Ministerio de Ganadería, Agricultura y Pesca

INIA URUGUAY

With support from

Federal Ministry of Food and Agriculture

by decision of the German Bundestag

Uruguayan-German Dialogue on Agriculture

STUDY REPORT

Bioinputs landscape in Germany and the European Union

Authors:

Rossbach, A., Christl, H. and Stehle, S. (Consultants)

tier3 solutions GmbH, Kolberger Str. 61-63, 51381 Leverkusen, Germany

10/2024

Implemented by:

GFA CONSULTING GROUP Mandatario General del BMEL Oficina Berlín

IAK AGRAR CONSULTING

GOPA AFC

JKI Julius Kühn-Institut

Disclaimer:

This study is published under the responsibility of the Uruguayan-German Dialogue on Agriculture, funded by the German Federal Ministry of Food and Agriculture (BMEL). Any opinions, conclusions, suggestions or recommendations expressed in it are those of the authors and do not necessarily reflect the views of BMEL.

Published by:
Uruguayan-German Dialogue on Agriculture

info@dialogoagro.uy / www.dialogoagro.uy / DAUA en Linkedin

Editorial Coordination:

Dagmar Wittine, Ignacio Sommer, Michael Bödecker

Contents

Abbreviations

AS	Active Substance
BfR	Federal Institute for Risk Assessment = Bundesamt für Risikobewertung
BMEL	German Federal Ministry of Food and Agriculture
BVL	Federal Office of Consumer Protection and Food Safety = Bundesamt für Verbraucherschutz und Lebensmittelsicherheit
CfS	Candidates for substitution
DAR	Draft Assessment Report
DAUA	Uruguayan German Dialogue on Agriculture
EBIC	European Biostimulants Industry Council
EC	European Commission
EFSA	European Food Safety Authority
EPN	Entomopathogenic Nematodes
EU	European Union
EURL-FA	European Reference Laboratory for Feed Additives
FPR	Fertilizing Products Regulation
IBMA	International Biocontrol Manufacturers Association
INIA	Uruguayan National Institute for Agricultural Research
IPM	Integrated Pest Management
JKI	Julius Kühn Institut (Germany)
MGAP	Ministry of Livestock Agriculture and fisheries
MiOs	Microorganisms
MS	Member State
OECD	Organisation for Economic Co-operation and Development
PPP	Plant Protection Product
R&D	Research and Development
RMS	Reference Member State
rRMS	Reporting Member State
SCPAFF	Standing Committee on Plants, Animals, Food and Feed
SUD	Sustainable Use Directive
SUR	Sustainable Use Regulation
UBA	Environmental Agency = Umweltbundesamt
zRMS	Zonal Regional Member States

Background

The aim of the **Uruguayan-German Dialogue on Agriculture** (DAUA – for its abbreviation in Spanish) is to promote the further development of agroecological and climate-resilient production systems in Uruguay and Germany. To this end, an expert dialogue between different actors from the political and scientific community is carried out. The expert dialogue discusses innovative, resource-saving and climate-friendly measures in the agricultural sector and develops concrete recommendations for action. Furthermore, scientific cooperation between the German Julius Kühn Institute (JKI) and the Uruguayan National Institute for Agricultural Research (INIA) is being promoted. In addition, a bilateral political and technical dialogue is being established between the German Federal Ministry of Food and Agriculture (BMEL) and the Uruguayan Ministry of Livestock, Agriculture and Fisheries (MGAP) and possible other actors of the private sector and civil society sphere. The aim is to develop innovative processes and framework conditions to increase the sustainability of agricultural production systems.

Bioinputs play a crucial role in enhancing the sustainability of agricultural practices. Bioinputs are understood as agricultural inputs, based on biological origin – compared to chemical inputs. They refer to usage in plant-based production as well as animal production. In Uruguay, a National Bioinputs Plan is under development as an element of the National Bioeconomy Strategy. The regulatory framework and research and development (R&D) of bioinputs are still evolving, with an increasing focus on integrating these sustainable products into agricultural practices. Germany has its own established regulatory environment and bioinputs development. The exchange of knowledge and expertise between Uruguay and Germany aims to strengthen the understanding of the development, regulation, production and use of bioinputs in both countries, ensuring that agricultural production becomes more sustainable.

In August 2022, the operational plan of the "**German-Argentine Technical Dialogue on Innovations for Climate and Environmentally Friendly Agriculture**" was implemented. The primary objective of the dialogue is to support Argentina's approach to promote climate and environmentally-friendly innovations in the agricultural sector. The dialogue aims to bring together policymakers and experts from business, academia, and the agricultural sector and promote the exchange of experience and knowledge in various areas. Both countries are working to reduce the quantity and types of chemical phytosanitary products. In Germany, the tendency is to increase organic production, and in Argentina, the approach is to work with different molecules using nanotechnology, safer products, and directed sprays[1].

While many companies and research institutes worldwide work on biological alternatives to chemical phytosanitary products, the development and market penetration are not yet sufficient to replace chemical phytosanitary products at a large scale. At the same time, the challenges linked to the negative effects of phytosanitary products on biodiversity, soil health, weed resistance and human health are pressing sustainability issues.

In a context where Germany, Argentina, and Uruguay share the goal to reduce chemical phytosanitary products with, however, partly different approaches to reach this goal, the scientific dialogue between these countries seems a promising tool to foster exchange and mutual learning. Exchanging information, scientific data, and expertise about bio-phytosanitary products, fertilisers, and biotechnology are fruitful for both countries.

[1] Direct Spraying refers to precise application of pesticides or other crop protection products directly onto specific parts of the plants or target areas, as opposed to broad, blanket spraying over entire fields.

Introduction

The aim of this paper is to give a comprehensive understanding of Germany's legal and operational framework regarding bioinputs in agricultural production, its national strategies, developments, experiences and key actors involved in the process.

The legislative framework is largely set by European Union (EU) regulations. Therefore, German national strategies will be described in a European context where necessary. However, national specifics differ on how to reach the EU goals.

The farm-to-fork strategy laid out by the EU Commission is the core of the European Green Deal, aiming to make food systems fair, healthy and environmentally-friendly [1]. The Sustainable Use Directive 2009/128/EC (SUD) specifically addresses sustainable use of pesticides in the EU, promoting integrated pest management and alternative approaches and techniques, such as non-chemical alternatives to pesticides. One of the main targets is to reduce the use of chemical pesticides by 50% by 2030. The SUD has not been voted into a binding regulation (SUR: Sustainable Use Regulation) by the EU parliament. However, the farm-to-fork strategy fosters research and development as well as practical implementation of alternatives in conventional farming.

1. Definition of 'bioinputs'

The term 'bioinput' does not exist as such in Germany and the EU. In fact, there is no common term for products of biological origin in the context of agriculture.

In order to have a common understanding, we define and use the term 'bio-input' for 'any substance or product of animal, plant or micro-organism origin, either consisting of the organism itself or any form of extracts, metabolites, derivates etc. which are used for phytosanitary purposes in crop production, including biocontrol and fertilizers, or as animal feed´.

Many terms are used for phytosanitary products, as e.g. biopesticides, biocontrol agents, biostimulants, biologicals, biocontrols, bioprotectants etc, and are often used simultaneously without clear definition regarding their diverse properties and modes-of-action.

For better understanding in the following a rough characterisation of two main categories: Bioprotectants which mainly refer to biocontrol agents, and biostimulants, which mainly refer to fertilizers.

