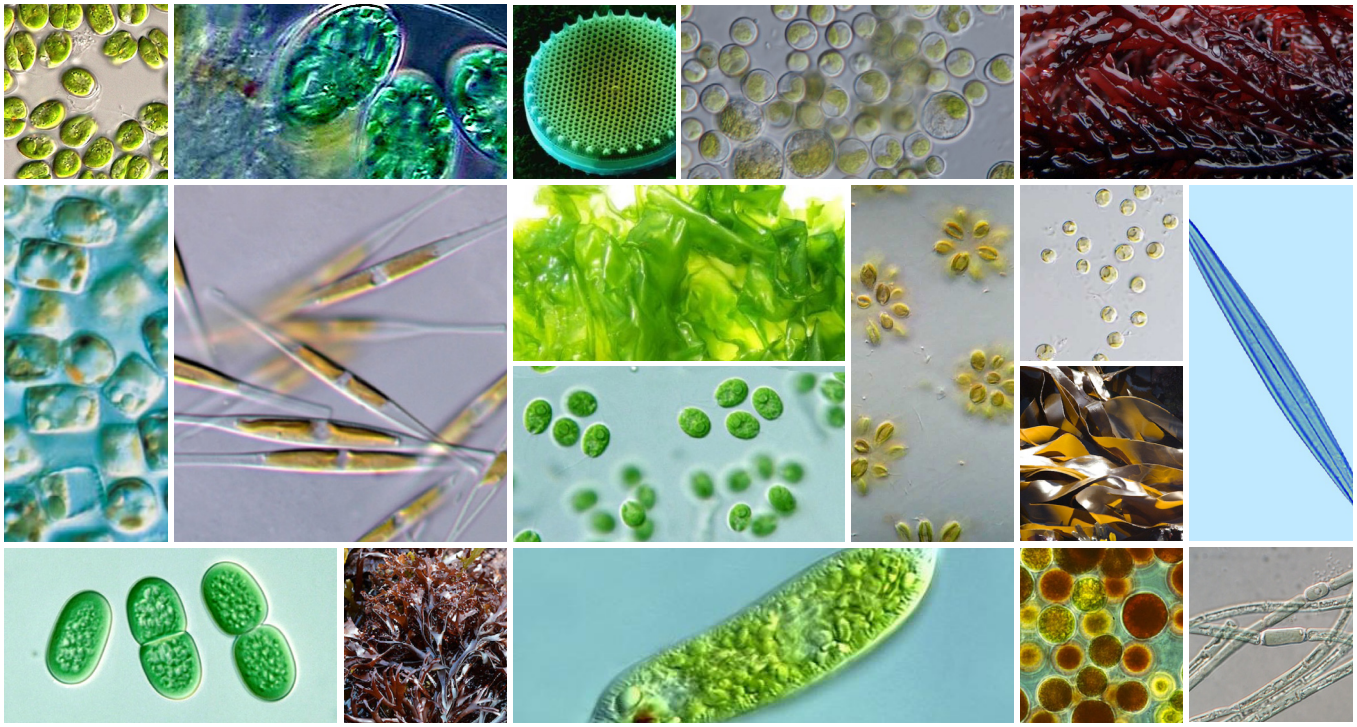

#4 EABA - INFORMATION PAPER - VERSION 2.0 - APRIL 2021

Algae as Novel Food in Europe.

EUROPEAN ALGAE BIOMASS ASSOCIATION

EXECUTIVE SUMMARY

This Information Paper aims to explain in a simple and informative way 'What are Novel Food Requirements for Algae?' and how we can answer to the most relevant questions that are brought by the different players that interact with 'algae', including: academia, industry, trade organizations, consumers, business investors, - local, national authorities, international oganizations and any other interested parts or stakeholders. This Position Paper represents the position of EABA as the Algae Biomass sector Association and brings toghether existing information from the science, technology and business levels impacted by 'algae' biomass.

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EABA

The European Algae Biomass Association (EABA) was established in Florence in June 2009 as the European association representing both research and industry in the field of algal technologies. EABA is representing both macro- and microalgae biomass interested organizations and individuals.

The general objective of EABA is to promote mutual interaction and cooperation in the field of algae biomass production, transformation and use for the whole range of algae applications. It aims at creating, developing, promoting and maintaining solidarity, contact, interaction and collaboration among its members and at defending their scientific and commercial interests at the European and international level. Its main target is to act as a catalyst for fostering synergies among scientists, industrialists and decision makers in order to promote the development of research, technology and industrial capacities in the field of algology.

The Association is technology neutral and does not aim at favouring a particular kind of production, processing or use of the algae biomass or biotechnology. This approach reflects the fact that all production technologies and uses of algae biomass or related services are to be considered as interdependent.
With these aims in mind, the Members of EABA share with each other accurate non-confidential information about the algae biomass sector (adapted from EABA STATUTES).

OPENING REMARKS

Algae, including microalgae and seaweeds have a long history and increasingly important applications as both food ingredients and animal feed, but also for other raw materials such constituents of cosmetics, agrochemicals, biomaterials and as renewable bioenergy feedstocks. The vast majority of algal species have yet to be evaluated for these applications. However, due to their extensive diversity, it is likely that they will lead to the discovery of many new algal products and processes in the future.

Most companies tend to expand by producing new products and addressing new markets. However, this must be done strictly in compliance with the relevant regulation. The one applied to foodstuff in Europe aims to ensure food safety, whatever the origin of the primary matter, including algae. Algae are a new frontier with high potential as alternative food sources/ingredients as their exploration reveals products with numerous virtues, especially for health and welfare. The paradox is that their biodiversity, which is probably the richest of the biosphere, is nearly untapped with only a handful of species authorized to be put on the market according to EU food law. With few exceptions, algae are considered a “Novel Foods” (NF) and as such subject to safety assessments.

At present the time and money required to obtain the allowance of marketing a new species and its extracts is such that a simplification of the regulation is expected.

1. FROM REGULATION (EC) NO 258/97 TO THE NEW DISCIPLINE OF NOVEL FOODS

Regulation n. 258/97 of the European Parliament and the Council sets out the legal framework for the marketing of “Novel Foods”. Aiming at granting a high level of consumer protection and the functioning of the internal market, the Regulation provides a system of authorization for the marketing of novel foods. However, the application of these rules highlights the critical issues of the system, such as the ambiguities of the notions, the slowness of the procedures (on the average 3 years.) and the high costs to obtain NF permission (€200,000 to €400,000). These problems, together with the development of the modern technologies, have determined the need for a reform.

WHAT CONSTITUTES A NOVEL FOOD

On 25 November 2015, the European Parliament and the Council adopted the Regulation (EU 2015/2283) of the European Parliament and of the Council on Novel Foods which repealed Regulation (EC) No 258/97. The Regulation requires that all applications for the authorization of novel foods shall be submitted to the Commission who may then request a risk assessment from the European Food Safety Authority (EFSA). In the context of this document, food consisting of, isolated or produced from algae or from an algae cell culture will be novel food if it has not been **consumed to a significant degree within the Union before May 15, 1997**.

