HIGH COURT OF JUDICATURE FOR RAJASTHAN
BENCH AT JAIPUR

D.B. Civil Writ (PIL) Petition No. 9095/2019

1. Kritesh Oswal [redacted]
2. Abhay Singla [redacted]
3. Deepesh Oswal [redacted]

----Petitioners

Versus

1. Union Of India, through its Cabinet Secretary, Cabinet Secretariat of India, South Block, New Delhi
2. Ministry Of Health and Family Welfare, Government Of India Through its Secretary, Near Udyog Bhawan Metro Station, Maulana Azad Rd, New Delhi, Delhi 110011
3. The Food Safety and Standards Authority Of India, Through its Chief Executive Officer 03Rd And 04Th Floor, FDA Bhawan, Near Bal Bhavan, Kotla Road, New Delhi - 110002
4. The Ministry of Environment, Forest And Climate Change, Government of India Through its Secretary (EF & CC), Cabinet Secretariat of India, New Delhi.
5. The Genetic Engineering Appraisal Committee (GEAC), through its Chairman-Special Secretary/Additional Secretary, Union Ministry Of Environment, Forest And Climate Change (MoEF & CC), Indira Paryavaran Bhawan, Aliganj Road, Jorbagh, New Delhi, 110003, India
6. The Department Of Consumer Affairs, Ministry Of Consumer Affairs, Food And public Distribution, Government Of India Through Its Secretary, Krishi Bhawan, Rafi Marg, Connaught Place, New Delhi, Delhi 110001.

----Respondents

For Petitioner(s) : Mr. Kritesh Oswal, present in person
Mr. Pratyush Sharma

For Respondent(s) : Mr. Devesh Yadav with
Mr. Yatharth Asopa &
Mr. Chinmay Surolia for
Mr. R. D. Rastogi, ASG
Ms. Priya Khushalani for
Mr. Mudit Singhvi

HON'BLE THE ACTING CHIEF JUSTICE MR. SANJEEV PRAKASH SHARMA
HON'BLE MR. JUSTICE SANJEET PUROHIT

JUDGMENT

RESERVED ON:- **11/08/2025**

PRONOUNCED ON:- **13/10/2025**

PORTABLE

Per, HON'BLE MR. SANJEET PUROHIT, J:

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I. PREFACE:

1. Food is the foundation of life, sustaining not merely the physical body but nourishing the very essence of human existence and consciousness. The profound wisdom embedded in our ancient Vedic scriptures establishes food safety as the supreme principle underlying all existence. The Taittiriya Upanishad, in it's Brahmanandavalli (2nd Anuvaka), verse 1 says:

"अन्नाद्वै प्रजाः प्रजायन्ते। याः काश्च पृथिवीं श्रिताः।
अथो अन्नेनैव जीवन्ति। अथैनदपियन्त्यन्ततः।
अन्नं हि भूतानां ज्येष्ठम्। तस्मात् सर्वौषधमुच्यते।

— तैत्तिरीयोपनिषद् , ब्रह्मानन्दवल्ली द्वितीयोऽनुवाकः Verse १"

"Indeed, all species of living beings on Earth originate from food; therefore, they live by food and in the end, they merge back into food. Since among all created substances, food is the oldest, it is called the 'Supreme Medicine' of the entire universe."

This reveals food as the primordial source, sustainer, and ultimate destination of all life forms in the Cosmos.

2. The Chandogya Upanishad also illuminates in verse 6.5.4 says:

"अन्नमयं हि सोम्य मनः आपोमयः प्राणस्तेजोमयी वाग्"

"O Somya, the mind is nourished by food, prāṇa by water, and speech by fire."

This sacred teaching demonstrates that food constitutes not merely physical sustenance but forms the very essence of mental faculties and also consciousness. The finest portion of consumed food ascends to create the mind, establishing an inextricable connection between physical nourishment and intellectual capacity.

3. These eternal Vedic precepts find profound resonance in the constitutional framework and judicial pronouncements of modern India, where the right to food has been recognized as an integral component of the fundamental Right to Life under Article 21. The judiciary has consistently held that access to safe and nutritious food is not a privilege but an inalienable right essential for human dignity and existence.

4. The question as how far our nation has advanced in safeguarding the food safety values enshrined in our constitutional framework and the role of constitutional courts in ensuring the adherence to and enforcement of food safety values, lies at the heart of the present petition.

More specifically, where does the Food Safety and Standards regime stand in fulfilling its duty to protect public health amid the increasing presence of genetically modified foods?

4.1 The principle concern expressed in the present petition is that Section 22 of the Food Safety and Standards Act, 2006 (hereinafter referred to as **"Act of 2006"**) vests the Central Government / Food Safety Authority of India (hereinafter referred to as "**FSSAI**") with the authority to frame detailed regulations governing the manufacture, sale, import and distribution of genetically engineered foods. Notwithstanding the clear mandate, no such regulations have been notified till date.

4.2 Question thus arises as to whether, in the absence of such regulations, the legislative scheme envisaged under Section 22 has been rendered nugatory, thereby frustrating the very objectives of the said provision and leaving the statutory

framework incomplete and unenforceable. Consequently, what is the appropriate course of action until such regulations are formulated and notified to ensure protection of public health and consumer interests? These matters form the very basis of present Public Interest Litigation.

II. BRIEF FACTS AND GROUNDS:

5. Present writ titled as Public Interest Litigation (hereinafter referred to as "**PIL**") has been filed raising concerns regarding the sale, manufacture, distribution or import of genetically modified (hereinafter referred to as "**GM**") articles of food in India, in violation of Section 22 of the Act of 2006. The following prayers are made in the present writ petition:-

> ***"1.*** *That to direct the respondents in accordance of Section 22 of Food Safety and Standards Act 2006 that all the genetically modified food/processed food being imported, manufacture, sale, distributed in India shall be immediately prohibited.*
>
> ***2.*** *To direct the respondents that all the stock of genetically modified food already available in Indian market should be ceased and prohibited for any further sale or distribution.*
>
> ***3.*** *That all the permissions given by GEARC to anybody to import manufacture sale, distribute any genetically modified food shall be declared as bad in law and be immediately withdrawn.*
>
> ***4.*** *To direct GEAC to not issue any fresh permission to anybody for sale, manufacture, import, distribute of any genetically modified food and to take down Form No. III "Application for Import of Food as Living Organism/ Per Se As Food/ Feed/Processing" & Form No. IV "Application for Import of Food AS Living Modified Organism/ Per Se Food/ Feed/Processing" of GEAC from its record and further practice.*
>
> ***5.*** *That rule 6(7) of the Legal Metrology (Packaged Commodities) Rules, 2011 shall be declared inconsistent, ultra-virus to section 22 of Food Safety And Standards Act 2006 and shall be stuck down"*

6. The facts and grounds germane to the writ petition are mentioned in succinct, below:

6.1 The petitioner highlighted the issue of absence of Food Safety Standards and proper regulatory mechanism regarding Genetically Modified / Genetically Engineered Food in India.

6.2 Section 22 of the Act of 2006 clearly prohibits GM food from being manufactured, distributed, sold or imported in India except as provided under the Act or the regulations made thereunder. However, till date no regulations in relation to the GM / genetically engineered food have been framed, but the import of the genetically modified edible oils is being permitted in India.

6.3 The petitioner has placed on record the study being conducted by an organisation named **Center for Science and Environment** (hereinafter referred to as "**CSE**"), which, after sampling, has concluded the presence of genetical organisms or the food containing GM ingredients in India.

