Interreg
North-West Europe
ALG-AD
European Regional Development Fund

EUROPEAN UNION

THEMATIC PRIORITY

RESOURCE AND MATERIAL EFFICIENCY

POLICY RECOMMENDATIONS FOR THE COMMERCIALISATION OF ALG-AD TECHNOLOGY

Prepared by NNFCC for ALG-AD

The Bioeconomy Consultants
NNFCC

EDITION : DECEMBER 2020

Release Date: December 2020

Author(s): Sotirios Sourmelis Consultant

Reviewer(s): Lucy Hopwood Director and Lead Consultant

NNFCC is a leading international consultancy with expertise on the conversion of biomass to bioenergy, biofuels and biobased products.

The Bioeconomy Consultants
NNFCC

NNFCC, Biocentre,
York Science Park,
Innovation Way,
Heslington,
York, YO10 5NY

Phone: +44 (0)1904 435182
Fax: +44 (0)1904 435345
Email: enquiries@nnfcc.co.uk
Web: www.nnfcc.co.uk

TABLE OF CONTENT

1 INTRODUCTION

Throughout the EU, anaerobic digestion (AD) is widely used as an effective means of managing food waste, livestock waste and other agricultural wastes via their conversion into biogas and nutrient-rich digestate (NRD). Whilst biogas is the primary product of this process, digestate is widely recognised as a valuable by-product and is used across the continent in fertiliser applications. Spreading of digestate is regulated as it can have negative and potentially damaging impacts on the environment, with the most significant risk being eutrophication of water bodies. Therefore, strict limits are imposed on the use of fertilisers around Europe and it is often not possible to return all digestate produced in AD facilities back to land, thus causing a build-up of material with no alternative application.

The Interreg North-West Europe ALG-AD project intends to integrate NRD-grown microalgae cultivation systems with existing AD facilities, to create value from Nutrient-Rich Digestate (NRD) that is produced in excess of that permitted for land-spreading, and therefore currently has no industrial application. Soluble nutrients contained within digestate could be used to feed microalgae, which in turn will be used as a sustainable protein source for animal feed.

This study examines the EU legislation across the entire microalgae production value chain, focusing first on how the requirements apply to the use of microalgae as a 'feed material', the main market being targeted by ALG-AD, before investigating the regulatory framework for accessing alternative markets and drawing together a series of policy recommendations to address the main barriers identified. The report is intended to inform project partners initially, then a broader set of stakeholders and end users with an interest in this value chain.

More specifically, this report presents:

1. The key regulatory framework applicable to the production and use of NRD-grown microalgae as 'feed material' for 'farmed animals' (agricultural livestock, aquaculture, and non-food producing animals), as the main market being targeted by ALG-AD.
2. Safety aspects of using NRD-grown algae in animal feed applications in the EU.
3. Key regulatory barriers affecting the commercialisation of the ALG-AD value chain.
4. Policy alternatives for using ALG-AD products in different markets, such as feed additives, biostimulants, and novel foods.
5. A series of actions required to support ALG-AD technology adoption and address identified barriers, from a regulatory perspective.

This report is a follow-up of an in-depth regulatory review, also conducted by NNFCC. The findings from the in-depth review are summarised and discussed below, in relation to their impact and specific actions that need to be taken in order to commercialise the technology.

2 EU REGULATORY FRAMEWORK APPLICABLE TO THE ALG-AD TECHNOLOGY FOR THE PRODUCTION OF FEED FOR FARMED ANIMALS

This chapter deals with the EU regulatory framework applicable to the production and use of NRD-grown microalgae for feeding **farmed animals**, including agricultural livestock, aquaculture, and non-food producing animals, as these are the main markets being targeted by ALG-AD. The regulatory requirements for accessing alternative markets for NRD-grown microalgae are discussed in Chapter 4.

2.1 Regulations applicable to microalgae production

The European Union does not have a single policy dedicated to microalgae production, but rather a suite of policies that touch upon different elements of production, either directly or indirectly [1].

Among them, **Regulation (EC) No 1069/2009** on animal by-products and derived products appears to be the most relevant, with strong implications for marketing of the ALG-AD technology. This regulation aims to lay down strict controls on how animal by-products (ABP) can be processed, and what end-uses are acceptable for them [2]. As animal by-products are often used as feedstock for AD, biogas operators must abide by these regulations, as must producers of any materials derived from animal by-products.

Acceptable disposal or treatment methods for ABPs are determined by what Category they fall into (Table 1), based on the risks they pose. Any mixture of ABPs from multiple categories is considered to be of the lowest-numbered category and thus subject to the strictest available regulations.

Even though categories 2 and 3 are acceptable for use in biogas generation, only Category 3 ABPs, with the exception of catering food waste (restricted by Article 11 of Regulation (EC) No 1069/2009), can be used to produce animal feed for farmed animals, including agricultural livestock, aquaculture, and non-food producing animals[1]. The exception specifically applies to catering waste, which is likely to contain animal by-products (or other contaminants such as packaging or other materials) and not food supply chain waste from non-ABP facilities, such as vegetable wastes. However, in order to comply, specific streams need to be well defined.

To take account of the related progress in science and technology, according to preamble 44 of the same Regulation, novel technologies that offer advantageous ways of treating animal by-products should be authorised as 'alternative methods' for the disposal or use of all ABPs throughout the community. Applications can be submitted to the competent authority of the Member State where developers intend to use the alternative method, while the application will also be reviewed by the European Food Safety Authority (EFSA).

Guidance on the format for applications for new methods of treatment for animal by-products has been published by EFSA [3], providing technical assistance on expected contents and appropriate evidence. EFSA will assess whether the process reduces risks to human and animal health from ABPs and will decide whether to authorise the use of this alternative method for the processing and/or use of ABPs.

[1] With regard to animal feed production, Regulation 1069/2009 applies to both animal by-products and derived products. According to the same regulation, 'Derived products' are defined as products obtained from one or more treatments, transformations or steps of processing of animal by-products.

Table 1: Categories of animal by-products

Categories of ABPs	ABPs fall into these Categories
Category 3 (classed as Low Risk)	✔ carcasses or body parts passed fit for humans to eat, at a slaughterhouse ✔ products or foods of animal origin originally meant for human consumption but withdrawn for commercial reasons, not because it is unfit to eat ✔ domestic catering waste ✔ shells from shellfish with soft tissue ✔ eggs, egg by-products, hatchery by-products and eggshells ✔ aquatic animals, aquatic and terrestrial invertebrates ✔ processed animal proteins (PAP)
Category 2 (classed as High Risk)	✔ animals rejected from abattoirs due to having infectious diseases ✔ carcasses containing residues from authorised treatments ✔ unhatched poultry that has died in its shell ✔ carcasses of animals killed for disease control purposes ✔ carcasses of dead livestock ✔ digestive tract content ✔ manure
Category 1 (classed as Very High Risk)	✔ carcasses and all body parts of animals suspected of being infected with TSE (transmissible spongiform encephalopathy) ✔ carcasses of wild animals suspected of being infected with a disease that humans or animals could contract ✔ carcasses of animals used in experiments ✔ parts of animals that are contaminated due to illegal treatments ✔ carcasses and body parts from zoo and circus animals or pets ✔ body parts that pose a particular disease risk, e.g. cows' spinal cords ✔ international catering waste (from international transport operators)

Another EU regulation that may be directly relevant to NRD-grown microalgae production, in situations where organic status is desired, is the **(EC) 2018/848** [4], which lays down a legal framework for organic products. Organic certification and labelling of ALG-AD products is possible, but they need to be derived from digestate that is exclusively of plant origin[2] (although the plants used for digestion do not need to be organically certified).

