



**Dunham Trimmer**<sup>®</sup>  
International Bio Intelligence

Where is the Market for  
**Plant Growth Regulators**  
(PGRs) Going in the Face of  
**Evolving Regulations**  
in the US and EU?

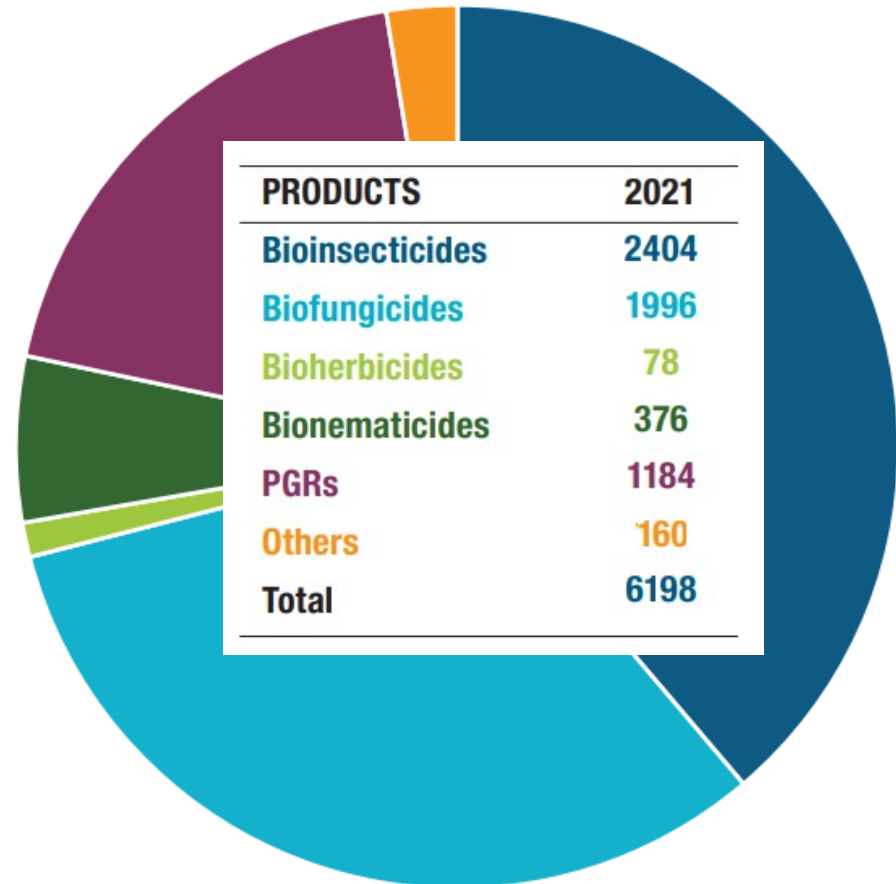
February 22, 2023  
Reno, Nevada



Rick Melnick, Dunham Trimmer  
Vice President, Global Business

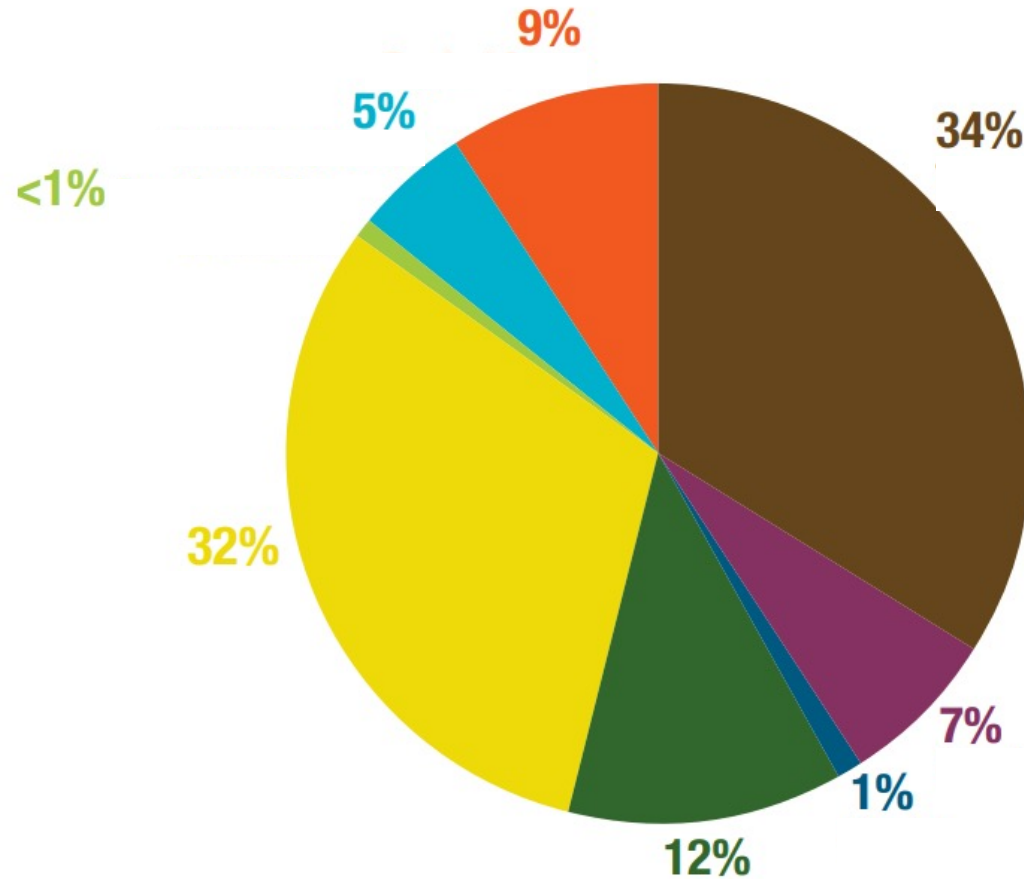
# Global Biocontrol Market 2021

Shares by Use Segment



# Global PGR Market 2021

## Shares by Crop Group





# Valent BioSciences and Our PGR Portfolio

Ted Melnik



# Sumitomo Chemical & Valent BioSciences



- Valent BioSciences is the biorational and biostimulant business of Sumitomo Chemical Company
- Sumitomo Chemical is a global leader in creative solutions for health and crop science and delivers on its promises:
  - Proven reliability
  - Steadfast quality control
  - Commitment to society and the environment for centuries
- Valent BioSciences operates with a Sumitomo Spirit mindset of Jiri Rita - striking a balance between our business interests and that of society

# Valent BioSciences' Biorational Portfolio

*Biorational Crop Enhancement*



Quality, Yield, & Stress Management

*Biorational Crop Protection*



Foliar Insect & Disease Protection

*Biorational Rhizosphere*



Plant & Soil Health, Bionematicide, Biofungicide

*Public Health & Forest Health*



Vector Control, Forest Protection



*Pace International*



Sustainable Postharvest Products

# Valent BioSciences' Centers of Operation

**Biorational Research  
Center, SynBio Hub  
and Global Headquarters**  
Libertyville, IL



**Valent BioSciences  
Osage Manufacturing**  
Osage, IA



**Mycorrhizal Applications**  
Grants Pass, OR



**Pace International**  
Wapato, WA



**Mycorrhizae & Root Imaging  
Danforth Center**  
St. Louis, MO



**Health & Crop Sciences  
Research Laboratory**  
Takarazuka, Japan

# Fermentation Plant in Osage, Iowa

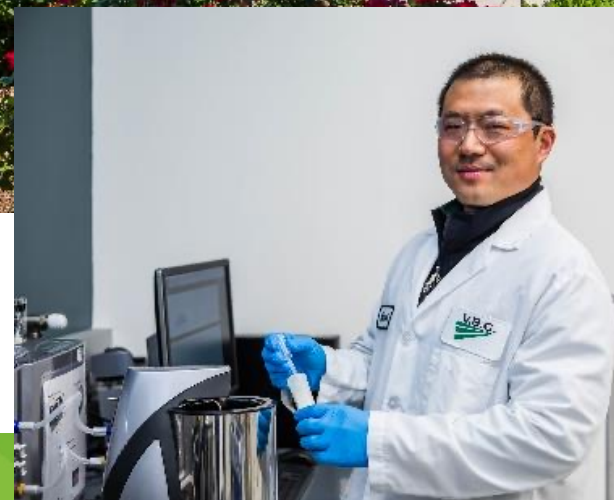
- Began production in 2014 with multiple 100,000 liter scale fermenters
- Our second expansion will be completed in mid-2024 (additional fermentation and recovery equipment, new pilot plant and expanded laboratory space)
- Home to two major sustainability initiatives:
  - 12-acre solar field that offsets some of the facility's energy usage
  - 34-acre prairie reconstruction supports diverse plant and wildlife habitat





