IN THE SUPREME COURT OF INDIA

CIVIL ORIGINAL JURISDICTION

I.A. NO. _____OF 2016

IN

WRIT PETITION (CIVIL) NO. 260 OF 2005

IN THE MATTER OF:-

Aruna Rodrigues & Ors.

...Petitioners

Versus

Union of India & Ors. \ ...Respondents

APPLICATION FOR DIRECTIONS ON BEHALF OF THE PETITIONERS

To, The Hon'ble Chief Justice and his companion Judges of the Supreme Court of India: -

The Humble Application of the petitioners above-named **MOST RESPECTFULLY SHEWETH**:-

- 1. That abovementioned Writ Petition has been filed by Petitioners seeking a moratorium on the release of any genetically modified organisms (GMOs) into the environment pending a comprehensive, transparent and rigorous biosafety protocol in the public domain conducted by agencies of independent expert bodies, the results of which are made public.
- 2. This Application is being filed by Petitioners in the specific matter of the agronomic field testing of HT GM Mustard called DMH 11, and its 2 parental line HT GMOs, which are now awaiting commercial approval; and in the aftermath of a long series of Affidavits in 2013 to 2015 and like them, in the aftermath of the TEC Report (2012), and is in the nature of 'concluding' evidence to this Hon'ble Court. Collectively, the evidence

provides added clarity and validates the 5-Member unanimous TEC reports and the science that underpins those Reports. Petitioners reiterate that 3 other OFFICIAL G of I reports also support the unanimous findings of the TEC 5-Member Committee in terms of the abysmal state of GMO regulatory oversight, and the need for the Precautionary Principle (PP) to be applied without delay. Of these 4 Reports, the TEC alone had the specific mandate of this Hon'ble Court to examine the critical issue of RISK ASSESSMENT PROTOCOLS AND THEIR SEQUENCING FOR OPEN FIELD TRIALS. The relevance of this report now and the need for the implementation of its recommendations has become super critical to overturn a slew of illegal regulatory decisions to bring HT hybrid Mustard DMH 11 and its two HT parental lines, to the point of imminent commercialisation (scheduled for early Oct). India faces a 3 in 1 regulatory jugglery in a brazen display of collusion to fraud the Nation, by our regulatory institutions of governance across three Ministries (MoEF, MoA & S&T) and the Developers, the Centre for Genetic Manipulation of Crop Plants (CGMCP) of Delhi University South Campus (DUSC), that are without precedence. These Ministries are also proven and open promoters of GM crop technology and may not be tasked any longer with the regulation of hazardous GMOs.

In the absence of the implementation of the recommendations of this vital 5-member unanimous TEC Report of 2012, we are having to contend with an on-going and accelerating down-sizing of precautionary regulation and rigorous and sceptical oversight of GMOs, even unremitting and clear fraud. This steep descent from 2002, when Bt cotton was commercialised, to the commercial approval of Bt brinjal in October 2009, negated by the sanity of erstwhile Minister of the MoEF,

Shri Jairam Ramesh in February 2010 and onward to the anvil on which we now stand, of the commercial approval of 3 HT Mustard GMOs has been unbelievably rapid and un-nerving. We are in dire straits. This Application may be read in conjunction with the Contempt Petition and Petitioners' Additional Affidavit both of 2015. The Additional Affidavit of July 2015 exposes the serious cover-up, even fraud in global norms of risk assessment of GMOs, emanating from the USA, and which has had direct repercussions on India. HT DMH 11 is full evidence of this fact.

DMH 11: RECAP OF THE HISTORICAL EVIDENCE: (ref. Add. Aff of Sept 2015: Points 16-19).

In 2002 Proagro Seed Company (now Bayer), applied for commercial approval for exactly the same construct that Prof Pental and his team are now promoting as HT Mustard DMH 11. The reason today matches Bayer's claim then of 20% better yield increase (than conventional mustard). Bayer was turned down because the ICAR said that their field trials did not give evidence of superior yield. Yet 14 years later as this Application proves, invalid field trials and unremittingly fraudulent data, (the nation is asked to believe), now provide superior yield of 25%! HT DMH 11 is the same Bayer HT GMO construct ie an herbicide tolerant GMO of 3 alien genes. It employs like the Bayer construct, pollen sterilisation technology BARNASE, with the fertility restorer gene BARSTAR (B & B system) (modified from the original genes sourced from a soil bacterium), and the herbicidal bar gene in each GMO parental line, Bayer's Glufosinate, ('Liberty' and 'Basta'. Bayer has now merged with Monsanto). The employment of the B & B system is to facilitate the making of hybrids as mustard is largely a self-pollinating crop (but outcrosses at rates of up to 20%). THERE IS NO TRAIT FOR

YIELD. HT DMH 11 is straightforwardly an herbicide tolerant (HT) crop though this aspect has been consistently marginalised by the Developers over the last several years. HT crops represent 80% of GMOs worldwide (Monsanto's Roundup Glyphosate) and have not yet been introduced into India; but every attempt is being made to do so (Illegal HT RRFlex cotton has been allowed to flourish by the regulators for the last 10 years in several States). But the plan is that the OFFICIAL ROUTE FOR THE FIRST-TIME RELEASE OF AN HT CROP AND A FOOD CROP, WILL BE THROUGH HT DMH 11 AND/OR its TWO HT PARENTAL LINES by STEALTH. Since the claimed YIELD superiority of HT DMH 11 through the B & B system over Non-GMO varieties and hybrids is quite simply NOT TRUE, in fact a hoax as will be amply demonstrated, there is no purpose to this GMO HT mustard for India. But the opportunity to make an infinite number of HT mustard DMH hybrids all of them herbicide tolerant using India's best germ plasm as was done for Bt cotton is an irresistible money spinner for the Developers and chemical manufacturers (Bayer-Monsanto). India will be forced to accept a highly toxic and unsustainable technology (ref pt. 14) --- HT Canola in Canada (rape seed employing the B&B system, had by 2002 resulted in the emergence of TRIPLE herbicide tolerant weeds in just a couple of years (Petitioners' WP of 2005).

3.1 The TEC Report recommends that HT Crops as well as Crops in a Centre of Origin/Diversity should be barred: HT DMH 11 and its 2 HT GMO parental lines, which have suddenly emerged in the line-up for commercial approval, are straightforwardly pesticidal HT crops. HT crops are like sponges, absorbing significant quantities of herbicide into the plant. They also retain herbicide residues on the plant, in this case Glufosinate. HT Crops are empirically proven (in over 20 years of USDA

data) to have failed as a GMO technology and are unsustainable (pt. 14). India's agriculture is particularly unsuited to HT crops. Weeding operations provide significant employment for landless labourers in India where small-scale farming is predominant, unlike corporate farming in developed countries. For example COTTON (CROP) ALONE PROVIDES ABOUT 400 ΤO 500 MILLION MAN-DAYS OF EMPLOYMENT FOR MANUAL WEEDING PER SEASON IN INDIA, (CICR – Central Institute of Cotton Research) whereas in all developed countries, due to the absence of manual labour, weeding is done by aerial spraying with herbicides on HT crops in large farm holdings, each of which could be at least a few thousand hectares, such as those in USA, Canada, Brazil, Mexico and Australia. HT crops have become a necessary evil in these countries. The TEC recommends a bar on HT crops as well as on crops of 'origin'. INDIA IS THE CENTRE OF ORIGIN AND / DIVERSITY OF BOTH MUSTARD and BRINJAL. (Bt brinjal is under an indefinite moratorium in great part for this reason). All 3 Mustard HT GMOs are therefore, DOUBLY BARRED UNDER TEC RECOMMENDATIONS. Glufosinate is an analogue of glutamic acid and a neurotoxin. It has been clearly implicated in brain developmental abnormalities in animal studies and is very persistent in the environment, so it will certainly contaminate water supplies in addition to food where it will be absorbed. Also the chemicals in the formulation that will be sprayed are known to be toxic (Prof David Schubert). GLUFOSINATE IS DUE TO BE PROHIBITED ACROSS THE EU FROM 2017 although GM Maize 59122 has been designed to tolerate it. The empirical evidence proves that intended use of these herbicides on GM crops creates a vicious cycle of increasing weed resistance, even triple herbicide resistant weeds (they will eventually be resistant to all known

herbicides), and a significant scaling-up of indiscriminate herbicide-use. It is quite incomprehensible, even given their agenda to promote GMOs, as to why our regulators would move so completely against the national interest in a rank betrayal of India to push HT mustard DMH 11 and its parental line HT GMOs into commercial cultivation.

The history of HT Mustard DMH 11 in this Hon'ble Court dates 3.2 from 2006 when Petitioners prior in 2005, won an interim injunction on open field trials and Dr Pental requested 'exceptional' status to field-test HT mustard DMH 11 in SMALL-SCALE open field trials for noncommercial purposes (Point 18). This claim was challenged then and is now proven false as these same field trials are part of the record for regulatory approval of HT DMH 11. The Respondents and Prof Pental committed perjury. The permission came with a rider: Dr Pental would UPROOT THE TRIALS BEFORE THE "FLOWERING" STAGE (to avoid risk of contamination, which is the outstanding issue). Yet, 10 years later, India has been subjected to large-scale field trials of HT DMH 11 to produce seed for commercial planting, greatly increasing the risk of contamination. (Unfortunately, at the time this GM crop paled in comparison with the imminent approval of large-scale field trials of Bt brinjal. HT Mustard DMH 11 was sacrificed at the altar of the greater danger. Such are the exigencies in the WP. Now we face a repeat, but this time, an even greater potential catastrophe).

The current evidence focusses essentially on the agronomic evidence and the HT DMH construct, outside of bio-safety health and environmental issues, in the absence of any biosafety data in the public domain. However, the earlier Submissions dating back to 2006, provide scientific evidence and sufficient evidence to demonstrate that HT mustard DMH 11 is substantially untested.

4. CURRENT ON-GOING SITUATION

Two recent letters attest to the full cooperation being provided by the Regulators to the developers of HT DMH 11 to bring their 3 products on to the market through the virtual non-regulation of GMOs and the consequent mortgaging of the public interest.

4.1 Ruse by the GEAC re public-domain access of HT DMH11 data

Annexure M1: Prashant Bhushan Notice to Dr Amita Prasad, Chairperson GEAC with regard to 'Mustard DMH 11 and Contempt Petition against the GEAC in the Supreme Court'.

