

# Edible seaweed and microalgae - Regulatory status in France and Europe 2019 update

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## 1. Food-grade algae in France

France was the first European country to establish a specific evaluation of the use of seaweeds for human consumption as non-traditional food substances.

From 1990, several opinions of the French Superior Council for Public Health paved the way for edible seaweed. They were followed by assessments of history of consumption to a significant degree before May 15<sup>th</sup> 1997, the date at which the European Novel Food Regulation was enforced (CSHPF 01/1990, 02/1992, 10/1997; DGCCRF 04/2009).

The marine microalga *Odontella aurita* also received a positive opinion from EFSA regarding its use as a food ingredient (condiment in finished products) and was authorized on the basis of its substantial equivalence with other authorized edible seaweed under regulation (CE) n° 258/97 (AFSSA 2002; DGCCRF 04/2009).

In France, 25 algae species of which 3 microalgae, were listed so far as food (vegetables or condiments). Among the macroalgae, 9 brown seaweed species, 11 red seaweed species and 2 green seaweed species are listed.

**Table 1 : Algae listed for food consumption in France**

Scientific name	Common name
<ul style="list-style-type: none"> <li>• <b>Brown seaweed</b></li> <li>- <i>Ascophyllum nodosum</i></li> <li>- <i>Fucus vesiculosus</i></li> <li>- <i>Fucus serratus</i></li> <li>- <i>Himantalia elongata</i></li> <li>- <i>Undaria pinnatifida</i></li> <li>- <i>Laminaria digitata</i></li> <li>- <i>Laminaria saccharina</i></li> <li>- <i>Laminaria japonica</i></li> <li>- <i>Alaria esculenta</i></li> </ul>	<ul style="list-style-type: none"> <li>Sea Spaghetti</li> <li>Wakame</li> <li>Kombu</li> <li>Royal Kombu</li> <li>Kombu</li> <li>Atlantic wakame</li> </ul>
<ul style="list-style-type: none"> <li>• <b>Red seaweed</b></li> <li>- <i>Palmaria palmata</i></li> <li>- <i>Porphyra umbilicalis</i></li> <li>- <i>Porphyra tenera</i></li> <li>- <i>Porphyra yezoensis</i></li> <li>- <i>Porphyra dioica</i></li> <li>- <i>Porphyra purpurea</i></li> <li>- <i>Porphyra laciniata</i></li> <li>- <i>Porphyra leucostica</i></li> <li>- <i>Chondrus crispus</i></li> <li>- <i>Gracilaria verrucosa</i></li> <li>- <i>Lithothamnium calcareum</i></li> </ul>	<ul style="list-style-type: none"> <li>Dulse</li> <li>Nori</li> <li>"</li> <li>"</li> <li>"</li> <li>"</li> <li>"</li> <li>"</li> <li>"</li> <li>Pioca, lichen</li> <li>Ogonori</li> <li>Mäerl</li> </ul>
<ul style="list-style-type: none"> <li>• <b>Green seaweed</b></li> <li>- <i>Ulva sp.</i></li> <li>- <i>Enteromorpha sp.</i></li> </ul>	<ul style="list-style-type: none"> <li>Sea lettuce</li> <li>Aonori</li> </ul>
<ul style="list-style-type: none"> <li>• <b>Microalgae</b></li> <li>- <i>Spirulina sp.</i></li> <li>- <i>Odontella aurita</i></li> <li>- <i>Chlorella sp.</i></li> </ul>	

It shall be noted that several of the listed species have undergone taxonomic revisions since the publication of the opinions. An updated list, with valid taxons, is available in the synthetic tables at the end of the document.