A requirement for a permit in accordance with the **(EC) No 708/2007** (Alien Species Legislation) [5] may also apply to ALG-AD developments, but this is subject to whether ALG-AD activities are considered aquaculture, which relies heavily on interpretation of a number of definitions provided in the legislation, such as 'aquatic organisms', and 'closed aquaculture facility'.

Therefore, it is advised that developers should discuss individual cases with the competent authority of the receiving Member State, and subsequently apply for a permit if necessary. Securing a permit is not expected to be an issue as ALG-AD activities are performed in closed reactors and will be classified as 'routine movements'[3] , which are not subject to a prior 'environmental risk assessment' and provision are less stringent, as opposed to 'non-routine movements'[4] . However, if produced in open systems and classified as aquaculture, this may be deemed 'non-routine movement' and may be subject to a prior risk assessment. Any activity identified as posing a high risk to the environment as a result of such assessment would not be eligible to secure a Permit.

Similarly, developers should confirm with Environment Departments at Member State level, whether there is a requirement for an Environmental Impact Assessment (EIA) for setting up a new NRD-grown microalgae cultivation plant in accordance with **(EC) 2011/92** [6].

As a side note, NRD-grown microalgae produced as part of the ALG-AD project are not genetically modified, and therefore EU directives on GM algae (2009/41/EC and 2001/18/EC) do not apply in this instance [7],[8].

[2] There are AD facilities in Europe using solely energy crops, such as grass silage or other type of feedstock, such as distillery waste (draff), that are exclusively of "plant" origin which would be eligible.

[3] 'Routine movement' means the movement of aquatic organisms from a source which has a low risk of transferring non-target species and which, on account of the characteristics of the aquatic organisms and/or the method of aquaculture to be used, for example closed systems, does not give rise to adverse ecological effects.

[4] 'Non-routine movement' shall mean any movement of aquatic organisms which does not fulfil the criteria for routine movement.

2.2 Regulations that apply to NRD-grown microalgae-based feed applications

Legislation on animal feed is harmonised at European Union (EU) level and applies to a wide range of animal feed businesses and activities, including the manufacture, sale, and supply stages of the value chain. It applies to feed for farmed animals (for food-producing animals, including farmed fish, and also to feed for non-food producing animals, such as pets, zoo animals), as well as creatures living freely in the wild, although specific requirements can differ between animal categories.

EU Regulation 178/2002 provides a framework for the development of food and feed legislation at Community and national level and lays down procedures in matters of food safety [9]. This regulation established the European Food Safety Authority (EFSA) and applies to all stages of production, processing and distribution of food and feed. In accordance with the principles laid down in 178/2002, EU animal feed legislation has been developed and divided according to the main set of regulations[5].

It is important to recognise that there are regulations and rules in the legislation that do not apply to every type of animal feed. For assisting feed business operators to enforce and to apply the relevant legislation, the EU commission established guidelines for the distinction between feed materials, feed additives, biocidal products, and veterinary medical products [10]. Based on EU guidelines, the products developed by ALG-AD partners can be considered as 'feed materials', as they are not chemically well-defined and their principal purpose is to meet the animals' nutritional needs, unlike feed additives.

Table 3 presents the legislation applicable to 'feed materials', as this is the main market being targeted by ALG-AD, excluding, for example, **Regulation 1831/2003** [11], which establishes a common procedure for authorising feed additives and lays down rules for their placing on the market [11]. In addition, the algal biomass growing on waste nutrients (NRD-grown microalgae) are non-GMO and therefore, the requirements of the **Regulation 1829/2003** on genetically modified food and feed do not apply [12], which simplifies the process of commercialisation from a regulatory perspective. The regulatory requirements for accessing alternative markets are discussed in Chapter 4.

2.3 Safety aspects of using NRD-grown algae to feed farmed animals in the EU

The EU has no system for pre-market authorisation of feed materials [13] and microalgae-based feed materials, in general, are not included in the list of prohibited or restricted feed materials under (EC) 767/2009 (see Table 2 for more details). This means that they can be safely used as feed materials in the EU, given that:

1. they are not genetically modified.
2. their production fulfils the requirements of Regulation (EC) No 1069/2009 on the use of animal by-products,
3. and the feed product complies with Article 4 of Regulation (EC) No 767/2009, which lays down safety and marketing requirements.

The Joint Research Centre (JRC), the EU Commission's science and knowledge service, provides a list of microalgae species currently used in food or feed applications (Table 2).

[5] A full list of EU legislation and other rules applicable to or of relevance to pet food specifically can be found at https://fediaf.org/self-regulation/legislation.html

Table 2: Microalgae relevant for food/feed applications and their safety aspects [14]

Organism	Species	Safety aspect	Organism	Species	Safety aspect
Cyanophyta	*Spirulina / Arthrospira sp.*	GRAS	**Haptophyta**	*Isochrysis sp.*	NT
	Synechococcus sp.	NT		*Pavlova sp.*	NT
Chlorophyta	*Tetraselmis sp.*	NT	**Heterokontophyta**	*Navicula sp.*	NT
	Chlamydomonas reinhardtii	NT		*Nitzschia dissipata*	NT
	Haematococcus pluvialis	NT		*Phaeodactylum tricornutum*	NT
	Dunaliella sp.	NT		*Thalassiosira pseudonana*	NT
	Chlorococcum sp.	NT		*Odontella aurita*	NT
	Scenedesmus	NT		*Skeletonema sp.*	NT
	Desmodesmus sp.	NT		*Monodus subterraneus*	NT
	Chlorella sp.	GRAS		*Nannochloropsis sp.*	NT
	Parietochloris incisa	NT			
Rhodophyta	*Porphyridium cruentum*	*GRAS*	**Dinophyta**	*Crypthecodinium cohnii*	GRAS

* NT = no toxins known, GRAS = Generally Recognised as Safe

This list includes species that are used for the production of feed materials as part of the ALG-AD project (*Chlorella, Scenedesmus, Desmodesmus*). *Chlorella* has been given the GRAS (generally recognised as safe) status by the FDA (Food and Drug Administration) of the USA, while *Scenedesmus* and *Desmodesmus* were reported not to produce any toxins [14].

It should be noted that *Schizochytrium* (e.g. *Traustochytrids*), that are cultivated in the ALG-AD pilot plant in Brittany, are not mentioned in the JRC list. Nevertheless, this list is not exhaustive, meaning that *Traustochytrids* are allowed to be used as 'feed materials' in the EU, given that they meet the requirements listed earlier in this section.

2.4 A summary of the regulatory framework applicable to the ALG-AD value chain

Table 3 presents a summary the EU Regulations that are potentially applicable to NRD-grown microalgae.

Table 3: Summary of regulations/policies considered applicable to ALG-AD.