6.4 The petitioner has further referred to the answer given by the Government of India, **Ministry of Health and Family Welfare** in Lok Sabha in Starred Question-171 on 29th December, 2017 (Annexure-7), wherein the Ministry has admitted that the FSSAI has not framed any standards for GM food and have not notified the same till date.

It was further admitted that the **Genetic Engineering Appraisal Committee** (hereinafter referred to as "**GEAC**") of **Ministry of Environment, Forest & Climate Change** (hereinafter referred to as "**MoEF&CC**") has permitted the import of GM food edible oil ("soybean oil and canola oil") on various occasions from 2007 to 2015 and the details of the same have also been provided in the Annexures attached along with the said answer.

6.5 The petitioner contended that the GM edible oil has been permitted to be imported in India for consumption without any scientific research or impact assessment on human body, which is violative of Article 21 of the Constitution of India.

6.6 The petitioner stated that the Ministry of Environment & Forests vide its notification dated 5th December, 1989 has framed "*Rules for the Manufacture, Use / Import / Export and Storage of Hazardous Micro Organism / Genetically Engineered Organisms or Cells, 1989*" (hereinafter referred to as "**the Rules of 1989**"), which provided for constitution of GEAC and the rules further provided for the power of GEAC for grant of approval for sale, storage, import, processing, production, etc. of genetically engineered articles in India. Rule 11 of the Rules of 1989 deals with the permission and approval for foodstuffs by GEAC.

6.7 The petitioner contended that the Ministry of Environment & Forests vide its notification dated 23rd August, 2007 (Annexure-5), while exercising the powers under Rule 20 of the Rules of 1989 has exempted Rule 11 from the purview of GEAC. By virtue of the said notification, the GEAC has no power to approve the sale, manufacture or import of the GM food in India; however, time and again the GEAC has permitted the import of the GM edible oil in India, which is wholly without jurisdiction.

6.8 Additionally, challenging Rule 6(7) the Legal Metrology (Packaged Commodities) Rules, 2011 (hereinafter "**the Rules of 2011"**), it was stated that the said Rule 6(7) provides that every GM Packaged food must contain a term "GM" on its label, however, in absence of any regulations being framed under Section 22, the GM food's sale or distribution itself is illegal, therefore, the provision for GM labels cannot be sustained. Hence, the said Rule

is liable to be struck down as being *ultra vires* to Section 22 of the Act of 2006.

6.9 The writ petitioner while referring to some International studies regarding health / biological impact of GM food has stated that owing to the side effects of GM food on human body, the permission of its sale, distribution, import or manufacture in India, without specifying the food safety standards and regulatory mechanism, is violative of Right to Health, which is an intrinsic part of Right to Life enshrined under Article 21 of the Constitution of India.

6.10 The petitioner has prayed that the import, manufacture and distribution of all genetically modified foods in India be prohibited immediately.

III. REPLY FILED BY THE RESPONDENTS:

7. A joint counter affidavit has also been filed on behalf of the Union of India (hereinafter referred to as "**UOI**"), MoEF&CC, GEAC and Department of Consumer Affairs stating therein that although the notification dated 23rd August 2007 has been issued by the MoEF&CC, exempting the GM food (Rule 11 of Rules of 1989) from the purview of GEAC, however, since no regulations / standards / guidelines regulating GM food have been framed by the FSSAI under Section 22 of the Act, 2006, therefore, supplemental notifications were issued by the MoEF&CC from time to time in order to keep the notification dated 23rd August, 2007 in abeyance. The last Gazette Notification was issued on 26th March, 2015 which expired on 31st March, 2016. By virtue of the supplemental notifications, the GEAC continued to deal with the application for approval with regard to the GM food also.

7.1. It was admitted that the GEAC in its 134th Meeting held on 21.03.2018 decided that all the applications regarding the GM food will be forwarded to the FSSAI for its final approval.

7.2. In response to the challenge to Rule 6(7) of the Rules of 2011, it was contended that the Rules of 2011 are only enabling provisions regarding label upon the pre-packaged food products and the same in itself neither permits, nor prohibits / restricts the manufacturing, import, sale or distribution of packages containing GM food products in the country. Therefore, the said provision cannot be considered as *ultra-vires* to any provisions of the Act of 2006.

8. A reply to the writ petition was filed on behalf of respondent No.3 (FSSAI), mentioning that the Act of 2006 came into force w.e.f. 15.10.2007 for application of certain Sections, and Section 22 of the Act of 2006 came into force on 18th August 2010 except in respect of matters relating to the genetically engineered or modified food as explained in Clause 2 of Section 22 of the Act of 2006. It was admitted that no regulations have been notified, hence the GM food is not permitted to be sold in the country.

8.1. It was averred that in relation to GM organisms, the aspect of environmental safety falls within the domain of GEAC, whereas the aspect of food safety falls within the domain of FSSAI.

8.2. The respondent no.3 in para 11 of its reply contended that in a Multi-Departmental Meeting held on 24th August, 2017, it was decided that Genetically Engineered Organisms (GEOs) or Living Modified Organisms (LMOs) intended for direct use as food or for processing would require approval from GEAC for environmental safety followed by FSSAI for Food Safety.

8.3. The respondent No.3 while objecting to the study of the CSE, stated that the FSSAI has issued notice to the Food Business Operators (hereinafter referred to as "**FBOs**"). The said FBOs have denied the presence of Genetically Modified Organisms (GMOs) traces / ingredients in their food and have also submitted the National Accreditation Board for Testing and Calibration Laboratories (hereinafter referred to as **"NABL"**) reports to establish that the allegation of presence of GMO traces / ingredients is not correct.

8.4. It was stated that although the regulations have been formulated and draft regulations have been sent to the Ministry of Health and Family Welfare for further action but the Central Government has not notified the regulation under Section 22 (2) of the Act of 2006.

8.5. By submitting the said reply, the respondent No.3 prayed that the Hon'ble Court may please to pass appropriate order in view of the averments made hereinabove.

IV. ARGUMENTS OF RIVAL PARTIES:

9. The counsel for the petitioner argued that in view of the mandatory provision of Section 22 of the Act of 2006, read with the over-riding effect provided under Section 89 of the Act of 2006, no permission/approval can be granted for sale, manufacturing, import or distribution of GM food in India in absence of the Regulations to be framed under the Act of 2006. Further, the approvals for GM food granted in absence of the Regulations are invalid and without jurisdiction.

9.1 The learned counsel for the petitioner contended that the last supplemental notification was expired on 31.03.2016 and

thereafter, even GEAC is not authorized to grant any approval for any GM edible item in India.

9.2 Referring to the contents of reply, the counsel for the petitioner submitted that since it has been admitted on behalf of the GEAC and FSSAI that no regulations are notified till date, therefore, a restrain order is required to be issued in the present case.

9.3 Advancing the arguments relating to the challenge given to the validity of Rule 6(7) of the Rules of 2011, the learned counsel for the petitioner submitted that instead of permitting the mention of 'GM' over the food label, the directions are required to be issued to the Authorities to permit the import, sale or manufacture of the food stuffs only under the 'GM Free' certificate.

9.4 The learned counsel for the petitioner contended that the issue involved in the present case is relating to the human health, hence the same is an issue of larger public importance and urgent interference of this Court is called for in the present case.

10. The learned counsels appearing on behalf of the respondents have reiterated the averments made in the respective replies.

10.1 The counsel of Union of India stated that by virtue of supplement agreement, the exemption notification was kept in abeyance, therefore, the permissions so granted by the GEAC for import of the GM edible oil were duly authorized and have been issued after following the due process of law. It was also contended that the petitioners have not challenged the orders of approval so granted for said import of edible oil.

