2024 INSC 545

REPORTABLE

IN THE SUPREME COURT OF INDIA

CIVIL ORIGINAL/APPELLATE/INHERENT JURISDICTION

WRIT PETITION (CIVIL) NO.115 OF 2004

GENE CAMPAIGN & ANOTHER ... PETITIONERS

VERSUS

UNION OF INDIA & OTHERS ... RESPONDENTS

WITH

WRIT PETITION (CIVIL) NO.260 of 2005

WRIT PETITION (CIVIL) NO.840 OF 2016

CIVIL APPEAL NO.4086 OF 2006

CONTEMPT PETITION (CIVIL) NO.295 OF 2007
IN
WRIT PETITION (CIVIL) NO.260 of 2005

CONTEMPT PETITION (CIVIL) NO.6 OF 2016
IN
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J U D G M E N T

NAGARATHNA, J

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Acronyms

AFES	Assessment of Food/Feed and Environmental Safety
AICRP	All India Coordinated Research Project
ASHA	Alliance for Sustainable and Holistic Agriculture
BG-II	Bollgard-II
BRAI	Biotechnology Regulatory Authority of India
BRL	Biosafety Research Level
BSU	Biosafety Support Unit
Bt	Bacillus thuringiensis
CAC	Codex Alimentarius Commission
CBD	Convention on Biological Diversity
CCMB	Centre for Cellular & Molecular Biology
CGMCP	Centre for Genetic Manipulation of Crop Plants
CIB&RC	Central Insecticide Board & Registration Committee
CPB	Cartagena Protocol on Biosafety
CSIR	Council of Scientific and Industrial Research
DARE	Department of Agricultural Research and Education
DBT	Department of Biotechnology
DGFT	Directorate General of Foreign Trade
DLC	District Level Committee
DMH-11	Dhara Mustard Hybrid-11
DoAC	Department of Agriculture and Cooperation
DRMR	Directorate of Rapeseed and Mustard Research
ECHR	European Convention on Human Rights

ERA	Environmental Risk Assessment
FAO	Food and Agriculture Organization
FSSA, 2006	Food Safety and Standards Act, 2006
FSSAI	Food Safety and Standards Authority of India
GE	Genetically Engineered
GEAC	Genetic Engineering Appraisal Committee
GEF	Global Environment Facility
GEO	Genetically Engineered Organism
GM	Gene Modification or Genetically Modified
GMO	Genetically Modified Organisms
HPV	Human Papilloma Virus
HT	Herbicide Tolerant or Tolerance
IAASTD	International Assessment of Agricultural Knowledge, Science and Technology for Development
IARI	Indian Agricultural Research Institute
IBSC	Institutional Biosafety Committee
ICAR	Indian Council of Agricultural Research
ICMR	Indian Council of Medical Research
IMTECH	Institute Of Microbial Technology
IPR	Intellectual Property Rights
LMO	Living Modified Organism
MoA	Ministry of Agriculture
MoEF	Ministry of Environment and Forests
MoEF&CC	Ministry of Environment, Forest and Climate Change

MoHFW	Ministry of Health and Family Welfare
NARS	National Agricultural Research System
NBPGR	National Bureau of Plant Genetic Resources
NGO	Non-Governmental Organisation
NGT	National Green Tribunal
NIN	National Institute of Nutrition
NKSPLR	Nagoya Kuala Lumpur Supplementary Protocol on Liability and Redress
PAU	Punjab Agricultural University
PRMC	Post Release Monitoring Committee
PSC	Parliamentary Standing Committee
R&D	Research and Development
RARM	Risk Assessment and Risk Management
RAU	Risk Assessment Unit
RCGM	Review Committee on Genetic Manipulation
RDAC	Recombinant DNA Advisory Committee
rDNA	recombinant DNA
SBCC	State Biotechnology Co-ordination Committee
SOP	Standard Operating Procedures
TEC	Technical Expert Committee
UK	United Kingdom
UNEP	United Nations Environment Programme
USA	United States of America

Preface:

The ideas drawn from sacred texts of the world have proffered to worship and respect nature and impel mankind to preserve the same. This, in essence, is the doctrine of intergenerational equity.

(i) The verses in Srimad Bhagavata Mahapurana depict nature and its creations to embody the divine, as it states 'Ether, air, fire, water, earth, planets, all creatures, trees and plants, rivers, and seas, they all are organs of God's body, remembering this, a devotee respects all species".

(ii) In all other faiths practised in India, the earth is deemed to be the sacred creation of God.

(iii) Nature and all her elements are considered sacred. Human beings are said to be composed of five elements of nature, which teach lessons and inspire strength in the formulation of our character:

> "Earth teaches us patience, love; Air teaches us mobility, liberty; Fire teaches us warmth, courage; Sky teaches us equality, broad-mindedness; Water teaches us purity, cleanliness."

1.1 Faced with the widespread destruction of the environment, people everywhere are coming together to understand that we cannot continue to use the benefits of the earth as we have in the past. A new ecological awareness is beginning to emerge which, rather than being downplayed, ought to be encouraged to develop into concrete programs and initiatives.

2. This Court, in ***State of Bihar vs. Murad Ali Khan, (1988) 4 SCC 655 ("Murad Ali Khan")*** speaking through Venkatachaliah, J. (as the learned Chief Justice then was) observed that "*the tragedy of the predicament of the civilised man is that, 'Every source from which man has increased his power on earth has been used to diminish the prospects of his successors. All his progress is being made at the expense of damage to the environment which he cannot repair and cannot foresee'*."

3. This Court in ***M.C. Mehta vs. Kamal Nath, (1997) 1 SCC 388 ("M.C. Mehta")***, speaking through Kuldip Singh, J. observed that, *"…the executive acting under the doctrine of public trust cannot abdicate the natural resources and convert them into private ownership, or for commercial use. The aesthetic use and the pristine glory of the natural resources, the environment and the ecosystems of our country cannot be permitted to be eroded for private, commercial or any other use unless the courts find it necessary, in good faith, for the public good and in public interest to encroach upon the said resources."*

4. These writ petitions, filed in public interest in the years 2004 and 2005, have been pending since then. However, IA No.47 of 2016 and IA No. 122182 of 2021 were filed by the petitioner (Aruna Rodrigues) in Writ Petition (Civil) No.260 of 2005, leading to the hearing of the said applications and consequently, the writ petitions also.

The catalyst for considering these writ petitions on merits is the approval of Genetic Engineering Approval (now Appraisal) Committee (GEAC) dated 18.10.2022 culminating in the decision dated 25.10.2022 being questioned by the petitioners. It would therefore be useful to initially state the bird's eye view of the controversy.

Bird's eye view of the controversy:

5. What does it mean to preserve, protect and respect the citizens' right to a safe and healthy environment while exploring and experimenting with era-altering novel technologies? That is the crux of the controversy in these cases. The factual aspects of the controversy were crystallised to some extent when this Court had set up Technical Expert Committee (TEC) on 10.05.2012.

5.1 In the immediate context, these cases impugn the decision taken by GEAC to grant approval for environmental release of Dhara Mustard Hybrid-11 (DMH-11) mustard at the 147th meeting held on 18.10.2022. Whether the said approval was in compliance or in derogation of the recommendations of the TEC Report is a foundational aspect. Whether the said decision is in consonance with due process of law, as understood in the context of the public trust doctrine? There is also the question whether the right to a safe and healthy environment under Article 21 has been violated and whether there has been a violation of the precautionary principle.

5.2 In these cases, the said controversy has been considered from several angles. Arguments at length have been heard by us. Therefore, we propose to encapsulate the pleadings, arguments and voluminous materials that has been submitted during the course of the hearing while arriving at the findings and conclusion in this matter.

Pleadings:

Writ Petition (Civil) No.115 of 2004:

6. According to petitioner in Writ Petition (Civil) No.115 of 2004, namely, Gene Campaign, it is a society registered under the Societies Registration Act, 1860. It consists of lawyers, geneticists, social scientists, agriculturalists, economists, environmentalists, farmers etc. who work towards the cause of protecting genetic resources and ensuring that the rights of rural and tribal communities to access the same are not infringed. Petitioner No.2, Dr. Suman Sahai is the President of Gene Campaign, a researcher and instructor in several institutions in India and abroad. It is his considered opinion that the use of Gene Modification (GM) technology must not be permissible without having the requisite safeguards and regulatory regimes in place.

6.1 The prayers in Writ Petition (Civil) No.115 of 2004 filed by the petitioners read as under:

"The petitioner therefore, prays that in the facts and circumstances of the present case, this Hon'ble Court may be pleased to issue a writ of mandamus or writ or direction of like nature to:

i) direct the respondents to bring the Rules for Manufacture, Use, Import, Export and the Storage of Hazardous Micro-organisms, Genetically Engineered Organisms or Cells, 1989 in consonance with Article 14, 19, 21, 38, 47, 48, 48A read with 51-A(g) of the Constitution and in the eventuality of the respondents failing to do so, declare the Rules of 1989 as unconstitutional;

ii) direct the Respondents to set-up a High-Power Committee to formulate a National Policy on Genetically Engineered Organisms (GEOs) through a multi-stakeholder consultation process;

iii) direct the Respondents to observe a moratorium on various permissions/approvals/trials concerning GEOs, in particular of commercial nature, particularly of crops for which India is a Centre of Origin/Diversity, till the Rules are amended and a sound Regulatory and Monitoring System is put in place;

iv) pass such other and further orders as this Hon'ble Court may deem fit and proper in the facts and circumstances of the case."

7. The pleadings in the aforesaid writ petition could be encapsulated as under:

7.1 Writ Petition (Civil) No.115 of 2004 has been filed for the issuance of a writ of mandamus or similar writ directing the respondent-State to bring the Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro-Organisms, Genetically Engineered Organisms or Cells, 1989 ("the 1989

Rules", for the sake of convenience), which have been framed under Sections 6, 8 and 25 of the Environment (Protection) Act, 1986 ("EP Act, 1986", for short) in consonance with Articles 14, 19, 21, 38, 47, 48, 48A read with Article 51-A(g) of the Constitution and if there is a failure to do so, to declare the said Rules as unconstitutional. It is averred that this Court has on various occasions interpreted Article 21 of the Constitution to include the right to health of the individual as well as to a clean and safe environment. That tenets of the precautionary principle, sustainable development, polluter pays principle and inter-generational equity doctrine have been held by this Court to form a part of Articles 14 and 21 of the Constitution. That there is a need for the 1989 Rules to be in accordance with the aforesaid principles so as to be held constitutional. That the public need to be provided sufficient opportunity to participate in the process of decision-making when there is an actual or likely possibility of their fundamental rights being affected and necessary information needs to be made available to facilitate the same. The said right has been recognized by the decision of this Court in ***Research Foundation for Science Technology National Resource Policy vs. Union of India, (2003) 9 SCALE 303 : (2005) 10 SCC 510 ("RFSTE").***

7.2 It is further averred that the 1989 Rules as they exist are not in conformity with established principles of environmental law as elucidated by this Court. The 1989 Rules are also stated

to be not in conformity with international instruments such as the Convention on Biological Diversity (CBD) and the Cartagena Protocol on Biosafety (CPB), that have been ratified by India. That, a reading of these along with the fundamental rights conferred by the Constitution would serve the purpose of furthering the said rights and such an approach should be adopted by this Court.

7.3 That Genetically Modified Organisms (GMOs) are an emerging area of research and study but the 1989 Rules are still inadequate to meet the challenges of the limited findings and evidence that are a product of this research. That overseas jurisdictions have established robust regimes that regulate GMOs, in recognition of the risk they may pose to the environment. But the 1989 Rules as they stand do not appear to contain any of the safeguards found in the regulatory regimes of other jurisdictions. The aforesaid absence of safeguards has contributed to India being used as a "dumping ground" and the Country being used to test experimental crop varieties that have not been sufficiently studied, with these possibly posing a serious risk to the country's biodiversity. That this would directly impact the economic prospects of a large section of the population that works in the agricultural sector and could further harm the country's food security. Small and marginal farmers are to be the most disadvantaged in the aforesaid scenario.

7.4 That the 1989 Rules were enacted owing to mounting evidence of the possible adverse effects of GMOs on agricultural ecosystems and the country's biodiversity as well as on human and animal health. It is the petitioners' case that the said Rules are riddled with lacunae that lead to them being applied arbitrarily and in violation of the Constitution. That the said Rules do not bear any mention as to the qualifications required to be eligible for membership in the various regulatory agencies constituted thereunder. This renders the functioning of these agencies largely ineffective as they often lack the necessary technical competence, particularly in the fields of Risk Assessment and Risk Management (RARM).

7.5 Further, the prescribed constitution of various agencies, in particular those of the Review Committee on Genetic Manipulation (RCGM), GEAC, the State Biotechnology Co-ordination Committees (SBCC) and District Level Committees (DLC), include representatives of various authorities who do not possess the necessary qualifications, technical expertise, competence, skills and knowledge to carry out the respective mandates of each agency. Majority of the members are only in *ex-officio* capacity and lack competence in the field of operation.

7.6 That, there is a complete lack of transparency at each stage of the regulatory process. The 1989 Rules do not allow for public to access information despite GMOs having possible adverse effects on human and animal health, socio-economic conditions

as well as the environment which directly pertains to the public's rights and interests. These Rules do not allow public to sufficiently participate in the decision-making at any stage, *viz.* grant of approval for research, field trials or commercial-scale cultivation of a GM crop. Public participation is needed to both accurately gauge the risks and benefits as well as to increase the confidence of public in GMOs.

7.7 That the 1989 Rules do not require taking prior informed consent from those farmers and Gram Sabhas which are located in the vicinity where a field trial would be conducted. This is in violation of the 73rd and 74th Constitutional Amendments which make the involvement of Gram Sabhas and Gram Panchayats in such decisions necessary and non-optional.

7.8 That the Rules envision a regulatory regime that lacks accountability and there is no indication as to who would bear the liability in case of an erroneous decision being made that has an adverse impact on human and animal health, the environment and the socio-economic conditions of the country. Such harm may take the form of personal injury, property damage or financial loss, however, the liability corresponding to each of these has not been considered in the 1989 Rules at all.

7.9 Further, the penal provisions contained in the said Rules do not sufficiently deter prospective offenders as these provisions just mention "measures" that may be taken by the concerned agency, which do not include the description of a penalty of any

kind. The actions that can be taken by the concerned agencies are only in a corrective capacity to ensure damage is minimized.

7.10 That neither SBCC nor DLC had been made functional at the time of filing of this Petition despite the commercial cultivation of the *Bacillus thuringiensis* (Bt) cotton crop which is a GMO.

7.11 That GM technology is an emerging technology that enables outcomes that were hitherto unimagined such as the transposition of the genes of fish into those of tomatoes, genes of bacteria into those of plants etc. There is an inherent uncertainty to this technology and its effect on the environment and on human life. This necessitates the re-examination of extant regulations and regulatory regimes so as to mould them in light of newer developments.

7.12 That till these uncertainties have been clarified through the process of scientific research thereby enabling a thorough consideration of the risks and benefits, there must be a moratorium on the commercial release of GMOs.

7.13 That the impact of GM technology would vary based on the socio-economic, cultural, and ecological context of each country and any research conducted must evaluate the specific impact of such technology in the Indian context. On the other hand, GM technology have evolved in industrialized and developed economies with highly mechanized agricultural processes and

vast monocultural tracts that are generally isolated from natural ecosystems. Unlike India, these countries do not possess similarly rich biodiversity.

7.14 That India, being the centre of origin for many food crops, has to be more vigilant and cautious in adopting this new technology which is still in the process of evolution. In particular, transgenic varieties of crops for which India is the centre of origin should not be released for commercial cultivation until its impact is adequately assessed. That there are serious concerns about contamination of the natural gene pool of crops originating in India. These are some of the potential consequences:

i. Contamination of non-GM crops and their wild relatives;
ii. Proliferation of weeds and creation of new weeds due to flow of foreign genes from GM crops to non-GM crops and their wild relatives;
iii. The likely formation of difficult-to control novel weed types due to transfer of foreign genes that confer hardiness;
iv. Destruction of soil micro-organisms due to release of toxins from genes, like Bt gene, leading to adverse impact on crop productivity.

7.15 That farm lands in India are small and closely packed together as agriculture is practiced in close proximity to natural biodiversity, often bordering forest areas or even within forest areas, where natural gene pools are found. A GM crop cultivated in one field is likely to impact other fields as well as the natural

ecosystems. No research has been undertaken to assess the adverse effects of such transfers.

7.16 Moreover, GM crops could directly impact the economic prospects of a large section of the population that works in the agricultural sector. Small and marginal farmers are likely to be the most disadvantaged. Other socio-economic risks include market concentration, the loss of livelihood of small farmers, and restriction on the consumers' right to choose.

Writ Petition (Civil) No.260 of 2005:

8. The petitioner who is a public-spirited citizen in this case has made the following prayers and has averred as follows in the context of GM Technology and GM Crops:

> "The petitioners therefore, pray that in the facts and circumstances of the case, this Hon'ble Court may be pleased to issue appropriate writs or directions to:
>
> A) Direct the Union of India not to allow any release of GMOs into the environment by way of import, manufacture, use or any other manner unless the following precautions are taken.
>
> > (a) a protocol for all the required bio-safety tests of the GMOs proposed to be released is prepared by the GEAC after processes of public notice and public hearing.
> >
> > (b) The GMO has been subjected to all the required bio-safety tests, prepared on the basis of the required Biosafety tests on the basis of the above protocol, by agencies of independent expert bodies, and results of which have been made public.

B) Direct the Union of India to ban 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.

C) Direct the Union of India to put in place rules to ensure that it shall be compulsory for any dealer or grower selling GMOs to label them as such.

D) Pass such other and further orders as this Hon'ble Court may deem fit and proper in the facts and circumstances of the case."

(i) According to this petitioner, there are outstanding safety concerns linked with Genetically Engineered (GE) technology. Transgenic contamination is unavoidable and there can be no co-existence between GM and Non-GM agriculture.

(ii) That research shows that Bt proteins, incorporated into 25% of all transgenic crops worldwide, to be harmful to a range of non-target insects, worms and amphibians. Some of them are potent immunogens and allergens. In fact, glyphosate and the Roundup herbicide used on most herbicide resistant crops is shown by studies to be lethal to amphibians.

(iii) That GM crops have led to an increase in pesticide use, financially hurting farmers and harming the environment.

(iv) That GE technology is a fit case for the application of the precautionary principle which necessitates that if there are reasonable scientific grounds for believing that a new process or product may not be safe, it should not be

introduced until convincing evidence of reasonable certainty of no harm is obtained. In addition, if the dangers are considered serious enough, then the principle may require withdrawal of GM products or impose a ban or a moratorium on further use thereof.

(v) That safety testing for GE food is absolutely necessary for India before the release of any GMO into the Indian environment. However, there are very few established protocols for assessing the potential health impacts of GE crops. All one finds is loose guidelines that in most cases only list certain tests or procedures without specifying how they are to be conducted.

(vi) That biotechnology companies frequently deny access or allow strictly conditioned access, to data on crop materials on the basis of confidentiality and IP concerns, making it very difficult for regulatory authorities and independent researchers to verify or review test claims on the safety of GE crops and foods.

(vii) That the extant regulatory system in India is ill-equipped to handle challenges outlined above, as past experience also confirms. Circumstances surrounding the initial approvals of Bt cotton in India is a good example. The RCGM, under the Department of Biotechnology (DBT), is a body that did not have the jurisdiction to grant permission for the release of GMOs into the environment. Yet, it was originally the RCGM which illegally permitted the release of the GMOs

into the country for the first time. It was only when there was a public outcry over the serious illegality of these clearances that attempts were made to get the release of GMOs cleared retrospectively.

(viii) That even for technologies which have been tried and tested, and found to be far safer than GE, for instance Hydro-electric projects, the relevant statutes mandate a public notice and public hearing as well as Environmental Impact Assessment. Hence, it is arbitrary and unreasonable not to have a mandatory public notice and public hearing before approvals for the release of GMOs are granted.

(ix) That as per current practice, the applicant company itself is asked to do testing. The test results are not available for public scrutiny. This is entirely without logic and is a clear conflict of interest involving the same biotech company that has a commercial interest in the approval of the GMO.

(x) That in India, like many other developing countries, organizations which are substantially funded by the biotech industry have sought to influence regulatory and other decision-making processes by conducting "awareness" and "educational" programmes. The Governments of advanced countries too, have been a handmaiden to GE Industry, often arm-twisting developing countries to adopt pro-GM stances.

8.1 It is further averred that the CPB was adopted in 2002 and came into force on 11.09.2003. It is a binding International agreement on Biosafety and India being a signatory, is bound to implement its provisions. According to Article 10(6) of the Protocol, the lack of scientific certainty due to relevant scientific information and knowledge regarding the extent of potential adverse effects shall not prevent the contracting party from taking a decision, as appropriate, in order to avoid and/or minimize potential adverse effects. In addition, Annexure-III of the said protocol includes, *inter alia*, the general principles of risk assessment. It states that risk assessment should be carried out in a scientifically sound and transparent manner and implores states to take into account expert advice as well as guidelines developed by relevant international organizations. Further, Article 21(6) of the said Protocol prescribes that the information about the risk assessment cannot be kept confidential.

8.2 That the United Nations Convention on Biological Diversity (CBD), 1992, to which India is a party, *inter alia*, requires that the contracting parties shall domestically regulate or manage the risks associated with the use and release of Living Modified Organisms (LMOs) resulting from Biotechnology and which are likely to have adverse environmental impacts and risks to human health. It also implores states to introduce appropriate procedures to require impact assessment of proposed projects

likely to have significant adverse effects on biodiversity and to allow public participation in the procedure.

8.3 That in addition to implementing a moratorium on the release of any GMO into the domestic environment until adequate biosafety tests demonstrate safety beyond reasonable doubt, labelling for imports sourced from countries which produce GM crops and foods should be mandated. Therefore, both moratorium and labelling must be concurrent mandatory requirements.

8.4 That farmers have the right to save seed for sowing in the next season, which a patent-based regime of GM seeds will effectively deny. This choice is a fundamental right and must be retained as such for better farming prospects and livelihoods. Therefore, the petitioner has sought the aforesaid reliefs.

Writ Petition (Civil) No.840 of 2016:

8.5 The petitioner is stated to be a public-spirited citizen based in Chennai and is involved in a consumer movement in Tamil Nadu called 'Safe Food Alliance'. The petitioner is stated to be one of the National Convenors of Alliance for Sustainable and Holistic Agriculture (ASHA), which is an organization that has been actively involved in the cause of the genetic modification of crops and its effects on human health.

8.6 It is averred by the petitioner that in September 2015, the Centre for Genetic Manipulation of Crop Plants (CGMCP)

submitted an application to GEAC, seeking approval for the environmental release of GE mustard hybrid (DMH-11) seeds and the use of parental events, i.e., Varuna bn 3.6 and EH-2 modbs 2.99, for development of new generation hybrids. Upon receipt of the application, GEAC, in its 125th meeting held on 11.12.2015, appraised the same and decided that the CGMCP will be invited to give a presentation before GEAC in the subsequent meeting. Pursuant to the same, the CGMCP made a presentation before GEAC in the 126th meeting held on 04.01.2016 and the CGMCP was directed to furnish clarifications with respect to some issues in para 3.3 of the Minutes of the Meeting. It was further decided in the meeting that a sub-committee would be constituted under the chairmanship of Dr. K. Veluthambi, Co-Chair of GEAC, and the said sub-committee would have the duty of examining the issues raised by GEAC in para 3.3 and submit a report with recommendations to GEAC.

8.7 On 02.02.2016, the sub-committee appointed by GEAC convened its first meeting and in that meeting, it voiced concerns over the clarifications furnished by the CGMCP on the issues mentioned in para 3.3. However, in the 127th meeting of GEAC held on 05.02.2016, GEAC adopted the recommendations of the sub-committee and directed the CGMCP to revise the biosafety dossier, in light of the comments of the sub-committee and the biosafety unit, and prepare an RARM document for further

review. It is stated that GEAC had decided to put the biosafety dossier in the public domain, but this was not carried out.

8.8 In its 128th Meeting held on 04.03.2016, GEAC decided to await the completion of the Biosafety Support Unit's (BSU) review of the revised dossier before further consideration. On 11.04.2016, the sub-committee, in its 2nd Meeting, recommended incorporating expert comments and remarks from the Biosafety Unit into its report. The report was to be presented to GEAC and uploaded onto its website. In its 129th Meeting on 20.06.2016, GEAC noted the Sub-Committee's request for an additional month to finalize recommendations. Subsequently, in its 130th Meeting, GEAC concluded that a report had been submitted by the sub-committee, titled "Assessment of Food and Environmental Safety (AFES)". It was published on GEAC's website for stakeholder comments within a period of 30 days. However, it was complained that the biosafety dossier was deliberately not disclosed on the website for public scrutiny.

8.9 On 07.09.2016, Dr. Bhargava, a member of GEAC, made a startling revelation. He stated that the so-called Report of the sub-committee titled "Assessment of Food and Environmental Safety" was never shared or discussed before GEAC. Following this revelation, on 22.09.2016, various scholars and public activists endorsed an email addressed to the Hon'ble Minister of Environment, Forest and Climate Change. The email raised serious objections to the conduct of the appraisal process,

particularly the refusal to disclose the biosafety dossier to the general public. It urged the Ministry of Environment, Forest and Climate Change (MoEF&CC) to extend the consultation process by another 120 days. In addition to the email, on 24.09.2016, eminent scholars and experts sent a letter to the Hon'ble Minister of Environment, Forests and Climate Change, expressing grave concerns regarding GEAC's blatant refusal to disclose the biosafety data to the general public, hindering a meaningful exercise of public consultation. It also requested an extension of the consultation process for another 120 days. Despite objections and requests for transparency, it is stated that GEAC continued the consultation process, culminating in a comment note published on 30.09.2016, refusing to extend the consultation period and setting the deadline for receiving comments as 05.10.2016.

8.10 Challenging the appraisal procedure adopted by GEAC, the petitioner has preferred the writ petition before this Court, under Article 32 of the Constitution of India, primarily contending that the aforesaid procedure adopted by GEAC was not only arbitrary but also lacked proper application of mind, rendering it illegal and violative of the fundamental rights enshrined under Articles 14 and 21 of the Constitution.

This assertion was underscored by instances such as the failure to disclose crucial information, including the biosafety dossier, and the opaque nature of the consultation process,

which impedes meaningful public participation. Further, the petitioner has emphasized the statutory obligations of GEAC to exercise its power of granting approvals for environmental release of GE products in a fair, transparent, and reasonable manner, especially considering the lack of any procedure laid down under the 1989 Rules for the exercise of its powers by GEAC. It is stated that the potential impact of the GM crops on health and environment can only be known after a long gestation period and therefore, a stricter scrutiny ought to have been undertaken.

8.11 Furthermore, the petitioner has criticized the sub-committee formed by GEAC, arguing that such delegation of statutory functions to another body is *ultra vires* the 1989 Rules. Additionally, concerns regarding the non-disclosure of the biosafety dossier despite assurances and directives from authorities has been raised, which undermine the transparency and integrity of the decision-making process.

8.12 The petitioner has also questioned the validity and adequacy of the AFES Report uploaded by GEAC, highlighting discrepancies in its findings, the lack of application of mind and the lack of comprehensive scientific scrutiny. It is averred that the said document was merely a 133-page summary document that does not explain to the public the data collected and the studies/tests conducted by the CGMCP. It is further pointed out from the AFES report that no study was conducted to examine

the physiological impact of the transgene products from the transgenic mustard hybrid DMH-11 on the insects, no testing was done under the herbicide-sprayed conditions on an HT crop, and no testing was done on the honey quality, despite the questionable study of the impact on honey bees by the crop developers having vested interests in the subject.

8.13 Moreover, the restricted access to the biosafety dossier, despite assurances and directives to disclose it, has also been criticized, since it impedes meaningful public engagement and violates the rights of stakeholders to be informed and participate effectively in the consultation process. In terms of the consultation process, the petitioner has contended that GEAC ought to have adhered to the principles of fairness and transparency and ought not to have made a mockery of the entire process of public consultation to defeat the valuable rights of the general public to be informed about the critical date pertaining to the transgenic mustard hybrid DMH-11 crop. It was asserted that the present consultation process couldn't be completed without making available to the public the critical scientific data. Further, the petitioner avers that it was also highly arbitrary to expect all the interest stakeholders from all corners of the country to travel to New Delhi and conduct a physical examination of the 3000 odd pages at the premises of the MoEF&CC and submit meaningful inputs.

8.14 It is averred that there has also been a failure to involve State Governments in the process, despite agriculture being a state subject and mustard being a highly important crop for the country.

8.15 Finally, the petitioner has drawn attention to the comparative inadequacy of the testing and consultation processes for genetically modified (GM) mustard, compared to previous cases like Bt brinjal.

8.16 Overall, the petitioner has contended that the appraisal process for transgenic mustard hybrid DMH-11 lacks transparency, has violated legal mandates, and fails to adequately consider the concerns of stakeholders, thereby warranting judicial intervention to ensure procedural fairness and safeguard public interest.

Civil Appeal No.4086 of 2006:

8.17 This appeal assails order dated 08.10.2003 passed by the Appellate Authority in Appeal No.2 of 2002, constituted under Rule 19 of the 1989 Rules notified under the EP Act, 1986. The Appeal No.2 of 2002 was filed against the order dated 05.04.2002 of GEAC granting conditional clearance to M/s. Maharashtra Hybrid Seeds Co. Ltd. for three transgenic Bt hybrid cotton varieties, namely, Bt MECH 12, Bt MECH 162 and Bt MECH 184. By the impugned order, the appeal was dismissed by the Appellate Authority.

8.18 *Vide* Order dated 08.09.2006, leave was granted and *vide* order dated 13.07.2017, the appeal was directed to be tagged with Writ Petition (Civil) No.260 of 2005.

Contempt Petition (Civil) No.295 of 2007 in Writ Petition (Civil) No.260 Of 2005; and, Contempt Petition (Civil) No.6 of 2016 in Writ Petition (Civil) No.260 Of 2005:

8.19 These contempt petitions have been filed alleging violation of orders dated 22.09.2006, 08.05.2007, 01.08.2007; and orders dated 15.02.2007, 08.05.2007, 08.04.2008 and 12.08.2008 respectively passed by this Court in Writ Petition (Civil) No.260 of 2005.

Significant Orders passed by this Court in Writ Petitions:

9. By order dated 01.05.2006, this Court had directed that until further orders, field trials of GMOs shall be conducted only with the approval of GEAC. Order dated 10.05.2012 referred to above also notes that as of the year 2007, nearly 91 varieties of plants, i.e., GMOs, were being subjected to open-field tests. However, in terms of the aforesaid order of this Court, no further open-field tests were permitted nor had GEAC granted any such approval except with the authorization of this Court. This had given rise to serious controversies before this Court as to, whether, or not, the field tests of GMOs should be banned, wholly or partially, in the country.

9.1 This Court, feeling that it had no expertise to determine such an issue, which, besides being a scientific question, would

have very serious and far-reaching policy consequences, by order dated 08.05.2007 lifted the moratorium on open-field trials, subject, however, to certain conditions. These included a directive in regard to the maintenance of 200 metres isolation distance while performing field tests of GMOs.

9.2 A further clarification was given *vide* order dated 08.04.2008, by which all concerned were directed to comply with the specific protocol of Level of Detection of 0.01 per cent. Since there was non-adherence to the said protocol and in the face of the report of one of the independent Experts, Dr. P.M. Bhargava, who was appointed to meet GEAC by the order of this Court dated 30.04.2009, the Government of India, on its own, imposed a complete ban on Bt brinjal.

9.3 Later, while hearing the Additional Solicitor General for Union of India as well as the learned counsel for the petitioners, this Court found that there was a consensus on the constitution of an Expert Committee on certain terms of reference as suggested in the Minutes of the Ministry's meeting dated 15.03.2011 as there was a joint prayer for its constitution.

9.4 In these writ petitions, *vide* order dated 10.05.2012, this Court had noted the prayers of the petitioners seeking issuance of directions or order to the respondent, namely the Union of India, *inter alia,* not to allow the release of GMOs into the environment by way of import, manufacture, use or any other manner. An ancillary prayer was for the prescription of a protocol

to which all the GMOs release would be subjected to. In addition, a direction was sought to the Union of India to frame relevant Rules in this regard and to ensure its implementation was sought.

Constitution of the Technical Expert Committee (TEC):

10. In view of the above plea, this Court, after several dates of hearing, *vide* order dated 10.05.2012 constituted a Technical Expert Committee (TEC), the constitution of which was as follows:

> "1. Prof. V.L. Chopra, Former Member, Planning Commission and Former Member, Science & Advisory Committee to the PMO, Recipient of Padma Bhushan.
>
> 2. Dr. Imran Siddiqui, Group Leader, Centre for Cellular & Molecular Biology (CCMB).
>
> 3. Prof. P.S. Ramakrishnan, Emeritus Prof. JNU.
>
> 4. Dr. P.C. Chauhan, D. Phil (Sci).
>
> 5. Prof. P.C. Kesavan, Distinguished Fellow, MS SRF (Research Foundation), Emeritus Professor, CSD, IGNOU, New Delhi.
>
> 6. Dr. B. Sivakumar, Former Director, National Institute of Nutrition (NIN), Hyderabad."

10.1 The Terms of Reference of the TEC were as follows:

> "A. To review and recommend the nature of sequencing of risk assessment (environment and health safety) studies that need to be done for all GM crops before they are released into the environment.

B. To recommend the sequencing of these tests in order to specify the point at which environmental release though Open Field Trials can be permitted.

C. To advise on whether a proper evaluation of the genetically engineered crop/plants is scientifically tenable in the greenhouse conditions and whether it is possible to replicate the conditions for testing under different agro ecological regions and seasons in greenhouse?

D. To advise on whether specific conditions imposed by the regulatory agencies for Open Field Trials are adequate. If not, recommend what additional measures/safeguards are required to prevent potential risks to the environment.

E. Examine the feasibility of prescribing validated protocols and active testing for contamination at a level that would preclude any escaped material from causing an adverse effect on the environment.

F. To advise on whether institutions/laboratories in India have the state-of-art testing facilities and professional expertise to conduct various biosafety tests and recommend mechanisms to strengthen the same. If no such institutions are available in India, recommend setting up an independent testing laboratory/institution.

G. The Expert Committee would be free to review reports or studies authored by national and international scientists if deemed necessary. The petitioners opined that they would like to formally propose three Expert Reports from Prof. David Andow, Prof. Jack Heinemann and Dr. Doug Gurian Sherman to be a formal part of the Committee's deliberations. The MoEF may similarly nominate which experts they choose in this exercise."

10.2 This Court directed the TEC to hear the Government, petitioners and any other intervenor, who, in the opinion of the TEC, could assist the cause of expeditious and accurate finalization of its report. A direction was also given to the TEC to submit an interim report on the following issue:

> "Whether there should or should not be any ban, partial or otherwise, on conducting open field tests of GMOs? In the event open field trials are permitted, what protocol should be followed and conditions, if any, that may be imposed by the Court for implementation of open field trials."

10.3 Thereafter, an order was passed by this Court on 09.11.2012 recording the filing of an interim report dated 07.12.2012 and the objections filed to the said Report by the Union of India and others. Six weeks' time was granted to the TEC to finalise and submit its final report. In the meantime, Dr. R.S. Paroda was appointed as a sixth member to the TEC in place of Prof. V.L. Chopra by order dated 09.11.2012. The TEC submitted its final report dated 30.06.2013. This included two reports, one, by the majority of five members of the TEC, and a separate note by Dr. R.S. Paroda.

Final Report of TEC:

10.4 The Final Report of TEC is divided into following two topics:

I. Background and Context of the TEC's Recommendations in the Interim Report; and

II. Agricultural Policy Considerations in Relation to Knowledge and Practices:

- ✓ Biotechnology and Agriculture
- ✓ Usage of GM Crops
- ✓ International Agreements and Instruments for Food Safety, Conservation and Regulation
- ✓ The Indian GMO Regulatory Structure
- ✓ Discussion of Recommendation of the Interim Report (IR) in the Context of the Terms of Reference for the TEC
- ✓ Deliberations of the TEC Following Submission of the Interim Report
- ✓ Issues that were discussed in the course of deliberations by the TEC
- ✓ Examination/Study of the Safety Dossiers
- ✓ Molecular data
- ✓ Health Safety Data
- ✓ Examples of differences
- ✓ Environmental Risk Assessments
- ✓ Summary
- ✓ Recommendations

10.5 The recommendations contained in the majority report are as follows:

"Recommendations

Based on the deliberations of the TEC and particularly the examination/study of the safety dossiers, it is apparent that there are major gaps in the regulatory system. These need to be addressed before issues related to tests can be meaningfully

considered, till such time it would not be advisable to conduct more field trials:

1. A secretariat comprising dedicated scientists with area expertise as well as expertise in biosafety needs to be established. This will require consultation with experts having experience at the international level in biosafety testing and evaluation of GM safety dossiers in reputed regulatory bodies. The TEC recommends doing it in collaboration with the Norwegian Government and GM regulatory body since the Norwegian system has an established commitment and experience in, is one of the few that are attuned to considering socio-economic issues that would be important in the Indian context. The regulatory body should have area-wise subcommittees/expert groups in for example:

    - Health (human and animal)
    - Environment and Ecology
    - Agroeconomics and Socioeconomics
    - Molecular biology
    - Entomology
    - Agricultural and Aquacultural Systems
    - Public Health
    - Soil science and microbiology
    - Plant biology
    - Regulatory toxicology
    - Plant and animal breeding and genetics

    A single committee such as the GEAC or RCGM doing all the valuation is not sufficient.

2. Conflict of interest in terms of location of the regulatory body needs to be addressed. The suggestion of the TEC is that the regulatory bodies to be located in the MoEF (environmental safety) and the MoHFW (health safety). At a different level, it is evident that members of the regulatory bodies should also be free of conflict of interest.

3. Specific sites for conducting confined field trials need to be designated, certified, and sufficient mechanisms put in place for monitoring the trials and ensuring restricted access, disposal of material, associated testing and other facilities, These sites should be used only for field trials of GM crops (GM and control material). The sites could be in ICAR institutes or State Agricultural Universities and required conditions for isolation should be established and supported appropriately by ICAR. Sites in company premises may also be considered for certification for trials, however the land should be permanently owned by the applicant/tester. Trials should not be conducted on leased land so as to avoid the possibility that it may be used for a different purpose following the trials.

4. Stakeholder participation, need, socio-economic considerations, societal impact, and sustainability should be some of the dimensions to be incorporated in the risk assessment and this should be done at an early stage in the risk assessment process."

10.6 The specific findings of the Report of the majority of TEC on the terms of reference may be discussed at this stage.

(i) *Firstly*, as to the nature of sequencing of risk assessment studies that need to be done for GM crops before they are released into the environment, the majority recommended the following:

a. The majority recommended consultation, ideally prior to the development of the GM product intended for field trials, wherein the applicant would provide information to the regulator about the product, its purpose (including whether it is intended for research only or commercialization), and how it is to be deployed in India. At this stage, the scope of issues that needs to be addressed relating to health and environmental safety can be discussed and defined on a case-wise basis keeping in mind the overall phases of risk assessment: hazard identification; hazard characterization; exposure assessment; risk characterization; and mitigation options. Need, socio-economic factors and sustainability should also be considered and thoroughly discussed at this stage. If a GMO is initially declared for research and at a later stage it is to be considered for commercialization then that would be treated as a fresh application. The overall process of risk assessment should follow the Flowchart for the Risk Assessment Process in the Guidance on Risk Assessment of LMIOs (UNEP/CBD/BS/COP MOP/6/13/Add.1) of the

Cartagena Protocol on Biosafety (CPB). In the case of health safety, the regulator should expect a suitable response to all relevant paragraphs of the Codex Alimentarius Commission (CAC) Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant DNA (rDNA) Plants (CAC/GL 45-2003) and any other chosen risk assessment procedure. In doing so the regulator establishes a minimum expectation of the risk assessment meeting international requirements. It was pointed out that both the CPB and CAC guidelines provide guidance with regard to principles and issues that are to be addressed. They leave open the details of specific tests to be carried out which is left to the national system and the regulator.

b. The majority, thus, noted the need to include chronic and transgenerational toxicity testing in feeding studies of rodents based on the fact that food is consumed over the entire lifetime and that nutritional stress can also lead to adverse or unintended effects over long-term exposure. The sensitive stages of reproduction also need to be included.

c. In addition, the majority emphasized that the regulatory process should be open to new scientific information that may have a bearing on the risk assessment, if necessary, even after deregulation of an event.

d. The majority also emphasised that the applicant should be responsible for providing to the regulator, all information that has a bearing on the risk assessment, regardless of whether it was obtained for the purpose of the risk assessment. In cases where the applicant is a collaborator/partner/ subsidiary in the development of the GMO, the applicant should provide this information along with the consent of all parties.

e. With regard to the nature of tests for Bt in food crops, the majority was of the view that the safety of Bt transgenics with regard to chronic toxicity has not been established and this needs to be done before it can be considered safe. In this regard, it was pointed out that by far, the largest deployment of transgenics worldwide is in soyabean, corn, cotton, and canola, all of which are used primarily for oil or feed after processing. Nowhere are Bt transgenics being widely consumed in large amounts for any major food crop, that is, directly used for human consumption. The majority could not find any compelling reason for India to be the first to do so. It, therefore recommended that there should be a moratorium on field trials for Bt in food crops (those that are directly used for food) intended for commercialization (not research) until there is more definitive information from sufficient number of studies as to the long-term safety of Bt in food crops.

f. The majority also examined issues in relation to Herbicide Tolerant (HT) crops. The conclusion here was that HT crops would most likely exert a highly adverse impact over time on sustainable agriculture, rural livelihoods, and environment. The majority, therefore, found them completely unsuitable in the Indian context.

g. The majority also highlighted how crops in their centres of origin and diversity often have a deep cultural significance that can get lost when utilitarian considerations predominate the discourse. Ceremonial and medicinal varieties can also be put at risk from GM crops by reduction of diversity and genetic purity. For example, in the case of brinjal, the Malapur variety in Karnataka is an essential accompaniment at temple festivals and religious ceremonies. Likewise, Oryza nivara, a medicinal rice, can also be at risk if GM rice comes to dominate the crop as has happened for example, in the case of cotton, in India.

h. The release of a GM crop into its area of origin or diversity has far greater ramifications and potential for negative impact than for other species. To justify this, the majority suggested a requirement of extraordinarily compelling reasons. GM crops that offer incremental advantages or solutions to specific and limited problems were not to be deemed sufficient reasons to justify such release. Not finding any such compelling reasons under

the present conditions, it recommended that release of GM crops for which India is a centre of origin or diversity should not be allowed at all.

(ii) *Secondly*, as for, when environmental release through open-field trials should be permitted, the majority recommended that the sequence of testing should be carried out in order of increasing environmental exposure required to perform the test. Tests should be done under the minimum conditions of exposure required for the test. In other words, the testing should proceed in a progressive manner that increases confidence with regard to safety. While not covering all possible tests for all crops, it laid down certain minimum tests possible to carry out under contained conditions within the laboratory of greenhouse, before the GMO is taken out of containment. These include tests based on bioinformatics such as possible allergenicity and toxicity; acute toxicity of the purified protein; in-vitro digestibility and any other biochemical tests on the purified protein. Where appropriate and necessary, tests such as those for general growth characteristics and plant habit as part of event selections may be performed under confined conditions in consultation with the regulator. Those tests on the plant that can be performed under contained conditions as judged by the regulator on a case-wise basis should be performed under contained conditions.

(iii) *Thirdly*, as for whether a proper evaluation of the GE plant is scientifically tenable in greenhouse conditions and whether it is possible to replicate the conditions for testing under different agro-ecological regions and seasons in greenhouse, the majority noted that it cannot be said that it is generally possible to replicate the conditions for testing under different agro-ecological regions and conditions in the greenhouse.

(iv) *Fourthly*, the majority noted the need to develop specific sites for conducting field trials. It also emphasised the need for sufficient mechanisms for monitoring the trials and ensuring restricted access, disposal of material, associated testing and other facilities. These sites were recommended to be used only for field trials of GM crops (GM and control material). The sites could be in Indian Council of Agricultural Research (ICAR) Institutes or State Agricultural Universities and required conditions for isolation should be established and supported appropriately by ICAR. Sites in company premises may also be considered for certification for trials, however the land should be permanently owned by the applicant/tester. Trials should not be conducted on leased land so as to avoid the possibility that it may be used for a different purpose following the trials.

(v) *Fifthly*, on the feasibility of prescribing validated protocols and active testing for contamination with the view to preclude any escaped material from causing an adverse

effect on the environment, the majority noted that the tests for detecting contamination at the stipulated level (0.01 %) are possible and have been demonstrated in some of the dossiers. However, it was emphasized that these in themselves do not preclude material from escaping. There are several ways in which contamination can occur and it probably will not be possible to deploy the tests at a level that will preclude the possibility of escape. Even in the most careful of conditions, contamination can occur. There are well-known examples of contamination having occurred as well.

(vi) *Finally*, on whether institutions and laboratories in India have the state-of-art testing facilities and professional expertise to conduct various biosafety tests, the majority noted that the professional expertise and standards across the institutions appeared unsatisfactory. However, it noted that it is ultimately the expertise available in the regulatory system that sets the standards for conducting and evaluating the biosafety tests. Unless this expertise and capacity is present, no amount of facility creation will be able to address the issues. Based on the examination of the safety dossiers the majority found that at present, the regulatory system has major gaps and these will require rethinking, investment, and re-learning to fix. A deeper understanding of the process of Risk Assessment is needed within the regulatory system for it to meet the needs of a proper

biosafety evaluation. This is not available in the country as per the majority. It, therefore, recommended that the requisite understanding be developed through consultation, collaboration, and capacity building. It is of critical importance that the Indian regulatory system develops the ability to assess how any GM product is likely to impact different sections of society.

10.7 Dr. R.S. Paroda submitted a separate dissenting report. A brief discussion of the Report may be adverted to.

(i) *Firstly*, as for the nature of sequencing of risk assessment studies that need to be done for GM crops before they are released into the environment, Dr. Paroda, in his dissenting report recommended the following:

a. The sequencing of studies provided in the "Guidance for Information/Data Generation and Documentation for Safety Assessment of Regulated, Genetically Engineered (GE) Plants", which is in draft stage, should henceforth be adopted quickly by the RCGM and GEAC.

b. The sequencing of studies presented in "Guidance for Information Generation and Documentation for Safety Assessment of Regulated, Genetically Engineered (GE) Plants" should, in future, be reviewed at regular intervals of no less than three years to ensure

that these guidelines remain consistent with internationally accepted best practices and standards.

c. Guidelines for the conduct of confined field trials and for GM food safety assessment that meet the international norms have currently been adopted by RCGM and GEAC. However, it was noted that the present approach for the environmental risk assessment (ERA) in the guidelines for research in transgenic plants was rather broad, whereas there is an urgent need for developing and adopting comprehensive guidelines for the ERA by RCGM and GEAC. The process for the same should be transparent and consultative, involving all stakeholders and it must start immediately.

d. A Risk Assessment Unit (RAU), as also suggested in the "Draft Establishment Plan for the National Biotechnology Regulatory Authority" should be established. Further, the RAU should serve both RCGM and GEAC and be permanently staffed by a multi-disciplinary team of scientists/experts competent enough and responsible for undertaking science-based risk assessments, including but not limited to those required to approve clinical or confined

field trials for the experimental GMOs as well as for their commercial release of GMOs (i.e., product specific risk assessments). The proposed RAU could be transitioned to the Biotechnology Regulatory Authority of India (BRAI), as and when the BRAI Bill is promulgated by the Parliament.

e. In addition to establishing the RAU, RCGM and GEAC should immediately establish a roster of qualified scientific experts in relevant disciplines to provide sound scientific advice/information on biosafety issues that could impact on human and animal health as well as the environment. The issue concerning conflict of interest should also be addressed while including experienced scientists to the roster.

f. Although, the safety assessment is completed after GEAC approval and subsequently the GM crops are to be treated in the same manner as their non-GM counterparts for the purpose of variety/hybrid release and registration, seed multiplication and cultivation; as a measure to ensure quality products for the farmers, the National Agricultural Research System (NARS) should have an assigned responsibility for the

conduct of confined field trials for assessing the agronomic performance, an essential requirement for the release of GM varieties/ hybrids in accordance with the National Seed Policy as well as National Seed Act. For this, ICAR Delhi can make good use of established infrastructure under the All India Crop Coordinated Programmes. It is advised that a single window system for managing the testing and release of GM varieties and hybrids should be established taking into account special considerations involved with GM crops *viz.* expression levels of inserted proteins, confirmation of the events etc., irrespective of whether these are produced by the private or public sector. In this context, the Ministry of Agriculture (MoA) should consider establishing a high-level committee of experts: including socio-economists, tanners, Non-Governmental Organisations (NGOs) and the representative of the private sector to review finally, for commercial release, the cases that are cleared by GEAC.

g. Once a GM variety hybrid is released, a post-release monitoring mechanism must be put in place.

(ii) *Secondly*, as to when environmental release through open-field trials should be permitted, the dissenting report noted that “open-field trial" is a misnomer in the context of trials of GM crops. This is because even though the trial is done in the open field, the GM plants and genetic material being tested are confined to the field trial site using measures to ensure that the “genes in pollen or seed do not escape from the trial site”. Thus, the right term is “Confined Field Trials”. It, then proceeded to suggest that Confined Field Trials should only be permitted by RCGM and GEAC after careful consideration of submissions that adhere exactly to the "Application for Confined Field Trial" form. This form, in combination with the "Guidelines and Standard Operating Procedures for Confined Field Trials of Regulated, Genetically Engineered Plants", clearly specifies the information required by the competent authorities to determine if a Confined Field Trial should be permitted or not. The application form was developed through a transparent, consultative process that included a period for public review and comment. Hence, both the approach and procedure for permitting Confined Field Trials in India have already been peer-reviewed and public-reviewed. In sum, the tests that are required prior to obtaining a permit for a confined field trial are:

a. Amino acid sequence homology comparisons to assess the extent to which the transgenic protein is similar in structure to known toxins;
b. Amino acid sequence homology comparisons to assess the extent to which the transgenic protein is similar in structure to known allergens.

It was also considered desirable, but not mandatory, to determine the maximum level of expression of the transgenic protein in the edible portions of the plant.

(iii) *Thirdly*, as to whether a proper evaluation of the GE plant is scientifically tenable in the greenhouse conditions, the dissenting report answered in the negative. It noted that a proper evaluation of a GE plant is scientifically not tenable in a contained greenhouse since it would not be feasible to replicate the conditions prevailing under natural field conditions representing different agro-ecological regions and growing seasons. Therefore, it was advised that confined field testing, as recommended under the present regulatory system, is the right option for a realistic evaluation of any GE plant to know its suitability for any agronomic trait of economic importance.

(iv) *Fourthly*, whether specific conditions imposed by the regulatory agencies for open-field trials (or "Confined Field Tests", as Dr. Paroda prefers) are adequate, the dissenting

report expressed concerns about the existing system in India and recommended, among other things, the following:

a. The RCGM, GEAC and ICAR must work hand in hand to conduct the confined field trials at the specified sites as well as improve the quality and timeliness of inspections by qualified monitoring teams. A roster of such monitors, with required expertise needs to be maintained and updated regularly by these agencies.

b. Crop-specific Standard Operating Procedures (SOP) should be developed and made available online. Such SOPs should incorporate, in addition to the existing procedures, i) methods for reproductive isolation of the confined field trial site, ii) schedules for monitoring the field trial during and after the growing season, iii) required duration of post-harvest restrictions on the trial site, and iv) methods for on-site/off-site disposal of regulated plant materials.

c. A system for notification of confined field trial sites located in different agro-ecological zones should be developed by RCGM and GEAC in consultation with the ICAR. These sites could include both public and private sector institutions/facilities, meeting the specified

conditions. However, no trials should be allowed on farmers' fields, leased or otherwise.

d. Integrate the existing system of testing and standard protocols under All India Coordinated Research Project (AICRP) with the three years of confined field testing in Biosafety Research Level (BRL)-I and BRL-II. The agronomic evaluation should be against the best national check, regional check, and the latest released variety or hybrid in the state concerned. For all the new events, the decision of RCGM and GEAC on biosafety and environmental concerns must be final at either of the testing stages (BRL-I or BRL-II), irrespective of good agronomic performance of the variety.

e. Monitoring for biosafety compliance as well as agronomic performance of each confined field trial must be made mandatory, and should be carried out by GEAC through an inter-ministerial monitoring compliance committee including people drawn from a roster of experts. In addition, each confined field trial must be monitored by a site-specific monitoring committee.

f. In cases where an already approved event is incorporated into a new genetic background, after being verified for its stability, such variety or hybrid shall be evaluated independently by the AICRP protocol for agronomic performance and the expression of the event concerned for a period of two years, as per the existing practice under the New Seed Policy.

g. Varieties or hybrids evaluated by the above process shall then be approved for general cultivation by a Central GM-Crop Release Committee at par with the Variety Release Committee under the MoA. This committee shall include experts from the disciplines concerned including the Crop Project Coordinators or Director, officials of Seed or Crops Divisions of DAC and ICAR, socio-economists, progressive farmers, NGOs and the private sector representatives.

h. Once a GM crop variety/hybrid is released, a well-designed case-by-case post-release monitoring system must be put in place jointly by the Department of Agriculture and Cooperation (DoAC) and ICAR to address specific post-release issues identified during the event approval by GEAC. Such a system should

also monitor the long term effects from the point of view of food safety, soil health, environment and agronomic performance.

i. Finally, the MoA may also consider issuing a separate notification on priority for the general release of GM crops at par with New Seeds Policy, while legally ensuring much needed harmonization of both EPA under Ministry of Environment and Forests (MoEF) and the Seed Act under MoA.

