

IN THE SUPREME COURT OF INDIA

CIVIL ORIGINAL JURISDICTION

I.A. NO. OF 2018

IN

WRIT PETITION (CIVIL) NO. 260 OF 2005

IN THE MATTER OF:-

Aruna Rodrigues & Others ... Petitioners

Versus

Union of India & Others ... Respondents

**APPLICATION FOR DIRECTIONS REGARDING
ILLEGAL GMO IMPORTS & CULTIVATION**

PAPER BOOK

NIKHIL NAYYAR
ADVOCATE ON RECORD

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To,

Hon'ble the Chief Justice of India and
His Companion Judges of the
Supreme Court of India

MOST RESPECTFULLY SHOWETH:

1. The captioned Writ Petition, *inter alia*, seeks a moratorium on the environmental release of any genetically modified, living modified organisms ('GMOs' or 'LMOs') in the absence of (a) comprehensive, transparent and rigorous biosafety protocols; (b) biosafety studies conducted by independent expert bodies; and (c) access to biosafety protocols and data in the public domain. As an ad-interim measure, the Petitioners have also prayed "*for a ban on the import of any biological organism, food or animal feed unless they*

have been certified and labelled to be GM-free by the exporting Country.”(emphasis added) [See **I.A. No. 1 of 2005**] The Petitioners submit that a moratorium and such specific labelling for No-GMO content are concurrent requirements to avoid contamination of the environment and sexually compatible species that are vital for maintaining integrity of agriculture and food safety. While India requires labelling by law for GMO content, Petitioners challenge any relaxation to allow any GMO content what-so-ever; there must be zero tolerance for GMO content in imports.

2. The present Application is being filed because unauthorised viable seed of Herbicide Tolerant (**HT**) Soy and viable seed in other GM food products are being imported into India, unchecked; as also the illegal cultivation of HT (GM) soy in Gujarat, which is being allowed/condoned/ignored. The import of viable GMO seeds (which are Living Modified Organisms) and the cultivation of HT soy present a dire and irreversible biosecurity risk to India through the certain contamination in time, of her agriculture and this through the back-door, with grave and even unforeseeable consequences. The specific and immediate concern is India’s cultivation of non-GMO Soy. India is the only country currently, to *‘exclusively’* grow Non-GMO soy, meaning the there is no possibility of any contamination with GMO soy because the latter is not allowed to be cultivated. Thus far, the response from the Regulatory

bodies and other relevant authorities including the Director General of Foreign Trade ('DGFT') has been entirely cavalier and lackadaisical with blame being tossed around from one authority to the other. To this end, the Petitioners seek appropriate directions from this Hon'ble Court to mandate the Respondents to take swift and effective action to prohibit both the import of viable HT Soy and other viable GMO seeds, as well as the cultivation of HT Soy in Gujarat (before it spreads to other States) to prevent Indian agriculture and seeds from being irreversibly contaminated.

3. In addition, the present Application also draws attention to significant and serious health risks posed by illegal imports of GMOs in processed foods and GMO food products; viz., edible oils from countries like the United States, Brazil and Argentina derived from GM food crops such as Soy because in these countries, these food crops and their products are either mainly GM, or contaminated with GMOs. Today, 10 years later, the list of GMO-producing countries and their products has expanded to include for example, Canada from where India imports up to 2% of its edible oil, called GM canola oil which is GM rape seed oil. [See **Add. Affidavit dated 28.07.2017 in I.A. No. 47 of 2016**] Given the widespread use of GMOs in the exporting countries, the Indian authorities have failed to put in place a robust monitoring mechanism to prevent entry of GMOs in processed food.

4. The Ministry of Health & Family Welfare, which houses the FSSAI (Food Safety & Standards Authority of India), in their affidavit dated 24.05.2017 filed before this Hon'ble Court in W.P.(C) No. 173 of 2006, which is very clear on this matter, as follows: *"It is submitted that till date the Central Government has not notified any regulation under Section 22 of the Food Safety and Standards Act in regard to the manufacture, distribution, sale and import of GM foods. Hence, GM foods are not allowed in the Country and neither can be regulated till such notification is issued"*.

5. **GEAC illegally permits GMO imports as food/feed or in processed foods:** Yet, and to the contrary, ever since 2005 the Government of India has allowed vast quantities of imports of processed food products from the above countries/and others in contravention of the 1989 'Rules' framed under the Environment Protection Act, 1986. On 23rd August 2007, the GEAC even took the unprecedented step to issue a Notification (of the MoEF), through which imports of GMOs in processed food/feed would no longer be subject to its permission whereby imports were permitted without restrictions. Petitioners filed an Application. [**I.A. No. 20 of 2007**] Though this Notification was subsequently kept in abeyance until its expiry in March 2016, GMOs in processed foods were nevertheless imported without hindrance! The implications of this 'Notification' are

extraordinary. The Regulator thereby implicitly admits that in its own view, it is not responsible and accountable for the health impacts of GM Foods on the citizens of this nation. Yet, the enactment of the EPA of 1986 clearly sees that the health of the people is an integral part of the 'Environment' of India and is therefore part and parcel of the purpose of the Act. This is spelt out unambiguously in the 'preamble' and Chapter 2, DEFINITIONS (a) & (e).

6. Be that as it may, it is relevant to note that the MoEF has kept the notification dated 23.08.2007 in abeyance. Relevant excerpts from the affidavit filed by Ministry of Health and Family Welfare dated 24.05.2017 states that:

(iii) It is respectfully submitted that the Ministry of Environment thereafter vide SO 411 € dated 25 february 2008 notified that the notification SO 519 € dated 23rd August 2007 is kept in abeyance for a period of six months ie up to 30 Sept 2008 or until issue of further notification by the Min. of Health and Family Welfare (M of H&FW) regarding regulation of GM processed foods by the FSSAI, whichever is earlier. The notification dated 23.08.2007 was extended from time to time by the M of H&FW and finally up to 31-03.2016”.

(iv) ...the GEAC is responsible for risk assessment and approval of GM organism and products into the environment. As and when any GM food is approved by the GEAC, as per provision in the Section 22 of the FSS Act, 2006 FSSAI has the responsibility to regulate it. --- its manufacture, distribution, sale and import. However, since regulations in this regard have yet to be framed, it follows that GM food is not permitted to be sold in the country”.

7. This action by the GEAC demonstrated very clearly that:

- (a) It acted to provide legal cover for the thoroughly illegal trade in imports of GM processed foods including huge quantities of processed and crude soy oil that has now been going on for several years. It is a serious matter that the Regulator has also taken it upon itself in practise, to effectively abrogate its responsibility with regard to the health impacts of GM food, contravening the Rules of 1989 under the EPA of 1986.
- (b) India does not grow GM crops apart from Bt cotton. Allowing unrestricted imports of GM processed foods without a stringent and impartial testing regimen in place as prayed for, essentially means that

the Indian Government accepts the exporting country's bio-safety regulations including health safety concerning GM crops (food/feed), per se and in principle. This is of course dangerous for national health, a real and serious problem and clearly in error. As has already been pointed out, the US FDA regulation of GMOs is thoroughly weak and it does not approve any GM crop released on to the market as safe for human consumption. On the basis of this Notification then neither does the Indian Government. It therefore, ipso facto subjected our people to the notoriously weak and lax US GM regulation, including that of other countries like Argentina, Brazil and Canada, all of which are GMO producing nations.

- (c) In the absence of the required labelling mechanisms in place for 'No GMO Content', the GEAC, under the guise of legality, sought to deliberately allow the contamination of India's food chain with untested GMOs, thereby potentially endangering the health of Indians as also, denying and circumventing the right of the citizens of this country to make reasoned, free and informed food choices for nourishment and health.

However, as stated above, it subsequently transpired that the controversial Notification was kept in abeyance until its expiry on 31 March 2016. Therefore, the fact is that illegal imports of GMOs in processed foods and as GMO edible oils were 'allowed' and is currently continuing. India's food chain is illegally awash with GMOs in these products and in a vast range of foods. In this, the FSSAI has been fully complicit. It has failed miserably to check import of such products: *"there is no check on GM processed food coming from outside the Country or being produced here"* (the latter is a reference to cotton seed oil being awash in India's food chain --- Chair of the PSC on Agriculture 2012). True copy of article titled *Indians consuming imported GM-processed food, parliamentary panel says* published in Times of India dated 29.03.2014 is annexed herewith as **ANNEXURE A-1 (Page Nos. 69 to 71)**.