Policy/Legislation	Relevance to ALG-AD	Description	Implications on ALG-AD value chain	Competent Authority
Regulations applicable to NRD-grown microalgae production				
Regulation on animal by-products and derived-products – (EC) 1069/2009 [2]	Directly relevant.	Lays down strict controls on how animal by-products (ABP) can be processed, and what end-uses are acceptable for them.	▪ Prohibits the use of microalgae derived from digestate generated in AD facilities which use Category 2 ABPs and catering waste as feedstock, for use as feed for farmed animals and as pet food. ▪ Allows the application for authorisation of novel technologies that demonstrate risk reduction to human and animal health, as 'alternative methods' for the disposal or use of animal by-products of certain categories throughout the community.	Agriculture & Environment departments at Member State level; EFSA.
Production and labelling of organic products – (EC) 2018/848 [4]	Directly relevant, in situations where organic status is desired.	Lays down a legal framework for organic products. It contains the basic objectives and general principles for organic farming and illustrates the rules on production, labelling, controls and trade with non-EU countries.	▪ Organic certification and labelling for ALG-AD products are possible, although a (conversion) transition period will apply throughout which organic-status rules will apply, but organic-status will not be achieved until this period is complete. ▪ (EC) 2018/848 allows only the use of nutrients of plant or mineral origin for land-based microalgae cultivation systems, otherwise, the end-product does not comply with the rules of organic production and cannot be labelled accordingly.	Agriculture & Environment departments at Member State level.
Environmental Impact Assessment – (EC) 2011/92 [6]	Requires confirmation	Assesses the effects of certain public and private projects on the environment.	▪ Aquaculture projects are listed in Annex II; National authorities have to decide whether an EIA is needed regardless of the nature or type of cultivation system. ▪ An EIA is compulsory for any new operators applying for organic production and producing more than 20 tonnes of aquaculture products per year [4].	Environment departments at Member State level.

Policy/Legislation	Relevance to ALG-AD	Description	Implications on ALG-AD value chain	Competent Authority
Alien species legislation – (EC) 708/2007 [5]	Requires confirmation *subject to whether ALG-AD activities are considered aquaculture.	Establishes a framework governing aquaculture practices in relation to alien and locally absent species to assess and minimise the possible impact of these and any associated non-target species on aquatic habitats and in this manner contribute to the sustainable development of the sector.	▪ Aquaculture operators intending to undertake the introduction of an alien species or the translocation of a locally absent species shall apply for a permit from the competent authority of the receiving Member State. ▪ As NRD-grown microalgae will be cultivated outside their known natural range, albeit in closed reactors, it is envisaged that the requirements of (EC) No 708/2007 may apply to the ALG-AD value chains and developers should discuss individual cases with the competent authority of the receiving Member State and apply for a permit if necessary. ▪ If required, ALG-AD developments will not be subject to a prior 'environmental risk assessment' and securing a permit by the competent authority is not expected to be an issue.	Marine & Environment departments at Member State level.
Regulations applicable to the production and marketing of NRD-grown microalgae-based 'feed materials'				
Placing on the market and use of feed – (EC) 767/2009 [15]	Directly relevant.	Addresses the placing on the market and use of feed within the European Community [19]. The objective of this regulation is to harmonise the conditions for the use of feed, in order to ensure a high level of feed safety and thus a high level of protection of public health.	▪ Prohibits the placing on the market of feed containing or consisting of certain materials, as listed in Annex III of the regulation, including, among other things commonly used as feedstock in AD, faeces and urine (manure) irrespective of any form of treatment or admixture. This may, therefore, prohibit the use of digestate despite the end-product having undergone several transformation steps (from manure to digestate to microalgae). ▪ Requires operators placing feed on the market to ensure that the feed is sound, genuine, unadulterated, fit for purpose, and of merchantable quality, as well as labelled, packaged, and presented in accordance.	EFSA and Food Safety departments or authorities at Member State level.

Policy/Legislation	Relevance to ALG-AD	Description	Implications on ALG-AD value chain	Competent Authority
Feed hygiene – (EC) 183/2005 [16]	Directly relevant to feed businesses, manufacturing or supplying feed products.	Lays down the general rules on feed hygiene, the conditions and arrangements to ensure traceability of feed, as well as the requirements for registration and approval of feed business operators.	▪ Business operators involved in the production and transport of algae-based feed, need to implement a HACCP system to identify where control is critical to ensure feed safety. ▪ Business operators involved in the production, processing, and distribution of 'feed materials', shall not operate unless their establishments are registered by the competent authorities.	EFSA and National assurance body at Member State level.
Undesirable substances in animal feed – Directive 2002/32/EC [17]	Directly relevant.	Regulates maximum levels of undesirable substances in products intended for animal feed, such as heavy metals, dioxin, aflatoxin, and certain pesticides, while it also prohibits the dilution of contaminated feed materials	▪ Provides maximum levels of heavy metals and other undesirable substances for 'feed materials', including the ones destined for aquaculture. Different heavy metal maximum levels apply for feed additives or for products intended to be used as a complete feed. ▪ Limits are subject to interpretation, dependent on whether microalgae are considered aquatic animals, organisms or plant material under the circumstances in which they are produced.	EFSA and National assurance body at Member State level.

3 KEY REGULATORY ISSUES AFFECTING THE COMMERCIALISATION OF ALG-AD TECHNOLOGY

This chapter presents regulatory barriers affecting the commercialisation of the ALG-AD value chain, focusing on issues related to the production of feed for farmed animals, including agricultural livestock, aquaculture, and non-food producing animals, as these are the main markets being targeted by ALG-AD.

3.1 Key regulatory issues affecting the use of NRD-grown algae for feeding farmed animals

The main regulatory issue affecting the commercialisation of the ALG-AD technology relates to the provenance of the digestate on which the algae is grown. Digestate generated in AD facilities that use either food supply chain waste that contain Category 2 ABPs or catering waste as feedstock, or derivatives thereof, is currently prohibited to be used as feed for farmed animals, under **EU Regulation 1069/2009**. This is a barrier that limits the market opportunities for the production of feed intended for farmed animals, considering that manure (Category 2 ABP) and food waste are the most common feedstocks in AD in Europe and used by many current operators.

ALG-AD technology developers can submit an application to the relevant competent authority requesting the authorisation of microalgae derived from animal by-products to be used in feed applications, demonstrating that the ALG-AD technology reduces risks to the food and feed chain to adequate levels. However, there is always the chance that the application, which will also be reviewed by EFSA, could be rejected and this is likely to be the case where it is not possible to demonstrate appropriate evidence of risk reduction, in the absence of any specific safety guidance relating to NRD-grown microalgae.

No authorisation is required in the case of animal feed derived from digestate of solely plant or Category 3 ABPs origin, as part of the Regulation 1069/2009. However, any mixture with non-compliant feedstock will be subject to the strictest measures and will require pre-market authorisation.

In addition, in accordance with Regulation (EC) No 767/2009, "feed shall not contain or consist of materials whose placing on the market or use for animal nutritional purposes is restricted or prohibited". The list of these feed materials is set out in Annex III of the Regulation and includes, among other things commonly used as feedstock in AD, faeces and urine (manure) irrespective of any form of treatment or admixture. Therefore, **Regulation (EC) No 767/2009** prohibits the use of digestate derived from manure and other materials listed in Annex III of the same regulation, despite the end-product having undergone several transformation steps (from manure to digestate to microalgae).

