineered nanomaterials are defined in the NFR as

"Any 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, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic of the nanoscale. Properties that are characteristic of the nanoscale include:

- (i) those related to the large specific surface area of the materials considered; and/or*
- (ii) specific physico-chemical properties that are different from those of the non-nanoform of the same material."*

This definition was moved from the Food Information to Consumers Regulation (EU) 1169/2011 to the NFR. Discussions on a new definition are ongoing at EU level.

Products that meet the above definitions fall under the scope of the NFR and need pre-market approval if they have not been used for human consumption to a significant degree prior to 15 May 1997.

It is important to consider that it is the food that consists of engineered nanomaterials that would fall under the scope of the NFR, not all products in which such an approved food would be used as ingredient. Still under Regulation (EU) 1169/2011 the presence of intentionally engineered nanomaterials needs to be labelled, irrespective of whether the engineered nanomaterial is a novel food or not. It is therefore important for food business operators to ensure they obtain this information. FoodDrinkEurope has developed a template letter that can be used for such purpose.¹¹

Essential elements to consider when assessing whether the food falls under this definition include:

- The nanomaterial must be intentionally produced.
- The nanomaterial must be present as such in the product.
- The size of the particles must meet the definition.
- The characteristic properties must be present and different from those of the non-nanoform of the same material.

It is important also to consider that only those foods consisting of engineered nanomaterials that were not used for human consumption to a significant degree within the EU before 15 May would fall under the scope of the NFR.

Substances containing engineered nanomaterials, authorised as additive fall out of the scope of the NFR when used as additive in food.

11. http://www.fooddrinkeurope.eu/uploads/focus_documents/Nano_-_request_to_suppliers.pdf

5.9. Category (ix): Sources of vitamins, minerals and other substances.

Article 3.2.a.(ix) specifies the ninth category of foods to be considered novel:

"vitamins, minerals and other substances used in accordance with Directive 2002/46/EC, Regulation (EC) 1925/2006 or Regulation (EU) 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."*

This definition has no counterpart in the original Regulation. Still, it can be argued that such products were covered by the original definition, and more particularly by part f.

This specific part of the new definition could actually be considered redundant as, legally speaking sources of vitamins, minerals and other substances are foods, covered by the General Food Law Regulation and can be covered by the other sub-parts of the definition.

Vitamin and mineral forms that are allowed for use in food are covered by the provisions of Directive 2002/46/EC (food supplements), by Regulation (EC) 1925/2006 (Fortified foods) by Regulation (EU) 609/2013 (infant formula and follow-on formula, processed cereal-based food and baby food for infants and young children, food for special medical purposes, and total diet replacement for weight control). Only the sources of vitamins and minerals included in these provisions are permitted for addition to the respective foods.

For vitamin formulations and mineral substances listed in these provisions purity criteria apply. This covers purity criteria that are specified by EU legislation for their use in the manufacture of foodstuffs for purposes other than as nutritional substances as well as generally acceptable purity criteria recommended by international bodies in cases where purity criteria are not specified in EU legislation.

In case of new sources that have undergone novel food approval, the specifications in the respective authorising decisions apply. These will be included in the Union List of Novel Foods from 1 January 2018. This list is established by Regulation (EU) 2017/2470.

There is no legal text covering the procedure for the risk assessment of new nutritional substances to be included in the provisions of the Directive or these Regulations. Instead, this forms part of the request for the extension of the lists that needs to be made to the European Commission. Based on this request, the Commission will ask EFSA for a scientific opinion and on the basis of this outcome decide on whether or not to include the substance in the lists.

Many substances not currently included in the provisions of the Directive or the Regulations had a history of use before the establishment of the lists in accordance with national legislation. If such substances were used to a significant degree in products before 15 May 1997, they would not be considered novel food. Such substances can be requested for inclusion in the EU provisions by an application directly to the Commission. They would not require novel foods approval.