A food business operator who wants to bring a food to the EU market has the responsibility to assess and determine its novel food status based on the evidence available to them. If they cannot decide on the novel food status of their food, they may consult the authorities in the Member State in which they intend to first place the food on the market according to the provisions of Article 4 of the Novel Food Regulation (EU) 2015/2283 and the provisions of Commission Implementing Regulation (EU) 2018/456. In this process, the potential applicant can submit a consultation request electronically to a competent authority of a Member State that comprises the following: (a) a cover letter; (b) a technical dossier; (c) supporting documentation; (d) an explanatory note clarifying the purpose and relevance of the submitted documentation (see COMMISSION IMPLEMENTING REGULATION (EU) 2018/456).

The decision whether a food constitutes a novel food or not is taken by the Member State that received the request. The decision to conclude the food is a novel food is done on a case by case. Even if the product is very similar to a product already on the market, if it is produced by or with an algae species that was not used for this purpose before, it may be considered as a novel food. The outcome of the decision (Yes, No, FS, ?) is published by EU in the Novel Food Catalog (NFC)

» Food safety risks related to products that have not carried out food safety studies.
When non-authorized novel food products are placed in the market, these may represent a risk to consumers. These products have not carried out

food safety studies and have not been evaluated by EFSA. These products may be hazardous and may eventually have an adverse effect in human health.

» Negative impact for the Algae sector and bad press. The impact of a hazardous product that may have adverse effect in human health would put in risk the Algae sector. Any bad press or eventually a health alert would jeopardize the commercialization of any algae related products. These situations must be avoided and prevented.

As a similar example, recently (Early in 2018) European Commission investigation showed that many companies are selling non-authorised Novel Foods and food supplements with medicinal claims. Especially the ones marketed through the Internet, where two thirds of the online traders placed in the market unauthorised foods. Authorities checked nearly 1.100 websites and found 779 non-compliant offers. This was made up of 428 offers of unauthorized novel foods and 351 food supplements with unauthorized/false medical claims. The 25 member states as well as Norway and Switzerland which took part in the first EU coordinated control plan on online offered food products orchestrated by the European Commission.

https://ec.europa.eu/food/sites/food/files/oc_oof_analysis_main_outcome_en.pdf

The high number of non-compliant offers is a clear sign that e-commerce control across Europe needs to be strengthened. Whether purchasing from a physical store or online, consumers have the right to buy safe food which does not mislead. It is expected that controls and investigations will increase in the near future and will imply penalties and market restrictions.

Today, although concrete evidence is not available, there may be algae products in the EU market (both online and offline stores) for which the novel food status has not been established. *Nannochloropsis gaditana* microalgae species is such an example and of course there could be others. The Algae sector as a new emerging sector should carefully ensure compliance with the Novel food Regulation. Lack of controls and penalties may lead to an increasing fraudulent activity.

NOVEL FOODS DEFINITION

The notion of “Novel Foods” is not new. Throughout history new types of food, food ingredients or ways of producing food have found their way to Europe from all corners of the globe. Bananas, tomatoes, tropical fruit, maize, rice, a wide range of spices – all originally came to Europe as novel foods. Among the recent arrivals are chia seeds, algae-based foods, Baobab fruit and insects.

According to the new “Novel Foods” Regulation (EU) 2015/2283 of the European Parliament and of the Council (European Union, 2015a), replacing Regulation (EC) No. 258/97 (European Union, 1997) of the European Parliament and of the Council:

“Novel Food means any food that was not used for human consumption to a significant degree within the EU before 15 May 1997 (when the first Regulation n° 258/97 on novel food came into force) irrespective of the dates of accession of member states to the Union”

According to the new Regulation which will come into effect in January 2018, Novel Foods fall within at least one of the categories listed in Article 3 (for more detail see Annex 1):

» Food with a new or intentionally modified molecular structure

» Food consisting of, isolated from or produced from microorganisms, fungi or algae

» Food consisting of, isolated from or produced from material of mineral origin

» Food consisting of, isolated from or produced from plants or their parts obtained by non-traditional propagating practices if significant changes in the composition or structure of the food affect its nutritional value, metabolism or level of undesirable substances

» Food consisting of, isolated from or produced from animals or their parts obtained by non-traditional breeding techniques

» Food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, microorganisms, fungi or algae

» Food resulting from a new production process if significant changes in the composition or structure of the food affect its nutritional value, metabolism or level of undesirable substances

» Food consisting of engineered nanomaterials

» Vitamins and minerals and other substances used in accordance with Food Supplements Directive 2002/46/EC obtained by a new food production process or containing engineered nanomaterials

» Food used exclusively in food supplements within the EU before May 15, 1997, intended to be used in foods other than food supplements

» Traditional foods from a third country with a history of safe food use in a third country

Novel Foods Regulation does not apply to:

- GM foods or foods produced from GM organisms, covered by Regulation EC 1829/2003
- Food enzymes, within Regulation (EC) 1829/2003
- Food additives, within Regulation (EC) 1333/2008
- Food flavourings , within Regulation (EC) 1334/2008
- Extraction solvents used in the production of foods, within Directive 2009/32/EC

Novel Food refers to new food sources or newly developed and innovative food, food produced using new technologies and production processes, and food traditionally consumed in countries outside the EU, but not within the EU. These "traditional food from third countries" include foods made from plants, microorganisms, fungi, algae and animals.

"NOT NOVEL" EDIBLE ALGAE IN EU: CURRENT LANDSCAPE

In Europe, algae (macro and micro) are considered NF. They can be used as food if put on market as food or food ingredient and consumed to a significant degree before May 15, 1997. Up to day, 11 macroalgal and 5 microalgal species are authorized as food or food ingredient and listed as "not novel" (or old) in the EU Novel Food Catalogue (Table 1). In France since 1990, some other species of seaweed have been authorized for food consumption. France was one the first European country to establish a specific regulation concerning the use of seaweeds for human consumption as non–traditional food substances (Centre d'Etudes et de Valorisation des Algues, CEVA, 2014).

- According this regulation 24 macroalgae (by counting the French authorizations + the EU novel food catalogue) are authorized as vegetable and condiments (Table 1).

The microalgae used prior to May 1997 in Europe and thus authorized as food in the EU are *Aphanizomenon flos-aquae* from Klamath Lake, *Arthrospira platensis*, *Chlorella luteoviridis*, *Chlorella pyrenoidosa*, *Chlorella vulgaris* and an undefined Spirulina sp. (European Union, Novel Food catalogue). The diatom *Odontella aurita* was authorized in 2005 (European Union, 2005), and, in 2009, DHA-rich oil from *Ulkenia* sp. has been approved as novel food ingredient (European Union, 2009). In 2014, *Tetraselmis chuii* and astaxanthin from *Haematococcus pluvialis* have been approved as food (AECOSAN 2014; EFSA 2014). In 2015, oil from *Schizochytrium* sp. was also authorized (European Union, 2015b,c).

The European Novel Foods Catalogue is an informal and non-exhaustive tool listing products of animal and plant origin and other substances that are subject or not to the novel food regulation. It is based on information regarding history of consumption of these products in the EU. The catalogue has no legal value for producers and importers seeking to market the substances and ingredients included in the catalogue. A non–European exporter would have a very difficult time determining which novel foods or substances are authorized, since some Member States may further restrict the marketing of a novel food through specific legislation.

