FIT FOR FUTURE Platform Opinion

Topic title	Biosolutions	
	AWP 2022	
	Legislation on plant protection products & Regulation 2015/2283 on novel foods & Regulation 1924/2006 on health claims (not exhaustive list)	
	Legal reference	
Date of adoption	13 December 2022	
Opinion reference	2022/SBGR3/08	
Policy cycle reference	☐	Contribution to ongoing legislative process
		-
		Commission work programme reference
		No
	☐	Contribution to the (ongoing) evaluation process
		-
		Title of the (ongoing) evaluation
		No
	☐	Included in Annex VI of the Task force for subsidiarity and proportionality
		No
	☑	Other
		It is a cross-cutting opinion looking into a number of laws which regulate biosolutions or have an impact on them
Have your say: Simplify!	- IBMA - International Biocontrol Manufacturers Association (S30728593), including position paper - Submissions concerning protection of pollinators	
Commission follow up	REFIT Scoreboard:	Biosolutions
	Have your say portal:	New Genomic Techniques
		Approval criteria for microbial active substances

	New data requirements for approving active substances
	New data requirements for authorising products
	New uniform principles for evaluating and authorising products
Other:	EFSA work on microorganisms
Annual Burden Survey:	The EU's efforts to simplify legislation (2022)

SUGGESTIONS SUMMARY

Suggestion 1: Modifications of the current regulatory framework to speed up the authorisations of microbiological and low-risk products within Regulation (EC) 1107/2009

Suggestion 2: Further develop legally binding data requirements for other biological control categories than microbial products, namely semiochemicals, natural substances within Regulation (EU) 283/2013 and Regulation (EU) 284/2013 setting the data requirements under Regulation (EC) 1107/2009

Suggestion 3: Adopt fast-track approval procedures for innovative, low-risk biological and sustainability-enabling pesticides

Suggestion 4: Allow extension of the use on one crop to all other crops without the addition of upfront efficacy data for biological control product under Regulation (EC) 1107/2009

Suggestion 5: Further develop the regulatory framework for biological control products

Suggestion 6: Analyse opportunities and challenges when revising existing relevant legislation to focus on the potential risk pertaining to the product itself rather than the production process employed

Suggestion 7: Support adoption of novel food products while ensuring food safety

Suggestion 8: Improve the harmonization of the use of the term 'probiotics' in the context of the health claims across the EU Member States to provide clarity for industry and consumers

Suggestion 9: Develop industry guideline for food cultures as food ingredients

Suggestion 10: Update EU NACE codes

SHORT DESCRIPTION OF THE LEGISLATION ANALYSED

The following, non-exclusive legislation is deemed most relevant for this opinion[1].

1. Plant protection products legislation

Plant protection products (PPPs) are used to protect plants against pests or diseases. PPPs and their residues are regulated respectively in the EU by Regulation (EC) No 1107/2009 as regards their placing on the market, by Directive 2009/128/EC as regards their sustainable use and by Regulation (EC) No 396/2005 as regards their residues in food and feed. The Commission approves active substances, i.e. the agent used to achieve the protective effect, for the use in PPPs, which are authorised by the Member States. In order to protect consumers, the Commission also sets maximum residue levels (MRLs) for pesticides, i.e., the highest levels of pesticide residues that are legally tolerated in or on food or feed, including imported products.

[1] A stakeholder has also pointed out that Regulation 1272/2008 would have been relevant, however that Regulation was not analyzed in this opinion

2. Regulation 2015/2283 on novel foods

Regulation 2015/2283 on novel foods applies since January 2018 and replaces older rules in such a way as to simplify and centralise the authorisation procedure, which ensures conditions so that the authorization process has become more streamlined and made free of charge, which makes it less burdensome to put novel foods on the EU market while maintaining a high level of food safety for European consumer. It expanded the categories of novel foods, describing the various situations of foods originating from plants, animals, microorganisms, cell cultures, minerals, etc., specific categories of foods (e.g., insects, vitamins, minerals, food supplements, etc.), foods resulting from production processes and practices, and state of the art. It also established a Union list of authorised novel foods, which included all authorisations of novel foods under the previous novel food regulation, making them generic and improving conditions for safety evaluations.

3. Regulation 1924/2006 on nutrition and health claims made on food-

Regulation 1924/2006 (Claims Regulation) is the legal framework used by food business operators when they want to highlight the particular beneficial effects of their products, in relation to health and nutrition, on the product label or in its advertising. The objective of this Regulation is to ensure the effective functioning of the internal market whilst providing a high level of consumer protection. The rules of the regulation apply to *nutrition claims* (such as "low fat", "high fibre") – which are listed in the annex of the regulation - and to *health claims* (such as "Vitamin D is needed for the normal growth and development of bone in children"), which have to be authorised on a case-by-case basis. It applies to nutrition and health claims made in commercial communications, whether in the labelling, presentation or advertising of foods to be delivered as such to the final consumer, including foods which are placed on the market unpacked or supplied in bulk. It also applies to foods intended for supply to restaurants, hospitals, schools, canteens and similar mass caterers. The objective of those rules is to ensure that any claim made on a food's labelling, presentation or advertising in the European Union is clear, accurate and based on scientific evidence.

