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Multi-Str3am

A sustainable multi-strain, multi-method, multi-product microalgae biorefinery integrating industrial side streams to create high-value products for food, feed and fragrance

BBI-2019-SO1-D2 - Produce components for various materials, including for food and feed, from microalgae

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Report on the regulatory landscape for microalgae biomass valorisation across market applications

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Deliverable abstract

This document presents a comprehensive compilation and systematization of the existing European regulatory landscape applicable to the area of microalgae production and biorefinery. It clarifies the different levels of enforcement of the described regulatory landscape, which includes Regulations, Directives, Decisions, Recommendations, Opinions. When considered relevant it includes international standards, guides and certification schemes for microalgae and microalgae products. The applicability of this document is not limited to microalgae, encompassing also cyanobacteria and labyrinthulomycetes, and targets the fields of food ingredients, feed ingredients and home and personal care products.

Depending on the field of applications and/or the end-product or ingredient of interest, this report describes the decision on the selection of documents to guides its user through and to relevant information to ensure a correct compliance with the requirements of the competent authorities and the needs of the market and the consumer.

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1 Introduction

The algae production and commercialization does not have a unique EU policy. The field relies on several policies that cover different areas related to climate change, sustainability, fisheries, aquatic resources, and renewable biological resources management. These policies lead to the publication of different levels of documentation in the EU that applies to algae production, processing, and marketing.

The European institutions may adopt 5 types of legal acts:

- Regulations
- Directives
- Decisions
- Recommendations
- Opinions

Regulations, directives, and decisions are binding legal acts, while the recommendation and the opinion are not (a definition of each act is presented in the Terms and definitions section).

The “relationship” of a company with regulations and directives always happens through the national competent authorities of a given country for the specific scope of each legal document. So, all the regulations and directives mentioned here were selected as the ones that can lead the authorities to question a company.

Another level of compliance is the use of national or international standards. The European Committee for Standardisation (CEN) upon requested by the European Commission (EC) has the responsibility to produce the European standards to support the implementation of the legislation. At national level, standardisation is managed by national standardisation bodies (NSBs) who adopt and publish national standards. The NSBs also transpose all European standards as identical national standards and withdraw any conflicting national standards. Standards and other standardisation publications are voluntary guidelines providing technical specifications for products, services, and processes. In some cases, specific standards have been incorporated into a piece of legislation and are of mandatory compliance by law or are referenced in legislation as a preferred way of acting. Standards are the documents that organizations use in their daily routine to reach a desired level of organization, characteristic of a process or a product, and standardise quality and safety of products. They are selected according to the market envisaged by the company. In this overview some general standards will be mentioned as they are of paramount importance for companies producing, food or feed additives. Compliance with these standards is an added value in terms of credibility, opening of international markets and competitiveness.

Finally, when considered relevant, certification schemes for some types of products will be mentioned.

2 Terms and definitions

Along this report, the definitions below must be considered:

Microalgae

Microscopic eukaryotic organisms composed of single differentiated cells able to obtain energy using chromophores. Generally single-celled, but can occur as filamentous or colonial.

Note 1 to entry: For the sake of this report, the terminology microalgae will also be used to describe cyanobacteria and Labyrinthulomycetes. Cyanobacteria can be defined as photoautotrophic, mixotrophic or

heterotrophic prokaryotic organisms, able to obtain energy by using chromophores. Labyrinthulomycetes can be defined as a class of protists or chromista that produce a network of filaments or tubes and includes the family Thraustochytriaceae. Thraustochytriaceae are a family of mostly marine, heterotrophic, fungus-like, unicellular eukaryotic microorganisms that lack a plastid, which include industrially relevant genera, such as Schizochytrium and Ulkenia, used to produce Omega-3 “algae oils” even though they are not “algae” in a scientific sense, because of the absence of plastid.

Note 2 to entry: Definitions taken from EN 17399:2020 - Algae and algae products - Terms and definitions.

Food Ingredients

Any substance, including food additives, used in the manufacturing or preparation of food and which is present, whether maintaining its original aspect or modified, in the end product.

Note 1 to entry: Definition taken from ISO/TS 22002-2:2013(en) - Prerequisite programmes on food safety — Part 2: Catering

Feed Ingredients

Component part or constituent of any combination or mixture making up a feed, whether or not it has a nutritional value in the animal’s diet, including feed additives.

Note 1 to entry: Ingredients are of plant or animal origin, whether terrestrial or aquatic, or other organic or inorganic substances.

Note 2 to entry: Definition taken from ISO/TS 22002-3:2011(en) - Prerequisite programmes on food safety — Part 3: Farming

Home care products

The home care products market is segmented into laundry products, cleaning products (surface cleaners, glass cleaners, specialty cleaners and bleaches), and air fresheners.

Personal care products

Personal care products market includes different types of products: skin care, hair care, sun care, teeth care, baths and shower products, bar and hand soaps, deodorants, anti-perspirants, and body sprays.

Certification

Certification is a formal attestation or confirmation of certain characteristics of a product or organization. This confirmation can be given by external evaluation (i.e., audit). Certification has traditionally arisen when a group of professionals determines the need to publicly sets standards for a field.