# Biorational Research Center and Headquarters

- Opened in 2018 in Libertyville, Illinois
- Global headquarters opened in 2020
- Includes numerous research areas
- First major R&D expansion for lab space, pilot fermentation and greenhouse will be completed in early 2024



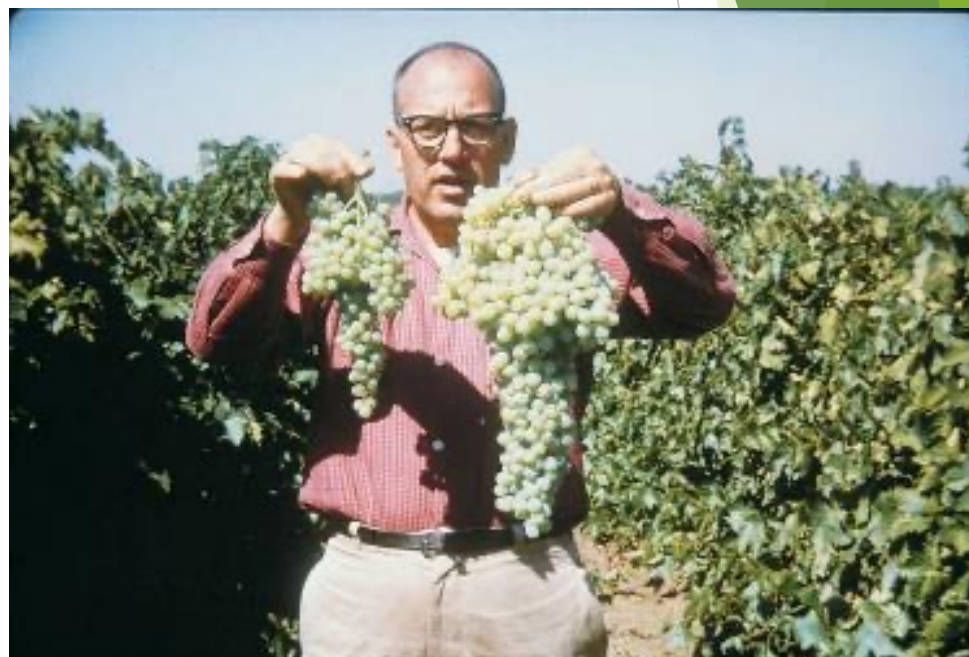
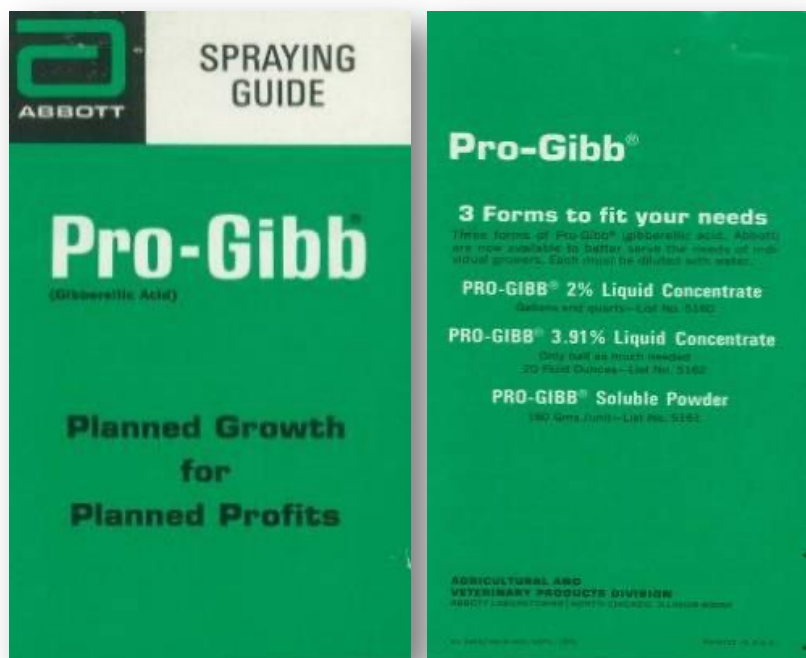
# FBSciences Acquisition

- Valent BioSciences announced the acquisition of FBSciences in January
- FBSciences is a leader in discovering and commercializing crop health technologies
- Products include biostimulants, biopesticides, and crop nutrition for seed, soil, and foliar applications
- Expands biostimulant product family and broadens integrated biorational product portfolio
- Accelerates Valent BioSciences' strategy to bring sustainable technologies and products to growers



# It All Started with ProGibb® on Grapes

## 1962 ProGibb Label and Spray Guide



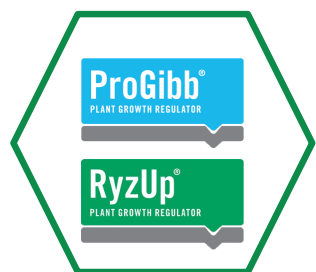
# Plant Growth Regulators: Benefits for Growers

PGRs precisely influence plant physiology to:

- Improve fruit and grain quality
- Optimize crop management (saving labor, equipment)
- Maximize nutrients and water utilization
- Manage biotic and abiotic stress
- Modify crop cycle (germination, senescence)



# Valent BioSciences Has Commercial Products in Each of the 5 Classic Classes of PGRs



## Gibberellins

Plant & Fruit  
Development And Size  
Seed Germination  
Crop and Fruit Quality



## Cytokinins

Fruit Abscission  
Fruit Size  
Branch Initiation



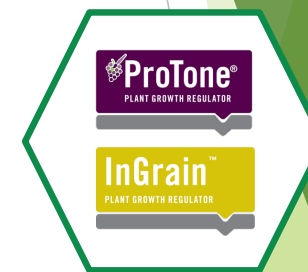
## Auxins

Fruit Thinning  
Fruit Drop Prevention  
Improve Return Bloom



## Ethylene

Fruit Ripening  
Flowering Induction  
Harvest Management  
Fruit Drop Prevention  
Fruit Set



