Food safety regulation and recommendations involving Algae and Algae based Products

EUROPEAN ALGAE BIOMASS ASSOCIATION

EU4Algae - Working Group 3

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CONTEXT

Algae biomass or algae based products are progressively entering a large variety of recipes and even staple diets when considering vegan or vegetarian communities. Several EU countries already have their national recommendations and regulations in terms of Food safety regarding algae, notably France which is advanced on the topic due to the historical and growing algae food industry in Brittany. However, maximum levels of certain contaminants allowed in algae for Food vary between countries, which creates confusion and in some cases threats in terms of competition. An official harmonised EU regulation can release these tensions which exist in the algae sector throughout the EU.

This document has the aim to bring forward the existing regulation on contaminants applied to any food product. In addition, complementary information is brought by certain countries already applying internal regulations or recommendations. Indeed, **algae biomass commercialised as food or food supplements must comply with all food product regulations with regards to contaminants**. Some contaminants are not specific to algae (general regulation), others are present in algae with levels which need to monitored. Algae as stated in the below tables is the term extracted from published documents and refers to all algae forms (microalgae and seaweed biomass) unless it is specifically indicated seaweed (notably for the iodine levels).

Contaminants are defined as “substances that have not been intentionally added to food” (EFSA, Codex) and “hazardous and/or undesired substance, material or organism that can result in physical, chemical and/or biological modifications of properties” (EN 17399). Food production processes can lead to substances entering the food at any moment: during manufacturing, handling, storage, processing or distribution. Contaminants can also enter the food from the environment. Most issues related to contamination are not algae-speciifc but common to all agrofood system, some contaminants however are typical of algae e.g. microcystins.

Contaminants can be grouped in three categories:

1. Physical contaminants, e.g. glass particles, plastics etc
2. Chemical contaminants, e.g. heavy metals, pesticide residues, dioxins, toxins (mycotoxins, phycotoxins), perchlorate, etc
3. Biological contaminants, e.g. bacteria, fungi, yeasts and moulds

NB:
Contaminants in food are managed according to their impact to human health. The firstIn the light of this perspective Maximum Levels (MLs) for specific contaminants are set by Codex and Regulatory Authorities e.g. EU. ML is the maximum content of a contaminant allowed in food to ensure global its safety. This is expressed in sub-units of kg of the contaminant per kg of food. This value is estimated by summarising all daily consumed products.
In certain cases, e.g. iodine, the same substance behaves as micronutrients that can have an impact on human health depending on their bioavailability. Certain minerals, such as iron and zinc, are essential nutrients that the body needs to function properly. However, consuming too much of these minerals can be harmful to health. Therefore, it is important to establish safe intake levels for these micronutrients to avoid potential toxicity.

A. Microbial contamination and biotoxin regulation

This section presents the official list of contaminants found in any food product (bacteria and toxins from mould occurring during preservation). A list of biotoxins produced by naturally occurring micro-algae species are specified in

the table. Some biotoxins are able to contaminate seaweed biomass when grown at sea. Terrestrial plant toxins (tropane alkaloids, hydrocyanic acid, pyrrolizidine alkaloids, opium alkaloids, TCH) were judged not relevant in terms of algae-based food and not added in the below table. Only erucic acid, an omega-9 fatty acid is found is certain microalgae species and detailed in section C. Organic contaminants.