A. VIOLATION OF FOOD SAFETY REGULATIONS

8. The Food Safety and Standards Act, 2006 ('FSSA') prohibits manufacture, distribution, sale or import of any GMO products (i.e., food, dietary supplements, nutraceuticals, etc.) except in accordance with the regulations which the Central Government may notify. Section 22 of the said Act reads as below:

22. Genetically modified foods, organic foods, functional foods, proprietary foods, etc. - Save as otherwise provided under this Act and regulations made thereunder, no person shall manufacture, distribute, sell or import any novel food, genetically modified articles of food, irradiated food, organic foods, foods for special dietary uses, functional foods, nutraceuticals, health supplements, proprietary foods and such other articles of food which the Central Government may notify in this behalf.

Till date, however, no regulations have been notified so as to enable the Central Government to permit manufacture, import or sell GMO foods in accordance with Section 22 above. In this matter, The Parliamentary Standing Committee ('PSC') on Agriculture, in 2012, Para 7.60 (pg. 249), states:

“Surprisingly, however, the GM foods were not included when Section 22 was notified by the Government. The Ministry of Health and Family Welfare instead asked GEAC to continue regulating GM foods under Rule 11 of Rules 1989 by keeping the notification of 23 August, 2007 in abeyance for six months or until the Ministry of Health and Family Welfare notified regulation of GM processed food by FSSAI whichever was earlier. The Committee were

able to track five extensions of six months and a sixth one of one year up to September, 2011 but still the FSSAI regulation for GM processed food is nowhere in sight though so many years have gone by. Resultantly, there is no check on GM processed food and other items coming from outside the Country or being produced here viz. cottonseed oil produced from Bt. cotton in the Country. To compound this inaction further, now the Government seems to entrust this responsibility to the proposed BRAI. The Committee wonder when actually the regulation of GM food and products thereof will commence when BRAI itself is nowhere in sight. In the opinion of the Committee this dilly dallying and delay in bringing GM food and products, thereof, is not a simple act of oversight or a genuine inability to do the needful and needs to be thoroughly investigated and responsibility for this callous neglect of health safety be fixed at the earliest. The Committee would like to be apprised of the results of the investigation and the action taken in pursuance thereof'. (Emphasis added).

Therefore, as stated above, no exemptions under Section 22 have been notified till date. Therefore, the import of any GM food is entirely illegal.

9. **The FSSAI abrogates its responsibility in allowing GMOs in food/feed/processed foods:** Under Section 3 of the Food Safety and Standards (FSS) Act, 2006, *“food”* means *“any substance, whether processed, partially processed or unprocessed, which is intended for human consumption and includes genetically modified or engineered food or food containing such ingredients—.”* Clearly food or feed may not be toxic or allowed to be toxic. Yet, the FSSAI whose singular and exclusive mandate is food-safety, has by their *“callous neglect”* allowed (a) imports of GMOs in foods or as processed foods, without the required health-safety studies for allergenic reaction and long term toxicity/cancers etc., thereby, endangering public health. In doing so, it too has accepted safety regulations of such exporting countries, which as stated earlier, are essentially absent (USA/Argentina/Brazil/Canada); and (b) domestic Bt. cotton-seed oil and Bt. cotton seed cake (for animal feed), which are by-products of Indian Bt. cotton. (India has one GMO product namely Bt. cotton, which was introduced in 2002). These products too have illegally entered India’s food chain. They remain untested for their potential health hazards. Year after year, millions of tonnes of Bt cotton-seed oil are consumed; and are now an integral part of the food chain in India. For example, Bt. cotton-seed oil is mixed with other edible vegetable oils, which means that there is wide-spread contamination of cooking oil that further penetrates into other food products like pickles etc.,

all of it unlabelled and all of it with illegal GMO content. As worrying, is that cotton-seed cake used in animal feed particularly for milch cattle, is seriously implicated in toxic responses in cattle and a reduction in milk production. These have been the subject of particular Petitioner evidence in earlier submissions (of the last 12 years), to this Hon'ble Court. Secondary or 'stealth' GMO products mean that milk becomes specifically suspect. Even more worrying is the stream of other products, i.e., baby foods, ice creams, etc., that are derived from milk, all stealth GMO products, may be hazardous for health.

10. A recent study by the Centre for Science and the Environment ('CSE') tested 65 samples of processed foods with a view to detect presence of GMO ingredients. The findings of the study, published on 26.07.2018, revealed that:
 - i. 32% samples tested positive for GMO markers, including alarmingly infant food, and without labelling (manufactured by US pharma Company, Abbott Labs).
 - ii. "The partial good news is that the majority (80%) of the food samples that tested GMO positive were imported. India is still more or less GMO-free. The one food that did test positive is cottonseed edible oil

... This should worry us because no permission has ever been given for the use of GM cottonseed oil for human consumption. Second, cottonseed oil is mixed particularly in *Vanaspati* --.”

True copy of article titled *Vacuum in governance on genetically modified foods in India* published in Down To Earth dated 02.08.2016 is annexed herewith as **ANNEXURE A-2 (Page Nos. 72 to 76)**. True copy of article titled *Genetically modified food: Whose health, whose business* published in Down To Earth dated 02.08.2016 is annexed herewith as **ANNEXURE A-3 (Page Nos. 77 to 78)**.

11. In respect of imports, moreover, the Foreign Trade Policy ('FTP') states that “*all imported goods shall also be subject to domestic laws, acts, rules, orders, regulations, technical specifications, environmental and safety norms as applicable to domestically produced goods.*” To this end, the DGFT who is responsible for implementing the Trade Policy has also noted that the prior approval of GEAC is a mandatory condition for importing any GMOs or LMOs, including foods (processed or otherwise), raw materials, ingredients or other food products. Pertinently, the latest ‘**General Notes Regarding Trade Policy, 2017**’ specifically states that [Pr. 6(b)]:

“The import of any Food, Feed, raw or processed or any ingredient of food, food additives or any food product that contains GM material and is being used either for Industrial production, Environmental release, or field application will be allowed only with the approval of the Genetic Engineering Approval Committee (GEAC) ...”

12. However, the ground realities are extremely disturbing inasmuch as the DGFT have admitted that there is no screening on entry of food products at the ports. To this end, it is relevant to refer to the 37th Report of Parliamentary Standing Committee ('PSC') on Agriculture presented before the Lok Sabha on 09.08.2012 which recorded a categorical admission of DGFT representative as below:

“7.38. With a view to assess the ground reality while this game of musical chairs is going on for years together, the Committee sought the views of Department of Commerce on the reports about GM food products coming into India. They were informed that the import guidelines for the genetically modified products issued by the Directorate General of Foreign Trade very clearly stipulate that imports will be allowed only with the approval of GEAC. ...”

7.39. *Queried further as to what is the surveillance mechanism to check that the imports of such products are in conformity with the stipulated guidelines, she admitted:*

“To be honest, Sir, there are no checks”.
(emphasis added)

13. Based on the ‘Action Taken Report’ submitted by the Union of India, the PSC issued yet another report (59th) and scathingly noted that:

**ABSENCE OF MONITORING
MECHANISM
(Recommendation Para No. 6.155)**

1.64. *In the opinion of the Committee, the Government should have realized the magnitude of the task to be performed by FSSAI. Apart from regulating local food and food products, the Authority has to ensure food safety of food items imported into the Country. Imports in India are permitted through 255 entry points. These include 82 custom ports, 32 customs airports, 132 land customs stations and 9 foreign port offices, sub foreign post offices. During 2007-08 and 2008-09, 76 lakh metric tonnes of food items were imported into the Country. For the Committee, the most worrying aspect in the matter had been the admission of the representative*

of Directorate General of Foreign Trade before the Committee during oral evidence that there were absolutely no monitoring of the food items being imported into the Country.

1.65. The Department in their Action Taken Note have stated that the FSSAI and the Ministry of Health and Family Welfare are fully apprised of this situation and during 12th plan adequate financial support and expansion plans have been proposed.

1.66 The Committee take a serious view that there is no response from the Government on the question of absence of monitoring mechanism regarding safety of food items imported into the Country. Failure of Food Safety and Standards Authority of India (FSSAI) in this regard, which has been in existence for the last five years, is glaring. The Committee would like to know what steps have been proposed and how soon will these be implemented to ensure safety of food items imported into India.”

14. THE GEAC AND THE DGFT FLOUT THE RULES

By-passing the FSSAI, the GEAC in a ‘one time approval’ in 2007 allowed imports of GM Soybean oil, only for the purpose of consumption after refining. However, the DGFT

indefinitely exempted the trade condition for import of GM Soybean. In pertinent part, the notification dated 27.12.2007 issued by DGFT states that:

“The Genetic Engineering Approval Committee (GEAC), set up by the Ministry of Environment & Forests has accorded ‘one time approval’ for import of GM Soyabean oil (crude de-gummed/ refined form) derived from Round-up-Ready Soybean for the purpose of consumption after refining. Therefore, Condition No. 18 of Chapter 1A (General Notes Regarding Import Policy) notified vide Notification No.2 (RE-2006)/2004-2009 dated 7.4.2006 will not apply to the import of said Soyabean Oil till further orders.”