On 9 September 2016, Petitioners' advocate Prashant Bhushan sent a Legal Notice to the Chair of the GEAC (copy to Shri Anil Dave, MoEF), pointing out that the ploy in the 1st week of September 2016, of confining the DMH 11 dossier (presumably with its raw data) to the premises of the MoEF for serious comment by scientists was a ruse they had tried before in the case of Bt brinjal. It didn't work and this Hon'ble Court in a final reminder to the GEAC on 8 April 2008 directed the GEAC to publish the FULL DOSSIER with its RAW DATA on the Ministry's website. These orders of public domain access also covered a full range of GMOs including specifically HT DMH 11, which has a history in this Hon'ble Court. Therefore, the Contempt of Court with regard to HT mustard is <u>chronic</u>, a full 9 years old since the first Order of May 2007. It is now also <u>acute</u> and extends to the irreversible issue of contamination through large-scale BRL II field trials conducted in 2014-15, which were resorted

to with no regulatory oversight and outright fraud as the clear and incontrovertible evidence shows. Mr Bhushan said in his legal notice:

"Apparently, our regulatory bodies continue to repeat their historical mistakes of serious non-governance of GMOs and then take recourse to an underground process of regulation to hide their misdeed that is in violation of Constitutional rights of the people of this country. --- we have strong reason to believe that in the case of DMH 11 and its two parental line GMOs, these concerns take on an even more serious aspect. The strictures and location boundaries set by you to 'view' the data are quite inappropriate to any scientific study and analyses. The time period of 30 days is equally absurd.

The GEAC is therefore, required to immediately upload the <u>full dossier</u> <u>with its raw data on the Ministry website</u> with a <u>minimum timescale for</u> <u>feed-back of 120 days</u> to allow independent scientists nationally and internationally to respond – it would be good if the GEAC would show more respect for science and independent scientists who engage in this process".

4.2 No oversight by the GEAC as the push for commercialisation is cleared by an Expert Committee: Dr Pushpa M Bhargava, SC 'Invitee' to the GEAC to specifically observe their functioning, accuses the GEAC of abrogating its functioning entirely as the Apex Regulator:

"I do not understand why the AFES report as put up on the website, was not first shown to members of GEAC. This is the report of a subcommittee appointed by GEAC. Therefore, it was only appropriate that GEAC had the first right to see and comment on the report. It was very embarrassing for me to say as a nominee of Supreme Court on GEAC that I had not seen the report when I was asked by the media about the report just after it was put up on the website on 5th September 2016". Annexure M2: Dr Bhargava's letter to the GEAC 'Comments on the RARM (risk assessment & risk management) document on GE mustard'. Petitioner Comment: The above two issues underscore the quite bizarre regulatory failure and abrogation of duty in the oversight of HT Mustard DMH 11. The evidence in this Application fully supports these conclusions: there is evidence of 'sleight of hand' and 3 counts of serious fraud in the agronomic evaluation of HT DMH11, which has been 'accepted' by the regulators; they are now on record as saying that there are no biosafety impediments to the market release of HT DMH 11. We have statistical manipulation of a huge kind, and breath-taking regulatory collusion, (across 3 Ministries of GMO governance), with Dr Pental and his team at DUSC. The ensuing outcome can only be described, with considered deliberation, as 'the great regulatory delinguency'. Petitioners provide specific evidence of the these matters and the justification, scientific, rational and ethical, of why India must therefore, be provided urgent protection from unconscionable regulators and Ministries through an immediate injunction on any approval of the commercial release of any crop most specifically HT Mustard DMH 11, with its GMO parents HT Varuna-Barnase and HT EH2-Barstar, and along with a full moratorium on open field trials including Bt cotton among other Prayers.

MUSTARD DMH 11: THE GREAT REGULATORY DELINQUENCY

5. The further evidence with regard to the HT Mustard DMH 11 and its 2 HT Mustard GMO parents was uncovered as a result of the RTI filed by Petitioner No. 1 with the DRMR (Directorate of Rapeseed Mustard Research, India's apex body for mustard research) and exemplary work by members of civil society. The evidence amplifies that GMO regulation has moved far beyond polite descriptions of misdemeanour and oversight. The huge conflict of interest and specifically in the biosafety research and regulation of HT DMH 11 is at the heart of the rot that has set-in.

Overview and Conflict of Interest: The DBT (Min. of Science &Technology – M o S&T), is active partner and funder in this venture of HT DMH 11 (the NDDB has now pulled out of this partnership and funding of HT Mustard DHM 11). The DBT directly oversees the regulation of GMOs including HT mustard and houses the Regulators, the RCGM. It would appear that the Nation is facing the astounding notion that conflict of interest in GMO Regulators and relevant Ministries is not recognised as an unconscionable offence and ETHICAL BREECH of the PUBLIC TRUST. Dr Pental himself has been involved in the regulatory oversight of Bt brinjal. There is a real cosy relationship that obscures the line of separation that must be rigorously maintained between the Regulators and regulated if stringent norms of GMO risk assessment & biosafety are to be maintained for this hazardous technology. That line of separation has disappeared and in any case, cannot be maintained within a partnership of the Regulator, with the Developer which is therefore, invested in the 3 HT Mustard GMOs. There is now deliberate and collective malfeasance in regulatory governance by Regulators and 3 Institutions of GMO governance (MoEF, S&T and MoA), of mala fide intent to mislead the entire Country, typified by the stealth, deception and shortcutting of processes that have been allowed to bring the 3 HT Mustard GMOs to the point of imminent commercial approval. In the light of the facts that have emerged, it is abundantly clear that this could not have taken place without a conniving, secretive, and subterranean process of regulation that has

been illegally deployed to approve the 3 HT mustard GMOs for commercial release. We have full-blown serious fraud at each stage of their agronomic testing that beggars the imagination, (leaving aside other bio-safety issues that remain undisclosed).

DR PENTAL CLAIMS THAT HT DMH 11 <u>OUTPERFORMS INDIA'S</u> <u>BEST NON-GMO HYBRIDS AND VARIETIES BY 25-30%, GIVING</u> A MEAN SEED YIELD FOR DMH 11 OF <u>2824 KG/Ha.</u> THIS FIGURE HAS BEEN ACTIVELY MANIPULATED. IT IS CALLED FUDGING OR PLAIN CHEATING. THERE IS IN FACT NO STATISTICALLY VALID FIGURE BECAUSE THE FIELD TRIALS COMPREHENSIVELY FLOUTED SENSIBLE, ESTABLISHED AICRP-RM NORMS, WHICH MAKE THEM PLAINLY INVALID. However, if the field trial data is taken at face value then these are the figures of MSY/Ha (Mean seed Yield/hectare):

 MSY of HT DMH 11: BRL I & II field trials (2010 onwards): 2626 kg/Ha

• MSY of DMH 11: 2006-7 PLUS BRL I & II field trials: 2028 kg/Ha

Petitioners provide the evidence that exposes the ploys and manoeuvers that have been employed by the regulator and regulated to justify the claim of superior yield of 25-30% against India's best performing Non-GMO cultivars. The 3 HT Mustard GMOs must therefore, also be investigated in a comprehensive Lodha-type Commission of Enquiry that includes Bt cotton and Bt brinjal, (please refer to Petitioners concurrent Application of the admitted failure of Bt cotton by the Central Government).

6. SLEIGHT OF HAND: EMPLOYING TWO 'AVATARS' OF DMH 11 (evidence at Point 10)

The Regulatory bar in India has been lowered for easier compliance to an 'event'-based system of regulation that many leading scientists disagree with because it circumvents potentially serious biosafety issues (Prof Dave Schubert amongst others). Thus, CGMCP/DUSC is able to legally designate HT DMH 11 as one Event through back-crossing (traditional breeding techniques), as opposed to having to create a new Event through genetic insertions into the DNA of the plant).

Mother Gene: In the Barnase-Barstar system, there are two GMO parental lines. CGMCP/DUSC swapped the genes in the parental lines (through back-crossing) in the 2 separate phases of open field testing (in 2006-7 and the later BRL field trials which started in 2010), CHANGING THE MATERNAL INHERITANCE of HT Mustard DMH 11. Maternal inheritance is strongly determined in hybrids, as opposed to open pollinated crop varieties. From a biosafety perspective, there should be full biosafety testing of both maternal lines of DMH 11 and for full transparency, they should be designated by different names, say DMH 10 and DMH 11.

There are almost always some effects on the function of transgenes due to the genetic background e.g., which parent mustard lines are male and female, used to produce these mustard hybrids. This is because the female parent supplies so-called cytoplasmic genes to the hybrid seed (found in mitochondria and chloroplasts), while the male fertile parent variety does not. These cytoplasmic genes can differ in different crop varieties (e.g. Varuna vs. EH II, which are the Non-GMO parental lines of DMH 11), and those differences may have <u>practical</u> <u>consequences for agronomy, and therefore the well-being of farmers,</u> <u>and for risk.</u> As with all genes, the transgenes may also interact with the different CYTOPLASMIC GENES in different ways, which also may have agronomic and risk implications. The nature of hybrids--in that one variety is entirely male fertile and one entirely male sterile--is different than in breeding most non-hybrid crops, so this is a particular concern for the production of hybrids (Gurian-Sherman). Naturally bred crop varieties go through field trials to see how they perform. This is evident from the extensive trials for mustard varieties and CMS hybrids (Cytoplasm Male Sterile CMS-based hybrids) conducted under the AICRP-RM over several years. It would be entirely irresponsible to release crop varieties to farmers whose livelihoods depend on them without extensive testing to make sure they perform well, ie are stable and consistent performers in the field. This conspicuously was not done for HT DMH 11, which as a GMO requires more stringent norms not less.

The importance of cytoplasmic genes can be illustrated with an example from the United States. Petitioners point to the well attested historical occurrence in 1970 of the Southern Corn Leaf Blight. About 85% of US corn fields was planted with one type of corn, called Texas cytoplasmic male sterile (T-CMS) corn. Unfortunately, this type of corn was highly susceptible to a new type (race) of the pathogenic fungus *B. maydis.* It resulted in about a billion dollars in economic damage and harm to farmers, and huge losses of the corn crop. The losses of corn were catastrophic, reaching as high as 50-100% in some areas of the US. <u>The actual food energy losses were considered to be greater than those caused by the potato late blight epidemic of the 1840's.</u> (Heinemann J, et al 2014)

In India, in an example, a CMS cotton hybrid called PKV Hybrid-3 was more susceptible to aphids as compared to the conventional PKV Hybrid-2 and thus had to be phased out. CMS is a Non-GMO system of making hybrids. Furthermore, in addition to the 'sleight of hand' of HT DMH 11 Petitioners show 3 clear cases of serious fraud and regulatory collusion in that fraud, in the field trials conducted for HT mustard DMH11. Independent and supervised field trials in rigorous compliance with norms and protocols of the AICRP-RM were/is absolutely critical to their proper agronomic evaluation and the critical judgment that was required to conclude if HT DMH 11 is indeed a significantly superior/advanced hybrid technology providing superior yield based on the B & B system.