1.1. Bioprotectants

In this document, we follow the definition given by the International Biocontrol Manufacturers Association (IBMA) for biocontrol items [2]:

Bioprotectants have their origin in nature and should cause no harm to humans and have minimal impact in the environment. Bioprotectants include in particular:

- Invertebrate biocontrol agents (= macrobials, macroorganisms) (insects, mites, nematodes as antagonists to insect pests)
- Plant protection products containing microorganisms (=microbials) (bacteria, fungi, viruses and protozoa)
- Natural substances (plant/algae extracts, animal or mineral origin and components of microorganisms)
- Semiochemicals (chemical mediators such as pheromones, kairomones)

- RNAi-sprays (ribonucleic acid interference sprays) (not yet included by IBMA)

1.2. Biostimulants

According to the European Biostimulants Industry Council (EBIC), biostimulant refers to material which contains substance(s) and/or microorganisms whose function, when applied to plants or the rhizosphere, is to stimulate natural processes to enhance/benefit nutrient uptake, nutrient efficiency, tolerance to abiotic stress and crop quality, regardless of its nutrient content. Common ingredients include microorganisms, plant and seaweed extracts, amino acids, humic acids, mineral salts [3].

- Microorganisms (mycorrhizal and non-mycorrhizal fungi, bacterial endosymbionts like Rhizobium and plant growth promotors (Rhizobacteria)
- Plant extracts
- Amino acid and peptide mixtures
- Biopolymers
- Inorganic salts (chlorides, phosphates, carbonates etc)

With regard to regulation in the EU, biostimulants are not yet clearly defined. Depending on their origin, they are either categorized as biocontrol agent, pesticide or fertilizer. And thus, fall under different regulations.

1.3. Animal related bioinputs

There is no separate list for “bioinputs” in animal feed, but the categories are differently defined so they appear together with conventional pesticides, food additives, biocides etc.

Regarding types of bioinputs the following categories could be considered

- Additives in feed and foodstuff (E.g. soybean meal, corn, alfalfa, barley, wheat bran)
- Additives to Manure (as fertilizer)
- Biopesticides used on feed and foodstuff
- Beneficials used on feed and foodstuff
- Pheromones and other attractants
- Growth regulators and biostimulants
- Repellents

Depending on how exactly the term “bioinput” is defined, the lists will vary, also there is some overlap between categories.

2. Regulation of bioinputs

For the different types of substances that can be regarded as ‘bioinputs’ entirely, different legislations apply in the EU either on EU or on national level, e.g.

- for bioprotectants the regulation EU 1107/2009 [4],
- for biostimulants the EU fertilizing products regulation EU 2019/2009 [5] and
- for feed additives Regulation (EU) No 1831/2003 (Feed Additives Regulation) [7] (see Table 1).

Table 1: Regulations for agricultural bioinputs in the EU

Compound	Notification process	EU regulation
Bioprotectants*:		
Microorganisms (MiOs) (Microbials)	• EU level for active ingredient approval • Member state level for formulation approval for regulatory zone	• EU 1107/2009 Placing plant protection products on the market (MiOs amended) [4] • Data requirements (MiOs included end of 2022 (EU2022/1439 and 1440) amending:283/2013 (a.i.); 284/2014 (formulation) • Guidance: SANCO/12545/2014–rev3
Natural substances and Semiochemicals	• EU level for active ingredient approval • Member state level for formulation approval for regulatory zone	• EU 1107/2009 Placing plant protection products on the market • Additional guidance for plant extracts (botanicals): SANCO/11470/2012-rev8 • Semiochemicals: SANTE/12815/2014-rev5.2 • Straight chain lepidopteran pheromones: SANCO/5272/2009-rev3
Macroorganisms (Macrobials)	• Member state level (no harmonisation on EU level)	• EU 1143/2014 Invasive alien species [9] • EU 2016/2031 Protective measures against pests of plants [10]
Non-bioprotectants:		
Biostimulants	• EU level *Depending on their nature and primary properties, data packages need to be submitted under one or several regulations, i.e. fertilizers or pesticides*	• EU 2019/2009 EU fertilizing products regulation (FPR) [5] • EU 1107/2009 Placing plant protection products on the market
Feed and foodstuffs	EU-level only	• EU 70/524/EEC, so-called existing substances' Regulation (until 2003) EU 1831/2003 (Feed Additives Regulation) [7]

* RNAi sprays are still in the R&D process and to our knowledge not yet submitted for approval to use in the EU.

Substances that are regarded as bioprotectants, or more commonly termed biopesticides, have to follow the same European notification process as chemical pesticides, which is defined in **Regulation EC 1107/2009** [4] and further regulations that are mentioned within. Microorganisms (MiOs), natural substances and semiochemicals are covered by this regulation. Macroorganisms such as beneficial insects are not.

As the mode of action of microorganisms differs substantially from chemical compounds, data requirements have been adapted in 2022 in Regulations (EU) 283/2013 for active substances and Regulation EU 284/2013 for formulations. This adaptation is supposed to speed up the authorisation process for microorganisms and fast-track approvals should be guaranteed.

Up to date, the EU does not have a specific regulatory framework for natural substances and semiochemicals, which means that the data requirements for the approval process are the same as for conventional pesticides. However, non-binding guidance for plant extracts and semiochemicals does exist. But in general, due to the lack of guidance, authorities can derive very different conclusions when evaluating the same data package.

A simplified overview on legislative requirements is depicted in Figure 1. More details are found in Table 1.

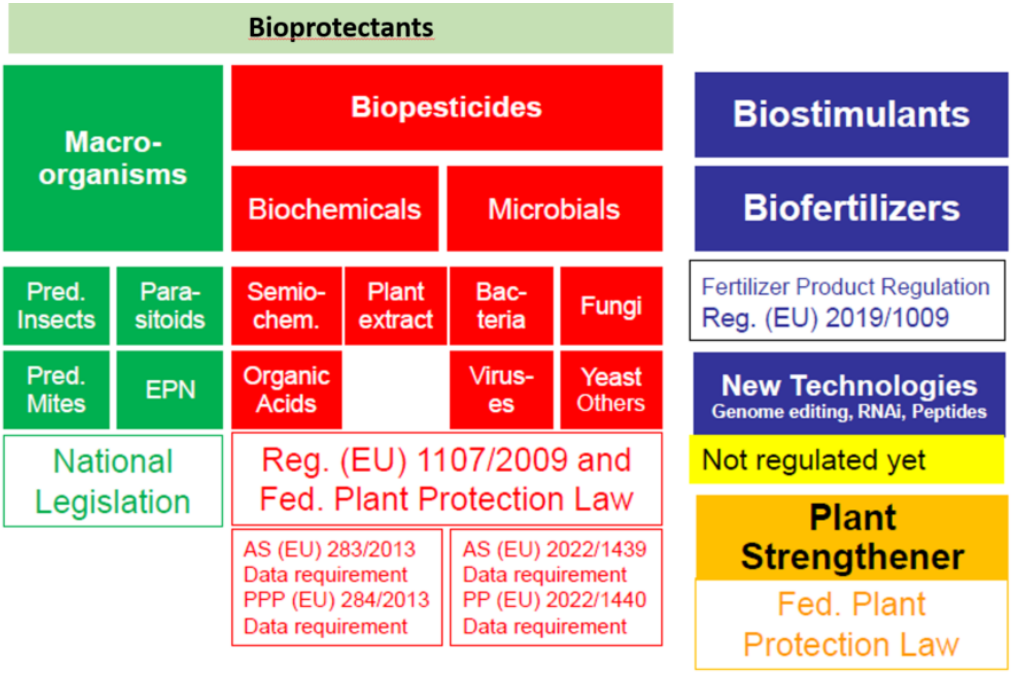

Figure 1: Overview of legislation for bioprotectants in Germany. Abbreviations: AS = active substance, PPP = plant protection product, Green column: predatory insects and mites, EPN = entomopathogenic nematodes. Source: Presentation by Johannes Jehle, Julius-Kühn-Institute 2024)

2.1. Authorization process of chemical and biological plant protection products in the EU

As for any pesticide to be notified in the EU, the authorisation process is divided into two separate processes, the authorisation of an active substance (the substance as such that is the cause for the desired effects, which also may be a microorganism) and the products based on this active substance. The active substance as such is regulated at EU-Level. Approval e.g. just for Germany is not possible[2]. An application at EU-Level encompasses two dossiers, the active substance dossier and at least one product (termed "representative product") dossier with at least one representative use, e.g. against a particular pest on a particular crop. The notifier would select for this a product-use combination with best chances to obtain an approval. Once approval for the active substance as such has been granted at EU-level, also applications for individual products can be submitted.

