

NEXTGEN

PROTEINS

Bioconversion of Underutilized Resources into Next Generation Proteins for Food and Feed

Project start: 01 October 2019

Project duration: 48 months

Deliverable No 1.2.

Documentation on EU legal/regulatory landscape and the safety of alternative proteins for feed

Lead author: VTT

Due Date of Submission: 31st March 2020
Submission Date: 31st March 2020



This Project has received funding from the European Union's Horizon 2020 Research and Innovation programme under grant agreement no. 862704.
www.nextgenproteins.eu

1 Document Information

Document Data

Work package related	Work package 1: Regulation, safety and legal requirements
Task related	Task 1.1. EU regulatory landscape for production and use of alternative proteins
Type	Report
Dissemination level	PU
Keywords	Legislation, feed, EU

Contributors

Authors	Organisations name	E-Mail
Hanna-Leena Alakomi	VTT	Hanna-Leena.Alakomi@vtt.fi
Tiina Hyytiäinen-Pabst	VTT	Tiina.Hyytiainen-Pabst@vtt.fi
Marie Shrestha	TTZ-Bremenhaven	MShrestha@ttz-bremerhaven.de
Sveinn Agnarsson	Synesta	sveinnag@hi.is
Birgir Örn Smáráson	Matis	birgir@matis.is
Christophe Trespeuch	Mutatec	c.trespeuch@mutatec.com
Isaac Berzin	AlgaeInnovatio	isaac@algaennovation.com
Jaakko Korpela	EntoCube	Jaakko.Korpela@entocube.com
Ricardo Ekmay	Arbiom	rekmay@arbiom.com
Melissa Tillotson	Waitrose	melissa.tillotson@waitrose.co.uk
Ann-Kristin Schwarze	Biozoon	Schwarze@biozoon.de

Document history

Document version #	Date	Notes/Change	Status
V. 1	13/03/20	First draft prepared by VTT	draft
V. 2	23/03/20	Reviewed by Jaakko Paasi (VTT)	Reviewed
V. 3	31/03/20	Final revision by Matis PST	Final

Document Data

Work package related	Work package 1
Task related	Task 1.1.2
Keywords	Feed, legislation, protein

Table of content

1	Document Information.....	II
2	Executive Summary.....	4
3	Introduction	5
3.1	The NextGenProteins project	5
3.2	EU regulation of food and feed.....	5
3.2.1	General Food Law	5
3.2.2	Food Law General Principles.....	6
3.2.3	Food Law General Requirements.....	8
3.2.4	Food Law Procedures.....	9
4	EU Feed regulation.....	10
4.1	Feed Hygiene.....	10
4.2	Feed Marketing.....	11
4.3	Legislation on feed additives	11
4.4	Undesirable Substances.....	12
4.5	Qualified presumption of safety (QPS) and Generally Regarded as Safe (FDA)	12
4.6	Microalgae proteins.....	14
4.7	Single cell protein.....	16
4.8	Insect protein	17
5	Analysis of earlier cases	19
5.1	Industry interviews	19
6	Conclusions	21
7	References.....	22

2 Executive Summary

In order to ensure food safety, it is important to consider the whole food chain from farm to fork. All the aspects and players within the supply chain, starting from the production of animal feed and primary production, through production, distribution and sales of food to the consumers influence food safety.

This open report is based on the EU regulation for feeds, 767/2009 as well as other regulations governing the production, safety and application of alternative proteins as feed materials. The report highlights knowledge gaps and regulatory safety barriers with a focus on the three NextGen Proteins, microalgae, single cell protein and insects.

In interviews with the industrial partners in the consortium the following main conclusions were drawn: :

- Consumer health is the most important and therefore scientific information about e.g. toxicology, microbiological and chemical safety and quality of the new proteins is needed.
- Traceability and labelling of the products (e.g. allergens) is important.
- Associations can be beneficial in providing information and training.
- Education of consumers/farmers/other stakeholders about new protein sources is needed. Information about sustainability, Eco footprint, LCA, safety and nutritional value should be available for these purposes. A harmonized coalition of alternative protein producers (like the Sustainable Seafood Coalition SSC) and stakeholders would be beneficial in sharing of information about sustainability and other important consumer issues.
- Novel proteins might be more easily accepted by the consumers in feed applications (e.g. aquafeed, broilers, companion animals, pet food) than in human food.
- Organic certificate would benefit the industrial partners both in food and feed applications.
- Different retail trade operators can have their internal guidelines where they specify e.g. quality limits and requirements for the products. These can be different compared to the legislative limits.

3 Introduction

3.1 The NextGenProteins project

Demand for proteins is increasing for food and feed applications. To meet the increasing demand, production will have to double by 2050. However, current protein production, both animal-based and vegetal-based, has severe negative environmental impacts in terms of greenhouse gas (GHG) emissions, land and water use, as well as biodiversity loss. The EU is not self-sufficient when it comes to protein production and a large proportion of the demand is met with imported proteins with concerns regarding food security and the general competitiveness of the EU. It is therefore of vital importance to find sustainable alternative protein sources that can be economically produced in quantities that meet growing food and feed sectors.

NextGenProteins has identified microalgae, single cell protein and insects as three promising sources of alternative proteins that can be produced through innovative and environmentally sustainable bioconversion processes using industrial waste streams. These processes cause limited environmental impacts and pressure on natural resources. Through collaboration between industry and RTD, the project will address key barriers that currently prohibit or limit the application of the three alternative proteins in food and feed, such as production scalability and optimisation, production costs, value chain risks, safety, regulations and consumer trust and acceptance. The project will demonstrate the suitability and economic viability of the alternative proteins in food and feed value chains and explore their market opportunities with the industry, stakeholders, policy makers and consumers.