However, substances that have not been used in food before 15 May 1997 would fall under the NFR (under categories (ii), (iii), (iv) or (v) depending on the source material) and thus require a novel foods assessment first, before they can be requested to be added to the lists.

This was the case under the original Regulation and is maintained under the new NFR.

Even if the request for assessment as novel foods and the request to be added to the positive list(s) can be submitted simultaneously, the novel food process needs to be completed first and only then, the process of adding to the positive list(s) can start, resulting in additional time required.

Examples of nutritional substances that have been authorised as novel food include:

- (6S)-Methyltetrahydrofolic acid, Glucosamine salt as a source of folate (Decision 2014/154/EU, corrected by Decision 2014/916/EU)
- Organic silicon (monomethylsilanetriol MMST) as source of silicon (Decision (EU) 2016/1344)

New guidelines for the data required for the assessment of sources of nutrients for the purpose of inclusion in the lists are scheduled to be published by EFSA early 2018. These will replace the guidelines published by the Scientific Committee on Food in 2001.¹²

Part (ix) of the definition covers vitamin and mineral sources already approved and included in the lists and requires a new novel food assessment if such substances would either be produced by a production process not used for food production within the EU before 15 May 1997 or when they contain or consist of engineered nanomaterials. In that case a re-assessment of those specific foods sources would be required.

Recital 10 specifies that food consisting of engineered nanomaterials should be considered novel food under the NFR. This is logic in the context of the definition of “engineered nanomaterials. It is not clear what “contains engineered nanomaterial” means in this context as the nutritional substances included in the provisions of the respective laws are well defined compounds and have to respect purity criteria. Therefore, the common understanding is that in this context “contains” and “consist of” have the same meaning.

It is noted however that in case of a production process not used for food production before 15 May 1997, the food would only fall under the NFR if the process gives rise to significant changes in the composition or structure of the food, affecting its nutritional value, metabolism or level of undesirable substances, as discussed under point 5.7.

If it concerns products that have been manufactured since 15 May 1997, the transition provisions of Article 35.2 apply (See chapter 6).

12. Scientific Committee on Food. Guidance on submissions for safety evaluation of sources of nutrients or of other ingredients proposed for use in the manufacture of foods. Opinion expressed on July 2001. https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scf_out100_en.pdf

5.10. Category (x): Food used exclusively in food supplements.

Article 3.2.a.(x) specifies the tenth and final category of foods to be considered novel:

"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."

This definition has no counterpart in the original Regulation. However, this approach has been the practice agreed by the Member States in the meeting of the Standing Committee of 14 February 2005. In this meeting, the Standing Committee on the Food Chain and Animal Health agreed that exclusive use of a substance in food supplements before 15 May 1997 would not be considered as "human consumption to a significant degree" according to the Regulation. Such substances can continue to be marketed in food supplements, but before adding them to regular foods they should be authorised as novel foods.

This principle has now been explicitly included in the new NFR. This means that when a substance was used in food supplements before 15 May 1997 it would not fall under the NFR as concerns its use in food supplements. The use of the substance in other food matrices however would fall under the NFR and require an application for authorisation.

Or as Recital 13 words it:

"A food used before 15 May 1997 exclusively as, or in, a food supplement, as defined in Directive 2002/46/EC, should be permitted to be placed on the market within the Union after that date for the same use, as it should not be considered to be a novel food for the purposes of this Regulation. However, that use as, or in, a food supplement should not be taken into account for the assessment of whether the food was used for human consumption to a significant degree within the Union before 15 May 1997. Therefore, uses of the food concerned other than as, or in, a food supplement should be subject to this Regulation".

The status of certain foods is listed with this information in the EU novel food catalogue, which can be helpful.¹³ However, this catalogue is not complete. The status of any food or food ingredient not listed should be verified. In case of uncertainty, a national authority should be consulted.

13. https://ec.europa.eu/food/safety/novel_food/catalogue_en

6. 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 is a non-exhaustive list and 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.

