IN THE SUPREME COURT OF INDIA

CIVIL ORIGINAL JURISDICTION

I.A. NO. 47 OF 2016

IN

WRIT PETITION (CIVIL) NO. 260 OF 2005

IN THE MATTER OF:-

Aruna Rodrigues & Others	…	Petitioners
Versus		
Union of India & Others	…	Respondents

ADDITIONAL AFFIDAVIT ON BEHALF OF PETITIONERS IN REPLY TO THE AFFIDAVITS DATED 21.07.2017 & 28.07.2017 FILED ON BEHALF OF UNION OF INDIA

PAPER BOOK

NIKHIL NAYYAR
ADVOCATE ON RECORD

INDEX

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I, Aruna Rodrigues, D/o Theresa Rodrigues, R/o Bungalow 69, Mhow Cantt., Madhya Pradesh- 453441, presently at New Delhi, do hereby solemnly state and affirm as under:

1. That I am Petitioner No.1 in the Writ Petition mentioned above and am fully acquainted with the facts and circumstances of this case and as such authorised to swear this affidavit on behalf of all the other Petitioners.

2. To briefly recapitulate, the Writ Petition filed by the Petitioners, *inter alia,* seeks a moratorium on the environmental release of any genetically modified organisms ('**GMOs**') in the absence of (a) comprehensive, transparent and rigorous biosafety protocols in the public domain and (b) biosafety studies conducted by independent expert bodies the results of which are made available in public domain. In 2016, the Petitioners were constrained to approach this Hon'ble Court to seek appropriate directions against the impending grant of approval to the Centre for Genetic Manipulation of Crop Plants ('**CGMCP**'), University of Delhi, for environmental release of

transgenic mustard namely DMH-11 and its *transgenic* parental events (Varuna bn 3.6 and EH-2 modbs 2.99) by the Central Government. To this end, the Petitioners submitted that the present circumstances warranted a prohibition on commercial release of DMH-11 in view of the fact that (*i*) mustard (*brassica juncea*) is a crop of origin/diversity in India; (*ii*) DMH-11 and their parental lines contain herbicide tolerant ('**HT**') traits; (*iii*) DMH-11 has failed to satisfy the prior requirement of '*need*' of this crop as evidenced from the results of the open field trials including BRL trials; and (*iv*) the conduct of Biosafety Research Level ('**BRL**') trials were comprehensively flawed and are invalid.

ADDITIONAL AFFIDVIT DATED 21.07.2017 & 28.07.2017

3. On 21.07.2017 and 28.07.2017, the Union of India tendered two (2) Additional Affidavits stating that no decision has been taken on the recommendations of the Genetic Engineering Appraisal Committee ('**GEAC**') at their 133rd meeting (held on 11.05.2017) to permit environmental release of DMH-11 and its *transgenic* parental lines. Broadly, the submissions of the Central Government are summarized herein below:

(i) **I.A. No. 47 of 2016 is Premature:** The Central Government averred that only fifteen (15) kilograms of DMH-11 would be planted in the upcoming winter season (i.e., beginning from Oct. 2017) to demonstrate its yield potential and commercial viability (presumably in farmers' fields). [*See* **Pr. 21(i)** | Add. Affidavit(***II***)] Moreover, and 'parallel to these demonstrations', the Central Government has revealed their plans for hybrid seed production in preparation for commercial use in approx. two (2) years. [*See* **Pr. 21(ii)&(iii)** | Add. Affidavit(***II***)] In view of this, the Central Government contends that the present Application for Directions is premature as there is substantial time for the Petitioners

to approach this Hon'ble Court, for redressal if required, before commercialisation. [*See* **Pr**. **23** | Add. Affidavit(***II***)]

(ii) **DMH-11 is not a HT Crop:** Shockingly, the Union of India reiterated their claims that the "GE Mustard (DMH-11) is not a HT crop." [*See* **Pr. 12** | Add. Affidavit(***II***)] Moreover, in an Office Memorandum dated 01.08.2017 issued by Ministry of Environment, Forest & Climate Change ('**MoEF&CC**'), the Central Government claimed that DMH-11 has been developed through 'hybridization technology'. On the other hand, the Central Government admitted that the herbicide (i.e., *glufosinate ammonium*) – although unapproved by GEAC and Central Insecticide Board & Registration Committee ('**CIB&RC**') – would be used 'only for the selection of female parent plants during the production of hybrid seed.' [*See* **Pr**. **12** | Add. Affidavit(***II***)]

(iii) **Safe for Environmental Release**: Based on the Report on Assessment for Food & Environmental Safety ('**AFES**') submitted by the Sub-Committee of GEAC, the Central Government averred that DMH-11 does not pose any risk to human/animal health or the environment. [*See* **Pr**. **11** | Add. Affidavit(***II***)] To this end, the Central Government cited example of GE Canola (*brassica napus*) in Canada, USA and Australia. Furthermore, the Central Government urged that the DMH-11 and other hybrids using this technology are necessary to improve yields in mustard in India which has been 'stagnant around 7-8 MT for the last 20 years'. [*See* **Pr**. **15** | Add. Affidavit(***II***)]

4. From the above, it is evident that the Central Government has not only projected the hybrid seed production of DMH-11 as an innocuous and harmless procedure, but also revealed their predisposed mind to permit commercialisation of GE Mustard.

Be that as it may, by way of the present affidavit, the Petitioners seek to rebut the submissions made in the above Add. Affidavits. At the outset, it is stated that the above Affidavits hide more than they reveal. The stand of the Central Government reflects a high degree of technical incompetence and a deliberate intent to obfuscate science. [*See* **Pr. 10** below] The claims made are also straightforwardly untrue; broad statements, without evidence, presented as fact. [*See* **Pr. 7 & 11** below] As such, the AFES Report is not a detailed scientific description of the biosafety of HT DMH-11. [*See* **Pr. 11** below] The dossier with the raw biosafety data submitted by CGMCP running into thousands of pages is still concealed, for which the Petitioners were constrained to initiate contempt proceedings (bearing C.P.(C) No. 6 of 2016) against the Respondents which is currently pending for consideration by this Hon'ble Court. It is of deep concern that the Union of India is attempting to confuse and even mislead this Hon'ble Court on matters of core importance to biosafety. It is further obvious that the omission to append the minutes of the 133rd Meeting of the GEAC is not an oversight, but suppressed as is the bio-safety dossier. It is submitted that the Respondents may be directed to provide the Minutes of the said meeting. Apart from this, the plan vaguely outlined in Pr. 21 of Add. Affidavit(***II***) is profoundly disturbing and, if allowed, it will contaminate India's rich mustard germplasm irreversibly. [*See* **Pr. 12** below]

5. The present Additional Affidavit may kindly be read along with the following Submissions of the Petitioners in I.A. No. 47 of 2016, Rejoinder Affidavit dated 15.11.2016, Mustard Submissions of 2006 and 2007, Written Submission (2014), Additional Affidavit dated 14.09.2015 and the Contempt Petition No. 6 of 2016.

BIOSAFETY REGULATION IN SHAMBLES

6. **THE 301ST REPORT OF THE PARLIAMENTARY STANDING COMMITTEE (DATED 25 AUGUST 2017) UNDERPINS THE**

CONCLUSIONS OF FOUR PREVIOUS GOVT. OF INDIA REPORTS.

6.1 Recently, on 25.8.2017, the Parliamentary Standing Committee on Science & Technology, Environment and Forests submitted its 301st Report: 'Genetically Modified Crops and its Impact on Environment' ('**301st PSC Report**'). The 301st PSC is scathing in its criticism of the regulation, and risk assessment of GMOs, including GM HT mustard and ultimately concludes that *"No GM crop should be introduced in the Country"*. [at **Pr. 86**] The PSC in its independent assessment of GMOs and their impact on the environment - having heard the Regulators [i.e., GEAC and the Review Committee on Genetic Manipulation ('**RCGM**')], relevant Ministries [i.e., MoEF&CC, Ministry of Science & Technology, Ministry of Agriculture and their Departments] and members from the civil society - finds the agencies concerned as shockingly casual and *"takes serious note of the apathy of the concerned government agencies"* about the impact of GMOs on the environment (including agriculture) and on human & animal health. It finds the current regulatory framework to lack rigour, expertise, transparency and is seriously 'conflicted' (conflict of interest). Furthermore, the 301st PSC noted that the absence of long term testing for chronic toxicity defeats the very purpose of risk assessment and claims of safety, contrary to the *"Government conclusion that GM crops would not have any adverse impact on human as well as animal health".* True copy of the PSC 301st Report titled 'Genetically Modified Crops and its Impact on Environment' dated 25.08.2017 is annexed herewith as **ANNEXURE A-1 (Page Nos. 44 to 78)**.