These applications are at the level of individual member states, which however are grouped in three regulatory zones (Figure 2) into which Europe has been divided. Germany belongs to the Central zone, and normally one would select a reporting member state (rRMS) that will evaluate the application for all uses in a given zone. A product that has been evaluated by Germany on behalf of the Central Zone, can also be approved easily in other member states of the Central Zone. However, it is important to note that general approval of the active substance is an obligatory precondition for marketing any plant protection product in a member state of the EU.

[2] The reason for submitting both dossiers is that while an active substance may be approved at the EU level, the formulation of that substance into an actual product and its intended use need to be assessed separately at the member state level. The notifier typically chooses a product-use combination that offers the best chance of approval. If the active substance is not approved, the entire product development process might be halted, leading to significant economic implications.

Figure 2: EU Regulatory zones for plant protection products (PPP)

In a nutshell, the European notification process for plant protection active substances and products is as follows:

Companies submit complete data package (dossier) to a rapporteur member state (RMS)

- on the active substance
- on at least one formulated plant protection product containing that active substance

Data requirements:

- the identity of an active substance and plant protection product
- the physical and chemical or biological properties
- the effects on target pests (efficacy)
- the risks to operators, workers, consumers,
- the risks for the environment
- the risks for non-target organisms (birds, mammals, aquatic organisms, pollinators and other non-target arthropods, soil organisms and non-target plants).

Depicted in

Figure 3 are the key actors in the authorization process.

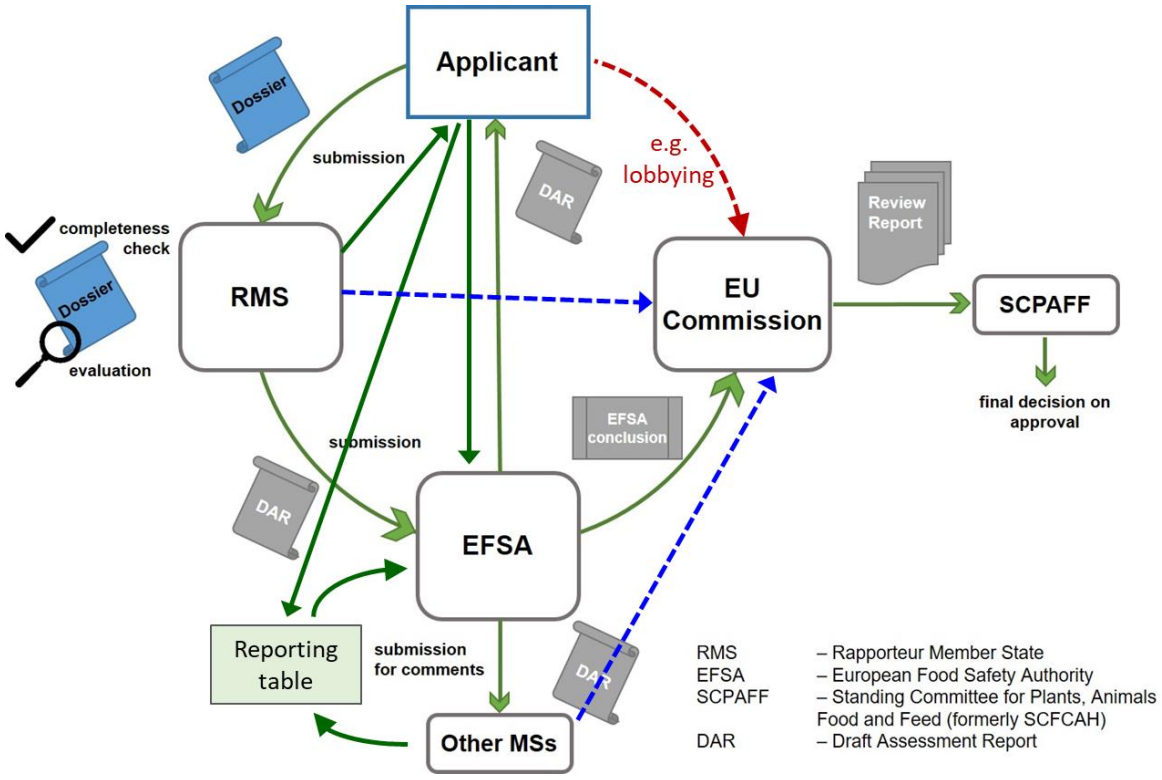

Figure 3: Key players and main information ways between them in the process of the registration of plant protection products (PPP) in the European Union

The **applicant** (notifiers), which are mostly private companies submit a dossier to the regulatory authorities of the Reporting Member State (**RMS**), which they can select within the EU for approval of the active substance and a representative formulation with this substance. They might have to later on address open points – often by submitting additional data and information.

The RMS bears most of the assessment and evaluation and based on the dossier they generate a Draft Assessment Report (**DAR**). The DAR will be reviewed by the European Food Safety Authority (**EFSA**). They organize review by other stakeholders, in particular other Member States (**MS**). At this stage also the applicant can address any concerns raised by the RMS or EFSA. Based on this review process EFSA generates an **EFSA Conclusion Report**. This report will then be sent to the **European Commission**, who organises the ultimate voting within the **SCPAFF** (Standing Committee on Plants, Animals, Food and Feed), which normally - but not always - follows the recommendations made by the EFSA (approval, non-approval, or approval with restrictions).

Once the active substance is approved by SCPAFF, it is registered for the entire EU. Products containing the registered active substance will afterwards be approved on **zonal level** (Figure 2). Again, one zonal member state (**zRMS**) within the zone can evaluate the core dossiers submitted by the applicant for all countries in the zone whereas individual MS will still do their own evaluations.

The green arrows in

Figure 3 indicate formal information flows, and the blue and red, informal ones; the latter are not a mandatory part of the registration process yet may be instrumental in case of complex cases with room for interpretation. For example, in case of borderline risk assessments, the decision may be influenced by feedback from the RMS about potential

alternatives, candidates for substitution, or in the other direction by MS who gathered experience with an emergency approval, or an MS indicating that a particular local use might be of outstanding economic importance and without economically viable alternative.

Within the regulatory framework of the EU 1107/2009 (placing of plant protection products on the market and repealing Council Directives), further regulations and guidance documents are available on how to perform the evaluation, and which testing is required to comply with the requirements of the different sections of the dossier. These are produced by the European Commission (Health and Consumers Directorate General-SANCO documents), EFSA (EFSA guidance documents) and the OECD (Organisation for Economic Co-operation and Development-OECD guidance documents). Validated test methods are mainly issued by the OECD (OECD guidelines) with additional test guidelines according to ISO standards and some US EPA OCSPP guidelines are also in use. Additionally, scientific publications can also be used as reference for test methods. The entire set of documents (excluding scientific papers) is published on the website of the European Commission [6].

2.2. German institutions in the authorization process

The relevant authority representing Germany as reporting member state (RMS) is the **BVL** (Federal Office of Consumer Protection and Food Safety = **B**undesamt für **V**erbraucherschutz und **L**ebensmittelsicherheit), acting as national coordination point in the EU cooperation and is responsible for authorisation of plant protection products (Figure 4).

Evaluation of the different dossier sections and risk assessments are split between three further government related institutes. The **BfR** (Federal Institute for Risk Assessment = **B**undesamt **f**ür **R**isikobewertung) is responsible to evaluate human health risks. The **JKI** (Julius-Kühn-Institute) is giving scientific support, e.g. regarding efficacy. The **UBA** (German Federal Environmental Agency = **U**mwelt**b**undesa**a**mt) is responsible for reviewing the submitted dossier parts related to environmental effects (effects on soil, ground- and surface water as well non-target organisms) for the active substance (if Germany is RMS) and for national product submissions.

