



**Producing novel non-plant biomass feedstocks
and bio-based products through upcycling and
the cascading use of brewery side-streams**

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Table of contents

1	Introduction	6
1.1	Introduction	6
1.2	Brief summary of CHEERS project	6
2	Overview of EU rules on waste and by-products	8
2.1	By-products legal regime	8
2.2	Impact of by-products legal regime	10
3	Relevant EU policies for bio-based products	12
3.1	Introduction	12
3.2	European Bioeconomy Strategy	12
3.3	European Green Deal	13
3.4	Circular Economy Action Plan	13
4	European legal framework on novel food	15
4.1	Introduction	15
4.2	Novel food definition	15
4.3	Authorization procedure	17
4.4	Summary of insect species authorized for EU food market	18
4.5	Legal feasibility of feed <i>Tenebrio molitor</i> with beer bagasse	21
4.6	Use of insect protein in non-alcoholic beverages	21
4.7	Impact about the commercialization of the product	24
5	European legal framework on animal feed	25
5.1	Introduction	25
5.2	European Union rules on marketing of animal feed	26
5.3	European Union rules on marketing of feed additives	29
5.4	European Union rules on marketing of medicated feed	32
5.5	Impact about the commercialization of the product	32
6	European legal framework on petfood	34
6.1	Introduction	34
6.2	Single cell proteins used in petfood	34
6.3	Impact about the commercialization of the product	35
7	European legal framework on disinfectants products	37
7.1	Introduction	37
7.1.1	Biocidal Products Regulation (BPR, Regulation (EU) 528/2012)	37

7.2	Regulatory framework for disinfection products in food industry	38
7.2.1	Food additives.....	38
7.2.2	Technological adjuvants.....	38
7.2.3	Surface decontaminants for products of animal origin	38
7.2.4	Phytopsanitary products	38
7.3	Regulatory framework for disinfection products in drinking water	39
7.4	Impact about the commercialization of the product	40
8	European legal framework on cosmetic products	42
8.1	Introduction	42
8.2	European Union rules on marketing of cosmetic products.....	43
8.3	Ectoine used as ingredient of cosmetic products	45
8.4	Impact about the commercialization of the product	46
9	Sustainability of bio-based products.....	47
10	Conclusions	49
11	References	50

Executive Summary

Report on the bio-based products regulatory and market uptake barriers in the framework of the CHEERS project.

It provides a legal analysis of regulatory framework of the products obtained from the side-streams of brewery industry, to identify legal and administrative requirements to put them on the market.

In addition to the above, the report includes a brief study regarding the bio-products advantages in terms of sustainability compared with existing alternatives in the market.

The deliverable is classified as PUB.

1 Introduction

1.1 Introduction

The present document constitutes Deliverable D1.3. “*Report on the bio-based products regulatory and market uptake barriers*” in the framework of the CHEERS project, which is an EU-funded project in the Horizon 2020 research and innovation programme.

This report refers to activities carried out within Work Package 1, and specifically within Task 1.3. “*Study of regulatory and market uptake barriers of the bio-based products*”. The aim of this report is to review the European regulations to analyse the requirements for use of the products concerned, to ensure that not represent any danger to human health, animal health or environment. In this context also this report highlight legal and administrative obstacles to put them on the market.

In addition to the above, the report includes a brief study regarding the bio-products advantages in terms of sustainability compared with existing alternatives in the market.

1.2 Brief summary of CHEERS project

The challenge behind CHEERS project is the valorisation of by-products and side-streams of brewery sector, via two novel bio-based transformation platforms (insect and microbial) to obtain five valuable circular bio-based products.

The technologies that are used for transformation of unused side-streams (such as bagasse, wastewater and biogenic gases, such as CO₂ and CH₄) to valuable ingredients for the formulation of protein rich drinks, feed ingredient, disinfectants, petfood and cosmetics, are the following:

- Insect platform. Through this platform is produced insect from bagasse. The aim of this development is to use *Tenebrio molitor* to transform beer bagasse combined with brewer’s yeasts into defatted and soluble protein flours for food protein ingredient. In particular, it is intended to use the protein ingredient for the development of new insect protein-based drinks with high protein content.
- Microbial platform. Through this platform CH₄, CO₂ and wastewater are bioconvert into bio-based products for industrial applications. Specifically, the aim of this procedure is to achieve the following products:
 - i) First, to produce caproic acid of volatile fatty acids from side-streams of brewery and CO₂ emitted during beer fermentation, using a novel biotechnological process based on microbial chain elongation. Its intended use would be an alternative feed ingredient.
 - ii) Second, to convert CO₂ from biogas trough bioelectrochemical systems (BES) into hypochlorite. The hypochlorite generated will be post-treated physically and chemically to formulate the final product, which is chlorine-based disinfectant.
 - iii) Furthermore, to produce high-quality single cell protein from CH₄ fermentations, which will be generated in a forced-circulation loop fermentor using CH₄ from biogas. The single cell protein will be evaluated as alternative protein source for petfood.
 - iv) Finally, by using halotolerant methanotrophic consortium to convert CH₄ to ectoine. The microbial osmoprotectan ectoine is intended to be incorporated in basic cosmetic formulations.

It should be noted that the European Union legislations influence the current production and commercialization of products, so it is necessary to review current legislation which has a bearing on the area, to analyse the requirements for use of the products concerned, if exist, and highlight regulatory obstacles to the commercialization of the products concerned in the European market.

There is no legal framework in European Union on bio-based products, but there are some policies related to these products, which should be considered because bio-based products play an important role in developing a circular economy.

Nevertheless, there are European regulations for food and feed, chemical substances, cosmetic products and biocides, among others, which lay down the general principles governing each product and define its characteristics, with which products should comply to be placed on the market. These regulations could represent the major obstacle to market the new and innovative developed the CHEERS bio-based products.

Therefore, the aim of this report is to analyse the framework of these European legislation to highlight the main barriers that may be exist from legislative perspective, for industrial applications of the products concerned.

2 Overview of EU rules on waste and by-products

2.1 By-products legal regime

On the premise that the unused side-streams concerned in this project (such as bagasse, wastewater and biogenic gases) resulting from a production process the primary aim of which is not the production of that substances, they would be considered waste.

In that sense, this fits in the definition of “waste”, contained in Article 3.1 of the Directive 2008/98¹, according to which “‘waste’ means any substance or object which the holder discards or intends or is required to discard”.

However, based on the aim is not discard or intend to discard the substance, but to be a valuable ingredient, there should be considered its classification as a by-product. The Article 5 of the Directive 2008/98 defines “by-products” as follows:

“1. Member States shall take appropriate measures to ensure that a substance or object resulting from a production process the primary aim of which is not the production of that substance or object is considered not to be waste, but to be a by-product if the following conditions are met:

(a) further use of the substance or object is certain;

(b) the substance or object can be used directly without any further processing other than normal industrial practice;

(c) the substance or object is produced as an integral part of a production process; and

(d) further use is lawful, i.e. the substance or object fulfils all relevant product, environmental and health protection requirements for the specific use and will not lead to overall adverse environmental or human health impacts”.

Based on the previous definition, the four conditions must be met for a substance to be considered a by-product. Thus, the substance will be considered a “by-product” if it must have a specific subsequent destination without prior transformation and without interruption in the production process, and the subsequent use of the product must not pose a danger to human health and the environment.

The conditions where a production residue would not be waste are cumulative:

1. First, the further use of the material must be certain (not a mere possibility).
2. In addition, the material must be used again without any further processing.

¹ Directive 2008/98/EC of the European Parliament and of the Council, of 19 November 2008, on waste and repealing certain Directives.

3. Furthermore, the material must be made ready for a further use as an integral part of the continuing process of production.
4. Finally, the use of the material should not have an impact on environmental or human health.

It should be noted that the application of these conditions is subject to the corresponding authorization by the competent authorities, so that the consideration of by-product is subject to obtaining the corresponding authorization.

In that sense, in Spain Law 7/2022² incorporates into the Spanish legal system the abovementioned directive. Regarding by-products, Article 4 states as follows:

“1. A substance or object, resulting from a production process, the primary purpose of which is not the production of such substance or object, may be considered a by-product and not waste, when all of the following conditions are met:

- a) That there is certainty that the substance or object shall be used for further use.*
- b) That the substance or object can be used directly without further processing other than normal industrial practice.*
- c) The substance or object is produced as an integral part of a production process.*
- d) That the subsequent use complies with all relevant product, human health and environmental protection requirements for the specific application, and does not result in overall adverse impacts on human health or the environment”.*

Based on the previous definition, the four conditions must be met for a substance to be considered a by-product. However, it should be noted that the classification of a by-product is subject to prior evaluation by the Ministry for Ecological Transition and Demographic Challenge, or the competent authorities of the autonomous communities.

In this regard, the evaluation criteria and the procedure for considering a substance as a by-product must be developed by regulation, in accordance with Article 4.2, which establishes the following:

“2. The evaluation criteria and the procedure for the consideration of these substances or objects as by-products shall be developed by regulation, following consultation with the Waste Coordination Committee, taking into account the relevant provisions of EU legislation, ensuring a high level of protection of the environment and human health and facilitating the prudent and rational use of natural resources”.

It should be noted that the necessary regulatory provisions to establish the evaluation criteria and the procedure for considering a substance as a by-product have yet to be developed. These provisions must be adopted by the Government, as indicated in the fourth final provision of the Law.

Therefore, the procedure for classifying a substance or object as a “by-product” requires prior evaluation by the competent authority, as previously indicated. Thus, in accordance with the provisions of Article 4.3 of Law 7/2022, “the assessment and approval, where appropriate, shall be carried out either by the Ministry for the

² Law 7/2022, of April 8, on waste and contaminated soils for a circular economy.

Ecological Transition and the Demographic Challenge or by the competent authorities of the autonomous communities by means of an authorisation, in accordance with the following points”.

In this regard, Article 4.4 confers powers to the Autonomous Communities to evaluate and authorize by-products. Its literal wording is as follows:

“4. The competent authorities of the autonomous communities shall evaluate and authorise as by-products, if appropriate, substances or objects originating from a production facility located in their territory provided that they are intended for a specific industrial activity or process in the territory of the autonomous community itself or, when intended for an activity or process in the territory of another autonomous community, following a favourable report from the latter, which shall be deemed to have been issued if there is no express and duly justified statement to the contrary within a period of one month.

These authorisations shall only be valid for the authorised use of the by-product in the activity or industrial process of destination. The autonomous community that has granted the authorisation shall inform the Waste Coordination Committee and may request, if deemed appropriate, a state-level declaration as a by-product. Once the declarations of by-products have been authorised, they shall be entered in the Register of By-products of the Electronic Waste Information System provided for in Article 66, following the procedure determined by regulation.

Any substance or object that has been reported unfavourably by the Ministry of Ecological Transition and Demographic Challenge pursuant to point 5 may not be approved as a by-product, provided that the conditions that made the initial decision unfavourable remain unchanged”.

Therefore, to initiate the process of evaluating materials as by-products, applicants must submit an evaluation request to the authority of the autonomous community, given that the Ministry will only conduct evaluations with a general scope across the entire Spanish territory, either ex officio when it is of interest to the whole State or at the request of an autonomous community, as established in Article 4.5 of the Law 7/2022.

In conclusion, unused side-streams such as bagasse, wastewater, and biogenic gases, which result from a production process where the primary aim is not the production of these substances, would generally be considered waste. To legally reclassify these production residues as by-products, it is necessary to undergo a prior evaluation by the competent authority. This evaluation ensures that the materials meet the criteria established by law, facilitating their reuse and integration into other production processes, thereby promoting sustainability and reducing environmental impact.