10.8 A corrigendum was issued to the final report of TEC on 12.07.2013. Paragraph 6 of the Majority Report is modified by the corrigendum, which reads as under:

> "6. page 71, lines 3-5: "… exert a highly adverse impact over time on sustainable agriculture, rural livelihoods, and environment. The TEC finds them completely unsuitable in the Indian context."
>
> Corrected: "… exert a highly adverse impact on sustainable agriculture, rural livelihoods, and environment. The TEC finds them completely unsuitable in the Indian context and recommends that field trials and release of HT crops not be allowed in India."

Parliamentary Standing Committee (PSC) on Agriculture's Report on "Cultivation of Genetically Modified Food Crops – Prospects and Effects" – 2012:

11. The aforesaid Report, submitted on 09.08.2012, has been relied upon by the learned counsel Sri Prashant Bhushan. The

salient observations and recommendations of the said Committee are encapsulated in the following paragraphs:

i. To ascertain the efficacy of the extant system in general and the role of GEAC as the apex regulator in particular, the Committee sought the views of Dr. P.M. Bhargava, founder Director of CCMB, Hyderabad and then the Supreme Court nominee on GEAC. The gist of the testimony of Dr. P.M. Bhargava given on 22.12.2010 can be crystallised in the following points:

    a. All the tests on Bt cotton have either been conducted by the concerned applicant for approval, or by an accredited laboratory on the samples given by the applicant. The Bt cotton was tested and approved surreptitiously without adequate information being available to the public.

    b. The Bt brinjal was approved on the basis of an expert committee report, which lacked in scientific quality, credibility, consistency and rigour. Relying upon a private conversation with the then Co-Chairman of GEAC, Prof. Arjula Reddy, Dr. Bhargava claimed that the former was under pressure to approve Bt brinjal and to give a go by to the chronic toxicity and other tests which had been proposed by the latter. He

also claimed that the Co-Chairman confided in him that even the tests undertaken were performed badly.

c. That no chronic toxic studies have been conducted on GM crops.

d. Despite a specific proposal for establishing a lab to conduct indigenous and independent assessment studies, the erstwhile Director General of ICAR, Dr. R.S. Paroda, the erstwhile Director General of Council of Scientific and Industrial Research (CSIR), Dr. R.A. Mashelkar and GEAC were reluctant to support the same.

ii. The Committee, discussing the status, composition and functioning of GEAC, highlighted the following deficiencies:

a. GEAC is headed by a civil servant, who is also functioning in another capacity in the MoEF, the controlling authority of GEAC.

b. The Co-Chairman of GEAC is a biotechnologist who, though purportedly from outside, is nominated by the DBT, the Department that funds and promotes projects on transgenic products. Therefore, primacy is accorded to the DBT nominated Co-Chair in the decision-making process.

c. The Vice-Chairman is again a civil servant, simultaneously discharging a few more responsibilities in another role in the MoEF.

d. GEAC being an entity created under the Rules rather than an Act of Parliament deprives it of the status, powers and more importantly, autonomy and independence that a statutory regulator ought to have.

iii. The Committee noted the findings of several scientific reports, including the International Assessment of Agricultural Knowledge, Science and Technology for Development (IAASTD) Report – 'Agriculture at a Crossroads', and underlined the following shortcomings of modern biotechnology in agriculture:

a. Modern biotechnologies have yet to prove their efficacy, safety and sustainability in the case of GM crops. There are significant limitations in its ability to conserve the resilience of small and subsistence agricultural systems, etc.

b. Containment of harm would be a very challenging task even for some of the most well-equipped developed countries and simply impossible in a country like India.

c. The integration of biotechnology must be within an enabling environment, supported by local

research and education that empowers local communities.

iv. With respect to regulation and labelling of GM foodstuffs, the Committee observed the casual approach on the part of both MoEF and Ministry of Health and Family Welfare (MoHFW). While the MoEF, on 23.08.2007, exempted all GM food categories from regulations under Rule 11 if the end product was not an LMO, the MoHFW did not include GM foods from the restrictions on manufacture, distribution and selling when it issued the notification under Section 22, Food Safety and Standards Act, 2006 (for short, "FSSA, 2006"). The Committee noted that the Food Safety and Standards Authority of India (FSSAI) regulation for GM processed food was nowhere in sight, even though so many years had gone by. While noting that Section 23 of FSSA, 2006 requires FSSAI to notify labelling, the Committee observed that FSSAI had not been able to do so.

v. It was concluded that the tendency of the regulatory mechanism, in the absence of specialized infrastructure and research and development (R&D) facilities in India, is to base their decision-making on practices and studies elsewhere, as also on the assessments and data generated by the applicant concerned. This was particularly concerning in light of the testimony of Dr. Bhargava, as the contents of his testimony were "*not merely slippages due to oversight or human error but indicative of collusion of the worst kind*". By its very

composition, GEAC does not have regular existence and meets monthly only when some decisions are to be taken. It is also a sad reality that modern biotechnology being a nascent discipline in the Country, we have a serious dearth of scientists of eminence in sufficient numbers, therefore, more or less the same set of people sit on both the sides, i.e., to develop technologies and products, as also to assess, evaluate and approve them.

vi. The Committee noted that Article 246 of the Constitution of India, read with Entry 14, List II, assigns "*agriculture, including agricultural education and research, protection against pest and prevention of plant diseases*" to the States. However, it observed that for a thing as crucial as field trials, the State Governments were not even consulted till recently.

vii. The Committee concluded that in a regulatory set-up where the promoter has an overwhelming say and presence in the regulatory mechanism, an element of subjectivity in assessment and evaluation is unavoidable. The entire system, therefore, reflects a pro-DBT/pro-industry tilt which is best avoided. Apart from this major shortcoming, the Committee's examination has revealed that the extant system is grossly inadequate and antiquated to face the typical challenges a population-intensive, agrarian economy (primarily) like India poses when the question of introduction of such modern technologies in the agriculture sector crops up.

Parliamentary Standing Committee (PSC) on Science and Technology, Environment and Forests' Report titled "Genetically Modified Crops and its impact on Environment" - 2017:

12. The aforesaid Report has been perused by us. The salient observations and recommendations of the said Committee are encapsulated in the following paragraphs:

i. The Committee considered the legal and administrative architecture for the regulation of biotechnology and GE techniques and the extant process of health and environmental safety assessment.

ii. It observed that as a party to several International Conventions, India should ensure the safe usage of GM crops through the "Precautionary Approach". In line with the same, India ratified International Protocols like the CBD, the CPB and the Nagoya Kuala Lumpur Supplementary Protocol on Liability and Redress (NKSPLR).

iii. The Committee took note of the divergent views on the efficacy of the existing regulatory mechanism. It expressed certain apprehensions about the stance of the MoEF&CC that the existing regulatory regime left no scope for any non-adherence. It also observed that the MoEF&CC and GEAC's casual approach indicated indifference towards the environmental safety and health hazards of humans and animals. Specifically, it concluded that the regulatory agencies had turned a blind eye to the negative impact of GM

crops on the environment. It was observed that the existing regulatory mechanism was susceptible to manipulation, due to the following processual infirmities and substantive deficiencies:

a. The whole process of regulation depends upon the data made available to the regulators by the technology developers.
b. None of the Committees established under the 1989 Rules conduct the closed field trials on their own but are solely dependent on the data provided to them by the technology developer.
c. There was a scope for the technology developers to manipulate the data to suit their own requirements.
d. The Government failed to put in place the desired protocols as late as 2011, while the GM crops were introduced in 2002.
e. Two of the top three positions of GEAC are held by the bureaucrats of the MoEF&CC. There is a conflict of interest in the appointment of some of the members of GEAC.
f. The members of GEAC were mostly from the Government and Government-aided institutions and there was hardly any representation of the civil society or the State Governments on the Board.

g. Even though the DLCs are provided for in the 1989 Rules, the importance of this Committee had not been realised, thereby further weakening the confidence level of farmers, civil societies, environmentalists, etc.

h. There was lack of clarity on the impact of the adoption of Bt cotton on crop yield. Therefore, the Committee was not persuaded about the claims of success of Bt cotton as India's cotton yields increased by 69% in the five years (2000-2005) when Bt cotton was less than 6% of total cotton area, but by only 10% in the ten years from 2005 to 2015 when Bt cotton grew to 94% of the total cotton area. There was also lack of clarity on whether traditional methods of farming could achieve better outcomes.

i. It also expressed its apprehensions about the stated benefit of reduced dependence on chemical pesticides. Based on consultations with members of civil society, it observed that after the advent of Bt cotton, the insecticide use on bollworm, both sucking and secondary pests took over the ecological niche vacated by the bollworm. Therefore, the per hectare insecticide use had almost doubled. The issue of pesticide resistivity was also a matter of concern, as it was

observed that the pink bollworm had developed resistance to Bt cotton variety, i.e., Bollgard-II (BG-II).

j. Since transgenic mustard hybrid DMH-11is a HT GMO, there exists clear evidence of the adverse impacts thereof from elsewhere in the world. In the case of transgenic mustard hybrid DMH-11, thus, there are serious unanswered questions.

k. The cultivation of GM crops in the midst of other indigenous farming would cause unstoppable contamination and cross-pollination. It would also adversely affect non-target organisms like soil microbes, insects, bees, butterflies, birds or even mammals which are critical to the agro-ecosystem.

l. There is a glaring lack of indigenous study on the impact of GM crops on human health. It is particularly worrying because certain studies on animals revealed complications including infertility, immune problems, accelerated aging, insulin regulation, and changes in major organs. The Department of Health Research has accorded its approval for commercial release without scrutinising any indigenous study. Only acute and sub-chronic studies have been

conducted but chronic and transgenerational studies have not been conducted, therefore, risking the health of future generations.

13. As is well-settled, the Parliamentary Select Committees are entities through which Parliament scrutinises the policies and actions of the Government and enforces executive accountability. Select Committees are constituted with specifically nominated Members of Parliament and exercise the authority delegated by the House. The role of Select Committees has been outlined in Erskine May's *Treatise on The Law, Privileges, Proceedings and Usage of Parliament*, (Lexis Nexis, 24th Edn. 2011, p.37.] as under:

> "Select Committees are appointed by the House to perform a wide range of functions on the House's behalf. Most notably they have become over recent years the principal mechanism by which the House discharges its responsibilities for the scrutiny of government policy and actions. Increasingly this scrutiny work has become the most widely recognised and public means by which Parliament holds Government Ministers and their departments to account."

13.1 Parliamentary material, such as the reports submitted by Select Committees, is an aid to the construction of legislation, as such material may disclose the legislative intention lying behind the ambiguous words and expressions, *vide* ***Pepper (Inspector of Taxes) vs. Hart, 1992 UKHL 3 (HL) ("Pepper")***. Noting the evolution of Indian law, Justice G.P. Singh, in *Principles of Statutory Interpretation* (14th Edn.), has stated that this Court

has pressed the parliamentary materials as an aid in resolving questions of construction. This Court has clarified that courts may seek recourse to background parliamentary material, including a statement of position by the Government, to understand the reasons of the enactment of a law and the problems sought to be remedied *vide* ***Kalpana Mehta vs. Union of India, (2018) 7 SCC 1 ("Kalpana Mehta")***.

13.2 The pertinent facts in ***Kalpana Mehta*** were that a writ petitioner, who had challenged the grant of approval to an HPV (Human Papilloma Virus) vaccine by the Drugs Controller General of India, had invited the attention of this Court to a report of the PSC and this Court had directed the Government to file an affidavit about the status of compliance with the contents of the report. At that stage, the State and private respondents raised doubts about the appropriateness of adverting to a report of the PSC while exercising jurisdiction under Article 32 in a public interest litigation. Therefore, the core question raised therein that came to be referred to the Constitution Bench was whether a PSC report can be placed reliance upon for adjudication of a fact in issue and also for what other purposes it can be taken aid of.

13.3 It was concluded that the reports of the Parliamentary Committee can be relied upon to adduce the position adopted by the Government. In this respect, reliance can be placed upon the responses given by the Government to the queries raised by the Parliamentary Committee. The Union of India has filed Action Taken Reports with respect to the recommendations made by the Standing Committee.

Conditional approval by Government of India for Environmental Release of DMH-11:

14. We shall now proceed to the actual controversy. According to Union of India, the conditional approval for environmental release of transgenic mustard hybrid DMH-11 and parental lines bn 3.6 and modbs 2.99 containing *barnase, barstar* and *bar* genes has been made after following the detailed procedure in law and after considering the biosafety data accumulated over several years. Also, the conditional approval has been made in accordance with the guidelines and framework which enable a consistent and rigorous risk-analysis approach to evaluating applications for the environmental release of GE plants is the contention of the Union of India.

14.1 That in the instant case, after recommendation of RCGM, GEAC had considered the recommendations of RCGM in the following meetings in regard to confined field trials:

Date of GEAC Meeting	Meeting under which considered	Purpose of Trial	Permission Granted
29.09.2010	103rd meeting	Study under confined conditions for environmental and food and feed safety assessments at three locations namely Agricultural Research station experimental Farm, Navgaon, Agricultural Research Station, Sriganganagar and KVK, Kumher during Oct, 2010. Also, gave approval for experimental seed production under confined condition at Jaunti Village, Delhi and Environmental safety studies (Crossability Studies) at Bawana, Delhi during Oct, 2010.	1st year BRL-I application dated 20.08.2010 to RCGM.
21.09.2011	112th meeting	On transgenic mustard (*Brassica Juncea*) containing *bar, barnase* and *barstar* genes [Events bn 3.6	2nd year BRL-I application dated 15.07.2011 to RCGM.

Date of GEAC Meeting	Meeting under which considered	Purpose of Trial	Permission Granted
		(*Barnase* Line), modbs 2.99 (*Barstar* Line) and bn 3.6x modbs 2.99 (Hybrid DMH-11) under the coordination of Directorate of Rapeseed Mustard Research, Bharatpur during the appropriate season in 2011-12.	
18.07.2014	121st meeting	On transgenic mustard hybrid (DMH-11) (*Brassica juncea*) Events bn 3.6 (*Barnase* Line), modbs 2.99 (*Barstar* Line) & bn 3.6 x modbs 2.99 containing *bar*, *barnase* and *barstar* genes at Navgaon, Sriganganagar, Kumher, Delhi, Bawal, Ludhiana, Bhatinda, Bharatpur, Morena, Kanpur and Faizabad during appropriate season.	BRL-II trials application dated 17.08.2012.

14.2 After confined field trials, the facts leading to conditional approval for grant of environmental release by GEAC are as under:

(i) The CGMCP, University of Delhi, New Delhi, on 15.09.2015, submitted an application for approval of environmental release of the GE mustard (*Brassica juncea*) hybrid DMH-11 and use of parental events (Varuna bn 3.6 and EH-2 modbs2.99) for development of new generation of hybrids, along with a dossier of 3285 pages as a compilation of the results of the food and environmental safety studies that were carried out at the time of research/experiments/ confined field trials and the application for the environmental release of transgenic mustard DMH-11 hybrid and parental lines bn 3.6 and modbs 2.99 containing *barnase*, *barstar* and *bar* genes to GEAC.

(ii) The said application for environmental release was considered in the 125th meeting of GEAC held on 11.12.2015, wherein GEAC deliberated on the application submitted by CGMCP for environmental release of mustard. After a detailed deliberation, it was decided that the applicant may be invited to give a presentation to GEAC on 04.01.2016.

(iii) In its 126th meeting held on 04.01.2016, GEAC constituted a sub-committee under the Chairmanship of Dr. K. Veluthambi, Co-Chair of GEAC, with the following members for examination of the dossier:

a. Dr. K. Veluthambi, Chairman (Biotechnologist)

b. Dr. S R Rao, Adivser, DBT, Member (Agriculture Expert)

c. Dr. S.K. Apte Member (Molecular Biology Expert)

d. Dr. Ramesh V Sonti Member (Plant Genetics Expert)

e. Dr. B. Sesikeran, Member (Nutritional Pathologist and Food Safety Expert)

f. Dr. C R Babu Member (Environmental Science Expert)

g. Dr. K V Prabhu, Joint Director (Research), IARI Member (Plant Breeding Expert)

h. Member Secretary, GEAC to facilitate the sub-committee.

(iv) Pursuant to the recommendation of the above-mentioned meeting, GEAC was informed in its 127th meeting held on 05.02.2016, that the 1st meeting of the sub-committee was held on 02.02.2016. The Chair of the sub-committee also informed GEAC that the outcome of the review of the biosafety dossier submitted by the BSU set-up by DBT was also deliberated in detail. It was further informed that the sub-committee recommended revision of the biosafety dossier by incorporating additional information/ clarifications/gaps identified by the sub-committee and the BSU. Considering the above, GEAC, in its 127th meeting, adopted the recommendations of the sub-committee and directed for the revision of biosafety dossier. GEAC also discussed the procedure for further review and consultation

on the biosafety data in respect of transgenic mustard hybrid DMH-11 developed by CGMCP and Biosafety RARM report to be prepared for consideration of GEAC. It was also decided that if the biosafety dossier is found to be complete in all respects, the biosafety dossier/RARM report, excluding confidential information, will be put in the public domain for comments. Thereafter, a detailed response to the comments received would be prepared and considered before a final decision is taken by GEAC.

(v) The first meeting of the sub-committee was held on 02.02.2016 and the second meeting of the sub-committee was held on 11.04.2016.

Sub-committee meetings:

14.2.1 In the first sub-committee meeting, held on 02.02.2016, the sub-committee made the following submissions:

a) That the mandate given to it included review of the biosafety dossier for its adequacy and accuracy in all respects, and indicate gaps, if any.

b) That Dr. S.R. Rao Advisor, DBT informed that the biosafety dossier had been examined in detail by the BSU set up in DBT and points for further clarification and dossier revision had been prepared for consideration and discussion.

c) That on the application submitted by the applicant CGMCP, University of Delhi, South Campus, for environmental release of transgenic mustard hybrid DMH-11 and parental

lines containing events bn 3.6 and modbs 2.99 developed using *barnase*, *barstar* and *bar* genes, was taken up.

d) That discussion was held with the applicant and the sub-committee advised for continuous monitoring and further investigation for fitness and the transfer of transgenic trait from DMH-11 to their progenies and feral populations that will be essential for implementing management strategies to minimize persistence and dissemination from release site. The sub-committee also advised that a suitable post-release management strategy should be implemented.

e) That certain data had to be incorporated in the revised dossier, along with the details of oil content and other measured parameters in the revised dossier.

f) That the data suggested that the activities of *barnase* need to be presented quantitatively and UDSC-*barnase* specific activity can be compared with any other over expressed *barnase* specific activity to compare activity status of the proteins.

g) That the updated statistics data from National Institute of Nutrition (NIN) may be included in the revised dossier.

h) That Intellectual Property Rights (IPR) for *Barnase* promoter has not been registered in India.

i) Requested the University to check whether DMH-11 hybrid accumulated complexes of *barnase* + *barstar.*

j) Questioned whether grazing of transgenic mustard by farm animals would affect them.

k) That the *bar* gene is present in the two parental varieties and continues to be present in the hybrid but release of marker free hybrid would have been desirable. For that, reply by the applicant was that *barnase/barstar* technology requires a herbicide gene for hybrid seed production and for maintaining the male sterile line.

l) That the regulatory guidelines provide an overall list of principles for conducting biosafety studies and therefore, case specific issues need to be addressed by the applicant.

m) That sub-chronic toxicity was evaluated in rats, though it would have been much more relevant to do so in rabbits, goats and other cattle which are likely to consume mustard leaves.

n) That issues regarding deliberate introduction of a protein that induces cell death into our food were raised/discussed.

o) That in the case of canola, only oil is consumed, but mustard leaves and seeds are consumed as food by humans and this is a matter of concern. To this, the reply of the applicant was as under:

> "It is a fact that a fear-psychosis has been created around transgenic crops. Transgenic technologies are heavily patented and mainly with transnationals-many fear that dependence on proprietary technologies may jeopardize food security of developing countries like India. Although European continent is scientifically very advanced – they seem to have opted for chemical control rather than biological control. Europe is a huge importer of food and has no ambition of increasing food

production. They are only interested in high-value agriculture. Europe has not released even any cisgenic event. Japan gave biosafety clearance for environmental release of barnase/barstar Canola in 1996 – but has chosen not to grow it. However, Japan is the largest importer of Canola seed, oil and meal. Decisions on not growing GM crops are political and economic in nature – rather than related to biosafety."

p) That long-term post-release monitoring should be implemented to study (i) weediness, (ii) pollen flow to wild relatives, (iii) the impact on beneficial insects, and (iv) the impact on beneficial soil microbes, if any.

14.2.2 The second sub-committee meeting of GEAC was held on 11.04.2016. In the said meeting, Dr. S.R. Rao briefed the sub-committee members on the follow up actions taken by BSU pursuant to the 128th GEAC meeting held on 04.03.2016 regarding the application for environmental release of transgenic mustard (*Brassica juncea*) hybrid DMH-11 by the CGMCP, University of Delhi (South Campus). The sub-committee was made aware of the fact that the 128th GEAC meeting held on 04.03.2016, had sought further information/clarifications from CGMCP and accordingly, a revised document was submitted by the applicant. Accordingly, the revised biosafety dossier and draft RARM report of the sub-committee was circulated amongst the sub-committee members and comments of the experts were tabulated along with remarks of the BSU.

14.2.3 Observation of one of the members of the sub-committee was regarding the sustainable use of deregulated GE mustard in future and as to how honey derived from GE mustard be tested for the absence of *barnase* for a definite period as a part of post-release monitoring.

14.2.4 The sub-committee opined that one of the members of the sub-committee explained that self-reproducible populations of mustard *(Brassica juncea)* may get established in the hills (not in the plains) and though probability of such occurrence may be low, this question needs to be addressed. The sub-committee opined that this should be taken as a scientific question, which should be addressed from a research angle in the interest of long-term sustainability of transgenic mustard hybrid DMH-11 technology.

14.2.5 The sub-committee sought time to analyse and review the revised dossier and results obtained in the 129th GEAC meeting, which was held on 20.06.2016.

14.2.6 In the meantime, GEAC invited two groups of NGOs for presenting their views/concerns regarding release of transgenic mustard hybrid DMH-11 in India.

14.2.7 The sub-committee constituted by GEAC suggested a report being placed on the MoEF&CC website for thirty days, to invite comments from stakeholders in the 130th GEAC meeting held on 11.08.2016.

14.2.8 Accordingly, the AFES Report was uploaded on the website of MoEF&CC, inviting comments from all stakeholders. The comments received were to be reviewed by the sub-committee and GEAC prior to taking an appropriate decision. The full biosafety dossier submitted by the applicant was available in GEAC Secretariat and any person interested in studying the same could access the dossier during working hours in person, by prior appointment during the public consultation period, at Indira Paryavaran Bhawan, Jorbagh, New Delhi – 110 003, till the closing of working hours, i.e., 05:30 PM on 05.10.2016. A total of 759 comments were received between 05.09.2016 and 05.10.2016.

14.2.9 It is also to be noted that about 29 persons (including from places other than Delhi) personally inspected the dossier at the premises of the MoEF&CC and provided their comments. It is stated that thereafter, all these comments were analyzed and deliberated by the sub-committee of GEAC.

14.2.10 The instant proposal was again considered on 11.05.2017 in the 133rd GEAC meeting, wherein the report submitted by the sub-committee was examined in detail and GEAC recommended the proposal with certain terms and conditions for further approval by the Competent Authority. But pursuant to receipt of various representations from different stakeholders, matters related to environmental release of transgenic mustard were kept pending for further review.

14.2.11 In the 134th meeting of GEAC held on 21.03.2018, it was recorded that the instant proposal was referred back to GEAC for its re-examination, pursuant to receipt of several representations, both in support and against, after the 133rd meeting of GEAC held on 11.05.2017. In this meeting, GEAC examined all the representations and reiterated that these representations were already deliberated extensively while taking the decision in the 133rd meeting of GEAC. After a detailed discussion, GEAC agreed that the applicant may be advised to undertake field demonstration on transgenic mustard hybrid DMH-11 in an area of five acres at two to three different locations, with a view to generate additional data on honey bees and other pollinators and on soil microbial diversity.

14.2.12 The instant matter was re-examined in the 136th meeting of GEAC held on 20.09.2018, wherein the said Committee accorded permission for conduct of field demonstration studies on honey bees and other pollinators at two locations of up to five acres in each location namely Punjab Agricultural University (PAU), Ludhiana and Indian Agricultural Research Institute (IARI), New Delhi.

14.2.13 Thereafter, in the 137th meeting of GEAC held on 20.03.2019, the Committee noted the response from the applicant regarding the reasons for deferment of field demonstration studies on transgenic mustard during the season

2018-19 and the deferment was further extended for the seasons 2019-20 and 2020-21.

14.2.14 At this stage, Prof. Deepak Pental, Former Professor of Genetics and Vice-Chancellor, University of Delhi, on behalf of CGMCP, University of Delhi, South Campus, New Delhi, made a representation on 10.05.2022 to the Hon'ble Minister for Environment, Forest and Climate Change, to accept the recommendations for environmental release of transgenic mustard hybrid DMH-11 made in 133rd GEAC meeting. Accordingly, comments were sought from the concerned Department, namely DBT and Department of Agricultural Research and Education (DARE). Some of the relevant comments related to the present matter are reproduced herein below:

> "The comments received from DARE: "GEAC may consider exempting additional studies on the impact of GM Mustard hybrid DMH-11 containing the bar, barnase, and barstar genes on honey bees and other pollinators as decided in its 136th meeting and the recommendation of the 133rd meeting of GEAC may be considered. The environmental release of the proposed events will broaden the scope for developing many high yielding mustard hybrids in future.
>
> The comments received from DBT: Based on the scientific evidence and the available data from various international agencies, it seems likely that there were no major deviations in the behavior of honey bees when compared among the transgenic and non-transgenic comparator lines; and suggested that GEAC may consider its recommendations of the 133rd meeting on the environmental release of GE mustard."

Soon thereafter, ICAR by its letter dated 30.07.2022 wrote to MoEF&CC for GEAC to consider the recommendation for environmental release of transgenic mustard hybrid DMH-11 made in its 133rd GEAC meeting. DBT, by its letter dated 01.08.2022, also wrote to MoEF&CC for GEAC to consider the recommendation for environmental release of transgenic mustard hybrid DMH-11 made in its 133rd GEAC meeting, in light of the biosafety data received from the applicant as well as reviewing the international evidence of safety of the concerned technology.

14.2.15 Thereafter, on 25.08.2022, at the 146th GEAC meeting, the applicant made a detailed presentation on all aspects of the proposal for environmental release of DMH-11. In this meeting of GEAC, it was recommended that an Expert Committee be constituted to examine the request letter dated 10.05.2022, with respect to availability of adequate evidence about impact of transgenic mustard on honey bees and other pollinators, in order to assess the need for conducting field demonstration studies on honey bees and other pollinators. The composition of this Expert Committee was as follows:

a. Dr. Sanjay Kumar Mishra, Chairman
b. Dr. Ashok Kumar Singh, Member (Expertise in Molecular Genetics and Breeding)
c. Dr. D.K. Yadav, Member (Expertise in Plant Breeding and Seed)

d. Dr. A.H. Prakash, Member (Expertise in Plant Physiology)

e. Dr. K. Annapurna, Member (Expertise in Microbiology)

f. Dr. S. J. Rahman, Member (Expertise in Entomology)

g. Dr. Nitin K. Jain, Member (Present Member Secretary of RCGM)

h. Dr. K. C. Bansal, Member (Expertise in Plant Biotechnology, Functional Genomics)

i. Dr. Abhilasha Singh Mathuriya, Member Secretary.

14.2.16 First and second meeting of this Expert Committee were convened on 23.09.2022 and 30.09.2022 respectively. The recommendations of the Expert Committee constituted in 146th meeting were submitted to GEAC and were as under:

> "Based on the examination of scientific evidences available globally, and as per the recommendations of concerned ministries, it seems unlikely that the bar, barnase, and barstar system will pose an adverse impact on honey bees and other pollinators. Therefore, the Committee was of the view that GEAC may consider the environmental release of GE mustard and further evaluation to be carried out as per ICAR guidelines for release and notification.
>
> However, to generate scientific evidences in Indian agro-climatic situation and also as a precautionary mechanism, the Expert Committee suggests that the field demonstration studies with respect to the effect of GE mustard on honey bees and other pollinators, as recommended in the 136th GEAC meeting, may also be conducted post-environmental release, simultaneously

by the applicant, within two years under supervision of ICAR and the report be submitted to the GEAC."

14.2.17 Based on the comments of the DARE and the DBT, and recommendations of the sub-committee, GEAC, in its 147th meeting held on 18.10.2022, recommended environmental release of transgenic mustard hybrid DMH-11, which was accepted by the Central Government on 25.10.2022.

14.3 It is clear from a bare perusal of the abovementioned events that the Union of India has taken the decision on the environmental release on the basis of the aforesaid procedure which was followed by GEAC. That the conditional permission granted by Union of India to the CGMCP for environmental release of transgenic mustard hybrid DMH-11 is said to be for the following purposes:

a. The environmental release of GE mustard parental lines bn 3.6 carrying *barnase* and *bar* genes and modbs 2.99 containing *barstar* and *bar* genes, is to use the developing new parental lines and hybrids under supervision of ICAR. The environmental release of mustard hybrid DMH-11 for its seed production and testing, as per existing ICAR guidelines and other extant rules/regulations, is prior to commercial release.

b. Further, to generate scientific evidences in Indian agro-climatic situation and also as a precautionary mechanism, the field demonstration studies with respect to the effect of GE mustard on honey bees and other pollinators, as recommended in the 136th GEAC meeting, shall also be conducted post-environmental release simultaneously by the

applicant, within two years, under the supervision of ICAR, as per ICAR guidelines and other extant rules/guidelines/regulations and the report be submitted to GEAC.

14.4 The environmental release of transgenic mustard hybrid DMH-11 hybrid DMH-11 for its seed production and testing as per ICAR guidelines was recommended by GEAC in its 147th meeting. The seed production and testing was to require three crop seasons, unless otherwise decided by ICAR, before the seeds are commercially available to the farmers.

14.5 It is further pertinent to note that the permission for environmental release was to be subjected to terms and conditions to ensure environmental safeguards, for example:

(i) It provides that during the period of approval, a Post-Release Monitoring Committee (PRMC) would be constituted by GEAC, consisting of two subject matter external experts and a nominee each from the RCGM, GEAC and the PRMC, who will visit the growing sites of the approved biological material(s) at least once during each season and submit their report to GEAC on the matters of compliance.

(ii) Usage of any formulation or herbicide is not permitted for cultivation in the farmer's field under any situation and such use would require necessary permission as per the procedures and protocols for safety assessment of insecticides/herbicides by the Central Insecticide Board & Registration Committee (CIB&RC). Any such use in the farmer's field without due approval from the CIB&RC would attract appropriate legal action under the Insecticides Act, 1968 and the Rules, 1971, made under the said Act

and the EP Act, 1986, and the Rules made thereunder.

(iii) The production of seeds of transgenic mustard hybrid DMH-11 will take place under the supervision of ICAR, as per the existing ICAR guidelines and other extant rules/regulations, after which the commercial cultivation of mustard will start. Commercial use will be subject to the Seeds Act, 1966 and the related rules and regulations.

(iv) As a precautionary mechanism, the data in regard to the impact of transgenic mustard hybrid DMH-11 on honey bees and other pollinators will be generated during these two years under the supervision of ICAR. This may help create additional data in regard to the impact of transgenic mustard hybrid DMH-11 on honey bees and other pollinators.

(v) The approval may be revoked under Rule 13(2) of the 1989 Rules, if any evidences regarding harmful effects of the approved GE mustard, such as damage to the environment, nature or health as could not be envisaged when the approval was given, come under notice of GEAC and on non-compliance of any condition stipulated by GEAC.

14.6 Within two months, on 18.10.2022, at the 147th GEAC meeting, it was recommended that environmental release of DMH-11 be approved subject to some conditions and safeguards. The recommendations and the conditions were communicated by the MoEF&CC to the applicant-Prof. Deepak Pental on 25.10.2022 and the same are extracted as under:

> "... the Genetic Engineering Appraisal Committee (GEAC) in its 147th meeting held on 18.10.2022, has recommended the following:

I. The environmental release of genetically engineered mustard parental lines bn 3.6 carrying *barnase* and *bar* genes, and modbs 2.99 containing barstar and bar genes, so that these events can be used for developing new parental lines and hybrids under supervision of ICAR.

II. The environmental release of mustard hybrid DMH-11 for undertaking its seed production and testing as per existing ICAR guidelines and other extant rules/regulations prior to commercial release.

III. Further, to generate scientific evidences in Indian agro-climatic situation and also as a precautionary mechanism, the field demonstration studies with respect to the effect of GE mustard on honey bees and other pollinators, as recommended in the 136th GEAC meeting, shall also be conducted post-environmental release, simultaneously by the applicant, within two years under supervision of ICAR, as per ICAR guidelines and other extant rules/ guidelines/regulations and the report be submitted to the GEAC.

These recommendations are subject to the following conditions:

I. The approval is for a limited period of four years from the date of issue of approval letter as per clause 13 of Rules 1989 and is renewable for two years at a time based on compliance report.

II. During the period of approval, a Post Release Monitoring Committee (PRMC) would be constituted by GEAC consisting of 2 subject matter external experts and a nominee each from RCGM and GEAC and PRMC will visit the growing sites of the approved biological material(s) at least once during each season and submit their report to GEAC on the

matters of compliance. Chairperson, GEAC is authorized to constitute the Committee.

III. Applicant shall deposit 100 grams each of approved hybrids as well as their parental lines with the ICAR-National Bureau of Plant Genetic Resources (ICAR-NBPGR) and communicate the same to GEAC within 30 days of issue of this clearance letter for purposes of future reference in case of trade, traceability and dispute on account of ownership.

IV. The applicant shall provide detailed step-by-step testing procedures for identifying approved event in the transgenic hybrids (bar, barnase and barstar) and parental lines, to the GEAC within 30 days from the receipt of approval letter.

V. Applicant shall develop and deposit the DNA fingerprints of the approved Transgenic Mustard varieties within 30 days from the receipt of approval letter to the ICAR-NBPGR.

VI. Usage of any formulation of herbicide is recommended only under controlled and specified conditions exclusively for hybrid seed production after obtaining label claim and approval from Central Insecticide Board & Registration Committee (CIB&RC).

VII. Usage of any formulation of herbicide is not permitted for cultivation in the farmer's field under any situation and such use would require the necessary permission as per the procedures and protocols of safety assessment of insecticides/ herbicides by CIB&RC. Any such use in the farmer's field without due approval from CIB&RC would attract appropriate legal action under Central Insecticides Act 1968 and Rules 1971, EP Act 1986 and the Rules made there under.

VIII. Commercial use of DMH-11 hybrid shall be subject to Seed Act 1966 and related rules and regulations, its amendments and Gazette notifications from time to time as applicable.

IX. The applicant shall prepare and submit the annual/seasonal reports on acreage, yield and states/ regions where the transgenic mustard is sown during the approval period to the GEAC.

X. It is mandatory that all seed packets of GE mustard Hybrid DMH-11 and subsequent hybrids derived from the technology should be appropriately labelled indicating the contents including the name of the transgenes, physical and genetic purity of the seeds etc. Each packet should also contain detailed description for use including sowing pattern, pest management, suitability of agro-climatic conditions etc. in English, Hindi and vernacular language.

XI. All efforts should be made by applicant and licensees to undertake an awareness and education programme interlaid through development and distribution of educational material on GE Mustard Hybrid DMH-11 for farmers, dealers and others.

XII. Indian Council of Agricultural Research (ICAR) would be the authorized agency to accord necessary permissions for development of any other Brassica juncea hybrids resulting from events approved and their descendants, provided the intended use is similar. However, all hybrids released using this technology shall also be regulated under Seed Act 1966 and related rules and regulations, its amendments and Gazette notification from time to time as applicable. ICAR shall also ensure the following conditions prior to release of any new hybrids:

- Confirmation of events through molecular characterization to be submitted from accredited lab, in original, as notified for the purpose.
- Data on level of transgenes (Barnase, Barstar and Bar) expression in the events/ hybrids at seedling stage from accredited lab, in original, as notified for the purpose.
- Morphological characters using Distinctiveness, Uniformity and Stability (DUS) descriptors as per Protection of Plant Varieties and Farmers Rights Act, (PPVFRA) guidelines for the hybrids.
- Source of germplasm/ pedigree and biotech traits must be provided with self-declaration by the applicant.
- Affidavit on the ownership of hybrid/ variety/ events.
- Performance trial report including agronomic parameters, yield with coefficient of variation (CV) and critical difference (CD), pest & disease reaction etc. as per ICAR guidelines.

XIII. If at any time, the applicant or the responsible parties become aware of any information regarding risk to the environment, or risk to animal or human health, that could result from release of these materials in India, or elsewhere, the applicant must immediately provide in writing such information to regulatory bodies.

XIV. The approval may be revoked under Rule 13(2) of Rules, 1989, if any evidences regarding harmful effects of the approved GE mustard, such as damage to the environment, nature or health as could not be envisaged when the approval was given comes under notice of GEAC and on noncompliance of any condition stipulated by GEAC.

XV. MoEF&CC/ GEAC may prescribe any additional conditions/ requirements or constitute any Sub-Committees or commission any studies if felt appropriate during the period of approval.

XVI. The recommendations are subject to other statuary clearances, as applicable, including the clearance from FSSAI."

Interlocutory Applications filed by the petitioners:

15. **I.A. No.185604 of 2022** has been filed by the petitioner in Writ Petition (Civil) No.840 of 2016 seeking quashing of the approval letter F.No.C-12013/35/2010-CSIII dated 25.10.2022 issued by respondent Nos.1 and 2 to respondent No.3 therein being *void ab initio*; *secondly,* to disclose all the sites/locations where the environmental release of transgenic mustard hybrid DMH-11 is planned/commenced; *thirdly,* to direct the respondents to immediately uproot/remove/destroy all transgenic mustard hybrid DMH-11 that has been planted pursuant to the environment clearance issued in 147th meeting of respondent No.2 held on 18.10.2022 and the subsequent approval letter number F.No.C-12013/35/2010-CSIII dated 25.10.2022; and, *fourthly*, a direction is sought that the TEC report recommendation be adopted and to ban all HT crops and crops for which India is a Centre of Origin/Diversity. It is unnecessary to narrate the pleadings accompanying the aforesaid prayers as the same shall be dealt with while considering the main petition.

I.A. No.209550 of 2023 has been filed in Writ Petition (Civil) No.115 of 2004 by the petitioner therein, seeking a direction to the respondent Union of India to destroy the planted material of transgenic mustard hybrid DMH-11 in view of the undertaking given to this Court and there being violations of the same.

The aforesaid prayer made by the petitioner has also to be considered in light of the prayer made by the Union of India, which has also filed an application **(I.A. No.167110 of 2023)**, seeking discharge from the oral statement made before this Court on 08.11.2022 to the effect that no precipitative steps for environmental release of transgenic mustard hybrid DMH-11 would be taken.

Additional Affidavit of Union of India:

16. It would be useful to refer to the additional affidavit dated 09.11.2022 filed by the Union of India through Scientist 'G' in the MoEF&CC, New Delhi.

16.1 That on 03.11.2022, it was brought to the notice of this Court that permission of environmental release of transgenic mustard hybrid DMH-11 had been granted by the Government of India to the CGMCP at the University of Delhi on 25.10.2022. Pursuant to the said order, the Union of India has sought to place on record the decision-making process employed by the Government of India and the regulatory framework under which this permission was granted.

16.2 In addition to the above, the Union of India has stated in its Additional Affidavit dated 09.11.2022 that the research, development, and use of GE technologies is a highly technical matter guided by the views of subject experts. As such, the inquiry before this court is limited to whether there exists an adequate regulatory mechanism governing this field and whether material compliance with the same has been made.

16.3 The conditional approval for environmental release of transgenic mustard hybrid DMH-11 and its parental lines *Varuna bn* 3.6 and *EH-2 modbs* 2.99 containing *barnase, barstar*, and *bar* genes prior to commercial release has been made after a long and exhaustive regulatory process which commenced as far back as in 2010 and is outlined as below:

i. The initial R&D was conducted by the CGMCP in accordance with the Revised Guidelines for Research in Transgenic Plants, 1998 in the laboratory as well as greenhouse conditions. The R&D was regulated by the Institutional Biosafety Committee (IBSC) and RCGM as prescribed by the Guidelines.

ii. Based on the information generated, an application was made to the IBSC for permission to conduct a confined field trial. After the recommendation of the IBSC, the CGMCP submitted a further application to RCGM. After the recommendation of the RCGM, GEAC considered the

recommendation of the RCGM in its meetings dated 29.09.2010, 21.09.2011, and 18.07.2014.

iii. After the completion of confined field tests, the CGMCP submitted an application dated 15.09.2015, along with a dossier of 3285 pages, seeking approval for environmental release of the GE mustard hybrid DMH-11 and its parental lines *Varuna bn* 3.6 and *EH-2 modbs* 2.99.

iv. The said application was considered by GEAC in its 125th meeting dated 11.12.2015. After a detailed discussion, the applicant was invited to give a presentation to GEAC on 04.01.2016. Accordingly, on 04.01.2016, GEAC formed an eight-member sub-committee under the chairmanship of Dr. K. Veluthambi, Co-chair, GEAC.

v. The meeting of the sub-committee took place on 02.02.2016 and the sub-committee recommended revision of the biosafety dossier by the applicant. Considering the above, GEAC, in its 127th meeting dated 05.02.2016, adopted the recommendations of the sub-committee and directed the revision of the dossier. In addition, GEAC directed preparation of the Biosafety RARM Report.

vi. The sub-committee requested GEAC for an additional one month's time to submit its final recommendations. The request was granted by GEAC in its 129th meeting dated 20.06.2016. GEAC also invited two groups of NGOs to present their views on the release of transgenic mustard hybrid DMH-11 in India.

vii. Thereafter, on 11.08.2016, GEAC considered the report titled "Assessment of Food and Environmental Safety", incorporating the evaluation of biosafety data generated by the applicant CGMCP and prepared by the sub-committee along with the inputs of RAU of the RCGM. The report was then placed on MoEF&CC website for a period of 30 days, from 05.09.2016 to 05.10.2016, for inviting comments.

viii. A total of 759 comments were received on the AFES Report and the sub-committee proceeded to analyse the same.

ix. In the 133rd meeting of GEAC dated 11.05.2017, the report submitted by the sub-committee was examined in detail. In the 134th meeting of GEAC dated 21.03.2018, the proposal was referred back to GEAC for re-examination. GEAC also advised the applicant to undertake field demonstration on transgenic mustard hybrid DMH-11 in an area of five acres at two-three different locations, with a view to generate additional data on honey bees and other pollinators and on soil microbial diversity.

x. The proposal came up for re-examination by GEAC in its 136th meeting dated 20.09.2018, wherein GEAC accorded permission for conducting field demonstration studies at two locations of up to five acres each in PAU, Ludhiana and IARI, New Delhi.

xi. In the 137th meeting of GEAC dated 20.03.2019, GEAC deferred field demonstration studies to the seasons 2019-20 and 2020-21.

xii. Thereafter, Prof. Deepak Pental, *vide* letter dated 10.05.2022 requested the MoEF&CC to okay the environmental release of GE mustard.

xiii. GEAC sought comments from the DBT and the DARE. Both opined that GEAC may consider exempting additional field demonstration studies.

xiv. In the 146th meeting of GEAC held on 25.08.2022, GEAC recommended that a nine-member expert committee be constituted to examine the request letter dated 10.05.2022 with respect to availability of adequate evidence about the impact of transgenic mustard on honey bees and other pollinators in order to assess the need for conducting field demonstration studies.

xv. The abovesaid sub-committee met on 23.09.2022 and 30.09.2022 and submitted recommendations to GEAC, stating that the field demonstration studies may be conducted even after the environmental release of GE mustard.

xvi. *Finally*, GEAC, in its 147th meeting held on 18.10.2022, recommended environmental release of transgenic mustard hybrid DMH-11, which came to be accepted by the Central Government on 25.10.2022.

16.4 It is further averred that the production of seeds of transgenic mustard hybrid DMH-11 would take place under the supervision of ICAR, as per existing guidelines and other extant

rules and regulations. As a precautionary measure, the data with regard to the impact of transgenic mustard hybrid DMH-11 on honey bees and other pollinators is to be generated during these two years of supervision by ICAR and approval could be revoked under Rule 13 (2) of the 1989 Rules, if any harmful effects are found. In addition, during the period of approval, a PRMC would visit the growing sites at least once during each season and submit its report to GEAC. Only after this elaborate process would the commercial cultivation of transgenic mustard hybrid DMH-11 start. Commercial cultivation, too, shall be subject to the Seeds Act, 1966 and the rules and regulations made thereunder.

16.5 *Finally*, emphasizing the importance of mustard as a prominent edible oil and seed meal crop of India, the economic need to increase its domestic yield was highlighted. It was also submitted that internationally, the United States of America (USA), Canada, and Australia have allowed cultivation of GE rapeseed containing the *bar, barnase,* and *barstar* genes. Parental lines and hybrids were also released for cultivation in Canada (1996), the USA (2002), and Australia (2003). In all three countries, yields of rapeseed increased with the introduction of GM hybrids. Therefore, if employed, the DMH-11 hybrid technology would contribute to increase in the domestic yield of mustard in India.

Submissions:

17. Elaborate submissions have been advanced by the learned senior counsel, Sri Sanjay Parekh and learned counsel, Sri Prashant Bhushan for the petitioners as well as learned Senior Counsel Sri Pais and other learned Counsel for other petitioners and intervenors. Learned Attorney General and the learned Solicitor General have appeared for the respondents. A summary of the submissions is set out hereinbelow.

Submissions of the petitioners:

17.1 Sri Prashant Bhushan, learned counsel has made the following submissions:

The decision dated 18.10.2022 of GEAC to approve environmental and commercial release of DMH-11/GM mustard/ HT mustard is violative of Articles 14 and 21 of the Constitution as it suffers from non-application of mind and is, therefore, arbitrary and unreasonable. Elaborating on the same, it was contended that the said decision would lead to irreversible contamination of the environment and threaten biodiversity. The decision was also said to violate the choice of consumers to consume non-GM food and that of farmers to grow non-GM crops in violation of Article 21 of the Constitution. In this regard, the following points were highlighted:

a. It is an admitted fact that DMH-11 is an HT crop (*vide* para 16 page 12 of the Additional Affidavit of Union of India).

b. The TEC appointed by this Court, in its detailed report, recommended a complete ban on all HT crops.

c. It is an admitted fact that DMH-11 has no yield advantage over non-GM/HT mustard hybrids/varieties.

d. The sole advantage for environmental release of DMH-11 is that it is robust at cross pollination and there are absolutely no immediate advantages to the environmental release of DMH-11, rather there are attendant risks that come with the environment release of HT crops and it is only a hope that the same could be used to produce new hybrids with better yield in future. If that is the hope, then the new hybrids with better yield could be developed in hybrid conditions and not be released into the environment, as there would be no rational nexus to the object sought to be achieved by the release.

e. Condition Nos. VI and VII of the order or decision dated 18.10.2022 directed that the farmers may not lawfully spray herbicide/glufosinate on DMH-11, thereby ensuring that there can be no lawful beneficial effect therefrom in terms of weed management from HT crops to farmers.

f. If there is no real yield advantage, DMH-11 cannot be marketed to the farmers as having yield advantage, as this would be misleading for supporting its environmental and commercial release.

g. In the 134th meeting of GEAC, the applicant of DMH-11 was advised to conduct research on the effect thereof on honey

bees. The said advisory was given a go by and the study was directed to be done *after environmental* release of DMH-11. It is submitted that the DBT has funded the development of DMH-11 and therefore, its recommendation to forego studies on honey bees is a case of conflict of interest and ignores all precautionary principles.

h. That even though there is no immediate advantage from the environmental release of DMH-11, the immediate and irreversible disadvantage from its release is the scientific certainty of contamination of non-GM/non-HT mustard hybrids/varieties through cross pollination from bees, thereby:

- irreversibly threatening biodiversity, as eventually all non-GM/non-HT mustard will be contaminated;
- irreversibly eliminating choice of consumers to eat non-GM/non-HT mustard, in the absence of any mechanism to prevent pollination by bees, which is accentuated by the absence of any laws for labelling;
- irreversibly coercing farmers who do not wish to grow GM crops to be susceptible to their crops being contaminated with transgenic mustard hybrid DMH-11 with no legal mechanism for redress or liability for losses suffered;
- irreversibly causing loss to organic farmers and the entire agro-economic system relying on non-GM crops as their products can no longer be certified as GM-free.

For instance, honey, which is produced in the country from mustard flowers, can no longer be certified as organic or GM-free in the absence of elaborate testing for each and every product. Hence, there is a need for studies with regard to long-term effects on biosafety and the hazards from environmental release of DMH-11.

i. The present writ petition has been filed seeking to put in place a comprehensive, stringent, scientifically rigorous and transparent biosafety test protocol in the public domain for GMOs before they may be released into the environment. This is because GMOs are a serious potential hazard and several dimensions of biosafety are necessary before their release into the environment. The proper and independent testing of GMOs is essential in view of the concern of the irreversible contamination of non-GMOs crops and the environment at large. This is unlike a drug, which when tested to be unsafe, can be recalled. It is contended that the GMO contamination of the environment would affect the nation's foundational seed stock and change the structure of the food at the molecular level without recourse.

j. The right to health being a fundamental right, it is necessary that the Union Government and the Regulators put in place a rigorous mechanism so as to avoid the harm caused by GMOs, such as chronic toxicity and other unattended effects including health hazards. Therefore, the precautionary

principles must be purposefully applied to insulate from the scientific uncertainty about hazardous GMOs in future.

17.2 On the decision of GEAC to approve HT mustard/GM mustard/DMH-11 for environmental and commercial release, learned counsel contended that GEAC in its 147th meeting decided to permit environmental release/commercial cultivation of HT mustard. Based on the recommendation of the Expert Committee as well as the comments received from DBT and DARE, the Committee recommended the following:

> "VI. Usage of any formulation of herbicide is recommended only under controlled and specified conditions exclusively for hybrid seed production after obtaining label claim and approval from Central Insecticide Board & Registration Committee (CIB&RC).
>
> VII. Usage of any formulation of herbicide is not permitted for cultivation in the farmer's field under any situation and such use would require the necessary permission as per the procedures and protocols of safety assessment of insecticides/herbides by CIB&RC. Any such use in the farmer's field without due approval from CIB&RC would attract appropriate legal action under Central Insecticides Act 1968 and Rules 1971, EP Act 1986 and the Rules made thereunder."

17.3 It is learnt by the petitioners that HT transgenic mustard hybrid DMH-11 seed was sown for seed selection in Kanpur and Bharatpur at the Directorate of Rapeseed and Mustard Research (DRMR). The 301st report of the Department related PSC on Science and Technology, Environment & Forests, titled "Genetically Modified Crops and its impact on Environment"

(2017) ("301st Report of PSC", for the sake of convenience) noted that the Government put on hold the earlier approval given by GEAC to DMH-11 (*vide* Page 26 of the 301st PSC report/Pg.672, Compilation). This is because in undertaking seed selection, it would be necessary to spray illegal glufosinate on the seedlings, for it is only seedlings which have been successfully engineered for resistance to the herbicide which could be selected for seed production. The concomitant advisory to farmers not to spray would then go meaningless, as the farmers would definitely spray for the short-term gain to kill weeds. In this regard, it is mentioned that planting of HT – Bt cotton and Bt brinjal and other such crops on commercial scale have gone on despite illegal effects of the same.

17.4 It was also submitted that the National Bureau of Plant Genetic Resources (NBPGR) had stated that India has rich biodiversity in mustard. The Indian Gene Banks have 5477 *Brassica juncea* ("Indian mustard") accessions, which would all be at the risk of contamination.

17.5 On the recommendations of the TEC as regards HT/GM crops, it was submitted that HT crops being a potent carcinogen may lead to breast cancer. Therefore, the TEC recommended a complete ban on HT crops.

17.6 It was next contended that the first crop given *de facto* approval by GEAC was Bt cotton, followed by Bt brinjal, in respect of which there was a moratorium *vide* order dated

09.02.2010 of the Ministry of Science, Environment & Forests. In the case of transgenic mustard hybrid DMH-11 (HT crop), the technical dossier running into thousands of pages was made available for 30 days at the headquarters of GEAC in New Delhi for physical inspection. This was contrary to the earlier process, wherein biosafety dossier as regards Bt cotton and Bt brinjal was put in the public domain on the website of GEAC upon being directed by this Court and whereupon on critical examination of the same by national and international experts, the approval given by GEAC had to be put on hold by the Ministry, as it became apparent that GEAC had not complied with the regulatory mechanism and the biosafety and ERA of Bt brinjal was totally lacking.