6.2 Some of the key findings of the 301st PSC Report are excerpted below:

(a) **At Pr. 87 (Overall Conclusions):** *The Committee strongly believes that unless the bio-safety and socio-economic desirability, taking into consideration long run*

effects, is evaluated by a participatory, independent and transparent process and a retrieval and accountability regime is put in place, no GM crop should be introduced in the country --- The GEAC has given its approval for commercialisation of GM mustard in spite of the fact that the matter is pending for decision in the Hon'ble Supreme Court of India. We understand – "*that GM mustard being an herbicide tolerant GMO, there is clear evidence on the adverse impacts of such GMOs from elsewhere in the world. In the case of GM mustard, --- there are serious unanswered questions. The Committee has also come to know that many State Governments in the country are opposed to its entry even in the form of field trials, leave alone commercial cultivation.*

(b) **At Pr. 52:** *The Ministry informed the Committee that biodiversity preservation is unanimously considered a priority by the scientific community and society at large.*

(c) **At Pr. 77 (Undue *"Haste to commercialise"*):** *The Committee is of the considered view that without having been scientifically proven that GM crops would have no adverse impact on human health and solely relying on the studies which have not been done here in India --- in the context of our climate and environment negating any adverse impact on human health, the Government should reconsider its decision to commercialise GM crops in the country.*

(d) **At Pr. 47:** *The Committee finds it very surprising that despite having so many levels of scrutiny in place, none of these levels of scrutiny is directly involved in the process of Environmental Impact Assessment and the regulators are predominantly relying upon the data made available by the applicant himself. The Committee is of the view that inspite of claiming to have the most stringent*

assessment process, we are lacking on the very basis of the same. The Committee, therefore, recommends that the whole process of evaluation should be carried out by an independent agency consisting of the people of impeccable credentials in the relevant field to ensure that there is no violation of the existing regulations in this regard.

(e) **At Pr. 48:** *It was also brought to the notice of the Committee that ICAR - Directorate of Rapeseed - Mustard Research has informed in response to an RTI application that DRMR has not conducted any trial and the data received from the technology developer was passed to DRMR for onward transmission to GEAC.*

6.3 **REMARKABLE CONSENSUS OF 5 OFFICIAL GOVERNMENT OF INDIA REPORTS WITH RESPECT TO THE DEEP MALAISE IN GMO REGULATION IN INDIA**

The above findings of the 301st PSC are entirely in sync with four previous official (Government of India) reports, including the vital Supreme Court-appointed Technical Expert Committee ('**TEC**') Reports. Amongst them, The TEC was the only scientific body of the 5 Committees with a broad mandate (vide Order dated 10.05.2012 of this Hon'ble Court) to critique risk assessment protocols and their inter-twining with open field trials, their sequencing for biosafety before environmental release, among other matters specified in the Terms of Reference. A short description of these reports is as follows:

i. **The 'Jairam Ramesh Report'** (9th Feb. 2010, available at moef.nic.in/downloads/public-information/minister_REPORT.pdf) imposed an *'indefinite moratorium'* on *Bt.* brinjal, citing no shortage of brinjal, lack of scientific rigour, etc., overturning the GEAC approval to permit commercialisation.

ii. **The Sopory Committee Report** (Aug. 2012, available at: icar.org.in/files/BN-Bt-cotton-report.pdf): A Scientific Committee constituted by the Indian Council of Agricultural Research ('**ICAR**') with the specific mandate to investigate the contamination of *desi Bt*. cotton (BNBt), with a Monsanto gene. It found gross regulatory misconduct, significant untruth and lack of expertise.

iii. **37th & 59th PSC Reports on GM Crops** (Aug. 2012 & Mar. 2014, respectively): In reaction to the Government's action on field trials, the 59th PSC Report with regard to the **'**Action Taken by the Government on its 37th Report', made the following observations:

> "(iv) **Regulatory Mechanism for Transgenics and Containment of Trials**
>
> (Recommendation Para No. 1.20, 3.40, 3.41, 3.42, 3.48, 5.46, 5.49, 5.52, 5.53, 6.144, 6.145, 6.147, 8.116, 8.117, 8.119 and 8.120):
>
> 1.5 The Committee are not satisfied with the replies furnished by the Government in respect of the above-mentioned recommendations. They therefore, reiterate their earlier recommendations and desire 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. The Committee note from press reports that the Minister of Environment and Forests has decided to allow field trials of transgenics which is contrary to the recommendations

of the Committee in the Thirty-Seventh report. The Committee strongly deprecate this."

iv. **TEC Reports** (Interim Report of Oct. 2012 & Final Report of Jun-Jul 2013): By Order dated 10.5.2012, this Hon'ble Court appointed an Expert Committee ('**TEC**'), *inter alia*, to review and recommend the nature of sequencing of risk assessment and other terms as mentioned in the said order. 5 out of 6 members of the TEC unanimously recommended are (a) that there should be an indefinite stoppage of all *open* field trials (environmental release) of GM crops, with a specific focus on *Bt*. food crops, conditional on systemic corrections being implemented as stated above including comprehensive risk assessment protocols (which must start with the prior requirement of the *'need for the GM crop'*, and must include long-term rat feeding studies) that are rigorous, independent and trust worthy; (b) HT Crops are to be banned entirely inasmuch as the TEC found them ***"completely unsuitable in the Indian context as HT crops are likely to exert a highly adverse impact over time on sustainable agriculture, rural livelihoods, and environment"***; and (c) crops for which India is a centre of origin/diversity are also required to be banned.

NOTE: The recommendations of the Interim and Final Reports by TEC at (b) and (c) above would mean that HT DMH-11 and its HT *transgenic* parental lines are doubly barred. The decision of the GEAC to permit field tests on HT mustard in the first place, is gravely unconscionable.

6.4 The conclusions drawn by the Final Report of TEC (submitted by 5 members) also finds support from the two (2) PSC Reports (i.e., 37th, 59th & 301st Reports). In particular, the 37th and 59th PSC Reports and the TEC Report suggested the need to frame

a Biotechnology Regulatory Act with a focus on '*bio-safety-first'* and the Precautionary Principle, and the need for an independent institute of testing and analyses outside the system. The latter is also required by the 301st PSC. Moreover, the TEC Report squarely raises serious issues of the lack of integrity, lack of proper protocols of risk assessment and the expertise to carry them out, conflict of interest in the GM Regulators and our agri-institutions, which makes sound and rigorous regulation of GMOs impossible. It is the 4th official report barring GM crops' field trials singly or collectively. This consensus is remarkable. The Respondents, therefore, stand seriously isolated in the untruth of their constant refrain of *'step-by-step'* exemplary regulation of GMOs.

6.5 **The late Dr Bhargava list of 29 biosafety tests:** Appointed by this Hon'ble Court as an 'invitee' to the GEAC Meetings (vide Order dated 13.02.2008), Dr. Bhargava found that risk assessment was essentially absent and first blew the whistle on the virtual state of non-regulation that is the prevailing norm in India, when he stated that of a possible 29 bio-safety tests that are required to assess a GMO for bio-safety, only 4 were done and even those in a perfunctory manner as if they were deemed not to have been done. [*See* Pr. 11 & Annex. B-7 | **I.A. No. 25 of 2008**] He also addressed Petitioners' long requested prayer for an *'institute of independent testing and analyses'*. It is indeed critical to have an independent *institute of safety testing of GM crops, which* was insisted upon by Dr. Bhargava and agreed to in principle by the Regulator, (AGENDA ITEM 4: POINT 5.5 OF THE 85TH MEETING). Dr Bhargava has also provided a blue print of such an institution at the request of the GEAC. [Pr. 8.1 & Annex. G19 at Pg. 214-218 **| Written Submissions (Apr. 2009)**] This proposal has also been noted by this Hon'ble Court in its order dated 30.04.2009 and till date no response has been filed by the Union of India on this aspect.

6.6 It may be pointed out that at Pr. 6, 7, 8 and 17 of the Add. Affidavit(***II***), the Central Government has routinely claimed that they deliver exemplary regulation and provide a long list of tick-marks, of the step-by-step approach taken in the regulation of GMOs in full compliance of the '1989 Rules'. Tick marks are not biosafety. The lack of regulation must also be seen in the context of the proven serious conflict of interest that engulfs GMO regulation in India, where the divide between regulator and regulated is obliterated. [*See* several submissions over 11 years: example (a) Dr. Paroda, the 6th member of the TEC was insinuated by the Ministry of Agriculture after the 1st report of the TEC. He is a promoter of GM crops and is funded by the Industry in this work, as highlighted in the Petitioners' Affidavit of July 2013; (b) 5 official Government of India reports address this conflict and with reference to HT DMH-11 specifically, where this conflict is admitted by the Respondents themselves. [*See* **Pr. 14** below] These matters are exemplified by the contrivance attempted by the Respondents in the matter of HT DMH 11 not being an HT crop.]