2.2 Impact of by-products legal regime

Starting from the above, the legal regime governing by-products has significant implications for the management and utilization of production residues such as bagasse, wastewater, and biogenic gases. These materials, which are often generated as secondary outputs in production processes not primarily aimed at producing them, would typically be classified as waste. However, they can be reclassified as by-products, provided specific conditions are met.

Regarding bagasse, it should be noted that in Spain, bagasse intended for animal feed are recognized as by-products. According to the provisions of Order APM/189/2018³, when a production residue from the food industry is destined for animal feed and is included in one of the three community lists of substances authorized for animal feed (such as bagasse, included in the community catalogue of feed materials under Regulation No. 68/2013), it will be classified as a by-product.

Therefore, bagasse which are a production residue from the agri-food industry, are considered a by-product as long as they are intended for animal feed.

Regarding the use of wastewater and biogenic gases, no Ministerial Order has been identified in Spain declaring these materials as by-products. Therefore, the appropriate procedure should be initiated to obtain the declaration of by-product status.

This implies that the food business operator must contact the authority to initiate the appropriate procedure to declare these production residues as by-products.

From a regulatory standpoint, obtaining by-product status involves complying with specific criteria and undergoing a thorough evaluation process. There is a market access barrier considering that their specific use must be authorized beforehand.

Once recognized as by-products for a specific use, these materials can be legally utilized in their specific applications. This approach can significantly reduce the environmental burden associated with waste disposal and effectively manage side-streams from an operational standpoint of industry.

³ Order APM/189/2018, of February 20, which determines when production residues from the agri-food industry intended for animal feed are considered by-products under Law 22/2011, of July 28, on waste and contaminated soils.

3 Relevant EU policies for bio-based products

3.1 Introduction

At European level, there are some policies related to bio-based products, such as EU Bioeconomy Strategy (2018), EU Green Deal (2019) and EU Circular Economy Action Plan (2020), to mention just a few. The following is an overview of the policy framework relevant for the bio-based products, which confirm that this sector is a priority to the European institutions and these products have an important role on its development.

3.2 European Bioeconomy Strategy

The European Commission adopted a strategy for “*Innovating for Sustainable Growth: A Bioeconomy for Europe*” on 13 February 2012 (COM(2012)60)⁴, which calls for a bioeconomy as a key element for smart and green growth in Europe.

In that sense, the European Bioeconomy Strategy proposes a comprehensive approach to address food security, natural resource scarcity, fossil resource dependence and climate change, while achieving sustainable economic growth.

The strategy is accompanied with an Action Plan that describes the Commission’s main actions for the implementation of the Bioeconomy Strategy objectives, that focuses on the following three key aspects:

- Investments in bioeconomy research and innovation, as well as build the skills required to support the growth and further integration of bioeconomy sectors.
- Reinforced policy interaction, throughout the creation of Bioeconomy Panel and establishment a Bioeconomy Observatory, among other actions, to enhancing synergies and coherence between policies and initiatives related to the bioeconomy.
- Enhancement of markets and competitiveness in bioeconomy. It should be noted that one goal in this area is support the expansion of new markets by developing standards and standardised sustainability assessment methodologies for bio-based products and food production systems.

Thus, the strategy recognizes the importance of the bio-based products to develop a sustainable economy based on renewable biological resources in Europe.

The European Bioeconomy Strategy was updated in 2018 in order to respond to the new policy priorities, in particular the renewed Industrial Policy Strategy, the Circular Economy Action Plan and the Communication on Accelerating Clean Energy Innovation, all of which highlight the importance of a sustainable, circular bioeconomy to achieve their objectives⁵.

⁴ COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS *Innovating for Sustainable Growth: A Bioeconomy for Europe*. COM/2012/060 final.

⁵ Official website of the European Union: https://knowledge4policy.ec.europa.eu/publication/updated-bioeconomy-strategy-2018_en [10th November 2022].

In line with the new policies, the updated European Bioeconomy Strategy, called “*A sustainable Bioeconomy for Europe: Strengthening the connection between economy, society and the environment*” (SWD(2018) 431 final)⁶ proposes an action plan with different concrete measures, based on three action areas:

- Strengthen and scale up the bio-based sectors, unlock investments and markets.
- Deploy local bio economies rapidly across the whole of Europe.
- Understand the ecological boundaries of the bioeconomy.

Therefore, in the main vision of the European Union, bio-based products are expected to contribute significantly to the future European economy because they have a high potential to promote the development of different sectors.

3.3 European Green Deal

The European Green Deal (COM (2019) 640 final)⁷, adopted on 11 December 2019, is the European Union's long-term growth strategy, that aims to transform the European Union in a modern, resource-efficient and competitive economy. Likewise, plans to decouple economic growth from resource use.

In that context, the bioeconomy is included as a part of Commission’s sustainable strategy, with the objective to support research and innovation on circular bio-based sectors, among others.

In that sense, the European Commission made a commitment to adopt a Circular Economy Action Plan, with a new model in the use of resources, recognizing the potential of the bioeconomy to contribute to the circular economy by providing alternatives to the current products, for example, developing a regulatory framework for biodegradable and bio-based plastics.

To transform the European economy for a sustainable future, the European Green Deal is the seed of a new approach which requires to rethink policies for every aspect of the economy, industry, production and consumption, including energy use and food use.

3.4 Circular Economy Action Plan

The Circular Economy Action Plan (COM(2020) 98 final)⁸, adopted on 11 March 2020, presents a set of interrelated initiatives to transform the European production and consumption system so that changes consumption patterns to use the resources in a more sustainable way and reduce waste. In this line, the plan calls for the creation of new, circular and bio-based business opportunities.

The Circular Economy Action Plan proposes some actions that contribute to closing the loop of product lifecycles, on the basis that this model can bring benefits for both the environment and the economy.

⁶ COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS A sustainable Bioeconomy for Europe: Strengthening the connection between economy, society and the environment. SWD(2018) 431 final.

⁷ COMMUNICATION FROM THE COMMISSION The European Green Deal. COM(2019) 640 final.

⁸ COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS A new Circular Economy Action Plan For a cleaner and more competitive Europe. COM/2020/98 final.

In that sense, this initiative plans to circularity in production processes, which is an essential part of a wider transformation of industry. One way to enable greater circularity in industry is by supporting the sustainable and circular bio-based sector through the implementation of the Bioeconomy Action Plan.

Within the sustainable product policy framework, and more particularly in the European Union Strategy for Plastics in the Circular Economy (COM(2018) 28 final)⁹, the Commission proposes developing a policy framework on sourcing, labelling and use of bio-based plastics.

Furthermore, the Circular Economy Action Plan states that biological resources are a key input to the economy of the European Union and will play an even more important role in the future. For that reason, the Commission will aim at ensuring the sustainability of renewable bio-based materials, including through actions following the Bioeconomy Strategy and Action Plan, abovementioned.

So, the circular economy is a high-level strategy to move our current systems to sustainable models, on bio-based sectors (such as food, feed, chemicals, etc.) play a central role in this Commission's strategy.

In view of the above policies, although there is no regulatory framework for bio-based products at European Union level, there are some initiatives underway which show that the European Union has made efforts in last years to implement the bioeconomy in Europe, and most probably it will adopt a regulation in the future for those products.

⁹ COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS A European Strategy for Plastics in a Circular Economy. COM(2018) 28 final.

4 European legal framework on novel food

4.1 Introduction

Whereas the intended final use of *Tenebrio molitor* is food, this part analyses the use of insects in food.

The food sector is one of the most highly regulated sectors in the European Union, to guarantee a high level of food safety. Therefore, the food safety is the primary objective of food law, to ensure that food do not present any risk for public health, among other reasons.

The basis for the assurance of a high level of protection of human health and consumers' interest in relation to food are in Regulation No 178/2002¹⁰, which provides the general framework for all food legislation in the European Union, and sets out general principles, requirements and procedures that are the basis of food safety, covering the whole food chain from “*farm to fork*”, because it is important to consider all stages of food production and distribution to ensure the safety of food.

In this regard, for ensure a safe food supply, there are regulations about all aspects that may have an effect on public health, like additives, contaminants, food hygiene, materials in contact and novel foods.

The European legal framework on novel food is regulated by the Regulation No 2015/2283¹¹, which applies to all foods and food ingredients that have not been consumed to a significant degree by humans in the European Union before 15 May 1997.

This regulation establishes an EU-wide authorization procedure for novel foods to ensure their safety for human consumption, which involves a scientific assessment by the European Food Safety Authority (EFSA) and a decision by the European Commission. Therefore, novel food must be authorized before they can be marketed and sold within the European Union. Once a novel food is authorized, it can be placed on the Union market and sold in all Member States.

These aspects of the Regulation are provided in the chapters below.

4.2 Novel food definition

The Regulation No 2015/2283 updated its scope of application with respect to the previous regulation, in order to clarify and update, on the basis of scientific and technological developments registered since 1997, the concept of novel food, including new categories, such as insects.

In that sense, it should be mentioned the recital 8 of the Regulation, which states that is appropriate to review the categories of food which constitute novel foods and expressly indicates that “*those categories should cover whole insects and their parts*”, among others.

¹⁰ Regulation (EC) No 178/2002 of the European Parliament and of the Council, of 28 January 2002, laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

¹¹ Regulation (EU) 2015/2283 of the European Parliament and of the Council, of 25 November 2015, on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001.

In view of the above, it should be noted the definition of “*novel food*”, contained in Article 3.2 of the Regulation No 2015/2283, which defines it thus:

“(a) ‘novel food’ means any food that was not used for human consumption to a significant degree within the Union before 15 May 1997, irrespective of the dates of accession of Member States to the Union, and that falls under at least one of the following categories:

- (i) food with a new or intentionally modified molecular structure, where that structure was not used as, or in, a food within the Union before 15 May 1997;*
- (ii) food consisting of, isolated from or produced from microorganisms, fungi or algae;*
- (iii) food consisting of, isolated from or produced from material of mineral origin;*
- (iv) food consisting of, isolated from or produced from plants or their parts, except when the food has a history of safe food use within the Union and is consisting of, isolated from or produced from a plant or a variety of the same species obtained by:
 - traditional propagating practices which have been used for food production within the Union before 15 May 1997; or*
 - non-traditional propagating practices which have not been used for food production within the Union before 15 May 1997, where those practices do not give rise to significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances;**
- (v) food consisting of, isolated from or produced from animals or their parts, except for animals obtained by traditional breeding practices which have been used for food production within the Union before 15 May 1997 and the food from those animals has a history of safe food use within the Union;*
- (vi) food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, micro-organisms, fungi or algae;*
- (vii) food resulting from a production process not used for food production within the Union before 15 May 1997, which gives rise to significant changes in the composition or structure of a food, affecting its nutritional value, metabolism or level of undesirable substances;*
- (viii) food consisting of engineered nanomaterials as defined in point (f) of this paragraph;*
- (ix) vitamins, minerals and other substances used in accordance with Directive 2002/46/EC, Regulation (EC) No 1925/2006 or Regulation (EU) No 609/2013, where:
 - a production process not used for food production within the Union before 15 May 1997 has been applied as referred to in point (a) (vii) of this paragraph; or*
 - they contain or consist of engineered nanomaterials as defined in point (f) of this paragraph;**
- (x) food used exclusively in food supplements within the Union before 15 May 1997, where it is intended to be used in foods other than food supplements as defined in point (a) of Article 2 of Directive 2002/46/EC”.*

According to the terms of the Article cited above, novel foods are those foods and food ingredients which have not been used for human consumption to a significant degree in the European Union before to 15 May 1997, and that can be included in one of the categories mentioned, which includes, among others, insects, that are comprised in the category of food produced from animals or their parts.