On the other hand, the GEAC has stated that no approval has been accorded for manufacture, sale or environmental release of HT Soy. The GEAC, in their communication addressed to DGFT, dated 23.02.2018, stated: *“it is informed that the Genetic Engineering Appraisal Committee (‘GEAC’), which is the regulatory body for Genetically Modified Organisms (GMOs) and products thereof, has not authorized or approved Genetically Modified (GM) Soybean or any other products derived from GM Soybean seeds for import or cultivation in India.”* True Copy of the Letter, dated 23.02.2018, addressed by the Ministry of Environment, Forest &

Climate Change is annexed herewith as **ANNEXURE A-4** (Page Nos. 79 to 80).

15. This clarification is pertinent to the legal position with regard to any other GM oil like GM rape-seed oil, (Canola) and processed foods as clarified in para 4 above, based on Section 22, whereby the imports of all GM foods is currently illegal. Shockingly, however, the Union of India in their Additional Affidavit (dated 28.07.2017) admitted that large quantities of GE edible oil, viz., GE Soybean and GM Canola are imported. The relevant portion of the Add. Affidavit reads as follows:

“16. That, as per statistics published from time to time by the Solvent Extractor’s Association of India, out of total 20-21 MT edible oil consumption in India, 5.6 MT is derived from GE crops including 4.6 MT of imported GE soybean and GM canola oil and 1.2 MT of domestically produced GE Bt cotton seed oil. India imported edible oils worth around Rs. 67000/- crores in the fiscal year 2015-16. It is expected that with the increase of production of mustard due to hybrids developed using GM technology, there would be substantial savings in foreign exchange;” (emphasis added).

16. **FSSAI: IMPORT OF GM EDIBLE OILS IS ILLEGAL**

In response to a question raised in Lok Sabha, on 29.12.2017, Hon'ble Minister of Health and Family Welfare JP Nadda effectively admitted that the Central Government allowed the import of GM edible oil in violation of food safety law; that between 2007 and 2015 it allowed at least four companies including Monsanto and Bayer to import GM soybean and GM rape seed oil called Canola into India. It was further stated that **“FSSAI has not permitted import of any edible GM oil into India.”** However, the Union Minister shrugged off responsibility and put the onus on Food Safety Departments under various State & UT Governments to carry out *“regular surveillance, monitoring, inspection and sampling of food products.”* However, it also admitted that the food safety authority is unable to stop the illegal import of GM edible oils because it lacks the technology to detect GM content in oils. In 2016, the apex food regulatory authority and the Union Health Ministry also did away with the need for specialised food safety experts to inspect imported food consignments at India's ports, handing over the responsibility to unqualified customs authorities instead. True Copy of the article titled *‘GM Crops: Since 2007, Centre has allowed import of GM edible oil, violating food safety laws’* dated 05.01.2018 published in Scroll.in is annexed herewith as **ANNEXURE A-5 (Page Nos. 81 to 86)**.

17. IMPORT OF VIABLE GMO SEEDS IS ILLEGAL

The import of viable GMO seeds of all kinds are unambiguously illegal because they are 'Living Modified Organisms (LMOs) that can be and may be planted out, deliberately or accidentally. In either case, this action would amount to unauthorised environmental release of untested GMOs into Indian agriculture. This is why such imports present an unacceptable biosecurity risk for India through the potential contamination of Indian agriculture, in what would in essence be, the introduction of GMOs into Indian farming through the backdoor.

18. Moreover, the issue is not limited to import of viable GMO seed. This risk to India, which does not grow GMOs apart from Bt. cotton, is present from imports of viable seed of any crop, which is a commercialised GMO anywhere in the world, because contamination of non-GMO seeds is spreading beyond country borders for reasons that include: (a) shipping of supposedly non-GMO produce that has been contaminated by GMO, (b) 'mid-ocean transshipment' (a common shipping practice) that obscures the source country from where the shipment originated; (c) in addition, India offers very low or zero import duties to Least Developed Countries (LDC), mainly African countries, which in the case of soy bean amounts to a 49.50% duty advantage over the USA. Such preferential

duty rates provide a huge incentive to re-route exports through LDCs thereby, concealing the true source-country from where the shipment originates. Both latter factors confound traceability efforts, raising valid suspicion about the origin of shipments.

19. **PLANT QUARANTINE IMPORT REGULATION 2003**

Both latter issues have been represented by D. N. Pathak, Executive Director, of the Soybean Processors Association of India (SOPA) in his letter dated 03.01.2018, to Dr. B. S. Phogat (Plant Protection Advisor, Directorate of Plant Protection, and Quarantine& Storage).

“The current duty advantage on import of soybean from Least Developed Countries is 49.5% (45% basic+10% cess) and this huge advantage may be misused for importing soybean from other countries by either mis-declaring the origin or by actually rerouting the material through these countries, to avoid payment of 49.5% duty.

Pathak also alerts Dr Phogat to the fact that under the Plant Quarantine (Regulation of Import into India) Order 2003, *“some traders are importing soybean for crushing and sowing, in total violation of the Plant Quarantine Rules of the Government of India ---“*

He furthermore points out:

“The strict Plant Quarantine Rules for import of soybean were made for the purpose of saving Indian soybean cultivation from attack of pests and diseases which are, so far, not found in India but are prevalent in other countries. Therefore, even for crushing, imported soybean is subject to strict conditions including --- management of handling, transportation, milling – disposal ---.However, no action seems to have been taken, as the imports continue without following the PQ Rules”

“In view of the very serious nature of the violation of PQ Rules, we (SOPA) would request the following”:

- (a) Investigate all past soybean imports to ascertain whether plant quarantine regulations were followed. If not, strict action should be taken against those responsible for flouting the rules including impounding the imported soybean.*
- (b) Issue instructions to all plant quarantine stations and customs authorities to ensure that import of soybean is done in strict compliance with the plant quarantine rules.*

- (c) *Remove soybean from the list of items eligible for duty free imports from LDCs.”*

True Copy of the letter dated 03.01.2018 addressed by D.N. Pathak (on behalf of Soybean Processors Association of India) is annexed herewith as **ANNEXURE A-6 (Page Nos. 87 to 88)**. Two months later, on 07.03.2018, the SOPA similarly wrote to the Hon’ble Minister of Commerce, Government of India with a request for immediate action. True Copy of the letter dated 07.03.2018 addressed by D.N. Pathak (on behalf of Soybean Processors Association of India) to Hon’ble Minister of Commerce is annexed herewith as **ANNEXURE A-7 (Page Nos. 89 to 90)**.

B. BREACH OF BIOSECURITY & AGRI-SAFETY

20. LACK OF INSTITUTIONAL WILL AND TECHNICAL AIDS TO STOP GMO IMPORTS

It is clear from the foregoing that India’s biosecurity and her agriculture are being put at severe, and irreversible risk by a degree of nonchalance resulting in the most serious collective failure, across Ministries, to protect India through the enforcement of attendant laws to stop GMOs from entering the country as viable seed (LMOs), foods and edible oils. This must invite the gravest charges. At least 4 institutions stand accused of unconscionable gross mal

administration in these matters: The GEAC, Ministry of Commerce, FSSAI (Ministry of Health and Family Welfare), the DGFT and the Directorate of Plant Protection, and Quarantine & Storage. It is also clear that despite the scathing comments of the PSC (2012), highlighting the admission by the DGFT of the complete vacuum in monitoring the entry of food items into India for the last several years (ref para 12 above), no effort has still been made for the provision of the necessary technical facilities at various entry points into India, including ports, that must critically include the provision of accredited seed testing labs to international standards and capable of routine testing to the lowest technologically feasible LOD (Limit of Detection), but at least to an LOD of 0.01% (current testing capability), being necessary and fundamental to detect and ensure that no GMO seeds, foods, or oils, enter India and also that plant quarantine laws are complied with. In particular, the import of GMO viable seeds into India requires draconian measures to detect and stop any such entry.

