

Statutory Regulatory Violations & Procedural Infirmities in GM Mustard Appraisal & Approval in India –

A Short Report by
Coalition for a GM-Free India
(January 2023)

Do GM HT mustard appraisal & approval reflect a robust regulatory regime?

What about the egregious violations and numerous regulatory infirmities that plague GM mustard appraisal and approval?

In ongoing hearings in the Supreme Court of India related to GM mustard approval by the Government of India, the [Attorney General R Venkataramani gently challenged the Bench](#) of Justices Shri Dinesh Maheshwari and Smt BV Nagaratna on whether they will/can make a value judgement on what is good science and bad science. The Bench later expressed its opinion that it will not go into the core scientific matters beyond a point, but that it is certainly expected to look at the recommendations of the Court's own Technical Expert Committee (TEC) recommendations, and is interested to know about the Government's compliance with the same.

The AG meanwhile pleaded that the Indian regulatory regime is robust, and one of the best in the world. He stated that GM mustard passed through this rigorous regulation over a long period of time – that 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 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”, argued the Attorney General, on December 1st 2022 in the Supreme Court. “It is most humbly submitted that the inquiry of this Hon’ble Court may be limited to whether there is an adequate regulatory mechanism in place governing this field and whether there has been material compliance with the same”, stated the [Union of India’s November 9th 2022 Additional Affidavit](#) in the ongoing litigation. (Writ Petition (Civil) 115 of 2004, 260 of 2005 and 840 of 2016).

This brief report in January 2023 by the Coalition for a GM-Free India is to present glimpses of serious deficiencies, lapses and violations in GM mustard appraisal and approval, to counter the picture the AG is presenting to the Hon’ble Bench. We show objectionable regulatory compromises to showcase the Union of India’s many falsehoods in the highest court of the country. In this document, we are intentionally not focusing on GM mustard yields or its safety or such issues.

We have put together 15 examples of the violations of statutory regulations and serious procedural infirmities with regard to GM mustard appraisal and approval in India. Some of these were applicable to other GM crops like Bt cotton and Bt brinjal too – in the case of Bt brinjal, these kind of egregious violations and compromises were incidentally made the grounds for the Government of India to impose an indefinite moratorium on the environmental release/commercial cultivation of Bt brinjal.

- 1. FAIT ACCOMPLI, BEFORE FORMAL APPROVAL?** Let’s begin with a brazen effort by the Government of India at delivering a fait accompli on the country – that of planting GM mustard, by apparently delivering GM mustard seed to DRMR for planting, on [October 22nd 2022](#) itself, a few days before a formal approval letter was issued to the crop applicant on [October 25th 2022](#)! Further, even the planting of GM mustard is a violation in itself by Government of India, of its own undertaking in Court where on July 28th 2017, as it kept assuring the Supreme Court of India that the Government of India has not yet taken a decision. In [this Additional Affidavit](#), the UoI stated 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 effective interim orders after

the decision is taken". However, the planting of GM mustard in 6 locations of Rajasthan, Uttar Pradesh and Punjab, reportedly without even isolation distances being maintained, is deliverance of *fait accompli*. The Government of India, despite its undertaking in the Supreme Court of India, has delivered a *fait accompli*, in a highly orchestrated fashion, violative of procedures that ought to have been followed.

- Government of India gives an undertaking in July 2017 in the Supreme Court that it will not create a situation of *fait accompli* with regard to any decision with GM mustard.
- Genetic Engineering Appraisal Committee (GEAC), the statutory regulatory body, gives a "recommendation" for environmental release of GM mustard on 18th October 2022 in its 147th meeting.
- Seeds are picked up by ICAR functionaries from the crop applicant CGMCP of Delhi University on October 22nd 2022 and delivered to Directorate of Rapeseed-Mustard Research (DRMR) for planting.
- Formal approval letter is issued only on October 25th 2022.
- Seeds are dispatched to eight centres and six of them plant GM mustard before the Court hears the matter on November 3rd 2022.

- 2. GM HT MUSTARD DID NOT UNDERGO EVEN THE LIMITED TESTING THAT BT BRINJAL UNDERWENT:** In India, while brinjal is grown on about 6-7 lakh hectares, mustard is grown on around 80 lakh hectares (more than ten-fold higher extent). In terms of livelihoods too, a significantly higher number of people are dependent on mustard, including agricultural workers and bee-keepers. Despite mustard occupying such a prominent position in our agriculture sector in India, with this oilseed contributing the largest share of domestic production of oil, [GM mustard was not tested even to the limited extent to which Bt brinjal got tested](#).

