



Global Biostimulant Regulations **2016**

**Legislation and administration; Registration process,
data requirements and guidance documents;
Regulatory issues and challenges; Registered products**

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Executive Summary

Definition and scope

Plant biostimulants are a diverse group of substances and/or microorganisms that are applied to plants or soils to improve crop vigour, yield, quality and/or abiotic stress tolerance. Other names sometimes used for these products include plant strengtheners and conditioners, elicitors, phytostimulants, phytoprotectants, biofertilisers, bioactivators, and soil/yield/ crop/plant growth enhancers.

The range of substances and modes of action covered by the term biostimulant has progressively expanded over recent years. Major categories include humic substances, seaweed and other plant extracts, protein hydrolysates and amino acids, chitosan and other biopolymers, inorganic compounds, beneficial microorganisms and other complex organic materials. Novel materials continue to be discovered.

No common legal or regulatory definition currently exists – the precise terminology and scope varies between countries. In the present study, a plant biostimulant is defined as ‘A material that contains substance(s) and/or microorganisms whose function, when applied to plants or the rhizosphere, is to stimulate natural processes to benefit nutrient uptake, nutrient efficiency, tolerance to abiotic stress, and/or crop quality, independent of its nutrient content’.

Market

Estimates of market size vary widely but there is broad agreement that the market is growing rapidly: global sales were around US\$1.4bn in 2015 and are projected to reach US\$2.9bn by 2021 with a CAGR of 10-12%. The largest regional market is Europe, followed by North America, Asia Pacific, Latin America and Africa Middle East, respectively. The value and growth of different product types varies by region but, overall, microbial inoculants is the largest and most rapidly growing segment.

Key drivers of growth include political and societal pressure to promote high performance sustainable agriculture (combining high productivity with high resource efficiency whilst also contributing to protecting water, soil and air); an increasingly tough regulatory climate for conventional chemical inputs; improvement in product efficacy and reliability; new product innovations that target unmet needs and attract new customers; and market expansion beyond traditional niche sectors (organic and high value horticulture) to conventional agricultural field crops.

The sector has attracted increasing attention from the major agrochemical companies who see opportunities for offering integrated packages of services and customised solutions throughout the growing season to help growers maximise yield potential and return on investment. This new ‘holistic’ approach embraces plant health, plant nutrition and crop protection needs and helps meet broader sustainability objectives related to soil health and water protection.

The entry of the multi-nationals has significantly improved market access and expansion for biostimulants through faster product commercialisation, increased R&D investment and more effective technology transfer to growers. It has also brought discipline and an increased professionalism that has helped to improve the credibility of a sector that has previously suffered from a reputation borne of 'hucksters selling snake oils'.

Current and emerging approaches to regulation

The report examines how regulatory frameworks for biostimulants are evolving in key markets around the world. For each country, the key competent authority/authorities and legislation is identified and the specific regulatory requirements are described along with information on timescales and costs (where available). Key regulatory challenges and issues are discussed based on feedback from regulators, industry and other interested stakeholders.

The existing regulatory landscape is fragmented and contradictory. Biostimulant products are entirely unregulated in some countries, classified as fertilisers in others and treated as plant protection products elsewhere. In some countries, products could conceivably be sold under both regimes (e.g. South Africa), and in others (e.g. Germany), a product can either be a plant strengthener (covered by plant protection regulation) or a plant growth enhancer (subject to fertiliser law), but not both.

Where registration is required, specific data requirements may vary considerably between different regulatory authorities and often fail to take account of the unique properties of biostimulant products such as their mode of action (via the plant response) and their intended effects (on nutrient efficiency, crop quality traits and/or abiotic stress tolerance). Even where regulations exist, products are often incorrectly classified which makes it difficult for growers to recognise their benefits and/or use them effectively.

There are also inconsistencies between the rules for products destined for organic and conventional agricultural production.

The analysis reveals that the global picture is complex and dynamic:

Europe

Europe is generally recognised as being the most advanced region in terms of regulatory thinking about biostimulants. Within the EU, biostimulants are currently regulated under national legislation and each Member State has developed its own definition and regulatory requirements which can differ enormously from one country to another. The lack of a single market creates uncertainty, raises the costs of doing business, slows down innovation and means that farmers living in different Member States do not have equal access to these valuable tools.

