

Serious & Objectionable Regulatory Lapses with regard to Delhi University's GM HT Mustard

Coalition for a GM-Free India

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In the ongoing SC Hearings....

TOP STORIES

"Is There A Compelling Reason To Release GM Mustard Now?": Supreme Court Asks Centre Reasons For Deviating From Expert Committee's Opinion

Awstika Das

1 Dec 2022 7:10 PM

https://www.livelaw.in/top-stories/is-there-a-compelling-reason-to-release-gm-mustard-now-supreme-court-asks-centre-reasons-for-deviating-fro...

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The **Attorney-General for India, R. Venkataramani**, took the court through the decisions of several meetings of the Genetic Engineering Appraisal Committee to illustrate the stages in which the approval for the environmental release of the genetically modified mustard was granted. Over a long period of time, the question of releasing the transgenic food crop has been "minutely looked at and carefully examined", with experts from reputed institutions "applying themselves periodically, year after year", the top law officer submitted. "Since the protocol has been complied with, there is no need for a 'compelling reason' to make this decision. We have crossed the stage where all the anxieties and concerns regarding this issue have been addressed, and by and large, resolved. The environmental release of the genetically modified mustard is the next logical step," he told the Bench.

Also Read - 100 Important Supreme Court Judgments Of 2022 [Part 1]

Earlier, **Advocate Prashant Bhushan and Senior Advocate Sanjay Parikh**, appearing on behalf of the petitioners, had drawn the attention of the court to the reports of several committees, including a technical expert committee constituted pursuant to an order of the apex court, which in 2013 had categorically stated that it would be inadvisable to conduct more open field trials before, *inter alia*, addressing the gaps in the regulatory system and enhancing the understanding of the long-term impacts of introducing genetically modified crops on human and animal health and the ecology. Although in the interim report, this panel had suggested a moratorium of ten months on field trials of Bt transgenics, in its final report, an indefinite and complete ban on herbicide-tolerant crops was recommended. The Attorney-General took great exception to the report of this technical expert committee and the heavy reliance placed on it by the petitioners. He said, "The sum and substance of this report is that it is an ideological report. A scientist can also take an ideological stand. And now, on the basis of this report, this court is invited to make a value judgement." The apex court, the Attorney-General strenuously argued, was not permitted to venture beyond the limited question of whether the process envisioned under the law has been followed by the competent authorities. "The Court cannot go into the question of which science is good and which science is bad. Unless you find deficiencies in those processes and procedures, it would not be possible for the court to intervene only on the basis of this report," Venkataramani insisted.

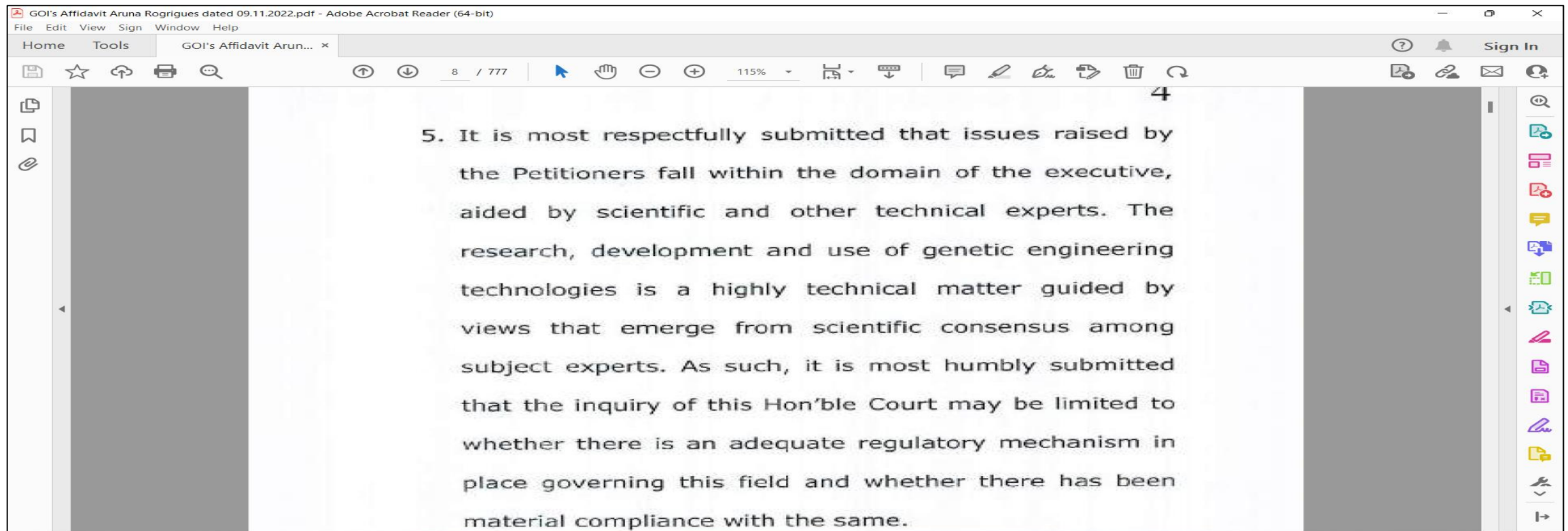
“Over a long period of time, the question of releasing transgenic food crop has been minutely looked at and carefully examined, with experts from reputed institutions applying themselves periodically year after year....” – AG, on behalf of UoI

“The Court should look into the limited question of whether the process envisioned under the law has been followed by competent authorities... Unless you find deficiencies in those processes and procedures, it would not be possible for the Court to intervene only on the basis of this (TEC) report” – AG R Venkataramani

Source: ["Is There A Compelling Reason To Release GM Mustard Now?": Supreme Court Asks Centre \(livelaw.in\)](https://www.livelaw.in/top-stories/is-there-a-compelling-reason-to-release-gm-mustard-now-supreme-court-asks-centre-reasons-for-deviating-fro...)

AG of UoI is trying to limit the Court's inquiry to regulatory matters, while this Coalition does not agree. It is very pertinent to look at the body of evidence on S&T of GM tech and HT crops in particular, and follow TEC ban recommendation for all HT crops—

However, we show objectionable regulatory compromises too to showcase the Union of India's brazen falsehoods in the Court....



https://drive.google.com/file/d/1DI_5b78inEXhS4NKNM6Xzv1efDfNd05K/view?usp=share_link

Here, we show you only 10 examples of the violations of statutory regulations and serious procedural infirmities with regard to GM mustard appraisal and approval in India –

We are intentionally not focusing on GM mustard yields, or its safety or such issues, but focusing on the regulatory regime.....

1. *Fait accompli*, before Formal Approval...

In the Court, UoI assures in July 2017 there will not be any situation of creating *fait accompli*. Any decision taken is ordered to be placed on Court record, in Nov.2017. **This undertaking in the SC, and SC's order have not been complied with!**

GEAC recommends in its meeting on October 18th 2022. Seed reaches DRMR from the applicant party on **October 22nd**, and formal approval given only on **25th October 2022!**

3. That I respectfully submit the following facts for kind consideration of this Hon'ble Court:-

4. That the said prayer of petitioner seeking stay in advance, a preventive even before the decision is taken by the Competent Authority, is wholly misconceived. It is reiterated that even if the decision is taken, there will not be any situation of creating *fait accompli* and this Hon'ble Court, if satisfied on merits, would be in a position to grant an effective interim orders after the decision is taken.

5. That the Union of India has already filed a detailed reply Affidavit in response to the IA No. 47 of 2016 which has

GM mustard sown in 6 field trial plots days before SC took up plea against it

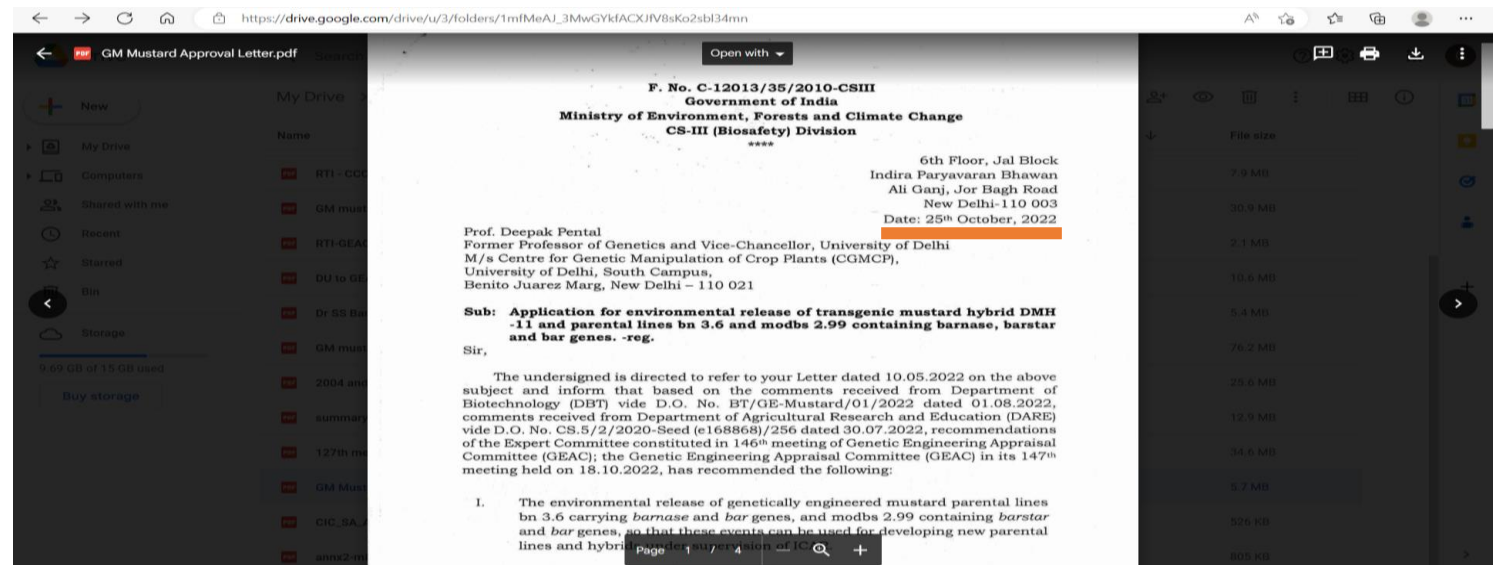
Besides for field trials, 600 grams of seeds were already sown in two demonstration plots, Directorate of Rapeseed-Mustard Research (DRMR) P K Rai said



PTI, Bharatpur, NOV 14 2022, 14:57 IST | UPDATED: NOV 14 2022, 14:57 IST

Speaking to *PTI*, Directorate of Rapeseed-Mustard Research (DRMR) P K Rai said: "We received the seeds on October 22 and a case was listed in the top court on November 3. The seeds were already planted in between this period in field trial plots for evaluating the yields."

