



NATURAL SUBSTANCES AS PLANT PROTECTION PRODUCTS: EUROPE IS LAGGING BEHIND

IBMA NATURAL SUBSTANCES REGULATORY GROUP

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Summary

Aim...

...was to compare the regulatory framework for natural substances used as bioprotectants in Australia, Brazil, the EU, and the US and draw policy recommendations for the EU to enable natural substance authorisation.

Results...

...showed that the EU is the only of these regions without clear data requirements specifically for registration of natural substances.

Natural substances are currently being assessed under the regulatory framework developed for conventional plant protection products in the EU.

Based on these findings, will conclude with policy recommendations are proposed for the EU.

Definitions

Bioprotectants have their origin in nature and should cause no harm to humans and have minimal impact in the environment. Bioprotectants include, in particular, macro-organisms (invertebrate biocontrol agents) and plant protection products containing micro-organisms, semio-chemicals (such as pheromones and kairomones), and natural substances of plant, animal or mineral origin.

Natural substances that consist of one or more components that originate from nature, including but not limited to: plants, algae/micro algae, animals, minerals, bacteria, fungi, protozoans, viruses, viroids and mycoplasmas. They can either be sourced from nature or are nature identical if synthesized. This definition excludes semio-chemical and microbials.”

Conventional chemical pesticide synthetic protectants that do not originate from nature.

Europe in the title is generally referring to the EU and EU processes for PPP approval.



Introduction

Several global and regional initiatives exist to promote market access for plant protection products containing bioprotectants.

Some countries and regions have policy plans to limit the use of conventional chemical pesticides e.g. the EU which is targeting the reduction of conventional chemical pesticides by 50% by 2030.

Other countries do not have restrictions on conventional chemical pesticides but promote the registration of innovative bioprotectants with a tailor-made regulatory system that matches the characteristics of these low hazard substances.



Introduction – Natural substances

Natural substances can provide effective pest management in plant protection with key advantages, such as a more sustainable protection against the pest.

They can support farmers in reducing chemical pesticide inputs in crop production while still maintaining yield, potentially transforming the food system.

Previous studies have mainly compared different regulatory systems for microorganisms in multiple regions. Some of these recognise methodology difficulties of comparing different regulatory frameworks due to differences in market and authority size required to enable different regulatory frameworks. Interpretation from previous studies is that there is no one ideal regulatory system. From the available literature targeted bioprotectant regulations are not suitable for all bioprotectants (e.g. natural substances).

The EU does not have a separate framework for bioprotectants when compared with regions of similar, or even smaller, sizes due to its complex regulatory system.