This situation is set to change under new proposals to revise and extend the scope of the Fertiliser Regulation (EC) No. 2003/2003 which will include biostimulants as a discrete category of 'fertilising product'. The revised Regulation will establish a new legislative framework with generic safety and quality requirements, standards and conformity assessment procedures. The proposed 'optional harmonisation' model will enable companies to choose whether to register their products at the EC level or to continue to register on a country by country basis following national regulatory requirements. Full harmonisation (and a

single market) may follow at a later date. The industry has broadly welcomed the new Regulation but continues to push for improvements in several key areas. Reaching entry into force is likely to be complicated and is expected in 2019.

It is widely anticipated that the new Fertiliser Regulation could set the benchmark for biostimulant regulation elsewhere - regulatory authorities around the world are closely monitoring developments.

North America

In the US, fertilisers and plant biostimulants are regulated at state rather than federal level. Each state has its own fertiliser regulatory program with many different and often conflicting standards, making it difficult for companies to easily register their products across several states. Complicating the issue, the US EPA considers some products should be registered as plant growth regulators under pesticide legislation.

As the market for plant biostimulants grows, other U.S. agencies and organisations are getting involved. The Association of American Plant Food Control officials (AAPFCO) is responsible for harmonising fertiliser regulation across states through common definitions and voluntary standards. AAPFCO is working with the Biostimulant Coalition to accommodate biostimulants within AAPFCO's 'Beneficial Substance or Compounds' standard. These materials cannot be termed 'biostimulants' but the AAPFCO-defined material will be allowed on product labels, along with claims consistent with the approved definition. In the longer term, an overarching definition for 'biostimulant' may be considered to describe biostimulants as a stand-alone category of ingredients.

Meanwhile, the case for federal level regulation increases. One possible scenario is that some of the biostimulants could fall under EPA jurisdiction while others would be registered as fertilisers or soil amendments at the state level. The Biostimulant Coalition is working with EPA to develop a guidance document explaining the different categories of plant biostimulant products, sources, and use sites. This will clarify the difference between products classified as plant growth regulators (i.e. liable for registration as pesticides) and those that are intended for use as plant nutrients/nutritional chemicals, trace elements, plant inoculants, soil amendments and/or vitamin-hormone horticultural products (i.e. excluded from pesticide registration).

In contrast, Canada regulates biostimulants at a federal level as 'supplements' under fertiliser legislation. Most supplements are subject to registration and require a comprehensive pre-market assessment prior to their import or sale in Canada. This consists of a detailed, science-based evaluation of product safety information and labelling. The main focus is on evaluating product safety towards humans, plants, animals and the environment; requirements for efficacy data have recently been removed.

South America

Brazil's Fertiliser law of 1980 defined a category named 'biofertilisers' but there are few products officially registered. On the other hand, there are many biostimulant and biofertiliser product on the market which have been incorrectly registered as organo-mineral or organic fertilisers, inoculants, soil improvers or simply not registered at all. Some products claim to deliver plant protection effects as well as nutritional or plant health benefits – a situation which threatens to compromise the reputation of Brazil's nascent biopesticide industry.

Recent developments may bring change. ABISOLO, the industry association representing the plant nutrition sector, has been working with regulators and other stakeholders to redefine the biofertiliser category to include a wider range of biostimulant product types and to develop more appropriate norms and technical evaluation procedures for these products. The Working Group's proposals were formally adopted by the Brazilian government in May 2016 through the introduction of new legislation - an important step forward in strengthening regulation of the sector.

Asia Pacific

China has recently strengthened legislation on fertiliser use and introduced tax reductions and subsidy policies to encourage the adoption of 'highly-efficient and environmentally-friendly products'. In the absence of an official definition of 'biostimulant', these products are most frequently marketed as microbial fertilisers or water soluble fertilisers. A series of standards has been developed to support the registration, labelling and marketing of these products. Despite these measures, many producers believe that registration is a waste to time and money and inadequate inspection and supervisory capacity means that the circulation of substandard products and unlawful behaviour remains a serious problem for the Chinese market.