EXECUTIVE SUMMARY

- A total of 29 algae species currently considered NOT NOVEL
- Only 6 microalgae species are authorized as NOVEL FOOD (old regulation 258/1997)
- All the others have to follow the NOVEL FOOD REGULATION (new regulation 2283/2015)

NOVEL FOODS AUTHORIZATION PROCEDURE

Novel foods need permission to be marketed in Europe. They need to be safe for consumers and properly labelled as to identify them as novel to the consumer. Authorization and use of novel foods and food ingredients have been harmonized in the European Union since 1997 when **Regulation 258/1997** (European Union, 1997) on novel foods and novel food ingredients was adopted. In 2013, the EU Commission presented a proposal for a new Regulation and in November 2015 the European Parliament and the Council have reached an agreement with the new **Regulation EU 2015/2283** (European Union, 2015).

- This revision is aimed to guarantee shorter and less expensive authorization processes, while still maintaining a high level of consumer protection. Figure 1 shows diagrams of the two procedures, the first that refers to Regulation EC 258/97 is valid until 31 December 2017, the second based on the Regulation EU2015/2283 will come into force since 1 January 2018. Applications not finalized under the current rules by 1 January 2018 (when the new regulation comes into effect) will be decided under the new regulation.

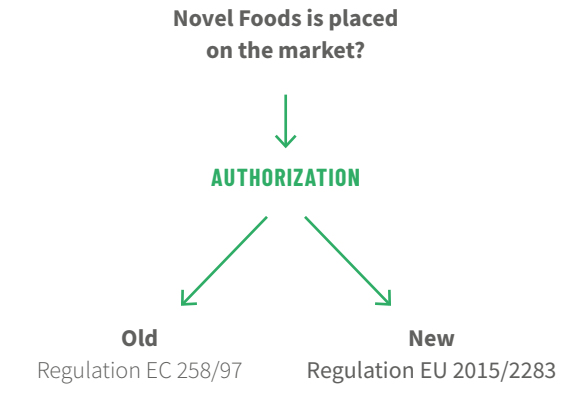


Fig.1. Novel Food market placing.

TYPE	GROUP	SCIENTIFIC NAME	COMMON NAME	NOTES
MACROALGAE (SEAWEEDS)	Brown	*Ascophyllum nodosum*		In EU NF catalogue
		Eisenia bicyclis		In EU NF catalogue
		Fucus vesiculosus		In EU NF catalogue
		Hizikia fusiforme		"
		Laminaria digitata	Kombu	"
		Laminaria longicruris	Kelp	"
		Saccharina latissima (formerly *Laminaria saccharina)*	Royal Kombu	"
		Saccharina japonica (formerly *Laminaria japonica)*	» Kombu	"
		Undaria pinnatifida	Wakame	"
		Himanthalia elongata	Sea spaghetti	In EU NF catalogue
		Alaria esculenta	Atlantic wakame	In EU NF catalogue
	Red	*Palmaria palmata (Rhodymenia palmata)*	Dulse	In EU NF catalogue
		Porphyra tenera	Nori	In EU NF catalogue
		Porphyra umbilicalis	"	French authorization
		Porphyra yezoensis	"	"
		Porphyra dioica	"	"
		Porphyra purpurea	"	"
		Porphyra laciniata	"	"
		Porphyra leucostica	"	"
		Chondrus crispus	Pioca, lichen	In EU NF catalogue
		Gracilaria verrucosa	Ogonori	In EU NF catalogue
		Lithothamnium calcareum	Mäerl	In EU NF catalogue
	Green	*Ulva lectuce*	Sea lettuce	In EU NF catalogue
		Enteromorpha sp.	Aonori	In EU NF catalogue
MICROALGAE		*Aphanizomenon flos-aquae*	Alga Klamat	In EU NF catalogue
		Arthrospira platensis	Spirulina	"
		Chlorella luteoviridis		"
		Chlorella pyrenoidosa		"
		Chlorella vulgaris		"

Table 1. Algae used prior to 15th of May 1997 listed as "not novel" in the EU Novel Foods Catalogue.
They do not require authorization under the Novel Foods Regulation. Additional macroalgae authorized in France before 1997 are also shown.

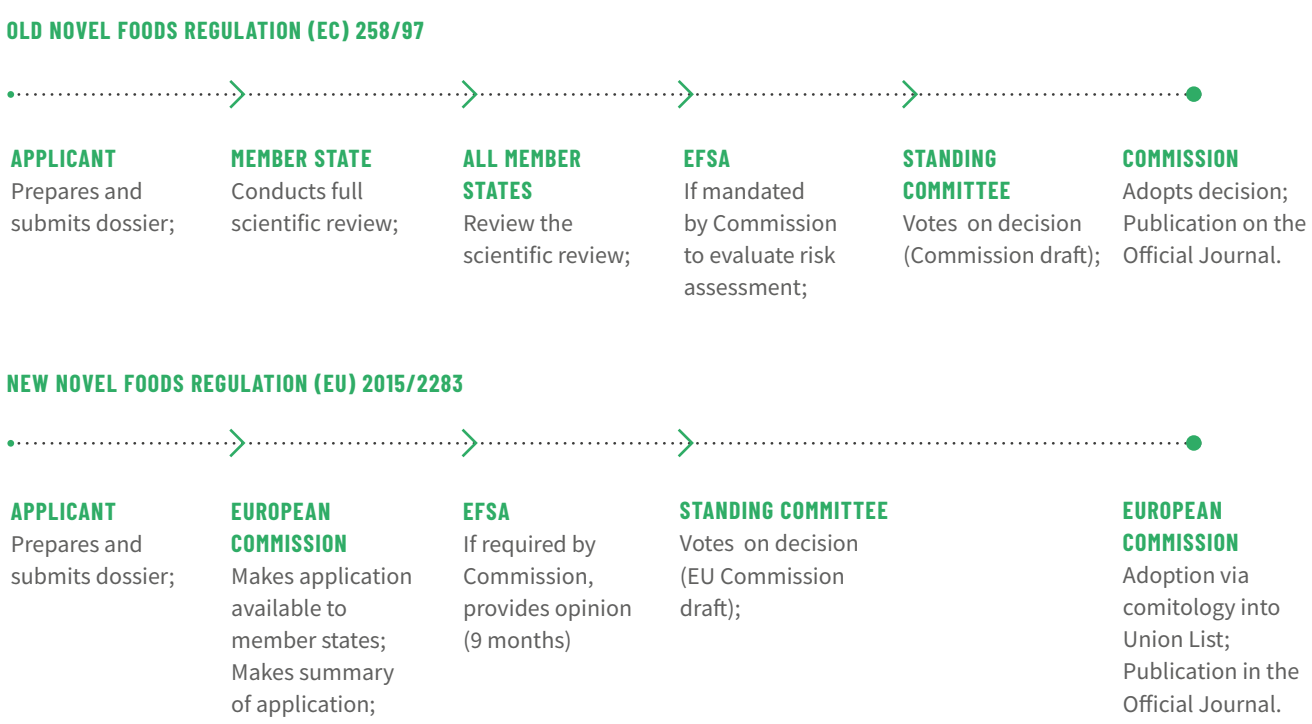


Fig.2. Simplified diagrams of the two NF regulation procedures, the old one that refers to Regulation EC 258/97, was valid until 31 December 2017, the new one is based on the Regulation EU2015/2283 is in force since 1 January 2018.