For instance, in the case of Bt brinjal, pollen flow studies were done for 3 years in two locations. In the case of GM mustard, it was one location and one season. When it came to soil impact studies, in Bt brinjal, it was 4 years in all, and included impacts on earthworms and collembola populations. In the case of GM mustard, it did not include earthworm and collembola populations. When it comes to health safety testing, GM mustard did not undergo (a) mucous membrane irritation test, or (b) primary skin irritation test, or (c) allergenicity test in rats, or (d) feeding studies on fish or (e) rabbits or (f) broiler chicken or (g) goats or (h) dairy cows; whereas such tests were done in the case of Bt brinjal. Some tests were done over more seasons and more locations in the case of Bt brinjal.

For instance, livestock feeding studies as part of BRL-I second year trials were discussed and permitted in the [112th meeting of GEAC](#) on 21/09/2011. However, it is only in 2014, that exemption is sought by the applicant, with the RCGM (Review Committee on Genetic Manipulation in the DBT, with DBT being the main funder of GM mustard) Member as the interlocutor for the request. No decision is recorded of an exemption actually having been accorded by GEAC. However, the whole application suddenly moves into a phase where environmental release permission is considered in late 2015-early 2016.

The reason for this irresponsible compromise in testing and appraisal could be a US-AID supported project implemented in India, in the name of “harmonisation” of regulation, which resulted in dilution of testing in the regulatory regime. The [ICMR guidelines of 2008](#), which India follows now for Safety Assessment of Foods derived from Genetically Engineered Plants, along with [Protocols for Food and Feed Safety Assessment of GE Crops](#) (2008), left the crop applicant in the case of GM mustard arguing that they can be exempted from livestock feeding studies, for example. All these dilutions were made, despite mustard leaves and flowers also being edible parts used as food.

Many studies that were prescribed and done for Bt brinjal were not conducted for GM HT mustard. This dilution happened despite the fact that mustard is grown in far larger area than Brinjal in India, despite the fact that it is not just mustard seeds that are consumed but its leaves and flowers also, and despite the fact that significantly more livelihoods are directly dependent on mustard crop, when compared to Brinjal. The tests done on Bt brinjal revealed its lack of safety as per independent public scrutiny. Government is clearly avoiding that distinct possibility arising with GM mustard too, by limiting the testing drastically.

- 3. NO (INDEPENDENT) HEALTH EXPERT PARTICIPATED IN GM MUSTARD APPRAISAL:** [RTI replies](#) from MoEFCC show that Dr B Sesikeran, nominated into the sub-committee of 2016 as the health expert (but also controversial because of his [industry links](#)) did not participate in all the three meetings of the sub-committee. However, the Sub-Committee went ahead and gave a clean chit to GM mustard even on the health front, and based on this, GEAC gave a green signal too.

In the 2022 Expert Committee set up by GEAC, there was no health expert, and when GM mustard got its final green signal on October 18th 2022 in [GEAC’s 147th meeting](#), ICMR representative was not even present in the meeting. In effect, a herbicide tolerant crop which was never tested as a HT crop, was cleared by non-health experts as being safe for human health.

GM mustard was appraised for its safety by a Sub-Committee set up by GEAC in 2016, and later by an Expert Committee constituted in 2022. However, no health expert participated in either of these processes, as per RTI information obtained. Dr B Sesikeran was the health expert nominated in the 2016 Sub-Committee by GEAC. He is an industry-linked person. Additionally, National Institute of Nutrition (NIN) did some studies on GM mustard, and Dr Sesikeran used to head NIN at that time. Importantly, he never joined any of the 3 meetings of the GM mustard sub-committee. The 2022 Expert Committee had no health expert in any case. Despite no health expert participating, GEAC gave a green signal to even the health safety aspects of GM mustard.

- 4. GM MUSTARD WAS NEVER TESTED AS A HT CROP:** India does not have any [guidelines and protocols](#) for testing of HT crops, even as the petitioners are arguing that HT crops should be completely banned and while the Union of India is proceeding forward with approvals. This is apparent from the discussions and decisions on other herbicide tolerant crops (other than GM mustard) in [GEAC’s 117th, 119th, 120th, 121st and 122nd meetings](#).

This GM mustard did not get tested as a HT crop at all. This is irresponsible given that even the Union of India, the regulator and the crop applicant are saying that in the seed production phase,

herbicides are essential to be applied on this GM crop. For herbicide tolerant crops other than GM mustard, 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. (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 an instance. (119th meeting). Visual observations on herbicide treated plots for yellowing, scorching and wilting were prescribed to be recorded. Control treatments will 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. GEAC however abdicated even this kind of responsibility when it came to GM mustard.