Source: <https://www.deccanherald.com/national/gm-mustard-sown-in-6-field-trial-plots-days-before-sc-took-up-plea-against-it-1162227.html>



UoI affidavit, July 28th 2017 - [SC cases - Google Drive](#)

Approval Letter dated October 25th 2022: [DMH 11 scanned materials - Google Drive](#)

2. No Health Expert Participation in Appraisal – But green signal on health safety front of GM HT mustard!

bees and other pollinators. The composition of this Expert Committee constituted is as below:

- Dr. Sanjay Kumar Mishra, Chairman
- Dr. Ashok Kumar Singh, Member (Expertise in Molecular Genetics and Breeding)
- Dr. D. K. Yadav, Member (Expertise in Plant Breeding and Seed)
- Dr. A. H. Prakash, Member (Expertise in Plant Physiology)
- Dr. K. Annapurna, Member (Expertise in Microbiology)
- Dr. S. J. Rahman, Member (Expertise in Entomology)
- Dr. Nitin K. Jain, Member (Present Member Secretary of RCGM)



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- Dr. K. C. Bansal, Member (Expertise in Plant Biotechnology, Functional Genomics)
- Dr. Abhilasha Singh Mathuriya, Member Secretary.

First and second meetings of this Sub-Committee were convened on 23.09.2022 and 30.09.2022, respectively. The recommendations of the Sub-Committee constituted

UoI's Additional Affidavit filed in SC on Nov.9th 2022, Page 47-48.

Expert Committee of 2022 which gave green signal to GM HT mustard has no Health Expert:

https://drive.google.com/file/d/1DI_5b78inEXhS4NKNM6Xzv1efDfNd05K/view?usp=share_link

to 489).

Accordingly, on 04.01.2016 GEAC in its 126th meeting held on 04.01.2016 constituted a sub-Committee under the Chairmanship of Dr. K. Veluthambi, Co-Chair of the GEAC with the following Members for examination of the dossier:

- Dr. K. Veluthambi, Chairman (Biotechnologist)



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- Dr. S R Rao, Adviser, DBT, Member (Agriculture expert)
- Dr. S.K. Apte Member (Molecular Biology Expert)
- Dr. Ramesh V Sonti Member (Plant Genetics Expert)
- Dr. B. Sesikeran, Member (Nutritional pathologist and Food Safety Expert)
- Dr. C R Babu Member (Environmental Science Expert)
- Dr. K V Prabhu, Joint Director (Research), IARI Member (Plant Breeding Expert)
- Member Secretary, GEAC To facilitate the Sub-Committee

True copy of MoM dated 04.01.2016 is attached

UoI's Additional Affidavit filed in SC on Nov.9th 2022, Page 37-38.

Sub-Committee of 2016 has Dr B Sesikeran as the designated Health Expert:

https://drive.google.com/file/d/1DI_5b78inEXhS4NKNM6Xzv1efDfNd05K/view?usp=share_link

Dr B Sesikeran is an industry-linked man as this New York Times article shows: <https://www.nytimes.com/2019/09/16/health/ilsa-food-policy-india-brazil-china.html>. NIN did some studies on GM mustard and Dr Sesikeran headed NIN.

Importantly, he never joined any of the 3 meetings of the GM mustard sub-committee of GEAC in 2016, and **despite no health expert participating, GEAC gave a green signal to even the health safety aspects of GM HT mustard (see next page for RTI replies)**

A Shadowy Industry Group Shapes Food Policy Around the World



A supermarket in Mumbai, in India and in other countries, an organization funded by food and beverage companies quietly fights restrictions on sugary or processed foods.

By Andrew Jacobs

Sept. 16, 2019



When the Indian government bowed to powerful food companies last year and postponed its decision to put red warning labels on unhealthy packaged food, officials also sought to placate critics of the delay by creating an expert panel to review the proposed labeling system, which would have gone far beyond what other countries have done in the battle to combat soaring obesity rates.

But the man chosen to head the three-person committee, Dr. Boindala Sesikeran, a veteran nutritionist and former adviser to Nestle, only further enraged health advocates.

That's because Dr. Sesikeran is a trustee of the International Life Sciences Institute, an American nonprofit with an innocuous sounding name that has been quietly infiltrating government health and nutrition bodies around the world.

Created four decades ago by a top Coca-Cola executive, the institute now has branches in 17 countries. It is almost entirely funded by Goliaths of the agribusiness, food and pharmaceutical industries.

(Industry-linked) Dr B Sesikeran did not participate in GEAC's 2016 Sub-Committee meetings and **he was the only designated health expert!....**

https://drive.google.com/drive/u/3/folders/1mfMeAJ_3MwGYkACXJfV8sKo2sbl34mn

Minutes of the 1st Meeting of the Sub-Committee meeting of the Genetic Engineering Appraisal Committee (GEAC) held on 02.02.2016

The Sub-Committee meeting of the GEAC was held on 2nd February, 2016 in the Ministry of Environment, Forest and Climate Change (MoEF&CC) at Narmada Conference Hall, Jal Wing from 11:00 am under the Chairmanship of Dr. K. Veluthambi (co-chair of the GEAC). The list of participants is annexed at Annexure- I. Leave of absence was granted to Dr. B. Sesikeran as requested by him.

- At the outset the Chairman welcomed all members of the Sub-committee and indicated that the GEAC in its 126th meeting held on 4th January, 2016 had constituted the sub-committee to consider the response received from the applicant to all issues raised in the GEAC meeting and additional sought by the members. He also informed that the mandate given to the Sub-committee also includes review of the Biosafety Dossier for its adequacy and accuracy in all respect and indicate gaps, if any.
- The Vice-Chairperson of the meeting Dr. Ranjini Warriar (Advisor) welcomed the members of the Sub-Committee on behalf of the Ministry and introduced Ms. Madhumita Biswas, Director as the Member Secretary of the GEAC. She further informed that clarifications on issues raised by the Members in the last GEAC meeting have been received from the applicant and the same has been circulated to all the Members.
- Dr. S. R Rao Advisor, DBT informed that the Biosafety Dossier has been examined in detail by the Biosafety support unit set up in DBT and points for further clarifications and dossier revision have been prepared for consideration and discussion in the Sub-committee meeting. A copy of the issues raised by DBT is annexed as **Annexure II**.
- After a brief introduction of all members, discussion on the agenda item was initiated by the Chair.
- Discussion on the application for environmental release of transgenic mustard hybrid DMH-11 and parental lines containing bar genes by the Centre for Genetic Manipulation of Crop**

Minutes of the 2nd Sub-Committee meeting of the Genetic Engineering Appraisal Committee (GEAC) held on 11.04.2016

The Sub-Committee meeting of the GEAC was held on 11th April, 2016 in the Ministry of Environment, Forest and Climate Change (MoEF&CC) at Narmada Conference Hall, Jal Wing from 11:00 am under the Chairmanship of Dr.K.Veluthambi (co-chair of the GEAC).The list of participants is annexed at Annexure- I. Leave of absence was granted to Dr. B. Sesikeran as requested by him.

- At the outset the Chairman welcomed all members of the Sub-Committee and Dr.RanjiniWarriar (Advisor) welcomed the members of the Sub-Committee on behalf of the Ministry and informed the Sub-Committee members about the Central Information Commission (CIC) judgement regarding making data on GM Mustard Public by April 30, 2016.Dr. S. R. Rao briefed the Sub-Committee members on the follow up actions taken by Biosafety Support Unit (BSU) pursuant to the 128th GEAC meeting held on 04.03.2016 regarding the application for environmental release of transgenic mustard (*Brassica juncea*) hybrid DMH-11 by the Department of Genetics, Centre for Genetic Manipulation of Crop Plants (CGMCP), University of Delhi (South Campus).
- Discussion on the Sub-Committee report on the application for environmental release of transgenic mustard (*Brassica juncea*) hybrid DMH-11 by the Department of Genetics, Centre for Genetic Manipulation of Crop Plants (CGMCP), University of Delhi (South Campus)**

The GEAC in its 128th meeting held on 4th March, 2016 had sought further information/clarifications from CGMCP and accordingly a revised document was submitted by the Applicant. It was informed that pursuant to receiving the revised dossier from the Applicant, the revised biosafety dossier and draft RARM report of the Sub-Committee was circulated among the Sub-Committee members. Comments of the experts were tabulated along with the remarks of the BSU and circulated in the 2nd Sub-Committee meeting. After a brief discussion, the following points were raised by the members of the Sub-Committee:

Record Notes of the Third Meeting of the Sub-Committee constituted by Genetic Engineering Appraisal Committee (GEAC) for assessment of food and environmental safety of GE mustard

Date: November 01, 2016
Time: 11.00 AM
Venue: Narmada Conference Hall, Ground Floor, Jal Block, Indira Paryavaran Bhawan, Jorbagh, New Delhi-110003

- The third meeting of the Sub-Committee constituted by Genetic Engineering Appraisal Committee (GEAC) for assessment of food and environmental safety of GE Mustard was held on 1st November, 2016 under the Chairmanship of Prof. K. Veluthambi, former professor, Madhurai Kamaraj University and Co-chair, GEAC. The following members participated :
 - Dr. K. Veluthambi, Co-Chair, GEAC / Chairman, Sub-Committee
 - Dr. C.R. Babu, Emeritus Professor, Delhi University, Delhi
 - Dr. S.K. Apte, Emeritus Professor, HBNI, BARC, Mumbai
 - Dr. K.V. Prabhu, Joint Director (Research), IARI (ICAR), New Delhi
 - Dr. Ramesh Sonti, Chief Scientist, CSIR-CCMB, Hyderabad
 - Dr. S.R. Rao, Advisor, DBT, MoS&T, New Delhi
 - Ms. Madhumita Biswas, Director, Member Secretary, GEAC / Sub-Committee, MoEF&CC, New Delhi
 - Dr. P. Saranya, Scientist-C, MoEF&CC, New Delhi
- Chairman welcomed all the members for the meeting and requested Ms. Madhumita Biswas, Director and Member Secretary, GEAC to provide the genesis and objective of the third meeting. Member Secretary informed that as per recommendation of GEAC the document on the Assessment of Food and Environmental Safety (AFES) for "Environmental Release of Genetically Engineered Mustard (*Brassica juncea*) Hybrid DMH-11 and use of Parental Events (*Varuna bn 3.6* and *EH-2 modbs 2.99*) for

MoEFCC's RTI reply to Kavitha Kuruganti dated 8/6/2017: [DMH 11 scanned materials - Google Drive](#)

3. Conflict of Interest – Dr Akshay Pradhan GM mustard developer of CGMCP, Dr Swapan Datta a GM Rice developer & Dr B Sesikeran in GEAC – Col is not just about one application, but overall shaping of regulatory regime by vested interests!