According to new Regulation an applicant who intends to place on the EU market a novel foods should submit an application to the European Commission that, after having verified its validity (1 month), will make it available to the Member States and give mandate to European Food Safety Authority (EFSA) for a safety assessment. EFSA shall adopt its opinion within 9 months from the date of receipt of a valid application from the EC. Within 7 months from the date of publication of EFSA's opinion, the Commission must submit a draft proposal authorizing the novel food to the Standing Committee on Plants, Animals, Food and Feed (PAFF). If no EFSA opinion is requested, the 7-month period starts from the date on which the Commission receives a valid application.
The main changes of the new regulation are:

1. Authorization procedure centralized at EU level with fixed time limits;
2. All applications for NF authorization are submitted to the EC which may require a risk assessment to the European Food Safety Authority (EFSA). The EU bases authorization decisions on the outcome of EFSA's evaluations;
3. Introduction of a simplified procedure for traditional foods consumed to a significant degree in third countries but not in the EU prior to 1997 (see below);
4. EU sets up and updates a "Union List" of NF authorized or notified to be placed on the EU market;
5. Efficiency and transparency will be improved by establishing deadlines for the safety evaluation and authorization procedure, thus reducing the overall time spent in the authorization process;
6. Generic novel food authorizations which remove the need for a separate application seeking to demonstrate substantial equivalence to an authorized novel food;
7. A maximum 5 year period (from the date of authorization) of intellectual property protection for new scientific evidence and data produced in support of applications;

TRADITIONAL FOODS FROM THIRD COUNTRIES

The procedure for safety assessment for traditional foods from third countries, is based on a history of safe food use. It means 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. The history of safe food use should not include non-food uses or uses not related to normal diets.

If the traditional food in question can historically be demonstrated to be safe, and no safety concerns are raised by EU Member States or EFSA, that traditional food may be placed on the market on the basis of a notification from the applicant. A Member State or EFSA may submit duly reasoned safety objections on the placing on the market of the notified food. In this latter case, the applicant may transform the notification into an application, for which a safety

evaluation will be requested from EFSA. In assessing the safety of these types of novel foods, EFSA shall consider the following:

- Whether the composition of the food and the conditions of its use do not pose a safety risk to human health in the Union;
- Where the traditional food from the third country is intended to replace another food, whether it does not differ from that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer.

On 10 November 2016, EFSA published two guidance documents on novel food and on traditional food following the new European regulation on novel food (EFSA, 2016a,b). EFSA new guidance documents explain in detail the kind of information applicants need to provide when a risk assessment is required and how to present this information to EFSA.

POSITIVE UNION LIST

Article 6 of Regulation 2015/2283 requires the Commission to establish an EU list of authorized novel foods by January 1, 2018. The list will initially include novel foods that have already been authorized under Regulation 258/97. The list would also include, where appropriate, the conditions of use, additional labeling requirements and post-market monitoring requirements. In the case of authorized traditional foods, the entry in the union list shall specify that it concerns of traditional food from a third country. The list is available by 1 January 2018 and regularly updated. An Union Draft List of novel foods authorized or notified under Regulation (EC) No 258/97 has been to published at the beginning of October, 2017 (Ref. Ares (2017) 4851094 - 04/10/2017 https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-4851094_en). The Union list shall consist of Tables 1 (Authorized NF) and 2 (Specifications). The Annex 2 shows microalgae authorized to be marketed in EU as currently reported in the Union List.

GENERIC NATURE OF AUTHORIZATIONS AND "DATA PROTECTION"

As a general rule, authorizations will be generic. Under the new regulation there are two options:

- Generic approval which is product specification and uses specific. This will be most of the existing novel food approvals – they will be transferred to the Union List. There is no time limit on this.
- Approval based on proprietary data – company specific. This will have 5 years timeout before becoming a generic approval. During that time another company must have their own data to replace that data considered proprietary by the first applicant. If that was also cited and agreed as proprietary then indeed two companies could have exclusivity.

The "initial applicant" has the faculty to ask that scientific evidence or scientific data presented in support of the application for authorization, cannot - without his consent - be used for the benefit of a subsequent application within non-renewable 5-year period from the date of authorization and if the data are eligible for protection. The criteria for eligibility are as follows:

- The newly developed scientific evidence or scientific data was designated as proprietary by the initial applicant at the time the first application was made,
- The initial applicant had exclusive right of reference to the proprietary scientific evidence or scientific data at the time the first application was made, and
- The novel food could not have been assessed by the EFSA and authorized without the submission of the proprietary scientific evidence or scientific data by the initial applicant.

EXECUTIVE SUMMARY

The new EU Regulation delivers:

- An updated definition of what constitutes a 'Novel food' based on technological and scientific advancements;
- Centralised risk assessments to be carried out by the European Food Safety Authority within 9 months (time may be stopped if further information is required);
- The establishment of a Union list of authorised novel foods (newly authorised food to be added within 6 months);
- Generic novel food authorisations which remove the need for a separate application seeking to demonstrate substantial equivalence to an authorised novel food;
- A maximum 5 year period (from the date of authorisation) of intellectual property protection for new scientific evidence and data produced in support of applications;
- A simpler notification procedure for traditional foods from third countries, facilitating free trade.

SAFETY AND HEALTH CONSIDERATIONS OF NOVEL FOODS: THE CASE OF ALGAE

The purpose of a risk assessment for a novel food is to evaluate its potential impact on public health and safety status. During the evaluation of the public health and safety of a novel food, a variety of toxicological and nutritional issues have to be considered together with information on its chemistry and the amount of peo-

ple expected to eat it. In assessing the safety of novel foods under the Regulation2015/2283, EFSA shall consider the following:

- Whether the novel food concerned is as safe as food from a comparable food category already existing on the market within the Union;
- Whether the composition of the novel food and the conditions of its use do not pose a safety risk to human health in the Union;
- A novel food, which is intended to replace another food, does not differ from that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer.

Consumption of any food is not without risk, so the promotion of algal consumption must also consider potential harm to consumers. Possible risks associated with algae include excess intake of toxic metals, allergenicity, cyanotoxins, and certainly secondary metabolites) as well as contamination with pathogens, radioisotopes, and toxic synthetic compounds (Wells et al., 2017).

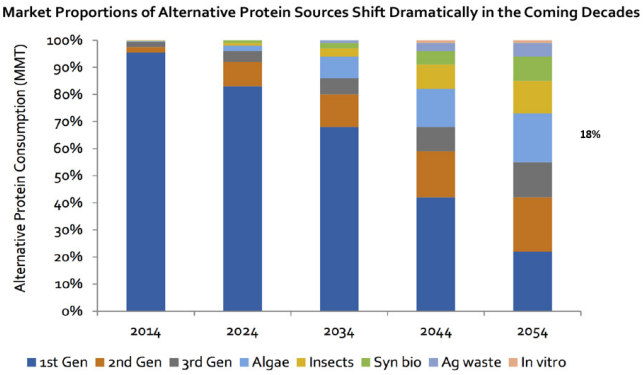
2. WHY THE NOVEL FOOD REQUIREMENT?