Further sources of evidence:

Legislation on Plant Protection Products

Sustainable use of Pesticides

Evaluation of the EU legislation on plant protection products and pesticides residues

Novel Food legislative framework webpage

EU nutrition and health claims legislative framework website

Probiotics - European legal framework

PROBLEM DESCRIPTION

Existing evidence from the Platform (a Member State) suggests the following issues:

Biosolutions are based on the unique properties of e.g. enzymes, micro-organisms/ microbial cultures and pheromones, often and constitute sustainable alternatives to fossil-based products and production methods in a wide range of sectors, including the food-, ingredients-, agriculture- and industry-sectors[2]. This includes, inter alia, the development of biological alternatives to chemical pesticides and chemical fertilisers, new protein sources for food and feed production, bio-based plastics and textiles as well as water purification processes.

Biosolutions can contribute to reducing global CO_2 emissions as well as support transition to a circular economy, pollution reduction and more sustainable water consumption. With the Horizon 2020 program, biotechnology was selected as one of six key enabling technologies that can lead the development of sustainable and competitive European industries. Furthermore, the European Council has acknowledged the importance of plant-based proteins, for which biosolutions is the basis[3], to tackle food security issues.

However, today most biosolutions are categorized, regulated and legislated as chemicals[4], although biosolutions are defined by their biological traits. While the Member States recently endorsed four legal acts which aims to simplify the process of approval and authorisation of biological plant protection products which contain micro-organisms[5], generally there are administrative problems for companies as they must provide data, which may not be appropriate to such products as much legislation has historically been based on chemical characteristics rather than biological ones as currently endorsed. In addition, Member States need to improve their organisational capacities to properly evaluate biosolutions and guidance on how to better assess applications as they carry a significant part of the responsibility in the approval procedure but have insufficient capacities to handle caseloads in the biosolutions segment. Meanwhile, potentially sustainable alternatives cannot enter the market or access is cumbersome because existing legislation in large part regulates chemicals rather than micro-organisms.

A Member State initiative conducted during spring of 2022 to map regulatory and other barriers to biosolutions identified, that biosolution companies have encountered the following **main problems in relation to burden reduction, simplification and modernization of rules**:

Approval of microbiological plant protection products lacks relevant and clear criteria for biosolutions and case handling times are very long

[2] According to the report 'Biosolutions in Denmark' by HBS Economics (also referenced under further sources of evidence) biosolutions are defined as follows on page 6 (translated from Danish):
"Biosolutions are the development and production of biological products and technologies for production processes within industry, agriculture, food technology, supply and maritime industries. The biological products in the biosolutions sector are often linked to microorganisms or to producing substances or chemical building blocks with certain properties that cannot be achieved with conventional methods. The biosolutions sector is a subcategory of the wider biotech sector. A significant difference between the two is that the biosolutions sector does not contain biotech targeted at the pharmaceutical industry."
[3] European Council Conclusions 10-11 March 2022, Versailles
[4] It should be noted though that there are specific regulations on micro-organisms PPP Regulation, which consider their specific traits;
[5] https://food.ec.europa.eu/plants/pesticides/micro-organisms_en

The main parts of the Regulation (EC) 1107/2009 (concerning the placing of plant protection products on the market) is built upon the EU's first plant protection products directive from 1991 (Directive 91/414/EEC). The regulation states an intention of creating a simpler process for approval of low-risk substances, including a shorter deadline for deciding on authorisation applications concerning the plant protection products containing them. The regulation also contained criteria for categorising low risk substances, which were updated in 2017 while guidance on interpretation of criteria for micro-organisms was published in 2020. New data requirements and assessment criteria for micro-organisms have been adopted by the Commission on 31 August 2022 and will enter into application on 21 November 2022.

The **complete process**, from the company perspective, currently takes 6-9 years for companies to complete from pre-notification to final Member State level authorisation, costing around EUR 1 mil[6][7]. In comparison, the same products can reach market within 2-3 years in the US, Brazil and China, leaving European companies at a disadvantage and increasing the incentive for larger European biosolutions companies to relocate their production to non-European countries, where time-to-market is shorter and less costly[8]. While some biocontrol products may not be approved under an EU legislative regime, their assessments should not be delayed: fast rejection and explanation is also valuable to companies and a significant burden easing. In addition, slow case handling and processing blocks access for many products and substances that would be approved but face extraordinarily long case handling times to the detriment of companies and consumers. The European Commission has proclaimed a goal of reaching a 50% reduction in the use of chemical pesticides in the EU by 2030. The availability of biocontrol products is an important prerequisite to reach this target.

Approval of novel food lacks relevant and clear criteria for proteins produced with biosolutions and case handling times are long

Regulation on novel foods 2015/2283 is tailored to dealing with all kinds of new food and ingredients including products produced by non-conventional methods like alternative biobased proteins produced with fermentation. Furthermore, according to a recent study, the Regulation on novel foods may prove insurmountable for small companies, and it is demanding and time-consuming even for larger companies, dampening the transformative potential of all novel foods[9]. With the Farm to Fork Strategy, the European Commission has adopted an ambition to promote circular business models and incentivize sustainable food production. The biosolutions industry is able to provide a range of innovative solutions in these two areas, but this

[6] It should be noted that the slowness of the process is partly due to problems with enforcement of the legislation, in particular the lack of respect by Member States of the deadlines set in the pesticides Regulation for completing assessment. The Plant Protection Products Regulation already sets a deadline of 120 days for granting authorisations for low risk products (and many micro-organisms would qualify for that status) instead of 1 year as it applies for non-low risk products. There is also a lack of expertise amongst the Member States to carry out the risk assessment of such dossiers. To address it, the Commission financed Better Training for Safer Food for Member States and EFSA to increase knowledge and expertise about the specificities of micro-organisms and the differences with chemicals;

[7] No exact figures are available, however, one company explained that the cost of regulatory studies easily amounted to 500.000 EUR before field trials for product registration were undertaken and registration fees were concluded. These could easily add up to another 500.000 EUR. The cost of 1 million EUR therefore seems very likely;

[8] It should though be recognized that procedures in the EU, US, Brazil and China differ and cannot be directly compared

[9] "Alternative proteins and EU food law", published in 2021 by Environmental Policy Centre, Finnish Environment Institute and Department of Food Chemistry and Food Development, University of Turku, Finland;

contribution is made difficult by the current regulatory environment.