No.C-12017/48/2008-CS-III
Government of India
Ministry of Environment & Forests
CS- III Division

Paryavaran Bhavan
C.G.O.Complex,
Lodi Road
New Delhi-110003
Dated: 21.03.2014

OFFICE ORDER

Subject: Genetic Engineering Appraisal Committee (GEAC) – modification in the office order dated 11.03.2013 regarding

In continuation of this Ministry's office order of even number dated 11.03.2013 and in accordance with Section (4), subsection 2 (i) to (v) of the notification No GSR 1307 (E) dated 5th December, 1989 of the "Rules for the Manufacture, Use /Import /Export and Storage of Hazardous Microorganisms / Genetically Engineering Organisms or Cells, 1989" (notified under the Environment (Protection) Act, 1986, the Ministry known as Rules 1989), notified under the Environment (Protection) Act, 1986, the Ministry of Environment and Forests hereby, partially modifies the composition of the GEAC, to the extent to include Co-Chairman, Vice Chairman and Co-opted Members / Experts to the GEAC. The revised composition is as follows:

1.	Shri Hem Pande ,Additional Secretary Ministry of Environment & Forests CGO Complex, Lodhi Road, New Delhi-11003	Chairman
2.	Dr. Veluthambi, (retd.) Professor, Madurai Kamraj University, Madurai	Co-Chairman
3.	Shri Bishwanath Sinha, Joint Secretary, Ministry of Environment & Forests, CGO Complex, Lodhi Road, New Delhi	Vice Chairman
Independent Outside Experts		
4.	Prof. C.R.Babu, Centre for Environmental Management of Degraded Ecosystems, School of Environmental Studies, University of Delhi, Delhi-110007	Member
5.	Dr. B. Sesikeran, Former Director, National Institute of Nutrition, Hyderabad.	Member
6.	Dr. S.S. Banga, Plant Breeder, Punjab Agriculture University, Ludhiana	Member
Member – Ministerial/Departmental Nominee		
7.	Shri K.K.Sinha, Industrial Advisor, Department of Industrial Policy & Promotion, Ministry of Commerce & Industry, New Delhi.	Member
8.	Dr S.R Rao, Advisor, Department of Biotechnology	Member

9.	Dr. S.K.Apte, Associated Director, Bio-Medical Group, BARC, Mumbai.	Member
Expert Members – Institutional Nominee		
10.	Dr. Swapan Kumar Datta, DDG (Crop Science) Indian Council of Agricultural Research, Krishi Bhawan, New Delhi-110001.	Member
11.	Dr K Satyanarayan, Scientist G, Indian Council of Medical Research (ICMR) Ministry of Health and Family Welfare, V Ramalingaswami Bhavan, Ansari Nagar, New Delhi 110029	Member
12.	Dr. Ramesh V.Sonti, Chief Scientist, CSIR, Centre for cellular &Molular Biology (CSI- CCMB) Uppal Road, Hyderabad-500007.	Member
13.	Mrs. Swati Srivastava, Assistant Drugs Controller, (India) Central Drugs Standard Control Organizations, FDA Bhawan, Kotla Road, New Delhi-110002.	Member
14.	Dr. V.K.Yadav, Plant Protection Advisor, Directorate of Plant Protection , Quram- fine &Storage NH IV, Faridabad-121001. New Delhi	Member
15.	Chairman CPCB New Delhi.	Member
Co-opted Members		
16.	Dr. Vijendra Mishra, Associate Professor National Institute of Food Technology Enterprenuraship of Management (NIFTEM) Kundli, Sonapat, Haryana	Member
17.	Prof. O.P. Govila, Former Prof. of Genetics, Indian Agricultural Research Institute, "MANAS" House No. BU- 58, Pitampura, Delhi 110034	Member
18.	Prof. Akshay Kumar Pradhan, Department of Genetics, University of Delhi, South Campus, Benito Juarez Road, New Delhi	Member
19.	Dr. V V Ramamurthy, Principal Scientist, Entomology, Division, IARI, New Delhi	Member
20.	Dr. Renee M Borges, Professor, Centre for Ecological Sciences, Indian Institute of Science, Bangalore	Member
21.	Prof. B.P Srinivasan, Director, Delhi Institute of Pharmaceutical Science and Research, PushpVihar, Sector 3, M. B. Road, New Delhi	Member
22.	Dr. Luther Rangrejji, Associate Professor, Faculty of Legal Studies, South Asian University, 233, Akbar Bhavan, Chankyapuri, New Delhi-21	Member

GEAC gets [re-constituted in 2014](#), soon after it is [constituted in 2013](#)!

- Dr Akshay Pradhan, **part of the GM Mustard development team is brought in as a GEAC member, close to GM mustard commercialisation.**
- Dr Swapan Kumar Datta, a GM Rice developer (his wife is also a GM Rice developer) is also part of GEAC.
- Dr B Sesikeran, Trustee in an industry body called ILSI is also included.

What is interesting is what the AG read out during the SC Hearing from one GEAC meeting minutes....(PTO)

On 1/12/2022, AG Venkataramani seeks to convince the Bench that GEAC deals with conflict of interest very well

121st Meeting Minutes AG reads out from:

Non-Sanitised, non-abridged version of Minutes:

dia.gov.in/Uploads/MoMPublished/2014-geac-121.pdf

iii. Toxicity studies to be examined by a sub-Committee.

4.4 Permission to conduct BRL-II trials for transgenic mustard hybrid (DMH-11) (*Brassica juncea*) Events bn 3.6 (Barnase Line), modbs 2.99 (Barstar Line) &bn 3.6xmodbs 2.99 containing *bar*, *barnase* and *barstar* genes by Centre for Genetic Manipulation of Crop Plants, (CGMCP), University of Delhi South Campus, New Delhi.

4.4.1. The Committee considered the request of CGMCP, to conduct Biosafety Research Level-II (BRL-II) trials on transgenic mustard hybrid (DMH-11) (*Brassica juncea*) containing *bar*, *barnase* and *barstar* genes [Events bn 3.6 (Barnase Line), modbs 2.99 (Barstar Line) &bn 3.6xmodbs 2.99. The trials will be conducted by India Council of Agriculture Research (ICAR) in their respective university's land at ten locations namely; Navgaon, Sriganaganagar, Kumher, Delhi, Bawal, Ludhiana, Bhatinda, (Zone II), Bharatpur, Morena, Kanpur and Faizabad (Zone III). The size of each trial will be 2142 sq m. At the outset, Dr Akshay Pradhan, Member GEAC informed that as a Scientist from CGMCP, he would like to be excused from the deliberations to avoid any conflict of issue unless the committee desires to seek any clarifications.

4.4.2 The Committee noted that the GEAC in its meetings held on 29.9.2010 and 21.09.2011 had approved BRL-I (first year and 2nd year) trial of above mentioned two events bn 3.6 (Barnase Line), modbs 2.99 (Barstar Line) at Bharatpur, Alwar, Sriganaganagar, Kanpur, Ludhiana and Morena.

4.4.3 The Committee also noted the objectives of the trials are to:

- Collect data on reproductive and survival biology parameters such as growth, life cycle, plant height, biomass, impact on pollinators etc. of transgenic *Brassica juncea* lines and their non-transgenic counterparts.

indiagminfo.org/wp-content/uploads/2015/08/MINUTES-121ST-MEETINGminutes-1.pdf

glufosinate ammonium by acetylation. *Streptomyces spp.* are saprophytic, soil borne microbes and are not considered to be a pathogen of plants, humans, or other animals.

4.4.9 Dr Sonti informed that the Barnase Protein is fundamentally a toxic protein and used as an anti-cancer drug. It was clarified that the protein is expressed only in the tapetum and is not expressed in any other tissue as per the analysis carried out in the report. Clarifications were also sought on why very low level of expression barstar is found in other tissues in addition to anthers but not barnase even though both the genes are expressed under the same tapetum specific promoter. At the request of the Committee, Dr Pradhan clarified that in the barstar construct the selection marker bar gene is driven by 35S double enhancer promoter (a stronger promoter than the normal 35S promoter) and the barstar gene by tapetum specific TA29 promoter. In the barnase construct the bar gene is driven by normal 35S promoter and barnase gene by TA29. The barstar expression observed in tissues other than the anthers could be due to the enhancer element of 35S double

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Confidential and Restricted Circulation

enhancer promoter influencing the TA29 promoter and thus resulting in very low expression of barstar in tissues other than anthers.

4.4.10 On the issue of the toxicology studies consensus were expressed that unlike in the west, GM Canola is used as oil where as in India mustard leaves and seeds are also consumed and therefore, toxicology data should be reviewed with great caution. The Committee decided to refer the matter to the sub-committee proposed under agenda item no 4.3.