Therefore, considering that Novel Food Regulation explicitly considers whole insects as novel foods, in accordance with Article 2.1 of the Regulation No 2015/2283, the placing on the market within the Union is subject to the legal requirements established in this regulation, without prejudice to the applicable rules on food safety and hygiene, and other national legislation, if any.

4.3 Authorization procedure

The main consequence of the consideration of insects as a novel food is that they are subject to a safety evaluation and authorization before they are placed on the Union market. The authorization is granted after a procedure which evaluates the risks to human health and concludes with the inclusion of the novel food in the Union list. Then, the novel food is authorized to be placed on the market within the Union.

In that sense, it is important to note that the Article 6.2 of the Regulation No 2015/2283 states that *“only novel foods authorized and included in the Union list may be placed on the market within the Union as such, or used in or on foods, in accordance with the conditions of use and the labelling requirements specified therein”*.

The authorization procedure for a novel food is governed by the mentioned Regulation No 2015/2283, and includes the following steps:

- First, the procedure for authorising the placing on the Union market of a novel food starts either on the Commission's initiative or following an application to the Commission by an applicant.

In this late case, the food business operator must submit a notification to this competent authority according to the administrative and scientific requirements laid down in the Commission Implementing Regulation (EU) 2017/2469¹².

- After verifying the validity of the application, the Commission can request the European Food Safety Authority (EFSA) to give its scientific opinion on the safety of the novel food, not later than one month after having verified the validity of application.

Therefore, if there is a possibility a new food could affect people's health, then the EFSA would have to carry out an assessment, within nine months from the date of receipt of a valid application.

In its opinion, the Authority should assess all the characteristics of the novel food that may pose a safety risk to human health, including their nutritional profile and potential allergens, and consider possible effects on vulnerable groups of the population.

- Based on the EFSA opinion, the Commission decides on the authorization of the novel food, within seven months from the date of publication of that.

The authorisation of a novel food is made by an implementing act. Usually, the acts include the specification of the novel food and, where appropriate, the conditions under which the novel food may

¹² Commission Implementing Regulation (EU) 2017/2469, of 20 December 2017, laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods.

be use and additional specific labelling requirements to inform the final consumer of any specific characteristic or food property.

The acts also include a reference of data protection, if the applicant requested a protection of the investment. Therefore, during a period of five years from the date of the authorisation of the novel food, the data and information provided in support of an application should not be used to the benefit of a subsequent applicant, without the agreement of the initial applicant.

In addition, it should be noted that the acts may include post-market monitoring requirements.

- In that sense, the Commission has the power to introduce post-market monitoring requirements to monitor the use of the authorised novel food to ensure that the use is within safe limits as established in the risk assessment by EFSA.
- Finally, when a novel food is authorised, it is included in the Union list, which is established in Commission Implementing Regulation (EU) 2017/2470¹³.

It should be noted that this Regulation is applied without prejudice to other provisions laid down in sector specific legislation. Accordingly, Union legislation applicable to food is also applicable to novel foods placed on the market within the Union.

The Regulation No 2015/2283 also regulates a procedure for traditional foods from a third country, with specific rules, to facilitate the authorization where the history of safe food use in a third country has been demonstrated. Those foods should have been consumed in at least one third country for at least 25 years as a part of the customary diet of a significant number of people.

4.4 Summary of insect species authorized for EU food market

Based on the above, insects are considered novel food under Novel Food Regulation and are included in the scope of Regulation No 2015/2283 application. Consequently, are subject to pre-market approval, based on a safety assessment, before they can be sold to consumers.

For the time being, the European Commission has approved the use of four insect species as food for human consumption, based on scientific assessments that demonstrated their safety. The species authorized under Regulation No 2015/2283 are the larvae of the mealworm (*Tenebrio molitor*), the migratory locust (*Locusta migratoria*), the house cricket (*Acheta domesticus*) and the larvae of lesser mealworm (*Alphitobius diaperinus*).

Specific information about this species, along with the implementing act and the food business authorized to place them on the market within the Union, are detailed below:

1) *Tenebrio molitor*

Commission Implementing Regulation (EU) 2021/882¹⁴ authorized dried *Tenebrio molitor* larva (yellow mealworm) as a novel food to be used, whole or in powder, in protein products, biscuits, legumes-based dishes and pasta-based products, under the terms by this Act.

¹³ Commission Implementing Regulation (EU) 2017/2470, of 20 December 2017, establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods.

¹⁴ Commission Implementing Regulation (EU) 2021/882, of 1 June 2021, authorising the placing on the market of dried *Tenebrio molitor* larva as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) 2017/2470.

It was authorised on 22 June 2021, and for a period of five years only the initial applicant, SAS EAP Group, is authorised for placing on the market within the Union, unless a subsequent applicant obtains authorisation for that novel food without reference to the proprietary scientific evidence or scientific data protected, or with its agreement.

Commission Implementing Regulation (EU) 2022/169¹⁵ authorized frozen, dried and powder forms of yellow mealworm (*Tenebrio molitor* larva) as a novel food to be used in a number of foods intended for the general population, such as multigrain bread, cereal bars, sauces, whey powder, to name just a few, and beverages, such as beer-like beverages, mixed alcoholic drinks and alcoholic drink mixes.

It was authorised on 1 March 2022 and only Fair Insects BV is authorised to place this novel food on the Union market until 1 March 2027, unless a subsequent applicant obtains a novel food authorisation without reference to the data protected, or with the company's agreement.

2) *Locusta migratoria*

Commission Implementing Regulation (EU) 2021/1975¹⁶ authorized frozen, dried and powder forms of *Locusta migratoria* (migratory locust) as a novel food to be used as a food ingredient in a number of food products for the general population, such as meat analogues, beer-like beverages, alcoholic drink mixes, chocolate confectionery and frozen fermented milk-based products, among others.

It was authorised on 5 December 2021, and for a period of five years only the initial applicant, Fair Insects BV, is authorised for placing on the market within the Union, unless a subsequent applicant obtains authorisation for that novel food without reference to the data protected, or with its agreement.

3) *Acheta domesticus*

Commission Implementing Regulation (EU) 2022/188¹⁷ authorized on 3 March 2022 frozen, dried and powder forms of *Acheta domesticus* (house cricket) as a novel food to be used in a wide range of products, amongst the ones it could be highlighted protein products other than meat analogues, meat analogues, meat preparations, biscuits, beer-like beverages and alcoholic drink mixes.

For a period of 5 years from this date, only Fair Insects BV is authorised to place it on the market within the Union, unless a subsequent applicant obtains authorisation for that novel food without reference to the data protected, or with the company's agreement.

¹⁵ Commission Implementing Regulation (EU) 2022/169, of 8 February 2022, authorising the placing on the market of frozen, dried and powder forms of yellow mealworm (*Tenebrio molitor* larva) as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) 2017/2470.

¹⁶ Commission Implementing Regulation (EU) 2021/1975, of 12 November 2021, authorising the placing on the market of frozen, dried and powder forms of *Locusta migratoria* as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470.

¹⁷ Commission Implementing Regulation (EU) 2022/188, of 10 February 2022, authorising the placing on the market of frozen, dried and powder forms of *Acheta domesticus* as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) 2017/2470.

Commission Implementing Regulation (EU) 2023/5¹⁸ authorized *Acheta domestica* (house cricket) partially defatted powder as a novel food to be used in specific food categories, such as multigrain bread and rolls, cereal bars, snacks other than chips and beer-like beverages, among others.

It was authorised on 24 January 2023, and for a period of 5 years from that, only the company Cricket One Co. Ltd is authorised to place on the market within the Union this novel food, unless a subsequent applicant obtains an authorisation without reference to the scientific data protected or with the agreement of the company.

4) *Alphitobius diaperinus*

Commission Implementing Regulation (EU) 2023/58¹⁹ authorized the placing on the market of the frozen, paste, dried and powder forms of *Alphitobius diaperinus* larvae (lesser mealworm) as a novel food.

It may be used in frozen, paste (ground), dried, and powder (ground) forms as a food ingredient in a number of food products for the general population, such as cereal bars, porridges, chips, milk and dairy analogues, among others, and in powder form in food supplements.

It was authorised on 26 January 2023, and for a period of 5 years from that, only the first applicant Ynsect NL B.V. is authorised to place on the market within the Union this novel food, unless a subsequent applicant obtains an authorisation without reference to the scientific data protected or with the agreement of the company.

Notwithstanding, it should be noted that the Novel Food Regulation includes transitional measures in which insects are included. Thus, the Article 35.2 of the Regulation No 2015/2283 sets out the following:

“2. Foods not falling within the scope of Regulation (EC) No 258/97, which are lawfully placed on the market by 1 January 2018 and which fall within the scope of this Regulation may continue to be placed on the market until a decision is taken in accordance with Articles 10 to 12 or Articles 14 to 19 of this Regulation following an application for authorization of a novel food or a notification of a traditional food from a third country submitted by the date specified in the implementing rules adopted in accordance with Article 13 or 20 of this Regulation respectively, but no later than 2 January 2020”.

In accordance with this Article, those species of whole animals which were lawfully placed on the market by 1 January 2018, because they were tolerated in the national market of certain Member States, may continue to be placed on the Union market provided that an application for the same concerned specie is submitted in accordance with the Regulation No 2015/2283, before 1 January 2019.

It is important to note that, although the end date 2 January 2020 planned on this Regulation has been exceeded, the transitional regime provided by the Novel Food Regulation continues to be applied, until a final decision on the authorization of the product is taken.

¹⁸ Commission Implementing Regulation (EU) 2023/5, of 3 January 2023, authorising the placing on the market of *Acheta domestica* (house cricket) partially defatted powder as a novel food and amending Implementing Regulation (EU) 2017/2470.

¹⁹ Commission Implementing Regulation (EU) 2023/58 of 5 January 2023 authorising the placing on the market of the frozen, paste, dried and powder forms of *Alphitobius diaperinus* larvae (lesser mealworm) as a novel food and amending Implementing Regulation (EU) 2017/2470.

In view of the above, the companies SAS EAP Group and Fair Insects BV currently have the exclusive rights to commercialize *Tenebrio molitor* in the European Union, whose use is authorized in the products requested by the companies in the application dossier of novel food, which explicitly does not include drinks with high protein content. Therefore, the placing on the market of protein drinks that contain as an ingredient *Tenebrio molitor* larva (yellow mealworm) in a powder form, will require its prior authorization as a novel food for its use in this product.

4.5 Legal feasibility of feed *Tenebrio molitor* with beer bagasse

Within the framework of the project, it is intended to feed *Tenebrio molitor* with beer bagasse, so it is necessary to assess its legal feasibility.

Based on the above, it should be noted that beer bagasse is included in the Community catalog of feed materials, established in Commission Regulation (EU) No 68/2013²⁰.

In Part C of the Annex of this Regulation, related to the list of cereal grains and products derived thereof, there is a reference to brewers' grains, described as "*product of brewing composed of residues from malted and unmalted cereals and other starchy products, which may contain hop materials. Typically marketed in a moist condition but may also be sold in a dried form. May contain up to 0,3 % dimethyl polysiloxane, may contain up to 1,5 % enzymes, may contain up to 1,8 % bentonite*" (1.12.12).

