



## Biocontrol & Biostimulants Europe

Regulation (EU) 2019/1009 on fertilizing products vs Regulation (EC) 1107/2009 on plant protection products

### About us

We are a scientific consultancy with expertise in human health and environmental regulatory affairs that transforms knowledge into value for the benefit of our clients.

### Where we work

We offer our services mainly in Europe, Latin America, USA and Canada.

### Offices

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## DUALITY IN THE FUNCTION OF AN ACTIVE SUBSTANCE

- The same substance can have both biostimulant and biocontrol properties.
- Their classification and requirements will depend on the declared function in the commercial label.
- The regulatory framework will be defined according to the designated claim.
- If its function is biocontrol, it will be regulated under Reg. 1107/2009. If it is a biostimulant, it will go under Reg. 2019/1009. If it is both, it must comply with both regulations in order to be marketed.

### General considerations

Features	Biostimulants	Biocontrol
<b>Definition</b>	Substances or microorganisms that improve nutrient use, abiotic stress tolerance, quality characteristics and availability of immobilized nutrients in the soil and rhizosphere.	The control of organisms harmful to plants or plant products using natural means of biological origin or substances identical to them, such as micro-organisms, semiochemicals, extracts from plant products as defined in Article 3(6) of Regulation (EC) No 1107/2009, and other natural substances, or invertebrate macro-organisms.
<b>Main regulation</b>	<b>Regulation (EU) 2019/1009</b> on fertilizing products and subsequent amendments.	<b>Regulation (EC) 1107/2009</b> on plant protection products and subsequent amendments.
<b>Competent Authority</b>	Notified Bodies (NBs) designated under Regulation 2019/1009.	National authorities for PPP registration (Ministries of Agriculture).
<b>Registration timeline</b>	Less time, between 6–12 months depending on the selected NB and their workload.	Longer (2–12 years) depending on the required studies, the evaluating Authority and whether or not the active substance is approved in Europe.
<b>Safety approach</b>	CLP and brief assessment of potential risks. More requirements in the near future.	Comprehensive risk assessment for humans, animals and the environment.
<b>Costs involved</b>	Lower: due to less data required, not expensive studies and lower fees.	Higher: due to exhaustive studies, some very expensive and higher Authority fees.
<b>Marketing mechanism</b>	CE marking on the label.	PPP registration number by country, on each label.
<b>Time to market</b>	Faster: due to shorter evaluation time and less data required to be generated.	Longer: due to greater complexity of the process, longer time to generate studies and approval the active substance prior to the product application.

### Data requirements

Requirements	Biostimulant	Biocontrol
<b>Product identity</b>	• Qualitative and quantitative composition (active ingredients and excipients). • Identity of microorganisms (genus, species, strain), if applicable.	• Identity of active substance (chemical name, structure). • Qualitative and quantitative composition (a.s. + excip.). • Identity of microorganisms (genus, species, strain), if applicable.
<b>Physicochemical properties</b>	• Solubility, pH, density, viscosity, particle size (if applicable) for product / REACH+ for the active.	• Stability in the commercial package (product) and complete physicochemical properties/hazards (product and a.s.)
<b>Microbiological profile</b>	• Required only if it contains microorganisms. • Evidence of absence of pathogenic contaminants	• Required only if it contains microorganisms. • Complete microbiological description. • Safety studies and absence of pathogenicity.
<b>Analytical tests</b>	• Analytical methods for the identification and quantification of active components.	• Validated analytical methods to determine the a.s. / metabolites / SoC.
<b>Mechanism of action</b>	• Description of the biostimulant mode of action (accord. to Regulation).	• Description of the mechanism of action as a pest or disease control agent.
<b>Efficacy studies</b>	• Agronomic CEN / TC Standard tests 17.700: 1–5 that demonstrate its biostimulant effect on crops. 1 crop species: 3 trials with the same species. 1 crop group: 6 trials (2 different species). 2 crop groups: 8 trials = 4+4 trials/group 3 crop groups: 9 trials = 3+3+3 trials/group	• Efficacy studies EPPO standards to demonstrate its ability to control specific pests or diseases. Pest/crop combination= 10 trials  (Low risk PPP 1/296 EPPO Guide, less no. of trials)
<b>Toxicity studies</b>	• Generally not required, except of risk (product) and REACH+ data for the active.	• Complete acute and chronic toxicity s.a./MO/ metabolites (a.s. and product dossiers)
<b>Environmental impact</b>	• Environmental risk assessment only if there is potential for impact (product). • REACH+ data for the active.	• Ecotox studies on NTOs: bees, birds, fish, earthworms, <i>Daphnia</i> , algae (a.s. and product dossiers) • Persistence and degradation in soil, sediment and water systems (a.s./MO/metabolites).
<b>Residue data</b>	• Not applicable in most cases. Estimation.	• Residue studies on treated crops (if consumed). Except for microorganism-based PPP (in principle).
<b>Human 's risks</b>	• No	• Yes
<b>Environmental 's risks</b>	• No	• Yes
<b>Consumer's risk</b>	• No	• Yes, if the product is for consumption.
<b>REACH registration</b>	• Yes, all except exempt substances.	• Yes, except for the s.a./MO.
<b>Metabolite data</b>	• No (only at national level).	• Yes, metabolites of concern: identity, analytical methods, tox, ecotox, efate and/or residues.

## Authorization procedure

	Active Ingredient dossier					Commercial Product dossier				
	Preparation, submission, evaluation and approval	Validation	Evaluation	Community review	Authorization	Dossier preparation and submission	Validation	Evaluation	Community review	Authorization
<b>Biostimulant</b>	• Data generation • Dossier preparation • Submission to ECHA • REACH+ registration,	ECHA	ECHA	ECHA	• If no exemption ECHA registration (1 year)	• Data generation • Preparation of the product dossier • Submission to the Notified Body	Not applicable	Verification of conformity (depending on the module)	Only once.	• 6–12 months • CE marking
<b>Biocontrol</b>	• Data generation • Dossier preparation • Submission of application	Member State validation	Member State evaluation	EFSA peer review process	• Commission Decision (3–10 years)	• Data generation • Preparation of the product dossier • Submission to the Reference Member State (RMS)	RMS conducts a review of the dossier and issues a pre-assessment report	RMS carries out the full evaluation (1st authorization in Europe)	• (Inter)zonal evaluation. • Country by country (cMS or MR MS)	• 2–4 years (Low Risk 1–2y) • PPP Registr. Number • Valid 5–10y • Renewal

## Conclusions

- The same active ingredient may have both biostimulant and biocontrol properties. Their classification and requirements will depend on the claimed function.
- Biostimulants improve nutrient use, abiotic stress tolerance, quality traits and the availability of confined nutrients in the soil and rhizosphere. Biocontrol products control pests or diseases in crops.
- The requirements for the preparation of biocontrol dossiers are more exhaustive than those required for biostimulant dossiers.
- The registration timelines and the costs associated with the authorization of biocontrol products are higher compared to biostimulant products (CE marking).

