



**Biological Agri Solutions
Association of India**

MEMBER BRIEF

For Internal Use Only

Sub. : Draft Regulatory Guidelines at the Center & State level for Bio stimulants
Ref. : Bio stimulant Regulations: INDIA (Volume II)
Date : 24.03.2019

**By
Vipin Saini
Executive Director**



A RECAP

- **No guidelines on Bio-Stimulants at present**
 - ▶ Recently, Govt of India, Ministry of Agriculture has appointed a Committee under chairmanship of ADG(PP&B) for registration of bio stimulants.
- **Import challenges for Bio-pesticide**
 - ▶ Rejecting microbial product import may not be the solution, instead have effective guidelines to ensure safety of imported strains
 - ▶ Multiple Compliance Issues
- **Separate mandate for Biologicals, apart from Agrochemicals ?**
 - ▶ Biostimulants can be both of Chemical & Biological nature
- **Counterfeit products**
 - ▶ Counterfeit products tarnish the image of genuine bio-products
- **Low investment & innovation**

REGISTRATION OF EXISTING BIOSTIMULANTS IN THE MARKET u/s 9(3B) **WITH COMMERCIALISATION**

For the existing biostimulants in the market, there may be option for 9(3b) registration with commercialization like Biopesticides. Window for filling registration of application u/s 9(3b) for existing biostimulants in the market can be kept open for 6 months. The secretariat of CIB &RC may issue the registration u/s 9(3b) with commercialization within 6 months. The total cut-off period for implementation of the guidelines can be kept one year. The applicant has to provide request letter for the Schedule inclusion of active ingredient if not already included in the schedule.

The applicant may submit following data / information to obtain 9(3b).

DATA REQUIREMENT FOR REGISTRATION OF EXISTING BIOSTIMULANTS IN THE MARKET u/s 9(3B) WITH COMMERCIALISATION

1. LEGAL:

1. Form 1
2. Manufacturing license/NOC from State Directorate for new factory
3. Affidavit by the manufacturer on non-judicial stamp paper stating that the product is not laced with pesticide (> 0.01 ppm) *and heavy metal*.

2. Chemistry:

1. Chemical composition (chemical analysis by GLP/NABL accredited lab)
2. Physicochemical properties of a.i and adjuvants, if any
3. Method for determination of chemical composition and physical parameters (Solid/Liquid- pH, moisture content, solubility, particle size (if applicable), specific gravity (if applicable), density, etc.) where MOA is cumbersome
4. Shelf-life claim
5. Sample for analysis in CIL

3. Packaging:

1. Manner of packaging – Primary, secondary and transport packing

Label and leaflet requirements:

The following particulars shall be printed on the label of the innermost container and on the outer most covering in which the container is packed:

1. Name of the manufacturer/importer (including country of origin)
2. Name of the marketer, if any.
3. Name of the bio-stimulant (brand name or trade mark under which the bio-stimulant is sold).
4. Use recommendations.
5. Precautions/storage conditions
6. Net content.
7. Batch number and date of manufacturing/repacking.
8. Expiry date
9. The label shall be so affixed to the containers that it cannot be ordinarily removed.
10. The label to be affixed or attached to the package shall be printed in English and Hindi.
11. Maximum Retail Price of the product

The State of Jammu & Kashmir- March 2018

Government of Jammu and Kashmir
Agriculture Production Department
Civil Secretariat, Jammu.

Government Order No: 86-Agri of 2018
Dated: 20-03-2018

Subject: Imposition of restriction on the import of Organic/Bio Fertilizer Non-FCO and FCO products in the J&K State.

Sanction is hereby accorded to:-

- a) Imposition of ban on the import/movement of the Non-FCO Organic/Bio Fertilizers and other products into the territorial limits of J&K State w.e.f. 01-04-2018.
- b) Promotion of indigenous organic/Bio fertilizer development under various state/Government of India sponsored schemes/initiatives.
- c) The import of the below mentioned Bio-Fertilizer and organic fertilizer specified under Clause-2 (h) and (g) in Scheduled (III), and Schedule (IV) of Fertilizer (Control) order, 1985 if only the said products are accompanied with batch-wise Quality Analysis report (Form L2) from Government Notified/Accredited Laboratory.

Specification of Bio-Fertilizers (Schedule III)

- a) Rhizobium
- b) Azotobacter
- c) Azospirillum
- d) Phosphate Solubilizing Bacteria.
- e) Mycorrhizal Bio Fertilizers.
- f) Pottasium, Mobilizing Bio Fertilizers (KBM)
- g) Zinc Solubilising Biofertilizers (ZSB).
- h) Acetobacter.
- i) Carrier Based Consortia.
- j) Liquid Consortia.

Specification of Organic Fertilizers (Schedule IV)

- a. City Compost.
- b. Vermicompost.
- c. Phosphate Rich Organic Manure (PROM)
- d. Organic Manure.

However, organic fertilizers specified in Schedule (IV) of Fertilizer (Control) Act, 1985 shall be allowed in very rare cases in the absence of local organic fertilizers duly certified by Director Agriculture, Kashmir.

By order of the Government of Jammu and Kashmir.

Sd/-
(Muhammad Afzal)IAS
Commissioner/Secretary to Government
Agriculture Production Department

The State of Maharashtra - Dec. 2018

SHOW CAUSE NOTICE

By HAND/R.P.A.D.

District Superintending Agril. Office Dhule
Dhule, Dated- 19/12/2018

From,

Manojkumar R. Shisode
Insecticide Inspector &
District Quality Control Inspector
O/o. District Superintending Agril Office, Dhule

To,

[Redacted]

Subject:- Contravention of The Insecticide Act 1968...
Explanation Called for...

