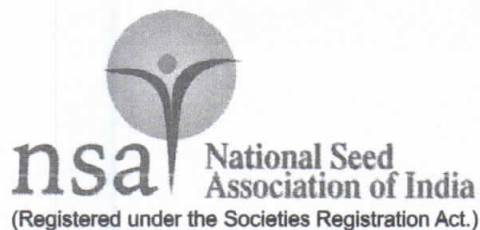


Dr. Kalyan B. Goswami
Executive Director



Ref. NSAI/2016/118

Date: 01.10.2016

Shri Gyanesh Bharti
Joint Secretary
Dept. of Environment, Forests & Climate Change
Ministry of Environment, Forests & Climate Change
New Delhi

Dear Sir,

This is with reference to the discussions we had with you on 22nd and 23rd September, 2016 on the removal of the GEAC stipulation of "No Objection Certificate" (NOC) and "Letter of Confirmation" (LOC) for release of new Bt cotton hybrids. We have clarified to you that the stipulation of NOC and LOC by GEAC has resulted in a situation where MMBL was able to make the seed companies to sign one sided and restrictive technology license agreements and monopolize cotton seed market. As we have explained to you, using of a trait in a transgenic plant variety is provided as a right to the breeders under Section 30 of the PPVFR Act. We have also clarified that the Patent Act does not provide any rights on plant varieties or seeds. The agreements have been mischievously titled as "Technology License Agreements" by MMBL, whereas the seed companies carry out the breeding activity and do not require either the transformation technology or the transgene perse. As mentioned in the agreement itself, only seeds of a transgenic variety are provided by MMBL to the sub licensees. The seeds of the transgenic variety cannot be patented as clarified under Section 3(j) of the Patent Act. The Dept. of Agriculture, Cooperation & Farmers Welfare and State level Departments of Agriculture are vested with powers and responsibilities of ensuring seed quality including Bt cotton seeds as explained below.

The claim of MMBL that for issuing NOC, they are regulating the gene expression thereby ensuring the quality of the seeds sold to the farmers, is incorrect. On the other hand, they are using this to create a monopoly contrary to the provisions of country's IPR policy. Regulation of seed quality is the power vested with the Seed Inspectors and Seed Analysts notified under the Seeds Act. Such statutory power cannot be taken over by or delegated to a private party who is actually competitor to the seed companies as both the partners of MMBL also happen to be seed companies undertaking cotton breeding and have conflict of interest in cotton seed business. At best they could have provided the inputs for fixing the gene expression standards to the Central Seeds Committee empowered to decide the seed quality standards. The Central Seeds Committee through their empowered sub committees could have got examined the proposals and notified the quality standards for gene expression levels which would have to be mandatorily followed by the seed companies and enforced by the Seed Inspectors with the help of Seed

Analysts, duly notified under the Seeds Act, 1966. The licensing authority under the Seed (Control) Order, 1983 would also enforce such quality standards with the powers drawn from not only the Seeds Act but also from the EC Act, 1955.

The seed business is regulated under the following Statutes in our country:

- 1) Seeds Act, 1966 and
- 2) Seeds (Control) Order, 1983.

The Seeds Act, 1966 is a Central enactment and the Seeds (Control) Order, 1983 is also promulgated by the Central Government under section 3 of the Essential Commodities Act, 1955.

The object of the Seeds Act is to regulate the quality of seeds. And the object of the Seeds (Control) Order is to regulate the trading activity as well as quality of seeds. The Seeds Act provides for constitution of Central Seed Committee under section 3 to advise the Central Government and the State Governments on matters relating to administration of the Act and to carry out the other functions assigned to it by or under the Seeds Act. Under section 3(5), the Central Seed Committee (hereinafter referred to as "Committee") is authorized to appoint one or more sub-committees for discharging such of its functions as may be delegated to such sub-committee or sub-committees by the Committee. Functions of the Committee have been specified under Part II rule 3 of the Seeds Rules, 1968, issued under section 25 of the Seeds Act. Thereby under the Seeds Act, there is a robust system in place to advise the Central Government and State Governments on matters relating to administration of the Seeds Act and also other functions under the Seeds Act. The Central Government, after consultation with the Committee, specifies, under section 6 the Seeds Act, the quality parameters and the mark or label [to be affixed on the seed container under section 7 (c)].

