Regulatory requirements for biocontrol and biostimulants compared

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CONTENT

- Biostimulant or biocontrol product?
- Access to the market
- Data requirements
- Authorisation process
- Take-home messages

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THE KEY DEFINITIONS

BIOSTIMULANT

Stimulates plant nutrition processes independently of the product's nutrient content

- nutrient use efficiency
- tolerance to abiotic stress
- quality traits
- availability of confined nutrients in soil or rhizosphere

BIOCONTROL

Control of organisms harmful to plants or plant products using natural means of biological origin or substances identical to them


Micro-organisms


Extracts from plant products


Semiochemicals

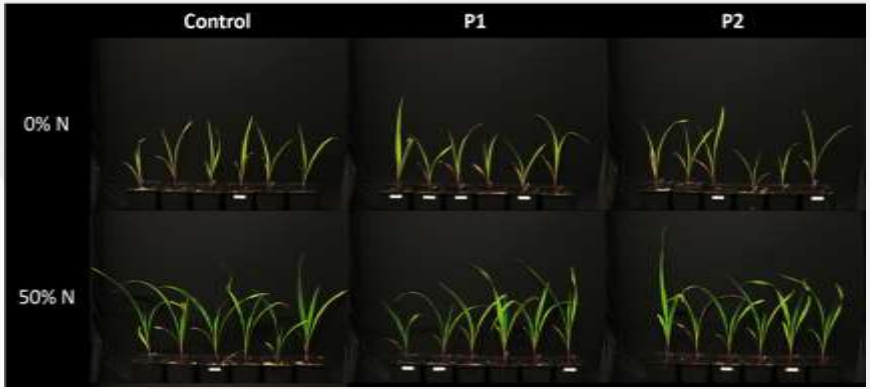

Invertebrate macro-organisms

DETERMINE THE CLAIM

Detect & identify active molecules

Check literature for available information

Small-scale experiments to identify phenotypic traits, phosphorus solubilization, nitrogen fixation,…



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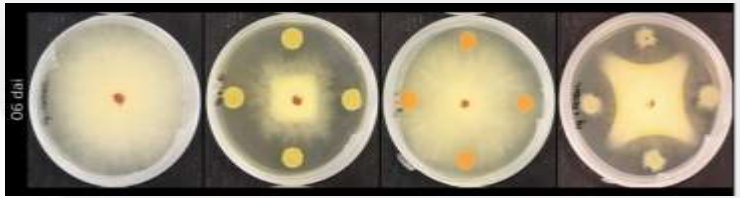
DETERMINE THE CLAIM

Detect & identify active molecules

Check literature for available information

Small-scale experiments to identify phenotypic traits, phosphorus solubilization, nitrogen fixation,…

In-vitro tox tests



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GAINING MARKET ACCESS

Derogation

National

Registration

EU-wide

Conformity assessment

Authorisation

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BIOSTIMULANTS: 2 ROUTES TO MARKET

Fertilising Products Regulation (FPR)
Regulation (EU) No 2019/1009

- Market access across Europe
- CE label
- Restricted list of micro-organisms
- Only compliant ingredients
- Conformity assessment
- Validity 3-5 years

Notified bodies (NoBo's)

National legislations

- Procedures vary per member state
- No regulation <> extensive evaluation
- Marketing limited to specific member states

National authorities

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BIOCONTROL: A 2-STEP PROCESS

Plant Protection Products Regulation (PPPR)
Regulation (EU) No 1107/2009

efsa
European Food Safety Authority

Active substance approval

- EU-wide
- Evaluation by RMS
- Peer review
- Publication of Approval Regulation

Product authorisation

- Zonal system
- Evaluation of the core dossier by the zRMS
- National addenda for cMS
- Authorisation per MS