Regulation

Regulations are legal acts that have general application, are binding in their entirety, and directly applicable in all EU countries’ internal law immediately after its entry into force.

Directive

Directives are legal acts that once adopted at EU level, they are then incorporated — or transposed — by all EU countries so they become law in their countries.

Decision

Decisions are binding legal acts which may either be of general application or may have a specific addressee. Like a regulation, it cannot be applied incompletely, selectively, or partially.

Recommendation

Recommendations are non-binding EU acts. Although recommendations do not have legal consequences, they may offer guidance on the interpretation or content of EU law.

Opinion

Opinions are the second form of non-binding EU acts and they are a way for an institution to make its views known on draft EU legislation or other matters without these having the force of law.

3 Production chain stages

The area of microalgae production and biorefinery, by integrating industrial side streams to create high-value products for food, feed and fragrance, comprises different stages of the value chain. These different stages include the production of raw materials, the downstream processing and fractioning, if needed, of the intermediates, further conversions and reactions of the intermediates, if further processing is required, and final product formulations.

Regarding these different production chain stages, the existing European regulatory landscape can, in some general cases, have an overarching application over the whole microalgae sector. However, when considering certain features of the production processes, there are some specificities in the regulation that have its particular applicability. Also, each product typology, such as food ingredients, feed ingredients, and home and personal care products, has its own regulations to ensure the compliance to EU requirements.

3.1 General

Upon the establishment of a company of the algae sector, upfront obligations have to be identified and discussed with national authorities. These obligations can be related with conservation of natural habitats, marine environmental and planning policies, use of renewable sources of energy, and policies of water use. Some of the most important Directives that apply to the algae sector at a high level concerning those issues are:

- [Regulation \(EU\) 2020/741](#) of the European Parliament and of the Council of 25 May 2020 on minimum requirements for water reuse.
- [Directive 92/43/EEC](#) of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora. (Consolidated version)

- [Directive 2000/60/EC](#) of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (Consolidated version)
- [Directive 2008/56/EC](#) of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive) (Consolidated version)
- [Directive 2009/28/EC](#) of the European Parliament and of the Council of 23 April 2009 on the promotion of the use of energy from renewable sources and amending and subsequently repealing Directives 2001/77/EC and 2003/30/EC. (Consolidated version)
- [Directive 2014/89/EU](#) of the European Parliament and of the Council of 23 July 2014 establishing a framework for maritime spatial planning.

3.2 Production process features

EU has specific legislation / standards / certification schemes that can be used for production and harvest of algae and algae products. Those documents cover the selection of the species to be produced; the rules for genetically modified organism (GMO) use; procedures for organic/bio production; requests for authorisation if the algae and algae product is a novel food and if specific health claims are aimed; certification schemes for Kosher, Halal, and vegetarian/vegan products. The main documents identified are mentioned below.

3.2.1 Use of alien species

Regulation (EC) No 708/2007 rules the translocation of species within their natural range to areas where they are locally absent as this may present risks for ecosystems in these areas. Level of stringency of measures consider that movements of alien or locally absent species to be held in closed aquaculture facilities which are secure, and which present a very low risk of escape.

- [Regulation \(EC\) No 708/2007](#) of 11 June 2007 concerning use of alien and locally absent species in aquaculture

3.2.2 Organic/bio production

Regulation (EC) No 834/2007 sets the rules for organic production. In Commission Regulation (EC) No 889/2008 no detailed production rules had been laid down for microalgae used as food. Questions arose in regard to which production rules operators must respect when growing microalgae for use as food, so there was a need to clarify the situation and lay down detailed production rules for such products. The Commission issued the Commission Implementing Regulation (EU) 2016/673.

More recently Council Regulation (EC) No 834/2007 was repealed and Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018, in Part III lays down the rules to be followed in all stages of production, preparation, and distribution production of organic algae. An environmental assessment that is appropriate to the production unit shall be required for any new operators applying for organic production and producing more than 20 tonnes of aquaculture products per year. The content of the environmental assessment shall be based on Annex IV to Directive 2011/92/EU.

With regards to standardizing the labelling, one major issue is the quality-indicating parameters for which methodologies must be defined (e.g., organic, halal). In particular, CEN/BT/WG 218 recommends elaborating in a technical report (TR) with the specificities for organic microalgae production as an amendment to the standard for seaweed organic production (Article 6a of Regulation (EC) No 889/2008), for the food and feed markets.

- [Regulation \(EC\) No 889/2008](#) of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products regarding organic production, labelling and control. (Consolidated version).
- [Regulation \(EU\) 2018/848](#) of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007 (Consolidated version).
- [Directive 2011/92/EU](#) of the European Parliament and of the Council of 13 December 2011 on the assessment of the effects of certain public and private projects on the environment.
- Commission Implementing [Regulation \(EU\) 2016/673](#) of 29 April 2016 amending Regulation (EC) No 889/2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regards to organic production, labelling and control.

3.2.3 Novel foods

Most species of algae are considered as novel foods according to the definitions in Regulations (EU) 2015/2283 and the definitions laid down in Articles 2 and 3 of Regulation (EC) No 178/2002. The authorization process to use a new species must be submitted to the European Food Safety Authority (EFSA). Regulation (EU) 2017/2470 establishes the Union list of novel foods. That consolidated version of this regulation also has the Union List of Novel Foods with the list of microalgae or microalgae products authorized in EU.