In view of the above, brewers' grain is legally recognized for use in the feed industry, inasmuch as it is listed in the catalog of feed materials. Consequently, it is legal feasible to feed *Tenebrio molitor* (mealworms) with beer bagasse, which is a by-product of the beer production process authorized for its intended use as a feed material.

4.6 Use of insect protein in non-alcoholic beverages

Whereas the use of insect protein is intended as an ingredient for the manufacture of smoothies and other beverages (such as nutritional aqueous drinks), the specific regulations governing these products should be considered.

It should be noted that no regulations have been established at the community level to govern the characteristics of these products. In the absence of harmonized regulations at the European Union level for a specific product category, the provisions established by national legislation must be adhered to. In that sense, in Spain non-alcoholic beverages are regulated by Royal Decree 650/2011, of May 9²¹.

In light of the information provided, the products concerned (smoothies and other soft drinks such as nutritional aqueous drinks) would fall under the aforementioned regulation, whose Article 2.1 defines non-alcoholic beverages as "*non-alcoholic beverages, carbonated or not, prepared with drinking water, processed water, natural mineral water, or spring water (hereinafter water), that contain one or more of the following ingredients: carbon dioxide, sugars, juices, purees, fruit and/or vegetable disintegrates, plant extracts, vitamins and minerals, flavors, authorized additives, or other food ingredients*".

²⁰ Commission Regulation (EU) No 68/2013, of 16 January 2013, on the Catalog of Feed Raw Materials.

²¹ Royal Decree 650/2011, of May 9, which approves the technical-sanitary regulations for non-alcoholic beverages.

The Article 2.2 of this Royal Decree establishes the designations applicable to the products covered by the scope of the regulation, including the following designations:

“a) 'Seltzer water': a beverage consisting of water and a minimum of six grams per liter of carbon dioxide.

b) 'Soda water': a beverage consisting of water and a minimum of six grams per liter of carbon dioxide that is characterized by containing sodium bicarbonate.

c) 'Flavored water': water, with or without carbon dioxide, that contains flavors.

d) 'Soda': a colorless beverage prepared with water, carbon dioxide, flavors, sugars and/or sweeteners, and authorized additives.

e) 'Other non-alcoholic beverages': the generic designation of non-alcoholic beverage can be specified with a name that corresponds to its composition or characteristics. Including, but not limited to, the following:

Non-alcoholic fruit juice beverages, characterized by containing juices, purees, fruit disintegrates, or their mixtures.

Non-alcoholic extract beverages, characterized by containing extracts of fruits, other vegetables, or both.

Mixed non-alcoholic beverages, consisting of non-alcoholic beverages and other foods.

Non-alcoholic beverages for diluting and solid products for the preparation of non-alcoholic beverages, which, once reconstituted, comply with the provisions of this regulation.

Flavored non-alcoholic beverages, characterized by containing flavoring agents with the addition of other food ingredients”.

Furthermore, regarding the characteristics of the finished products, the regulation stipulates in section 3 that they must *“not contain alcohol in an amount exceeding 0.5 percent by volume”*.

In view of the above, smoothies and other soft drinks would fall under the definition of *“non-alcoholic beverage”* and consequently must comply with the composition requirements established in Royal Decree 650/2011.

In this regard, Article 3 establishes the requirements that non-alcoholic beverages must meet, stipulating, with respect to the ingredients they may contain, the following:

“Non-alcoholic beverages may contain any of the following ingredients, which must comply with their corresponding regulations:

1. Drinking water, processed water, natural mineral water, or spring water, as defined in Royal Decree 140/2003 of February 7, which establishes sanitary criteria for the quality of drinking water, Royal Decree 1798/2010 of December 30, regulating the exploitation and marketing of natural mineral waters and spring waters packaged for human consumption, and Royal Decree 1799/2010 of December 30, which regulates the production and marketing process of packaged processed waters for human consumption. This water may undergo authorized treatments to meet the necessary characteristics for the manufacture of refreshment beverages.

2. Carbon dioxide, which must comply with the purity criteria established in Royal Decree 1466/2009 of September 18, which sets identity and purity standards for food additives other than colorants and sweeteners used in food products.

3. *Sugars, as defined in current regulations on certain sugars intended for human consumption, including those obtained from fruit.*
4. *Juices, purees, fruit or vegetable disintegrates, or their mixtures.*
5. *Compound syrup or basic preparation.*
6. *Extracts of fruits, vegetables, or both.*
7. *Caffeine and quinine.*
8. *Authorized additives and flavors in accordance with the following regulations:*
 - a) *Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008, on food additives.*
 - b) *Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008, on flavourings and certain food ingredients with flavouring properties used in food and amending Council Regulation (EEC) No 1601/1991, Regulations (EC) No 2232/1996 and (EC) No 110/2008, and Directive 2000/13/EC.*
 - c) *Royal Decree 2001/1995 of December 7, approving the positive list of colorants authorized for use in the manufacture of food products, as well as their conditions of use.*
 - d) *Royal Decree 2002/1995 of December 7, approving the positive list of sweeteners authorized for use in the manufacture of food products, as well as their conditions of use.*
 - e) *Royal Decree 142/2002 of February 1, approving the positive list of food additives other than colorants and sweeteners for use in the manufacture of food products, as well as their conditions of use.*
 - f) *Royal Decree 299/2009 of March 6, establishing identity and purity standards for sweeteners used in food products.*
 - g) *Royal Decree 1465/2009 of September 18, establishing identity and purity standards for colorants used in food products.*
 - h) *Royal Decree 1466/2009 of September 18, establishing identity and purity standards for food additives other than colorants and sweeteners used in food products.*
9. *Vitamins and minerals.*
10. *Other ingredients used in human food or authorized in accordance with Regulation (EC) No 258/97 of the European Parliament and of the Council of January 27, 1997, on novel foods and novel food ingredients.*
11. *The ingredients mentioned in the above sections may only be used in the production of non-alcoholic beverages if they lead to the production of safe products and do not pose risks to consumer health, as established in generally accepted scientific studies. Competent authorities may require marketers of such products to provide technical documentation related to their products and ingredients”.*

According to these provisions, any food ingredient could be used in the production of soft drinks provided that it is suitable for human consumption and meets the requirements set forth in its specific corresponding regulations. Specifically, regarding the use of insect protein, to the extent that it is authorized as a novel food, it may be used in the production of these products.

4.7 Impact on the commercialization of the product

The placing on the market of soft drinks that contain *Tenebrio molitor* larva (yellow mealworm) in powder form as a protein ingredient will necessitate prior authorization as a novel food for its use in human consumption.

Therefore, pre-market authorization would be required before its use as an ingredient of soft drinks, among other products. This process involves a thorough safety evaluation about the product and regulatory approval to ensure consumer protection.

According to the Regulation No 2015/2283, food business operator must present an application to European Commission to demonstrate the safety of the novel food.

The applicant should prepare a dossier with comprehensive scientific data and information regarding the novel food, among others, the description of the novel food, production process, compositional data, specification, proposed uses and use levels, and anticipated intake of the novel food. Then, the Commission validates the application and conducts a confidentiality assessment if necessary to protect proprietary information.

Following validation, the safety assessment is conducted by the European Food Safety Authority (EFSA) to evaluate potential risks associated with the novel food, considering factors such as composition, production process, and intended use.

Subsequently, the evaluation process involves the European Commission and Member States, who review EFSA's assessment and the applicant's data to make an informed decision on authorization. Upon successful evaluation and approval, the novel food is authorized for placement on the market within the European Union.

Considering the above, it can be inferred that the complexity of the regulatory system applicable to the commercialization of food products in the European Union may constitute a barrier to market entry. This is due to the necessity of obtaining novel food authorization before placing the product on the market.

In this regard, the timelines for a novel food application process are lengthy, the process can often take between 1.5 to 3.5 years to complete.

The impact of this regulatory complexity and extended timeline can be significant for business operators looking to introduce new and innovative food products to the market, but it should be noted that obtaining novel food authorization also offers opportunities, specially this can be a competitive advantage in a market increasingly focused on sustainability and alternative protein sources.

To achieve successful product commercialization, food business operator must be well-prepared for the rigorous novel food application process for navigating the complex landscape and ensuring that novel food can safely and effectively reach the market.

5 European legal framework on animal feed

5.1 Introduction

Whereas the intended final use of caproic acid is feed ingredient, this part analyses the European legal framework on animal feed.

The Regulation No 178/2002, mentioned above, lays down the general principles and requirements of food law, but also of feed in general. One of its fundamental objectives is to ensure a high level of protection of human and animal health, and in line with the “farm to fork” approach, which covers the whole food chain, feed is included because is a sensitive stage at the beginning of the food chain.

The legal definition of feed is included in this Regulation, Article 3 of which states that “‘feed’ (or ‘feeding stuff’) means any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animal”.

It should be noted that it is a broad definition, and feed may take the form of feed materials, compound feed, feed additives, premixtures or medicated feeding stuffs, and the distinction between them has implications for the conditions for the placing of such products on the market, depending on the applicable legislation. The different kinds of products concerned have its own regulation, which are detailed as follows:

- Regulation No 767/2009²² regulates the circulation and use of feed materials and compound feed, which includes pet food. In accordance with the general principles laid down in Regulation No 178/2002, this Regulation lays down the conditions for the placing on the market and the use of feed, to ensure a high level of feed safety and thus a high level of protection of public health.
- Regulation No 1831/2003²³ establishes a procedure for authorising the placing on the market and use of feed additives in the European Union, to ensure a high level of protection of human health, animal health and welfare.
- Regulation No 2019/4²⁴ establishes specific provisions for medicated feed and intermediate products and sets out rules from production to distribution and use of medicated feed to ensure a high level of protection of human and animal health.

Therefore, different European regulations affect to production and distribution to feed, to ensure their safety. Thus, ingredients for feed must comply with European Union regulations and must be produced and placed on the market complying feed legislation requirements.

²² Regulation (EC) No 767/2009 of the European Parliament and of the Council, of 13 July 2009, on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC.

²³ Regulation (EC) No 1831/2003 of the European Parliament and of the Council, of 22 September 2003, on additives for use in animal nutrition.

²⁴ Regulation (EU) 2019/4 of the European Parliament and of the Council, of 11 December 2018, on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC.

The basic requirements of each above-mentioned regulations are provided in the chapters below.

5.2 European Union rules on marketing of animal feed

The placing on the market and the use of feed in the European Union, including labelling, packaging and presentation requirements, are regulated under Regulation No 767/2009.

The Regulation covers any substance or product, including additives, intended to be used for oral feeding to animals. In that sense, the Regulation defines the concepts of feed materials and compound feed. The regulation also contains other definitions, such as complementary feed and feed intended for particular nutritional purposes, to clarify the distinction between these and premixtures, in order to allow a uniform application of the legislation.

For the purposes of this Regulation, the definition of “*feed materials*”, contained in Article 3.2, is the following:

“(g) ‘Feed materials’ means products of vegetable or animal origin, whose principal purpose is to meet animals’ nutritional needs, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, whether or not containing feed additives, which are intended for use in oral animal-feeding either directly as such, or after processing, or in the preparation of compound feed, or as carrier of premixtures”.