4.4.11 In addition, it was decided to obtain the following additional information:

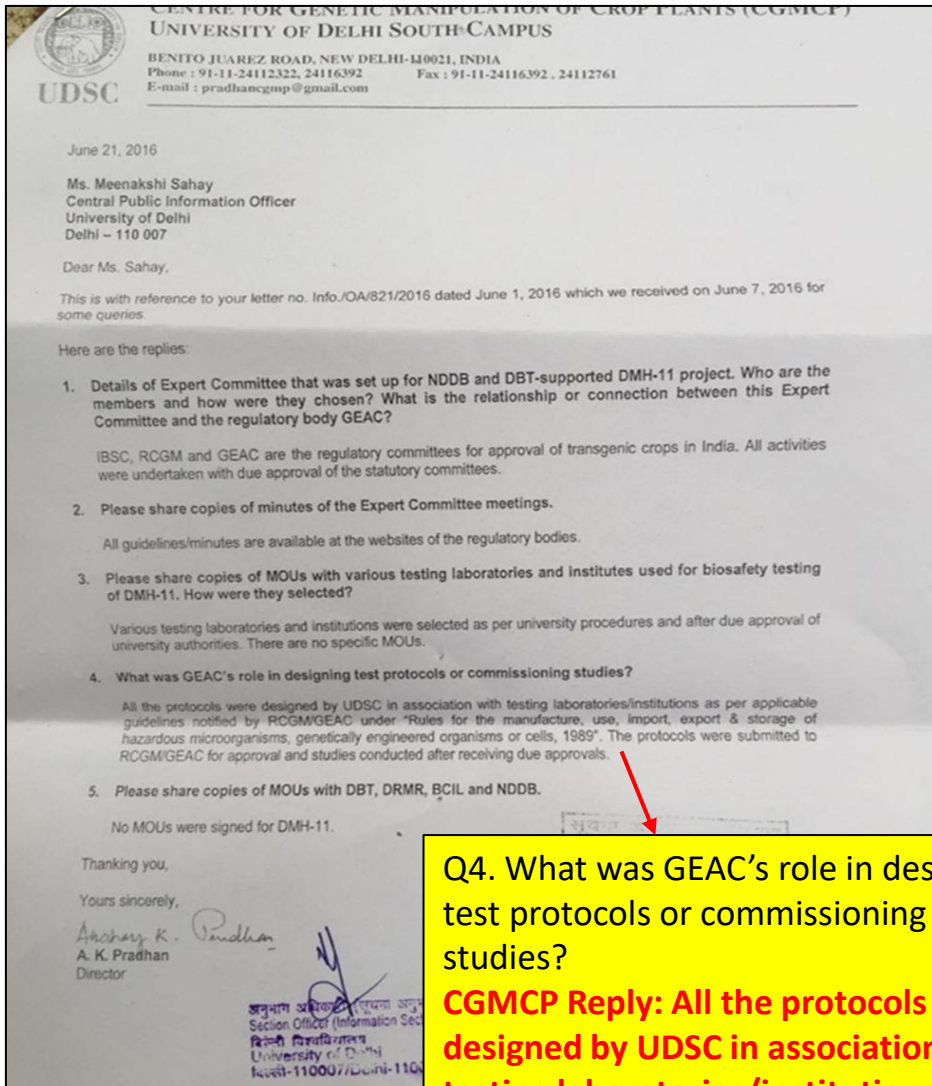
- What are the other hybrids of Canola approved for commercial cultivation in the West and how much of the cultivated hybrids fall under barnase and barstar genes.
- Whether Barnase is expressed in other tissues
- Whether Barstar is expressed in other tissues.

4.4.12 In view of the above stated facts and taking into consideration the

17 pages of Minutes, where this agenda ends at 4.4.8.
[2014-geac-121.pdf \(geacindia.gov.in\)](#)

29 pages of Minutes obtained under RTI Act, where this agenda ends at 4.4.12. Dr Pradhan participates in the meeting later on, for clarifications! In any case, Col is more than participation with regard to one's own application. [MINUTES-121ST-MEETINGminutes-1.pdf \(indiagminfo.org\)](#)

4. Conflict of Interest – Crop Developer evolves protocols & does most tests



Q4. What was GEAC's role in designing test protocols or commissioning studies?
CGMCP Reply: All the protocols were designed by UDSC in association with testing laboratories/institutions as per applicable guidelines notified by RCGM/GEAC....

WHO DID THE TESTS?

The Learned Bench was interested in knowing if industry does safety studies itself. Yes, is the reply.

In the case of this GM mustard too, most studies were done by the crop developer. At least seven tests ((i) Weediness potential, (ii) Crossability study, (iii) Pollen flow study, (iv) Pollination behaviour, (v) Studies on Pests, Diseases and Beneficial Organisms, (vi) Expression Levels of Proteins and (vii) Molecular Characterisation) were done by the crop developer. Additionally, where agronomic trials were supposed to have been coordinated by ICAR's DRMR as per the crop applicant, [DRMR in an RTI response](#) (below) denied the same and stated that crop developer did the studies. **That means 8 tests were done by crop developer himself. Only 5 other studies are supposed to have been done by other agencies** with no independent health expert appraising them! (Allergenicity Assessment, Acute Oral Toxicity, Sub-Chronic Toxicity, Compositional Analyses and Study on soil microflora). ([Safety-assessment-report-on-GE-Mustard_0.pdf \(moef.gov.in\)](#))

	the comparative data for DMH 11. What is the farmer-preference and processors' preference in this matter and why.	shattering habit varieties
D	THE ROLE AND AUTHORITY OF THE DRMR IN TESTING TRANSGENIC MUSTARD	
i	Please clarify whether the DRMR has been/is responsible for the entire protocol of testing transgenic Mustard DMH 11 and is a decision-making authority in this matter.	No, DRMR is not a decision making body. Testing protocol was given by DUSC. DRMR is not the decision body as is being regulated. However, the trial location of AICRP was used for evaluation. <u>DRMR has not conducted any trial and the data received by DU/NDDB staff was passed to DRMR for onward transmission to DUSC/GEAC. Hence, no raw data of each location replication wise is not available with DRMR</u>
	4	
ii	The claim of DrPental is that hybrids made with DMH 11 Barnase-Barstar will provide improved yields of 25-30% more than non-GMO hybrids/varieties of rapeseed-Mustard. Based on your analyses, is this true? Does DMH 11 perform better than non-GM mustard hybrids/Varieties? If not, why was DMH 11 allowed to progress to BRL II or pre-commercial field trials where the risk of	expect 2014-15. It does not hold true while comparing the average performance of varieties/ hybrids in different trials under AICRP- R&M and FLD's Annexure-IV

BCIL's Expert Committee to advise on Roadmap of Regulatory Approval

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Expert Committee f...
11 / 27 154%

MINUTES OF THE FIRST MEETING OF THE EXPERT COMMITTEE TO ADVISE ON ROADMAP OF REGULATORY APPROVAL OF TRANSGENIC *B. JUNCEA* CONTAINING BARNASE/BARSTAR GENES DEVELOPED BY UDSC

The first meeting of the Expert Committee to advise on the studies that need to be conducted for regulatory approval of transgenic *B. juncea* containing three transgenes namely, *bar*, *barnase* and *barstar* developed by the University of Delhi South Campus (UDSC) was held under the chairmanship of Dr. Anupam Varma, Retired National Professor, Indian Council of Agricultural Research (ICAR) and former Vice President, INSA on June 21, 2010 at the India International Centre, New Delhi. List of the participants is placed at Annexure-1.

At the outset, Dr. Anupam Varma welcomed the members of the Expert Committee. Stressing on the need for development of high yielding hybrids of mustard to increase productivity, he appreciated the initiative taken by UDSC for preparing a structured action plan for seeking regulatory approvals for mustard hybrid DMH-11. He requested Prof. Deepak Pental, Vice Chancellor, University of Delhi to give his introductory remarks and asked the members of the committee to share their views on the proposed action plan.

Annexure-1

List of participants

1. Dr. Anupam Varma, Retired National Professor, Indian Council of Agricultural Research (ICAR) and Former Vice President, INSA
2. Prof. Deepak Pental, Director, Centre for Genetic Manipulation of Crop Plants and Vice Chancellor, University of Delhi
3. Dr. Swapan K. Datta, Deputy Director General (Crop Science), Indian Council of Agricultural Research (ICAR), New Delhi
4. Dr. Raj Kumar, Professor & Head, Respiratory Allergy & Applied Immunology, Dept. of Respiratory Medicine, VP Chest Institute and Head, Dept. Pulmonary Medicine Faculty of Medical Sciences, University of Delhi
5. Dr. K.V. Prabhu, Head, Division of Genetics, Indian Agricultural Research Institute (ARI), New Delhi
6. Dr. J.S. Chauhan, Director, Directorate Research of Rapeseed-Mustard, Bharatpur
7. Dr. B. Dinesh Kumar, Assistant Director, National Institute of Nutrition (NIN), Hyderabad representing Dr. Sesikeran, Director, NIN.
8. Dr. R.K. Gupta, Deputy General Manager, Mother Dairy Fruits and Vegetables Private Limited, New Delhi
9. Dr. A.K. Pradhan, Professor (Plant Genetics and Molecular Breeding), University of Delhi South Campus, New Delhi
10. Dr. Y.S. Sochi, Principal Scientist, Mother Dairy Fruits and Vegetables Private Limited, New Delhi
11. Dr. Vibha Gupta, Principal Scientist, Mother Dairy Fruits and Vegetables Private Limited, New Delhi
12. Dr. O.P. Govila, Retired Professor of Genetics, IARI, New Delhi
13. Dr. Vibha Ahuja, General Manager, Biotech Consortium India Limited, New Delhi

MINUTES OF THE SECOND MEETING OF THE EXPERT COMMITTEE ON TRANSGENIC *BRASSICA JUNCEA* HELD ON DECEMBER 9, 2010

The second meeting of the Expert Committee to review the progress of the project on "Data generation for biosafety assessment of transgenic *Brassica juncea*" developed by the Centre for Genetic Manipulation of Crop Plants (CGMCP), University of Delhi South Campus (UDSC) was held on December 9, 2010 at India International Centre, New Delhi. The meeting was chaired by Dr. Anupam Varma, Retired National Professor, Indian Council of Agricultural Research (ICAR) and former Vice President, INSA. The list of the participants is placed as Annexure-1.

