Legal status of new product innovations must be determined before launch in the EU consumer market

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Due to the rising interest in climate aspects, animal welfare as well as the environment and health, consumers' food choices are rapidly changing. In a relatively short time, a large number of food innovations have entered the stores and the online market. Numerous product innovations from new plants, fungi, algae, micro-organisms, cell cultures and new by-product ingredients from different industries are constantly being designed and tested in laboratories and production lines. In the heat of this wave of innovations, companies may be unaware of the legislative framework, and therefore, some surprises may lie ahead. For instance, many new products might be classified as novel foods that are not allowed to be marketed in the EU without permission. The key question is therefore whether the new food ingredient will fall under the Novel Food Regulation (EU) 2015/2283 and, if it does, what this means in practice.

Businesses often want to avoid the novel food status, as falling within the scope of the Novel Food Regulation means they need to invest a lot of time, money and work. However, if the innovation is promising, going through the novel food application process may be worthwhile. Not to mention that for novel foods, it also is the only way to the consumer market. During the process, the safety of the novel food for consumers is fully established, which is the ultimate purpose of the Novel Food Regulation. When the marketing authorisation is granted, it is also possible, in certain cases, to have the data related to the safety studies protected for a period of full five years.

So, when a new product idea is born, it is

Table 1. Novel food categories (summarised from Regulation (EU) 2015/2283)
"Previous use" refers to use before 15 May 1997"

i) food with a new or intentionally modified molecular structure, if the structure was not previously used as a food or in a food

ii) food consisting of, isolated from or produced from microorganisms, fungi or algae

iii) food consisting of, isolated from or produced from material of mineral origin

iv) food consisting of, isolated from or produced from plants or their parts, except when it has a history of safe food use in the EU and is consisting of, isolated from or produced from a plant or a variety of the same species obtained by either:
- a. traditional propagating practices which have been used for food production previously; or
- b. non-traditional propagating practices which have not been used for food production previously, where those practices do not significantly change the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances

v) food consisting of, isolated from or produced from animals or their parts, except for animals obtained by traditional breeding practices which have been used for food production previously and the food from those animals has a history of safe food use within the Union

vi) food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, micro-organisms, fungi or algae

vii) food resulting from a production process that has not been used for food production previously, which significantly changes the composition or structure of a food, affecting its nutritional value, metabolism or level of undesirable substances

viii) food consisting of engineered nanomaterials as defined in the regulation
- a. a production process that has not used for food production previously has been applied (see vii), or
- b. they contain or consist of engineered nanomaterials

ix) vitamins, minerals and other substances used in food supplements, traditional foods or foods for special groups, if:

x) food used exclusively in food supplements previously, now intended to be used in other than food supplements

important to let it grow, as that is how the best results often come about. Businesses would nonetheless be smart to find out the legislative requirements and keep them in mind, already from the beginning of the project.

Is my product a novel food?

The term 'novel food' refers to a new food or ingredient that has no history of use by humans in the EU. In this context, 'previous use' refers to use before 15 May 1997.

The safety of a novel food must be ensured through an authorisation procedure before the novel food can be placed on the EU market. So, if a food has not been consumed previously to a significant degree and if it falls into at least one of the categories defined in the Novel Food Regulation, it is likely to be classified as a novel food. The categories according to the Novel Food Regulation are presented in Table 1.

It is good to remember that human use outside the EU, for example in the United States or Asia, is not taken into account when considering previous use of the food.

This means that also traditional foods used in third countries but not used to a significant degree in the EU before 15 May 1997 are considered novel foods.

Food business operator is responsible for the regulatory positioning of the product

Only safe foods can be placed on the market (Regulation (EC) No 178/2002). The food business operator (FBO, defined in the legislation as 'natural or legal person responsible for ensuring that the requirements of food law are met within the food business under their control') is responsible for ensuring that the product is safe and complies with food regulations. The FBO must verify the regulatory positioning of the food or food ingredient, i.e. whether it falls within the scope of Novel Food Regulation or not.

We at Medfiles have experience of several cases where regulatory positioning has not been easy – for many different reasons. For example, it can be difficult or even impossible to find proof of a temporary history of use that has taken place for more than twenty years ago. Also, even if the source plant or animal of the new product is safe and traditional (e.g. pea) and is not classified as novel, an ingredient isolated or made from it (e.g. a selected protein fraction or peptides) most often is novel. On the other hand, traditionally used pea-based products, such as pea flour and pea protein, are not novel.

Regulatory positioning is not always easy, as the Novel Food Regulation does not provide precise quantitative or qualitative criteria for determining when a product is considered novel. Therefore, comprehensive legislative expertise is needed.

