No. 3-14/2017 Fert. Law
Government of India
Ministry of Agriculture and Farmers' Welfare
D/O Agriculture, Cooperation and Farmers' Welfare

Krishi Bhavan, New Delhi
Dated the 2nd August , 2021

To

Bio-Stimulants Associations
(As per the list attached)

Subject: Inclusion of Bio- stimulants under Fertilizer (Control) Order, 1985 (FCO) vide notification S.O.882 (E) dated 23.2.2021- issue of clarifications regarding

Dear Sir/Madam,

As you are aware it has been decided to include bio- stimulants in Schedule VI of FCO 1985 and guidelines thereon were issued vide the above mentioned Notification dated 23.2.2021. Concerns were being raised by the State Governments as well as associations with reference to the implementation of various provisions of Notification.

2) To address these issues, two rounds of discussions were held with the State Governments and bio-stimulant manufacturer associations in the month of April, 2021. These issues were placed before the Central Bio-stimulant Committee (CBC) in its meeting held on 2nd June, 2021 and clarifications on various issues are tabulated as under:-

S.No.	**A. Procedural issues for smooth implementation of Notification S.O.882 (E) dated 23.2.2021**	
	Issue	**Clarification**
i.	Time bound process for issuance of Form G-2	States have been advised to expedite the issue of G-2 form within 15-20 days of receipt of application from the manufacturer, in order to facilitate all manufacturers to submit their G-1 Form for provisional registration, by the month of December, 2021.

ii.	Simplification of procedures - manufacturer/ importer/ formulator declare the information as per their convenience and validated by their authorised signatory, endorsement by the State Govt. to be waived off.	State Governments have been advised to adopt the following procedure:- **a) verification of sale for the last three years**: self-attested label of products along with self-attested sale figures of products sold in their State, for the last three years, from an authorized representative of the company or GST data for the last three years. Or stock, production/ trade of the product for last 3 years duly verified by CA. **b) Hazardous effect of the product:** States may consider self-declaration of 'No reported ill - effect or hazardous effect' Or Any international publication or world wide acceptable test report supporting non hazardous effect of product.
iii.	Format for product information to be attached with the G2 (from the State where the manufacturing unit is located / OR State where the importing firm is located / registered)	States are required to issue a certificate in G-2 form for a product and its brand name. If a product is being sold in different brands, all brand names may be mentioned or annexed with G-2 form. However, separate G-2 Form is required for each different product.
iv.	States have started stop sale to store and manufacture bio-stimulants. State Government to be advised not to take any action in 6 months	During the period available for provisional registration to manufacturers in the notification dated 23.2.2021 and subsequent amendment dated 14.6.2021, States have been advised to allow manufacture, sale or stock of these products, unless otherwise necessary to stop, upto 31st March, 2022. Those products which could not be registered during this period, shall not be allowed to manufacture, sale and store after 31st March, 2022.

v.	Govt. should grant at least 2-3 years as a transiting period for stock clearance and during which sampling should not be done.	Provisional registration period of two years is already available. Any manufacturer may use this period for stock clearance subject to getting provisionally registered. All the provisions of FCO including sampling shall be applicable after provisional registration. States have, however, been advised to analyse only those parameters, limits for which have been prescribed in the Notification and also based on the label claims, for provisionally registered products.
vi.	A uniform procedure to be laid down for issuance of G-3 form	As per the Notification dated 23rd February, 2021, manufacturers are required to submit an application in Form G-1 to the Controller of Fertilisers (i.e. Joint Secretary (INM), DAC&FW) alongwith a certificate from the State Government in G-2 Form. On receipt of application from the manufacturer along with G 2 Form issued by at least one State Government, Controller of Fertilisers, after due scrutiny and following the prescribed procedure, will issue certificate of provisional registration under clause 20 C of FCO, in Form G-3 to the manufacturer. Once a product is provisionally registered, a bio-stimulant manufacturer is authorised to sell such provisionally registered product in the country. Other States may consider issue of authorisation letter to the manufacturer based on the provisional registration.
vii.	If the product is being sold since last 2 years only from the date of Gazette Notification, will 2 years data will be acceptable for provisional registration.	3 years of successful sale without any complaint indicates the genuineness of the biostimulant. However, those manufacturers, not covered under this category, may initiate procedure for permanent registration