3 COUNTS OF SERIOUS FRAUD AND REGULATORY COLLUSION IN FIELD TRIALS

7. COUNT 1: FRAUD IN FLOUTING ESTABLISHED AICRP-RM NORMS & PROTOCOLS FOR FIELD TESTING DMH 11 (Evidence at point 11)

The established norms of the All India Co-ordinated Research Protocols of Rape-Mustard (AICRP-RM) were comprehensively flouted in field trials to test seed yield. In the absence of adequate and proper agronomic testing and sufficiency of data, no meaningful and statistically valid conclusions could be drawn. Yet, they were drawn by both the <u>Regulators and Developers (CGMCP/DUSC)</u> that furthermore, selfconducted and supervised the trials. Shockingly, without valid data to justify it, HT DMH 11 was allowed in pre-commercial BRL II (large scale) field trials in 2014-15. The depth of the wrong-doing is only now fully apparent and therefore, the corresponding seriousness of the Contempt of Court (see Petitioners Contempt Application of 2015), because of the undoubted risk of contamination. HT DMH 11 is now being considered for commercial release along with its 2 parent HT GMOs.

8. COUNT 2: FRAUD IN THE USE OF THE WRONG 'COMPARATORS' FOR HT DMH 11 IN FIELD TRIALS (Evidence at point 15.2 pg. 31)

For an adequate basis for a comparative assessment, IT WAS NECESSARY FOR THE COMPARISON TO INCLUDE THE CROSS (HYBRID) BETWEEN THE NON-MODIFIED PARENTAL LINES (NEAREST ISOGENIC LINE), AT THE VERY START OF THE RISK ASSESSMENT and throughout the subsequent stages of field testing, in ADDITION TO OTHER RECOMMENDED 'COMPARATORS'. This was not done.

Deliberately poor Non-GMO mustard varieties were chosen to promote prospects for HT DMH 11 as a superior yielding GMO hybrid, which then passed through 'the system' and was ALLOWED by the regulators, a classic non-sequitur by both the Regulators and Dr Pental. Furthermore, Hybrid must also be tested against hybrid. In all cases the best varieties and hybrids tested under AICRP-RM should have been used. No hybrid 'Comparators' were used for HT DMH 11 in the 2nd phase of testing (starting 2010). In fact, it can be said that in effect no relevant 'Comparators' were used. The two that were used were either irrelevant/discontinued and were poorer-yield varietal Checks. Specifically, the 'Comparator/s' for HT DMH 11 must include the CMS HYBRID DMH 1 and CMS HYBRID NRCHB - 506 (as also recommended by the GEAC) and/ CMS 'Coral'. These 3 selections are Non-GMO (CMS) HYBRID CHECKS. The HT DMH 11 Barnase-Barstar (B&B) system provides 'male-sterile' technology and is being claimed as the greatly superior technology to make hybrids, AND THIS IS ITS

ONLY PURPOSE, THERE ARE NO TRAITS FOR YIELD. The proper comparison therefore, of HT DMH-11 with its non-modified crossed parental lines (nearest isogenic lines), CMS-based hybrids and varietal checks (as 'Comparators') for seed-production economics and yield was CRITICAL. This is the essential starting point to provide answers to the following specifically relevant questions:

Q 1: IS THE GM BARNASE-BARSTAR SYSTEM FOR MAKING HYBRIDS SUPERIOR TO -

(a) ITS NON-GMO PARENTAL LINES (HYBRID) (nearest isogenic line)

(b) THE NON-GMO CMS-BASED/OTHER HYBRIDSIN TERMS OF ECONOMICS OF SEED PRODUCTION AND YIELD?Q 2: DOES HT DMH 11 ALSO CONSISTENTLY OUT-YIELD THE

BEST VARIETAL CHECKS UNDER THE AICRP-RM?

Q 3: IS THERE EVIDENCE FROM AGRI-ECOLOGY OF SUPERIOR YIELDS to HT DMH 11

The fact is that every GMO must prove in the FIRST INSTANCE THAT IT IS NEEDED, satisfying all the relevant criteria of yield/trait superiority, before being allowed to proceed to an evaluation of the GMO in a comprehensive and rigorous risk assessment protocol conducted by independent experts (TEC Report). It was vital that this aspect of the testing of HT DMH 11 was stringently addressed to demonstrate without doubt that it consistently bettered every one of the 3 conditions above. As the evidence shows, it comprehensively failed all 3 conditions. There was no entry at all in any of the field tests, of the non-modified conventionally crossed parental lines, as 'comparator'

9. COUNT 3: FRAUD IN ACTIVELY FUDGING YIELD DATA OF HT DMH 11 BY 15.2% TO SHOW HIGHER MSY (Evidence at point 15.2 iii Tbl G)

The DRMR submitted MSY (mean seed yield) data of HT DMH 11 to the regulators (2626 kg/Ha). The figures which pertain to 2nd year BRL I field trials conducted in 2011-12 of HT DMH 11 along with the other entries were changed upwards by 15.2% by CGMCP/DUSC in its own submission to the Regulators in order to raise the declared yield of HT DMH 11 by an <u>overall 7.5% to 2824 kg/Hc</u> to justify its request for commercial approval.

10. EVENT HT DMH 11: SLEIGHT OF HAND: EVIDENCE OF 2 DIFFERENT MOTHER GENES IN FIELD TRIALS (ref pt. 6 above)

Annexure M3: DBT Letter to Prof D Pental No. BT/BS/17/30/97 –PID of 30-10-2006: 'Application submitted for permission to carry out multi-location trials of ---- DMH 11 ---' with 2 Annexures.

Annexure M4: 'Conclusions and justification for BRL II trials': Source ----"Safety Studies and Field Trials conducted on Transgenic *Brassica juncea* containing *bar, barnase,* and *barstar* Genes" submitted to RCGM by CGMCP, University of Delhi South campus, New Delhi on April 2, 2014.

HT DMH 11 was field tested in two phases: (i) in 2006-7 in multilocation trials (small scale, under 'exceptional status' granted by this Hon'ble Court in 2006) and (ii) subsequently, under the new regulations of BRL I in 2010-11, 2011-12 and BRL II in 2014-15.

The evidence:

10.1 2006-7 Multi-location trials: The letter from the DBT (Annexure M3, at (a) i) specifically mentions that the OBJECTIVE of the multi-location trials in 2006 is "to test the yield performance and stability of transgenic mustard hybrid DMH 11 BASED ON EH2 *BARNASE /* VARUNA *BARSTAR TRANGENICS* IN <u>A</u> LIMITED OPEN FIELD TRIAL" -- just 1 Field Trial (emphasis in Capitals by Petitioners). EH2 and Varuna are the (non-GMO) parental lines of HT DMH 11.

10.2 2010-11 and after, in BRL I & II trials: (Annexure M4): In this 2nd phase of testing, the Event HT DMH 11 changed its 'avatar'! HT DMH 11 now has a different maternal gene in a parental swap; Varuna is now the mother line instead of EH 2. (Annexure M4, 1st line below table). It says: *"as may be seen from the extensive data generated on the two events* <u>Varuna bn (barnase) and EH-2 modbs (barstar), and the hybrid DMH 11"</u>

The document is remarkable for two 'confessions': (a) this document seeks permission to conduct BRL II (large-scale field trials) <u>based</u> on a history of agronomic testing that goes back to 2004 -2007 when the maternal inheritance of DMH 11 was different (ref 10.1 above), but then encompasses the results of BRL I & II trials conducted from 2010 onwards with a different 'mother' gene in HT DMH 11 as part of that history; (b) Therefore, the entire history of trials and environmental studies (from at least 2002) is claimed to have been conducted for the same HT Mustard DMH 11 and permission for BRL II trials justified on this basis. Biologically, (Pt 6, changed maternal inheritance), DMH should have been identified under different names, say HT DMH 10 and HT DMH 11 and subjected to independent testing in a full protocol of studies and field trials for biosafety.

The gross insufficiency of field testing of HT DMH 11 is sort to be smothered in this garbled history of inclusions and exclusions. However, and the point is vitally important to demonstrate the extent of the statistical jugglery that has been resorted to, this Hon'ble Court's attention is invited to the fact that the statistics of MSY of the 2006-7 field trials are entirely left out in the reckoning of HT DMH 11 because these results drastically reduce the overall MSY of HT DMH 11. Petitioners repeat the data provided earlier:

MSY of DMH 11: BRL I & II field trials (2010 onwards): 2626 kg/Ha

• MSY of DMH 11: 2006-7 PLUS BRL I & II field trials: 2028 kg/Ha

HT DMH 11 along with its' HT parental lines are serious regulatory 'sleight-of-hand' that is permissible under diluted rules of an Event-based system, and new BRL field testing rules. The Event-based system defines these 3 GMOs as a single Event, takes advantage of the lacunae and ignores important bio-safety issues arising from them. DMH-11 hybrid seeds contain at least two independently developed GM events (bn 3.6 and modbs 2.9). DMH-11 hybrid seeds are developed by crossing the HT parents Varuna bn 3.6 & EH2 modbs 2.99, which are grown in open fields for hybrid SEED PRODUCTION. THE GM HT PLANTS ARE IDENTIFIED IN OPEN FIELDS AND USED FOR CROSSING ESSENTIALLY AFTER SPRAYING THE HERBICIDE GLUFOSINATE (Bayer's Basta) AND SELECTING THE GM PLANTS THAT SURVIVE THE HERBICIDE. THUS THE TWO HT PARENTS AND THE HYBRID DMH-11 REQUIRE FULL INDEPENDENT TESTING OF THE TWO PARENTS as EVENTS AND ALSO AFTER STACKING TOGETHER IN THE FORM OF A HYBRID/HYBRIDS.

10.3 Was the GEAC aware that the maternal inheritance genes had been swapped in the parental lines during the 2 phases of field trials? The point of course is that the GEAC has continued to act as a mere rubber-stamping authority for the RCGM/DBT, without independent application of mind or the necessary expertise in GMO oversight. This Hon'ble Court granted Petitioners an interim injunction on field trials in September 2005 for this very reason. This time the GEAC has gone further and not even looked at the Expert Committee report (please see Annexure M2).

10.4 HT DMH 11: No prior testing with a different 'Mother' gene before BRL I Trials: It is abundantly clear from Annexure M4, (please see the Developers' consolidated table of studies), that HT DMH 11 with a different maternal inheritance, field tested in BRL I trials in 2010-11 and 2011-12 had no prior testing in confined conditions or studies in biosafety, before being cleared for these open field trials of just 2 years. HT DMH 11 was catapulted straight into BRL field trials. The revised regulatory norms of BRL trials have demonstrated their utter inadequacy as a field testing norm in the case of HT DMH 11 and therefore, for all GMOs. And the biological and bio-safety implications of a different maternal inheritance must be given priority over drastically diluted biosafety protocols.