Pursuant this definition, feed materials are primarily used to meet animals’ needs, for example for energy, nutrients, minerals, or dietary fibres, intended to be used for oral feeding to animals. This Article 3.2 also sets out what is meant by “*oral feeding for animals*”, which has the following definition:

“(b) ‘oral feeding of animals’ means the introduction of feed into an animal’s gastrointestinal tract through the mouth with the aim of meeting the animal’s nutritional needs and/or maintaining the productivity of normally healthy animals”.

Taking into account the primary function of feed, it is relevant to point out other definitions provided in the same article, such as “*compound feed*”, which is defined as follows:

“(h) ‘compound feed’ means a mixture of at least two feed materials, whether or not containing feed additives, for oral animal-feeding in the form of complete or complementary feed”.

In this regard, it should be noted the definition of “*complementary feed*”, which is the following:

“(j) ‘complementary feed’ means compound feed which has a high content of certain substances but which, by reason of its composition, is sufficient for a daily ration only if used in combination with other feed”.

Also of note the definition of “*feed intended for particular nutritional purposes*”, which the Regulation No 767/2009 distinguishes from medicated feed, for the purpose of the application of the legislation. According to the mentioned Article 3.2, the definition is as follows:

“(o) ‘feed intended for particular nutritional purposes’ means feed which can satisfy a particular nutritional purpose by virtue of its particular composition or method of manufacture, which clearly distinguishes it from ordinary feed. Feed intended for particular nutritional purposes does not include medicated feedingstuffs within the meaning of Directive 90/167/EEC”.

As noted earlier, the objective of the Regulation No 767/2009 is to ensure a high level of feed safety and to achieve this, the article 4 of Regulation No 767/2009 establishes the following safety and marketing requirements:

“1. Feed may only be placed on the market and used if:

(a) it is safe; and

(b) it does not have a direct adverse effect on the environment or animal welfare.

The requirements set out in Article 15 of Regulation (EC) No 178/2002 shall apply, mutatis mutandis, to feed for non-food producing animals.

2. In addition to the requirements set out in paragraph 1 of this Article, feed business operators placing feed on the market shall ensure that the feed:

(a) is sound, genuine, unadulterated, fit for its purpose and of merchantable quality; and

(b) is labelled, packaged and presented in accordance with the provisions laid down in this Regulation and other applicable Community legislation.

The requirements set out in Article 16 of Regulation (EC) No 178/2002 shall apply, mutatis mutandis, to feed for non-food producing animals.

3. Feed shall comply with the technical provisions on impurities and other chemical determinants set out in Annex I to this Regulation”.

Therefore, animal feed must comply with safety and marketing requirements. In particular, it must be safe, not have a direct adverse effect on the environment or animal welfare, be sound, genuine, unadulterated, fit for its purpose and of merchantable quality, be labelled, packaged and presented in accordance with the applicable legislation.

There are lists of feed materials, such as the Catalogue of the European Union for Feed Materials, which is contained in Regulation No 68/2013 and provides a list of feed materials commonly used in animal nutrition in the European Union, with the name of the product and a description of the feed, including in some cases information on the production process.

However, it should be noted that this Catalogue is not exclusive, so operators who place on the market for the first time a feed material that is not listed therein, must notify its use to the representatives of the European feed production sectors, who will publish a register of such notifications on the Feed Materials Register and update it periodically.

In addition to the safety requirements, animal feed must not contain materials which are restricted or prohibited from being placed on the market. In that sense, Article 6 of Regulation No 767/2009 establishes the following restrictions and prohibitions:

“1. 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 such materials is set out in Annex III.

2. The Commission shall amend the list of materials whose placing on the market or use for animal nutritional purposes is restricted or prohibited taking into account in particular scientific evidence, technological developments, notifications under the Rapid Alert System for Food and Feed (RASFF) or results of official controls pursuant to Regulation (EC) No 882/2004.

Those measures, designed to amend non-essential elements of this Regulation, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 28(4).

On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 28(5) with a view to adopting those measures”.

According to its wording, there are a list of materials whose placing on the market or use for animal nutritional purposes is restricted or prohibited, and the list of such materials is set out in Annex III of Regulation No 767/2009.

In this sense, the prohibited materials listed in Chapter 1 of the mentioned Annex are as follows:

- “1. Faeces, urine and separated digestive tract content resulting from the emptying or removal of digestive tract, irrespective of any form of treatment or admixture.*
- 2. Hide treated with tanning substances, including its waste.*
- 3. Seeds and other plant-propagating materials which, after harvest, have undergone specific treatment with plant-protection products for their intended use (propagation), and any by-products derived therefrom.*
- 4. Wood, including sawdust or other materials derived from wood, which has been treated with wood preservatives as defined in Annex V to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market.*
- 5. All waste obtained from the various phases of the treatment of the urban, domestic and industrial waste water, as defined in Article 2 of Council Directive 91/271/EEC of 21 May 1991 concerning urban waste water treatment, irrespective of any further processing of that waste and irrespective of the origin of the waste waters.*
- 6. Solid urban waste, such as household waste.*
- 7. Packaging from the use of products from the agri-food industry, and parts thereof.*
- 8. Protein products obtained from yeasts of the Candida variety cultivated on n-alkanes”.*

In the context of transform wastewater to valuable ingredients for the formulation of feed ingredients, it is important to note that, according to the point 5 of the list, all waste obtained from the different phases of the treatment of the industrial wastewater is prohibited for animal nutritional purposes, irrespective of any further processing of that waste and irrespective of the origin of the waste waters.

Regarding with that, the footnote of the point 5 indicates that *“the term “wastewater” does not refer to “process water”, which is water from independent conduits integrated in food or feed industries. In that sense, where these conduits are supplied with water, no water may be used for animal nutrition unless it is wholesome and clean water as specified in legislation concerns the quality of water intended for human consumption”.* And adds that *“process water may not be used for animal nutrition unless it carries feed or food material and is technically free from cleaning agents, disinfectants or other substances not authorised by the animal nutrition legislation”.*

Consequently, it would not be legally feasible to use caproic acid obtained of beer wastewater to animal feed, because all waste obtained from the treatment of industrial wastewater is prohibited for animal nutrition purposes. However, it would be possible to use process water for animal nutrition if it carries feed animal and the water has the quality of water intended for human consumption.

Once this note is made, it should be noted that water used during the manufacture of feed shall be of suitable quality, according to Regulation No 1831/2003²⁵, which lays down the general rules on feed hygiene.

In view of the above, it can be concluded that Regulation No 767/2009 imposes strict requirements concerning safety of animal feed so that feed materials only be placed on the market and used if they are safe. Therefore, in the frame of the production of feed, they must comply with European health and safety requirements, to guarantee such safety.

5.3 European Union rules on marketing of feed additives

The use of feed additives is governed by Regulation No 1831/2003 which establishes a procedure before being placed on the market, used or processed within the European Union, in order to protect human health, animal health and the environment.

For the purpose of this Regulation, the definition of “*feed additives*” is provided in Article 2.2, which states the following:

“(a) ‘feed additives’ means substances, micro-organisms 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 of the functions mentioned in Article 5(3)”.

According to these functions, the mentioned Article 5.3 sets out the following:

“3. The feed additive shall:

- (a) favourably affect the characteristics of feed,*
- (b) favourably affect the characteristics of animal products,*
- (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 feedingstuffs, or*
- (g) have a coccidiostatic or histomonostatic effect”.*

Therefore, a substance shall be considered a feed additive if has one or some of the above-mentioned effects, which must be justified in the relevant assessment procedure.

The basic principle is that only those additives approved under the procedure provided for in the Regulation No 1831/2003 may be placed on the market, used and processed in animal feeding under conditions set out in the authorisation.

²⁵ Regulation (EC) No 1831/2003 of the European Parliament and of the Council, of 12 January 2003, laying down requirements for feed hygiene.

Regarding to placing on the market, processing and use of feed additives, Article 3.1 reads as follows:

“1. No person shall place on the market, process or use a feed additive unless:

(a) it is covered by an authorisation granted in accordance with this Regulation;

(b) the conditions for use set out in this Regulation, including the general conditions set out in Annex IV, unless otherwise provided for in the authorisation, and in the authorisation of the substance are met; and

(c) the conditions on labelling set out in this Regulation are met”.

Consequently, feed additives, before being placed on the market or used in the European Union, are subjected to a safety assessment through a community procedure, in order to protect human health, animal health and the environment.

In this regard, the Regulation No 1831/2003 defines different categories of feed additives in order to facilitate the assessment procedure with a view to authorisation. Article 6 provides the following:

“1. A feed additive shall be allocated to one or more of the following categories, depending on its functions and properties, in accordance with the procedure set out at Articles 7, 8 and 9:

(a) technological additives: any substance added to feed for a technological purpose;

(b) sensory additives: any substance, the addition of which to feed improves or changes the organoleptic properties of the feed, or the visual characteristics of the food derived from animals;

(c) nutritional additives;

(d) zootechnical additives: any additive used to affect favourably the performance of animals in good health or used to affect favourably the environment;

(e) coccidiostats and histomonostats.

2. Within the categories referred to in paragraph 1, feed additives shall further be allocated within one or more of the functional groups mentioned in Annex I, according to their principal function or functions, in accordance with the procedure specified in Articles 7, 8 and 9.

3. The Commission is empowered to adopt delegated acts in accordance with Article 21a amending Annex I in order to adapt feed additive categories and functional groups as a result of technological progress or scientific development”.

Further, these categories are themselves divided into functional groups depending on the additives' main functions, as provided in Annex I:

- In the category *“technological additives”*, the following functional groups are included: preservatives, antioxidants, emulsifiers, stabilisers, thickeners, gelling agents, binders, substances for control of radionuclide contamination, anticaking agents, acidity regulators, silage additives, denaturants, substances for reduction of the contamination of feed by mycotoxins, hygiene condition enhancers, and others technological additives.
- In the category *“sensory additives”*, the following functional groups are included: colourants and flavourings compounds.
- In the category *“nutritional additives”* the following functional groups are included: vitamins, compounds of trace elements, amino acids, urea and its derivatives.

- In the category “*zootechnical additives*” the following functional groups are included: digestibility enhancers, gut flora stabilizers, substances which favourably affect the environment, other zootechnical additives, and physiological condition stabilisers.

Once the authorization procedure under Regulation No 1831/2003 is complete, and the authorisation is granted, the feed additive is entered in the Community Register of Feed Additives, which includes the specific requirements for placing the additives in European market. The Register is established by European Commission and regularly updated with the relevant authorisations of feed additives²⁶.

Based on the above, it should be noted that caproic acid is not include in the current list of additives, so that it is not authorized for use as a feed additive. In this regard, as indicated above, only authorised additives, which must be included in the above-mentioned Register, may be placed on the market and used.

In accordance with that, the use of caproic acid in animal feed will require the necessary authorization as a technological and/or nutritional additive, depending on its functions and properties.

The authorization procedure for a feed additive is governed by the mentioned Regulation No 1831/2003, and includes the following steps:

- First, an applicant must send to the Commission an application for the authorisation of a feed additive, in accordance with standard data formats.

In that sense, the Commission Regulation No 429/2008²⁷ regulates the application form and the administrative data to be included. In addition, this Regulation provides for the requirements to be satisfied by the dossier accompanying the application by listing the scientific data to be submitted for the identification and the characterisation of the additive concerned and the studies to be submitted to demonstrate its efficacy and its safety for humans, animals and the environment. It also indicates specific requirements depending on the category of the additive, where necessary.

- After that, the Commission must inform the Member States and forward the application to the EFSA, which shall give an opinion within six months of receipt of a valid application.