India has one of the most comprehensive regulatory frameworks for microbial inoculants. However, the highly fragmented market with many small, local players offering poor quality, spurious and 'me-too' brands remains a problem. The entry of larger multi-national companies should help to raise standards and increase confidence in the sector but there remains an urgent need to improve grower and advisor awareness of the benefits of these products and to improve market oversight of quality control by officials.

In Japan, there is no official definition of a 'biostimulant' and there is a rather piecemeal approach to handling them under three different sets of legislation (fertiliser/soil amendments, agricultural chemicals and organic agriculture). However, many products falling under the biostimulant definition used in this report are not formally regulated at the present time and are typically sold on a rather casual basis (i.e. by word of mouth) and without supporting scientific data.

Africa Middle East

The challenges for most countries in the Africa Middle East region revolve around inadequate legislation, insufficient institutional capacity and weak implementation of policies (where they exist).

One exception is South Africa which has recently published new regulatory guidelines covering biological remedies/biopesticides and biofertilisers/plant biostimulants/plant growth enhancers/plant strengtheners (also known as 'Group 3' fertilisers). The same product may be registered either as a bio-fertiliser or a biological remedy or both.

Biostimulants are classified as fertilisers or soil amendments in Morocco, Egypt and Israel but regulatory thinking about these products remains at a very early stage in all three countries with no official definitions or appropriate regulatory processes in place for managing their marketing and sale.

Conclusions – Challenges, opportunities and future prospects

Regulatory uncertainty is perhaps the single largest constraint to future growth of the biostimulant sector. Poor or inappropriate regulation allows the market to be infiltrated by illegal or substandard products which,

at worst, can threaten human and/or environmental safety, destroy the confidence of growers, regulators and other key stakeholders and seriously damage the industry's reputation. It will also stifle innovation and investment in the sector. Conversely, good regulation helps safeguard human health and the environment. It protects lawful trade and commerce by ensuring that useful products are available, controls are justified and procedures are transparent. There is a degree of dynamic tension between the need to ensure safety and at the same time promote the adoption of newer safer technologies. Good regulation will build confidence, expand markets and encourage innovation and investment.

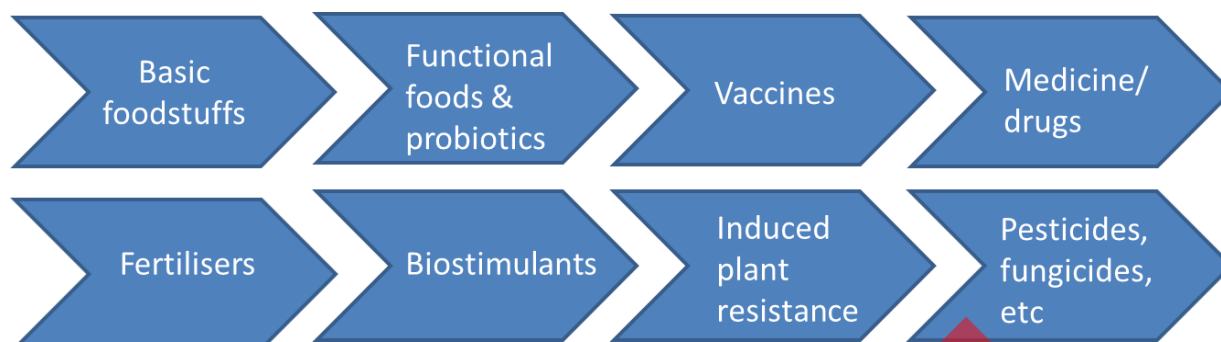
The European Biostimulant Industry Council (EBIC) has set out the industry's view on the key requirements for an optimal regulatory framework for biostimulants: A clear, precise definition of 'biostimulant'; recognition of the unique features of biostimulants; proportionate data requirements that avoid duplication across regulations; intellectual protection; encouragement of innovation; promotion of fair competition; and the ability to clearly distinguish between biostimulants, plant protection products, and biopesticides.

There is a high expectation that the revised Regulation (EC) on Fertilising Products could satisfy many of these requirements. If so, then there is a real possibility that the European system could provide the benchmark for a more appropriate and harmonised approach to biostimulant regulation elsewhere.

Furthermore, it is anticipated that the new regulatory framework will deliver clear benefits to the Circular Economy in Europe (and beyond) through fostering green innovation, boosting investment, creating employment, increasing farmer profits and reducing public expenditure to address nutrient losses to the environment.