17.7 Learned counsel also brought to our notice the following three reports which have discussed in detail the issue of GM crops:

a. Thirty-Seventh (37th) report of PSC on Agriculture (2011-2012) titled "Cultivation of Genetically Modified Food Crops – Prospects and Effects" (hereinafter referred to as the "37th Report of PSC").
b. Final Report of the five original members of the TEC submitted to this Court on 30.06.2013.
c. Three Hundred and First (301st) report of the Department related PSC on Science and Technology, Environment &

Forests, titled, “Genetically Modified Crops and its impact on Environment” (2017).

17.8 The deposition of Dr. P.M. Bhargava, Molecular Biologist, Founder Director, CCMB, Hyderabad, appointed as an independent expert on GEAC by this Court *vide* order dated 13.02.2008, as recorded in the 37th report of PSC, was also read out to us. Similarly, the observations and recommendations of the TEC as regards GEAC being the regulator have been read out to us during the course of the submissions. We shall refer to the relevant portions of these reports a little later.

17.9 It was next contended that although the ubiquitous glyphosate has been used for over four decades as the safest herbicide, glufosinate is acknowledged as more toxic than glyphosate as it kills indiscriminately soil organisms, beneficial insects etc. It was also submitted that neurotoxin can cause birth defects and damage to most plants that it comes into contact with. It is banned in Europe and not permitted in India under the Insecticides Act, 1968 for mustard. It is an organophosphorus compound (toxic to biology) very similar in structure to glyphosate and as weeds become more resistant, they will eventually be resistant to all known herbicides.

17.10 It was lastly submitted that the DBT, Ministry of Science & Technology is an active partner and funder in this venture of HT DMH-11. The DBT directly oversees the regulation of GMOs including HT mustard and houses the Regulators and

the RCGM. The conflict of interest in GMO Regulators and relevant Ministry has not been recognised as unconscionable and an ethical breach of public trust doctrine. Attention was drawn to the fact that Prof. Pental himself had been involved in the regulatory oversight of Bt brinjal and there is a tied-in relationship that obscures the line of separation that must be rigorously maintained between the Regulators and the regulated, if stringent norms of GMO risk assessment and biosafety are to be maintained for this hazardous technology. There cannot be a partnership between the Regulator and the Developer which is invested in the HT mustard GMOs. Therefore, the submission was that the environmental release of DMH-11/GM mustard/HT mustard needs to be halted in line with the precautionary principle.

17.11 Learned senior counsel Sri Sanjay Parikh contended that one of the reliefs sought for in the writ petition is for the formulation of a National Policy on GM by a High-Powered Committee till a sound regulatory and monitoring system is put in place and till then there should be a moratorium on release of GM. Although, the Union of India in its counter affidavit, filed in November, 2004, attempted to justify the 1989 Rules, till date, there is no National Policy on GM food and "Inter-Ministerial Task Force" under the Chairmanship of Dr. M.S. Swaminathan, which has submitted a final report, is still under consideration.

It was contended that in the absence of a National Policy, the regulatory system, at present, continues to be deficient.

17.12 It was also contended that while transgenic mustard hybrid DMH-11 is an HT crop, the Government of India has proceeded on the basis that it is not an HT crop. The question of the consequences, if transgenic mustard hybrid DMH-11 is indeed an HT crop, remains unanswered. The Union of India in its additional affidavit dated 09.11.2022 has acknowledged that transgenic mustard hybrid DMH-11 possesses HT through the inherited *bar* gene from both parents, making it fully HT. Yet, the Government asserts that it cannot be officially labelled as such, and therefore, it should not be referred to as a HT crop.

17.13 The crucial inquiry remains regarding the impact of herbicide spraying on a transgenic mustard hybrid DMH-11 field — whether the crop will exhibit herbicide tolerance or succumb to the herbicide. The definition of an HT crop hinges on the introduction of a new trait, in this case, HT *via* the *bar* genes in the mustard plant. This trait specifically confers tolerance to the herbicide glufosinate ammonium, as also acknowledged in the approval letter number F.No.C-12013/35/2010-CSIII dated 25.10.2022. That despite GEAC imposing conditions and warning against unauthorized herbicide use, initiating legal action against farmers is impractical, given that farmers may use herbicides believing that DMH-11 is an HT crop. Consequently, the Government is unable to pursue legal action based on this

misunderstanding amongst farmers. In the case of HT-Bt cotton, extensively grown nationwide since 2017 along with the unauthorized herbicide glyphosate, the Government has failed to undertake any legal or corrective measures against entities endorsing and facilitating its cultivation. The cultivation of Bt cotton has led to the development of resistance to the Bt toxin, giving rise to robust secondary pests. This, in turn, has resulted in an increased application of pesticides, contradicting the initial purpose of Bt cotton. Consequently, it is doubtful that control over herbicide use and the penalization of farmers employing herbicides will be effective in the case of DMH-11. It was further contended that the potential adverse impacts of using HT crops along with their matching herbicides have to be understood and are enumerated as under:

a. Herbicide use destroys all the vegetation in and around the fields where the HT crop is cultivated, which is used by the rural community in significant ways.
b. In India, the biodiversity found in and around fields is not considered “weeds” and therefore, not useless, as they are in the west. These plants, so called “weeds”, provide:
    i. leafy green vegetables and many kinds of *saag* like *chaulai* and *bathua* that provide valuable nutrition for free to poor rural families;
    ii. they also provide green fodder for rural livestock;

iii. such “weeds” are also medicinal plants that traditional healers such as *vaids* and *hakeems* use in the treatment of human and animal diseases.

c. Introduction of the HT trait will destroy the opportunity to do mixed farming which is prevalent in Indian agriculture.

d. The HT trait will also strike against any efforts to promote organic agriculture, since it involves heavy chemical use of herbicides.

e. The use of herbicides and their accumulation in the soil will damage soil health and the chemicals will enter the food chain to the detriment of human health.

17.14 It was also contended that GM has never been tested as an HT crop, despite having HT properties and in fact, India does not have any regulatory guidelines and protocols for testing of HT crops. Reliance has been placed on the TEC Report and our attention was drawn to various portions thereof, which we shall consider later. Similarly, reference was made to the 301st Report of the PSC.

17.15 Sri Parikh also submitted that the manner in which the conditional clearance was granted makes apparent the loopholes in the regulatory system. In this regard, it was submitted that on 21.03.2018, a decision was taken by GEAC in its 134th meeting to generate additional data on honey bees and other pollinators on soil microbial diversity. The same was given a go by subsequently after receipt of a letter from Prof. Deepak

Pental dated 10.05.2022 and contrary to precautionary principles, it was decided by GEAC in its 147th Meeting dated 18.10.2022 that the field demonstration studies with respect to the effect of GE mustard on honey bees and other pollinators may be conducted **post-environmental release**. The said decision, besides causing adverse effects on the environment, would also be against the principle of assessing any harmful socio-economic impact in time, i.e., before granting approval.

17.16 Our attention was also drawn to various points regarding conflict of interest, details of which have also been given in the written submissions, which we shall advert to during the course of our discussion.

17.17 It was next submitted that the 1989 Rules are not compliant with the CPB, which was ratified by India on 17.01.2003 and which came into effect on 11.09.2003. This is because the question of liability and redress are not addressed by the 1989 Rules. Sri Parekh noted that the CPB reaffirms the precautionary approach, which is also contained in Principle 15 of the Rio Declaration on Environment and Development. Therefore, the decision of GEAC dated 25.10.2022 that tests with regard to the environmental impact of the release would be done post-release and not prior thereto, violates the aforesaid precautionary principle.

17.18 Finally, it was urged that HT seeds of transgenic mustard hybrid DMH-11 have been sown in five locations and in the absence of a proper and lawful approval of the same, the plants should be uprooted and destroyed immediately, so that no environmental contamination takes place.

17.19 Learned senior counsel, Sri Trideep Pais submitted that the procedure adopted by GEAC in the instant case, culminating in the order dated 25.10.2022, is not in accordance with law. In this regard, it was submitted that GEAC is a Committee which has been constituted under the 1989 Rules and is therefore, a statutory body. The said body cannot further delegate its functions to sub-committees or Expert Committees. Even if the assistance of such sub-committees or Expert Committees is taken, there has to be detailed deliberations of the recommendations made by the said Expert Committees and not simply accepted without any application of mind as has happened in the instant case.

17.20 It was further submitted that the health expert was consistently absent in all the crucial meetings of GEAC, and thereafter, the said expert sent an e-mail simply concurring with the deliberations of GEAC without any application of mind and in the absence of any participation in the deliberations. Consequently, the health aspect in the context of granting approval for environmental release of transgenic mustard hybrid DMH-11 has been totally ignored and kept apart, which is the

reason why the petitioners as well as the interveners are pressing for appropriate reliefs on quashing of the decision dated 25.10.2022. In this regard, learned senior counsel drew our attention to the various deliberations of the meetings with reference to the compilation of documents that he submitted.

17.21 Learned senior counsel Sri Pais further submitted that despite the order of this Court dated 12.08.2008 and the earlier order dated 08.04.2008 stating that the primary data pertaining to field trials must be placed in the public domain and on the website of GEAC, there has been absolute non-compliance of the same and as a result, it is neither in the public domain nor placed on record.

17.22 It was further contended that on the reconstitution of GEAC dated 17.07.2022, one of the members, Dr. Geeta Jotwani, was not present in the meeting held on 18.10.2022. GEAC simply approved the agenda Item No.4 on the said date. As already noted on 02.02.2016 in the 1st meeting of the sub-Committee of GEAC, Dr. B. Sesikeran, the Nutrition and Food Safety expert, was absent. The said expert was continuously absent thereafter on 11.04.2016, 20.06.2016 and 11.08.2016 in the meetings of the sub-committee. Learned senior counsel therefore, submitted that GEAC, not having complied with the requisite procedures, has arrived at a decision to grant approval of the environmental release of transgenic mustard hybrid DMH-11 without taking

into consideration all aspects of the matter in a comprehensive manner.

17.23 Sri Dhruv Dwivedi learned counsel submitted that the recommendation of the Parliamentary Committee on agriculture has not been considered by GEAC in its proper perspective. Further, the sub-committee of GEAC had recommended that the adverse impacts on honeybees and other pollinators had to be studied prior to the environmental release. However, the said decision was given a go by and it was decided that the said study would be conducted subsequent to the environmental release of DMH-11. This volte-face in the stand of GEAC is without any reason and also not in consonance with the precautionary principles which are relevant in the instant case.

17.24 Dr. Ravindra Chingale learned counsel appearing on behalf of Bharatiya Kisan Sangh as an intervenor, at the outset, submitted that these matters cannot be considered to be an adversarial litigation but wholly in public interest. Therefore, the respondent Union of India would have to adhere to the directions issued and to be issued by this Court in the matter. He further drew our attention to three unstarred questions answered in the Rajya Sabha by Hon'ble Minister of State for Environment. One of them was with regard to Section 22 of the FSSA, 2006, that the Central Government has not yet conducted any study on GM food and therefore, has not issued a notification under the aforesaid provision. In the absence of such a notification, there

can be no steps taken having regard to the provisions of the FSSA, 2006. As per Section 2 of the said Act, the Union has declared that the food industry is taken under its control, which is expedient in the public interest in view of Entry 52, List I of the Seventh Schedule of the Constitution. The same shall be considered later.

17.25 He also drew our attention to Section 3(b) of the Patents Act, 1970, which states that an invention, the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment, is not an invention within the meaning of the said Act and therefore, not patentable.

Submissions of the Respondents:

PART-I

18. Sri R. Venkataramani, learned Attorney General, while defending the action of GEAC, contended that the petitioners have raised two concerns, namely, (i) the non-negotiable importance of having credible regulatory procedures, mechanism and institutions which are free from commercial incentives to ensure that proposals for release and use of GM crops and plants are subject to strict scrutiny through well-accepted regimes; and, (ii) all information and materials in relation to the regulatory procedures be made public to ensure participation of the public in order to bring about transparency and informed debate.

18.1 Based on the above contentions, the petitioners have sought that unless certain precautions are taken, the Union of India shall not release GMOs into the environment by way of import, manufacture, use or any other manner. More specifically, the petitioners have sought directions with regard to approval dated 25.10.2022 recommended by GEAC by clearing for environmental release transgenic mustard hybrid DMH-11 following fairly long stages of trial conducted by ICAR, CGMCP; Institute of Microbial Technology, Chandigarh (IMTECH), NIN, Hyderabad, Amar Immunodiagnostics Pvt. Ltd., Hyderabad and Premas Biotech Pvt. Ltd., Manesar.

18.2 It was submitted by learned Attorney General that by order dated 10.05.2012 in Writ Petition (Civil) No.260 of 2005, this Court was pleased to appoint an expert committee (TEC) consisting of technical experts to submit a report with certain terms of reference. TEC submitted an interim report on 07.10.2012 and Union of India raised objections in response to the said report, which were referred to TEC on 09.11.2012. On 30.06.2013, the TEC submitted its final report making certain suggestions. According to the learned Attorney General, the TEC Report goes beyond the terms of reference, to the extreme extent of observing that HT crops are completely unsuitable in the Indian context. But, Dr. Paroda has filed a separate dissenting report raising serious objections to the procedures and

deliberations of the TEC that virtually worked with a closed mind.

18.3 It was then submitted that these writ petitions were filed in 2004-2005 respectively and since then, there has been development in the regulatory framework governing the field and the following guidelines and protocols are applicable to the research and testing of GMOs:

i. Guidelines and SOPs for Conduct of Confined Field Trials of Regulated GE Plants, 2008.
ii. Revised Guidelines for Research in Transgenic Plants, 1998.
iii. Guidelines for Safety Assessment of Foods Derived from GE plants, 2008 (updated in 2012).
iv. Protocols for Food and Feed Safety Assessment of GE Crops, 2008.
v. Guidelines for the Environmental Risk Assessment (ERA) of GE Plants, 2016.
vi. Environmental Risk Assessment (ERA) of GE Plants: A Guide for Stakeholders, 2016.
vii. Risk Analysis Framework, 2016.

18.4 The aforesaid regulatory framework has been developed after the filing of the present petitions and in view of these developments, these petitions have been rendered infructuous. That in view of the adequacy of the current regulatory regime in place, the petitions have lost their efficacy inasmuch there is no challenge to the constitutionality of the statute, rules or

executive action and that a writ court cannot embark on a roving and fishing inquiry in a public interest litigation.

18.5 Emphasising that the focus of the writ petition is now confined to the environmental release of transgenic mustard DMH-11, it was submitted that on receipt of the application requesting a trial of DMH-11 to be conducted, approval was given by GEAC on 29.09.2010 and subsequently, approvals were granted to conduct BRL-I and BRL-II trials. Only after several meetings, deliberations and consideration of the reports of the trials, on 18.10.2022, GEAC recommended environmental release of DMH-11 subject to strict conditions and safeguards and accordingly, permission for environmental release of DMH-11 was issued on 25.10.2022.

18.6 It was further submitted that the regulatory requirements are adequate to address all aspects of the concerns voiced by the petitioners and the rules and guidelines are in consonance with the CPB and Codex principles and guidelines on foods derived from biotechnology.

18.7 It was further argued that even the concerns expressed by the TEC Report have since been adequately addressed by the Union of India. The TEC Report was written in the background of the existing regulatory regime, which as noted above, has subsequently been updated. The regulatory regime in place has been strengthened to ensure that a comprehensive, transparent and science-based framework of GM crops is in place for ERA of

GM crops. That rigorous risk analysis approach has been applied to ensure the safety of both the environmental and health risks *vis-à-vis* transgenic mustard hybrid DMH-11 for the past ten years.

18.8 Therefore, learned Attorney General submitted that the scope of adjudication now stands confined to the question of due procedure being followed under the relevant rules and the guidelines and there is no need to traverse beyond this limited inquiry. It was emphasised that the question that should be addressed by this Court would revolve around due processes being followed and deliberations on the varying understandings on applications of science and technology would lie in the domain of the Government alone and mere differences of opinions cannot invite the Court's attention into the evaluation of views and adopting or rejecting any one of them.

18.9 Learned Attorney General then proceeded to argue that the petitioners' concern regarding risk with regard to environmental release of transgenic mustard hybrid DMH-11 is purely hypothetical and there is a distinction between a risk which is clearly known and demonstrated and presumption of risk on unproven hypotheses. Even under the precautionary principle approach, a rigid and uncompromising approach is not encouraged insofar as it stifles technological advancement. That the Food and Agriculture Organization (FAO) describes risk assessment as a scientific process consisting of the following

steps: (i) hazard identification, (ii) hazard characterisation, (iii) exposure assessment, and (iv) risk categorization. There is also a principle that an analysis of benefit versus risk is undertaken to determine the actions that provide the greatest benefits while encountering the least risk. In the instant case, the procedures adopted for the environmental clearance are argued to be in consonance with the above said steps. To seek judicial scrutiny of the same would, thus, be inappropriate and will amount to dislodging governance responsibility in taking decisions on a consideration of all relevant factors. Therefore, this Court ought not to enter into any evaluation of rival views on the subject of GMOs in general and the issue of environmental release of DMH-11 in particular.

PART-II

I. *Overview of the Technology:*

18.10 It was contended that the conditional approval was given on 25.10.2022 to the CGMCP, University of Delhi, for environmental release of transgenic mustard hybrid DMH-11 and parental lines bn.36 and modbs 2.99 containing *barnase, barstar* and *bar* genes. The object was to create DMH-11 – a hybrid obtained by crossing *Varuna* bn 3.6 (containing *bar, barnase* genes) with EH-2 modbs 2.99 (containing *bar*, *barstar* genes). The three relevant genes used in the process of creating DMH-11 are as follows: *barnase gene* which makes the plant

male sterile*; barstar gene* which restores male fertility*;* and *bar* gene which confers HT.

Presently, *Varuna* mustard seed contains both male and female parts and is self-pollinating (self-fertilization). It is first made male sterile so that it can be pollinated and crossed with another variety. This is achieved by introducing the *barnase* gene. Hence, a male sterile *Varuna bn 3.6* is created (containing *bar, barnase genes).* Since *Varuna bn 3.6 is male sterile, it cannot self-pollinate to reproduce.* For multiplying this parental line, it is crossed with normal *Varuna which* produces a crop which is 50% *Varuna* bn 3.6 (male sterile) and 50% normal *Varuna* (fertile). This progeny crop is then planted in an alternating arrangement with EH-2 modbs 2.99 plants (containing *bar, barstar* genes). At this stage, herbicide is sprayed at the site which eliminates the fertile (normal *varuna*) portion of the progeny crop (since it does not have HT) leaving behind the portion of the progeny crop which is male sterile, i.e. *Varuna bn 3.6* (since it contains the *bar* gene which confers HT). This is termed a *selection event*. The male sterile *Varuna bn* 3.6 remaining from the progeny crop gets fertilized by the adjacent EH-2 modbs 2.99 crop (which also contains the *bar* gene and survives the herbicide) and produces the hybrid seed DMH-11.

18.11 Thus, DMH-11 is produced, containing all three genes i.e. *barnase, barstar and bar.* It is fully fertile since the *barnase* gene inherited from EH-2 modbs 2.99 restores the male fertility

of the resulting hybrid. The *bar* gene inherited in DMH-11 is of no utility in the hybrid. Its utility is at the *selection event*, namely, to multiply the male sterile *Varuna* bn 3.6. This male sterility/restorer system is a highly promising technology which can be used to produce new hybrids with higher yields in future, thereby increasing agricultural output and farmer income.

II. *Herbicide Tolerance (HT):*

18.12 It was contended that a crop is referred to as an HT variety if its commercial trait is HT, but DMH-11 is not such a crop since the HT trait in DMH-11 is of no commercial utility. In fact, transgenic mustard hybrid DMH-11 is not developed as HT Technology and it is unnecessary to use herbicide in the cultivation of transgenic mustard hybrid DMH-11. In fact, the HT trait is useful only at the *selection event* during the development phase of the event and is of no utility when the crop is being cultivated by a farmer.

18.13 It was also pointed out that under the EP Act, 1986, and the Insecticides Act, 1968, use of herbicide is, anyway, not permitted in the field for cultivation of transgenic mustard hybrid DMH-11.

III. *Yield:*

18.14 Learned Attorney General contended that in the BRL-I and BRL-II trials, an increase in per-hectare yield by 25-30 per cent has been demonstrated against national check *Varuna* and zonal check RL1359. Only after the environmental release of

DMH-11, significant clarity would emerge from the trials that are conducted by ICAR. Therefore, environmental release is the first step in a long process of evolution of this technology which will lead to even better hybrids in future.

18.15 According to the learned Attorney General, there is proven use and safety of genes used in transgenic mustard hybrid DMH-11. The three genes, *barnase, barstar* and *bar* have more than twenty years of safe history of being in the food chain in GE rapeseed, a sister crop of transgenic mustard hybrid DMH-11. The regulatory authorities in the USA, Canada and Australia have allowed the cultivation of GE rapeseed containing the *bar, barnase* and *barstar* genes. Between 1996 – 2003, parental lines and hybrids were released for cultivation in Canada, USA and Australia.

18.16 It was submitted that under Rule 4 of the 1989 Rules, the following bodies namely, GEAC, Recombinant DNA Advisory Committee (RDAC), RCGM, IBSC and SBCC have been constituted and the applicable guidelines have been enumerated above.

18.17 Emphasising that the RCGM and GEAC together examine the safety assessment data submitted by the applicant at every step of the regulatory process, the learned Attorney General noted that the regulatory mechanism is completely transparent. All the data, reports, decisions etc. are made publicly available. Therefore, the conditional approval for

environmental release prior to commercial release is subject to necessary regulatory and technical oversight and the approval has been granted after following detailed and exhaustive procedure in law, including after considering biosafety data and rigorous scrutiny over a period of twelve years. GEAC considered the application for environmental release only when the applicant had completed three years of BRL Trials (two years of BRL-I trials and one year of BRL-II trials) and a 3251 page dossier containing results of all the biosafety studies was submitted to GEAC and its sub-committees. As per the public consultation process prescribed in the Risk Analysis Framework 2016, the AFES Report was uploaded on the official website of MoEF&CC for inviting comments from 05.09.2016 to 05.10.2016 and about twenty-nine persons personally inspected the complete dossier at the premises and provided their comments.

18.18 It was submitted that in fact, the permission for environment release of transgenic mustard hybrid DMH-11 is granted for following limited purpose:

i. To use the events of environmental release of transgenic mustard hybrid DMH-11 for developing new parental lines and hybrids under the supervision of ICAR.
ii. To undertake seed production of transgenic mustard hybrid DMH-11 and its testing as per existing ICAR guidelines and other extant rules/regulations prior to its commercial release.

iii. To generate scientific evidence in the Indian agro-climatic situation of the environment release.

iv. As a precautionary mechanism, post-environmental release, conduct the field demonstration studies with respect to the effect of GE mustard on honeybees and other pollinators, as recommended in the 136th GEAC meeting within two years under supervision of ICAR, as per its guidelines and other extant rules, guidelines and regulations and the report be submitted to GEAC.

However, the above is subjected to stringent terms and conditions to ensure environmental safeguards.

18.19 On the TEC Report, learned Attorney General submitted that though HT crops were not a part of terms of reference, the five-member TEC report has referred to the same and recommended against the use thereof in India. The Union of India too had filed objections stating that this recommendation was beyond the scope of terms of references and such a decision must be left to the regulatory system. In any case, the focus in the instant matter is only on DMH-11, which is not an HT crop. According to the learned Attorney General, since 2012, the regulatory regime has been strengthened to ensure that a comprehensive transparent and science-based framework of GM crops is in place for ERA of GM crops.

18.20 Finally, it was contended that mustard is the most important edible oil and seed meal crop of India and at present, 55-60 percent of the edible oil demand is met through imports. It was stated that canola oil is made from GM canola seeds; and soyabean oil largely comprises GM soyabean oil. Thus, the petitioners have voiced unfounded fears of adverse impact of GM crops, even when India is already importing and consuming oil derived from said GM crops. The transgenic mustard hybrid DMH-11 has shown an increase per-hectare yield by 25-30 per cent over the traditional varieties due to exploitation of hybrid vigour. As mustard is one of the highest oil-bearing of oilseeds utilised in India, the domestic production of edible oil would considerably increase if DMH-11 hybrid technology is employed.

Hence, learned Attorney General sought for dismissal of the writ petitions.

Submissions of Learned Solicitor General:

19. Learned Solicitor General Sri Tushar Mehta, while supporting the arguments of the learned Attorney General, at the outset contended that any ban on commercial/public release of GM crops in India will be against public and national interest. 55-60 percent of the edible oil in India is imported and mustard oil is one of the most important edible oils. In order to ensure food security and reduction of foreign dependency, it is necessary to strengthen the plant breeding programmes in India, including use of new genetic technologies such as GE technology.

19.1 Drawing our attention to statistics regarding the demand for total edible oil in India, it was submitted that 55.76 per cent of the total demand of edible oil is made through import, out of which palm oil, soyabean oil, sunflower oil and a small quantity of canola quality mustard oil are being imported. It was contended that owing to increasing population and oil consumption over the years, the imports have significantly increased in India.

19.2 Reiterating that globally around 80 percent of soyabean is GM soyabean variety, it was underlined that the petitioners were only voicing unfounded fears. The transgenic mustard hybrid DMH-11 having shown increased per-hectare yield over the traditional varieties, domestic production of edible oil is bound to rise considerably through the GM variety.

19.3 It was next submitted that competing fundamental rights of different sections of the society would have to be balanced. On the one hand, essential food including edible oil at affordable prices has to be made available, while at the same time, the dependency on import has to be reduced. That owing to the increasing demand for edible oil in India, making available the same at an economic price is a fundamental right of the citizens. Therefore, the production of indigenous edible oil is necessary to meet the increasing demand for such oil. It was argued by the learned Solicitor General that there were certain sections of the population who did not wish that India should be self-sufficient

and self-reliant in essential food and instead encouraged importing edible oil, which is not in the interest of the Indian economy.

19.4 It was submitted that the petitioners have failed to satisfy as to how restricting the trials would, in any way, have an adverse impact on the environment or otherwise. The public interest and fundamental rights of the citizens of the country to have the benefit of reasonable price of mustard oil has to outweigh the so-called concerns expressed by the petitioners herein. The learned Solicitor General accused that the petitions have been filed only to arm twist the State and in order to support greater imports of the essential commodities. In this context, it was submitted by him that the Union of India is committed to increasing crop productivity and the income of farmers through development of low input – high output agriculture and making the country self-sufficient in edible oil and grain legumes and that the strengthening of plant breeding programme, including the use of new genetic technologies, is critical for that purpose.

19.5 He noted that an elaborate statutory scheme exists to ensure effective regulatory review for the research, development and commercial use of GE technologies. The petitioners have not, however, pointed out a single flaw on record in the existing statutory regime or its implementation in the trial of DMH-11. Therefore, the writ petitions have to be dismissed with heavy costs. In this regard, reliance was placed on a recent judgment

of this Court in the case of ***Jacob Puliye vs. Union of India, (2022) SCC OnLine SC 533 ("Jacob Puliye")*** with special reference to paragraph Nos.21, 22, 62 and 80-81, and three other judgments of this Court, namely, ***National High Speed Rail Corporation Limited vs. Montecarlo Limited, (2022) 6 SCC 401 ("Montecarlo Limited"), Narmada Bachao Andolan vs. Union of India, (2000) 10 SCC 664 ("Narmada Bachao")*** and ***Uflex Limited vs. Government of Tamil Nadu, (2022) 1 SCC 165 ("Uflex Limited")*** to contend that frivolous public interest litigation must be dismissed with heavy costs, particularly, when an interim injunction affects the public interest. This is because, in the instant case, there is no material produced to demonstrate as to how the existing statutory regime relating to GM crops violates the fundamental rights of the citizens or is opposed to the provisions of the Constitution, or is opposed to any statutory provisions, or is otherwise manifestly arbitrary. Hence, the writ petitions may be dismissed with costs.

Reply Arguments:

20. Sri Prashant Bhushan submitted his rejoinder arguments with reference to the arguments of the learned Attorney General by contending that DMH-11 is a HT Crop, as is evident from the admission of the Union of India in the note submitted by the learned Attorney General himself to the effect that "the presence of the third HT gene (*Bar*) is essential for hybrid seed production". Therefore, the presence of the HT gene (*Bar*) makes DMH-11 an

HT Crop. This was also said to be in accordance with the finding of the 2017 PSC Report which stated that transgenic mustard hybrid DMH-11 is an HT Crop.

20.1 It was then pointed out that there is clear evidence on the adverse impacts of such GMOs from other places in the world. In this regard, reference was made to various experts' opinions as under:

(i) Dr. Jack Heinemann, Director, Centre for Integrated Research in Biosafety, University of Canterbury, Christchurch, Netherlands, who served as an advisor to the Food & Agriculture Organisation, stated that DMH-11 is an HT crop.

(ii) In an "*Open Statement on Bar Gene in GM Mustard*" published on 10.12.2022, by Dr. Soma Sundar Marla, Former Principal Scientist, Crop Bioinformatics & Genomics, ICAR-NBPGR, New Delhi and other scientists and experts, it was stated that DMH-11 is an HT crop in the following words:

> "Technically, it is the presence of the gene construct the Bar gene which defines whether a crop is Herbicide Tolerant (HT) or not. Given that both parents of DMH-11 carry gene constructs containing Bar, which confers herbicide tolerance towards glufosinate, any offspring from such parents including DMH-11 shall carry the HT trait. Therefore not only parental lines, but DMH-11 is also tolerant to herbicide without any doubt."

(iii) Further, in the article titled, "*Long-term ecological, environmental effects of herbicide tolerant crops haven't been considered*" published on 29.11.2022 in the Indian Express, by Dr. Renee Borges and other distinguished professors and scientists, DMH-11 was confirmed as an HT crop. It was stated as under:

> "A central feature of DMH-11 is that it carries a gene for herbicide resistance (also termed herbicide tolerance or HT). This fact has not received appropriate consideration. The deployment of herbicide-resistant or HT crops has been accompanied by deleterious outcomes in several places including the US, Australia, and Canada (so-called developed countries) as well as Argentina (a developing country). The most well-established harmful consequences have been the spread of herbicide-resistant weeds across large tracts of agricultural land, which can spell disaster for the normal crop.
>
> Thus, notwithstanding the statement of the developers and its implicit acceptance by GEAC, DMH-11 does meet the definition of an HT crop. The answers to two questions show this. Is DMH-11 herbicide tolerant? Yes. Is it a crop? Yes. The intent of the developer on how it is actually likely to be used, especially if that usage appears to confer obvious advantages."

(iv) It was contended that as DMH-11 is an HT crop, all hybrids produced therefrom will also be HT crops and the TEC appointed by this Court has in its detailed report submitted to this Court recommended a complete ban on all HT crops.

20.2 It was further submitted that the report titled, "*Biology of Brassica Juncea (Indian mustard)*" prepared by the MoEF&CC and DRMR, Bharatpur under United Nations Environment Programme (UNEP)/ Global Environment Facility (GEF) supported the regions of South Western China and North Western Himalayas, which constitute two secondary centres where there is enormous diversity in *Brassica Juncea* forms; that there is evidence for the existence of two geographical races of *Brassica Juncea*, the Chinese pool and the Indian pool. Further, five countries share nearly 60% of Brassica germplasm holdings led by China (17%) and followed by India (15%), United Kingdom (UK) (10%), USA (9%) and Germany (8%). India presents a rich diversity of rapeseed- mustard group of crops.

20.3 It was next submitted that glufosinate is banned for all other uses except for tea plantations and is specifically banned for use on DMH-11 by farmers; this is because glufosinate causes toxicity which would lead to resistance. However, glufosinate is otherwise available to farmers who have access to it.

20.4 That, the TEC report has pointed to the acute toxicity and health concerns such as carcinogenicity, reproductive and developmental toxicity, and endocrine disruption. That, long term studies show that an exposure to glufosinate would have adverse effects, which may not be evident in short term studies. That, even as per the information made available by Bayer,

BASTA containing glufosinate ammonium is neurotoxic and has adverse effect on aquatic life.

20.5 It was reiterated that in the biosafety dossier of HT mustard, the primary data dossier, is, in fact, not in the public domain. The biosafety dossier contains the primary data on the basis of which the AFES Report was prepared. However, the biosafety dossier containing 3251 pages was only available for physical inspection at the MoEF&CC headquarters and in response, petitioner's counsel had written to GEAC requesting the dossier to be put on the website so that it could be examined by independent experts. It was replied that in no country with functional regulatory system is the full dossier made available publicly due to reasons of protection of intellectual property.

20.6 That, in fact Dr. P.M. Bhargava, in his critique of the AFES Report, had pointed out that it was not possible to evaluate the statements made in the said Report as the primary data had not been provided in the Report. Therefore, it is all the more necessary that the biosafety dossier be put in the public domain so as to enable independent experts to review the same.

20.7 It was next submitted that no chronic/long term studies have been conducted on HT mustard. It was stressed that the petitioners' concern is the irreversible risk of contamination that the country faces, if environmental release of GMOs is permitted in the absence of any chronic studies *vis-à-vis* human health, livestock, environment, biodiversity etc. It was pointed out that

Union of India was silent as to the measures undertaken to ensure non-contamination. The Union of India was also silent about the measures undertaken in respect of labelling of GM foods, in light of the fact that no chronic studies have been commissioned as regards the consumption of GM foods. Also, the Union of India was silent as to the liability of the applicant and GEAC for potential losses to farmers and consumers on account of irreversible contamination.

20.8 In this regard, the TEC Report was referred to, wherein it has been stated that currently eighteen new food crop species, for which applications for field trial have been received in the Indian system, are - cauliflower, cabbage, corn, rice, wheat, tomato, groundnut, potato, sorghum, okra, brinjal, mustard, papaya, watermelon, sugarcane, etc. Also, the growth of GM crop would impact organic food producers and given the difficulties in segregation of GM and non-GM foods, it would be difficult to meet the criteria for organic food. This was said to have potential adverse impact on export of organic food, as the importers would closely examine the conditions under which organic food is being grown and any concern about contamination could lead to an adverse impact and loss of markets for organic food producers.

20.9 It was further submitted that GEAC, the regulator, has failed to deal with the illegal plantation of HT Bt cotton and the same is being grown in the country illegally on commercial basis. In fact, the intervenor in the present proceedings, Shetkari

Sangathan, has also been illegally planting Bt brinjal and has been encouraging farmers to do so, and GEAC has failed to check the same.

20.10 It was next submitted that large quantities of GM processed oil was being imported in the form of canola oil sourced largely from GM canola seeds and soyabean oil sourced from GM soyabean seeds. It was argued that this is in violation of the law.

20.11 Section 22 of the FSSA, 2006 prohibits manufacture, distribution, sale or import of any GMO products, except in accordance with the regulations which the Central Government may notify. This has been a subject matter of a judgment of this Court in ***Writ Petition (Civil) No.173 of 2006, Vandana Shiva vs. Union of India,*** disposed of on 11.08.2017, wherein it was recorded that there was no notification or regulation allowing any activity in connection with GE and modified food and such activity was permissible only under the regulations framed under Section 22 of the FSSA, 2006. The said writ petition was disposed of by allowing liberty to the petitioner therein to approach this Court again after regulations framed in connection with GE and modified food under Section 22 of the FSSA, 2006, are placed for consideration by the Parliament, in order to test their legality upon constitutional sustainability. However, till date, no notification has been issued by the Union of India.

20.12 In addition, it was pointed out that GEAC in their communication addressed to Directorate General of Foreign Trade (DGFT), dated 23.02.2018, had informed that it had not authorised or approved GM soyabean or any other products derived from GM soyabean seeds for import or cultivation in India. That being the case, it is not known on what basis is GM food being imported to India.

20.13 It was next submitted that there was a failure to undertake any socio-economic risk analysis by GEAC with regard to the failure of Bt cotton in accordance with the CBD and CPB. The need for such an assessment was also highlighted by TEC.

20.14 In this regard, reference was made to ***Mahyco Monsanto Biotec (India) Private Ltd. vs. Union of India, Writ Petition (Civil) No.12069 of 2015,*** filed before the Delhi High Court, in which the petitioner therein had challenged the price control order issued by the Union of India under the Essential Commodities Act, 1955 as regards Bt cotton seeds. The challenge is pending before the Delhi High Court. Pertinently, the Ministry of Agriculture and Farmers Welfare, Government of India, in the said case, has stated that the farmers across the country have been financially burdened due to the increasing prices of Bt cotton seeds. They have also to spend on pesticides and other resources to make the crops more pest resistant and high-yielding. This has resulted in escalated expenses and reduced the margin of profit for the farmers.

20.15 It was also brought to our notice that the pink bollworm, a major pest to the cotton crop, has developed resistance in the last two or three years and has worried the farmers who have sown Bt cotton seeds. That, the cotton yields were stagnant in the last five years due to the fact that the technology was used not for yield improvement but only for prevention of loss.

20.16 Referring to Article 14(1)(b) of the Argentina Convention, it was submitted that a duty is cast on the Government of India to assess the impact of its policies and minimize adverse impacts, as India is a signatory to the said convention.

20.17 It was, thus, argued that the 1989 Rules, which are prior in time to the CPB, have to be brought in line with the said protocol. Similarly, the Biological Diversity Act, 2002, casts a duty on the Central Government to protect biodiversity as per Section 36 of the said Act. In this regard, reference was made to the judgment of this Court in ***Gramophone Company of India Ltd. vs. Birendra Bahadur Pandey, (1984) 2 SCC 534 ("Gramophone Co. of India Ltd.")***, and ***Vishaka vs. State of Rajasthan, (1997) 6 SCC 241 ("Vishaka")***, which dealt with the doctrine of incorporation of international law into Indian law and how the same could be read to be part of national law unless they are in conflict with an Act of Parliament.

20.18 Further, any international convention not inconsistent with the fundamental rights and in harmony with its spirit must

be read into these provisions to enlarge the meaning and content thereof, so as to promote the object of the constitutional guarantee.

20.19 Similarly, reference was made to ***Nilabati Behera vs. State of Orissa, (1993) 2 SCC 746 ("Nilabati Behera")***, wherein the absence of an enacted law to provide for effective enforcement of the basic human right of gender equality was held to give the basis for using international conventions and norms to construe and give meaning to fundamental rights guaranteed under the Constitution of India.

20.20 It was also submitted that the present regulatory system continues to be deficient and therefore, there is a need for putting in place a suitable regulatory system which would work within the framework of its mandate.

20.21 In conclusion, it was submitted that the petitioners were seeking implementation of the recommendations of the TEC. That the TEC Report has been given a go-by by GEAC in consideration of the application made by Prof. Pental, Former Professor of Genetics and Vice-Chancellor, University of Delhi, South Campus, New Delhi. Therefore, the petitioners have sought the aforesaid reliefs.

Points for Consideration:

21. Before framing the points for consideration, we make it clear that this case does not decide the competing claims made

in the scientific literature about the desirability of GMOs, their impact on increasing crop yield in the short or long term and other subjects that belong to the domain of scientific and agricultural experts. This Court is not conducting a review or an evaluation of various scientific studies submitted by the petitioners and the respondents on GMOs. This Court does not have the institutional competence and therefore any conclusion raised on that basis would be a futile exercise.

21.1 The purpose of our adjudication is to satisfy our judicial conscience on the subject of critical public interest. We have viewed the matter from the perspective of compliances of the principles of exercise of discretion and use of administrative power in a niche area where opinions of scientists and experts in the field would determine the course of action to be taken in a matter as significant as the steps leading to the decision for environmental release of DMH-11 mustard in an altered technology.

21.2 This case also does not decide on the divergent substantive content and recommendations made by the TEC or GEAC. The ambit of the present case is strictly limited to compliance with constitutional and legal requirements in the decision-making process impugned herein. In light of the aforesaid, and the submissions advanced by learned senior counsel and counsel for respective parties, the following points would arise for our consideration:

(i) Whether GEAC approval dated 18.10.2022 and the consequent decision dated 25.10.2022 for the environmental release of DMH-11 is in accordance with law?

(ii) Whether the decision to grant approval for environmental release of DMH-11 violates the right to safe and healthy environment under Article 21?

(iii) Whether GEAC's grant of approval dated 18.10.2022 and the decision dated 25.10.2022 for the environmental release of DMH-11 violate the precautionary principle?

(iv) What order?

Since there is a difference of opinion between the Members of this Bench *vis-à-vis* the validity of the decision taken for environmental release of DMH-11, from this stage onwards, I propose to opine for myself while my learned brother Karol, J. has prepared his separate opinion.

Legal Framework:

22. Before I proceed further, it would be useful to note that agriculture, including agricultural education and research, protection against pests and prevention of plant diseases, is a State subject enumerated as Entry 14 in List II (State List). Trade and commerce in, and the production, supply and distribution of, *inter alia,* foodstuffs, including edible oil seeds and oils, is in Entry 33(b) in List III (Concurrent List) of the Seventh Schedule. Rules and regulations made under the EP Act, 1986 are possibly referrable to Entry 97 of List I (Union List) since environment

protection has not been specifically mentioned in either List II or List III of the Seventh Schedule, except for forest. For ease of reference, the aforesaid Entries of the Seventh Schedule as well as others are extracted as under:

> **"Entry 52, List I:**
>
> 52. Industries, the control of which by the Union is declared by Parliament by law to be expedient in the public interest.
>
> **Entry 97, List I:**
>
> 97. Any other matter not enumerated in List II or List III including any tax not mentioned in either of those Lists.
>
> **Entry 6, List II:**
>
> 6. Public health and sanitation; hospitals and dispensaries.
>
> **Entry 14, List II:**
>
> 14. Agriculture, including agricultural education and research, protection against pests and prevention of plant diseases.
>
> **Entry 33(b), List III:**
>
> 33. Trade and commerce in, and the production, supply and distribution of,-
>
> … … …
>
> (b) foodstuffs, including edible oilseeds and oils;"

22.1 Article 48A of the Constitution of India is a Directive Principle of State Policy which speaks about protection and improvement of environment and safeguarding of forests and wild life. Likewise, Article 51A(g) casts upon citizens a

fundamental duty to protect and improve the natural environment including forests, lakes, rivers and wildlife. These Articles have to be read in the context of Article 21 of the Constitution, which has been expansively interpreted by this Court to include within its scope and ambit of the right to health and clean environment and ecology. For ready reference, the aforesaid Articles are extracted as under:

> **"21. Protection of life and personal liberty.—**No person shall be deprived of his life or personal liberty except according to procedure established by law.
>
> x x x
>
> **48A. Protection and improvement of environment and safeguarding of forests and wild life.—**The State shall endeavour to protect and improve the environment and to safeguard the forests and wild life of the country.
>
> x x x
>
> **51A. Fundamental duties.—**It shall be the duty of every citizen of India—
>
> x x x
>
> (g) to protect and improve the natural environment including forests, lakes, rivers and wild life, and to have compassion for living creatures;"

23. At this point, it is also observed that Article 21 also encompasses the right to food safety. It is in this context that the FSSA, 2006 has been enacted and I would now advert to the provisions contained therein as well.

23.1 FSSA, 2006 has been enacted pursuant to Entry 52, List I of the Seventh Schedule of the Constitution.

Section 2 of the said Act has declared that it is expedient in the public interest that the Union should take under its control the food industry.

23.2 The Preamble of the FSSA, 2006, *inter alia,* states that it is an Act to consolidate the laws relating to food and to establish the FSSAI for laying down science-based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import, to ensure availability of safe and wholesome food for human consumption. The following provisions under the FSSA, 2006 could be adverted to:

> **"2. Declaration as to expediency of control by the Union**.- It is hereby declared that it is expedient in the public interest that the Union should take under its control the food industry.
>
> **3. Definitions.** (1) In this Act, unless the context otherwise requires, –
>
> (a) "adulterant" means any material which is or could be employed for making the food unsafe or sub-standard or mis-branded or containing extraneous matter;
>
> x x x
>
> (j) "Food" means any substance, whether processed, partially processed or unprocessed, which is intended for human consumption and includes primary food, to the extent defined in clause (ZK) genetically modified or engineered food or food containing such ingredients, infant food, packaged drinking water, alcoholic drink, chewing gum, and any substance, including water used into the food during its manufacture, preparation or treatment but does not include any animal feed, live animals unless they are prepared or processed for placing on the market for human consumption, plants,

prior to harvesting, drugs and medicinal products, cosmetics, narcotic or psychotropic substances :

Provided that the Central Government may declare, by notification in the Official Gazette, any other article as food for the purposes of this Act having regards to its use, nature, substance or quality;

x x x

(q) "food safety" means assurance that food is acceptable for human consumption according to its intended use;

x x x

(u) "hazard" means a biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect;

x x x

(v) "import" means bringing into India any article of food by land, sea or air;

x x x

(zk) "primary food" means an article of food, being a produce of agriculture or horticulture or animal husbandry and dairying or aquaculture in its natural form, resulting from the growing, raising, cultivation, picking, harvesting, collection or catching in the hands of a person other than a farmer or fisherman;

x x x

(zm) "risk", in relation to any article of food, means the probability of an adverse effect on the health of consumers of such food and the severity of that effect, consequential to a food hazard;

(zn) "risk analysis", in relation to any article of food, means a process consisting of three components, i.e. risk assessment, risk management and risk communication;

(zo) "risk assessment" means a scientifically based process consisting of the following steps: (i) hazard

identification, (ii) hazard characterisation; (iii) exposure assessment, and (iv) risk characterisation;

(zp) "risk communication" means the interactive exchange of information and opinions throughout the risk analysis process concerning risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions;

(zq) "risk management" means the process, distinct from risk assessment, of evaluating policy alternatives, in consultation with all interested parties considering risk assessment and other factors relevant for the protection of health of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options;

x x x

(zu) "standard", in relation to any article of food, means the standards notified by the Food Authority;

x x x

(zw) "substance" includes any natural or artificial substance or other matter, whether it is in a solid state or in liquid form or in the form of gas or vapour;

(zx) "Sub-standard" - an article of food shall be deemed to be sub-standard if it does not meet the specified standards but not so as to render the article of food unsafe;"

23.3 It would be necessary to refer to Section 22 of the said Act, which deals with GM foods, organic foods, functional foods, proprietary foods, etc. The said Section reads as under:

"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, neutraceuticals, health supplements, proprietary foods and such other articles of food which the Central Government may notify in this behalf.

Explanation.– For the purposes of this section,–

(1) "foods for special dietary uses or functional foods or nutraceuticals or health supplements" means:

(a) foods which are specially processed or formulated to satisfy particular dietary requirements which exist because of a particular physical or physiological condition or specific diseases and disorders and which are presented as such, wherein the composition of these foodstuffs must differ significantly from the composition of ordinary foods of comparable nature, if such ordinary foods exist, and may contain one or more of the following ingredients, namely:-

(i) plants or botanicals or their parts in the form of powder, concentrate or extract in water, ethyl alcohol or hydro alcoholic extract, single or in combination;

(ii) minerals or vitamins or proteins or metals or their compounds or amino acids (in amounts not exceeding the Recommended Daily Allowance for Indians) or enzymes (within permissible limits);

(iii) substances from animal origin;

(iv) a dietary substance for use by human beings to supplement the diet by increasing the total dietary intake;

(b) (i) a product that is labelled as a "Food for special dietary uses or functional foods or nutraceuticals or health supplements or similar such foods" which is not represented for use as a conventional food and whereby such products may be formulated in the form of powders, granules, tablets, capsules, liquids, jelly and other dosage forms but not parenterals, and are meant for oral administration;

(ii) such product does not include a drug as defined in clause (b) and ayurvedic, sidha and unani drugs as defined in clauses (a) and (h) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940) and rules made thereunder;

(iii) does not claim to cure or mitigate any specific disease, disorder or condition (except for certain health benefit or such promotion claims) as may be permitted by the regulations made under this Act;

(iv) does not include a narcotic drug or a psychotropic substance as defined in the Schedule of the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985) and rules made thereunder and substances listed in Schedules E and EI of the Drugs and Cosmetics Rules, 1945;

(2) “genetically engineered or modified food” means food and food ingredients composed of or containing genetically modified or engineered organisms obtained through modern biotechnology, or food and food ingredients produced from but not containing genetically modified or engineered organisms obtained through modern biotechnology;

(3) “organic food” means food products that have been produced in accordance with specified organic production standards;

(4) “proprietary and novel food” means an article of food for which standards have not been specified but is not unsafe:

Provided that such food does not contain any of the foods and ingredients prohibited under this Act and regulations made thereunder.”

23.4 Since I am dealing with GE or modified food, it would be useful to note the definition thereof under sub-section (2) of Section 22, which defines it as food and food ingredients composed of or containing GM or engineered organisms obtained through modern biotechnology, or food and food ingredients produced from but not containing GM or engineered organisms obtained through modern biotechnology.

23.5 The Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011 (hereinafter referred to as, “the Food Safety Regulations, 2011”) have been framed under Section 92(2)(e) read with Section 16 of the FSSA, 2006 by the FSSAI. In Regulation 2.9.13(1), details regarding mustard (Rai, Sarson) are mentioned as under:

"**2.9.13: Mustard (Rai, Sarson)**

1. Mustard (Rai, Sarson) Whole means the dried, clean mature seeds of one or more of the plants of Brassica alba. (L). Boiss (Safed rai), Brassica compestris L.var, dichotoma (Kali Sarson), Brasssica Compestris, L. Var, yellow Sarson, Syn, Brassica compestris L, var glauca (Pili Sarson), Brassica, compestris L. Var. toria (Toria), Barassicajuncea, (L). Coss et Czern (Rai, Lotni) and Brassica nigra (L); Koch (Benarasi rai). It shall be free from mould, living and dead insects, insect fragments, rodent contamination. The product shall be free from the seeds of Argemone Maxicana L, any other harmful substances and added colouring matter.

It shall conform to the following standards:

(i) Extraneous matter	Not more than 2.0 percent by weight.
(ii) Damaged or Shrivelled Seeds	Not more than 2.0 percent by weight.
(iii) Moisture	Not more than 10.0 percent by weight.
(iv) Total ash on dry basis	Not more than 6.5 percent by weight.
(v) Ash insoluble in dilute HCl on dry basis	Not more than 1.0 percent by weight.
(vi) Non volatile ether extract on dry basis	Not less than 28.0 percent by weight.

(vii) Violatile oil content on dry basis	Not less than 0.3 percent by v/w.
(viii) Insect damaged matter	Not more than 1.0 percent by weight.
(ix) Allyl iso thiocyanate (m/m) on dry basis	
(a) B nigra	Not less than 1.0 percent by Weight.
(b) B Juncea	Not less than 0.7 percent by Weight.
(x) P-hydroxybenzyl percent by iso-thiocyanate (m/m) on dry basis in sinapist alba	Not less than 2.3 weight.
(xi) Argemone seeds	Absent."

Environment (Protection) Act, 1986 (EP Act, 1986):

24. EP Act, 1986 has been enacted to provide for the protection and improvement of environment and for matters connected therewith. The relevant provisions of the said Act are extracted as under:

> **"2. Definitions.-** In this Act, unless the context otherwise requires,-
>
> (a) "environment" includes water, air and land and the inter-relationship which exists among and between water, air and land, and human beings, other living creatures, plants, micro-organism and property;

(b) "environmental pollutant" means any solid, liquid or gaseous substance present in such concentration as may be, or tend to be, injurious to environment;

(c) "environmental pollution" means the presence in the environment of any environmental pollutant;"

1989 Rules:

25. In exercise of the powers conferred by Sections 6, 8 and 25 of the EP Act, 1986 and with a view to protect the environment, nature and health in connection with the application of gene-technology and micro-organisms, the Central Government has framed the 1989 Rules. The said Rules dealing with manufacture, use, import, export and storage of hazardous micro-organisms/GE organisms or cells were notified with a view to protect the environment, nature and health in connection with the application of gene-technology and micro-organisms. These Rules were gazetted on 05.12.1989 and are applicable to Genetically Engineered Organisms (GEOs)/micro-organisms and cells and correspondingly to any substances and products and food stuffs, etc., of which such cells, organisms or tissues thereof form part. The Rules also apply to new gene-technologies, apart from those referred to in clause (ii) and (iv) of Rule 3, and to organisms/micro-organisms and cells generated by the utilisation of such other gene-technologies and to substances and products of which such organisms and cells form part. The conditions under which the Rules are applicable have been stated in sub-paragraph (4) of Rule 2 of the said Rules.

25.1 Rule 3 defines, *inter alia,* the expressions, "biotechnology", "gene technology" and "genetic engineering", which read as under:

> **"3. Definitions:-** In these rules unless the context requires.
>
> (i) "Biotechnology" means the application of scientific and engineering principles to the processing of materials by biological agents to produce goods and services;
>
> (ii) x x x
>
> (iii) "Gene Technology" means the application of the gene technique called genetic engineering, include self cloning and deletion as well as cell hybridisation;
>
> (iv) "Genetic engineering" means the technique by which heritable material, which does not usually occur or will not occur naturally in the organism or cell concerned, generated outside the organism or the cell is inserted into the said cell or organism. It shall also mean the formation of new combinations of genetic material by incorporation of a cell into a host cell, where they occur naturally (self cloning) as well as modification of an organism or in a cell by deletion and removal of parts of the heritable material;"

25.2 Rule 4 speaks of the competent authorities constituted under the Rules and the said Rule reads as under:

> **"4. Competent Authorities:-**
>
> **(1) Recombinant DNA Advisory Committee (RDAC).**
>
> This Committee shall review developments in Biotechnology at national and international levels and shall recommend suitable and appropriate safety regulations for India in recombinant research, use and

applications from time to time. The Committee shall function in the Department of Biotechnology.