Based on the dossier submitted by the applicant, EFSA shall prepare its opinion, and may seeks for supplementary information to the applicant, so the time can be extended.

- Having evaluated, EFSA must forward its opinion to the Commission, the Member States and the applicant, including a report describing its assessment of the feed additive and stating the reasons for its conclusion.

In the opinion is favourable and it authorises the feed additive, it must include specific conditions or restrictions in relation to handling, post-market monitoring requirements and use, including animal species and categories of animal species for which the additive is to be used and, where appropriate, information on specific additional requirements for labelling of the additive. Also, sometimes it includes a proposal for the establishment of maximum residue limits in the relevant foodstuffs of animal origin.

²⁶ European Union Register of Feed Additives pursuant to Regulation (EC) No 1831/2003. Edition 07/2022 (302), available on European Commission website: https://food.ec.europa.eu/safety/animal-feed/feed-additives/eu-register_es [22nd February 2023].

²⁷ Commission Regulation (EC) No 429/2008, of 25 April 2008, on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives.

- Based on the EFSA opinion, and within three months of its receipt, the Commission decides whether grant or deny the authorisation, through by the relevant Implementing Regulation. It should be noted that, the authorization granted the feed additive will be valid throughout the European Union for 10 years and will be able renewable.
- Finally, if the feed additive is authorised as additive in animal nutrition, it will be included in the European Union Register of Feed Additives.

5.4 European Union rules on marketing of medicated feed

The last type of feed is medicated feed, which is a homogeneous mixture of feed and veterinary medicinal products, regulated by Regulation No 2019/4, which provides the following definition in Article 3.2:

“(a) ‘medicated feed’ means a feed, which is ready to be directly fed to animals without further processing, consisting of a homogenous mixture of one or more veterinary medicinal products or intermediate products with feed materials or compound feed”.

In order to ensure the safe use of medicated feed, it should be noted that its supply and use require a veterinary prescription which has been issued by a veterinarian after examination or any other proper assessment of the health status of the animals to be treated.

With this aim, the Regulation requires that medicated feed only be manufactured from veterinary medicinal products, in accordance with the Regulation No 2019/6²⁸, and establishes specific provisions concerning its manufacture, quality control and labelling.

Under the definition of medicated feed and its composition, which can only incorporate veterinary medicines for administration via feed, the use of caproic acid in this type of feed would not be feasible.

5.5 Impact on the commercialization of the product

Based on the above, the first market barrier about the commercialization of caproic acid as feed ingredient is the complexity of the regulatory system applicable to the commercialization of feed in the European Union.

The Regulation No 767/2009 states that feed must be safe and not have a direct adverse effect on the environment or animal welfare, as well as not contain or consist of materials whose placing on the market or use for animal nutritional purposes is restricted or prohibited.

In that sense, in the context of transform wastewater to valuable ingredients for the formulation of feed ingredients, it is important to note that all waste obtained from the different phases of the treatment of the industrial wastewater is prohibited for animal nutritional purposes, irrespective of any further processing of that waste and irrespective of the origin of the waste waters.

According to the mentioned Regulation, feed cannot contain or consist of any of these materials whose commercialization or use for animal nutritional purposes is restricted or prohibited. Therefore, since the use of wastewater as a material for feed is prohibited, it would not be legally viable to use wastewater to produce caproic acid intended for animal feed. However, it would be possible to use process water in the terms

²⁸ Regulation (EU) 2019/6 of the European Parliament and of the Council, of 11 December 2018, on veterinary medicinal products and repealing Directive 2001/82/EC.

established by the regulation. Furthermore, it should be noted that water used during the manufacture of feed shall be of suitable quality.

On the other hand, regarding the use of caproic acid as antimicrobial agent and flavour and nutritional additive, it must be authorized as additive prior to its use as such.

In that sense, the second market barrier about the commercialization of caproic acid as feed ingredient is the requirement for necessary authorization as a technological and/or nutritional additive, depending on its functions and properties.

According to the Regulation No 1831/2003, food business operator must present an application to European Commission to demonstrate the safety of the novel food, along with a technical dossier to EFSA, which will evaluate the safety and efficacy of additives used in animal feed before they can be authorized for use in the European Union.

This entails thorough evaluation of the product to ensure its safety, efficacy, and compliance with current regulations before it can be marketed or used in feed.

The application process involves a great deal of work, insofar as the business operator must build a robust dossier with extensive documentation that substantiates the safety. In that sense, it must include characterization and efficacy studies, followed by detailed planning for statistical analyses, just to mention a few. Typically, this entire process can take from 3 to 4 years to complete.

However, it is important to highlight that this application represents an opportunity for innovation to enhance animal health, improve nutrition absorption, and provide environmental benefits, such as reducing methane emissions from enteric fermentation.

6 European legal framework on petfood

6.1 Introduction

Whereas the intended final use of single cell protein is petfood ingredient, this part analyses the European legal framework on petfood.

As noted in the previous section, the Regulation No 767/2009 lays down rules on the placing on the market and use of feed for both food-producing and non-food producing animals, including labelling, packaging and presentation requirements.

For the purposes of this Regulation, the definition of “*non-food producing animals*”, contained in Article 3.2, is the following:

“(d) ‘non-food producing animals’ means any animal that is fed, bred or kept but that is not used for human consumption, such as fur animals, pets and animals kept in laboratories, zoos or circuses”.

Likewise, the same Article defines “*pet animal*” as follows:

“(f) ‘pet’ or ‘pet animal’ means any non-food producing animal belonging to species fed, bred or kept, but not normally used for human consumption in the Community”.

According to this Regulation, petfood must comply with safety and marketing requirements, established in Article 4, which demands that feed only be placed on the market and used if it is safe and it does not have a direct adverse effect on the environment or animal welfare.

In addition, pet food must be sound, genuine, unadulterated, fit for its purpose and of merchantable quality, and be labelled, packaged and presented in accordance with the applicable legislation.

Therefore, pet food is highly regulated, just as animal feed, and must meet the same requirements of European legislation establish for these, as already described in the previous section, to ensure that pet food is safe for the purpose of feeding pets.

Concerning the requirements to place on the market and use pet food, reference is made to point 5.2, related European Union rules on marketing of animal feed, to avoid duplication.

6.2 Single cell proteins used in petfood

In advance, it should be noted what constitutes single cell proteins. Single cell proteins are a type of protein that have different sources, such as yeast, fungi and bacteria.

There are provisions in our legal system that contemplate its use as a material for animal feed. Thus, in the European Union, the use of single cell protein in pet food is regulated by Regulation No 767/2009 and Regulation 68/2013.

The Regulation No 767/2009 establishes the safety requirements that must be met by all animal feed products, including single cell protein. Likewise, single cell proteins are listed in the Regulation No 68/2013, which establishes the European Union Catalogue of Feed Materials.

In accordance with this Catalogue, single cell protein are products obtained by fermentation using whole microorganisms or their parts. Currently, the Catalogue of Feed Materials includes single cell proteins from fungi and single cell proteins from bacteria as a feed material.

A description of the feed, as provided for in the Regulation No 68/2013 is featured below:

Number	Name	Description	Compulsory declarations
12.1.9	Single cell proteins from fungi ⁽⁴⁾	Fermentation product obtained from culture of <i>Aspergillus oryzae</i> , <i>Paecilomyces varioti</i> or <i>Trichoderma viride</i> on substrates mostly of vegetable origin such as molasses, sugar syrup, alcohol, distillery residues, cereals and products containing starch, fruit juice, whey, lactic acid, sugar, hydrolysed vegetable fibres and fermentation nutrients such as ammonia or mineral salts	Crude protein Crude ash Propionic acid if > 0,5 %
12.1.13	Single cell proteins from bacteria ⁽⁴⁾	Protein products obtained by fermentation with bacteria on a substrate/culture medium consisting of methanol (fermented with <i>Methylophilus methylotrophus</i>) or natural gas (fermented with <i>Methylococcus capsulatus</i> , <i>Alcaligenes acidovorans</i> , <i>Aneurinibacillus danicus</i> (previously known as <i>Bacillus brevis</i>) and/or <i>Bacillus firmus</i>) as carbon source, a nitrogen source of vegetal or chemical origin, vitamins and minerals	Crude protein Crude ash

⁽⁴⁾ The species of microorganism(s) shall be indicated with the name of the feed material, and the term 'inactivated' may be added (i.e. 'name as in the catalogue' + 'name of the species'; examples (i) 'Single cell proteins from *Methylococcus capsulatus*', (ii) 'Inactivated *Lactobacillus acidophilus*').

Therefore, single cell proteins from bacteria *Methylococcus* are recognized as feed material. Regarding these bacteria, the Catalogue of Feed Materials indicates that protein products obtained by fermentation with bacteria on a substrate/culture medium consisting of natural gas (fermented with *Methylococcus capsulatus*, among others) as carbon source, a nitrogen source of vegetal or chemical origin, vitamins and minerals, are a type of protein that can be used as feed.

In all events, single cell proteins from bacteria must comply with the requirements on the use of feed materials in accordance with applicable legislation and, specially, must comply with safety and marketing requirements established in Article 4 of Regulation No 767/2009, be considered safe and do not have adverse effects on animal health, human health, the environment or animal welfare.

6.3 Impact on the commercialization of the product

In light of the above, under Regulation No 767/2009 and considering the Catalogue of Feed Materials outlined in Regulation No 68/2013, single cell proteins from bacteria are recognized as feed material for use in animal feed production, provided it is safe and does not have direct adverse effects on the environment or animal welfare.

The Regulation No 68/2013 recognizes that protein products obtained by fermentation with bacteria on a substrate/culture medium consisting of natural gas (fermented with *Methylococcus capsulatus*, among others) as carbon source, a nitrogen source of vegetal or chemical origin, vitamins and minerals, are a type of protein that can be used as feed.

Single cell proteins from bacteria, produced through fermentation with bacteria using natural gas and other essential nutrients, represent a sustainable alternative to traditional feed ingredients. The legal recognition of these proteins opens doors for innovative feed formulations that can enhance nutrition absorption in animals while potentially reducing environmental impacts associated with conventional feed production methods.

Finally, the impact of *Methylococcus* bacteria classified under feed status means they can use in animal feed. However, not having novel food status implies that they can not be used for human consumption according to European food regulations.

7 European legal framework on disinfectants products

7.1 Introduction

This section focuses on the applicable legislation for disinfectants for food&beverage industry and drinking water disinfection, which are the envisaged uses of the chlorine-based disinfectant developed within CHEERS.

Disinfection products are biocidal products whose constituents may present a risk to humans, animals and the environment. A biocidal product contains one or more active substances, or generates one or more active substances, with the purpose to destroy, deter, render harmless, prevent the action of, or exert a controlling effect on, harmful organisms by means other than mere physical or mechanical action. Chemical disinfectants for both drinking water disinfection and food&beverage industry are therefore rated as biocidal products.

7.1.1 Biocidal Products Regulation (BPR, Regulation (EU) 528/2012)

Historically each European country has set its own rules as to the way biocidal products are handled and registered within its borders. In 1998, the biocidal Products Directive Directive 98/8/EC (BPD) was implemented. Furthermore, on 22 May 2012 the Biocidal Products Regulation (BPR, Regulation (EU) 528/2012) was adopted, which repealed the Biocidal Products Directive (Directive 98/8/EC). The last one concerns the placing on the market and use of biocidal products, which are used to protect humans, animals, materials or articles against harmful organisms like pests or bacteria, through the action of the active substances contained in the biocidal product. These substances and biocidal products have to be authorised before being used or sold on the European Union market.