New nutrient sources are needed to face the challenges that are putting food security under great stress. The crushing weight of the world's population, projected to soar up to 10 billion by 2050, will inevitably result in an increased demand for food. Animal proteins account for about 40% of global protein consumption, but their production is highly inefficient, with about 2 to 15 kg of plant material being required for 1 kg of animal products. Furthermore, cattle breeding and meat consumption are associated with a high environmental footprint and greenhouse gas release, thus making these practices unsustainable.

It becomes imperative to find innovative nutrient sources for a "Sustainable, Safe and Nutritious Food" of the future. One of the most promising alternatives to animal proteins for both human consumption and feed applications are algae. Alternative proteins are estimated to make up 33% (i.e. 310 million metric tonnes) of global protein consumption by 2054, with algae accounting for about 18%.

The most common varieties of edible seaweed that include Nori, Wakame, Kombu, Dulse and Carrageen, are associated with many health benefits, including lowering blood pressure and preventing strokes, but most importantly, they are a valuable source of protein minerals and vitamins, not to mention their negligible fat and cholesterol content. On the other hand, microalgae positively affect humans and animal health due to their original chemical composition, namely high protein content, with balanced amino acids pattern, carotenoids, fatty acids, vitamins, polysaccharides, sterols, phycobilins and other biologically active compounds.

- Production of novel food sources will also have a major positive impact on environmental protection, helping to address specific concerns such as climate change, land use and ocean depletion. Firstly, algae and insects are important actors in the circular economy, having the ability to thrive on GHGs and waste streams, thus "closing the loop". In particular, algae can be grown in wastewater using carbon dioxide pumped directly from CO2 generating activities, such as a power plants and factories.
- Secondly, new food sources score positively on land use. In particular algae cultivation does not put a stress on land availability, since it uses both land and water sources that are unsuitable for traditional agriculture, such as sea and brackish water.
- Thirdly, the integration of algae in feed for aquaculture would contribute to relieving ocean depletion reducing the dependency on fishmeal and solve the paradox of using fish to feed fish. New nutrient sources also have a considerable social impact across several interlinked areas. Their large scale production could revive the European agricultural industry, offer opportunities for economic diversification, and offset job losses across the sector.



From a public health perspective, new sources of nutrients could help ensure food security and decrease the incidence of cardiovascular diseases related to unhealthy food. The diffusion of new nutrient sources is supported by their numerous social and environmental benefits, which contribute to their public acceptance and future uptake. However, several obstacles are faced by companies trying to promote their production and commercialization. These include cultural barriers affecting customer acceptance, the restrictive EU regulatory environment as well as production and scaling-up costs.

EXECUTIVE SUMMARY

- Talking about novel foods identifies what is likely to be the food of the future
- Novel foods will bring a number of improvements, including:
  - Human nutrition: both in terms of nutrition and access to food
  - Environment: will be produced with a small impact on the ecosystem
- Food companies may want to introduce novel foods for different reasons:
  - they can be produced more efficiently
  - they provide health benefits for consumers
  - algae biomass industry is estimated at up to EUR 6.3 billion
- Novel foods: still too much distrust

3. WHICH ALGAE SPECIES ARE IN THE PIPELINE (SAFETY AND COMMERCIAL REASONS)

Data in Table 2 refer to global microalgae production, with the currently contribution of the EU quite limited. It was estimated the EU production share at around 5% of the global figures in Table 2.

MARKET FIGURES OF MICRO-ALGAE BASED PRODUCTS

MICROALGAE-BASED PRODUCT	PRODUCTION VOLUME (TONS/YEAR DRY WEIGHT)	NUMBER OF PRODUCERS	PRODUCTION VALUE (ANUAL TURNOVER, MIO US $)	PRODUCTION VALUE OF ALTERNATIVE SOURCES (ANNUAL TURNOVER, MIO US $)
Whole-dryed micro-algae				
Spirulina	5000 (2012) [a]	15	40 (2015) [b]	No alternative
Chlorella	2000 (2003) [a]	70	38 (2006) [c]	No alternative
High-value molecules				
Astaxanthin	300 (2004) [a]	8	10 (2004) [c]	200 (2004) [b]
Phycobiliprotein (incl. phycocyanin)	(NA)	2	(NA)	50 (2004) [b]
Omega-2 fatty acids	240 (2003) [b]	4	300 (2004) [b]	14390 (2009) [d]
Beta-Carotene	1200 (2010) [c]	10	(NA)	285 (2012) [b]

Table 2. Market Figures of Micro-Algae based products.

Note: In brackets the year of which the estimation was done.

[a] Norser *et al*., 2011; [b] Millege, 2012; [c] Spolaore *et al*., 2016; [d] Ismail, 2010.

Source: Enzing *et al*., 2014. Reproduction is authorized provided the source is acknowledged.

The actual production capacity is closely related to human applications, estimated around 10,000 t/year. Regarding market price, the actual microalgae biomass production cost ranges from minimum 5 €/kg in raceway ponds to 50 €/kg in photobioreactors; the market value of human-related products exceeds 103 M€/ year.

Microalgae biomass contains proteins, lipids, and carbohydrates, all of them of high quality for human consumption. Thus, microalgae biomass contains large amounts of essential amino acids and polyunsaturated fatty acids, in addition to sterols and carotenoids with antioxidant activity, thus this biomass being considered as a superfood. Microalgae have been reported to be a "sustainable" source of food and nutraceuticals for human uses, by its higher nutritional and functional properties versus conventional crops as cereals and vegetables and its lower land requirement also reducing the risks related to food insecurity supply in the world.

Microalgae biomass can be used as food directly, in different mixtures with other foods, or alternatively by consuming extracts of valuable compounds. Dry biomass of *Chlorella* and *Spirulina* is commercialized as powder or in capsules, also it being incorporated to juices, cakes, pasta, and other foods to enhance the nutritional value or provide healthy properties as antioxidant, among others. Regarding extracts, carotenoids as astaxanthin and ß-carotene are extracted from the biomass of *Haematococcus* and *Dunaliella*, and incorporated to suspension as health enhancer. Other compounds as polyunsaturated fatty acids, i.e., eicosapentaenoic cid (EPA), arachidonic acid (AA), and docosahexaenoic acid (DHA), are also extracted mainly from the biomass of marine strains, as *Nannochloropsis* and T-ISO, also mainly using supercritical CO2, and incorporated to oils and capsules for human consumption. Special mention is the case of the production of docosahexaenoic acid (DHA) from *Schizochytrium* that is incorporated to infant milks in a high-value application (Enzing et al. 2014; Vigani et al., 2015).

Major concern about the incorporation of microalgae biomass to foods is related to EU regulation. In spite of largely reported advantages of microalgae biomass for human consumption, only the microalgae now generally recognized as safe (GRAS) can be sold for human consumption. These only include Chlorella, Spirulina, Dunaliella, and Haematococcus. Other microalgae must be registered as novel food. Anyway, independent of the strain to be produced, the overall production system must be approved for "food industry"; this certification involves the materials, systems, and protocols used during the production process. In this way, the involvement of food companies in the development of microalgae-based processes is mandatory.