Consultation can be requested from the national authorities

If, after careful examination of the Regulation, an FBO still is unsure of the regulatory positioning of the product, an official classification can be requested. This procedure was recently enabled via the Commission Implementing Regulation (EU) 2018/456. The request for consultation is submitted to the EU Member State (national authority) where the product is planned to be placed on the market for the first time. The information needed for the request can be found in the Regulation and i

Table 2. Examples of food ingredients having received an official classification in the consultation process

Novel	Not novel
Several plant extracts: aqueous extracts from fig leaves in foods (not novel in food supplements) and olive fruit with max 10 % hydroxytyrosol, *Epimedium brevicornum* Maxim leaves	*Coix lacryma-jobi L.* seeds in food supplements
Cocoa pulp juice	Cold pressed *Nigella sativa* seed oil
Casein hydrolysate with elevated tripeptide levels (VPP and IPP)	Mineral enriched fungal biomass (*Aspergillus oryzae*)
CBD isolate (purity > 98 %)	
Mung bean (*Vigna radiata*) protein isolate	Olio di lentisco (oil obtained from *Pistacia lentiscus* berries)
Several mycelium powders: *Agarixcus plazei, Coprinus comatus, Ganoderma lucidum, Grifola frondosa, Hericium erinaceus, Lentinula edodes, Pleurotus eryngii, Pleurotus ostreatus, Polyporus umbellatus*	Gulupa (*Passiflora edulis f. edulis Sims*)
Plant protein concentrate fermented with the mycelium of shiitake (*Lentinus edades*)	Pea (*Pisum sativum*) protein hydrolysate and soy (*Glycine max*) protein hydrolysate
Selenium mushrooms (*Agaricus bisporus*)	Preserved pine cones (*Pinus sylvestris*) in food supplements
Vitamin B mushrooms (Agaricus bisporus)	Pine cone (*Pinus sylvestris*) syrup

ncludes for example the characterisations of the food, its conditions of use, production process and history of human consumption in the EU. The national authority provides its conclusion on the novel food status within four months after validating the consultation request. The result of the conclusion is public and will be published on the European Commission's website.

The consultation process has been possible since April 2018, and it has been widely used. By 19 October 2020, 45 conclusions have been published. Most of the requests have concerned foods that are isolated or produced from plants, micro-organisms, fungi or algae. So far, no consultations have been requested regarding animal-derived products. The majority of the consultations have resulted in 'novel food' status of the product (35) and a minority with 'not novel food' (7) or 'not novel in food supplements' (5). We have summarised some examples of these officially classified foods in Table 2.

Reviewing the results of the consultation process interestingly shows that when a company is unsure whether or not their product is a novel food, it often is. The main reason in most cases is that there is no history of use in the EU before 15 May 1997, in other words, the food is considered a new (novel) food. However, in many cases it has been possible to demonstrate a history of use to a significant degree in the Union, thereby avoiding the novel food status, such as is the case for pine cone syrup used traditionally in Romania and Hungary.

Another interesting example concerns mung bean protein isolate. It was classified as a novel food, the reason being that although mung bean (*Vigna radiata*) and mung bean flour have been used as food, there is no history of use for the protein isolate. In contrast, a pea (*Pisum sativum*) protein and soy (*Glycine max*) protein hydrolysate product was classified as non-novel food. The reasoning was that 'while the complexity of the protein structure will likely be affected by hydrolysis, the ultimate content and proportion of amino acids should not be significantly altered'.

Application or notification needed for novel foods

If a product meets the criteria for a novel food, an application for official assessment must be submitted to the Commission. The application must include comprehensive product information, studies on safety with the intended use, the food groups in which the product will be used and the amount that it is intended to be used. The application process takes 1.5 to 2 years. During the process, the Commission will request that the European Food Safety Authority (EFSA) carry out a risk assessment, which may take up to 9 months, whereafter the Commission gives its draft implementing act at the latest 7 months after the risk assessment. After acceptance from the Standing Committee on Plants, Animals, Food and Feed, the product can be included in the Union's list of novel foods and can be launched in the EU.

Currently, applicants can submit novel food applications and traditional food notifications online via an electronic submission system. Unfortunately, according to the authorities, this has led to an increased number of incomplete dossiers, which causes delays in validation and the processing times, as several requests for further information have to be made to the applicant.

Instead of the application procedure, it is possible to use a notification procedure for novel foods that have traditionally been consumed in a country outside the EU. This is a shorter and lighter process. A safe history of use of at least 25 years must be shown as part of the notification. For example, cacao fruit pulp and pulp juice as well as syrup from *Sorghum bicolor* (L.) Moench have received novel food approvals based on their traditional use in non-EU countries.