viii.	In case, manufacturing company manufactures and sell the products to a marketer which in turn supplies in different states. If manufacturing company needs to apply form G2 in all states, there will be difficulty in applying. The manufacturing company doesn't have any godown or sales in all the states. Only the marketing company sells the products in all the states. For Provisional registration, marketer has to provide Form G-2 from all states where it has been sold or two/three states would be enough.	In case of those manufacturers who are not selling or marketing their product on their own, States have been advised to consider the data required in para "ii" above provided by the marketer to the manufacturer along with sale record of manufacturer to marketer, for the purpose of issuance of G-2 Form.
ix.	Instead of an individual sheet for separate products from each manufacturer/ formulator /importer, let marketer submit the information in a single sheet for all the products; and highlighting each product in the sheet, it can be attached in the separate application i.e. G 1 for every product.	The manufacturer is being allowed to use the data provided by the marketer. Inclusion of all data for all products marketed by any marketer in a single sheet would make it cumbersome to understand.
x.	Whether provisions of FCO applicable on biostimulants?	The provisions of FCO and the ECA would be applicable on all such products which are being sold as bio-stimulants.
xi.	What happens if provisional registration of manufacturers of 3 or more years' experience is not done?	Bio-stimulants which could not be provisionally registered within a period i.e. upto 31.3.2022 under clause 20 C of FCO, will not be allowed to sale after the expiry of the prescribed period.

xii.	Establishment of Notified laboratories & equipment needed	As per the notification, a sample of biostimulants can be analysed in CFQC&TI, Faridabad or its regional laboratories or any other laboratory notified by the State Government with prior approval of the Central Government. The requirement of equipment and facilities in such laboratories may be notified by the central government in due course.
xiii.	Can Manufacturers / Importers of Bio-stimulants market (Sell & distribute) same bio-stimulant (One category of Product like botanical / Seaweed Extracts, amino acids, microbial products etc. with same chemical composition) under different brand names (Trade names) through different companies? If answer of above question is YES, then can the Manufacturers / Importers of Bio-stimulants in One application i.e. Form G, Form - G1 & G 2 under the Name of the Bio-stimulant (Category of Bio-stimulant) mentioned all the Brand names for inclusion in Schedule VI, Provisional Registration & Permanent registrations.	There is no restriction on the sale/distribution of any product under different brands (of same category and chemical composition). However, a manufacturer has to indicate all brand names at the time of submitting application in prescribed Forms G1 alongwith G2 Form and to certify that category & chemical composition of all the brands are same.

xiv.	The publication of the name of the manufacturers / importers in Schedule VI, Provisional Registration (Form - G 3) & Permanent Registration be the Brand name with the Name of the Bio-stimulant (Category) or in one copy mentioning all the Brands of Bio-stimulant products.	Specifications of products are included in FCO with their chemical names and not brand names. Specification of each product including main active ingredients or chemical compositions, crops to which it may be applied, its benefits etc. will be included in schedule VI. However, in case of provisional registration, brand names of same category & chemical composition products will be included in Form G-3.
xv.	Permanent Registration for Bulk / Technical manufacturer and / or Importer - In order to ensure the quality of the final commercial product, it is important to ensure the uniform quality of the technical or bulk product (with varying concentrations) which is either imported or manufactured within India. This, however, does not require any toxicology and bio-efficacy tests as not being used directly in farmers' fields.	Specifications of finished products alongwith testing protocols, are only provided in FCO and not of raw material. Hence, it is the duty of manufacturer/importer to ensure that good quality raw material is used to produce the product as per the FCO specifications.
xvi.	Can Manufacturers or Importers of Bio-stimulants continue to Manufacture, Import & repackage, Sell, Stock or Exhibit the New bio-stimulant products (brands) not yet commercialized in the country as it was before the notification of the said order for a maximum period of 2 years (i.e. till Feb 22, 2023) on those States where presently No	Only manufacturers of bio-stimulants can continue to manufacture, sale, exhibit or stock those products, which were being sold in the market for the last three years and subject to getting provisional registration, for a period of two years from the date of issue of notification.