Microbial contaminants and toxins	Maximum levels	Targeted product	Reference	Limits for algae as food (French regulation) *
Salmonella, Salmonella typhimurium and enteritidis	Absence in 25g of final product	Meat, dairy, egg, spouted seeds, precut fruits and vegetables and juices, live and cooked bivalves and crustaceans; Products placed on the market during their shelf-life	EUROPEAN COMMISSION REGULATION (EC) No 2073/2005 (1)	Absence in 25g of final dry product
Listeria monocytogenes	Absence in 25g of final product	All ready to eat foods. Products placed on the market during their shelf-life		nd
Escherichia coli	230 MPN/ 100 g of flesh and intervalvular liquid	Live molluscs, echinoderms, tunicates and gastropods placed on the market during their shelf life.		nd
Histamine	200 - 400 mg/kg	Fishery products from fish species associated with a high amount of histidine.		nd
Shiga toxin produced by *Escherichia coli*	Absence in 25g of final product	Sprouts, Products placed on the market during their shelf-life		nd
Aerobic mesophilic germs	nd			< 100 000 cfu / g DW
Faecal coliforms	nd			< 10 cfu / g DW
Sulphite reducing anaerobic bacteria	nd			< 100 cfu / g DW
Staphylococcus aureus	nd			< 100 cfu / g DW
Clostridium perfringens	nd			< 1 cfu / g DW
Cyanotoxins (2) produced by cyanobacteria blooms (environment)				
● Microcystins (MC) produced by *Microcystis, Aphanizomenon, Dolichospermum (ex Anabaena), Nostoc, Limnothrix, Phormidium, Oscillatoria, and Planktothrix)*	Provisional guideline 1µg /L (long term exposure) and 12µg/L (short term exposure)	Drinking water	- WHO Guidelines for Drinking-Water Quality: Geneva, Switzerland, 2003. - European Union Directive (EU). 2020/2184, EU (revised) Drinking Water Directive	Preparations of Aphanizomenon flos-aquae are only authorised if it can be demonstrated by analytical reports that they do not contain microcystin (< 1g/g) and other marine toxins (Arreté du 24 Juin 2014)
● Anatoxin-a (ANTX) produced by *Dolichospermum, Oscillatoria, Cylindrospermum, and Aphanizomenon*	30µg/L (short term exposure)			
● Saxitoxin (STX) produced by *Dolichospermum, Aphanizomenon, Cylindrospermopsis, Lyngbya, Planktothrix, Raphidiopsis, Fischerella, Geitlerinema and Scytonema*	3 µg/L (short term exposure)			
● Cylindrospermin (CYN) produced by *Cylindrospermopsis, Aphanizomenon, Dolichospermum, Lyngbya, Rhadiopsis, Planktothrix, and Umezakia*	0.7 µg/L ((long term exposure) and 3 µg/L (short term exposure)			
● Nodularins (NODs)	nd	nd	nd	

produced by *Nodularia spumigena* and *Nodularia sphaerocarpa*				
Biotoxins from Dinoflagellates				
Brevetoxins (BTX) from *Karenia brevis* formerly *Gymnodinium breve* and *Ptychodiscus brevis* (cause neurotoxic shellfish poisoning)	200 mouse units (MU^3)/kg	Shellfish or fish (meat) Shellfish (meat)	International Food Regulation Standard CODEXSTAN 292–2008. ● No EU regulation ● US, Australia/New Zealand and Mexico apply a threshold of 800 µg /kg ● ANSES guidance level of 180 µg BTX-3 eq./kg	
Yessotoxins (cause gastrointestinal symptoms)	3.75 µg/kg		COMMISSION REGULATION (EU) No 786/2013 amending (EC) No 853/2004	
Pectenotoxins (cause diarrhetic shellfish poisoning)	160 mg/kg		COMMISSION REGULATION (EU) No 853/2004	
Okadaic acid (cause diarrhetic shellfish poisoning)	160 mg/kg			
Azaspiracids from *Azadinium spinosum* (cause gastrointestinal symptoms)	160 mg/kg			
Gymnodimines from *Alexandrium ostenfeldii and Karenia selliformis* (cause diarrhetic shellfish poisoning)			Not found	
Ciguatoxins (cause ciguatera fish poisoning)			Not found	
Saxitoxin			Not found	
Mycotoxins produced during storage				
Patulin (produced by molds)	10-50 µg/kg	Fruit juices, spirit drinks and baby food.	EUROPEAN COMMISSION REGULATION (EU) 2023/915	
Ochratoxin A	0.5-80 µg/kg	Unprocessed and processed cereals, vine fruits (dried and juice), roasted coffee beans, soluble coffee, dietary foods, spices, liquorice, wheat gluten.		
Deoxynivalenol:	200-1750 µg/kg	Unprocessed cereals, Patsa, bread, maize, processed cereals and maize based products		
Citrinin:	100 µg/kg	Fermented rice with red yeast food supplements		
Fumonisins:	200-4000 µg/kg	Unprocessed and processed maize based food products.		
Zearalenone:	20-400 µg/kg	Unprocessed cereals, bread, maize oil,		
Aflatoxins (sum)	4-15 µg/kg	Cereals, nuts, oilseed, dried fruit, maize, rice, processed cereals and dairy based foods		

(1) EC regulation COMMISSION REGULATION (EC) No 2073/2005 describes general microbiological food safety criteria for foodstuffs. Micro-organisms means bacteria, viruses, yeasts, moulds, algae, parasitic protozoa, microscopic parasitic helminths, and their toxins and metabolites. Food safety criterion means a criterion defining the acceptability of a product or a batch of foodstuff applicable to products placed on the market.