Table 3. Examples of approved plant-, fungus- and animal-derived novel foods

Plant-derived	Chia seeds and chia oil
	Cranberry extract powder (only allowed in food supplements)
	Coagulated potato proteins and their hydrolysates
	Rapeseed protein
	Non-fat cocoa powder extract and low-fat cocoa extract
	Sugar cane fiber
	Lycopene and lycopene extract from tomatoes
	Wheat bran extract
Fungus-derived	Arachidonic acid-rich oil from the fungus *Mortierella alpina*
	Chitosan extract from fungi (*Agaricus bisporus*; *Aspergillus niger*)
	Chitin-glucan complex from *Fomes fomentarius*
Animal-derived	Antarctic krill oil from *Euphausia superba*
	Bovine milk basic whey protein isolate
	Calanus finmarchicus oil
	Fish peptides from *Sardinops sagax*
	Oil extracted from squids
	Refined shrimp peptide concentrate
	Protein extract from pig kidneys

Examples of authorised novel foods

The Union list of novel foods in (EU) 2017/2470 contains all authorised novel foods with their conditions of use and labelling requirements. The list contains many plant- and fungus-derived products that can already be found in the supermarkets, such as chia seeds and chia oil (Table 3). Other examples of products made from familiar plant sources include coagulated potato proteins and their hydrolysates as well as rapeseed protein (specified as an aqueous protein-rich extract from rapeseed press cake originating from non-genetically modified *Brassica napus* L. and *Brassica rapa* L.; protein content ≠ 90 %).

Plant-based foods make the majority of the authorised novel foods on the list, but there are a few products of fungal and animal origin also (Table 3). As an example of an animal-derived by-product, refined shrimp (*Pandalus borealis*) peptide concentrate is manufactured from leftovers of shrimp production, i.e. from shrimp head and shells, and is to be used as ingredient in food supplements.

As an example from Finland, a novel food application on rapeseed powder by Finnish Avena Nordic Grain Oy received a favourable opinion on its safety from EFSA in late July 2020. Commission authorisation is expected in 2021. Rapeseed powder is made from a rapeseed press cake which is a by-product of rapeseed oil production. The proposed use includes breakfast cereals, breads and rolls, snacks and meat imitations.

Number of novel food dossiers is increasing

Several companies have performed regulatory positioning for their products – either by themselves or via the consultation process. As a result, the number of submitted novel food applications has significantly increased during the last few years. When looking at the list of submitted applications that are currently in process, there are several interesting by-products and new types of non-animal-origin protein ingredients that we might hear from in the future. Some examples of these are given in Table 4.

Table 4. Examples of submitted novel food applications in process

Coffee husk (cascara) – the dried husk of the coffee fruit or coffee cherry
Coffee flour (defatted coffee dietary fibers)
Brassica napus whole seeds
Fungal protein-fiber rich biomass
Several insects, such as house cricket, whole and ground crickets, whole and ground lesser mealworm larvae products, mealworm, migratory locus
Antrodia camphorata mycelia powder
Pea and rice protein fermented by shiitake (*Lentinula edodes*) mycelia
Rapeseed powder from *Brassica rapa* L. and *Brassica napus* L.

In addition, nine notifications of traditional foods from non-EU countries have been submitted to the Commission by 19 October 2020, one example being the berries of *Lonicera caerulea* L. (haskap).

Novel food catalogue will be renewed

In addition to the Union list of novel foods (EU) 2017/2470, also the EU novel food catalogue gives information on the novel food status of substances. It is a non-exhaustive list and serves as orientation on whether or not a product will need novel food authorisation. The catalogue is available on the Commission's website and is a good extra help as it also contains substances that have not been classified as novel. The novel food catalogue will be renewed as regards both appearance and content in the future. The results of the official consultation processes will also be added to the catalogue as a part of the renewal.

Illegal novel foods on market

Illegal novel foods are occasionally found on the market, for example as ingredients in food supplements. Unapproved novel foods are immediately withdrawn from the market. The Rapid Alert System for Food and Feed (RASFF) notification is also given by authorities to all EU Member States. In 2018, more than 50 such notifications were given. In some EU countries, this also results in an immediate fine for the responsible operator.

If you are unsure about your ingredient's or product's legal status, the national authorities and expert service companies are a good help. A thorough plan for product launch will help you do the right things at the right time – and eventually save both time and money.

Further reading and references

Novel food. European Commission. Available at: https://ec.europa.eu/food/safety/novel_food_en

Register of Questions. European Food Safety Authority (EFSA). Available at: http://registerofquestions.efsa.europa.eu/roqFrontend/ListOfQuestionsNoLogin?1&panel=ALL

Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001. Official Journal of the European Union L 327/1.

Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods. Official Journal of the European Union L 351/72.