Many of the challenges associated with the development of suitable regulatory frameworks for biostimulants resemble those faced by the biopesticide sector. Regulatory thinking on biopesticides has developed rapidly over recent years and there are many valuable learning points that could certainly benefit the biostimulants industry. Examples include the development of guidance on priority topics; formats and guidance for submission and evaluation of biostimulants test data; capacity-building within the regulatory community as well as officials responsible for market oversight; training for industry members and other relevant stakeholders; the creation of fora for sharing experience and best practice; and grower/advisor awareness programmes. Most important of all is the need to ensure a co-ordinated industry approach.

Figure 1: Use of biostimulants in agriculture is analogous to the use of functional foods/probiotics for treatment of human health and nutrition



Source: Adapted from Valagro (2014)

The range of substances and modes of action covered by the term biostimulant has progressively expanded over recent years. Despite the lack of a common legal, regulatory or scientific definition, several major categories of biostimulant product are widely recognised by industry, regulators and academic stakeholders (Table 1).

Table 1: Major categories of biostimulant used in agriculture and horticulture (continued)	
Category	Brief description of key features
Inorganic compounds	<p>Beneficial chemical elements</p> <ul style="list-style-type: none"> • Most important are Al, Co, Na, Se and Si. • Promote growth and may be essential to particular taxa but are not required by all plants. • Often found in biostimulant product mixes. • Si may be the most promising in terms of biostimulant benefits - demonstrated effects include alleviation of salt stress; tolerance of adverse climatic conditions, alkaline stress, drought stress and nutrient stress; delay of plant senescence.
	<p>Inorganic salts of both beneficial and essential elements.</p> <ul style="list-style-type: none"> • Phosphite has both pesticide and biostimulant effects (e.g. increased growth, P content, grain quality, mycorrhizal colonisation, chlorophyll content). • Other inorganic salts (biocarbonates, phosphates, silicates and chlorides) are more often used as fertilisers and/or pesticides. May promote growth by acting on nutrition efficiency and abiotic stress response in ways distinct from their fungicidal and/or fertiliser functions.
Microorganisms: Beneficial fungi	<p>Mycorrhizal fungi</p> <ul style="list-style-type: none"> • A diverse group of taxa which can establish symbiotic relationships with over 90% of plant species and benefit nutrition efficiency, water balance and tolerance to stress. • Arbuscular mycorrhizal fungi (AMF) are the most well-known but their use is limited by challenges with large-scale production and poor understanding of host specificities and population dynamics in agroecosystems.
	<p>Other fungal endophytes</p> <ul style="list-style-type: none"> • Can live at least part of their lives away from the plant and are therefore produced more easily on a commercial scale than AMF. • The most common species in inoculants are <i>Trichoderma</i>, <i>Penicillium</i>, <i>Piriformospora</i> and yeast species. • Demonstrated effects include plant growth stimulation; improved nutrition; protection against plant diseases; tolerance to abiotic stress; bioremediation via the sequestration of harmful substances. • Agricultural uses are currently supported mainly by claims as biopesticides.
Microorganisms Beneficial bacteria	<p>Key groups include:</p> <ul style="list-style-type: none"> • Free-living, plant growth-promoting rhizobacteria (PGPRs) which are multifunctional and can affect all aspects of plant life including nutrition and growth, morphogenesis and development, stress responses and interactions with other organisms in the agroecosystem; and • Endosymbiotic <i>Rhizobium</i> and related taxa which facilitate nutrient acquisition by plants including nitrogen fixers; phosphorus, potassium and zinc solubilisers. Commercialised as biofertilisers.
Sources: Adapted from du Jardin (2015) and Storer et al (2016)	