## Abscisic Acid

Grapes Color  
Development  
Carbohydrate  
Manipulation  
Stress Management

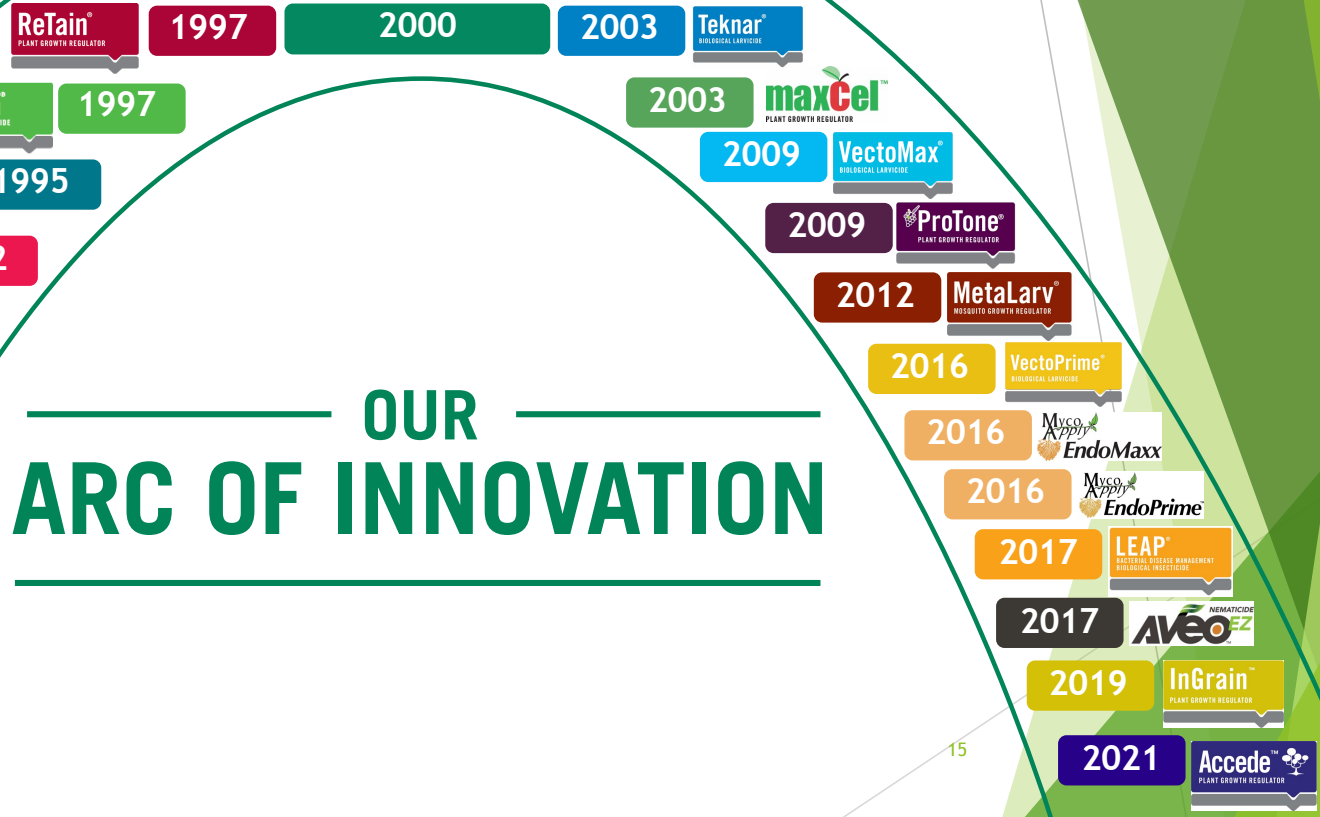
# Next-Gen Fruit Thinner

The Next Game-Changing Plant Growth Regulator



- **Apples:** First commercial product for late-season thinning
- **Stone Fruit:** First commercial thinning product
- **Grapes:** Ethephon replacement / partner with ProTone® Plant Growth Regulator





OUR  
**ARC OF INNOVATION**

15



**Thank you!**





# The future of Plant Growth Regulators (PGRs) in the US

2023 BPIA Annual Meeting  
Reno, Nevada

Kelly Rahn, Managing Director, State Affairs  
TSG Consulting



## EPA's draft guidance

- EPA's Draft Guidance for Plant Regulator Products and Claims, Including Plant Biostimulants
  - Pivotal document generated because of category overlaps
  - Never finalized
  - Updated guidance issued with softer stance on active ingredients
  - Never finalized but used by the states as a reference for determining whether a biostimulant is really a PGR





## PGR determination

Products that alter the physiological aspects of a plant in order to change a characteristic of the plant are PGRs as opposed to products that stimulate the natural process of the plant

### Categorization factors:

- The claims being made
- The mode of action of the active ingredient
- The amount of active ingredient used



## Sample claims of PGRs vs biostimulants

PGR claims	Biostimulant claims
Enhances/promotes/stimulates fruit growth & development	Optimizes nutrient use efficiency
Induce/promote/retard/suppress bud break	Enhances/aids/supports/helps microbial populations
Fruit and nut thinner/sizer	Improves overall plant nutrition





## Some active ingredients are dual use

- Substances that have no significant use other than as a PGR include corn glutens, GABA, Brassinosteroids, LPE, 1-Octanol and 3 nitrophenolates
- Regardless of the claims being made, the products must be registered as PGRs
- EPA recognizes that other substances, like seaweed extract, may have non-PGR uses but the burden of proof lies with the registrant



## Path to registration

- PGR's path to registration is through EPA's BPPD, followed by state registrations
  - PGRs are tolerance exempt (with the exception of the auxin, 1-naphthalene acetic acid and salts)
- EPA – New product and need to address tolerance - \$14,074 and 13 months
- EPA – New product, tolerance previously established, \$5,632 and 7 months
- “51” states – all products - \$18,000 and majority issued within 4 months or less
- CA can take significantly longer, especially if the data has an ecotox volume



## Pros and cons of PGR registration

### Pros

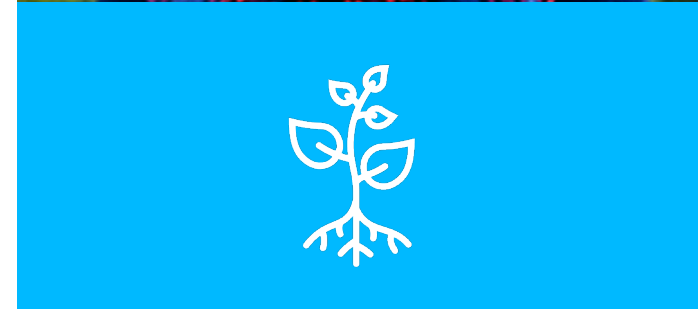
- Ability to make stronger claims
- Clear regulatory landscape which is straightforward to navigate

### Cons

- Cost and timing of federal registration

### A word to the wise

- Consider the global market potential during the data development stage



# Thank you

Questions?

Get in touch: [kelly.rahm@tsgconsulting.com](mailto:kelly.rahm@tsgconsulting.com)

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# PGRs and the EU Fertilising Products Regulation

Dr Alison Hamer

Partner, ERM

Product Stewardship and Regulatory Affairs

BPIA 2023 Annual Meeting

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# Sustainability is our business



## We are the world's largest pure play sustainability consultancy

Founded in 1971, we are the largest advisory firm in the world focusing solely on sustainability, offering unparalleled depth and breadth of expertise.

## We shape a sustainable future with the world's leading organizations

Our purpose guides everything we do. We create a better future by helping the world's biggest brands address today's sustainability imperatives.

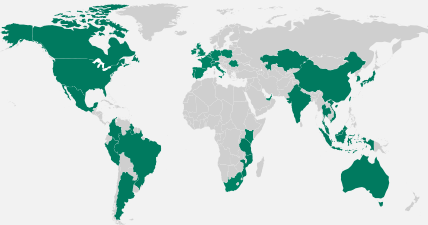
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Numerous industry benchmarks attest to our market leadership and the majority of our work is sole-sourced, reflecting trusted partnerships we build with our clients.

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Offices

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experience

We partner with...