Introduction – Scope

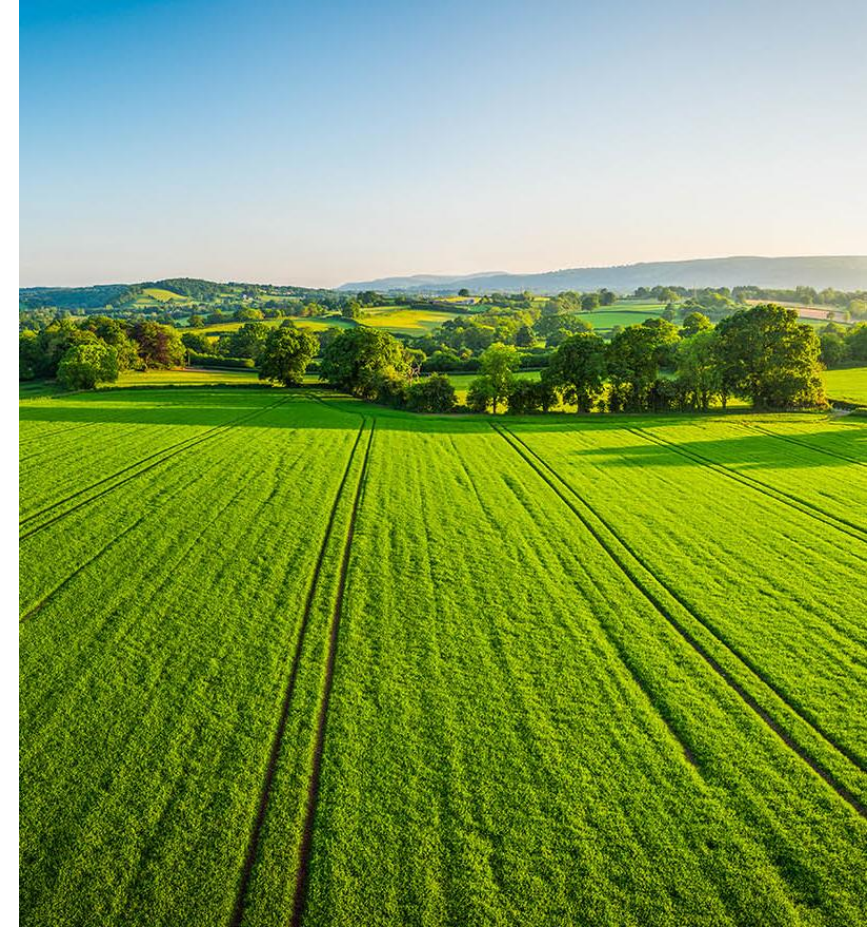
As most publications focus on micro-organisms or specific groups of natural substances, general statements are difficult to draw from published literature. This study specifically covers natural substances as a general group and to our knowledge, this is the first study to do so. Here we compare the regulatory framework for natural substances for plant protection uses in selected countries or geographic regions:

Australia, Brazil, EU and US

This is done by:

1. Comparing data requirements within the respective frameworks
2. Analysing key performance indicators of the different systems

Aim from this analysis was to create a structured policy framework to improve the registration process in the EU for natural substances



Methodology – A comparative approach

COMPARISON OF DATA REQUIREMENTS

The objective of this comparison was to review the regulatory processes in different regions.

This done by defining questions from manufacturers of natural substances, and posing the questions for each selected region: Australia, Brazil, EU and US.

Group members with relevant expertise were tasked to answer questions based on their experience, and interviews with regional experts and authorities.

If contradictory responses were found, clarification was sought, and if this was not possible, they were omitted from the assessment.

KEY PERFORMANCE INDICATORS

One of the KPIs of a regulatory system is the availability of natural substances expressed as a number of active substances available to farmers in different regions or countries.

To compare numbers of registered natural substances in the EU and US as two major regions with comparably large population sizes, we followed a stepwise approach.

As a first step, all available registrations were extracted.

Comparing key requirements in EU, USA, Brazil & Australia

18 questions applied to each region, divided into 5 groupings...

1. GENERAL

Q. Is there a Natural Substance framework / legislation available?

2. PROCEDURES, FEES & TIMELINES

Q. How much does an a.s. registration cost and what is the registration timeline?

3. DATA REQUIREMENTS

Q. Is there a specific set of data requirements?

4. EFFICACY

Q. Are there specific guidance documents?

5. MRL/RESIDUES

Q. Are natural substances excluded from MRL setting?



Methodology – A comparative approach

In the US, the EPA has a specific biopesticide list of the registered a.i.'s following the EPA definition. This was extracted from the EPA website mid-2019 and all registrations up to the end of 2018 were categorized as being natural substances according to the IBMA definition.

Such a biopesticide list was not available for the EU.

For the EU, the authors extracted all registered active substances in mid-2019, which were then compared with the EPA list characterized and categorized as being natural substances according to the IBMA definition.

If possible, the assessment was also cross-checked with the France biocontrol list to double check if any entries were missed.

Based upon the expert knowledge of the IBMA Natural Substances Regulatory Group, these trends of available solutions in the EU and US remain valid or have become even more pronounced due to the UK leaving the EU and resulting bottlenecks in other EU members for available submission slots.