	YEAR	EVENT	MATERNAL INHERITANCE / TYPE OF TRIALS		
DMH	Up to	<u>EH2 BARNASE x</u>	MATERNAL LINE		
(10)?	2006-7	VARUNA <u>BARSTAR</u>	Multi-location:- 1 TRIAL		
			in 10 locations		
		<u>VARUNA BARNASE x</u>	MATERNAL LINE		
		EH 2 <u>BARSTAR</u>			
DMH	2010-11	(in all 3 years)	BRL 1 (first year)		
11	2011-12		BRL I (second year)		
	2014-15		BRL II (pre-commercial)		

TABLE A: Mustard DMH 11 in Two Avatars (Ref: 10.1 & 10.2 above)

Source: DBT (Annexures M3 & M4)

11. AICRP-RM NORMS FOR FIELD TRIALS: HT DMH 11 FLOUTS ESTABLISHED PROTOCOLS OF FIELD TESTING (ref point 7)

Annexure M5: DRMR 'Reply' to RTI (filed by Petitioner No 1, Aruna Rodrigues) dated 19 August 2016.

The AICRP-RM (All India Co-ordinated Research Protocols for Rape-Mustard), is used for testing mustard varieties and hybrids. After an initial two years evaluation in 'station trials, promising entries are evaluated in AICRP-RM: One year in Initial Varietal/Hybrid trials (IVT / IHT); 1 year in Advance Varietal/Hybrid Trials 1 (AVT/AHT -1); and 1 year in Advance Varietal/hybrid Trials 2 (AVT-2), a total of 3 years after 'station trials'. For each year of trials there must be a <u>minimum of three locations per zone</u> (per year) or a minimum of nine locations over 3 years for each entry. The main norms (ref. pg. 2 of 'Reply') are:

- **IVT /IHT:** (Initial Varietal/Hybrid Trials): 1 year 3 locations per zone): "based on one year yield and ancillary data in station trials, the entry in the IVTIHT of the AICRP-RM coordinated breeding trials is compared with National checks, Zonal checks and latest releases zone wise/ situation wise". Any entry which "registers an advantage of MORE THAN 10% seed yield/oil yield over the BEST CHECK", is promoted to the next stage of AVT/AHT-1 trials.
- **AVT/AHT -1**: (Advanced Varietal/Hybrid Trials): 1 year, 3 locations per zone): The same criteria is followed as in IVT/IHT for qualifying for the next stage of AVT/AHT-2 trials.
- **AVT/AHT -2:** At the end of AVT/AHT -2 trials or after 3 years of evaluation, an 'identification proposal' is submitted to the *Varietal/hybrid Identification Committee*, where the entry is identified for release. The structure of the Committee is comprehensive.
- **The experimental mean seed yield** (MSY) should be equal to or greater than the State Mean for seed yield.

In practice, the frequency and number of years to which Zonal and National checks of hybrids/ varieties are subjected to for yield consistency, stability/reliability far exceeds these minimum norms in the interest of getting the best possible and reliable varieties/hybrids to farmers' fields. This involves much more than mere statistics of yield, but a 'clinical' approach to scrutinising performance and yield. Aberrations high or low and 'insignificant' data are discarded. A variety/hybrid categorised as a Zonal/National Check is based on deliberations/ decisions taken in the "Annual Group Meeting of Rapeseed-Mustard Research".

HT mustard DMH 11 therefore, should have been subjected to norms that exceeded the protocols of the AICRP-RM for NON-GMO mustard trials.

11.1 HT DMH 11 --- the norms that were followed instead: None of the above prescribed norms including evaluation were followed by the developers and promoters of mustard DMH 11. In its 'Reply' (ref. Annexure M5) the DRMR responded: *"The evaluation of DMH 11 was done separately as per guidelines of GEAC, which differs with AICRP policy" --- and "as per the protocol provided by GEAC through DUSC".*

- Locations & frequency: Critically, the number of FT, representative number of locations, repeats and frequency (years of testing) of field trials were woefully deficient in both phases. Thus, even bare, leave alone robust, scientifically valid conclusions and analyses are not possible.
- **Conflict of Interest**: Independent testing and assessment of HT DMH 11 and its parent GMOs were absent. The serious conflict of interest in these 3 GMOs involving the GEAC/DBT/ICAR as its partners, promoters and regulators, means that no confidence or reliance may be placed in the results of the field trials of HT DMH 11. The "DRMR has not conducted any GMO trial and the data received by DU/NDDB staff was passed to DRMR for onward transmission to <u>DUSC/GEAC</u>. Hence, no raw data from each location --- is available with DRMR" (refer pg. 3 of 'Reply').

12. DMH 11: 2006-7 A SINGLE FIELD TRIAL IN 10 LOCATIONS: VALIDITY AND ANALYSES OF NORMS AND 'COMPARATORS' (ref point 8)

This <u>single field trial</u> (Annexure M5, table 3) runs afoul of norms of frequency and repeats. Not much can be deduced from a SINGLE field trial (even in 10 locations), least of all a test as a test of *'stability'*, which was the DBT mandate to the Developers. Nevertheless, for the sake argument, the data is analysed at face value especially because these field trials were the justification presumably, for BRL I & II trials (three years), beginning in 2010-11. In Zone IV there is just one location which invalidates it. Trial data for Bharatpur and Hisar are below the State Mean Average for the year and disqualifies them (Annexure M5, Table 4). The number of valid locations accordingly therefore, number 7(not 10) as below:

TABLE B: DMH 11: 2006-7 Single FT in 7 Locations with 'Comparators'

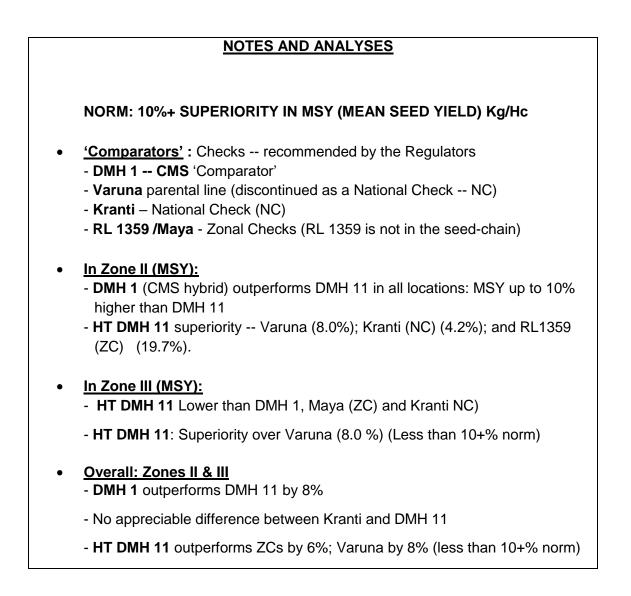
MSY in Kg/Ha

Zone II								
Location	Zonal Check							
Sriganganag ar	1527	1501	1606	1370	1344			
Delhi	1395	1884	1503	1748	1313			
Navgaon (Alwar) 1111		1434	1097	1264	1002			
Mean Yield (kg/ha)	1344	1606	1402	1461	1220			
	Zone III							
Kanpur	1168	1110	1380	1319	1577			
Pantnagar	952	1666	1232	1311	1208			
Kota	2466	2488	2433	2325	2368			
Mean yield (kg/ha) Zone III	1529	1755	1682	1652	1718			
Mean yield (kg/ha): Zone II & III	1437	1681	1542	<u>1556</u>	1469			

(Maternal Inheritance of DMH 11 – <u>EH 2-Barnase</u>)

Source: RTI 'Reply' (Annexure M 5 Tables 5 - 7).

NOTE: No appreciable change in the MSY of 7 locations against 10 locations (1550 kg/Hc).



12.1 Conclusion: HT DMH 11 fails yield comparisons with 'Comparators' in 2006-7 trials: The disquieting evidence above clearly demonstrates that based on the MSY results of the multi-location field trials in 2006-7, DMH 11 should have been barred from progressing to the subsequent BRL field-testing. Its overall performance was decidedly poor. It failed and failed convincingly to show superior yields against the Non-GMO 'Comparators' and CMS Hybrid DMH 1 that were part of these field trials. The prior question in the risk assessment of GMOs is:

IS THE GMO REQUIRED IN THE FIRST PLACE? THE CLEAR ANSWER FROM THE TRIALS IN 2006-7 FOR DMH 11 WAS "NO".

However, it went on to be admitted to BRL I & II field trials in 2010-11 onwards. Furthermore, the National Check Kranti and the CMS hybrid

DMH1 were dropped by CGMCP/DUSC in these later trials (BRL) as required 'Comparators' (required by the regulators and by the AICRP-RM as well). This requires serious investigation.

PETITIONERS REITERATE: THE CHOICE OF CORRECT COMPATATORS IS AT THE HEART OF GMO AGRONOMIC EVALUATION AND LIKEWISE, AT THE HEART OF THE FRAUD.

13. AICRP-RM FIELD TESTING NORMS: PROPER FIELD TESTING IS NECESSARY TO GET STABLE & RELIABLE CULTIVARS TO FARMERS (ref pt.7)

The data below attests to long years of testing in multiple and repeat locations to supply reliable high performing mustard varieties and hybrids to farmers' fields. They are also tested under different conditions including rain-fed conditions and agri systems eg. 'System of Mustard Intensification'. National Checks like Kranti have undergone as many as 11 years of field testing in different zones in over 60-75 locations including 'repeats' in order to provide farmers the best possible opportunity for agronomic success in the field (Annexure M5, tables 14 &15). It is in this light that the HT mustard DMH 11 trials must be judged. This is a GMO. It must be subject to even more stringent protocols (than Non-GMO cultivars), for agronomic field testing in SEQUENTIAL PROTOCOLS of risk assessment as recommended by this Hon'ble Court's TEC, which was mandated to answer this specific question.

As the evidence in this Submission proves, not only has this standard manifestly not been met, HT DMH 11 remains supremely <u>untested</u> in field trials, both in the first phase of the SINGLE trial in 2006-7, which it

failed and should have been abandoned, as well as the subsequent phase of BRL trials I & II starting in 2010-11.

The latest 4-5 year AICRP –RM statistics of the performance (MSY) of the best cultivars over several years and locations is given in Table C below. This is an important analyses with a direct bearing on the great genetic fraud of HT DMH 11 being perpetrated on our farmers and our Nation. This data in Table C contrasts sharply with how DMH 11 trials were conducted under BRL I & II in in 2010 onwards (Table D page 27).