NextGenProteins will find means to improve the acceptability and trust of consumers towards alternative proteins and processes. The project will contribute to strengthening food security, sustainability and self-sufficiency of EU protein production with future-proof supply, as well as long-term reduction of land use, water use, GHG emissions and energy of EU food sector.

3.2 EU regulation of food and feed

3.2.1 General Food Law

Several regulations control the food chain (incl. feed) in the European Union. The general principles and requirements are set down in the [Regulation \(EC\) No 178/2002](#) of the European Parliament and the Council (General Food Law legislation). In addition, this law established an independent agency responsible for scientific advice and support, the **European Food Safety Authority (EFSA)**. The General Food Law legislation is the regulatory framework and cornerstone, which lays down the procedures of food safety in the whole agro-food chain (from farm to fork), both at EU level and in national feed and food laws. Likewise, it lays down **general principles, requirements and procedures** for decision making related to food and feed safety, covering food and feed production and distribution. The General Food Law also creates main procedures and tools for management of emergencies and crises as well as the [Rapid Alert System for Food and Feed](#) (RASFF). Important aspect in

the General Food Law is to guarantee high level of protection of human life and health and the protection of consumers' interests.

In order to ensure food safety, it is important to consider the whole food chain from farm to fork. All the aspects and players within the supply chain, starting from the production of animal feed and primary production, through production, distribution and sales of food to the consumers influence food safety.

“In order to ensure the safety of food, it is necessary to consider all aspects of the food production chain as a continuum from and including primary production and the production of animal feed up to and including sale or supply of food to the consumer because each element may have a potential impact on food safety.”

General food law [Regulation \(EC\) No 178/2002](#)

Figure 1. Example of the General Food Law principles ([Regulation \(EC\) No 178/2002](#)).

3.2.2 Food Law General Principles

The general principles and requirements of the EU food law are set down in the [Regulation \(EC\) No 178/2002](#) of the European Parliament and the Council (General Food Law legislation). Examples of the general objectives of the General Food Law legislation are presented in Table 1. Important points are risk assessment principle, precautionary principle and transparency.

Table 1. General objectives of food and feed law in the European Union (https://ec.europa.eu/food/safety/general_food_law/principles).

General objectives of food and feed law

- “Guarantee high level of protection of human life and health and the protection of consumers' interests”.
- “Guarantee fair practices in food trade, taking into account animal health and welfare, plant health and the environment”.
- “Ensure free movement of food and feed manufactured and marketed in the Union, in accordance with the General Food Law Regulation”.
- “Facilitate global trade of safe feed, and safe, wholesome food by taking into account international standard and agreements when developing Union legislation, except where this might undermine the high level of consumer protection pursued by the Union”.
- Implement risk analysis (risk assessment, risk management and risk communication) in decision-making.

Risk analysis principle

The EU food and feed safety and law is based on science and on the three inter-related components of risk analysis: risk assessment, risk management and risk communication (General Food Law, Table 2). In EU the scientific and technical evaluations are performed by the EFSA. EFSA works in close collaboration with national authorities and in open consultation with its stakeholders and provides independent scientific advice and communication on existing and emerging risks.

Precautionary principle

According to the precautionary principle (Article 7 of the General Food Law) decision makers or risk managers can take measures or actions based on the precautionary principle, while seeking for more complete scientific data. The precautionary principle refers to specific situations e.g. where there are reasonable grounds for concern that an unacceptable level of risk to health exists or the available supporting information and data are not sufficiently complete to enable a comprehensive risks assessment to be made (<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52000DC0001&from=EN>).

Table 2. Brief description of risk analysis principles.

Risk assessment	Risk management	Risk communication
must be undertaken in an independent, objective and transparent manner based on the best available science.	<p>process of weighing policy alternatives in the light of results of a risk assessment and, if required, selecting the appropriate actions necessary to prevent, reduce or eliminate the risk. In the risk management phase, the decision makers need to consider a range of other information in addition to the scientific risk assessment. These include, for example:</p> <ul style="list-style-type: none"> • most effective risk reduction actions depending on the part of the food supply chain where the problem occurs • feasibility of controlling a risk • socio-economic effects • environmental impact • a wide range of other factors legitimate to the matter under consideration. 	interactive exchange of information and opinion throughout the risk analysis process among risk assessors, risk managers, consumers, feed and food businesses, academics, other interested parties.

Transparency and sustainability

Transparency of decision-making is most important for the EU. The General Food Law Regulation provides mechanisms to increase consumer confidence and trust, incl. effective public consultation during the preparation, evaluation and revision of food and feed law. In addition, authorities have the obligation to inform the general public where there are reasonable grounds to suspect that food or feed may present a risk for human or animal health. A new regulation on the transparency and sustainability of the EU risk assessment in the food chain (<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32019R1381>) was published in the Official Journal in September 2019 and entered in to force 20 days after publication and will be become applicable on 27th March 2021.