21. The absence of accredited testing labs is a matter that has been copiously documented and placed before this Hon'ble Court by the late Dr. Pushpa Mitra Bhargava who was appointed to the GEAC as an independent nominee by this Hon'ble Court. Dr. Bhargava was the Founder of the CCMB – Centre for Cellular and Molecular Biology,

Hyderabad. Dr. Bhargava insisted and the GEAC accepted and recorded that there must be independent testing institutions across the Country for risk assessment of GMOs. This decision was taken in view of orders passed by this Hon'ble Court dated 8.5.2007(as an enabling measure to avoid contamination), that all open (small scale) field trials, must be subject to validated event specific protocols to an LOD of at least 0.01 %. Thereafter, no active testing has ever been carried out by the Regulators to ensure that there is "no contamination". *"The whole nation does not have a lab where all the required tests could be done on GMOs"*. Dr PM Bhargava to the PSC 2012 (ref para 2.18 & 2.19)

22. IMPORT DATA OF VIABLE GMO/LMO SEEDS

Imports of viable soy bean seed from various countries including the US, Ukraine, Ethiopia, Benin and few other African countries is sizeable, as follows:

S.No.	Financial Year	Total Import (MT)
1.	2017-18 (1 st & 2 nd FQ)	7,407.92
2.	2016-17	1,645.44
3.	2015-16	154.00
4.	2014-15	00.00

Source: DGFT: research by SOPA (letter to Directorate: Plant Quarantine

While these are composite data, the USDA (United States Department of Agriculture) data shows that Soybean viable seed exports to India were 500 tons in 2017-18 and 1,200

tons in 2016-17. In the US, there is virtual deregulation of GMOs. GM Soy is a commercialised crop with a market share of near 95%. Therefore, imports from the USA of viable soy seed is either GMO or contaminated with GMO and likewise for the Argentine, (GM Soy virtually 100%) among other examples. Data for other commodity crops are: Cotton, over 90%; Canola (rapeseed) 90%+. In Canada, GM Canola is virtually 100%. The list also includes squash, sugar beet, papaya (Hawaii), which have caused widespread contamination. With a commercialised crop contamination is a certainty. However, the example of wheat below involves contamination from GM HT wheat field trials, which demonstrate just how critical and chronic GMO contamination has become.

23. **GM HT Wheat contamination from field trials:** GM wheat has not been commercialised anywhere in the world. It is the largest acreage crop of the US and Canada. The first case of wheat contamination documented by Petitioners was from Oregon, USA in 2013. Several Asian countries including Japan and Korea temporarily suspended U.S. wheat imports after GM wheat was found unexpectedly on a farm in Oregon 8 years after it was field tested. Eventually, Monsanto reached a \$2.4 million settlement with Pacific Northwest wheat farmers. The current case of contamination, again from field trials, involves GM HT Canadian wheat and serves as an abject warning. Canada is

one of the world's largest wheat exporters. In the summer of 2017 Monsanto's HT wheat tolerant to Roundup (glyphosate), was discovered in Alberta province. Field trials had been conducted almost 20 years before, but not within 100 Kms. of the discovery site. The wheat was destroyed and the CFIA (Canadian Food Inspection Agency) will monitor the area for three years to verify that it does not become established. Japan has since suspended its tender and sale of wheat from Canada. Japan is Canada's second largest global buyer of wheat at around 1.5 million tonnes a year. South Korea has joined Japan in also suspending trade in Canadian wheat. True copy of the article titled *Biosafety Info: Unapproved GM Wheat Found in Canada, Imports Suspended by Japan and South Korea* published in TWN dated 26.06.2018 is annexed herewith as **ANNEXURE A-8 (Page Nos. 91 to 94)**.

24. It is frightening to note that India imports various other seed varieties from United States, Brazil and other GM growing countries. The following table shows import of seeds from countries that also grow GMOs:

S.No.	Seeds	Quantities Imported
1.	Maize or Corn Seeds [HS Code: 10051000]	During 2007-08 to 2017-18:
		Country* Quantity (Kg)
		United States 20,160
		Brazil 110

		Argentina	5,28,160
		Spain	390
		Philippines	30
		<i>* Source: DGFT</i>	
2.	Canola Seeds [HS Code: 12059000]	During 2007-08 to 2017-18:	
		Country	Quantity (Kg)
		Australia*	1,00,260
		United States†	1,49,200
		<i>* Source: DGFT</i>	
		<i>† Source: Zauba</i>	
3.	Beet Sugar Seeds [HS Code: 12059000]	During 2007-08 to 2017-18:	
		Country*	Quantity (Kg)
		United States	1,29,850
		<i>* Source: DGFT</i>	
4.	Squash Seeds	During 2014-16:	
		Country*	Quantity (Kg)
		United States	10,647
		<i>* Source: Zauba</i>	
5.	Papaya	In 2016:	
		Country*	Quantity (Kg)
		China	5
		<i>* Source: Zauba</i>	

25. It is submitted that the above factors must necessarily be taken into account in the matter of the import of viable seed into India. Imports of viable seeds from countries, which permit or grow GMOs including in field trials pose a grave

threat to India's biosecurity and agriculture and must be straightforwardly banned. However, the dimensions of the problem extend beyond borders and must be taken to its logical conclusion (ref. para 10 & 14 above). For example, the Ukraine does not grow GMO soybean; yet Russia recently cancelled soybean imports from the Ukraine because they were GMO. [See Pavel Polityuk, *Ukraine strengthening GMO export control to defend producers* Reuters (Dec. 06, 2016)] This means that India may not under any circumstances allow imports of viable seed, in any crop that is a commercialised GMO anywhere in the world, to ensure there is no risk to Indian agriculture and no breach of our biosecurity. At this point in time, the Respondents must take steps to prohibit import of soy, corn, cotton, rape, sugar-beet, squash, papaya, all of which are commercialised GMOs. To this must be added, wheat from the USA and Canada (even though not commercialised) because field trials have resulted in serious contamination events in these countries.

C. BREACH OF BIOSECURITY: ILLEGAL CULTIVATION OF HT SOY IN GUJARAT

26. Illegal cultivation of HT (herbicide tolerant) soy bean was discovered in Gujarat in November 2017. The Bhartiya Kisan Sangh ('BKS'), a national farmers' organisation lodged a complaint with the Gujarat State Government and

the GEAC about the illegal cultivation of GM soy in Modasa town (Gujarat). The Gujarat government seized the stocks and tested them. They tested positive for herbicide tolerant resistance to Monsanto's glyphosate. This was confirmed by the Ministry of Environment, Forest and Climate Change ('MOEF') in reply to an RTI request filed by Ms. Kavita Kuruganti. In pertinent part, the reply stated:

“email communication from the Director of Agri, Govt. of Gujarat was received on 7-11-2017 regarding illegal unauthorised cultivation of HT soybean crop and two out of 3 samples drawn were found to be positive”.

True Copy of the RTI Reply, dated 05.03.2018, issued by Ministry of Environment, Forest and Climate Change is annexed herewith as **ANNEXURE A-9 (Page Nos. 95 to 96)**.

27. In addition to the tests conducted by the State Government, the BKS also collected samples of soy bean (*approx. 10gms*), which were sent to a private lab, SGS India Pvt. Ltd. These samples also tested positive for GMO event, RoundupReady (glyphosate) soy to an LOD of 0.1%. True Copy of the Test Report, dated 01.11.2017, conducted by

SGS India Pvt. Ltd. is annexed herewith as **ANNEXURE A-10 (Page Nos. 97)**.

28. **Illegal cultivation of GM HT soy, is a ‘red alert’:** discovered in early Nov 2017, it is a food crop. The degree of regulatory misadventure is alarming and it raises the risk stakes for Indian soy agriculture to ‘extreme’. In a strongly worded press release the ‘Coalition for a GM-Free India’ stated: *“This illegal fait accompli delivered by such unauthorised cultivation marks the cultivation of the first GM food crop on Indian soil. The regulatory system in the country is clearly in tatters. Incident after incident shows that with the current regulatory regime in the country, citizens’ interests cannot be protected. If the regulators had acted decisively in the past with severe deterrence, against illegal Bt cotton and later, HT cotton cultivation and other illegal imports of GM foods, this situation could have been prevented to a large extent”*. True Copy of the Press Release titled ‘Regulators caught napping again, while illegal GM soy cultivation starts in India’ dated 06.11.2017 issued by Coalition for a GM-Free India is annexed herewith as **ANNEXURE A-11 (Page Nos. 98 to 101)**.