10.2 During the course of argument, the learned counsel appearing on behalf of FSSAI has drawn our attention to the draft notification dated 18.11.2022 regarding draft GM Food Regulations, 2022, whereby the suggestions have been invited from various stakeholders. However, it has been stated that the final notification of Regulation has not been issued so far.

10.3 The learned counsel for the respondents has further contended that the petitioner has failed to establish any violation of the provisions of Part-III of the Constitution of India or violation of the parent Act and therefore, the challenge given to the Rule 6(7) of the Rules of 2011 is wholly misconceived.

10.4 The learned counsel for the respondents stated that looking to the issue involved in the present case, the appropriate orders may be passed by the Hon'ble Court.

Before dealing with the rival submissions, we deem it appropriate to first examine the statutory regime governing the field of Genetically Modified Food/Genetically Engineered Food in India.

V. ANALYSIS OF STATUTORY REGIME:

(a). Statutory Provisions (Pre Act of 2006) The Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms or Cells Rules, 1989.

11. Since GM organisms were considered as an emerging field of research and development, to regulate the manufacture, use, import / export and storage of genetic engineering organism or sales in India, the first regulatory framework was introduced by the Ministry of Environment and Forest through promulgation of the Rules of 1989, while exercising powers under Sections 6, 8 &

25 and the Environment Protection Act, 1986. The relevant provisions of the said rules are quoted below:-

"***2. Application***

(1) ----------

(2) These rules 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.

3. Definition

(i) ----------

(ii) ----------

(iii) ----------

(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 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;"*

The said rules provided for constitution of various authorities for regulation of genetic modified organisms. The authorities provided under the rules are:-

(1) Recombinant DNA Advisory Committee (RDAC)
(2) Review Committee on Genetic Manipulation (RCGM)
(3) Institutional Biosafety Committee (IBSC)
(4) Genetic Engineering Approval Committee (GEAC)
(5) State Biotechnology Co-Ordination Committee (SBCC)
(6) District Level Committee (DLC)

Rule (7) Approval and Prohibitions

"*(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.

……..”

Rule (11) Permission and Approval for food stuffs

“Food stuffs, ingredients in food stuffs and additives including processing aids 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.”

Rule (20) Exemption

The Ministry of Environment and Forests shall, wherever necessary, exempt an occupier handling a particular microorganism/genetically engineered organism from rule 7-11”

12. By promulgation of the Rules of 1989, the GEAC was constituted as a regulatory body for grant of approval of the proposals relating to release of genetic engineered organism and product into environment including experimental field trials. By virtue of Rule 11, the GM foodstuffs were also kept within the ambit of GEAC. Up till year 2006, the GEAC was the sole authority to deal with and regulate the entire mechanism of sale, distribution, manufacture and import of Genetically Engineered (GE) or Genetically Modified (GM) organisms, including both edible and non-edible articles, in India.

(b) Statutory Provisions (Post 2006)

Food Safety and Standards Act, 2006

13. In the year 2006, to consolidate the laws related to food and to establish the Food Safety and Standards Authority of India (FSSAI), the Parliament of India enacted the Act of 2006 for allowing science-based standards for articles of food and to

regulate their manufacture, storage, sale, and import to ensure the availability of safe and wholesome food for human consumption and the same came into effect on 23th August 2006. The relevant provisions of the Act, 2006 are as under:-

"***Statement of Objects and Reasons:-***

1. ----------

2. ----------

3. As an on going process, the then Member-Secretary, Law Commission of India, was asked to make a comprehensive review of Food Laws of various developing and developed countries and other relevant international agreements and instruments on the subject. After making an in depth survey of the international scenario, the then Member-Secretary recommended that the new Food Law be seen in the overall perspective of promoting nascent food processing industry given its income, employment and export potential. It has been suggested that all acts and orders relating to food be subsumed within the proposed Integrated Food Law as the international trend is towards modernisation and convergence of regulations of Food Standards with the elimination of multi-level and multi-departmental control. ***Presently, the emphasis is on (a) responsibility with manufacturers, (b) recall, (c) Genetically Modified and Functional Foods, (d) emergency control, (e) risk analysis and communication and (f) food safety and good Manufacturing Practices and process control viz., Hazard Analysis and Critical Control Point.****"*

"1. Short title, extent and commencement:-

…….

(3) It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint, ***and different dates may be appointed for different provisions of this Act*** *and any reference in any such provision to the commencement of this Act shall be construed as a reference to t*he coming into force of that provision.

3. Definitions.–

.....

(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.

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

(y) ***"ingredient"*** *means any substance, including a food additive used in the manufacture or preparation of food and present in the final product, possibly in a modified form;*

(z) ***"label"*** *means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed, graphic, perforated, stamped or impressed on or attached to container, cover, lid or crown of any food package and includes a product insert*

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) ".....";

(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 the regulations made thereunder."

***23. Packaging and labelling of foods:**–(1) No person shall manufacture, distribute, sell or expose for sale or dispatch or deliver to any agent or broker for the purpose of sale, any packaged food products which are not marked and labelled in the manner as may be specified by regulations: Provided that the labels shall not contain any statement, claim, design or device which is false or misleading in any particular concerning the food products contained in the package or concerning the quantity or the nutritive value implying medicinal or therapeutic claims or in relation to the place of origin of the said food products. (2) Every food business operator shall ensure that the labelling and presentation of food, including their shape, appearance or packaging, the packaging materials used, the manner in which they are arranged and the setting in which they are displayed, and the information which is made available about them through whatever medium, does not mislead consumers.*

***89. Overriding effect of this Act over all other food related laws:**–The provisions of this Act shall have effect notwithstanding anything inconsistent therewith contained in any other law for the time being*

> *in force or in any instrument having effect by virtue of any law other than this Act.*
>
> ***92. Power of Food Authority to make regulations:****–(1) The Food Authority may, with the previous approval of the Central Government and after previous publication, by notification, make regulations consistent with this Act and the rules made thereunder to carry out the provisions of this Act.*
>
> *(2) In particular, and without prejudice to the generality of the foregoing power, such regulations may provide for all or any of the following matters, namely:–*
>
> *……*
> *(v) any other matter which is required to be, or may be, specified by regulations or in respect of which provision is to be made by regulations.*

14. Although, the said Act was promulgated in the year 2006, but the provisions of the Act came into effect on different dates. Initially, by virtue of Notification dated 15th October, 2007, the Sections 4, 5, 6, 7, 8, 9, 10, 87, 88, 91 and 101 came into effect on the same date. Subsequently, Section 89 of the Act of 2006 came into force vide Notification dated 29th July, 2010. Further, Section 22 (except the matters relating to the genetically engineered or modified food) came into force on 18th August, 2010; **however, vide Notification dated 2nd November, 2021, the clause 2 of the explanation of Section 22 deals with genetically engineered or modified food came into force w.e.f. 2nd November, 2021.**

(c) International Conventions

(i) United Nations Convention on Biological Diversity (UNCBD) 1992

15. In the international arena, the subject of genetic engineered / genetically modified organism was first addressed in

the UNCBD 1992. The same was adopted at the 1992 Rio Earth Summit, aimed at conserving biological diversity, ensuring the sustainable use of its components, and promoting the fair and equitable sharing of benefits from genetic resource utilization. Total 196 countries are party to the UNCBD and India has also ratified the same in the year 1994. The Convention has three main objectives:

(i) to conserve biodiversity

(ii) promote sustainable use of its parts and

(iii) ensure fair sharing of benefits from genetic resources.