3.2 Key regulatory issues affecting the organic certification of NRD-grown microalgae

Organic certification can potentially determine the scale of the opportunity for microalgae-based products developed as part of the project, but significant amendments to the legislation might be required for technology users to be able to utilise it.

The main barrier is that **EU Regulation (2018/848)** allows only the use of nutrients of plant or mineral origin for land-based microalgae cultivation systems, otherwise the end-product (on this occasion feed) does not comply with the rules of organic production and cannot be labelled accordingly. The use of animal by-products (e.g. manure or food waste) as a source of nutrients for microalgae cultivation is therefore restricted in organic production. This means that digestate is not an eligible feedstock unless it is produced exclusively from non-waste plant materials, such as crops and residues (such feedstocks include all plant materials not subject to further processing off-farm, such as maize, grass, cereals, oilseeds, pulses, fruits or vegetables grown on-farm, or outgrades or damaged produce not fit for sale or human consumption).

It should be noted that, even if it is of plant origin, digestate still requires authorisation so that it can be included in the restrictive list of materials (external inputs) that can be used in organic production systems. However, as the regulation will only apply from January 2021, these lists do not yet exist. Seemingly, consideration of whether a product or substance should be added to the lists shall occur at Member State level. The Member State that wishes to authorise an external input material shall ensure that a dossier giving the reasons for the inclusion is issued to the Commission and to the other Member States. The Commission may then authorise the use of this external input in organic production and adopt an implementing act.

4 INVESTIGATION OF POLICY ALTERNATIVES FOR USING NRD-GROWN MICROALGAE PRODUCTS IN DIFFERENT MARKETS

This chapter explores alternative markets for NRD-grown micro-algae grown on digestate as produced as part of the ALG-AD project, from a regulatory perspective, and investigates whether accessing those markets resolves the barriers identified in section 3.1, related to feeding farmed animals with NRD-grown microalgae. Figure 1 presents authorisation requirements for NRD-grown (Non-GMO) microalgae specifically for accessing EU Feed, Food, and Biostimulant markets.

4.1 Alternative markets for feed materials

The feedstock restriction barriers identified in section 3.1 for the production of feed for 'farmed animals' do not apply, to the same extent, to all animal categories. Table 4 summarises AD feedstocks permitted to produce NRD-grown microalgae intended for feed production for different animal categories.

Table 4: Summary of AD feedstocks permitted for feed production for different animal categories.

Digestate generated from:	Farmed animals	Pets	Zoo animals	Circus animals	Dogs/cats in shelters	Fur animals	Wild animals
Food waste: Cat 1 ABPs*	X	X	X	X	X	X	X
Food waste: Cat 2 ABPs (excl. manure)	X	X	X**	X**	X**	X**	X**
Food waste: Cat 3 ABPs (incl. catering waste)	X	X	X**	X**	X**	X**	X**
Food waste: Cat 3 ABPs (excl. catering waste)	✔	✔	✔	✔	✔	✔	✔
Manure/slurry	X	X	X	X	X	X	X
Plant material (e.g. crops/veg waste)	✔	✔	✔	✔	✔	✔	✔

* Category 1 ABPs are not allowed to be processed in AD applications in the EU, and therefore they are not present in the digestate produced.

** The competent authority may, by way of derogation from Articles 13 and 14, authorise, under conditions which ensure the control of risks to public and animal health, the collection and use of Category 2 material.

According to Article 18 of the **Regulation 1069/2009**, by way of derogation, competent authorities can authorise the use of NRD-grown microalgae derived from Category 2 materials as well as catering waste, for special feeding purposes to animals that are not classified as 'farmed animals', such as zoo animals, circus animals, dogs and cats in shelters, fur animals, and wild animals. However, this should be done under conditions which ensure the control of risks to public and animal health. This provision can potentially simplify the commercialisation process of the ALG-AD technology, increasing the compliant feedstock types for certain markets.

Even though manure is classified as 'Category 2' feedstock under **Regulation 1069/2009**, microalgae derived from this type of feedstock cannot be used as animal feed. This is because the requirements of **Regulation 767/2009** on the placing on the market and use of feed apply to both food-producing and non-food producing animals. According to this regulation, 'non-food producing animals' means any animal that is fed, bred, or kept, but is not used for human consumption, such as fur animals, pets and animals kept in laboratories, zoos or circuses.

It should be noted that according to Article 35 of the **Regulation 1069/2009**, similar feedstock restriction rules apply for placing on the market of pet food like in the case of 'farmed animals'.

4.2 Feed additives

Based on EU guidelines [10], 'Feed additives' are defined as substances, microorganisms or preparations, other than feed material and premixtures, which are intentionally added to feed or water in order to perform, in particular, one or more specific functions that are enumerated in Article 5(3) of the **Regulation (EC) No 1831/2003** [11]:

a) favourably affect the characteristics of feed,

b) favourably affect the characteristics of animal products; Compound feed including pet food

c) favourably affect the colour of ornamental fish and birds,

d) satisfy the nutritional needs of animals,

e) favourably affect the environmental consequences of animal production,

f) favourably affect animal production, performance, or welfare, particularly by affecting the gastro-intestinal flora or digestibility of feeding stuff, or

g) have a coccidiostatic or histomonostatic effect.

4.2.1 Feedstock restriction rules

Feed additives appear to fall within the same feedstock restriction rules as feed materials, according to the requirements of **Regulation 1069/2009**. This is because for the requirements of this regulation, 'feed' is defined any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals. Therefore, the list of feedstocks permitted in different animal feed applications, presented in table 4, remains relevant.

4.2.2 Additional authorisation requirements

According to the requirements of **Regulation (EC) No 1831/2003**, feed additives are subject to an additional authorisation procedure, which intends to evaluate their safety and/or efficacy in animal feed applications. The procedure for feed additive applications requires (1) submission of an application to the European Commission, (2) a technical dossier to EFSA, and (3) three reference samples of the feed additive to the European Union Reference Laboratory [18][6]. This Regulation also establishes labelling and packaging requirements for feed additives or premixtures.

The Commission has established the European Union Register of Feed Additives, which is regularly updated, and among other things, it contains a list of additives that are currently authorised. Authorisations are granted for use in feed intended for specific animal species or categories, and for specific conditions of use.

Regulation (EC) No 1831/2003 is currently under evaluation by the European Commission to address whether it has delivered its objectives and to what extent it is still relevant. A public consultation was held from 12 December 2018 to 3 April 2019, while an external study is currently ongoing, requested by the European Commission, that will support the evaluation work.

[6] Authorisations are valid for 10 years throughout the EU and the European Economic Area (EEA). An application for renewal shall be sent to the Commission at least 1 year before the expiry date of the authorisation. The procedure for renewal is described in Article 14 of Regulation (EC) No 1831/2003.

4.3 Plant bio-stimulants

Plant bio-stimulants are not subject to the same feedstock restriction rules as products intended for animal feed production. Still, their placing on the market is controlled under Regulation 1069/2009, subject to certain conditions.