While there are no regulatory guidelines & protocols for testing of herbicide tolerant crops in the Indian regulatory regime, GEAC had prescribed various pertinent tests for other HT crops, where it sought for additional information. This is apparent from GEAC meetings' minutes in its 117th, 119th, 120th and 121st meetings. 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. GM mustard did not get tested as a HT crop at all.

- 5. PARENTAL LINES DID NOT UNDERGO EVEN THE LIMITED TESTS THAT DMH-11 WAS PUT THROUGH:** Similarly, parental lines have not undergone even the limited testing that DMH-11 hybrid has been subjected to, whereas in hybrid technology, these parental lines have to be maintained and multiplied separately. In fact, GM mustard hybrid cultivation will necessarily mean three generations of GMOs being exposed to the environment. However, no pollen flow studies or weediness studies exist of the parental lines, which are distinct GMOs in themselves, different from the hybrid.

No data of biosafety or seed setting/yields has been presented of 'experimental seed production' data generated, which would have certainly used herbicide Glufosinate Ammonium, and its environmental and health impacts. This, despite the fact that seed production trials have been permitted.

No health safety studies were done even for Varuna barnase line using herbicide sprays, even though it is being admitted that in the seed production phase, usage of herbicide is essential.

The parental lines of GM mustard hybrids 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 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 spread of sterility trait would prove risky.

6. **(LIMITED) STATUTORY REGULATORY GUIDELINES AND PROTOCOLS VIOLATED, WHEN IT COMES TO GM MUSTARD TESTING:** The petitions in the Supreme Court are mainly centred around the regulatory regime being inadequate in India. In that sense, the existing statutory guidelines and protocols are narrow in their scope. However, even these limited guidelines and protocols were violated in GM mustard testing.

[Environmental Risk Assessment Guidelines 2016](#) are violated for instance (Page 15, 9.6), by pollen flow study in only one location, crossability study in only one location, by weediness study in one location and one season etc. The guidelines state that *“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 the plant species will be cultivated is adequately represented”*. GM mustard environmental safety testing violated these guidelines. This is simply unscientific and incomplete appraisal.

Even when it comes to the **ICMR guidelines of 2008 for Food Safety Assessment, compositional analyses violated the protocols laid down**, for instance. (Page 15, 7.3 of [Microsoft Word - Coverpage.doc \(geacindia.gov.in\)](#)). Here, this is 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.”

However, the actual Compositional Analysis done shows clear violations of the guidelines. No herbicide was used in testing, since GM mustard was not tested as a HT crop. (i) Only one zone (III) and 2 locations may have contributed samples, given that Sriganganagar trial was supposed to have been destroyed by Rajasthan Government. (ii) This study was not done by NIN as claimed, but was outsourced to a private company. (iii) Study did not happen over sufficient number of generations. (iv) 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 inspite 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 were not done.

The **same kind of violations can be shown in the case of agronomic evaluation too.** [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...”. Same is the instruction in the [Permission Letter for BRL II trials](#), dated 28/10/2014 with the same protocol mentioned under ‘Point 7.0 Trial Protocol’. In reality, these conditions and protocols are not followed. 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!

India has an inadequate regulatory regime for appraisal and risk management of GMOs. In the case of GM mustard, the guidelines and protocols of even this limited regime were violated. This can be seen in the case of environmental safety testing, as well as food safety/health safety testing. Additionally, even in the agronomic evaluation of GM mustard, the laid-down conditions and protocols were not followed.

- 7. CONFLICT OF INTEREST IN THE REGULATORY REGIME – CGMCP SCIENTIST BROUGHT IN AS A GEAC MEMBER:** Dr Akshay Pradhan of CGMCP of Delhi University was appointed as a [GEAC Member in 2014](#), at a time when Delhi University’s GM mustard application was progressing inexorably towards a permission for environmental release. This was done soon after [GEAC constitution in 2013](#) (page11), for unclear reasons. It is completely objectionable that this was done.

During the recent court hearings, the AG read out a particular line from a GEAC meeting ([121st meeting](#)) to show the Hon’ble Supreme Court how GEAC deals with conflict of interest, about how Dr Akshay Pradhan who is part of the team that developed GM mustard excused himself from discussions related to GM mustard. What the AG failed to disclose the Court is that in a [non-sanitised version of the Minutes of the same meeting obtained under RTI](#), it is clear that Dr Akshay Pradhan of CGMCP (the applicant for GM mustard clearance) participated in the discussions related to GM mustard, where he was requested to clarify something pertaining to GM mustard.