Non-harmonized approach of fermentation technology using food cultures hinders the full exploitation of the potential of food cultures to fight food waste

Food cultures are used in food fermentation, transforming foods, contributing to the characteristic taste and texture, preserving them and extending their shelf life. This technology has brought well-known fermented products, such as yoghurt, cheese, cured meats and fermented beverages. Fermentation technology has been refined and can now also be applied to 'non-traditionally fermented products' with the purpose of enhancing food safety and prolonging shelf life without necessarily altering the characteristics of such foods significantly, e.g., in meat cuts, ready-to-eat foods, salads and fish. In these products, fermentation by help of safe food cultures helps protect the food from a decay due to an un-controlled deteriorating fermentation from indigenous microflora and protect against potential pathogens present also in the microflora of the food, with a substantial potential to contribute to the fight against food waste.[10] Under the General Food Law, food cultures for fermentation have generally been regarded as normal food ingredients. However, several EU Member States consider new applications of fermentation technology as falling under the EU additives regulation (1333/2008)[11]. This leads to an unclear, unharmonized and potentially disproportionate approach of food cultures at the EU level. There has been an ongoing discussion in the EU foods additives working group regarding this subject, which was never fully concluded[12].

Regulation of health claims

Regulation (EC) No 1924/2006 on nutrition and health claims made on foods (Claims Regulation) sets out the framework for using nutrition and health claims in the EU. The Claims Regulation requires that only permitted nutrition and health claims can be used on foods placed on the EU market. The objective of the Claims Regulation is to ensure the effective functioning of the internal market as regards nutrition and health claims whilst providing a high level of consumer protection.

In the Guidance document on the implementation of the Claims Regulation[13], the term 'probiotic' is considered a health claim, because this term is deemed to include an implied health benefit. Therefore, the word 'probiotics' can only be used in combination with an approved authorised specific health claim, despite the fact that this term is broadly used all

[10] It should be noted that these can be foods that are not traditionally fermented. The uses of cultures to prolong shelf-life and protect against other microorganisms may fall within the scope of the FA legislation (and/or Regulation 853/2004 laying down specific hygiene rules for food of animal origin);

[11] It should be noted that according to the vast majority of Member States experts on additives, non-traditional use of food cultures for a technological purpose (i.e. as a preservative defined in Regulation on additives as *a substance which prolong the shelf-life of foods by protecting them against deterioration caused by micro-organisms and/or which protect against growth of pathogenic micro-organisms*) would fall within the scope of the food additive legislation. It can lead to problem with clear distinction of some borderline cases – and thus varied interpretation. When the food additives legislation applies (i.e. the difference between the use of cultures as characteristic food ingredients, which is out of the scope of the food additives legislation, and the use of cultures as a food additive (preservative)) and whether the food additives legislation is appropriate/ proportionate and suitable to address the use of cultures). Furthermore, Regulation 853/2004 does not allow to use any substance to remove surface contamination from products of animal origin, unless use of the substance has been approved by the Commission;

[12] The guidance on cultures had been discussed between 2006-2010 although the document has not been officially endorsed. However, the vast majority of Member States consider that the principles outlined therein are still valid. In addition, the Working Group on Additives discusses, based on the request of Member States particular cases of cultures used to achieve a harmonised understanding/ approach;

[13] https://www.fsai.ie/uploadedFiles/EU_guidance_ClaimsRegulation.pdf

over the world. The Commission has received a number of applications for authorisation of specific health claims regarding the effect of 'probiotics', however, to date, none of them has received a favourable opinion by the European Food Safety Authority (EFSA)[14]. In third countries, the use of the term 'probiotic' is or can be regulated differently, allowing 'probiotics' to be readily available and well-known to consumers, globally.

In addition, among EU Member States, there is currently a diverging approach concerning the labelling of 'probiotics', resulting in an de facto unharmonized approach. Some Member States consider that 'probiotics' can encompass a category of nutrients to be mandatory labelled on food supplements. This situation leads to an apparent inconsistency between the Commission Guidance Document[15], and the fact on the ground where a number of Member States interpret the rules concerning the use of the term 'probiotics' in different ways. This is obviously not intended and creates an uncertain environment for companies and an unfortunate fragmentation in the Single Market.

In addition, the situation leads to an unequal treatment of probiotic ingredients in food vis-à-vis probiotic food supplements, which ought to be implemented in a harmonised way to ensure equal and consistent treatment of probiotics and give consumers a non-contradictory information.

EU NACE codes

The EU's industrial NACE codes are used for general statistical classification and reflect the many different types of economic activities that take place. Due to their nature and technology-neutral approach, the EU NACE codes classification does not include biotechnology as an overarching category nor segmented sub-activity such as biosolutions. Economic activities involving biotechnology are difficult to identify and this hinders statistical data gathering on the evolution of activities in the related *biosolutions* industry. Additionally, the lack of proper NACE codes for economic sub-activities for biotechnology and biosolutions means they are currently categorised with chemical industries which leads or are active in research only. Currently, they are grouped together under two primary NACE codes: C.20.2 (Manufacture of pesticides and other agrochemical products) and M721.1 (Research and experimental development on biotechnology), leading to incorrect classifications in the EU's taxonomy for sustainable investments.