(ii) Cartagena Protocol on Biosafety (CPB), 2003

16. This Protocol was introduced and adopted as a supplement to the UNCBD. The said Protocol seeks to protect biological diversity from the potential risks posed by genetically modified organisms resulting from modern biotechnology. The said Protocol makes it clear that products arising from new technologies must be guided by the precautionary principle, enabling developing nations to balance public health with economic benefits. The protocol applies to trans-boundary movement, transit, handling and use of all LMOs that may have adverse effects on the conservation and sustainable use of biological diversity, while also taking into account risks to human health.

Categories of LMOs Covered under the Protocol are:

(i) LMOs for intentional introduction into the environment (e.g. seeds, live fish).

(ii) LMOs intended for direct use as food or feed, or for processing (e.g. agricultural commodities -corn, canola, cotton).

(iii) LMOs for contained use (e.g. bacteria for laboratory scientific experiment).

The CPB was adopted in 2000 and came into force on 11th September 2003, and India being a signatory, was bound to implement its provisions.

VI. ISSUES:

17. The issues derivable from the above discussion, to be adjudicated by us in the present case are:

1. Whether there is an urgent need for the regulations to be framed for Explanation-2 of Section 22 of the Act of 2006?

2. Whether the permission/approval for manufacture, distribute, sale or import GM articles of food can be granted in absence of regulations framed under Section 22 of the Act of 2006?

3. Whether Rule 6(7) of the Rules of 2011 is ultra vires?

VII. ANALYSIS AND REASONING:

a. Whether there is an urgent need for the regulations to be framed for Explanation-2 of Section 22 of the Act of 2006?

18. India's population is at present, approximately 1.46 billion. This places overwhelming pressure on the nation's food security systems, exposing significant nutritional challenges and supply vulnerabilities. The growing import dependence alongside strong export activity reflects complex supply-demand dynamics and highlights an urgent need for policymakers to govern all viable agricultural technologies, especially GM foods, to ensure sufficient, safe, and nutritious food supplies.

19. The potential benefits and challenges associated with GM food always remains a matter of ongoing debate, involving

considerations such as crop resilience, food safety, environmental impact, impact on human health, socio-economic effects, and trade-related issues. However, despite the challenges and complexities mentioned above, the Central government is yet to frame regulations for providing the food safety standards and regulatory mechanism for GM articles of food in India.

20. The submissions of both parties, along with the statutory framework discussed above, indicate that the regulation of genetically modified organisms (GMOs), whether edible or non-edible, was initially governed by the 1989 Rules. However, a shift occurred with the enactment of special law on Food Safety i.e. Act of 2006. In this context, the MoEF&CC, issued exemption notification and as a result thereof, food products containing GMOs were excluded from the jurisdiction of the GEAC.

21. Since, the explanation 2 of Section 22 of the Act of 2006 had not come into force, therefore, the exemption Notification dated 23.08.2007 was kept in abeyance, vide 13 supplemental Notifications (hereinafter referred to as "Abeyance Notifications"). Consequently, the GM food continued to be governed by GEAC. The last abeyance Notification in this regard was issued on 26.03.2015 (Annexure-CA/1) which expired on 31.03.2016, resultantly, the exemption Notification dated 23.08.2007 came into effect and therefore, the GM foodstuffs is now exempted from the purview of GEAC.

22. The explanation 2 of Section 22 of the Act, 2006 has come into force vide notification dated 02.11.2021 and by virtue of overriding mandate of provisions of the Act, 2006, the sale, manufacture, distribution and import of the genetically modified

foodstuffs can only be governed as per the Act of 2006 as well as the regulations to be made thereunder.

23. It is astonishing that while the issue of genetically modified organisms in edible products is a matter of significant concern, yet the relevant regulations have not been finalized and notified by the Central Government. Although the FSSAI has been established, yet the GEAC has been allowed to approve the import of GM edible oil in India under the "Abeyance Notifications," solely due to the absence of regulations under Section 22 of the 2006 Act.

24. Our attention has also been drawn to the judgment order dated 11.08.2017 passed by the Hon'ble Supreme Court, in the case of ***Vandana Shiva Vs. Union of India; Writ Petition (C) No.173 of 2006,*** wherein it was held as under:-

"2. Mr. Ajit Kumar Sinha, learned senior counsel appearing on behalf of Respondent Nos.1 to 3, namely, the Union of India, the Ministry of Environment, Forest & Wildlife and the Ministry of Health & Family Welfare, states that ***at the present juncture, there is no notification/regulation allowing any activity in connection with genetically engineered and modified food. It is also submitted, that such an activity is permissible only under the regulations framed under Section 22 of the Food Safety and Standards Act, 2006.***

3. Learned counsel further points out, that even though the matter is under active consideration, no final determination has been recorded as of now. It is also pointed out, that the regulations framed under the Food Safety and Standards Act, 2006, have to be laid before the Parliament under Section 93 of the above Act and they are enforceable only after the expiry of a period of 30 days. ***It is therefore contended, that the instant petition may be disposed of by granting liberty to the petitioner to approach this Court on the issue in hand, as and when such regulations are framed by the Central Government and laid before the Parliament.*** *The*

submissions made before us at the behest of the respondents are contained in an independent affidavit and in the status report filed in the Court. The same is taken on record.

4.

The instant writ petition is disposed of by allowing liberty to the petitioner to approach this Court again after regulations framed in connection with genetically engineered and modified food, under Section 22 of the Food Safety and Standards Act, 2006, are placed for consideration by the Parliament, if they are legally or constitutionally unsustainable."

25. Union of India has thus, clearly admitted that any activity in connection with genetically modified and engineered food is permissible only after the regulations are framed under Section 22 of the Act of 2006. Despite the fact that the said petition was disposed of in the month of August 2017, the required regulations have not been notified till date.

26. During the course of arguments, the counsel appearing on behalf of Union of India has placed before us the Notification dated 18.11.2022 issued under Section 92(ii)(v) r/w Section 22(2) of the Act, 2006 providing for draft regulation in the name of ***"Food Safety and Standards (Genetically Modified Foods) Regulations, 2022"***. By the said notification, the objections / suggestions from the general public were invited. However, no further action in this regard was taken by the Union of India so far.

27. Apart from the statutory requirement, India being signatory to UNCBD read with the Cartagena Protocol, is under obligation to provide specific statutory regime in this regard. however, there is complete vacuum regarding safety standards / regulatory mechanism relating to genetically modified / genetically engineered articles of food in India.

28. Our attention has been drawn also to the fact that the issue pertaining to need of regulations for sale, manufacture, distribution or import of GM articles of food has been highlighted on various occasions even in the Parliamentary Standing Committee Reports. The relevant part of the Parliamentary Standing Committee Reports is quoted below:

(a) 59th Report of the Committee On Agriculture (2014):

> *"The Committee had pointed out that there is no check on GM processed food and other items coming from outside the Country or being produced here viz. Cotton seed oil produced from Bt. Cotton in the Country"*

(b) 110th Report of the Department-Related Parliamentary Standing Committee On Health and Family Welfare (2018):

> ***"5.50** The Committee observes that in India, the GM food imports require approvals under the Environment Protection Act of 1986 and the Food Safety and Standards Act of 2006. While the former law covers the environmental impacts of the food products, the latter assesses the food's impact on human health. **Since no regulation has been finalized for GM products, it is still banned in the country.** Further, even after the Environment Ministry gives clearances for imports, permission is also required under the food safety law but importers have got away without having the mandatory approval under the Food Safety and Standards Act. **A large number of products are coming in India with GM ingredients but neither consumers nor authorities are aware of what is inside because there is nothing mentioned on the label. Taking the above fact into account, the Committee recommends formulation of regulations to the effect that those importing foods must provide mandatory declaration on the label mentioning that "this food is from GM free source".** Countries like China, Australia and the European Union nations have strict regulations about GM foods labelling so that the consumer makes informed choices.*