(2) Review Committee on Genetic Manipulation (RCGM).

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

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

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

(3) Institutional Biosafety Committee (IBSC).

This Committee shall be constituted by an occupier or any person including research institutions handling microorganism/genetically engineered organisms. The

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

(4) Genetic Engineering Approval Committee (GEAC).

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

The composition of the Committee shall be -

(i) Chairman – Additional Secretary, Department of Environment, Forests and Wildlife.

Co-Chairman – Representative of Department of Biotechnology.

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

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

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

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

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

(5) State Biotechnology Co-ordination Committee (SBCC).

There shall be a State Biotechnology Coordination Committee in the States wherever necessary. It shall have powers to inspect, investigate and take punitive action in case of violations of statutory provisions through the Nodal Department and the State Pollution Control Board/Directorate of Health/Medical Services. The Committee shall review periodically the safety and control measures in the various industries/institutions handling genetically engineered organisms/hazardous microorganisms. The composition of the Coordination Committee shall be:

(i) Chief Secretary – Chairman
(ii) Secretary, Department of Environment – Member Secretary
(iii) Secretary, Department of Health – Member
(iv) Secretary, Department of Agriculture – Member

(v) Secretary, Department of Industries and Commerce – Member
(vi) Secretary, Department of Forests - Member
(vii) Secretary, Department of Public Works/Chief Engineer, Department of Public Health Engineering – Member
(viii) State Microbiologists and Pathologists – Member
(ix) Chairman of State Pollution Control Board

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

(6) District Level Committee (DLC).

There shall be a District Level Biotechnology Committee (DLC) in the districts wherever necessary under the District Collectors to monitor the safety regulations in installations engaged in the use of genetically modified organisms/hazardous microorganisms and its applications in the environment.

The District Level Committee/or any other persons/s authorised in this behalf shall visit the installation engaged in activity involving genetically engineered organisms, hazardous microorganisms, formulate information chart, find out hazards and risks associated with each of these installations and coordinate activities with a view to meeting any emergency. They shall also prepare an off-site emergency plan. The District Level Committee shall regularly submits its report to the State Biotechnology Co-ordination Committee/Genetic Engineering Approval Committee.

The District Level Committee shall comprise of:-

(i) District Collector – Chairman
(ii) Factory Inspector – Member
(iii) A representative of the Pollution Control Board – Member
(iv) Chief Medical Officer (District Health Officer) –Member (Convenor)

(v) District Agricultural Officer – Member
(vi) A representative of the Public Health Engineering Department – Member
(vii) District Microbiologists/ Pathologist (technical expert) – Member
(viii) Commissioner Municipal Corporation – Member

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

25.3 Rule 5 speaks of classification of micro-organisms or GE products, while Rule 7 deals with approval and prohibitions. The same read as under:

"5. Classification of microorganisms or genetically engineered product - (1) For the purpose of these rules, microorganisms or genetically engineered organisms, products or cells shall be dealt with under two major heads; animal pathogens and plant pests and these shall be classified in the manner specified in the Schedule.

(2) If any of the microorganism, genetically engineered organism or cell falls within the limits of more than one risk class as specified in the Schedule, it shall be deemed to belong exclusively to the last in number of such classes.

x x x

7. Approval and Prohibitions, etc. :- (1) No person shall import, export, transport, manufacture, process, use or cell any hazardous microorganisms or genetically engineered organisms/substances or cells except with the approval of the Genetic Engineering Approval Committee.

(2) Use of pathogenic microorganism or any genetically engineered organisms or cell for the purpose of research shall only be allowed in laboratories or inside laboratory areas notified by the Ministry of Environment

and Forests for this purpose under the Environment (Protection) Act, 1986.

(3) The Genetic Engineering Approval Committee shall give directions to the occupier to determine or take measures concerning the discharge of microorganisms/genetically engineered organisms or cells mentioned in the Schedule from the laboratories, hospitals and other areas including prohibition of such discharges and laying down measures to be taken to prevent such discharges.

(4) Any person operating or using genetically engineered organisms/microorganisms mentioned in the schedule for scale up or pilot operations shall have to obtain licence issued by the Genetic Engineering Approval Committee for any such activity. The possessor shall have to apply for licence in prescribed proforma.

(5) Certain experiments for the purpose of education within the field of gene technology or microorganism may be carried out outside the laboratories and laboratory areas mentioned in sub-rule (2) and will be looked after by the Institutional Biosafety Committee."

25.4 Rule 8 deals with production, while Rule 11 deals with permission and approval for food stuffs. The same are extracted as under:

"8. Production:- Production in which genetically engineered organisms or cells or micro-organism are generated or used shall not be commenced except with the consent of Genetic Engineering Approval Committee with respect of discharge of genetically engineered organisms or cells into the environment. This shall also apply to production taking place in connection with development, testing and experiments where such production, etc., is not subject to rule 7.

x x x

11. Permission and Approval for Food Stuffs :- Food stuffs, ingredients in food stuffs and additives including processing and containing or consisting of genetically engineered organisms or cells, shall not be produced, sold, imported or used except with the approval of the Genetic Engineering Approval Committee."

25.5 The guidelines and grant of approval are as per Rules 12 and 13, which read as under:

"12. Guidelines :- (1) Any person who applies for approval under rules 8-11 shall, as determined by the Genetic Engineering Approval Committee submit information and make examinations or cause examinations to be made to elucidate the case, including examinations according to specific directions and at specific laboratories. He shall also make available an on-site emergency plan to GEAC before obtaining the approval. If the authority makes examination itself, it may order the applicant to defray the expenses incurred by it in so doing.

(2) Any person to whom an approval has been granted under rules 8-11 above shall notify the Genetic Engineering Approval Committee of any change in or addition to the information already submitted.

13. Grant of Approval :- (1) In connection with the granting of approval under rules 8 to 11 above, terms and conditions shall be stipulated, including terms and conditions as to the control to be exercised by the applicant, supervision, restriction on use, the layout of the enterprise and as to the submission of information to the State Biotechnology Coordination Committee or to the District Level Committee.

(2) All approvals of the Genetic Engineering Approval Committee shall be for a specific period not exceeding four year at the first instance renewable for 2 years at a time. The Genetic Engineering Approval Committee shall have powers to revoke such approval in the following situations:-

(a) If there is any new information as to the harmful effects of the genetically engineered organisms or cells.

(b) If the genetically engineered organisms or cells cause such damage to the environment, nature or health as could not be envisaged when the approval was given, or

(c) Non compliance of any condition stipulated by Genetic Engineering Approval Committee."

Regulatory Framework:

26. MoEF&CC is the nodal ministry for regulation of GMOs including GE plants. 1989 Rules under the EP Act, 1986 provide the statutory scheme for regulation of GE technologies. The 1989 Rules are implemented by the MoEF&CC, the DBT, Ministry of Science & Technology and State Governments.

26.1 The following authorities/committees are created under the 1989 Rules:

(i) Recombinant DNA Advisory Committee (RDAC):

The RDAC is involved in reviewing the developments in biotechnology, both at national as well as international levels, and recommending safety regulations as per the indigenous requirements of our country in recombinant research, use and

applications from time to time. The RDAC's functions are advisory in nature.

(ii) Genetic Engineering Appraisal Committee (GEAC):

GEAC is the apex body to accord approval of activities involving large scale use of hazardous micro-organisms and recombinants in research and industrial production from the environmental perspective. GEAC is also responsible for granting approvals relating to release of GE organisms and products into the environment, including experimental field trials (BRL-II). This Committee functions as a body under the Department of Environment, Forest and Wildlife for approval of activities involving large scale use of hazardous micro-organisms and recombinants in research and industrial production from the environmental angle delineated under Rule 4.

Rules 7, 8 and 10 of the 1989 Rules state that no research, development, import, export, manufacture, process, use or sale of any GE technology or products/substances derived therefrom can be attempted without the approval of GEAC.

(iii) Review Committee on Genetic Manipulation (RCGM):

The RCGM is established under the DBT and is mandated to monitor the safety-related aspects in respect of on-going research projects and activities and bring out manuals and guidelines specifying procedure for regulatory process with respect to activities involving GEO in research, use and applications, including industry, with a view to ensure environmental safety. The RCGM is the authority for BRL-I trials. This Committee

includes representatives of the DBT, Indian Council of Medical Research (ICMR), ICAR, CSIR and other experts in their individual capacity. The Committee may appoint sub groups. This Committee also lays down procedures for restricting or prohibiting production, sale, importation and use of such GEOs of cells as are mentioned in the Schedule to the 1989 Rules.

(iv) Institutional Biosafety Committee (IBSC):

The IBSC is established under the institution engaged in GMO research, to oversee such research and to interface with the RCGM in regulating it.

This Committee is constituted by the research institutions handling micro-organism/GEO. The Committee comprises of the Head of the Institution, scientists engaged in DNA work, a medical expert and a nominee of the DBT. The research institutions handling micro-organisms/GEOs are mandated to prepare, with the assistance of the IBSC, an up to date on-site emergency plan according to the manuals/guidelines of the RCGM and make available copies to the DLC/SBCC and GEAC.

(v) State Biotechnology Co-Ordination Committee (SBCC):

The SBCC plays a major role in monitoring and has powers to inspect, investigate and take punitive action in case of violations of statutory provisions.

This Committee is constituted in the States to periodically review the safety and control measures in the various industries/ institutions handling GEOs/hazardous micro-organisms. It has power to inspect, investigate and take punitive action in case of

violations of statutory provisions, through the Nodal Department and the State Pollution Control Board/Directorate of Health/Medical Services. The Committee is chaired by the Chief Secretary of the State Government. The Members of the Committee include Secretaries from the Departments of Health, Agriculture, Industries & Commerce, Forests, Public Works/ Chief Engineer, Public Health Engineering, State Microbiologists and Pathologists, Chairman of State Pollution Control Board. The Secretary, Department of Environment is the Member Secretary of the Committee. The Committee may co-opt other members/experts as necessary.

(vi) District Level Committee (DLC):

The DLC has a major role in monitoring the safety regulations in installations engaged in the use of GMOs/ hazardous micro-organisms and its application in the environment.

This Committee is constituted in the districts to monitor the safety regulations in installations engaged in the use of GMOs/ hazardous micro-organisms and its applications in the environment. This Committee is chaired by the District Collector. The Chief Medical Officer (District Health Officer) is the Member (Convenor). The Members of the Committee include Factory Inspector, a representative from Pollution Control Board, District Agricultural Officer, a representative of the Public Health Engineering Department, District Microbiologists, Pathologist

(Technical expert), and Commissioner of Municipal Corporation. The Committee may co-opt other members/experts as necessary.

26.2 According to learned Attorney General, the 1989 Rules are implemented by the aforesaid competent authorities through a series of biosafety guidelines issued from time to time. The Guidelines applicable to GE plants are:

(i) Guidelines and SOP for Conduct of Confined Field Trials of Regulated GE Plants, 2008.

(ii) Revised Guidelines for Research in Transgenic Plants, 1998;

(iii) Regulations and Guidelines for Recombinant DNA Research and Biocontainment, 2017.

(iv) Guidelines for Safety Assessment of Foods Derived from GE Plants, 2008 (updated in 2012)

(v) Protocols for Food and Feed Safety Assessment of GE Crops, 2008.

(vi) Environmental Risk Assessment (ERA) of GE Plants: A Guide for Stakeholders, 2016.

(vii) Risk Analysis Framework, 2016.

(vii) Guidelines for the Environmental Risk Assessment of GE Plants, 2016.

26.3 The research and development (R&D) with respect to GE plants has to be conducted in accordance with the Revised Guidelines for Research in Transgenic Plants, 1998. As per these Guidelines, the experiments conducted on research of transgenic plants are broadly categorized into three categories based on the risk involved, namely, Category I that involves routine rDNA

experiments, Category II involving evaluation of transgenic plants in green house/net house, and Category III that pertains to high-risk experiments. These experiments have to be regulated by the IBSC and/or the RCGM, as prescribed in the Guidelines.

26.4 Subsequent to the above experiments conducted under the contained conditions, the confined field trials have to be conducted as prescribed under the Guidelines and SOP for the Conduct of Confined Field Trials of Regulated GE Plants, 2008.

26.5 The initial assessment of an application for a confined field trial begins at the institutional level itself. Based on information generated by the applicant in the laboratory and the greenhouse, an application is made to the IBSC for permission to conduct a confined field trial. The IBSC evaluates the proposal for conducting a field trial and further recommends it to the other Regulatory Authorities. The confined field trials are categorized as under:

(i) Biosafety Research Level-I (BRL-I) Trials: These trials are limited in size to no more than 1 acre (0.4 ha) per trial site location and a maximum cumulative total of 20 acres (8.1 ha) for all locations for each plant species/construct combination (e.g., one or more events originating from transformation of a plant species with the same genetic construct), per applicant, per crop season.

(ii) Biosafety Research Level-II (BRL-II) Trials: These are limited in size to no more than 2.5 acres (1 ha) per trial site

location and number of locations to be decided on a case by case basis for each plant species/construct combination (e.g., one or more events originating from transformation of a plant species with the same genetic construct), per applicant, per crop season.

The RCGM is the regulatory authority for BRL-I trials and GEAC is the regulatory authority for BRL-II trials, as per the Guidelines for the Conduct of Confined Field Trials of Regulated GE Plants, 2008.

26.6 Applications for environmental release are processed in accordance with Guidelines for the Environmental Risk Assessment (ERA) of GE Plants, 2016.

26.7 The Risk Analysis Framework, 2016 prescribes the Regulatory Agency's approach to risk analysis. It is based on national and international standards and guidance, including the CPB to which India is a party. In accordance with the Risk Analysis Framework, 2016, assessment of safety of GM plants is a comprehensive process involving subject experts and ensures transparency in the regulatory decision-making process by incorporating stakeholder consultations.

26.8 As per this framework, regulatory agencies seek views from various stakeholders and the steps followed in this consultation process include:

(i) The communication of information about submission of applications for environmental release of GE plants to the regulatory agency.

(ii) Preparation of a RARM plan for each application by the regulatory agencies.

(iii) RARM plan uploaded on the official website for receiving comments from the stakeholders for a period of 30 days.

(iv) The regulatory agency gives its recommendations after due consideration of the responses received from the stakeholders.

26.9 That in line with the above, the applicant has to follow a clearly laid out step by step process for biosafety data generation from laboratory to field trials, safety tests and submission of application for environmental release. The biosafety data is generated in laboratories and by confined field trials under conditions authorized by the RCGM and GEAC, as per the guidelines and protocols and in recognized laboratories/ institutions/universities.

27. In the context of the crucial role of the regulatory bodies, particularly with regard to food safety and environment, this Court in Writ Petition (Civil) No.202 of 1995 ***(In Re: T.N. Godavarman Thirumulpad vs. Union of India)***, order dated 31.01.2024, speaking through Gavai, J. in paragraphs 22-25 and 28-32, has observed as under:

"22. As new bodies, authorities, and regulators for environmental governance emerge from time to time, their institutionalisation assumes extraordinary importance. Institutionalisation means that these bodies must work in compliance with institutional norms of efficiency, integrity and certainty. In this context, the role of the constitutional courts is even greater.

23. Environmental Rule of Law: Environmental rule of law refers to environmental governance that is undergirded by the fundamental tenets of rule of law. The rule of law regime is one that has effective, accountable, and transparent institutions; responsive, inclusive, participatory, and representative decision making; and public access to information. It recognises the vital role that institutions play in governance and focuses on defining the structural norms and processes that guide institutional decision making.

24. While several laws, rules, and regulations exist for protection of the environment, their objective is not achieved as there is a considerable gap as these laws remain unenforced or ineffectively implemented. Rule of law in environmental governance seeks to redress this issue as the implementation gap has a direct bearing on the protection of the environment, forests, wildlife, sustainable development, and public health, eventually affecting fundamental human rights to a clean environment that are intrinsically tied to right to life. Accountability of the authorities impressed with the duty to enforce and implement environmental and other ecological laws is an important feature of judicial governance. In the context of accountability, this Court in ***Vijay Rajmohan vs. CBI, (2023) 1 SCC 329*** has held:

> "34. Accountability in itself is an essential principle of administrative law. Judicial review of administrative action will be effective and

meaningful by ensuring accountability of the officer or authority in charge.

35. The principle of accountability is considered as a cornerstone of the human rights framework. It is a crucial feature that must govern the relationship between "duty bearers" in authority and "right holders" affected by their actions. Accountability of institutions is also one of the development goals adopted by the United Nations in 2015 and is also recognised as one of the six principles of the Citizens Charter Movement.

36. Accountability has three essential constituent dimensions: (i) responsibility, (ii) answerability, and (iii) enforceability. Responsibility requires the identification of duties and performance obligations of individuals in authority and with authorities. Answerability requires reasoned decision making so that those affected by their decisions, including the public, are aware of the same. Enforceability requires appropriate corrective and remedial action against lack of responsibility and accountability to be taken. Accountability has a corrective function, making it possible to address individual or collective grievances. It enables action against officials or institutions for dereliction of duty. It also has a preventive function that helps to identify the procedure or policy which has become non-functional and to improve upon it."

25. In India, environmental rule of law must draw attention to the existing legal regime, rules, processes, and norms that environmental regulatory institutions follow to achieve the goal of effective and good governance and implementation of environmental laws. More importantly, the focus must be on the policy and regulatory and implementation agencies. In doing so, environmental rule of law fosters open, accountable, and transparent decision making and participatory

governance. The renewed role of constitutional courts will be to undertake judicial review to ensure that institutions and regulatory bodies comply with the principles of environmental rule of law.

x x x

28. We may ask a simple question – how effectively are these environmental bodies functioning today? This question has a direct bearing on the protection and restoration of ecological balance.

29. As environmental governance through these bodies emerges, the obligation of the constitutional courts is even greater. Hitherto, the constitutional courts focused on decisions and actions taken by the executive or private persons impacting the environment and ecology because the scrutiny by regulators was felt to be insufficient. Their judgment, review, and consideration did not inspire confidence and therefore, the Court took up the issue and would decide the case. In this process, a large number of decisions rendered by this Court on sensitive environmental, forest, and ecological matters constitute the critical mass of our environmental jurisprudence. This Court would continue to exercise judicial review, particularly in environmental matters, whenever necessary.

30. We however seek to emphasise and reiterate the importance of ensuring the effective functioning of these environmental bodies as this is imperative for the protection, restitution, and development of the ecology. The role of the constitutional courts is therefore to monitor the proper institutionalisation of environmental regulatory bodies and authorities.

31. In furtherance of the principles of environmental rule of law, the bodies, authorities, regulators, and executive offices entrusted with environmental duties must function with the following institutional features:

i. The composition, qualifications, tenure, method of appointment and removal of the members of these authorities must be clearly laid down. Further, the appointments must be regularly made to ensure continuity and these bodies must be staffed with persons who have the requisite knowledge, technical expertise, and specialisation to ensure their efficient functioning.

ii. The authorities and bodies must receive adequate funding and their finances must be certain and clear.

iii. The mandate and role of each authority and body must be clearly demarcated so as to avoid overlap and duplication of work and the method for constructive coordination between institutions must be prescribed.

iv. The authorities and bodies must notify and make available the rules, regulations, and other guidelines and make them accessible by providing them on the website, including in regional languages, to the extent possible. If the authority or body does not have the power to frame rules or regulations, it may issue comprehensive guidelines in a standardised form and notify them rather than office memoranda.

v. These bodies must clearly lay down the applicable rules and regulations in detail and the procedure for application, consideration, and grant of permissions, consent, and approvals.

vi. The authorities and bodies must notify norms for public hearing, the process of decision-making, prescription of right to appeal, and timelines.

vii. These bodies must prescribe the method of accountability by clearly indicating the allocation of duties and responsibilities of their officers.

viii. There must be regular and systematic audit of the functioning of these authorities.

32. The role of the constitutional courts is to ensure that such environmental bodies function vibrantly, and are assisted by robust infrastructure and human resources. The constitutional courts will monitor the functioning of these institutions so that the environment and ecology is not only protected but also enriched.

Constitutional Court and the Environmental Rule of Law:

28. Before I proceed further in the matter, it would be necessary to know the role of the Constitutional Court in matters concerning science and technology and environment. The observations of this Court in the following cases are noted as under:

(i) On the aspect of the approach of the Constitutional Courts towards questions arising in the realm of science and environment, this Court has time and again struck a balance between exercising restraint and answering questions arising in the realm of pure science by, *inter alia*, placing reliance on the principle of sustainable development, precautionary principle and polluter pays principle. This Court has not only incorporated progressive ideals and frameworks to strengthen the process of sustainable development but has repeatedly emphasised the contours of its adjudication in concerns touching upon environment. However, growth of jurisprudence in environmental rule of law provides ample guidance for the present adjudication.

(ii) In ***Hanuman Laxman Aroskar vs. Union of India, (2019) 15 SCC 401 ("Hanuman Laxman Aroskar")***, this Court recognised the need to imbue institutional decision-making on questions of environment with the central precepts of the rule of law to achieve the lofty goal of sustainable development. Placing reliance upon the United Nations Environment Programme's First Global Report on Environmental Rule of Law, this Court articulated the following seven components of the framework of Environmental Rule of Law:

i. Fair, clear, and implementable environmental laws;

ii. Access to information, public participation, and access to justice through courts, tribunals, commissions, and other bodies;

iii. Accountability and integrity of decision-makers and institutions;

iv. Clear and coordinated mandates and roles, across and within institutions;

v. Accessible, fair, impartial, timely and responsive dispute resolution mechanisms;

vi. Recognition of the mutually reinforcing relationship between rights and environmental rule of law; and

vii. Specific criteria for the interpretation of environmental law.

It further acknowledged how the contemporary environmental challenges such as the climate change crisis could be effectively addressed through a creative synergy of constitutional values of fairness, accountability and

transparency with core ideals of environmental protection in the following words:

> **"156.** The rule of law requires a regime which has effective, accountable and transparent institutions. Responsive, inclusive, participatory and representative decision making are key ingredients to the rule of law. Public access to information is, in similar terms, fundamental to the preservation of the rule of law. In a domestic context, environmental governance that is founded on the rule of law emerges from the values of our Constitution. The health of the environment is key to preserving the right to life as a constitutionally recognised value under Article 21 of the Constitution. Proper structures for environmental decision making find expression in the guarantee against arbitrary action and the affirmative duty of fair treatment under Article 14 of the Constitution."

(iii) The judgment in ***Himachal Pradesh Bus-Stand Management & Development Authority vs. Central Empowered Committee, (2021) 4 SCC 309 ("H.P. Bus-Stand")*** expanded the framework of environmental rule of law to include within it the State's positive obligations to create conceptual, procedural and institutional structures that guide environmental regulation in furtherance of the environmental rule of law. Emphasising the critical need for multi-disciplinary perspectives, this Court held that:

> "49. The environmental rule of law, at a certain level, is a facet of the concept of the rule of law. But it includes specific features that are unique to environmental governance, features which are sui generis. The environmental rule of law seeks to

create essential tools — conceptual, procedural and institutional to bring structure to the discourse on environmental protection. It does so to enhance our understanding of environmental challenges — of how they have been shaped by humanity's interface with nature in the past, how they continue to be affected by its engagement with nature in the present and the prospects for the future, if we were not to radically alter the course of destruction which humanity's actions have charted. The environmental rule of law seeks to facilitate a multi-disciplinary analysis of the nature and consequences of carbon footprints and in doing so it brings a shared understanding between science, regulatory decisions and policy perspectives in the field of environmental protection. It recognises that the "law" element in the environmental rule of law does not make the concept peculiarly the preserve of lawyers and Judges. On the contrary, it seeks to draw within the fold all stakeholders in formulating strategies to deal with current challenges posed by environmental degradation, climate change and the destruction of habitats. The environmental rule of law seeks a unified understanding of these concepts. There are significant linkages between concepts such as sustainable development, the polluter pays principle and the trust doctrine. The universe of nature is indivisible and integrated. The state of the environment in one part of the earth affects and is fundamentally affected by what occurs in another part. Every element of the environment shares a symbiotic relationship with the others. It is this inseparable bond and connect which the environmental rule of law seeks to explore and understand in order to find solutions to the pressing problems which threaten the existence of humanity. The environmental rule of law is founded on the need to understand the consequences of our

actions going beyond local, State and national boundaries. The rise in the oceans threatens not just maritime communities. The rise in temperatures, dilution of glaciers and growing desertification have consequences which go beyond the communities and creatures whose habitats are threatened. They affect the future survival of the entire ecosystem. The environmental rule of law attempts to weave an understanding of the connections in the natural environment which make the issue of survival a unified challenge which confronts human societies everywhere. It seeks to build on experiential learnings of the past to formulate principles which must become the building pillars of environmental regulation in the present and future. The environmental rule of law recognises the overlap between and seeks to amalgamate scientific learning, legal principle and policy intervention. Significantly, it brings attention to the rules, processes and norms followed by institutions which provide regulatory governance on the environment. In doing so, it fosters a regime of open, accountable and transparent decision making on concerns of the environment. It fosters the importance of participatory governance — of the value in giving a voice to those who are most affected by environmental policies and public projects. The structural design of the environmental rule of law composes of substantive, procedural and institutional elements. The tools of analysis go beyond legal concepts. The result of the framework is more than just the sum total of its parts. Together, the elements which it embodies aspire to safeguard the bounties of nature against existential threats. For it is founded on the universal recognition that the future of human existence depends on how we conserve, protect and regenerate the environment today."

This Court distilled the challenges that confront a constitutional court in using the framework of an environmental rule of law. Noting the often-intractable problem of adjudicating environmental infractions in the absence of precise, quantifiable and concrete evidence, this Court appreciated the valuable principled guidance rendered by environmental rule of law in the following words:

> "54. … The point, therefore, is simply this — the environmental rule of law calls on us, as Judges, to marshal the knowledge emerging from the record, limited though it may sometimes be, to respond in a stern and decisive fashion to violations of environmental law. We cannot be stupefied into inaction by not having access to complete details about the manner in which an environmental law violation has occurred or its full implications. Instead, the framework, acknowledging the imperfect world that we inhabit, provides a roadmap to deal with environmental law violations, an absence of clear evidence of consequences notwithstanding."
>
> (emphasis supplied)

Public Trust Doctrine:

29. At this stage, I shall refer to certain observations made by this Court in the context of preservation of environment and on public trust doctrine. According to this Court, all environment-related developmental activities should benefit more people while maintaining the environmental balance. This could be ensured only by strict adherence to sustainable development, without which the lives of the coming generations will be in jeopardy. In ***M.C. Mehta vs. Union of India, (1991) 2 SCC 353***, it was

observed that law alone also cannot help in restoring a balance in the biospheric disturbance. Nor can funds help effectively. The situation requires a clear perception and imaginative planning. It also requires sustained effort and result oriented strategic action.

30. This Court's jurisprudence on the right to a safe and healthy environment is a firewall against unscrupulous and unsustainable decision-making. It encapsulates a concomitant duty for the State, as understood in light of Articles 48 and 51A(g) of the Constitution of India. In ***Charan Lal Sahu vs. Union of India, (1990) 1 SCC 613 ("Charan Lal Sahu")*** and ***Subhash Kumar vs. State of Bihar, (1991) 1 SCC 598 ("Subhash Kumar"),*** this Court expressly observed that Article 21 includes the right of enjoyment of pollution-free water and air. ***Virender Gaur vs. State of Haryana, (1995) 2 SCC 577 ("Virender Gaur")*** expanded the scope of the right to the effect that a hygienic environment is an integral facet of the right to a healthy life. The right was so construed in terms of the State's duty under Articles 48 and 51A(g) to forge policies to maintain ecological balance by taking concrete measures to 'promote, protect and improve' the environment.

30.1 Thereafter, in ***M.C. Mehta vs. Kamal Nath, (2000) 6 SCC 213 ("Kamal Nath"),*** it was expounded that the fundamental right to life under Article 21 would take within its breadth a protection against disturbance of basic environmental elements

such as air, water and soil. This Court articulated the positive duties of the State to take all necessary measures for the protection and promotion of the environment under the EP Act, 1986 in ***Indian Council for Enviro-Legal Action vs. Union of India, (1996) 3 SCC 212 ("Enviro-Legal Action")***. It was also held that if the Central Government omits to fulfil any of its duties under the Sections 3 and 5 of the EP Act, 1986, this Court could issue appropriate directions to it to take necessary measures.

30.2 Therefore, the right to a safe and healthy environment encompasses a corresponding duty on the State to faithfully implement the environmental statutes and take all necessary measures.

30.3 The substantive concern of the right to environmental protection now also encompasses the adverse effects of climate change. This Court, speaking through Hon'ble Dr. Justice D.Y. Chandrachud in ***M.K. Ranjitsinh vs. Union of India, 2024 (4) Scale 779 : 2024 INSC 280 ("M.K. Ranjitsinh")*** has explicitly recognised that adverse environmental consequences, such as sea level rise, have a disproportionate impact on socially, geographically and economically marginalised classes of citizens.

30.4 The aforesaid elucidation of the right to a safe and healthy environment and the concept of environmental rule of law as applied in the Indian jurisprudential context reveals that the concept is one of the ways of embedding a consciousness about

adverse effects on the environment into the sub-structure of the legal framework to inform an environment-protecting legal reasoning. Therefore, environmental legislation such as the EP Act, 1986 and the 1989 Rules ought to be interpreted so as not to infringe the fundamental right to a safe and healthy environment under Article 21. Where there is a choice of statutory construction, this Court would be bound to proffer an interpretation that effectively protects the right to a safe and healthy environment.

Precautionary Principle:

31. The essence of the precautionary principle lies in the notion that 'decision makers should act in advance of scientific certainty to protect the environment.' [Source: Andrew Jordan and Timothy O' Riordan, 'The Precautionary Principle in Contemporary Environmental Politics' (1995) 4(3) Environmental Values 191, 194]. The adoption of the precautionary principle reflects a paradigm shift from the traditional reactive approach, wherein the environmental regulator responded to apparent environmental hazards. It is a significant shift even from the preventive approach that sought to prevent the environmental damage arising from risks that are bound to actualize in the foreseeable future. On the other hand, the precautionary principle seeks to avoid such future environmental damage which may arise from uncertain eventualities. In other words, the precautionary principle mandates cautiously taking

appropriate measures to identify potentially harmful activities even in the face of scientific uncertainty. Precaution, in other words, is the expression of a well-founded fear of the unknown and the unknowable environmental consequences of certain human actions. For a fear to be well-founded, it must emerge from a robust risk analysis of potentially hazardous consequences for environmental health.

32. The 1982 World Charter for Nature first articulated the idea of the precautionary principle in General Principle 11, which postulates the control of activities which might have an impact on nature and the use of the best available technologies that minimize significant risks to nature or other adverse effects. The General Principle 11 recommends a graded approach to varying levels of environmental risks and damage, while instantiating that:

i. those activities which are likely to cause irreversible damage to nature shall be avoided;
ii. those activities which cause a significant risk to nature shall only be permitted upon exhaustive examination if the proponents of such activities would demonstrate that the expected benefits outweigh the potential damage to nature; and
iii. those activities which cause a significant risk to nature but where the potential adverse effects are not fully understood should not be proceeded with;

iv. those activities which may disturb nature shall be proceeded only upon *ex-ante* assessment of their consequences through environmental impact studies and requisite planning to minimize potential adverse effects.

32.1 Thereafter, the principle was enshrined in Principle 15 of the Rio Declaration on Environment and Development 1992, which states:

> "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

32.2 It also finds expression in Article 10(6) of the CPB to the CBD, which states that:

> "6. Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question as referred to in paragraph 3 above, in order to avoid or minimize such potential adverse effects."

32.3 While Section 20 of the National Green Tribunal Act, 2010 exhorts the National Green Tribunal (NGT) to take precaution into account in passing orders, this Court's jurisprudence, as

explained below, had long recognized and deepened the precautionary principle.

33. This Court in the following cases has discussed at length the precautionary principle, which are adverted to at this stage.

(i) In ***Vellore Citizens' Welfare Forum vs. Union of India, (1996) 5 SCC 647 ("Vellore Citizens")***, this Court was seized of a Writ Petition filed by a citizens' group to seek enforcement of the provisions of the Water (Prevention and Control of Pollution) Act, 1974 against tanneries that were discharging untreated effluent into nearby lands. While directing strict enforcement of environmental law and holding the authorities accountable for their failure to exercise statutory powers, this Court expounded on the significance of the precautionary principle. It traced the origins of the precautionary principle in international law and located the same in domestic environmental law. This Court's formulation of the precautionary principle constitutes three propositions:

i. The environmental measures undertaken by the State Government and the statutory authorities must anticipate, prevent and attack the causes of environmental degradation.

ii. Where there are threats of serious and irreversible damage, lack of scientific certainty should not be used as a reason for postponing measures to

prevent environmental degradation.

iii. The reversal of the "burden of proof" to the proponent of a potentially hazardous activity which could disrupt the natural environment was critical for ecologically balanced and sustainable development.

This Court construed the precautionary principle in light of Articles 47, 48A and 51A(g) of the Constitution. Further, it was concluded that the extant legislative framework, specifically the EP Act, 1986, included the application of the precautionary principle in addition to the polluter pays principle. Consequently, this Court passed a direction to the authority to be appointed under Section 3(3) of the EP Act, 1986 to implement the 'precautionary principle.'

(ii) The precautionary principle was explained in greater detail by this Court in ***A.P. Pollution Control Board vs. Prof. M.V. Nayudu, (1999) 2 SCC 718 ("A.P. Pollution Control Board")*** from the lens of international environmental law. Here, this Court was considering whether the establishment of a hazardous industry could be countenanced within ten kilometre of reservoirs used for drinking water. This Court noted that the "assimilative capacity" rule was embedded in Principle 6 of the Stockholm Declaration of the U.N. Conference on Human Environment, 1972. This "assimilative capacity" principle was premised on the

assumption of perfect scientific predictability that would allow the internalisation of ecological risks within industrial processes. It was reasoned that the preponderance of unpredictability of adverse environmental effects led to the adoption of the 11th Principle of the U.N. General Assembly Resolution on World Charter for Nature, 1982, and the Principle 15 of the Rio Conference of 1992.

Quite axiomatically, precautionary principle changes the role and significance of scientific data in environmental disputes. Once a threat to the environment has been identified, action should be taken to abate environmental interference, even though there may be scientific uncertainty as to the effects of the activities. [Source: Lavanya Rajamani, 'The precautionary principle' in Shibani Ghosh (ed.) Indian Environmental Law (Orient Blackswan, 1994]. Certain anticipated environmental harms and available environmental data may warrant a strong and strict application, i.e., the potentially hazardous activity is banned until the proponent of the activity demonstrates that it poses no (or acceptable) risk. In such a case, the burden to prove the acceptable standard of risk shifts to the proponent of such an activity. In this context, reliance was placed upon an article authored by Charmian Barton, in Volume 22 of Harvard Environmental Law Review (1998) and inferred that the environmental decision-makers must acknowledge the inadequacy of information about environmental risks and

'err on the side of caution' to prevent serious and irreversible harm.

(iii) In ***M.C. Mehta vs. Union of India, (2004) 12 SCC 118 ("M.C. Mehta")***, this Court advanced the view that the precautionary principle enjoined the State to take affirmative action to prevent environmental harm, even when the nature and extent of such harm could not be anticipated with scientific precision and certainty. It was reasoned that when it was difficult to strike a balance between the protection of the environment and economic development due to prevailing uncertainty and lack of direct evidence of actual harm, reasonable suspicion of harm would be adequate to press the precautionary principle into service and take anticipatory action.

Analysis and Findings:

34. In light of the aforesaid observations, the PSC Report, 2012 made a range of recommendations. The MoEF&CC responded to each of the recommendations in the Action Taken Report. The pertinent recommendations and the action taken are explained in the table below:

S. No.	Recommendation	Action Taken Report
1.	Conduct a thorough probe into the Bt brinjal matter from the beginning till the imposing of moratorium	Views of Dr. Bhargava are his personal views and are not subscribed by most of the scientists. Prof. Reddy has clarified that the pressure he

S. No.	Recommendation	Action Taken Report
	on its commercialization in 09.02.2010.	adverted to was for meeting the deadline as he had been pre-occupied with his other responsibilities.
2.	Review the organisational set-up of GEAC.	GEAC comprises of both experts and bureaucrats, and takes aid of expert committees.
3.	Sought information about concrete action taken by the Government on each of the findings contained in IAASTD Report during the four years after the release of the Report.	IAASTD Report has been criticised by an independent evaluation group at the World Bank in its Global Programme Review. The Government of India recognises the importance of biosafety and sustainable agriculture and these goals remain its policy priority.
4.	Fix responsibility for the laxity in regulating and labelling GM foods, and issue regulations for labelling of GM products including food crops, food and food products	The Department of Consumer Affairs has issued a notification on the labelling of GM foods.
5.	Upon consultation with all stakeholders, immediately evolve an all-encompassing umbrella legislation on biosafety, which is focused on ensuring the biosafety,	The BRAI Bill, 2013 has been pending in Parliament. Such an Act would establish the National Biotechnology Regulatory Authority.

S. No.	Recommendation	Action Taken Report
	biodiversity, human and livestock health, environmental protection, and which specifically describes the extent to which biotechnology, including modern biotechnology, fits in the scheme of things without compromising with the safety of any of the elements mentioned above.	Administrative and other support continues to be expected to RCGM and GEAC.

35. Similarly, the PSC Report, 2017 made a range of recommendations. The MoEF&CC responded to each of the recommendations in the Action Taken Report. The pertinent recommendations and the action taken are explained in the table below:

S. No.	Recommendation	Action Taken Report
1.	The Central Government should, in consultation with the State Governments and Administrations of Union Territories, ensure that the whole process of field trials should be done in closed environment, keeping biosafety and health safety in mind and in collaboration with the agricultural universities so as to minimise	Confined-field trials are conducted as per detailed guidance documents and protocols framed for the purpose. Conduct of confined field trials is inspected by members of regulatory committees, experts, State Government and State Agricultural Universities.

S. No.	Recommendation	Action Taken Report
	the scope of fudging the primary data.	
2.	GEAC should be headed by an expert from the field of Biotechnology, given the understanding of scientific data and analysis of research and its implication, before coming to a conclusion in the matter.	GEAC comprises of both experts and representatives of respective ministries. Sub-committees are routinely engaged to render technical inputs.
3.	The MoEF&CC should review the functioning of GEAC along with the organisational set up of GEAC and take necessary corrective measures to make the whole process of assessment and approval more transparent, so as to ensure environmental safety, biodiversity safety, health safety, food and feed safety of our country.	Minutes of all the meetings of GEAC are regularly published on the website, along with all the relevant regulatory formats. Various stakeholders such as farmers and civil society have given inputs on transgenic mustard hybrid DMH-11 by way of comments on the AFES study and as part of special hearings.
4.	Members of Parliament should be nominated as members in the DLCs, so that the activities of these Committees are also shared with the public.	DLCs are only mandated to play a role in monitoring of the facilities. Inclusion of MPs would not be commensurate with the tasks of the Committee, as the Committee reports to the Deputy Collector.
5.	MoEF&CC should undertake a comprehensive study and bring clarity on the issue of	The adoption of Bt cotton has nearly doubled the yield and substantially

S. No.	Recommendation	Action Taken Report
	increase in the yield of cotton after its commercialisation in the country.	increased productivity from 308 kgs. per Ha. in 2001-2002 to 568 kgs. per Ha. in 2016-2017.
6.	MoEF&CC should obtain results of Ministry of Agriculture's scientific study about the impact of adopting Bt cotton on use of chemical herbicides and pesticides. Thereafter, the MoEF&CC should bring out a comprehensive note on usages of pesticide details state wise after the increase in area cultivated under Bt cotton.	The aforementioned data shows that Bt cotton has successfully countered the menace of American bollworm and significantly increased the yield.
7.	MoEF&CC should scientifically evaluate the impact of GM crops on sustainability, safety and competitive advantage of Indian agriculture. i. It should specifically inform the nation whether the cultivation is not going to have any negative impact on the microbes, soil and water. ii. It should specially study the impact on beneficial organisms like bees, earthworms and monarch butterflies.	Gene flow from GM crops to wild relatives poses no risk to the environment. The regulatory process has addressed each and every concern pertaining to environmental safety. Genes that make GM crops HT have very minimal quantity of Bt proteins. Studies on the impact on non-target organisms and beneficial organisms are part of the regulatory process.

S. No.	Recommendation	Action Taken Report
8.	Assessment of threats and adverse effects of GM crops in foreign countries should not be mechanically transplanted by agencies. The Government agencies conduct indigenous studies to substantiate their claim that there is no threat posed to our environment on account of GM crops. Any study that conducts impact assessment should be funded by DBT for sheer credibility.	Similar to other regulatory processes, the developer/applicant furnishes studies about safety assessment of crops. In case of DMH-11, developed by Delhi University, all studies have been funded by DBT.
9.	The hasty decision to commercialise GM crops should be reconsidered in light of lack of scientific evidence about chronic and transgenerational impact of such crops.	There is no scientific evidence to justify the need for such studies as there exists no biologically relevant difference between GM crops and their non-GM counterparts.

36. I have perused and discussed the contents of the PSC Reports, their recommendations of critical import to the regulatory framework as well as the action taken and observe on the following aspects:

I. *Thorough Probe into Bt Brinjal Approval:* Although the Report of the PSC, 2012, had recommended that the MoEF&CC should conduct a thorough probe into the concerns raised by Dr. P.M. Bhargava regarding the approval for commercialisation of Bt brinjal till the imposition of the moratorium on 09.02.2010, the Action Taken Report does

not point to the particulars of any enquiry or investigation. It appears that the justification offered by the erstwhile Co-Chairman, GEAC, Prof. Reddy, has been accepted without a fair and comprehensive investigation.

II. *Institutional Architecture of GEAC:* Although both the PSC Reports recommended reforms in the institutional architecture of GEAC, by way of having a full-time body with a leadership that is competent to conduct impartial and sound scrutiny of applications for approval under the 1989 Rules, the Action Taken Report denies the very need for such reforms. I infer that the Government is reluctant to reform the composition and criteria for appointment to GEAC. No response is forthcoming on the PSC's recommendation that the conflict of interest in the composition, caused by the presence of a nominee of DBT, should be minimised. This accentuates the concern about the lack of indigenous and independent research institutions.

III. *Labelling and Regulation of GM Foods:* The Action Taken Report does not address the question of labelling of GM foods under Section 23 of the FSSA, 2006. There is inadequate clarity about the issuance of the notification under Section 22 for regulating sale, distribution and consumption of GM food.

IV. *Legislation:* With respect to the recommendation to initiate the process of consultation to enact a comprehensive legislation on regulation of biotechnology, I note that the

Action Taken Report refers to the Biotechnology Regulatory Authority of India, 2013 ("BRAI Bill, 2013"). On 28.08.2013, this Court noted that Sri K.K. Venugopal, learned senior counsel, appearing for one of the contesting respondents had informed that the Central Government has prepared a Bill bearing Bill No.57 of 2013, which is named the BRAI Bill, 2013. However, this Bill lapsed at the end of the 15th Lok Sabha. Therefore, there is no statutory regulatory framework in the form of a Parliamentary law that is in place. The 1989 Rules govern the existing procedure which are in fact subordinate legislation, which is contented to be inadequate.

V. *Impact on Agricultural Ecosystem:* The blanket denial of adverse ecological effects by way of cross-pollination or otherwise is mostly on the basis of research conducted in foreign contexts. This may not at all be relevant in the Indian context and ecosystem. The PSC has rightly observed that the role of non-target organisms and beneficial organisms is critical to the agricultural ecosystem.

37. My understanding is that GM crops are those crops whose genomes have been modified by the insertion of usually foreign (for example, bacterial) genes through rDNA technology. Such modification serves to incorporate traits into plants that are either absent or rare in their domesticated and/or wild varieties. For instance, Bt cotton is cotton modified with a set of genes (or a gene construct) that codes for the Bt toxin. Bt toxin acts as an

insecticide against pink and American bollworms. This specific insecticidal trait is absent in wild as well as domesticated varieties of cotton.

38. According to the petitioners, two traits dominate commercialized GM crops – HT (47 percent of the acreage), and insect resistance or Bt (12 percent). Another 41 percent is under stacked traits, i.e., both HT and Bt HT crops that obviate manual weeding and one can simply spray the corresponding herbicide (glyphosate, glufosinate, and dicamba) on the entire field, and everything other than the HT crop will perish. In theory, the Bt crop reduces the applications of external insecticides. Thus, most of the GM crops commercialized globally, in particular HT and stacked crops, are tailored for the routines of capital-intensive agriculture, i.e., agriculture that relies on monoculture (rather than mixed and intercropping), purchased seeds, fossil fuels, and intensive applications of synthetic chemicals which in effect is not sustainable in the long run.

39. In my view, the controversy in these writ petitions converges upon a foundational aspect, which is, the extent of implementation of the recommendations of the TEC constituted by this Court. Only upon considering this foundational aspect can I proceed to determine the points for consideration. I cannot ignore the TEC Report as suggested by learned Attorney General, for it would result in undermining the earlier orders of this Court, which would be an improper approach in the matter.

39.1 The subject matter of this case is indeed technical, as it involves scrutinising the adoption of a technology that would enable the modification of genomes through the insertion of foreign genes. The aim of the modification is often to craft hybrid varieties that have certain desirable characteristics from the point of view of agricultural productivity, sustainability and resilience.

40. At the outset, learned Attorney General submitted that the TEC Report submitted to this Court goes beyond the terms of reference to the extent of observing that HT crops are completely unsuitable in the Indian context which is not just and proper. Dr. Paroda, also a member of TEC, has filed a separate report raising objections to the TEC report submitted by the majority of the members which could be considered by this Court.

40.1 In the backdrop of identifying the actual controversy in these matters, at the outset, the terms of reference of TEC, *inter alia,* could be revisited as follows:

(i) to review and recommend the nature of sequencing of risk assessment (environment and health safety) *vis-à-vis* all GM crops before they are released into the environment;

(ii) to recommend the point at which environmental release through open-field trials can be permitted;

(iii) to advise whether GE crops or plants could be replicated under different agro-ecological regions and different seasons as compared to greenhouse conditions;

(iv) to advise measures or safeguards required to prevent potential risks to the environment *vis-à-vis* open-field trials and to recommend protocols necessary to preclude any escaped material from causing an adverse effect on the environment;

(v) to advise whether in India, there are state-of-the-art testing facilities and professional expertise available to conduct various biosafety tests and if not, recommend setting up an independent testing laboratory and institutions.

40.2 An interim report, and thereafter, a final report were submitted by the TEC. As already noted, the final report was in two parts: the first part of the report was by a majority of five members of the TEC and a separate note was submitted by Dr. R.S. Paroda. Since the views of the majority and the separate note have been recorded hereinabove, I would only discuss whether the TEC did indeed breach the terms of reference.

40.3 A perusal of the terms of the reference reveals an emphasis on four aspects: sequencing; scientific tenability; adequacy of regulatory conditions and availability of technological facilities. The direction of this Court regarding the interim report was specifically to seek recommendations on the desirability of a partial or complete ban on open-field tests and what biosafety protocol ought to be followed and under what conditions.

40.4 It is clear that the terms of reference relate to this Court's concern about the regulatory conditions for the release of GMO

crops and the existence, or otherwise, of any gaps in the same. It is discernable that the final recommendations responded to these queries regarding the adequacy of regulatory conditions, biosafety protocols and available technological framework, by recommending various measures to fill the gaps that existed in the regulatory regime at a general level. The first gap, as I understand is that of technical expertise. The TEC *inter alia*, recommended as under:

(i) Constitution of sub-committees with domain expertise in the fields of health, environment, agro-economics and socioeconomics, molecular biology, etc. which could replace the single committee structure devised by the 1989 Rules.

(ii) Another recommendation pointed to the elimination of conflict of interest, earmarking of specific sites for field trials and stakeholder participation.

(iii) It also stated that there is a need to develop consultation, collaboration and capacity building, and that the Indian regulatory system must develop the ability to assess as to how any GM product is likely to impact different sections of the society.

Therefore, having regard to the discussion made by it, I find that the TEC did not breach its Terms of Reference.

41. The petitioners herein have sought for implementation of the aforesaid recommendations of the majority by contending that the question of the consequences of transgenic mustard

hybrid DMH-11 being an HT crop remains unanswered. This is because the Union of India, in its additional affidavit dated 09.11.2022, has acknowledged that transgenic mustard hybrid DMH-11 possesses HT characteristics. Yet, the Union of India asserts that it cannot be officially labelled as such and therefore, it should not be referred to as HT corp. That transgenic mustard hybrid DMH-11 has never been tested as a HT crop because India does not have any regulatory guidelines and protocols for testing of HT crops, is the contention of the petitioners.

41.1 The petitioners have further countered the stand of the Union of India by submitting as under:

(i) "… that the presence of third HT gene (*Bar*) is essential for hybrid seed production", according to the Union of India. The presence of HT gene (*Bar*) makes DMH-11 an HT crop. This is also the finding of the PSC Reports which have stated that transgenic mustard hybrid DMH-11 is a HT crop. There is clear evidence on the adverse impacts of environmental release of DMH-11, which is a HT crop in various writings which have been ignored by GEAC;

(ii) that the Union of India is silent as to the measures undertaken to ensure non-contamination, in case environmental release of GMOs is permitted, as irreversible risk of contamination on human health is enormous;

(iii) that the Union of India is also silent on the liability of the applicant for potential losses to farmers and consumers on account of irreversible contamination;

(iv) that glufosinate is banned for all other uses except for tea plantations and is specifically banned for use on DMH-11 by farmers. This is because of the acute toxicity and health concerns. That, long term studies would show the adverse effects of glufosinate which may not show up in short term studies. Hence, it is necessary to have adequate studies on the use of glufosinate on plants;

(v) that GEAC has failed to deal with illegal plantation of Bt cotton and the same is being grown in the country illegally on commercial basis. That organisations such as Shetkari Sangathan have been encouraging farmers to do illegal planting of Bt brinjal, which GEAC as a regulator has failed to check;

(vi) that there is a failure to undertake any socio-economic risk analysis by GEAC with regard to the failure of Bt cotton in accordance with the CBD and the CPB. The need for such an assessment was also highlighted by TEC in its report. Such an assessment was required because farmers across the country have been financially burdened due to the increasing prices of Bt cotton seeds and they have to spend on pesticides and other resources to make the crops more pest-resistant and high-yielding. This has resulted in

escalated expenses and has reduced the margin of profit for the farmers;

(vii) that the pink bollworm, a major pest to the cotton crop, has developed resistance in last few years which has worried the farmers who have sown Bt cotton seeds. Therefore, cotton yields were stagnant in the last five years due to the fact that the technology was used for yield improvement but not for loss prevention;

(viii) that large quantities of GM processed oil is being imported in the form of canola oil and soyabean oil, which is in violation of the constitutional and legal rights of the citizens under Articles 21 and 14 of the Constitution. That GEAC, in their communication dated 23.02.2018 addressed to the DGFT, had informed that it had not authorised or approved GM soyabean or any other product derived from GM soyabean seeds for import or cultivation in India. If that is so, as to how, subsequently, GM food is being imported to India is not known;

(ix) that the Union of India is silent about the measures undertaken in respect of labelling of GM foods, as there are no studies which have been commissioned as regards the consumption of GM foods.

41.2 The petitioners have contended that there is a need for formulation of a national policy of GM crops for the following reasons:

(i) that apart from South Western China, North Western Himalayas constitute an important centre where there is enormous diversity in *Brassica Juncea* forms. Therefore, there are two geographical races of *Brassica Juncea*, the Chinese pool and the Indian pool. The share of holding by the Chinese pool is 17 per cent and by the Indian pool is 15 per cent;

(ii) that the growth of GM crops in India would impact organic food producers having regard to the difficulties in segregation of GM and non-GM foods. This would have an adverse effect on export of organic food as importers would closely examine the conditions under which organic food is being grown and any concerns about contamination could lead to an adverse impact and loss of markets for organic food producers;

(iii) that India is a signatory to the CPB, therefore, a duty is cast on the Government to assess the impact of its policies and minimize adverse impacts of the same *vide* Article 26 thereof.

(iv) that the 1989 Rules were framed prior to the coming into force of the CPB but there is a distinct inconsistency between the same and therefore, the 1989 Rules should be amended in line with the said protocol, otherwise, international law could be applied as part of the national law, unless it is in conflict with any Act of Parliament.

(v) In sum and substance, it was contended that there is a need for putting in place a suitable policy and an effective

regulatory mechanism which would work within the framework of its mandate.

41.3 *Per contra*, the Union of India urged this Court to not intervene in the matter as the questions involved are highly technical and polycentric in character. This proposition is indeed attractive at a first blush, for it invites the Court to trust the process of the grant of approval for the environmental release of GMOs under the applicable legal regime. But, it is settled law that expert opinion is not beyond the pale of judicial review, especially when there are serious infirmities in the decision-making process, *vide* ***Institute of Chartered Financial Analysts of India vs. Council of The Institute of Chartered Accountants of India, (2007) 12 SCC 210 ("Institute of Chartered Financial Analysts of India")***.