4.3.1 Definition and relevance to Regulation 1069/2009

Biostimulants fall under the regulations on fertilisers and are excluded from the regulatory framework relating to pesticides as they do not have any direct action on pests. From a strict regulatory point of view, as biostimulants influence the life processes of plants by mechanisms other than direct nutrition, they are often referred to as a plant protection product (PPP's), as the Regulation (EC) 1107/2009 on plant protection products applies to all categories of Biostimulant [19]. However, due to the lengthy and costly process involved in placing the product under PPP's, most industries prefer the fertiliser route.

In 2019, The Fertilising Products Regulation (FPR) (EU) 2019/1009 defined a plant biostimulant as "a product the function of which is to stimulate plant nutrition processes independently of the product's nutrient content with the sole aim of improving one or more of the following characteristics of the plant or the plant rhizosphere: (a) nutrient use efficiency, (b) tolerance to abiotic stress, (c) quality traits, or (d) availability of confined nutrients in the soil or rhizosphere" [19]. The regulation also specifies that a plant biostimulant "shall have the effects that are claimed on the label for the plants specified thereon". Consequently, the justification of the agronomic claim is important to allow it to be placed on the EU market. In this regard, algae-based products might face a challenge, as results reported in field-based application can be variable.

Biostimulants are considered as 'organic fertilisers and soil amendments' as part of Regulation 1069/2009. Under this Regulation, 'organic fertilisers and soil amendments' are defined as materials of animal origin used to maintain or improve plant nutrition and the physical and chemical properties and biological activities of soils, either separately or together.

The definition above can be considered relevant as there is a strong interconnection between Regulation 1069/2009 and Regulation 2019/1009, with regards to EU fertilising products.

4.3.2 Feedstock restriction rules

According to Article 32 of the Regulation 1069/2009, 'Organic fertilisers and soil improvers' derived from Category 2 and Category 3 ABPs (including catering waste) can be placed on the market, without any requirement for pre-market authorisation, given that they have been produced in accordance with the conditions for pressure sterilisation or with other conditions to prevent risks arising to public and animal health.

Category 1 ABPs cannot be used for the production of 'Organic fertilisers and soil improvers', but this is not an issue for the commercialisation of the ALG-AD technology, as these feedstock types are not allowed to be processed in AD applications in the EU, and therefore they will not present in the digestate produced.

Based on a recent amendment of the Regulation 1069/2009 [19], for 'Organic fertilisers and soil improvers' which no longer pose any significant risk to public or animal health, an end point in the manufacturing chain may be determined, beyond which they are no longer subject to the requirements of this Regulation (e.g. official controls)[7].

At the time of writing, the end point in the manufacturing chain, beyond which organic fertilisers are no longer subject to the requirements of this regulation, has yet to be determined. According to the amended Article 5, within six months after 15 July 2019, the Commission shall initiate a first assessment of 'Organic fertilisers and soil improvers' that are already widely used in the Union, including AD residues. Where the assessment concludes that derived products no longer pose any significant risk to public or animal health, the Commission shall determine an end point in the manufacturing chain, no later than six months after the assessment is finalised[8].

Consequently, when the goal is to grow microalgae intended for the production of biostimulants or other fertilising products, ALG-AD equipment can be installed at any AD facility, without any regulatory barriers related to the feedstock being used during the process.

[7] Before end point, ABP rules still apply, such as the requirement for registration of operators, establishments, or plants.

[8] As a side note, based on the preamble (22) of the Regulation 1089/2009, an end-point in the manufacturing chain cannot be determined for products that have direct relevance with the safety of the feed chain.

4.3.3 Placing on the market of fertilising products

Regulation 2019/1009 opens the single market for fertilising products which are not currently covered by harmonisation rules, such as organic and organo-mineral fertilisers, soil improvers, inhibitors, plant biostimulants, growing media or blends. It sets out rules for EU fertilising products carrying the 'CE marking'[9] including requirements for:

1. maximum levels of contaminants and pathogens (disease-causing microorganisms)

2. minimum content of nutrients and other relevant characteristics depending on the category of the product

3. labelling

Table 5: Limit values for contaminants present in biostimulants [19]

Contaminants	Limit values (in mg/kg dry matter)
Cadmium (Cd)	1,5
Hexavalent chromium (Cr VI)	2
Lead (Pb)	120
Mercury (Hg)	1
Nickel (Ni)	50
Inorganic arsenic (As)	40

With regard to plant biostimulants, contaminants must not exceed the limit values presented in Table 5. In addition to these values, the content of copper (Cu) and zinc (Zn) in plant biostimulants must not exceed 600 and 1,500 mg/kg dry matter, respectively.

Annex III of Regulation 2019/1009 sets out the labelling requirements for EU fertilising products. In particular, Part 1 of this Annex sets out general labelling requirements that apply to every EU fertilising product, while Part II (PFC 6) presents additional information that needs to be provided in the specific case of biostimulants.

It is important to note that, according to the preamble 18 of the Regulation 2019/1009, fertilising products of ABP origin for which an end-point in the manufacturing chain has not been reached at the time of making available on the market, should not be subject to this Regulation and therefore a CE marking cannot be provided. For example, untreated animal by-products should only be subject to the Regulation 1069/2009.

Harmonisation remains optional, meaning that non-harmonised fertilising products can be placed on the internal market in accordance with national law and general free-movement rules.

[9] According to Regulation 2019/1009, 'CE marking' means a marking by which the manufacturer indicates that the EU fertilising product is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing.

4.4 Novel food products and food supplements

Regulation 1069/2009 applies to animal by-products and derived products which are excluded from human consumption under Community legislation. Therefore, once ABPs are treated in AD, the production of products for human consumption, using digestate as feedstock, is not subject to this regulation.

4.4.1 The Regulation (EU) 2015/2283 on novel foods

The requirements for the placing on the market of food products derived from microalgae depend, to a large extent, on whether they are considered 'novel' in accordance with the **Regulation (EU) 2015/2283** [20]. According to this regulation, 'Novel food' is defined as any food that was not used for human consumption to a significant degree within the Union before 15 May 1997[10], and that falls under at least one of the categories included in Article 3 of the same regulation, which include among other things, 'food consisting of, isolated from or produced from microorganisms, fungi or algae', as well as 'food supplements' (mainly vitamins and minerals), which are of particular interest of ALG-AD technology developers[11].

Novel food products can only be placed on the European market after the Commission has processed an application for the authorisation of a novel food and has adopted an implementing act authorising the placing on the market of a novel food and updating the Union list of authorised novel foods. According to Article 7 of the Regulation (EU) 2015/2283, the Commission shall only authorise and include a novel food in the Union list if it complies with the following conditions:

(a) the food does not, on the basis of scientific evidence available, pose a safety risk to human health;

(b) the food's intended use does not mislead the consumer, especially when the food is intended to replace another food and there is a significant change in the nutritional value;

(c) where the food is intended to replace another food, it does not differ from that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer.

The authorisation and entry for a novel food in the Union list include, where appropriate:

(a) Specifications

(b) Conditions of use

(c) Additional specific labelling requirements

(d) Post-market monitoring requirements

Under the Regulation (EU) 2015/2283, authorisations are generic, meaning that any food business operator can place an authorised Novel Food on the European Union market, provided the authorised conditions of use, labelling requirements, and specifications are respected.