Dr. Anupam Varma, Chairman, Expert Committee welcomed the members of the Expert Committee and informed that the objective of the second meeting is to review the developments with respect to initiation of various studies and facilitate their smooth execution as per the roadmap discussed in the first meeting of the Expert Committee. Prof. Deepak Pental, Director, CGMCP provided an update on the progress of the project. He informed that the project on biosafety assessment has been sanctioned under the BIPP Scheme of the

Annexure-1

List of Participant

1. Dr. Anupam Varma, Retired National Professor, Indian Council of Agricultural Research (ICAR) and Former Vice President, INSA
2. Prof. Deepak Pental, Director, Centre for Genetic Manipulation of Crop Plants, University of Delhi South Campus
3. Dr. Swapan K. Datta, Deputy Director General (Crop Science), Indian Council of Agricultural Research (ICAR), New Delhi
4. Dr. K.V. Prabhu, Head, Division of Genetics, Indian Agricultural Research Institute (IARI), New Delhi
5. Dr. J.S. Chauhan, Director, Directorate Research of Rapeseed-Mustard, Bharatpur
6. Dr. B. Sesikeran, Director, National Institute of Nutrition (NIN), Hyderabad
7. Dr. R.K. Gupta, Deputy General Manager, Mother Dairy Fruits and Vegetables Private Limited, Noida
8. Dr. A.K. Pradhan, Professor (Plant Genetics and Molecular Breeding), University of Delhi South Campus, New Delhi
9. Mr. Mahesh Gupta, Mother Dairy Fruit and Vegetable Private Limited, Noida
10. Dr. Vibha Gupta, Principal Scientist, Mother Dairy Fruit and Vegetable Private Limited, Noida
11. Dr. O.P. Govila, Retired Professor of Genetics, IARI, New Delhi
12. Dr. Vibha Ahuja, General Manager, Biotech Consortium India Limited, New Delhi
13. Ms. Pragati Mehra, Project Executive, Biotech Consortium India Limited, New Delhi

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https://drive.google.com/file/d/1Ake_UISiLtWpvqtqn0m2y0IltPGyilp5/view?usp=share_link

BCIL-constituted-Expert Committee to advise on roadmap of regulatory approval consisted of crop applicants, ones who will do the tests AND REGULATORS together – this includes Dr KV Prabhu who was brought into the Sub-Committee of 2016 + Dr Swapan Datta, Dr Sesikeran, Dr AK Pradhan. They advised on protocols, some also did the testing, and then sat in judgement of the test results.

5. GM HT Mustard did not get tested as a HT crop – India's regulatory regime has no protocols for testing of HT crops

The screenshot shows the website of the Genetic Engineering Appraisal Committee (GEAC), Ministry of Environment, Forest and Climate Change, Government of India. The page is titled 'Guidelines and Protocols' and lists various documents issued by the Department of Biotechnology and Ministry of Environment and Forests. The list includes:

- Recombinant DNA Safety Guidelines, 1990
- Revised Guidelines for Research in Transgenic Plants, 1998
- Guidelines for Generating Pre-clinical and Clinical Data for r-DNA based Vaccines, Diagnostics and other Biologicals, 1999
- Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants, 2008
- Guidelines for Confined Field Trials of Regulated Genetically Engineered (GE) Plants
- Guidelines for the monitoring of Confined Field Trials of Regulated, Genetically Engineered (GE) Plants, 2008
- Standard Operating Procedures (SOPs) for Confined Field Trials of Regulated, Genetically Engineered (GE) Plants, 2008
- Protocol for Food and Feed Safety Assessment of GE crops, 2008
- Guidelines and Handbook for Institutional Biosafety Committees (IBSCs), 2011
- Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India, 2012
- Environmental Risk Assessment of Genetically Engineered Plants: A Guide for Stakeholders, 2016
- Guidelines for the Environmental Risk Assessment of Genetically Engineered Plants, 2016
- Risk Analysis Framework, 2016

At the bottom of the page, there is a copyright notice: 'Copyrights © 2017 All Rights Reserved by The Ministry Of Environment, Forests & Climate Change' and a navigation menu: 'HOME / GEAC / REGULATIONS / INDIA BCH / APPLICATIONS / CONTACT Disclaimer'.

WHILE THERE ARE NO REGULATORY GUIDELINES & PROTOCOLS, for herbicide tolerant crops, GEAC had prescribed tests on bio-efficacy of the herbicide, residue analysis in HT crop soil, effect of leftover residues on succeeding crops, untreated controls etc. for other applications (117th meeting). Protein expression data was prescribed to be recorded at the time of each herbicide application in one case (119th meeting). Data related to soil microflora, earthworms and soil insects related to soil rhizosphere was also prescribed to be recorded during pre- and post-spray of herbicide, in one instance (119th meeting). Visual observations on herbicide treated plots for yellowing, scorching and wilting were prescribed to be recorded. Control treatments were to be manually weeded in this case. Dosage of herbicide sprays, approval of CIBRC, nature and extent of bio-degradation, residue estimations etc., were all areas of additional information sought for other HT crops.

All of this shows that GEAC did apply its mind to HT crop testing, for other applications, in the absence of guidelines/protocols. GEAC however abdicated even this responsibility when it came to GM mustard. IT DID NOT GET TESTED AS A HT CROP AT ALL.....

[Guidelines & Protocols listed here do not show any protocols for HT crops – In existing guidelines, only two minor references exist, that is all - GEAC \(geacindia.gov.in\)](#)

Ref. [GEAC's 117th, 119th, 120th, 121st and 122nd meetings](#)

6. Parental Lines are distinct GMOs but did not undergo even the limited tests that DMH-11 hybrid was put through

F. No. C-12013/35/2010-CSIII
Government of India
Ministry of Environment, Forests and Climate Change
CS-III (Biosafety) Division

6th Floor, Jal Block
Indira Paryavaran Bhawan
Ali Ganj, Jor Bagh Road
New Delhi-110 003
Date: 25th October, 2022

Prof. Deepak Pental
Former Professor of Genetics and Vice-Chancellor, University of Delhi
M/s Centre for Genetic Manipulation of Crop Plants (CGMCP),
University of Delhi, South Campus,
Benito Juarez Marg, New Delhi - 110 021

Sub: Application for environmental release of transgenic mustard hybrid DMH-11 and parental lines bn 3.6 and modbs 2.99 containing barnase, barstar and bar genes. -reg.

Sir,

The undersigned is directed to refer to your Letter dated 10.05.2022 on the above subject and inform that based on the comments received from Department of Biotechnology (DBT) vide D.O. No. BT/GE-Mustard/01/2022 dated 01.08.2022, comments received from Department of Agricultural Research and Education (DARE) vide D.O. No. CS.5/2/2020-Seed (e168868)/256 dated 30.07.2022, recommendations of the Expert Committee constituted in 146th meeting of Genetic Engineering Appraisal Committee (GEAC); the Genetic Engineering Appraisal Committee (GEAC) in its 147th meeting held on 18.10.2022, has recommended the following:

- I. The environmental release of genetically engineered mustard parental lines bn 3.6 carrying barnase and bar genes, and modbs 2.99 containing barstar and bar genes, so that these events can be used for developing new parental lines and hybrids under supervision of ICAR.
- II. The environmental release of mustard hybrid DMH-11 for undertaking its seed production and testing as per existing ICAR guidelines and other extant rules/regulations prior to commercial release.

- The **parental lines are two distinct GMOs in themselves**. They have separate “events” each, distinct from each other, and distinct from DMH-11 hybrid.
- However, the parental lines which were also released by GEAC’s October 25th 2022 approval letter, have not undergone even the limited tests that DMH-11 has undergone.
 - No pollen flow studies
 - No weediness & aggressiveness studies for eg.
- No cognisance was taken when several issues about parental lines were raised in Aug. 2016 itself: [IndiaGMInfo - Coalition writes to GEAC on parental lines of GM mustard hybrid](#)
- This, despite the fact that parental lines themselves, for their maintenance & multiplication, will be exposed to their environment for one additional/separate generation before DMH-11 is produced! One of the parental lines is MALE STERILE, and sterility trait spreading is hazardous....
- Even at the seed production stage where Glufosinate is admittedly used as stated by the AG and Union of India, no testing as HT crop took place – WHY?

7a. Even the limited statutory regulatory guidelines and protocols related to ERA in India were not complied with in GM mustard testing

Environmental Risk Assessment Guidelines 2016 (Page 15, 9.6):

5. To confirm the identity and expression pattern of any new fusion proteins.

9.6 PHENOTYPIC AND AGRONOMIC CHARACTERISTICS OF GE EVENT(S)

Data should be collected from test plants grown in replicated confined field trials over at least two years, from a minimum of three trial site locations representative of the range of agro-ecosystems where the GE event may be cultivated. Multiple field trial sites may be required to ensure that the normal range of agro-ecosystems where that plant species will be cultivated is adequately represented. Each field trial should include at least two negative controls: the non-transformed parental line and at least one other non-transformed control variety/hybrid representative of varieties/hybrids of that plant species typically cultivated in the area where the trial is planted.

Phenotypic data should address the following considerations:¹⁰

⁹ It may be necessary to examine the inheritance of the DNA insert itself or the expression of the corresponding RNA or expressed protein, if the phenotypic characteristics cannot be measured directly.

¹⁰ Based on the case-specific problem formulation, additional studies may be required, or some studies may not be warranted, based on the biology and phenotype of the GE event or where the applicant can justify the exclusion of a study using scientific rationale.

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GM mustard testing **violated** these guidelines, however. Examples are:

- Pollen flow study in **only one location**
- Crossability study in **only one location**
- Pollen morphology study in **only one location**
- Weediness study in **one location and one season only**

Ref: [Safety-assessment-report-on-GE-Mustard_0.pdf \(moef.gov.in\)](#)

https://moef.gov.in/wp-content/uploads/2017/08/Safety-assessment-report-on-GE-Mustard_0.pdf

To study the crossability of GE *B. juncea* hybrid DMH-11 with the various related species and also to study the extent of pollen flow from the GE hybrid to non-GE lines of *B. juncea*, an experiment was conducted at the Delhi University Research Farm in Bawana, New Delhi in the year 2010. Crossability studies were conducted as per the Guidelines and Standard Operating Procedures (SOPs) for Confined Field Trials of Regulated, Genetically Engineered (GE) Plants, 2008.

https://geacindia.gov.in/Uploads/MoMPublished/2011-geac-112.pdf

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5.15.2 The Committee noted that the trial will be conducted under the coordination of Directorate of Rapeseed-Mustard Research, Bharatpur at one location (Bawana, Delhi).