3.2.3 Food Law General Requirements

The safety of food and feed is critical and the consumers need to have confidence and trust in the food chain. The General Food Law Regulation establishes that only **safe food and feed** can be placed on the market or fed to food-producing animals. In addition, the criteria for safe food or feed are set in the General Food Law (Table 3). Tracing food and feed throughout the food chain is vital for the protection of consumers. Therefore, **traceability** is compulsory for all food and feed operators. Traceability provides the ability to track any item that will be used for consumption, throughout all stages of production, processing and distribution. Business operators have the primary **responsibility** for ensuring compliance with food law and the food safety. The national authorities support and guide companies in the activities. The business operators are obligated to **withdraw** or recall products if the food or feed is unsafe.

Table 3. Main Food Law requirements.

Main Food Law requirements
Food safety requirements
Traceability of food and feed products
Responsibility of operators
Withdrawal, recall and notification for food and feed in relation to safety requirements
Import and export

THE KEY OBLIGATIONS OF FOOD AND FEED BUSINESS OPERATORS

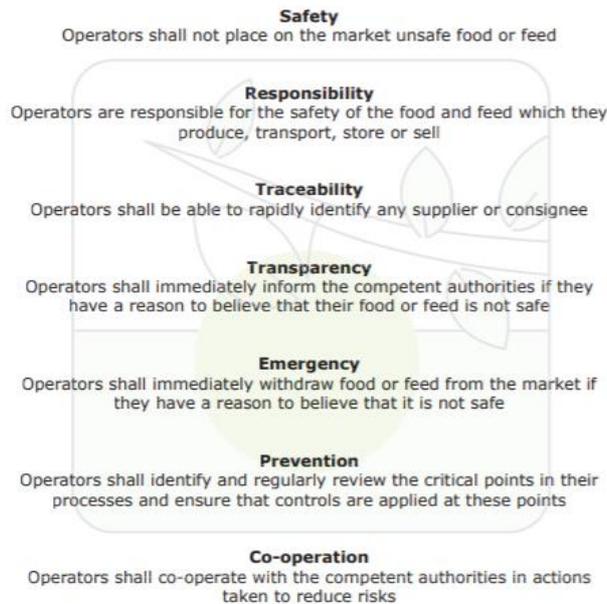


Figure 1. The key obligations of food and feed business operators according to EU. (https://ec.europa.eu/food/sites/food/files/safety/docs/gfl_req_business_operators_obligations_en.pdf).

3.2.4 Food Law Procedures

The General Food Law Regulation provides certain procedures and measures incl., the establishment of the Rapid Alert System for Food and Feed (RASFF), establishment of the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee), adaptation of emergency measures and general plan for crisis management.

4 EU Feed regulation

According to the General Food Law ‘feed’ (or ‘feedingstuff’) means any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals.

In Europe **feed** is controlled by the Union [Regulation \(EC\) No 882/2004](#) of the European Parliament and of the council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. The general principles of food and feed safety are set in the Regulation (EC) No 172/2002. The Regulation (EC) No 1069/2009 lays down rules as regards animal by-products and derived compounds and regulates production, processing, use, storage and transport of raw materials of animal origin for feed. In addition, Regulation (EC) No 183/2005 of the European Parliament and of the Council lays down requirements for feed hygiene contains general rules on feed hygiene, conditions and arrangements for registration and approval of establishments.

Regulation (EC) No 767/2009 of the European Parliament and 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 is the framework for placing on the market and use of feed.

In EU, there are also national level acts, which regulate e.g. transport, circulation, use, trade, storage and import and export of feed stuffs (e.g. The Feed Act (No 86/2008 in Finland) or the veterinary border inspections (e.g. The Act of Veterinary Border Inspection 1192/1666 in Finland). In addition, more specific feed and food law covers different areas such as animal nutrition, feed and food hygiene, zoonoses, animal by-products, residues and contaminants, feed and food labelling, additives etc. [Commission Regulation \(EC\) No 152/2009](#) lays down the methods of sampling and analysis for the official control of feed establishes the sampling method and the methods of analysis of feed for control purposes.

4.1 Feed Hygiene

The [Regulation 183/2005 EC](#) lays down the requirements for feed hygiene. The principal objective of the hygiene rules is to ensure a high level of consumer protection about food and feed safety, taking particular account of the following principles:

- that primary responsibility for feed safety rests with the feed business operator;
- the need to ensure feed safety throughout the food chain, starting with primary production of feed, up to and including, the feeding of food-producing animals;
- the general implementation of procedures based on the principles of hazard analysis and critical control points (HACCP), which, together with the application of good hygiene practice, should reinforce feed business operators’ responsibility;

- that guides to good practice are a valuable instrument to help feed business operators at all levels of the feed chain comply with feed hygiene rules and with the application of HACCP principles;
- the establishment of microbiological criteria based on scientific risk criteria;
- the need to ensure that imported feed attains a standard that is at least equivalent to that of feed produced in the Community.

Since the adoption of the Feed Hygiene Regulation, competent authorities of the EU countries and stakeholders have asked the Commission to clarify several aspects. The guidance document provides additional information and answers to these requests. A Commission Notice was published on 5 July 2019 intitled "[Guidance document on the implementation of certain provisions of Regulation \(EC\) No 1831/2003 laying down requirements for feed hygiene](#)". In addition, community and national guides to good practice in feed production has been provided ([Good practice guidelines](#)).