41.4 In the above backdrop, the points for consideration shall be answered.

Re: Point No.1: Whether GEAC approval dated 18.10.2022 and the consequent decision dated 25.10.2022 for the environmental release of DMH-11 is in accordance with law?

42. I have adverted to in detail several meetings of GEAC held with regard to the application submitted by the applicant, namely, CGMCP, University of Delhi (South Campus) on 15.09.2015 seeking approval for environmental release of the GE mustard hybrid DMH-11. This was after conclusion of the closed or confined trials and was accompanied with a dossier of 3285

pages compiling the results of the food and environmental safety studies that were carried out at the time of the confined trials for the environmental release of transgenic mustard hybrid DMH-11, parental lines bn 3.6 and modbs 2.99 containing *barnase*, *barstar* and *bar* genes. In the 125th meeting held on 11.12.2015, GEAC requested the applicant to give a presentation and thereafter on 04.01.2016, a sub-committee was constituted for examination of the dossier.

42.1 The sub-committee held two meetings. After the first meeting, it recommended revision of the biosafety dossier by incorporating additional information regarding certain lacunae or gaps which it had identified and were also identified by the BSU. GEAC decided that if the biosafety dossier is found to be complete in all respects, then the same excluding confidential information, could be put in the public domain for comments. After the first sub-committee meeting, several submissions and recommendations were made which are detailed above. Thereafter, the second sub-committee meeting was held and the sub-committee sought time to analyse and review the revised dossier and results obtained in 129th GEAC meeting held on 20.06.2016. The sub-committee suggested that the AFES report, prepared upon evaluation of biosafety data, be placed on the MoEF&CC website for thirty days to invite comments from stakeholders and the dossier also be made available in GEAC Secretariat for any person interested in studying the same. A

total of 759 comments were received between 05.09.2016 and 05.10.2016 and 29 persons personally inspected the dossier at the premises of the MoEF&CC and provided their comments. However, the dossier was not put up on the website of GEAC. This is in fact a violation of the order of this Court dated 08.04.2008 in respect of which contempt petition has been filed.

42.2 On 07.10.2016, this Court recorded the submission of the Union of India that no release of GMOs shall take place till 17.10.2016 because the Government had sought views from the public and upon receipt of such views and objections, the matter was to be considered by a Committee of experts, which process could not be completed by 17.10.2016. However on 11.05.2017, GEAC, in its 133rd Meeting, made the recommendation for the commercial release of DMH-11. However, on 31.07.2017, this Court recorded the submission of the Union of India that the Government has not yet taken a final decision, whether or not to permit the plantation of transgenic mustard hybrid DMH-11, and a final decision with reference to the approval would be taken by the Government in September, 2017. It was also pointed out that the plantation is likely to commence in October 2017. At a subsequent hearing on 22.11.2017, this Court recorded the Union of India's submission that the Government of India had not yet taken a decision in the matter and that all the representations of the stakeholders would be considered before taking the final decision.

42.3 Thereafter, in its 136th Meeting on 20.09.2018, GEAC re-examined the matter in light of the representations received and on a detailed discussion, agreed that the applicant may be advised to undertake field demonstration on transgenic mustard hybrid DMH-11 in an area of five acres at two to three different locations with a view to generate additional data on honeybees and other pollinators and on soil microbial diversity. Thereafter, in the 137th GEAC meeting held on 20.03.2019, there was a deferment of field demonstration studies on transgenic mustard during the year 2018-19 and it was extended for the seasons 2019-20 and 2020-21. Thus, it is significant to note that GEAC itself had deferred field demonstration studies on transgenic mustard and this was in supersession of the earlier decision taken on 20.09.2018 in the 136th meeting of GEAC wherein the applicant was advised to undertake field demonstration in an area of five acres at two to three different locations. Therefore, till the year 2020-2021, the stage of field demonstration within an area of five acres at two or three different locations had not yet been cleared by GEAC with regard to transgenic mustard hybrid DMH-11.

42.4 When the matter stood thus, Prof. Deepak Pental, on behalf of CGMCP, Delhi University (South Campus), the applicant, *vide* his letter dated 10.05.2022, wrote directly to the Hon'ble Minister for Environment, Forest and Climate Change seeking acceptance of the recommendations for environmental release of transgenic

mustard hybrid DMH-11 made in the 133rd GEAC meeting. The aforesaid letter is extracted as under:

"CENTRE FOR GENETIC MANIPULATION OF CROP PLANT (CGMCP)
UNIVERSITY OF DELHI SOUTH CAMPUS
BENTO JUAREZ ROAD, NEW DELHI-110021, INDIA

Phone : 91-11-24112609, 24116392 Fax: 91-11-24116392

Shri Bhupender Yadav May 10, 2022
Hon'ble Minister
Minister of Environment, Forest & Climate Change (MoEFCC)
Indira Paryavaran Bhawan
Aliganj Road, Jorbagh
New Delhi – 110 003

Subject: Request for environmental release of GE mustard

Respected Minister,

I am writing to you on the environmental release of the Genetic Engineering-based technology for hybrid seed production in mustard, a major oilseed crop of our country. Some recent positive, as well as negative developments, have induced me to write to you on the matter which is pending with MoEFCC.

The positive development is the Union Governments' decision to put SDN-1 and SDN-2 types of gene edited crops out of the biosafety regimes stipulated for the Generally Engineered (GE) crops. This is indeed a major step forward. Barring the EU, most of the development countries have already reduced biosafety requirements for genome-edited crops. The negative development is continuing stagnation of the edible oil sector in India. While the demand for edible oils is increasing globally, the

supplies are under stress leading to a spurt in the prices of edible oils in the international markets. As our country imports more than fifty per cent of its edible oil requirement there is an urgency to increase our domestic production.

Our group at the Centre for Genetic Manipulation of Crop Plants (CGMCP), University of Delhi South Campus has been working on increasing the yield of mustard for the past 30 years. A report on the research work being caried out at the Centre is being attached with this letter. The most appropriate technology for yield increase in mustard is hybrid breeding for which a robust hybrid seed production system is foundational; our GE-based hybrid seed production system meets the need. I believe the time has come for MoEFCC to permit environmental release of the GE technology for hybrid seed production to increase edible oil production in the country.

To brief you on the past developments, the biosafety studies on the transgenic parental lines Varuna bn 3.6 and EH2 modbs 2.99 and the first generation hybrid DMH-11 were initiated in the year 2010. All the stipulated biosafety studies including field testing under isolation were carried out and a 3251-page dossier was submitted to GEAC on September 15, 2015. The biosafety studies were supported by public funding of around Rs.8 crores. The GEAC in its 133rd meeting held on May 11, 2017, recommended the environmental release of the parental lines and the first generation hybrid DMH-11 and permitted the development of a new generation of hybrids. Unfortunately, a few days later the MoEFCC website displayed the Ministry's decision – 'matters related to environmental release of Mustard transgenic are kept pending for further review'. Later in communication from GEAC, some additional experiments on honey bees were sought but no efforts were made to facilitate the execution of those experiments. We pointed out to GEAC that such tests were not required.

The technology we have used for hybrid seed production in mustard was first deployed in rapeseed, a sister crop of mustard – in 1996 in Canada, in 2002 in the USA, and in 2003 in Australia. Rapeseed hybrids developed using the GE technologies are currently being cultivated in Canada on almost 9-10 million hectares. No untoward effect of GE rapeseed has been reported either from Canada or from USA and Australia. Canada is a big exporter of rapeseed oil and meal to all parts of the world as well as honey. There is no record of any harm to apiculture in Canada or from any other country that has released the GE hybrid seed production system.

The point I want to make for your kind consideration is that the GE technology for hybrid seed production developed by us for mustard is well tested, has been used for more than 20 years in rapeseed, and over and above – we have carried out all the necessary biosafety tests on the transgenic mustard lines.

I request that the MoEFCC may accept the recommendations of the 133rd meeting of GEAC recommending the environmental release of the GE-based technology for hybrid seed production in mustard. If required, GEAC could meet again. We would be very happy to interact with GEAC to resolve any lingering doubts or questions.

I would be most grateful for your kind help in resolving the issue of the environmental release of GE-based hybrid seed production technology.

With kind regards,

Yours sincerely,

Deepak Pental
SERB-National Science Chair
Former Professor of Genetics and Vice-Chancellor, University of Delhi
Cc: Chairman, GEAC"

On receiving the said communication, immediately comments were sought from the DBT, DARE and ICAR. On 25.08.2022, the applicant once again made a presentation of the proposal for environmental release of DMH-11 to GEAC at its 146th meeting. At that meeting, GEAC once again constituted another Expert Committee to examine the request letter dated 10.05.2022 with respect to availability of adequate evidence about impact of transgenic mustard on honeybees and other pollinators in order to assess the need for conducting field demonstration studies on honeybees and other pollinators. The reason for constitution of another Expert Committee is not known or forthcoming. This Expert Committee, headed by Dr. Sanjay Kumar Mishra, Scientist H, DBT, Government of India and Co-Chairman, GEAC, held two meetings in September, 2022 and it outrightly recommended environmental release of transgenic mustard hybrid DMH-11. Also, further evaluation was to be carried out as per ICAR guidelines. Thus, the Expert Committee took a dramatically opposite view as compared to GEAC with regard to the field demonstration studies on the effect of GE mustard on honeybees and other pollinators. In the 136th GEAC meeting, it was recommended by GEAC that the same be conducted prior to the environmental release. This Expert Committee, on the other hand, suggested that within two years, ***post-environmental release*** under the supervision of ICAR, the effect of GE mustard on honeybees and other pollinators may be

studied and a report be submitted to GEAC. For immediate reference, the relevant extracts of the Expert Committee recommendation is extracted as under:

> "The Expert Committee had deliberations and in-depth consideration of the scientific evidences, including data available on GM Canola cultivation & honey production in other countries and correlated all the concerned issues of contemporary relevance under Indian scenario. Additionally, inputs on the above issues from Members of the Expert Committee, Department of Biotechnology (DBT), Ministry of Science and Technology; and Department of Agriculture Research & Education (DARE), Ministry of Agriculture and Farmers Welfare were also considered and deliberated. The DBT opined that "it seems likely that there were no major deviations in the behaviour of honey bees when compared among the transgenic and non-transgenic comparator lines. GEAC may consider its recommendations of the 133rd meeting on the environmental release of GE mustard". The DARE opined that "GEAC may consider exempting additional studies on the impact of GM mustard hybrid DMH-11 containing the bar, barnase, and barstar genes on honey bees and honey as decided in its 136th meeting and the recommendation of the 133rd meeting of GEAC may be considered".
>
> Based on the examination of scientific evidences available globally, and as per the recommendations of concerned ministries, it seems unlikely that the bar, barnase, and barstar system will pose an adverse impact on honey bees and other pollinators. Therefore, the Committee was of the view that GEAC may consider the environmental release of GE mustard and further evaluation to be carried out as per ICAR guidelines for release and notification.

> However, to generate scientific evidences in Indian agro-climatic situation and also as a precautionary mechanism, the Expert Committee suggests that the field demonstration studies with respect to the effect of GE mustard on honey bees and other pollinators, as recommended in the 136th GEAC meeting, may also be conducted post-environmental release, simultaneously by the applicant, within two years under supervision of ICAR and the report be submitted to the GEAC."
>
> (underlining by me)

42.5 Further, on 18.10.2022, when the 147th Meeting of the GEAC was convened, as many as seven members communicated their inability to attend the meeting and Dr. Geeta Jotwani, Scientist 'G' at Indian Council of Medica Research (ICMR) did not attend the meeting. Consequently, eight persons remained absent and only fourteen members participated i.e. almost one-third of the GEAC did not attend the crucial meeting, the GEAC took into consideration only the recommendations of the Expert Committee constituted few weeks before which had given its recommendations on 08.10.2022 and noting the same, the recommendations were accepted by pursuing the comments received from DBT and DARE. The above is evident on perusal of the Minutes of the 147th Meeting of the GEAC held on 18.10.2022 as well as the Agenda Item No.4 which concerns the application relating to environmental release made by the applicant. Thus, GEAC simply recommended the environmental release of transgenic mustard hybrid DMH-11 without any deliberation as such, which recommendation was accepted by the Central Government. As a result, the following consequences are noted:

(i) all the previous deliberations and decisions of GEAC as well as the recommendations and suggestions of the sub-committee to GEAC were given a go by and totally ignored.

(ii) the deferring of the field demonstration between the years 2018 to 2021, which was for valid reasons, was also ignored.

(iii) on 25.10.2022, no reason was assigned for the change in stance, insofar as conducting studies on the effect of GE mustard on honeybees and other pollinators post-environmental release. This was contrary to what was decided earlier by GEAC.

(iv) thus, on the basis of the opinion of this Expert Committee, GEAC brushed aside its earlier decision taken in the 134th and 136th meetings to undertake field demonstration and restrict the area to only five acres at two to three different locations with a view to generate additional data on honeybees and other pollinators, and on soil microbial diversity, which decision was also put on hold by GEAC.

42.6 There is no reason forthcoming as to why GEAC completely changed its stance in the 147th meeting held on 18.10.2022. This resulted in the decision of the Union Government on 25.10.2022 impugned herein. However, it is apparent that the trigger for this volte-face in the stand of GEAC was the letter dated 10.05.2022

written by Prof. Deepak Pental to the Hon'ble Union Minister for Environment, Forest and Climate Change. There is no material put forth for the sudden decision taken by the Union Government on receiving the changed recommendation of GEAC, when earlier, it was submitted before this Court that the Union Government was still deliberating on the matter, which aspect is evident from the orders passed by this Court when in fact field demonstration was also put on hold by GEAC. Such being the position from the year 2018 onwards, all of a sudden environmental release of DMH-11 was approved even in the absence of field trials for conducting studies on the impact of honeybees and other pollinators.

42.7 I observe that a statutory functionary entrusted or authorised to carry out certain functions contemplated under a statute must do so in accordance with law and known procedure. Where a statutory authority exercises its jurisdiction, conferred on it by a statute or rules made thereunder, it has to apply its own mind and the procedures laid, therefore, must be scrupulously followed. (*vide* ***V.K. Ashokan vs. Assistant Excise Commissioner, (2009) 14 SCC 85 (paras 52 and 54).*** Every statutory authority is also bound by the rule of reasonableness and fairness and its action must be free from arbitrariness.

42.8 Moreover, when an authority changes its policy decision, it is expected to give valid reasons and act in the larger interest of the entire community. The persons representing a public body

are expected to discharge their functions faithfully and in keeping with the trust reposed in them. A statutory body, when it acts in terms of a statute, is bound by its action. It cannot supplement or supplant the reasons later on by way of an affidavit. It is well settled that while a power is exercised by an authority, ordinarily the reasons contained in the order should be supported by the material on record. It is absolutely essential that the authority making the order is alive to the material on the basis of which it purports to take the decision. It cannot act mechanically or under an impulse, but after due and proper application of mind. A statutory authority exercising its power does so in trust, only to be exercised for a legitimate purpose and along the settled principles of administrative law. Application of mind is best demonstrated by disclosure of mind by the authority making the order and said disclosure is best done through recording the reasons that led the authority to pass the order in question. Absence of reasons either in the order passed by the authority or in the record contemporaneously maintained, is clearly suggestive of the order being arbitrary, hence legally unsustainable.

42.9 The authority cannot neglect to do that which the law mandates and requires doing. It is necessary that an executive or administrative function should be exercised with clarity, so as to enable legal certainty in the decision-making process bearing in mind the requisites for a valid exercise of power.

Public Trust Doctrine:

42.10 The aforementioned curious lapses of procedure and propriety are especially acute because they are in the teeth of the public trust doctrine applicable in the instant case, which holds immense significance when a decision impacting environmental and ecological vitality is impugned. The public trust doctrine enjoins upon the Government to protect the natural resources as well as the environment for the enjoyment of the general public rather than to permit their use for private ownership or commercial purposes. In ***M.C. Mehta vs. Kamal Nath, 1996 (9) Scale 141,*** this Court has observed that there is no reason why the public trust doctrine should not be expanded to include all ecosystems operating in our natural resources. The State is the trustee of all natural resources and the public at large is the beneficiary of the same. The State is, therefore, under a legal duty to protect the natural resources. Similarly, in ***Lal Bahadur vs. State of U.P., (2018) 15 SCC 407 ("Lal Bahadur"),*** this Court held that the Government has a duty to protect the environment and the Courts also must bear in mind that in cases concerning environmental governance, it has to discharge its duties by assessing the case on the basis of the material placed before it. This is because matters concerning environmental governance concern not just the living, but also generations to come, which is the basis of the doctrine of inter-generational equity.

42.11 Similarly, in ***Centre for Public Interest Litigation vs. Union of India, (2012) 3 SCC 1 ("Centre for Public Interest Litigation"),*** it was observed that the doctrine of equality which emerges from the concept of justice and fairness, must guide the State in determining the actual mechanism for distribution of natural resources. This Court has further observed that every holder of public office by virtue of which he acts on behalf of the State or public body is ultimately accountable to the people in whom the sovereignty vests. As such, all powers so vested in a public officer are meant to be exercised for public good and promoting the public interest. Every holder of a public office is therefore a trustee. If a decision is taken without any principle or without any rule, it is unpredictable and such a decision is an antithesis to the decision taken in accordance with the rule of law. This Court had further observed that the public trust doctrine is a part of the law of the land and it has grown from Article 21 of the Constitution of India. This implies that the power vested by the State in a public authority should be used as a trust coupled with duty to be exercised in larger public and social interest. Power is to be exercised strictly adhering to the statutory provisions and fact situation of a case.

42.12 It is observed that in the instant case, while the Union of India made a submission before this Court that no final decision had been taken by it regarding the environmental release of transgenic mustard hybrid DMH-11, yet, pursuant to

the letter written on behalf of the applicant to the Hon'ble Minister for Environment, the matter moved swiftly possibly "from the top" and GEAC responded by constituting another Expert Committee which gave its recommendation to GEAC as desired.

42.13 Furthermore, while granting permission of the environmental release of transgenic mustard hybrid DMH-11, the condition imposed was that usage of any formulation or herbicide would not be permitted for cultivation in the farmer's field and any such use in the farmer's field without due approval would attract appropriate legal action under various enactments. There is no indication as to how the use of any herbicide could be prevented, rather, the condition not to use any herbicide was open-ended without having any means to check whether any herbicide would be used in the farmer's field pursuant to the environmental release. The adverse effects of use of herbicide were also totally given a go by.

42.14 I also note that on granting permission for the environmental release of transgenic mustard hybrid DMH-11, there was no procedure envisaged for any study or research on the impact on non-target organisms and soil microbes to be conducted ***prior to*** the commercial cultivation of transgenic mustard hybrid DMH-11. I find that it was necessary to have requisite studies and research carried out on the experimental environmental release of transgenic mustard hybrid DMH-11,

not only prior to the environmental release but, if permitted, subsequently before commercial cultivation of the said crop. I find this to be a serious lacuna under Rule 13(2) of the 1989 Rules.

42.15 Further, any evidence of harmful effects or damage to the environment, nature and health owing to non-compliance of conditions stipulated by GEAC was also left open-ended. While recommending environmental release of transgenic mustard hybrid DMH-11 parental lines bn 3.6 carrying *barnase* and *bar* genes, and modbs 2.99 containing *barstar* and *bar* genes, it is not clear whether the conditions imposed by GEAC were adequate and sufficient and in the interest of environment, particularly in light of the sub-committee's recommendations to GEAC as the same were to be acted upon as the matter was seized by this Court and was being monitored.

42.16 Moreover, I find that GEAC's proposal was simply accepted by the MoEF&CC and immediately notified without any further consideration at the level of the Ministry and without having any inter-departmental consultation with the Ministry of Health, MoA and DBT in the Ministry of Science and Technology. It appears that GEAC recommended what MoEF&CC wanted pursuant to Prof. Pental's letter to the Hon'ble Minister himself in May, 2022.

42.17 Also, no consultation was held with the States wherein mustard is grown, although agriculture is a State subject under

Entry 14 of List II of the Constitution. The other concerned stakeholders also ought to have been consulted before a decision was taken by the Union of India in terms of the recommendation of GEAC. The Union of India could not have unilaterally acted on such a serious matter without bringing to the notice of the States, particularly in the northern and northwestern States of the country where mustard is being grown. I also record that the States of Bihar, Kerala, Madhya Pradesh, Haryana, Tamil Nadu, Delhi, Andhra Pradesh, Rajasthan, Odisha, West Bengal and Karnataka had earlier expressed reservations against field testing and release of transgenic mustard hybrid DMH-11. In my view, the States cannot be treated as satellites of the Union of India as they have constitutional identity and powers and responsibilities conferred under the Constitution of India and therefore, their views in the matter are of significance, *vide* ***S.R. Bommai vs. Union of India, (1994) 3 SCC 1, Para 99 ("S.R. Bommai"),*** reiterated in ***State (NCT of Delhi) vs. Union of India, (2018) 8 SCC 501.*** The consideration of the views of the pertinent States by a regional or national consultation would have made the decision-making process wholesome, as a wider consultation in matters such as the one under consideration would make the decision to be taken less vulnerable to attack and less arbitrary. But the impugned decision of the Union of India, based on a flawed procedure adopted by GEAC at the instance of the applicant, is arbitrary and liable to be interfered with by this Court when it is justified. In these circumstances,

the decision of the respondent-Union of India dated 25.10.2022, as well as the recommendation of GEAC dated 18.10.2022, are liable to be set aside.

42.18 Further, no material has been brought before us to point out as to how the decision of GEAC was accepted by MoEF&CC and the recommendation of the environmental release of transgenic mustard hybrid DMH-11 was simply permitted. As discussed hereinabove, the grant of approval by GEAC is governed by Rule13. The said Rule does not contemplate any role for the Ministry of Environment, Forest and Climate Change (MoEF&CC) in the decision-making process. Therefore, the lateral intervention by the said Ministry seriously undermines the credibility and integrity of the decision making as well as the regulatory process. Although the applicant is not a private entity but a Centre in Delhi University (South Campus), the status of the applicant would not matter in arriving at a decision as in the instant case.

42.19 I observe that the principle of public accountability and transparency in State action are applicable to the cases of execution or statutory exercise of power. Every officer in the hierarchy of the State by virtue of his being a public officer/servant is accountable for his decisions to the public as well as to the State. The concept of dual responsibility should be applied in larger public interest and proper governance. In other words, where a power is given to do a certain thing in a certain

way, the thing must be done in that way or not at all and other methods of performance are necessarily forbidden. This principle has also been expressed in terms of the Latin maxim *expressio unius est exclusio alterius*, which means that when a manner is specified for doing a certain thing, then all other modes for carrying out such act are expressly excluded. *Vide*, ***Taylor vs. Taylor, (1875) LR 1 Ch D 426 ("Taylor")*** and ***Nazir Ahmad vs. King-Emperor, 1936 SCC OnLine PC 41 : (1935-36) 63 IA 372 ("Nazir Ahmad")***. This Court too has applied this maxim in the following cases:

(i) ***Parbhani Transport Cooperative Society Ltd. vs. Regional Transport Authority Aurangabad, (1960) 3 SCR 177 : AIR 1960 SC 801 ("Parbhani Transport Coop. Society")***, wherein it was observed that the rule provides that an expressly laid down mode of doing something necessarily implies a prohibition of doing it in any other way.

(ii) In ***Dipak Babaria vs. State of Gujarat, (2014) 3 SCC 502 ("Dipak Babaria")***, this Court set aside the sale of agricultural land on the ground that the sale was not in compliance with the statutory procedure prescribed in that regard under the Bombay Tenancy and Agricultural Lands (Vidarbha Region and Kutch area) Act, 1958. The matter was examined on the anvil of the aforestated maxim and

it was held that alienation of agricultural land by adopting any alternate procedure to the one prescribed under the Act was necessarily forbidden.

(iii) In ***Kameng Dolo vs. Atum Welly, (2017) 7 SCC 512 ("Kameng Dolo")***, election of an unopposed candidate was declared as invalid on the ground that the nomination of his opponent was not withdrawn as per the procedure statutorily mandated. It was held that the nomination of the opposite candidate ought to have been withdrawn in the manner provided for under the relevant statute and withdrawing the same in any other manner was necessarily forbidden. Hence, his election was declared as void.

(iv) Similarly, in ***Tahsildar, Taluk Office, Thanjore vs. G. Thambidurai, (2017) 12 SCC 642 ("Tahsildar")***, the assignment of land was cancelled on the ground that statutory requirements were not followed in assigning the land. It was held that when a statute prescribes that a certain Act is to be carried out in a given manner, the said Act could not be carried out through any mode other than the one statutorily prescribed.

(v) It may also be apposite to refer to the decision of this Court in ***Union of India vs. Charanjit S. Gill, (2000) 5 SCC 742 ("Charanjit S. Gill")***, wherein

this Court held that any provisions introduced by way of "Notes" appended to the sections of the Army Act, 1950, could not be read as a part of the Act and therefore such "Notes" could not take away any right vested under the said Act. It was observed that issuance of an administrative order or a "Note" pertaining to a special type of weapon to bring it within the ambit of the Army Act, which was hitherto not included therein, could not be said to have been included in the manner in which it was supposed to be included. It was noted that the Army Act empowers the Central Government to make rules and regulations for carrying into effect the provisions of the Act; however, no power was conferred upon the Central Government of issuing "Notes" or "issuing orders" which could have the effect of the Rules made under the Act. As Rules and Regulations or administrative instructions can neither be supplemented nor substituted by "Notes", administrative instructions issued or the "Notes" attached to the Rules which are not referable to any statutory authority were not be permitted to bring about a result, which is supposed to be achieved through enactment of Rules.

42.20 What emerges from the above discussion is that when a statute contemplates a specific procedure to be adhered to in order to arrive at a desired end, such procedure cannot be substituted by an alternative procedure which is not contemplated under the statute. Further, if an action is to be carried out by way of issuance of a particular statutory instrument on the basis of certain requirements, such action cannot be validly carried out by way of issuance of an instrument when the same is not contemplated under the statute.

42.21 It is also noted that at the crucial 147th meeting of GEAC held on 18.10.2022, there was no representative of the ICMR, Ministry of Health. Hence, the matter was not considered from the paradigm of the adverse effect on the health of human beings and animals as well as on other plants in the event of environmental release. Dr. Geeta Jotwani, Scientist F, ICMR, who did not participate in the meeting of GEAC held on 18.10.2022, simply sent an e-mail to the effect that she had concurred with the recommendation of GEAC even in the absence of knowledge about the deliberations of the GEAC.

42.22 In this regard, I also find that the recommendations of the TEC submitted to this Court have been completely ignored by GEAC, as another Expert Committee was constituted by it pursuant to the letter dated 10.05.2022 submitted by Prof. Pental to the Hon'ble Minister for Environment, Forest and Climate Change. It is also not known whether the TEC report was

placed before GEAC as well as the Expert Committee or that they had ever been apprised of the same. I observe that Prof. Pental's letter dated 10.05.2022 to the Hon'ble Minister of Environment, Forest and Climate Change is a classic case of seeking a lateral intervention by the Minister of the Union of India, bypassing what had been decided by GEAC in its 137th meeting held on 20.03.2019. It is clear that pursuant to the intervention of the Ministry, GEAC constituted another Expert Committee and simply accepted its recommendations for the environmental release of DMH-11 hybrid mustard. This was by ignoring all previous deliberation made by GEAC, its sub-committee constituted earlier and its decision to proceed with precaution.

43. Having regard to the aforesaid discussion, I am of the view that the GEAC approval dated 18.10.2022 and the consequent decision dated 25.10.2022 regarding the environmental release of transgenic mustard hybrid DMH-11 is vitiated. I also find that the impugned approval was in gross violation of the principle of public trust.

Re: Point No.2: Whether the decision to grant approval for environmental release of DMH-11 violates the right to safe and healthy environment under Article 21?

Right to safe and healthy Environment:

43.1 I next consider whether the right to safe and healthy environment would be violated by unanticipated adverse effects of the impugned approval for environmental release of DMH-11.

While I am cognizant of the submission of the learned Attorney General that the Court cannot go into the nuances of science and technology and give a finding on their merits, at the same time, I do not find substance in his argument that the petitioners' apprehensions are only a baseless hypothesis. In the instant case, the complexity of reasonable risk assessment in the context of preserving the right to a safe and healthy environment can be understood with reference to some comparative perspectives.

(i) The judgment of the Supreme Court of the Netherlands in ***State of the Netherlands (Ministry of Economic Affairs and Climate Policy) vs. Stichting Urgenda, 19/00135*** dated 20.12.2019 is apposite to appreciate the scope of judicial review, when the State, as in the present case, argued that the decision to fulfil obligations under environmental law is within the policy domain and cannot be interfered with by courts of law. The controversy raised by the State of the Netherlands before the Netherland's Supreme Court was that the Hague District Court ought not to have directed the State to limit the combined volume of Dutch annual greenhouse gas emissions in such a manner that they have reduced by at least 25% at the end of 2020 compared to the level of the year 1990. The Netherland's Supreme Court dismissed the State's challenge by applying the precautionary principle. The Netherland's Supreme Court took note of the real risks of dangerous climate change which necessitate more stringent measures. It reasoned that

mere lack of complete scientific certainty about the efficacy of the ordered reduction scenario does not exempt the State from its duty to undertake sufficient measures. Also, in the absence of certainty, a high degree of plausibility of the efficacy of the more stringent pathway was sufficient. The Netherland's Supreme Court held that the obligation to take measures exists if there is a risk that serious environmental contamination may affect people's well-being and prevent them from enjoying their homes in such a way as to affect their private and family life adversely. The Netherland's Supreme Court specifically repelled the argument that in the system of the separation of powers, courts should not interfere with the democratically legitimised Government's attendant policy choices. It proffered the reason that in the given context, the State's violation of the right to life and right to respect for private and family life necessitated judicial direction for remedial measures.

Therefore, disputes seeking review of administrative decisions impacting the environment turn on the relative weight that a decision maker accorded to competing considerations while perceiving the larger public interest. Environmental regulation is supposed to be a reasoning process that takes account of the social context in which the putative environmental effects could occur, the reliability of available information regarding the consequences, the existing institutional history of prevention and containment,

and the probability of perceived consequences. It was concluded that while an excessive focus on probabilities can benefit the proponent of a potentially hazardous activity, the imbalanced deference to consequences can give way to the prohibition of such activities.

(ii) The judgment of the European Court of Human Rights (ECHR) in ***Fadeyeva vs. Russia, [2005] ECHR 376: (2007) 45 EHRR 10 ("Fadeyeva")*** is apposite in this regard. The case concerned an application filed by a Russian citizen who averred that the operation of a steel plant in close proximity to her home endangered her health and well-being and thereby violated Article 8 of the ECHR. Article 8 guarantees the right to respect private and family life. The ECHR considered Article 42 of the Constitution of the Russian Federation which states, "Everyone has the right to a favourable environment, to reliable information about its state, and to compensation for damage caused to his health or property by ecological offences." The ECHR acknowledged that given the information asymmetry between the claimant of a rights violation and the State, it would be impossible to apply the rule of *affirmanti, non neganti, incumbit probation* (the burden of proof is upon him who affirms - not on him who denies) rigorously. It was held that the very strong combination of indirect evidence and presumptions makes it possible to conclude that the applicant's health deteriorated as a result of her prolonged exposure to the industrial

emissions from the Severstal steel plant. Even assuming that the pollution did not cause any quantifiable harm to her health, it inevitably made the applicant therein more vulnerable to various illnesses. Moreover, there can be no doubt that it adversely affected her quality of life at home. Therefore, the ECHR accepted that the actual detriment to the applicant's health and well-being reached a level sufficient to bring it within the scope of Article 8 of the Convention and cast a positive duty on the State to take reasonable and appropriate measures. Having held so, it was concluded that the State had failed to design or apply effective measures to protect the local population from pollution.

(iii) Therefore, the application of a rigorous reasoning process that emphasizes potential consequences, as manifested in the final report of the TEC, is expedient when there exists a fundamental asymmetry between the probability and consequences of the activity, such as the environmental release of GMOs. The failure to conduct chronic and transgenerational studies to study the impact on human health is a significant omission within the risk assessment process in the instant case. As noted hereinabove, conducting the said studies was a critical facet of the TEC's recommendations and the same was fortified by the PSC Report, 2017. In my view, this asymmetry between probable benefits and adverse consequences cannot be adequately

counter-balanced by economic or policy safeguards because of the serious and irreversible public and environmental health effects if such consequences occur. In this regard, the reasoning of this Court in ***T.N. Godavarman Thirumulpad (104) vs. Union of India, (2008) 2 SCC 222 ("T.N. Godavarman")*** fortifies my view. It was reasoned therein that while mining was a revenue generating industry, the constitutional requirement of sustainable development could not be lost sight of. It was held that courts are required to balance development needs with the protection of the environment and ecology. It is the duty of the State under our Constitution to devise and implement a coherent and coordinated programme to meet its obligation of sustainable development based on inter-generational equity.

(iv) Such asymmetry becomes especially acute in light of the long acknowledged disparity between polluters and those adversely affected by pollution. A reference to this Court's judgment in ***Municipal Corporation of Greater Mumbai vs. Ankita Sinha, (2022) 13 SCC 401 ("Ankita Sinha")*** would be relevant as it recognized the asymmetrical relationship between the polluters and those affected by their actions in the following words:

> "78. When substantive justice is elusive for a large segment, disengaging with substantive rights at the very altar, for a perceived procedural lacuna, would surely bring in a process, which furthers inequality, both economic and social. An "equal footing"

> conception may not therefore be feasible to adequately address the asymmetrical relationship between the polluters and those affected by their actions. Instead, a recognition of the historical experience of marginalised classes of persons while accessing and effectively using the legal system, will allow for necessary appreciation of social realities and balancing the arm of justice."

43.2 Nothing explains this asymmetry better than the subsisting grievance of the petitioners about the failure to make the biosafety dossier, i.e., the primary data on which the AFES report is based, accessible to affected parties, i.e., the farmers, the farm workers, the consumers, other experts in the field and the citizenry at large, thereby, seriously undermining the right to environmental information. This is more so because such denial of access to environmental information is in contravention of the order of this Court dated 08.04.2008 and subsequent order dated 12.08.2008. The order dated 08.04.2008 records that in the absence of toxicity and allergenicity data, the members of the public and the scientists would not be able to make effective representations to the concerned authorities. It was on the solemn assurance of the then ASG - that the said primary data pertaining to field trials will be placed in the public domain and on the website of GEAC - that this Court had disposed of the applications made by the petitioner. There has been absolute non-adherence of the said assurance. I also note that the Reply Affidavit filed by the Union of India had specifically stated that the full dossier could not be made available on the website and

that an independent review of such a dossier by members of the public would undermine the credibility of the extant regulatory regime.

43.3 I observe that the right to environmental information comes within the scope of the right to information, which came to be articulated by this court in ***State of Uttar Pradesh vs. Raj Narain, (1975) 4 SCC 428, para 74 ("Raj Narain"),*** as the public's right to know every public act that is done by public functionaries subject, of course, to absolute secrecy to be maintained in certain circumstances. It is also a critical aspect of the right to freedom of speech and expression, *vide* ***Chief Information Commissioner vs. State of Manipur, (2011) 15 SCC 1 ("Chief Information Commissioner")***. Disclosure of information is the rule in our system of open governance, and secrecy is an exception *vide* ***S. P. Gupta vs. Union of India, (1981) Supp SCC 87 (para 67) ("S. P. Gupta")***. Transparency is critical to preserve the integrity of the decision-making process. Public scrutiny would be crucial to evaluate the putative separation of interests and influence between scientific research and regulatory policy formulation.

43.4 The access to environmental information facilitates 'meaningful engagement' and rights-conscious decision-making. The engagement with stakeholders through the participative process inspires confidence in the decision-making process and

leads to more sound outcomes which are less vulnerable to legal challenge.

43.5 The presence of sufficient safeguards such as transparency, accountability and public participation wherever permissible within the decision-making process is critical to ensure that regulatory decisions are not made on partial and uncontested scientific evidence. In this context, I take note of the dicta in ***Harvester Co. vs. Ruckelshaus, 478 F.2d 615, 652 (D.C. Cir. 1973) ("Harvester Co."),*** wherein the US Court of Appeal, DC Circuit held that prior to adjudicating difficult technological questions, the judiciary ought to be assured that such questions are first "resolved in the crucible of debate through the clash of informed but opposing scientific and technological viewpoints." But the approach of GEAC has been quite contrary to the approach explained above. The record shows that on 22.09.2016, various scholars and public activists endorsed an email addressed to the Hon'ble Minister of Environment, Forest and Climate Change raising serious objections to the conduct of the appraisal process, particularly the refusal to disclose the biosafety dossier to the general public. They urged the MoEF&CC to extend the consultation process by another 120 days. In addition to the email, on 24.09.2016, scholars, experts, and eminent citizens sent a letter to the Hon'ble Minister of Environment, Forest and Climate Change, expressing grave concerns regarding GEAC's refusal to disclose the biosafety data

to the general public, hindering a meaningful exercise of public consultation. These objections initially weighed with GEAC to defer environmental release of DMH-11 in the years 2019-2021. But in the year 2022, things moved with an undue haste and speed and thereby GEAC ignored all precautionary measures suggested by TEC as well as by the sub-committee constituted by it and simply leaf frogged into the impugned decision dated 18.10.2022. This, I find, has adverse legal and environmental consequences.

The other critical right is that of public participation in environmental decision-making.

44. Moving further, learned Attorney General submitted that pursuant to the TEC Report submitted to this Court, several guidelines and a legal framework were put in place. In this regard, I have perused the specific guidance documents issued in the year 2016, said to be in accordance with the CPB, to further strengthen the risk assessment procedure.

The same are discussed as under:

i. Risk Analysis Framework, 2016 provides a step-by-step consultation process for seeking views from stakeholders:
   a) Information about submission of applications is communicated through the minutes of the meetings.
   b) A RARM plan for each application is prepared by the regulatory agencies and is uploaded on the official website for receiving comments for a period of 30 days.

c) Regulatory agencies give recommendations after duly considering the responses.

ii. Guidelines for Environmental Risk Assessment (ERA) for Genetically Engineered Plants, 2016:

a) The guidelines require that a risk assessment be performed prior to the commercial release of a GE plant in India.

b) The purpose of the risk assessment is to identify risks to the health and safety of people and the environment from the cultivation of the GE plant, when compared with the cultivation of the non-GE version of the plant.

c) Information requirements include characteristics of genetic modification, cultivation practices and post-release environmental monitoring.

iii. Regulations and Guidelines for Recombinant DNA Research and Biocontainment, 2017 seek to ensure appropriate containment strategy ensuring safety to laboratory workers as well as others and the environment from hazardous micro-organisms, GE organisms or cells.

iv. Guidelines and SOPs for the Conduct of Confined Field Trials: Confined Field Trials are monitored by RCGM/GEAC-appointed Central Compliance Committees which are site-specific and comprise subject experts.

44.1 Given their import to the issue at hand, I limit my analysis to the Risk Analysis Framework, 2016 and the Guidelines for

Environmental Risk Assessment (ERA) for Genetically Engineered (GE) Plants, 2016. While one of the stated purposes of the Risk Analysis Framework includes provision of transparency on the use of risk analysis to support decision-making, the continued reluctance to publish the biosafety dossier and respond to concerns about long-term effects by provisioning requisite chronic and transgenerational toxicity studies shows that it is inadequate. The modalities of communicating the RARM plan must be inclusive and transparent. The failure to publish the biosafety dossier on the website reveals a deficiency in the Guidelines for Environmental Risk Assessment (ERA) for Genetically Engineered (GE) Plants, 2016. Furthermore, the failure to furnish cogent reasons for giving a go by to field demonstration studies to study the impact on honeybees also reveals the lack of safeguards against misuse of discretion. With respect to post-release monitoring, I note that the MoEF&CC issued an office order on 10.11.2022 to constitute an Expert Committee of four members for Post Release Monitoring Committee (PRMC). The terms of reference are to visit the growing sites of DMH-11 at least once during each season. However, the term of its functioning is limited to a period of four years from the date of issue.

44.2 Given the fact that the unanticipated consequences of the environmental release of DMH-11 remain in the sphere of uncertainty, I am impelled to construe the failure to undertake

necessary measures in light of the TEC and the PSC recommendations and the non-compliance with directions of this Court as a violation of the right to a safe and healthy environment. The violation is particularly serious in light of the benchmarks of environmental regulation prescribed by this Court in ***T.N. Godavarman.***

44.3 The failure to adequately assess health and environmental impact of GM crops seriously infringes upon intergenerational equity as it potentially endangers the ability of future citizens to enjoy the highest attainable standard of health. This Court in ***State of Himachal Pradesh vs. Ganesh Wood Products (1995) 6 SCC 363 ("Ganesh Wood Products")*** had invoked intergenerational equity while taking cognizance of the *'totally faulty and a myopic approach'* of the State towards forest management and regulation. This Court held that mechanically granting approvals for manufacturing 'katha' by felling khair trees was 'contrary to public interest involved in preserving forest wealth, maintenance of environment and ecology and considerations of sustainable growth and inter-generational equity.' This Court reasoned that 'the present generation has no right to deplete all the existing forests and leave nothing for the next and future generations' and therefore, the approvals were vitiated. This Court also emphasized that the obligation of sustainable development mandates proper assessment and

monitoring so that forest industries function in a balanced manner.

44.4 The State's obligation to ensure intergenerational equity was also invoked while directing the preparation of appropriate management plans for regulating the use of fragile coastlines *vide* ***Indian Council for Enviro-legal Action vs. Union of India (1996) 5 SCC 281.***

44.5 In view of the aforesaid discussion, I am of the view that the decision to grant approval for environmental release of transgenic mustard hybrid DMH-11 violates the right to safe and healthy environment under Article 21 of the Constitution of India because the safeguards which were necessary to be taken prior to the grant of the approval have not been taken in the instant case.

Consequently, directions have been issued in the succeeding paragraphs.

Re: Point No.3: Whether GEAC's grant of approval dated 18.10.2022 and the decision dated 25.10.2022 for the environmental release of DMH-11 violate the precautionary principle?

Precautionary Principle:

45. As discussed earlier, the precautionary principle is one of the doctrinal foundations of Indian environmental law. The principle is an instance of distillation of ecological wisdom. Given the fact that genetic engineering has made what was inconceivable a reality, precaution is the need of the hour. For

billions of years, each living organism would exchange DNA with others of its kind. Genetic engineering transcends this natural principle by combining genes sourced from widely different species and transferring genes between organisms that had no natural possibility of interbreeding. Scientific research of such a novel nature must therefore happen under supervision and in a manner that inspires public confidence.

45.1 It is said that the regulatory regime should recognize sufficiently the limits of scientific knowledge, and adopt a wider system-based interdisciplinary analysis. A diversity of expert opinions ranging from the disciplines of biotechnology, environmental law, ethics, sociology, agriculture, and sustainable economics should engage in open and public dialogue. Such an open dialogue is necessary in order to mitigate the possibility of regulatory agencies and applicants exaggerating the benefits of a proposed technology or diluting the rigours of environmental safety or health standards.

46. Having regard to the conclusions of the TEC, I find that the apprehensions of the petitioners that HT crops would exert a highly adverse impact over time on sustainable agriculture, rural livelihoods, and the environment are not unfounded. It is reasonable to infer that there is a potential of loss of species of indigenous mustard crop, as India is the centre of origin and diversity, which fact cannot be doubted. The concerns about the impact on other beneficial organisms, such as honeybees,

earthworms etc. are also well-founded and serious. As per the precautionary principle, those activities which may disturb nature shall be proceeded only upon *ex-ante* assessment of their consequences. Such a sound risk and impact assessment is also a binding obligation under Article 14(1)(b) of the CBD and Article 26 of the CPB. Therefore, GEAC is duty bound, both under domestic and international law, to sanction long-term chronic and intergenerational studies, as recommended by the TEC. The reluctance to conduct such studies would risk the health of future generations as well as the farmers' right to conduct their agricultural activities in the most suitable manner. In this regard, it would be pertinent to quote the paragraph 28 of the 301st Report of PSC as under:

> "28. The Committee notes that the currently, twenty years after their introduction in 1996, only 6 countries continue to account for over 90% of all GM crop area globally (USA 40%, Brazil 23%, Argentina 14%, India 6%, Canada 6%, China 2%). The Committee was informed by the members of civil society during the deliberation on the subject that there was a decline in GM crop area in 2015. The Committee notes with surprise that inspite of the fact that GM technology is being propagated as the most advanced agricultural technology, 17 of the 20 most developed countries (HDI) do not grow it which includes most of Europe, Japan, Russia, Israel etc. The Committee opines that there is increasing evidence about the lack of safety of GM crops and little or no benefits to justify the risks, most countries in the world do not grow GM crops. The Committee also feels that the policy makers of these countries, as custodians for both present and future generations, have seen that GM organisms spread

rapidly, that the impacts have been unpredictable, potentially hazardous, uncontrollable and irreversible, assessed the benefits and risks, taken note of emerging evidence of harm, and therefore do not permit GM crops. The non acceptance of the most advanced agricultural technology, GM technology, by the most developed countries raises doubts about the efficacy of the technology. The Committee, therefore, feels that the Government of India should conduct a comparative study to examine the reasons for not accepting this technology by these developed countries *viz-a-viz* the reasons led to its acceptance."

(underlining by me)

47. There are considerable concerns that the HT GM technology depends on huge chemical spraying. In this regard, learned counsel Dr. Ravindra Chingale brought to my notice the three unstarred questions raised before the Rajya Sabha on 15.03.2021, 22.03.2021 and 08.12.2022 (the latest being after the decision taken by GEAC and the MoEF&CC for environmental release of transgenic mustard DMH-11 hybrid). Law courts under Section 57(4) of the Indian Evidence Act, 1872, can take judicial notice of the course of proceedings of the Parliament. The answering of parliamentary questions is a part of the conduct of business of the Parliament. Therefore, no question about its admissibility under Section 74, the Indian Evidence Act, 1872 would arise.

For ease of reference, the said questions and answers are extracted as under:

"GOVERNMENT OF INDIA

MINISTRY OF ENVIRONMENT, FOREST AND CLIMATE CHANGE

RAJYA SABHA

UNSTARRED QUESTION No.2118
TO BE ANSWERED ON 15.03.2021

Commercial cultivation of GM crops and foods made from GM ingredients

2118. SHRI KANAKAMEDALA RAVINDRA KUMAR:

Will the Minister of ENVIRONMENT, FOREST AND CLIMATE CHANGE be pleased to state:

(a) Whether it is a fact that Government has approved commercial cultivation of Genetically Modified (GM) crops and also manufacturing, import and selling of processed foods made from GM ingredients;
(b) If so, the details thereof;
(c) Whether Government has undertaken any study regarding impact of GM crops cultivation on environment and impact of GM foods on health of individuals in the country;
(d) If so, the details thereof; and
(e) If not, the reasons therefore?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF ENVIRONMENT, FOREST AND CLIMATE CHANGE (SHRI BABUL SUPRIYO)

(a) and (b) Bt cotton is the only genetically modified (GM) crop that has been approved for commercial cultivation. Further, at present matters related to processed GM foods is being dealt under Section 22 of the Food Safety and Standards Act (2006), which has not yet been operationalised.

(c) to (e) Long term studies conducted by Indian Council of Agricultural Research (ICAR) on the impact of

Bt cotton cultivation found no adverse effect on soil, microflora and animal health. Food Safety and Standards Authority of India (FSSAI) has not undertaken any study on impact of GM foods on health of individuals in the country.

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GOVERNMENT OF INDIA

MINISTRY OF ENVIRONMENT, FOREST AND CLIMATE CHANGE

RAJYA SABHA

UNSTARRED QUESTION No.2931
TO BE ANSWERED ON 22.03.2021

Genetically Modified seeds

2931. SHRI PRASANNA ACHARYA:

Will the Minister of ENVIRONMENT, FOREST AND CLIMATE CHANGE be pleased to state:

(a) whether Government has assessed the outcome of the Genetically Modified (GM) seeds so far its impact on production, cost of production, environment and public health is concerned;
(b) the other items that the Genetic Engineering Appraisal Committee has recommended for commercial use of GM seeds; and
(c) whether Government taken any final decision in this regard, if so, by when it will be implemented, if not, the reasons therefor?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF ENVIRONMENT, FOREST AND CLIMATE CHANGE (SHRI BABUL SUPRIYO)

(a) to (c) Bt cotton is the only genetically modified (GM) crop that has been approved for commercial cultivation in India.

As per the information received from Ministry of Agriculture and Farmers Welfare, around 90% of the cotton area is under the cultivation of Bt cotton and the productivity has increased from 191 Kg per hectare in 2002-03 to 455.00 Kg per hectare in 2019-20. Per hectare income of the farmer has also increased. There has also been a reduction in the usage of insecticide for bollworm damage from 24 sprays to 2-3 sprays in a season.

Long term studies conducted by Indian Council of Agricultural Research (ICAR) on the impact of Bt cotton cultivating states has not reported any adverse effect on soil, microflora and animal health.

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GOVERNMENT OF INDIA

MINISTRY OF ENVIRONMENT, FOREST AND CLIMATE CHANGE

RAJYA SABHA

UNSTARRED QUESTION No.222
TO BE ANSWERED ON 18.12.2022

Conferment of herbicide tolerance to genetically modified mustard

222. SHRI ANEEL PRASAD HEGDE:

Will the Minister of ENVIRONMENT, FOREST AND CLIMATE CHANGE be pleased to state:

(a) whether the bar gene in parental lines and hybrid offspring of Delhi University's GM mustard confers herbicide tolerance to genetically modified mustard plants, even as it is useful as a marker gene;

(b) whether India has put into place regulatory protocols to specifically test for the safety of HT GM crops as opposed to any other GM crop, and whether the parental lines of DMH-11 and DMH-11 itself have been tested for this

herbicide tolerance trait, even if only for seed production purposes; and

(c) if not, the reason thereof?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF ENVIRONMENT, FOREST AND CLIMATE CHANGE (SHRI ASHWINI KUMAR CHOUBEY)

(a) to (c) The bar gene in Mustard hybrid DMH-11 is expressed which encodes phosphinothricin N-acetyl transferase enzyme that confers resistant to herbicide glufosinate ammonium.

Genetically Modified (GM) Hybrid Mustard DMH-11 has not been approved for Herbicide Tolerant (HT) trait but for a GM technology for hybrid seed production. The HT characteristic/trait present in the GM Mustard hybrid seed is essential for eliminating fertile plants that are not transgenic in the hybrid seed production plots to maintain the purity of hybrid seed. The use of herbicide will be limited to seed production stage by the seed producing company/institute and not during the commercial cultivation of DMH-11 by the farmers. The use of herbicide will be after obtaining label claim and approval from Central Insecticide Board and Registration Committee (CIB&RC).

The biosafety research trials including environmental safety studies have been conducted for transgenic mustard hybrid DMH-11 containing barnase, barstar and bar genes, events bn 3.6 (Barnase line) and modbs 2.99 (Barstarline).

> The issue of environmental release of GM Mustard is under adjudication in the Writ Petition (Civil) 115/2004 and Writ Petition (Civil) 260 of 2005 titled as Gene Campaign vs. UoI & Ors. and Aruna Rodrigues vs. UoI & Ors., respectively before the Hon'ble Supreme Court of India.
>
> (underlining by us)

47.1 It is needless to observe that taking note of the said questions and answers so as to appreciate the stance of the Government at the particular point of time would be in line with the constitutional scheme in general and the Rules of Procedure and Conduct of Business in the Council of States (Rajya Sabha) ('Rajya Sabha Rules').

47.2 On a reading of the above, it is clear that the stand of the MoEF&CC before the Parliament has been as follows:

(i) that processed GM foods is dealt with under Section 22 of the FSSA, 2006, which had not yet been operationalised. This was as on 15.03.2021, but thereafter on 02.11.2021, the Central Government has appointed the said date as the date on which clause (2) of Explanation of Section 2 of the FSSA, 2006 shall come into force. The said clause deals with GM or engineered organisms obtained through modern biotechnology.

(ii) More critically, it is also admitted by the MoEF&CC that the FSSAI has not undertaken any study on impact of GM foods on the health of individuals in the country.

(iii) Subsequently, on 22.03.2021, it has been stated that Bt cotton is the only GM crop that has been approved for commercial cultivation in India.

(iv) Thereafter, on 08.12.2022 a specific question, namely, whether the *bar* gene in parental lines and hybrid offspring of Delhi University's transgenic mustard hybrid DMH-11confers HT to transgenic mustard hybrid DMH-11 plants, even as it is useful as a marker gene was asked. The answer given was that the *bar* gene in mustard hybrid DMH-11 is expressed which encodes enzyme that confers resistance to herbicide glufosinate ammonium.