Table 4: Recent examples of collaborations and partnerships			
Date	Company 1	Company 2	Comments
2016	Eurochem Group AG	Agrinos	Marketing, distribution & sales agreement covering Agrinos HYT products within specific international territories; R&D agreement for next generation fertiliser products; equity investment allowing Eurochem to purchase Agrinos shares.
	Agrinos	Zuari Agri Services	Zuari will distribute Agrinos' HYT products in India.
	Marrone Bio Innovations	Groundwork BioAg, Israel	Collaboration on development of a seed treatment combining biopesticides and a mycorrhizal biostimulant
	Valagro	InVivo	Co-development and distribution deal covering Valagro's biostimulant products in France
2015	Dow	Radiant Genomics	Development of novel natural crop protection products
	Syngenta	DSM Food Specialties	Joint development & commercialisation of microbial-based ag solutions
	FMC	Chr Hansen	Global strategic alliance for biological solutions for plant protection
	Valent	Evolva	Co-development of bioactives
	Koppert	Som, India	Joint venture on biopesticides and biostimulants
	Agrinos	Russia EuroChem Group AG	Distribution, research and development investment cooperation agreement
	Biolchim	WinField Solutions	Distribution agreement covering BiolChims's Fyllotron and Kriss in US market
	Tradecorp	European Investment Bank	USD 25 million loan from ECB for innovative R&D projects
	FMC	Valagro	Agreement in China
	Brandt	Noposion & XHF	Distribution license agreement covering Brandt's Inside & Manni-Plex® for Chinese market
	Valagro	Italian Institute of Scuola Superiore Sant'Anna di Pisa	R&D cooperation agreement
2014	Monsanto	MIT	Formation of Preceres LLC to develop new bioactives
	Valagro	Marrone Bio Innovations	Discovery and development of bioactives and biopesticides
2013	Monsanto	Novozymes	Formed BioAg Alliance to research and commercialise microbials
	Arysta	Delbon	Licensing agreement for Delbon's <i>Pseudomonas</i> biostimulant
2012	Syngenta	Novozymes	Marketing agreement for Novozyme's Teagro biofungicide

Table 6: Statutory definitions relevant to plant biostimulants in Canada

Fertiliser legislation	Fertiliser	Any substance containing plant nutrients ¹
	Supplement	Any substance or mixture of substances, other than a fertiliser, that is manufactured, sold or represented for use in the improvement of the physical condition of soils or to aid plant growth or crop yields ¹
¹ As defined in the Fertiliser Act 1985.		

3.2.3 Legislation and administration

In Canada, all three levels of government (federal, provincial and municipal) are involved in the regulation of fertiliser and plant protection products. The federal government registers fertilisers and plant protection products whereas the provinces regulate their sale, use, storage, transportation and disposal. Provincial authorities can prohibit or restrict the use of a federally registered pesticides and fertiliser products but may also act to promote use of low risk 'bio-solutions'; their legislation can often be far stricter than federal legislation. Finally, municipal authorities have authority over local pesticide and fertiliser use including in landscape design and lawn care.

A summary of the main regulatory bodies and key legislation regulating plant biostimulants in Canada is presented in Table 7.

At a federal level, plant biostimulants are regulated by the Canadian Food Inspection Agency (CFIA) as 'supplements' under the authority of the federal Fertiliser Act (1985) and Fertilisers Regulations.

The mandate of the CFIA's Fertiliser Program covers a wide range of products sold for agricultural, commercial, and home and garden purposes. Regulated products include farm fertilisers, micronutrients, lawn and garden products as well as supplements such as water holding polymers, microbial inoculants, plant growth regulators, liming materials, and waste-derived materials such as composts and municipal biosolids.

The Fertiliser Act (1985) and Fertilisers Regulations requires that all regulated fertiliser and supplement products must be safe for humans, plants, animals, and the environment. They must also be properly labelled to ensure safe and appropriate use. Under the federal Fertiliser Act, 'fertiliser' is defined as any substance containing plant nutrients whereas a 'supplement' is defined as any substance or mixture of substances, other than a fertiliser, that is manufactured, sold or represented for use in the improvement of the physical condition of soils or to aid plant growth or crop yields.

All fertilisers and supplements imported or sold in Canada are regulated by the CFIA. The manufacture, proper use and safe disposal of these products are controlled by provincial and municipal rules and regulations. The CFIA works together with provinces and municipalities to ensure that all fertilisers and supplements meet high standards for safety.

Table 11: Official definitions relevant to plant biostimulants in Spain ¹	
'Fortificantes'; 'Fitofortificantes'; Plant strengtheners (Otros Medios de Defensa Fitosanitaria (OMDF)) ¹	'Products that can enhance the resistance of plants to harmful organisms and protect plants against non-parasitic impairments'.
Group 4 fertilisers and specialty products ²	'Products that provide fertiliser material, soil or the plant with substances to promote and regulate the absorption of nutrients or correct certain physiological anomalies'.
¹ Originally defined under ORDEN APA/1470/2007 - subsequently repealed and replaced by Royal Decree 951/2004; ² Defined in Annex 1 of Orden AAA/2564/2015.	