5.15.3 The Committee also noted that the purpose of the proposed study is to:

- The pollen morphology and physiology
- Biomass production studies will be conducted where sample will be taken at different intervals such 30 days after sowing, 60 days after sowing and at maturity.
- Weediness potential and aggressiveness parameters such as seed germination and vigour test and speed of germination
- The expression analysis of *bar*, *barnase* and *barstar* genes in different tissues of transgenic *B. juncea*.

5.15.4 It was further noted that the IBSC in its meeting held on 24.06.2011 has recommended the proposal. RCGM also recommended the proposal in its 103rd meeting held on 26.07.2011.

5.15.5 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request to conduct environmental safety studies on transgenic mustard (*Brassica juncea*) containing *bar*, *barnase* and *barstar* genes [Events bn 3.6 (Barnase Line), modbs 2.99 (Barstar Line) & bn 3.6xmodbs 2.99 (Hybrid DMH-11)] under the coordination of Directorate of Rapeseed-Mustard Research, Bharatpur at one location (Bawana, Delhi) during the appropriate season in 2011-12 subject to submission of NOC from the respective State Department of Agriculture where the trials would be conducted.

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7b. Even the limited statutory regulatory guidelines and protocols were not complied with, when it comes to GM mustard food safety testing

ICMR guidelines of 2008 for **Food Safety Assessment** Page 15, 7.3 of [Microsoft Word - Coverpage.doc \(geacindia.gov.in\)](#)

7.3 COMPOSITIONAL ANALYSES OF KEY COMPONENTS

Analyses of concentrations of key components of the GE plant and, especially those typical of the food, need to be compared with an equivalent analysis of a conventional counterpart grown and harvested under the same conditions:

1. Key nutrients or key anti-nutrients of those components in a particular food that may have a substantial impact in the overall diet.
2. Major constituents (fats, proteins, carbohydrates as nutrients or enzyme inhibitors as anti-nutrients)
3. Minor compounds (minerals, vitamins).
4. Key toxicants or toxicologically significant compounds known to be inherently present in the plant, whose toxic potency and level may be significant to health (e.g. solanine in potatoes if the level is increased, selenium in wheat) and allergens.
5. A comparison with the GE plant grown under its expected agronomic conditions may need to be considered (e.g. application of an herbicide) in some cases. The statistical significance of any observed differences should be assessed in the context of the range of natural variations for that parameter to determine its

biological significance. The comparator(s) used in this assessment need to be ideally the near isogenic parental line. In practice, this may not be feasible at all times, in which case a line as close as possible should be chosen.

WHAT THE GUIDELINES SAY:

5. A comparison with the GE plant grown under its expected agronomic conditions may need to be considered (eg., application of a herbicide) in some cases.
7. Trial Sites: (a) **The location of trial sites needs to be representative of the range of environmental conditions under which the plant varieties would be expected to be grown.** (b) **The number of trial sites need to be sufficient to allow accurate assessment of compositional characteristics over this range. Trials have to be conducted over a sufficient number of generations to allow adequate exposure to the variety of conditions met in nature.** (c) **Each trial site is required to be replicated to minimise environmental effects, and to reduce any effect from naturally occurring genotypic variation within a crop variety.** (d) Sampling of adequate number of plants and the methods of analysis need to be sufficiently sensitive and specific to detect variations in key components.

Actual Compositional Analyses done:

1. No herbicide was used in testing, since GM mustard was not tested as a HT crop
2. Only one zone (III) and 2 locations may have contributed samples, given that Sriganganagar trial was supposed to have been destroyed by Rajasthan Govt.
3. Study not done by NIN as claimed, but was outsourced to a private company.
4. Study did not happen over sufficient number of generations
5. Results section of report (No. 7, pg 124/360 and 125/360) shows that under different parameters, there were indeed significant differences for various parameters (minerals, vitamins, secondary metabolites, amino acids etc. in either the leaf or the seed). However, the conclusion section (8) says: **“The compositional analysis includes macro, micro nutrients were *substantially equivalent in spite of the significant changes which may be due to agro-climatic changes*”!! This means that the basic instruction in the guidelines above was not followed. Based on this conclusion, other studies not done.**

7c. Agronomic trials done with incorrect comparators

NOT A SINGLE BRL TRIAL IS CONDUCTED USING APPROPRIATE NATIONAL & LOCAL CHECKS!

Permission Letter for BRL I second year trials, dated 17/10/2011 clearly mentions under (d) Trial protocol that the replicated trial shall be conducted in triplicate repeats with RBD, and adds : “appropriate National and Local checks and spacing are to be included...”

Permission Letter for BRL II trials, dated 28/10/2014 clearly mentions under Point 7.0 Trial protocol that the replicated trial shall be conducted with RBD, and adds : “appropriate National and Local checks and spacing are to be included...”

https://drive.google.com/drive/folders/1GS8c0zixYPlzAzXtc-sOCfOEzaHC_cVC?usp=share_link

are being conducted.

7.0 Trial Protocol: The replicated Biosafety Research Level II Trial (BRL-II) shall be conducted with randomized block design (RBD) as per the prescribed trial specifications.

Appropriate national and local checks and spacing are to be included for comparison of the efficacy of the transgenic mustard hybrid and parental lines in term of productivity, germination, weediness, aggressiveness and other parameters with non-transgenic counterparts.

8.0 Trial size and reproductive Isolation

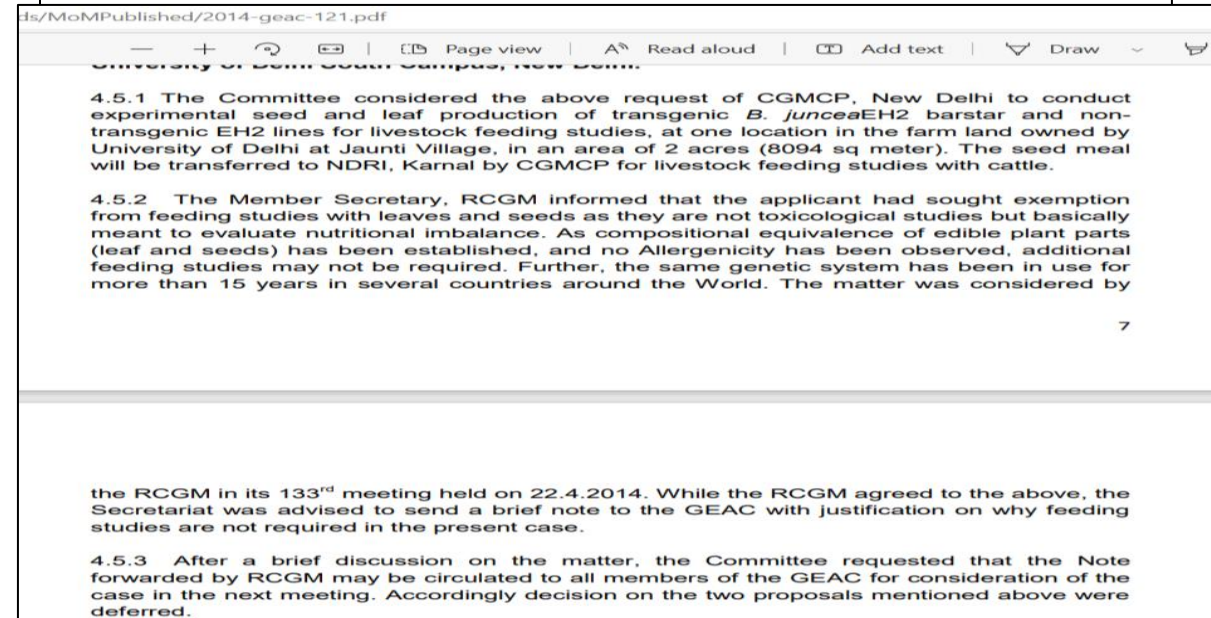
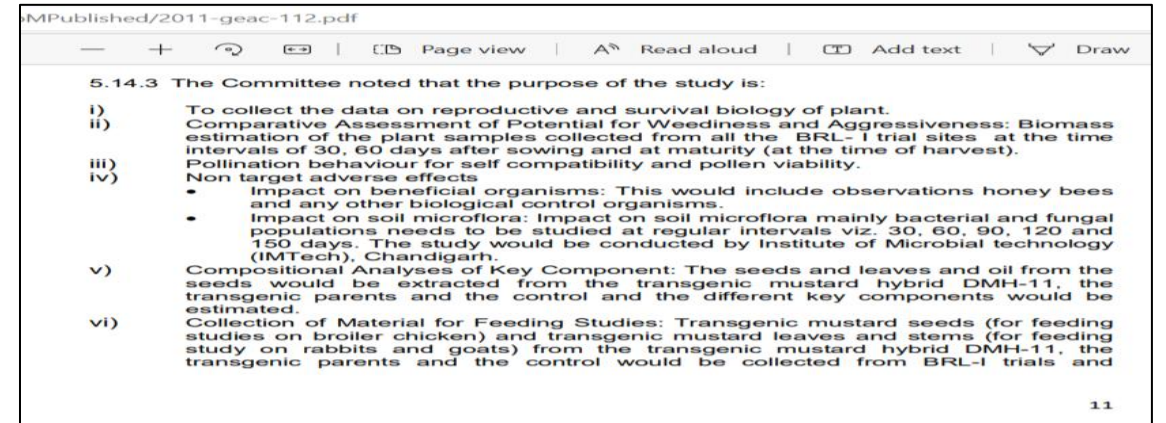
- The National and Local Checks that are used are Varuna and Maya/RL-1359 for DMH-11 testing.
- **However, the Checks recommended by AICRP-RM from 2008 were:**
 - Kranti at the National level in 2010-11, 2011-12 and 2014-15 in Zone II as well as Zone III
 - NRCDR-2 as the Zonal Check in 2010-11 and 2011-12, and
 - RH-0749 as the Zonal Check in 2014-15 in Zone II, and
 - RGN-73 as the Zonal Check in all 3 years in Zone III
 - Hybrid Checks that should have been used are DMH-1 and NRCHB-506 in all three years in Zone II and DMH-1 in Zone III
- **DMH-11 is never compared against any other Mustard Hybrid!**

8. Multiple tests are prescribed by GEAC, then discarded

GEAC KEPT PRESCRIBING TESTS TO BE UNDERTAKEN ON GM MUSTARD, BUT WHEN THE APPLICANT SOUGHT EXEMPTION, KEPT AGREEING TO THE REQUESTS FOR EXEMPTION AND CHANGED ITS OWN RECOMMENDATIONS REPEATEDLY – IS THIS ROBUST??

a. Livestock feeding studies approved but not done, even though AG Mr Venkataramani read out from one GEAC meeting minutes in the Supreme Court, about studies on goats and rabbits!