TABLE C: CULTIVARS: TESTING FOR STABILITY & PERFORMANCE:

Zone-II							
		Seed Yield (Kg/ha)	Locations	Year of Evaluation	No. of Years		
New	RH 749	2561	34	2009-10 to 2014-15	5		
Released							
Variety	DRMRIJ 31	2481	28	2010-11 to 2014-15	4		
Hybrid (CMS)	CORAL 437	2542	20	2006-07 to 2010-11	4		
Latest							
Release	NRCDR 2	2382	27	2009-10 to 2012-13	4		
Hybrid check	NRCHB 506	2386	26	2010-11 to 2014-15	5		
(CMS)	DMH 1	2586	52	2009-10 to 2014-15	5		
National							
check	KRANTI	2374	33	2010-11 to 2014-15	5		
Zonal check	RL 1359	2420	33	2010-11 to 2014-15	5		
		Z	one-III				
Latest							
Release	RGN 73	1959	25	2010-11 to 2014-15	5		
National							
check	Kranti	1842	25	2010-11 to 2014-15	5		
Zonal check	Maya	1840	26	2010-11 to 2014-15	5		
Hybrid	NRCHB 506	2168	27	2010-11 to 2014-15	5		
checks (CMS)							
	DMH 1	2098	27	2010-11 to 2014-15	5		

NEW VARIETIES, HYBRIDS, LATEST RELEASES, NATIONAL CHECKS, ZONAL CHECKS IN ZONE II AND ZONE III

Source: Annexure M5 Table 16: ACRIP-RM = All India Coordinated Research Impr Programme of Rape-Mustard

In Bold: Recommended DRMR Checks as 'Comparators' for DMH 11

NOTE: In Zone II (which has within it, significant mustard-growing locations), the MSY of all Releases is around 2465 kg/Ha

DMH 11: BRL FIELD TRIALS AN UNREMITTING FRAUD ON ALL 3 COUNTS (ref. (previous) pts 8-10)

14. BRL Field Trials: 2010-11; 2011-12 (BRL I) & 2014-15 (BRL II)

14.1 The Maternal inheritance of HT DMH 11 in these trials is the female line HT Varuna-Barnase. It is emphasised that the change in the Mother line (from the trials of 2006-7, HT EH2-Barnase) should have triggered comprehensive biosafety studies. There is no record of any trials (confined to greenhouses) or safety assessment preceding these BRL trials. We are suddenly confronted with 3 GMOs, DMH 11 + its 2 parental lines HT GMOs being field tested in both BRL I and II and which are now, furthermore being considered for commercial release. We face a potentially serious bio-security and biosafety risk for India, across several disciplines, (including contamination, impact on bees, which are the main pollinators of this crop), which have not been investigated. This is India's first food crop. The situation is dire.

14.2 Comparison between testing norms of AICRP-RM (Table C pg.
26) and DMH11 (Table D pg. 27): Table D below shows the deviation from AICRP-RM norms of the DMH 11 BRL I & II trials in terms of years of testing and no of locations.

Table D: Hybrid DMH 11: BRL: Trial years & locations: (Ref

Annexure M5, Table 1)

Name of the trial	Year	Zone-II		Zone-III	
		Location Number		Location	No.
BRL-I (1st Year)	2010-11	Alwar Sriganganagar**	2	Kumher*	1
BRL-I (2 nd Year)	2011-12	Alwar	1	Kumher*	1
BRL-II	2014-15	Delhi/Bhatinda/Ludhiana	3	-	
Number of locations	In 3 years		6		2

NOTE: (source RTI Reply)

*Kumher: Not used as a trial location under AICRP-R&M trials since a Scientist of Plant Breeding is unavailable

**Sriganganagar: the trial was not done under the supervision of a Breeder.

Analyses

BRL Trials invalid: It is difficult to know just how these trials are to be dealt with; the flouting of AICRP norms is so extreme. The statistical method fundamentally requires statistical significance to validate data. With regard to seeds in particular, reliable results are demanded to provide stable seeds to protect our farmers (DBT mandate to the DUSC – Annexure M3). The official protocols of the AICRP-RM are exhaustive for this reason, many years, (as many as 11 for Kranti NC), many locations (20 at the lower end and near 70 at the higher end), in agreed methods of the AICRP-RM in order to get proper cultivars to famers. These field trials appear to be a rather bad joke. Inadequacy is a gross understatement. The sheer paucity of locations and time-testing makes these trials invalid. As a statistical measure of reliable and stable yields these trials are a fiction. As a measure of independent scientific supervision and analyses they are a similar fiction (the large swings in DMH 11 yields from 2006-7 by over 65 % and other abberations invited a

telling comment in the RTI 'Reply' that these trials need to be scrutinised beyond just MSY data (ref.see Table E). For example:

- Khumer and Sriganganagar: the trials in these two locations are on a shaky foundation in the absence of the expert supervision of a Breeder. Yet, in both these locations, reported yields of DMH 11 are the highest of all entries and it is similarly the case for Khumer in both years of BRL I trials. (ref Annexure M5 Table 8). One doubt like this is sufficient to throw the results, lock, stock and barrel in what are already invalid trials that have breeched every scientific norm.
- BRL I trials in <u>both years</u> in Zone II have been conducted in a total of only 3 locations and with a single repeat, in Alwar
- **BRL I in <u>both years</u>**, **Zone III is a complete wash-out** with just 1 trial in each of the 2 years of BRL I trials.
- **BRL I 2nd year trials (2011-12):** in both Zones II and III there is just 1 location in each Zone.

• BRL I trial results of a mere 2 years for HT DMH 11 and its 2 HT parental lines get regulatory clearance to advance to BRL II: (ref Annexure M4). Despite such serious anomalies the Regulators accepted the results of BRL I trials and allowed CGMCP/DUSC to advance the 3 HT GMOs to the next stage ie of precommercial planting for seed production (in 2014-15). This regulatory approval together with a vaccuum in risk assessment of these 3 HT mustard GMOs can hardly be believed for its unremitting fraud. It also exposes the sheer degree of contempt the Regulators have for the specific Order of this Hon'ble Court of "NO CONTAMINATION". The further data that follow for mean seed yield (MSY) and poor choice of Comparators for DMH 11 effectively means that all restraining boundaries of fraud/lies/cheating have been psychologically breeched. The Country is devoid of any checks. The anomalies of locations and zones of BRL II are:

- BRL II trials (2014-15) in Zone II were conducted in non-mustard areas of this leading Zone for mustard in India (Delhi, Bhatinda and Ludhiana are not significant mustard-growing areas); and just 1 zone. The objective of these trials was for the production of seed for commercial cultivation. But, the yield results of BRL II were added to the pot of experience, so to speak, to BRL I (two years). The choice and number of locations is completely inadequate All 3 years were provided as justification of the sufficiency and the reliability of HT DMH 11 to out-yield the best AICRP-RM varieites and hybrids, and to perform reliably in farmers' fields. Regulatory approval was requested for commercial release. The Expert Committee has stated there are no bio-safety reasons for rejection!.

In the true meaning of the term, these BRL I & II trials can only be described as one-off TRIAL RUNS for experimentation, (self supervised) not to be considered for evaluation at all. But they were! They require the greatest scrutiny.

Annexure M6: 'Request for Approval of Environmental release of transgenic HT Mustard lines Including HT hybrid DMH 11' by the Developers led by Prof Pental, pg 58 of BRL II Report.

15. BRL TRIALS: UNPRECEDENTED FRAUD IN CHOICE OF 'COMPARATORS' AND Mean Seed Yield (MSY) OF DMH 11 AND THE ENTRY OF 2 PARENTAL GMOS (ref Annexure M5 Table 18) Table E below is a consolidated 'summary' of RTI 'Reply' detailed data in Annexure M5 tables 8-10: all entries including the 3 HT GMOs, the Comparators and corresponding MSY.

SUMMARY

TABLE E: HT DMH 11 TRIALS: COMPARATORS, ENTRIES & CONSOLIDATED MSY

BRL I & II ZONE-WISE: 2010-11; 2011-12 & 2014-15 (ref Annexure M5: Table 18)

	BRL 1	BRL I	BRL I	BRL II	BRL I & II
ENTRY	2010-2012	2010-12	SUB-	2014-15	MSY
	2yrs	2yrs	TOTAL	A 11 77	0 11
	Z II MCN		MSY	All Zones	Overall
	<u>Zone II MSY</u>	Zone III MSY	Zone II & III	(Zone II)	TOTAL
			111		
Varuna (barnase)*	2133	2235	2174	1861	2057
EH-2 (barstar)	1960	1685	1850	1557	1740
Varuna	2194	2121	2165	1887	2061
EH-2	1835	1833	1834	1378	1663
DMH-11	2891	2589	2770	2385	2626 ^
RL-1359/Maya (ZC)	1963	2126	2028	1775	1933

*Maternal Inheritance HT Varuna-Barnase

Source: Summary: RTI Reply (Annexure M5, Table 18)

[^] DMH 11 MSY of 2626 kg/Ha for BRL I & II -- and taken at face value (DRMR statistic of MSY provided to the GEAC, Annexure M5 Table 18). This figure is 69% higher than the MSY for HT DMH 11 in the 2006-7 MLT (1550Kg/Ha). And these MLTs have not been reflected in the above MSY of 2626 kg.ha of DMH 11 in BRL trials) for this obvious reason that it significantly reduces the overall MSY to 2028 kg/Ha. (Prof Pental of DUSC claims a history of testing HT DMH 11 since at least 2002).

15.1 Analyses BRL Trials (Table E): Entries of 2 HT GMO Parental

Lines: The 'entries' were the same in all trials, BRL I (2 years) & BRL II. For the first time, 'Parental line' herbicide tolerant (HT) GMOs, Varunabarnase (the sterility gene in the switched maternal inheritance), and EH 2-barstar (fertility restorer gene) make an entry into these trials without a known previous history of biosafety testing. Their presence here was simply and directly to comply with whatever minimal regulatory formalities were required to gain regulatory approval for commercialisation in a heavily watered-down regulation for easy compliance. The Developers spelt out their objective in the last para of their Submission to the Regulators requesting permission for ccommercialisation (ref Annexure M6 page 58), thus: *"Use of the two events bn 3.6 and modbs 2.99 for introgressing the bar-barnase and bar- barstar genes <u>into new set of</u>* parental line to develop next generation of hybrids with higher yields, disease resistance and quality traits" - (emphasis Petitioners).

Aim - to introduce HT crops into Indian Agri: The claims of disease resistance and quality traits are a myth. This extraordinary admission confirms that the future plan for any number of HT (hybrid) DMH versions of mustard IS INVESTED IN THESE TWO GMOs. THESE WILL BE THE ROUTE TO DEVELOP HUNDREDS OF HT mustard HYBRIDS (as was done for failed Bt cotton with a present count above 1500 Bt hybrids), USING INDIA'S BEST MUSTARD CULTIVARS. IT IS EMPHASISED THAT ALL OF THESE WILL BE HT MUSTARD TRANSGENICS CAMOUFLAGED IN POOR-YIELDING HYBRIDS through the BARNASE- BARSTAR SYSTEM. Petitioners correctly charge on the evidence:

That it matters not if hybrid DMH 11 is commercialised or not. What is vital is the commercialisation of these two HT parental lines, which will allow the Developers in COLLUSION with the Regulators to 'trot out' hundreds of HT hybrid DMHs. This is the duplicity through which unsustainable HT technology will be introduced into India and through a food crop – Mustard. This is a mind-boggling, quite awful fraud perpetrated on our country, devoid of any science and any ethic. The 'cover' is the single 'underground' dossier of HT DMH 11 serving as a sort of 3-for-the-price-of-one sale-offer and regulatory gimmick. There is no scientific purpose to the inclusion of these HT parent lines in these field trials. They offer no heterosis for comparison. AS MENTIONED EARLIER, EVEN A SIMPLE COMPARISON BETWEEN THE GM DMH-AND VEH2F1 (CONVENTIONAL HYBRID DEVELOPED BY 11 VARUNA X EH2, NEAREST ISOGENIC LINE) HAS NOT BEEN DONE, TO PROVE EQUIVALENCE. Their purpose is clear as annunciated

above, and is akin to an undercover process of serious and dangerous deregulation of GM crops and the take-over our food and agriculture.