The Central Government, exercising powers conferred under **section 23 of the Environment (Protection) Act, 1986 (EPA)**, vide Notification S.O.No.588(E) dated 1-9-2006 of Ministry of Agriculture (Department of Agriculture and Co-operation), delegated the powers vested in it under section 14 of the EPA to the Seed Inspectors, notified under section 13 of the Seeds Act and clause 12 of the Seeds (Control) Order to take samples of genetically modified crops for analysis and to regulate the quality thereon as conferred under sections 10 and 11 of the EPA. Similarly, the Central Government, vide Notification S.O. No.589(E) dated 1-9-2006 of Ministry of Agriculture (Department of Agriculture and Co-operation), delegated the powers vested in it under section 14 of EPA to the Seed Analysts, notified under section 12 of the Seeds Act. Both the above notifications are enclosed herewith as Annexure-I. Section 10 of the EPA provides powers of entry and inspection by designated officer, section 11 of EPA provides power to take sample and procedure to be followed in connection therewith and section 14 of EPA provides for using report of Government Analyst as evidence of the fact stated therein in any proceeding under this Act.

The Central Government, after consultation with the Central Seed Committee, has also specified gene purity standard for Bt cotton seeds under section 6 of the Seeds Act vide Notification S.O. No.1567(E) dated 5-11-2005. Copy of the said notification is enclosed herewith as Annexure-II.

The Central and State Governments, under section 4 of the Seeds Act, have established by notification the Central Seed Laboratory and State Seed Laboratories respectively. Thereby, there is a very strong network, under the State Governments, for regulating and checking the quality of seeds including hybrid Bt cotton seeds, placed in the market, which is rendering its job very effectively. During the peak sale seasons, the State Governments constitute Squads including Vigilance Squad to conduct surprise checks to ensure that there is no deficiency in the quality of seed or no irregularity in its distribution. The Department of Agriculture at Central and State level is well equipped to ensure and maintain the quality standards, specified under the Seeds Act.

It is pertinent mention here that Genetic Engineering Appraisal Committee (GEAC) under the Ministry of Environment, Forests and Climate Change does not have mandate to specify quality standards for the seeds including transgenic varieties' seeds and to regulate quality of seeds put on the market. Similarly the GEAC has also nothing to do with hybrid release. It falls under the domain of Seeds Act and the Seed (Control) Order, 1983. The designated authorities under these legislations have the expertise and scientific knowledge to conduct trials so as to select and release hybrids/varieties under the provisions of the Seeds Act. Therefore, GEAC has to limit itself to extent of bio-safety clearance of transgenic events conferring a transgenic trait like Herbicide resistance, Bollworm resistance in cotton or male sterility to facilitate hybrid seed production in Mustard etc., under EPA and Rules, framed thereunder. GEAC may advise MMBL to submit the gene expression levels that need to be ensured by the breeders of new Bt cotton hybrids so that after due consideration, the Central Seeds Committee may specify the minimum standards through a notification under Section 6 of the Seeds Act. Such minimum standards specified by the Central Seeds Committee will have to be ensured by the seed companies and the standards of the seed quality will be enforced by the Seed Inspectors and Seed Analysts across the country.

It is clear from the above that Government of India and State Governments have a robust seed quality regulatory mechanism under their control. It would be disastrous, if the parties, which have to be themselves regulated and have conflict of interest (Ex: MMBL), are allowed to be a part of the regulatory system. This has gone to such an extent that the biotechnology trait providers are allowed so much of liberty, that they are exerting more control than the regulators and licensing authorities over the seed companies. This liberty is being misused against the companies, which do not submit to their dictates and terms. This is resulting in serious discrimination, monopolization of cotton seed markets which is against the interest of the seed industry and would render them to sub-serve the interest of the biotechnology trait provider undermining the farmers' larger interest. The partners of biotechnology trait provider themselves are in the cotton seed business, which is again a serious conflict of interest. Therefore, the

regulatory body has to function independently without being assisted or helped by the parties, having conflict of interest. A private party can be partisan and biased for its own reasons. Hence, the Government has put in place regulatory bodies under EPA, Seeds Act and Seeds (Control) Order. It is pertinent to mention here that no private parties are allowed or involved in enforcing the quality standards under Seeds Act and Seeds (Control) Order.