4.2 Feed Marketing

[EC Regulation 767/2009](#) provides rules on the placing on the market and use of feed. The objectives of the regulation are to harmonise the conditions for the placing on the market and use of feed, in order to ensure a high level of feed safety and thereby high level of protection of public health. To implement this regulation, the Commission has adopted several acts e.g. Commission Regulation (EU) 2017/1017 of 15 June 2017 amending Regulation (EU) No 68/2013 on the Catalogue of feed materials ([Catalogue of feed material](#)), Commission Notice — Guidelines for the feed use of food no longer intended for human consumption ([Guidelines for the feed use of food no longer intended for human consumption](#)), 2011/25/EU: Commission Recommendation of 14 January 2011 establishing guidelines for the distinction between feed materials, feed additives, biocidal products and veterinary medicinal products ([Guidelines for the distinction between feed materials, feed additives, biocidal products and veterinary medicinal products](#)), Commission 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 ([Revision of the tolerances for analytical constituents and provisions for the labelling of feed additives](#)). There is other related legislation e.g. related to pet food labelling.

4.3 Legislation on feed additives

The Feed Additives Regulation (Regulation (EC) No 1831/2003) lays down rules for feed additive authorisation, placing on the market, labelling and use. The European Commission is currently carrying out an evaluation of the Feed Additives regulation (https://ec.europa.eu/food/safety/animal-feed/evaluation-eu-legislation_en), European Commission keeps updated [Register of Feed Additives](#).

4.4 Undesirable Substances

The EU legislation on undesirable substances in animal nutrition aims to ensure that “*the feed put into circulation is sound, genuine and of merchantable quality, and when correctly used, does not represent any danger to human health, animal health or the environment or do not adversely affect livestock production*”. [Directive 2002/32/EC \(consolidated version\)](#) of the European Parliament and of the Council, of 7 May 2002, on undesirable substances in animal feed. The Directive 2002/32/EC prohibits the dilution of contaminated feed material. In addition, it includes maximum limits for selected heavy metals (incl. arsenic, lead, mercury and cadmium) as well as dioxin and aflatoxin.

There are also several Commission Recommendations related to presence of mycotoxins (e.g. ochratoxin A, deoxynivalenol, zearalenone, fumonisins, T-2 and HT-2 toxin in cereals and cereal products intended for animal feed. Commission Recommendation 2006/583/EC of 17 August 2006 on the prevention and reduction of Fusarium toxins in cereals and cereal products

4.5 Qualified presumption of safety (QPS) and Generally Regarded as Safe (FDA)

In EU the EFSA assesses safety of all new food and feedstuffs and microorganisms used in them. After EFSA grants a microorganism **qualified presumption of safety (QPS) status**, it is included in the [list of QPS status recommended biological agents for safety risk assessments](#). A [QPS list](#) is also available. The qualified presumption of safety (QPS) is based on reasonable evidence (<https://www.efsa.europa.eu/en/topics/topic/qualified-presumption-safety-qps>). If an EFSA assessment concludes that a group of microorganisms does not raise safety concerns, the group is granted “QPS status”. No microorganism belonging to that group needs to undergo a full safety assessment. The publication of the next scientific opinion updating the QPS list is planned for December 2022 and will be based on the 6-month assessments carried out by the EFSA BIOHAZ Panel. In the EU a QPS assessment is done after EFSA receives an application for market authorisation of a regulated product that requires a safety assessment.

Table 3. In order to be granted QPS status, a microorganism must meet the following criteria (EFSA, <https://www.efsa.europa.eu/en/topics/topic/qualified-presumption-safety-qps>).

- Its taxonomic identity must be well defined.
- The available body of knowledge must be sufficient to establish its safety.
- The lack of pathogenic properties must be established and substantiated.
- Its intended use must be clearly described.

Microorganisms that are not well defined, for which some safety concerns are identified or for which it is not possible to conclude whether they pose a safety concern to humans, animals or the environment are not considered suitable for QPS status and must undergo a full safety assessment.

In the United States the food ingredients may be "food additives" that are approved by Food and Drug Authority (FDA) for specific uses or **GRAS (generally recognized as safe)** substances. A substance may be GRAS only if its general recognition of safety is based on the views of experts qualified to evaluate the safety of the substance. GRAS status may be based either on a history of safe use in food prior to 1958 or on scientific procedures, which require the same quantity and quality of evidence as would be required to obtain a food additive regulation. Because GRAS status may be either affirmed by FDA or determined independently by qualified experts, FDA's regulations do not include all GRAS ingredients and the specific uses described in the GRAS regulations may not be comprehensive for the listed ingredients. <https://www.fda.gov/food/generally-recognized-safe-gras/microorganisms-microbial-derived-ingredients-used-food-partial-list>

4.6 Microalgae proteins

Microalgae are plant-like single cell organisms, which are rich in nutrients. Microalgae such as *Spirulina* and *Chlorella* can be used as dried whole cells in feed products. In addition, microalgae can be used as host for producing high-value supplements (Kagan and Matulka, 2015). Microalgae can be produced in open basins or closed photobioreactor-systems (Moomaw *et al.*, 2017). Advantage of closed system is better process optimization and control, which affects the quality of microalgae products. Using open basins or natural water for producing microalgae causes a risk for algae or pathogen bacteria contamination (Tzachor, 2019). Likewise, some cyanobacteria contaminants can produce toxins in open outdoor culture basins. Hazards related to algae may include allergens, toxins, pathogens, heavy metals and pesticides and therefore there are regulatory guidelines for these (C 178/2002). Microalgae offer a wide range of compounds useful as feed ingredients (Madeira *et al.*, 2017).