## 2. Requirements for algae commercialization

The algae brought to the market have to fulfill a number of criteria related to heavy metals and iodine, which are summarized in the table below (CSHPF 01/1990; AFSSA 04/2009; European Commission 07/2008):

**Table 2 : Maximum levels of iodine and heavy metals authorized in algae**

	<b>Algae (vegetables or condiments)</b> mg per kg (dry weight)
Inorganic Arsenic ( $As_i$ )	3
Cadmium (Cd)	0,5
Mercury (Hg)	0,1
Lead (Pb)	5
Tin (Sn)	5
Iodine (I)	2 000

Note : For food supplements consisting exclusively or mainly of dried seaweed or of products derived from seaweed, the maximum allowed level of cadmium is set at 3.0 mg/kg in the European Regulation n°629/2008 (European Commission 07/2008), in order to take into account naturally occurring cadmium levels in seaweed.

Historically, recommendations were also published for microbiological quality of packaged dried algae, which had to fulfill the following criteria (CSHPF 01/1990; BID 1987):

**Table 3 : Microbiological criteria for dried algae**

Mesophilic aerobic germs	$\leq 10^5$ / gram
Faecal coliforms	$\leq 10$ / gram
Anaerobic sulfite-reducing bacteria	$\leq 10^2$ / gram
<i>Staphylococcus aureus</i>	$\leq 10^2$ / gram
<i>Clostridium perfringens</i>	$\leq 1$ / gram
<i>Salmonella</i>	absence in 25 grams

The reform of the European regulations on food hygiene, known as the “Hygiene Package”, came into force on 1 January 2006. It simplified and harmonised the legislation applicable in the European Union (European Commission 04/2004). Its aim is to harmonise and improve the level of food safety “from farm to fork” by involving all stakeholders in the food chain and subjecting them to the same requirements.

Nevertheless, no specific criteria were set for algae at the European level, or during implementation in France. One can still mention the maximum limit for *Listeria monocytogenes* introduced for all food products by Regulation n°2073/2005 (European Commission 11/2005).

### 3. Food supplements

For food supplements, the ministerial order of June 24th 2014, known as « Arrêté Plantes » establishes a list of plant and mushrooms which are allowed in food supplements, as well as their conditions of use. It includes a number of algae (JORF 06/2014):

- 8 of the listed algae species were not present in the food species list mentioned previously (circled in blue in the table below).
- Inversely, 9 seaweed species from the food species list are not included in the « Arrêté Plantes »

**Table 4 : Algae species listed in the “Arrêté Plantes”**

Macro/Micro	NOM SCIENTIFIQUE
Macro	Ascophyllum nodosum
Macro	Chondrus crispus
Macro	Fucus serratus
Macro	Fucus vesiculosus
Macro	Gelidium corneum
Macro	Gracilaria gracilis
Macro	Himanthalia elongata
Macro	Laminaria digitata
Macro	Laminaria hyperborea
Macro	Macrocystis pyrifera
Macro	Mastocarpus stellatus
Macro	Palmaria palmata
Macro	Phymatolithon calcareum
Macro	Porphyra umbilicalis
Macro	Saccharina japonica
Macro	Saccharina latissima
Macro	Sargassum fusiforme
Macro	Ulva lactuca
Macro	Undaria pinnatifida
Micro	Aphanizomenon flos aquae
Micro	Chlorella vulgaris
Micro	Dunaliella salina (Dunal) Teodoresco
Micro	Haematococcus pluvialis Flotow
Micro	Spirulina major
Micro	Spirulina maxima
Micro	Spirulina platensis

In January 2019, French DGCCRF (General Directorate for Competition Policy, Consumer Affairs and Fraud Control) published a list of over 50 algae species which can be used in food supplements, on the basis of their traditional consumption or their authorization under the Mutual Recognition Principle as outlined in Article 16 of the Food supplements Decree n°2006-352 (JORF 05/2006; DGCCRF 2019a).

The presence of an algae in this « Liste Algues » does not preclude the safety of use of the preparations including it, which remain the responsibility of the operator. Specific sanitary recommendations can also be included for some of them (DGCCRF 2019b).

These two lists (« Arrêté Plantes » and « Liste Algues ») are compiled in the synthetic tables at the end of the document.

## 4. European situation

There is no harmonized seaweed/algae regulation in Europe.