xviii.	Member companies who are into export of these biostimulants esp Amino Acids and they are not selling in India, whether they have to follow the proposed guidelines or they will be waived off under export registration.	FCO provisions are applicable only on those imported or manufactured products which are intended for sale in the country.
xix.	The role/ responsibility of the co-marketer under this regulation needs to be clarified?	It is the responsibility of the manufacturer/importer/wholesaler/retailer/ marketer to ensure quality product as per FCO specifications. There is no concept of 'co-marketer' in FCO.
	B. Non-procedural issues	
i.	Separate Act for biostimulants	After detailed discussions with all stake holders and in view of the close proximity of bio-stimulants with fertilisers, it has been decided to keep bio-stimulants in FCO. However, it is being contemplated to bring a new Act under which regulatory and promotional functions could be differentiated.
ii.	One nation, one licence	As of now, authorisation letters are issued by the State Governments as per the provisions of FCO in respect of all fertilisers. This helps them to monitor the supply & availability of fertilisers in their respective states. Any change in licensing procedure would require consultation with the State Government. However, State Governments are being encouraged to bring in IT platforms for issue of licenses and this would lessen the hassles involved in the matter.
iii.	Inadequate capacity of SAUs to conduct trials -	A total of 100 institutes including ICAR institutes are available. The matter will be taken up with ICAR to expedite the process.

	restrictions on sales of bio-stimulants and in the interim obtain the Registration by submitting the information / data as required / decided by the Central Bio-stimulant Committee	
xvii.	Can Manufacturers or Importers of New Bio-stimulants not yet introduced in country submit the application in Form – G (Except Point XI - Quantity manufactured and sold during last three years (attach sale document)) along with required technical details of new bio-stimulants as decided by Central Bio-stimulant Committee on Chemistry, Toxicity, Heavy Metal Analysis report & Bio-efficacy trials report (Pending) a. for inclusion in Schedule VI (Under clause 20 C (3)), b. Provisional Registration without Form G – 2 from State(s) for immediate commercialization on those States where presently No restrictions on sales of bio-stimulants Grant of Permanent registration after submission of Bio-efficacy trial report on or before 2 years from the date of publication of this order	Manufacturers or importers of new bio-stimulants can apply for schedule VI registration in form G, giving all requisite details of bio-efficacy trials and toxicity reports. Provisional registration is not applicable to new products. It is further clarified that commercialization of new products, which were not being sold for the last three years prior to issue of notification, is not allowed without their inclusion in Schedule VI.

iv.	Since the inclusion and listing of Active Ingredients (AI))/Products would take long time, it is therefore important that a product or AI of a different category (other than the listed one) should be allowed to import or manufacture during this transition phase.	After provisional registration, manufacturers are permitted to manufacture or sale these products till these are notified in Schedule VI specifying therein AI or chemical composition. However, importers need to apply for Schedule VI registration immediately along with all requisite information.
v.	GST of 5% to be applicable to bio-stimulants at par with other fertilisers	The matter will be taken up GST council for its consideration.
vi.	a. If there is any provision for propriety products b. Whether this notification extends the basic essence of other schedules of FCO, allowing all listed products of schedule VI open for manufacturing and marketing to all without any special protection as followed in case other agrochemicals.	There is no provision for propriety products in FCO. Any product which is notified in any schedule of FCO can be manufactured by any manufacturer and is not a propriety product. However, as of now, all manufacturers/importers of bio-stimulants all required to make an application in Form G even the specifications of the product are listed in Schedule VI of FCO.

vii.	Deletion of Sub-clause 8 of clause 3 – "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 in FCO". There is no known precedence of permanent listing of specifications with the name of Manufacturer or Importer. Once a specification is registered in FCO, the same is open for manufacturing by any entity fulfilling minimum criterion of laboratory equipment and plant machinery. This clause will lead to exclusivity, profiteering and monopoly of an essential commodity.	It is true that any product which is notified in any schedule of FCO can be manufactured by any manufacturer and is not a propriety product. However, in case of non-availability of any information on existing products and especially due to provisional registration, this clause has been kept. Deletion or otherwise of this clause will be considered by CBC in due course of time.
viii.	The need for having aadhar number and PAN. Will the PAN number of company suffice and company will not have an aadhar number?	Aadhar and PAN number of authorised officials of the company are required and not of the company.
ix.	What will happen to Web Portals like Big haat, Agrebegri who are also one of the big sources who deliver products to the end users, does this act brings any special guidelines for web portals also?	As of now e-marketing of fertilisers is not permitted under FCO. Any decision to introduce this concept will be taken in due course.