Two other members also reflect conflict of interest because of their industry linkages and their involvement in GM crop development – [Dr B Sesikeran](#) and [Dr Swapan Kumar Datta](#). It is unclear why in a country of such vast expertise in various fields, that GEAC constitution should repeatedly include such conflict of interest again and again, for decades now. ([Enscript Output \(sci.gov.in\)](#))

Conflict of interest cannot be addressed narrowly by a member stepping out for a few minutes when a particular application is being discussed. GEAC’s discussions and decisions are not just about individual applications, but of shaping the entire regulatory regime, about guidelines, protocols, prescriptions of tests and other matters involved. This cannot be brushed aside or defended by Union of India frivolously by showing some meeting minutes where a member representing conflict of interest offers to step out of the meeting for one agenda item.

GEAC got re-constituted in 2014, months after it was constituted in 2013, just as GM mustard moved inexorably towards environmental release. Dr Akshay Pradhan, part of the GM Mustard

development team was 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, to show how GEAC deals with conflict of interest, where Dr Pradhan offers to excuse himself from the GEAC discussions when GM mustard is discussed. The non-sanitised, non-abridged version of the Minutes that the AG did not read in the Court show that he indeed participated in the meeting. In any case, Conflict of Interest is a much-deeper problem than being addressed by a Member stepping out for a brief while for one agenda item of the meeting.

- 8. CONFLICT OF INTEREST IS ALSO REFLECTED IN WHO DESIGNS TEST PROTOCOLS AND WHO DOES THE TESTING:** In the case of GM mustard itself, an [RTI reply from Delhi University](#) shows that test protocols were all evolved by the crop developer/applicant. Even without the RTI reply from Delhi University, GEAC meeting minutes also reflect that regulator asks the applicant to evolve test protocols. ([134th meeting minutes](#) and [135th meeting minutes](#)).

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](#) denied the same and stated that crop developer did the studies. That means 8 tests done by crop developer himself. Only 5 other studies are supposed to have been done by other agencies (Allergenicity Assessment, Acute Oral Toxicity, Sub-Chronic Toxicity, Compositional Analyses and Study on soil microflora). ([Safety-assessment-report-on-GE-Mustard 0.pdf \(moef.gov.in\)](#)).

Information available with the Coalition shows that Biotech Consortium of India Limited (BCIL) set up an Expert Committee for DU's GM mustard to navigate the regulatory approval process and in that Committee were people like Dr KV Prabhu, who was also parachuted into the Sub-Committee constituted in 2016, apart from NIN Director and scientist who did the studies on behalf of NIN. Meeting minutes of this Expert Committee from 2010 can be accessed [here](#) and [here](#).

All test protocols for GM mustard testing were evolved by the crop developer itself. Further, 8 of the tests that were done to prove safety and efficacy of GM mustard were done by the applicant itself. Only 5 other studies were done by other agencies. Members of these other agencies were also closely connected to study protocol designing, or conducting of tests and even appraisal of the results later on.

- 9. 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:** There are at least four instances when GEAC (or its sub-committee) in its meeting minutes would have recorded that some study or the

other is to be undertaken by the applicant, but that study does not actually get done, in this entire GM mustard story.

Livestock feeding studies approved and then exempted: For instance, livestock feeding studies as part of BRL-I second year trials are [discussed and permitted in 2011](#). However, it is [only in 2014](#), that exemption is sought by the applicant. **No decision is recorded of an exemption actually having been accorded by GEAC**. However, the whole application suddenly moves into a phase where environmental release permission is considered in late 2015-early 2016.

3 studies recommended by the sub-committee: [In its 133rd meeting in May 2017](#), GEAC recommends the environmental release of GM mustard hybrid and accepts the proposal as put forward by the Sub-Committee. As per the [Minutes available](#) of the 3rd Meeting of the Sub-Committee on 1st November 2016, 3 studies are recommended with a caveat that these are recommended “although there has been no measurable risk, for sustained use of technology in breeding for new hybrids”/ “to dispel apprehensions, as a precautionary approach for sustainable use of this MS-RF technology of mustard”/ “from an academic angle”: (a) a study to assess the effect of GE mustard on honey bees and honey should be undertaken involving experts from AICRP on Honeybees and Pollinators during the first year of cultivation; (b) a study with special reference to beneficial microbes should be undertaken during the first year of cultivation in involving ICAR-National Bureau of Agriculturally Important Microorganisms (NBAIM). (c) studies may be undertaken on issues of biology of crossability in the interest of long term sustainability of GM mustard technology. **However, recommendations have not been taken seriously/tests done.**