It is noted that the catalogue is not a comprehensive list and that many foods are not listed. Their status will nevertheless need to be verified by food business operators intending to use them in their products.

It is also noted that non-novel food status does not automatically mean that the food is accepted for use in all Member States. This will depend on national legislation in place and it should be verified if any further restrictions of use exist.

The catalogue is regularly updated based on new information. The catalogue has no legal power but is a useful tool to be used in the verification of a product's status.

The Commission amends the catalogue as EU countries send in new information. Food business operators can submit information to the national authorities of the respective EU country for verification e.g. the history of significant consumption of a food or food ingredient prior to 15 May 1997 in the EU.

It is noted that the European Commission intends to completely rethink the layout of the Novel Food Catalogue to make it easier to use and more complete. However, no timing has been given for this complex exercise.

It is likely that the procedure in Article 4, by which food business operators are required to consult national authorities if they are unsure whether or not a food which they intend to place on the market falls within the scope of the NFR, will be an important element for further updating the catalogue.

One example of a food that is listed in the Novel Food Catalogue as having been used only in food supplements is betaine. A request was introduced to add betaine also to foods, including beverages, cereals and dairy products, which was subsequently refused after the risk assessment (Decision 2005/580/EC).

The Novel Food Catalogue can be consulted on the European Commission website (https://ec.europa.eu/food/safety/novel_food/catalogue_en).

7. Procedures applicable to foods that are considered novel under the new NFR but not under the original Regulation

As indicated before, although the scope of the NFR should in principle be the same as that of the original Regulation, some categories have been phrased differently and others added, resulting in a limited number of food categories now considered novel food, whereas they were not under the original Regulation.

This is the case e.g. for foods consisting of, isolated or produced from whole insects, mineral material, cell or tissue culture, etc.

Given that these products were not considered novel by certain Member States under the original Regulation, some of such foods may have been lawfully marketed in those Member States since 15 May 1997 without the need for novel food authorisation. However, since the new NFR retains the date of 15 May 1997, these products would now fall under the new NFR and need authorisation.

This was recognised and article 35.2 specifies a transition period for such foods. Foods not falling within the scope of the original Regulation, which are lawfully placed on the market in a Member State before 1 January 2018 and which fall within the scope of the new NFR may continue to be placed on the market until a decision is taken following an application for authorisation submitted by the date specified in the implementing rules adopted in accordance with Article 13 or 20 of this Regulation respectively, but no later than 2 January 2020.

This date was set to 1 January 2019 in the implementing Regulation (EU) 2017/2469. This means that if such an application is not submitted by this date, the food cannot remain on the market.

It is therefore important for food business operators to verify their product portfolio and identify any product that would be in this situation.

8. The value of the principles of substantial equivalence

The new NFR removes the possibility for a notification procedure for certain novel foods that, on the basis of the scientific evidence available, are generally recognised as shown to be substantially equivalent to existing foods or food ingredients as regards their composition, nutritional value, metabolism, intended use and the level of undesirable substances contained therein.

Still many new foods, while not being identical still are substantially equivalent to a conventional counterpart and therefore requiring a full novel food assessment for all such foods would greatly extend the scope of the NFR, which would not be feasible and is not envisaged in the light of Recital 8 that states that “the scope of this Regulation should, in principle, remain the same as the scope of Regulation (EC) 258/97”.

In addition, 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 also be a helpful tool in the verification process of the status of the food.

The concept of 'substantial equivalence' is not unique to the original novel foods Regulation. It has originally been introduced by WHO and OECD with particular reference to foods produced by modern biotechnology.¹⁴ It embodies the idea that existing food can serve as a basis when assessing the safety of human consumption of a food or food component. If a new food or food component is found to be substantially equivalent to an existing food or food component, it can be treated in the same manner with respect to safety, keeping in mind that establishment of substantial equivalence is not a safety or nutritional assessment in itself, but an approach to compare a potential new food with its conventional counterpart. Therefore, its principles can be very helpful in helping companies decide whether or not their new food is significantly different from foods that were marketed before 15 May 1997 in terms of composition or structure, and thus of nutritional value, metabolism or level of undesirable substances.