- [GEAC in its 112th meeting on 21/09/2011](#), was told that BRL-I trials need to be taken up for different kinds of studies, including 5.14.3.vi “Collection of Material for Feeding Studies” (Transgenic mustard seeds for feeding studies on broiler chicken and transgenic mustard leaves and stems for feeding study on rabbits and goats). **GEAC approved the second year BRL-I trials based on this, amongst other things.**
- However, in the [121st meeting of GEAC, nearly three years later on 18/07/2014](#), an exemption is sought from undertaking livestock feeding studies. Minutes record the following as the conclusion of the discussion: “4.5.3 After a brief discussion on the matter, the Committee requested that the Note forwarded by RCGM may be circulated to all members of the GEAC for consideration of the case in the next meeting. **Accordingly, decision on the two proposals mentioned above were deferred.**”
- **No decision is recorded of an exemption actually having been accorded by GEAC. SO, WHAT HAPPENED TO THESE STUDIES?**
- After this, the next GEAC meeting which discusses GM mustard is the 125th meeting where permission for environmental release is considered!



8. Multiple tests are prescribed & then dropped (contd.)

b. Soil Microflora Studies Dropped:

a. In the 134th meeting of [GEAC on 21/3/2018](#), applicant is asked to undertake “Field Demonstration Studies” to generate additional data on soil microbial diversity.

b. In the 135th meeting of [GEAC on 25/07/2018](#), about 4 months after a certain study is prescribed to be undertaken, CGMCP requests for exemption to conduct soil microflora studies on the grounds that these studies were already completed during the conduct of BRL-I and BRL-II trials, and **GEAC agreed to such an exemption!**

ts/MoMPublished/2018-geac-134.pdf

Page view | Read aloud | Add text | Draw

Agenda Item No. 4: Applications related to Commercial/ Environmental Release

4.1 Application for Environmental release of Transgenic Mustard Hybrid DMH-11 and Parental lines containing events *bn 3.6 and modbs 2.99* developed using barnase, barstar and bar genes by M/s. Centre for Genetic Manipulation of Crop Plants (CGMCP), University of Delhi.

The Members took note that the application related to “Environmental release of Transgenic Mustard Hybrid DMH-11 and parental lines containing events *bn 3.6 and modbs 2.99* developed using barnase, barstar and bar genes” submitted by M/s. Centre for Genetic Manipulation of Crop Plants (CGMCP), University of Delhi was referred back to GEAC for its re-examination pursuant to receipt of several representations both in support and against after the 133rd meeting of GEAC held on 11.05.2017.

Keeping in view the above, the GEAC examined all the representations and reiterated that these representations have already been deliberated extensively while taking the decision in 133rd meeting of GEAC.

After detailed discussion and keeping in view that the application has been referred back to GEAC for re-examination, the committee agreed that the applicant may be advised to undertake field demonstration in an area of 5 acres at 2-3 different locations subject to the conditions proposed in recommendations of Sub-committee on GM Mustard, accepted by GEAC in its 133rd meeting, for the purpose of generating additional data on effect of GM Mustard on honey bees and other pollinators and honey, and on soil microbial diversity. Towards this, the applicant may submit a detailed protocol to GEAC for its consideration and approval.

Decision:

- Applicant may be advised to undertake field demonstration on GM Mustard in an area of 5 acres at 2-3 different locations with a view to generate additional data on honey bees and other pollinators and honey, and on soil microbial diversity.

Action: GEAC Secretariat

//geacindia.gov.in/Uploads/MoMPublished/MoMPublishedOn20180830201015.pdf

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Agenda Item No. 4: Applications related to Environmental / Commercial release

4.1 Application for Environmental release of Transgenic Mustard Hybrid DMH-11 and Parental lines containing events *bn 3.6 and modbs 2.99* developed using barnase, barstar and bar genes by M/s. Centre for Genetic Manipulation of Crop Plants (CGMCP), University of Delhi.

The application related to transgenic Mustard along with the protocols and response received from Delhi University was deliberated by the members in the 135th meeting. The members agreed to the request of applicant for exemption to conduct soil microflora studies, as these studies were already completed during the conduct of BRL-I & BRL-II trials.

Further, the members noted that the applicant proposes to undertake studies on Honeybees at two locations namely, Punjab Agriculture University, Ludhiana and Indian Agricultural Research Institute, New Delhi. Noting that the applicant proposes to undertake two field demonstration studies at Delhi to assess hybrid seed efficiency and also for maintenance of male sterile *barnase* line *bn 3.6*, the committee deliberated on the issue of requirement of No Objection Certificate (NOC) from the State Governments for conduct of these field demonstration studies. It was agreed that the State Governments of Delhi and Punjab may be requested to exempt the requirement of NOC for these field demonstrations studies, as these are continuation of BRL-I & BRL-II trials for which the State Governments has already given NOC earlier to the applicant. Further, the members also noted that the total area for conduct of these demonstration studies including non GM plantation would be in an area of 5 acres.

8. Multiple tests are prescribed by GEAC, then discarded (Contd. from earlier slide)

c. “Field Demonstration Studies” on Honeybees & Other Pollinators, and on Honey not done:

- a. In the [134th meeting](#) on 21/3/2018, GEAC decides to advise the applicant to undertake “field demonstration studies” to generate additional data on honey bees and other pollinators and on honey.
- b. In the [135th meeting](#) on 25/7/2018, more details are firmed up in terms of studies in 2 locations.
- c. In the [136th meeting](#) on 20/9/2018, protocols are approved by GEAC.
- d. In the [137th meeting](#) on 20/3/2019 and [138th meeting](#) on 11/11/2019, deferment of studies is discussed.
- e. Nothing is heard about GM mustard in the 139th, 140th, 141st, 142nd, 143rd 144th and 145th GEAC meetings.
- f. In the [146th meeting](#) on 25/8/2022, GEAC deliberates on the claim of CGCMP in respect of availability of adequate evidence about impact of transgenic mustard on honeybees and other pollinators. An Expert Committee is constituted by GEAC for examining this claim, and for environmental release of GM mustard hybrid and its parental lines!
- g. Then in the [147th meeting](#) on 18/10/2022, GEAC accepts the Expert Committee’s recommendations, **which means an exemption from these “field demonstration studies”** and a straight walk into “environmental release”.

9. GM mustard did not undergo even the limited testing of Bt brinjal

HEALTH SAFETY ASSESSMENT	
Acute Oral Toxicity Test in Rats (2003)	Acute Oral Toxicity in Swiss Albino Mice (Year NA)
Mucous Member Irritation Test in Female Rats (2004)	NOT DONE
Primary Skin Irritation Test in Rabbit (2004)	NOT DONE
Sub-chronic oral toxicity study in Sprague Dawley Rats (2005)	Sub-Chronic Oral Toxicity in Sprague Dawley Rats
Assessment of allergenicity of protein extract using Brown Norway Rats (2005)	NOT DONE; ONLY a BioInformatics Analysis and Pepsin Digestibility Assay of the three proteins
Food cooking and protein estimation in cooked fruits (2005)	Thermal Stability done
Feeding study on Common Carp (2005)	NOT DONE
Sub-chronic feeding study using New Zealand Rabbit (2006)	NOT DONE
Effect on performance and health of broiler chickens (2006)	NOT DONE
Sub-chronic feeding studies in goats (2006)	NOT DONE
Feeding studies in lactating crossbred dairy cows (2006)	NOT DONE
Detailed Compositional Analysis (2008-09) including estimation of alkaloid content	Compositional Analysis of seeds and leaves, from BRL-I 1 st year trial plants, including glucosinolates estimation
Note: MANY OF THE STUDIES PRESCRIBED BY THE EXPERT COMMITTEE 1 AND THROUGH GEAC DECISIONS WERE ACTUALLY NOT TAKEN UP IN THE CASE OF BT BRINJAL!	Justification that regulatory processes are being improved with changed guidelines is untenable given the importance of this food crop, that this is a HT GM crop, where non-GM hybrids already exist)

Peer Review of Bt brinjal biosafety dossier showed up clear inadequacies in testing, analyses and conclusions. However, GM mustard has not been put through any such peer review. No testing as HT crop, as already pointed out.

10. Agriculture is a State Subject – GM mustard approval ignores this

IndiaGMInfo - State Govts & GM x +

← ↻ 🏠 ⚠ Not secure | indiagminfo.org/state-govts-gm-mustard/

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State Govts & GM Mustard

State governments have not been in favour of GM mustard approval in India. In fact, most have not even allowed field trials. Some have formally written to the Union Government. Some state governments have issued statements to media and others, as and when an opportunity arose. The Centre, despite its talk about "federal polity", had been ignoring the opposition from state governments on this matter. Here, we bring share some letters, videos and media reports on this subject.