5.51 The Committee observes that even after more than a decade of enactment of FSS Act, a regulatory vacuum exists in the import of GM Food. *FSSAI has neither put the regulations for such approvals in place nor taken any measures to stop the imports.* ***The Committee recommends that the FSSAI should urgently finalise "Guidelines for safety assessment of food derived by GM technology" and implement them within three months of presentation of the Report to the Parliament.*** *FSSAI should also work to upgrade the GM food testing infrastructure and make use of the already present laboratories in the country and equip them with latest technology.*

5.52 *The Committee is perturbed to note that the action (or lack of it) in regulation of GM foods by FSSAI has been painstakingly slow. Recently, FSSAI has decided to have the labelling norms for genetically modified food products in order to give informed choice to the consumers. All food products having total Genetically Engineered (GE) ingredients 5% or more shall be labelled. The labelling shall be as -- "Contains GMO/Ingredients derived from GMO".* ***The absence of regulation for a decade in respect of GM foods would have caused irreversible damage to the consumers, who are the core constituency for whom FSSAI was set up.*** *The Committee strongly censures the FSSAI for this lackadaisical attitude and implores upon it to pull up its socks and ensure that the regulation made in respect to GM foods be implemented within a time bound period and also provide training to its personnel involved in regulation of GM foods.* ***The Committee also directs that FSSAI should also educate the citizens of the country as to what constitutes GM foods as a vast majority of people are not aware of the concept of GM foods.''***

29. This Court can very well take note of Parliamentary Standing Committee reports as an aid for the purpose of interpretation as well as regarding existence of a fact. While dealing with the evidentiary value accorded to the Parliamentary Standing

Committee Reports, the Constitutional Bench of the Hon'ble Supreme Court in ***Kalpana Mehta vs Union of India, 2018 (7) SCC 1*** observed that:

> ***"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 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."*

30. In the present case, the contents of the extract taken from the 110th Report of the Department-Related Parliamentary Standing Committee On Health and Family Welfare (2018) is also fortified from the admission made by the Ministry of Health & Family Welfare in an answer given in the Lok Sabha as well as the reply submitted by the Union of India and FSSAI in the present case. Thus, the contents of the said Parliamentary Standing Committee Report extend support to the averments made in the present writ petition. The apathy of the respondent-authorities is quite concerning as inspite of the need for the regulations

regarding GM Food being expressed by various ministries, the statutory mandate of Section 22 of the Act of 2006 has not been complied with, till date.

31. We are also in agreement with the contention of the petitioner that the absence of food safety protocols regarding GM food as well as regulatory mechanism is violative of Article 21 of the Constitution of India. The Hon'ble Apex Court in various authoritative pronouncements has held that the Right to Life enshrined under Article 21 also includes the Right to Health, Right to Hygienic Food and Food Safety. In the case of ***Centre for Public Interest Litigation v. Union of India, (2013) 16 SCC 279,*** it was held:-

> *"25.We may emphasise that any food article which is hazardous or injurious to public health is a potential danger to the fundamental right to life guaranteed under Article 21 of the Constitution of India. A paramount duty is cast on the States and its authorities to achieve an appropriate level of protection to human life and health which is a fundamental right guaranteed to the citizens under Article 21 read with Article 47 of the Constitution of India.*
>
> *26. We are, therefore, of the view that the provisions of the FSS Act and PFA Act and the rules and regulations framed thereunder have to be interpreted and applied in the light of the Constitutional Principles, discussed above and endeavour has to be made to achieve an appropriate level of protection of human life and health. Considerable responsibility is cast on the Authorities as well as the other officers functioning under the above mentioned Acts to achieve the desired results. Authorities are also obliged to maintain a system of control and other activities as appropriate to the circumstances, including public communication on food safety and risk, food safety surveillance and other monitoring activities covering all stages of food business.*

> *27. Enjoyment of life and its attainment, including right to life and human dignity encompasses, within its ambit availability of articles of food, without insecticide or pesticide residues, veterinary drugs residues, antibiotic residues, solvent residues, etc. But the fact remains, many of the food articles like rice, vegetables, meat, fish, milk, fruits available in the market contain insecticide or pesticide residues, beyond the tolerable limits, causing serious health hazards. We notice, fruit based soft drinks available in various fruit stalls contain such pesticide residues in alarming proportion, but no attention is made to examine its contents. Children and infants are uniquely susceptible to the effects of pesticides because of their physiological immaturity and greater exposure to soft drinks, fruit based or otherwise.*

32. The Hon'ble Apex Court in the case of ***Swami Achyutanand Tirth & Ors. vs. Union of India & Ors. 2016 (9) SCC 699*** has accepted the contention of the petitioner that the inaction and apathy on the part of the respondents to take appropriate measures to rule out sale and circulation of synthetic milk and adulterated milk products in the country has resulted in violation of fundamental rights of the public at large guaranteed under Article 21 of the Constitution of India. The Hon'ble Apex Court has issued various directions including introduction of penal provisions in the Act of 2006 by making suitable amendments. The relevant extract is quoted below:

> "*20. Since in India traditionally infants/children are fed milk, adulteration of milk and its products is a concern and stringent measures need to be taken to combat it. The consumption of adulterated milk and adulterated milk products is hazardous to human health.* ***As directed by this Court by order dated 10.12.2014, it will be in order that the Union of India come up with suitable amendments in the Food Safety and Standards Act, 2006 and the respondent-Union of India shall also make penal provisions at par with***

the provisions contained in the State amendments as indicated above.

22. Considering the seriousness of the matter and in the light of various orders passed by this Court, the Writ Petition is disposed of with the following directions and observations:-

i. Union of India and the State Governments shall take appropriate steps to implement Food Safety and Standards Act, 2006 in a more effective manner.

iv. State Food Safety Authorities should also ensure that there is adequate lab testing infrastructure and ensure that all labs have/obtain NABL accreditation to facilitate precise testing. State Government to ensure that State food testing laboratories/district food laboratories are well-equipped with the technical persons and testing facilities."

33. While giving constitutional perspective regarding food safety, the Hon'ble High Court of Gujarat in the case of ***Patel Dharmeshbhai Naranbhai vs Dharmendrabhai Pravinbhai Fofani 2023 SCC OnLine Guj 986,*** made the following observations:

"*The right to food with hygiene is also concomitant to Article 21 of the Constitution, as the right to food itself is…...Article 21 would also envelope in it a right to safe food. Right to ensure such safe food is also an obligation on the State authorities, which they discharge by implementing and enforcing the food safety norms and other regulatory measures prescribed in the different statutes*"

34. To safeguards the fundamental rights enshrined under Part III, the constitutional framework also provide for corresponding duties of the State under Part IV - Directive Principles of State Policy. In the context of the controversy involved in present case, Article 47 of the Constitution of India is also of considerable significance. The same is reproduced below:

> ***"47. Duty of the State to raise the level of nutrition and the standard of living and to improve public health.—****The State shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties and, in particular, the State shall endeavour to bring about prohibition of the consumption except for medicinal purposes of intoxicating drinks and of drugs which are injurious to health."*

35. We understand that while Directive Principles of State Policy are ordinarily not enforceable but they can be used as tool to interpret other constitutional provisions. The said aspect was also considered by the Hon'ble Supreme Court in the case of ***Bandhua Mukti Morcha vs Union of India 1983 SCC OnLine SC 323****, while observing*:

> *"This right to live with human dignity enshrined in Article 21 derives its life breath from the Directive Principles of State Policy and particularly clauses (e) and (f) of Article 39 and Articles 41 and 42...."*

In order to safeguard and promote the rights guaranteed under Article 21 of the Constitution of India, Article 47 imposes duty upon the State to ensure the food safety of its citizens. The enactment of the 2006 Act is a clear manifestation of the State's attempt to discharge this duty. However, the absence of necessary regulations has rendered the statutory provisions largely ineffective.