It is important to note that under the original Regulation, novel foods that could be shown to be substantially equivalent to a traditional food or already approved novel food could benefit from a simpler procedure but nevertheless still are novel foods. The use of the principles of substantial equivalence therefore should by no means be a justification to avoid novel foods legislation for products that are plainly falling under the definition of the new NFR. These principles should only be used to judge to what extend a new food is significantly different from foods that have a history of use before 15 May 1997. This also means that the principle cannot be used to justify as non-novel any food that does not comply with the specifications or conditions of use of already authorised novel foods, as specified in the Union List.

On basis of the outcome of this verification, a food business operator could conclude that the composition of the new food, matches that of similar foods marketed to a significant degree in the EU before 15 May 1997 and thus that the food does not fall under the scope of the NFR. It still remains the obligation of the food business operator to ensure the safety of its food. The elements that are covered below therefore are elements that should be addressed and be kept on file as justification for the outcome of this verification in case no premarket authorisation under the NFR is required.

14. OECD 1993. Safety Evaluation of Foods Derived by Modern Biotechnology: Concepts And Principles

This section addresses the aspects to consider when judging on the extent of changes that are acceptable before a food is considered novel.

The choice of an appropriate reference food

Substantial equivalence requires a comparison of all aspects of the food with a reference counterpart food. The reference food must exist and have a history of significant food use in the EU before 15 May 1997 or be an already approved novel food.

Comparison with reference foods that have been assessed under different legal frameworks may be used to illustrate safety. However, it is not appropriate to choose such foods when conditions of use have been established to ensure safe use, such as maximum levels. In the case of a food that is approved as additive but is covered by the NFR when used as a nutrient or other substance without technological function, only the use of those additives that are allowed in food in general at quantum satis could be used as reference counterpart.

It is essential that the composition of both the food and the reference food be well characterised and in sufficient detail to enable a comparison of all aspects that are relevant for safety.

The closer the reference counterpart food is to the food, the higher the chance of having a meaningful comparison from which conclusions can be drawn. This does not only apply to the analytical composition but also to the source material and the way it is processed. In addition, both foods should have similar conditions of use or pattern of consumption.

In particular for plant derived products, the food and its reference counterpart should be derived from the same or closely related species, grown and harvested under similar conditions, unless it concerns purified compounds or preparations with a limited number of defined chemical components. The general principle is that it must be possible to demonstrate compositional similarity and absence of undesirable substances.

If the food contains significant amounts of substances that are not present in the reference counterpart, it may prove difficult to justify substantial equivalence.

What elements to consider in the comparison?

Analytical data should be available to the same level of detail for both the food and its reference counterpart.

The data available should be representative of the food and cover a sufficiently wide range of products or batches. Appropriate methodologies should be used both for the analysis of the products as for (statistical) treatment of the data, including the use of accredited laboratories and detailed information on the methods used and the levels of detection.

Information on normal ranges of variability in product composition can be supported by data from literature.

If the food has specifications and all compounds of concern are included, this provides a sufficient basis to characterise the composition of the new food that covers all production batches. The condition is obviously that the specifications should be sufficiently detailed.

Both the nutritional and non-nutritional composition should be covered. 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. In order to ensure all compounds of safety concern are identified, a detailed literature search to identify any undesirable substances that could be associated with the food and its source should be carried out. The presence or absence of these substances of relevance for health and safety should be analytically verified to assess the difference between the food and the reference counterpart.

Information on the evolution of these amounts over time is also required, e.g. from stability testing to ensure that no degradation or bioconversion occurs over the shelf life of the food.

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.