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Fortune 500

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service provider  
– HFS 2022

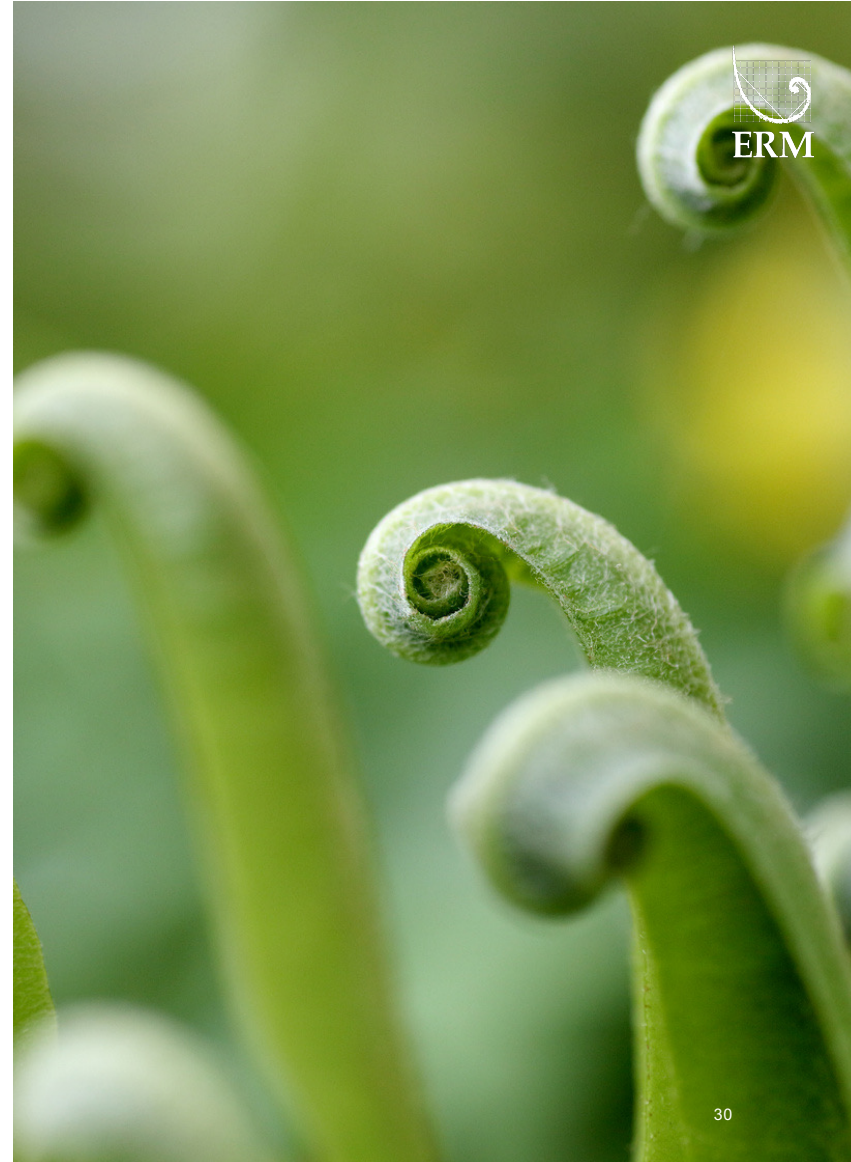
**“The end-to-end provider  
of ESG and sustainability  
consulting services”**  
– Verdantix Green Quadrant 2022

# Topics

The European Regulations

Regulatory pathways for Plant Growth Regulators

Towards a More Sustainable Future



# The European Regulations





## Which regulatory routes for PGRs?

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2019/1009 or 1107/2009?

Let's look at definitions  
and scope

# The 'Fertilising Products Regulation' (EU) 2019/1009

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Into force June 2019, applicable July 2022

Regulation not mandatory, national norms still valid

A FP complying with the Regulation and approval from a notified body **allowed to move freely on the internal market** and **eligible for CE marking**

Biostimulant definition is mirrored in Article 3 of 1107/2009

Differentiation based on the **effects claimed on the label**

## PFC 6: PLANT BIOSTIMULANT

1. A plant biostimulant shall be an EU fertilising product the function of which is to stimulate plant nutrition processes independently of the product's nutrient content with the sole aim of improving one or more of the following characteristics of the plant or the plant rhizosphere:
  - (a) nutrient use efficiency,
  - (b) tolerance to abiotic stress,
  - (c) quality traits, or
  - (d) availability of confined nutrients in the soil or rhizosphere.

# The Plant Protection Products Regulation (EC) 1107/2009



- Relates to placing PPP on the market in Europe
- Entered into force June 2011
- Mandatory process of
  - approving active substances by the European Commission
  - and then authorising plant protection products by the Member States
- Supported by much subsidiary pesticides legislation and aligned with legislation running parallel to 1107/2009

24.11.2009	EN	Official Journal of the European Union	L 309/1
I			
(Acts adopted under the EC Treaty/Euratom Treaty whose publication is obligatory)			
REGULATIONS			
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			
THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	Parliament by its Resolution of 30 May 2002 <sup>(*)</sup> and the Council in its Conclusions of 12 December 2001 asked the Commission to review Directive 91/414/EEC and identified a number of issues for the Commission to address.		
Having regard to the Treaty establishing the European Community, and in particular Article 37(2), Article 95 and Article 152(4)(b) thereof,	(3)	In the light of the experience gained from the application of Directive 91/414/EEC and of recent scientific and technical developments, that Directive should be replaced.	
Having regard to the proposal from the Commission,	(4)	By way of simplification, the new act should also repeal Council Directive 79/117/EEC of 21 December 1978 prohibiting the placing on the market and use of plant protection products containing certain active substances <sup>(*)</sup> .	
Having regard to the opinion of the European Economic and Social Committee <sup>(*)</sup> ,	(5)	To simplify application of the new act and to ensure consistency throughout the Member States, it should take the form of a Regulation.	
Having regard to the opinion of the Committee of the Regions <sup>(*)</sup> ,			
Acting in accordance with the procedure laid down in Article 251 of the Treaty <sup>(*)</sup> ,			
Whereas:	(1)	Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market <sup>(*)</sup> provides for rules governing plant protection products and the active substances contained in those products.	
	(6)	Plant production has a very important place in the Community. One of the most important ways of protecting plants and plant products against harmful organisms, including weeds, and of improving agricultural production is the use of plant protection products.	

# Active Substances and Plant Protection Products

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- An **Active Substance** is any chemical, plant extract, pheromone or micro-organism that has action against 'pests' or on plants, parts of plants or plant products
- A **Plant Protection Product** must contain at least one active substance and have one of the following functions:
  - protect plants or plant products against pests/diseases, before or after harvest
  - **Influencing the life processes of plants, such as substances influencing their growth, other than as a nutrient or a plant biostimulant**
  - preserve plant products
  - destroy or prevent growth of undesired plants or parts of plants
  - Check or prevent undesired growth of plants

## Low-risk substances

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- Part of Regulation 1107
- Compatible with Green Deal and Farm to Fork objectives
- Article 22 of Regulation 1107 - defines low-risk criteria
- Approved for up to 15 years (incentive!)
- Shorter evaluation time for products, longer data protection (incentive!)
- Low-risk products (Article 47) face additional hurdles to ensure low-risk product status



# How many PGRs are low-risk substances?

**454 approved active substances in total**

74 are micro-organisms

60 (ish) are 'natural substances'

63 are **low-risk** active substances

- 24 of these are **micro-organisms**
  - Insecticides, nematicides and fungicides
  - None have **PGR claims** in their representative uses
- 39 of these are **conventionals** and **natural substances**
  - Some have **PGR claims** in their representative uses



The screenshot shows the European Commission's EU Pesticides database search interface. The page title is "Search Active substances, safeners and synergists". The breadcrumb trail is "European Commission > Food Safety > Plants > Pesticides > EU Pesticides database > Active substances". The search options are set to "Type: Low risk Active substance" and "Status: Nothing selected". The search results show "Active substances, safeners and synergists (63 matching records)" and an "Export Active substances" button. A search bar at the top right contains the text "Search" and a "Search" button.