36. In this context, the Statement of Objects and Reasons of the Act of 2006 acquires much relevance as the Statement of Objects and Reasons is an important document that accompanies the introduction of a Bill in the legislature to explain the purpose and objectives behind the proposed law. In essence, the Statement of Objects and Reasons serves as a brief summary that justifies the

need for the legislation and explains the objectives to be achieved by its enactment.

37. The Hon'ble Supreme Court in various cases has relied on the Statement of Objects and Reasons as a tool to understand the legislative intent, providing useful insights into the background and purpose behind laws.

In ***S.C. Prashar, Income-Tax Officer, Market Ward, Bombay and Anr. Vs. Vasantsen Dwarkadas and Ors. AIR 1963 SC 1356***, the Supreme Court ruled-

> *"It is indeed true that the Statement of Objects and Reasons for introducing a particular piece of legislation cannot be used for interpreting the legislation if the words used therein are clear enough. But the Statement of Objects and Reasons can be referred to for the purpose of ascertaining the circumstances which led to the legislation in order to find out what was the mischief which the legislation aimed at."*

Similarly, the Hon'ble Apex Court in the case of ***Hira Singh v. Union of India, (2020) 20 SCC 272*** has held as under:

> ***"10.1.*** *In Directorate of Enforcement v. Deepak Mahajan [Directorate of Enforcement v. Deepak Mahajan, (1994) 3 SCC 440 : 1994 SCC (Cri) 785], it is observed by this Court that every law is designed to further ends of justice but not to frustrate on the mere technicalities. It is further observed that though the intention of the Court is only to expound the law and not to legislate, nonetheless the legislature cannot be asked to sit to resolve the difficulties in the implementation of its intention and the spirit of the law. It is the duty of the Court to mould or creatively interpret the legislation by liberally interpreting the statute.*
>
> *Thereafter, it is further observed that to winch up the legislative intent, it is permissible for courts to take into account the ostensible purpose and object and the real legislative intent. Otherwise, a bare mechanical interpretation of the words and application of the legislative intent devoid of concept of purpose and*

object will render the legislature inane. It is further observed that in given circumstances, it is permissible for courts to have functional approaches and look into the legislative intention and sometimes it may be even necessary to go behind the words and enactment and take other factors into consideration to give effect to the legislative intention and to the purpose and spirit of the enactment so that no absurdity or practical inconvenience may result and the legislative exercise and its scope and object may not become futile."

38. A plain reading of the Statement of Objects and Reasons of the 2006 Act clearly reveals the intent behind introducing special legislation for Food Safety Standards in India, with a distinct emphasis on genetically modified food. However, the said specific objective of regulating genetically modified food, as envisioned under the 2006 Act, has remained unfulfilled due to the respondent authorities' failure to frame the necessary regulations under Section 22 of the Act.

39. The impact of GM foods on human health has long been a topic of global scientific debate. While definitive conclusions remain elusive, the potential for adverse health effects cannot be ruled out. Research has indicated that GMOs in food products may lead to various health concerns, including toxicity, allergic reactions, antibiotic resistance, immunosuppression, cancer, and nutritional deficiencies.

Unlike conventional foods, genetically engineered products involve the introduction of foreign genes, bacterial and viral vectors, viral promoters, and antibiotic marker systems into the food supply. These genetic constructs, often referred to as "genetic cassettes," are novel to the human diet and, therefore, warrant thorough and rigorous safety testing before widespread consumption.

The need to establish food safety standards and a regulatory framework prior to approving GM articles of food is rooted in the 'Precautionary Principle'. The regulatory regime for the GM foods in India began with the Rules of 1989. Yet, in practice, over these three decades, the regulatory execution has been inconsistent, creating substantial gaps that put public confidence and food safety at risk. The framing of such regulations is not only important but critically necessary.

40. While it is a settled position that the Constitutional Court while exercising powers under Article 32 or 226 of the Constitution of India cannot issue a writ of Mandamus compelling the State to enact a legislation (refer to ***State of Jammu & Kashmir vs A.R. Zakki, 1992 SCC (SUPP)1 548***), however, an exception to this Rule has been recognized by the Hon'ble Apex Court in the case of ***Union of India vs K. Pushpavanam (2023) 20 SCC 736,*** wherein the Hon'ble Supreme Court observed that:

> "*The law regarding power of the writ court to issue a mandate to the legislature to legislate is well settled. No constitutional court can issue a writ of mandamus to a legislature to enact a law on a particular subject in a particular manner. The Court may, at the highest, record its opinion or recommendation on the necessity of either amending the existing law or coming out with a new law. The law has been laid down in this behalf in several decision including a decision of this court in Supreme Court Employees' Welfare Assn. v. Union of India and State of J&K v. A.R. Zakki.* ***The only exception is where the Court finds that unless a rule-making power is exercised, the legislation cannot be effectively implemented.***"

41. Further reliance in this regard is placed on the judgment passed in the case of ***Makhan Lal vs Union Territory of J&K***

MANU/JK/0395/2020, wherein the Hon'ble High Court of Jammu and Kashmir observed that:

> *"6. Legislating laws whether by way of primary legislation or under a delegated legislation is essentially a legislative function falling squarely within the domain of the legislature and, therefore, the Courts are more than reluctant to issue mandamus compelling the legislature or the government to perform its legislative function. While the position of law in this regard is well established, yet in the case of delegated legislation it is to be seen as to whether the duty enjoined by the primary legislation (Parent Act) on the government to frame rules is mandatory or discretionary. If the duty cast on the government/executive is mandatory in nature, then any neglect or indolence on the part of the government/executive to perform its statutory duty would invite the wrath of mandamus.*
>
> *7. Once it is demonstrated that the government/executive under a Statute or Act of legislature is enjoined a duty to frame rules to carry out its purposes and that there is corresponding right vested in the citizens or a class of citizens to have that duty enforced, writ of mandamus cannot be denied. The position, however, would be different, if the duty enjoined on the government/executive to frame rules is discretionary, in that, the government/executive has been left free to act in its discretion to frame rules, this Court would not issue mandamus to direct it to perform its delegated legislative function. A distinction, therefore, has to be drawn on the basis of nature of duty that is cast on the government/executive to frame rules under the Act of legislature."*

42. In light of the settled legal position, where a statute expressly requires the formulation of rules or regulations to give effect to its provisions, and the failure to do so frustrates the very purpose of the enactment, this Court is vested with the jurisdiction to direct the State to frame the necessary subordinate legislation to ensure effective implementation of the parent statute.

43. Considering the constitutional mandate, the binding provisions of the 2006 Act, and the acknowledged vacuum in food safety standards relating to genetically modified food in India, also in view of persistent demands from various sections of society and the need expressed even by the Parliamentary Standing Committee, it is imperative for the authorities under the Act of 2006 to frame the regulations envisaged under Section 22. The position remains paradoxical, while the import of genetically modified edible items is permitted but the corresponding regulatory framework has not been formulated even after the lapse of two decades. This continued inaction has rendered Explanation 2 of Section 22 virtually otiose and, more gravely, has deprived the citizens of their fundamental right to food safety, an integral facet of Article 21 of the Constitution. A Constitutional Court cannot remain a passive spectator to such a serious lapse in the discharge of statutory obligations by the FSSAI and the Union of India. **Accordingly, we answer the issue in the affirmative and deem it appropriate to issue a writ of Mandamus directing the authorities under the Act of 2006 to frame the requisite regulations on genetically modified food within a stipulated timeframe.**

b. Whether the permission/approval for manufacture, distribute, sale or import GM articles of food can be granted in absence of regulations framed under Section 22 of the Act of 2006?