Soil Microflora Studies Dropped: In the 135th meeting of GEAC on 25/07/2018, about 4 months after a certain study is prescribed to be undertaken, CGMCP requested 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**. Protocols are presented by the applicant for studies on honeybees at two locations, in addition to two “field demonstration studies to assess hybrid seed efficiency and for maintenance of male sterile line”. (Ref: [MoMPublishedOn20180830201015.pdf \(geacindia.gov.in\)](#))

Honeybee Studies (Without Pesticides in a HT crop): In the 136th meeting of GEAC on 20/09/2018, the protocols are approved by GEAC for conduct of “field demonstration studies on honey bees and other pollinators in two locations”. It was also decided that any pesticide that adversely impacts honeybees should not be used, which was an unusual thing to do, given that GM mustard is a HT crop, and HT crops have to be assessed as such. (Ref: [MoMPublishedOn20181012223929.pdf \(geacindia.gov.in\)](#)). In the 137th meeting of GEAC on 20/03/2019, the GEAC meeting minutes record the deferment of field demonstration studies during 2018-19 and the reasons are not recorded. (Ref: [Microsoft Word - Approved Minutes 11 April 2019.docx \(geacindia.gov.in\)](#)). In the 138th meeting on 11/11/2019, GEAC notes that the deferred studies are to be undertaken in 2019-20 instead of 2018-19. (Ref: [MoMPublishedOn20200115103927.pdf \(geacindia.gov.in\)](#)). Nothing is heard about GM mustard in the 139th meeting minutes, 140th meeting minutes, 141st meeting minutes, 142nd meeting minutes, 143rd meeting minutes, 144th meeting minutes and 145th meeting minutes.

Exemption from Field Demonstration Studies: In the 146th meeting, 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! Then in the 147th meeting, GEAC accepts the Expert Committee's recommendations, **which means an exemption from these "field demonstration studies"** and a straight walk into "environmental release". (Ref: [MoMPublishedOn20220909190233.pdf \(geacindia.gov.in\)](#) and [MoMPublishedOn20221025200345.pdf \(geacindia.gov.in\)](#))

Material in public domain clearly shows that GEAC kept prescribing studies to be undertaken on GM mustard, but when the applicant sought exemption from the same, kept agreeing to these exemption requests. This is visible in the case of livestock feeding studies, for which no decision of even an exemption has actually been recorded by GEAC, but GM mustard got approval! This is also applicable to Soil Microflora Studies, where within 4 months after prescribing this, GEAC agreed to an exemption request. Similarly is the case with Field Demonstration Studies on Honeybees and other pollinators and on Honey.

Several studies were prescribed by GEAC to be undertaken on GM mustard. However, the crop developer sought exemption from doing these studies, and with or without actually taking a decision on exemption, GEAC straightaway moved into approving GM mustard for environmental release!

10. FAULTY COMPOSITIONAL ANALYSIS MADE THE BASIS FOR NOT UNDERTAKING OTHER STUDIES:

This was briefly described in an earlier section of this report. Compositional Analysis was done by using leaf and seed samples from 3 locations in just one season. Report date is 02/04/2014 while trials were in Rabi 2011. The following needs to be noted about the Compositional Analysis studies. Report of NIN is dated 2/4/2014, numbered as Study No. 2/2012 while last field trials would have been only in 2011-12. It is not clear if the report was released in a delayed fashion. The actual testing was undertaken at M/s QPS Bioserve India Private Limited, though the study was claimed to have been done by NIN. The Results section (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 inspite of the significant changes which may be due to agro-climatic changes". This is exactly what the ICMR guidelines of 2008 ask applicants to avoid – this compositional analysis of GM mustard violated the regulatory protocols laid down, for instance (Page 15, 7.3 of [Microsoft Word - Coverpage.doc \(geacindia.gov.in\)](#)). It is important to note that the entire reasoning behind not taking up feeding studies or other food safety tests was an argument that no significant changes were detected in the Compositional Analysis. However, it is clear now, that there were significant changes, but have been discounted in an unreasonable fashion, and based on the same, other studies were not taken up even as a green signal was accorded to health safety of GM mustard.