# Low-risk PGRs in scope of PPP Regulation 1107/2009

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## Gibberellins

- *Gibberellic acid* approved
- *Gibberellins* approved

## Cytokinins

- *6-Benzyladenine* approved

## Auxins

- *Indolylacetic acid (aka auxins)* voluntarily withdrawn

## Ethylene

- *Ethylene* approved

## Abscisic Acid

- *S-Abscisic acid* approved

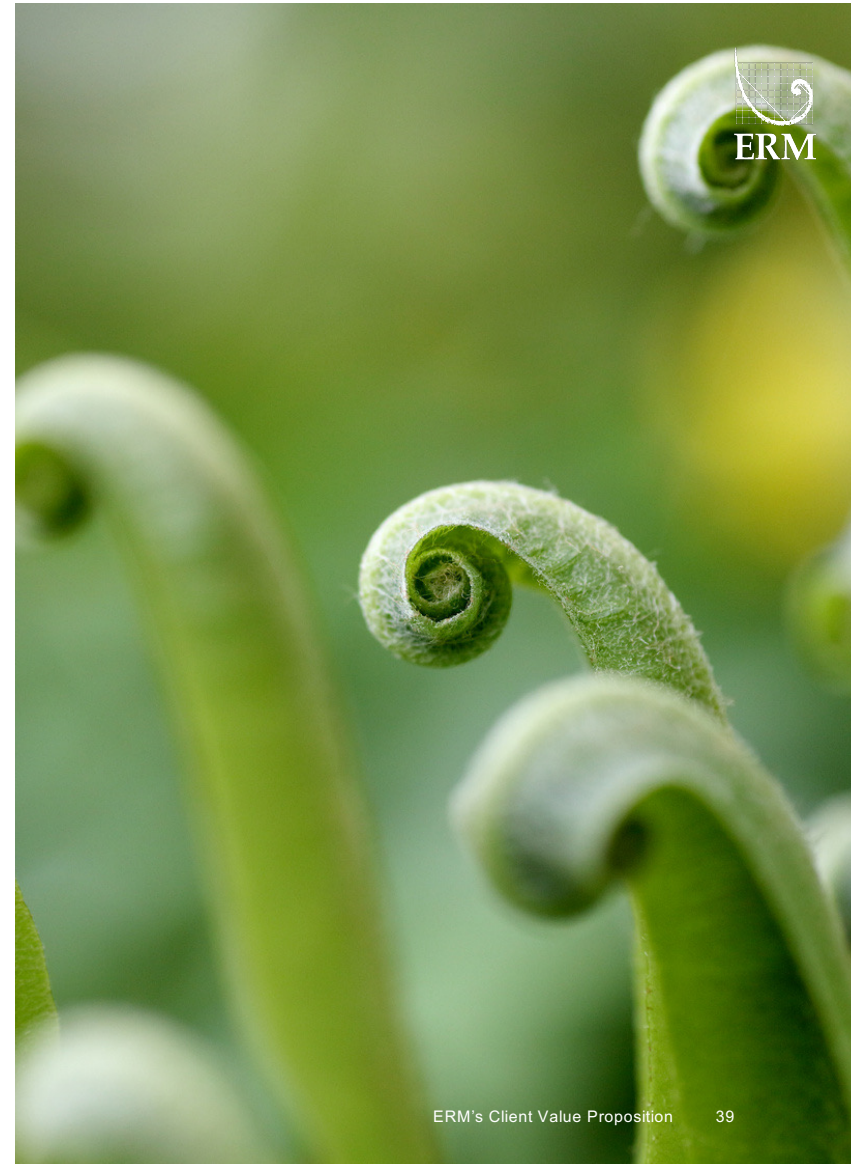
## Plus


- ▶ Plant oils / Spear mint oil
- ▶ 1,4-Dimethylnaphthalene
- ▶ 1-Decanol
- ▶ 1-Naphthylacetamide (1-NAD)
- ▶ 1-Naphthylacetic acid (1-NAA)
- ▶ Sodium 5-nitroguaiacolate
- ▶ Sodium o-nitrophenolate
- ▶ Sodium p-nitrophenolate

## Plant elicitors

- ▶ 24-Epibrassinolide
- ▶ Chitosan hydrochloride
- ▶ Heptamaloxyloglucan
- ▶ Laminarin