Regulatory process and data requirements in different regions

After reviewing registration processes in the selected regions it was found that US, Brazil and Australia have a framework for natural substances, which is different from that used for the conventional chemical pesticide the EU does not.

USA EPA has an established body (Biochemical Classification Committee) where applicants can establish if their substance falls under the dedicated framework.

In the other regions this information flow appears to be more ad-hoc and does not follow a similar structured process.

The EU was found to be the only region without clear dedicated framework for natural substances nor has it established any process whereby they can be considered as such.

Australia, Brazil and USA in addition to having a framework for natural substances also have data requirements for natural substances.

In the EU applicants need to follow the data requirements for conventional agrochemicals although it is mentioned in the data requirements that for plant extracts and semio-chemicals either “justified exemptions can be made” or “a different approach may be taken if adequately justified”.

Fees

The regulatory fees, expressed in US dollars, in Brazil and US are comparable at approximately 20K whereas for Australia the fees are 47K.

The situation for the EU is not transparent as different MS have different fees. In addition, the costs depend on the particular RMS, potentially the co-RMS and possible fees for MS to comment on the initial assessment.

Two examples: The registration of a new a.s. using Germany as RMS can cost up to **686K**. In the NLs the fee is circa **105K** if we assume the fees for “active substance based on low-risk substances, microorganisms, pheromones or a comparable substance” otherwise the fees in the NLs would be **267K**.

As a generalization, the study concluded fees in the EU are higher than other regions and countries.



Timelines

All regions state that they have defined timelines for evaluation.

In the US, Brazil and Australia, timelines are applicable that differ from conventional chemical pesticides. However, the exact legal timelines also depend on parameters such as an assessment of residue studies and whether a tolerance / maximum residue level setting is needed.

In the EU, as it does not have a dedicated natural substance pathway, dossier evaluations follow the timeline of conventional chemical pesticides, but these are often not followed and take significant longer.



Key performance indicators: number of registered natural substances

The starting point for the numerical analysis was the agreement on and use of the IBMA definition of natural substances.

Based on this definition, it is possible to give absolute numbers of registered natural substances between the two regulatory jurisdictions USA and EU.

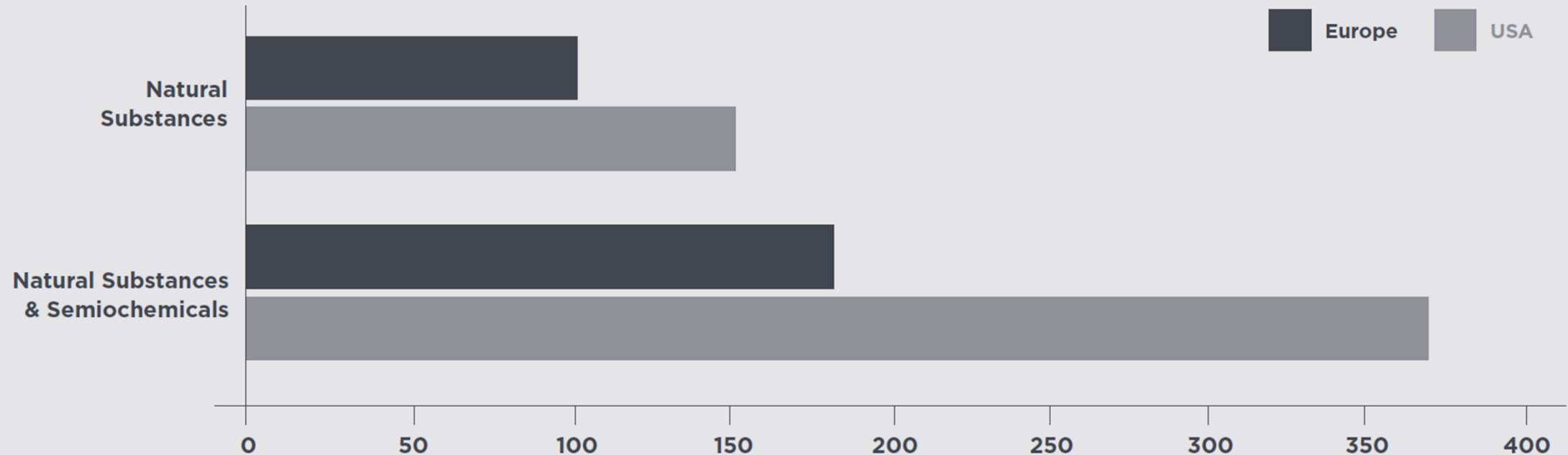
The EU Commission's database of active substances approved for plant protection contains a total of 479 active substances (mid-2019). According to the IBMA definition around 37% (176) may be regarded as natural substances & semio-chemicals. This list is reduced to a subset of 98 natural substances (without semio-chemicals).