Three microalgae species are classified as Generally Recognised as Safe (GRAS): *Spirulina/Arthrospira* sp. belonging to Cyanobacteria, *Chlorella* sp. (Chlorophyta) and *Porphyridium Cruentum* (Rhodophyta). In addition, some algal products have been granted GRAS status e.g. docosahexaenoic acid (DHA) algal oil from *Schyzochitrium* and *Ulkenia*, and whole algal protein powder from *Chlorella*. Polyunsaturated fatty acids incl. eicosapentaenoic acid (EPA from e.g. *Nannochlorophis*) and docosahexaenoic acid (DHA) are among the most valuable functional ingredients of microalgal lipids (Dineshbabu *et al.* 2019). Algal products are also defined within Section 12 of the Commission Regulation 68/2013 on the [Catalogue of feed materials](#) (2013).

Definitions and principles of feed production and distribution are on laid down in [European Community Regulation on Food Safety \(EC 178/2002\)](#). If gene modification is applied in microalgae production, EU regulations ([1829/2003](#) and [1830/2003](#)) define the boundary conditions. European Regulation on Nutrition and Health Claims made on Foods ([EC 1924/2006](#)) will be applied for food/ feed health claims. These claims require accepted scientific evidence.

Photobioreactors (PBRs) are characterized by low pathogen risks, low space requirements, and minimal ecological footprint: low water losses, efficient CO₂ utilization, high variability in regards to cultivable species, high degree of control over culture processes, high biomass concentration, high efficiency in down-stream processing and no dependence of weather conditions (indoor PBRs, Tzachor, 2019). Since 2018, the integrated system has been cultivating natural strains of protein-rich and high omega-3-marine microalgae for feed purposes. Production has mainly been based on *Nannochlorophila oculata*. Microalgae are commonly used for feed purposes and can partially replace soybean in animal husbandry, however microalgae still remain as under-exploited crop. Omega-3-rich microalgae could be the next sustainable aquafeed.

Organic certification for algae is difficult, because of the inadequacy of current guidelines, which were originally developed for terrestrial plants. For instance, most of the approved

organic fertilizers are not water soluble, inhibit light penetration to the culture and may increase the likelihood of contamination.

Algae are also an alternative source of protein for feeding. As with fish, feeding with marine microalgae can lead to an increased content of omega-3 fatty acids in meat, eggs and milk. However, the use of algae has so far been limited to a share of approximately 5% to 10% of total feeding due to undesirable side effects. Almost all marine microalgae that are used in feed and food are already optimized varieties through breeding (mostly through undirected mutagenesis). However, newer biotechnological processes could further improve the suitability of algae for use as animal feed.

Regulatory issues play a big role in the field. For example, currently some algae oil approved but the protein from the same algae is not approved. Some algae are known to be toxigenic and produce e.g. neurotoxins. However, the strains selected for production of food and feed proteins are non-toxic. In addition, in controlled photoreactors the production is under control (HACCP), food-grade and contamination issues are avoided. In addition, in closed bioreactors no pesticides, fungicides or antibiotics are used and there are no chemical residues to the environment.

For feed, e.g. aquafeed the barrier to the market is lower than with food products. However, in order to be profitable the production volumes needed are huge and protein content should be high. Food proteins would be more profitable for the companies, but regulatory issues are hindering entry to the market.

4.7 Single cell protein

Yeast and fungi have long history as animal feed ingredients (Jones *et al.* 2020). Single cell proteins (SCP) as any food or feed products need to be safe to produce and use (Ritala *et al.*, 2014) and the regulations differ based on the intended use. SCP has been applied as animal feed for decades, e.g. *Saccharomyces*, *Kluyveromyces*, *Torula/Candida utilis* yeasts have GRAS status and are on the QPS list. These SCP products are also defined within Section 12 of the Commission Regulation 68/2013 on the [Catalogue of feed materials](#) (2013, 2017). Approved feedstocks for cultivation are typically embedded within the product definition. Currently, some SCP products are entering the market as additives (e.g. providing colour) rather than protein source. The term SCP is often used to describe edible microbial biomass as whole, but the biomass does not consist solely of protein and it can also include non-protein compounds like lipids and carbohydrates (Ritala *et al.*, 2017). Microbial products, especially yeasts, have been reported to be suitable ingredient in aquafeed due to their ability to convert low-value non-food biomass from forestry and agriculture to high-value feed (Overland and Skrede, 2016). The conversion of cellulose and hemicellulose to protein-rich biomass is well established, e.g. *Torula/Candida utilis* has been commercially available more than 70 years as nutritional supplement to animal feed (Overland and Skrede, 2016).

In most of the cases the aim is to maximize cellular growth and co-product yield in economical processes. Therefore, various side-streams, by-products and industrial/agricultural residues have been utilized as feedstock for the SCP microbes (Ritala *et al.*, 2014; Jones *et al.*, 2020). Studies on bacterial SCP and production of proteins has increased during recent years especially with bacteria utilizing methane, methanol, syngas, CO₂, H₂ and second generation sugars (Sillman *et al.*, 2019, Jones *et al.*, 2020).

Registration of the new feed ingredient (if the producer has GRAS status or is on the QPS list) is relatively easy and straightforward and the on-line system supports this. However, if the producer strain is not on the QPS list or does not have GRAS status additional evidence is needed. Dried, inactive biomass from *Candida utilis* is already found within the EU feed register.

The nucleic acid content of crude microbial biomass is too high for direct consumption by humans as well as many animals and is due to elevated levels of uric acid in the blood following ingestion. Therefore, microbial biomass needs to be pre-treated to remove nucleic acids, e.g. through heat treatment (Linder, 2019). In many cases the consumption is usually limited rather than nucleic acids being removed. Upper limits of inclusion are usually provided to customers by species.