# Regulatory pathways for Plant Growth Regulators

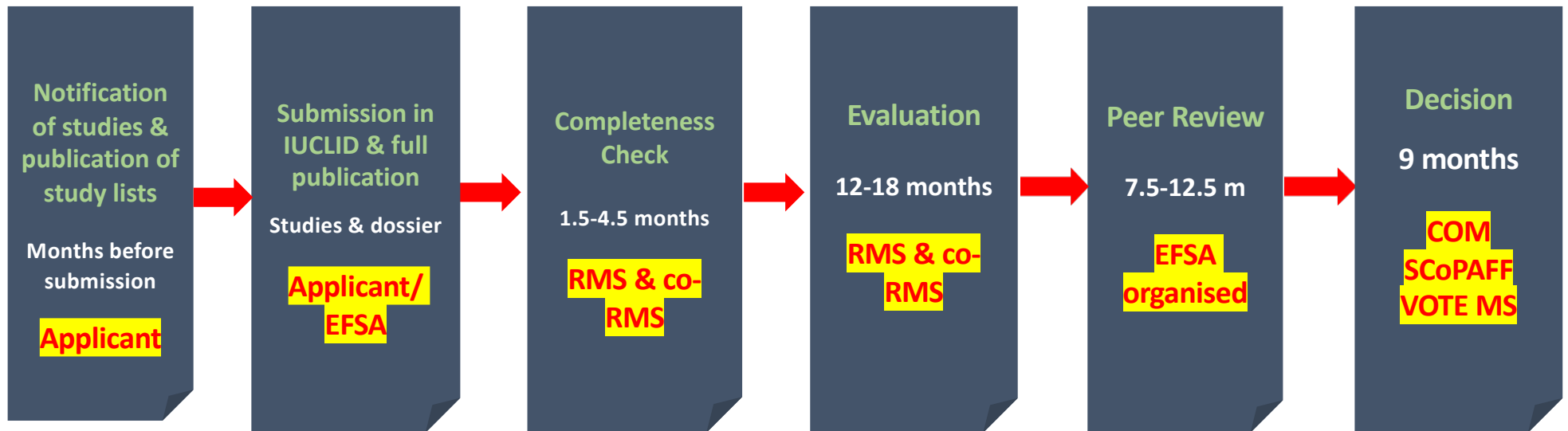




# Overview of process Regulation 1107/2009



## Approval process for a new active substance – 6 steps

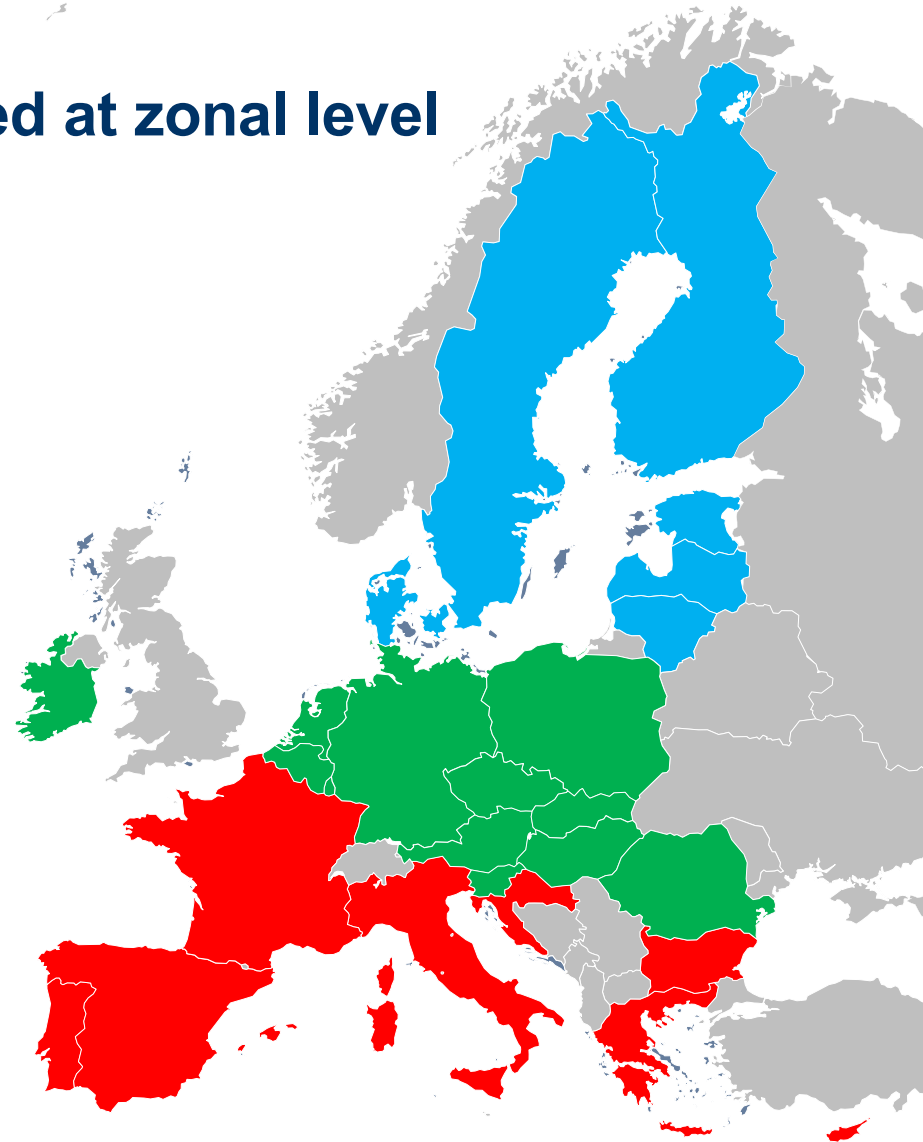


Assessment process takes minimum 2.5 years, often longer

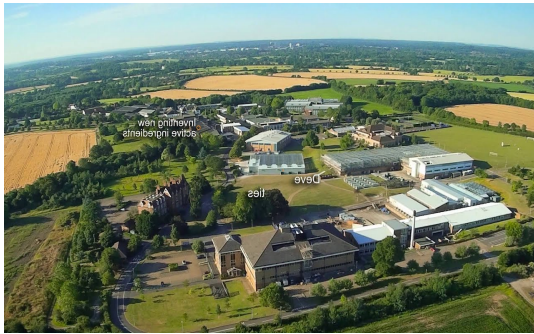


## Plant protection products assessed at zonal level

- Products are authorised at member state level, after the active substance is approved
- For every active substance there are products 10s to 1,000s products
- Northern Zone
- Central zone
- Southern Zone