Renewed every 10/15 y

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COMPILE YOUR DATA

01 Phys-chem/ analytical methods

02 Efficacy

03 Toxicity

04 Fate and behaviour

05 Ecotoxicology

06 Residues

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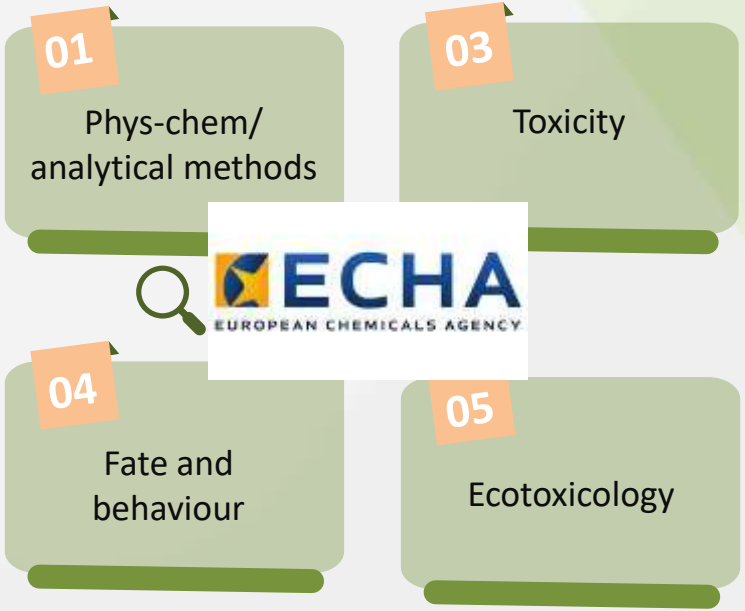
BIOSTIMULANTS: A MIX OF CONSTITUENTS

Registration, evaluation, authorisation and restriction of chemicals (REACH)
Regulation (EC) No 1907/2006

- Covered by REACH dossier for individual constituents
- REACH dossier > 10 tpa for all relevant constituents + CSR
- Fertilizer use (PC 12) should be included



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No systematic evaluation

BIOSTIMULANTS: PRODUCT EFFICACY

CROP GROUPS

- Broadacre
- Woody perennials
- Vegetables, ornamental & AMP crops

CEN/TS 17700

CLAIMS

- Nutrient use efficiency
- Tolerance to abiotic stress
- Quality traits
- Availability of confined nutrients

Plan in time (seasonality field trials)

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BIOCONTROL: DATA ON ACTIVE SUBSTANCE AND PRODUCT

Data requirements identical to chemical substances

Adapted data requirements

01 Phys-chem/ analytical methods

02 Efficacy

03 Toxicity

04 Fate and behaviour

05 Ecotoxicology

06 Residues

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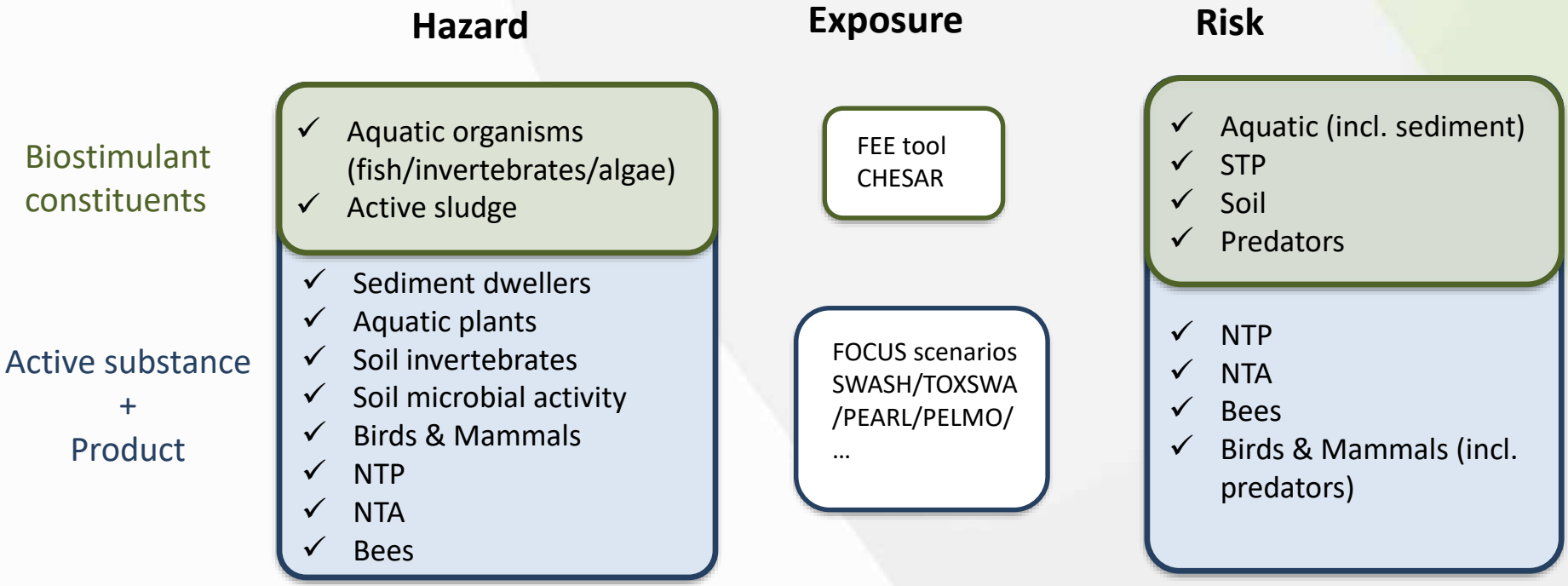
FOCUS ON ENVIRONMENTAL RISK ASSESSMENT