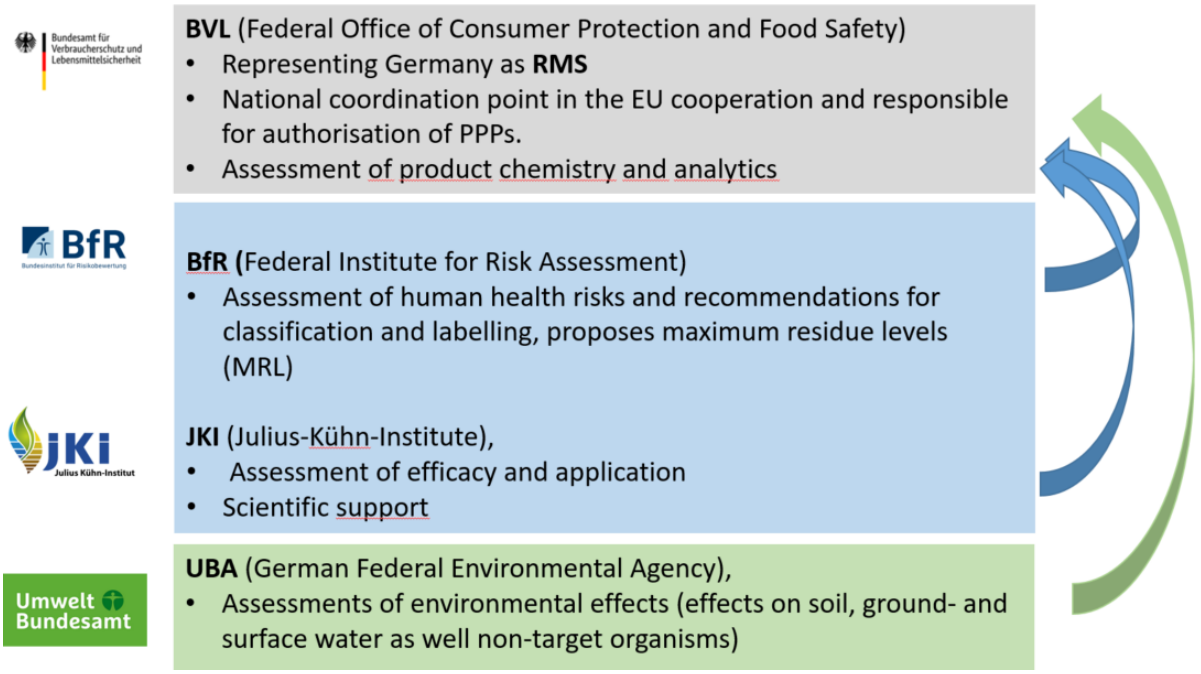

Figure 4: German institutions in the authorization process

2.3. Authorization of low-risk substances

Any classification as bioinput depends on whether a new active substance or organism can be classified as a "low-risk substance", as defined in Annex II, point 5 of Regulation (EC) 1107/2009 [4]. While in some instances a lighter data-package might be sufficient for these, there is no separate application procedure for products based on low risk active substances: a 'normal' authorisation is still required for these products (see e.g.[8]), in which the status "Low risk" will either be confirmed or be rejected. If it is confirmed, the approval is valid for 15 years (standard duration: only 10 years).

Criteria for approval as low-risk substances are

- the low-risk active substances, safeners and synergists contained in the product have been approved under Chapter II,
- the product does not contain a substance of concern,
- it is sufficiently effective,
- it does not cause unnecessary pain and suffering to vertebrates to be controlled,
- it complies with points (b), (c) and (f) to (i) of Article 29(1).

(Chapter II and Article 29 refer back to standard requirements for all substances aiming for authorisation [4]).

Further details are laid down in Annex VI of EU reg. 2229-2004

2.4. Authorisation of feed additives

"Regulation (EC) No 1831/2003 (Feed Additives Regulation) stipulates that no person may place on the market, process or use a feed additive unless a corresponding Community authorisation has been granted (Article 3(1) of the Regulation). The Feed Additives Regulation replaces the previous harmonised provisions of Directive 70/524/EEC.

Authorisations under the Feed Additives Regulation are granted by diverse individual regulations, which makes it difficult to maintain an overview, as legal regulation published in the Official Journal of the European Union may be overlooked. For additives that have been authorised under Regulation 70/524/EEC, so-called existing substances, the transitional provisions of Article 10 of the Feed Additives Regulation apply.

The following are general criteria that apply to all feed-additives [11], not just bioinputs.

The applicant must provide sufficient and appropriate evidence that the feed additive

- has a functional effect [13] that justifies its use [14],
- does not have a harmful effect on animal or human health or the environment,
- is not presented in such a way as to mislead the user,
- does not adversely affect the consumer by impairing the quality of the animal products, and
- must not mislead the consumer as to the nature of the animal products.

Applications must be submitted to the European Commission, and at the same time certain application documents. A dossier generated according to Regulation (EC) No 429/2008)[15] and [16] must be submitted directly to EFSA.

In addition, reference samples of the feed additive and an analytical method for the detection of the feed additive in feed must be sent to the European Reference Laboratory for Feed Additives (EURL-FA) in Geel (Germany), when the application is submitted. The

method must be suitable to detect any residues in the feed and also in the resulting animal products and will be tested by the EURL-FA.

Furthermore, maximum residue levels are set for some feed additives (coccidiostats and colourants).

The EFSA evaluates the application and forwards its opinion to the European Commission, the Member States and the applicant.

Within three months after EFSA's opinion arrived at the EC, the EFSA should prepare a draft regulation to grant or refuse authorisation of the feed additive. The member states vote on this in a committee procedure.

Authorisation under the current Feed Additives Regulation is limited to 10 years but can be extended on application. Substances notified under the previous regulation had been authorised for an unlimited period, which is the reason for the continued existence of two lists in parallel. Note that despite this, a number of substances from both list are no longer approved in the EU for various reasons; there is also a separate list for these substances that are being or have been phased out [17].

The role of the national authorities (BVL in Germany) is here only marginal (see [18]).

2.5. Timelines and costs of the authorization process in the EU

Criticism of the International Biocontrol Manufacturers Association (IBMA) has been raised regarding the long periods and high costs for the registration of natural substances which should be classified as low risk-substances [19]. In general, the actual duration of the authorization process is a lot longer than the target duration. Different reasons apply, lack of a specific framework for 'bioinputs', the high complexity of the process, as substances must go through the same process as conventional pesticides, limited capacities in reporting member state authorities, but also the differential interpretation of regulatory requirements. Regarding capacities, a fast-track approval process for biological compounds is not yet established at the BVL in Germany for example. However, this is planned to be changed.

The long timelines and high costs make it difficult especially for smaller companies to access the European market. They are therefore likely to refrain from submitting registration applications in the EU which might also contribute to the relatively low number of approved substances, including microorganisms.

Table 2: Comparison of timelines and costs between approval categories

	Active substances	Low-risk substances	Basic substances
Definition	-	'Less risk'	Primarily not used in plant protection
Approval	10 years 7 years for CfS*	15 years	unlimited
Estimated development costs: **Active substance** **Product**	7-10 M€ 0.5-1 M€	600 k€ 380k €	No info
Duration registration process (envisaged target for max. duration)	1 – 1.5 year	120 days	1.5 – 2 years
Duration registration process (actual)	3-5 years	4 – 7 years	No info
Number of approved substances (2023)	> 350 CfS 50	72	> 16
Examples	• CfS e.g. copper compounds, • cypermethrin,	• *Bacillus subtilis* strain IAB/BS03	• Vinegar, • onion oil, • sucrose,

	Active substances	Low-risk substances	Basic substances
	• tebuconazole	• *Cydia pomonella granulovirus* (CpGV) • *Trichoderma atroviride* • Urea	• calcium hydroxide

* Candidates for substitution (chemical pesticides for which national authorities should assess if alternatives exist. Sources [19][35]

3. Research and development for biological control

3.1. Development of new products

Research and development (R&D) of bioinputs for use in agriculture is mainly carried out by the private sector in Germany (and the EU). R&D for biological pesticides in the private sector is conducted specifically by smaller and mid-size companies specialised specifically on agricultural bioinput products, e.g., BioBest Group [20], Biocare GmbH [21], e-nema GmbH [22], or Neudorff [24], just to name a few which are based in Germany and neighbouring countries and who are renown for non-chemical solutions. Bigger players with entirely biological portfolio are Koppert [23] or Andermatt [25]. Recently, also large agro-chemical companies such as Bayer (e.g. [26]) or BASF (e.g. [27]) to name those with headquarters in Germany, have become involved in the bioinput market. This involvement is often based on in-licensing of products or technologies, joint ventures and acquisitions [28].