44. As previously discussed, the regulatory scope of the GEAC is limited to matters concerning environmental safety, whereas the aspect of food safety squarely falls within the domain of the FSSAI under the 2006 Act. Section 22 explicitly stipulates that no

approval or permission can be granted for the manufacture, sale, storage, import, or related activities concerning genetically modified (GM) food articles unless it is in accordance with the provisions of the Act or the regulations framed thereunder. Therefore, the formulation of specific food safety and standards regulations for GM food is pre-requisite and *sine-qua-non* for granting any such approval or permission.

45. It is a well-established legal principle that where the statutory scheme requires an action to be carried out in accordance with rules or regulations, the corresponding statutory powers become operative only upon the enactment of such subordinate legislation. In the absence of duly framed and enforced rules or regulations, no such action can be lawfully undertaken.

The Hon'ble Supreme Court in the case of ***Cherukuri Mani v. State of A.P., (2015) 13 SCC 722*** has held as under:

> ***14. Where the law prescribes a thing to be done in a particular manner following a particular procedure, it shall be done in the same manner following the provisions of law, without deviating from the prescribed procedure.*** *When the provisions of Section 3 of the Act clearly mandated the authorities to pass an order of detention at one time for a period not exceeding three months only, the government order in the present case, directing detention of the husband of the appellant for a period of twelve months at a stretch is clear violation of the prescribed manner and contrary to the provisions of law. The Government cannot direct or extend the period of detention up to the maximum period of twelve months in one stroke, ignoring the cautious legislative intention that even the order of extension of detention must not exceed three months at any one time. One should not ignore the underlying principles while passing orders of detention or extending the detention period from time to time.*

The Hon'ble Supreme Court in the case of ***Babu Verghese v. Bar Council of Kerala, (1999) 3 SCC 422*** has held as under:

> *31. It is the basic principle of law long settled that if the manner of doing a particular act is prescribed under any statute, the act must be done in that manner or not at all. The origin of this rule is traceable to the decision in Taylor v. Taylor [(1875) 1 Ch D 426 : 45 LJCh 373] which was followed by Lord Roche in Nazir Ahmad v. King Emperor [(1936) 63 IA 372 : AIR 1936 PC 253] who stated as under:*
> ***"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."***

46. Therefore, no permission or approval for the sale, manufacture, distribution or import of genetically modified (GM) food can be validly granted unless the requisite regulations under Section 22 of the 2006 Act are first brought into effect. The same has been admitted by the respondent No.3 in its reply.

In para 11 of the reply respondent-FSSAI, it was contended that the following decision has been taken in a Multi-Departmental Meeting held on 24th August, 2017 :-

> *"i. Genetically Engineered Organisms (GEOs) or Living Modified Organisms (LMOs) imported for the purposes other than direct use as food or processing would require approval from GEAC.*
>
> *ii. Genetically Engineered Organisms (GEOs) or Living Modified Organisms (LMOs) intended for direct use as food or for processing would require approval from GEAC for environmental safety followed by FSSAI for Food Safety.*
>
> *iii. Food or Processed food containing genetically modified ingredients produced from but not containing LMOs or GEOs shall be approved by FSSAI"*

The para 15 of the said reply also being relevant is reproduced hereunder:-

> ***"15.*** *It is respectfully submitted that sub-Section (2) of Section 22 of the Food Safety and Standards Act has not been enforced yet. The Central Government has not notified any regulation under Section 22(2) of the Food Safety and Standards Act in regard to the manufacture, distribution, sale and import of GM Foods. Hence, GM Foods are not allowed in the Country and nor can these be regulated till such notification is issued."*

47. In light of the scheme of the 2006 Act and the submissions made in the replies by the respondent authorities, it is an admitted position that until such regulations are duly formulated and notified, no authority can be permitted to grant any approval for the use, sale, manufacture, or import of genetically modified or engineered food in India.

48. Food safety, cannot be seen as a mere regulatory or market issue, rather its a constitutional imperative enshrined under Article 21 aimed at protecting public health and securing a dignified quality life to every citizen.

49. The Current population of nearly 1.46 billion, poses enormous responsibility upon the State to ensure health and well-being of its citizens. Despite numerous progressive steps, even today, for millions of households, affordability of food still outweighs the food safety. These demographic challenges become sharper in light of the weak regulatory framework for genetically modified (GM) foods in India. Parliamentry Standing committees also highlighted significant gaps in testing. Vulnerable populations, hindered by poverty and low literacy, cannot be expected to make informed choices about their food consumption, when specific regulations stipulating clear labeling, transparent studies, public awareness and safety assurances, are missing.

50. This gap in regulations has allowed GM foods quietly enter into the Indian market. Allowing GM foods into India's food chain without strict standards and regulations would undermine the fundamental right to life. To permit corporate or commercial interests to override public health would be unjust and contrary to Constitutional ethos.

Therefore, GM foods stuffs whether grown domestically or imported, including edible oils cannot be permitted to reach Indian kitchens without comprehensive legal checks, as already cautioned by parliamentary committees.

51. Furthermore, it has been brought on record that a substantial quantity of edible items are being imported into the country. In the absence of proper certification or testing, the presence of genetically modified organisms or cells in such imports cannot be conclusively ruled out. The import, sale, or distribution of genetically modified food products, without any prior assessment of their impact on human health, may pose potential risks to public health. Accordingly, it is imperative that the import of any edible food items into India be allowed only upon the production of a "GM-Free Certificate" issued by the competent authority of the exporting country.

52. In view of the clear admission made by the respondent authorities in their replies as well as in view of the statutory mandate, we answer the question in negative and deem it necessary to restrain the respondent authorities from granting any permission / approval for sale, manufacture, distribution or import of any GM food in India in absence of the Regulations to be framed under Explanation -2 of Section 22 of the Act of 2006.

c. Whether Rule 6(7) of the Rules of 2011 is ultra vires?

53. The challenge has been given to the Rule 6(7) of the Rules of 2011 on the ground that the same is *ultra-vires* to the Rule 22 of the Act of 2006. The petitioner contended that in absence of GM regulations, the sale of GM food itself is not permissible, therefore, the permission for labeling of GM would violate Section 22 of the Act of 2006.