The focus of this assessment is on the similarities in terms of product composition, not on potential exposure. However, the selection of an appropriate reference food presupposes that the intended use of the food be similar to that of the reference counterpart food. For foods that are intended to be incorporated in different food matrices (e.g. in beverages, regular foods, food supplements, etc), the reference food should have a similar use. Where differences are foreseen, the first question to ask is whether the choice of the reference food is right.

9. Traditional foods from a third country

The new NFR introduces an easier procedure to put on the EU market certain “traditional foods from third countries” for which the history of safe food use in a third country has been demonstrated.

In such cases an applicant is given the possibility to opt for a faster and simplified procedure to update the Union list if no duly reasoned safety objections are expressed by a Member State or EFSA.

At first sight this might seem a procedure that could facilitate the entry into the EU of certain foods, in particular botanicals, that would be considered to fall under the definition of the NFR. However, for such foods to be eligible, a number of conditions must be met:

The food should have been consumed in at least one third country

A third country is considered to be a country that is not a member of the EU. This includes all countries outside the EU and thus also certain countries on the EU mainland, such as Albania, Serbia, Macedonia, Switzerland and the smaller territories of Andorra, Monaco, San Marino and Vatican City State and certain islands, such as Jersey, Guernsey, Isle of Man. It is noted that despite the fact that countries that are members of the European Economic Area (Iceland, Liechtenstein, Norway) have access to the EU single market, they are not member of the EU and thus, for the purpose of the provisions of the NFR they will also be considered as third countries. After BREXIT, also the UK may be considered as a third country depending on the future relationship that will be established between the UK and the EU.

The food should have been consumed for at least 25 years

It should be demonstrated that the food has been consumed in the third country for at least 25 years. Data should be available to show that this consumption was as part of the customary diet of a significant number of people.

The main element of the application will be to demonstrate that such use has been safe over this time. This means that the safety of the food in question has been confirmed with compositional data and from experience of such continued use.

The administrative and scientific requirements concerning traditional foods from third countries are included in Commission Implementing Regulation (EU) 2017/2468.

EFSA also has published guidelines for the preparation and presentation of the data required for this notification process.¹⁵

The history of safe food use should not include non-food uses or uses not related to the customary diet

The definition of history of safe use refers to the consumption of the food as part of the customary diet in a third country. The customary diet is not defined, but it is logic to consider that the customary diet is the diet that is characteristic for the population in the third country. It is not equivalent to a normal diet, nor does it refer to the diet that is recommended in local dietary guidelines.

15. 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>

This would therefore also include particular foods that are consumed to supplement the diet or consumed for enjoyment and pleasure, not necessarily for nutritional purposes.

It is noted that the legislative framework in third countries is not identical to that of the EU and certain products can be regulated differently between jurisdictions. It is defendable to consider that all products that in the EU are intended to be marketed under food law and thus are subject to the NFR, are acceptable for the notification procedure as traditional food from a third country, irrespective of how these products are locally regulated.

Use of products for the prevention, treatment or cure of diseases, however would not be accepted for the purpose of such notification (e.g. use as traditional Chinese medicine, as part of Ayurveda medicine, etc). Likewise, foods that are only used by diseased people are not likely to be accepted as having a sufficient history of use, unless extensive data demonstrating use in healthy people is also available.

The food should be derived from primary production

In accordance with Regulation (EC) 178/2002, primary production means: “*the production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter. It also includes hunting and fishing and the harvesting of wild products*”.

This means that only products that are derived directly from plants or animals can qualify for this procedure. These are therefore the edible parts.

Such products may be unprocessed or processed. This means that more is covered than only the raw material. The extent of such processing is not explained. However, it is likely to mean that traditional food processing techniques can be applied. Thus, expressed juice, heated parts, extracts and preparations of a plant would in principle all be possible under this procedure. When a traditional food from a third country is locally produced and water is removed to accommodate transport (e.g. under the form of a concentrate) and added back again before further treatment or consumption, this would in principle not affect its status as traditional food from a third country. E.g. the juice of a local fruit that is concentrated and reconstituted after transport, is likely to be considered in the same way as the original juice. This could however lead to a labelling requirement to the effect that the juice is from concentrate.