3.3.3 Legislation and administration

At national level, the Ministry of Agriculture, Food and the Environment (MAGRAMA) is responsible for the regulation of plant biostimulants.

National legislation governing this group of products has undergone significant changes in recent years – the most recent developments are summarised in Table 12 and discussed in more detail below.

At regional level, local administrations can apply additional regulation. For example, the Regional Government of Andalucía, the region with the highest acreage of organic crop production, has introduced a category of products permitted for use in organic farming called 'biofertilisers' (see section 3.3.3.2).

Table 12: Key regulatory bodies and legislation governing plant biostimulants in Spain		
Product category	Competent authority	Key legislation
Otros medios de defensa fitosanitaria (OMDF) & Medios de defensa fitosanitaria (MDF)	MAGRAMA	Royal Decree 951/2014 (repealed and replaced ORDEN APA/1470/2007).
Fertilisers	MAGRAMA	Royal Decree 506/2013 of 28 June on fertilisers Correction to Royal Decree 506/2013 of 28 June on fertilisers Order AAA / 770/2014 of 28 April, approving the standard application form for fertiliser registration Order AAA / 2564/2015 of 27 November amending Annexes I, II, III, IV and VI of Royal Decree 506/2013 of 28 June on fertilisers Correction to the Order AAA / 2564/2015

Plant biostimulants are principally regulated under fertiliser law in Italy as part of a category of products known as '**Prodotti ad azione Specifica**' ('Specific Action Products'). However, national organic farming legislation also identifies a special class of products known as '**corroborantii**' or '**plant strengtheners**' which are neither plant protection products nor fertilisers but which display many of the characteristics of plant biostimulants as defined in section 1.3 (Table 14).

This chapter discusses the current status of biostimulant and plant strengthener regulation in Italy and gives details of the regulatory processes associated with registering each type of product.

Table 14: Official definitions of plant biostimulants and plant strengtheners in Italy	
Plant biostimulant¹ ('biostimolanti')	Any substance or microorganism which improves or regulates plant nutrient uptake, regardless of its nutrient content, with the exclusion of phyto-regulators or other products with a declared and specific phyto-sanitary function, whose addition is not allowed.
Plant strengtheners² ('corroborantii')	Materials of natural origin, which improve and increase plant resistance to abiotic and biotic stresses. They are able to: <ul style="list-style-type: none"> strengthen the plant to the abiotic stresses by activating specific physiological mechanisms to increase plant adaptation to stresses and repair damage caused by the same. Implement the natural plant defence mechanisms to parasites and pathogens by indirect processes (such as by physical-mechanical barrier).
¹ Definition provided in Decree n.75/2010; ² As defined in Article 2, Decree n.55 of 22 April 2013.	

3.4.3 Legislation and administration

The national authority responsible for regulating plant biostimulants and plant strengtheners in Italy is the Ministry of Agriculture, Food and Forestry Policies (MIPAAF). Key legislation relating to each product group is summarised below.

Table 15: Key legislation governing plant biostimulants and plant strengtheners in Italy	
Plant biostimulant¹ ('biostimolanti')	Decreto Legislativo (Legislative Decree 75/2010) on the Reorganisation and revision of the legislation on fertilisers in accordance with Article 13 of the Law of 7 July 2009, no. 88, and subsequent amendments.
Plant strengthener/ 'corroborantii'² (Organic agriculture)	Regulation (EC) No 834/2007, No 889/2008, No. 1235/2008 related to organic production and labelling of organic products. Ministerial Decree No 18345/2009 Provisions for the implementation of regulations (EC) No 834/2007, no. 889/2008 and no. 1235/2008 and subsequent conditions that relate to organic production and labelling of organic products. DPR No 55/2012 Plant strengtheners in organic farming.

nutrition and/or plant growth and/or plant development and/or enhance plant resistance against non-parasitic impairments (indirect nutritional effect).