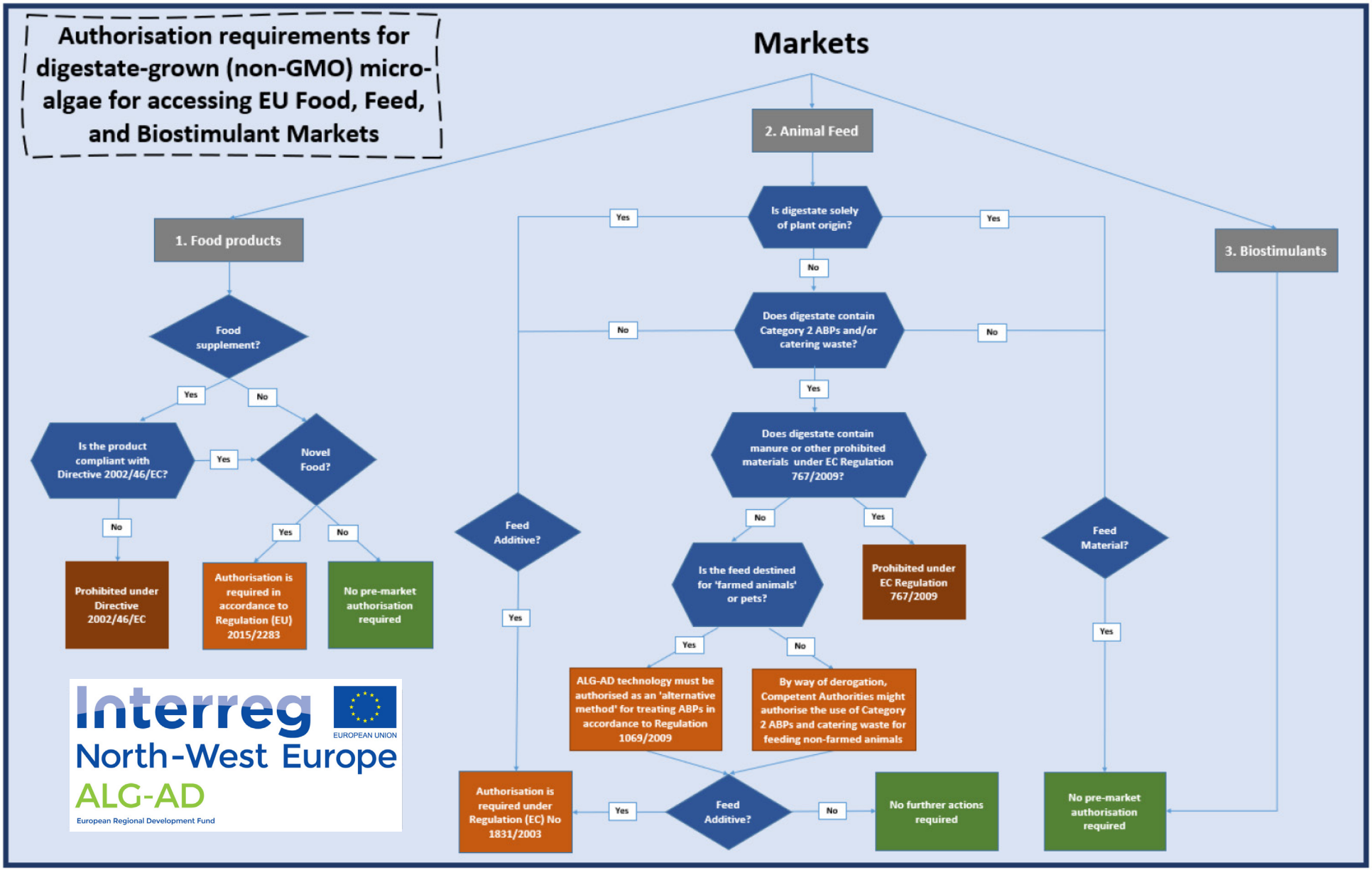
4.4.2 Additional requirements for food supplements

In addition to the requirements laid down in Regulation (EU) 2015/2283, food supplements are also subject to the Directive 2002/46/EC on the approximation of the laws of Member States relating to food supplements [21].

This Directive lays down a harmonised list of vitamins and minerals that may be added to food for nutritional purposes (in Annex I to the Directive), while Annex II contains a list of permitted sources from which those vitamins and minerals may be manufactured. The trade of products containing vitamins and minerals not listed in Annex II has been prohibited from 01 August 2005.

[10] Irrespective of the dates of accession of Member States to the Union.

[11] The Novel Food regulation does not apply in the following cases: a)Food enzymes within Regulation (EC) No 1332/2008, b) food additives within Regulation (EC) No 1333/2008, c) flavourings for use in foods within Regulation (EC) No 1334/2008, d) extraction solvents used in the production of foods within Directive 2009/32/EC approximating EU countries' laws, e) GMOs for food and feed, covered by Regulation (EC) No 1829/2003, f)If foods and/or food ingredients were used exclusively in food supplements, new uses in other foods require an authorisation under the Novel Food Regulation.


Authorisation requirements for digestate-grown (non-GMO) micro-algae for accessing EU Food, Feed, and Biostimulant Markets
Markets
1. Food products
Food supplement?
Yes
No
Is the product compliant with Directive 2002/46/EC?
Yes
No
Novel Food?
No
Prohibited under Directive 2002/46/EC
Yes
Authorisation is required in accordance to Regulation (EU) 2015/2283
No
No pre-market authorisation required
2. Animal Feed
Is digestate solely of plant origin?
Yes
No
Does digestate contain Category 2 ABPs and/or catering waste?
No
Yes
Does digestate contain manure or other prohibited materials under EC Regulation 767/2009?
No
Is the feed destined for 'farmed animals' or pets?
Yes
ALG-AD technology must be authorised as an 'alternative method' for treating ABPs in accordance to Regulation 1069/2009
No
By way of derogation, Competent Authorities might authorise the use of Category 2 ABPs and catering waste for feeding non-farmed animals
Yes
Prohibited under EC Regulation 767/2009
Feed Additive?
Yes
Authorisation is required under Regulation (EC) No 1831/2003
Feed Additive?
Yes
No
No furthrer actions required
Feed Material?
Yes
No pre-market authorisation required
3. Biostimulants
Interreg
EUROPEAN UNION
North-West Europe
ALG-AD
European Regional Development Fund

5 RECOMMENDATIONS ON THE ACTIONS REQUIRED FOR THE SUCCESSFUL ROLL-OUT OF ALG-AD TECHNOLOGY

This chapter identifies a series of actions required to support ALG-AD technology adoption, from a regulatory perspective. An indicative roadmap for key actions needed to commercialise the ALG-AD technology is also presented in Table 6. However, it would be helpful to initiate direct discussions with all key regulators at the earliest opportunity to focus on issues and opportunities for ALG-AD specifically, to establish a robust position for future developments. Confirming with each authority whether ALG-AD would be accepted as aquaculture would also be a critical step, to focus future work, as well as better understanding the specific application requirements for Task 2.2.

Table 6: An indicative roadmap for priority actions to commercialise the ALG-AD technology.