xi.	Need to fix timeframe by when the Schedule VI will be notified and also the frequency of its updation. Presuming that there is no schedule VI existing today. How does one apply for provisional registration	After receipt of applications, with complete details & trial reports, for registration in Schedule VI, these will be scrutinized by the CBC for making a recommendations to the competent authority and thereafter, with necessary approval and consultation with Law Ministry, specification of these products will be notified in Schedule VI. It may take about 2-3 months time. Meeting of CBC will be held on monthly basis to consider the applications received in the preceding month.. However, there is no relevance between submission of application for provisional registration of any product and listing of the same product under Schedule VI.
	C. Issues related to importers	
i.	The role of importer has not been clarified clearly. In case, an Indian manufacturer who imports raw material from different parts of countries, does importer also need to have toxicology data and bio-efficacy data of all respective Indian states where he supplies?	As per the notification, an importer has to submit an application in form G to Controller of Fertilisers for registration of product in Schedule VI along with bio-efficacy trials in agriculture research frame work (i.e. trials carried out in any of the SAUs/ICAR institutes with minimum three doses in one season at three agro-ecological locations) of the country and toxicology tests. For those importers who are supplying raw material to Indian Manufacturers, the matter is under consideration.
ii.	In case of import, if the product is not registered in the country of Origin and data/information as required in the Gazette Notification is submitted for registration [Provisional & Permanent], will FCO grant registration?	Procedure for importers is already specified at 'i.' above. There is no provision available for provisional registration in case of importers. As per the notification, Importers are required to furnish additional details of country of origin, certificate of registration from the source country and whether any efficacy /toxicity trials were conducted in the country of origin. In case of non-availability of this information, it is for the CBC to take a decision on registration of such products keeping in view other relevant factors.

iii.	On the pack will it be mentioned Imported & marketed by or it has to be imported, packed & marketed by	Central Government will notify the details to be printed on the fertilisers bags under clause 21 d of FCO.
iv.	Restriction on import during this period may lead to increase in prices.	Importers need to apply for Schedule VI registration immediately along with all requisite information.
v.	The respective CHAs (custom House Agents) has informed the importers for obtaining fertilizer license for clearance of import consignment as these products are being obtained from different parts of the world.	A communication may be issued to the Customs as clarified at 'i' above.
	D. Technical issues	
i.	Removal of toxicity requirements in case of natural products and also for SMEs/MSMEs – tests being very expensive.	Central Biostimulant Committee (CBC) has been empowered under the notification to consider the toxicity tests requirements, on case to case basis.
ii.	Bio-efficacy trials to be made for only one season & one location and to be considered for all crops.	This provision has been kept which is required in agricultural research framework. One seasonal trial with minimum three doses at 3 agro-ecological locations are required for biostimulants applicable for multiple crops.
iii.	Permission may be granted for outsourcing from NABL Lab for Batch wise analysis, as many of MSMEs cannot afford the establishment of a dedicated Lab infrastructure.	As per clause 21 of FCO, every manufacture is required to comply with minimum requirement for laboratory facilities as decided by the Central Government. CBC will provide the requirement in case of bio-stimulants in due course of time and may consider outsourcing of NABL labs by MSMEs at that time.

iv.	Development of Testing protocols	Each manufacturer has to indicate active ingredients or chemical composition/specifications of their product along with method of analysis. Testing protocols to be finalised by the CBC at the time of making recommendation for inclusion of the product in FCO.
v.	In many countries, Biostimulant guidelines is yet to be framed. In such cases, Biostimulant is to be defined & listed based on the characteristics of the product rather than the certificate of origin.	CBC will consider this aspect while scrutinizing the application.
vi.	Clarification is required - on the provision to smoothly manufacture / import small quantities of established/ new Bio-stimulants and coded compounds for performing Regulatory test trials /Field Trials/ Demonstration/ Studies for their registration in India	Guidelines on this will be framed in due course.
vii.	a. Need to specify the components to be tested for each product. For example, Seaweed extracts are rich in polysaccharides, also contain some proteins, so what is to be tested, needs to be specified. Currently, the percentages mentioned are as per the proportion (mostly by weight) mixed in the formulation. b. Unless the ingredient to be tested is specified, how the shelf-life could	Committee felt the need to develop the protocol like thermal effect, chemical composition whether organic / inorganic , min/ max temperature bearing capacity on crops, for each category of bio-stimulants the components to be tested. It was, viewed to form sub-committees for each category of bio-stimulants to identify broad components to be considered while testing the products.