Other groups of products that have recently been included under the biostimulant label belong to the **préparation naturelle peu préoccupante (PNPP) or natural preparations of low concern**. PNPPs constitute a special category of products that was previously administered under plant protection legislation in France. PNPPs comprise two main groups: basic substances and natural substances with biostimulant use.

Official definitions of these various groups are given in the following table.

Table 18: Official definitions of biostimulant product groups in France	
Agronomic additives	'Substances able to give additional properties to fertilisers, soil conditioners or mixtures of these' ¹ .
Plant growth and/or development stimulators. Other synonyms include phytostimulant, biofertiliser, soil activator	Fertilising materials promoting nutrition, growth and/or development of the plant or its resistance to abiotic stress (indirect nutritional effect) ¹ .
Natural preparations of low concern (PNPP): Natural substances with biostimulant uses	'Substances that are applied to plants or soils to regulate and enhance the crop's physiological processes, thus making them more efficient' ²
Natural preparations of low concern (PNPP): Basic substance	'Not a substance of concern; and is not predominantly used for plant protection purposes but nevertheless is useful in plant protection either directly or in a product consisting of the substances and a simple diluent; and is not placed on the market as a plant protection product.' ²
¹ As defined in French Normes NF U 44-204 and NF U 44-551;	
² As defined in Reg (EC) 1107/2009 Article 23	

3.5.3 Legislation and administration

Regulation of plant biostimulants in France is administered under the [French Rural and Maritime Fishing Code](#). The National Agency of Health Security of Food, Environment and Labour (ANSES) is responsible for issuing, withdrawing and amending marketing authorisations and permits for plant protection products, fertilisers and growing media, and adjuvants.

The following table summarises key legislation covering biostimulants classified as 1) agronomic additives, and 2) as PNPPs:

Plant biostimulants have been widely used in organic agriculture in Germany for many years but these products are now also becoming increasingly important in conventional cropping systems. Today, Germany is currently the fourth largest market for plant biostimulants in Europe with an estimated market value of around US\$6m (CPL, 2016).

There is no official definition of the term 'plant biostimulant' in Germany but three classes of agricultural products currently available to German growers could be considered to fall within the scope of the definition given in Section 1.3: **plant strengtheners**, **plant aid agents/plant growth improvers** and **soil improvers** (Table 21). The regulatory situation for these different groups is complicated - plant strengtheners are regulated under plant protection legislation whereas plant aid agents and soil improvers are regulated under fertiliser law.

Table 21: Official definitions of plant strengtheners, plant aid agents and soil improvers in Germany¹	
Plant strengthener (formerly known as plant resistance improvers) ¹ (Pflanzenstärkungsmittels)	Substances and mixtures including microorganisms which are <ul style="list-style-type: none"> exclusively intended to maintain plant health in general as long as they are not plant protection products according to §2 (1) of Regulation (EC) No 1107/2009 or intended to protect plants against non-parasitic impairments².
Plant aid agent or plant growth improver (Pflanzenhilfsmittel) ³	Substances without significant nutrient content which are intended to: <ul style="list-style-type: none"> act on plants biologically or chemically to obtain a beneficial effect on plant cultivation, production technology or performance, as long as these are not plant strengtheners as defined in § 2 point 16 of the Plant Protection Act.
Soil improver (Bodenhilfsstoffe) ³	Substances without significant concentrations of nutrients and also microorganisms which are intended to <ul style="list-style-type: none"> influence the biological, chemical or physical properties of the soil in order to improve the growth conditions for crops, or promote the nitrogen fixation by symbiotic organisms
¹ Definition provided in §2 No 10 German Plant Protection Act (2012); ² Examples in this second group include products for reducing water evaporation or anti-freezing agents; ³ As defined in § 2 German Fertilisers Act (DüngG)	

3.6.3 Legislation and administration

The competent authority responsible for regulating plant strengtheners is the German Federal Office of Consumer Protection and Food Safety (BVL) whereas plant aid agents and soil improvers are regulated by the Federal Ministry of Food and Agriculture (BMEL).

A summary of key legislation is given below:

Over 350 biostimulant products were registered as at September 1 2016.

Hungarian registration requirements are more demanding than most other EU Member States.