4. LEGISLATION GOVERNING USE OF ALGAE IN OTHER COUNTRIES

Although "novel foods" are not defined in the **United States**, any new food ingredient is considered either as a food additive (requiring a pre-market approval by the U.S. Food and Drug Administration (FDA)) or are Generally Recognized as Safe (GRAS) for specific uses, which can be determined by consensus of a panel of qualified experts. Substances that are GRAS under conditions of their intended use are not food additives and do not require premarket approval by FDA. Thus, for a food additive, FDA determines the safety of the ingredient; whereas a determination that an ingredient is GRAS can be made by qualified experts outside of government. While GRAS notifications to the FDA are voluntary, a "no questions" response from FDA provides additional assurances of the regulatory status to end users of the ingredient and is useful in importing ingredients manufactured outside of the U.S. Typically, new (novel) food ingredients undergo a GRAS determination (FDA, 2014).

According to the classification of the Center for Food Safety and Applied Nutrition, algal biomass is classified as "other dietary supplement". *Spirulina, Chlorella, Dunaliella, Haematococcus, Schizochytrium, Phorphyridium cruentum* and *Crypthecodinium cohnii* are classified as food sources falling into the GRAS. Other products derived from microalgae classified by FDA as GRAS are oils obtained from *Schizochytrium* and *Ulkenia*, as well as a whole microalgal protein powder and a lipid ingredient derived from *Chlorella* (http://www.accessdata.fda.gov/scripts/fcn/fcnnavigation.cfm?rpt=eafuslisting).

As there is no legal distinction between "new" and other foods in the United States, U.S. exporters should always check with their EU importers, who are responsible for putting products that comply with EU legislation on the EU market, whether a novel food authorization may be needed.

In addition to the USA, other extra-European countries have specific regulations. For instance, **Food Standards Australia New Zealand** (FSANZ) regulates the use of novel food ingredients, such as products from microalgae. The FSANZ considers as novel food all non-traditional food or its derivatives and requires safety assessment. Novel foods and novel food ingredients are regulated under Standard 1.5.1 – Novel Foods in the Food Standards Code (https://www.legislation.gov.au/Details/F2017C00324).

A novel food cannot be sold as food or used as a food ingredient unless it is listed in the Standard.

Anyone wanting to sell a novel food or a novel food ingredient must apply to FSANZ to request that the Standard be amended to include the food or ingredient in the list. Novel food applications are subject to a pre-market safety assessment. If the food passes this assessment, it is added to the list in the Standard and the manufacturer can go ahead and sell it, as long as it complies with any specified conditions. According to the Food Standard Code, they have granted permission for using *Schizochytrium* as a dried marine microalga, which is rich in omega-3 long-chain polyunsaturated fatty acid (DHA), as a novel food ingredient in a limited range of foods.

In Canada, under the Food and Drugs Act and Regulations, novel foods are defined as foods/ingredients without a history of safe use as a food in Canada, are produced via novel processes, or have been modified by genetic manipulation. These novel foods require a pre-market assessment by Health Canada prior to being put on the market. Health Canada is advising consumers to apply caution when using non Spirulina cyanobacterial products. In addition, it does not allow therapeutic claims for substances sold as foods.

» Health Canada maintains a list of accepted novel foods.

» Consult Guidelines for the Safety Assessment of Novel Foods Derived from Plants and Microorganisms for information on the notification process and data requirements for a safety assessment

The EU, USA and Canada have broadly similar approaches to Australia and New Zealand in the regulation of novel foods, insofar as some form of pre-market safety assessment is required before these foods can be sold to consumers. However, the identification of these foods, the form of pre-market assessment, the level of

regulatory oversight and the legislated powers of regulators does vary between countries. FSANZ has highlighted aspects from the international approaches that may be of assistance in improving the regulation of novel foods in Australia and New Zealand.
In particular:

- A cut-off date (EU, USA) can provide an objective parameter to assist in identifying new foods and substances that require pre-market assessment. It is not currently included in the Australia New Zealand Food Standards Code;
- A demonstrated history of safe use of a food in other markets can provide a level of confidence in the assessment of safety of novel foods (EU, Canada);
- The proposed EU novel food regulation suggests an approach that results in generic approvals of novel foods can achieve a level of protection for industry derived safety data that differs from the current exclusive permission provision in Standard 1.5.1.

EXECUTIVE SUMMARY

- In the USA, Chlorella protothecoides, A. platensis, Dunaliella bardawil, and astaxanthin from Haematococcus are included in the GRAS list (FDA, GRAS Notices).
- In Australia, all Chlorella (including Chlorella sorokiniana) and Arthrospira species and derivatives for which a novel food application was submitted have been so far considered as traditional food, whereas A. flos-aquae was considered as novel food and safety assessment was required due to the potential presence of cyanobacterial toxins such as microcystins and nodularin (FSANZ 2016).

The regulation of novel food and ingredients in China are regulated according to the Administrative Measures for Safety Review of New Food Materials (2013). Novel foods, under the new regulation becomes “new food raw material” – encompass animal, plant, or micro-organisms or substances derived from these sources, food substances with structural changes, or newly developed food materials. Pre-market approval of novel food materials is conducted by the National Health and Family Planning Commission (NHFPC).

Similarly to EU, China has established a comparable system to regulate novel foods, which takes into account the specific situation in China where novel food material and health food are closely linked, given that certain traditional materials can be used for both food and medicine. In light of this, the general evolution of novel foods regulation in China is related to the development of the food industry and the longstanding food culture.
(Sun, 2015; https://food.chemlinked.com/node/2818).

5. OTHER MICROALGAE SPECIES OF INTEREST IN THE EU: WHICH AND WHY

Despite microalgae are considered a potential source of functional foods and nutraceuticals thanks to their valuable and balanced biochemical composition, their use as food /food ingredients is still poorly developed in EU due to high production cost, low demand and strict legislation. As repeatedly noted, the approved microalgae (and microalgal products) in EU represent a very small number of species compared to the high number present in nature (Guiry, 2012). Other species than those reported in Table 3 could be suitable ingredients in innovative functional foods and as nutraceuticals.

ALGAE	YEAR OF EU APPROVAL AS FOOD
Arthrospira platensis (spirulina)	Used prior to May 1997
Chlorella luteoviridis	Used prior to May 1997
Chlorella pyrenoidosa	Used prior to May 1997
Chlorella vulgaris	Used prior to May 1997
Aphanizomenon flos-aquae	Used prior to May 1997
Odontella aurita	2005
Ulkenia sp.	2009
Tetraselmis chuii	2014
Haematococcus pluvialis	2014
Schizochytrium sp.	2015

Table 3. Microalgae approved for food use in EU.

In this section we want to highlight why other microalgal species and species currently produced in Europe but sold elsewhere and their bioactive constituents should be permitted for sale within the EU. This for the benefit of European producers and consumers,

the European economy and the quality of microalgal production and products. Table 4 intended to be a non-exhaustive proposal of new microalgae species and products to be introduced in the European food.