Further sources of evidence:

Article: the regulatory and safety requirements of food cultures

EU health claims are failing consumers and manufacturers

The Potential of Biosolutions (Report by Copenhagen Economics September 2022)

Biosolutions in Denmark (HBS Economics Report February 2021)

[14] It should be acknowledged though that the Claims Regulation provides that health claims have to be *substantiated by generally accepted scientific evidence* to ensure a high level of consumer protection. This is the condition to be granted a favourable opinion of the EFSA. However, so far EFSA has not considered any of the applications submitted to substantiate a health benefit;

SUGGESTIONS

Suggestion 1: Modifications of the current regulatory framework to speed up the authorisations of microbiological and low-risk products within Regulation (EC) 1107/2009

Description: Today, biosolution companies face extraordinary long approval procedures in order to bring their products to market.

According to Regulation (EC) 1107/2009 the minimum and maximum timelines are 30 months and 44 months respectively for the approval procedure. In reality, these timelines are much longer up to an average of 52 months. Furthermore, companies face a 'waiting period' of 1-3 years with the competent authority before the evaluation of the application for approval of the active substance can even start. Finally, to conclude the authorisation procedure and bring the product to the market an additional 1-2 years is necessary.

This can bring the total time from dossier to EU farmer up to 7-9 years.

Suggestions how to speed up market access for biological products are provided below:

- Start with assessing if the substance fulfils the low-risk criteria and make sure to apply low-risk process and timelines at the start of the evaluation process of biological control[16] active substances fulfilling the criteria. These can be reinstated, if the evaluation process reveals they are not low-risk.
- Extend **approval duration** to 15 years, as is the case for low risk - biocontrol products, thereby reducing strain on resources for EU Commission, Member States and applicants.
- Enhance the corporation within the EU the group of biological control experts from Member States and EFSA that, in close cooperation with the Commission, will be responsible for development of new guidance for substances falling under the definition of biological control. This would guarantee a consistent and scientifically sound approach that would at the same time considerably speed up procedures.
- Implement mutual recognition for low-risk substances properly to ensure that Member States do not reopen an already evaluated dossier.
- Adopt more appropriate and more tailored guidance documents for each of the biocontrol products, as presented in the Sustainable use Regulation to ensure a consistent and harmonized assessment of biological control products by all Member States[17].
- List closely related substances and strains, that are used for crop protection purposes and are proven to be safe under a single entry in the Annex to Regulation (EU) No 540/2011, as is currently done for straight chain lepidopteran pheromones and baculoviruses[18]. This can be an efficient process for future evaluations without

[16] For the purpose of this document, the term "biological control agents" refers to microorganisms, semiochemicals and natural substances used for plant protection purposes;
[17] As defined in the Sustainable use Regulation (currently under legislative review);
[18] Though this may change since the adoption of Commission implementing regulation (EU) 2022/1251;

compromising the safety aspects and it would speed up the market access for these biological control products.

- Promote the use of Article 37(3) of Regulation (EC) 1107/2009 for biological control products. Article 37(3) provides that for an application for authorisation of a plant protection product containing a substance not yet approved the Member State examining the application shall start the evaluation as soon as it has received the draft assessment report.

Small suggested modifications to Regulation (EC) No 1107/2009

- **Prioritise applications** for approval of biocontrol active substances.
- Re-instate the option of the **provisional authorization** (Article 30 of Regulation (EC) 1107/2009) to facilitate the placing on the market of plant protection products containing new biological active substances that have been evaluated and assessed by the Rapporteur Member State and concluded that the substance can be approved.
- Prioritize granting derogations according to the procedure of Article 53 of Regulation (EC) 1107/2009 for biological control products when no alternatives are available in the market to control specific pest or disease in specific crops. Derogations require a limited package of data to check for safety and, should be prioritised towards biocontrol in place of reusing of old chemistry products.

Expected benefits:

The approval timelines can be shortened considerably by implementation of the above-mentioned measures, especially those related to prioritization of applications and evaluations carried out by a group of biocontrol experts.

In the case (i) the 'waiting period' is shortened to 6 months, (ii) the evaluation is done within the minimum period of 30 months (or 44 months with a stop-the-clock to submit additional data) and (iii) an authorization is granted within 12 months **the whole procedure can be shortened with a maximum of 6 years to an average of 4 years** (or 5 years with a stop-the-clock).

These modifications can result in a shortening of consolidated approval and authorisation times **from up to 10 years to around 4 years**.

These changes will ensure more biocontrol products reach the market faster. They should be complemented by an extended approval period of 15 years for biocontrol active substances, more dedicated biocontrol experts and the re-introduction of provisional authorisation. This would help reach the 2030 Farm to Fork objective for chemical pesticide reduction.

To go even faster to reach approval and authorisation within 1-2 years, as achieved in the USA, a new biocontrol specific regulatory framework is necessary (see also suggestion 2-6).

Suggestion 2: Further develop legally binding data requirements for other biological control categories than microbial products, namely semiochemicals, natural substances within Regulation (EU) 283/2013 and Regulation (EU) 284/2013 setting the data requirements under Regulation (EC) 1107/2009[19]

Description: Extensive and inappropriate data requirements slow down the approval process for Biocontrol products, as these products are regulated as chemical pesticides under Regulation (EC) 1107/2009. Nevertheless, separate data requirements are applicable for microbial active substances (Part B) and plant protection products within the Regulation (EU) 283/2013 and Regulation (EU) 284/2013, respectively.