(2) Cyanotoxins and Food Contamination in Developing Countries: Review of Their Types, Toxicity, Analysis, Occurrence and Mitigation Strategies. *Toxins* 2021, *13*(11), 786; https://doi.org/10.3390/toxins13110786

(3) The mouse bioassay is an analytical method used to detect marine biotoxins in shellfish. A mouse unit (MU) is the amount of raw extract required to kill 50% of mice.

B. Inorganic contamination regulation including algae specificities

The content of some inorganic contaminants is found to be specific to certain algae species. Notably, Arsenic and Iodine content in brown seaweed have been under the light due to inherent levels which can be found beyond health regulation thresholds.

Inorganic contaminants	Maximum levels	Targeted product	Reference	Limits for algae as food (French recommendation) *
Metals				
Mercury Hg	0.1 - 1 mg/kg	Fish, meat, food supplements	EUROPEAN COMMISSION REGULATION (EU) 2023/915	0.1 mg/kg DW
Inorganic tin Sn^2 When tin is combined with chlorine, sulphur, or oxygen, it is called an inorganic tin.	50 - 200 mg/kg	Canned foods and beverages		5 mg/kg DW of Tin
Cadmium Cd	3 mg/kg for algae food supplements (consisting of at least 80% dried seaweed inclusion)	Vegetables, fruits, cereal grains, fungi, chocolate, meat, fish, molluscs, crustaceans, food supplements		0.35 mg/kg DW (1)
Lead Pb^{2+}	0.02 - 3 mg/kg	Milk, met, fish, molluscs, crustaceans, vegetables, cereals, wine, food supplements		5 mg/kg DW
Arsenic (inorganic)	0.03-0.5 mg/kg	Cereals, rice, juices, salt		3 mg/kg DW (2)
Arsenic (total) As_2O_3 and As_2O_5	0.5 mg/kg	Salt but level applied to all food stuff		nd
Nickel Ni^{2+} (3)	2.8 µg/kg	nd	nd	nd
Other inorganic contaminants				
Iodine (metaloid) elemental diatomic iodine (I2) and ionic monoatomic iodide (I-)	20 mg/kg DW	Dried algae	COMMISSION RECOMMENDATION (EU) 2018/464 of 19 March 2018. Levels extracted from the Scientific committee for food in 2006	2 000 mg/kg DW (4)
Nitrate NO_{3-}	200-7000 mg/kg	Spinach, lettuce, processed foods	EUROPEAN COMMISSION REGULATION (EU) 2023/915	nd
Perchlorate	0.05-0.75 mg/kg	Fruits and vegetable, herbs, Tea, dried herbal and fruit infusions, processed cereal based food.		nd

* French regulation : AVIS de l'Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail relatif au risque d'excès d'apport en iode lié à la consommation d'algues dans les denrées alimentaire. Saisine 2017-SA 0086. Link in French

(1) Cadmium in Algae
Results from an EU-Regional funded project named QUALITALG assessing the content of heavy metals and Iodine in a large selection of harvested seaweed in Britany has been provided to the French National Agency of Food Security (ANSES) as well as the EFSA in the scope of revising the current legislation. The request involves not only cadmium but also inorganic arsenic and mercury. From this study, a paper published in May 2023, specifies this request for revision with new recommended values of 1 mg/kg dw for cadmium, 10 mg/kg dw for inorganic arsenic, and 0.3 mg/kg dw for mercury (Ficheux et al., 2023).

(2) Arsenic in Algae

Certain algae species naturally bio-accumulate Arsenic to levels which do not comply with regulation. Arsenic in Algae can be found under organic forms (generally called arseno-sugars) and under inorganic form. Arsenic, only in its inorganic form, is a carcinogen and the consumption of food is the primary source of arsenic exposure for the general public. Inorganic arsenic levels in algae can reach roughly 0.3 mg/kg DW algae, while the total organic arsenic reaches up to more than 50 mg/kg DW mainly in Laminaria type species (brown seaweed)

Rice is also known to accumulate high concentrations of arsenic (As) and its consumption can be a vector of exposure to inorganic arsenic. The present regulation is based on rice food stuff and stipulates a threshold of 0.1 mg of inorganic arsenic/kg for rice intended to be used for the production of food products. Well known cooking practices of rice can reduce the proportion of inorganic arsenic in algae too (paraboiling for 5minutes, rinsed and cooked again).

However, the question of organic arsenic is still pending. Although not carcinogen, organic arsenic when digested can circulate under its inorganic form in the digestive tractus and hence become a health issue. Indeed, if the total organic arsenic is transformed to inorganic arsenic, exposure levels inside the body would be up to 500-fold the regulation threshold.