There are 22 product types (PT) of biocidal products that are regulated under BPR. PT 1 to 5 cover disinfectants and biocidal products for consumer or professional cleaning and hygiene applications.

All biocidal products require an authorisation before they can be placed on the market by the European Chemicals Agency (ECHA), and the active substances contained in that biocidal product must be previously approved.

The BPR aims to harmonize the market at EU level, and simplify the approval of active substances and authorization of biocidal products. According to the BPR, a biocidal product is an active substance or a preparation that contains an active substance, which is intended to kill or deactivate harmful or unwanted microorganisms, by means of biological or chemical resources. When a biocidal product is used incorrectly, it may cause damage to human, animal or plant health, or to the environment. The countries of the European Union determine whether a substance can be used for certain purposes. When a company needs permission to apply a certain biocidal product, it must be requested from the government of the country. A demand must also be sent to the EU government. The governments of countries mainly decide whether a substance is permitted. This may cause a substance to be permitted by a certain European country, but restricted by the European Union and viceversa.

7.2 Regulatory framework for disinfection products in food industry

Any cleaning and disinfection products used in the food industry are necessary to maintain safe and optimal conditions and best service in relation to food. There are also a number of legislative limitations applicable to disinfectants in the food sector, mainly determined by the uses to which they are put.

The use of disinfectants, whether on surfaces that do not come into contact with food, or used directly on food, is subject to different EU regulations. These are detailed below.

7.2.1 Food additives

First of all, it should be clarified that detergents would not fall within this scope, as they are not intended for food preservation, but for disinfection.

However, when the purpose of the disinfectant is to prolong the preservative effect of the food, its use is limited to the current legislation on additives. Its legal basis is laid down in Regulation (EC) 1333/2008, on food additives.

7.2.2 Technological adjuvants

There is no specific EU legislation to regulate this type of disinfectants, which generally are used to clean food surfaces of plant origin.

However, harvesting employees must adhere to the hygiene provisions for primary production as laid down in Regulation (EC) 852/2004, taking basic precautions in the subsequent rinsing with drinking water to remove traces of disinfectant products, any detergents and disinfectants from the wash water.

7.2.3 Surface decontaminants for products of animal origin

The legal basis for the use of such disinfectants is laid down in Regulation (EC) 853/2004.

In that regulation specific hygiene rules for food of animal origin are laid down, including any provisions to eliminate surface contamination of meat products.

At present, only lactic acid and hot recycled water are allowed to be used for this purpose.

7.2.4 Phytosanitary products

Regulation (EC) 1107/2009 applies to products intended to protect plants or plant products from all harmful organisms, to improve the preservation of fruit and vegetables, etc.

7.3 Regulatory framework for disinfection products in drinking water

The development of drinking water disinfection in Europe has taken the same course as drinking water disinfection in the USA. Most European countries applied drinking water disinfection at the end of the nineteenth century or the beginning of the twentieth century.

The European Union has a drinking water policy of over 30 years. In 1998, it issued a Directive (98/83/EC) that established the minimum standards for water intended for human consumption. This guideline is a framework of quality demands for European drinking water. The annexes include parameters that must be checked to determine drinking water quality. The countries of the European Union can add their own demands to this guideline.

The Directive includes disinfectants and disinfecting by-products limits similar to those recommended by the World Health Organization (WHO). This Directive ensures that water intended for human use is safe and harmless. The Directive aims to:

- Ensure the control of drinking water quality through applying the latest scientific achievements.
- Provide an effective monitoring and assessment of drinking water quality.
- Deliver adequate and correct information in time to the consumers.
- Contribute to the broader EU water and health policy.

The EU Drinking Water Directive (98/83/EC) applies to:

- All distribution systems serving more than 50 people or supplying more than 10 cubic meters per day.
- Drinking water from tankers.
- Drinking water in bottles or containers.
- Water used in the food processing industry.

However, the Drinking Water Directive does not apply to:

- natural mineral waters; and
- waters which are medicinal products.

In the Directive, a total of 48 microbiological, chemical and indicator parameters are encompassed and are subjected to regular monitoring and testing. When implementing the Drinking Water Directive into their own national legislations, Member States of the European Union can include additional requirements, e.g., they may regulate additional substances that are relevant within their territory or set higher standards.

Member States are not allowed, nevertheless, to set lower standards. In respect to the prescriptions of the Drinking Water Directive in Europe, most drinking water production companies use chlorine as a disinfectant. It is added to water as chlorine gas, calcium hypochlorite or sodium hypochlorite. Ozone is added for flavor and odor control. For drinking water preparation from surface water, chlorine is used as a primary disinfectant in most cases. For groundwater treatment, which is a simpler treatment process, chlorine is often the only proper disinfectant. Countries in Europe use alternative disinfectants for drinking water disinfection, as well. France, for example, mainly uses ozone. As early as 1906, ozone was introduced for drinking water disinfection. Italy and Germany use ozone or chlorine dioxide as a primary oxidant and disinfectant. Chlorine is added for residual disinfection. United Kingdom is one of few European countries that use chloramines for residual

disinfection in the distribution network and for removal of disinfection by-products. Finland, Spain and Sweden use chloramines for disinfection occasionally.

7.4 Impact on the commercialization of the product

In order to market and use sodium hypochlorite from DARE technology, it is important to comply with current directives and obtain registration and approval for the production process and raw materials used.

On one hand, the European Standard EN 901:2013 outlines the specifications for sodium hypochlorite used in treating water for human consumption. It describes the characteristics, requirements, and analysis methods for sodium hypochlorite, along with guidelines for its safe use. The standard also specifies the minimum purity requirements and limits for impurities present in sodium hypochlorite used for treating water for human consumption.

This regulation sets out the composition and impurities that hypochlorite must have to be used in drinking water. As is indicated in the Standard, commercial sodium hypochlorite is available as a solution with concentrations of up to 18% active chlorine at the time of distribution by the manufacturer, with a minimum of 12% active chlorine. Diluted solutions are also available. The concentration of sodium hypochlorite must meet the specified value by the manufacturer. Regarding impurities, sodium hypochlorite contains sodium chloride (NaCl) in equimolar amounts and a small fraction of sodium hydroxide (NaOH) to maintain the product's alkalinity. It may also contain a small amount of sodium carbonate (Na₂CO₃). The sodium chlorate (NaClO₃) content must not exceed a mass fraction of 5.4% of available chlorine at the time of distribution by the manufacturer. The product must be free from visible deposits or suspended matter.

In addition, the production of hypochlorite requires raw materials that meet specific standards, depending on the production technology used. For instance, the UNE-EN 14805 standard specifies the quality of sodium chloride for generating chlorine using membrane-free technology.

On the other hand, Regulation (EU) 528/2012 of the European Parliament and Council governs covers the marketing and use of biocidal products (BPR), including disinfectants based on sodium hypochlorite, which require authorization as biocidal products. Companies manufacturing biocidal products must be registered in the Official Register of Pesticide Establishments and Services and the disinfectant products based on sodium hypochlorite must have the corresponding authorization as a biocidal product, according to the application for which they are intended.

Therefore, authorization is required for all biocidal products before they can be marketed, and their active substances must be pre-approved, with some exceptions. Products with active substances under review and products with new active substances that are still being evaluated can be marketed with provisional authorizations. The Register for Biocidal Products (R4BP 3), a specific IT platform, will be used for application submission and data exchange between the applicant, ECHA, Member State Competent Authorities, and the European Commission.

For hypochlorite produced using DARE technology to be used and sold, it must be registered, authorized, and approved. This involves reviewing the raw materials used for its production, such as brine and CO₂, as well as the production process using a bioelectrochemical membrane technology. In addition, the hypochlorite produced using DARE technology must meet the standards outlined in EN 901:2013 for use in drinking water.

In the case of hypochlorite production using membrane electrolysis technologies, a concentrated brine prepared using salt for electrolysis used in drinking water applications is used (DIN 19604). Several state regulatory agencies currently require that the source material that powers on-site generators, i.e., salt, must be on the NSF-60 list to ensure that no hazardous materials ultimately enter the drinking water supply. NSF-60 ensures that chemicals in contact with drinking water are safe and non-toxic to the drinking water supply.

Salt with a purity level of 99.5% NaCl or higher should be used for the safety of equipment and linked to the registration made of precursors for the production of hypochlorite and its use for drinking water. For example, bromide in the salt used for electrolysis can raise the concentration of bromate in the treated water. Bromate is a water quality problem in drinking water applications, but not necessarily in industrial applications. There are three primary contaminants commonly listed on a salt product data sheet that impact the electrolytic cell: calcium (Ca), magnesium (Mg) and insoluble material. High concentrations of calcium and magnesium salts cause the buildup of calcium/magnesium carbonate and magnesium hydroxide in the electrolyte cell.

On the other hand, there is a regulation: COMMISSION IMPLEMENTING DECISION of December 9, 2013 establishing conclusions on the best available technologies (BAT) for the production of chlor-alkali in accordance with Directive 2010/75/ EU of the European Parliament and the Council on industrial emissions. This document contains good practice recommendations for a range of membrane technologies. Of course, DARE technology is not registered, but you could try to apply some practices that appear in this regulation for its proper use.

The hypochlorite generation process must be registered in ECHA. Potential manufacturers and importers of substances must submit a request to ECHA and register the substance before they can manufacture or import it. It is communicated to ECHA through a registration dossier containing information on the hazards and, where appropriate, an assessment of the risks that the use of the substance may pose and how these risks should be controlled. The process, which precursors are used for production and the list of applications, with the use of sodium hypochlorite and for which application within the BPR must be detailed (REGULATION (EU) No 528/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL regarding the marketing and use of biocides) the hypochlorite produced will be used. Depending on the application you want then the hypochlorite must meet certain requirements, e.g., quality and concentration.

Then, in addition, it will be necessary to demonstrate that the hypochlorite fulfills its function. To verify that the water produced by adding hypochlorite produced from DARE meets the requirements and limits detailed in the DWI directive Reg. 31 - Chemical products used for the treatment of water intended for human consumption - Sodium hypochlorite. A sample of untreated water, called "raw water", must be analyzed and a sample of post-treated water called "product" must be submitted for analysis in accordance with EN 901 Chemicals used for the treatment of water intended for consumption. human - Sodium hypochlorite.

8 European legal framework on cosmetic products

8.1 Introduction

Whereas the intended final use of ectoine is to be incorporated in cosmetic formulations, this part analyses the European legal framework on cosmetics.

The main regulation on cosmetic products in European Union is Regulation No 1223/2009²⁹, which establishes the rules to be complied with by any cosmetic product made available on the market in order to ensure a high level of protection of human health.

Regarding that, it is essential that cosmetic products on the European market be safe for human health when used under normal and reasonably foreseeable conditions of use. For that reason, the Regulation No 1223/2009 requires that cosmetic products undergo a safety assessment.

For the purposes of this Regulation, the definition of “*cosmetic product*”, contained in Article 2.1, is the following:

“(a) ‘cosmetic product’ means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours”.

According to the definition of cosmetic product, to decide whether a product must be legally classified as cosmetic product, it must be a substance or a mixture, intended to be applied on the external parts of the human body with a cosmetic purpose.

Taking into account their areas of application and the purposes of their use, cosmetic products are different from medicinal products, medical devices or biocidal products, but depending on its intended function, one of these regulations could apply.