The suitability of an algae for human food consumption is governed by the so-called “Novel Food” Regulation (Regulation (UE) 2015/2283), which applies to food and ingredients which were not consumed consumption to a significant degree in Europe before May 15<sup>th</sup> 1997.

### a. Algae that underwent a Novel Food assessment procedure

As mentioned previously, the use of the microalga *Odontella aurita* as condiment in finished products was authorized on the basis of its substantial equivalence with edible seaweed according to Regulation (CE) n° 258/97.

Another microalga, *Tetraselmis chuii*, was the object of a Novel Food dossier submitted to the Spanish authorities under the framework of Regulation (CE) n° 258/97. An authorization to commercialize it in sauces, special salts and condiments was notified to the company Fitoplancton Marino S.L. in March 2014 (AECOSAN 2014). This authorization was then subject to an extension of use in the field of food supplements in 2017 (AECOSAN 2017). The company Green Sea Bio System One S.L. also recently submitted a request to the EC to extend the product specifications (NF 2019/1062 (EFSA 2019a)).

Two other microalgae species are also undergoing Novel Food evaluation: a dossier was submitted to the Spanish authorities in 2011 for *Nannochloropsis gaditana* and, more recently, a dossier was submitted for *Euglena gracilis* (NF 2018/0669 (EFSA 2018a)).

### b. Novel Food ingredients extracted from algae

#### Microalgae extracts

In 2003, DHA-rich (>32%) oil from *Schizochytrium sp.* received an authorization to be placed on the market under Regulation (CE) n° 258/97 (European Commission 06/2003). Several dossiers for extension of use as well as new authorizations were subsequently submitted and accepted (European Commission 10/2009b, 07/2014, 07/2018, 03/2019), as well as several dossiers for substantial equivalence. A number of other dossiers from various suppliers are also pending for authorization as novel food or for extensions of use in vegetable and fruit purees, and infant nutrition (dossiers NF 2019/1213, NF 2019/1046 (EFSA 2019b), NF 2019/0983, NF 2019/0825, NF 2018/0576 (EFSA 2018e), NF 2018/0575 (EFSA 2018f)).

Another oil from *Schizochytrium sp.*, with high contents in DHA (>22%) and EPA (>10%) also received an authorization to be placed on the market under Regulation (CE) n° 258/97 (European Commission 06/2003) and a subsequent extension of use (European Commission 03/2015).

DHA-rich (>32%) oil from *Ulkenia sp.* was also the object of a substantial equivalence dossier in 2003 (equivalent to DHA-rich oil from *Schizochytrium sp.*). It was approved by the German authorities and subsequently received an extension of use for bakery, cereal bars and juices (European Commission 10/2009a).

An additional request from Simris Alg was also submitted for an EPA-rich oil from *Phaeodactylum tricornutum*, with a positive opinion of Irish FSAI on the ingredient's safety, and a Novel Food request still being reviewed (NF 2018/0207 (EFSA 2018b)). And more recently, Microphyt filed a request for an extract of *Phaeodactylum tricornutum* with a standardized fucoxanthin content (NF 2018/0626 (EFSA 2018c)).

Lastly, in an opinion published in 2004, UK Advisory Committee on Novel Foods and Processes (ACNFP) acknowledges the substantial equivalence of an oleoresin extracted from *Haematococcus pluvialis* with the whole algae meal (UK Food Standards Agency - Advisory Committee on Novel Foods and Processes (ACNFP) 2004). It is worth noting that, although ACNFP opinion establishes that *Haematococcus pluvialis* was commercialized as food supplement in Europe since at least 1995, it is currently not listed in the Novel Food catalogue.

Several additional "substantial equivalence" dossiers related to extracts of the same algae were submitted and accepted (for the same usage as food supplement only). They relate to oleoresins obtained via different extraction processes (supercritical CO<sub>2</sub>, solvents, ...). These oleoresins appear under the designation « Astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae » in the Union List of authorized novel foods (European Commission 12/2017), and can be labeled as « astaxanthin ».

However, requests for extension of use in food categories (dairy, drinks) were rejected.