- [Regulation \(EU\) 2015/2283](#) of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001. (Consolidated version).

This Regulation does not apply to:

- GMOs, that fall within the scope of [Regulation \(EC\) No 1829/2003](#)
- Foods:
 - When they are used as food enzymes, which fall within the scope of [Regulation \(EC\) No 1332/2008](#)
 - When they are used as food additives, which fall within the scope of [Regulation \(EC\) No 1333/2008](#)
 - When they are used as food flavourings, which fall within the scope of [Regulation \(EC\) No 1334/2008](#)
 - When extraction solvents are used or intended to be used in the production of foodstuffs or food ingredients, which fall within the scope of [Directive 2009/32/EC](#)
- Commission Implementing [Regulation \(EU\) 2017/2470](#) of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods. (Consolidated version)

3.2.4 Health claims

All nutrition and health claims made in commercial communications, including among other things generic advertising of food and promotional campaigns, must be supported by an authorisation from the EU. Regulation (EC) No 1924/2006 harmonises the provisions laid down by law, regulation or administrative action in Member

States which relate to nutrition and health claims. Nutrition claims shall only be permitted if they are listed in the Annex of the Regulation.

- [Regulation \(EC\) No 1924/2006](#) of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. (Consolidated version)

3.2.5 Kosher and Halal certification

“At present, algal oil represents less than 2% of human EPA/DHA consumption, but its contribution has been increasing due to several social attributes including its environmental friendliness, the absence of ocean borne contaminants, its vegetarian nature, as well as the possibility to be manufactured under kosher or halal conditions” (T. Lopes da Silva, P. Moniz, C. Silva and A. Reis. 2019. The Dark Side of Microalgae Biotechnology: A Heterotrophic Biorefinery Platform Directed to ω -3 Rich Lipid Production. *Microorganisms*, 7, 670).

So, kosher or halal certifications and the compliance to their rules can be of economical relevance to microalgae producers. Several Kosher certification agencies exist. Halal certification is country related.

3.2.6 Vegetarian/vegan certification

The EU Regulation 1169/2011 requires the European Commission to set out rules for the voluntary labelling of foods as “suitable for vegans” and/or “suitable for vegetarians.” Note that all foods that are suitable for vegans will meet the requirements to also be suitable for vegetarians. At the European level no binding, legal definitions of the terms “vegan” and “vegetarian” have been adopted in the food industry yet. The European Vegetarian Union (EVU) is the umbrella organization of vegetarian and vegan associations and societies throughout Europe (<https://www.euroveg.eu/> consulted on 13/04/2021). EVU is the background organisation for the V-label, a standardized voluntary European certification scheme with the aim of easy identification of vegetarian and vegan products and services (https://www.v-label.eu/regulations_text, consulted 13/04/2021)

- [Regulation \(EU\) No 1169/2011](#) of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004. (Consolidated version)

3.2.7 GMOs

The European Union has in place a comprehensive and strict legal regime on GMOs, food and feed made from GMOs, and food/feed consisting or containing GMOs.

- [Regulation \(EC\) No 1829/2003](#) of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. (Consolidated version)
- [Regulation \(EC\) No 1830/2003](#) of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC. (Consolidated version)
- [Regulation \(EU\) 2019/1381](#) of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC.

- [Directive 2001/18/EC](#) of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC - Commission Declaration. (Consolidated version)

3.3 Products

As referred in the scope, this report refers to the use of microalgae, also encompassing cyanobacteria and labyrinthulomycetes, and targeting the fields of Food Ingredients, Feed Ingredients, and Home and Personal Care products.

In many legal and standardization issues, food and feed come together and the same documentations applies to both sectors. In fact, some year ago EU along with many international institutions, developed strategies to implement cross-sectoral collaboration to implement the One Health concept that recognises that human health is tightly connected to the health of animals and the environment, for example that animal feed, human food, animal and human health, and environmental contamination are closely linked.

Microalgae can be produced and sold as biomass. This biomass can be used as such or can be an intermediate for different applications. Moreover, considering the exploitation of microalgae metabolites, in the context of a biorefinery, different fractions can be extracted and used for different purposes. Examples of the commercially relevant compounds are proteins (proteins, peptides, and amino acids), carbohydrates, lipids / oils, low molecular weight (LMW) organic compounds, polyphenols, and carotenoid fractions.

3.3.1 Food ingredients applications

The Farm to Fork Strategy, a central part of the Green Deal from EU, stresses the importance of algae industry, “as algae should become an important source of alternative protein for a sustainable food system and global food security”. But not only proteins are of importance, but a myriad of compounds should also be considered as commercially important food ingredients. Producers have a vast range of legislation and standards that apply to their production, quality and safety control, labelling or packaging. Also, the evaluation of those products as novel foods and the proposal of health claims are to be considered by companies.

Algae, either being farmed or collected, must comply with a complex regulatory framework, so for the sake of simplicity of search, the main legal documents are listed by area of application/subject.