11. BIOSAFETY DOSSIER NEVER PUBLISHED ON THE REGULATORS'/MOEFCC WEBSITE, DESPITE SUPREME COURT ORDERS, CIC ORDERS, GEAC MEETING MINUTES AND SPECIFIC ASSURANCES

ON THE SAME: [Supreme Court Orders](#) of 08/04/2008 and 12/08/2008 have been violated, where the Hon'ble Court asked the Government to place all biosafety data on GEAC website for different crops. This has not been done in the case of GM mustard to this day. This is surprising given that in 2016 itself, GEAC on its own, recorded in its Minutes of its [127th meeting](#) that it will share the biosafety dossier in public domain. On 11/03/2016, Ministry of Environment made a categorical statement/commitment to the Central Information Commission vide a Reply dated 11/03/2016 that the Biosafety Dossier as and when received by GEAC shall be posted on its own website. This was done as an undertaking in the 2nd Appeal filed by an activist with the Central Information Commission. The Central Information Commission has also passed [final orders](#) asking for the biosafety dossier to be published. ***Despite all the above, the biosafety dossier has not been published to this day, and GEAC has consciously, and with malafide intent, hidden the dossier from independent scientific scrutiny.***

Making public the entire biosafety dossier is one good way of ensuring that regulatory compromises in the form of conflict of interest or unscientific testing of any kind can be clearly addressed, by independent appraisal of the data submitted by the applicant. It was such independent scientific scrutiny that brought to light the serious deficiencies in the case of Bt brinjal. It is with a clear malafide intent that the GM mustard biosafety dossier has been kept hidden by the regulators, despite their own commitment to publish the dossier.

12. GM HT MUSTARD APPROVAL CLEARLY IGNORES REGULATORY INCAPABILITIES - THERE IS NOTHING LIKE "CONDITIONAL APPROVAL FOR ENVIRONMENTAL RELEASE PRIOR TO COMMERCIAL RELEASE" IN INDIAN REGULATORY REGIME: The regulatory incapacities with regard to both pesticides/insecticides and GM regulators when it comes to HT crops is reflected in the fact that lakhs of acres of cotton in India are being planted to illegal Herbicide Tolerant Cotton at this point of time, with both the seed and the usage of herbicide glyphosate being unapproved and illegal. However, governments are unable to stop this illegal proliferation despite a PMO-driven committee called Field Inspection and Scientific Evaluation Committee (FISEC) making several recommendations to stop this menace. The same fate can be expected of HT mustard, any glib and specious arguments from the government notwithstanding. Regulators cannot simply criminalise lakhs of farmers, by taking irresponsible and unneeded decisions in the first instance. ([Sale of illegal HTBt cotton seeds doubles - The Hindu](#)). ***Meanwhile, an ICAR meeting in 2004 clearly identifies the objective of Delhi University's GM mustard as Herbicide Tolerance.*** Further, published papers of CGMCP scientists reveal their intention to develop HT crops. (https://drive.google.com/file/d/1Pfd8rTU0hD3bsO9vn3O333LW7utfwFtY/view?usp=share_link)

GEAC is bringing in new terminology like "Conditional Approval for Environmental Release Prior to Commercial Release" which do not exist in the regulatory parlance, or in the existing guidelines and protocols. In the past, "Environmental Release" was clearly used in March 2002 for approval of Bt cotton commercial cultivation ([GEAC's 32nd meeting minutes](#)), and in October 2009, for Bt brinjal for commercial cultivation by farmers too ([GEAC's 97th meeting minutes](#)) which was subsequently placed under an indefinite moratorium. The conditional approval has no meaning in reality. A small example is the condition related to refugia that was laid down at the time of Bt cotton approval, which was never implemented on the ground.

Before this, GEAC approved “field demonstration studies” on 5 acres each at a time in its 134th meeting. This is a clear violation of “Guidelines for Conduct of Confined Field Trials of Regulated GE Plants, 2008” where the maximum size for BRL II trial is not more than 2.5 acres per trial site location. (Ref: [Starting Page.pmd \(geacindia.gov.in\)](#)). The protocols that got approved in the 136th meeting of the GEAC held on 20/09/2018 are therefore, a violation of the Guidelines for Confined Field Trials. (Ref: [MoMPublishedOn20181012223929.pdf \(geacindia.gov.in\)](#))

GEAC and the Government should maintain the clear distinction between testing, which ought to go back to “Confined Field Trials” guidelines and protocols, and “environmental release”.

Regulatory capabilities are clearly lacking with GEAC, as well as regulators under other statutes, to ensure farmer-level compliance of regulations or conditions laid down by GEAC. The clear attempt to criminalise farmers is also condemnable. In such a case, conditional approvals are just an abdication of the responsibility of the regulators. Further, if GM mustard has been released for further testing, the applicable guidelines and protocols are that of “confined field trials”, and this cannot be termed as “Conditional Approval for Environmental Release Prior to Commercial Release”.