Data requirements listed in Regulation 283/2013 and Regulation 284/2014 are developed for chemicals and for microorganisms. Today the option for "**justified exemptions** can be made" or "a **different approach** may be taken if adequately justified" exists under which natural substances and semiochemicals can be treated. Ultimately, this should lead to the creation of a **new set of legally binding data requirements** for natural substances and semiochemicals.

Updates on data requirements for microbial active substances and plant protection products is possible because a definition of micro-organisms is given under Regulation (EC) 1107/2009. The definition of micro-organism within Regulation (EU) 1107/2009 acknowledges that the product does not fall into the category of other chemical pesticide. As it is today, all other biological control products are regarded as chemical pesticide. A re-definition of biological control products, would therefore enable the creation of a separate data requirements for these. The microbiological category already has separate requirements from conventional synthetic active substances and plant protection products under Regulation (EU) 283/2013 and Regulation (EU) 284/2013.

Biological control products is not legally defined in the EU legislation at all Member States' level. Integrated Pest Management (IPM), despite it being defined in the Sustainable Use of Pesticides Directive and implementation of the IPM principles mandatory, their enforcement across the EU Member States has been – generally - lacking[20]. A common definition of biological control products and its categories will enable specific action for this group of products in existing and new legislation, including Common Agricultural Policy eco-schemes. It will allow derogations or fast-track procedures within Regulation (EC) 1107/2009 that are only allowed for the defined categories of biological products[21].

Semiochemicals, have no killing action against the target pest(s), and they are generally effective at low doses, often comparable to natural levels. They are often very volatile and dissipate and/or degrade rapidly in the environment. Data requirements for the registration of semiochemical active substances and plant protection products should take into account their natural occurrence and their non-toxic mode of action. Currently, data requirements for

[19] Amended in the course of preparation of this opinion by, respectively, Regulation (EU) 2022/1439 of 31 August 2022 and Regulation (EU) 2022/1440 of 31 August 2022;
[20] See: ECA Special Report on *Sustainable use of plant protection products: limited progress in measuring and reducing risks*;
[21] It should be noted that IPM and the definition of biological control is currently under review in the adopted revision of the Sustainable Use of Pesticides Directive, which may address this situation;

semiochemicals follow the same set of requirements as conventional chemical active substances which is clearly not appropriate due to the nature and action of these compounds.

According to the seventh recital of Commission Regulation (EU) 2017/1432 *"semiochemicals are substances emitted by plants, animals and other organisms which are used for intra- and inter-species communication, have a target-specific and non-toxic mode of action and are naturally occurring. They are generally effective at very low rates, often comparable to levels that occur naturally. In light of current scientific and technical knowledge it is also appropriate to provide that semiochemicals should be considered as low-risk substances"*. However, the regulation requires that semiochemicals satisfy the same exclusive criteria as conventional pesticides in order to be considered low-risk active substances. Since certain semiochemicals can exhibit a skin sensitisation potential, they are automatically excluded. Considering the intrinsically non-toxic mode of actions of semiochemicals and their natural occurrence, it should be discussed if they should be considered as low-risk regardless of its skin-sensitisation potential, as it currently happens for microorganisms, and if any further amendments of Regulation 1107/2009 to this extent would be necessary.

Natural substances consist of one or more components that originate from nature. They can either be sourced from nature or are nature identical if synthetized. When natural substances are used as pest control in agriculture, a European dossier evaluation and approval is needed, following the same system as for conventional synthetic pesticides.

However, this approach poses an unnecessarily high and inappropriate regulatory burden. Not all data requirements are relevant to all natural substances and the level of risk resulting from the use as a biological pest control agent are in some cases lower than for conventional chemical pesticides. Natural substances have known metabolic or degradation pathways, and any negligible negative impact on the environment would be transient resulting in no lasting reduction in biodiversity. These features of natural substances mean the conventional data requirements are inappropriate. In Regulation (EC) 1107/2009, article 3, 2 'substance' is defined as 'chemical elements and their compounds, as they occur naturally or by manufacture'. Hence, for natural substances to have their own requirements, this definition would have to be revised to allow regulators to set specific data requirements for natural substances known to be safe and harmless to human and environmental health.

To ensure that data requirements remain appropriate and proportional to the semiochemical or natural substance being considered, it is essential to focus on the potential risk areas and related data requirements.

Therefore, the regulations mentioned above setting the data requirements for active substances and plant protection products should be updated for each biocontrol category (e.g. creation of Part C for semiochemicals, Part D for natural substances), in order to establish appropriate and proportionate requirements for these products.

Expected benefits:

- Support the EU Commission in contributing to the achievement of the goals of the Farm to Fork initiative and Sustainable Use Directive.

- Facilitate the evaluation procedure by Member States and improve the quality of authorization dossiers by the applicants.
- Speed up the access to the market of all biocontrol categories by setting proportionate and adequate data requirements.
- Longer authorizations for semiochemical products based on low-risk timelines, would reduce the re-authorization workload for Member States, EU Commission, EFSA and applicants.

Suggestion 3: Adopt fast-track approval procedures for innovative, low-risk biological and sustainability-enabling pesticides

Description: Slow product approval processes are one of the main causes of the long time-to-market that bio solution companies face in the EU. The slow processes add additional costs, lower the economic viability of new biosolutions, and postpone EU decarbonisation for two reasons:

- Firstly, although the EU has the ambition that the approval process for pesticides should take 2.5-3.5 years, there are examples of the processes taking up to 10 years (see suggestion 1).
- Secondly, compliance and processing costs are particularly harmful to smaller biosolution companies. For example, costs for testing, dossier preparation and registration in the EU can be up to EUR 1 million[22], which is a relatively large cost for small companies.