# Stakeholders in the active substance approval process



Industry applicant



Member States



Public/lobby groups



EFSA



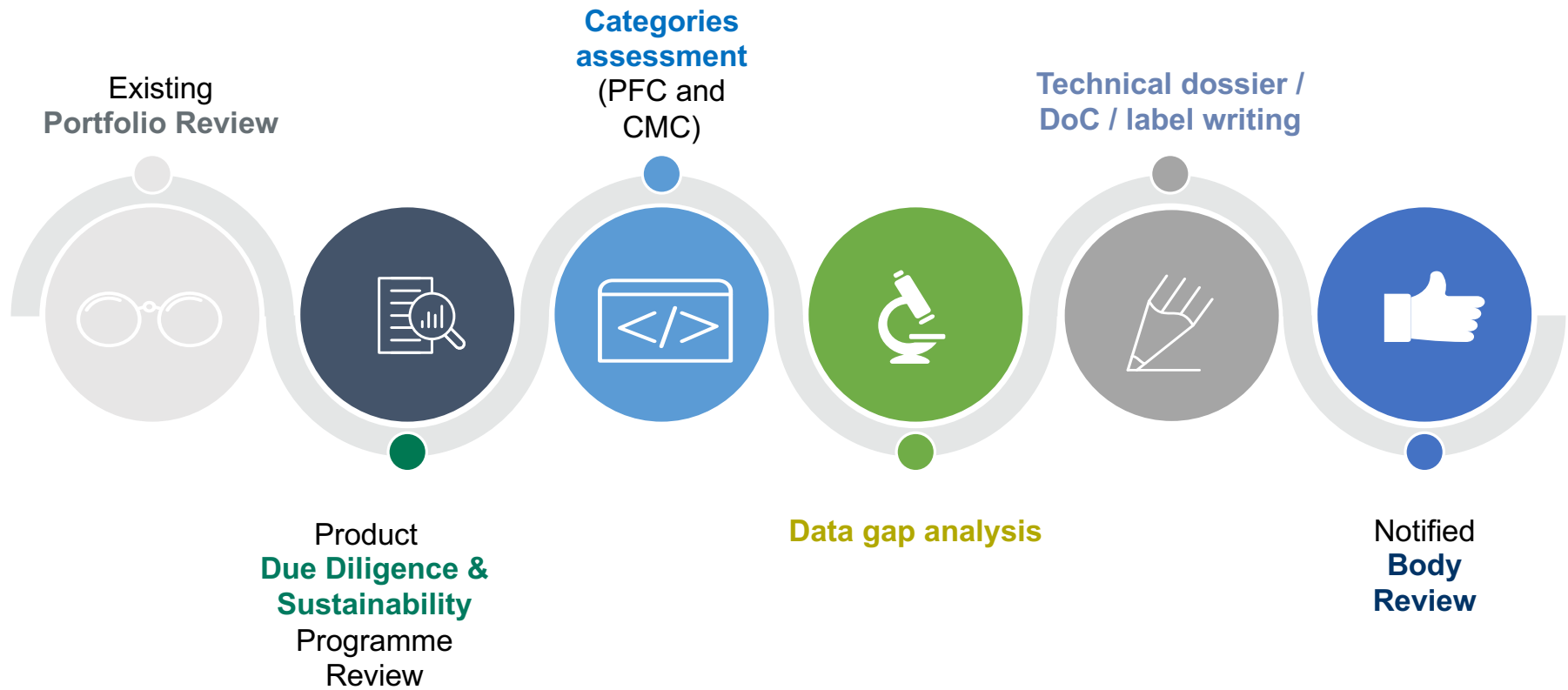
EU Commission



# Overview of process Biostimulants

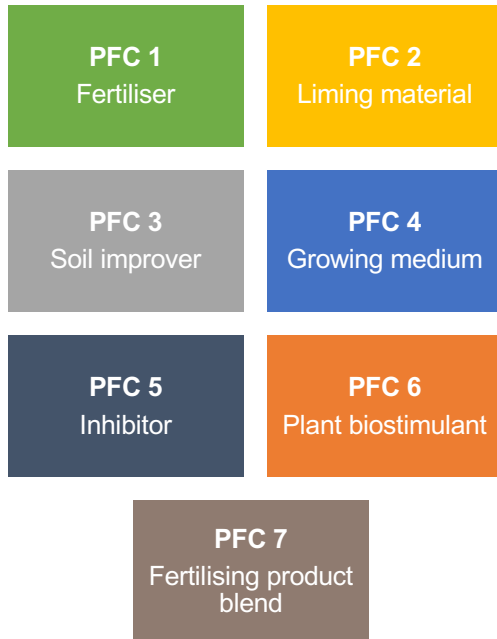


# Steps in EU fertiliser or national authorisation

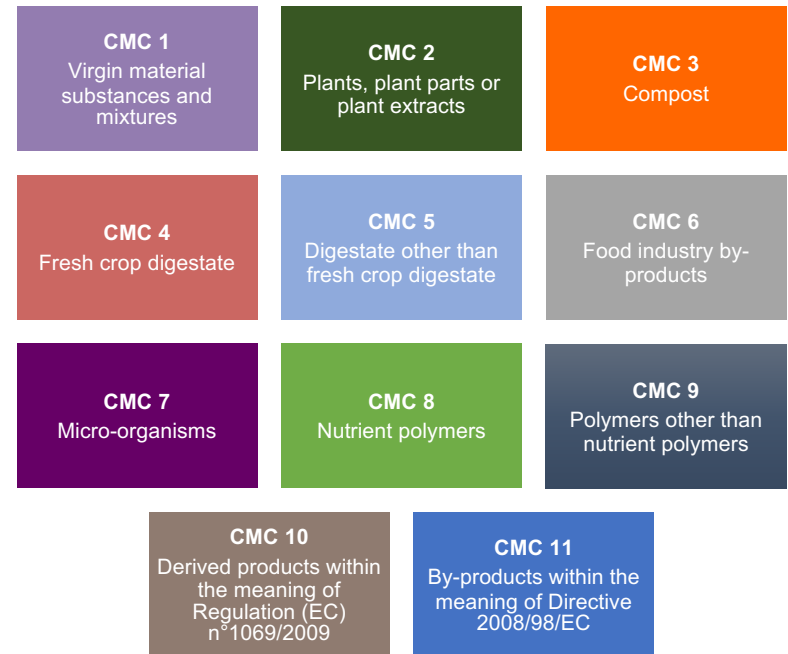




# Product Function Categories (PFC) / Component Material Categories (CMC)



PFCs are subject to safety and quality requirements



CMCs are subject to process requirements and control mechanisms

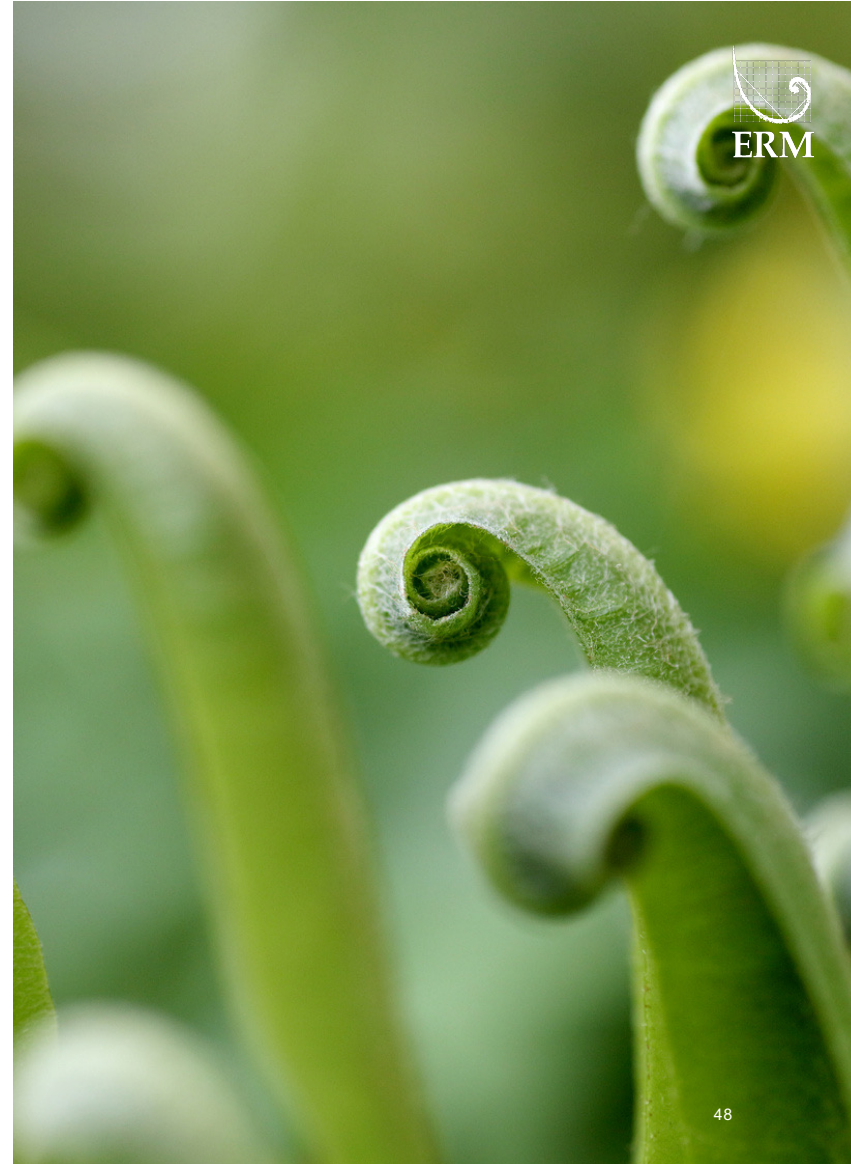


## Notified bodies available for Biostimulants under FPR

Body type ▲	Name ▲	Country ▲
▶ NB 2806	<a href="#">CerTrust Kft.</a>	Hungary
▶ NB 2947	<a href="#">Inspectorate Estonia AS</a>	Estonia
▶ NB 2949	<a href="#">Instytut Nadzoru Technicznego Sp. z o.o.</a>	Poland
▶ NB 2929	<a href="#">Kiwa VERIN B.V.</a>	Netherlands
▶ NB 0163	<a href="#">LABORATORIO OFICIAL JOSE MARIA DE MADARIAGA</a>	Spain
▶ NB 1326	<a href="#">LIMITED LIABILITY COMPANY LATVIAN CERTIFICATION CENTRE (LATSERT)</a>	Latvia
▶ NB 1434	<a href="#">POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A.</a>	Poland
▶ NB 2832	<a href="#">Stichting Global Network Group TIC trading as EMCI Register and EFCI Register</a>	Netherlands
▶ NB 1749	<a href="#">TNO Defense, Security and Safety</a>	Netherlands
▶ NB 0906	<a href="#">TUV AUSTRIA HELLAS LTD</a>	Greece

- Not clear whom should submit application to COM
- There is no EU evaluating body involved in the listing of micro-organisms according to the Regulation
- Time to market from submission to EUP on the market is 'a few months to <1 year'

# Towards a More Sustainable Future




# Many drivers



**EU Commission proposes cutting pesticides by half by 2030**

The European Union's executive arm on Wednesday proposed setting legally binding targets to reduce the use of chemical ...


**AP** Associated Press · 1d



**EU Commission proposes cutting pesticides by 50% by 2030**

A study by the group Pesticide Action Network Europe last month said the contamination of fruit and vegetables produced in ...

**BT** Business Today · 1d



More With Less Our priorities Commitments Collaborations Media Resources library About us

22 JUN 2022

## The Sustainable Use Regulation Must Embrace Innovation As Its Key Enabler

*We can contribute to the reduction in pesticide use and risk by continuing to innovate and provide solutions to protect crops from pests and diseases*

BRUSSELS, 22 June 2022 – In order for reduction targets to be achievable and realistic, they should be practical, evidence-based, and fully take into account any relevant historical reduction initiatives. Setting an arbitrary target will disregard the significant efforts that member states have made to reduce pesticide use as well as the various agronomic conditions across Europe.



Brussels, 22.6.2022  
COM(2022) 305 final  
2022-0196 (COD)

Proposal for a

**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**on the sustainable use of plant protection products and amending Regulation (EU) 2017/215**

Agrochemicals ▾ Agtech Sustainability

Read **AgriBusiness Global Direct** - The Next Generation of Magazines

## New European Regulation Opens Door to a More Sustainable Agriculture

By **Jose Alfredo Garcia** | 6 September 2022






**Urgent call for more alternatives: we all need fast-track biocontrol authorisation to achieve 2030 pesticide goals**

*For immediate release Brussels, 13th October 2022:*

A European Parliament seminar hosted by MEP Martin Hlaváček and co-organised by the International Biocontrol Manufacturers association (IBMA) and the Microbial Task Force, is addressing today the question: how policy makers can help nature-based biological control solutions come to the forefront to address the food security challenge rather than resort to recipes of the past which were proven detrimental to biodiversity and unsustainable. Several representatives from the biocontrol sector emphasize how their innovation pipelines are full of essential biocontrol solutions. Farmers are asking for biological control innovations which are facing major obstacles and delays to enter the EU market. MEPs state they support the need for more biological control solutions as soon as possible.