MICROALGAE	BIOACTIVE COMPOUNDS
Arthrospira maxima *	Protein, Peptides, Phycocyanin, GLA
Chlorella protothecoides	
Dunaliella salina	
Dunaliella sp.	ß-carotene, Lipids
Euglena viridis	
Isochrysis sp.	DHA, Fucoxanthin, Phytosterols, Lipids
Nannochloropsis	EPA, ARA, Lipids
Pavlova lutheri	DHA+EPA, Fucoxanthin, Phytosterols, Lipids
Phaeodactylum tricornutum	EPA, Fucoxanthin, ß-glucan
Porphyridium purpureum	Polysaccharides, Phycoerythrin
Scenedesmus almeriensis	Lutein
Tetraselmis suecica	Protein, Vit. E
Trachydiscus sp.	EPA

Table 4. Proposed new algal species to be introduced in EU.

* only *A. platensis* is now accepted in EU. *A. maxima*, most widely distributed in Central America, was harvested from Texcoco lake and used as food. Its biochemical composition has been extensively investigated, showing similar nutritional profile. Moreover, in the 1970s and 1980s Sosa Texcoco Co. cultivated *A. maxima* in El Caracol in Lake Texcoco near Mexico City. So, it could be assimilated to "Traditional foods from third countries"

The starting point for future development of algae-based food ingredients and nutraceuticals is an accurate selection of the most suitable algal species, the evaluation of their biochemical composition, toxicity, digestibility and nutrient bioavailability for humans. Nutritional composition across algal species, strictly depends by geographical regions, seasons, and analytical procedures adopted. It is necessary to define a number of parameters to be evaluated and to develop standard methods (STANDARDS) for their determination. Digestion and bioavailability of algae matrices are currently little known and further insights and improvements are required (Batista et al., 2017; Wells et al., 2017).

INFORMATION REQUIRED FOR EVALUATION

The application dossier should provide all of the available (proprietary, confidential and published) scientific data (including both data in favor and not in favor) that are pertinent to the safety of the novel food produced by or with strain of algae. Data pertinent to the safety of the novel food should be generated and studies performed and documented in order to demonstrate that the application covers the totality of information available on the novel food on which a conclusion on the safety of the novel food should be based.

Information on the literature search strategy, including the sources used to retrieve pertinent data (databases, other sources), the terms and limits used (e.g. publication dates, publication types, languages, population) should be provided. Where applicable, the published literature should be reviewed by taking into account systematic review principles (EFSA, 2010). Full study reports should be provided if available.

To help the applicant to put a dossier for authorization of a novel food together, the Commission has put a website on the internet that can be used to electronically submit applications (https://ec.europa.eu/food/sites/food/files/safety/docs/fs_novel-food_e-submission-system_user- guide_en.pdf). EFSA has published an administrative guidance on the submission of applications for authorisation of a novel food pursuant to Article 10 of Regulation (EU) 2015/2283 (2018), in addition to a Guidance Document that spells out the information requirement for evaluation of the novel food dossier (EFSA, Panel on Nutrition, Dietetic Products and Allergies (NDA) et al., 2016.

» This guidance presents a common format for the organization of the information in order to assist applicants in the preparation of well-structured applications. In addition, it spells out in detail what information is necessary within all of the headings mentioned in the guidance, for the evaluation by EFSA and the eventual authorization by the Commission. The current document should therefore be used in conjunction with the EFSA guidance on novel foods; here the main aspects of the novel food for which the information should be provided is presented.

Adherence to the format of the EFSA guidance will facilitate easy access to information and scientific data in applications to help the NDA Panel of EFSA to carry out its evaluation and to deliver its scientific opinion in an effective and consistent way. The information requirements relate to the description of the novel food, the production process, the compositional data, the stability of the novel food over time, the specification, the proposed uses and use levels, and the anticipated intake of the novel food. Further sections on the history of use of the novel food and/or its source, absorption, distribution, metabolism, excretion, nutritional information, toxicological information, information on studies in humans and allergenicity should be considered by the applicant by default. If any of these aspects are not covered in the application, the reason for this should be given and the

rationale how to come to a conclusion on the safety of the novel food without that specific information should be justified by the applicant.

The applicant should integrate all the data presented in the different sections to provide their overall considerations on how the information supports the safety of the novel food under the proposed conditions of use. Where potential health hazards have been identified (e.g. on the basis of the composition of the novel food, its production process, its history of use, results from animal or human studies), they should be discussed in relation to the anticipated intakes of the novel food and the proposed target populations. A thorough estimation of the anticipated intake, and of the combined intake from the novel food and other sources, is an important piece of information to conclude on where or not a food would pose the target population at risk under the proposed conditions of use.

The questions that need to be answered are the following: whether the composition of the novel food and the conditions of its use do not pose a safety risk to human health in the Union; whether the novel food concerned is as safe as food from a comparable food category already existing on the market within the Union; and whether a novel food, which is intended to replace another food, does not differ from that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer.

To help the applicant submit a dossier for traditional foods, EFSA has published a guidance on the preparation and presentation of the notification and application for authorisation of traditional foods from third countries (NDA et al., 2016). The information that is required for this evaluation comprises compositional data, and 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 intake from the novel food and other sources, is an important piece of information to conclude on where or not a food would pose the target population at risk under the proposed conditions of use.

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In order to conclude on the safety of a novel food, a clear estimation of the anticipated intake under the conditions of use is crucial for prediction of the anticipated intake, preferentially EU wide data bases are used, rather than national databases. In case a national data base is used, the reason for this should be justified, while in addition a rationale should be provided why the calculations would be of relevance for the European population.

Within EFSA there is the Comprehensive Food consumption Database can be used; summary statistics of food consumption are available on the EFSA website in the form of spreadsheets. Detailed information on the database and guidance on its use have been published by EFSA (EFSA, 2011). Anticipated daily intakes for mean and high-percentile consumers can be calculated through the combination of the intended use level in each food category with mean and high chronic consumption values from the database, respectively.

The use of the EFSA Food Additive Intake Model (FAIM) tool (which is also based on summary statistics of the EFSA Comprehensive Food Consumption Database) may serve as an appropriate alternative. The FAIM tool was developed to support the calculation of chronic exposure to food additives in the regulatory framework of food additives Regulation (EU) 1333/2008.

Exposure assessment of food additives and intake assessment of novel food ingredients share common principles. Thus, the FAIM tool may be used by applicants for the intake assessment of novel. The intake estimation depends to a large extent on the uses and conditions of use of the novel food. These conditions should therefore be chosen so, that they would not pose any risk to the target population. In addition, they should be chosen in a realistic manner, i.e. it should be considered that restrictions of use could realistically be adhered to.

For all aspects to be covered in the application dossier counts that if the dossier presents the data in biased way, credibility of the submission is affected, and hence the dossier is definitively not a one.

As indicated in the earlier paragraphs, a good dossier on products derived from algae cell culture should have detailed information on the history of safe food use in a third country, which should be confirmed by compositional data and experience of continued use for at least 25 years in the customary diet of a significant number of people in at least one third country.

The information requirements for evaluation of notifications for traditional foods pertain to compositional data, the extent of consumption of the traditional food in a non-EU country or countries, and the information on safe use.