### **Seaweed extracts**

Commission Implementing Regulation (UE) 2018/460 authorizes the placing on the market of *Ecklonia cava* phlorotannins as novel food for use in food supplements (European Commission 03/2018).

Fuoidan extracts from *Fucus vesiculosus* and *Undaria pinnatifida* are also authorized in food and food supplements (European Commission 12/2017).

Lastly, a dossier filed by par Islenska Saltbrennslan in Iceland is currently under evaluation for ash produced from the brown algae *Laminaria digitata* as a novel food (NF 2018/0728 (EFSA 2018d)).

### **c. The Novel Food Catalogue**

The Novel Food Catalogue lists products of animal and plant origin and other substances, whose history of consumption and status with regards to the Novel Food Regulation, were evaluated by EU Member States. It is available here:

[http://ec.europa.eu/food/safety/novel\\_food/catalogue/search/public/index.cfm](http://ec.europa.eu/food/safety/novel_food/catalogue/search/public/index.cfm)

It is a non-exhaustive list, based on information provided by the Member States, and serves as orientation on whether a product will need an authorization under the Novel Food Regulation. EU

countries may still restrict the marketing of a product through specific legislation. For information, businesses should address their national authorities.

The catalogue is regularly updated and the algae listed up to date are compiled in the synthetic tables below. It should be noted that some algae species listed as “Not Novel” in the catalogue, do not appear on the French list of edible species.

## **5. Conclusion - Summary tables**

As illustrated in this review, the use of edible seaweed and microalgae is still governed by several European and national regulations and guidances (Novel Food, food supplements, ...).

It is necessary to combine these sources to provide a list of algae and algae-derived ingredients authorized for food applications in Europe. This is what we propose to do in the following tables.

This list is not exhaustive, and will keep evolving over time when Member States share national lists, or following the introduction of new Novel Food requests.





## Brown seaweed

Scientific name	France	France	Europe	Europe	Europe
	CSHPF opinions, DGCCRF	"Arrêté plantes", DGCCRF "Liste algues"	Novel Food Catalogue : "not novel"	Novel Food dossier	Novel Food dossier
	Food	Food supplements	Food	Food / Food supplements	Extracts
<i>Ascophyllum nodosum</i> (= <i>Ascophyllum laevigata</i> )	x	x	x		
<i>Alaria esculenta</i>	x	x	x		
<i>Durvillaea antarctica</i>		x			
<i>Ecklonia cava</i>					Phlorotannins
<i>Eisenia bicyclis</i>		x	x		
<i>Fucus vesiculosus</i>	x	x	x		Fucoïdan
<i>Fucus serratus</i>	x	x	x		
<i>Fucus spiralis</i>			x		
<i>Himantalia elongata</i>	x	x	x		
<i>Laminaria digitata</i>	x	x	x		
<i>Laminaria hyperborea</i>		x			
<i>Laminaria palmata</i>		x			
<i>Macrocystis pyrifera</i>		x			
<i>Padina pavonica</i>		x			
( <i>Laminaria japonica</i> ) <i>Saccharina japonica</i>	x	x	x		
( <i>Laminaria saccharina</i> ) <i>Saccharina latissima</i>	x	x	x		
( <i>Laminaria longicuris</i> ) <i>Saccharina longicuris</i>		x	x		
<i>Sargassum fusiforme</i> (= <i>Hizikia fusiformis</i> )		x	x		
<i>Undaria pinnatifida</i>	x	x	x		Fucoïdan

Valid taxon in bold – names in brackets represent the designation in the original document cited





## Green seaweed

Scientific name	France	France	Europe	Europe	Europe
	CSHPPF opinions, DGCCRF	"Arrêté plantes", DGCCRF "Liste algues"	Novel Food Catalogue : "not novel"	Novel Food dossier	Novel Food dossier
	Food	Food supplements	Food	Food / Food supplements	Extracts
<i>Ulva sp.</i>	x				
<b><i>Ulva lactuca</i></b>		x	x		
( <i>Enteromorpha sp</i> ) <b><i>Ulva sp.</i></b>	x		x		
( <i>Enteromorpha intestinalis</i> ) <b><i>Ulva intestinalis</i></b>		x			