A product would however no longer be considered as derived from primary production if it concerns compounds that are isolated or produced from the raw material’s edible parts, such as specific component proteins, carbohydrates or fats or other compounds.

Extract 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. The products from selective extraction and/or purification processes would in general no longer be considered as products derived from primary production.

A product would also no longer be considered to be derived from primary production if it is incorporated in a food or mixed with other ingredients. As an example, a fruit puree would be acceptable, but a fruit jam would not.

It is however possible that a product derived from primary production is not consumed as such in the customary diet, but 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 such.

It is important to note that the above is the requirement to judge if a certain food is able to qualify for the notification procedure or not. It is not a criterion to judge if the food is novel or not. The demonstration of the history of safe use in the customary diet in the third country should be established for the food including its processing or specific preparation. Data will need to be provided for the specific way the food is used in the third country.

As examples;

- A plant or commodity may be processed to remove inedible parts or compounds that may be of safety concern.
- A plant or commodity may be used in the raw state, or traditionally processed to increase durability by e.g. heating, salting, acidifying or applying other traditional food processing techniques.
- A plant or commodity may be traditionally consumed in a certain physical state, such as powdered or used in a matrix, e.g. vinegar, alcohol, etc.
- A plant or commodity may be traditionally consumed as a specific preparation or extract.

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.

The food should not fall under points (a) (i), (iii), (vii), (viii), (ix) and (x) of the novel foods definition.

This concretely means that the procedure cannot be applied to the following categories of foods:

- (i) Food with a new or intentionally modified molecular structure
- (iii) Food consisting of, isolated from or produced from material of mineral origin
- (vii) Food resulting from a production process not used for food production within the Union before 15 May 1997
- (viii) Food consisting of engineered nanomaterial
- (ix) Vitamins, minerals and other substances in case a production process not used for food production in the EU has been applied or that consist of or contain engineered nanomaterials
- (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

Since it is unlikely that the products mentioned above are derived of primary production, these exclusions are not likely to affect the scope of this procedure.

This notification procedure is an option. It is possible to apply for authorisation for such foods also by submitting an application for authorisation under the full procedure. The full procedure should also be followed in case duly reasoned safety objections are raised by a Member State or EFSA during the 4-month period after submission.

If reasoned safety objections are raised, the Commission will not authorise the food and an application will need to be submitted. This is however not the same full authorisation procedure as is the case for other novel foods.

Such application should contain the information that is already required for the notification and in addition any relevant data relating to the reasoned safety objection that was raised.

It is therefore not needed to follow the requirements laid down in Commission Implementing Regulation (EU) 2017/2469 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.

It is therefore also not needed to follow the data requirements specified in the EFSA guidance document relating to the full application.¹⁶ Still, this guidance may help applicants in preparing and presenting an application in relation to the data other than those that relate to the 'history of safe food use in a third country' and are pertinent to the nature of the reasoned safety objections raised.