HT Crops are empirically proven to be a failed, unsustainable technology (quite apart from other safety issues --ref. Additional Affidavit 2015 pt. 14). HT crops (mainly based on Monsanto's glyphosate) have not provided increased yield. The most reliable peer-reviewed study estimates that from 1996-2011, about 527 MILLION POUNDS MORE TOTAL HERBICIDE was used in the US due to herbicide-resistant crops than would have been if the crops had not been commercialized. The emergence of super weeds include TRIPLE HERBICIDE RESISTANT WEEDS IN BOTH THE US AND IN CANADA (the latter though HT rape employing the same bar gene (glufosinate) and the B&B genes, Even the pro-Industry US NRC (National Research Council) has said they could find no evidence that GE had increased crop yields (HT SOY).

15.2 Analyses BRL Trials (Table E): Fraud in the Choice of 'Comparators' & MSY: These trials cumulatively, were the basis for the Developers request for commercial approval citing the yield superiority of HT DMH 11 over the best Indian cultivars, both varieties and hybrids. But hybrid must be compared with hybrid. Therefore the choice of 'Comparators' is super critical for DMH 11. And it is at the heart of the fraud of HT DMH 11.

15.2 (i) Deliberately poor choice of 'Comparators: For HT DMH 11 they are (a) Zonal Check **RL 1539** for Zone II (which has not been in the 'seed chain' since 2004-5), or **Maya** in Zone III (either one not both, in different zones) and (b) **Varuna,** which is both the Non-GMO parent of HT DMH 11, and 'has-been' National Check (dropped before the BRL trials). As the Non GMO parent, there is validity in the inclusion of Varuna, but NOT as a 'Comparator'. BUT, THE NON-MODIFIED

CROSSED PARENT LINES WERE A REQUIRED 'COMPARISON' WHICH WAS NOT DONE. Neither of the two 'Comparators' used for these BRL field trials are part of the list of recommended 'Comparators' by the DRMR. And both are varieties. There were no hybrid Checks. The National Check Kranti (variety) and CMS Hybrid DMH 1 were both dropped after the <u>single</u> MLT in 2006-7 where DMH 11 was a conspicuous failure and should have been discontinued in further testing. The big Q is why?

Table F below is a table of recommended 'Comparators' for DMH 11, ie the 'checks' used under the AICRP-RM. Not a single one of these was chosen for HT DMH11 BRL trials; and not a single hybrid, yet hybrid DMH 11 must be compared also with hybrid. The AICRP recommends 4 'Comparators' consisting of 2 varieties and 2 CMS-based hybrids (('cytoplasmic genetic male sterility'):

Hybrids (CMS): DMH 1 and NRCHB - 506

Varieties: (Zonal Check) RGN 73 and (National Check) Kranti

(as opposed to Maya/RL 1359)

The fraud is crystal clear. No valid 'Comparators' have been used in these trials. This is an abysmal choice of 'Comparators' calculated to make DMH 11 'look good'. They also flout the regulators recommendations (made at the time of the MLT of 2006-7). There can be no doubt that this choice of poor comparators was deliberate as was the deviation from the 2006-7 MLTs norms.

Table F: Recommended Checks used under AICRP-RM vis-a-vis

HT DMH 11 Checks in BRL I & II: 2010-11, 2011-12 & 2014-15

<u>ZONE II</u>

Year and	Recomm	ended by Al	CRP-R&M	Used for testing DMH-11		
Stage of trial	Zonal check	National Check	Hybrid Check CMS	Checks ZC	Abandoned as NC (before BRL I)	
BRL-I (First Year) 2010-11	NRCDR -2 (Variety)	Kranti (Variety)	DMH-I NRCHB 506 (Hybrids)	RL 1359* (Variety)	Varuna (Variety)	
BRL-I (Second Year) 2011-12	NRCDR -2 (Variety)	Kranti (Variety)	DMH-I NRCHB 506 (Hybrids)	RL 1359* (Variety)	Varuna (Variety)	
BRL-II 2014- 15	RH 0749 (Variety)	Kranti (Variety)	DMH-I NRCHB 506	RL 1359* (Variety)	Varuna (Variety)	

<u>ZONE III</u>

Year and	Recomm	ended by A	AICRP-R&M	Used for testing DMH-11		
Stage of trial	ZC	NC	Hybrid Check CMS	ZC	NC abandoned as NC (before BRL 1)	
BRL-I (First Year) 2010-11	RGN 73 (Variety)	Kranti (Variety)	DMH-I NRCHB 506 (Hybrid)	Maya (Variety)	Varuna (Variety)	
BRL-I (Second Year) 2011-12	RGN 73 (Variety)	Kranti (Variety)	DMH-I NRCHB 506 (Hybrid)	Maya (Variety)	Varuna (Variety)	
BRL-II 2014- 15	RGN 73 (Variety)	Kranti (Variety)	DMH-I NRCHB 506 (Hybrid)	Maya (Variety)	Varuna (Variety)	

Source: RTI Reply: Table 2. * **RL 1359** has not been in the 'seed chain since 2004-5

Analyses:

• Varuna as a 'Comparator' (dropped as a NC before BRL): (ref Annexure M5, RTI Tables 14 & 15). In a comparison of <u>varietal</u> yields for Kranti (NC) and 2 other Zonal checks vis-à-vis the DMH Comparators, the under-performance in MSY (Mean Seed Yield) of Varuna as well as Maya/RL 1359 is significant. In the above AICRP trials in both Zones II & III, Varuna is a significant low yielder.

Zone II: Against Kranti (NC) by 17%; NRCDR- 2 (ZC) by 21%;
 RH 0749 (ZC) by 33%.

<u>Zone III:</u> Against Kranti (NC) by 11+%; NRCDR-2 by 41%; RH
 0749 by 8%

RL 1359/Maya as 'Comparator':

<u>- Zone II:</u> **RL1359** underperformed against RH 0749 by 11%. It didn't out-perform any Checks

<u>- Zone III:</u> **Maya** under-performed against recommended ZCs NRCDR-2 and RGN 73 by approx. 8% and 11% respectively.

THE CHOICE OF THE CORRECT COMPARATORS FOR ANY GMO IS AT THE VERY HEART OF THE ANALYSES AND IS THE FIRST STAGE OF A RISK ASSESSMENT OF GMOS, OF WHETHER IT IS NEEDED IN THE FIRST PLACE. IN A SIMILAR CASE IN THE EU FOR A LYSINE ENRICHED CORN LY038 THE USE OF THE WRONG 'COMPARATOR' FORCED MONSANTO TO WITHDRAW ITS DOSSIER FOR REGULATORY APPROVAL UNDER CHALLENGE BY THE EU.

Petitioners invite this Hon'ble Court's attention to the fact that in the case of HT DMH 11, the deliberate use of the wrong comparators has on the contrary been accepted by our regulators in a serious deviation from every regulatory norm and ethical conduct. We have illusiory 'Comparator's. DMH 11 progressed from BRL I to largescale BRL II trials and then to the acceptance of its dossier for commercial approval (approved by the Expert Committee, but awaiting the 'nod' of the Apex Regulator, the GEAC). This is clear evidence of massive collusion and criminal intent to fraud the Nation, not just by the Regulators, but across the 3 regulationg Ministries of Governance (MoEF, S&T and MoA), which are involved in the assessment of these HT Mustard GMOs; but, and this is also a key issue for mustard HT DMH 11, there is the added assessment to be made of whether the B & B system of producing hybrids outperforms India's best cultivars both varieties and hybrids, and the latter by the Non-GMO CMS technology and others. HT DMH 11 fails conspicuously and comprehensively on both counts including in comparison with yields in agro-ecology and other systems.

Incredible as it is, instead of disqualifying HT DMH 11 from the 'arena' of consideration, the serious fraud and resulting invalidity of DMH 11 BRL trials is not considered to be any kind of impediment for the Regulators. CGMCP no doubt encouraged by the willing Regulatory collusion went one better. The 'crowning' touch to the fraud is the manipulation of data of MSY of BRL I, in 2nd year trials (Table G below).

15.2 ii MSYs: DMH 11 and GMO Varuna-barnase: (Ref Table E above) The agronomic assessment of the BRL I & II trials are essentially a question of sound statistical analyses, whether these trials lend themselves to the statistical method of significant vs non-significant data and VALIDITY. The scientific method also requires the ability to repeat the experiment. In the case of agri trials in the field, this aspect is even more important because "other things are not equal" (rain-fed conditions, temperature, drought etc). Repeated field testing over several years in several locations is the only known methodology to deliver reliable and consistent quality seeds to farmers. The contrast with field testing of HT DMH 11 could not be greater. As the evidence shows, norms were comprehensively by-passed, making valid conclusions of yield impossible. The conflict of interest in selfsupervised trials, the lack of oversight by experienced breeders and bypassing the apex body of mustard research in the Country the DRMR, do not add confidence to the results. BRL are bad trials by any yardstick. The figures show swings/extraordinarily high values of MSY for HT DMH 11 and large fluctuations in data causing the DRMR to comment that the statistics "need scrutiny 'beyond just MSYs". For example: (ref M5, Tables 8 and 9).

• **HT Varuna-barnase MSY:** (Ref Table E above): HT Varuna-Barnase is a pollen sterile GMO (sterility gene barnase). Despite this, its MSY consistently matches the performance of the Non-GMO comparator Vauna. This is impossible even with male fertile pollen carried by bees/wind from near-by fields. The yields should be hitting the floor, unless there is a lack of stability in the barnase insertion/other reason. Yet, this very important issue of the B & B system for HT DMH 11 does not invite any investigation.

• **Kumher (Zone III)** is not on the testing map for the AICRP in the absence of a senior scientist to supervise trials. And Zone III is not the primary mustard growing area. Yet, DMH 11 in BRL I, year 2 trials in Kumher show an odd brilliance twice over: virtually matching yield in Zone II (mustard area) in that year, but also showing an increase of 26% in MSY in the 2nd year over the 1st year of BRL I trials.

Alwar (in Zone II) similarly swings high to just under 26% in year
2 over year 1 of BRL I trials.

• **BRL I year 2**: The MSY of HT DMH11 is <u>3000 kg/Ha</u>, a similarly unexplained swing over year BRL I year 1. There was just 1 location in each Zone (Kumher in Zone III and Alwar in Zone II). THIS (YEAR 2) IS ALSO THE YEAR TO WHICH CGMCP ADDED 15.2% TO THE OFFICIAL FIGURES IN ITS OWN SUBMISSION TO THE REGULATORS (Please see Table G below).