Key actions	2021		2022		2023		2024		2025	
	Q1-2	Q3-4	Q1-2	Q3-4	Q1-2	Q3-4	Q1-2	Q3-4	Q1-2	Q3-4
Action 1: Promote ALG-AD technology to AD facilities that do not process Category 2 ABPs and catering waste										
Task 1.1: Identification of AD facilities.										
Task 1.2: Promotion of the ALG-AD technology.										
Action 2: Authorisation of ALG-AD technology as an 'alternative method' for use of Cat 2 ABPs and catering waste										
Task 2.1: Finalise safety assessments and feed trials (ALG-AD Tasks).										
Task 2.2: Preparation and submission of the application to the competent authority.										
Task 2.3: Evaluation of the application by EFSA and competent authorities.										
Task 2.4: Decision.										
Action 3: Development and marketing of products that do not need authorisation or are not subject to (EC) 069/2009.										
Task 3.1: Conduct market analysis on alternative products (ALG-AD task).										
Task 3.2: Securing funding for ALG-AD follow-up projects.										
Task 3.3: Follow-up project delivery.										
Task 3.4: Marketing of novel products.										

Table 7 presents actions required to overcome key regulatory barriers related to the production and use of NRD-grown microalgae for feeding farmed animals. Table 8 presents actions that can potentially support regulatory compliance of microalgae based 'feed materials'.

Table 7: Actions required to overcome key regulatory barriers related to the production and use of NRD-grown microalgae for feeding farmed animals.

Key regulatory barriers	Severity	Actions proposed to overcome key regulatory barriers
Regulatory Barrier 1 (RB1): The use of feed containing or consisting of manure is prohibited under (EC) No 767/2009, irrespective of any form of treatment or admixture.	**High**	**RB1a.** Confirmation with competent authorities that manure-derived algae is prohibited to be used as animal feed, under Article 6 of EC (No) 767/2009, although the end product has undergone several transformation steps (from manure to digestate to algae).
		RB1b. Initially target anaerobic digestion facilities that do not process manure or other feedstock prohibited under (EC) No 767/2009 for marketing the ALG-AD technology.
		RB1c. Opening discussions with policy makers to carry out an evaluation of the (EC) No 767/2009, considering authorisation options for prohibited materials, under Article 6, which have undergone several transformation steps (e.g. from manure to digestate to microalgae).
		RB1d. Conduct safety assessments for manure-derived microalgae that could be shared around the industry, proving that they are safe and suitable for use in animal feed applications.
		RB1e. Develop markets for NRD-grown microalgae, where the use of manure as feedstock is not prohibited (e.g. the production of bio-stimulants and other organic fertilisers).
Regulatory Barrier 2 (RB2): Category 2 ABPs and catering waste are not compliant feedstock for the production of microalgae that are intended to be used as animal feed for farmed animals and pets under Regulation (EC) 1069/2009.	**High**	**RB2a.** Identify AD facilities that do not process Category 2 ABPs and catering waste so that micro-algae based feed materials do not require pre-market authorisation to enter the EU market.
		RB2b. Submission to the relevant competent authority of an application for the authorisation of ALG-AD technology as an 'alternative method' for the use of Category 2 ABPs and catering waste in animal feed applications throughout the Community, demonstrating that it reduces the risks to food and feed chain to adequate levels.
		RB2c. Conduct market analysis and develop microalgae products that do not require premarket authorisation under Regulation 1069/2009, such as bio-stimulants.
		RB2d. Develop products that are not subject to Regulation 1069/2009, such as food supplements. Still, food supplements need to be compliant with Regulation (EC) 2015/2283 and Directive 2002/56/EC, before introduced in the market.
		RB2e. Contact competent authorities of different Member States to determine authorisation conditions for microalgae based products intended for special feeding purposes, such as zoo and circus animals.
Regulatory Barrier 3 (RB3): EU Regulation (2018/848) allows only the use of nutrients of plant or mineral origin for land-based microalgae cultivation systems, otherwise the end-product does not comply with the rules of organic production and cannot be labelled accordingly.	**Mid**	**RB3a.** Identify AD facilities that process well defined feedstock streams solely of plant origin, such as crops and agricultural residues.
		RB3b. Apply for digestate solely derived from plant materials to be included in the restrictive list of 'external inputs' that can be used in organic production systems.
		RB3c. Contribute to clearer guidelines as regulation EU Regulation (2018/848) does not distinguish microalgae from macroalgae; there is only reference to "algae" as a broader term.

Table 8: Actions to support regulatory compliance of micro-algae based 'feed materials'

Key regulatory requirements	Urgency	Actions to support regulatory compliance	Action owner
Regulatory Requirement 1 (RR1): NRD-grow microalgae for use as animal feed must be safe with no direct adverse effect on the environment, and at the same time genuine, fit for its purpose, and of merchantable quality, in order to ensure compliance with Regulation 767/2009.	**High**	**RR1a**. Specific limits on heavy metals and other undesirable substances, laid down in Directive 2002/32/EC, should be confirmed with EFSA and the relevant national assurance body in each Member State. **RR1b.** Safety and nutritional value assessments will be carried out as part of the ALG-AD project, proving that NRD-grown microalgae are safe and suitable for use in animal feed applications.	ALG-AD partners
Regulatory Requirement 2 (RR2): Microalgae-based feed materials shall not be placed on the market unless labelled in accordance with the requirements of EC Regulation 767/2009.	**Low**	**RR2.** Register of microalgae products in the 'Catalogue of feed materials', the main purpose of which is to support proper labelling of animal feed.	ALG-AD partners or Feed business operators
Regulatory Requirement 3 (RR3): For setting-up a new microalgae cultivation plant, an Environmental Impact Assessment based on the requirements of 2011/92/EU may be needed, on a case-by-case assessment of each Member State.	**Low**	**RR3a.** Confirm with Environment departments at Member State level, whether there is a requirement for an Environmental Impact Assessment for setting up a new microalgae cultivation plant. **RR3b.** Develop data packs for certain species/applications, to support future EIAs or approval applications.	ALG-AD partners & Feed business operators
Regulatory Requirement 4 (RR4): Business operators involved in the production, processing, and distribution of feed materials, shall not operate unless their establishments are registered by the competent authorities in accordance with Regulation 183/2005.	**Low**	**RR4.** A relatively simple procedure that does not require any specific actions before applying for registration.	Feed business operators
Regulatory Requirement 5 (RR5): According to Feed Hygiene Regulation, business operators involved in the production and transport of algae-based feed, need to implement a HACCP system to identify where control is critical to ensure feed safety. *Condition: ALG-AD activities are not considered as "primary production".	**Low**	**RR5a.** Implementation of a globally accepted international standard, which specifies the requirements of a HACCP system (e.g. ISO 22000 standard). **RR5b.** Contribution to the development of good practice guidelines at Member State level, for compliance with the HACCP requirements of Feed Hygiene Regulation. **RR5c.** Adoption of a HACCP software that will help to better manage feed safety protocols.	ALG-AD partners & Feed business operators
Regulatory Requirement 6 (RR6): Operators consigning, transporting or receiving ABPs and/or derived products shall keep a record of consignments and related commercial documents or health certificates (Regulation (EC) 1069/2009).	**Low**	**RR6.** Implementation of a management system by operators that ensures 'step by step' traceability of ABPs and derived products.	Feed business operators
Regulatory Requirement 7 (RR7): As microalgae will be cultivated outside their known natural range, albeit in closed reactors, it is envisaged that the requirements of (EC) No 708/2007 may apply to the ALG-AD value chains.	**Low**	**RR7.** Developers should discuss individual cases with the competent authority of the receiving Member State, and apply for a permit if necessary. Securing a permit at this stage is not expected to be an issue because algae cultivated in closed facilities on land pose little risk.	Feed business operators

6 CONCLUSIONS

This study examines the EU regulatory framework applicable to ALG-AD technology for the production of NRD-grown microalgae based 'feed materials' for farmed animals. The study aimed to identify key regulatory barriers affecting the commercialisation of the value chain and propose a series of actions to support technology adoption, considering among other things the regulatory requirements for accessing alternative markets.

