



# Bio-stimulant regulation in India

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## Auxilife Scientific Services Pvt. Ltd.



- Auxilife became operational in June 2012.
- Auxilife specialise in agrochemicals, bio-stimulant, disinfectants & biocides registrations.
- Auxilife Scientific Services Pvt. Ltd. is the fully owned subsidiary of Global Product Compliance (GPC) Europe AB, Sweden.
- Auxilife has built trust in the market with the quality regulatory support to the global chemical industry.

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## Auxilife services



### India

Agro-chemicals  
Fertilizer and Bio-stimulants  
Biocides and disinfectants  
Medical devices  
Exploratory field trials

### EU and UK

Agro-chemicals  
Biocides

We provide the related services in different countries through our partners

- We understand our customer's business and provide tailor made regulatory solutions for business decisions.
- Over the years with our experience we help companies by providing the right solutions in the most economical way
- Our strength lies in providing a comprehensive range of services including the complete registration procedure, from study management & monitoring to the final registration dossier and the appropriate support before, during and after the submission.

**One stop solution!**

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## Introduction

- Ministry of Agriculture and Farmers Welfare, Department of Agriculture, Co-operation & Farmers Welfare issued the Fertilizer (Inorganic, Organic or Mixed) (Control) Order (FCO), 1985 under the Essential Commodities Act, 1955. The FCO sets down the criteria for substances to be qualified for the use as a fertilizer in soil.
- The bio-stimulant regulation in India is recently notified by the government through the official Gazette, this order called as Fertilizer (Inorganic, Organic or Mixed) (Control) Amendment Order, 2021.
- India is now one of the few countries globally to define separate regulations for bio-stimulants. As per the guidelines, bio-stimulants will have to be first registered and to prove efficacy before hitting the market.

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## Fertilizer (Inorganic, Organic or Mixed) (Control) Amendment Order, 2021

- Fertilizer (Inorganic, Organic or Mixed) (Control) Amendment Order, 2021 sets down the regulatory framework for bio-stimulant registration in India.
- As per the order, ***'Bio-stimulant' means a substance or micro-organism or a combination of both whose primary function when applied to plants, seeds or rhizosphere is to stimulate physiological processes in plants and to enhance its nutrient uptake, growth, yield, nutrition efficiency, crop quality and tolerance to stress, regardless of its nutrient content, but does not include pesticides or plant growth regulators which are regulated under the Insecticide Act, 1968.***
- This bio-stimulant committee under the FCO amendment will control the quality and specifications of all bio-stimulants and ensure that safe molecule are used in manufacturing.

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## Fertilizer (Inorganic, Organic or Mixed) (Control) Amendment Order, 2021

- Regulatory bodies:
  - Central: Integrated Nutrient Management Division of Department of Agriculture, Cooperation & Farmers Welfare under Ministry of Agriculture and Farmers Welfare
  - State: Integrated Nutrient Management Division of State Agriculture Department
  
- No person shall manufacture or import any bio-stimulant unless such bio- stimulant is included in Schedule VI.
  
- In Schedule VI, the bio-stimulant list with the specification and tolerance limit shall be included.

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## Fertilizer (Inorganic, Organic or Mixed) (Control) Amendment Order, 2021

- The bio-stimulants specified in Schedule VI shall be classified under any of the following categories
  - botanical extracts, including seaweed extracts
  - bio-chemicals
  - protein hydrolysates and amino acids
  - vitamins
  - cell free microbial products
  - antioxidants
  - anti-transpirants
  - humic and fulvic acid and their derivatives

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## Fertilizer (Inorganic, Organic or Mixed) (Control) Amendment Order, 2021

### Data requirements

- Chemistry
- Bio-efficacy trials
- Toxicology and Ecotoxicology
- Heavy metal analysis report

- No bio-stimulant shall contain heavy metals content over and above the following maximum limit prescribed for various metals, namely:

In mg/kg (maximum)	
Cadmium (as Cd)	5.00
Chromium (VI) (as Cr)	50.00
Copper (as Cu)	300.00
Zinc (as Zn)	1000.00
Lead (as Pb)	100.00
Arsenic (as As <sub>2</sub> O <sub>3</sub> )	10.0.

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## Fertilizer (Inorganic, Organic or Mixed) (Control) Amendment Order, 2021

- The sample of the product along with an affidavit by the manufacturer or importer stating that the product is not laced with pesticide beyond permissible limit of 0.01 ppm.
- Also, bio-stimulant sample shall be drawn by an inspector for quality check and will be analysed in the FCO approved laboratory.
- **If the product is already in Indian market**, the applicant (manufacturer/importer) first needs to obtain the provisional certificate to continue to manufacture for sale, sell, offer for sale, stock or exhibit such bio-stimulant within 31<sup>st</sup> March, 2022.

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## Fertilizer (Inorganic, Organic or Mixed) (Control) Amendment Order, 2021

- The Provisional certificate application needs to be made to State Agriculture Department, after verifying the status of the product in last 3 years.
- The FCO (central) shall grant a provisional certificate of registration of bio stimulant and the certificate will be valid up to 22<sup>nd</sup> February, 2023.
- Within that period, applicant need to generate the required data and submit the registration application to FCO (central).

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## Fertilizer (Inorganic, Organic or Mixed) (Control) Amendment Order, 2021

- **To manufacture/sell/import the new product under bio stimulant category**, the product needs to be first included in the bio-stimulant Schedule VI.
- The manufacturer or importer of a bio stimulant shall make an application to the FCO (central) with the required data for specifying it as a bio stimulant in Schedule VI.
- The Controller shall by notification in the Official Gazette, publish the name of the manufacturer or importer of the bio stimulant included in Schedule VI.

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## Points to consider



- The bio-stimulant regulation in India is recently notified by the government through the official Gazette, Fertilizer (Inorganic, Organic or Mixed) (Control) Amendment Order, 2021.
- With the current order in place, the bio-stimulant label products cannot be sold/imported without having provisional certificate or inclusion in the Schedule VI. Only Indian applicant i.e. Indian manufacturer/importer/distributor/Indian agent can make an application under FCO amendment of bio-stimulants registration.
- As per the FCO amendment, the bio-stimulant products currently available in market require provisional certificate from Controller of Fertilizer' within 31<sup>st</sup> March 2021.

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## Points to consider



- For the products which are not yet marketed/imported or manufactured in India need to be included in the bio-stimulants schedule first by providing the all the required data.
- Currently the state and central authorities are accepting the applications only in physical mode. The authority is still working in order to streamline the entire process, which will take some time.
- We at Auxilife are in constant touch with the authorities and following the latest updates that helps to guide the applicant through all the required process.

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