(v) But it is stated in the same answer that Genetically Modified (GM) hybrid mustard DMH-11 has not been approved for herbicide tolerant (HT) trait but for a GM technology for hybrid seed production. The HT characteristic/trait present in the transgenic mustard hybrid DMH-11 seed is essential for eliminating fertile plants that are not transgenic in hybrid seed production plots to maintain the purity of hybrid seeds. It was also stated that the use of herbicide will be limited at the time of seed production stage and not during the commercial cultivation of DMH-11 by the farmers. Such use of herbicide, it was stated, will be after obtaining label claim approval from the Central Insecticide Board and Registration Committee (CIB&RC). The Minister noted that the biosafety research trials including environmental safety studies had been conducted for transgenic mustard hybrid DMH-11

containing *barnase, barstar* and *bar* genes, events bn 3.6 (*Barnase* line) and modbs 2.99 (*Barstarline*).

(vi) Further, he noted that the issue of environmental release of transgenic mustard hybrid DMH-11 is under adjudication in the present cases.

47.3 Having given my anxious consideration to the report of the TEC and the PSCs, I am convinced that the ability to conduct robust risk assessment hinges upon the availability of indigenous and independent studies and research. It follows that conclusions about safety assessment and ecological impact cannot be transplanted from research conducted in a foreign context. Crucially, the recommendation of Expert Committee constituted by GEAC in the year 2022 after Prof. Pental's letter to the Hon'ble Minister of Environment, which is the basis of GEAC's impugned approval, is entirely premised upon foreign studies and research and not on indigenous research or studies. This, I find, is a serious omission, on the part of GEAC in not applying its mind to research studies to be conducted within the country as India has a unique biodiversity and a socio-economic structure of society which is directly related to land holdings and conduct of agricultural operations.

47.4 It is also noted that Dr. Sanjay Kumar Mishra, Scientist 'H', DBT, New Delhi, who is one of the members of GEAC (Co-Chairman), was made Chairman of the Expert Committee constituted by GEAC in the 146th meeting which was held

pursuant to the letter written by Prof. Deepak Pental on behalf of the CGMCP, University of Delhi (South Campus) to the Hon'ble Minister of Environment. The crucial portions of the recommendations have been extracted above.

On a reading of the same, it is evident that the Expert Committee has made its recommendations on the opinion of the DBT and the DARE which are bodies within the Ministries of the Government. They are not independent scientific bodies. Therefore, the Expert Committee could not have relied upon the opinion of the DBT and the DARE. Also, based on the examination of scientific evidences available globally, and as per the recommendations of concerned Ministries, it was observed by the Expert Committee that it was unlikely that the *bar*, *barnase,* and *barstar* system would pose an adverse impact on honeybees and other pollinators. What is the pertinent scientific evidence available globally or in other countries and how the said evidence was co-related to all the concerned issues of contemporary relevance under Indian scenario, has not been explained. That the Expert Committee has been swayed by the opinion of the DBT and the DARE is opponent. DBT opined that, *"it seems likely that there were no major deviations in the behaviour of honeybees when compared among the transgenic and non-transgenic comparator lines. GEAC may consider its recommendations of the 133rd meeting on the environmental release of GE mustard."* The aforesaid opinion is contrary to what was expressed by the sub-committee constituted by the GEAC

when the matter was being considered prior to the 133rd meeting. DARE opined that, *"GEAC may consider exempting additional studies on the impact of GM mustard hybrid DMH-11 containing the bar, barnase, and barstar genes on honey bees and honey as decided in its 136th meeting and the recommendation of the 133rd meeting of GEAC may be considered."* There is no reason expressed as to why GEAC should exempt additional studies on the impact of transgenic mustard hybrid DMH-11 on honeybees and honey as decided in 136th meeting. In other words, the Expert Committee has recommended what exactly was required by the applicant i.e. to give effect to the recommendations of the 133rd meeting of GEAC.

47.5 In fact, the constitution of Expert Committee in the year 2022 itself is an eye-wash, inasmuch as the Ministry of Environment required the report of the so-called Expert Committee in order to approve the application given by CGMCP, University of Delhi (South Campus), which is contrary to the stand of GEAC in its earlier meetings. The report of this Expert Committee therefore was tailor-made and "suitable" in order that GEAC could accord approval to the application submitted by CGMCP. As already observed, the Expert Committee relied upon scientific evidence available globally and not based upon the agro-ecological realities in India. Therefore, not much credence can be given to the recognition of this Expert Committee which

was the basis of the decision/recommendation dated 18.10.2022 made to MoEF&CC.

47.6 Next, I have perused the conditions imposed by GEAC while according approval to CGMCP, University of Delhi (South Campus), the applicant. It is apparent that the precautionary principle has been seriously undermined in Condition VI and VII that have been prescribed by GEAC for the impugned release. Although Condition VII prohibits farmers from using any formulation of herbicide in the fields, it is unclear how such a prohibition would be enforced. Given the nature of the DMH-11 which according to the petitioners has HT characteristics, the impact upon non-target organisms and beneficial organisms could be seriously detrimental to agrarian ecology. The proposed conditions for approval are neither adequate nor feasible to limit these consequences. I observe that GEAC has failed to take into consideration the precautionary principles while approving the environmental release of the transgenic mustard DMH-11 hybrid.

48. Wisdom lies in precaution. As the upholder and protector of constitutional wisdom and values, this Court has no option but to hold that the decision-making process for the grant of approval for the environmental release of DMH-11 has violated the precautionary principle. Reiterating ***Vellore Citizens*** and ***A.P. Pollution Control Board,*** this Court in ***RFSTE***, noted that the position of the precautionary principle is well-entrenched in

our jurisprudence and would govern the law of the land in light of Articles 47, 48A and 51A(g) of the Constitution. Thereafter, in ***T. N. Godavarman Thirumulpad vs. Union of India, (2006) 1 SCC 1***, this Court applied the precautionary principle while directing that all precautionary measures must be taken when forest lands are diverted for non-forest use.

48.1 ***Karnataka Industrial Areas Development Board vs. C. Kenchappa, (2006) 6 SCC 371 ("C. Kenchappa")*** is another case where this Court applied the precautionary principle to emphasize on the requirement of carrying on an impact assessment and obtaining necessary environmental clearance before execution of an industrial activity. It was directed that, in future, before acquisition of lands for development, the consequence and adverse impact of development on the environment must be properly comprehended and the lands be acquired for development so that they do not gravely impair the ecology and environment.

48.2 The precautionary principle was pressed into service in ***Democratic Youth Federation of India vs. Union of India (2011) 15 SCC 530 ("Democratic Youth Foundation of India")*** to ban the use of the endosulfan pesticide until a court-appointed committee conducted a risk assessment of the same. It was also applied in ***Hospitality Association of Mudumalai vs. In Defence of Environment & Animals, (2020) 10 SCC 589***

("Hospitality Association of Mudumalai") where it was held that:

> "**39**. … The precautionary principle makes it mandatory for the State Government to anticipate, prevent and attack the causes of environmental degradation. In this light, we have no hesitation in holding that in order to protect the elephant population in the Sigur Plateau region, it was necessary and appropriate for the State Government to limit commercial activity in the areas falling within the elephant corridor."

48.3 Furthermore as noted above, this Court gave an expansive scope to the application of the precautionary principle beyond adjudicatory orders to any decision, administrative or commercial ought to be made by the Government or private parties in anticipation of serious environmental harm. In ***Pragnesh Shah vs. Dr. Arun Kumar Sharma, (2022) 11 SCC 493 ("Pragnesh Shah")***, it was explained that the precautionary principle requires the State to act in advance to ***prevent*** environmental harm from taking place, rather than by adopting measures ***once*** the harm has taken place. In deciding when to adopt such action, the State cannot hide behind the veil of scientific uncertainty in calculating the exact scientific harm by observing as under:

> "36. The precautionary principle envisages that the State cannot refuse to act to preserve the environment simply because all the scientific data may not be available. If there is some data to suggest that environmental degradation is possible, the State must step into action to prevent it from taking place. Indeed, it was this thought that compelled this Court in *T.N.*

Godavarman [*T.N. Godavarman Thirumulpad* v. *Union of India* Writ Petition No. 202 of 1995] to direct the State to identify ESZs across India, so that steps can be taken to identify areas where there is a greater *possibility* of environmental degradation and a plan is put in place to *prevent* such degradation before it actually makes the harm irreversible."

48.4 Relying upon ***H.P. Bus-Stand***, this Court held that actualising the framework of environmental rule of law requires that the courts cannot be stupefied into inaction due to scientific uncertainty but must take decisions to protect the environment based on whatever information is available.

48.5 Recently this Court in ***M.K. Ranjitsinh*** while considering protection of the Great Indian Bustard and the Lesser Florican both kinds of birds which are on the verge of extinction, observed as under:

"35. India faces a number of pressing near-term challenges that directly impact the right to a healthy environment, particularly for vulnerable and indigenous communities including forest dwellers. The lack of reliable electricity supply for many citizens not only hinders economic development but also disproportionately affects communities, including women and low-income households, further perpetuating inequalities. Therefore, the right to a healthy environment encapsulates the principle that every individual has the entitlement to live in an environment that is clean, safe, and conducive to their well-being. By recognizing the right to a healthy environment and the right to be free from the adverse effects of climate change, states are compelled to prioritize environmental protection and sustainable development, thereby addressing the root causes of

> climate change and safeguarding the wellbeing of present and future generations. It is imperative for states like India, to uphold their obligations under international law, including their responsibilities to mitigate greenhouse gas emissions, adapt to climate impacts, and protect the fundamental rights of all individuals to live in a healthy and sustainable environment."

48.6 In this context, I would also like to refer to the relevant Articles of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity which specifically deals with living modified organisms to mean any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology (Article 3g) as well as Articles 15 and 16 of the said Protocol which deal with risk assessment and risk management respectively. It is necessary to refer to the said Articles as India is a signatory to the said Protocol and Convention.

I may further refer to the Convention on Biological Diversity and particularly, on Article 8(g) which states that each contracting party shall, as far as possible and as appropriate establish or maintain means to regulate, manage or control the risks associated with the use of release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health.

48.7 It is too late in the day to even entertain the proposition that the protection of our natural environment and ecology is not a constitutional imperative. The evolution of the right to a safe and healthy environment and the concomitant duty of the State to uphold public trust and abide by inter-generational equity and the precautionary principle in environmental regulation is the bedrock of environmental constitutionalism. The environmental rights regime is a product of decades of environmental litigation by civil society, social movements, affected communities and the general citizenry. In that sense, environmental constitutionalism is a facet of transformative constitutionalism touching upon the socio-economic lives of citizens. In other words, the affected communities must have a substantive role in environmental governance.

48.8 While this court in ***T.N. Godavarman*** has crystallised the role of environmental regulators and the Executive arm of the State since it mandates adequate technical capacity and effectiveness so as to attain optimal environmental performance, a weak regulatory regime can render environmental rights illusory. At the same time, technical capacity and effective regulation cannot be realised without democratic engagement, dialogue and deliberation. The aspiration of transformative environmental governance cannot be realised merely through an effective bureaucracy and sound technical expertise. Environmental democracy and environmental rights are two

sides of the same coin. In this regard, the facts of this case shed light on the salience of the legislative role in preserving environmental democracy.

48.9 Environmental decision-making in a rapidly changing climate requires healthy contestation of alternative worldviews, interests and rights. Only through such contestation can a fine and sustainable balance between development and the environment be arrived at. The Department-related Parliamentary Standing Committees and other legislative committees discharge important functions. In the context of the environment, these committees are mandated to scrutinise public issues from multiple perspectives, appreciate available evidence, consult experts and the members of the affected communities and thereafter render a principled and considered report. Open and transparent deliberation on expert knowledge increases accountability and acts as a safeguard against conflict of interest but not a closed door decision making process.

48.10 Consequently, I hold that the approval dated 18.10.2022 and consequent decision dated 25.10.2022 for environmental release of transgenic mustard hybrid DMH-11 violate the precautionary principle inasmuch as there has been no determination made, as to, whether, transgenic mustard hybrid DMH-11 is a HT crop and if so, the nature of risk that would be caused by the said plant to the environment including other plants as well as to human beings and animals. The

deliberations have not focussed *inter alia*, on the aspects of biosafety, risk assessment, soil health, micro-biology and socio-economic aspects etc. Moreover, the recommendations of the TEC and Parliamentary Standing Committees' Reports on Agriculture and on Science and Technology, Environment and Forest have not been considered. Consequently, directions have been issued in the succeeding paragraphs.

Conclusion:

49. In view of the aforesaid discussion and findings, I conclude as under:

(i) the recommendations of GEAC dated 18.10.2022 as well as the decision taken by the respondent Union of India on 25.10.2022 with regard to approving environmental release of transgenic mustard hybrid DMH-11 on the application made by the applicant, namely, CGMCP, University of Delhi (South Campus') are vitiated and hence, they are liable to be quashed and are quashed.

(ii) I further observe that the recommendation of the Expert Committee constituted by the GEAC in the year 2022 is of no consequence and not binding.

50. Consequently, I issue the following directions:

(a) With regard to approving environmental release of transgenic mustard hybrid in future on the application made by the applicant, namely, CGMCP, University of Delhi (South Campus) or by any other applicant:

(i) there shall be a decision taken by GEAC, in the first instance, on whether, transgenic mustard hybrid DMH-11 is a HT crop or not, by having a wide and meaningful consultation on the report of TEC submitted to this Court with all stakeholders, including experts in the field of agriculture, biotechnology, health experts and other scientists/experts preferably within a period of four months from today. A report on this aspect must be submitted by GEAC to MoEF&CC.

(ii) MoEF&CC must publish an official report, with adequate publicity to the said report, on whether the GE mustard hybrid DMH-11 is indeed a HT crop or not, preferably within a period of one month from the date of receipt from GEAC.

(iii) for the aforesaid purposes, GEAC is directed to upload the applicant's biosafety dossier comprising 3285 pages on its website after prior intimation to the applicant CGMCP, University of Delhi (South Campus) within a period of two weeks from today. This is with a view to bring in transparency in the matter.

(iv) The aforesaid biosafety dossier shall remain on the website of GEAC for a minimum period of 30 days from the date it is uploaded so as to enable the stakeholders to respond to the said dossier. On

receipt of such response, if any, GEAC shall collate the said responses, and take the same into consideration for its future course of action.

(v) In the event, GEAC and MoEF&CC conclude that transgenic mustard hybrid DMH-11 is a HT crop, then the nature of risk that would be caused by the said plant to the environment including other plants as well as to human beings and animals must be researched and deliberated upon. The deliberations must take into consideration different aspects, such as biosafety, risk assessment, soil health, micro-biology and socio-economic aspects etc.

(vi) After taking a decision on the nature and characteristic of transgenic mustard hybrid DMH-11, the respondent shall take a policy decision in the matter afresh on environmental release of transgenic mustard hybrid DMH-11 on receipt of the report from GEAC in future bearing in mind health and environmental aspects of transgenic mustard hybrid DMH-11.

(vii) In the above context, the respondent-Union of India shall also comply with the recommendations made by Technical Expert Committee (TEC) on Agriculture, Science and Technology, discussed above to the extent they are not contrary to the

aforesaid directions and if not already complied with.

(viii) The respondent-Union of India shall also comply with the recommendations made by the Parliamentary Standing Committees (PSCs) on Agriculture and on Science and Technology, Environment and Forest, to the extent they are not contrary to the aforesaid directions if not already complied with.

(ix) With regard to import of GM edible oil such as mustard or canola being made, the requirements of Section 23 of FSSA, 2006 in the matter of packaging and labelling shall be complied with by the respondent-Union of India as early as practicable.

I also issue certain general directions in relation to GM crops as under:

(b) The respondent-Union of India is directed to evolve a National Policy with regard to GM crops in the realm of research, cultivation, trade and commerce in the country. The said National Policy shall be formulated in consultation with all stakeholders, such as, experts in the field of agriculture, biotechnology, State Governments, representatives

of the farmers, etc. The National Policy to be formulated shall be given due publicity.

(c) For the aforesaid purpose, the MoEF&CC shall conduct a national consultation, preferably within the next four months, with the aim of formulating the National Policy on GM crops. The State Governments shall be involved in evolving the National Policy on GM crops.

(d) That the composition of GEAC shall be suitably reformed bearing in mind the recommendations of the TEC and the PSC Reports and the dictum of this Court in the case of ***T.N. Godavarman*** discussed above. The reformed composition shall comprise of experts in the field of agriculture, biotechnology, ethics, sociology, health as well as experts in the field of environment and shall be an independent and autonomous body. This could be done either by a statute or amendments being brought to the existing Rules as thought fit by the respondent-Union.

(e) Respondent – Union of India must ensure that all credentials and past records of any expert who participates in the decision-making process should be scrupulously verified and conflict of interest, if any, should be declared and suitably mitigated by ensuring representation to wide range of interests.

Rules in this regard may be formulated having statutory force.

(f) The specific guidance documents referred to above in paragraph No.42 that have been adopted in conformity with the Cartagena Protocol on Biosafety (CPB) shall be complied with in letter and spirit insofar as they are applicable to the Indian context. These guidance documents shall be accorded statutory status by framing and issuing appropriate Rules under Section 25 of the EP Act, 1986.

(g) In the matter of importing of GM food and more particularly GM edible oil, the respondent shall comply with the requirements of Section 23 of FSSA, 2006, which deals with packaging and labelling of foods.

The aforesaid directions have been issued by me bearing in mind, Articles 14 and 21 of the Fundamental Rights; Article 48A of the Directive Principles of State Policy of the Constitution as well as the statutory framework applicable to the controversy under consideration.

51. The writ petitions are disposed of in the aforesaid terms and the civil appeal does not survive for any further consideration and hence stands disposed of.

The contempt proceedings are dropped without expressing any opinion on the merits of those petitions.

.....J.
(B.V. NAGARATHNA)

New Delhi;
July 23, 2024.

REPORTABLE

IN THE SUPREME COURT OF INDIA

EXTRAORDINARY CIVIL ORIGINAL JURISDICTION

WRIT PETITION (C) NO. 115/2004

GENE CAMPAIGN & ANR. ...PETITIONER(S)

VERSUS

UNION OF INDIA & ORS. ...RESPONDENT(S)

WITH

WRIT PETITION (C) NO. 260/2005

WRIT PETITION (C) NO. 840/2016

CONTEMPT PETITION (C) NO. 295/2007 IN WRIT PETITION (C) NO. 260/2005

CONTEMPT PETITION (C) NO. 6/2016 IN WRIT PETITION (C) NO. 260/2005

CIVIL APPEAL NO. 4086/2006

J U D G M E N T

SANJAY KAROL J.

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1. I have perused the erudite opinion of my sister, Hon'ble Mrs. Justice B.V. Nagarathna. However, I am unable to agree with the findings, conclusions so drawn and certain directions given, therefore I deem it appropriate to pen down my independent opinion and issue directions.

Preface

2. The present *lis* concerns 6 petitions: 3 Writ Petitions (*W.P. (C) No. 115 of 2004; W.P. (C) No. 260 of 2005 and W.P. (C) No. 840 of 2016*), 2 Contempt Petitions (*Contempt Petition (C) No. 295 of 2007 and Contempt Petition No.6 of 2016*) and 1 Civil Appeal (*Civil Appeal No. 4086 of 2006*).

3. In the batch of Writ Petitions, under Article 32 of the Constitution of India, the lead matter was filed in 2004 (**W.P. (C) No.115 of 2004**) praying for issuance of the Writ of Mandamus to the Respondents directing them to:

   i. Bring the Rules for Manufacture, Use, Import, Export and Storage of Hazardous Micro-organisms, Genetically Engineered Organisms or Cells, 1989, in consonance with Articles 14, 19, 21, 38, 47, 48, 48A read with 51-A(g) of the

Constitution of India and in alternative, declaration of the above rules as unconstitutional.

ii. Set-up a High Power Committee to formulate a National Policy on genetically engineered organisms through a multi-stakeholder consultation process.

iii. Observe a moratorium on various trials/approvals concerning genetically engineered organisms, particularly for which India is a Centre of Origin/Diversity till the Rules are amended and a sound regulatory and monitoring system is put in place.

4. **Writ Petition (C) No.260 of 2005** came to be filed seeking the following directions to the Union of India:

i. To not allow any release of GMO's into the environment by way of import, manufacture, use or any other manner unless the following precautions are taken.

(a) A protocol for all the required bio-safety tests of the GMOs proposed to be released is prepared by the GEAC after processes of public notice and public hearing.

(b) The GMO has been subjected to all the required bio-safety tests, prepared on the basis of the required Biosafety tests on the basis of the above protocol, by agencies of independent expert bodies, and results of which have been made public.

ii. To ban 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.

iii. To put in place rules to ensure that it shall be compulsory for any dealer or grower selling GMOs to label them as such.

5. **Writ Petition (C) No.840 of 2016** was filed seeking a Writ of Mandamus or direction to the effect of:

i. Quashing the Notice dated 05.09.2016 issued by Union of India inviting comments from stakeholders and general public within 30 days as being violative of Article 14 and Article 21 of the Constitution of India.

ii. The process adopted by GEAC as arbitrary and violative of Article 14 and Article 21 of the Constitution of India.

iii. Union of India to frame appropriate procedural guidelines for appraisal of application seeking environmental release under Rules for Manufacture, Use, Import, Export and Storage of Hazardous Micro-organisms, Genetically Engineered Organisms or Cells, 1989.

6. **Contempt Petition (C) No.295 of 2007** was filed alleging contempt of orders of this Court dated 22.09.2006, 08.05.2007 and 01.08.2007. **Contempt Petition (C) No.06 of 2016** was filed alleging contempt of orders of this Court dated 15.02.2007, 08.05.2007, 08.04.2008 and 12.08.2008. These orders come to be discussed in the foregoing paragraphs.

7. **Civil Appeal No.4086 of 2006** came to be filed against order of the Appellate Authority dated 08.10.2003, dismissing the appeal filed by the Appellant in Appeal No.2 of 2002, whereby the approval granted to Bt Cotton dated 05.04.2002 was assailed.

8. This Court is often presented with situations where two competent interests call upon it to undertake a balancing act which is akin to threading a needle or, in other words, undertake

a task of considerable difficulty. This case is one such task. On the one hand, is a group of concerned, informed individuals and organisations apprehensive about the potential impacts of new technology on the environment, agriculture, health and other socio-economic parameters; and on the other, is the government/competent authority batting for a cautious but optimistic approach furthering scientific and agricultural development, underscoring its importance in line with growing concerns of food security, population, economics and other matters of national interest.

9. The former argues the dangers of unpredictability, unknowability of the effect of human intervention in seed production and otherwise pushes for the adoption of a precautionary approach while the latter insists on a stand which is not governed by fear of the unknown and the importance of backing scientific advancement and adventures, exploring its positive aspects and their integration into human society. This Court now hangs in the balance, upon being asked to adjudicate these *prima facie* well

founded concerns and interests which are ostensibly at variance with one another.

10. Throughout this judgment, certain terms will form the mainstay of the discussion, and adequate understanding of which, is imperative for arriving at a just conclusion. At the core, the question revolves around genetically modified organisms, their regulation and release into the environment. For ease of understanding, some of those terms are defined at the outset.

10.1 Genetically Modified Organisms (**hereinafter referred to as 'GMOs'**) have been defined by the World Health Organisation (WHO) as follows:

> "Genetically modified organisms (GMOs) can be defined as organisms (i.e. plants, animals or microorganisms) in which the genetic material (DNA) has been altered in a way that does not occur naturally by mating and/or natural recombination. The technology is often called "modern biotechnology" or "gene technology", sometimes also "recombinant DNA technology" or "genetic engineering". It allows selected individual genes to be transferred from one organism into another, also between nonrelated species."

10.2 GMOs, for our purposes, have two types- Bt (Bacillus thuringiensis) [a preparation of a bacterium (*Bacillus*

Thuringiensis) often modified by genetic engineering for use as a biopesticide against insects and especially lepidopteran larvae[1]], and Ht (Herbicide Tolerant). [Herbicide-tolerant crops can be produced by either insertion of a "foreign" gene from another organism into a crop, or by regenerating herbicide-tolerant mutants from existing crop germplasm.[2]]

10.3 Genetic Engineering Approval[3] Committee (**hereinafter referred to as 'GEAC'**) is a committee constituted under The Manufacture, Use, Import, Export And Storage Of Hazardous Micro Organisms Genetically Engineered Organisms Or Cells Rules, 1989 (**hereinafter referred to as '1989 Rules'**) which are in turn framed under the Environment Protection Act, 1986 (**hereinafter referred to as EPA, 1986**) responsible for approval of proposals relating to release of genetically engineered organisms

[1] Merriam Webster dictionary https://www.merriam-webster.com/dictionary/Bt
[2] https://extensionpubs.unl.edu/publication/g1484/html/view#target2
[3] The name of GEAC, Genetic Engineering Approval Committee, stands substituted by Genetic Engineering Appraisal Committee vide Gazette Notification dated 22.7.2010.

and products into the environment including experiment Field trials.

10.4 Review Committee on Genetic Manipulation (**hereinafter referred to as 'RCGM'**) is a committee under 1989 Rules tasked with monitoring the safety related aspects in respect of on-going research projects and activities involving genetically engineered organisms/hazardous microorganisms.

Procedural History

11. This Court has been actively engaged since 2004, with regard to the trial of GMOs, which is the subject matter at hand. Over the intervening years, this Court has issued a slew of orders and accordingly, in the subsequent paragraphs, I have traced the brief history of them.

11.1 On 29.03.2004, notice was issued in the matter. Thereafter, on 01.05.2006, this Court directed that the field trials of GMOs shall be conducted only with the express approval of the GEAC. On 22.09.2006, it was

directed that the GEAC will withhold approvals until further orders of this Court and it was suggested to the Union of India, that they should consider associating independent experts in the GEAC.

11.2 On 13.10.2006, this Court granted permission to plant the newly developed DMH-11 (Mustard) for experimental purpose in specifically identified fields. Thereafter, on 15.12.2006, the attention of this Court was drawn to Clause (23) of the Convention on Biological Diversity, which recommended that there is inadequate basis to assess the potential risks of genetic use technologies due to which the use of products involving this technology or field testing should not be approved till there is appropriate scientific data, in accordance with the precautionary principle. Taking note of this, the Court directed the GEAC to consider the impact of field testing being carried out.

11.3 On 15.02.2007, this Court recorded the submission of the Union of India that within 6 weeks, it would bring on

record the implications and the biological results of the field tests being conducted.

11.4 Thereafter, on 08.05.2007, the Union of India sought modification of the order dated 22.09.2006 whereby further approvals by GEAC were halted. This Court allowed the GEAC to consider applications for use of Bt Cotton varieties for commercial use, subject to the usual conditions imposed provided that the GEAC verifies the creation of any toxicity with the use of varieties of Bt Cotton. It further directed the GEAC:

a. To take sufficient precautions to see that the trials are not causing any contamination to the cultivation of neighbouring fields.
b. Distance of at least 200 meters to be maintained from the neighbouring fields having the same type of cultivations.
c. Names of scientists and other details of the person responsible for all aspects of the trial should be recorded with the GEAC.

11.5 On 01.08.2007, this Court recorded the submission of the learned Additional Solicitor General, that allergenicity and toxicity tests have been conducted on Bt Cotton and the information would be put on the website of the GEAC.

11.6 On 08.04.2008, the Petitioners sought modification of order dated 08.05.2007, to the effect that the distance between fields must depend on the nature of the crop. Further, the Petitioners contended that the validated protocol for field testing should be 0.01%. This Court directed the GEAC to examine both these issues and recorded the submission of the learned Additional Solicitor General that the data *qua* Bt brinjal and Bt cotton has been put on the website of the GEAC.

11.7 On 12.08.2008, the Petitioners raised objection to non-compliance of Order dated 08.04.2008, thereafter, this Court directed the Union of India to file proof regarding compliance of the said order.

11.8 Pertinently, vide Order dated 10.05.2012, this Court appointed a Technical Expert Committee **(hereinafter "TEC")** to look into various issues raised in the pleadings before the Court and submit a report within 3 months. The members of this Committee were: 1. Prof. VL Chopra; 2. Dr. Imran Siddiqui; 3. Dr. PS Ramakrishna; 4. Prof. PC Chauhan; 5. Prof. PC Kesavan and 6. Dr. B Siva Kumar. Vide this Order, the Court also granted TEC the liberty to file an interim report, in case the final report is not prepared within the abovementioned time period. The terms of reference and the report of the TEC will be discussed in detail in the discussion which follows.

11.9 The interim report of the TEC was received by this Court on 07.10.2012. *Vide* order dated 09.11.2012, the Union of India was directed to file its objections to the interim report, with the TEC itself for consideration. Furthermore, in place of Prof. VL Chopra, Dr. Rajendra Singh Paroda was appointed as a member of the Committee. On

23.08.2013, this Court acknowledged receipt of the final report of the TEC.

11.10 Thereafter, on 07.10.2016, the Union of India submitted that no release of GMOs will be made till 17.10.2016 since the Government has sought views from the public and on receipt of such views, they will be considered by a committee of experts. On 22.11.2017, when this matter was taken up for consideration, the Union of India apprised the Court that it had not taken a final decision, on the issue of plantation of GM Mustard and that all stakeholders shall be considered before taking a final decision.

11.11 Coming to the present timeline, on 18.10.2022 the GEAC granted conditional approval for conducting trials of DMH-11/GM Mustard. The same was communicated to the applicants on 25.10.2022. In terms of the above developments, the Petitioners have handed over updated prayers in Court seeking:

i. Complete ban on Ht Crops. The decision of GEAC to approve release of DMH-11 is violative of Article 14 and Article 21 of the Constitution of India being vitiated by non-application of mind.

ii. The overall process of risk assessment must be in conformity with the Cartagena Protocol on Biosafety.

iii. Stakeholder participation, socioeconomic considerations, societal impact and sustainability should be incorporated in the risk assessment process at an early stage.

iv. Studies must be conducted by the Regulatory Body itself and the regulator must not depend solely on the data provided by the applicant itself.

v. The Biosafety Dossier containing results of these studies must be published on the website of the GEAC.

vi. Confined Field Trials should be only in isolated conditions to prevent any contamination in ICAR institutes/State Agricultural Universities.

vii. No Genetically Modified Crops should be permitted where India is the centre of origin or diversity.

viii. There should be chronic toxicity testing in terms of long-term exposure before declaring those crops safe.

ix. State of the art bio-regulatory systems must be set up in collaboration with countries having the necessary expertise in socio-economic risk assessment.

Statutory Framework

12. At the outset, it is imperative to discuss the statutory framework relating to GMOs. The Seeds Act enacted by the Legislature in 1966, notified on 29.12.1966, regulates the quality of seeds for sale and other connected matters. S.3 of this Act, created the Central Seed Committee to advise the Government on matters relating to the said Act. S.4 mandates creation of the Central Seed Laboratory and State Seed Laboratory. S.7 regulates the sale of certain varieties of seeds, which have been so notified.

13. The Insecticides Act, 1968 was enacted to regulate the use of insecticides with a view to prevent risk to human beings or animals. S.4 of this Act, constitutes the Central Insecticides Board to "*advise the Central Government and State Government*

on technical matters arising out of the administration of this Act." S.5 constitutes a Registration Committee, to "*register insecticides after scrutinising their formulae and verifying claims made by the importer or the manufacturer, as the case may be, as regards their efficacy and safety to human beings and animals*."

14. The EPA, 1986 was enacted with a view to improve the environment and its protection mechanisms.

i. Under the definition Clause, S.2, certain terms require reference:

> "(a) "environment" includes water, air and land and the inter- relationship which exists among and between water, air and land, and human beings, other living creatures, plants, micro-organism and property;
>
> (b) "environmental pollutant" means any solid, liquid or gaseous substance present in such concentration as may be, or tend to be, injurious to environment;
>
> (c) "environmental pollution" means the presence in the environment of any environmental pollutant;
>
> x x x
>
> (e) "hazardous substance" means any substance or preparation which, by reason of its chemical or physico-chemical properties or handling, is liable to cause harm to human beings, other living creatures, plant, micro-organism, property or the environment;
>
> (f) "occupier", in relation to any factory or premises, means a person who has, control over the affairs of

> the factory or the premises and includes in relation to any substance, the person in possession of the substance;"

ii. S.3 of the Act empowers the Central Government to undertake wide-ranging measures for the protection and improvement of the environment. S.3(2) lays down the matters wherein such measures are to be exercised. Some pertinent areas are:

> "…..
>
> (vi) laying down procedures and safeguards for the prevention of accidents which may cause environmental pollution and remedial measures for such accidents;
>
> (vii) laying down procedures and safeguards for the handling of hazardous substances;
>
> (viii) examination of such manufacturing processes, materials and substances as are likely to cause environmental pollution;
>
> (x) inspection of any premises, plant, equipment, machinery, manufacturing or other processes, materials or substances and giving, by order, of such directions to such authorities, officers or persons as it may consider necessary to take steps for the prevention, control and abatement of environmental pollution;
>
> (xi) establishment or recognition of environmental laboratories and institutes to carry out the functions entrusted to such environmental laboratories and institutes under this Act;"

iii. S.5 empowers the Central Government to issue directions to any person for the purposes of the Act, and such person will be bound to comply with such directions.

iv. S.6 further provides the Central Government with the power to make rules for the matters enumerated in S.3. Particularly, the following have been expressly laid down in S.6(2), amongst others:

> "…
>
> (b) the maximum allowable limits of concentration of various environmental pollutants (including noise) for different areas;
>
> (c) the procedures and safeguards for the handling of hazardous substances;
>
> (d) the prohibition and restrictions on the handling of hazardous substances in different areas;"

v. S.7 prohibits the discharge of environmental pollutants in excess of the standards as may be prescribed under S.3. S.8 provides that those persons handling hazardous substances shall not do so except in accordance with the procedure and safeguards prescribed in respect thereto.

vi. S.10 empowers the Central Government or any person empowered under it with the power of entry and inspection at all reasonable times, for the following purposes:

> "(a) for the purpose of performing any of the functions of the Central Government entrusted to him;
>
> (b) for the purpose of determining whether and if so in what manner, any such functions are to be performed or whether any provisions of this Act or the rules made thereunder or any notice, order, direction or authorisation served, made, given or granted under this Act is being or has been complied with;
>
> (c) for the purpose of examining and testing any equipment, industrial plant, record, register, document or any other material object or for conducting a search of any building in which he has reason to believe that an offence under this Act or the rules made thereunder has been or is being or is about to be committed and for seizing any such equipment, industrial plant, record, register, document or other material object if he has reason to believe that it may furnish evidence of the commission of an offence punishable under this Act or the rules made thereunder or that such seizure is necessary to prevent or mitigate environmental pollution."

vii. S.11 empowers the Central Government or any person empowered under it with the power to take samples of air, water, soil or other substances and lays down detailed procedure to be followed for this purpose.

viii. S.12 permits the Central Government to establish and recognise laboratories or institutes to carry out functions enumerated for such laboratories which have to be notified in the gazette in accordance with S.12(2).

ix. S.25 empowers the Central Government to make rules for carrying out the purposes of the Act. In particular, under S.25(2):

> "(a) the standards in excess of which environmental pollutants shall not be discharged or emitted under section 7;
>
> (b) the procedure in accordance with and the safeguards in compliance with which hazardous substances shall be handled or caused to be handled under section 8;
>
> x x x
>
> (e) the form in which notice of intention to have a sample analysed shall be served under clause (a) of sub section (3) of section 11;
>
> (f) the functions of the environmental laboratories, the procedure for the submission to such laboratories of samples of air, water, soil and other substances for analysis or test; the form of laboratory report; the fees payable for such report and other matters to enable such laboratories to carry out their functions under sub-section (2) of section 12;"

15. The 1989 Rules were enacted by the Central Government under the EPA, 1986 with a view to protecting the environment, nature

and health, in connection with the application of gene-technology and micro-organisms.

i. Rule 2 specifies the application of these rules. Clause 2 specifies that "*These shall apply to genetically engineered organisms micro-organisms and cells and correspondingly to any substances and products and food stuffs, etc. of which such cells, organisms or tissues hereof form part.*"

ii. Rule 3(3) defines Gene Technology as "*the application of the gene technique called genetic engineering, include self-cloning and deletion as well as cell hybridisation.*"

iii. Rule 3(4) defines Genetic Engineering as "*the technique by which heritable material, which does not usually occur or will not occur naturally in the organism or cell concerned, generated outside the organism or the cell is inserted into said cell or organism. It shall also mean the formation of new combinations of genetic material by incorporation of a cell into a host cell, where they occur naturally (self-cloning) as well as modification of an organism or in a cell by deletion and removal of parts of the heritable material.*"

iv. Rule 4(4) of the aforesaid rules, provide for setting up of the GEAC as a body under the Department of Environment, Forests and Wildlife, for approval of proposals relating to release of genetically engineered organisms and products into the environment, including experimental field trials. These proposals are to be examined from the environmental angle. Other committees therein, the membership of the GEAC and other aspects will come to be discussed in the foregoing paragraphs.

v. Rule 7 prohibits any import, export, manufacture, process or use of genetically engineered organisms except with the approval of the GEAC. It also provides that genetically engineered organisms for the purpose of research are only allowed in areas notified by the Ministry of Environment and Forests for this purpose under the EPA, 1986.

vi. Rule 9 empowers the GEAC to grant special approval for deliberate release of genetically engineered organisms.

vii. Rule 10 extends the requirement of approval of GEAC to all substances and products that contain genetically engineered organisms.

viii. Rule 13 provides for stipulation of terms and conditions while granting approval including terms and conditions as to the control to be exercised by the applicant, supervision, restriction on use, the layout of the enterprise and as to the submission of information to the State Biosafety Co-ordination Committee (**hereinafter referred to as 'SBCC'**) or to the District Level Committee **(hereinafter referred to as 'DLC')**. It lays down the time period for GEAC approval (cannot exceed 4 years) and specific criteria wherein the GEAC can revoke approval granted for a genetically engineered organism. Rule 14 gives an authority to GEAC for supervising the implementation of the conditions laid down while granting approval.

ix. Further, Rule 15 provides for penalties imposed for non-compliance of orders. The DLC or SBCC is empowered to take actions against person who is responsible for non-compliance. In situations which require immediate interference, DLC or SBCC could take action even without issuing any order or notice. DLC or SBCC are also empowered to take samples for a more detailed examination of organisms and cells and for

these purposes, these Committees could take assistance from any Government authority.

x. Rule 18 grants the GEAC and other committees, the power to carry out inspections.

xi. Rule 19 allows for appeal from the any decision made by the GEAC or the SBCC to the Appellate Authority (as may be appointed by the Ministry of Environment, Forests and Climate Change **(hereinafter referred to as 'MoEFCC')** within 30 days of such decisions.

16. In furtherance of the United Nations Convention on Biological Diversity, which has been ratified by India, The Biological Diversity Act, 2002 came to be introduced into the statute book. The aim and objective of this Act is to provide for conservation of biological diversity and its sustainable use. S.36 of this Act directs the Central Government to take measures for protection of biological diversity, its resources and habitats from environmental degradation and neglect.

17. The Food Safety and Standards Act, 2006 is aimed at laying down science based standards for articles of food and to ensure

availability of safe and wholesome food for human consumption. S.22 provides that no person shall manufacture, distribute or import any genetically modified articles of food or other articles of food enumerated therein.

Issues for Consideration

18. I have heard extensive arguments on both sides, Mr. Sanjay Parikh, Mr. Trideep Pais, learned senior counsel, learned Advocates-on-Record Mr. Prashant Bhushan and Dr. Ravindra Chingale for the Petitioners and, Mr. R. Venkatramani learned Attorney General, Mr. Tushar Mehta learned Solicitor General and Ms. Preeti Kumari for the Respondents. The judgment proposed by my esteemed colleague, Hon'ble Mrs. Justice B.V. Nagarathna, records in detail the submissions advanced by all the learned counsel and so, for the sake of brevity I avoid doing the same. Principally, following issues are to be considered :

    a. Whether the conditional approval of DMH-11 by the GEAC is vitiated be it by arbitrariness/delegation/non-application of mind or any other principle of law?

b. Whether in view of the precautionary principle, a complete ban on *Ht Crops* is warranted or if not, the suitable directions that are required to be given by this Court?

Here, it stands clarified that sub-issues/ancillary aspects to the above questions, have been dealt with as the opinion progresses.

Conditional Approval of the GEAC

19. The pressing challenge raised by the Petitioners, is the decision of the GEAC to conditionally approve environmental release of transgenic mustard, DMH-11 on varied grounds granted to the applicant namely the Centre for Genetic Manipulation of Crop Plants (CGMCP), University of Delhi, New Delhi. This Centre was set up to undertake research on genetic engineering and molecular breeding of oilseed brassicas[4]. Before adverting to the challenges made, this Court must note the timeline leading up to the impugned approval.

20. On 29.09.2010, in the 103rd GEAC Meeting was where for the first time approval was granted for BRL-I level trials at 3 locations,

[4] https://www.du.ac.in/index.php?page=centre-for-genetic-manipulation-of-crop-plants

namely, Krishi Vigyan Kendra, Kumher, Bharatpur, Rajasthan; Agricultural Research Station, Navgaon, Alwar, Rajasthan; Agricultural Research Station, Sriganganagar, Rajasthan. The Committee also approved the conduct of crossibility studies and limited seed production within the institutional research farm located at Jaunti village and Bawana, Delhi respectively. Thereafter on 21.09.2011, the GEAC granted further approval to conduct environmental safety studies on DMH-11. In the 121st meeting dated 18.07.2014, BRL-II trials in respect of DMH-11 were approved at different locations subject to submission of NOC from the State Government.

21. In the 126th Meeting of the GEAC, on 04.01.2016, a sub-committee was constituted to further deliberate on the issues raised during deliberations of DMH-11. This was followed by the GEAC on 11.05.2017, examining the report of this sub-committee and recommending the proposal for environmental release of DMH-11 with terms and conditions for further approval by Competent Authority. In the next meeting on 21.03.2018, the GEAC re-examined its decision to grant permission for

environmental release of DMH-11 and advised the applicant to undertake field demonstration studies on GM Mustard to generate additional data.

22. On 20.09.2018 in its 136th meeting GEAC approved the application and the protocols for conduct of field demonstration studies on honeybees and other pollinators prepared by University of Delhi and ICAR-AICRP on honeybees at two locations up to 5 acres in each location namely PAU, Ludhiana and IARI, New Delhi and, for conduct of two field studies to assess hybrid seed efficiency and for maintenance of male sterile barnase line bn 3.6.

23. This brings us to the 146th Meeting of GEAC held on 25.08.2022, wherein pursuant to a presentation by the applicant, the GEAC constituted a committee to examine availability of adequate evidence about impact of transgenic mustard on honeybees and other pollinators to assess the need for conducting field demonstration studies.

24. On 18.10.2022, the 147th Meeting of the GEAC was held wherein it considered the report of the Committee and recommended environmental release of DMH-11. Thereafter on 25.10.2022, a letter was issued to the Applicant stating that the environmental release of genetically engineered mustard/DMH-11 has been recommended. The following conditions, amongst others, were imposed on this release:

    i. The approval is for 4 years and renewable for two years at a time based on compliance report pursuant to Clause 13 of the 1989 Rules.

    ii. A Post-Release Monitoring Committee would be constituted by GEAC consisting of 2 subject matter external experts who will visit the growing sites of the approved biological material.

    iii. The Applicant shall provide detailed step by step testing procedures to the GEAC.

    iv. Usage of any formulation of herbicide is not permitted for cultivation in farmers' fields under any situation.

    v. Commercial use of DMH-11 hybrid shall be subject to Seeds Act, 1966.

vi. It is mandatory that all seed packets of DMH-11 and subsequent hybrids derived from the technology should be appropriately labelled indicating the contents including the name of the transgenes, physical and genetic purity etc., in English, Hindi and vernacular language(s).

Judicial Review of the Impugned Decision

25. The challenges raised by the Petitioners to this decision can be summarised as follows:

a. The GEAC could not have delegated its function to a sub-committee/expert committee, since it is not within the scope of the 1989 Rules.

b. Further, in any case, that the GEAC has not independently applied its mind to the report of its expert committee and has not considered other independent scientific reports.

25 (a) 1. At the outset, I must consider, the scope of judicial review to be exercised in such matters. This Court in the case of **N.D.**

Jayal v. **Union of India (3-Judge Bench)[5],** which related to the safety of dams, observed that:

> "**...**This Court cannot sit in judgment over the cutting edge of scientific analysis relating to the safety of any project. Experts in science may themselves differ in their opinions while taking decisions on matters related to safety and allied aspects. The opposing viewpoints of the experts will also have to be given due consideration after full application of mind. When the Government or the authorities concerned after due consideration of all viewpoints and full application of mind took a decision, then it is not appropriate for the court to interfere. Such matters must be left to the mature wisdom of the Government or the implementing agency. It is their forte. In such cases, if the situation demands, the courts should take only a detached decision based on the pattern of the well-settled principles of administrative law. If any such decision is based on irrelevant consideration or non-consideration of material or is thoroughly arbitrary, then the court will get in the way. Here the only point to consider is whether the decision-making agency took a well-informed decision or not. If the answer is "yes", then there is no need to interfere. The consideration in such cases is in the process of decision and not in its merits.**"**
>
> (Emphasis supplied)

25 (a) 2. Furthermore, this Court in the case **State of NCT of Delhi** v. **Sanjeev** (**2-Judge Bench**)[6] elaborated on when judicial

[5] (2004) 9 SCC 362
[6] (2005) 5 SCC 181

review should be exercised *vis-à-vis* decisions of the Government. It was observed:

> "16. If the power has been exercised on a non-consideration or non-application of mind to relevant factors, the exercise of power will be regarded as manifestly erroneous. If a power (whether legislative or administrative) is exercised on the basis of facts which do not exist and which are patently erroneous, such exercise of power will stand vitiated. (See CIT v. Mahindra and Mahindra Ltd. [(1983) 4 SCC 392 : 1983 SCC (Tax) 336 : AIR 1984 SC 1182]
>
> 17. The court will be slow to interfere in such matters relating to administrative functions unless decision is tainted by any vulnerability enumerated above; like illegality, irrationality and procedural impropriety. Whether action falls within any of the categories has to be established. Mere assertion in that regard would not be sufficient.
>
> x x x x
>
> 21. In other words, to characterise a decision of the administrator as "irrational" the court has to hold, on material, that it is a decision "so outrageous" as to be in total defiance of logic or moral standards. Adoption of "proportionality" into administrative law was left for the future.
>
> 22. These principles have been noted in the aforesaid terms in Union of India v. G. Ganayutham [(1997) 7 SCC 463 : 1997 SCC (L&S) 1806]. In essence, the test is to see whether there is any infirmity in the decision-making process and not in the decision itself. (See Indian Rly. Construction Co. Ltd. v. Ajay Kumar [(2003) 4 SCC 579 : 2003 SCC (L&S) 528]."
>
> (Emphasis supplied)

25 (a) 3. The scope of this judicial review of administrative action was also discussed by this Court in **Jagdish Mandal** v. **State**

of Orissa (**2 - Judge Bench**)[7]. In this case, the Court held that the purpose of judicial review is to check whether the decision has been made lawfully and not as to whether such decision is sound or not.

25 (a) 4. This Court in **Villianur Iyarkkai Padukappu Maiyam** v. **Union of India, (3-Judge Bench)[8]** observed that:

> "**167.** In the matter of policy decisions and economic tests the scope of judicial review is very limited. Unless the decision is shown to be contrary to any statutory provision or the Constitution, the Court would not interfere with an economic decision taken by the State. The court cannot examine the relative merits of different economic policies and cannot strike down the same merely on ground that another policy would have been fairer and better.
>
> …
>
> **169.** It is neither within the domain of the courts nor the scope of judicial review to embark upon an inquiry as to whether a particular public policy is wise or whether better public policy can be evolved. Nor are the courts inclined to strike down a policy at the behest of a petitioner merely because it has been urged that a different policy would have been fairer or wiser or more scientific or more logical. Wisdom and advisability of economic policy are ordinarily not amenable to judicial review. In matters relating to economic issues the Government has, while taking a decision, right to "trial and error" as long as both trial and error are bona fide and within the limits of the authority. For testing the correctness of a policy, the appropriate forum is Parliament and not the courts.

[7] (2007) 14 SCC 517
[8] (2009) 7 SCC 561

> **170**. Normally, there is always a presumption that the governmental action is reasonable and in public interest and it is for the party challenging its validity to show that it is wanting in reasonableness or is not informed with public interest. This burden is a heavy one and it has to be discharged to the satisfaction of the court by proper and adequate material. The court cannot lightly assume that the action taken by the Government is unreasonable or against public interest because there are a large number of considerations, which necessarily weigh with the Government in taking an action."
>
> (Emphasis supplied)

25 (a) 5. In **Academy of Nutrition Improvement** v. **Union of India, (2-Judge Bench)**[9] where the challenge to iodised salt was made and it was reiterated that:

> "…. courts should not rush in where even scientists and medical experts are careful to tread. The rule of prudence is that courts will be reluctant to interfere with policy decisions taken by the Government, in matters of public health, after collecting and analysing inputs from surveys and research. Nor will courts attempt to substitute their own views as to what is wise, safe, prudent or proper, in relation to technical issues relating to public health in preference of those formulated by persons said to possess technical expertise and rich experience."
>
> (Emphasis supplied)

[9] (2011) 8 SCC 274

25 (a) 6. A similar view was taken in **Lafarge Umiam Mining (P) Ltd.** v. **Union of India (3-Judge Bench)**[10], wherein this Court observed:

> "**119.** The time has come for us to apply the constitutional "doctrine of proportionality" to the matters concerning environment as a part of the process of judicial review in contradistinction to merit review. It cannot be gainsaid that utilisation of the environment and its natural resources has to be in a way that is consistent with principles of sustainable development and intergenerational equity, but balancing of these equities may entail policy choices. In the circumstances, barring exceptions, decisions relating to utilisation of natural resources have to be tested on the anvil of the well-recognised principles of judicial review. Have all the relevant factors been taken into account? Have any extraneous factors influenced the decision? Is the decision strictly in accordance with the legislative policy underlying the law (if any) that governs the field? Is the decision consistent with the principles of sustainable development in the sense that has the decision-maker taken into account the said principle and, on the basis of relevant considerations, arrived at a balanced decision? Thus, the Court should review the decision-making process to ensure that the decision of MoEF is fair and fully informed, based on the correct principles, and free from any bias or restraint. Once this is ensured, then the doctrine of "margin of appreciation" in favour of the decision-maker would come into play."
>
> (Emphasis supplied)

[10] (2011) 7 SCC 338

25 (a) 7. Recently in **Jacob Puliyel** v. **Union of India and Ors.**[11] **(2-Judge Bench)**, while considering the vaccination policy due to COVID-19, this Court reiterated the scope of judicial review with policy decisions of the executive. Arbitrariness, irrationality, perversity and mala fide will render the policy unconstitutional. Relying on **Delhi Development Authority** v. **Joint Action Committee, Allottee of SFS Flats (2-Judge Bench)**[12], this Court explained that a policy decisions can be subject to judicial review (a) if it is unconstitutional; (b) if it is *dehors* the provisions of the Act and the regulations; (c) if the delegatee has acted beyond its powers of delegation; (d) if the executive policy is contrary to the statutory or a larger policy. It was further stated:

> "22. This Court in a series of decisions has reiterated that courts should not rush in where even scientists and medical experts are careful to tread. The rule of prudence is that courts will be reluctant to interfere with policy decisions taken by the Government, in matters of public health, after collecting and analysing inputs from surveys and research. Nor will courts attempt to substitute their own views as to what is wise, safe, prudent or proper, in relation to technical issues relating to public health in preference to those formulated by persons said to possess technical expertise and rich experience.

[11] 2022 SCCOnline SC 533
[12] (2007) 4 SCC 737

> Where expertise of a complex nature is expected of the State in framing rules, the exercise of that power not demonstrated as arbitrary must be presumed to be valid as a reasonable restriction on the fundamental right of the citizen and judicial review must halt at the frontiers. The Court cannot re-weigh and substitute its notion of expedient solution."

25 (a) 8. A perusal of the above decisions makes clear two important factors. It is evident that judicial review so far as economic or policy matters is concerned is circumscribed but at the same time it is also apparent that the scope of the possibility of the Court's intervention has been expanded over time. The generally accepted yardstick would be that the merits of a decision are ordinarily not examined to accommodate the possibility of a better alternative nor does it scuttle the government's ability to achieve the best outcome through trial and error but at the same time if any of the decisions made are such that the vires of the process would be affected or in other words, that the decision taken is compromised in regard to the manner in which it was arrived at, then, the Courts would be within terms to exercise its jurisdiction of judicial review.

25 (a) 9. Keeping in mind the above standard of judicial review, I now proceed to examine the first issue at hand.