Academic R&D of bioinputs in Germany is conducted by research institutes such as the Fraunhofer Institute for Interfacial Engineering and Biotechnology (IGB) [29] or at the Institute for Biological Control of the Federal Research institute for Cultivated Plants (Julius Kühn Institute, [30]). In addition, fundamental research on bioinputs is conducted at universities e.g., at the University of Hohenheim, Faculty of Agricultural Sciences [31], or the University of Giessen, Department of Phytopathology [32]. The academic research conducted at universities in Germany is generally funded by public research grants, whereas the profit-oriented R&D of bioinputs in the private sector is financed directly by the respective companies. Further, research cooperation on bioinput R&D between the private sector and academic research institutes exists, e.g., the research cooperation “Phenotyping for Products”, a strategic research alliance between the Bayer AG and the Jülich Research Centre [33].

Compared to the R&D by the private sector and universities, the role of farmers in bioinput R&D is less pronounced, than in conventional farming systems based on synthetic pesticides and fertilisers predominate in German agriculture. The R&D and use of bioinputs require specialised knowledge and training, and the effectiveness of new bioinput products is not guaranteed, potentially hampering large-scale farmer involvement in the R&D process. Also, sound knowledge on the bioinput substance, the biology of pests and crop diseases is needed to obtain best results when researching on bioinputs. However, there are initiatives by farmers, agricultural advisors and manufacturers to test the effectiveness of bioinput products and to disseminate successful bioinput strategies.

Subsequent to the R&D of new bioinput compounds including positive results on efficacy from controlled lab-based studies, efficacy trials in the field are conducted during R&D to demonstrate the respective bioinput effects to be significant and sustainable under actual farming conditions. For the market position of bioinputs it is particularly important to clearly demonstrate the practical value and efficacy rather than their intrinsic effectiveness only.

3.2. Regulatory challenges from development to the market

When developing a new product, the regulatory framework has to be kept in mind, due to differential data requirements and registration processes. Importantly, bioinputs are often multi-use compounds (e.g., plant extracts, proteins, microorganisms), that is a single bioinput component can fulfil a range of functions, i.e., acting as biostimulant, fertilizer or exhibiting plant protection function. During authorisation, manufacturers must prove that a bioinput product fulfils all product functions given on the label.

Challenges in the R&D and registration of bioinputs include the clear identification and definition of the respective modes of action of bioinput compounds, particularly when they were previously unknown. For example, a biopesticide based on microorganisms might be effective against a given pest due to a direct antagonistic pest effect of the microorganisms or – in contrast – the effect results from secondary molecules produced by the microorganisms. In addition, definite identification and information on whether a bioinput substance has a preventive or curative effect on crops and agricultural production is needed to define optimal application strategies. When bioinputs are used in combination with conventional farming methods (e.g., crop protection measures using biopesticides and conventional pesticides), interaction of molecules and pest suppression effects need to be considered for Good Agricultural Practice (GAP) definition.

Further challenges in R&D and regulation of bioinput result from the fact that accurate and complete characterisation of a bioinput substances can be complex. For microorganisms, in particular, the strain has to be exactly characterized, and methods are needed to identify mutant microorganisms and differences to parent strains. For natural substances such as botanical and animal extracts, the active compound of a bioinput substance is often unknown or of variable composition.

Generally, the use of bioinputs in agriculture requires a holistic phytosanitary treatment approach, as individual bioinputs are often not sufficiently effective on their own. It is thus important to incorporate new bioinput substances and products into the existing phytosanitary approaches. Also, comprehensive information and farmers training on the product, its application and its curative or pre-emptive effects need to be ensured, to achieve optimum results and efficacies of a new bioinput product.

3.3. Available bioprotectants in Germany

There are currently 120 active substances (of 1479 in the Commission's Pesticide Database [35]) listed that are based on microorganisms, 72 of them are approved, 21 not approved and the rest pending or not yet assessed at EU-level. These include several *Bacillus* strains, *Pasteuria* to *Saccharomyces*, fungi like *Verticillium albo-atrum*, *Beauveria bassiana* or e.g. mosaic-virus isolates. Further 28 substances are classified as basic substances (substances that are in widespread use and contact with humans, animals and the environment). Also, this group includes substances that could be classified as bioinputs (being low-risk, microorganisms or basic substances), such as *Allium cepa* (onion) bulb extract, the plant *Equisetum arvense*, mustard seeds, sunflower oil and other plant extracts. For details, please see the EU Pesticides Database [35].

3.4. Available feed additives in Germany

There is no separate list for approved bio-feed additives. All feed additives are entered in the common Community Register by the European Commission [34]. A new online interface [17] lists also feed additives that are not authorized or being phased out. The list with currently 1682 matching records would have to be filtered by other criteria.

The list is very long and not very clear, so it is divided into 21 functional subcategories.

There are two lists (20 years after Regulation 1831/2003 came into force), one of existing substances authorised under 70/524/EEC, and one of substances authorised under the current regulation. The former were authorised for an unlimited period, whereas those authorised under Reg. 1831/2003 must be renewed every 10 years.

Also there are various informal lists e.g. by national authorities, but only one that is formally valid. The last official version was published as a distinct document, which can be found here [7]. Meanwhile it has been replaced by the online database [37] mentioned further up.

3.5. Bioinputs prohibited in the EU

Pesticides: Among the active substances, safeners and synergists[3] not approved in the EU are 23 substances based on microorganisms or viruses. Most of them are not/no longer approved because there are better alternatives, often submitted by the same applicants. Examples for no longer approved microbiologicals are e.g. a weak strain of the zucchini yellow mosaic virus, some *Agrobacterium*, *Chromobacterium* or *Fusarium* strains. Also, a *Bacillus thuringiensis* (BT)-strain that had been approved previously was not extended (BT. subsp. *tenebrionis* strain NB 176 (TM 14 1), expiry of approval early 2020). However, note that all of these related strains with better performance are still approved an on the market. Those not approved or expired were generally inferior in terms of efficacy. For further details see again the EU Pesticides Database [35].

Among the **feed additives** that were not authorized or are being phased out (see [17] for details) there are again surprising entries such as some sunflower extract, lactic acid, a black currant extract and also various microbial agents or extracts of fungi. Among products currently being phased out are *Camphor* essential oil, various *cinnamyl* preparations, various essential oils form citrus fruits, a cumin oil, *Echinacea angustifolia* DC. (*Blacksamson echinacea* tincture), *Endo-1,4-beta-xylanases* produced by different *Trichoderma* species, *Erythrosine* (as colouring agent), *Ascoetida* oil, *fenne* and *gentiana* tinctures etc. (This list is far from complete, a complete list would cover several pages, again see [17] for details). However, also in case of not-approved feed additives there are often similar substances and products that are still approved and being used, e.g. 15 preparations of citrus extracts are authorized while 10 are being phased out.

For most of these phased out substances no positive effect could be demonstrated unequivocally. Again, in absence of a separate list for bioinputs it is cumbersome to get further details: The reasons for non-inclusion onto Annex I (the list of approved active substances), must be looked up for every single entry.