BIHAR

1. Shri Nitish Kumar, Hon'ble Chief Minister of Bihar writes to (then) Union Environment Minister Prakash Javadekar, 18/01/2016
2. Shri Nitish Kumar follows up with a letter to the Prime Minister on 6/10/2016, after GEAC's sub-committee's green signal
3. Shri Nitish Kumar sends a letter to Late Shri Anil Madhav Dave, MoEFCC on 16/05/2016, after regulatory clearance by GEAC to GM mustard
4. Shri Nitish Kumar's speech on GM mustard in a JD(U) meeting

KERALA

1. Kerala Agriculture Minister writes to Union Agriculture Minister, 28/09/2016
2. Kerala Legislative Assembly passes a unanimous resolution against GM mustard, first time in the history of any state assembly, 18/05/2017

TAMIL NADU

1. Tamil Nadu Chief Minister's Memorandum to the Prime Minister, 19/12/2016 - Page 1 and Page 2
2. TN Agri Minister's statement quoted in media reports
3. Tamil Nadu's (then) Opposition Leader Shri MK Stalin's Letter to MoEF, GoI, 24/07/2017: Page 1 and Page 2

DELHI

1. Delhi Deputy Chief Minister's letter to Prime Minister, 02/02/2016

ANDHRA PRADESH

1. Andhra Pradesh Chief Minister writes to Union Agriculture Minister and Union Environment Minister on August 10th 2017: Page 1 and Page 2

RAJASTHAN

1. Rajasthan Agriculture Minister stating that Rajasthan will not allow any field trials of GM mustard/ crops, 29/02/2016, CM "shuts door on GM seeds"

ODISHA

1. Odisha Agriculture Minister, Dr Damodar Raut, points to dangers of GM mustard in this video: <https://www.youtube.com/watch?v=voE0qYmk6G>
From 00:56 seconds to 01:12 minutes in this video, he says: "The adverse effect of GM Mustard goes beyond agriculture and directly affects people's health as well. Who will be responsible for the health effects it will have? We will experiment with local varieties of seeds in an organic way to improve the yield."

MADHYA PRADESH

1. Madhya Pradesh government rejects GM mustard (media byte by topmost bureaucrat in Agriculture, May 15th 2017)

WEST BENGAL

1. Media report (May 2017) on WB Agri Minister writing to the Centre against GM mustard environmental release
2. West Bengal government says NO to GM mustard cultivation

KARNATAKA

1. Karnataka Chief Minister promises to write to the Centre against GM mustard commercialisation

HARYANA

1. "Haryana government will not allow GM crop testing in the state" (though this report does not refer to GM mustard or commercialisation of GM crops, it was a development around the same time as Punjab government's announcement on GM mustard)

1. Agriculture is a State Subject as per India's Constitution.
2. Most states in India have already spoken out against GM mustard – they include Bihar, Kerala, Tamil Nadu, Delhi, Andhra Pradesh, Rajasthan, Odisha, Madhya Pradesh, West Bengal, Karnataka and Haryana. It is noteworthy that major mustard-producing states have been opposed to GM mustard.
3. Rajasthan had in fact destroyed a field trial plot, citing precautionary approach.
4. GEAC had in fact, taken cognisance of this stand of state governments and Rajasthan's action in its [116th meeting](#). ("6.1.2. However, notwithstanding the above, the Committee also reiterated that agriculture is a State subject and **decision of the State Government** on whether to allow GM crop field trials or not **should be honored.**")
5. However, GM mustard was approved without upholding state governments' policy position on this. No consultations were held, unlike in the case of Bt brinjal. **NO HONORING OF STATE GOVT DECISIONS.**

GEAC in fact not permitted to set up Sub-Committees & Expert Committees...

Rules For The Manufacture, Use/Import/Export And Storage Of Hazardous Micro Organisms/ Genetically Engineered Organisms Or Cells, 1989 under Environment Protection Act 1986 do **not** allow GEAC to set up any Sub-Committees & Expert Committees (while RCGM is allowed to).

GEAC has been visualized as a broad based, inter-ministerial, multi-disciplinary body – not a body that works as smaller units, that too with external members parachuted in. This was done in Bt brinjal case too.

GM HT mustard was also approved in this manner with larger GEAC abdicating its role!

https://geacindia.gov.in/resource-documents/biosafety-regulations/acts-and-rules/Rules-for-the-manufacture-use-import-export-and-storage-1989.pdf

4. **COMPETENT AUTHORITIES**

(1) **Recombinant DNA Advisory Committee (RDAC):** This committee shall review developments in Biotechnology at national and international levels and shall recommend suitable and appropriate safety regulations for India in recombinant research, use and applications from time to time. The Committee shall function in the Department of Biotechnology.

(2) **Review Committee on Genetic Manipulation (RCGM):** This committee shall function in the Department of Biotechnology to monitor the safety related aspects in respect of on-going research projects and activities involving genetically engineered organisms/hazardous microorganisms. The Review Committee on Genetic Manipulation shall include representatives of (a) Department of Biotechnology (b) Indian Council of Medical Research (c) Indian Council of Agricultural Research (d) Council of Scientific and Industrial Research (e) other experts in their individual capacity. Review Committee on Genetic Manipulation may appoint sub groups.

It shall bring out Manuals of guidelines specifying procedure for regulatory process with respect to activities involving genetically engineered organisms in research, use and applications including industry with a view to ensure environmental safety. All ongoing projects involving high risk category and controlled field experiments shall be reviewed to ensure that adequate precautions and containment conditions are followed as per the guidelines.

The Review Committee on Genetic Manipulation shall lay down procedures restricting or prohibiting production, sale, importation and use of such genetically engineered organism of cells as are mentioned in the Schedule.

(3) **Institutional Biosafety Committee (IBSC):** This committee shall be constituted by an occupier or any person including research institutions handling microorganism/genetically engineered organisms. The committee shall comprise the Head of the Institution, Scientists engaged in DNA work, a medical expert and a nominee of the Department of Biotechnology. The occupier or any person including research institutions handling microorganisms/genetically engineered organisms shall prepare, with the assistance of the Institutional Biosafety Committee (IBSC) an up-to-date on site emergency plan according to the manuals/guidelines of the RCGM and make available copies to the District Level Committee/State Biotechnology Co-ordination Committee and the Genetic Engineering Approval Committee.

(1) **Genetic Engineering Approval Committee (GEAC):**

This committee shall function as a body under the Department of Environment, Forest and Wildlife for approval of activities involving large scale use of hazardous microorganisms and recombinants in research and industrial production from the environmental angle. The Committee shall also be responsible for approval of proposals relating to release of genetically engineered organisms and products into the environment including experimental field trials.

The composition of the Committee shall be

(i) Chairman-Additional Secretary, Department of Environment, Forests and Wild life Co-Chairman-Representative of Department of Bio-technology

(ii) Members: Representative of concerned Agencies and Departments, namely, Ministry

ments/biosafety-regulations/acts-and-rules/Rules-for-the-manufacture-use-import-export-and-storage-1

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The composition of the Committee shall be

(i) Chairman-Additional Secretary, Department of Environment, Forests and Wild life Co-Chairman-Representative of Department of Bio-technology

(ii) Members: Representative of concerned Agencies and Departments, namely, Ministry of Industrial Development, Department of Biotechnology and the Department of Atomic Energy:

(iii) Expert members: Director General Indian Council of Agricultural Research, Director General-Indian Council of Medical Research, Director General-Council of Scientific and Industrial Research, Director General-Health Services, Plant Protection Adviser, Director of Plant Protection, Quarantine and storage, Chairman, Central Pollution Control Board and three outside experts in individual capacity.

(iv) Member Secretary: An official of the Department of Environment, Forest and Wild life.

The committee may co-opt other members/experts as necessary.

The committee or any person/s authorised by it shall have powers to take punitive action under the Environment (Protection) Act.

(4) **State Biotechnology Co-Ordination Committee (SBCC):** There shall be a State Biotechnology

GM mustard violated other protocols/regulations too!

- **AICRP-RM protocols** were violated in terms of number of seasons of testing, number of locations of testing in each zone
- **AICRP-RM protocols** were violated in terms of National and Zonal Checks to be used for testing
- **Insecticides Act 1968 regulations** in terms of registered uses of Glufosinate ammonium violated
- EPA 1989 Rules' **Guidelines and Protocols for Confined Field Trials** violated in **Bathinda in 2014-15 trial** – the Coalition complained to GEAC with photographic evidence but no action was taken.

Union of India, therefore, is making patently incorrect statements in the Hon'ble SC when it says:

- *“Conditional approval for environmental release of transgenic mustard hybrid DMH-11 and parental lines bn3.6 and modbs2.99 containing barnase, barstar and bar genes has been made after following detailed procedure in law and after considering biosafety data accumulated over several years*
- *Conditional approval has been made in accordance with guidelines and framework which enable a consistent and rigorous risk analysis approach to evaluating applications for environmental release of GE plants*
- *Complete procedure for safety assessment of the GE mustard from environmental and health risks including cross-pollination has been followed prior to grant of permission for environmental release.”*

THE EARLIER SET OF SLIDES CLEARLY SHOW THAT ALL OF THIS IS UNTRUE. OUR LONGER REPORT LISTS MANY OTHER ILLUSTRATIONS OF VIOLATIONS TOO: [Regulatory-Violations-GM-mustard-Final-Report-January-2023.pdf \(indiagminfo.org\)](https://indiagminfo.org/regulatory-violations-gm-mustard-final-report-january-2023.pdf)

Cartagena Protocol on Biosafety's Article 26 (Socio-Economic Considerations) and 28 (Liability & Redressal) violated too, in addition to Precautionary Principle (Article 1) being ignored

- Approval of GM HT Mustard in fact demonstrates total failure of India's limited biosafety regulations and also showcases the serious deficiencies in the regulatory regime
- Public Health and Environmental Safety seriously compromised in GM mustard approval
- State Governments' Constitutional authority over Agriculture bypassed and violated – States not even consulted, the way they were in the case of Bt brinjal
- India, a signatory to the Cartagena Protocol on Biosafety, violates international commitments too

INDIAN GOVERNMENT IGNORES & NEGLECTS SUPREME COURT'S TECHNICAL EXPERT COMMITTEE'S RECOMMENDATION TO BAN HT CROPS IN INDIA, APART FROM BANNING TRANSGENICS IN THOSE CROPS FOR WHICH WE ARE THE CENTRE OF ORIGIN/DIVERSITY