25 (a) 10. Adverting to the first contention, the Petitioners have sought to place reliance on the judgment of this Court in **Kantha Vibhag Yuva Koli Samaj Parivartan Trust** v. **State of Gujarat** (**2-Judge Bench**)[13], wherein this Court while considering the functions of the NGT observed:

> "**16.** Sections 14 and Section 15 entrust adjudicatory functions to the NGT. The NGT is a specialized body comprising of judicial and expert members. Judicial members bring to bear their experience in adjudicating cases. On the other hand, expert members bring into the decision-making process scientific knowledge on issues concerning the environment. In ***Hanuman Laxman Aroskar* v. *Union of India*** **(2019) 15 SCC 401**, a two-Judge Bench of this Court noted that the NGT is an expert adjudicatory body on the environment. The Court held:
>
> "*133. The NGT Act provides for the constitution of a tribunal consisting both of judicial and expert members. The mix of judicial and technical members envisaged by the statute is for the reason that the Tribunal is called upon to consider questions which involve the application and assessment of science and its interface with the environment…*
>
> *134. NGT is an expert adjudicatory body on the environment.*"

[13] 2022 SCC Online SC 120

> **17.** The NGT does not have a dearth of 'expertise' when it comes to the issues of environment.
>
> **18.** Section 15 empowers the NGT to award compensation to the victims of pollution and for environmental damage, to provide for restitution of property which has been damaged and for the restitution of the environment. The NGT cannot abdicate its jurisdiction by entrusting these core adjudicatory functions to administrative expert committees. Expert committees may be appointed to assist the NGT in the performance of its task and as an adjunct to its fact-finding role.**"**
>
> (Emphasis supplied)

25 (a) 11. This decision has come to be followed by this Court in **Singrauli Super Thermal Power Station** v. **Ashwani Kumar Dubey (2-Judge Bench)**[14].

25 (a) 12. Keeping in view of the above, what this Court must examine is whether in the appointment and acceptance of the recommendation of the expert committee, the GEAC has delegated its *core* function, in view of the 1989 Rules.

25 (a) 13. Under the 1989 Rules, the GEAC functioning as a body under the Department of Environment, Forests and Wildlife has been made responsible for approval of proposals relating to release of genetically engineered organisms and products

[14] (2023) 8 SCC 35

into the environment including experimental field trials. Therefore, the primary function that has been given to the GEAC, is this process of granting approvals. The composition of this Committee, along with representatives from different departments of the executive, has to include three outside experts in individual capacity.

25 (a) 14. On a perusal of the timeline for conditional approval of DMH-11, the GEAC has constituted a sub-committee and expert committee respectively, in its 126th and 146th meeting, with a specific purpose on each occasion. In my considered view, this cannot be said to be delegating its core function.

25 (a) 15. In **Kantha Vibhag Yuva Koli Samaj (supra)**, which the Petitioners place reliance on, the body involved, i.e., the NGT exercises judicial functions, which is clearly distinct from the GEAC which is responsible for granting approvals for the release of GMOs and not performing any quasi-judicial function. Therefore, it cannot be said that the exposition in the above case, applies squarely to the case at hand.

25 (a) 16. Furthermore, in the said decision, it was explicitly stated in paragraph 22 that *"expert committees may be appointed to assist the NGT in the performance of its task and as an adjunct to its fact-finding role".* In my view, this is squarely, the function performed by the sub-committee/expert committee constituted by the GEAC, i.e., assistance in granting approvals.

25 (a) 17. The present factual circumstance is not a case, where the approval process itself has been delegated to the sub-committee/expert committee. A specific purpose was set out for the committee, on which a report was submitted back to the GEAC. Illustratively, the mandate of the expert committee may be referred to, the relevant extract is as under:

> "…In accordance with the decision taken in the aforementioned meeting of the GEAC, the Expert Committee has been constituted to examine the claim of CGMCP, University of Delhi in respect of availability of adequate evidence about impact of transgenic mustard on honey bees and other pollinators, in order to assess the need for conducting field demonstration studies on honeybees and other pollinators."

25 (a) 18. It is evident from the above extract that the expert committee was constituted for a limited purpose and was only a part of the larger decision-making process. On the perusal of said report and other materials, the impugned decision came to be passed.

25 (a) 19. As submitted on behalf of Union of India, a Constitution Bench of this Court in **State of U.P.** v. **Batuk Deo Pati Tripathi (5-Judge Bench)**[15] expounded that:

> "**10**... The power to do a thing necessarily carries with it the power to regulate the manner in which the thing may be done. It is an incident of the power itself and indeed, without it, the exercise of the power may in practice be fraught with difficulties which will frustrate, rather than further, the object of the power. It is undoubtedly true that the rules framed for prescribing the manner in which a power may be exercised have to be truly regulatory in character."
>
> (Emphasis supplied)

25 (a) 20. This decision was followed in **Khargram Panchayat Samiti** v. **State of West Bengal (2-Judge Bench)**[16], wherein it was observed:

> "**5....** It had earlier been laid down by a Constitution Bench in the case of State of U.P. v. Batuk Deo Pati

[15] (1978) 2 SCC 102
[16] (1987) 3 SCC 82

> Tripathi [(1978) 2 SCC 102 : 1978 SCC (L & S) 147] that a power to do a thing necessarily carries with it the power to regulate the manner in which the thing may be done. The High Court failed to appreciate that the power to grant a licence for the holding of a hat or fair under Section 117 of the Act necessarily carries with it the power to specify a day on which such hat or fair shall be held. Such power to specify a day must be held to be a power incidental to or consequential upon the principal power of issuing a licence under Section 117 of the Act for holding of a hat or fair. The Rules or the absence of it do not detract from the substantive power conferred by a statute."
>
> (Emphasis supplied)

25 (a) 21. Applying the above observations of this Court, would mean that the power of the GEAC, to grant approvals, necessarily carries with it the power to regulate the manner, in which the approvals are so granted. The mere absence of a specific statement in the 1989 Rules allowing assistance of expert committees, would not preclude the GEAC from doing so, in furtherance of its main objective.

25 (a) 22. Reference must also be made to the decision of this Court in **Inspector General of Registration** v. **K. Baskaran (2-Judge Bench)**[17]**,** wherein after consideration of a number of judgments concluded as under:

[17] (2020) 14 SCC 345

> "**14.** The following principles can thus be culled out from the decisions of this Court: (*i*) A statutory functionary exercising a power cannot be said to have delegated his functions merely by deputing a responsible and competent official to enquire and report, as that is the ordinary mode of exercise of any administrative power; (*ii*) If a statutory authority empowers a delegate to undertake preparatory work, and to take an initial decision in matters entrusted to it, but retains in its own hands the power to approve or disapprove the decision after it has been taken, the decision will be held to have been validly made if the degree of control maintained by the authority is close enough for the decision to be regarded as the authority's own; (*iii*) Even in cases of sub-delegation, so long as the essential function of decision-making is performed by the delegate, the burden of performing the ancillary and clerical task need not be shouldered by the primary delegate and it is not necessary that the primary delegate himself should perform the ministerial acts as well; and (*iv*) Practical necessities or exigencies of administration require that the decision-making authority who has been conferred with statutory power, be able to delegate tasks when the situation so requires."
>
> (Emphasis supplied)

25 (a) 23. Therefore, in view of the above conspectus, the decision of the GEAC cannot be said to be vitiated by delegation.

25 (b) 1. Another challenge that has been laid by the Petitioners to the impugned decision, is non-application of mind. In my considered view, this submission does not stand.

25 (b) 2. The expert committee appointed in the 146th meeting of the GEAC dated 25.08.2022, submitted its report and a reading

of the same would show that a barnase/barstar proteins introduced in GE Mustard are not novel to honeybees and thus they do not discriminate between GE and non GE canola, it further relied on data collected from Canada and Australia. Pursuant to which it recommended the environmental release of GE Mustard. The conditional approval granted *vide* letter dated 08.10.2022 of the MoEFCC shows that the approval so granted was on the basis of multiple documents and not only the comments of the expert committee, as alleged by the Petitioners. Considering the importance of the issue, the potential magnitude of its (the decision of the GEAC's) impact, it was found prudent by the decision-making authority to call for the comments of the Department of Biotechnology (received on 01.08.2022) and the Department of Agricultural Research and Education (received on 30.07.2022), which are departments under their respective Ministries. It would be apposite to briefly advert to their mission, roles, responsibilities and mandates.

Department of Biotechnology under the Ministry of Science and Technology:

"Mission

…The Department shall provide services in the areas of research, infrastructure, generation of human resource, popularization of biotechnology, promotion of industries, creation of centers of excellence, implementation of biosafety guidelines for genetically modified organisms and recombinant DNA products and biotechnology-based programs for societal benefits. Bioinformatics is a major mission to establish an information network for the scientific community, nationally and internationally.

Mandate

…

- Promote large scale use of Biotechnology
- Support R&D and manufacturing in Biology

…

- Serve as Nodal Point for specific International Collaborations
- Establishment of Infrastructure Facilities to support R&D and production

…

- Evolve Bio Safety Guidelines, manufacture and application of cell based vaccines
- Serve as nodal point for the collection and dissemination of information relating to biotechnology."

(Emphasis supplied)

Department of Agricultural Research and Education under the Ministry of Agriculture

"About the Departments

…

DARE provides the necessary government linkages for the Indian Council of Agricultural Research (ICAR), the premier research organisation for co-ordinating, guiding and managing research and education in

agriculture including horticulture, fisheries and animal sciences in the entire country. With over 97 ICAR institutes, 53 agricultural universities, 6 Bureaux, 18 National Research Centres, 25 Project Directorates, and 89 All India Coordinated Research Projects spread across the country this is one of the largest national agricultural research systems in the world.

Mission

Interfacing agricultural research and technology, higher education and frontline extension initiatives with institutional, infrastructural and policy support for sustainable growth of agriculture.

Major Functions

- To look after all aspects of the agricultural research and Education (including horticulture, natural resources management, agriculture engineering, agricultural extension, animal science, economic statistics and marketing and fisheries) involving coordination between the central and state agencies.
- To attend all matters relating to Indian Council of Agricultural Research.
- To attend all matters concerning the development of new technology in agriculture, horticulture, natural resources management, agriculture engineering, agricultural extension, animal science, economic statistics and marketing and fisheries, including such functions as plant and animal introduction and exploration and soil and land use survey and planning.
- International co-operation in the field of agricultural research and education including relations with foreign and international agricultural research and educational institutions and organizations, including participation in international conferences, associations and other bodies dealing with agricultural research and education and follow-up decisions at such international conferences etc.
- Fundamental, applied and operational research and higher education including co-ordination of such research and higher education in agriculture including agro forestry, animal husbandry, dairying,

fisheries, agricultural statistics, economics and marketing."

(Emphasis Supplied)

25 (b) 3. Taking in consideration all the above aspects, one cannot possibly fault the GEAC in asking for the opinion and understanding of these two departments. Having so received their comments, an expert committee within the GEAC was formed to evaluate the presence/absence of sufficient literature regarding the effect of GM crops on honeybees, exemption from further trial for which, was sought by the applicant. This Committee then, also considered such comments and gave its finding, in conformity with the mandate given to it.

25 (b) 4. Also, it is to be noted that the conditional release of DMH-11 was made subject to several conditions including, among others, that the MoEFCC/GEAC may impose further conditions as may be necessary. Such conditions include the revocation of approval in case adverse impact is shown on environment or human health; it is made subject to other statutory clearances including the clearance from Food Safety and Standards Authority of India, Seeds Act. Additionally, it imposes certain

obligations on the applicant including obligation to inform regulatory bodies as soon as any adverse impact is shown; obligation to submit annual/seasonal report of the yield etc. to the GEAC.

25 (b) 5. Therefore, the contentions that the primary function of the GEAC has been delegated to the expert committee and that it was granted without application of mind is sufficiently contravened by record. In that view of the matter, the conditional approval of DMH-11 granted by the GEAC, is upheld as being independent, reasoned and in consonance with the rules.

Constitutionality of the 1989 Rules

26. The Petitioners have also laid challenge to the constitutional validity of the 1989 Rules on the ground that they are violative of Article 14 and Article 21 of the Constitution of India. The primary prong of this attack is that the constitution of the GEAC, in the submission of the Petitioners is lopsided with bureaucratic influence with the same being evidenced by the top three positions therein being occupied by such persons. Before delving into the substance of the challenge, it would be apposite to appreciate

certain pronouncements of this Court wherein such challenges were adjudicated.

26.1. In the landmark case of **E.P. Royappa** v. **State of T.N.** [18] **(5-Judge Bench)**, this Court while dealing with Article 14 and Article 16 observed that :

> "In fact equality and arbitrariness are sworn enemies; one belongs to the rule of law in a republic while the other, to the whim and caprice of an absolute monarch. Where an act is arbitrary, it is implicit in it that it is unequal both according to political logic and constitutional law and is therefore violative of Article 14, and if it effects any matter relating to public employment, it is also violative of Article 16. Articles 14 and 16 strike at arbitrariness in State action and ensure fairness and equality of treatment. They require that State action must be based on valid relevant principles applicable alike to all similarly situate and it must not be guided by any extraneous or irrelevant considerations because that would be denial of equality. Where the operative reason for State action, as distinguished from motive inducing from the antechamber of the mind, is not legitimate and relevant but is extraneous and outside the area of permissible considerations, it would amount to mala fide exercise of power and that is hit by Articles 14 and 16. Mala fide exercise of power and arbitrariness are different lethal radiations emanating from the same vice: in fact the latter comprehends the former. Both are inhibited by Articles 14 and 16."
>
> (Emphasis supplied)

[18] (1974) 4 SCC 3

26.2. On similar lines, in **State of T. N. & Ors.** v. **Ananthi Ammal**[19] **(3-Judge Bench)** this Court observed:

> "*7.* When a statute is impugned under Article 14 what the court has to decide is whether the statute is so arbitrary or unreasonable that it must be struck down. At best, a statute upon a similar subject which derives its authority from another source can be referred to, if its provisions have been held to be reasonable or have stood the test of time, only for the purpose of indicating what may be said to be reasonable in the context..."
>
> (Emphasis supplied)

26.3. Furthermore, in **State of A.P.** v. **McDowell & Co.,**[20] **(3-Judge Bench),** this Court observed that the restrictions on the law-making power of legislatures is similar to those under the Federal Constitution of the United States of America. The two grounds on which a law made by the Parliament or the legislature can be struck down are - (1) lack of legislative competence; and (2) violation of any of the fundamental rights guaranteed in Part III of the Constitution or of any other constitutional provision. There is no third ground. It held:

[19] (1995) 1 SCC 519
[20] (1996) 3 SCC 709

> "43. ... The main criticism against the ground of substantive due process being that it seeks to set up the courts as arbiters of the wisdom of the legislature in enacting the particular piece of legislation. It is enough for us to say that by whatever name it is characterised, the ground of invalidation must fall within the four corners of the two grounds mentioned above. In other words, say, if an enactment is challenged as violative of Article 14, it can be struck down only if it is found that it is violative of the equality clause/equal protection clause enshrined therein. Similarly, if an enactment is challenged as violative of any of the fundamental rights guaranteed by sub-clauses (*a*) to (*g*) of Article 19(1), it can be struck down only if it is found not saved by any of the clauses (2) to (6) of Article 19 and so on. No enactment can be struck down by just saying that it is arbitrary or unreasonable. Some or other constitutional infirmity has to be found before invalidating an Act. An enactment cannot be struck down on the ground that the court thinks it unjustified. Parliament and the legislatures, composed as they are of the representatives of the people, are supposed to know and be aware of the needs of the people and what is good and bad for them. The court cannot sit in judgment over their wisdom**.** In this connection, it should be remembered that even in the case of administrative action, the scope of judicial review is limited to three grounds, viz., (*i*) unreasonableness, which can more appropriately be called irrationality, (*ii*) illegality and (*iii*) procedural impropriety."
>
> (Emphasis supplied)

26.4. In **Onkar Lal Bajaj** v. **Union of India[21] (2-Judge Bench),** it was held:

> "**27.** Article 14 guarantees to everyone equality before law. Unequals cannot be clubbed. The proposition is well settled and does not require reference to any precedent though many decisions were cited.

[21] (2003) 2 SCC 673

> Likewise, an arbitrary exercise of executive power deserves to be quashed, is a proposition which again does not require support of any precedent. It is equally well settled that an order passed without application of mind deserves to be annulled being an arbitrary exercise of power. At the same time, we have no difficulty in accepting the proposition urged on behalf of the Government that if two views are possible and the Government takes one of it, it would not be amenable to judicial review on the ground that the other view, according to the court, is a better view."
>
> (Emphasis supplied)

26.5. In **5 M & T Consultants** v. **S.Y. Nawab (2-Judge Bench)**[22] this Court reiterated the principle given in **Delhi Science Forum** v. **Union of India (3-Judge Bench)**[23] wherein it was observed:

> "…parting with privilege exclusively vested with the Government must be reasonably rational and in the public interest besides conforming to law governing the same and the decision pertaining to the same can be questioned only on grounds of bad faith, being based on irrational or irrelevant considerations, non-compliance with the prescribed procedure or violation of any constitutional or statutory provision and the onus in respect of establishing the same not only heavily rests on the person alleging it but it is not satisfied by merely raising a doubt in the mind of the Court as to the validity of the decision."

[22] (2003) 8 SCC 100
[23] (1996) 2 SCC 405

26.6. In order to declare a legislation violative of Article 14 of the Constitution of India, arbitrariness on the part of the legislature should, ordinarily, be manifest arbitrariness, as has been held by this Court in **Bombay Dyeing & Mfg. Co. Ltd. (3)** v. **Bombay Environmental Action Group (2-Judge Bench)**[24].

26.7. Similarly, in **A.P. Dairy Development Corpn. Federation** v. **B. Narasimha Reddy, (2-Judge Bench)**[25], this Court held that substantive unreasonableness should be shown in the statute itself in order to declare it ultra vires the Constitution. It has been held that

> "A party has to satisfy that the action was reasonable, not done in unreasonable manner or capriciously or at pleasure without adequate determining principle, rational, and has been done according to reason or judgment, and certainly does not depend on the will alone. However, the action of the legislature, violative of Article 14 of the Constitution, should ordinarily be manifestly arbitrary."

26.8. The principle that to declare an Act *ultra vires* under Article 14, the Court must be satisfied in respect of substantive

[24] (2006) 3 SCC 434
[25] (2011) 9 SCC 286

unreasonableness in the statute itself stood reiterated by this Court in **State of T.N.** v. **K. Shyam Sunder (3-Judge Bench)**[26].

26.9. Recently, this Court in **Association for Democratic Reforms & Anr** v. **Union of India & Ors. (5-Judge Bench)**[27], while relying on **Dharam Dutt** v. **Union of India (2-Judge Bench)**[28] extensively discussed this principle. It held as follows:

> *"***44.** The presumption of constitutionality is based on two premises. First, it is based on democratic accountability, that is, legislators are elected representatives who are aware of the needs of the citizens and are best placed to frame policies to resolve them. Second, legislators are privy to information necessary for policy making which the Courts as an adjudicating authority are not. However, the policy underlying the legislation must not violate the freedoms and rights which are entrenched in Part III of the Constitution and other constitutional provisions. It is for this reason that previous judgments of this Court have held that the presumption of constitutionality is rebutted when a prima facie case of violation of a fundamental right is established. The onus then shifts on the State to prove that the violation of the fundamental right is justified.*"*
>
> (Emphasis supplied)

[26] (2011) 8 SCC 737
[27] 2024 SCCOnline SC 661
[28] (2004) 1 SCC 712

26.10. A perusal of the judgments referred to supra shows two primary grounds upon which the validity of a legislation or, in our case Rules made under a legislation, may be put to challenge. One is legislative competence and the second is manifest arbitrariness. The former is not an aspect of challenge. In view of S.6 (*rules to regulate environmental pollution*), S.8 (*persons handling hazardous substances to comply with procedural safeguards*) and S.25 (*empowers the Central Government for making rules to carry out the purposes of the EPA*) of the EPA 1986, 1989 Rules were made to protect the environment, nature and health, in connection with the application of gene-technology and micro-organisms.

26.11. The latter, that is manifest arbitrariness, has been recognized as a ground upon which a legislative enactment can be judicially reviewed. [**See: K.S. Puttaswamy** v. **Union of India (5-Judge Bench)**[29] and **Madras Bar Association** v. **Union of India & Anr. (3-Judge Bench)**[30]] Equally, it is to be noticed that in **Indian Express Newspaper** v. **Union of India**

[29] (2019) 1 SCC 1
[30] (2022) 12 SCC 455

(3-Judge Bench)[31] it was stated that subordinate legislation can be challenged on any ground available against the plenary legislation. In other words, the distinction between subordinate and plenary legislation is erased when it comes to a challenge under Article 14 of the Constitution of India.

26.12. In **Khoday Distilleries Ltd.** v. **State of Karnataka (3-Judge Bench)**[32], this Court held :

> "13. It is next submitted before us that the amended Rules are arbitrary, unreasonable and cause undue hardship and, therefore, violate Article 14 of the Constitution. Although the protection of Article 19(1)(g) may not be available to the appellants, the Rules must, undoubtedly, satisfy the test of Article 14, which is a guarantee against arbitrary action. However, one must bear in mind that what is being challenged here under Article 14 is not executive action but delegated legislation. The tests of arbitrary action which apply to executive actions do not necessarily apply to delegated legislation. In order that delegated legislation can be struck down, such legislation must be manifestly arbitrary; a law which could not be reasonably expected to emanate from an authority delegated with the law-making power. In Indian Express Newspapers (Bombay) (P) Ltd. v. Union of India [(1985) 1 SCC 641 : 1985 SCC (Tax) 121], this Court said that a piece of subordinate legislation does not carry the same degree of immunity which is enjoyed by a statute passed by a competent legislature. A subordinate legislation may be questioned under Article 14 on the ground that it is unreasonable; 'unreasonable not in the sense of not being reasonable, but in the sense that it is manifestly

[31] (1985) 1 SCC 641
[32] (1996) 10 SCC 304

> arbitrary'. Drawing a comparison between the law in England and in India, the Court further observed that in England the Judges would say, 'Parliament never intended the authority to make such Rules; they are unreasonable and ultra vires'. In India, arbitrariness is not a separate ground since it will come within the embargo of Article 14 of the Constitution. But subordinate legislation must be so arbitrary that it could not be said to be in conformity with the statute or that it offends Article 14 of the Constitution."
>
> (Emphasis supplied)

26.13. In **Shayara Bano** v. **Union of India & Ors. (5-Judge Bench)**[33], RF Nariman J., while dissenting with the majority, observed :

> "Manifest arbitrariness, therefore, must be something done by the legislature capriciously, irrationally and/or without adequate determining principle. Also**,** when something is done which is excessive and disproportionate, such legislation would be manifestly arbitrary."
>
> (Emphasis supplied)

26.14. Neither in the limited pleadings made before this Court nor in the extensive oral arguments advanced was the point of the rules being allegedly manifestly arbitrary, addressed adequately. On an independent analysis, I am unable to find any of the aspects of manifest arbitrariness to have been met, much less on the ground that bureaucratic influence taints the

[33] (2017) 9 SCC 1

functioning of the GEAC. This aspect further stands amplified herein, later.

27. On a further count, this challenge, in my view fails. The 1989 Rules present a well-rounded mechanism to deal with GMOs and their introduction into fields of common usage.

27.1. Rule 4 of the 1989 Rules provide for the six different competent authorities to oversee the research and regulations in the field of GMOs, whose functions are elaborated herein.

i. **Recombinant DNA Advisory Committee (RDAC)** is responsible to review developments in Biotechnology at national and international levels and recommend safety regulations in recombinant research, use and applications from time to time.

ii. The committee - **Review Committee on Genetic Manipulation (RCGM)** - is made responsible to monitor the safety related aspect in respect of on-going research projects and activities involving genetically engineered organisms/hazardous microorganisms. It is further tasked with bringing out manuals of guidelines specifying procedure

for regulatory process with respect to activities involving GMOs in research, use and applications including industry with a view to ensure environmental safety. They are responsible to review all ongoing projects involving high risk category and controlled field experiments and to ensure that adequate precautions and containment conditions are followed as per the guidelines.

iii **Institutional Biosafety Committee (IBSC)** - They are given the responsibility to assist the occupier or any person (including research institutions handling microorganisms/genetically engineered organisms) in preparing an up to date on site emergency plan according to the manuals/guidelines of the RCGM and make available copies to the DLC/SBCC and the GEAC.

iv. **Genetic Engineering Approval Committee (GEAC)** - This committee is constituted for approval of activities involving large scale use of hazardous microorganisms and recombinants in research and industrial production from the environmental angle. It shall be responsible for approval of proposals relating to release of genetically engineered

organisms and products into the environment including experimental field trials. The committee or any person authorised by it, is empowered to take punitive action under the EPA, 1986.

v. **State Biotechnology Co-Ordination Committee (SBCC)** - At State level, this Committee has powers to inspect, investigate and take punitive action in case of violations of statutory provisions. It shall also periodically review the safety and control measures in various industries/institutions handling genetically engineered organisms/hazardous microorganisms.

vi. **District Level Committee (DLC)** - At the district level, in order to supervise the safety measures, this Committee is constituted wherever necessary under the District Collectors to monitor the safety regulations in installations engaged in the use of genetically modified organisms/hazardous microorganisms and its applications in the environment. It shall visit the installation engaged in activity involving genetically engineered organisms, hazardous microorganisms, formulate information chart, find out hazards and risks associated with each of these installations and coordinate

activities with a view to meeting any emergency. This Committee shall regularly submit its report to the SBCC/GEAC.

27.2. Rule 7 of the 1989 Rules deals with approval and prohibitions. It reads thus:

> "(1) No person shall import, export, transport, manufacture, process, use or sell any hazardous microorganisms or genetically engineered organisms/substances or cells except with the approval of the Genetic Engineering Approval Committee.
>
> (2) Use of pathogenic microorganism or any genetically engineered organisms or cell for the purpose of research shall only be allowed in laboratories or inside laboratory areas notified by the Ministry of Environment and Forests for this purpose under the Environment (Protection) Act, 1986.
>
> (3) The Genetic Engineering Approval Committee shall give directions to the occupier to determine or take measures concerning the discharge of micro-organisms/genetically engineered organisms or cells mentioned in the schedule from the laboratories, hospitals and other areas including prohibition of such discharges and laying down measures to be taken to prevent such discharges.
>
> (4) Any person operating or using genetically engineered organism microorganisms mentioned in the schedule for scale up or pilot operations shall have to obtain licence issued by the Genetic Engineering Approval Committee for any such activity. The possessor shall have to apply for licence in prescribed proforma.

> (5) Certain experiments for the purpose of education within the field of gene technology or microorganism may be carried out outside the laboratories and laboratory areas mentioned in subrule (2) and will be looked after by the Institutional Biosafety Committee."
>
> (Emphasis supplied)

27.3. Rule 10 states that except with the approval GEAC, no substances and products containing genetically engineered organisms or cells or microorganisms shall be produced, sold, imported or used.

27.4. Rule 12 provides for guidelines wherein person who applies for approval under the Rules 8-11 is obligated to submit information and make examinations or cause examinations to be made to elucidate its case, including examinations according to specific directions and at specific laboratories. Before obtaining the approval, it is his responsibility to make available an on-site emergency plan to the GEAC. Further, an obligation is imposed upon the person to whom an approval has been granted, to notify the GEAC of any change in or addition to the information already submitted.

27.5. Rule 13 provides for grant of approval and the same is reproduced herein:

> "(1) In connection with the granting of approval under rules 8 to 11 above, terms and conditions shall be stipulated, including terms and conditions as to the control to be excercised by the applicant, supervision, restriction on use, the layout of the enterprise and as to the submission of information to the State Biotechnology Co-ordination Committee or to the District Level Committee
>
> (2) All approvals of the Genetic Engineering Approval Committee shall be for a specified period not exceeding four years at the first instance renewable for 2 years at a time. The Genetic Engineering Approval Committee shall have powers to revoke such approval in the following situations:
>
> (a) If there is any new information as to the harmful effects of the genetically engineered organisms or cells.
>
> (b) If the genetically engineered organisms or cells cause such damage to the environment, nature or health as could not be envisaged when the approval was given, or
>
> (c) Non compliance of any condition stipulated by Genetic Engineering Approval Committee."
>
> (Emphasis supplied)

27.6. Rule 14 deals with general supervision of GEAC in the implementation of the terms and conditions laid down in connection with the approvals accorded by it and such supervision could be carried out through the SBCC or the State

Pollution Control Boards/DLC or through any person authorised in this behalf.

27.7. Rule 15 deals with penalties which can be imposed. It reads as:

> "(1) If an order is not complied with, the District Level Committee or State Biotechnology Coordination Committee may take measures at the expenses of the person who is responsible.
>
> (2) In cases where immediate interventions is required in order to prevent any damage to the environment, nature or health, the District level Committee or State Biotechnology Coordination Committee may take the necessary steps without issuing any orders or notice. The expenses incurred for this purpose will be repayable by the person responsible for such damage.
>
> (3) The State Biotechnology Co-ordination Committee /District Level Committee may take samples for a more detailed examination of organisms and cells.
>
> (4)The State Biotechnology Co-ordination Committee/District Level Committee shall be competent to ask for assistance from any other Government authority to carry out its instructions."

27.8. Rule 19, as noted above, provides for mechanism of appeal from the decision of GEAC.

27.9. The above extracted rules, as is evident lay down a clear mandate for functioning in respect of approvals that are to be granted by the GEAC. All aspects of immediate relevance are

covered thereunder, i.e., the monitoring of safety regulations, preparing on-site emergency plans, research, inspection, release, penalties, use and approval with respect to GMOs/hazardous microorganisms/cells. The existence of various committees with certain, specified responsibilities, their composition; the providing of procedure for the most essential function which is the grant of approvals; appeals on being dissatisfied therefrom (grant or denial) shows that each body within the Rules has a role to play and the fate of an application is not solely in the hands of one body. In none of these Rules could I find even the slightest hint of manifest arbitrariness. None of the parts of the Rules can be said to be irrational, capricious or without adequate determining principle, on the contrary, as displayed, a clear rationale is discernible.

27.10. In particular, the primary ground of challenge by the Petitioner as noticed above must be addressed. To do so, notice must also be taken of the Union of India's submission that it is mandatory for all expert/members/Government officials of

GEAC and RCGM to sign a declaration of independence, confirming that they have no involvement or financial interest in the development, promotion or commercialisation of GM/transgenic crops. Members are also required to inform the RCGM and GEAC in case they have a conflict of interest, in such cases, the member involved does not participate in the deliberations. It has to be said that the composition of one of the Committees framed under the Rules allegedly suffering from some infirmity is not sufficient ground in the least, to vitiate the Rules on the whole. At the same time, it is also recognised that the GEAC is the apex body and its constitution therefrom assumes importance. Therefore, if the Petitioners had any qualms about its members, their objections should have been limited only thereto. As a secondary aide, a sweeping submission has been made that the 1989 Rules violates the Precautionary Principle however, how that is so is yet unclear.

27.11. Adverting particularly to the composition of the GEAC, the relevant rule reads as under:

"The composition of the Committee shall be

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

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

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

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

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

(Emphasis supplied)

27.12. It is evident that the top position in the GEAC is occupied by a person of the rank of Additional Secretary to the Government of India and the Vice Chairman is the member of the Department of Biotechnology, however, other members such as in Clause (iii) while being Government employees, possibly are still members working in specialized departments whose knowledge and expertise would be relevant to the functioning

of GEAC. Expert members are those who are directors/heads of eminent institutions as also others in individual capacity. The GEAC is also given the freedom to co-opt other members as and when may be required. The constitution of this Committee itself ensures that bureaucrats, in *stricto senso*, do not outweigh the presence of experts therein.

27.13. The Petitioner(s) contend that since the experts made part of the process, are members of Government bodies, therefore, they arguably would be unfit to be appointed. Conversely, it is averred by the Union of India that there exists a three-tier safety assessment process which involves around 60 experts most of whom are external experts from public sector institutions and universities. The effect of accepting the submission of the Petitioner(s) would mean that a person of science, by being a member *simpliciter* of the Government body, would be discounted as an 'expert'. In other words, the effect would be that working for the Government is made equal to a curse, for experts who otherwise would have been inducted to the GEAC without batting so much as an eyelid.

27.14. Additionally, nowhere in the Rules can it be seen that the Chairman of the GEAC or any other 'bureaucratic member' possesses any additional power in the functioning of the body, nor has it come on record that without the Chairman or any other Government member, the quorum with which a decision is to be reached, is incomplete.

27.15. As such, challenge to the 1989 Rules, as a consequence of the above discussion fails.

Precautionary Principle

28. I now proceed to examine, the second principle issue, which is as to whether in view of the precautionary principle, a complete ban on Ht crops is warranted or if not, what are the suitable directions that are required to be given by this Court?

TEC

28.1. Before discussing the precautionary principle, the view of the TEC appointed by this Court must be brought on record when probing the issue at hand. As discussed above, *vide* Order dated 10.05.2012, this Court appointed a TEC with 6

members. The terms of reference **(hereinafter referred to as 'Tor')** given to the TEC were:

a. To review and recommend the nature of sequencing of risk assessment (environment and health safety) studies that need to be done for all GM crops before they are released into the environment. [*Tor A*]

b. To recommend the sequencing of these tests in order to specify the point at which environmental release though Open Field Trials can be permitted. [*Tor B*]

c. To advise on whether a proper evaluation of the genetically engineered crop/plants is scientifically tenable in the greenhouse conditions and whether it is possible to replicate the conditions for testing under different agro ecological regions and seasons in greenhouse. [*Tor C*]

d. To advise on whether specific conditions imposed by the regulatory agencies for Open Field Trials are adequate. If not, recommend what additional measures/safeguards are required to prevent potential risks to the environment. [*Tor D*]

e. Examine the feasibility of prescribing validated protocols and active testing for contamination at a level that would preclude any escaped material from causing an adverse effect on the environment. [*Tor E*]

f. To advise on whether institutions/laboratories in India have the state-of-art testing facilities and professional expertise to conduct various bio safety tests and recommend mechanism to strengthen the same. If no such institutions are available in India, recommend setting up an independent testing laboratory/institution. [*Tor F*]

28.2. The interim report of the TEC was received on 07.10.2012. In this interim report the TEC stated:

i. Three major issues were highlighted in the evaluation process which require attention:

a) Apparent lack of qualified full-time personnel in the regulatory bodies: The TEC was not convinced that the regulatory bodies in their present form are in a position to rigorously evaluate all data that comes before them. Further,

many of the field trials seem to have been delegated or left to the applicant (applying for approval to GEAC) and there is very limited mechanism to ensure compliance and accountability.

b) Need for removing conflicts of interest

c) Increasing inclusiveness of stakeholders with regard to decision making on GM products

ii. All members unanimously felt that the present regulatory system and protocol(s) for conducting field trials was unsatisfactory and inadequate, requiring major changes, restructuring and strengthening.

iii. Introduction of transgenics in crops for which India is a centre of origin or diversity will contaminate the biodiversity and it should not be allowed to happen.

iv. Field Trials should be stopped until the above conditions are addressed.

v. The TEC further recommends a 10 year moratorium on field trials of Bt transgenics in all food crops in accordance with the precautionary principle.

28.3. The final report of the TEC was received by this Court thereafter, wherein it was stated:

(i) Bt technology involves engineering plants for insect resistance by incorporating the gene for the toxin within the plant's genetic constitution, so that the plant becomes naturally resistant to the insect. The benefit of this is a reduced requirement for externally applied chemical pesticides, most of which are toxic and cause environmental damage.

(ii) The other major usage of genetically modified crops has been for Ht crops, which is herbicide tolerance which makes the plant genetically engineered to be resistant to the herbicide. The use of Ht technology allows more extensive application of the herbicide leading to more complete elimination of weeds without killing the crop.

(iii) GM technology comes with the promise of a number of benefits as well as associated risks with regard to health and environmental safety.

(iv) The TEC was informed that it will not be possible to segregate genetically modified from non-genetically modified material

during collection and storage in India, which would have serious implications when it comes to labelling of food.

(v) Most countries such as China and those in Europe are approaching this issue with a fair amount of caution.

Bt Crops

(vi) The TEC has noted that in several cases that they examined, the characterization of the inserted DNA is limited and insufficient for comprehensively addressing the issues to regulatory approval. Overall the quality of information in several of the applications is far below what would be expected, and required for rigorous evaluation by a regulatory body and is unlikely to meet international regulatory guidelines.

(vii) The TEC examined the approved Bt Cotton and Bt Brinjal files relating to toxicity and what emerged from this examination is that in several cases, the methodology and results are not clearly reported.

(viii) The TEC considered the process of Environmental Risk Assessments (**hereinafter "ERA"**) in India. It referred to the

report of Prof. David Andow on ERA for Bt Brinjal wherein it was stated that the GEAC set too narrow a scope for the ERA and further, much of the effort towards the ERA was misdirected, which did not assess the actual adverse environmental consequences in India. The TEC concluded that ERAs are inadequately understood and addressed in Indian guidelines and regulatory system. The deficiencies are likely to be a consequence of the way in which ERA has been treated in the guidelines as a set of tests to be carried out instead of issues to be investigated and addressed. This kind of treatment has resulted in oversimplification, omission, and the real purpose of an ERA being missed.

(ix) The precautionary principle as present in the CPB international guidelines would strongly point towards erring on the side of caution. The TEC highlighted the critical importance of having as complete and comprehensive information as possible on the biology of the species when considering release of GMOs. It was further pointed out that no GMO intended directly as food has been commercially introduced into its Centre of Origin, which was happening

with the case of Bt Brinjal until ministerial intervention took place.

(x) There are serious deficiencies in reporting of the data in the dossiers and more importantly in the way in which these have been examined and the conclusions accepted by the Regulatory Body. The deficiencies are serious enough that several of the dossiers are unlikely to meet international guidelines. The regulator (GEAC) has frequently accepted conclusions based on incompletely reported data or without appropriate statistical analysis.

(xi) Some tests need to be carried out for longer duration in order to increase the time, of exposure so as to detect possible effects with greater confidence.

Ht Crops

(xii) Information relating to long term chronic toxicity is limited for most herbicides. Soybean accounts for the major share of Ht crops.

(xiii) The use of Ht crops would encourage increased use of the herbicides with likely negative consequences for biodiversity

in agricultural fields and the environment. Experimental studies of the possible impact that Ht crops can have on the biodiversity and abundance of wildlife have been limited.

(xiv) Another consideration in the Indian context is a socioeconomic one wherein a significant part of the agricultural workforce is employed for manual labour in the fields. Introduction of Ht crops would be likely to reduce access to employment for some of the vulnerable sections of rural society.

Recommendations

(xv) It is apparent that there are major gaps in the regulatory system. These need to be addressed before issues related to tests can be meaningfully considered.

(xvi) A secretariat comprising dedicated scientists with area expertise as well as expertise in biosafety needs to be established, with consultation with experts having experience at the international level in biosafety testing evaluation of GM safety.

(xvii) Conflict of interest in terms of location of the regulatory body needs to be addressed.

(xviii) Specific sites for conducting confined field trials need to be designated, certified, and sufficient mechanisms put in place for monitoring the trials and ensuring restricted access, disposal of material, associated testing and other facilities.

(xix) Stakeholder participation, socioeconomic considerations, societal impact and sustainability should be incorporated at an early stage in the risk assessment process.

28.4. After the above observations and discussion, the TEC answered the terms of reference in the following manner:

1. *Tor A*

The TEC reiterated its recommendation made in the Interim Report that there should be a moratorium on field trials for Bt in food crops intended for commercialization until there is more definitive information as to long term safety of Bt in food crops.

The TEC stated that it has examined the issues in relation to Ht with regard to sustainability and the likely socioeconomic impact on major sections of rural society. It reached the conclusion that Ht crops would most likely exert a highly adverse impact on sustainable agriculture, rural livelihoods and environment. The TEC found them completely unsuitable in the Indian Context.

It is pertinent here to notice the corrigendum brought by the TEC dated 12.07.2013 wherein the above line was expanded and a complete ban on Ht crops in India was recommended by the TEC.

The TEC further recommended that release of genetically modified crops for which India is a centre of origin or diversity should not be allowed.

2. *Tor B*

The sequence of testing should be carried out in order of increasing environmental exposure required to perform the test. Tests should be done under the minimum conditions of

exposure required for the test. The testing therefore proceeds in a progressive manner.

3. *Tor C*

There is published evidence that the characteristics of a GMO can differ significantly depending upon whether it is grown in the greenhouse or in the field. It cannot be said that it is possible to replicate the conditions for testing under different agro-ecological regions and conditions in the greenhouse.

4. *Tor D*

Specific sites for conducting field trials need to be designated, certified and sufficient mechanisms put in place for monitoring the trials and ensuring restricted access, associated testing and other facilities. The trials should not be conducted on leased land.

5. *Tor E*

There are several ways in which contamination can occur and it probably will not be possible to deploy the tests at a level that will preclude the possibility of escape.

6. Tor F

Based on the review of the dossiers, the professional expertise and standards across the institutions appear unsatisfactory. The TEC has found in unambiguous terms that at present, the regulatory system has major gaps and these will require rethinking, investment and relearning to fix.

28.5. As noted above, the TEC consisted of six members, with Dr. Rajendra Paroda substituting Prof. VL Chopra on 09.11.2012 which is post submission of the interim report, the findings of which have been noted above.

28.6. Unable to agree with the conclusions of the majority, Dr. Paroda submitted his dissent to the final report of the majority, alleging various lapses in the decision-making process. Those lapses, as pointed out are:

> "....
>
> • To my surprise, the TEC members were not willing to take cognizance of any objections/submissions to the Interim Report made by different respondents, despite clear directive by the Hon'ble Supreme Court. As mentioned earlier, a compilation of all objections received was shared (Annex-IV) but members seemed to have serious reservations to discuss these on the plea that there was nothing new, including in fresh

submissions by UOI, NAAS, NSAI, Prof. Deepak Pental etc.

• On having gone through the minutes of the earlier meetings of TEC, prior to my becoming a member (Annex-Ill), and the submissions made by various respondents, it became apparent that TEC members had possibly taken one sided view in their Interim Report.

• The TEC members seemed to take an ideological stance favouring an anti GM as well as an anti transnational approach and possibly believed that imposing moratorium on field trials of GM crops was the only way to move forward. On the contrary, any such move will harm Indian science enormously.

• At the same time, members seemed to have proceeded with an assumption that the Indian regulatory system was faulty and full of lapses. Accordingly, all deliberations of TEC sounded to me like a fault finding mission.

• Some members continued relying solely on reports of contrarian scientists and propounded their views/opinions, while ignoring the fact that such - isolated research claims had been examined thoroughly and rejected by a wide section of scientific community as well as by the regulatory authorities of their respective countries as well as other well reputed regulatory bodies.

• As mentioned earlier, no other member provided any input on the TOR nor did they respond to any of the write-ups provided by me. As a result, no substantive evidence-based discussion could take place during the meetings in order to arrive at general consensus/understanding.

• The only shared document was the part draft report (26 pages), which did not reflect general deliberations held nor did it follow the agreed format. I did convey my concern over adopting this entirely different approach with utter disregard to decisions taken in earlier meetings, but with no positive output.

> • In a scenario like this, reflecting considerable lack of transparency, I am left with no other alternative but to submit this report separately - the last thing I would have wished otherwise."

28.7. While these lapses pointed out by Dr. Paroda pertained to procedural aspects of the TEC however among other minor differences, twin substantial differences in respect of a) conducting field trials which the former recommends continuation in the interest of scientific development and the latter recommends against given numerous regulatory lacunae; and b) the former does not oppose the development of HT crops while the latter, once again in view of the lacunae, bats for a wholesale ban.

28.8. Dr. Paroda recommended that there should be development of comprehensive guidelines for Environmental Risk Assessment (ERA) with consultation with all stakeholders and the general public. A full time Risk Assessment Unit with permanent staff consisting of a multidisciplinary team of scientists should be established. National Agriculture Research System (NARS) should lead agronomic performance

testing and release of GM varieties/hybrids in line with the National Seed Policy while making use of already existing procedures under AICRP.

28.9. He was further of the view that the proper evaluation of a Genetically Engineered plant is scientifically not tenable in a contained greenhouse and confined field testing is the right option for a realistic evaluation of any GE plant. Each confined field trial must be monitored by a 'site specific monitoring committee'. A well-designed case-to-case post-release monitoring system must be put in place to address specific post-release issues identified during the event approval by GEAC. RCGM and GEAC should review isolation distances for confined field trials and suitability of additional measures. Research projects must be funded by DBT, ICAR and relevant arm of the Government. Accredited laboratories must be notified for detection of GM crops. The regulatory authorities should develop a system of examining papers or reports about the adverse effects of GM crops and communicate the same to public. Special fund allocation is desirable for the purpose of creating public awareness.

28.10. I am not inclined to accept the objections raised by the Petitioners, for consideration of the report of Dr. Paroda. Given that the substance in issue is scientific in nature, the minority report cannot be ignored entirely. After perusing both the reports, while there are certain differences, one also finds substantial similarities. They may be noted:

TEC (5 Members)	**Dr. Paroda**
The overall process of risk assessment should follow the flowchart for the Risk Assessment process in the Guidance on Risk assessment of Living Modified Organisms of the Cartagena Protocol on Biosafety.	For environmental risk assessment there is an urgent need for developing comprehensive guidelines in consultation with all stakeholders and general public. There should be establishment of risk assessment unit which should be permanently staffed by a multi-disciplinary team.
It is generally not possible to replicate the conditions for testing under different agro-ecological regions and conditions in the greenhouse.	Proper evaluation of GE plants is not scientifically tenable in contained greenhouses as natural, varying conditions representing different agro-ecological regions and growing seasons cannot be feasibly replicated.
Specific sites for conducting field trials need to be designated, certified and sufficient mechanism put in place for monitoring the trials and ensuring restricted access, disposal of material, associated testing and other facilities. These sites should be used only for field trials of GM crops. Trials should not be conducted on leased land.	No trials should be allowed in non-notified fields, leased or otherwise. A system should be evolved for notification of confined field trial sites which should include both public and private sector institutions subject to certain conditions.

A requisite understanding of the process of Risk assessment be developed through consultation, collaboration and capacity building as the regulatory system has gaps and require rethinking, investment and relearning.	There is a need to strengthen the public sector laboratories through funding in order to have required infrastructure and human resource development. There should be a major human resource development initiative for training in national and international institutions. Government may establish inter-ministerial coordination and monitoring mechanism to create/strengthen public research institutions for regulatory process.

28.11. With respect to the objections raised by the Union of India, to the TEC report, that the TEC went beyond its scope, a perusal of the recommendations made, juxtaposed with the Tor, one finds that the latter are largely within the scope of the question that had been put to them. The TEC has confined itself only to issues relevant to answering Tors.

28.12. As discussed earlier, in **Kantha Vibhag** (supra), this Court observed that:

> "**15.** It is first important to differentiate expert committees which are set by the courts/tribunals from those set up by the Government in exercise of executive powers or under a particular statute. The latter are set up due to their technical expertise in a given area, and their reports are, subject to judicially observed restraints, open to judicial review before courts when decisions are taken solely based upon

> them. The precedents of this court unanimously note that courts should be circumspect in rejecting the opinion of these committees, unless they find their decision to be manifestly arbitrary or *mala fide*. On the other hand, courts/tribunals themselves set up expert committees on occasion. These committees are set up because the fact-finding exercise in many matters can be complex, technical and time-consuming, and may often require the committees to conduct field visits. These committees are set up with specific terms of reference outlining their mandate, and their reports have to conform to the mandate. Once these committees submit their final reports to the court/tribunal, it is open to the parties to object to them, which is then adjudicated upon. The role of these expert committees does not substitute the adjudicatory role of the court or tribunal. The role of an expert committee appointed by an adjudicatory forum is only to assist it in the exercise of adjudicatory functions by providing them better data and factual clarity, which is also open to challenge by all concerned parties. Allowing for objections to be raised and considered makes the process fair and participatory for all stakeholders."
>
> (Emphasis supplied)

28.13. The above observations make it abundantly clear that this Court is not bound by the conclusions reached by its own expert committee. The report of the expert committee is important for the court to be apprised of the technical aspects of a particular dispute by independent experts. For a court or tribunal to rely entirely on the report of an expert committee would be improper as this would amount to the court

abdicating its own adjudicatory function and replacing its wisdom with that of the expert committee.

Parliamentary Standing Committee Reports

29. There are two reports of Parliamentary Standing Committees on this issue. The first one being, the **37th Report of the Committee on Agriculture** (2011-2012) titled 'Cultivation of Genetically Modified Food Crops - Prospects and Effects' dated 09.08.2012. The Committee considered oral and documentary evidence, thereafter made the following observations:

    i. Bio-technology offers many advantages over traditional techniques of plant breeding in major food crops such as low production cost, conservation of bio-diversity and economic-social benefits including poverty alleviation. This technology (transgenics/genetic engineering) is environmentally friendly, sustainable and affordable.

    ii. In respect of field trials which is a highly contested issue before us it is observed that they serve a multiplicity of purposes:

> "(i) For the plant breeder, they provide the first opportunity to evaluate the agronomic potential of novel-plant trait combinations in open environment which is not possible in contained conditions of greenhouse.
>
> (ii) It is necessary to measure the level of protein expression from any newly introduced genes in the plant tissues to assess its efficacy in the open environment and impact on the target and non target organisms consuming the genetically modified plant.
>
> (iii) It allows the production of sufficient quantities of plant material for use in livestock feeding studies/trials and to conduct compositional analyses, which are necessary for human food safety assessment.
>
> (iv) Such trials are also necessary to collect the agronomic and ecological data required to complete the environment safety assessment of genetically modified plant."

iii. The views of Dr. P.M. Bhargava were taken by the Committee and his stand was not a permanent ban on release of GMOs but ensuring that they are adequately tested before any such release take place. At the same time he stated that the refusal to do chronic toxicity studies was against the interest of the nation and that despite the technological advancements, there is not an Indian lab in which testing can be done.

iv. It was noted that the GEAC does not directly perform studies of safety assessment and it is the applicant who is to submit data of its studies to the RCGM and GEAC, and after comments thereon final decision is taken.

v. In conclusion, with respect to the regulatory mechanism, it was observed:

> "**2.92** … The Committee can safely conclude that all is not well with the regulatory mechanism put in place by the Government for oversight of cutting edge technology as sensitive as GMOs and products thereof. Firstly, GEAC being an entity created under rules rather than an Act of Parliament deprives it of the status, powers and more importantly autonomy and independence that a statutory regulator ought to have. The enforceability of Rules, albeit made under some Act only, does not have as much definitiveness and clarity as under an Act. Furthermore, unlike an Act, there is a lot of scope for varied interpretation of Rules as also flexibility to implement them. The confusion about the recommendatory/approving authority of GEAC whether due to genuine confusion or deliberate; the confession of the Co-Chairman of GEAC, the only technocrat in the top three positions of GEAC, about minister/GEAC/industry pressuring him to favour a bad technology; the various acts of omission and commission of GEAC that have been documented in various chapters of this Report, all go on to cement the view of the Committee that the regulatory mechanism definitely requires the protection and support of an Act of the Parliament which leaves no scope for ambiguity or complacency."

vi. The Committee lamented that even after the Cartagena Protocol on Biosafety was adopted on 17.01.2003, many

key issues such as risk assessment, liability and redress, identification of living modified organisms etc. are still in the discussion stage.

vii. Having taken note of the various shortcomings and gaps in the regulatory mechanism, the Committee expressed a desire that all research and development be done in containment and field trial be discontinued forthwith.

viii. Labelling of GM and non-GM products was also an issue considered by the Committee and it was recommended that such labelling be made mandatory so that a consumer can make an informed choice.

ix. Referring to the Dr. M.S. Swaminathan Report, the Department of Agriculture stated that:

> "biotechnology provides an opportunity to convert bio resources into economic wealth. This has to be done in a manner that there is no adverse impact either on the environment or on human or animal health. The guiding principle for following the National agricultural biotechnology policy should be the economic well-being of farm families, food security of the nation, health security of the consumer, protection of the environment and security of our national and international trade in farm commodities".

x. The Committee recorded the admission of the concerned official of the Department of the Agriculture that if the dependence on Bt crops goes beyond a point, it would "be a gigantic task to revive the traditional cotton varieties from the gene bank and may take years together" at the same time it was recorded that, efforts and the direction were proceeding and it was not that the ship had sailed.

xi. Certain other observations recorded by the Committee are essential:

> "**8.97** India also entered the scene in developing and deploying transgenic crops (genetically modified crops) since early 1990s, with very good intentions and preparations to deal with ensuring the safety of such technology so that it does not harm the environment and human health. The policy and regulatory frameworks suggested, developed and implemented had all the good provisions to ensure public safety and ensure food sovereignty of the country. The policy and regulatory frameworks were put in place using well thought-out plans. However, the developments in technology and deployment over-took the speed of policy implementation which caused apprehensions in the minds of general public about the technology and the over-sight for its deployment."