To conclude, there are bioinputs in different categories such as biopesticides and feed additives that have not been authorized in the EU or are being phased out, but largely only because of insufficient efficacy data and the availability of better alternatives.

4. Marketing and outreach to farmers

In Germany, farming is a profession with a three-year apprenticeship, which includes specialized vocational schools for farmers [56]. Hence, the vast majority of German farmers

[3] A safener is a substance added to pesticide formulations to eliminate or reduce the harmful effects of the pesticide active substance on specific crops. These safeners are often applied to seeds or used in combination with herbicides. Synergists are chemicals that in theory lack pesticidal properties on their own but which can increase the activity of the active substance(s) in a pesticide formulation.

is knowledgeable much beyond the old concepts and procedures taught by their farming parents.

Traditionally, farmers purchased their animal feed, fertilizers and plant protection products from local companies specialized in such provisions. In Germany there are about 40 wholesalers and 30 nationwide suppliers that sell fertilizers, feed and foodstuff, or plant protection products. Also, there are cooperative banks such as Volksbank & Raiffeisen [57] that have particular local branches or departments, including shops that sell or also deliver operating resources such as phytosanitary products, fertilizers, feed and seeds to farmers. Farmers are supported by governmental institutions called Chambers of Agriculture (Landwirtschaftskammern, (e.g. [44]), [60]) that offer general and specific consultancy, provide representative lists of prices e.g. [60], both for agricultural products the farmers sell, and the products the farmers purchase to support their products, including any bioinputs. Companies selling such products to the farmers would traditionally advertise their products with the local suppliers, and today also via internet. There does not seem to be any other specific marketing solely for bioinputs, but there is a range of smaller specialized companies (Examples see Chapter 3) that are renown for non-chemical solutions, which would be considered by farmers. There are special farmers magazines (e.g. [45]), in which suppliers advertise, and reporters publish experiences with new products, both for conventional and biological farming, the latter being most interested in bioinputs. Last but not least, there are many local farmers associations where farmers exchange informally about their current topics and share their own experiences with their peers (e.g. the German Farmer Association).

In addition, the larger chemical companies offer information and training e.g. on integrated pest management (IPM - the optimised strategy to combine both chemical and non-chemical practices for economic and environmentally aware control of pests different approaches to control a given pest, e.g. [41], [42]), to interested farmers (e.g. [43]). These agricultural advisors, being paid by the big agrochemical companies, are obviously not independent, which farmers are aware of. External agricultural advisors also offer their service, being financed by governmental and/or private resources (e.g. [44]), and train farmers in certain areas.

In Germany there is no formal differentiation between “family farmers” and other agribusinesses, i.e. larger agro-companies. Due to German’s history, there are a lot of larger agriculture-companies [46] active in the eastern counties (succeeding the 'Agricultural Production Cooperatives' of the former German Democratic Republic), with paid employees that do not own the ground [45], [48], [49]. In contrast, in the West of Germany many smaller farmers still work their own land [47]. However, also in the West, numbers of family farmers have been decreasing for decades, the smaller ones being bought up by larger ones or by externally financed agribusiness companies [46]. However both the traditional farmers and the larger agro-companies face similar challenges and have to obey the same rules, and both depend to some extend on direct subsidiaries linked to certain conditions [45], which sometimes smaller farms can easier comply with than the larger companies.

German farmers only very occasionally further develop their products on-site. However, there are some, e.g. small dairies still working in extremely remote areas where no lorry can pick up milk (in the Alps), so the milk can only be processed immediately and locally to cheese. These micro-dairies are operating in a grey zone in terms of regulations (requirements regarding hygiene mandatory for large dairies could not be followed in these subsistence mountain dairies). However, consider that the latter also provide just a negligible fraction of the dairy products produced and marketed in Germany. Another type of local biofactory would be the fermentation of cut grass or maize into silage which is used as feed mainly for cattle, or the utilisation of gas from manure for heating and the generation of electricity. This is normally done based on the farmer’ traditional experience and formal training [56], and there are no specific regulations for it.

Some farmers also sell a part of their products directly ("direct marketing"). When doing so, the standard EU-regulation [58], [59] regarding hygiene in their farmers' shops apply also to them.

5. Role of organic agriculture

Germany has got the ambitious goal to increase the agricultural area for organic farming from currently below 10% to 30% of the total of approx. 18 million hectares until 2030 (BMEL National Bio-Strategy Plan 2030 [50]). Adoption will on the one hand depend on consumer reaction due to increasing costs of living, which has slowed the more costly bio-market. Therefore, to boost consumer demand, organically produced food is promoted to be served in kindergardens, schools, company canteens and retirement homes. On the other hand, yields are substantially lower in organic farming as compared to conventional production with losses – depending on crops - between 15% and 55%, which refrains farmers of taking up organic farming.

However, innovations emerging from further research for optimizing organic farming can be and are already used also in conventional farming (e.g. mechanical weeding, crop rotation and soil nutrient management).

The aim, set in the national action plan on sustainable use of plant protection products [51] is the consideration of Integrated Pest management (IPM) and use of non-chemical crop protection measures, such as crop rotation, mechanical measures, precision applications and digital solutions.

Market analysis data for 2024-2029 [52] predict an annual growth of 15% of the biopesticide (probably referring to bioprotectants and biostimulants combined) market in Germany, fostered by organic farming and the incorporation in IPM measures in conventional farming.

6. Use of bioinputs in animal production

There is a variety of additives in feed and foodstuff, including microorganisms such as *Bacillus*, *Clostridium* or *Enterococcus* [53] that stabilise gut flora, or the plant *Onobrychis viciifolia* known for its antihelminthic properties that can replace chemical drugs to control nematode parasitism in the guts of small ruminants [54], all these could be termed bioinput in feed stuff. Also, there are bioinputs acting as biocides such as preservatives that increase shelf-life. There are no bioinputs for manure that we are aware of. In contrast there is an increasing number of biopesticides, some of them on the market for 30 year or more, e.g. insecticidal products based on *Bacillus thuringiensis*, plant oils that form a physical barrier over insects' stigmata, essential oils that act as repellent or are even toxic to specific pests, or nematodes that infect various pests (e.g. insects or slugs), though most of them will be more relevant for plant production, not necessarily in animal production, unless the plants are fodder for the animals. The same applies to beneficials such as parasitic wasps or predators such as mites or beetles that control insect pests on the foliage, which again might be relevant for animal production if the latter is used as feed. Pheromones and other attractants could per se be regarded as bioinputs, though they might be synthesized chemically or in fermenters. The same might apply to growth regulators, biostimulants and repellents, which often are available at low concentrations naturally, but are supplemented deliberately to achieve a particular effect.

7. Conclusions

In the EU and subsequently in Germany, there exists no single term that defines 'bioinput' in one single concept, referring to biologically-based substances and organisms used in agricultural production. Thus, there is no specific regulatory framework or legislation for so-called bioinputs. They are either regulated by national legislation (macroorganisms), EU1107/2009 for all other bioprotectants with only microorganisms having specific data requirements or the Fertilizer Product Regulation for biostimulants and biofertilizers.

The lack of a specific bioinput legislation leads to further complexity to an already complex registration system. Biopesticides for example have to follow the same path as conventional pesticides. Timelines for the process are long and costs are high. There is a lack of transparency which data packages to submit and according to which guidance, which often leads to differential interpretation of regulatory requirements and risk evaluations between member states. Additionally, regulatory authorities in the EU have a serious issue with capacities as submissions pile on their desks.

There is a need to speed up the process of product registration in EU in order to reach the goals of the Farm-to-fork strategy, reducing chemical pesticides by half until 2030. The number of biological products currently registered in the EU is still low with currently 72 low-risk substances. Additionally, research on optimal application strategies and adaptation of farming techniques to the use of bioinputs in agricultural production are required in a holistic approach.