It is of interest to compare this subset of natural substances with the other subset, micro-organisms (species and strains) which totals 99, that is often cited as the most significant component of the bioprotectant sector, and have been prioritised in both existence of, and review of, specific data requirements.

In the US, the demarcation within the EPA database of approved active substances for "biopesticides" uses identifies 365 as natural substances & semio-chemicals. Of this 40% (149) fit the IBMA definition of a natural substance, 62 are common between the two (EU/USA) jurisdictions, 87 are specific to the US only.

Number of registered natural substances

Figure 1: Number of Natural Substances as defined by the IBMA definition and the total number of Natural Substances & Semiochemicals in Europe (Dark Grey) and USA (Light Grey)



Key performance indicators: number of registered natural substances

What is the explanation for the startling difference in numbers between the EU and US?

Comparison of the range of crops and growing conditions between the US and the EU is not the answer.

The regulatory system in the US to bring products to the market is faster and thus expediting growers' access compared to the EU.

The US system allows for identification of substances of natural origin early in the process, facilitating an appropriate level of regulatory compliance for these types of compounds. The EU system, beyond specific microbial requirements, does not.

The current EU system has high costs, a convoluted process and lengthy unrespected timelines for evaluations of natural substances.

The commercial disadvantage between the EU and US industry and growers is keenly felt, and while there may be good intention amongst the EU regulatory community to bring change to address, this disparity there is thus far little hard evidence to demonstrate that the EU plant protection product approval process is being better redesigned in this respect.

Conclusions

Natural substances are a highly diverse group of substances. This diversity is also reflected in the different definitions that are used.

Most regulatory frameworks examined recognize the differences between conventional chemical pesticides and natural substances in terms of a more favourable safety profile, their specific mode of action and faster biodegradability.

The EU, with its lack of a specific regulatory framework for natural substances, is the exception compared to Australia, Brazil & USA. Even if there is a natural substance specific regulatory framework, data requirements and study recommendations for natural substances are often not suitable or not validated due to their diversity. Even if studies are required and conducted, the risk assessment and evaluation criteria are not laid down in legislative documents and can be subject to subjective evaluation.

There are however strong regional differences in both the number of active substances that are registered as well as the data requirements and clarity in the data requirements for natural substances. Compared to the US, the EU has a reduced number of registered natural substances and ranks high in the uncertainty level on the data requirements. Regulatory unpredictability, high costs and long approval timelines impact investments and how industry select projects and target markets.

Recommendations

To be able to make more natural substance based products available to farmers faster it is important to improve the regulatory system in all regions and countries.

Agricultural production efficiency need not compromise safety to humans and the environment from products and practices. To kick-start this process, based on the study findings, suggest the following actions:

Clear regulatory definitions and processes to classify natural substances are needed. In the literature overview and the review of the different regulatory schemes, it became clear that there are globally different definitions for natural substances. Some definitions are based on mode of action, some on origin, some on risk, some on a mixture of parameters. Some regions have no clear definition of natural substances. We recommend internationally harmonized definitions of the different classes of bioprotectants, the IBMA definitions would be a good starting point.