D. GMO CONTAMINATION IS THE OUTSTANDING CONCERN & RISK TO BIOSECURITY: A RECAP

29. GMO contamination is irremediable and irreversible, which is why it is the outstanding concern. GMOs are self-

replicating, “*hazardous*” organisms, (as defined in the ‘Rules’), which at the point of environmental release, through gene flow and other means, will contaminate the environment. Even under the most stringent conditions imposed for small field trials, there is no assurance that contamination will not occur. In fact as the evidence makes plain, it has occurred. In India, stringency and rigour are conspicuous by their absence. The worrying issue is the complete regulatory unconcern; and no testing has been done to ascertain whether, as a consequence of the several thousand open field trials conducted in the last 20 years, any contamination has occurred. The following findings/examples typify the concerns expressed:

- (a) **No co-existence possible between GMO & Non-GMO agri:** The study conducted by The Institute for Prospective Technological Studies (European Commission Joint Research Centre), in May 2002, established that GMO presence detected to an LOD of 0.1%, makes co-existence of GMO and Non-GMO agriculture impossible. [See **Writ Petition | Annex. P-40 at Pg. 590 (Vol. III)**]
- (b) **Bayer LL 601 Rice (single field test in the US):** In 2006 an unapproved (for human consumption) variety of HT genetically modified (GM) rice (LL601 RICE), of Bayer Crop Science, was detected at low

levels (0.01% LOD) in US Non-GM long-grain rice. The contamination apparently occurred from a single and stringent field test of LL 601 in 2001, (5 years before the contamination was detected ie in 2006), modified to be tolerant to Bayer's herbicide (weed killer), Liberty Link (glufosinate – the same herbicide used in Indian Mustard HT DMH 11). The contamination effected all US long grain rice exports to countries like Switzerland, Germany, France, Sweden, Ireland, UK and Japan, which refused to allow imports of US long grain rice. US exports collapsed causing a revenue loss of nearly 2 billion dollars. The impact on rice farmers was severe and eventually Bayer negotiated an out-of-court settlement of USD 750 million. [See **Short Note (dated 23.09.2010), Annex. A-1 (Pg. 6 to 11)**]

- (c) **Wheat Contamination from HT field trials:** The case of the contamination of non-GMO wheat fields in Oregon (US) and Alberta (Canada), (see para 14), is potentially much more serious than the case of rice above. Wheat is the leading high acreage crop in the US and Canada. HT wheat has never been commercialised. It was found growing in non-GM wheat fields several years after HT wheat was field-tested in both countries. In the case of Alberta province, where HT wheat was found growing, field

testing had occurred 20 years before and in a field site more than 100km away.

(d) Basmati Rice Exports: contamination fears: In its 75th meeting of March 2007, the GEAC, at the instance of the basmati rice exporters and the Ministry of Commerce, (fearing a ban on exports to the EU and other countries), decided *not to allow field trials of GM rice in the basmati growing areas of the country, because of the threat of contamination*". [See **Written Submission** (2014), Pg. 24-25] But the logic of such an admission of contamination must then be valid for all crops including most critically India's food crops which must not be contaminated, a concern highlighted by Agricultural and Processed Food Products Export Development Authority ('**APEDA**'), below.

(e) Non-GMO Certification for APEDA: The 81st Meeting of the GEAC held on 22.11.2007 records that APEDA requested a certificate stating that no GM rice, groundnut and sesame seeds have been permitted in India. The request was made because of a ban imposed by Russia on these crops, fearing GMO contamination. The minutes states that "*Measures (have been) agreed upon between the two sides and the format for quality testing certification mutually agreed upon. One of the requirements in the certificate is confirmation*

from the Government of India that no GM crops in rice, groundnuts and sesame seeds exist in India". The Member Secretary, GEAC was authorised to issue a letter to APEDA confirming that "*no GM crops in rice, groundnuts and sesame seeds exist in commercial production in India*". The answer was clearly evasive and side-stepped the intent of the Russian requirement of no GMO contamination, because as evidenced, serious contamination incidents have occurred through open field trials. [See **Written Submission** (Feb. 2008), Pg. 10].

30. It is pertinent to reiterate that:

- (a) India has no accredited testing labs to international standards in the public sector that can routinely test for GMO content to an LOD of 0.01% (requiring quantitative PCR (polymerase chain reaction)). Bayer's rice HT LL601, which contaminated US Long Grain Rice was tested in a European Lab, which detected contamination to an LOD of 0.01%.
- (b) **Contamination and Order dated 08.05.2007:** This Hon'ble Court recognising these concerns, and as an enabling condition to its Order of "*no contamination*" required the Regulators to establish '*event specific*' protocols of testing for every field trial, to at least the

above LOD of 0.01%, in order to detect and avoid any contamination. However, the Respondents have failed to comply with the '*no contamination*' order passed by this Hon'ble Court, and as a result, the Petitioners were constrained to prefer Contempt Petition No. 6 of 2016 which is currently pending before this Hon'ble Court.

31. The cumulative evidence of several years chronicles an alarming situation in India in the governance of GMOs. Several expert bodies and standing committees, in fact now, 5 official reports (with the latest report under the Chairpersonship of Renuka Chaudhuri), have attested to the serious vacuum in GMO regulatory oversight, porous enforcement, the serious and endemic conflict of interest that even openly provisions for public-private partnerships to promote GMOs in agriculture, and the lack of independent expertise in regulating and testing GMOs/LMOs. Notwithstanding the above, and even so, under the existing regulatory regime, the illegal import of GMOs/LMOs as viable seed and the cultivation of illegal HT soy, a food crop in Gujarat are without precedence; a pointer to 'extreme' regulatory unconcern and 'extreme' risk to biosecurity. The import of GMOs in processed foods and GM edible oils (soy and Canola) are also illegal, casually and deliberately pushed under the regulatory radar by a deeply errant GEAC and lackadaisical FSSAI for over

10 years. It has given way to confusion and a complete vacuum in responsibility, where a lucrative and illegal trade in GMO foods is flourishing under an official 'Nelson's eye'. Egregious GMO regulation is dangerously compromising India's biosecurity.

E. IMPACT ON DOMESTIC NON-GM SOY

32. India is the only country worldwide, which grows only non-GMO soy, meaning that there is no GM soy cultivation authorised in India and therefore, there is no possibility of contamination. However, the implications of the illegal cultivation of HT soy in Gujarat and imports of viable seed of GM soy are truly staggering for soy cultivation and may already be catastrophic because contamination may have already occurred. Hence, immediate action is required in the way of import bans on viable seed and the immediate up-rooting and destruction of HT soy planted by farmers with harsh deterrents for illegal cultivation of GMOs.
33. India has a '*Unique Selling Strength/Point*' (USP) in its non-GMO soy production, every bit the same as Basmati rice. In the first official test of public opinion in the National GM Debate in the UK, 80% of Britons are opposed to GM crops and only 2% will eat GM food. [London Times, 25th Sept. 2003]. Worldwide, 90% of the world's consumers are demanding mandatory labelling of GE foods, so they can

avoid them [**See Pr. 68 of the Writ Petition**]. Since then, in the last decade the demand for labelling for GMO content worldwide makes it clear that consumers, Mothers, many doctors, India's public health doctors, do not want GM foods. Labelling for GMO content would have the effect of marking GMO food products with a '*skull & cross bones*'.

34. In fact, the EU requires non-GMO soy meal for animal feed as *even secondary products* with GMO content are coming under scrutiny. Even the US, where 95% of soy is GMO, has sought to buy Indian soy for animal feed. Lecithin is a food emulsifier used in the manufacture of chocolate and derived from soy. The demand for Non-GMO sources of lecithin are growing.
35. GM Watch published a report by Rabobank, which coincidentally underscores the above issues:

“Demand for organic, certified or non-GM soybeans is expected to rise as consumers want to verify sustainability and traceability.

We see significant and volatile price premiums for organic and non-GM, but for other schemes, it is more challenging to recover the extra costs down the supply chain,”

The report also makes the following points:

- (a) The biggest increase in demand is coming out of the EU which will, in the long-term, rely heavily on imports of non-GM soybean;
- (b) About 350 million MT (metric tonnes) of soybean are traded annually, but just 14% are not genetically modified (GM), as major producing countries in the America's use up to 95% of genetically modified seed;
- (c) The Dutch bank estimates that only 11%, or 38 million MT is kept separate from GM beans. The majority of that is consumed domestically, largely in China and the EU, leaving only 9 million MT. traded globally in 2017; and
- (d) 50% of the volume is plain non-GM soybeans, with a third certified RTRS (Round Table Responsible Soy), and the rest, (around 17%) certified as organic.

True Copy of the news report titled 'Global Non-GM soybean demand to rise, driven by the EU' published in GM Watch, dated 11.04.2018, is annexed herewith as **ANNEXURE A-12 (Page Nos. 102)**.