- 13. [CARTAGENA PROTOCOL ON BIOSAFETY VIOLATED IN VARIOUS WAYS](#):** India is a signatory to the Cartagena Protocol on Biosafety, an international agreement under the Convention on Biological Diversity.

13A. GM MUSTARD APPRAISAL NOT IN LINE WITH CARTAGENA PROTOCOL ON BIOSAFETY – NO SOCIO-ECONOMIC CONSIDERATIONS TAKEN INTO ACCOUNT: While [Article 26](#) of the Cartagena Protocol on Biosafety to which India is a signatory talks about Socio-Economic Considerations, the Indian regulatory regime does not have [any guidelines and protocols](#) to assess this. In the case of GM HT mustard, for instance, the huge adverse repercussions on poor agricultural workers, their employment, fodder, biodiversity, nutritious greens for the household etc., are all being ignored by the approval to a HT crop. The impacts could be particularly bad for poor female agricultural workers, in fact.

13B. CARTAGENA PROTOCOL VIOLATIONS - NO LIABILITY & REDRESSAL REGIME IN PLACE: While GEAC has approved GM mustard environmental release, which is an irreversible and uncontrollable biological process set into motion by the planting that took place already, there is no liability and redressal regime in place (Article 27 of the Cartagena Protocol is about this). Who is to be held liable for contamination or adverse health impacts flowing out this HT mustard? What should organic farmers do when their organic certification is affected, and they lose markets and incur losses? What can bee-keepers and honey exporters do for redressal? What is to be done when the sterility gene spreads, or the herbicide tolerance trait spreads in native germplasm? Importantly, what is the liability on irresponsible regulators?

13C. NO OPERATIONALISATION OF PRECAUTIONARY PRINCIPLE: India is a signatory to the [Cartagena Protocol on Biosafety](#) (CPB), under the Convention on Biological Diversity, that came into force on 11th September 2003. The Protocol reaffirms the precaution language in Principle

15 of Rio Declaration on Environment and Development. The very Objective in Article 1 states: *“In accordance with the precautionary approach* contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements”. In addition to case laws and judgements that have rested on precautionary principle in India’s jurisprudence, the Government of India’s moratorium decision on Bt brinjal in 2010 was based on the precautionary principle. ([Para 16, and Para 24](#)). However, the current approval and planting of GM HT mustard is a clear violation of the precautionary principle that should have been at the centre of regulatory decision-making. In fact, the Approval Letter reveals how the Government is making a mockery of the Precautionary Approach where it is written that some tests will be done post-environmental release as a “precautionary measure”, after causing irreversible damage. (Point III of [Approval Letter](#)).

Several key provisions of the Cartagena Protocol on Biosafety have not been operationalised in the Indian regulatory regime. There are no mechanisms for fixing liability for damages, nor redressal for such damages or losses. No guidelines and protocols have been instituted to include Socio Economic Considerations into the appraisal mandate given to the regulatory body. In fact, GEAC’s lack of understanding of the Precautionary Principle, which is the cornerstone for the Cartagena Protocol, is very apparent.

- 14. GEAC IS AN APPRAISAL COMMITTEE AND NOT AN APPROVAL COMMITTEE:** In 2010, Government of India, through a [Gazette Notification](#) renamed Genetic Engineering *Approval* Committee to Genetic Engineering *Appraisal* Committee. This happened after widespread public consultations, including soliciting of views of state governments, during the Bt brinjal environmental release debates and as per the Union of India’s [moratorium decision](#). The mandate of this Committee squarely overlaps with the very mandate of the 1989 Rules (which were made *“with a view to protecting the environment, nature and health, in connection with the application of gene technology and micro-organisms”*). GEAC itself knows that it is not the Competent Authority for approvals and in the [133rd meeting](#) which gave the first green signal to GM mustard in May 2017, recorded that while GEAC was recommending, further approval will be given by “competent authority”. However, the October 25th 2022 [approval letter](#) was signed off by Member-Secretary, GEAC which is not the competent authority.

After being renamed as an Appraisal Committee, from being an Approval Committee, Genetic Engineering Appraisal Committee (GEAC) itself knows that it is not the competent authority for approving GM mustard. This is reflected in its meeting minutes as well as submissions in the Supreme Court. However, GEAC issued the approval letter to GM mustard crop developer, and this is invalid.

- 15. AGRICULTURE IS A STATE SUBJECT – GM MUSTARD BEING THRUST EVEN WHEN STATE GOVERNMENTS HAVE OPPOSED THIS TRANSGENIC FOOD CROP:** Many state governments have

come out in vocal opposition against GM mustard and wrote to the Central Government again and again, voicing concerns and opposition against GM mustard. This includes states like Rajasthan, Madhya Pradesh, Delhi, Bihar, Haryana, West Bengal, Tamil Nadu, Kerala, Andhra Pradesh etc. Most state governments which grow mustard on a large scale did not even allow field trials, while Rajasthan destroyed a field trial close to its harvest stage. However, this approval for Environmental Release of GM mustard, given by GEAC, is ignoring such opposition from state governments which are stating a policy position that they have taken. This is outright against the Constitutional Authority vested in state governments over both Agriculture and Health, which are state subjects. It is also surprising that when a regulatory regime can take cognisance of the right of state government when it comes to field trials (Ref: [GEAC's 116th meeting](#)), it would not do so when it comes to 'environmental release'! [IndiaGMInfo - State Govts & GM Mustard](#)

GEAC's approval of GM mustard environmental release clearly ignores and bypasses the constitutional authority that state governments have been vested with, when it comes to Agriculture and Health. What is even more surprising is that GEAC takes into account the rights of state governments when it comes to Field Trials, but is choosing to ignore the same when it comes to Environmental Release, despite stated policy positions of state governments against GM crops.

THE ATTEMPT TO CONTAMINATE FIRST, AND GET REGULATORY APPROVAL LATER IS ROUTINE: The biotech industry's strategy of "contaminate first, get approval subsequently" is notorious the world over. In India too, Bt cotton was given a regulatory clearance after illegal cultivation was discovered on a large scale, following leakage of seeds from field trials. Now, there is talk about giving regulatory clearance to HT cotton. In the case of GM mustard too, biosafety norms related to confined field trials got violated; this was also a violation of Supreme Court Orders, in fact. Biosafety norms were violated in Bathinda trial in 2014-15; alert civil society groups complained but there was no action from GEAC. Here, the [08.05.2007 Orders of Hon'ble Supreme Court](#) got breached. On 16th June 2015, the Coalition for a GM-Free India complained to the GEAC about serious biosafety violations in the trials of GM mustard in Bathinda, Punjab. [IndiaGMInfo - Coalition letter urging GEAC to take action on serious biosafety violations](#) and <https://www.dropbox.com/sh/4c8fys8okwchoej/AACZITRziVrAu1De6TX7T2cka?dl=0> (photographic evidence). However, no response was received from the regulators to this complaint made by alert citizens. This is being incorporated into this report, to point out that the AG's affirmation of a robust regulatory regime in India is misplaced.

GEAC NOT PERMITTED TO WORK THROUGH SUB-COMMITTEES & EXPERT COMMITTEES: Importantly, GEAC is not supposed to work through Sub-Committees and Expert Committees, as per the EPA 1989 Rules. Genetic Engineering Appraisal Committee (GEAC, earlier called Genetic Engineering *Approval* Committee but renamed as an Appraisal body after the Bt brinjal debate in 2009-2010 through a [Gazette Notification](#)) has been visualised by the Environment Protection Act's 1989 Rules as a broad-based inter-ministerial, multi-disciplinary team. Even a body like this has been found to be deficient with regard to many fields of expertise required to appraise applications pertaining to gene technologies, by the Supreme Court's Technical Expert Committee. While that is so, GEAC in reality does not work as a body that it has been conceptualised to be. In the case of GM mustard too, GEAC worked through a "Sub"-Committee in 2016, and an Expert Committee in 2022. It is these bodies to which the task had been out-sourced, which are supposed to have appraised GM mustard, and not GEAC itself. However, the [1989 Rules](#) do not permit GEAC to set up such sub-

committees (while they explicitly allow RCGM to work through such sub-groups if required). This route was adopted by GEAC in the case of Bt brinjal too, which ultimately ended up being placed under an indefinite moratorium.

CONCLUSION:

Union of India is making patently untrue submissions in the Supreme Court of India when it asserted the following: *“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.”*

This short report, which showcases with evidence several violations and regulatory infirmities in the appraisal and approval of GM mustard, clearly exposes the falsehoods of the Government of India.

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 have been seriously compromised in GM mustard approval. State Governments’ Constitutional authority over Agriculture has been bypassed and violated – States have not even been consulted, the way they were in the case of Bt brinjal. India, a signatory to the Cartagena Protocol on Biosafety, has also violated international commitments in the approval of GM mustard. Indian Government and regulators have clearly ignored and neglected the Supreme Court’s Technical Expert Committee’s science-based recommendation to ban HT crops in India, apart from banning transgenics in those crops for which we are the Centre of Origin and/or Diversity.