Needless to say, these data resist credibility. The huge question of the deliberate and illusory use of the wrong/poor 'Comparators' and the subsequent active manipulation of data, should have resulted in immediate disqualification. But, regulatory collusion makes evidence irrelevant and corrective action impossible.

15.2 iii HT DMH 11: MSY of BRL trials fudged by the CGMCP: BRL I, 2nd year data (Table G) was increased by the CGMCP for all entries by 15.2%. in its submission to the RCGM. The new overall MSY is: **2824 kg/Ha** or an increase of **7.5 %** on **2626 kg/Ha**. (the official MSY).

Annexure M7: 'Report of Biosafety Research Level-I (BRL-I) Second Year Trials conducted on transgenic Brassica juncea containing bar, barnase and barstar genes' submitted to the RCGM by the CGMCP, DUSC New Delhi on April 2 2014: Pg 27. (Yield Reported to RCGM by CGMCP).

Analyses: The fluctuations in the MSY of HT DMH 11 are even wider after the data fudging, <u>of around 45% in both zones.</u> It should have raised a red flag. Nevertheless, despite the anomalies and invalidity of the BRL data, for the sake of the argument and debate, Petitioners undertake the exercise of taking the MSY of DMH 11 at face value. The evidence provides 3 values as follows:

(a) HT DMH 11 MSY: <u>2626 kg/Ha</u> of 3 year BRL trials: ref Table E: (Annexure M5: Table 18 official DRMR data).

(b) HT DMH 11 MSY: <u>2028 kg/Ha:</u> MLT (2006-7) + BRL trials: (ref RTI Annexure M5 11A): Given that these 2006-7 trials are an official part of the bio-safety history of DMH 11, then this is the legitimate way to calculate its MSY over the two stages of field trials, (not confining it to merely BRL field testing).

(c) HT DMH 11 MSY: <u>2824 kg/Ha</u>: Manipulted MSY by the CGMCP submitted to RCGM as shown in Table G below (ref. Annexure M7, pg 27)

Table G: DMH 11: COMPARATIVE MSY OF ALWAR & KUMHER TRIALS BRL - I 2010 -11 & 2011- 12 ZONE-WISE

	DATA of MSY				CGMCP DATA RIGGED MSY		
					BRL I: 2 nd yr. 2011-12		
BRL I Zone	Entry	BRL I 1 st Year 2010-11 ALWAR	BRL I 2 nd Year 2011-12 ALWAR	BRL I % change yr. on yr. (yr. 2 over yr. 1) ALWAR		All Entries increased by 15.2% ALWAR * (new %s) 2 nd yr. over 1 st yr.	
	Varuna	1789	2098	17%	2419		
	(barnase)					(35.0%)	
II	EH-2 (barstar)	1842	1581	(16%)	1823	NIL	
	Varuna	1741	2169	24.6%	2499	(43.5%)	
	EH-2	1716	1608		1854	(0.8.0%)	
	DMH-11	2515	3157	25.5%	3638	(44.7%	
	RL-1359(ZC)	1767	1836		2116	(19.8%)	
		KUMHER	KUMHER		KUMHER *		
	Varuna (barnase)	1986	2484	25%	2862	(44.1%)	
III	EH-2 (barstar)	1730	1640		1890	(09.0%)	
	Varuna	1866	2375	27%	2736	(46.6%)	
	EH-2	1793	1873		2159	(20.4%)	
	DMH-11	2285	2892	26%	3332	(45.8%)	
	Maya (ZC)	2057	2195		2530	(23.0%)	

AND CGMCP/DUSC RIGGED DATA

* Yield Reported to RCGM by CGMCP: **SOURCE:** : Report on Biosafety Research Level-I (BRL-I) Second Year Trials conducted on transgenic Brassica juncea containing bar, barnase and barstar genes submitted to the RCGM by the CGMCP, DUSC New Delhi on April 2 2014: Pg 27 (ref Annexure M7.)

Note: The new overall MSY therefore, is: **2824 kg/Ha** or an increase of **7.5** % on the official DRMR MSY of **2626 kg/Ha** submitted to the regulators.

To reiterate, during BRL I trials, in year 2, Alwar & Kumher were the only 2 locations (1 in each Zone): The analyses are therfore, confined to these locations.

15.2 iv Mean Seed Yield (MSY): The Comparative analyses of HT DMH

11 with Non-GMO varieties and CMS Hybrids (a; b; & c above):

• The MSY of HT DMH 11 under (a) & (b) above (at 2626kg/ha & 2028 kg/Ha respectively) are easily dismissed. Annexure M5 Table 16 shows several varieties, hybrids and 'Checks' tested over 5 years in several locations and the CMS hybrid DMH 1 tested in 52 locations with MSYs that are only marginally lower (less than the 10%+ rule, than (a) of 2626 kg/Ha. CMS DMH 1 with a MSY of 2586 kg/H is virtually at par. DMH 1 is the CMS hybrid check and 'Comparator' which was deliberately dropped in the BRL trials starting 2010-11. Petitioners state that the DMH 11 data even at face value FAILS to deliver.

• (Non-GMO) CMS Hybrids DMH 4; DMH 1 and 12 other cultivars (ref Annexure M5 Table 19); Dr YS Sodhi is part of the 'mustard' team at the CGMCP/ DUSC. He delivered a lecture at the DRMR during a National Seminar on 'strategic interventions to enhance oilseed production in India' in 2015. His presentation in Table 19 (of Annexure M5) shows the performance of yet another CMS hybrid called DMH 4, in comparison with DMH 1 the recommended hybrid check (in multilocation trials in 2013-14 at 4 locations). The results speak for themselves. Any claim of the superiority of DMH 11 even at the contrived MSY of 2824 kg/ha are comprehensively demolished:

- CMS hybrid DMH 1 MSY: 2924 kg /Ha
- CMS hybrid DMH 4 MSY: 3012 kg/Ha

- CMS Hybrid Pioneer 45 S -42 MSY: 2819 kg/ha

AICRP RM field tests of varieties and checks in 2014 at 6
locations: (ref Annexure M5 Table 20). These single year trials also show superior performance to the best MSY of HT DMH 11 of 2824
kg/H) (manipulated MSY), ie data of 11 varieties delivering average
MSYs in the region of 2800 kg/Ha with the top 3 varieties between 2850
– 3080 kg/Ha. These trial data under the AICRP-RM will be repeated

over several years and locations to confirm reliable and consistentlyyielding strains for farmers' fields.

BUT, AND THE POINT IS THAT EVEN THOUGH BOTH ABOVE EXAMPLES ARE 1 YEAR TRIALS, THE COMPARISON WITH HT DMH 11 STANDS ON THE BASIS THAT 'SAUCE FOR THE GOOSE IS SAUCE FOR THE GANDER'.

SUMMING-UP AND CONCLUSIONS

16. The GMO story in India has been illegal from its inception ie the commercialisation of Bt cotton in 2002. The Bt brinjal episode is a test case in this Hon'ble court of fraud in that studies said to have been done were not done, oversight covertly negligent and commercial approval still given; a decision overturned by the sanity of erstwhile Minister of the MoEF, Shri Jairam Ramesh. But there is nothing that begins to match the breath-taking fraud of the agronomic testing of HT DMH11 and its 2 parental HT GMOs. Any remaining inhibitions of maintaining a semblance of regulatory oversight have been discarded by our Regulators and relevant Ministries, their unconscionable fraud protected by a subterranean process of regulation that has also broken India's Constitutional safeguards by keeping the biosafety data hidden from the Nation. These matters require criminal prosecution.

16.1 Sleight of hand and 3 counts of proven fraud: The BRL field testing on its own gross demerits, requires nothing more in the way of further evidence from whatever gaps and irregularities the biosafety dossier may throw up (which is still under MoEF location-wraps), like in the case of Bt brinjal. Going by the sheer extent of proven agronomic fraud in this Submission, and the great resistance to transparency, it

would be unrealistic to expect an independent, up-standing rigorous biosafety dossier. That must be fully revealed in compliance with the law and Order of this Hon'ble Court. Notwithstanding this, the proven evidence of BRL I & II involves the criminal collusion of regulators and institutions of governance (in 3 Government Ministries of the MoEF, S&T & MoA) and the regulated (the CGMCP/DUSC) to fraud the nation. The evidence is quite sufficient to disqualify the 3 HT GMOs and they must be barred. The changed maternal inheritance for the BRL trials should have triggered the need for a full safety dossier. It didn't and these 3 HT GMOs remain untested. Thus, the field testing reveals SLEIGHT OF HAND as well as 3 MAJOR COUNTS OF SERIOUS FRAUD, of (a) a wholesale deviation from norms of the AICRP-RM (All India Co-ordinated Research Programme of Rape-seed Mustard) that make these trials statistically invalid; (b) deliberate use of wrong, low-yielding 'Comparators'; (c) Cheating – changing data of MSY among other statistical manipulations of data. BRL I & II field trials were invalid.

16.2 HT DMH 11 and its 2 HT Parental Lines – the Backdoor Entry into India of Herbicide Tolerant GMOs: The superiority of HT hybrid DMH 11 employing the B&B system to make ostensibly superior (yielding) hybrids was never a reality. And this is not the objective. Petitioners charge that the manipulating and statistical jugglery of the HT DMH 11 MSYs in field trials were a cover to hide a dark intent, ie OPENING UP INDIAN AGRICULTURE TO HERBICIDE TOLERANT GM CROPS; a proven unsustainable and dangerous technology (based on empirical USDA data and other evidence), especially for India. It matters not a jot if HT DMH 11 is not approved. What does matter is that its 2 HT parental lines are. In the light of the evidence of the Developers own submission to the RCGM, (GMO) herbicide tolerant Varuna-barnase and (GMO) herbicide tolerant EH 2-barstar will be used to "for introgressing the <u>bar</u>-barnase and <u>bar</u>- barstar genes <u>into new set of parental line to</u> <u>develop next generation of hybrids</u> with higher yields ---". This extraordinary admission confirms that the thrust of the whole plan for any number of HT DMH versions of mustard IS INVESTED IN THESE TWO GMOs. THESE WILL BE THE ROUTE TO DEVELOP HUNDREDS OF HT mustard HYBRIDS (as was done for failed Bt cotton with a present count above 1500 Bt hybrids), USING INDIA'S BEST MUSTARD CULTIVARS at great harm to our farmers and contaminating our seeds and mustard germ plasm irreversibly. This is not in doubt. The evidence clearly shows that hybridisation for superior yield through the barnasebarstar system is inferior to Non-GMO CMS hybrids (for example) as well as our proven open pollinated high yielding varieties. THIS IS ESSENTIALLY AN HT CROP and THIS IS THE THRUST. Petitioners emphasise the following main points:

Glufosinate neurotoxin: Bayer's herbicide tolerant is а (glufosinate) Mustard DMH 11 and its potential infinite variants is a Bayer technology with its counterpart in HT Rape in Canada (Canola). Petitioners reiterate that the herbicide glufosinate, is a known neurotoxin, an analogue of glutamic acid. It has been clearly implicated in brain developmental abnormalities in animal studies and is very persistent in the environment, so it will certainly contaminate water supplies in addition to food where it will be absorbed. Also the chemicals in the formulation that will be sprayed are known to be toxic. It will be banned in the EU from 2017. Surfactants are used to get the active ingredient into the plant, which is engineered to withstand the herbicide so it doesn't die when sprayed. The herbicide and surfactant are sprayed directly on the crops and significant quantities are then taken up into the plant. The

weeds die – or used to! THEREFORE, THE FOOD CROP ITSELF which acts like a sponge, CONTAINS THE HERBICIDE WHICH IT HAS ABSORBED, AS WELL AS A MIXTURE OF SURFACTANTS. The IARC report finding that Monsanto's glyphosate (presumed to be the safest herbicide) is a possible human carcinogenic (2nd highest category 2A – affidavit of 2015) is the added reason for banning HT crops. Glufosinate is not approved in India by the Central Insecticides Board and Registration Committee (CIBRC) for use on mustard.