In the US, the product approval process for biological pesticides takes 2 to 4 years due to a fast-track process, and similar solutions have also been adopted in other countries.

EU authorities should allow applicants of biocontrol products to request guidance so that high quality dossiers are submitted, and legal evaluation timelines are met. Improving communication between applicant and regulators will allow applicants to be able to submit high quality dossiers (avoiding long Q&A or evaluation timelines because of missing data) and it will allow regulators meet the evaluation timelines set in the legislation[23].

EU policymakers should adopt fast-track approval procedures for innovative, low-risk biological and sustainability-enabling solutions by allocating targeted resources in the European Food Safety Authority and the Member States to secure fast time-to-market.

Policymakers should furthermore consider lowering the costs, particularly for smaller companies, where the costs are relatively larger, e.g., by differentiating procedural cost by company size, while still ensuring proper risk assessment of the product.

[22] See footnote on page 5 for explanation of costs;
[23] While guidance is available today several stakeholders consider it inadequate

Expected benefits:

- Increase usage of innovative, low-risk microbiological and sustainability-enabling pesticides.
- Substituting chemical pesticides for microbiological alternatives could benefit the environment.
- Professional users could benefit as they will avoid exposure to some dangerous high-risk products.
- Consumers would be exposed to less residue from chemical pesticides.

Suggestion 4: Allow extension of the use on one crop to all other crops without the addition of upfront efficacy data for biological control product under Regulation (EC) 1107/2009

Description: Allow **extension of the use** from one crop to all other crops without the addition of upfront efficacy data. Since *maximum residue levels* (MRLs) are not relevant for most biocontrol solutions, and data may be available to show the efficacy on a broad range of pests or diseases the extension of use could be permitted for a period while data is generated, speeding up label broadening for biocontrol products. This is currently the case for minor uses for the same crop group in Europe and the case for applications in the USA.

Expected benefits: This has the advantage of helping fill gaps in the biocontrol pest and disease control quickly, improving return on investment and maximizing the use spectrum of an active ingredient enabling expansion into different crops. This would be especially important in arable markets where biocontrol is needed more urgently and historically the return on investment has not been adequate for companies to invest.

Suggestion 5: Further develop the regulatory framework for biological control products

Description: Modifications to the current regulatory framework[24] (Regulation (EC) 1107/2009) is a short/mid-term solution that has the potential to speed up the authorizations of biological control products. Nevertheless, as seen with the current rules applicable to micro-organisms in plant protection products, adopted on 31 August 2022 by the Commission and entering into applicability on 21 November 2022, the improvements concerning time to the market are still limited and **insufficiently conducive to achievement of the Farm to Fork targets** for reduction of chemical pesticides in particular, as no procedural changes have been proposed.

To significantly ease the burdens and simplify rules while ensuring the highest standards and ensure that the most appropriate data is collected and analysed before any new product is put on the EU market, there is a need to further develop the legislative framework for biological control products and streamlined provisions. This could aim to further clarify the data requirements and provide guidance to applicants and Member States. A further reform of the regulatory framework would ideally consider including a dedicated decentralized regulatory

[24] https://food.ec.europa.eu/plants/pesticides/micro-organisms_en

body, a permanent network of Member States experts, presumption of safe use, tiered assessment, and tailored data requirements. In addition, a thorough reform of EU regulation of biological control could include procedural changes for biological control products. Similarly, in an overhaul of the regulatory framework, evaluation could follow the same principle as green-house and seed treatment uses. This would ensure the best and fastest application process and avoid unnecessary burdens on companies.

Expected benefits:

- Accelerate the market access of biological control solutions.
- Support the EU Commission to reach the goals of the Farm to Fork initiative and Sustainable Use Directive.
- Facilitate the creation of dedicated regulatory body for biological control solutions at Member State level.
- Facilitate application of biological control products by applying a system of reduced or no fees
- Promote and assist applicants in applying for biological control products
- A permanent network of experts within Member States will ensure quicker and better evaluations.

Suggestion 6: Analyse opportunities and challenges when revising existing relevant legislation to focus on the potential risk pertaining to the product itself rather than the production process employed

Description: The EU GMO Directive sets up the same requirements for 'traditional' genetic modification as newer genetic technologies, which lowers the incentive to innovate using modern gene-editing. The directive relies on the technology used to develop an organism for safety evaluation procedures. This approach was developed in the 1980s before biotechnological innovation accelerated in more recent years. Today, the regulations still focus on product technology rather than product characteristics in the safety evaluation, which has led to research investment being pulled out of the EU and a stalling of innovation there. In addition, sustainability criteria are not considered in the evaluation. Therefore, for example, the European Commission's Chief Group of Scientific Advisers have recommended revising "the existing GMO directive to reflect current knowledge and scientific evidence, in particular on gene-editing and established techniques of genetic modification"[25]. Furthermore, according to a study conducted by the Commission, the current GMO-regulation is not fit for handling certain targeted mutagenesis techniques and other new genome techniques[26].