In a three step approach to address these problems, sector representatives called for:

1. A proper definition of biological control accompanied by positive targets.
2. Fast-track authorisation for biocontrol products is required.
3. Farmers need to be trained and incentivize for using biocontrol.




Multiple biological control solutions and their benefits for biodiversity, health and soil are essential for sustainable regenerative agriculture, to reach the EU Green Deal goals.


Agribusiness Can Lead the Shift to Sustainable Farming

RELATED EXPERTISE: AGRIBUSINESS INDUSTRY, SOCIAL IMPACT

## Agribusiness Can Lead the Shift to Sustainable Farming

FEBRUARY 21, 2022  
By **Matthias Baumler, Benjamin Subel, and Torsten Kurth**



New regulations are pushing farmers and their suppliers to adopt environmental practices. Traditionalists see this as a disruption, but leaders will treat it as an opportunity.



## The Sustainable Use Regulation

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- Member States have positive target for biocontrol in National Action Plans
- Mandatory training for professional users and advisors on IPM and biocontrol
- Farm to Fork Strategy: to reduce by 50% the overall use and risk from chemical pesticides by 2030 and reduce by 50% the use of more hazardous pesticides by 2030

*“In no case may any of the 2030 national reduction targets be lower than 35%”*



# Product Sustainability



The decade of action to 2030 is evident in our daily work



Biological product use is increasing across the globe every year

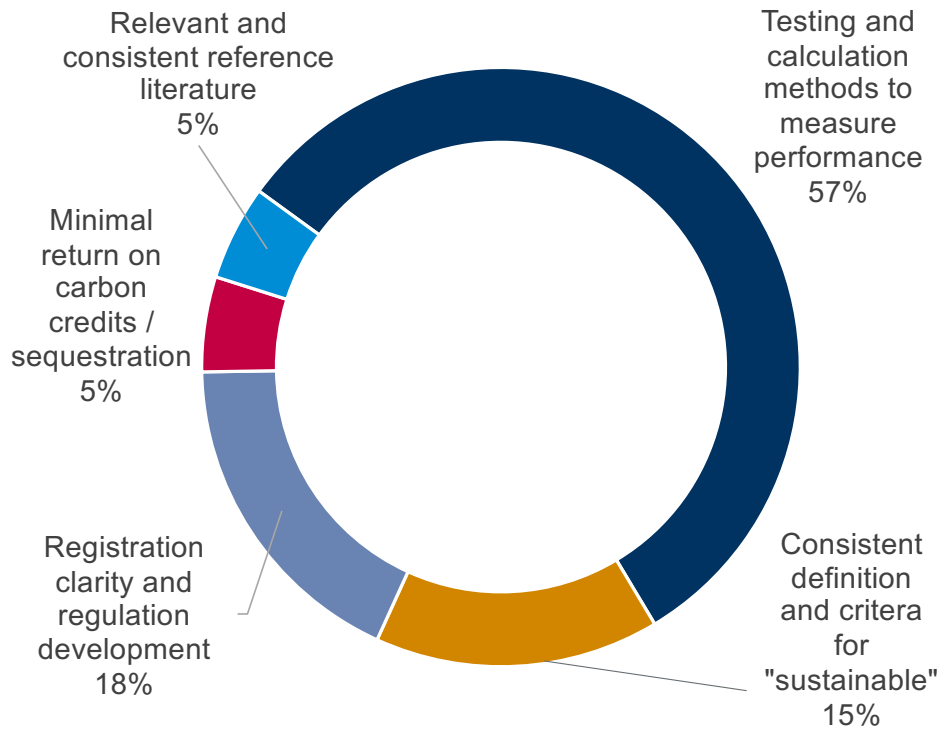


Time is short, in view of lengthy regulatory processes

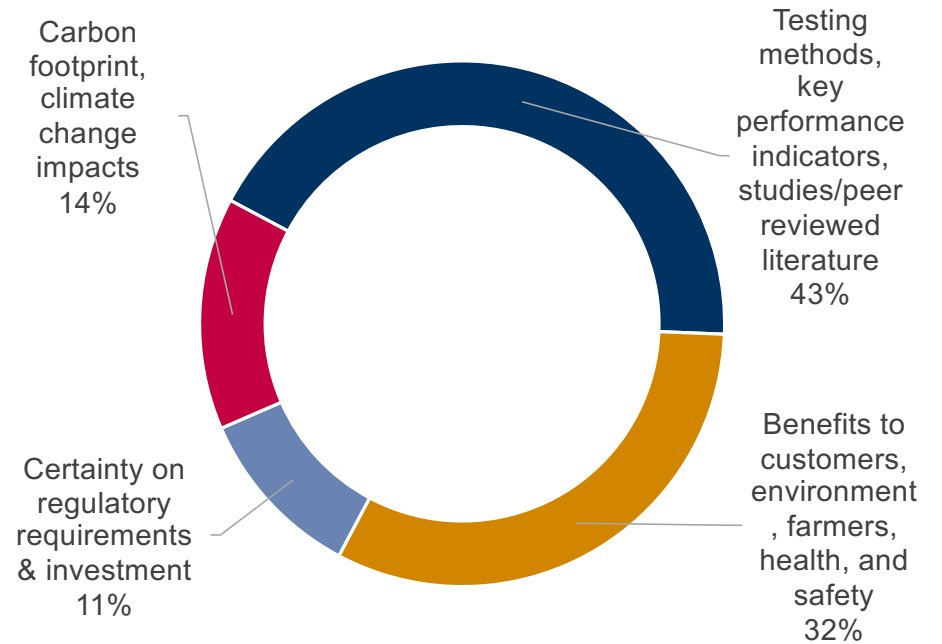
 <p>2 ZERO HUNGER</p>	<b>END HUNGER, ACHIEVE FOOD SECURITY AND IMPROVED NUTRITION AND PROMOTE SUSTAINABLE AGRICULTURE</b>
 <p>3 GOOD HEALTH AND WELL-BEING</p>	<b>ENSURE HEALTHY LIVES AND PROMOTE WELL-BEING FOR ALL AT ALL AGES</b>
 <p>6 CLEAN WATER AND SANITATION</p>	<b>ENSURE AVAILABILITY AND SUSTAINABLE MANAGEMENT OF WATER AND SANITATION FOR ALL</b>
 <p>12 RESPONSIBLE CONSUMPTION AND PRODUCTION</p>	<b>ENSURE SUSTAINABLE CONSUMPTION AND PRODUCTION PATTERNS</b>
 <p>13 CLIMATE ACTION</p>	<b>TAKE URGENT ACTION TO COMBAT CLIMATE CHANGE AND ITS IMPACTS</b>
 <p>15 LIFE ON LAND</p>	<b>PROTECT, RESTORE AND PROMOTE SUSTAINABLE USE OF TERRESTRIAL ECOSYSTEMS, SUSTAINABLY MANAGE FORESTS, COMBAT DESERTIFICATION, AND HALT AND REVERSE LAND DEGRADATION AND HALT BIODIVERSITY LOSS</b>

# We asked our clients

## Hurdles encountered in measuring sustainability of biologicals



## Evidence used to demonstrate sustainability of biologicals, what would be helpful?



## To conclude

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“The SDGs can only be realized with strong global partnerships and cooperation”

“Improving access to technology and knowledge is an important way to share ideas and foster innovation”



**STRENGTHEN THE MEANS OF IMPLEMENTATION AND REVITALIZE  
THE GLOBAL PARTNERSHIP FOR SUSTAINABLE DEVELOPMENT**

## In other words teamwork

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*The business of sustainability*

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