4.8 Insect protein

The use of insects as feed material has increased and they are currently been authorised to be used in aquaculture animals ([Commission Regulation \(EU\) 2017/893](#)). DG Sante has elaborate [strategic safety concept for insects as feed](#). Currently insect protein is used in fish feed and pet food, but not for other animals feed (e.g. poultry or pig). In addition, the insects cannot be fed with former foodstuff containing meat, fish or food losses originating from restaurants or catering. The legislative framework specifically related to insects used as food and feed, however, is still under development (EFSA, 2015).

Regulations (EC) No 178/2002 (General Food Law) and 183/2005 (Feed Hygiene) apply to all feed business operators, incl. those rearing insects. These acts ensure that general feed safety requirements, traceability and manufacturing requirements apply to insect farming. Producers of insects for feed use are feed business operators according to the Feed Hygiene Regulation as their activity is considered a primary production of feed. This implies hygiene requirements, safeguard measures and manufacturing standards, which needs to be respected by the insect farmers. These measures aim to maintain low level of biological, chemical and physical contamination.

Moreover, Regulation (EC) No 1069/2009 (Animal By-Products, ABP) establishes that insects kept in the EU to produce food, feed or other purposes are "farmed animals". This status has repercussions on the animal health status of the farmed insects: Article 10 of the Animal Health Law establishes biosecurity measures for establishments keeping animals and establishes responsibilities for the operators in the area of animal health and biosecurity. Feeding livestock from insects is covered by animal feed health regulations (Regulation (EC) No.999/2001). A specific section (Chapter IV, Section F) has been created for PAPs in Appendix IV of Regulation (EC) No. 999/2001. It describes the conditions under which these PAPs are produced and used.

Regulation 893/2017 - amending Regulation 142/2011 on processed animal protein provisions - allows Processed Animal Proteins (PAP) derived from insects in the diet of aquatic animals (defined in Appendix I of Regulation (EC) No.999/2001). Farmed insects must be part of a list of authorized insects. The substrate used should contain only non-animal products or animal products from a positive list.

Article 14 of Regulation (EC) 1069/2009 does not authorize the use of animal by-products in the feeding of livestock without prior processing. In this text, different methods of transformation are listed. There are seven of them which aim to ensure the sanitary quality of the processed product, that is put on the market, respects microbiological criteria. Regulation (EC) 767/2009 regulates the marketing of food authorized for animal feed, its use, packaging and presentation, including labelling for which control is the responsibility of the DGCCRF (Sanitary inspection in France).

The references to be applied on the products marketed are defined by Article 12 of the order of 23/04/07. For the PAP: on the Commercial Accompanying Document the label: "Processed

animal proteins derived from insects - do not use in the diet of farm animals with the exception of aquaculture animals and furry animals". The presence of a green C3 label is mandatory. For composed feed by stating: "contains processed animal proteins from non-ruminants - do not use livestock in the diet except aquaculture animals and fur animals". Regulated health hazards and their thresholds for feeding animals are reported in 2002/32/CE.

EU Regulation 2017/893, amending previous regulations, allowed a shortlist of seven insect species (*Hermetia illucens*, *Musca domestica*, *Tenebrio molitor*, *Alphitobius diaperinus*, *Acheta domesticus*, *Grylloides sigillatus* and *Gryllus assimilis*) to be included in the formulation of feeds for aquaculture. Accordingly, a specific method to detect the presence of insects in these feeds and to discriminate between allowed and not allowed species needs to be developed.

Table 4. Potential hazard linked with insect proteins and identified as points needing additional research:

<ul style="list-style-type: none"> ➤ Anti-nutrients ➤ Toxic potential (production, accumulation of plant toxins, pesticides, heavy metals, mycotoxins) ➤ Allergenic potential (e.g. tropomyosin) ➤ Zoonotic risk (insects act as vectors) incl. parasites ➤ Microbial safety (pathogens, spores, intestinal flora and surface colonization) ➤ Controlled breeding conditions (substrate, breeding, personnel) and safe and effective processing ➤ Decontamination and storage required

According to EFSA opinion paper, studies on the occurrence of microbial pathogens of vertebrates as well as published data on hazardous chemicals in reared insects are scarce (EFSA, 2015). However, according to the EFSA opinion (2015), the substrate used and the farming environment strongly influence insects' microbiota, and therefore the foodborne risk is influenced by the nature and the hygienic conditions of the substrate and the farming environment. In general, food and feed-grade substrates, if maintained in good hygienic conditions, should not pose any additional risk when fed to insects as compared with other approved foods or feeds. Insects can cause allergic reactions and need to be mentioned in the label.

In the discussion held with EU, regulatory progress is quite focused on enlarging "authorized substrates", access to new raw materials and "organic production". In addition, there are ongoing discussion about extension from aquaculture to broiler feed. Organic farming status would benefit the industry. Fractionation and milling of the crickets is not currently approved and needs to be taken account in future legislation. The legal framework was identified by International Platform of Insects for food and food (IPIFF) 2019 questionnaire as the main factor impacting the growth of the insect sector (<https://ipiff.org/>).

There is also a need for research to identify possible allergens and to process insects for the isolation of protein and / or other components. In larger production plants utilization of antibiotics could be necessary to prevent infections. Feasibility studies and pilot projects are needed here to test the potential and risks of large-scale insect production in practice. Ethical aspects of keeping insects should also be discussed early enough.