EU guidance for natural substances. Currently they can only be evaluated under Regulation (EC) No 1107/2009 with data requirements for conventional chemical pesticides. For active substances that are semio-chemical or botanicals, there is specific non-binding guidance, and the process seems to be a bit smoother, but both still suffer from long timelines, high fees and unclear data requirements and exposure calculations.

Recommendations

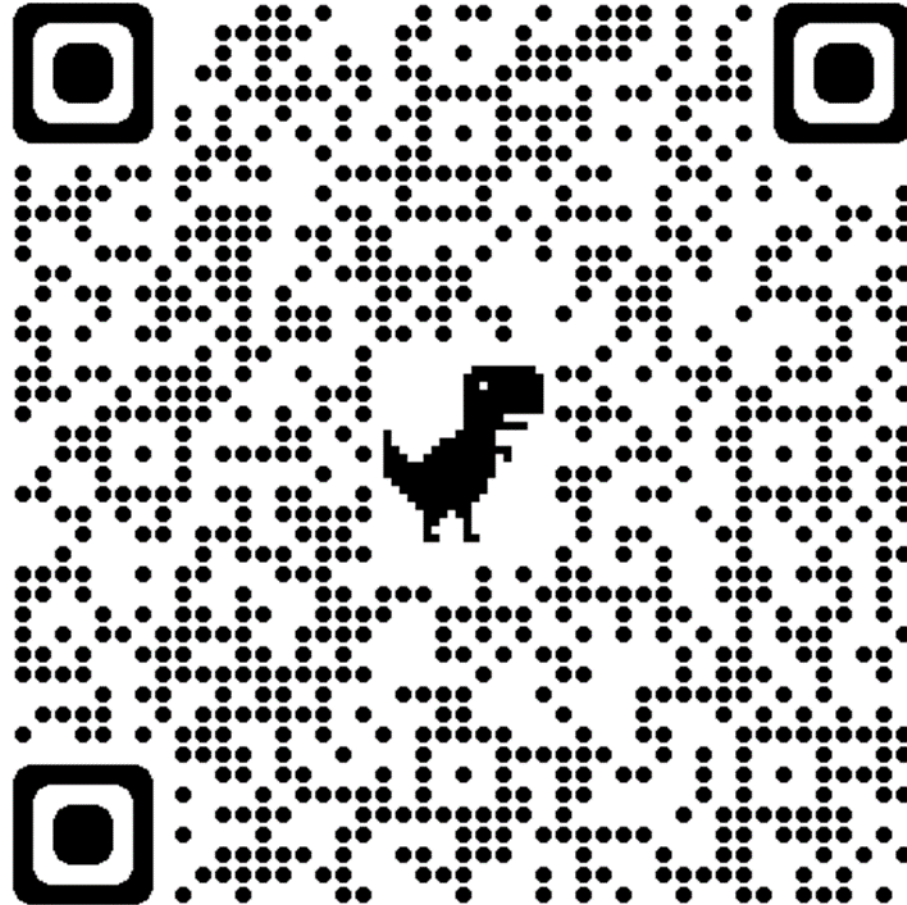
Resources are dedicated for enhancing the capacity and capability of RMS and other EU bodies to assess applications for natural substances.

The establishment of a separate fast-track evaluation, authorization and registration process for natural substances and products, as stressed by the European Parliament in its resolution of 13 September 2018.

The scientific assessment can be based on IBMA Decision Trees. As a large number of the new natural substances are developed by SMEs, this fast-track evaluation process should be complemented by reduced registration fees in order to promote and ease the development of natural substance products.

- These points need attention for an urgent solution.
- Propose a quick and long-term solution.
- As a quick fix and using the IBMA Decision Tree (under publication) as an intermediate tool, we recommend development of a natural substance guidance document. A long-term solution to avoid the current bottlenecks which are experienced, we recommend a detailed set of data requirements as part of a dedicated biocontrol substance regulation.

Scan here – Find the full analysis as a green paper



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