29.1. At this stage, the Petitioners have placed reliance on the **301st Report** of the Parliamentary Standing Committee on Science and Technology, Environment and Forest titled "*Genetically*

Modified Crops and its Impact on Environment" dated 25.08.2017.

i. The Committee after taking an overview of the regulatory mechanism as also taking note of the official and non-official witnesses recorded as under:

> "The Committee takes note of the divergent views on the efficacy of existing regulatory mechanism. On the one hand, the Government claims that are very stringent regulatory mechanism has been put in place leaving no scope for any non-whatsoever by the technology developer whereas on the contrary, the Committee has been given to understand by some representatives of the civil society that the existing regulatory mechanism is stringent on paper only and the whole process of regulation depends upon the data made available to the regulators by the technology developers. The Committee is surprised to know that none of the Committees referred to in the preceding paragraphs conduct the closed field trials on their own but are solely dependent on the data provided to them by the technology developer. The Committee feels that this leaves the scope for the technology developers to fudge the data to suit their own requirements. The existing regulatory mechanism is, therefore, susceptible to manipulations. The Committee, therefore, recommends that the Central Government should, in consultation with the State Governments and Administrations of the Union Territories ensure that the whole process of field trials should be done in close environment keeping biosafety and health safety in mind and in collaboration with agricultural universities so as to minimise the scope of fudging the primary data."

ii. The Committee noticed that the production of GM crops was concentrated only in a select few countries, India being one of them but also noted the general hesitation of developed economies to use this technology at a wide scale. The observation in this regard is as extracted hereunder:

> "The Committee notes that currently, twenty years after their introduction in 1996, only 6 countries continue to account for over 90% of all GM crop area globally (USA 40%, Brazil 23%, Argentina 14%, India 6%, Canada 6%, China 2%). The Committee was informed by the members of civil society during the deliberation on the subject that there was a decline in GM crop area in 2015. The Committee notes with surprise that inspite of the fact that GM technology is being propagated as the most advanced agricultural technology, 17 of the 20 most developed countries (HDI) do not grow it which includes most of Europe, Japan, Russia, Israel etc. The Committee opines that there is increasing evidence about the lack of safety of GM crops and little or no benefits to justify the risks, most countries in the world do not grow GM crops. The Committee also feels that the policy makers of these countries, as custodians for both present and future generations, have seen that GM organisms spread rapidly, that the impacts have been unpredictable, potentially hazardous, uncontrollable and irreversible, assessed the benefits and risks, taken note of emerging evidence of harm, and therefore do not permit GM crops. The non acceptance of the most advanced agricultural technology, GM technology, by the most developed countries raises doubts about the efficacy of the technology. The Committee, therefore, feels that the Government of India should conduct a comparative study to examine the reasons for not accepting this

technology by these developed countries viz-a-viz the reasons led to its acceptance."

iii. The Committee has noted that despite the tiered regulatory system in place, there is no scrutiny of the process of Environmental Impact Assessment and reliance is predominantly on the data supplied by the Applicant. It was recommended that an independent agency consisting of persons with impeccable credentials should carry out the process of evaluation to ensure that there is no violation of the existing regulations.

iv. The Committee has come out in support of placing every piece of information, in public scrutiny. It is wise to ensure that the entire process reflects the values of participation and transparency with the overall goal being to clear out the doubts in the mind of the public.

v. In respect of cross-contamination of GM and non-GM crops the acceptance of the Department of Agricultural Research and Education was noted, that a herbicide tolerant gene may escape by way of pollination to

another farm that is to another GM or non-GM crop and, therefore, the committee was of the view that if cultivation, side-by-side or in other words simultaneously, was allowed there would be no way to stop contamination. It therefore recommended that the MoEFCC undertake a study in that regard and take "desired measures".

vi. The Committee underscored the need for India based studies to be undertaken to examine the effect of GM crops on "our environment on account of GM crops" keeping in view the "topography of our country and its diversity". It was also noted that the impact of these crops on human as well as animal health has not been adequately studied.

29.2. In response to the above reports, the Union of India has submitted a compliance chart, stating that most of the *lacunae* that has been pointed out by the Committees, has been complied with and that the present regulatory system is in consonance with international standards and safeguards, to

ensure that the precautionary approach is complied with. Another argument that has been put forth on behalf of the Union of India is that these reports are from the year 2012 and 2017, respectively and thereafter, in the past 7 years, the scientific research has come a long way.

29.3. The evidentiary value of such reports is no longer *res integra* and was clarified by a Constitution Bench of this Court in **Kalpana Mehta** v. **Union of India (5-Judge Bench)[34].** Dipak Misra, CJI (as he then was), observed:

> "**159.1.** Parliamentary Standing Committee report can be taken aid of for the purpose of interpretation of a statutory provision wherever it is so necessary and also it can be taken note of as existence of a historical fact.
>
> **159.2.** Judicial notice can be taken of the Parliamentary Standing Committee report under Section 57(4) of the Evidence Act and it is admissible under Section 74 of the said Act.
>
> **159.3.** In a litigation filed either under Article 32 or Article 136 of the Constitution of India, this Court can take on record the report of the Parliamentary Standing Committee. However, the report cannot be impinged or challenged in a court of law.
>
> **159.4.** Where the fact is contentious, the petitioner can always collect the facts from many a source and produce such facts by way of affidavits, and the court

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> can render its verdict by way of independent adjudication
>
> **159.5.** The Parliamentary Standing Committee report being in the public domain can invite fair comments and criticism from the citizens as in such a situation, the citizens do not really comment upon any Member of Parliament to invite the hazard of violation of parliamentary privilege."

Dr D.Y. Chandrachud, J. (as he then was) in his detailed consideration of the issue at hand, observed:

> "**275.** Parliamentary Committees are an intrinsic part of the process by which the elected legislature in a democracy exacts accountability on the part of the Government. Department related Parliamentary Standing Committees undertake the meticulous exercise of scrutinising the implementation of law, including welfare legislation and the performance of the departments of the State. The purpose of law is to promote order for the benefit of the citizen and to protect rights and entitlements guaranteed by the Constitution and by statute. Access to justice as a means of securing fundamental freedoms and realising socio-economic entitlements is complementary to the work of other organs of the State. The modern doctrine of separation of powers has moved away from a "one organ - one function" approach, to a more realistic perspective which recognises the complementarity in the work which is performed by institutions of governance. Judicial review is founded on the need to ensure accountable governance in the administration of law as an instrument of realising the rights guaranteed by the Constitution. If the function of judicial review in facilitating the realisation of socio-economic rights is construed in the context of the modern notion of separation of powers, there is no real conflict between the independence of the judicial process and its reliance on published reports of Parliamentary

Committees. Ultimately it is for the court in each case to determine the relevance of a report to the case at hand and the extent to which reliance can be placed upon it to facilitate access to justice. Reports of Parliamentary Committees become part of the published record of the State. As a matter of principle, there is no reason or justification to exclude them from the purview of the judicial process, for purposes such as understanding the historical background of a law, the nature of the problem, the causes of a social evil and the remedies which may provide answers to intractable problems of governance. The court will in the facts of a case determine when a matter which is contentious between the parties would have to be adjudicated upon independently on the basis of the evidence adduced in accordance with law.

276. In the circumstances, the reference is answered by holding that:

276.1. As a matter of principle, there is no reason why reliance upon the report of a Parliamentary Standing Committee cannot be placed in proceedings under Article 32 or Article 136 of the Constitution;

276.2. Once the report of a Parliamentary Committee has been published, reference to it in the course of judicial proceedings will not constitute a breach of parliamentary privilege;

276.3. The validity of the report of a Parliamentary Committee cannot be called into question in the court. No Member of Parliament or person can be made liable for what is stated in the course of the proceedings before a Parliamentary Committee or for a vote tendered or given; and

276.4. When a matter before the court assumes a contentious character, a finding of fact by the court must be premised on the evidence adduced in the judicial proceeding as explained in paras 265 and 274."

The final conclusions of the Bench were as follows:

"**449.1.** According to clause (2) of Article 105 of Constitution of India no Member of Parliament can be

held liable for anything said by him in Parliament or in any committee. The reports submitted by Members of Parliament are also fully covered by protection extended under clause (2) of Article 105 of the Constitution of India.

449.2. The publication of the reports not being only permitted, but also are being encouraged by Parliament. The general public is keenly interested in knowing about the parliamentary proceedings including parliamentary reports which are steps towards the governance of the country. The right to know about the reports only arises when they have been published for use of the public in general.

449.3. Section 57(4) of the Evidence Act, 1872 makes it clear that the course of proceedings of Parliament and the Legislature, established under any law are facts of which judicial notice shall be taken by the Court.

449.4. Parliament has already adopted a report of "privilege committee", that for those documents which are public documents within the meaning of the Evidence Act, there is no requirement of any permission of the Speaker of Lok Sabha for producing such documents as evidence in court.

449.5. That mere fact that document is admissible in evidence whether a public or private document does not lead to draw any presumption that the contents of the documents are also true and correct.

449.6. When a party relies on any fact stated in the Parliamentary Committee report as the matter of noticing an event or history no exception can be taken on such reliance of the report. However, no party can be allowed to "question" or "impeach" report of Parliamentary Committee. The parliamentary privilege, that it shall not be impeached or questioned outside Parliament shall equally apply both to a party who files claim in the court and other who objects to it. Any observation in the report or inference of the Committee cannot be held to be binding between the parties. The parties are at liberty to lead evidence independently to prove their stand in a court of law.

449.7. Both the parties have not disputed that parliamentary reports can be used for the purposes of legislative history of a statute as well as for considering the statement made by a minister. When

there is no breach of privilege in considering the parliamentary materials and reports of the Committee by the Court for the above two purposes, we fail to see any valid reason for not accepting the submission of the petitioner that courts are not debarred from accepting the parliamentary materials and reports, on record, before it, provided the court does not proceed to permit the parties to question and impeach the reports.

449.8. The Constitution does not envisage supremacy of any of the three organs of the State. But, functioning of all the three organs is controlled by the Constitution. Wherever, interaction and deliberations among the three organs have been envisaged, a delicate balance and mutual respect are contemplated. All the three organs have to strive to achieve the constitutional goal set out for "We the People". Mutual harmony and respect have to be maintained by all the three organs to serve the Constitution under which we all live.

449.9. We are of the view that fair comments on report of the Parliamentary Committee are fully protected under the rights guaranteed under Article 19(1)(*a*). However, the comments when turn into personal attack on the individual Member of Parliament or the House or made in vulgar or abusive language tarnishing the image of the Member or the House, the said comments amount to contempt of the House and breach of privilege.

449.10. The function of adjudicating rights of the parties has been entrusted to the constituted courts as per constitutional scheme, which adjudication has to be made after observing the procedural safeguards which include the right to be heard and the right to produce evidence. Parliament, however, is not vested with any adjudicatory jurisdiction which belongs to judicature under the constitutional scheme.

449.11. Admissibility of a Parliamentary Committee report in evidence does not mean that facts stated in the Report stand proved. When issues of facts come before a court of law for adjudication, the court is to decide the issues on the basis of evidence and materials brought before it."

(Emphasis supplied)

29.4. The detailed discussion on the value of Parliamentary Committee reports as undertaken by the Constitution Bench sheds light by holding that there is no bar in taking into consideration such reports under Article 32 or Article 136 of the Constitution of India. At the same time, it has been observed that they are not to be taken as conclusive proof of fact and the Court in performing its adjudicatory functions has to decide on the basis of materials before it, however the latter should not be taken to mean that credit of such report is impeached.

29.5. The question at hand is the adequacy of the assessment and approval procedures for GM Crops. The task of this Court, is therefore to examine whether the impugned procedures rise to the level of a violation of fundamental rights. This is a legal determination to be made by this Court, based on all materials placed before it and a wholistic view of the matter. Even if the TEC and parliamentary standing committees have found certain issues with the procedures governing GM crops, that cannot automatically lead to the conclusion that gaps in the impugned procedures result in a violation of Part III of the

Constitution of India and must be invalidated or that the impugned action be stalled. Therefore, I now proceed to examine, whether the gaps pointed out in the abovementioned reports, would reach the threshold of violating the precautionary principle and in that view of the matter, what directions must be given.

Scope of Precautionary Principle

30. The genesis of the precautionary principle in India can be traced back to the decision of this Court in **Vellore Citizens Welfare Forum** v. **Union of India (3-Judge Bench)**[35], wherein it was held that the precautionary principle is an essential feature of the principle of sustainable development. It went on to explain the precautionary principle in the following terms:

> "i. Environmental measures - by the State Government and the statutory authorities - must anticipate, prevent, and attack the causes of environmental degradation.
>
> ii. Where there are threats of serious and irreversible damage, lack of scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation.

[35] (1996) 5 SCC 647

> iii. The "onus of proof" is on the actor or the developer/industrialist to show that his action is environmentally benign."

30.1. This principle over the years, has been developed further and recognised as an integral part of the Indian Constitution. Recently, in **Hospitality Association of Mudumalai** v. **In Defence of Environment & Animals (3-Judge Bench)**[36], this Court reiterated that the precautionary principle forms part of the Constitution of India under Articles 21, 47, 48 and 51-A(g). The requirement placed on the Government under the precautionary principle to "anticipate, prevent and attack the causes of environmental degradation" was emphatically reiterated.

30.2. This Court has clarified that a precautionary approach, is not one which is opposed to development. In **N.D. Jayal** (Supra) while relying on **Vellore Citizens' Welfare Forum** (Supra) and **M.C. Mehta** v. **Union of India (3-Judge Bench)**[37], emphasis was laid on sustainable development. This Court

[36] (2020) 10 SCC 589
[37] (2002) 4 SCC 356

observed that the balance between environmental protection and developmental activities could only be maintained by strictly following the principle of "sustainable development". This is a development strategy that caters to the needs of the present without negotiating the ability of upcoming generations to satisfy their needs. The strict observance of sustainable development will put us on a path that ensures development while protecting the environment, a path that works for all people and for all generations. It is a guarantee to the present and a bequeath to the future. All environment-related developmental activities should benefit more people while maintaining the environmental balance. This could be ensured only by strict adherence to sustainable development without which the life of the coming generations will be in jeopardy.

Further it was opined that:

> "24. The right to development cannot be treated as a mere right to economic betterment or cannot be limited as a misnomer to simple construction activities. The right to development encompasses much more than economic well-being, and includes within its definition the guarantee of fundamental human rights. The "development" is not related only to the growth of GNP. In the classic work,

> Development As Freedom, the Nobel prize winner Amartya Sen pointed out that "the issue of development cannot be separated from the conceptual framework of human right". This idea is also part of the UN Declaration on the Right to Development. The right to development includes the whole spectrum of civil, cultural, economic, political and social process, for the improvement of peoples' well-being and realization of their full potential. It is an integral part of human rights. Of course, construction of a dam or a mega project is definitely an attempt to achieve the goal of wholesome development. Such works could very well be treated as integral component for development."

30.3. The necessity to strike a balance between development and ecology was reiterated by this Court in **Karnataka Industrial Areas Development Board** v. **C. Kenchappa (2-Judge Bench)**[38] wherein it was observed:

> "**61.** The priority of developing nations is urgent industrialisation and development. We have reached at a point where it is necessary to strike a golden balance between development and ecology.
>
> **62.** The development should be such as it can be sustained by ecology. All this has given rise to the concept of sustainable development.
>
> x x x x
>
> **67.** A nation's progress largely depends on development, therefore, the development cannot be stopped, but we need to control it rationally. No Government can cope with the problem of environmental repair by itself alone; people's voluntary participation in environmental management is a must for sustainable development.

[38] (2006) 6 SCC 371

> There is a need to create environmental awareness which may be propagated through formal and informal education. We must scientifically assess the ecological impact of various developmental schemes. To meet the challenge of current environmental issues, the entire globe should be considered the proper arena for environmental adjustment. Unity of mankind is not just a dream of the enlightenment but a biophysical fact."
>
> (Emphasis supplied)

30.4. In **Electrosteel Steels Limited** v. **Union of India and Ors.** (**2-Judge Bench**)[39] while dealing with ex-post facto environmental clearances, this Court observed that the Court cannot be oblivious to the economy or others dependent on a project, if the project in question complies with environmental considerations.

30.5. Recently, in **NHAI** v. **Pandarinathan Govindarajulu (3-Judge Bench)**[40], it was observed:

> "**18.** While economic development should not be allowed at the cost of ecology or by causing widespread environmental destruction, the necessity to preserve ecology and environment should not hamper economic and other development. Both development and environment must go hand in hand. In other words, there should not be development at the cost of environment and vice versa, but there should be development while taking due care and

[39] (2023) 6 SCC 615
[40] (2021) 6 SCC 693

ensuring the protection of environment [*Indian Council For Enviro-Legal Action* v. *Union of India*, (1996) 5 SCC 281]. The traditional concept that development and ecology are opposed to each other is no longer acceptable [*Vellore Citizens' Welfare Forum* v. *Union of India*, (1996) 5 SCC 647]."

(Emphasis supplied)

30.6. A similar approach was taken in **Rajeev Suri** v. **DDA (3-Judge Bench)**[41] wherein judicial review of the Central Vista Project was sought. The majority, in this case, observed:

"**519.** Indubitably, environment and development are not sworn enemies of each other. It would be an anomalous approach to consider environment as a hurdle in development and vice versa. The entities like EAC and NGT are created to strike a just balance between two competing interests and a time-tested principle of striking this balance is timely invocation of mitigating environmental measures amidst a development activity. True that mere application of certain mitigating measures may not alleviate environmental concerns in all matters and in some circumstances, the project is simply incomprehensible with the environment. But as long as a legitimate development activity can be carried on in harmony with the idea of environmental protection and preservation including sustainable development, the Courts as well as expert bodies should make their best endeavour to ensure that harmony is upheld and hurdles are minimised by resorting to active mitigating measures.

520... The primary requirement underlying this principle is to ensure that every development work is *sustainable*; and this requirement of sustainability demands that the first attempt of every agency enforcing environmental rule of law in the country

[41] (2022) 11 SCC 1

ought to be to alleviate environmental concerns by proper mitigating measures. The future generations have an equal stake in the environment and development. They are as much entitled to a developed society as they are to an environmentally secure society.

x x x

524. The precautionary principle duly mandates that all agencies of the State, including Courts, must make their best endeavour to ensure that precaution is instilled in the process of development. The very requirement of prior EC is born out of this need for precaution. It is a manifestation of the precautionary principle in India and if development work is carried out in furtherance of prior EC and such EC is not vitiated by illegality, it would be a case of proper adherence with the precautionary principle.

525. In matters of balancing between competing environmental and development concerns, the Court has to be project-specific. In environmental matters, even one fact here or there may have the effect of attributing a totally distinct character to the project and accordingly, the scope of judicial review may vary.

x x x

528. They must always look for a careful balance when two equally relevant interests compete with each other. The task may not be easy, but is the only reasonable recourse. For the proper application of these principles, the first and foremost thing to be kept in mind is the nature of the project. In the present case, the subject project is an independent building and construction project wherein one-time construction activity is to be carried out. It is not a perpetual or continuous activity like a running industry. It is absolutely incomprehensible to accept that a project of this nature would be unsustainable with the needs and aspirations of future generations. Furthermore, the increase in footprint is not shown to be substantial and the inclusion of new Members of Parliament after the delimitation exercise is anyway

> going to lead to an inevitable increase in footprint (floating though) that cannot be countenanced as a concern here."
>
> (Emphasis supplied)

30.7. In **M K Ranjitsinh & Ors.** v. **Union of India and Ors. (3-Judge Bench)**[42], the need for adopting a nuanced approach, balancing two environmental goals, i.e., fighting the climatic crisis as also protection of wildlife ecology was underscored in following words:

> "**53**... Unlike the conventional notion of sustainable development, which often pits economic growth against environmental conservation, the dilemma here involves a nuanced interplay between safeguarding biodiversity and mitigating the impact of climate change. It is not a binary choice between conservation and development but rather a dynamic interplay between protecting a critically endangered species and addressing the pressing global challenge of climate change."

Additional Guidelines

31. We must also, at this point, make references to the guidelines that have been brought by the Union of India, to supplement the existing framework:

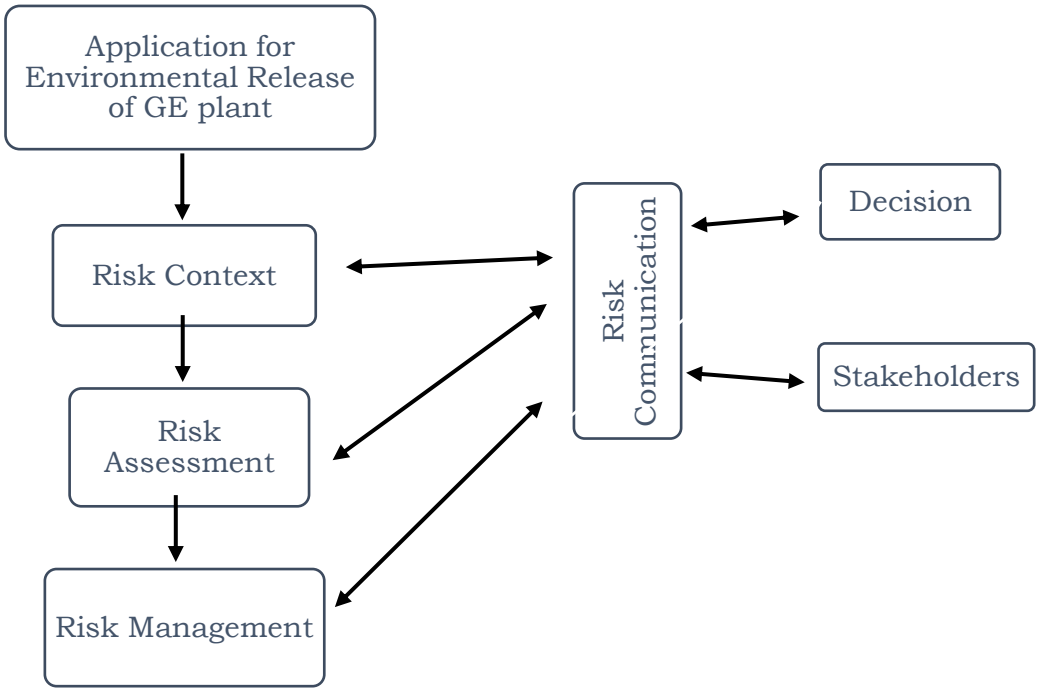
[42] 2024 SCC Online SC 570

i. **Guidelines for Environmental Risk Assessment of Genetically Engineered Plants, 2016 and Environmental Risk Assessment of Genetically Engineered Plants- A Guide for Stakeholders, 2016** - The objective of these Guidelines is to ensure safe development and use of plant resulting from modern biotechnology after assessment of any potential negative impacts through a comprehensive, transparent and science based framework of identification of harms using a conventional case to case approach. These guidelines profess to provide a practical elaboration of the risk assessment framework included in the Indian regulation and in Annex III of the Cartagena Protocol on Biosafety as also the Working Committee on Harmonisation of Regulatory Oversight in Biotechnology of the Organisation for Economic Cooperation and Development (OECD).

They provide a detailed roadmap for Environmental Risk Assessment right from the approach to be adopted to problem formulation (development of risk hypothesis), to detailed instructions on data quality to informational requirement and

description of the non-transgenic parental plants/donor organisms, characterization of genetic modification to cultivation practices to potential adverse non-target effects of GMOs on biodiversity to post release environmental monitoring.

ii. **Risk Analysis Framework 2016** - These guidelines provide the risk analysis method for the environmental release of GE plants and divides them into different stages which can be shown through a following chart:



(a) Risk Context being the preparatory stage defines the scope and boundaries, sets the criteria against which risk will be evaluated and describes the structures and process for the analysis. Decisions on application for the environmental release of a GE plant require case-by-case assessment and details of the GE plant and the proposed activities, including any proposed controls, limits or containment measures, form the specific risk context.

(b) This framework includes Risk Assessment, Risk Management and Risk Communication. Risk Assessment and Risk Management form an essential part of decision making in respect to the applications for environmental release of GE plants.

(c) The chapter on Risk Assessment provides comprehensive methodology to identify and characterize risks to the health and safety of people or to the environment from the release of GE plants. It includes risk identification (postulating risk scenarios); risk characterization (includes quantitative as well as qualitative assessment); ensuring the quality of data used in such assessment and risk evaluation. The risk

assessor is obliged to search beyond the application to identify additional data and other information that will help in the completion of the risk assessment.

(d) The next stage of Risk Management includes preparing a risk management plan; and monitoring/reviewing measures, if any, to assess the effectiveness of all steps in risk analysis, including post-release review. It further provides that in case of non-compliance of any condition considered necessary to manage the risk associated with the environmental release and imposed by the regulatory authorities, the Regulatory Authorities may investigate the nature and extent of such non-compliance. If proven, resort may be made to the EPA, 1986 which provides for a range of remedies, including provisions for criminal sanctions or large fines and/or imprisonment for failing to abide by the legislation, conditions or directions when significant damage occurs to health and safety of people or the environment.

(e) Another relevant aspect dealt in this document is Risk Communication which is a two-way process 'to provide,

share or obtain information and to engage in dialogue with stakeholders regarding the analysis of risk' and Risk perception. This is based on a principle that Risk Assessment should be 'in a scientifically sound and transparent manner'. It includes engagement of 'internal and external stakeholders in the risk analysis process through dialogue'; informing so as 'to foster understanding of the risks amongst different constituencies (e.g., authorized parties and others from the regulated community, as well as researchers, farmers, health workers, industry, consumers, interest groups and the general community)'; and building trust 'to promote trust and credibility in the ability of the Regulatory Agencies and the Indian government to effectively regulate modern biotechnology'.

(f) At this juncture, it becomes pertinent to refer to the Cartagena Protocol and the Risk Analysis Framework provided under Annex-III of the said Protocol. The General Principles that are required to be followed by the Parties in developing risk assessment are:

" .....

3. Risk assessment should be carried out in a scientifically sound and transparent manner, and can take into account expert advice of, and guidelines developed by, relevant international organizations.

4. Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.

5. Risks associated with living modified organisms or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.

6. Risk assessment should be carried out on a case-by-case basis. The required information may vary in nature and level of detail from case to case, depending on the living modified organism concerned, its intended use and the likely potential receiving environment."

(Emphasis supplied)

(g) The steps provided under this Protocol for risk assessment:

"8. To fulfil its objective, risk assessment entails, as appropriate, the following steps:

(a) An identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health;

(b) An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism;

(c) An evaluation of the consequences should these adverse effects be realized;

(d) An estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized;

(e) A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks; and

(f) Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the living modified organism in the receiving environment."

(Emphasis supplied)

(h) After perusing the Cartagena Protocol and the Risk Analysis Framework developed by the concerned ministries, it is safe to deduce that Indian regulatory system has a sufficient and robust framework of risk analysis/assessment which can be used by the regulatory authorities to protect the health and ensure safety of the people as well as the environment, in accordance with

EPA,1986 ; also to foster the research and development in the field of GE plants.

iii. **Regulations and Guidelines for Recombinant DNA and Biocontainment, 2017**

(a) These guidelines were issued on 1st April 2018 with the following objectives:

> "i. Outline the general principles of containment and establish a minimum standard for laboratories that must be adopted pan India for all handling of genetically engineered (GE) organisms (organism includes microorganisms, animals, plants, arthropods, aquatic animals, etc.) and non-genetically engineered (non-GE) hazardous microorganisms (microorganism includes parasites, protozoa, algae, fungi, bacteria, virus, prions, etc.).
>
> ii. Identify the levels of risk(s) associated with GE organisms and non-GE hazardous microorganisms and classification of those organisms into their respective risk groups to select appropriate containment facilities. It also covers certification of containment facilities.
>
> iii. Prescribe criteria for Manufacture, Use, Import, Export, Exchange and Storage of any hazardous microorganisms, GE organisms or cells and products) produce through exploration of such organisms.
>
> iv. Ensure that national authorities, institutions and all other stakeholders involved in research & development are well informed or have access to information on safety thereby facilitating the safe use and handling of hazardous microorganisms, GE organisms or cells and product(s) produce through exploration of such organisms.
>
> v. Emphasis the need and responsibility of all national authorities, institutions and all other stakeholders

involved in research to ensure that the public is well informed about the containment strategies followed in India."

"**SCOPE**

This document covers regulatory scope on rDNA research and handling of hazardous microorganisms and GE organisms or cells in India.

Adoption of these guidelines shall be binding pan India for all public and private organisations involved in research, development and handling of GE organisms (organism includes microorganisms, animals, plants, arthropods, aquatic animals etc.) and non-GE hazardous microorganisms (microorganism includes parasites, protozoa, algae, fungi, bacteria, virus, prions, etc.) and products produced through exploration of such organisms.
Note: These guidelines do not overwrite any other existing regulations or guidelines, unless specified here."

(Emphasis supplied)

(b) These guidelines are divided into 4 chapters- Chapter 1: Regulations and Competent Authorities; Chapter 2: Principles and Components of Containment; Chapter 3: Operational Guides on Containment; Chapter 4: Containment Requirement for Import, Export and Exchange. Each of these issues covered in the Chapter is dealt with in considerable detail and I have perused the same however refrain from dealing with them *in extenso*.

iv. **Guidelines and SOPs for confined field trials of Regulated, GE plants 2008** - The scope of these guidelines is defined as under:

> "These guidelines are intended to provide guidance to applicants for the conduct of confined trials. They are not intended to explicitly define all the requirements for the conduct of a confined field trial, as further terms and conditions/requirements may be identified during the review process by the Regulatory Authorities. This document covers all GE/transgenic plants modified through recombinant DNA (rDNA) technology."

32. It is in this background, having taken note of and considered the law, the relevant documents and all other essentialities, that the challenge raised by the Petitioners must be seen.

33. The conditional approval, leading to field trials for DMH-11 is in line with a developmental approach, of a scientific temper. The same has been supplemented with conditions imposed by the expert body, to facilitate mitigating measures *qua* the environment, which I have discussed above.

34. While examining the propriety of the conditional approval granted by the GEAC (to DMH-11) *qua* the precautionary principle, it becomes essential to look to the past orders of this Court, in these

petitions, in order to understand the position taken, thus far, *qua* the activities of this body.

(a) On 22.09.2006, the Court observed that on 01.05.2006, while issuing orders in an Interlocutory Application, held that all trials will be conducted only with the approval of the GEAC. On this date, it was further observed that the Court was not inclined to direct the stoppage of field trials but, it did direct a pause on approvals, subject to having heard all sides.

(b) On 13.10.2006, as an interim measure, the Court permitted the applicant to plant DMH-11 variety for experimental purpose in its field subject to all precautions.

(c) On 15.12.2006, on being presented with some information which questioned the permission to plant the DMH-11 variety for testing, and a prayer regarding uprooting thereof, directions were issued to the GEAC to examine the impact of field tests being carried out, with reference to the experts referred to. An independent view was directed to be furnished by the GEAC. It was observed as under:

> "Today, our attention has been drawn by the learned counsel for the petitioner to clause (23) of the Convention on Biological Diversity which, inter alia, recommends that in the current absence of reliable data on genetic use restriction technologies [GURT], without which there is an inadequate basis on which to assess their potential risks, and in accordance with the precautionary approach, products incorporating such technologies should not be approved by parties or field testing until appropriate scientific data can justify such testing. Further, reliance has been placed on the expert opinion of Professor Joe Cummins, Professor Jack Heinemann and Professor Dough Gurian Sherman to contend that barnase unaccompanied by its specific inhibitor barstar is known to be a potent cell poison. Traces of barnase are toxic to the rat kidney and to human cell lines. Barnase is actually being exploited as a conditional suicide gene to cause cell death in mammalian and human cells when it is induced, and cell toxicity caused by barnase may be affected by RNA interference. Relying on these experts, learned counsel contends that, as indicated in the order dated 13th October, 2006, direction be issued for uprooting the plant otherwise risk is being run for permanent escape of the gene and other damages which it may cause. Before we consider this prayer further, we deem it appropriate to direct G.E.A.C. to examine in detail the impact of the field test being carried also with reference to the expert opinion. We may, however, note that the applicant's case is that it has modified its technology and is not using GURT. We say nothing on this aspect. We expect independent expert opinion from G.E.A.C. on this subject."
>
> (Emphasis supplied)

(d) On 08.05.2007, it was observed that in total, 91 field testing operations were being undertaken. It was further directed that-

> "The GEAC shall take sufficient precautions to see that these trials are not causing any contamination to the cultivation of neighboring fields. There should be at least 200 meters distance from the trial fields from the neighboring field having same type of cultivations. All the trials which are being conducted, the name of the scientist and other details who will be responsible for all aspects of the trials should be reported to GEAC and they should be regular supervision by them. Prior to bringing out the GM material from the green house for conduct of open field trials, the approved institution should submit a validated event specific test protocol at an LOD of at least 0.01% to detect and confirm that there has been no contamination… GEAC should also verify whether these species by commercial use create any toxicity or allergenicity to any of the users in organic conducted with these varieties of Bt cotton. If any such test has been conducted, the data should be made available to this Court."
>
> (Emphasis supplied)

(e) On 13.02.2008, the restriction placed by this Court upon granting approvals was lifted and GEAC was permitted to consider all applications. To assuage the worries of the Petitioner in regard to the proper constitution of the GEAC, the latter was requested to invite Dr. P.M. Bhargava and Prof. M.S. Swaminathan to its meetings. It was further observed that if any person was dissatisfied by the decision arrived at by the Committee, an appeal may be preferred to the Appellate Committee and, that the apprehensions in

regard to negative effect of open field trials, be also considered by the Committee. It was further directed that the guidelines to grant approvals be published on the website of the Committee.

(f) On 07.10.2016, this Court recorded the submission of the Additional Solicitor General, that release was not allowed till 17.10.2016 because the Government had sought views from the public and after receiving public views/objections, the committee of experts would consider such matter.

34.1 As the above referred orders point out, throughout the entire process of field testing, being taken stock of, at regular intervals by the Court, it has not, even for a moment doubted the authority of the GEAC and its ability to function properly. Repeatedly, it has been emphasised that the GEAC, being the apex body would be responsible for taking all precautions/adopting safeguards and ensuring that no contamination takes place in planting of GM seeds.

34.2 In one of the orders referred above, it has been noted that 91 field trials were underway at one point. In the extensive

arguments made by the Petitioners, not even a single negative instance could be pointed out to show that the field trials impacted the agriculture, environment, biodiversity negatively or irrevocably. Furthermore, as pointed out by the Union of India, trials of DMH-11 have commenced in 6 out of the 8 sanctioned locations (seeds have been planted) and no adverse change therein has been reported thus far. The fears, raised by the Petitioners, therefore, are not substantiated by any negative occurrence.

34.3 The members of the GEAC under the 1989 Rules, are experts in their relevant fields. The approval has come, as discussed above, in consonance with the relevant statutory framework. Furthermore, adequate safeguards have been included in the approval itself, in accordance with the precautionary principle. There is an additional ground, upon whose anvil, the decision to grant conditional approval as also the general introduction of GMOs into the sphere of common consumption, which has been sought to be banned by the present petitions, has to be weighed.

35. Whether or not the State allows or disallows the scientific experimentation of a particular kind of crop, particularly when the Central Government is the primary authority entrusted with such function, is a decision squarely within their domain and the role of the Courts therein is circumscribed to the violation of fundamental rights; manifest arbitrariness; conflict with any other law and/or other grounds of similar nature.

36. In reference to public interest, in this particular context, Article 48 of the Directive Principle of the State Policy (**hereinafter referred to as 'DPSP'**) would be instructive in order for the concerned branch of the Government to frame policy and take steps in this regard being whilst being entirely in line with the Constitution of India which undoubtedly is the source of all power, legitimacy and is the ultimate guide for all actions. It states that there shall be an endeavour to organise agriculture on modern and scientific lines. **State of Gujarat** v. **Mirzapur Moti Kureshi Kassab Jamat (7-Judge Bench)**[43], observed:

> "Article 48 consists of two parts. The first part enjoins the State to "endeavour to organise agricultural and

[43] (2005) 8 SCC 534

> animal husbandry" and that too "on modern and scientific lines". The emphasis is not only on "organisation" but also on "modern and scientific lines". The subject is "agricultural and animal husbandry"."

37. A wholistically aware adoption of GMOs into agriculture appears to be in furtherance of this goal. The phrase 'wholistically aware' may require some exposition. What this means is that while GMOs are brought into the agricultural scene and eventually made available for commercial use, it should be so done keeping in mind the essentiality of preserving naturally occurring seeds, ensuring that all other factors such as health, socio-economic impact, environmental/biodiversity impact, accessibility to farmers, proper control and marking of such modified crops etc. would be required to be in place.

38. In continuation to the above, reference has also to be made to Article 51A(h) of the Constitution of India which imposes a fundamental duty upon all in the following terms:

> "h) to develop the scientific temper, humanism and the spirit of inquiry and reform;"

38.1 This Court in **AIIMS Students' Union** v. **AIIMS (3-Judge Bench)**[44] observed:

> "**58.** … Fundamental duties, as defined in Article 51-A, are not made enforceable by a writ of court just as the fundamental rights are, but it cannot be lost sight of that "duties" in Part IV-A Article 51-A are prefixed by the same word "fundamental" which was prefixed by the founding fathers of the Constitution to "rights" in Part III. Every citizen of India is fundamentally obligated to develop a scientific temper and humanism. He is fundamentally duty-bound to strive towards excellence in all spheres of individual and collective activity so that the nation constantly rises to higher levels of endeavour and achievements. State is, all the citizens placed together and hence though Article 51-A does not expressly cast any fundamental duty on the State, the fact remains that the duty of every citizen of India is the collective duty of the State. … In the era of globalisation, where the nation as a whole has to compete with other nations of the world so as to survive, excellence cannot be given an unreasonable go-by and certainly not compromised in its entirety. Fundamental duties, though not enforceable by a writ of the court, yet provide a valuable guide and aid to interpretation of constitutional and legal issues. In case of doubt or choice, people's wish as manifested through Article 51-A, can serve as a guide not only for resolving the issue but also for constructing or moulding the relief to be given by the courts. Constitutional enactment of fundamental duties, if it has to have any meaning, must be used by courts as a tool to tab, even a taboo, on State action drifting away from constitutional values."
>
> (Emphasis supplied)

[44] (2002) 1 SCC 428

38.2 Similarly, in **Charu Khurana** v. **Union of India (2-Judge Bench)**[45] **,** this Court observed:

> "**32.** The purpose of referring to the same is to understand and appreciate how the directive principles of State policy and the fundamental duties enshrined under Article 51-A have been elevated by the interpretative process of this Court. The directive principles have been regarded as the soul of the Constitution as India is a welfare State. At this juncture, it is apt to notice the view expressed by a two-Judge Bench of this Court in *Ashoka Smokeless Coal India (P) Ltd.* v. *Union of India* [(2007) 2 SCC 640] wherein it has been laid down that: (SCC p. 683, para 106)
>
> "*106.* … the directive principles of State policy provide for a guidance to interpretation of fundamental rights of a citizen as also the statutory rights."
>
> (Emphasis supplied)

39. The Union of India has submitted that comprehensive risk assessment *qua* GMOs cannot be done at the initial research stage and all consultations cannot take place for each application on GM crops at an early stage. It was further submitted that toxicology studies are varied on product by product basis, as per international best practices and therefore toxicity studies are undertaken as per guidelines on a case-by-case basis.

[45] (2015) 1 SCC 192

40. The experimentation in respect of GMOs, i.e. field trials, lab testing etc. would be in line with the development of a scientific temper along with the precautionary principle which has found its place within Article 21 of the Constitution of India. Field trials are a significant step in the development of crop varieties as the data representing the plant's response to a particular agro-ecological environment can be collected only when such plant is grown outside in confined field trials. Without field trials, the performance of the plant in the field or environmental safety of such plant cannot be known. Studies, being conducted in open environment is necessary for studying the impact on human health and biodiversity, for the performance of a GM crop is dependent on a host environment. This would be essential to developing appropriate biosafety mechanisms as well.

41. The judgments referred above recognise fundamental duties as an important guide to interpretation of the Constitution, which obviously would apply to the understanding of Article 21 as well. In **Ramlila Maidan Incident, In re (2-Judge Bench)**[46]**,** the

[46] (2012) 5 SCC 1

interdependency of the three parts of the constitution was highlighted by Swatanter Kumar J. (as he then was) in the following words:

> "**22.** Thus, a common thread runs through Parts III, IV and IV-A of the Constitution of India. One Part enumerates the fundamental rights, the second declares the fundamental principles of governance and the third lays down the fundamental duties of the citizens. While interpreting any of these provisions, it shall always be advisable to examine the scope and impact of such interpretation on all the three constitutional aspects emerging from these Parts."
>
> (Emphasis supplied)

42. The development of scientific temper is to be read with another limb of the DPSPs and Fundamental Duties enshrined in the Constitution that is Article 48A and Article 51A(g) respectively which speaks of protection of the environment. As already noticed above, these three parts forming the heart and soul of the Constitution have to be read as a whole and as such any and all considerations of modernising agriculture or building a scientific temper would also be required to necessarily consider and abide by the duty to protect the environment.

43. It is also to be noted that, similar to when a legislative body enacts a legislation there is a presumption of constitutionality unless proven otherwise, similarly, a policy decision when taken by the competent authority enters the fray of enforcement with a presumption in its favour of being in public interest, unless otherwise shown, demonstarted and proven to be among other grounds, manifestly arbitrary. This presumption extends, subject of course to just exceptions, to the authority having considered duties as discussed above in framing policies for GMOs.

44. It must be kept in mind that India is a global agricultural powerhouse and from an economic standpoint, rural India is still largely dependent on agriculture. This court has stated in **Electrosteels** (supra) that the Court cannot be oblivious to the economy. Therefore, informed agricultural policy decisions must be viewed in that conspectus, which is to further and supplement India's development, growth and self-sustenance. The relevance of such policy decisions being that, for instance, as submitted by the Union of India, India has been dependent on imports to meet more than half of the edible oil demand [55.76%, 155.33 Lakh

Tonnes (2022-23) – Rs.1,15,000/- crores in 2020-21]. Therefore, in my view, the use of GM technology has to be seen in this backdrop.

45. On numerous occassions, this Court has reiterated the view discussed in the preceding paragraphs.

45.1 This Court in **State of U.P.** v. **Abhay Nandan Inter College**[47] **(2-Judge Bench)** observed:

> "**36.** A policy decision is presumed to be in public interest, and such a decision once made is not amenable to challenge, until and unless there is manifest or extreme arbitrariness, a constitutional court is expected to keep its hands off."

45.2 In **State of Punjab** v. **Khan Chand**[48] (**5-Judge Bench**), KK Mathew J. dissenting, observed:

> "**23.** ... Courts and parties all assume that the Legislature always wants protection of the public interest, to serve public cause and do things for public good or to exercise powers for public purpose and always intends that administrators act justly and reasonably whether the Legislature says so in the statute or not [see Kenneth Culp Davis, "*Administrative Law Treatise"*, (1958) Vol. I, p. 87]. Every legislative body must be presumed to favour the

[47] (2021) 15 SCC 600
[48] (1974) 1 SCC 549

> true, the good and above all the public interest and public good and whether it says so or not is of absolutely no consequence. …Government exists and its only title to exist is its claim to advance the public good and serve the public interest…."

45.3 On similar lines, in **Central Inland Water Transport Corpn.** v. **Brojo Nath Ganguly**[49] **(2-Judge Bench)** this Court observed:

> "**92.** …Public policy, however, is not the policy of a particular government. It connotes some matter which concerns the public good and the public interest. The concept of what is for the public good or in the public interest or what would be injurious or harmful to the public good or the public interest has varied from time to time…"
>
> (Emphasis supplied)

45.4 In **Premium Granites** v. **State of T.N**[50] **(2-Judge Bench)**, it was observed:

> "54. It is not the domain of the court to embark upon unchartered ocean of public policy in an exercise to consider as to whether a particular public policy is wise or a better public policy can be evolved. Such exercise must be left to the discretion of the executive and legislative authorities as the case may be. The court is called upon to consider the validity of a public policy only when a challenge is made that such policy decision infringes fundamental rights guaranteed by the Constitution of India or any other statutory right…"

[49] (1986) 3 SCC 156
[50] (1994) 2 SCC 691

45.5 In the well-known, **Narmada Bachao Andolan** v. **Union of India**[51]**, (3-Judge Bench),** this Court held:

> "229. It is now well settled that the courts, in the exercise of their jurisdiction, will not transgress into the field of policy decision. Whether to have an infrastructural project or not and what is the type of project to be undertaken and how it has to be executed, are part of policy-making process and the courts are ill-equipped to adjudicate on a policy decision so undertaken. The court, no doubt, has a duty to see that in the undertaking of a decision, no law is violated and people's fundamental rights are not transgressed upon except to the extent permissible under the Constitution.
>
> x x x
>
> 233. ...The courts must, therefore, act within their judicially permissible limitations to uphold the rule of law and harness their power in public interest. It is precisely for this reason that it has been consistently held by this Court that in matters of policy the court will not interfere. When there is a valid law requiring the Government to act in a particular manner the court ought not to, without striking down the law, give any direction which is not in accordance with law. In other words the court itself is not above the law."
>
> (Emphasis supplied)

45.6 Therefore, on this ground, interference by this Court would only be justified if it can be proven that the effect of such a decision standing would be detrimental to the public, against its interest and would ultimately impact the enjoyment of

[51] (2000) 10 SCC 664

fundamental rights guaranteed by the Constitution, to a degree which would be impermissible. As has been demonstrated in the preceding paragraphs, that threshold cannot be said to have been breached.

46. In view of the entire conspectus above, the field testing of DMH-11, pursuant to the conditional approval of the GEAC, with sufficient safeguards and precautions, ought to continue and cannot be said to be violative of the precautionary principle and therefore, the constitutional challenge thereto, fails.

47. Two additional aspects need to be clarified. Pursuant to the above discussion, when I consider the prayer made on behalf of the Petitioners, it is clear that whether or not there should be a complete ban on Ht crops is not something this Court can issue a direction on. Such a decision has to be taken, keeping in view the opinion of various experts who have the knowledge and ability to comprehend scientific literature on the point as also the views of those persons specifically tasked with taking decisions in such matters. Courts, only on the basis of material placed on record or the indirect understanding passed on to it through counsel, is not

in a position to take an informed decision. If such a decision is taken, it would be completely foreign to the standards of judicial review as discussed above, for it is not within the Court's purview to undertake cost benefit analysis of a policy decision of the executive.

48. The aspect of India being a centre of origin or diversity *qua* mustard was laid considerable emphasis on by the learned counsel for the Petitioners, however this, in my considered view, is another prayer with which this Court cannot do justice by returning or not returning a finding. Counsel on both sides supplied research material to support their own stand which argued contrarian viewpoints in this regard and so, it would be best if minds equipped to undertake detailed studies to come to a conclusion, would be the ones to decide this important issue.

Conclusions & Directions

49. In view of the above discussion, the conclusions arrived at in the discussion above are that:

i. Judicial review into the decision making of all bodies concerned with GMOs, is possible.

ii. The question of ban on Ht crops is not warranted in view of the precautionary principle and it is a decision squarely within the domain of policy.

iii. The composition of the GEAC is in accordance with the Rules, to which the challenge of constitutionality, has failed, and in the absence of any change in the Rules, no fault can be found with the same.

iv. The decision of the GEAC to grant conditional approval is not vitiated by non-application of mind, or any other principle of law, on part of the body, which itself is an expert body.

50. In view of the above, I deem it appropriate to give the following directions:

50.1. Field trials of DMH-11, shall continue in strict consonance with the conditions imposed. The Union of India and statutory authorities shall continue to strictly monitor the same. In case

of any adverse change in circumstances, the decision for field trials can be reviewed.

50.2. GEAC to ensure that the conditions mentioned in the conditional approval of DMH-11 are strictly complied with by the applicant in letter and spirit.

50.3. The GEAC to take into account all environmental factors before granting future approvals and make an endeavour to have specifically designated farms for field testing, in collaboration with the Union of India.

50.4. All studies conducted and received while granting such approvals, to be uploaded on the website of the GEAC in a time-bound manner, in accordance with the mandate of law. The GEAC to ensure public participation in this process and wider publicity of the same to be facilitated.

50.5. That apart, wider publicity should also be given to GMOs in general, enabling people to take a decision in regard thereto, keeping in view all factors and specifications.

50.6. All decisions to be taken in regard to GMOs should endeavour to strictly follow "wholistically aware" approach which takes the preservation of naturally occurring seeds hand in hand with popularising Genetically Modified seeds.

50.7. The condition imposed in this Court's order dated 08.05.2007 in respect of 200 meters distance being maintained between fields hosting GM crops versus those wherein regular seeds are planted, has to be strictly maintained.

50.8. The Post-Release Monitoring Committee be provided with adequate infrastructural and administrative facilities to closely monitor the field testing.

50.9. The Union of India may consider constituting a special cell under the MoEFCC to monitor all studies being undertaken with respect to GMO's.

50.10. Before commercial release of DMH-11 and other GMOs in the future, specific testing on their impact on human health must be conducted prior thereto.

50.11. The GEAC or any other body, possessing sufficient expertise, duly notified by the government, to consider conducting independent studies on GMOs to ascertain the veracity of the data submitted by the applicant(s) so as to ensure that the approval so granted are bolstered by independent data informing such decision.

50.12. The Union of India should consider implementing a national, all-encompassing policy in respect of GMOs so as to ensure a streamlined approach to this important issue. Connected thereto, is the setting up of infrastructure including laboratories with state of the art facilities, to aid the interplay of biotechnology and agriculture and the advancement thereof.

50.13. Union of India to ensure strict compliance *qua* labelling of GM foods, in accordance with the Food Safety and Security Act.

51. Before parting with the present *lis*, I lament the delay with which the present writ petition has come to be disposed. The genesis of this case was 20 years ago from the present day. The detrimental effect of such prolonged litigation was noted by this Court in **Rajeev Suri (supra)** wherein it was observed:

"**574...**the underlying principle at play is the duty of this Court to do complete justice as envisaged under Article 142 and to obviate the possibility of project of national importance being stuck, embroiled and delayed due to engagement of the project proponent before multiple legal forums/proceedings. We have had plethora of cases in the post-PIL period wherein prolonged litigation against infrastructural projects resulted in inordinate delays to the extent that the projects got buried forever or became unviable owing to excessive burden on the public exchequer (honest taxpayers' money). That is where this Court's power to do not only complete but substantial justice gets triggered.

x x x

576. There is ample support to the proposition that when larger national interest is involved and concerns of public exchequer are directly involved in the lis, the Court must act at the earliest opportunity. For, each day's delay has a direct impact on the exchequer. In Narmada Bachao Andolan v. Union of India [Narmada Bachao Andolan v. Union of India, (2000) 10 SCC 664] , the Court resonated this position and observed thus : (SCC pp. 761-62, para 227)

"227. There are three stages with regard to the undertaking of an infrastructural project. One is conception or planning, second is decision to undertake the project and the third is the execution of the project. The conception and the decision to undertake a project is to be regarded as a policy decision. While there is always a need for such projects not being unduly delayed, it is at the same time expected that a thorough possible study will be undertaken before a decision is taken to start a project. Once such a considered decision is taken, the proper execution of the same should be undertaken expeditiously. It is for the Government to decide how to do its job. When it has put a system in place for the execution of a project and such a system cannot be said to be arbitrary, then the only role which a court

> may have to play is to see that the system works in the manner it was envisaged."
>
> (Emphasis supplied)

52. The above proposition resonates with the present case. Unfortunately, despite the national and public interest involved, this case remained pending for two decades, which must lead to introspection on both sides of the bench.

53. I would like to place on record appreciation for all the counsel for taking us through the voluminous record and providing us with detailed hand-outs on the case file, which are purely a substance of their hard work.

54. The writ petitions are dismissed and disposed of in terms of the above judgment. The contempt petitions stand closed in the above terms. The Civil Appeal stands disposed of in light of the above. Pending applications, if any, stand disposed of.

.....J.
(SANJAY KAROL)

Dated: 23rd July 2024
Place : New Delhi

IN THE SUPREME COURT OF INDIA

CIVIL ORIGINAL/APPELLATE/INHERENT JURISDICTION

WRIT PETITION (CIVIL) NO.115 OF 2004

GENE CAMPAIGN & ANOTHER ... PETITIONERS

VERSUS

UNION OF INDIA & OTHERS ... RESPONDENTS

WITH

WRIT PETITION (CIVIL) NO.260 of 2005

WRIT PETITION (CIVIL) NO.840 OF 2016

CIVIL APPEAL NO.4086 OF 2006

CONTEMPT PETITION (CIVIL) NO.295 OF 2007
IN
WRIT PETITION (CIVIL) NO.260 of 2005

CONTEMPT PETITION (CIVIL) NO.6 OF 2016
IN
WRIT PETITION (CIVIL) NO.260 of 2005

O R D E R

1. On the following aspects, there is consensus on the Bench:

   That Judicial Review of the decision taken by the bodies concerned in the matter of GMOs is permissible.

2. We issue the following directions:

i. The respondent-Union of India is directed to evolve a National Policy with regard to GM crops in the realm of research, cultivation, trade and commerce in the country. The said National Policy shall be formulated in consultation with all stakeholders, such as, experts in the field of agriculture, biotechnology, State Governments, representatives of the farmers, etc. The National Policy to be formulated shall be given due publicity.

ii. For the aforesaid purpose, the MoEF&CC shall conduct a national consultation, preferably within the next four months, with the aim of formulating the National Policy on GM crops. The State Governments shall be involved in evolving the National Policy on GM crops.

iii. Respondent – Union of India must ensure that all credentials and past records of any expert who participates in the decision-making process should be scrupulously verified and conflict of interest, if any, should be declared and suitably mitigated by ensuring representation to wide range of interests. Rules in this regard may be formulated having a statutory force.

iv. In the matter of importing of GM food and more particularly GM edible oil, the respondent shall comply with the requirements of Section 23 of FSSA, 2006, which deals with packaging and labelling of foods.

3. Having regard to the difference of opinion expressed by us on the decision of the GEAC and MoEF granting conditional approval for environmental release of DMH-11, the Registry shall place the matter before Hon'ble the Chief Justice of India for constituting an appropriate Bench to consider the said aspect afresh.

.....J.
(B.V. NAGARATHNA)

.....J.
(SANJAY KAROL)

New Delhi;
July 23, 2024