	be verified at different time intervals, before it is certified for a specific period?	
viii.	Pesticides MRL to be increased to 3-5 ppm or residual limit to be increased to 10 ppm	CBC decided not to increase the limit.
ix.	Tolerance limits to be provided - only the LOWER Tolerance Limits to be given as in case of Micro- nutrients. This is owing to the very nature of Bio- stimulant and their natural active ingredient/ chemical composition	The matter is being referred to the sub-committee for consideration and to make a recommendation for consideration of CBC.
x.	Pool Data with the association may be allowed for registration	CBC decided not to allow it for association. It was agreed that sharing of pool data may be considered on case to case basis and also while formulating the guidelines for me too products.
xi.	The definition and the recent notification on labels includes live microbials, which is not listed in the categories of bio-stimulants published in the notification	CBC decided not to included microbials in the category of bio-stimulants as these are already covered in the specifications of bio-fertilisers in FCO. A mention of live microbials under bio-stimulant guidelines refer to those which occur during the process.
xii.	The category of biochemical needs to be elaborated for better clarity	CBC felt the need to do study on the matter and decided that based on the trends / product received for provisional registration, bio-chemical category will be defined.
xiii.	Zinc & copper limit to be deleted from heavy metals	The matter is being referred to the sub-committee for consideration and to make a recommendation for consideration of CBC.

xv.	Clause 3(C) Eye Irritation and skin irritation tests on rabbits are outdated and unethical and hence should be dropped from the list.	The matter is being referred to the sub-committee for consideration and to make a recommendation for consideration of CBC.
xvi.	While the definition excludes PGR's, what would be the scope of regulations for having products which have benefits of stimulants as well as crop protection	CBC considered that matter and viewed that the products having pesticides are required to be registered under the Insecticides Act.
xvii.	To broad base the categories of bio stimulants in line with advanced countries like soil conditioners etc.	CBC did not concur to the suggestion.
xviii.	Can any of the Biostimulants have presence of nutrients elements like NPK, trace element from natural sources only	CBC considered the matter and clarified that products having substantial NPK content needs to be registered under fertilisers.
xix.	There is no proper method to quantify the exact % of Humic so through which method or on what basis a supplier can claim the labels?	The matter is being referred to the sub-committee for consideration and to make a recommendation for consideration of CBC.

xx.	a. Can we apply registration [provisional & permanent] of combinations of two or more categories of Biostimulants specified in Schedule VI. Combination products may be enlisted based on one major substance and the remaining other substances should be considered as adjuvants/fillers/solubilizers. b. Microorganism produced during the natural process should not be considered in any criteria for Biostimulant.	It was viewed that only Combination of one bio-stimulant with another bio-stimulant can be considered. However, substance of combination product will have to be declared and tested. (this needs inclusion of one more category of bio-stimulants in the notification) (b) It was clarified that the guidelines issued on the subject already take care of the issue.
xxi.	As per the existing guidelines for water soluble fertilisers, B and Mo shall not be more than 1 % in the formulation. However, there are certain formulations of BioStimulants being manufactured and marketed that contain higher concentrations of B and Mo specified above. Whether they need to be included for provisional registration or shall continue to be sold without registration?	The matter is being referred to the sub-committee for consideration and to make a recommendation for consideration of CBC.

xxii.	**Me too products** (a) It is not stated explicitly that me-too products will not be allowed to be registered. The Me-too category should clearly be NOT allowed for Biostimulants including that of microbial origin, as these are complex mixtures containing multiple AIs. (b) The states should also not grant licenses for manufacturing/ sale of me too Biostimulant products, as the composition of Bio-stimulants is very complex due to presence of multiple ingredients and it is difficult to demonstrate product equivalence, by physico-chemical means, in such products.	The matter is being referred to the sub-committee for consideration and to make a recommendation for consideration of CBC.

Yours sincerely

(Rajni Taneja)

Deputy Secretary to the Govt. of India

Tel:23386741

Copy to:-

1. Fertilizer Association of India

Copy for information to:-

1. PPS to Secretary (DAC&FW)
2. PPS to Additional Secretary (INM)/Agriculture Commissioner
3. PS to JS(INM)