F. IMPLICATIONS FOR NON-GMO INDIAN AGRICULTURE

36. **Organic Standards** are consistent with the requirement of 'No *GMO content*'. Organic produce is the fastest growing segment worldwide at around 25% p.a. and India is the

largest producer of organic agri products and food. It is extremely unwise for the government to kill India's real USPs /strengths in agriculture, unique farmer opportunities to respond to this lucrative demand, world-wide, by allowing a back-door entry for the de facto conversion of Indian agriculture to GM crops. The consequences could not be graver. The 37thPSC Report (2012) makes several uncompromising statements reinforcing Petitioners evidence in these matters as follows:

“6.151 The Department of Commerce are entrusted with the responsibility of attending to policy matters relating to international trade in goods and services including agreements with other countries/various international trade body but excluding agreements relating to wheat, sugar, jute and cotton. The Committee note India exported agricultural products worth Rs. 89523 crore during the year 2009-10. From the data submitted by the Government to Committee it is observed that exports of agricultural products have shown a continuously rising trend in the last decade. A major chunk of our exports have been of rice mostly basmati. EU is one of the important importers along with several Middle East countries. The Department of Commerce admitted before the Committee that exports of transgenic crops will

depend upon international acceptance to transgenic food and food products. The Department also stated that there may be no real demand for GM crops when the emphasis is on organic production. It needs to be pointed out that the Department of Commerce are also a member of GEAC. From the inputs provided by the Department, the Committee feel that cultivation of genetically modified food crops will have a debilitating effect on the export of agricultural products. 231 EU already has a strict regime for not permitting import of genetically modified crops. With the awareness about the safety and other concerns about transgenic crops taking centre stage now, there is a strong possibility of several other countries following suit. The volume of global trade in GM food and food products being of the order of a paltry US dollar 4 billion speaks volumes about the acceptability of GM products. The Committee, therefore, strongly feel that the negative impact of genetically modified crops on the country's agricultural exports is another important aspect that needs to be factored in while taking a decision in regard to introduction of genetically modified crops. The Committee desire the considered views of the Government in the matter.”

37. **The superiority of Agri-ecology:** Petitioners have provided ample evidence of the unsustainability of both Bt and HT crops, which globally account for 98+% of planted GMO crops worldwide, and the conspicuous failure of Bt cotton in India [See **I.A. No. 48 of 2016 & Rejoinder Affidavit 2017**]. Therefore, in the light of this evidence it is utterly perverse for our government to take any risks with Indian agri. through pushing for unsustainable GMO technologies. Several Submissions provide key evidence of the superiority of traditional breeding/agricology, including the IAASTD Report to which India is a signatory, which outperform GMOs hands down. [See Doug Gurian Sherman: Failure to Yield].
38. **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)].*

39. The Petitioners submit that agroecological farming may also threaten the economic viability of genetic engineering, which is why it is being opposed tooth & nail and to protect profits through patents. Development of an engineered crop trait is very expensive, about \$136 million on average (the total cost is estimated at around \$300 million), according to an industry report, compared to \$1 million for conventional breeding. On the other hand, the converse is also true i.e., if India treads a path to promote GMOs in Indian agri then resources already scarce, will be unavailable to promote Indian agroecological farming with intent and meaning and with irreversible consequences.
40. **Prof MS Swaminathan with co-author Prof. PC Kesavan** (TEC member): in a recent editorial published in Current Science, the authors categorically stated the GMOs is an unsustainable technology, at present, to achieve the UN Sustainable Goal to end hunger and achieve food security. While examining specific instances of *Bt.* and *Ht.* varieties introduced in India, Prof. Swaminathan scathingly noted

that *“experiences over three decades has shown that pests develop resistance sooner than later. This results in farmers having to resort to the application of high levels of pesticides defeating the very purpose of developing these transgenic crops.”* In pertinent part, the Editorial reads as follows:

“GEcrop plants, as of now, mostly consist of Bt (Cry proteins) to provide resistance against borer pests and Ht (herbicide tolerant) cotton, corn and soybean. Experience over three decades has shown that pests develop resistance sooner than later. This results in farmers having to resort to the application of high levels of pesticides defeating the very purpose of developing these transgenic crops. Further, many herbicides such as glyphosate (used in ‘Round Up Ready’ Ht transgenics) and glufosinate (in HT rape and Indian HT Mustard DMH 11 – petitioner added comment), have been shown as genotoxins. In India, the Bt trait has been introduced into hybrid tetraploid cotton which requires not only expensive inputs but also denies the farmers the saving of seeds for subsequent cultivation. Resource-poor marginal farmers find it very difficult to buy seeds for sowing every time from developers at high costs and also incur high costs of cultivation. Transgenic herbicide-tolerant crops induce resistant ‘Super Weeds’.

“It is for these reasons that genetic engineering, as of now, is not a sustainable technology. Recently, the collapse of ‘Bollgard II’ cotton with the development of resistance by pink bollworm has led to a desperate plea to cotton farmers to adopt Integrated Pest Management (IPM) to sustain Bollgard II. This is an example of an inexpensive traditional technology to the rescue of an expensive and sophisticated, but failing technology.

“The evergreen revolution eliminates all the negative aspects of Green Revolution and provides for on-farm and non-farm rural livelihoods by conservation and use of local natural resources”.

“An untenable notion is that ‘eco-agriculture’ results in diminished productivity. This is not true. A very large study comprised the analysis of 286 projects in 57 countries. It was found that mean relative yield (in such agri, (petitioner clarification)) increased by 79% across a wide variety of systems and crop types”.

True Copy of Editorial titled ‘Science for sustainable agriculture to achieve UN SDG Goal 2’ published in CURRENT

SCIENCE Vol. 114 (8), dated 25.04.2018 is annexed herewith as **ANNEXURE A-13 (Page Nos. 103 to 104)**.

41. FIRST TRIAL AGAINST MONSANTO IN THE US: ROUNDUP (GLYPHOSATE) LINK TO CANCER

In the meanwhile, a first-of-its-kind lawsuit has been filed against Monsanto by Dewayne Johnson, a California-based farmer, who has been diagnosed with terminal non-Hodgkin's lymphoma, as a result of spraying the weed-killing pesticide RoundUp Ready (glyphosate being the active ingredient). Pertinently, the Trial Court has directed the jurors to examine not only the scientific evidence, but also the conduct of Monsanto in suppressing the harmful effects of Glyphosate (a known carcinogen). The International Agency for Research on Cancer (IARC) classified glyphosate as a "probable human carcinogen" in 2015. Given Mr. Johnson's present medical condition, the trial has been fast-tracked and has just been concluded. True copy of the news report titled *Landmark lawsuit claims Monsanto hid cancer danger of weedkiller for decades* published in The Guardian dated 22.05.2018 along with graphic photograph of the Plaintiff is annexed herewith as **ANNEXURE A-14 (Page Nos. 105 to 108)**.

42. **VERDICT IN THE DEWAYNE JOHNSON CASE OF ROUNDUP LINK TO CANCER FINDS MONSANTO GUILTY; IT MUST PAY \$289m IN DAMAGES**

In a stunning blow to Monsanto (now Bayer), one of the world's largest seed and chemical companies, the jury at San Francisco's Superior Court of California deliberated for three days before finding that Monsanto had failed to warn Johnson and other consumers of the cancer risks posed by its weed killers. It awarded USD39 million in compensatory and USD250 million in punitive damages. The main findings are:

- (a) *“The jury paid attention throughout this long trial and clearly understood the science and also understood Monsanto’s role in trying to hide the truth.”* The jury’s verdict found not only that Monsanto’s Roundup and related glyphosate-based brands presented a substantial danger to people using them, but that there was *“clear and convincing evidence”* that Monsanto’s officials acted with *“malice or oppression”* in failing to adequately warn of the risks. Monsanto’s secretive strategies have been laid bare. It was undone by the words of its own scientists, *“the damning truth illuminated through the company’s emails, internal strategy reports and other communications”* (emphasis added).

- (b) Monsanto has spent decades employing a range of tactics -- some drawn from the same playbook used by the tobacco industry in defending the safety of cigarettes – to suppress and manipulate scientific literature, harass journalists and scientists who did not parrot the company’s propaganda, and arm-twist and collude with regulators. Indeed, one of Monsanto’s lead defence attorneys in the case, George Lombardi, in his résumé boasts of his work defending big tobacco.
- (c) The evidence also showed that the warning signs seen in scientific research dated back to the early 1980s and have only increased over the decades. But, instead Monsanto worked not to warn users or redesign its products, but to create its own science, designed to appear independent and thus more credible, to show they were safe.
- (d) Evidence was also presented to jurors showing how closely the company had worked with Environmental Protection Agency officials to promote the safety message and suppress evidence of harm.
- (e) Ubiquitous Glyphosate-based herbicides are so widely used around the globe (roughly 826 million kg a year) that residues are commonly found in food and

water supplies, and in soil, air samples and in rainfall. Regulators, however, have failed to heed the warnings of independent scientists for too long, even shrugging off the findings of the World Health Organization's top cancer scientists who classified glyphosate as a "*probable human carcinogen*".