Certain biological products, including micro-organisms, are not adequately regulated by the current legal framework. Some micro-organisms cannot be distinguished from counterparts found in nature due to the increased accuracy of modern techniques. This constitutes a challenge

[25] European Commission, Directorate-General for Research and Innovation, New techniques in agricultural biotechnology, Publications Office, 2017, https://data.europa.eu/doi/10.2777/574498
[26] EC study on new genomic techniques (europa.eu);

for their traceability in the present framework. In addition, the European Commission does not include micro-organisms in its impact assessment for plants using new genomic techniques[27]. Consequently, micro-organisms remain subject to the current GMO legal framework in the EU while developments in other parts of the world are expected to continue rapidly. In addition, in GMO cultivation approvals, EU law allows Member States to restrict or prohibit the cultivation of an EU-approved crop on their national territory under certain conditions[28].

The opportunities to focus on the potential risk pertaining to the product itself rather than the production process, while still upholding safety requirements for the environment and consumers should be analysed. Further, the EU should step up efforts to gather additional scientific knowledge on microorganisms obtained by new genomic techniques.

In addition, challenges such as increased requirements for documentation and traceability of Targeted mutation/cisgenesis products (TM/CG) need to be addressed in the analysis. For organic production, traceability of TM/CG has to be ensured throughout the value chain in order to avoid the entrance of TM/CG products into the organic production where these are not allowed. Potentially, there also may be problems with coexistence and in long term, organic farmers may also lack suitable varieties, when varieties obtained by TM/CG become more common.

Expected benefits:

- Would increase the incentive to innovate using modern gene-editing, also for SME's.
- Biosolution companies would see significantly reduced burdens in their development of new products.
- Increased investments in the European biosolution sector.

Suggestion 7: Support adoption of novel food products while ensuring food safety[29]

Description: The main barriers for novel foods are time and expenses. These barriers can be reduced by decreasing the time from the moment a (complete) application is submitted until a product is approved as a novel food, and by providing better funding options, under the condition that safety is not compromised.

Further guidance from the Commission/EFSA in the application process for businesses will improve the quality of applications and speed up the process.

[27] Call for evidence, European Commission: *Legislation for plants produced by certain new genomic techniques;*
[28] Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory.
[29] See for example:
1) Industry shocked by EU Court decision to put gene editing technique under GM law – EURACTIV.com
2) GMO Regulations in Europe Are "Not Fit for Purpose" (labiotech.eu)
3) Strict EU ruling on gene-edited crops squeezes science (nature.com)
4) EuropaBio on NGT study: A positive step towards delivering innovation – Europabio
5) WTO Statement on the potential impacts on international trade of diverging regulatory regimes: GEN1658R2.pdf (netdna-ssl.com)

Funding for documentation of safety and help for drafting applications: An overview of relevant funding options could help businesses. There is a need for better coherence between the companies' development process and the application process. We recommend that the EU assesses funding possibilities to facilitate this. This could be done both by establishing better possibilities to get funding for documentation and help for drafting applications and by improving guidance on these possibilities.

Speed up the approval process: It should be explored how the approval process can be smoothed and thereby shortened in full respect of consumer and environmental protection requirements. Paying due respect to the EU decision making, this could take inspiration for example from the GRAS (Generally Recognised as Safe) procedure used in the United States, which lowers the time-to-market for novel food products as independent expert panels assess the safety of novel food products and food producers do not need to go through long procedures at the US Food and Drug Administration (FDA)[30]. Another option could be to allow for joint applications, where possible, while respecting businesses' sensitive information and applicable competition rules.

Promote and assist applicant of novel food products. This could take inspiration from the assistance provided to applicants for biological control in The Netherlands. This could entail a special contact point ('helpdesk') and/or specific information on website.

Expected benefits:

- The measures could help even the playing field between novel food products and products regulated under EU's General Food Law
- By decreasing the time from an application is submitted until a product is approved as a novel food, and by providing better funding options, these barriers can be reduced. This makes the application process easier for especially small businesses to overcome.

Suggestion 8: Improve the harmonization of the use of the term 'probiotics' in the context of the health claims across the EU Member States to provide clarity for industry and consumers

Description: The use of claims is regulated by Regulation (EC) 1924/2006. According to the Commission Guidance document[31], the term 'probiotic' is considered a health claim. The regulation does not per se prohibit the claim *as long as it is supported by scientific evidence.*

However, today the use of the term 'probiotic' is interpreted and administrated differently within the Member States, with about a third of the Member States allowing the labelling of food products to be labelled as 'probiotics'. Some Member States considers that 'probiotics'

[30] It should be noted that, unlike novel foods, GRAS substances are not subject to a premarket approval. Furthermore, in the US, FDA is the risk manager and the risk assessor whereas in the EU, EC together with the Member States are the risk managers and EFSA is the risk assessment body. Further, the US have no provisions on novel foods. GRAS determination can be made in 2 ways. For a substance used in food before 1958 as it is based on common use in food (in EU foods consumed before 15 May 1997 are not novel foods) or approval of the substance as GRAS if the scientific data and information about the use of the substance is widely known and there must be a consensus among qualified experts that this data and information establish that the substance is safe under the conditions of its intended use;

[31] https://www.fsai.ie/uploadedFiles/EU_guidance_ClaimsRegulation.pdf

encompass a category of nutrients to be mandatory labelled on food supplements[32]. In other words, according to these Member States, the mentioning of the term 'probiotics' is in fact obligatory on food supplements that contain probiotics strains. The current situation is therefore highly confusing for European consumers who experience different understandings of the same content/word depending on the Member State.

The Commission should consider appropriate actions to provide for a harmonised implementation and enforcement of the rules guiding industry stakeholders to uniformly implement EU rules related to probiotics content of food products. Such action should in particular pay due consideration to any related risks which may mislead consumers including unsubstantiated use of misleading terms. Furthermore, the Commission should facilitate a dialogue amongst stakeholders and Member States on the current situation regarding the use of the word "probiotic" and a way forward (e.g. through a comprehensive evaluation and if appropriate, revision).