Based on the experiences in the EU and Germany, it is recommendable to provide a specific regulatory framework for bioinputs used in agriculture, regardless if used as biostimulant or biopesticide with adequate data requirements for natural substances and microorganisms.

Some recommendations can be structured as follows:

7.1. Design Process for Bio-Input Registration Framework

- Clear and Separate Pathways: There should be a streamlined regulatory process specifically for bio-inputs (biostimulants, biopesticides, etc.) that distinguishes them from conventional chemical pesticides. This could involve creating a specific regulatory body or a dedicated division within existing bodies.
- Flexible Data Requirements: The design process should include more flexible and clear data requirements that take into account the nature of bio-inputs, such as microorganisms and natural substances, which may not require the same level of scrutiny as synthetic chemicals.
- Harmonized Evaluation: The process should encourage harmonization of guidelines and evaluations across member states to avoid differential interpretations of regulatory requirements.

7.2. Staffing Requirements for Regulatory Authorities

- Increase in Specialized Staff: Regulatory bodies need an increase in specialized personnel who understand the specific needs and risks of bio-inputs. This would require recruiting staff with expertise in biology, microbiology, and environmental science, alongside those familiar with conventional pesticides.
- Training on Bio-Inputs: There should be ongoing training and capacity-building programs to ensure that staff are knowledgeable about the latest developments in bio-input technologies, including microorganisms, natural extracts, and semiochemicals.

- Cross-border Coordination Teams: Teams that work specifically across borders and regulatory zones could help streamline approvals and reduce the redundancy in product evaluations across different member states.
- Resource Allocation: Regulatory authorities will need more resources—both in terms of human capital and technological support—to handle the increasing volume of submissions, particularly as the demand for bio-inputs grows under initiatives like the Farm-to-Fork Strategy.

8. List of references

[1] Farm-to-Fork Strategy of the European Union https://food.ec.europa.eu/horizontal-topics/farm-fork-strategy_en

[2] International Biocontrol Manufacturers Association (IBMA) (accessed 27.07.2024) https://ibma-global.org/wp-content/uploads/2022/06/IBMA-Natural-Substances-Green-Paper-web-single-page.pdf

[3] European Biostimulants Industry Council (EBIC) (accessed 27.07.2024) https://biostimulants.eu/wp-content/uploads/2019/10/EBIC-Brochure-English.pdf

[4] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (accessed 27.07.2024) https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32009R1107

[5] Regulation (EU) 2019/1009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003 - https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32019R1009

[6] European Commission - Guidelines and supporting documents on active substances and plant protection products - https://webgate.ec.europa.eu/dyna2/pgd/sections/283-A

[7] European Union 2021 European Union register of feed additives pursuant to Regulation (EC) No 1831/2003. Annex I, List of additives (Released date 21.09.2021) (accessed 28.07.2024) https://op.europa.eu/en/publication-detail/-/publication/26e4d8a4-1c17-11ec-b4fe-01aa75ed71a1/language-en

[8] CTGB 2024 Low-risk products - Low-risk plant protection products (accessed 20.07.2024). https://english.ctgb.nl/topics/low-risk-products/low-risk-plant-protection-products

[9] Regulation (EU) 1143/2014 of the European Parliament and the council of 22 October 2014 on the prevention and management of the introduction and spread of invasive alien species

[10] Regulation (EU) 2016/2031 of the European Parliament and the council of 26 October 2016 on protective measures against pests of plants, amending amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC

[11] European Union register of feed additives pursuant to Regulation (EC) No 1831/2003. Annex I, List of additives (Released date 21.09.2021, accessed 19.07.2024). https://op.europa.eu/en/publication-detail/-/publication/26e4d8a4-1c17-11ec-b4fe-01aa75ed71a1/language-en

[12] BVL (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit) = Federal Office of Consumer Protection and Food Safety (BVL) 2024 – Zulassung von Futtermittelzusatzstoffen (Notification and approval of feed and foodstuff adjuvants) accessed 20.07.2024. https://www.bvl.bund.de/DE/Arbeitsbereiche/02_Futtermittel/03_AntragstellerUnternehmen/05_Zusatzstoffe_FM/02_Zulassung_Zusatzstoffe/fm__zulassung_zusatzstoffe_node.html;jsessionid=97AD1B17C63B8821BB78EC6FBFABE3BE.internet971?cms_thema=Zulassung+von+Futtermittelzusatzstoffen

[13] BVL (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit) 2024 – Was sind Futtermittelzusatzstoffe? (What are feed additives?) (Overview on their regulation) Accessed 22.07.2024. https://www.bvl.bund.de/DE/Arbeitsbereiche/02_Futtermittel/03_AntragstellerUnternehmen/05_Zusatzstoffe_FM/01_Def_FM_Zusatzstoffe/fm_Def_FM_Zusatzstoffe_node.html

[14] EFSA 2023 Guidance on the assessment of the efficacy of feed additives Accessed 22.07.2024. https://www.efsa.europa.eu/en/efsajournal/pub/8856

[15] EFSA 2024 Feed additives (Overview on their regulation) Accessed 22.07.2024. https://www.efsa.europa.eu/en/applications/feedadditives/regulationsandguidance

[16] EC 2024 Feed additive authorisation - practical guidance document for applicants (accessed 22.07.2024). https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-guidance-applicants_en

[17] EFSA 2024 Food and Feed Information Portal Database (Accessed 23.07.2024). https://ec.europa.eu/food/food-feed-portal/screen/feed-additives/search

[18] UBA 2018 Futtermittel – Übersicht der vom Markt genommenen Zusatzstoffe, Lieferanten.de 2024 Tierfuttermittel direkt vom Großhandel oder Hersteller kaufen (List of distributors of animal feed and foodstuffs) (online, accessed 18-07-2024). https://www.bvl.bund.de/SharedDocs/Downloads/02_Futtermittel/fm_vom-markt-genommen_uebersicht.html;jsessionid=97AD1B17C63B8821BB78EC6FBFABE3BE.internet971?nn=11029054

[19] IBMA Natural Substance Regulatory Group (2023) – Natural substances as plant protection products: Europe is lagging behind. Position paper https://ibma-global.org/wp-content/uploads/2022/06/IBMA-Natural-Substances-Green-Paper-web-single-page.pdf

[20] BioBest Group headquarter 2260 Westerlo, Belgium https://www.biobestgroup.com

[21] Biocare GmbH - Dorfstraße 4 - 37574 Einbeck / Düsterweg 3, 37586 Dassel https://biocare.de/

[22] e-nema GmbH - Klausdorfer Str. 28-36 - 24223 Schwentinental https://www.e-nema.de/

[23] Koppert B.V. - Veilingweg 14 - 2651 BE Berkel en Rodenrijs - The Netherlands. (accessed 18-07-2024) https://www.koppert.com/

[24] W. Neudorff GmbH KG - An der Mühle 3 - 31860 Emmerthal – Germany (accessed 18-07-2024) https://www.neudorff.com

[25] Andermatt – Stahlermatten 6- 6146 Grossdietwil – Switzerland (accessed 27-08-2024) https://www.andermatt.com/

[26] Bayer//global 2024 Agriculture Biologicals - Innovation Inspired by Nature (accessed 22-07-2024) https://www.bayer.com/en/agriculture/agriculture-biologicals

[27] BASF 2024 Crop protection and seeds - BioSolutions (accessed 22-07-2024) https://agriculture.basf.com/global/en/business-areas/crop-protection-and-seeds/BioSolutions.html

[28] Marrone, P.G. 2024. Status of the biopesticide market and prospects for new bioherbicies. Pest Manag Sci 80: 81-86

[29] Fraunhofer Institute for Interfacial Engineering and Biotechnology IGB https://www.igb.fraunhofer.de/en.html

[30] Institute for Biological Control of the Federal Research institute for Cultivated Plants (Julius Kühn-Institut https://www.julius-kuehn.de/bi