- (f) Another trial will take place in October in St Louis involving roughly 4,000 plaintiffs whose claims are pending with the potential outcomes resulting in many more hundreds of millions, if not billions of dollars in damage awards. They all allege not only that their cancers were caused by exposure to Monsanto's herbicides, but that Monsanto has long known about, and covered up, the dangers. Plaintiffs' attorneys leading the litigation say they so far have brought to light only a fraction of evidence collected from Monsanto's internal files and plan to reveal much more in future trials.

The ramifications of this trial have broader and global implications, which include India: Petitioners reiterate that they have prayed for a ban on herbicide tolerant (HT) crops for over 5 years and have continued to do so in the background of feckless regulation evidenced repeatedly, and also in this Application, as well the on-going attempts by India's Regulators and attendant Ministries to introduce

GM Sarson ka Sag or HT DMH 11, which is resistant to glufosinate (Bayer's Basta) (ref Additional Affidavit dated 09.09.2017 in I.A. No. 47 of 2016). In support of this Prayer, Petitioners have relied on independent scientific studies that show that (a) Glyphosate is an endocrine disruptor and causes birth defects, (Antoniou/Carrasco/Seralini/others); (b) the IARC report, which gave glyphosate its second highest rating of 2A designating it as a "*probable human carcinogen*"; (c) that with other herbicides it causes '*immediate*' antibiotic resistance (Heinemann); (d) as in the case of the tobacco lobby, which hid tobacco's link to lung cancer for 40 years, that similarly Monsanto, conniving with the EPA, have both known for over 30 years that glyphosate and its formulations cause cancer (Antoniou/others); (e) this Hon'ble Court's own TEC recommendation of a BAN on HT crops (2013) and the Swaminathan Task Force Report (2004) recommendation that HT crops are completely unsuited to Indian agriculture. The Indian Regulators with the Ministries of Agriculture, Science & Technology have consistently side-lined the cumulative evidence, even to the point of cover-up in the specific matter of the HT mustard debacle. It may be borne in mind that glufosinate is more toxic than Glyphosate (for decades Roundup has been considered the safest herbicide, even advertised as suggesting it is safe enough to eat!). Now, the Dewayne Johnson verdict vindicates Petitioners' evidence in these matters. True copy of the news report

titled '*One Man's suffering exposed Monsanto's Secrets to the World*' published in The Guardian dated 11.08.2018 is annexed herewith as **ANNEXURE A-15 (Page Nos. 109 to 112)**.

43. Prof. Dave Schubert [Salk Institute for Biological Studies, California & member of GMO Science Expert Advisory Board], in his recent published document '*A Hidden Epidemic*' says that we have reached the point where the evidence against probable carcinogen, glyphosate, (the active ingredient in Monsanto's roundup used in commercial HT crops), is "*directly analogous with DDT, asbestos, lead and tobacco, where industries were able to block regulatory actions for many years by perpetually muddying the waters about their safety with false or misleading data*". Currently, 94% of soybeans, 89% of corn and in addition, GM sugar beet, cotton and canola also dominate US agriculture. "*It is time to eliminate this herbicide (glyphosate) and others like it --*". "*Nationally, standards must be set to monitor all major agricultural chemicals in foods, followed by regulatory goals of reducing them to zero*".

- (a) **The Paul Mill Study:** conducted by Dr. Paul Mills and associates at the University of California School of Medicine, published in the Journal of the American Medical Association is helping to expose a major health hazard. It shows that: "*that the amount of the*

probable carcinogen glyphosate in people has increased enormously over the last 20 years.” Schubert adds that “nearly 67% of total agricultural glyphosate use in the US since 1974 occurred in the period 2005–2014, when GM crops became widespread.” This increased use is reflected in the Mills’s study. Yet, Prof. Schubert lamented that there is no systematic monitoring of glyphosate levels in foods by any government agency.

- (b) That the US authorities themselves have admitted that GM crops have failed to achieve desired benefits as follows: “*Regarding drought tolerance, the USDA has admitted that Monsanto’s drought-tolerant corn performs no better than existing drought-tolerant varieties of Non-GM corn.*” Regarding yields, in 2016 the US National Academies of Sciences concluded, “*The nation-wide data on maize, cotton, or soybean in the United States do not show a significant signature of genetic engineering technology on the rate of yield increase.*”
- (c) **DDT, Asbestos and Glyphosate:** The current situation with glyphosate-based herbicides is “directly analogous to that of DDT, asbestos, lead and tobacco, ...” Now, however, lawsuits against the industry by individuals who believe that their cancers (a type known as non-Hodgkin’s lymphoma) were caused by glyphosate herbicide exposure are uncovering documents that call

into question the previous safety claims. Evidence has emerged indicating that scientific reviews that were used to support regulatory approval were ghostwritten by Monsanto employees and later attributed to academics. In addition, documents suggest that a former senior employee at the US Environmental Protection Agency worked with the company to suppress an investigation of glyphosate's health risks by another regulatory agency;

- (d) Prof. Schubert notes that Glyphosate herbicides cause damage to soil and plant health, wildlife, and bees:

Glyphosate is now found in most, if not all, food products, including baby foods, where the hazard to health is much greater due to the special vulnerability of children to toxicants. Glyphosate has even been detected in some organic processed foods, showing the mobility of the herbicide in the environment. Nonetheless, eating organic remains the best way to reduce exposure to pesticides in general: From the point of view of the environment, studies indicate that glyphosate herbicides cause damage to soil and plant health, wildlife, and bees.

- (e) **Contamination of Oats and there is no commercialised HT oats:**

“the highest levels of glyphosate were found in those based on oats (e.g. breakfast cereals), with amounts up to 1.1 ppm (milligrams per kilogram). Since there are no commercialized glyphosate-tolerant GM oats, the only conceivable source of the high levels of this herbicide found in these products is pre-harvest desiccation of the crop. Glyphosate has also been found in alcoholic beverages, including beer and wine.”

True Copy of the article titled ‘*A hidden epidemic*’ published in GMO Science, dated 17.03.2018 is annexed herewith as **ANNEXURE A-16 (Page Nos. 113 to 118)**.

G. CONCLUDING COMMENTS

44. The history of regulatory misconduct amounting to malfeasance, profiled in several Submissions in the present proceedings and now in this Application, of a gravity that is extreme, presents India with an attempted *fait accompli* by our collective bodies and institutions of governance, to contaminate Indian Agriculture and convert it, de facto into GMO. This may not be allowed to happen, and must be stopped, in urgent action, in its tracks. The Indian regulators have also clearly demonstrated an extraordinary zeal to protect Monsanto’s profits, indeed, Monsanto’s profiteering. BGI (Bt) Cotton was introduced in 2002 in

hybrids, (the only country to do so), allowing a ‘*value capture*’ for Monsanto and the Industry and a ‘royalty’ for Monsanto to be added to the price of seed, even though there was no patent on BG 1. We have proven farmer suicides linked to Bt cotton (see Para 45 below).

45. **Both Bt and HT crops have failed as sustainable technologies and in the intent of their promise to reduce pesticide use (Ref WS pages 21 and 22 of 2014):** In India, Bt cotton is a proven failure (ref Petitioner Application Bt cotton I.A. No. 48 of 2016 & Affidavit of 2017, in IA 48). Yet the GEAC is on record in this Hon’ble Court extolling an imaginary ‘run-away’ performance of Bt cotton. On the other hand, in its Counter Affidavit in the Delhi High Court, in WP (C) No. 12069 of 2015, the Union of India has clearly linked farmer suicides with the failure of Bt cotton, consequent to serious pest infestation in Bt cotton, along with the regulators unsuccessful and disastrous hybrid (Bt cotton) policy. These have contributed to steeply rising costs for farmers, the ultimate catastrophe being widespread Bt cotton crop failures. The U of I said:

At Para 5: “That the impugned Price control order was promulgated with the objective of regulating the maximum sale price of cotton seeds in India inclusive of various hybrid varieties of cotton seeds including BtCotton Seeds and it was done in the interest of the

farmers to make the cotton seeds available at fair prices.

The farmers across the country have been financially burdened due to the increasing prices of the Bt cotton seeds. In addition to the prices of the cotton seeds, the farmers also have to spend on pesticides and other resources to make the crop more pest resistant and high yielding. This results in escalated expenses. As a result, there is very less margin of profit for the farmers. Since Bt cotton seeds is the major seed used by cotton farmers, a farmer succumbs to the pressure to use the best seed available in the market even when he might not have the means to cultivate such a crop. Consequently, in case of a crop failure, the farmers incur enormous debts in view of the loans taken to cultivate such Bt cotton crop. In the event of failure to raise a profitable yield, the farmers end up piling up huge debts which in turn has caused a rise in farmers' suicides across various cotton growing states".

