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Food ● Feed ● Cosmetic

Regulatory Compendium for new algae products in the context on the Novel Food Regulation

Irene Minio, SAFE

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SAFE: who we are and our role

- SAFE is an independent non-profit organisation that **represents interests of European consumers** all over Europe on issues connected to food safety, health and environment.
- Our activities and goals:
  - Advocacy to improve the EU legislative framework
  - Raising public awareness and training consumers
  - Leading several EU projects on food safety and agriculture

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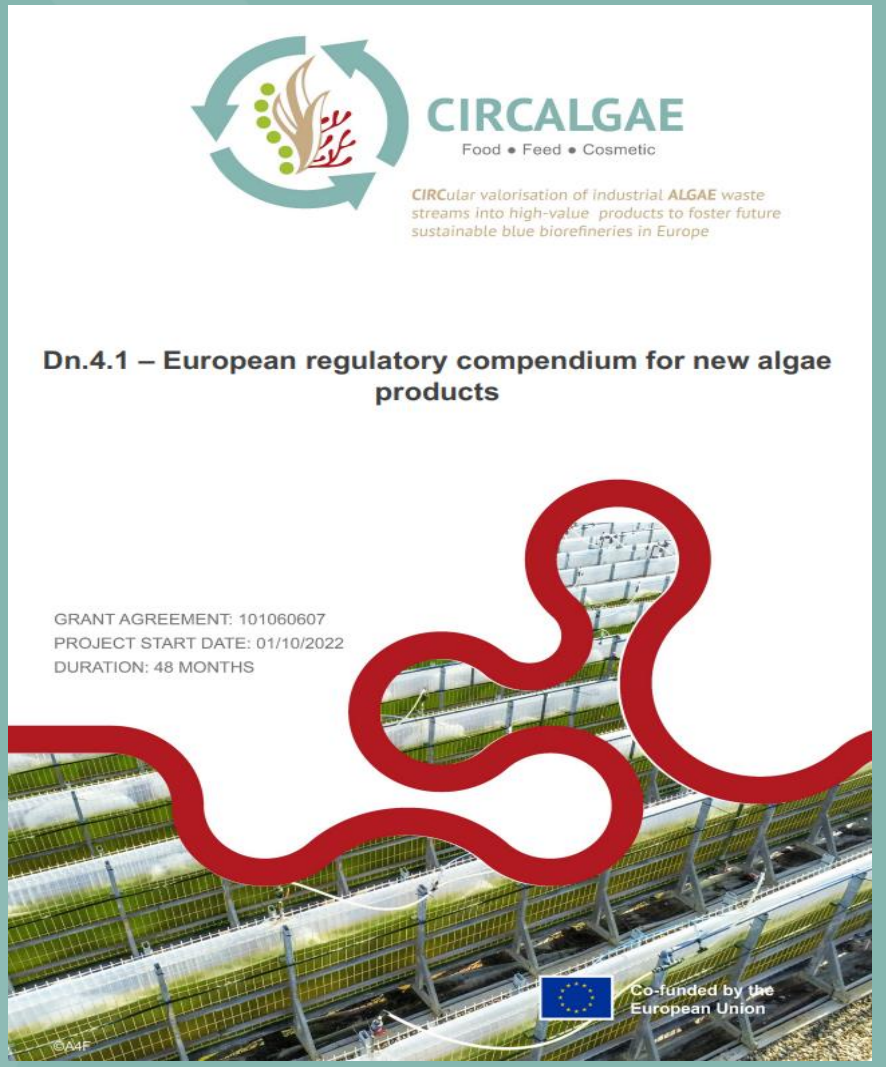
SAFE: who we are and our role

Contribution to CIRCALGAE Project

- **Task 4.1 Task Leader**: European regulatory aspects for new algae products (SAFE)
- Q&A from partners concerning regulatory concerns

Regulatory Compendium for new algae products

- **Objective:** provide comprehensive overview of applicable legislation governing the use of algae as novel products in EU market.
- Subject: food, feed and cosmetic products.
- **Practical tool** based on EU regulatory framework and live examples of project partners' experience.
- Strong focus on algae-based products and Novel Food Regulation.



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Regulatory Compendium for new algae products

Structure and themes

- Three thematic regulatory frameworks: **food**, **feed** and **cosmetics**.
- Overview of regulatory landscape for each theme.
- Novel food regulation as core of the document, with detailed analysis of application process and practical cases submitted for evaluation.
- Cross-sector regulations: (organic) labelling, contaminant levels, hygiene, health and nutritional claims.
- International outlook: Nagoya Protocol, worldwide market trends, EU esport rules.
- Consultation and Liaisons with EFSA and ECHA
- Recommendations

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Regulatory Compendium for new algae products

Added value of Compendium

- Reference manual and support tool, thought for innovators
- Compendium takes into account **ingredients** tested by partners.
- Co-written by partners: questions and answers, consultations and other contributions.
- Integration of section on international opportunities for European innovators expanding their market beyond borders.

Do feed formulations made from Spirulina, Gelidium and Laminaria comply with the maximum levels of heavy metals, minerals or toxin levels?

Based on the composition of Spirulina and the maximum level authorised:

Substance	Level in spirulina	EU maximum level	Status
Arsenic	0.26 mg/kg	2 mg/kg	OK
Cadmium	10.3 µg/kg	2 mg/kg	OK
Mercury	30.23 µg/kg	0.1 mg/kg	OK
Lead	1.29 mg/kg	10 mg/kg	OK
Fluorine	1141.7 mg/kg	150mg/kg (or 1250mg/kg for calcareous marine algae)	OK
WHO-PCDD/F-TEQ	0.15ng/kg	0.75ng/kg	OK
WHO-dl-PCB-TEQ	0.009ng/kg	No specific limit	OK
Sum of dioxins + dl-PCBs	0.159ng/kg	1.25ng/kg	OK
Sum of ndl-PCB (ICES-6)	0.57mg/kg	10 mg/kg	OK

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Based on the composition of Gelidium and the maximum level authorised:

Substance	Level in Gelidium	EU maximum level	Status
Arsenic	3.88 mg/kg	2 mg/kg (or 10 mg/kg for marine algae)	OK
Cadmium	51 µg/kg	2mg/kg	OK
Mercury	< 0,003 mg/kg	0.1 mg/kg	OK
Lead	0.471 mg/kg	10mg/kg	OK
Fluorine	45 mg/kg	150 mg/kg	OK
WHO-PCDD/F-TEQ	0.152 ng/kg	0.75 ng/kg	OK
WHO-dl-PCB-TEQ	0.009 ng/kg	No specific limit	OK
Sum of dioxins + dl-PCBs	0.161 ng/kg	1.25 ng/kg	OK

Based on the composition of Laminaria and the maximum level authorised:

Substance	Level in Laminaria	EU maximum level	Status
Arsenic	31.2 mg/kg	2 mg/kg (or 10 mg/kg for marine algae)	Level too high
Cadmium	1.6 mg/kg	1 mg/kg	Level too high
Mercury	0.03 mg/kg	0.1mg/kg	Level too high
Lead	0.25 mg/kg	10 mg/kg	OK
Fluorine	No information	150 mg/kg	
Copper	17 mg/kg	25 mg/kg	OK

For minerals in feed, there do not appear to be maximum values in EU regulations. However, according to the Regulation on the placing on the market and use of feed, there are compulsory declaration requirements as well as labelling requirements for minerals which can be found via this link.

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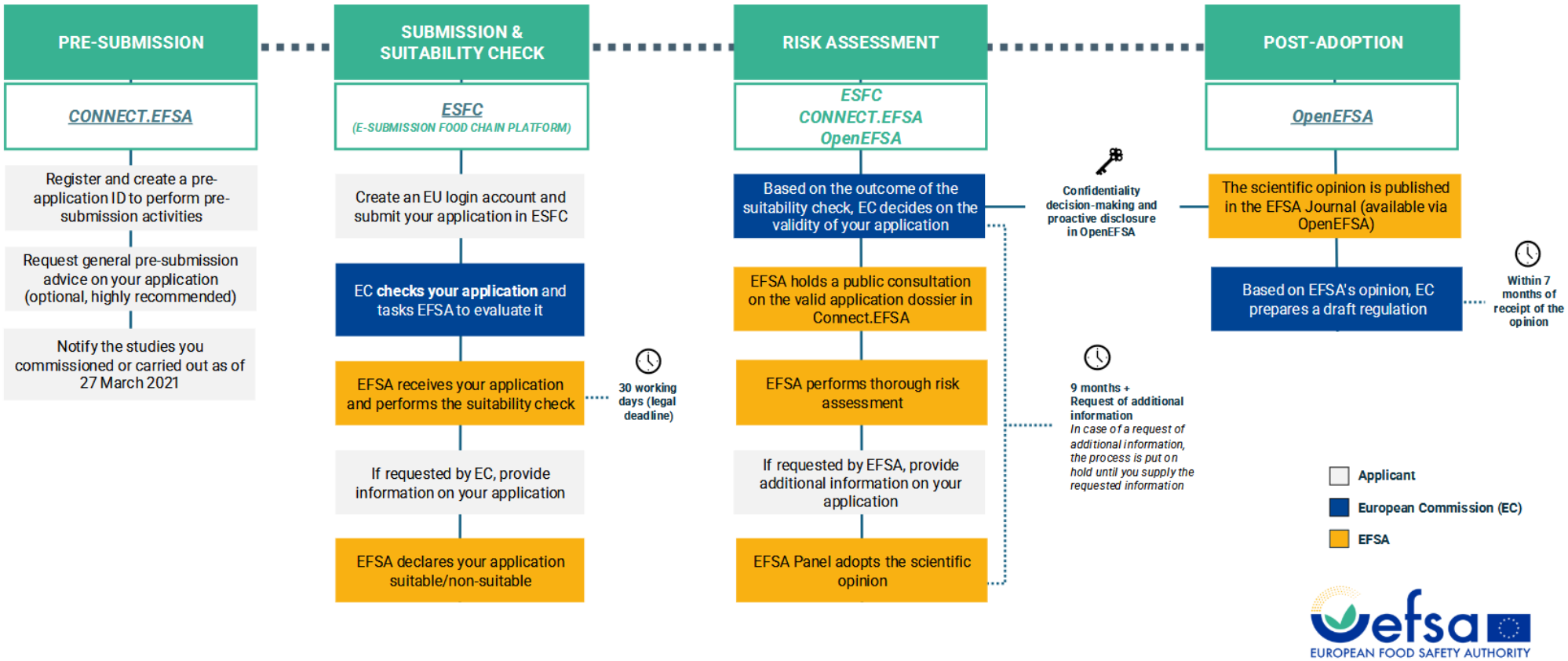
Novel Food application process



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Novel Food application process

EFSA's risk assessment

- Full safety review of the dossier.
- The review examines *human safety, nutritional value*, and *potential health risks* using data such as toxicology studies, compositional analysis, and production methods.
- EFSA may ask for **further data (minimum 9 months, up to 2 years on average)**.
- Final opinion is published with conditions and labelling advice.

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Recommendations from Compendium

How to prevent ‘clock stop’?

- **Early engagement with competent authorities** such as EFSA, ECHA and national agencies to clarify requirements and speed up market access.
- By registering to *Connect.EFSA,* potential applicants can submit inquiries to the General Pre-Submission Advice (GPSA).
- This system helps address early hurdles before starting the submission process.

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Recommendations from Compendium

How to prevent ‘clock stop’?

- Foster **cross-sector collaboration between food, feed and cosmetics developers** to share knowledge and align compliance approaches, especially where the same algae ingredients are used across sectors.
- Lesson learned from CIRCALGAE partners.

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Thank you

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