CONFIDENTIALITY

Applicants may request confidential treatment of certain information submitted under the Novel Food Regulation where disclosure of such information may harm their competitive position. In their application for confidentiality, applicants shall indicate which parts of the information provided they wish to be treated as confidential and provide all the necessary and verifiable information to substantiate their request for confidentiality. The Commission will then examine the submitted information and inform the applicant of its position.

After being informed of the Commission's position on the request, applicants may withdraw their application within three weeks, during which the confidentiality of the information provided shall be observed. After expiry of the 3 week period and if the applicant has not withdrawn the application, and in case of disagreement, the Commission shall decide which parts of the information are to remain confidential and, in case a decision has been taken, notify the Member States and the applicant accordingly.

Confidentiality shall not apply to the following information: (a) the name and address of the applicant; (b) the name and description of the novel food; (c) the proposed conditions of use of the novel food; (d) a summary of the studies submitted by the applicant; (e) the results of the studies carried out to demonstrate the safety of the food; (f) where appropriate, the analysis method(s); (g) any prohibition or restriction imposed in respect of the food by a third country.

DATA PROTECTION

Under the Novel Food Regulation (Article 26) the applicant may request that newly developed scientific evidence or scientific data supporting the application shall not be used for the benefit of a subsequent application during a period of five years from the date of the authorisation of the novel food without the agreement of the initial applicant. In that case the applicant needs to submit in the application appropriate and verifiable information supporting the data protection request.

Data protection is granted by the Commission (Article 27(1) of the Novel Food Regulation) where the following conditions are met: (a) the newly developed scientific evidence or scientific data was designated as proprietary by the initial applicant at the time the first application was made; (b) the initial applicant had exclusive right of reference to the proprietary scientific evidence or scientific data at the time the first application was made; and (c) the novel food could not have been assessed by the Authority and authorised without the submission of the proprietary scientific evidence or scientific data by the initial applicant. However, the initial applicant may agree with a subsequent applicant that such scientific evidence and scientific data may be used. Data protection is not applicable to traditional foods from third countries.

RECOMMENDATIONS

The following general recommendations will help a potential Novel Food applicant:

1. Contract the services of a consultancy company or regulatory experts in the field of Novel Foods;
2. Contact the Member State Novel Foods contact point before evaluating a Novel Food dossier preparation. Further checks will determine whether the novel food falls under Novel Foods regulation or not;
3. Make a good characterization of the Novel Food;
4. Before starting the application process, evaluate the Application budget and the novel food safety dossier budget.

As a general information the cost of consultancy may range from 50.000 € to 200.000 €, depending on the service provider. It may also be very helpful to consider indicative prices per batch of some of the most relevant toxicity assays:

TOXICITY ASSAY	APROX. COST (EURO)	LEAD TIME (WEEKS)
In vitro micronucleus assay OECD/GLP standard	41.250	4
Ames GLP	3.650-4.500	12
In vitro chromosomal aberration	9.031	10
Sub chronic toxicity OECD/GLP	91.300-172.652	40
Acute toxicity	780-1.100	4
Alergenicity	25.000-45.000	4

When considering a tentative budget applicant must have in mind the number of batches used per assay.
Algae derived novel foods have been approved since 1997, these examples may be useful for future applicants (EFSA 2006, 2014).

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DISCLAIMER

This report on "Algae as sources for Novel Foods – EABA White Paper", (2020nov27)" has been drafted by Dr. Graziella Chini-Zittelli (IBE-CNR), Mr. Carlos Unamunzaga (Fitoplancton Marino), Mr. Silvio Mangini (Archimede Ricerche), Dr Jean-Paul Cadoret (EABA President) and Dr Vitor Verdelho (A4F / EABA General Manager) on behalf of EABA. The information and conclusions in this report should not be treated as binding on the individuals, companies and organisations involved. The positions and recommendations listed hereafter do not necessarily reflect the official position either of the EABA or of the Organizations involved. The EABA does not guarantee the accuracy of the status included in this report and by no means should they be considered as official recommendations. Neither the EABA nor any person acting on the EABA, or the Organizations represented may be held responsible for the use which may be made of the information contained herein. The individuals concerned have offered their views in a personal capacity.

Questions and Answers about 'Algae Novel Foods in EU

Some key questions and straightforward answers to specific questions, in the view of EABA experts.

Algae are a crop?
Yes, algae are new crops, food and nutraceutical sources.

Why are you talking about new foods?
Need to Find Innovative Resources for a more Sustainable, Safe and Nutritious feeding.

Algae are Novel Food ?
Yes, if not consumed to any significant degree in the EU prior to May 1997 (when the first Novel Foods legislation entered into force).

GMO algae are Novel Food?
No GMOs have separate legislation (Regulation EC 1829/2003).

Traditional algae widely consumed as food in third countries are "new foods" in Europe?
Yes, algae fermentation and algae biomass transformation are industry, the secondary sector.

Why is the EU Commission revising the legislation for novel foods?
To increase the efficiency of the authorisation procedure, enable a quicker delivery of safe, innovative food to the market and remove unnecessary barriers to trade, while still ensuring food safety.

What are the main changes being introduced?
Centralised authorisation system (EU); EFSA responsible for carrying out the risk assessment on the novel food applications; data protection provisions; simpler procedure for traditional foods from third countries with demonstrated history of safe use.

What are the requirements for a novel food to be authorised for use inthe EU?
Do not present a danger to public health, are not nutritionally disadvantageous when replacing a similar food and are not misleading to the consumer. They must undergo a scientific assessment prior to authorization.

Are there any Algae novel food applications in the pipeline at the moment?
Any applications not finalised under the current rules by 1 January 2018 (when the new regulation comes into effect) will be decided under the new regulation.
An example of pending applications is the marine "Nannochloropsis gaditana" as food ingredients.

Can Member States ban / approve a novel food independently of the reasons?
No. Once a foodstuff is approved for marketing in the EU, it can be sold in any Member State. If a food is found to pose any risk to consumers, the Commission can immediately suspend its authorisation for marketing in the EU.

Phycocyanin from Spirulina and other algae is novel food?
Spirulina water extract is a coloring food according to French legislation (Cons Hyg France 1986) and in compliance with technical requirements described in JRC report about classification of extracts/ concentrates with coloring properties either as food colors or coloring foods (JRC 2015)
Pure Phycocyanin is not reported in the positive list of food colors (Additives, Reg. (EC) 1333/2008), is not in the current Union List nor in the Novel Foods Catalog, therefore could be considered a Novel Food.

***Dunaliella* (or ß-carotene from *Dunaliella*) requires novel food status even if is consumed in Japan for more than 20 years?**
Yes because not significantly used in EU before 1997. An applicant can require authorization as "traditional foods from third countries" producing all data necessary to demonstrate its safe use.

EU microalgae world to face more constraints than American or Eastern?
Yes. Major challenges: unfavorable climatic conditions for low-cost extensive production; insufficient domestic demand and the complexity of the EU Novel Food regulation.

Is the EU regulation more severe and restrictive than US (GRAS) one?
Compared to US, European regulations are more stringent or precautionary. As there is no legal distinction between "novel" and other foods in the United States, exporters may be unaware that a food which is currently lawfully marketed in the US may fall within one of the new categories established by Regulation 2015/2283.