Expected benefits: Both consumers and industry will benefit from a harmonised approach, as the current differences create unequal terms on the internal market. Consumers would gain more certainty on the meaning of probiotics and get harmonized labelling information across the EU.

Apart from that – a comprehensive dialogue about the use of the word "probiotic" could (if appropriate to the outcome of the dialogue) lead to changes that would ensure better legal certainty and better information to consumer about the products they are interested in.

Suggestion 9: Develop industry guideline for food cultures as food ingredients

Description: The use of food cultures as ingredients in foods that are not traditionally known as fermented should not be regulated under Regulation (EC) 1333/2008 on food additives, because it would be disproportionate to require pre-market approval of food cultures that have been used for fermentation for a very long time inside the EU. Instead, a harmonised approach could be achieved by the Commission of developing and promoting the development an industry guideline for the safe use and production of food cultures, as well as labelling requirements to ensure transparency and clear consumer information.

Expected benefits: Reduction of administrative burdens on the industry and a harmonised approach for the benefit of both industry, consumers and the environment.

Suggestion 10: Update EU NACE codes

Description: The EU's industrial NACE codes are used for general statistical classification and reflect the many different types of economic activities that take place. The increased use of NACE codes in, for example the Taxonomy Regulation ((EU) 2020/852), means that it is important to ensure the codes/classification reflect the development of society on a reasonable

[32] See IPEA (European International Probiotics Association): Use of the Term Probiotic. A European Overview, 9 June 2021; 9 EU Countries allow the term 'probiotic' on labels on reference to nutritional/physiological effects and as a category; 3 countries (6 in practice) allow it as a non-specific health claim that can be used with the authorized health claim; 7 countries follow the Commission interpretation of the use as a health claim only and therefore do not allow the use of 'probiotic'

timescale – and that other temporary solutions may be identified if revision of the NACE-classification cannot due to technical or process issues happen fast enough.

The Taxonomy Regulation aims to provide indications to companies, investors and policy makers on which economic activities can be considered sustainable from an environmental point of view and induce the entire financial system to support a more sustainable economy, through the integration of the taxonomy into all the reference standards of the financial sector. For this reason, the reformulation of the NCE codes also helps a new identification of the financial risk classes of the productive sectors, guaranteeing the Biosolutions sector clearly better risk positioning than the chemical sector, and therefore a greater possibility of obtaining investment capital.

The NACE code for the economic activities that involve what is commonly referred to as *biosolutions* can be numerous and classified under different divisions[33], making it difficult to extract statistical data on the activity in this field. The Commission could consider how to improve such statistical data, based for example on an index of relevant NACE codes for such economic activities. Creation of an index encompassing relevant NACE codes would bring some certainty and comparability of the economic activities involving *biosolutions,* whilst not addressing the legal problem of correct classification in other legislation where NACE-codes are utilised.

Instead, biosolutions are labelled under the NACE code with the chemistry sector (C20 Manufacture for manufacture of chemicals and chemical products) or M72.1.1 (Research and experimental development on biotechnology), which is an inaccurate description of the economic activity, as it does not reflect that biosolutions often seek to replace chemical products..

It would therefore be beneficial if the NACE-codes were updated to accurately reflect economic activities. The process for updates are complicated and long. It includes both assignment of economic activities to specific classes via implementing powers and using the regulatory procedure with scrutiny (RPS) to supplement non-essential elements in regard to technological and economic developments.

Expected benefits:

- In addition to better statistical information, the update of NACE codes would allow for an easier and more accurate use in the EU's Taxonomy on Sustainable Finance, which in large part relies on NACE code classification. Whilst the processes regarding the updating of such codes are very thorough and rather lengthy it would reduce burdens in the field was it to be adopted.

- Facilitated identification and extraction of the statistical data reflecting biosolutions could make investments in sustainable biosolutions companies more attractive by

[33] For example, but not excluding, C20 Manufacture of chemicals and chemical products or M72.1.1 Research and experimental development on biotechnology);

classifying them as sustainable – not in the NACE-codes themselves but in the many other regulations where NACE-codes are utilised.

- In particular, all the regulations of banking and credit sector, both national, European and international (e.g. Basel Regulation), use NACE codes to identify the financial risk classes; identifying the biosolutions with a specific code reduces the associated risk and therefore the cost of the investment.

DISSENTING VIEWS

While Austria supports the adoption of the opinion, we can support Suggestion 6 focusing on genetically modified microorganisms only with certain clarifications.

Rationale for dissenting views on the suggestion:

Austria emphasizes that supporting suggestion 6 does not mean that Austria supports any deregulation of the "newer genetic technologies" in the ongoing discussion. The wording in the first paragraph of the Suggestion 6 indicates that there is a priori a fundamental difference between the risk profiles of "traditional genetic modifications" and "newer genetic technologies". However, Austria stresses that there is no sound scientific proof that the "newer genetic techniques" have a lower risk profile than "traditional genetic modifications". Based on the current state of scientific knowledge Austria thus cannot support a possible deregulation of "certain biological products" (which include plants) produced by "newer genetic technologies". In the ongoing consultation by the European Commission concerning the plants produced by "targeted mutagenesis techniques and cisgenesis", Austria stressed that a mandatory risk assessment, traceability, authorization and labelling is of utmost importance also for these products.

ANNEX 1 – HAVE YOUR SAY: SIMPLIFY! SUBMISSIONS

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