Reference:- Notification No. 3385 Gov. of India Ministry of Agriculture, Department of
Agriculture and Cooperation New Delhi 27th October 2016

I, Undersigned, working as a Insecticide Inspector and District Quality Control Inspector in the office of District Superintending Agricultural Office, Dhule, vide clause 20, of Insecticide Act 1968.

During routine inspection at M/s Aashish Agencies, Bara Patthar Chowk, Dhule Tal. Dist. Dhule, I observed that you have manufactured the Plant Growth Promoter having content [Redacted] % and selling it by the trade name [Redacted]

As per the section 3 (e)(ii) of the Insecticide Act 1968 the [Redacted] have been added in the Schedule by the above referred notification. As your product contains [Redacted] and it is included in the schedule it should be manufactured as per the section 9(1) of Insecticide Act 1968.

As you are manufacturing the said products without registration, as per section, 3(k)(i), 3(k)(iii) and 3(k)(vi) of the Insecticide Act 1968, your products named [Redacted] is misbranded. As [Redacted] is included in the Schedule, you have also contravened the Rule 19(3) and 19(8) of the Insecticide Rule, 1971.

As you have contravened the Insecticide Act 1968, I have detained the stock of [Redacted] as per section 18(a)(a) and 21(1)(d) of The Insecticide Act, 1968. You are instructed to submit your reply to this notice in writing within 10 days after receipt of this notice, failure to which further action will be initiated against you as per The Insecticide Act 1968.


District Quality Control Inspector
Dhule.

The State of Andhra Pradesh- Excerpts 2017

GOVERNMENT OF ANDHRA PRADESH

ABSTRACT

Agriculture Department - Bio-products- Establishment of manufacturing units with fake and

Bogus addresses, selling of Bio-products mixed with chemicals- System Improvement -

regulation mechanism proposed – Convened of Technical High Level Committee Meetings -

Guidelines/Regulations finalized – Approved- Orders – Issued.

AGRICULTURE & COOPERATION (AGRI.III) DEPARTMENT

G.O.MS.No. 18 Dated: 10-03-2017

Read the following:

1. G. O. Rt. No. 309, Agriculture and Cooperation (Agri.V) Department, dt: 28.04.2014.

2. Minutes of the Technical High Level Committee meeting held on 20.12.2016, 06.01.2016 and 17.01.2016.

3. From the Director of Agriculture, A.P., Guntur, letter No. PP(3) 585/2016, dated:06.02.2017.

3/24/2019

NOTIFICATION

BIOPRODUCTS – DEFINITION :

Bio-Product means, any substance / product / preparation / formulation prepared from natural sources of Biological origin intended for use in agriculture either through soil application or foliar application, for the improvement of Crop or Crop produce and which are *for time being not covered under any of the laws of The Insecticides Act 1968 and Fertiliser (Control) Order 1985.*

7. Analysis of bio-products:

If any product found to be detected with chemicals / impurities etc during analysis at State Laboratories / Central laboratories, the necessary legal action will be initiated. The permissible limits as per the advice of Technical Committee are fixed as follows.

a) **FOR PRESENCE OF CHEMICAL SUBSTANCES IN BIO-PRODUCTS:**

The limit of Quantification (LOQ) should be **<0.01%** for all kinds of pesticides / other chemicals which are in Schedule of Insecticide Act, 1968 in Bio Products, and if any bio-product is detected with pesticide **>0.01%** shall be treated as **spurious**.

b) **FOR CONTENT ANALYSIS IN BIO-PRODUCTS:**

Any deviation in content / quantities described in the label within the range of + 2.00% will be treated as passed, and deviation beyond + 2.00% shall be treated as **Misbranded**

8. Label requirements:

The following particulars shall be either printed on the label of the innermost container of any bio-product and on the outer most covering in which the container is packed:

- a) Name of the manufacturer
- b) Name of the marketer, if any.
- c) Name of the bio-product (brand name or trade mark under which the bio-product is sold).
- d) Kind and name of active and other ingredients and percentage of each in common name accepted by trading community and research organizations for each of the ingredients shall be given.
- e) Net content of volume. (The net contents shall be exclusive of wrapper or other material. The correct statement of the net content to terms of weight, measure, number of units of activity, as the case may be, shall be given. The weight and volume shall be expressed in the metric system).
- f) Batch number and date of manufacturing.
- g) Expiry date, i.e. up to the date the bio-product shall retain its efficiency and safety.
- h) The label shall be so affixed to the containers that it cannot be ordinarily removed.
- i) The label and leaflets to be affixed or attached to the package containing bio-products shall be printed in English and Telugu language.
- j) Maximum Retail Price of the product

9. Field trials for efficacy of the bio-products:

The manufacturers / marketers of bio-products should furnish each bio-product with technical details for organizing paid up trials by scientists at State or Central Research Institutes to study the efficacy of the product.

10. Action on spurious, misbranded bio-products:

- a)** If any bio product is found laced with pesticides / chemicals, action will be taken as per the existing laws and statutes.
- b)** If any bio-product is imitation of any other brand / label, action will be initiated as per the existing laws.
- c)** If a bio-product is not according to specifications as per the composition, legal action shall be initiated as per existing laws.



**Biological Agri Solutions
Association of India**

Grow Safe Food



Department of Agriculture, Cooperation & Farmers Welfare
Ministry of Agriculture & Farmers Welfare

धन्यवाद

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