Novel protein sources and foods made from them are intended to increase sustainability in future protein supply. It does not have to be the goal to completely replace the consumption of animal products. Any reduction in the consumption of conventional animal products and their partial replacement with more sustainable protein sources can increase the sustainability of the food system. Studies show that most consumers want to eat more sustainably, but the observed behaviour of consumers differs from the stated intentions. New foods from more sustainable protein sources must therefore better meet the needs of consumers; they must taste good, be healthy, but at the same time be affordable and usable or available as needed. With foreign products, socio-cultural barriers are often difficult to overcome.

5 Analysis of earlier cases

5.1 Industry interviews

The industrial partners participating to the project were interviewed, included Algaenovation, Grimur Kokkur, MUTATEC, EntoCube, ARBIOM, Naturalleva, Amadori, WAITROSE and BIOZOON. These companies brought into the study a broader view of industry leaders as they all have interactions with other industry players in the field through e.g. industry associations.

The topics discussed during the interviews included: challenges of current regulatory framework, knowledge barriers and safety barriers, potential hazards related to new proteins, industries experiences of the co-operation with the authorities, EFSA and associations, experiences with the consumers, future outlook - need for changes, improvements, training, biggest challenges in the field. Aim was to identify the challenges industrial partners had faced in their business related to e.g. legislation and development of new products.

Main conclusions from the industry viewpoints

- Consumer health is the most important and therefore scientific information about e.g. toxicology, microbiological and chemical safety and quality of the new proteins is needed.
- Traceability and labelling of the products (e.g. allergens) is important.
- Associations can be beneficial in providing information and training.

- Education of consumers/farmers/other stakeholders about new protein sources is needed. Information about sustainability, Eco footprint, LCA, safety and nutritional value should be available for these purposes. A harmonized coalition of alternative protein producers (similar to Sustainable Seafood Coalition SSC) and stakeholders would be beneficial in sharing of information about sustainability and other.
- Novel proteins might be more easily accepted by the consumers in feed applications (e.g. aquafeed, broilers, companion animals, pet food) compared to human food.
- Organic certificate would benefit the industrial partners both in food and feed applications.
- Different retail trade operators can have internal guidelines where they specify e.g. quality limits and requirements for the products. These can be different compared to the legislative limits.

6 Conclusions

Consumer health is the most important and therefore scientific information about e.g. toxicology, allergenicity, microbiological and chemical safety and quality of the new proteins is needed. In addition, the raw materials, production facilities and processes need to fulfil all legislative requirements. Safety of the whole food chain needs to be assured.

Traceability and labelling of the products is important.

Associations can be beneficial in providing information and training. Application of alternative proteins might be more suitable for pet feed because of higher margins and smaller amounts of products required. E.g. German feed industry produces around 30.000-250.000 tons feed per year and need large amount of raw material. The alternative proteins are not available yet in such amounts.

As there is not scarcity of raw material for feed production, the industry is not yet pushing for alternative source, even if sustainability is a major concern. A much bigger topic for the feed industry is the use of former food as feed.

Associations can be beneficial in providing information and training.

Education of consumers/farmers/other stakeholders about new protein sources needed. Information about sustainability, Eco footprint, LCA, safety and nutritional value should be available for these purposes. A harmonized coalition of alternative protein producers (similar to Sustainable Seafood Coalition SSC) and stakeholders would be beneficial in sharing of information about sustainability and other.

Some novel proteins might be more easily accepted by the consumers in feed applications (e.g. aquafeed, broilers, companion animals, pet food) compared to human food.

Organic certificate would benefit the industrial partners both in feed applications.

Different retail trade operators can have their internal guidelines where they specify e.g. quality limits and requirements for the products. These can be different compared to the legislative limits.

7 References

Commission [Regulation \(EC\) No 882/2004](#) of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules is the legal framework for sampling methods and methods of analysis of feed for control purposes.

[Commission Regulation \(EC\) No 152/2009](#) of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed establishes the sampling method and the methods of analysis of feed for control purposes.

[Commission Regulation \(EU\) 2017/771 of 3 May 2017](#) amending Regulation (EC) No 152/2009 as regards the methods for the determination of the levels of dioxins and polychlorinated biphenyls updates the analytical requirements for the analysis of dioxins and polychlorinated biphenyls.

Reg (EC) No 1831/2003. European Union Register of Feed Additives. Edition 02/2020 (280). Appendixes 3e, 4 – 21.02.2020 European Union legislation on feed additives: https://ec.europa.eu/food/safety/animal-feed/feed-additives_en ; https://ec.europa.eu/food/sites/food/files/safety/docs/animal-feed-eu-reg-comm_register_feed_additives_1831-03.pdf

Dineshbabu, G., Goswami, G., Kumar, R., Sinha, Das, D. (2019) Microalgae–nutritious, sustainable aqua- and animal feed source. Journal of Functional Foods, 62 103545, <https://doi.org/10.1016/j.jff.2019.103545>

EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), Ricci A, Allende A, Bolton D, Chemaly M, Davies R, Fernandez Escamez PS, Girones R, Koutsoumanis K, Lindqvist R, Nørrung B, Robertson L, Ru G, Sanaa M, Simmons M, Skandamis P, Snary E, Speybroeck N, Ter Kuile B, Threlfall J, Wahlström H, Cocconcelli PS, Peixe L, Maradona MP, Querol A, Suarez JE, Sundh I, Vlcek J, Barizzone F, Correia S and Herman L, 2018. Statement on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA 8: suitability of taxonomic units notified to EFSA until March 2018. EFSA Journal 2018;16(7):5315, 42 pp. <https://doi.org/10.2903/j.efsa.2018.5315>