Regulation (EC) No 178/2002 (General Food Law Regulation) is the Regulation that laid down the general principles governing food and feed in general, and in particular food and feed safety, at the EU and national levels. It established the European Food Safety Authority and laid down procedures for matters with a direct or indirect impact on food and feed safety.

More information than the ones presented here can be found in the following links:

- https://ec.europa.eu/info/food-farming-fisheries/food-safety-and-quality_en
- https://eur-lex.europa.eu/summary/chapter/3010.html#arrow_301001

3.3.1.1 Food quality and safety

Food safety and quality is of paramount importance for the society and for producers. The regulations mentioned below have the principles that govern the food sector, which is the Food Law and the regulations that have the microbiological (Regulation (EC) No 2073/2005) and chemical (Regulation (EC) No 1881/2006) criteria for foodstuffs.

- [Regulation \(EC\) No 178/2002](#) of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. (Consolidated version).
- [Regulation \(EC\) No 2073/2005](#) of 15 November 2005 on microbiological criteria for foodstuffs. (Consolidated version).
- [Regulation \(EC\) No 1881/2006](#) of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs. (Consolidated version).
- [Regulation \(EC\) No 852/2004](#) of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs. (Consolidated version).
- [Regulation \(EEC\) No 315/93](#) of 8 February 1993 laying down Community procedures for contaminants in food (Consolidated version).
- [Regulation \(Euratom\) 2016/52](#) of 15 January 2016 laying down maximum permitted levels of radioactive contamination of food and feed following a nuclear accident or any other case of radiological emergency and repealing Regulation (Euratom) No 3954/87 and Commission Regulations (Euratom) No 944/89 and (Euratom) No 770/90.

In the food sector in EU, all types of producers along the food chain, no matter their size or type of product, have the responsibility to assure the safety of their products. They can use ISO 22000 as a tool to implement their food safety management system.

- [ISO 22000:2018](#) Food safety management systems - Requirements for any organization in the food chain.

3.3.1.2 Food additives

Regulation (EC) No 1331/2008 establishes the common authorisation procedure for food additives, food enzymes and food flavourings. Both Regulation (EC) No 178/2002 and Regulation (EC) No 1331/2008 were amended by Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain amended with effect from 27 March 2021.

Regulation (EC) 1333/2008 sets the rules on food additives: definitions, conditions of use, labelling, and procedures. The list of authorised food additives approved for use in food additives, enzymes, and flavourings can be found in the Annex of Regulation (EU) No 1130/2011. The additives approved for use in flavourings can be found in part 4 of this Annex. There is a union list of flavourings (Annex I of Regulation 1334/2008) and the adoption of the list of flavouring substances was published in 2012 (Implementing Regulation EU 872/2012). The food industry can only use flavouring substances that are on that list.

- [Regulation \(EC\) No 1331/2008](#) of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings. (Consolidated version)
- [Regulation \(EC\) No 1332/2008](#) of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97. (Consolidated version)
- [Regulation \(EC\) No 1333/2008](#) of the European Parliament and of the Council of 16 December 2008 on food additives. (Consolidated version)
- [Regulation \(EC\) No 1334/2008](#) of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC. (Consolidated version)

- [Regulation \(EU\) No 1130/2011](#) of 11 November 2011 amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives by establishing a Union list of food additives approved for use in food additives, food enzymes, food flavourings and nutrients.
- [Regulation \(EU\) 2019/1381](#) of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC.
- Commission Implementing [Regulation \(EU\) No 872/2012](#) of 1 October 2012 adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96 of the European Parliament and of the Council, introducing it in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council and repealing Commission Regulation (EC) No 1565/2000 and Commission Decision 1999/217/EC.

Producers can follow the standard ISO/TS 19657:2017 if they want to know the definitions and technical criteria (acceptable sources, materials, and processes) to be fulfilled for food ingredients to be considered as natural. This standard is applicable to food ingredients.

- [ISO/TS 19657:2017](#) Definitions and technical criteria for food ingredients to be considered as natural.

3.3.1.3 Use of extraction solvents

Due to the safety risks associated with the use of extraction solvents, the EU published and later revised a directive that applies to extraction solvents used or intended for use in the production of foodstuffs or food ingredients. The extraction solvents in the manufacture of foodstuffs or food ingredients of those substances and materials are listed in Annex I of Directive 2009/32/EC, as well as the conditions of use and where the appropriate maximum residue limits are specified.

- [Directive 2009/32/EC](#) of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (Recast). (Consolidated version)

3.3.1.4 Food packaging

Several safety issues can arise by the contact of materials with food. Therefore, several legislative acts were produced to clarify the type of materials that can be used. The first one was Regulation (EC) No 1935/2004 on materials and articles that could be in contact with food. This regulation has had many modifications along the years. Directive 2007/42/EC is a specific directive within the meaning of Article 5 of Regulation (EC) No 1935/2004. Regulation (EC) No 1895/2005 on the restriction of use of certain epoxy derivatives apply to materials and articles, including active and intelligent food contact materials and articles, as referred to in Article 1(2) of Regulation (EC) No 1935/2004, which are manufactured with or contain one or more of the epoxy derivatives. Also, Regulation (EU) No 10/2011 on plastic materials was published in 2011. Directive 94/62/EC to harmonize national measures concerning the management of packaging and packaging waste in order to prevent or reduce any impact thereof, and to ensure the functioning of the internal market and to avoid obstacles to trade and distortion and restriction of competition within the Community.