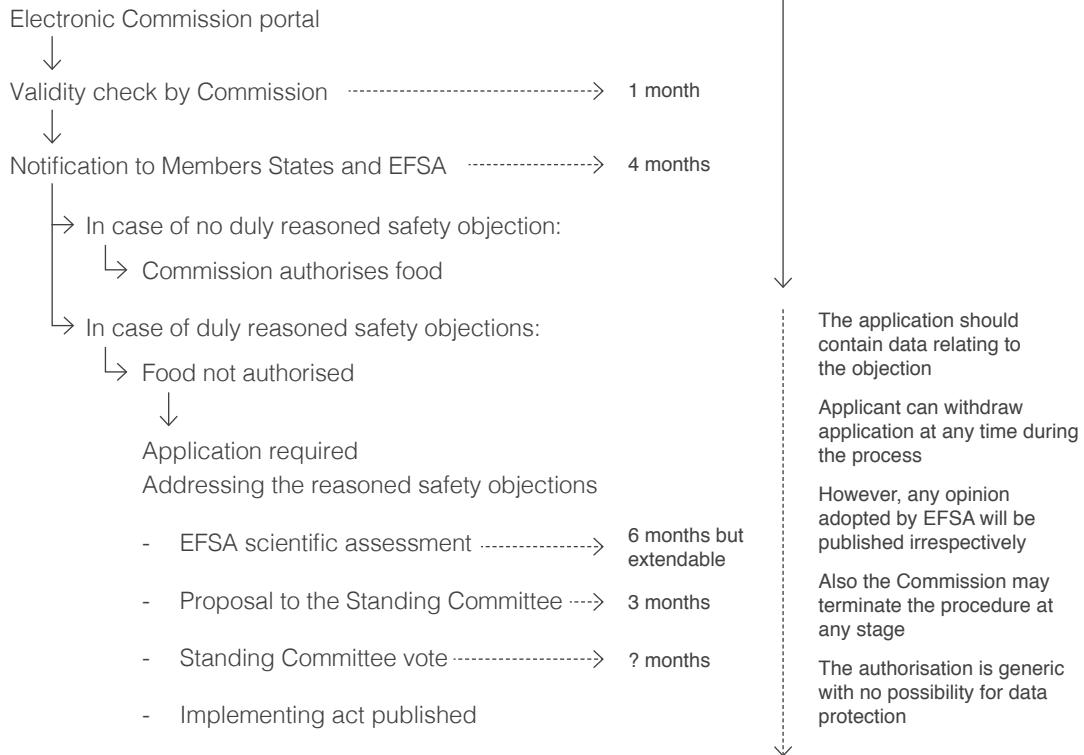
If safety concerns are suspected from the start, it may however be more appropriate to immediately apply the full procedure to save time, as the possibility that reasoned safety objections are raised is then real.

It should be noted that this easier "notification" procedure is still a pre-market authorisation procedure and that the food must have been included in the EU list of approved novel foods by means of an EU legislative act before it can be placed on the market in the EU.

It is also noted that no request for proprietary data protection can be introduced for traditional foods from third countries. This is the case both for the notification and for the full authorisation procedures.

16. 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>

Figure 9: Procedure for traditional foods from a third country

Notification by an applicant

10. The Union List of Authorised Novel Foods

The Union List of Authorised Novel Foods was initially published on 30 December 2017 as Regulation (EU) 2017/2470. A correction was published on 23 July 2018 as Regulation (EU) 2018/1023, and there have been further updates to the list since this date. A non-legal consolidated version of this legislation can be retrieved via www.eur-lex.europa.eu.

The Union List of authorised novel foods contains two tables: Table 1 contains the novel foods with conditions of use and any other criteria, such as specific labelling requirements; Table 2 provides the specifications for each authorised novel food.

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.

General principles:

- Any food that is included in the Union List can be used by any food operator in accordance with the conditions of use specified. One notable exception is when the food is authorised with data protection. In this case the food cannot be used by anyone else other than the applicant for a period of five years. The end date of this protection and the data that are protected are specified in the list. Any other applicant wanting to use the food first needs to obtain a new authorisation following the submission of an application for authorisation. The protected data cannot be used for the purpose of this application unless specific approval is obtained from the prior applicant.
- The food must be used in accordance with the specified conditions of use, listed in table 1 of the list. It can only be used in those specified foods or food categories for which it is authorised. Extension of the categories for use will require a new novel food authorisation. When there are specified maximum levels in the foods for which the novel food is authorised, these limits must be respected. Any additional labelling requirements must also be met.
- The food must meet the specifications listed in table 2 of the list. This means that the food should be properly characterised to show that it can be identified as the food subject of the authorisation and meets the specifications listed. Within the specifications there may also be reference to the required method of production; only this production method is covered by the novel food authorisation. If the food, its origin or method of production differ from the listed requirements, it must be ascertained if it needs to be authorised as a different novel food following an application for authorisation. The food may vary in aspects that are not listed in the authorisations (e.g. aspects or details of the specifications or composition, origin or method of production that are not specifically mentioned in the Union List. The safety of the food must nevertheless be verified under the responsibility of the food operator.