EFSA Scientific Committee, 2015. Scientific Opinion on a risk profile related to production and consumption of insects as food and feed. EFSA Journal 2015;13(10):4257, 60 pp. <https://doi.org/10.2903/j.efsa.2015.4257>

European Parliamentary Research Service (2016). Insects - soon to be a regulated food? Verfügbar unter

http://www.europarl.europa.eu/RegData/etudes/ATAG/2016/583830/EPRS_ATA%282016%29583830_EN.pdf

EFSA Scientific Committee (2015). Risk profile related to production and consumption of insects as food and feed. *EFSA Journal*, 13(10).

Halloran, A., Roos, N., Eilenberg, J., Cerutti, A., Bruun, S. (2016). Life cycle assessment of edible insects for food protein: a review. *Agronomy for Sustainable Development*, 36(4), 57.

Becker, E. W. (2007). Micro-algae as a source of protein. *Biotechnology Advances*, 25(2), 207–210.

German Federal Institute for Risk Assessment (BfR), National Reference Laboratory for Animal protein in Feed, NRL-AP, Garino C, Zagon J and Braeuning A, 2019. Insects in food and feed – allergenicity risk assessment and analytical detection. *EFSA Journal* 2019;17(S2): e170907, 12 pp. <https://doi.org/10.2903/j.efsa.2019.e170907>

IPIFF (2019) Briefing paper on the provisions relevant to the commercialization of insect-based products intended for human consumption in the EU http://ipiff.org/wp-content/uploads/2019/08/ipiff_briefing_update_03.pdf

Jones, S.W., Karpol, A., Friedman, S., Maru, B.T., Tracy, B.P. (2020) Recent advances in single cell protein use as a feed ingredient in aquaculture, *Current Opinion in Biotechnology*, 61: 189-197, <https://doi.org/10.1016/j.copbio.2019.12.026>

Linder, T. Making the case for edible microorganisms as an integral part of a more sustainable and resilient food production system. *Food Sec.* **11**, 265–278 (2019). <https://doi.org/10.1007/s12571-019-00912-3>

Marta S. Madeira, Carlos Cardoso, Paula A. Lopes, Diogo Coelho, Cláudia Afonso, Narcisa M. Bandarra, José A.M. Prates. (2017) Microalgae as feed ingredients for livestock production and meat quality: A review. *Livestock Science*, Volume 205, 111-121, <https://doi.org/10.1016/j.livsci.2017.09.020>

Makkar, H. P., Tran, G., Heuzé, V., Ankers, P. (2014). State-of-the-art on use of insects as animal feed. *Animal Feed Science and Technology*, 197, 1–33.

Moonaw, W., Berzin, I. and Tzachor (2017) Cutting Out the Middle Fish: Marine Microalgae as the Next Sustainable Omega-3 Fatty Acids and Protein Source. *Industrial Biotechnology*. Oct 2017.234-243. <http://doi.org/10.1089/ind.2017.29102.wmo>

[Overland, M. and Skrede, A. \(2016\). Yeast derived from lignocellulosic biomass as sustainable feed resource for use in aquaculture. *J Sci Food Agric* <https://onlinelibrary.wiley.com/doi/full/10.1002/jsfa.8007>](https://onlinelibrary.wiley.com/doi/full/10.1002/jsfa.8007)

- Rajेशa, J., Madhusudhan, B., Mahadevaswamy, M., Rao, R.J., Ravishankar, G.A. et al. (2011). Flaxseed and Spirulina in designer eggs: A potent blended functional food and a smart food choice. In: Martirosyan, D.M. (ed.), Functional foods in health and disease. Food Science Publisher, Richardson (Dallas), TX. pp. 124–139.
- Ritala, A., Häkkinen, S. T., Toivari, M. and Wiebe, M. G. (2017) Single cell protein – State of the art, industrial landscape and patents 2001-2016. Front Microbiol ;, 2009. doi: [10.3389/fmicb.2017.02009](https://doi.org/10.3389/fmicb.2017.02009)
- Sillman, J., Nygren, L., Kahiluoto, H., Ruuskanen, V., Tamminen, A., Bajamundi, C., Nappa, M., Wuokko, M., Lindh, T., Vainikka, P., Pitkänen, J-P and Ahola, J. (2019). Bacterial protein for food and feed generated via renewable energy and direct air capture of CO₂: Can it reduce land and water use? Global Food Security, 22: 25-32, doi.org/10.1016/j.gfs.2019.09.007
- Spolaore, P., Joannis-Cassan, C., Duran, E., Isambert, A. (2006). Commercial applications of microalgae. Journal of Bioscience and Bioengineering, 101(2), 87–96.
- Veldkamp T., van Duinkerken G., van Huis A., Lakemond C.M.M., Ottevanger E. et al. (2012). Insects as a sustainable feed ingredient in pig and poultry diets - a feasibility study. Wageningen UR Livestock Research. Niederlande.
- Tzachor, A. (2019) The future of feed: Integrating technologies to decouple feed production from environmental impacts. Industrial Biotechnology. Apr 2019.52-62. <http://doi.org/10.1089/ind.2019.29162.atz>