3.7.2 Introduction

In Hungary, plant biostimulants are regulated as part of a diverse group of products known collectively as 'yield enhancing substances' (YES) which include chemical fertilisers (excluding those authorised under Reg (EC) n 2003/2003), organic fertilisers, mineral fertilisers, composts, earthworm humus, soil improving substances, soil-conditioners, microbiological preparations and plant conditioners.

There is no official definition of the term 'plant biostimulant' in Hungarian law but three categories of yield-enhancing substance can be considered to meet the definition used in this report and described in section 1.3. These are the 'plant conditioners', the 'microbiological preparations' and the 'soil improvers'. Official definitions of these terms are given in Table 25.

Officials distinguish between microbials used as PPPs and those that are not PPPs. The latter include bacteria, fungi, and mycorrhizal preparations alone or in mixture.

Table 25: Official definitions of individual 'Yield Enhancing Substances' (YES) product categories relevant to plant biostimulants in Hungary¹	
Soil conditioners²	Yield enhancing substances manufactured in the industry and having a beneficial effect on the physical, chemical and biological properties of the soil.
Microbiological preparations (living)²	Yield enhancing substances containing microorganisms (bacteria, fungi, algae) improving soil fertility and exempt from agents infectious for man or influencing the natural micro flora of the soil adversely.
Plant strengthener/ plant conditioner²	Preparations manufactured from organic or inorganic materials with a favourable influence on growth, yield and general conditions of plants and which have an effect on plant life cycles primarily by influencing the nutrient supply.
¹ Definitions provided in Article 2 of Decree 36/2006 (V.18.) FVM concerning the authorisation, storage, marketing and utilization of yield increasing materials; ² Product categories considered to fall under definition of plant biostimulants used in this report.	

This chapter reviews the current approach to regulation of yield enhancing substances in Hungary. A summary of key legislation and the registration process is presented along with supporting activities.

3.7.3 Legislation and administration

The competent authority responsible for regulating plant protection products and yield enhancing substances is the Directorate of Plant Protection, Soil Conservation and Agricultural Environment which is part of the National Food Chain Safety Office (NFCSSO) of the Hungarian Ministry of Agriculture and Rural Development.

However, any development or revision to UK Regulation must complement and facilitate both current and future EU Regulations and more recent consultations have focused on defining the UK position on the revised Reg (EC) 2003/2003 on Fertilising Products. In other words, no significant changes to legislation have taken place so far.

3.8.3 Legislation and administration

The legal basis for fertiliser regulation is the [The Fertilisers Regulations 1991](#) (and amendments) which is administered by the [Chemicals Regulation Directorate](#) (CRD). This legislation specifies the labelling and packaging of the product and places a responsibility on the manufacturer to declare the nutrient content of the product. The Regulations include a series of Schedules listing existing fertiliser type designations.

Other relevant legislation includes the [The EC Fertilisers \(England and Wales\) Regulations 2006 – S.I. No 2486](#) which implements Regulation (EC) No. 2003/2003 relating to fertilisers. Additionally, the [Fertilisers \(Sampling and Analysis\) Regulations 1996 – S.I. No 1342](#) prescribes official methods for enforcement authorities when taking, handling samples and checking the accuracy of the nutrient declarations of fertilisers (Table 27).

Table 27: Key regulatory bodies and legislation governing plant biostimulants in the UK		
Product category	Competent authority	Key legislation
Fertilisers	CRD	The Fertilisers Regulations 1991 – S.I. No 2197 and amendments The Fertilisers (Sampling and Analysis) Regulations 1996 – S.I. No 1342 The EC Fertilisers (England and Wales) Regulations 2006 – S.I. No 2486

3.8.4 Registration process, key data requirements and guidance documents

As stated earlier, fertilisers for sale in the UK do not have to be registered. Thus, biostimulants do not have to be authorised as long as they do not claim any direct effect on pests or diseases. Manufacturers or importers of such products often check with CRD in advance to make sure their products and claims are considered outside the scope of the pesticide regulation. Some companies, however, have voluntarily registered products in order to make marketing claims relating to secondary effects on plant health that would otherwise be unregulated under the pesticide framework.

In both the UK and Ireland, mixtures of biostimulants with nutrients can be sold under the Fertilisers Regulations. They are marketed either as EC fertilisers or non-EC fertiliser. Only the nutrient content needs to be declared. It is not necessary to validate the claim of the biostimulant effect.