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 in terms of manufacturing process or specifications, and questions have arisen whether such authorisations would mean that all similar foods would need to satisfy the specifications as listed in the list of authorised novel foods or, in case data protection applies, whether all similar foods would require authorisation.

In principle, an authorisation of a novel food is food-specific. A food operator will need to assess for each new food whether it falls under the scope of the NFR and requires authorisation or whether it complies with the specifications and conditions of use of an already authorised novel food, listed in the Union List.

The information to consider in this context are the specifications, conditions of use, and factors that may impact safety. The information in the EFSA opinion or other relevant available information can be helpful to help in characterising the food, carry out a safety evaluation, or identifying the specific element of novelty.

Any food that complies with the specifications and conditions of use as listed in the Union List, is to be considered as novel food. In case the authorisation lists protection of proprietary data, such foods cannot be marketed by any other food operator without a new novel food authorisation. Similar foods, however, that do not meet the set specifications and do not have this element of novelty 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.

Examples:

Lycopene is listed in the Union List of authorised novel foods. This covers three different sources: a synthetically produced form, a form isolated from *Blakeslea trispora* and Lycopene from tomatoes. Only these forms of lycopene are authorised as novel foods and can be used only in conformity with the conditions of use, which includes a range of foods in which the substance is permitted. Lycopene however is listed in the Novel Food Catalogue as not novel for use in food supplements. Therefore, other forms are permitted to be used in food supplements, provided that the food operator establishes they were used before 15 May 1997 or uses the principles explained in this guidance document to justify that the specific preparation used does not fall within the definition of novel food.

Phytosterols/Phytostanols are listed in the Union List, authorised for use in food supplements at a level of 3 g/day. For these phytosterols/phytostanols specifications are included in table 2 of the Union list. This means that for this specific form, these specifications and conditions of use are binding. Phytosterols have however generally been recognised as not being novel in food supplements because of history of use before 15 May 1997. Therefore, other forms of phytosterols may not be considered as novel food. The food operator will however need to ensure with have verifiable proof that the form that is used for that purpose, is not falling under the NFR.

A specific cranberry extract was included in the Union List as authorised novel food by Regulation (EU) 2018/1631, at a maximum level of 350 mg/day in food supplements. Since the applicant obtained data protection for some of the data submitted, the authorisation cannot be used by other food operators. Therefore, any cranberry extract meeting the specifications of the authorised one, will be considered as novel food and require separate authorisation. However, cranberry extracts not meeting these specifications and/or conditions of use have been widely used in food supplements before and after 1997, without these preparations being considered as novel foods. Therefore, such preparations would also not now be considered novel, provided the food operator establishes its use before 15 May 1997 or uses the principles explained in this guidance document to justify that the specific preparation used does not fall within the definition of novel food.

Also, elements that are not covered by the specifications will not automatically result in the requirement to submit a new novel food application for authorisation. The only obligation by the company would be to ensure that part (ix) of the definition of novel foods is respected, meaning that when a production process not used for food production within the Union before 15 May 1997 has been applied it must be ascertained that this does not give rise to significant changes in the composition or structure of the food, affecting its nutritional value, metabolism or level of undesirable substances. In addition to a new production process, a new source (animal, mineral, plant or microbial), could also trigger the need for a new novel food authorisation. Finally, if the food would contain or consist of engineered nanomaterials, a novel food application would be required.

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.



Food Supplements Europe © January 2019

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