Therefore, the assessment of whether a product is a cosmetic product has to be made on the basis of a case-by-case assessment considering all characteristics of the product. In that sense, the first step is if they are made with substances or mixtures, which are defined by the same Article 2.1 of the Regulation No 1223/2009 as follows:

“(b) ‘substance’ means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;

(c) ‘mixture’ means a mixture or solution composed of two or more substances”.

²⁹ Regulation (EC) No 1223/2009 of the European Parliament and of the Council, of 30 November 2009, on cosmetic products.

Regarding that, it should be noted that additional requirements covered by other European legislation might apply to cosmetic products, such as Regulation No 1907/2006³⁰ with respect to substances used in cosmetic products.

The basic requirements of safety of cosmetic products as well as the REACH requirements for substances that are used and marketed as cosmetic ingredients are provided in the chapters below.

8.2 European Union rules on marketing of cosmetic products

Under Regulation No 1223/2009, cosmetic products must meet the following requirements to have access to the European market:

1) *Safety and responsibility of cosmetic products*

As noted before, cosmetic products should be safe under normal or reasonably foreseeable conditions of use. In order to establish clear responsibilities, each cosmetic product should be linked to a responsible person established within the Community.

In that sense, Article 4.1 of the Regulation No 1223/2009 sets out that “*only cosmetic products for which a legal or natural person is designated within the Community as ‘responsible person’ shall be placed on the market*”.

The responsible person is in charge to ensure that each cosmetic product placed on the market comply with this Regulation. It can be the manufacturer, the importer or a person established within the Community designated by them. It also can be the distributor where he places a cosmetic product on the market under his name or trademark.

To ensure their safety, cosmetic products placed on the market should be produced according to good manufacturing practice.

2) *Safety assessment, product information file and notification of cosmetic products*

Prior to placing a cosmetic product on the European market, the responsible must ensure that the cosmetic product has undergone a safety assessment by a qualified professional (safety assessor).

Likewise, when a cosmetic product is placed on the market, the responsible person must keep a product information file for it. The Regulation No 1223/2009 sets out that the product information file shall be kept for a period of ten years following the date on which the last batch of the cosmetic product was placed on the market.

The production information file must contain, among others, the cosmetic product safety report, which must also contain, according to the Annex I of the Regulation, information about the product (such as composition, physical and chemical characteristics, microbiological specifications and data on the exposure to the cosmetic product and its substances) and an explanation of the scientific reasoning on the safety of the cosmetic product by a safety assessor.

³⁰ Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency.

It should be noted that, in order to facilitate the understanding of the requirements of Annex I to Regulation No 1223/2009, the Commission has developed appropriate guidelines³¹ to comply with them.

Lastly, prior to placing the cosmetic product on the market, the responsible person must notify to the competent authorities some information about the cosmetic product placed on the market. This notification must be submitted by electronic means and addressed to Cosmetic Products Notification Portal (CPNP).

It should be noted that, in the event of serious undesirable effects, the responsible person must also report any adverse effects to the authorities, which shall transmit this information to the other Member States.

3) *Restrictions for certain substances*

Regarding the composition of the cosmetic products, it should be noted that the Regulation No 1223/2009 contains a list of prohibited substances that cannot be used in cosmetic products (listed in Annex II), and restricted substances that can only be used in accordance with the restrictions laid down in the Regulation (listen in Annex III).

The Regulation also contains a list of colorants (listed in Annex IV), preservatives (listed in Annex V) and UV-filters (listed in Annex VI) that can be used in cosmetic products and its conditions of use.

In addition to this, the Regulation also establishes that any substance classified as carcinogenic, mutagenic or toxic for reproduction (CMR) pursuant to Regulation (EC) No 1272/2008³² is also prohibited in cosmetic products.

In the view of the above, it should be concluded that a substance not listed as prohibited or restricted substance in Regulation No 1223/2009, can be used in a cosmetic product provided that is not a colorant, preservative, or UV-filer, either is not a CMR substance.

Notwithstanding the foregoing, the Regulation No 1223/2009 allows the presence of traces of prohibited substances if there is evidence for their technical unavoidability. Thus, Article 17 states out that *“the non-intended presence of a small quantity of a prohibited substance, stemming from impurities of natural or synthetic ingredients, the manufacturing process, storage, migration from packaging, which is technically unavoidable in good manufacturing practice, shall be permitted provided that such presence is in conformity with Article 3”*.

4) *Animal testing ban*

The cosmetics directive also provides a regulatory framework for the phasing out of animal testing for cosmetics purposes.

It specifically implies:

³¹ Commission Implementing Decision, of 25 November 2013, on Guidelines on Annex I to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (2013/674/EU).

³² Regulation (EC) No 1272/2008 of the European Parliament and of the Council, of 16 December 2008, on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

- A testing ban – this is intended to prohibit testing of finished cosmetic products and cosmetic ingredients on animals.
- A marketing ban – this is intended to prohibit to market finished cosmetic products and ingredients in the EU which were tested on animals.
- The testing ban on finished cosmetic products applies since 11 September 2004. The testing ban on ingredients or combination of ingredients applies since 11 March 2009.

The marketing ban applies since 11 March 2009 for all human health effects with the exception of repeated-dose toxicity, reproductive toxicity, and toxicokinetics. For these specific health effects, the marketing ban applies since 11 March 2013, irrespective of the availability of alternative non-animal tests.


As bringing a cosmetic product to the market needs a toxicologic assessment, the use of alternative methods to animal testing is mandatory. For the most of the toxicologic endpoints there is an alternative method available, for some there is not. For the moment this is a hurdle for the marketing of cosmetic products in Europe.

8.3 Ectoine used as ingredient of cosmetic products

On the basis of the above, it should be noted that ectoine is a substance that does not appear in Annex II or Annex III of Regulation No 1223/2009, then is not a substance prohibited or restricted in cosmetic products.

For informative purposes, it should be noted that this chemical substance is registered under the REACH Regulation with the CAS number 96702-03-3 and according with the information available on the European Chemicals Agency website³³, is currently used in cosmetics products and personal care products.

It also should be noted that, according to the cosmetic ingredient database (CosIng)³⁴, which is a glossary of common ingredient names, ectoine appears as cosmetic ingredient, with the following information:

NCI Name	ECTOIN
Description	
CAS #	96702-03-3
EC #	
Cosmetics Regulation provisions 	
Functions	SKIN CONDITIONING
SCCS opinions	
Identified INGREDIENTS or substances e.g.	

³³ Official website of the European Chemicals Agency: <https://echa.europa.eu/es/substance-information/-/substanceinfo/100.103.018> [27th February 2023].

³⁴ Official website of the European Union: <https://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.results> [9th March 2023].

However, it does not constitute a list of ingredients authorised for use in cosmetic products, it is only a compilation with common ingredient names.

In any case, to the extent that the substance of the ectoine is not banned or restricted pursuant to Regulation No 1223/2009, it could be used as a cosmetic ingredient, if comply with all requirements demanded by this Regulation, mentioned above.

8.4 Impact on the commercialization of the product

Based on the above, considering that ectoine is not prohibited or restricted under Regulation No 1223/2009, it may be used as a cosmetic ingredient provided it meets the safety requirements and the other market requirements established in this Regulation.

In that sense, it should be noted that cosmetic regulations have a significant impact on placing cosmetics in the market. They ensure that all cosmetic products meet specific safety, quality and efficacy standards before they can be sold to consumers.

These regulations require rigorous testing, documentation of ingredients, compliance with labelling requirements and adherence to good manufacturing practices.

By enforcing these standards, cosmetic regulations aim to protect consumer health and safety, prevent misleading claims, and maintain product quality throughout the market.

Compliance with these regulations is essential for operators and it is important for them to have a thorough understanding of the regulatory requirements to ensure the safety, quality and compliance of cosmetic products.

9 Sustainability of bio-based products

Achieving sustainability is in the centre of the Commission's political priorities, as set forth in the European action for sustainability (SWD(2016) 390 final)³⁵, which explains the 2030 Agenda for Sustainable Development and the Sustainable Development Goals (SDG), among other things.

One of the actions contributing to the SDG is that European Union is working on legislative approaches with other policies designed to “Ensure sustainable consumption and production patterns” (SDG 12), which is key to sustain livelihoods and preserve the future. In this area, it would point out the working on resource efficiency and circular economy.

The European Commission to delivery of the 2030 Agenda, has integrated the Sustainable Development Goals in its initiatives, including sustainable development as an essential guiding principle for all its policies.

Thus, the European Bioeconomy Strategy, abovementioned in part 3, related to relevant EU policies for bio-based products, recognizes the importance of the bio-based products to develop a sustainable economy based on renewable biological resources in Europe.

Bio-based products are materials, chemicals, or energy sources that are derived from renewable biological resources such as plant or animal biomass and have advantages in terms of sustainability.

In that sense, the document called “A sustainable Bioeconomy for Europe: Strengthening the connection between economy, society and the environment” (SWD/2018/431 final) highlight the advantages of bio-products in terms of sustainability compared to existing alternatives in the market. It should be mentioned at least the following advantages:

- First, the document indicates that the bio-based products have less environmental footprint when it points out that “the environmental footprint do speak in favour of supporting industrial use of biomass-based materials, products, and chemicals in the majority of economic sectors”.
- Likewise, it already emphasizes that bio-based products can contribute to more circularity and resource efficiency, indicating that “multi-product biorefineries can improve the efficiency of biomass utilisation by increasingly parallel exploitation of sideflows, reducing and/or recovering waste and residues, thereby boosting resource efficiency and waste prevention as well as recycling and circularity”.

In that sense, continued to say that “the transformation of waste and residues into higher added value products will further link various sources of biomass (agri/forest-based sector residues; woodworking and pulp and paper processing sideflows, food production and household “biodegradable waste”; aquatic resources) with the production of an array of products such as food, feed, biotextiles, biopolymers, chemicals, bioplastics and eventually bioenergy/biofuels, thereby increasing the value creation, jobs and competitiveness as well as sustainability of biomass production and use as well as the value creation”.

³⁵ COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS Next steps for a sustainable European future European action for sustainability. COM/2016/0739 final.



Therefore, bio-based products have reduced environmental impact, taking into account that they can offer a lower carbon footprint as well as reduced waste compared to traditional products.

Based on the above, it should be noted that the advantages of these products over conventional products are related with more sustainable production processes and minimised the generation of waste, in such a way that can promote and support a more environmentally and socially responsible economy.

10 Conclusions

The first barrier to put an innovative product in the European market is the complexity of the regulatory framework applicable to the placing on the market of food, substances used in food, feed, biocides and cosmetics in the European Union.

It is crucial for business operators to understand and navigate the specific legal requirements applicable to each case. In that sense, compliance with these safety standards is the key for successfully bringing products to market.

The European legislation is based on high safety requirements, so often mandates prior authorization of substances for specific uses, requiring rigorous adherence to detailed procedural requirements. Generally, these European procedures are lengthy and require stakeholders to submit a complex technical dossier along with their application.

Therefore, business operators or stakeholders must navigate lengthy European procedures and meticulously compile comprehensive technical dossiers to support their applications.

Furthermore, there are also barriers if the process involves a by-product of the food industry, in which case waste regulations stipulate an additional procedure to integrate the product into the value chain.

Despite the robust food safety regulations imposed by the European Union for the marketing of food, feed or cosmetic products, the ability to comprehend and effectively navigate the regulatory framework is crucial.

This understanding not only ensures regulatory compliance but also enhances market competitiveness and consumer trust, facilitating successful commercialization efforts.

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