The main regulatory issue affecting the introduction of the ALG-AD technology in the market relates to the origin of the digestate on which the algae is grown. Digestate generated in AD facilities that use either food supply chain waste that contain Category 2 ABPs or catering waste as feedstock, or derivatives thereof, is currently prohibited to be used as feed for farmed animals, under EU Regulation 1069/2009. In addition, Regulation (EC) 767/2009 prohibits the use of feed containing or consisting of manure, and other materials listed in Annex III of the same regulation, irrespective of any form of treatment or admixture. This rule applies to the production of animal feed for all animal categories, not just farmed animals.

The requirements of regulations (EC) 1069/2009 and (EC) 767/2009 limit market opportunities for the production of microalgae-based 'feed materials', considering that Category 2 ABPs (including manure) and catering waste are the most common feedstocks in AD in Europe. These barriers can be overcome through a number of key actions that include but are not limited to:

1. Submission of an application for the authorisation of ALG-AD technology as an 'alternative method' for the use of Category 2 ABPs and catering waste in animal feed applications.

2. Identification of AD facilities that do not process Category 2 ABPs and catering waste so that microalgae-based feed materials do not require pre-market authorisation to enter the EU market.

3. Development of microalgae products that do not require premarket authorisation under Regulation 1069/2009, such as bio-stimulants.

4. Development of products that are not subject to Regulation 1069/2009, such as food supplements[12].

An additional barrier has been identified and is related to the fact that EU Regulation (2018/848) allows only the use of nutrients of plant or mineral origin for land-based microalgae cultivation systems, otherwise the end-product does not comply with the rules of organic production and cannot be labelled accordingly. As a result, it will be highly unlikely, under the existing legislation, that any ALG-AD products could be labelled as organic, unless technology users (AD facilities) process well-defined feedstock streams solely of plant origin, such as crops and agricultural residues.

Further details on the actions required to overcome key regulatory barriers related to the production and use of NRD-grown microalgae for feeding farmed animals can be found in Table 7, while Table 8 presents additional actions that can potentially support regulatory compliance of microalgae based 'feed materials'.

This report has focussed the regulation associated with using ALG-AD technology to produce feed and related products. However, there are many other potential routes and markets for the cultivated algal biomass. Other routes, without regulatory issues, include the use of the cultivated biomass back into the AD process to improve methane yield and the hydrothermal liquefaction (HTL) of microalgae to generate a bio-crude oil and other products.

[12] Still, food supplements need to be compliant with Regulation (EC) 2015/2283 and Directive 2002/56/EC, before introduced in the market.

7 REFERENCES

[1] F. Leinemann and V. Mabilia, "European Union Legislation and Policies Relevant for Algae," 2019. [Online]. Available: https://link.springer.com/chapter/10.1007/978-3-030-25233-5_16.

[2] European Parliament and Council, "REGULATION (EC) No 1069/2009 laying down health rules as regards animal by-products and derived products not intended for human consumption." [Online]. Available: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32009R1069.

[3] European Food Safety Authority (EFSA), "Statement on technical assistance on the format for applications for new alternative methods for animal by-products," 2010. [Online]. Available: http://www.efsa.europa.eu/en/efsajournal/pub/1680.

[4] European Parliament and Council, "REGULATION (EU) 2018/848 on organic production and labelling of organic products." [Online]. Available: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2018.150.01.0001.01.ENG.

[5] European Parliament and Council, "REGULATION (EC) No 708/2007 concerning use of alien and locally absent species in aquaculture." [Online]. Available: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex:32007R0708.

[6] European Commission, "DIRECTIVE 2011/92/EU on the assessment of the effects of certain public and private projects on the environment." [Online]. Available: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32011L0092.

[7] European Parliament and Council, "DIRECTIVE 2009/41/EC on the contained use of genetically modified micro-organisms." [Online]. Available: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32009L0041.

[8] European Parliament and Council, "DIRECTIVE 2001/18/EC the deliberate release into the environment of genetically modified organisms." [Online]. Available: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32001L0018&from=EN.

[9] European Parliament and Council, "REGULATION (EC) No 178/2002 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." [Online]. Available: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32002R0178.

[10] European Commission, "COMMISSION RECOMMENDATION establishing guidelines for the distinction between feed materials, feed additives, biocidal products and veterinary medicinal products." [Online]. Available: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011H0025&from=GA.

[11] European Parliament and Council, "REGULATION (EC) No 1831/2003 on additives for use in animal nutrition." [Online]. Available: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32003R1831.

[12] European Parliament and Council, "REGULATION (EC) No 1829/2003 on genetically modified food and feed." [Online]. Available: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32003R1829&from=EN.

[13] O. Smedley, "Comparison of Regulatory Management of Authorized Ingredients, Approval Processes, and Risk-Assessment Procedures for Feed Ingredients," Int. Feed Ind. Fed., 2013.

[14] European Comission Joint Research Centre, "Microalgae-based products for the food and feed sector: an outlook for Europe," 2014. [Online]. Available: ftp://ftp.jrc.es/pub/EURdoc/JRC85709.pdf.

[15] European Parliament and Council, "REGULATION (EC) No 767/2009 on the placing on the market and use of feed." [Online]. Available: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32009R0767.

[16] European Parliament and Council, "REGULATION (EC) No 183/2005 laying down requirements for feed hygiene."

[17] European Parliament and Council, "DIRECTIVE 2002/32/EC on undesirable substances in animal feed." [Online]. Available: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32002L0032.

[18] European Food Safety Authority (EFSA), "Feed additive applications: overview and procedure." [Online]. Available: https://www.efsa.europa.eu/en/applications/feedadditives.

[19] European Parliament and Council, "REGULATION (EU) 2019/1009 laying down rules on the making available on the market of EU fertilising products." [Online]. Available: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32019R1009.

[20] European Parliament and Council, "Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods," 2015. [Online]. Available: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32015R2283.

[21] European Parliament and Council, "Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements," 2002. [Online]. Available: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32002L0046.

Interreg
North-West Europe
ALG-AD
European Regional Development Fund

EUROPEAN UNION

NNFCC is a leading international consultancy with expertise on the conversion of biomass to bioenergy, biofuels and biobased products.

The Bioeconomy Consultants
NNFCC

NNFCC, Biocentre,
York Science Park,
Innovation Way,
Heslington,
York, YO10 5NY

Phone: +44 (0)1904 435182
Fax: +44 (0)1904 435345
Email: enquiries@nnfcc.co.uk
Web: www.nnfcc.co.uk