(3) Nickel : an upcoming topic

According to the European Food Safety Authority (EFSA), food is the main source of nickel intake by the general population. Based on their risk assessment, EFSA determined that the tolerable daily intake (TDI) of nickel from all sources is 2.8 µg/kg body weight. This means that for an adult, the TDI would be 196 µg, while for a child it would be 56 µg. In most food products, the nickel content is less than 0.5 mg/kg fresh weight. However, cacao products and nuts may contain as much as 10 and 3 mg/kg respectively (Food as a source of exposure to nickel - PubMed (nih.gov) - https://pubmed.ncbi.nlm.nih.gov/31961102/ and 6.10-Nickel.doc (who.int): www.euro.who.int/__data/assets/pdf_file/0014/123080/AQG2ndEd_6_10Nickel.pdf).

(4) Iodine in Algae

The satisfactory intake (AI) of iodine in Europe is fixed at 150 µg for adult men and women. The upper safety limit is set to 600 µg (EFSA, 2014; ANSES 2017). France also recommends a maximum iodine content in algae of 2000 mg / kg dry. Laminaria species (brown seaweed) can reveal high levels of iodine exceeding the French regulation. This maximum level is recommended if consumers do not exceed 0.3 g of seaweed (Kombu) per day.

It is possible to reduce iodine content in brown algae before consuming the algae. Indeed, cooking practices can drastically reduce iodine content. Blanchiment has been demonstrated as the most effective process to reduce iodine content. Applying 80°C during 2minutes reduced iodine content by more than 10-fold which enables the algae to be in line with health regulations (Nielsen *et al*., 2020) but such treatment can reduce the nutritional value of the seaweed by destroying bioactives or removing nutrients. However more mild treatments to reduce iodine content and preserve the nutritious aspects have been investigated by soaking the biomass for 1 hour at 32°C in fresh water (Stevant *et al*., 2018).

Iodine – references

1- **Stévant Pierrick**, Hélène Marfaing, Arne Duinker, Joël Fleurence, Turid Rustad, Ingrid Sandbakken, Annelise Chapman. 2017. Biomass soaking treatments to reduce potentially undesirable compounds in the edible seaweeds sugar kelp (Saccharina latissima) and winged kelp (Alaria esculenta) and health risk estimation for human consumption. Journal of Applied Phycology 30 (1) .

2- **Nielsen Wirenfeldt Cecilie**, Susan Løvstad Holdt, Jens J. Sloth, Gonçalo Silva Marinho, Maren Sæther, Jon Funderud and Turid Rustad. 2020. Reducing the High Iodine Content of Saccharina latissima and Improving the Profile of Other Valuable Compounds by Water Blanching. Foods, 9, 569.

3- **Ficheux Anne-Sophie,** Bruno Boniou, Gaël Durand, Raphaële Le Garrec, Ophélie Pierre, Alain-Claude Roudot. 2023. Dietary exposure and risk assessment to trace elements and iodine in seaweeds. Journal of Trace Elements in Medicine and Biology 78 (2023) 127-187.

4- **European position**: The European Food Safety Authority (EFSA) has established an upper limit of 600 micrograms per day. The maximum level of iodine allowed in food varies by country. EFSA.

5- **France position**: There is a legal iodine limit of 150 micrograms in food supplements. Food Compliance International
Germany position: The Federal Institute for Risk Assessment recommends a maximum level of 100 micrograms (µg) of iodine per daily recommended dose of an individual food supplement1. For pregnant and lactating women, a maximum level of 150 µg iodine per recommended daily dose of a food supplement is recommended: BFR.

6- **United States position**: the Food and Drug Administration (FDA) developed Daily Values (DVs) to help consumers compare the nutrient contents of foods and dietary supplements within the context of a total diet. The DV for iodine is 150 mcg for adults and children aged 4 years and older: NIH publication.