It is a fact that, but for requirement of NOC as stipulated, the seed companies would not have signed the one-sided agreement having onerous terms and conditions with the biotechnology trait provider. And using these agreements, the Bt trait provider has collected Rs.6000 crores over the years. Under the provisions of PPVFR Act, the trait value fixation is vested with the PPVFR Authority before whom the trait developer should have made a claim. The Authority is empowered to not only fix the trait value but also facilitate recovery of the trait value from all the breeders as per the provisions of Section 26 of the Act. It is pertinent to note that Monsanto offered to sell Bt cotton trait for a one time lump sum amount of Rs. 18 Crores which itself was found to be high by the Government and therefore was rejected. If the trait value was fixed by the PPVFR Authority, it could have been reasonable to the farmers and would have been far lower than the Rs. 6000 Crores collected by MMBL by fixing the trait value unilaterally. Such power they could gain through misusing the NOC stipulation by GEAC. The Hon'ble MRTP Commission in 2006 and the Hon'ble CCI in 2016 independently have observed that there has been anti-competitive practices by Monsanto. The State Governments of Andhra Pradesh, Maharashtra, Gujarat, Karnataka etc., have to pass special legislations to regulate Bt cotton prices as they have found the practices of Monsanto to be exploitative of farmers. The Ministry of Agriculture, Govt. of India also had to promulgate Cotton Seeds Price (Control) Order, 2015 to regulate the trait value. We also draw your kind attention to the submissions made by DACFW in the WP No. 1776 of 2016 and 7583 of 2016 filed by MMBL against the Union of India and CCI before the Hon'ble Delhi High Court. These submissions also confirm the above explanations provided by NSAI.

From these submissions, it is evident that MMBL is able to create a monopoly without any legal IP rights on seeds or transgenic plant varieties under Patent Act by misusing the NOC and LOC stipulation by GEAC as well as hybrid wise approval mechanism instead of event based approval of a transgenic event.

We therefore request you to

1. Discontinue the stipulation of NOC for approval of new Bt cotton hybrids which has led to monopoly and over charging of the trait value in Bt cotton.
2. Take up biosafety approval of new transgenic events and allow release of new varieties or hybrids to the discretion of the authorities functioning under Seeds Act and Seeds Control Order, 1983. The GEAC may also give their inputs to the Central Seeds Committee to fix


the minimum standards of gene expression and gene presence for each of the transgenic event that is approved by it so that the seed quality is enforced by the regulatory mechanism already functioning under the seed legislations.

3. Suggest to biotech trait developers to adhere to the provisions of PPVFR Act to claim trait value so as to recover their investments with reasonable profits and based on agronomic value of trait as determined by the competent statutory authority.

We shall be grateful for your early action in this regard.

Thanking you,

Yours sincerely,


Kalyan B. Goswami

टी. जाय जयामती/T. JOY JAYAMATHY
प्रधान निजी सचिव/Principal Private Secretary
भारत सरकार / Government of India
कृषि एवं किसान कल्याण विभाग / Ministry of Agriculture & Farmers Welfare
कृषि सचिवालय / Secretariat of Agriculture & Farmers Welfare
नई दिल्ली / New Delhi

C.C:-

1. The Joint Secretary (Seeds), Dept. of Agriculture, Cooperation & Farmers Welfare, Ministry of Agriculture & Farmers Welfare, New Delhi
2. Dr. Trilochan Mohapatra, Director General, Indian Council of Agricultural Research (ICAR), Krishi Bhawan, New Delhi.
3. Dr. S. R. Rao, Member Secretary, RCGM & Scientist-G, Dept. of Biotechnology, Block 2, 7th Floor, CGO Complex, Lodhi Road, Delhi
4. Dr. K R Kranthi, Director, CICR, Nagpur
5. Dr. R.R. Hanchinal, Chairperson, PPVFR Authority, New Delhi