Valid taxon in bold – names in brackets represent the designation in the original document cited



## Red seaweed

Scientific name	France	France	Europe	Europe	Europe
	CSHPF opinions, DGCCRF	"Arrêté plantes", DGCCRF "Liste algues"	Novel Food Catalogue : "not novel"	Novel Food dossier	Novel Food dossier
	Food	Food supplements	Food	Food / Food supplements	Extracts
<i>Alsidium helminthochorton</i>		X			
<i>Chondrus crispus</i>	X	X	X		
<i>Corallina officinalis</i>		X			
<i>Euchemia horridum</i>		X			
<i>Euchemia denticulatum</i>		X			
<i>Euchemia spinosum</i>		X			
<i>Gelidium corneum</i>		X			
<i>Gelidium amansii</i>		X			
<i>Gelidium sesquipedale</i>		X			
<i>Gracilaria gracilis</i>		X			
<i>Gracilaria verrucosa</i>	X		X		
<i>Gracilariopsis longissima</i>		X			
<i>Mastocarpus stellatus</i>		X			
<i>(Rhodymenia palmata) Palmaria palmata</i>	X	X	X		
<i>Porphyra umbilicalis</i>	X	X			
<i>(Porphyra tenera) Pyropia tenera</i>	X	X	X		
<i>(Porphyra yezoensis) Pyropia yezoensis</i>	X	X			
<i>Porphyra dioica</i>	X	X			
<i>Porphyra purpurea</i>	X	X			
<i>Porphyra laciniata (= Erythrogllossum laciniatum)</i>	X	X			
<i>(Porphyra leucosticta) Pyropia leucosticta</i>	X	X			
<i>(Lithothamnion calcareum) Phymatolithon calcareum</i>	X	X	X		

Valid taxon in bold – names in brackets represent the designation in the original document cited



## Microalgae

Scientific name	France	France	Europe	Europe	Europe
	CSHPF opinions, DGCCRF	"Arrêté plantes", DGCCRF "Liste algues"	Novel Food Catalogue : "not novel"	Novel Food dossier	Novel Food dossier
	Food	Food supplements	Food	Food / Food supplements	Extracts
<i>Aphanizomenon flos aquae</i>		X	X		
( <i>Spirulina</i> sp) <i>Arthrospira</i> sp	X		X		
<i>Arthrospira fusiformis</i>					
<i>Arthrospira indica</i> (= <i>Limnospira indica</i> )		X			
( <i>Spirulina major</i> ) <i>Arthrospira major</i>		X			
<i>Arthrospira maxima</i>		X			
<i>Arthrospira platensis</i>		X	X		
<i>Chlorella</i> sp. *	X				
<i>Chlorella luteoviridis</i>			X		
<i>Chlorella pyrenoidosa</i>			X		
<i>Chlorella vulgaris</i>		X	X		
<i>Dunaliella salina</i>		X			
<i>Graesiella emersonii</i>		X			
<i>Haematococcus pluvialis</i>		X		X (supplements)	Oleoresin (supplements)
<i>Nannochloropsis oculata</i>		X			
<i>Odontella aurita</i>		X		X (condiment in finished products)	
<i>Scenedesmus vacuolatus</i>		X			
<i>Schizochytrium</i> sp.		X			Oil (specified categories and supplements)
<i>Tetraselmis chuii</i>				X (sauces,condiments + supplements)	
<i>Ulkenia</i> sp.		X			Oil (specified food categories)

\* Other species, whose taxonomy recently evolved, might have been placed on the market before 1997 under the designation "*Chlorella* sp": *Chlorella sorokiniana*, *Parachlorella kesleri*, *Auxenochlorella protothecoides*, *Auxenochlorella pyrenoidosa* or *Graesiella emersonii*,... (Champenois et al. 2015)



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