- [Regulation \(EC\) No 1935/2004](#) of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC. (Consolidated version)
- [Regulation \(EC\) No 1895/2005](#) of 18 November 2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food.

- [Regulation \(EU\) No 10/2011](#) of 14 January 2011 on plastic materials and articles intended to come into contact with food. (Consolidated version)
- [Regulation \(EC\) No 450/2009](#) of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food.
- [Regulation \(EC\) No 282/2008](#) of 27 March 2008 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No 2023/2006
- [Directive 2007/19/EC](#) of 30 March 2007 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food and Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs (Consolidated version)
- [Directive 2007/42/EC](#) of 29 June 2007 relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs.
- [Directive 94/62/EC](#) of 20 December 1994 on packaging and packaging waste. (Consolidated version)

3.3.1.5 Food labelling

Food labelling of products is meant to obtain a high level of protection of consumers' health and interests by providing a basis for final consumers to make informed choices and to make safe use of food, with particular regard to health, economic, environmental, social, and ethical considerations. Food labelling impacts on the free movement of legally produced and marketed food, considering, where appropriate, the protection of producers, and also the promotion of quality products production. The Regulation (EU) No 1169/2011 covers the food information to consumers, namely nutritional declaration. Products that are exempted from requirement of the nutrition declaration are unprocessed products that comprise a single ingredient or category of ingredients. The Food Labelling Information System provides an IT solution which enables its users to select the food and automatically retrieve the mandatory EU labelling indications.

- [Regulation \(EU\) No 1169/2011](#) of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004. (Consolidation version)
- Commission Implementing [Regulation \(EU\) 2018/775](#) of 28 May 2018 laying down rules for the application of Article 26(3) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers, as regards the rules for indicating the country of origin or place of provenance of the primary ingredient of a food (Consolidation version)

More information than the ones presented here can be found in the following links:

- https://ec.europa.eu/info/food-farming-fisheries/food-safety-and-quality_en
- https://eur-lex.europa.eu/summary/chapter/3010.html#arrow_301001

3.3.1.6 Traceability of pre-packed food

Trade of foodstuffs occupies a very important place in the internal EU market. Therefore, the traceability of food products should be ensured. Indication of the lot to which a foodstuff belongs meets the need for better information on the identity of products, being a useful source of information when foodstuffs are the subject of dispute or constitute a health hazard for consumers. Also considering markets beyond the EU, there is a general obligation to provide a reference to the manufacturing or packaging lot of pre-packaged foodstuffs to

contribute to the development of international trade. Directive 2011/91/EU covers traceability of pre-packed foodstuffs.

- [Directive 2011/91/EU](#) of the European Parliament and of the Council of 13 December 2011 on indications or marks identifying the lot to which a foodstuff belongs.

3.3.2 Feed ingredients applications

The use of microalgae for feed is a growing business. In fact, algae use in large scale for feedstock production has been identified in recent years as a renewable and environmentally sustainable strategy.

More information than the ones presented here can be found in:

- https://eur-lex.europa.eu/summary/chapter/3010.html#arrow_301001
- https://ec.europa.eu/food/food/animal-feed_en

3.3.2.1 Feed quality and safety

Regulation (EC) No 178/2002 harmonizes the conditions, according to the general principles laid (Food Law), for the placing on the market and the use of feed. This ensures a high level of feed safety and thus a high level of protection of public health, as well as to provide adequate information for users and consumers. The Community Catalogue of feed materials referred in Regulation (EC) No 767/2009 is established, with products authorized, as set out in the Annex of Commission Regulation (EU) No 68/2013. Under Directive 2002/32 on undesirable substances, several aspects are approached namely the definition of acceptability criteria for detoxification processes, setting a demarcation between complementary feeds and premixtures by limiting the amount of feed additives in complementary feeds.

Regulation (EU) No 68/2013 was later published specifically on the Catalogue of Feed Materials. The consolidated version of this regulation has the updates on the catalogue. Regulation 767/2009 also establishes the rules for the marketing of "dietetic" feed (feed for particular nutritional purposes). The list with the authorised intended uses for dietetic feed for pets and farmed animals can be found in Regulation (EU) 2020/354.

Recommendation 2011/25/EU establishes the guidelines for the distinction between feed materials, feed additives, biocidal products, and veterinary medicinal products. Although this document is a non-binding act it can be helpful in making distinctions between those materials.

Producers of feed can be certified as compliant with Good Manufacturing Practices by certification bodies, examples (not exhaustive) being: i) GMP+ ("Good Manufacturing Practices" and the + for the integration of HACCP ("Hazard Analysis and Critical Control Points")). The GMP+ International certification scheme consists of Feed Safety Assurance (GMP + FSA), for safe feed, and Feed Responsibility Assurance (GMP + FRA), for a sustainable working method; ii) OVOCOM (Belgium), a consultation platform for the animal feed sector that manages the Feed Chain Alliance Standard, serves as a guideline for companies belonging to the feed sector which is specifically designed for and by professionals belonging to this sector or iii) AIC (UK and Ireland) have developed a range of Trade Assurance Schemes covering areas of the Agri-supply industry, namely Food/ Feed Safety. The Universal Feed Assurance Scheme (UFAS) provides an assurance system to ensure that feed destined for UK livestock meets safety requirements defined by legislators and the industry.