6.7 The brief record of an 11-year history of dismal regulation of GMOs in open field trials and risk assessment protocols, are seen essentially through the prism of the Orders of this Hon'ble Court. [*See* **Pr**. **10** at Pg. 9-13 | Written Submissions (2014)]. They are remarkable for their grounding in biosafety; recognising that our environment and farmlands have been subjected to a huge number of field trials, and recognising the potential for the ensuing risk of contamination involved in even small scale open field trials, and the serious biosafety lapses during field trials that breeched fundamental basic rules.

6.8 ***Bt*. Brinjal - A Test Case:** *Bt*. brinjal is the ONLY CASE in India and an outstanding TEST CASE of a crop-developer's safety dossier (Mahyco-Monsanto) (made public) whose appraisal by eminent international scientists (including advisors to the UN/CBD) proved that it was a cover-up and even fraudulent, of

studies said to "*be done but not done".* Prof. Andow, a leading GMO environmental scientist stated that of 37 environmental studies that were required to be done, 36 were not conducted. [*See* 'Bt Brinjal: The Scope and adequacy of the GEAC environmental risk assessment', (Aug. 2010)] The Bt. brinjal biosafety dossier was finally forced into the public domain by virtue of Orders passed by this Hon'ble Court dated 15.02.2007 and 08.04.2008. That Order covers other crops' dossiers including HT mustard DMH-11, which is under wraps up to the present time. It is pivotal to trustworthy and rigorous regulation to establish up-to-date and evolving *'protocols of testing'* in keeping with the best available science and the need to conduct these in *independent GMO safety-testing institute/s* outside the Regulators. The self-assessed Mahyco-Monsanto Bt. brinjal bio-safety dossier should have been withdrawn from the regulatory record for its proven significant omissions in regulatory oversight even at the very starting point of protocols of risk assessment (the molecular analyses analysed by Prof. Heinemann) and for wrong claims of studies done, which were not done. These matters were upheld in the 37th PSC, which required the most serious investigation at the highest level into the corrupt process that led to its approval as follows:

> "**2.79** The Committee have been highly disconcerted to know about the confession of the Co-Chairman of Genetic Engineering Appraisal Committee (Prof. Arjula Reddy) that the tests asked for by Dr. P.M. Bhargava, the Supreme Court nominee on GEAC for assessing Bt. brinjal were not carried out and even the tests undertaken were performed badly and that he (Prof. Arjula Reddy) had been under tremendous pressure as he was getting calls from industry, GEAC and the Minister to approve Bt. brinjal. Convinced that these developments are not merely slippages due to oversight or human error

> but indicative of collusion of a worst kind, they have recommended a thorough probe into the Bt. brinjal matter from the beginning upto the imposing of moratorium on its commercialization by the then Minister of Environment and Forests (I/C) on 9 February, 2010 by a team of independent scientists and environmentalists."

Bt brinjal was approved by our collective regulatory body and their expert committees virtually without oversight. It was only because of the timely intervention of the then Environment Minister, Shri Jairam Ramesh, through an indefinite moratorium, that the irreversible contamination that would have resulted of around 2,500 wild and domesticated varieties of brinjal (India, has the greatest diversity worldwide of brinjal germplasm) was stopped and the right to health of 1 billion citizens was protected.

6.9 **HT mustard DMH-11 - Contempt Petition (No. 1 of 2016)**: Regrettably and alarmingly, in HT mustard DMH-11, India faces a repeat of the disastrous regulatory history of Bt brinjal. India is similarly a centre of diversity and domestication of over 5000 wild and domesticated varieties of mustard. As per National Bureau of Plant Genetic Resources-('**NBPGR**'), the wider 'family' of brassicas includes 9720 accessions. [*See* Radhamani J., et al., *Conservation of Trait-Specific Germplasm of brassicas in National Genebank*, NBPGR (Sept' 2013)] In December 2015, Petitioners filed a Contempt Petition (C.P.(C) No. 6 of 2016) against the GEAC for defying the directions issued by this Hon'ble Court on 08.05.2007 to ensure *"No Contamination"* and for not making the self-assessed biosafety dossier of the Developers, Delhi University, public on the Ministry website. Given that in the case of Bt brinjal, a similar Contempt Petition was necessary before compliance, the subterranean GM Mustard dossier, and secret processes involving the biosafety of any GM food, aside from being

markedly unethical, infringe constitutional safeguards. Both PSCs have been scathing about the lack of transparency by our Regulators and their lack of accountability to the Indian public. Petitioners state that these matters must be investigated by a high level commission of inquiry.

NOTE: The Contempt Petition also covers HT corn and HT cotton with stacked Bt. genes. This clearly proves the agenda to introduce HT (GM) technology into Indian agriculture. This will be disastrous for multiple reasons of biosafety, including the proven unsustainability of HT crops. HT mustard DMH-11 and its 2 HT parental lines if commercialised are the doorway, *'open sesame',* to that process. India will be contaminated.

6.10 **The outstanding concern is GMO contamination** of India's germplasm. India is a centre of mega diversity. Unlike a drug which can be recalled, if found to be dangerous, GMO contamination of our environment will be irreversible and will change the structure of our seeds and food at the molecular level. Any toxicity that there is will remain without remedy. In the present case, the reference is to GM HT mustard contaminating Non-GMO mustard germplasm, (domesticated, landraces, wild varieties and other species of the same genus). This matter is dealt with in adequate detail at **Pr. 12** below. The evidence shows that open field trials and in particular large scale field trials as have been conducted for HT DMH-11 and its HT parental lines, have significant potential to contaminate India's mustard germplasm. Small scale trials let alone large-scale, have been the Petitioners' focus – with a commercialised crop, contamination is certain. HT (GM) rape in Canada is the outstanding example. [*See* **Pr. 12.4** below] It is ironic that the 301st PSC Report of 25 August 2017 records at Pr. 52 that *"biodiversity preservation is unanimously considered a priority by the scientific community and society at large".* The Regulators pay lip service.

6.11 **HT DMH 11 and its HT parental lines contravene the Insecticide Act of India**: The Insecticides Act prohibits the use of Basta in mustard agriculture (active ingredient Glufosinate Ammonium, the herbicide linked with HT DMH-11 and its HT parental lines). It may be noted that the Regulators in allowing the Developers (i.e., Delhi University) to spray Basta for seed production over the last several years, have already contravened the law.

7. THE UNION OF INDIA CLAIMS MUSTARD HYBRID DMH 11 IS NOT HERBICIDE TOLERANT AND 'HT' MEANS 'HYBRID TECHNOLOGY'

7.1 *"Petitioners are accused of making repeatedly misleading statements"* that mustard DMH 11 and its parental lines are HT (herbicide tolerant) crops, (*See* **Pr**. **12** | Add**.** Affidavit***(II)***] and that HT is 'hybrid technology'. [*See* Pr. 59 | Reply Affidavit to I.A. No. 47 & Office Memorandum dated 01.08.2017] Based on the documents provided by the Developers and Respondents, i.e., the description of the construct of DMH-11 and Varuna-barnase and EH2-Barstar, it is unambiguous that the transgenic varieties are herbicide tolerant crops resistant to glufosinate.

7.2 Given the perverse and vexing issue of how herbicide tolerant (HT) mustard DMH-11 and its HT parental lines (Varuna bn3.6, EH2 modbs 2.99) are somehow and suddenly not HT crops, and the adoption of a hitherto unknown acronym for HT, i.e. 'hybrid technology' Petitioner No. 1, requested Prof. Jack Heinemann to provide his expert comments on these and other matters raised in the referenced documents.

Prof. Jack Heinemann gives evidence

7.3 Prof. Jack Heinemann is the Director, Centre for Integrated Research in Biosafety, Univ. of Canterbury, Christchurch (NZ). Prof. Heinemann specialises in the field of molecular genetics and has provided evidence in this writ petition over the last 11

years. His international eminence as a GE scientist and geneticist is not in doubt. He served the United Nations Convention on Biological Diversity Secretariat on the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management (2009-16) and was also advisor to the Food & Agriculture Organisation, amongst others. True copy of Expert Opinion dated 16.08.2017 by Prof. Jack Heinemann is annexed herewith as **ANNEXURE A-2 (Page Nos. 79 to 86)**.

7.4 A point wise rebuttal of the claims made by the Union of India in the Add Affidavit(***II***) and Office Memorandum dated 01.08.2017 with regard to the assertion that 'HT' is nothing but 'hybrid technology' is dealt with by Prof. Heinemann as under:

(a) **Claim 1:***"GE Mustard in not Herbicide (HT) crop"*

Prof. Heinemann: "The abbreviation 'HT' as applied to GM crops is to my knowledge historically and commonly, if not always, used to designate *'herbicide tolerant'* or *'herbicide tolerance'.* It was first used in 1986 and established as *"HT at least by 1997*". "This usage predates by six years the relevant patents (Bisht et al., 2003), I could find from the University of Delhi South Campus for work leading to the varieties Varuna bn3.6, EH2 modbs 2.99 and DMH-11. Moreover, I am not aware of a commercialized genetically modified crop with a herbicide tolerance gene categorized as <u>not</u> a herbicide tolerant plant".