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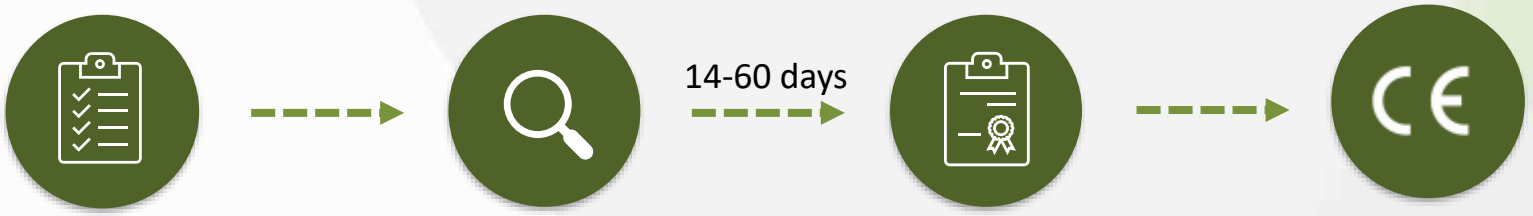
BIOSTIMULANTS: CONFORMITY ASSESSMENT MODULE B+C

Prepare technical documentation + samples

- ✓ description of product & intended uses
- ✓ list of component materials + info on origin & manufacturing process
- ✓ descripition manufacturing process
- ✓ test reports

...

BIOSTIMULANTS: CONFORMITY ASSESSMENT MODULE B+C



Prepare technical documentation + samples

Choose notified body

EU-type examination certificate

EU declaration of conformity

BIOSTIMULANTS: CONFORMITY ASSESSMENT MODULE D1

Applicable to multiple products

BIOCONTROL: AUTHORIZATION PROCESS

THEORETICAL TIMELINE

Active substance dossier submission

Active substance approval

Product authorization

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TAKE-HOME MESSAGES

- Categorize your product correctly
- Plan your efficacy trials well upfront
- Be mindful about the differences in data requirements
- Every product type has its own challenges…

BIOSTIMULANT

- Demonstrating efficacy
- Limited number of micro-organisms allowed & ingredients
- REACH dossiers >10 tpa for PC12
- Option for national procedures

BIOCONTROL

- Data requirements not adapted
- Lead time till registration
- Development & registration costs
- New dossier for each product

Visit us at BOOTH 94!

Thanks to Sabina Bajda-Wybouw from **CropFit services** of **Ghent University**

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Screening tests for biostimulants

- Multispectral analysis for non-destructive determination of N-status in plants.
- Multispectral analysis for non-destructive determination of P-status in plants.
- Bioassay for determining the biostimulant activity of microbial and non-microbial biostimulants on seed germination through spectral analysis and amylase activity.
- Bioassay for determining the biostimulant activity of microbial and non-microbial biostimulants on nutrient use efficiency and nutrient uptake.
- Bioassays for determining plant health through hyperspectral analysis.
- In vitro bioassays for determining relevant biostimulant activity of bacteria and fungi: P-solubilization, siderophore production, swimming and swarming motility, biofilm formation.

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