Moreover, FEDIAF (trade body representing the European pet food industry) published the EU accepted guides and guidelines that can be followed by feed industry, namely Guide to Good Practice for the Manufacture of Safe Pet Foods (February 2018) and the Nutritional Guidelines for Complete and Complementary Pet Food for Cats and Dogs (September 2020).

- [Regulation \(EC\) No 178/2002](#) of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
- [Regulation \(EC\) No 183/2005](#) of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene. (Consolidated version)
- [Regulation \(EU\) No 68/2013](#) of 16 January 2013 on the Catalogue of feed materials. (Consolidated version)
- [Regulation \(EC\) No 1831/2003](#) of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition. (Consolidated version)
 - [Regulation \(EC\) No 429/2008](#) of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives
 - [Implementing Regulation \(EU\) 2020/1773](#) of 26 November 2020 amending Regulation (EC) No 429/2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives.
- [Regulation \(EU\) 2020/354](#) of 4 March 2020 establishing a list of intended uses of feed intended for particular nutritional purposes and repealing Directive 2008/38/EC.
- [Directive 2002/32/EC](#) of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed. (Consolidated version)
- [Commission Recommendation \(2011/25/EU\)](#) of 14 January 2011 establishing guidelines for the distinction between feed materials, feed additives, biocidal products and veterinary medicinal products.
- [Commission Notice C/2018/2035](#) — Guidelines for the feed use of food no longer intended for human consumption. OJ C 133, 16.4.2018, p. 2–18.

3.3.2.2 Feed additives

Regulation (EC) No 1831/2003 sets out a standardised procedure for authorising feed additives and lays down rules for their labelling, placing on the market, and use. The EU has established the European Union Register of Feed Additives.

- [Regulation \(EC\) No 1831/2003](#) of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (Consolidated version).

3.3.2.3 Feed labelling

Regulation (EC) No 767/2009 lays down the minimum information to be provided to purchasers on feed labels; introduces a procedure for applications for the authorisation of new nutritional purposes; requires scientific substantiation for claims for a feed's composition or function; covers the names and descriptions to be applied to various feed materials (that is, ingredients either fed singly or included in compound – manufactured - feeds). Regulation 767/2009 also introduces a register of feed materials which lists the names of feed materials. Persons placing a feed material on the market for the first time must ensure it is placed on the Register which is published by the representatives of the European feed business sectors and updated on a regular basis. Regulation (EU) No 68/2013 was later published specifically on the Catalogue of Feed Materials. The consolidated version of this regulation has the updates on the catalogue.

Under Directive 2002/32 on undesirable substances, several aspects are approached namely the introduction of the basis for Community Codes of Practice for good labelling practice.

In accordance with Article 26 of Regulation (EC) No 767/2009, the Commission published the title and reference of the "Code for good labelling practice of pet food" in the Official Journal 2011/C no. 358. On 28 July 2016, the Commission published the title and reference of the "EU Code of good labelling practice for compound feed for food producing animals" in the Official Journal 2016/C no. 275/04. The code was equally updated and endorsed in 2018 endorsed by the Standing Committee – Section Animal Nutrition. The code, developed jointly by Copacogeca, and FEFAC was equally updated and endorsed in 2018.

- [Regulation \(EC\) No 767/2009](#) of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC. (Consolidated version)
- [Regulation \(EU\) 2017/2279](#) of 11 December 2017 amending Annexes II, IV, VI, VII and VIII to Regulation (EC) No 767/2009 of the European Parliament and of the Council on the placing on the market and use of feed.
- [Regulation \(EU\) No 68/2013](#) of 16 January 2013 on the Catalogue of feed materials (Consolidated version)
- [Regulation \(EU\) 2020/354](#) of 4 March 2020 establishing a list of intended uses of feed intended for particular nutritional purposes and repealing Directive 2008/38/EC (Text with EEA relevance)
- [Directive 2002/32/EC](#) of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed. (Consolidated version)
- [Commission Notice \(2011/C 358/07\)](#) on the Code of good labelling practice for pet food. OJ C 358, 8.12.2011, p. 49–49
- [Commission Notice \(2016/C 275/04\)](#) on the EU Code of good labelling practice for compound feed for food producing animals. OJ C 275, 28.7.2016, p. 3–3.

3.3.2.4 Feed placing on the market

In accordance with the general principles laid down, the Regulation (EC) No 178/2002 (Food Law) proposes the harmonization of the conditions for the placing on the market and the use of feed, in order to ensure a high level of feed safety and thus a high level of protection of public health, as well as to provide adequate information for users and consumers and to strengthen the effective functioning of the internal market. The Regulation also lays down rules on the placing on the market and use of feed for both food-producing and non-food producing animals within the EU, including requirements for labelling, packaging, and presentation. Directive 94/62/EC was set up to harmonize national measures concerning the management of packaging and packaging waste in order to prevent or reduce any impact thereof, and, to ensure the functioning of the internal market and to avoid obstacles to trade and distortion and restriction of competition within the Community.