C. Organic contamination regulation

Organic contaminants	Maximum Levels	Targeted product	Reference
Persistent contaminants			
Sum of Dioxins (WHO-TEQ/g)	1-5 pg / g fat 0.1-3.5 pg/wet weight	Meat and meat products, Marine oils, Milk	EUROPEAN COMMISSION REGULATION (EU) 2023/915
Sum Dioxin + Dioxin-like PCBs (WHO-TEQ/g)	1.25-10 pg / g fat 0.5-20 pg/g wet weight		
Non-dioxin-like PCBs: (ng.g)	40-200 µg/kg fat 3-300 µg/kg wet weight		

Sum of all Perfluoroalkyl substances (PFOS, PFOA, PFNA, PFHxS)	1.3-50 µg/kg	Meat, Fish meat, crustaceans and molluscs, eggs	
Processing contaminants			
Polycyclic Aromatic Hydrocarbons (PAH) (benzo(a)pyrene) and sum of 4 PAHs)	1-50 g/kg	Food supplements containing botanicals and their preparations (powdered plants, plants parts, algae, fingi, lichen, tinctures…) Food supplements containing propolis, royal jelly, spirulina or their preparations	EUROPEAN COMMISSION REGULATION (EU) 2023/915
3-monochloropropane-1,2-diol (3-MCPD) (1)	20 (for liquid product containing 40% dry matter)	Hydrolysed vegetable proteins, soy sauce	
Sum of 3-MCPD and fatty acid esters	15-2500µg/kg	Vegetable oils, fish oil and oils from marine organisms	
Glycidyl fatty acid esters, expressed as glycidol	6-1000 µg/kg	Vegetable oils and fats, fish oils and oils from other marine organisms	
Other relevant organic contaminants			
Melamine $C_3H_6N_6$	0.15 - 2.5 mg/kg	All food products	EUROPEAN COMMISSION REGULATION (EU) 2023/915
Erucic acid $C_{22}H_{42}O_2$ (2)	20 - 50 g/kg	Vegetable oils and fats, mustard	
Bromoform CHBr3 (3)	100 µg/litre	Drinking water	Guideline value - WHO/SDE/WSH/03.04/64

(1) 3-MCPD (3-monochloropropane 1,2-diol) is a carcinogenic contaminant of acid hydrolysed vegetable protein (acid-HVP), producing genotoxic intermediates on metabolism such as epoxide glycidol1. It was first identified as a contaminant of soy sauce and acid-hydrolysed vegetable protein (a savoury food ingredient) and has since been detected at low levels in a number of foods and ingredients. 2- and 3-MCPD and Their Esters in Vegetable Oils | Eufic - www.eufic.org/en/food-production/article/process-contaminants-in-vegetable-oils-and-foods-qa; Bioaccessibility and Bioavailability of Minerals in Relation to a Healthy Gut Microbiome - PubMed (nih.gov) - Int J Mol Sci . 2021 Jun 24;22(13):6803. doi: 10.3390/ijms22136803.

(2) Erucic acid is an omega-9 unsaturated fatty acid general found as a biotoxin in oil rich seeds from terrestrial plants (Rapeseed, Colza …) with levels able to reach 60% of the total fatty acids (FA). Selected varieties are now cultivated to respond to health concerns now exposing levels less than 2%, i.e below the 5% recommendation level (https://www.cfs.gov.hk/english/multimedia/multimedia_pub/multimedia_pub_fsf_162_02.html) . Certain micro-algae are also able to naturally produce this compound: erucic acid content in *Gloeocapsa* (cyanobacteria) for instance was reported with 8% of the total FA (10.47832/2717-8234.12.16)

(3) Bromoform is found in certain seaweed species, notably *Asparagopsis*. It is a volatile compound therefore the content measured in algae samples can vary (between 1µg / g DW algae to 23 mg / g DW) greatly depending on the biomass storage conditions but also depending on the growth temperature as well as geographical origin of the isolates, even on small spatial scale (doi.org/10.1007/s10811-022-02706-1). Bromoform is considered as the most important contributor to the anti-methanogenic activity of *Asparagopsis* when used in animal feed.

Regulation and Recommendation official documents

1. EC Regulation - EUROPEAN COMMISSION REGULATION (EC) No 1881/2006 - of 19 December 2006 Setting maximum levels for certain contaminants in foodstuffs.
2. EC Regulation - COMMISSION REGULATION (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006
3. EC Regulation - COMMISSION REGULATION (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs
4. EFSA Journal - Dietary exposure to heavy metals and iodine intake via consumption of seaweeds and halophytes in the European population, 2022.
5. EC Recommendations - COMMISSION RECOMMENDATION (EU) 2018/464 of 19 March 2018 on the monitoring of metals and iodine in seaweed, halophytes and products based on seaweed.
6. Anses Opinion - Opinion of the French Agency for Food, Environmental and on the state of knowledge on brevetoxins in shellfish, data on toxicity, occurrence and brevetoxin-producing microalgae; Request n° 2020-SA-0020
7. WHO Guidlines - Trihalomethanes in Drinking-water Background document for development of WHO Guidelines for Drinking-water Quality

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