[31] University of Hohenheim, Faculty of Agricultural Sciences https://agrar.uni-hohenheim.de/en

[32] University of Gießen, Department of Phytopathology https://www.uni-giessen.de/en/faculties/f09/institutes/phyto

[33] Bayer AG and the Jülich Research Centre 2024 Phenotyping for Products - a strategic research alliance – a research cooperation between Bayer AG and the Jülich Research Centre https://biooekonomie.de/nachrichten/neues-aus-der-biooekonomie/bayer-und-juelicher-forscher-formen-wurzel-allianz

[34] BVL (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit) = Federal Office of Consumer Protection and Food Safety (BVL) 2024 Liste der für Futtermittel zugelassenen Zusatzstoffe (List of feed supplements authorized for use in feed) https://www.bvl.bund.de/DE/Arbeitsbereiche/02_Futtermittel/03_AntragstellerUnternehmen/05_Zusatzstoffe_FM/03_Liste_zugelassene_Zusatzstoffe/fm_liste_zugelassener_zusatzstoffe_node.html

[35] EFSA 2024 EU Pesticides Database - Active substances, safeners and synergists (Accessed 24.07.2024) https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/start/screen/active-substances

[36] BVL (2024) Safe animal feed – who does what? Accessed 17.07.2024 https://www.bvl.bund.de/EN/Tasks/02_Feed/01_Tasks/tasks_node.html

[37] BVL (Bundesamt für Lebensmittelsicherheit = Federal Office for Food Safety) 2024 Liste der für Futtermittel zugelassenen Zusatzstoffe (List of additives authorized for animal feed) https://www.bvl.bund.de/DE/Arbeitsbereiche/02_Futtermittel/03_AntragstellerUnternehmen/05_Zusatzstoffe_FM/02_Zulassung_Zusatzstoffe/fm__zulassung_zusatzstoffe_node.html;jsessionid=97AD1B17C63B8821BB78EC6FBFABE3BE.internet971?cms_thema=Zulassung+von+Futtermittelzusatzstoffen

[38] Lieferanten.de 2024 Landwirtschaftsdünger direkt vom Großhandel oder Hersteller kaufen (List of distributors of agricultural fertilizers) (online, accessed 18-07-2024) https://www.lieferanten.de/produkt-Landwirtschaftsduenger.html

[39] Lieferanten.de 2024 Tierfuttermittel direkt vom Großhandel oder Hersteller kaufen (List of distributors of animal feed and foodstuffs) (online, accessed 18-07-2024) https://www.lieferanten.de/produkt-Tierfuttermittel.html?log=true

[40] Targos R. / agribusinessglobal.com 2024 Latest News (Articles, accessed 23.07.2024) https://www.agribusinessglobal.com/biopesticides/bayer-aims-to-launch-first-bioinsecticide-for-arable-crops/ https://www.agribusinessglobal.com/biopesticides/peptide-based-bioinsecticide-receives-emergency-use-authorization-in-italy-for-control-of-tomato-leafminer-infestations/

[41] USDA (U.S. Department of Agriculture) 2024 Integrated Pest Management (online, accessed 18-07-2024) https://www.usda.gov/oce/pest/integrated-pest-management

[42] Bayer 2024 FinAL – project on Integrated pest management (accessed 23.07.2024) https://www.final-projekt.de/en/landscape-transformation/integrated-pest-management

[43] Bayer Agrar Deutschland 2024 Meine Beratung... (accessed 23.07.2024) https://agrar.bayer.de/Regionales/Ansprechpartner

[44] Landwirtschaftskammer NRW 2024 Beratungsangebot – von Profis für Profis (Landwirtschaftsberatung – Kontaktformular) (accessed 23.07.2024) https://www.landwirtschaftskammer.de/landwirtschaft/angebot/

[45] Degner, J. 2021 Ackerbaubetriebe: Ost und West im Vergleich. Bauernzeitung (online, accessed 19-07-2024) https://www.bauernzeitung.de/news/ackerbaubetriebe-west-und-ost-vergleich/

[46] Crunchbase.com 2024 Germany Agriculture Companies (accessed 23.07.2024) https://www.crunchbase.com/hub/germany-agriculture-companies

[47] Wirth, H. (1994). Ostdeutsche Genossenschaftsbauern-Westdeutsche Landwirte. Agrarische Lebensweisen im Vergleich, Gegenwartskunde, (1), 27-40. (accessed 17.07.2024) https://www.gesis.org/gml/about-gml/forschung/ost-west-vergleich

[48] Hirte K. 2002 Die ostdeutschen Landwirte und die Wende. Die Entwicklung der ostdeutschen Landwirtschaftsstrukturen ab 1989 am Beispiel Thüringen. University Press Kassel, ISBN: 978-3-933146-96-0, (accessed 17.07.2024) https://www.researchgate.net/publication/360997528_Die_ostdeutschen_Landwirte_und_die_Wende_Die_Entwicklung_der_ostdeutschen_Landwirtschaftsstrukturen_ab_1989_am_Beispiel_Thuringen

[49] Schmidt, K. (Ed.). (2009). Landwirtschaft in der DDR: VEG, LPG und Kooperationen: wie sie wurden, was sie waren, was aus ihnen geworden ist. Agrimedia. (accessed 17.07.2024) https://www.deutsche-digitale-bibliothek.de/item/VNV3VNY5UO6EULKD7AFJ3V5T4VZ3RIBH

[50] Bundesministerium für Ernährung und Landwirtschaft (BMEL) 2024. Bio-Strategie 2030 – Nationale Strategie für 30% ökologische Land- und Lebensmittelwirtschaft bis 2030. www.bmel.de/publikationen

[51] Bundesministerium für Ernährung und Landwirtschaft (BMEL) 2021. Jahresbericht 2021 Nationaler Aktionsplan zur Anwendung von Pflanzenschutzmitteln. https://www.bmel.de/DE/themen/landwirtschaft/pflanzenbau/pflanzenschutz/aktionsplan-anwendung-pflanzenschutzmittel.html

[52] https://www.mordorintelligence.com/de/industry-reports/german-biopesticides-market

[53] Assessment of a feed additive containing *Enterococcus lactis* NCIMB 11181 (Lactiferm®) for weaned piglets, calves for fattening and calves for rearing for the renewal of its authorisation (Chr. Hansen A/S) (accessed 20.07.2024) https://www.efsa.europa.eu/en/efsajournal/pub/8466

[54] EC 2024 Latest updates on Active substances - Basic Substance *Onobrychis viciifolia* (sainfoin) dried pellets - Reg. (EU) 2024/1768 of 27/06/2024 (accessed 23.07.2024) https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/start/screen/active-substances/latest

[55] Annex VI of Reg. 2229-2004 (p. 9 therein) Criteria for clear indications of no harmful effects (accessed 24.07.2024) https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32007R1095

[56] Expatrio 2024 German dual Apprenticeship system. Online (accessed 23.07.2024) https://www.expatrio.com/about-germany/german-dual-apprenticeship-system

[57] Raiffeisen 2024 Raiffeisen-Düngershop - Raiffeisen Rhein-Ahr-Eifel Handelsges. mbH - Standort Ormont - Ulmenstraße 4 - 54597 Ormont (accessed 23.07.2024) https://www.raiffeisen-duengershop.de/produkt-kategorie/feste-duenger/

[58] Regulation (EC) No. 852/2004 of Regulation of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1–54) (accessed 15.07.2024) https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32004R0852

[59] Regulation (EC) No. 853/2004 of Regulation of 29 April 2004 laying down specific hygiene rules for food of animal origin. OJ L 139, 30/04/2004, p. 55-205 (accessed 15.07.2024). https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:32004R0853

[60] Landwirtschaftskammer Schleswig-Holstein 2024 Futtermittelpreise - Zukaufpreise Einzel- und Mischfuttermittel frei Hof, (online, accessed 22.07.2024) https://www.lksh.de/landwirtschaft/markt/futtermittelpreise/