(Emphasis added)

Further evidence on the failure of Bt cotton comes from P Sainath, the well-known journalist and commentator on rural India, in his deposition before the PSC of 2012 (ref PSC Report paras 8.88-890 on page 333 onwards):

“Suicides are overwhelmingly committed by cash crop farmers because the risks of cash crop are higher, the indebtedness is higher, the expenditure is higher, the bank loans and money lenders’ loans are higher and the prices are more volatile on the global market because cash crop prices are controlled by half-a-dozen multinational corporations in the world. Lastly, the highest number of suicides committed by cash crop farmers is that of cotton farmers...”

The peer reviewed study (ref Add. Affidavit (Jul. 2015), P-17):*“Deconstructing Indian cotton: weather, yields and suicides”* by Andrew Paul Gutierrez et al (2015, *Environmental Sciences Europe*, DOI 10.11.1186/s12302-015-0043-8) concludes that *“annual farmers’ suicide rates in rainfed areas are inversely related to farm size and yield and directly related to increases in Bt-cotton adoption (i.e. costs)”*. VIDARBHA in Maharashtra, which saw the highest number of suicides in India (referred to as the *‘killing fields’*) relies on rain fed conditions; yet Bt cotton is unsuited to such conditions requiring irrigated conditions.

46. Despite the evidence of the failure of Bt cotton, for the regulators it nevertheless remains the official template of ‘success’ for other Bt crops, and these are food crops. Virtually the entire range of our food crops have been and

are being actively tested in open field trials (FT) (that have been conducted over the last 15 years or so). Bt food crops employ the same Bt toxins or in combination, as in Bt cotton, and must therefore, be banned even in FTs. Furthermore, the evidence for the health and environmental risks of HT and Bt crops is growing over time. The US Court verdict against Monsanto over its herbicide Glyphosate is testimony to this (Ref para 42)

47. **The record shows:** GMO were approved fraudulently in the face of scientific warnings: clear, early warnings right from the start of possible harm. These early warnings have been confirmed and reinforced up to the present time, through independent studies; this despite great difficulties faced by scientists, which include ‘persecution’, and sackings, nothing short. Even the WHO’s, world renowned institute of cancer research, the IARC, which gave glyphosate a ‘2A’ classification as ‘*a probable carcinogenic*’ has not been spared, in a desperate attempt to discredit the Agency in order to force it to reverse its findings or even to cause it to be shut down! This is the collective evidence over 20 years of commercialised GM crops and their numerous ‘events’ released in open field trials. The systematic cover-up of safety concerns in conjunction with regulators in a number of countries includes the US first and foremost, India, the EU, Argentina, Bangladesh, among others.

48. Petitioners have drawn parallels (based on the evidence of studies of the health hazards of GMOs), with the historical evidence of 100 years of hazardous technologies, in the case of DDT, CFCs and Tobacco where the research analogies and disinformation campaigns are particularly apt. We are at that point where the data for GMOs is of the kind that matches the safety concerns that led to bans on tobacco and DDT.
49. **‘Latency Lacuna’**: In particular, is the *‘latency lacuna’*, or long period unravelling of harm. The impacts of GMOs are in the main chronic, may not be apparent in the short term, even though we have examples in the early years of GMOs of acute effects when people died in the US (the case of tryptophan). Cancers for example may only show-up after several years of ingesting GMOs. Other health impacts in the absence of epidemiological studies (and in the absence of labelling), particularly allergies are impossible to identify.
50. Even so, GMOs are uniquely differentiated in two key aspects from other hazardous technologies like CFCs and DDT. First, both CFCs and DDT were initially seen as almost magical in their effectiveness and benefits for the human race. The ‘malevolence’ of their impacts was revealed later. The distinction is important because in the case of GMOs, the ‘malevolence’ was acknowledged by scientists from the start. The so called ‘magic’ of this

technology, promoted as a technocratic fix for every agricultural malady was concocted in a series of self-reinforcing ‘myths’ that have now unravelled. Indian regulators faithfully endorse many of these myths, especially ‘*Substantial Equivalence*’, among others. The second point of differentiation is ‘timeliness’, (the GMO genie escapes at the point of environmental release), and the need for preventive action, a criticality we face globally, but especially in India, given our rich seed diversity. No parallels come to mind in the history of hazardous technologies that can be cited to match these two specific concerns with GMOs, as we wrestle with the problem of certain irreversible GMO CONTAMINATION of our genetic diversity in seeds and food if they are deployed. Genetic contamination of our foundation seed stock will change the molecular structure of our food for all time. Therefore, the need is for collective precautionary action now, because of their potential for irreversible global/widespread ecological disruption and impact on animal and human health.

51. **APPREHENSIONS OF TWO PARLIAMENTARY STANDING COMMITTEES ON GMOs**

The report of two PSCs on GMO recognise the serious lack of independent regulation of GMOs and conflict of interest. The Key recommendations/conclusions are:

(a)PSC Report on Agriculture, 2012 with the Govt. response (2013-14):

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)

At 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 for 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.

**CONFLICT OF INTEREST OF AGENCIES
INVOLVED IN EXISTING REGULATING
MECHANISM**

(Recommendation Para No. 3.46)

At 1.28 The Committee had observed that GEAC is headed by a civil servant who also functions in another capacity in MoEF, the controlling authority of GEAC. The Co-Chairman of GEAC, though purportedly from outside is nominated by DBT, the promoter Department. The Vice-Chairman is again a civil servant and simultaneously discharging responsibilities in another role in MoEF. By its very composition, the Committee does not have regular existence and meets monthly, only when some decisions are to be taken. There is a serious dearth of scientists of eminence in sufficient number. Therefore, more or less the same set of people sit on both sides to develop technologies/products and also assess/evaluate and approve them as well.

At 2.86 The Committee cannot but express their extreme displeasure at this mind set of a regulatory agency which is mandated with ensuring safety of environment, human health, food and feed of the Country. The above-cited response of GEAC (Petitioner clarification – this is with regard to antibiotic marker-

free GMOs at 2. 85) betrays a complete lack of concern towards its role and responsibility. Rather it conveys in unequivocal terms its strong inclination towards the benefit of the industry. The Committee, therefore, recommend the Government to not leave such a crucial decision in the hands of GEAC but come up with a clear-cut policy in this regard without any further loss of time. (emphasis added)

(b) PSC 2017: Three Hundred and First Report: ‘genetically modified crops and its impact on environment’

At 77 The Committee is also at a loss to understand the haste being made for the commercialisation of GM crops in the country. 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 and on our own population as well as 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

At 87 The Committee, further, learns that 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. The Committee has been given to understand that GM mustard being a 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, from what one can gather from different quarters, 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. 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 Committee, accordingly, recommends that the Ministry of Environment, Forest and Climate Change should examine the impact of GM crops on environment thoroughly, in consultation with the concerned Government agencies, experts, environmentalists, civil society, and other stakeholders so that the nation is very clear about all its probable impacts before taking a call in the matter.

52. The Petitioners respectfully reiterate that the TEC (Technical Expert Committee), comprising of scientific

experts, appointed by this Hon'ble Court have unanimously recommended: (i) a ban on the environmental release of HT crops; (ii) Crops where India is a centre of origin or genetic diversity and (iii) a moratorium on all field trials and an indefinite moratorium on Bt food crops (conditions attached). In view of the subsequent failure of Bt cotton, Bt food crops must also be banned.

53. The present application is being filed *bona fide* and in the interest of justice. No prejudice will be caused to the Respondents if the instant application is allowed.

PRAYER

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

- A. Direct a ban on the import of such viable seed of any crop:(a) from anywhere in the world, if there are commercialised GMO varieties in such crops; and (b) from such countries that are field testing GM varieties;
- B. Direct a ban on the environmental release of any HT GMO and the up-rooting of illegal HT soy in Gujarat and elsewhere;

- C. Direct a high level Commission of enquiry on (a) the cultivation of illegal GMOs on Indian soil, especially HT soy, (b) the illegal import of viable GMO seed into India and (c) the illegal import of GMOs in processed food/oil/seed cake etc;.
- D. Direct a ban on Bt crops along with a moratorium on all open field trials, excepting *Bt.* cotton;
- E. Issue such other directions or orders that this Hon'ble Court may deem fit and proper.

Filed By:

Drawn On : 20.08.2018

Filed On :

NIKHIL NAYYAR

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 ___ day of August, 2018 at Mhow, Madhya Pradesh.

DEPONENT