(b) **Claim 2:** "…*in fact it relates to Hybrid Technology (HT) and usage of herbicide is limited only for hybrid seed production…pertains to development of GE Mustard hybridization technology and it is evidenced through publication of all data in peer reviewed journals and substantiated by National and International Patents owned by University of Delhi."*

Prof. Heinemann: “There is no dispute that Varuna bn3.6, EH2 modbs 2.99 and DMH-11 and at least some progeny are able to survive normally lethal exposures to the herbicide active ingredient glufosinate ammonium, because they have a gene called *bar” (*Figure 1).

(i) Intention is not a defining characteristic of the definition of herbicide tolerant crops. What is a defining characteristic is having a gene that confers herbicide tolerance.

(ii) Furthermore, as India has already experienced from the early illegal releases of GM cotton (Jayaraman, 2004), intention of developers is not sufficient to preclude other uses.

(iii) The characterization of Varuna bn3.6, EH2 modbs 2.99 or DMH-11 as ‘*not a herbicide tolerant crop’* appears to me to be a description arising only, and only recently, from the Ministry of Environment or other sources.”

(c) **Hybrid Technology:** “The innovation in Varuna bn3.6, EH2 modbs 2.99 and DMH-11 makes it easier to produce hybrid mustard seeds and plants, but mustard is not the only or remotely the first crop plant that uses male sterility to do so.....The innovation is *male sterility* in mustard, allowing it to be used more easily *in already existing hybridization technology*”.

“The developer states clearly in an early publication that the trait introduced by genetic engineering is to be applied in making hybrid seeds, but the trait is not the act of making hybrid seeds and therefore, *not a hybridization technology itself* “. ---“Consistent with this, neither the term ‘*hybrid technology’* nor the abbreviation *‘HT’* are used in relevant University of Delhi South Campus

patents or publications" (Bisht et al., 2003; Jagannath et al., 2002).

(d) Conclusion

"I do not concur with what I understand to be the meaning of the statement (below) by the Ministry of Environment" (JH) that:

> *"GE Mustard is not Herbicide Tolerant (HT) crop infact it relates to Hybrid Technology (HT) and usage of herbicide is limited only for hybrid seed production. As on date, no herbicide has been approved for commercial use for mustard cultivation and the approval of herbicide could be as per relevant rules and regulations prescribed by Central Insecticide Board and Registration Committee[CIBRC) under Ministry of Agriculture. The application received by GEAC from University of Delhi, South Campus pertains to development of GE Mustard hybridization technology and it is evidenced through publication of all data in peer reviewed journals and substantiated by National and International Patents owned by University of Delhi".*

- Varuna bn3.6, EH2 modbs 2.99 and DMH-11 are by all previous convention and scientific understanding of the genes used in the events, herbicide tolerant GM plants.
- I found no use of the abbreviation 'HT' or the term 'Hybrid Technology' as a descriptor in the patents or publications preceding the application to release Varuna bn3.6, EH2 modbs 2.99 and DMH-11. From what I can tell, the Ministry is imposing a new and *post hoc* descriptor.

- I agree that the use of herbicide is a planned component of hybrid production. That makes the plant a herbicide tolerant plant.
- While it may be that the developer and the Government do not intend glufosinate-based herbicides to be used with this crop plant by farmers, I disagree that such hopes are relevant to its being a herbicide tolerant plant. Even the Ministry qualifies that *"as on date no herbicide has been approved"* (emphasis added) indicating that the status could change.
- It is <u>not</u> evident that the application pertains to the development of GE mustard hybridization technology, but to herbicide tolerant and/or male sterile varieties that may be used in conjunction with hybridization technology. No other claim, and certainly not the assertion made by the Ministry, has been made in the historical patent documents or publications that I have reviewed.

Evidence of the GEAC Sub-Committee (02/02/2016 to 01/11/2016)

7.5 The recommendation not to use Basta in farmers' fields is governed by the fact that the Central Insecticide Board and Registration Committee (CIB&RC) *"does not approve herbicide glufosinate as a weedicide <u>today</u>"* (emphasis added). *"<u>In view of the above</u> the GEAC may consider providing directives for not permitting commercial use of glufosinate, <u>unless otherwise</u> approved for such use through the safety assessment processes and procedures of the CIB &RC";* (emphasis added) [*See* **Pr**. **5.3** | Annex. A-3] True copy of the GEAC Sub-Committee Recommendations is herewith as **ANNEXURE A-3 (Page Nos. 87 to 104)**.

7.6 It is clear from the above evidence that the decision to legislate against the use of Basta by farmers for weed control is driven

purely by the current impasse of its illegality as a herbicide and is purely *pro tem*. The riders attached to the *'directive'* not to use, which circumscribe its use, such as *"today"* and *"unless otherwise approved*" bring great clarity to the intentions of the regulatory body. Quite apart from the gross lack of ethical conduct in putting the burden of its own actions (of commercialising an HT crop resistant to an illegal herbicide, i.e. *glufosinate*), on to farmers, the clear intent is to introduce HT crops into Indian agri., with HT DMH-11 blazing the trail for their introduction. This is clear from the fact that Petitioners' Contempt Petition covers large-scale trials of 2 other HT crops, HT corn and HT cotton (stacked genes). HT crops are proven to be an unsustainable technology [*See* **Pr. 11** below] and is recommended by the TEC to be banned [*See* **Pr. 6** above].

7.7 Notwithstanding the above, it is simply impractical even if the intention were there, to ban the use of Basta in farmers' fields. There are proven cases of non-compliance within GMO regulation of illegal *Bt*. cotton imports and trials that by-passed statutory approval by the GEAC [*See* W.P.(C) No. 71 of 1999 filed by Research Foundation for Science, Technology and Ecology; HT cotton BG II RR Flex cotton which has been planted widely in many States over the last 10 years, [*See* **Pr. 6** | Written Submissions (2014)]; the common knowledge of illegal use of pesticides and herbicides used by farmers (eg Monsanto's glyphosate, which is only allowed for tea and non-crop areas) etc. This kind of control is impossible anywhere including in the US (for instance, the recent of Dicamba (Soybeans) referred by Prof. Heinemann | *See* **Annex**. **A-2**) and is virtually impossible in India. As such, any undertaking from the Central Government is entirely insufficient for the added reason that 'agriculture' is a State subject as under List II to the Seventh Schedule. Action to control illegalities must be implemented at the State level; even in the few examples cited they have not proved implementable.

8. **OPEN FIELD TRIALS OF HT MUSTARD DMH 11 ARE SCIENTIFICALLY INVALID; THE LACK OF YIELD SUPERIORITY OVER NON-GMO CULTIVARS IS ADMITTED AND THE IMPLIED SUPERIORITY OVER NON-GMO CMS TECHNOLOGY IN HYBRID-MAKING IS UNTRUE.**

8.1 At the outset, it must be stated that any GM mustard, and even more an HT GM mustard, should not have been considered at all for field trials by a conscionable Regulator because it flags the intent to commercialise the crop. This mustard is barred by the TEC Report on two grounds of being (a) an HT crop and (b) a crop of genetic diversity, with a rich germplasm in mustard (NBPGR). Several countries do not allow GMOs in crops where they are a centre of diversity/origin. India will be contaminated. This is certain with a commercialised GM crop.

8.2 At this juncture, the Petitioners, briefly, sum up the submissions made in I.A. No. 47:

- **Need' as the first priority of a GMO assessment**: Is the GMO needed in the first place? Yield is one component (among others), based on Non-GMO comparators, as a starting point of analyses, or else, why would a hazardous GMO even be considered?
- **Invalid field trials. Norms flouted:** All India Co-ordinated Research Protocols of Rape-Mustard (AICRP-RM) trials co-ordinated by India's Apex institute the DRMR (Directorate of Rape-seed Mustard Research) attempt to implement tried and tested norms for selection of varieties/hybrids for *stability and performance* in farmers' fields. Respondents have stated in various documents that these are exactly the requirements for testing GMOs. At Pr. 5.2 of the GEAC Sub-Committee Recommendations (Annex. A-3), the Department of Agriculture Co-operation and Farmers' Welfare ('**DAC&FW**') has recommended a mechanism for GE crops and GM mustard in particular on

the lines of the AICRP varietal system as a post release requirement, thereby, admitting the lack of rigorous norms applied so far. BRL Trials are reduced norms in GMO field trials. GMOs must be tested to the most rigorous norms not less for proper assessment of the GMO, in this case HT DMH-11.

- **The 2006-07 trial** was a pivotal test of 'need' as the priority assessment of DMH 11. DMH 11 was out-yielded by DMH 1 and about level with Kranti. There was no 'mandated comparator'. It should have ended there. Yet, it was approved for the next stage of BRL trials, (BRL I (2years) and thereafter, BRLII (1 year)), without justification. The subsequent BRL trials had no hybrids at all and the varietal NC Kranti was also dropped.
- **HT DMH 11 BRL trials I &II:** These trials were a regulatory hoax; norms were comprehensively flouted, which meant that MSY data (mean seed yield) had no merit, statistically valid conclusions of performance/yield were impossible
- HT DMH 11 is a hybrid and must be tested against a hybrid/s.

In the above context, the Petitioners deal with the assertions made in the additional affidavits.

8.3 **Hybrid Yield (heterosis) of DMH-11:** The Union of India itself, has flagged the issue of superior yield of HT DMH-11 and continues to do so in the referenced Affidavits above, despite their admission accepting that this is not so (see below) thereby, endorsing the criteria of 'Need' as the first step in assessing HT DMH 11. Therefore, the lack of rigour and validity of the OFT (open field trials) in 2006-07 and subsequent BRL I & II trials (ending in 2014-15), the penultimate stage before commercial approval may be given for a GMO according to the amended and diluted 1989 Rules and exposed in I.A. No. 47, are crucial to these analyses. The present application and the rejoinder filed by the Petitioners record the flawed process that

allowed HT DMH 11 t to continue into BRL trials and the lack of validity of the field trials themselves. A summary of IA 47 dated NIL is annexed herewith as **ANNEXURE A-4 (Page Nos. 105 to 117)**.

8.4 The Respondents at Pr. 15 and 16 of the Add. Affidavit(***II***) reiterate their claim that "*the production of mustard will be substantially enhanced with the help of hybrids like DMH 11 and unlimited large number of other possible hybrids that can be developed using this hybrid production system"* and that *"with the increase of production of mustard due to hybrids developed using GM technology, there would be substantial savings in foreign exchange"* (currently edible oil imports of Rs. 67,000 crores). Confronted by the evidence in I.A. No. 47 of the yield superiority of India's Non-GMO cultivars both hybrids and varieties, Respondents, in their Reply to I.A. No. 47 were forced to admit that the 3 transgenes in DMH 11 (bar, barnase, barstar) had no trait for yield and that ***"****No such claim has been made in any of the submitted documents that DMH 11 out-performs Non-GMO hybrids. The comparison has only been made between hybrid DMH 11, NC (national Check) Varuna and the appropriate ZC (zonal checks) --- MSY of 2670 Kg/ha has been recorded over three years of BRL trials which is 28% and 37% more than the NC & ZC respectively".* [*See* **Pr. 88 at Pg. 55-56** | Reply Affidavit in I.A. No. 47] Therefore, there is no rationale for the opposite claim that HT DMH 11 is a superior yielding hybrid, but now the claim is the potential to create higher yield through heterosis (hybrid vigour) over parents.

NOTE: The yield comparison with parental lines where yields were superior does not establish the potential to create higher yields and it is misleading of the Union of India and Developers to suggest that it does. The developer has not established that yield gains from heterosis are a guaranteed outcome of the modification; he has not tried to even do limited crosses with modern high yielding varieties, to provide prima facie evidence

that the events have not caused a reduction in performance compared to the isogenic non-transgenic hybrid. Having not done this, or having done this but not reported the data, misleads this Hon'ble Court about the veracity of the claimed benefit. So no benefit has been demonstrated and potential harms have been ignored.

8.4 **The Mandated Comparator VEH2-F1**: Testing against the *'mandated comparator'* in this case is at the very heart of the analyses of the performance of a GMO. The 'mandated' Comparator for field trials of DMH-11 is ***VEH2-F1'*** (i.e. the Non-GMO cross of the parent lines Varuna x EH-2, whether CMS technology or hand- made). The failure to test against ***VEH2-F1*** in any of the field trials marks these trials as invalid based on this criteria alone. Since that testing was also not done, the claims of the Union of India above have no basis in science.

9. THE HYBRID NON-GMO 'COMPARATOR' 'VEH2-F1' WAS THE 'MANDATED COMPARATOR' FOR DMH 11

9.1 The Union of India has placed reliance on a document AFES Report. At Pg. 76-77 of the AFES Report, VEH 2-F1 has been described as the hand-made hybrid of Non-GE Varuna x EH2, and the Non-GE counterpart of GE DMH-11. The Respondents make the following admissions in their Reply Affidavit to I.A. No. 47 and make the unequivocal case for the 'mandated comparator' which was ignored in all the open field trials:

- **At Pr. 84: The thrust is:** "to *test "performance of target traits --- and productivity as prescribed of a GE entry for its similarity to its 'near- ISOGENIC parental genotype",* and
- **At Pr. 85:** *"the most important objective of BRL I&II trials is to stablish equivalence of the GE lines and their comparators-Non-GE near isogenic parents."---*

Note: The idea of a 'comparative' risk assessment is that when one examines the near isogenic parental line that has been grown side by side in the same conditions over multiple years to the GM line, one can identify unintended DIFFERENCES. These differences can then be investigated for potential to cause harm. The basis of the comparative assessment is that the differences will be genetic when the environments are the same, so the comparator must be near isogenic so that only changes to the genes caused by the engineering will produce differences between the plants. To establish a yield benefit, it could be argued that the benefit must exceed what is already available and that evidence has not been generated by the developer.

- **Heterosis or hybrid vigour:** the innovation in male sterility allows it to be used more easily in already existing hybridization technology. It is true of the barnase system in GM DMH-11 or Non-GMO CMS (cytoplasmic male sterility) systems (there are many variants). Hybrid vigour (heterosis in hybrids, over parental lines) is achieved through both these methods as also hand hand-made hybrids. Studies have shown ranges from 25% to even 100% [*See* Singh, Naveen, et. al., at **Table 5** | Annex. A-5] and is also supported by the statement of leading mustard breeder [Annex. A-6] below demonstrates the potential of hybrid vigour in Non-GMO CMS systems, the full range of which remains unexploited. True copy of the article published in Indian Journal of Agricultural Sciences (Vol. 85, Issue 4) in April 2015 is annexed herewith as **ANNEXURE A-5 (Page Nos. 118 to 123)**. True copy of the expert opinion of Dr. S. E. Pawar, dated 10.09.2017, is annexed herewith as **ANNEXURE A-6 (Page Nos. 124 to 125)**.

- Therefore, this conventional *'pollination control'* technology employing male sterility, 'CMS (cytoplasmic male sterility) is available for exactly the same purpose as that of 'GM-barnase-barstar'.

- **Understanding Heterosis**: It "appears that there is not a single, simple explanation for heterosis. Instead, it is likely that heterosis arises in crosses between genetically distinct individuals as a result of a diversity of mechanisms. Heterosis generally results from the action of multiple loci, and different loci affect heterosis for different traits and in different" [*See* Annual Review of Plant Biology: Vol: 64: 71-88 (Apr. 2013)]

9.2 **Mandated Comparator**: In the case of HT DMH 11, which is a hybrid, the mandated comparator is the Non-GMO hybrid, (handmade, CMS or other), **'VEH-2F1'** (the Non-GMO cross of the varietal parent lines Varuna x EH-2). Without this comparison, and this alone, it is scientifically invalid to claim superior yield against parental lines as the Respondents have done of 28% and 37%. [*See* **Pr. 8** above] It is even more unscientific to then infer as the Respondents have done, that on this basis future (GM) HT variants will similarly demonstrate hybrid vigour or heterosis at similar levels. The claim and justification of DMH-11 is wrong in science and cannot be made. This Hon'ble Court has been seriously misled and the consequences for India are dire. Petitioners offer the following additional refutation based on the facts:

- **Non-GMO CMS Hybrid DMH-1:** CMS hybrid DMH-1 is now a National Check (released in 2008). It was developed by DUSC (Delhi University South Campus) using Non-GMO CMS technology. In his research paper published in 2006 (Theor Appl Genet (2006) 114:93–99; DOI 10.1007/s00122-006-0413-0), Prof. Pental claimed that the CMS based non-GM *"B. juncea hybrid (DMH-1) developed with '126-1' cytoplasm has given around **30% heterosis** over the best national and regional checks in multi-site trials conducted in the north-western states of India where mustard is grown extensively during the winter growing season."* Further, Pental also claimed that *"As the*

male sterile lines with '126-1' cytoplasm are stable both under long day and short day conditions, CMS '126-1' besides its use in India may also be of value in developing B. juncea hybrids for regions where B. juncea is grown in the summer season."

NOTE 1: DMH-1 provided hybrid vigour according to its Developers of 30% against our best national and regional checks. It out-yielded HT DMH 11 in 2006-07 (the only field trials where it was a 'comparator') by the 10% norm. The point is simple: what then is the advantage that the Regulators are pushing? There is none. DMH 1 a CMS technology employing male sterility is better than HT DMH 11 (employing Barnase-Barstar) at delivering heterosis based on this field trial.

NOTE 2: Was CMS DMH dropped as a hybrid comparator from the subsequent BRL trials for the above reason?

NOTE 3: Non-GMO CMS is considered by the DRMR as a good conventional technology. Hybrids in the ICAR system of AICRP-RM, are held to the higher criteria for selection that they must also provide superior yield of 10% (which is the 'norm') over the best National and Zonal checks (hybrids/varieties).

Therefore, there is no case to be made for the presumed potential of HT DMH-11 and its HT parental lines**,** to offer superior yield to Non-GMO CMS systems to 'facilitate' better hybrid-making. But on the above evidence of DMH-1, CMS is the better system.

9.3 **Mandated Comparator - The Case of Monsanto's High Lysine Corn LY038):** In a similar case, the lack or failure to use a mandated comparator has a regulatory precedent in international protocols in Europe, where the Developer in this

case Monsanto, used the wrong comparator and was required to re-test using the correct comparator i.e. the Non-GMO Comparator corresponding to the product's (LY038) nearest isogenic line. Monsanto's high-lysine LY038 corn (intended as feed for animals) was approved as safe for human consumption in New Zealand in Dec. 2007 despite safety concerns from Canterbury University's Centre for Integrated Research in Biosafety (INBI), if it accidentally entered the human food chain. The application to have the high-lysine corn approved for use in Europe was withdrawn after the European Food Safety Authority ('**EFSA**') asked for further evidence of its safety. One of the questions to Renessen (the distributor) for LY038 was:

> *"The GMO Panel is of the opinion that a non-GM line with genetic background comparable to that of maize LY038 and a history of safe use should have been used as the non-GM counterpart in line with the EFSA Guidance Document (2006)".*

Monsanto used a GM product as its control, in contravention of international protocol. Rather than re-test, Monsanto withdrew its Application from EFSA citing reduced commercial interest, despite a Monsanto estimated street value of LY038 of US $1 billion/year. True copy of European Food Safety Authority (EFSA) letter dated 24.03.2009 to Renessen (distributors/Manager for Monsanto for LY038, is annexed herewith as **ANNEXURE A-7 (Page Nos. 126 to 128)**.

9.4 It is therefore submitted that all DMH-11 field trials starting with the 2006-07 trials excluded the mandated comparator VEH2-FI. In a step-by step regulation that is flagged as exemplary by the respondents, this is clear proof of a regulatory vacuum. HT DMH 11 should have been withdrawn in 2006-07.

Productivity of HT Rape in Canada & Indian Oilseed Stagnation

9.5 The statement made in Pr. 14 of the Add. Affidavit(***II***) on the productivity of HT rape in Canada is without supporting data, which largely reflects the quality of the claims made in Respondents Affidavit. At Pr. 15 & 16, likewise, simplistic statements are made on complex issues. Indian oilseeds production is a victim of India's trade policies/duties/exemptions etc., and domestic policy. On the other hand, it is quite clear that with no productivity edge over conventional mustard, and the male sterility technology provided by NON-GMO CMS systems, HT DMH 11 can have no impact on increasing mustard yields in Indian agriculture leave alone reducing India's edible oil-seeds imports.

10. CONCLUSION NOTE ON HT DMH 11 FIELD TRIALS

10.1 Despite such clear evidence of (a) the serious invalidity of the field trials of DMH-11 and its HT parental lines on several grounds including the failure to use the mandated comparator VEH2-F1; (b) the abject failure of regulation in the much acclaimed step-by step process; notwithstanding the above, (c) the failure of HT DMH-11 to provide superior yield against India's Non-GMO cultivars, varieties and hybrid, and admitted by the Respondents in their 'Reply Affidavit' and (d) the admission that the male sterility technology employed in DMH-11 (barnase-barstar combine) is not better than the CMS male sterility method and specifically the example of CMS DMH-1 to facilitate hybrid-making, the Regulators are nevertheless, pushing hard to commercialise HT DMH-11 and its HT parental lines without any scientific basis as follows.

At para 62, **Page 43 (Reply Affidavit to I.A. No. 47):** ***"****Once the GE mustard events Varuna bn 3.6 and EH2 modbs 2.99 are approved and <u>deregulated,</u> these would be immediately used by the National net-work programme".*

At para 63, **Page 43 (Reply Affidavit to I.A. No. 47):** *"Once a robust pollination control mechanism is in place, yield of hybrids can be further improved by breeding better parental lines".*

10.2 This Hon'ble Court is being seriously misled. The singular intent is to deregulate HT mustard. "B*reeding better parental lines*" has absolutely nothing to do with GM mustard. This is the job of the DRMR. What is clear however, is that the commercialisation of HT DMH 11 and its parental lines will put the important work being done in mustard of decades, by the DRMR and the AICRP-RP at risk because our mustard germplasm will be contaminated. This is the experience in Canada with HT rape. [*See* **Pr. 12.4** below]

11. BIOSAFETY HEALTH & THE PROVEN UNSUSTAINABILITY OF HT MUSTARD

11.1 In Pr. 11 of Add. Affidavit(***II***), the Union of India has claimed *"20 years of safe use"* of Canola in Canada and has sought to ascribe the same to HT DMH. The reference is to HT rape in Australia, Canada and the US. Based on the supposed safe use in these countries for 20 years, safety is presumed for HT mustard DMH-11 (described as a *'sister crop'*). Rape and mustard are different species. The lack of labelling in those countries does not allow post release epidemiological studies, so the statement of safety is entirely specious. Furthermore, the statement conveys that the regulators have not done the required biosafety testing of HT DMH-11 for health and the environment, but are relying instead on supposed safety-testing in other countries, that in fact does not exist. Both the US and Canada follow a voluntary system of safety disclosure. [*See* 'Safety Testing and Regulation of GE Foods' | **Annex. P-17 of Writ Petition**] The following evidence is clinching; voluntary disclosure by Developers and not independent biosafety regulation is undertaken by US Regulators. The text of the letter

from the US FDA to AgrEvo (now Bayer) for pre-market approval for Ms8/rf3 (HT rape) is extracted below:

> “This is in regard to AgrEvo's consultation on genetically modified canola that you initiated with the Agency on May 29, 1998, specifically transformation events MS8 and RF3. According to AgrEvo, the canola line MS8 has been modified to express the male sterile gene (barnase) and the herbicide glufosinate-ammonium resistance gene (bar). MS8 is used to produce F1 hybrids. The canola line RF3 has been modified to contain the fertility restorer gene (barstar) and the herbicide glufosinate-ammonium resistance gene (bar). Upon crossing MS8 with RF3, the fertility of the oilseed rape progeny will be restored. The use of these two lines allows for the production of seed that is 100% hybrid, 100% fertile, and 100% glufosinate tolerant. You submitted a summary of your safety and nutritional assessment of the AgrEvo hybrid canola containing transformation events MS8 and RF3. These communications informed FDA of the steps taken by AgrEvo to ensure that this product complies with those legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessment you have conducted, it is our understanding that AgrEvo has concluded that the canola lines are not materially different in composition, safety, or other relevant parameters from canola currently on the market, and that they do not raise issues that would require premarket review or approval of FDA. All materials relevant to this consultation have been placed in a file that has been designated BNF 0057 and will be maintained by the Office of Premarket Approval.

> Based on the information AgrEvo has presented to FDA, we have no further questions concerning the AgrEvo hybrid canola containing transformation events MS8 and RF3 at this time. However, as you are aware, it is AgrEvo's continued responsibility to ensure that foods the firm markets are safe, wholesome, and in compliance with all applicable legal and regulatory requirements".
>
> [*See* "The copy of the FDA's 'List of Completed Consultation on Bioengineered foods'; and the FDA's Response Letter to Vickie Foster of AgrEvo USA Company | **Annex. P-2 of Reply Affidavit in I.A. No. 5 (Nov. 2006)**]

11.2 **Proven unsustainability of HT crops:** HT DMH-11 is also an HT (herbicide tolerant) crop that confers resistance to glufosinate ammonium. HT crops are proven to be an unsustainable agri- technology in the US based on US data of more than 20 years of commercial planting (USDA data 2012: ref WS of April 2014 para 15 and Annexure M7, Vol 12). This is a failed technology which spawns super weeds, higher herbicide use and no added performance yield.

- **Super weeds**: HT crops have caused the emergence of some 60 MILLION ACRES or about 25% of US cropland (TEC) of 'super' weeds resistant to herbicides, doubling since 2010 or about 50% of crop area sown to herbicides.
- **Costs to farmers** of weed control have increased by some estimates, by 100%, seed prices have gone up 3 times (from 1996).
- **US data of herbicide use**, (ref. WS 2014 pt. 19 pg. 29): Overall herbicide use (US Geological Survey), has increased more than 10 fold, from 20 million pounds/year (prior to GE crops in 1992) to 280 million pounds/year by 2012 largely as a result of GE crops, or 527million pounds

more total herbicide was used in the US during this period (1992-2012) due to commercialised herbicide-resistant crops. The combined onslaught is putting US farmers out of business as they struggle with losses on a substantial scale.

- **HT crops are designed for monoculture**. They are completely unsuited to Indian small-holder farming that will harm small and marginal farmers' crops and 'jari-booti' herbs and plants, used in many Ayurvedic medicines, because of herbicide drift. It will also uniquely impact the employment of women in weeding (MS Swaminathan Task force 2004).
- **HT crops are pesticidal crops**. They should be tested as pesticidal crops but are not. The sprays include surfactants that force both weeds and the HT crop to absorb significant quantities of the herbicide that is sprayed on them. The resistant crop stands. Everything else dies including non-target organisms.

11.3 **Glufosinate Biosafety:** In the aftermath of the IARC Report (July 2015) (International Agency for Research on Cancer of the WHO), categorising Monsanto's 80% brand leader Glyphosate, (considered the safest herbicide in the world) as a *"Probable human carcinogen*" and *"sufficiently demonstrated for genotoxicity* (damage to DNA) *in animals*" (Group 2A, its second highest categorisation, ref Additional Affidavit of 2015, Annexure P-3), California's EPA has labelled 'Roundup' (active ingredient glyphosate), as a '*known human carcinogen'* under the State's Proposition 65. *"The state based its decision on the findings of the world's most reliable, transparent and science-based assessment of glyphosate", (*i.e. the IARC Report). True copy of the article dated 30.03.2017 by GM Watch titled 'California EPA becomes the first US agency to declare that Roundup causes cancer' is annexed herewith as **ANNEXURE A-8 (Page No. 129)**.

11.4 Glufosinate (like glyphosate) is a systemic, broad spectrum, non-selective herbicide (because it kills indiscriminately, soil

organisms, beneficial insects etc). It is an acknowledged neurotoxin (causes nerve damage) and birth defects and is damaging to most plants that it comes into contact with. The US Environmental Protection Agency (US EPA) classifies glufosinate ammonium as *'persistent'* and *'mobile'.* Studies demonstrate that it causes adverse health effects in animal studies, is likely to leach into drinking water sources, could increase nitrate leaching, and is toxic to beneficial soil micro-organisms. The US EPA has stated that glufosinate is *"expected to adversely affect non-target terrestrial plant species".* It is banned in Europe and not permitted in India, under the Insecticide Act for mustard. It is an organophosphorus compound (toxic to biology) very similar in structure to glyphosate. Glufosinate *" 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. As weeds become more resistant (they will eventually be resistant to all known herbicides)*". Bayer's data sheet confirms its status as a neurotoxin. True copy of Material Data Sheet for Basta® (Glufosinate), dated 15.04.2011, issued by Bayer CropScience is annexed herewith as **ANNEXURE A-9 (Page Nos. 130 to 135)**.

11.5 The TEC for the above reasons requires a ban on crops of origin/diversity, as well as HT crops. Therefore, HT DMH 11 is doubly barred under the TEC recommendations. The response to these issues by the Respondents was to (a) initially deny that India was a centre of origin/diversity of mustard, but which, in the face of incontrovertible evidence of this fact, does not find mention in the current Affidavit referenced; (b) that DMH 11 is not an HT crop and that HT is an acronym for '*hybrid technology'*.

12. **GM MUSTARD WILL CONTAMINATE INDIA'S MUSTARD GERMPLASM IRREVERSIBLY: THE GOVERNMENT'S UNCONCERN IS UNPRECEDENTED AND UNCOSCIONABLE**

12.1 **Environment –Contamination**: Mustard like rape more than other crops, has particular potential for wide dispersal through gene flow, insect mediated and wind, (because of its *"small seed size and sticky pollen which insects love"* - Bayer). Contamination of the natural and agri environment is the outstanding concern with GMOs, because these self-replicating organism cannot be recalled. India is a centre of diversity/domestication of mustard. This fact requires an outright ban on any GM mustard. Many countries, which are a centre of origin/diversity of crop plants do not for this reason allow GMOs in such crops.

12.2 **NBPGR**: According to the National Bureau of Plant Genetic Resources (NBPGR) *"India possesses rich diversity of oilseed brassicas. Brassica rapa var. toria, B. rapa var. brown sarson and B. juncea considered to be native of Indian gene centre (Arora, 1988)".* India's gene banks have 5477 Brassica juncea ('Indian Mustard') Accessions.

12.3 **Biological diversity** is vital for future agricultural resilience and particularly in an era of Climate Change and for our food security. GM crops are not *'climate friendly'*. The fact is that GE crops themselves must rely on Nature's genetic diversity to supply what is required in traits of parental lines to meet new problems and diseases like for example, drought, pest or saline resistance, in which it is so far unsuccessful. GE is an extraordinarily bad manifestation of industrial agriculture, -- -- "*for which we are paying a huge price in the long term. India could do the smart thing for farmers, the environment and food quality by using ecologically sophisticated breeding and agro-ecology instead of getting trapped in the problems the US is*

facing". dozens of traits have been successfully launched using conventional and high-tech-conventional breeding techniques such as marker assisted selection or MAS" "Conventional breeding outperforms GMO hands down" (Doug Gurian-Sherman). [*See* **Annex. C-39** | Written Submissions (2008)]

The Evidence of Contamination

12.4 HT Mustard like rape more than other crops, has particular potential for wide dispersal through gene flow, insect mediated and wind, (because of its *"small seed size and sticky pollen which insects love"* - Bayer). [*See* Respondent' Affidavit (2006) at Pg. 90] Conclusive evidence is presented with regard to the fact that Canada's certified Non-GM seed stock is pervasively contaminated. Key evidence in various earlier submissions is provided below to underscore the risk of contamination even from single small-scale field trials. Contamination from a commercialised crop is certain as the Canadian experience proves of the contamination of Canadian Non-GMO rape (Brassica species, which includes Indian mustard B juncea),

(a) **Bayer Rice LL 601 (herbicide glufosinate)**: The contamination from field trials in 2001 of Bayer Rice LL601 has particular relevance to mustard. Rice is *self-pollinating*. Indian mustard, brassica juncea, by contrast, out-crosses "pretty well", up to 18%, (AFES report, some estimates put this higher). Yet despite containment measures that went well beyond the regulated requirement (rice is self-pollinating), extensive contamination was discovered five years later through active testing by a certified European lab to a LOD (level of Detection) of 0.01%. [Ref. **Annex. W-9 (Colly) of *Volume-XXXIII***] The case of contamination by Bayer long grain rice LL601 remains an exemplary example of the disaster that can occur from *a single field* test. *The US LL601 Bayer long grain rice contamination incident (along with other varieties of rice) shut down US exports*

and caused in excess of $ 2 billion in export losses to farmers, which occurred as a result of a *single field test* by Louisiana University in 2001, despite extended caution and rigour in conducting the test. The field *test exceeded the recommended minimum isolation distance.*

(b) Ref Para 13 (respondents Affidavit): Isolation distances are frequently wrong/ ineffective. The evidence further demonstrates that contamination incidents worldwide are proven over several miles. Isolation distances as prescribed even when exceeded and stringently followed, have been proved repeatedly wrong; gene flow does not tail off to zero, but flattens out for larger additional distances *('leptokurtic' pollen distributions).* Contamination even beyond these longer distances does not end there; pollen flows beyond these distances level off at low amounts, for unknown distances. By the time contamination is discovered even by newer methods, the fact of contamination has happened. It is too late. **(Annexure C 14 at pages 92 to 93 *of WS of February 2008*)**.

(c) **Centre of origin/diversity: Indian Rice Exports and contamination:** India is a centre of origin for rice. In its 75th meeting of March 2007, the GEAC, at the instance of the basmati rice exporters and the Ministry of Commerce, decided *not to allow field trials of GM rice in the basmati growing areas of the country, because of the threat of contamination* ***(Annexure C 15 at pages 94 to 98 of WS of February 2008)***. The 81st Meeting of the GEAC held on 22nd November 2007 records **(Annexure C 16 at pages 99 to 104 *of WS of February 2008*)** that APEDA (Agricultural and Processed Food Products Export Development Authority) has requested a certificate stating that no GM rice, groundnut and sesame seeds have been permitted in India. The request had been

made because of a ban imposed by Russia on these crops, fearing GM contamination.

(d) **Rape contamination in Canada**: Bayer's own admission supports the contamination risk through rape (Respondents' Affidavit (2006) at Pg. 90, 9.a). Bayer says: "*oilseed rape is a crop capable of undergoing both self- pollination (70%) as well as cross-pollination (30%). The pollen which is heavy and sticky can be transferred from plant to plant through physical contact between neighbouring plants and by wind and insects -- in particular honey bees and bumble bees play a major role in B. napus pollination".* Friesen, Nelson and Van Acker in the University of Manitoba in Winnipeg, Manitoba, Canada, studied certified canola seed stocks for contamination due to transgenes for herbicide tolerance to glyphosate, glufosinate or thifensulfuron. *Certified seed stocks* were studied in field plots to which herbicides were applied. "*The results showed that 95%* of 27 certified seed lots were *contaminated with herbicide tolerance transgenes*; with *52% of the seed lots exceeding the 0.25% maximum contamination standard set for certified seed.* Some lots were tolerant to *both glyphosate and glufosinate*.

The extensive contamination of certified canola seed with transgenes for herbicide tolerance is staggering". The Canadian canola crop extends over some 5 million hectares, of which roughly 60% are planted with transgenic varieties. *It now seems unlikely that transgene- free canola can be produced in western Canada*. Canola seed growers no longer guarantee their seed as GM-free. Organic grain farmers in the Prairies largely stopped growing canola due to high levels of GM contamination.

- **Over 97%** of canola grown in Canada is now GM.

- **Studies** have found that canola pollen can travel nearly 3 km.
- **Contamination within 7 years**: Contamination from GM canola reached such an early high point in Canada that, by 2002, most, if not all, pedigreed seed growers in Saskatchewan could not guarantee their canola seed stocks as GM-free.
- The case of HT Rape (canola) shows that the seed industry was unable to prevent contamination, even with the pedigreed seed sector's strict varietal purity management control systems and the economic incentive to ensure that these controls work. If professional seed growers cannot avoid the unintended presence of GM in their seed, it is not reasonable to expect the general population of farmers to succeed in containing GM seed. And what will Indian farmers do about HT DMH 11and its HT variants?

True copy of the article 'GM Canola Contamination in Canada. Canadian Biotechnology Action Network, 23.04.2015 is annexed herewith as **ANNEXURE A-10 (Page Nos. 136 to 137)**.

13. **UNION OF INDIA'S AFFIDAVIT: A 2-STAGE COMMERCIALISATION PLAN FOR HT DMH 11 AND ITS HT VARIANTS**

13.1 The Affidavits are presented as an innocuous plan to plant *"only 15 kg"* of HT DMH 11 hybrid seed and some more seed as well (ref para 21). Petitioners reiterate, that HT DMH 11 should not have been considered at all for any kind of field testing the purpose of which, is eventual commercialisation. In the case of Bt brinjal, contamination concerns were thoroughly ignored. India faces the same crisis now with GM mustard. This indicates a disregard for India's priceless biodiversity, a heritage that we must ferociously guard and also status as a biodiversity 'hot spot'. Both PSCs have focussed on this issue. But lip service is

paid to the certain contamination of India's germplasm from HT DMH 11. This is outstanding issue that Petitioners emphasise repeatedly, because it is critical. If the GM 'genie' escapes, it cannot be bottled again.

13.2 **Seeking authorisation for 'Creeping Commercialisation 'of HT DMH 11 and its HT parents in 2 stages at para 21 of the Affidavit:** The essential plan of the Respondents is encapsulated in para 21 of the Affidavit of the 28th July. It amounts to, in effect, a request to this Hon'ble Court to allow planting for '*limited commercial release'* of 15 kg of DMH 11 which will involve an approximate area of 15 hectares (Petitioner's assessment). This is for the *"purpose of cultivation"* and "*demonstration";* therefore:

(i) These *"demonstrations*" are in farmers' fields, but this is not stated straightforwardly. Therefore, the produce will be eaten. There are serious biosafety implications here (Ref. Pr. 11 above). Furthermore, the inserts are toxic genes. Our regulators do not require long term testing for chronic toxicity, nor testing for endocrine disruption (hormones). The biosafety dossier is hidden. The biosafety implications are profoundly disturbing.

(ii) Since HT DMH 11 in field testing failed the priority test of 'Need', (it does not out-yield our best Non-GMO cultivars both varieties and CMS hybrids, and this is admitted, and it does not prove that male sterility through the GM barnase-Barstar system is superior to the Non-GMO pollination control CMS system), where is the question of demonstrating the *"yield potential and thereby commercial viability of hybrid DMH 11"*? In reality, the ruse is to obtain the authorisation of this Hon'ble Court now, to *'creeping commercialisation'* which will be undertaken in2 stages. This first stage, (limited to 15 kg of seed), will be the back-door entry to eventual full commercial release sometime in

the future, when there is sufficient seed produced from this first stage (ref. (ii) below) for full commercial planting. But seed production poses great danger for contamination. .

(iii) **Plan for Seed Production (ref 21 (ii)**: The Respondents also disclose at 21 (ii) that there is further stock of seed available of HT Parental Lines (it is not known what quantity nor many HT parental lines), which they plan to plant to produce more hybrid seed. By this means, the plan is to produce enough seed to be ready for a full-scale commercial launch at a time of their choosing, whether in 1 year from now or 2 years. Seed production is highly risky for contamination. It is emphasised that the Contempt Petition for flouting this Hon'ble Court Orders of *"No Contamination*" were because of large-scale field trials undertaken in 2014-15.

14. **CONCLUSIONS**

14.1 The outstanding concern is the certain contamination of India's rich mustard germplasm of 5477 mustard (*Brassica juncea*) accessions (NBPGR) if DMH 11 is commercialised. This GM mustard is also an HT mustard, i.e. HT DMH 11 and it is liable to be banned in view of the TEC Report on two grounds of it being a HT GMO and a crop of origin /diversity (mustard). It should never have been considered as a candidate for even open field trials, let alone commercialisation. The step-by step process of regulation of DMH 11 is conspicuous by its absence as is rigour. The field trials were seriously invalid, because of norms flouted, invalid comparators, no hybrid comparators with the single exception of the field trials of 2006-07, in which CMS (Non-GMO) hybrid DMH1 was a comparator and out-yielded DMH 11; yet hybrid must be compared with hybrid. Moreover, the failure to use the mandated comparator VEH2-F1 meant that HT DMH 11 should have been withdrawn. In 2006-07, DMH

11 failed the priority test of 'need', and it should have ended there in 2006-07. Most anything is contrived by the Respondents to eliminate the evidence no matter how absurd i.e.: DMH 11 is not an HT crop and the post hoc 'descriptor' that HT is an acronym for *'hybrid technology'*. Deeply flawed approvals, even collusion, has brought the country to an impossible criticality. HT DMH 11 has been approved for commercialisation by the GEAC despite the admission by the U of I that it does not out-yield our best conventional cultivars (hybrids and varieties). The Affidavit of the Union of India outlines a plan to plant 15 kg of seed of HT mustard DMH 11 and more seed of parental lines which amounts to a 2- stage process of *'creeping commercialisation'* presented as an innocuous plan. We face certain contamination if authorised.

14.2 **Conflict of interest**: (ref para 17 of the Respondents Affidavit and Para 5 of Petitioners Application IA 47): It is admitted that the DBT is active partner, funder and developer in HT DMH 11. The DBT houses the regulators, the RCGM. The MoA, Min. of Science and Technology and even the MoEF &CC (houses the GEAC) promotes GM crops. The NDDB has now pulled out of this partnership and funding of HT Mustard DHM 11. Therefore, the regulators and institutions of GMO governance are heavily invested, materially and intellectually in this venture and then regulate it. Several individual members of the GEAC and half the GEAC Sub-Committee are likewise conflicted. It explains the extraordinary approvals given to this GM mustard and in the face of failing key regulatory criteria. 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 was involved in the regulatory oversight of Bt brinjal. It is clear from the regulatory processes followed for HT DMH 11 and the 11 year dismal regulatory history recorded in this PIL, with independent corroboration of 5 official reports, that GMO regulation in India is a 'Post-Truth' phenomenon.

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

A. Direct a prohibition on the 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 a prohibition on open field trials

D. Direct the Respondents to implement the recommendations of the TEC Report;

E. Direct the constitution of an inquiry to inquire and submit a report on the field trials and application process of HT Mustard DMH 11; and

F. Issue such other directions or orders that this Hon'ble Court may deem fit and proper.

DEPONENT

VERIFICATION

I, the above named deponent, do hereby verify that the contents of above are true to my knowledge based on information received and believed to be true. No part of the same is false and nothing material has been concealed there from.

Verified on this 9th day of September, 2017 at New Delhi.

DEPONENT