Traceability issues are also covered by Regulation (EC) No 767/2009.

- [Regulation \(EC\) No 178/2002](#) of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
- [Regulation \(EC\) No 767/2009](#) of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council

Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC. (Consolidated version)

- [Directive 94/62/EC](#) of 20 December 1994 on packaging and packaging waste. (Consolidated version)

3.3.3 Home and personal care applications

For fragrances used in home and personal care applications, the following regulations exist in the EU. In the first part, legal acts covering chemicals in general are listed. Then, legal acts for specific areas of use of fragrances, like cosmetics and detergents are detailed.

The REACH regulation lays down provisions on substances and mixtures that shall apply to the manufacture, placing on the market, or use of dangerous substances on their own, in mixtures or in articles, and to the placing on the market of mixtures. The harmonisation of criteria for classification of substances and mixtures, and the rules on labelling and packaging for hazardous substances and mixtures, is detailed in Regulation (EC) No 1272/2008.

Regulation (EU) 528/2012 concerns the placing on the market and use of biocidal products, which are used to protect humans, animals, materials, or articles against harmful organisms like pests or bacteria, by the action of the active substances contained in the biocidal product.

Directive 94/62/EC to harmonize national measures concerning the management of packaging and packaging waste in order to prevent or reduce any impact thereof, and, to ensure the functioning of the internal market and to avoid obstacles to trade and distortion and restriction of competition within the Community.

- [Regulation \(EC\) No 1907/2006](#) of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. (Consolidated version)
- [Regulation \(EC\) No 1272/2008](#) of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. (Consolidated version)
- [Regulation \(EU\) No 528/2012](#) of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal product. (Consolidated version)
- [Directive 94/62/EC](#) of 20 December 1994 on packaging and packaging waste. (Consolidated version)

3.3.3.1 Cosmetics

Regulation (EC) N° 1223/2009 (Cosmetics Regulation) is the main regulatory framework for finished cosmetic products when placed on the EU. Annex II lists the substances that are prohibited in cosmetics, namely the prohibited compounds when used as a fragrance ingredient and, in annex III, the substances which cosmetic products must not contain except subject to the restrictions laid in the document.

According to Article 19 (1) of the regulation, cosmetic products should list their ingredients on the packaging. However, perfume aromatic compositions and their raw materials are referred to as 'parfum' or 'aroma'. Substances for which the cosmetics regulation provides individual labelling are an exception to this terminology.

CosIng is the European Commission database for information on cosmetic substances and ingredients contained in Regulation (EC) N° 1223/2009. Moreover, there is the INCI (International Nomenclature Cosmetic Ingredient) list which presents systematic names internationally recognized to identify cosmetic ingredients. They are

developed by the International Nomenclature Committee (INC) and published by the Personal Care Products Council (PCPC, USA). So, both can be consulted depending on the desired market.

For production of cosmetics, the manufacturer can comply with ISO 22716:2007 that gives guidelines for the production, control, storage, and shipment of cosmetic products.

- [Regulation \(EC\) No 1223/2009](#) of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast). (Consolidated version).
- [ISO 22716:2007](#) Cosmetics — Good Manufacturing Practices (GMP) — Guidelines on Good Manufacturing Practices.
- EC website: https://ec.europa.eu/growth/sectors/cosmetics/legislation_en

3.3.3.2 Detergents

Regulation No 648/2004 (Detergents Regulation) main goal is to protect consumers environment by setting and defining which surfactants are allowed to be used considering their biodegradability and informing the customers (via labels) over allergens containing in the product.

- [Regulation \(EC\) No 648/2004](#) of the European Parliament and of the Council of 31 March 2004 on detergents. (Consolidated version).

3.3.3.3 Home and personal care products certification schemes and standards

On top of EU Regulation there is also the IFRA - International Fragrance, which represents the collective interest of the fragrance industry to protect consumers and the environment. IFRA publishes standards to manage the safe use of fragrances and can issue Certificates of Conformity to the IFRA standards.

Standards specifically related to natural and organic products, ISO 9235 that specifies the terms and definitions relating to aromatic natural raw materials and ISO 16128 that provides guidelines on definitions for natural and organic cosmetic ingredients, can be adopted by manufacturers of fragrances to support their claims.

Regulation (EC) No 66/2010 establishes the voluntary EU Ecolabel scheme. The EU Ecolabel promotes Europe's transition to a circular economy, to promote green innovation and sustainable industries. The EU Ecolabel covers a wide range of product groups that use fragrances like hand and dishwasher detergents, hard surface cleaning products, or laundry products. In each country participating in the EU Ecolabel, a national competent body is available to give advice on EU Ecolabel application (i.e. Blue Angel, the German Ecolabel or Nordic Swan Ecolabel)

- [Regulation \(EC\) No 66/2010](#) of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel. (Consolidated version)
- [ISO 9235:2013](#) Aromatic natural raw materials - Vocabulary.
- [ISO 16128-1:2016](#) Guidelines on technical definitions and criteria for natural and organic cosmetic ingredients and products — Part 1: Definitions for ingredients.
- EC website: https://ec.europa.eu/environment/ecolabel/index_en.htm

4 Future perspectives

The existing regulatory landscape previously described provides a significant amount of information to guide microalgae industry producers, downstream, and end-users regarding the area of food, feed and fragrances. However, the need for a standardization process to specifically allow algae, algae-based products, and their intermediaries into existing systems is lacking and has been identified as essential in 2016 by the European Commission (EC).

The European Committee for Standardisation (CEN) was then requested by the EC to draft European standards or European standardisation deliverables to support the implementation of Article 3 of Directive 2009/28/EC for algae and algae-based products or intermediates. The creation of European Standards was considered needed to facilitate the market penetration of algae and algae-based products or intermediates. This request, presented as Mandate M/547, also contributes to the Communication on "Innovating for Sustainable Growth: A Bioeconomy for Europe", since algae do not need fertile or cultivation land to grow and their productions has no effect on food and land use.

A dedicated working group (CEN Technical Board Working Group 218 "Algae") was created in 2016 to develop a work programme as part of Mandate M/547. This group has determined that the interest in algae and algae-based products or intermediates has increased significantly in Europe as a valuable source including, but not limited to, carbohydrates, proteins, lipids, and several pigments. These materials are suitable for use in a wide range of applications from food and feed purposes to other sectors, such as textile, cosmetics, biopolymers, biofuel and fertilizer/biostimulants. Standardisation was identified as having an important role to promote the use of algae and algae products.

The technical committee [CEN/TC 454](#) 'Algae and algae products' was established to carry out the work programme developed by the previous working group that will prepare a series of standards. Algal biomass samples may contain a high and varying percentage of moisture, which can change rapidly when the sample is exposed to ambient humidity levels. Besides these changes in moisture content, algal biomass samples may contain varying percentages of valuable substances as proteins, saccharides, and lipids, depending on the species and the time the sample is taken during the growing season. The work of CEN/TC 454 should improve the reliability of the supply chain, thereby improving the confidence of industry and consumers in algae, which include macroalgae, microalgae, cyanobacteria, labyrinthulomycetes, algae-based products or intermediates and will promote and support commercialisation of the European algae industry.

CEN/TC 454 first mandate included several working groups with the aim to work on standards and or technical reports on the following subjects:

- CEN/TC 454/WG 1: Terminology
 - SCOPE: Develop standards for general terms and definitions of algae and algae-based products.
- CEN/TC 454/WG 2: Identification
 - SCOPE: Develop standards for classification of algae genera, products, and processes
- CEN/TC 454/WG 3: Algae processing
 - SCOPE: Develop standards describing algae specific process steps and quantifying specific steps, inputs or outputs of algae processes
- CEN/TC 454/WG 4: Specifications for food/ feed sector applications
 - SCOPE: Develop quality designations and indications for algae and directly derived products from algae production required for or by food/feed/nutraceuticals/ animal food producers and industry
- CEN/TC 454/WG 5: Specifications for non-food/feed sector applications

- SCOPE: Develop quality designations and indications for algae and directly derived products from algae production required for or by cosmetics, pharmaceuticals and chemicals/materials producers and industry
- CEN/TC 454/WG 6: Product test methods
 - SCOPE: Develop standards determination methods for algae and algae-based products.

The standards and technical reports that have already been published are the following:

- CEN/TC 454/WG 1: Terminology
 - EN 17399:2020 - Algae and algae products - Terms and definitions
 - Published 2020-03-18
- CEN/TC 454/WG 2: Identification
 - 1 standard under approval
- CEN/TC 454/WG 3: Algae processing
 - 1 standard under approval
- CEN/TC 454/WG 4: Specifications for food/ feed sector applications
 - CEN/TR 17559:2021 - Algae and algae products - Food and feed applications: General overview of limits, procedures, and analytical methods
 - Published 2021-03-03
 - 1 technical report under approval
- CEN/TC 454/WG 5: Specifications for non-food/ feed sector applications
 - CEN/TR 17611:2021 - Algae and algae products - Specifications for cosmetic sector applications
 - Published 2021-01-27
 - CEN/TR 17612:2021 - Algae and algae products - Specifications for pharmaceutical sector applications
 - Published 2021-01-27
 - 1 technical report under drafting
- CEN/TC 454/WG 6: Product test methods
 - 1 technical report under approval
 - 2 technical reports under drafting

This year (2021), CEN/TC 454 first mandate will come to completion. New work under Mandate M/547 has already been approved by the EC. CEN/TC 454 will continue to work on standards and/or technical reports within the already existing working groups as well as new groups that have been created:

- CEN/TC 454/WG 1 Terminology
- CEN/TC 454/WG 2 Identification
- CEN/TC 454/WG 3 Algae processing
- CEN/TC 454/WG 4 Specifications for food/feed sector applications
- CEN/TC 454/WG 5 Specifications for non-food/feed sector applications
- CEN/TC 454/WG 6 Product test methods
- CEN/TC 454/WG 7 Product test methods - saccharides, proteins, amino-acids

- New group
- SCOPE: Develop standards for analytical method(s) for the determination of saccharides, proteins, and amino-acids content in algae
- CEN/TC 454/WG 8 Sampling
 - New group
 - SCOPE: sampling methods and sample treatment of algae.



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