• HT crops have led to the emergence of super weeds, (ref several submissions,) even triple herbicide resistant weeds in both Canada and the US and greatly increased herbicide use. The US Geological survey noted that while 20 million pounds/year of glyphosate was used prior to GE crops (1992), 280 million pounds/year was used in 2012, largely as a result of GE glyphosate-resistant crops. In the U.S. alone, glyphosate-resistant weeds were estimated to occupy an area of over 24 million hectares as of 2012. This is a failed and unsustainable technology anywhere and for India it will be disastrous with our small farm-holdings and for manual weeding mostly done by women.

• Women displaced in farming: For example had Monsanto's RRFlex technology in cotton been approved, it could have easily displaced <u>400 to</u> <u>500 million woman-days of employment in India per season (CICR –</u> Central Institute of Cotton Research). Women who are employed for weeding do not get any alternate source of employment. This would have been a serious crisis.

• **TEC Recommendations:** The 5-Member unanimous TEC report require a ban on HT Crops and of those crops where we are a centre of diversity/origin --example brinjal, rice and mustard. Therefore, these mustard HT GMOs are doubly barred (on the recommendations).

16.3 Evidence from agroecology/ the role of the ICAR in HT DMH 11

Annexure M8: Seed Yield data in the 'system of mustard intensification': compiled by Ananthoo Restore

Data of the Bihar and MP governments, Department of Agriculture shows significant upward trends in productivity of mustard with the system of mustard intensification. Bihar tops MSY of 3000 kg/ha and MP shows an upward trend with MSY in 2012-13 higher than 4500 kg/ha. These figures dwarf the best that Dr Pental and is team at DUSC can offer of MSY of 2824 kg/ha and that after rigging their data. The ICAR has a clear mandate to our farmers with appropriate extension services to them. Why was HT DMH 11 not subjected to rigorous scrutiny against yields in our best farming systems, and at the very start of the risk assessment process necessary for all GMOs? The ICAR (MoA) is also aware of the UN/World Bank IAASTD report which India signed and every report since then from the UN and other agencies shows complete consensus opinion that the solution to food and nutritional security is through agro-ecological sustainable models of agriculture NOT GM CROPS; and especially in the age of serious Cc (Climate Change). The highest yielding varieties of GM crops are so because of ongoing and intensive genotype improvement through traditional breeding, not through the development of genetically engineered traits (Gurian-Sherman). Neither HT nor Bt crops nor the B&B system has a trait for yield. "Yields went up 214% in 44 projects in 20 countries in sub-Saharan Africa using agroecological farming techniques over a period of 3 to 10 years... far more than any GM crop has ever done." (Olivier De Schutter, UN Special Rapporteur: Right to Food). The evidence from agroecology is huge. Petitioners offer a microcosm from

several submissions, because the MoA and the regulators continue to brief the PMO and the Nithi Aayog (presumably, since this body on no evidence, repeats the same erroneous thinking), the standard myth in tune with GM crop developers that GM crops are the answer to India's food security.

The IAASTD makes it clear that the road map for agriculture for the **next 50 years** must be through localised solutions, combining scientific research with traditional knowledge in partnership with farmers and consumers. The Report calls for a systematic redirection of investment, funding, research and policy focus toward these alternative technologies, infrastructure like roads and food storage, and the needs of smallfarmers. Food security will follow not only from producing more food, but how we produce and consume it (IAASTD, 2009). Industrial agricultural practices on average require 10 calories of exogenous energy for every 1 calorie of food produced: (Giampietro, 1993; UNEP, 2011); (Heinemann).

The petitioners' counsel have now received a response from the Ministry of Environment, Forest and Climate Change on 15.09.2016 stating that the biosafety dossier of Mustard DMH 11 is available in the GEAC Secretariat. Thus, the Ministry has refused to put the dossier available on website and is also not allowing public to take copies of the dossier. A copy of the said reply of MoEFCC dated 15.09.2016 is annexed as **Annexure M9** (Pg _____).

17 CONCLUSIONS

17.1 HT DMH 11 with its SWAPPED MATERNAL GENES and its two herbicide tolerant parental GMOs are on the anvil of commercial approval, but have slipped under the regulatory radar on a technicality

and through a lacuna in the rules of an 'event-based system' and completely inadequate BRL field testing rules, which have allowed these 3 HT GMOS TO COME-UP FOR COMMERCIAL APPROVAL WITHOUT SAFETY TESTING. In effect, India is suddenly faced with the deregulation of GMOs. This is disastrous and alarming, without scientific rationale and unethical. This PIL risks becoming infructuous. YET, MUSTARD IS DOUBLY BARRED IN THE TEC RECOMMENDATIONS (REF 16.1 ABOVE). 3 other G o I Reports underpin the findings of the TEC, the latter receiving its mandate from this Hon'ble Court with specific terms of reference, which had they been implemented, would have resulted in the avoidance of the current great crisis. The four official G o I Reports (including the TEC) find common ground on the lack of integrity, scientific expertise in protocols of risk assessment, and independence; even fraud in the GM regulator and our agri-institutions, as the outcome of a pervasive conflict of interest, which makes sound and rigorous regulation of GMOs impossible. It is the 3rd official report barring GM crops' field trials singly or collectively. This consensus is remarkable. The other 3 reports are: (a) The 'Jairam Ramesh Report' (Feb. 2010) imposing an indefinite and unconditional moratorium on Bt brinjal, overturning the apex Regulator's approval to commercialise it; (b) the Sopory Committee Report (August 2012) was an enquiry into the contamination of the so-called 'desi' Bt cotton (BNBt), with a Monsanto gene; and (c) The Parliamentary Standing Committee **Report**, (2012 (37th Report)) and 2013, (59th Report)) which requires an inquiry into how Bt brinjal was approved and that "further research and development on transgenics in agricultural crops should be done only in strict containment and field trials should not be undertaken till the Government puts in place all regulatory, monitoring, oversight, surveillance and other structures". **PSC 59**th **Report 2013**.

Moreover, the fact is that over 25 other countries have bans on GMOs including Scotland, Wales, Switzerland, Austria, France, Germany, Hungary, Luxembourg, Greece, Bulgaria, Poland, Italy, Mexico and Russia. Significant restrictions on GMOs exist in about sixty other countries.

17.2 Petitioners Require a Commission of Inquiry: Finally, Petitioners find it necessary and expedient for the Nation to request the Hon'ble Court to institute such a Commission as was undertaken to look into the serious corruption and conflict of interest of the BCCI. The extent of the collusion, fraud and malfeasance in the matter of HT DMH 11 and its 2 parental HT GMOs is unprecedented. Petitioners humbly remind this Hon'ble Court of its unequivocal determination and sternness that the BCCI implement the Justice Lodha Committee recommendations for drastic restructuring to ensure transparency in its functioning saying "it won't get a second innings". That was cricket, albeit a 'national' game. In the matter of GMOs, the nation stands imperilled with significant impacts across several dimensions. The Contamination of our seed stock and germ plasm as will happen with mustard HT DMH 11 and its HT parents will be irremediable and irreversible making our food toxic at the molecular level (without recourse). The GEAC has continued to act as a rubberstamping authority for the RCGM, (which prompted this Hon'ble Court in 2005 to grant an interim injunction on open field trials). However, on the evidence of Dr Pushpa M Bhargava (ref point 4.2), the SCappointed invitee to the GEAC, the Apex Regulator has abrogated its' functioning. There is no oversight. Petitioners humbly state that the present situation requires the immediate recognition by the Hon'ble Court that the time-factor or 'TIMELINESS' of its decision to stop environmental release of GMOs has now become a CRITICALITY: GMO contamination must be avoided as the prior objective of GM crop policy and this criticality distinguishes it from other hazardous technologies.

NEITHER GOVERNMENTS NOR MULTINATIONAL COMPANIES HAVE A MANDATE FOR GLOBAL EXPERIMENTS.

17.3 The evidence is clear -- Regulatory anarchy: Petitioners state that India is faced with a level of regulatory and institutional irrationality driven by decades of a cancerous conflict of interest and a dogged adherence to the official agenda to promote GMOs that is beyond redemption. It presents the country with a CRITICALITY uniquely relevant to GMOs NOW (ref Additional Affidavit 2015 point 31). For the Regulators, no 'evidence is relevant and everything is possible'. For example, The Government officially admits the failure of Bt cotton in the Delhi High Court 14 years on in 2016, and the Regulators and relevant Ministries continue to field test Bt crops! A Commission of Inquiry is therefore, required to look beyond HT DMH 11 to Bt cotton and Bt brinjal,

The nation faces maverick regulators and regulatory tyranny seriously threatening and IRREVERSIBLY, India's biosafety, her food security and contravening India's Constitution. The agenda is policy-driven.

(ref concurrent Application on the officially admitted failure of Bt cotton).

PRAYERS

In light of the above facts and circumstances, the petitioners request that this Hon'ble Court may kindly pass the following ad-interim directions:

A. Direct a prohibition of open field trials and commercial release of Herbicide Tolerant (HT) crops including HT Mustard DMH 11 and its parent lines/variants as recommended by the TEC report.

- B. Direct a moratorium on the commercialisation of any other Genetically Modified Crop.
- C. Direct the Respondents to implement the recommendations of the TEC Report.
- D. Direct the constitution of an inquiry to inquire and submit a report on the field trials and application process of HT Mustard DMH 11.
- E. Issue such other directions or orders that this Hon'ble Court may deem fit and proper.

PRASHANT BHUSHAN

COUNSEL FOR THE PETITIONERS

NEW DELHI: DATED: