



Regulatory challenges of alternative proteins

Webinar on Safety & Regulatory of novel
protein Sources on Monday 13th December
2021 from 10:00-11:00 CET.

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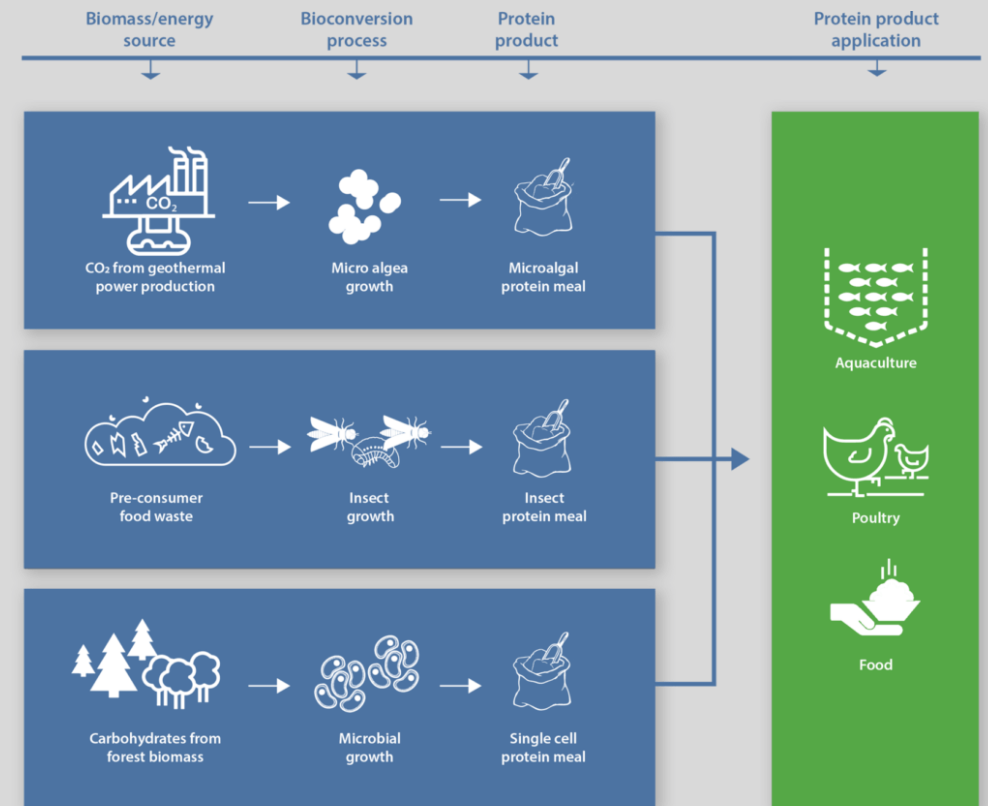
Objectives of project



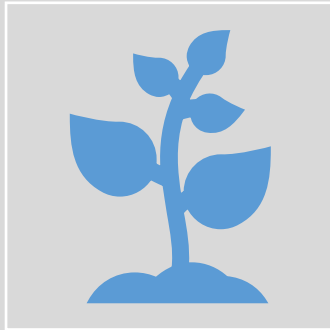
1
Optimise and validate the production of proteins from microalgae, single cells and insects

2
Demonstrate the suitability of these proteins as addition to, or substitute of, traditional protein sources in food and feed value chains.

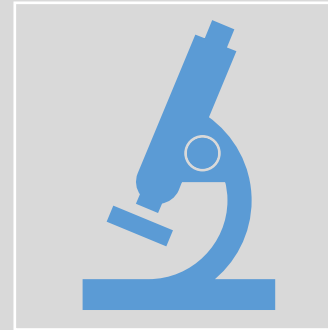
3
Contribute to strengthening food security, sustainability and self-sufficiency of EU protein production



Objectives of project



Assess food and feed regulatory and safety landscape



Identify main barriers for production and application of the three alternative proteins



Contribute to future EU policy

The underlying principles regarding Novel Food in the EU

- Safe for consumers
- Properly labelled, so as not to mislead consumers
- If Novel Food is intended to replace another food, it must not differ in a way that the consumption of the Novel Food would be nutritionally disadvantageous for the consumer
- Pre-market authorisation in line with these principles



Source: tomorrowsfoodandfeed.khlwa.com



Interviews

9 internal stakeholders from industry

- Industry partners associated with NextGenProteins

30 external stakeholders

- Seven countries; EU, Germany, Italy, Finland, the UK, Sweden, Iceland and the Faroe Islands
- Different levels; ministries, authorities, associations,

Interviews with industry partners – Regulatory challenges



- Need to harmonise globally novel food regulations
- Preparation of dossiers is expensive and time consuming
- Regulations can also be trade barriers
- Different retail trade operators can have their internal guidelines where they specify e.g. quality limits and requirements for the products that differ from the legislative limits



Interviews with industry partners – Consumer challenges

- Consumer health is of utmost importance – need scientific information on
 - Toxicology
 - Allergens
 - Microbiological and chemical safety
 - Quality of the new proteins
- Traceability and labelling of the products (e.g. allergens) is important
- Technological performance, nutritional and sensory quality of the new alternative proteins is important - must be acceptable for applications



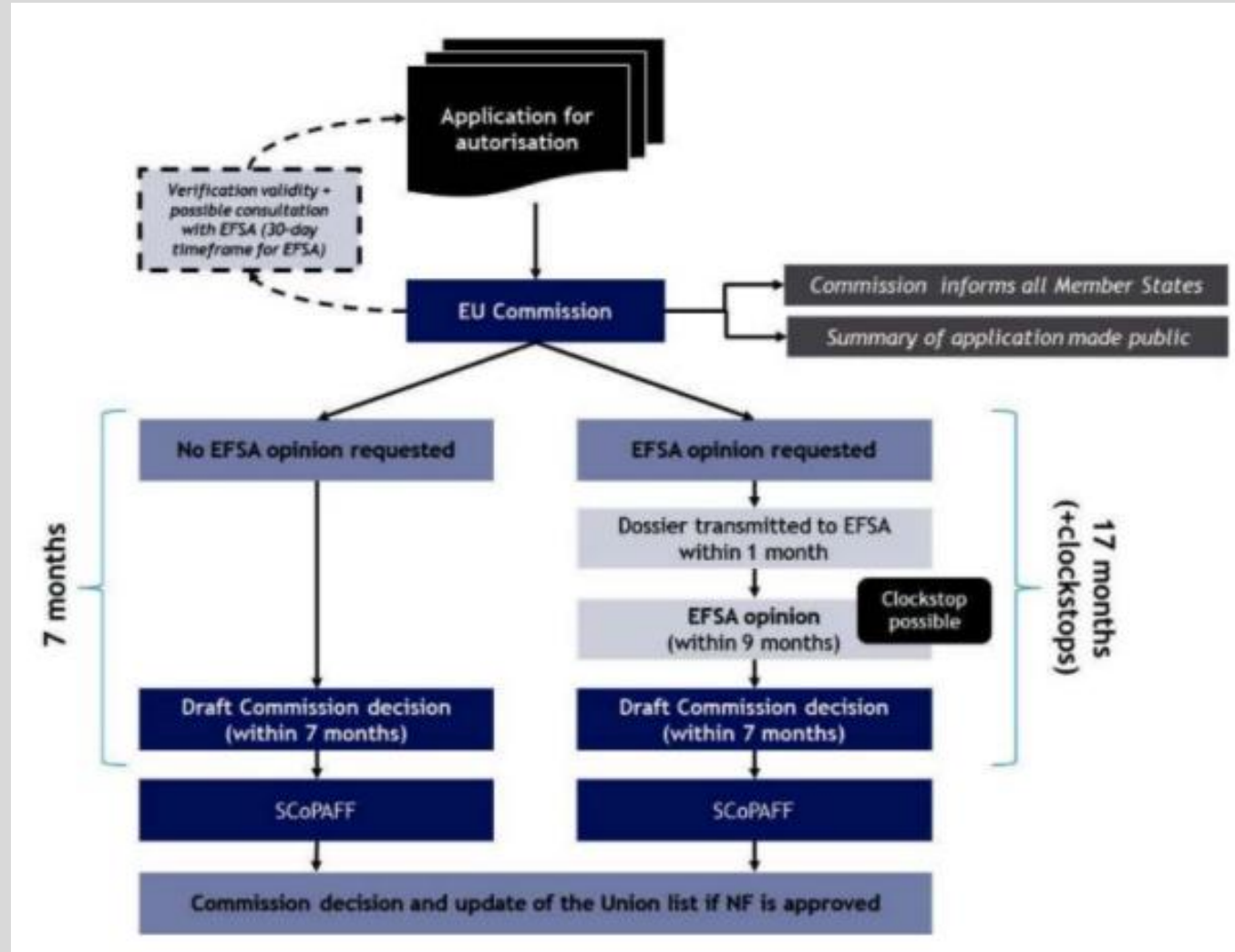
Interviews with industry partners – Consumer challenges

- Organic certificate would benefit the industrial partners in food applications
- Education of consumers/farmers/other stakeholders about new protein sources is needed, e.g. sustainability, ECO footprint, LCA, safety, nutritional value
- A harmonized coalition of alternative protein producers and stakeholders could be a good platform sharing information on sustainability and other important issues



Source: Foodnavigator.com

"Standard" procedure for Novel Food authorisation



Interviews with stakeholders— Accelerate the regulatory process and approval

- Improved guidance/clarity on information needed to submit a dossier
- Clearer definitions – greater transparency
- Shorter evaluation periods
- Better research – more data – more evidence – quicker decisions
- Adopt a top-down approach instead of the bottom-up approach driven by the novel food framework – decide which proteins should be developed, deliver clear requirements and safety manufacturing framework



Interviews with stakeholders— Accelerate the regulatory process and approval

- Emphasis on safety means that evaluation and assessment takes time
- Quality of the proposal is essential
- Risk assessment most time consuming – EFSA may be understaffed in this area
- Different regulatory speed outside Europe – competitiveness of the European industry harmed
- Bureaucracy is heavy and slow – but that’s the idea of the system

Interviews with stakeholders— Biggest challenges in terms of regulation

- Amount of science and evidence needed
- Economic strength of firms required for the process
- Ineffectiveness of the regulation process
- Training and education of control authorities
- Lobbying activities of producers of more traditional proteins
- Pace; innovations proceed faster than what regulations can adapt to

Interviews with stakeholders— Future improvement that could facilitate the cooperation of industry and authorities?

- Exchange and mutual information is very important
- A neutral venue/speaker to mediate between industry and authority
- Good dialogue, regular meetings with firms and industry associations
- Transparency and sharing of information
- Trust and willingness to cooperate at high levels
- Recognition that agricultural and food turnaround is just as important as transport and energy transition

Merry Christmas and a Happy
New Year