54. It is well settled that the Rules are in the nature of procedural law framed with a view to effectuate and implement the substantive provisions of its parent Act. To adjudicate the said issue, we have to first refer to the provisions of Rules of 2011 as well as it's parent Act i.e. The Legal Metrology Act, 2009 (hereinafter referred to as "**Act of 2009**"). The Rules of 2011 are framed under Section 52 read with Section 18 of the Act of 2009. Section 18 of the Act of 2009 reads as under:

> ***"18. Declarations on pre-packaged commodities.—***
>
> *(1) No person shall manufacture, pack, sell, import, distribute, deliver, offer, expose or possess for sale any pre-packaged commodity unless such package is in such standard quantities or number and bears thereon such declarations and particulars in such manner as may be prescribed.*
>
> *(2) Any advertisement mentioning the retail sale price of a pre-packaged commodity shall contain a declaration as to the net quantity or number of the commodity contained in the package in such form and manner as may be prescribed."*

The relevant part of Section 52 of the Act of 2009 is quoted below:

> ***52. Power of the Central Government to make rules.—*** *(1) The Central Government may, by notification, make rules for carrying out the provisions of this Act.*

> *(2) In particular, and without prejudice to the generality of the foregoing power, such rules may provide for all or any of the following matters, namely:—*
>
> *……..*
>
> ***(j) the standard quantities or number and the manner in which the packages shall bear the declarations and the particulars under sub-section (1) of section 18;***

The relevant part of Rule 6(7) of the Rules of 2011 is reproduced below:

> ***6. Declaration to be made on every package***–
>
> *(1) Every package shall bear on or on label securely affixed thereto, a definite, plain and conspicuous declaration made in accordance with the provisions of this chapter as to –*
>
> *……*
>
> ***(7) Every package containing the genetically modified food shall bear at the top of its principal display panel with words "GM".***

55. A plain reading of the Rule 6(7) shows that the same is in consonance with the mandate of its principal statute, i.e., the Act of 2009 and the same is meant to ensure that in case, packaged food is containing any GM ingredient then the label affixed over the product must have a clear mention of presence of "GM" ingredient of the said product so as to provide clear information to its consumers / users.

56. The said Rules of 2011 in itself neither permits nor imposes any restriction on the manufacture/import/sale of packages containing genetically modified food in the country. It is clear that the Act of 2006 and Rules of 2011 are operating in absolutely different spheres and therefore, the same by no stretch of imagination can be said to be violative of Section 22 of the Act of 2006. On the contrary, Section 23 of the Act of 2006 clearly requires that no person shall sell any packaged food products which are not marked and labelled in the manner as may be

specified by regulations. Thus, a clear and unambiguous declaration of the ingredients available in a packaged food is mandatorily required under the Act of 2006 and Rule 6(7) of the Rules of 2011 is in harmony with the same, advancing the objective of Section 23 of the Act of 2009.

57. Additionally, it is a well-established principle of law that a statutory provision or rule can be declared ultra vires only when there is a clear, convincing, and strong demonstration that it is violative of a constitutional provision or that it exceeds the legislative authority granted by the parent statute. This principle was firmly laid down by the Hon'ble Supreme Court in the landmark decision of ***McDowell & Co. Ltd. v. State of Andhra Pradesh, (1996) 3 SCC 709***, where the Court held that a provision cannot be invalidated merely because it is questioned; rather, it must be shown that the provision is wholly without legal basis or that it plainly violates the Constitution in an unmistakable and unequivocal manner.

Further, in the recent case of ***Anurag Kumar Agarwal v. Nikunj Dayal, (2024) 12 SCC 345***, the Hon'ble Supreme Court reiterated and reaffirmed the rigorous threshold that must be met before a law or rule can be held *ultra vires,* which reads as follows:

> "***21. In State of Tamil Nadu and Anr. v. P. Krishnamurthy and Ors.(2006) 4 SCC 517****, this Court recollected the following principles while adjudging the validity of subordinate legislation, including Regulations:*
>
> *15. There is a presumption in favour of constitutionality or validity of a subordinate legislation and the burden is upon him who attacks it to show that it is invalid. It is also well recognized that a*

subordinate legislation can be challenged under any of the following grounds:

(a) Lack of legislative competence to make the subordinate legislation.

(b) Violation of fundamental rights guaranteed under the Constitution of India.

(c) Violation of any provision of the Constitution of India.

(d) Failure to conform to the statute under which it is made or exceeding the limits of authority conferred by the enabling Act.

(e) Repugnancy to the laws of the land, that is, any enactment.

(f) Manifest arbitrariness/unreasonableness (to an extent where the court might well say that the legislature never intended to give authority to make such rules)

(emphasis supplied)''

58. In our considered opinion, the challenge so given to the Rule 6(7) of the Rules of 2011 vis-à-vis Section 22 of the Act of 2006 is wholly misconceived. The petitioner has failed to establish that the said Rule 6(7) of the Rules, 2011 is *ultra-vires* to any provision of the Part-III of the Constitution of India or to its parent Act i.e. Act of 2009. **Given the absence of any compelling or persuasive grounds brought forth by the petitioners, we answer this question in negative and hold that the challenge given to Rule 6(7) of the Rules, 2011 in the present case clearly fails.**

59. Before parting, it is imperative for us to take note of judgment dated 23.07.2024 passed by the Hon'ble Apex Court while deciding a bunch of writ petitions, lead case being ***Gene Campaign and Anr. Vs. Union of India & Ors., Writ Petition (Civil) No.115/2004 (2024 SCC Online SC 1793)***. The said bunch of writ petitions were filed at different point of time from

2004 to 2016, seeking directions for regulation of genetically modified / engineered organism in India and also to give challenge to the approval granted by the GEAC regarding environmental release of Dhara Mustard Hybrid-11 (hereinafter referred to as "DMH-11") Mustered seeds in India.

60. We have carefully gone through the said judgment in detail and found that the issue raised in the present writ petition, regarding implementation of Section 22 of the Act of 2006 i.e. Regulations to be framed for genetically modified / engineered food stuff has not been raised and discussed before the Hon'ble Apex Court. After considering the rival contentions advanced by the learned counsel for the parties, the Hon'ble Apex Court has framed the issues for adjudication and confined the same to the extent of adjudicating the scope of judicial review in relation to the approval granted by the GEAC and also regarding the validity of GEAC's approval dated 18.10.2022 and consequent decision dated 25.10.2022 regarding environmental release of DMH-11.

61. In the said judgment, the Hon'ble Judges of the Division Bench have given divergent views regarding the legality of the decision of GEAC for environmental release of DMH-11 and therefore, referred the matter to the registry to be placed before the Hon'ble Chief Justice of India for constituting an appropriate larger Bench to consider the said aspect afresh.

However, looking to the sensitivity of the issue, the Bench has expressed their consensus regarding issuance of certain directions to the Government of India. For ready reference, the concluding part of the judgment passed by the Hon'ble Supreme Court in the case of ***Gene Campaign (supra)*** is quoted below:-

> *"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 ".

The views expressed by us also get support from above said directions passed in the case of ***Gene Campaign (supra)*** as even the Hon’ble Apex Court has also expressed the need of evolving a National Policy with regard to GM crops in the country and also to provide a regulatory mechanism for the same.

VIII. CONCLUSION & DIRECTIONS:

62. Prior to delivering the operative part of the judgment, it is important to emphasize the need for dynamism and promptness in framing the requisite regulations, particularly where the statute itself mandates such exercise. This requirement becomes even more pressing when the same has a direct and vital bearing on public health. In this backdrop, the maxim ***salus populi suprema lex (the welfare of the people is the supreme law)*** assumes paramount relevance and must guide the timely and effective discharge of the statutory obligation.

63. In view of the above discussion, the present writ petition is allowed. We deem it appropriate to issue following directions:-

(i) The respondent-FSSAI as well as the Union of India are directed to implement Section 22 of the Act of 2006 in its true letter and spirit and to provide standards and safety protocols regarding genetically modified / genetically engineered articles of food in a time bound manner.

(ii) The respondent-FSSAI as well as the Union of India are directed to frame and notify the regulations under Section 22 of the Act of 2006 regarding GM articles of food, after following the procedure provided under the Act of 2006, preferably within a period of six months from today.

(iii) The FSSAI as well as GEAC are restrained for granting any permission for sale, manufacture, distribute or import of any genetically modified foodstuffs / edible items in India without first framing the regulations under Section 22 of the Act of 2006.

(iv) The FSSAI as well as Union of India are directed to ensure that no import of any food-stuff / edible items / packaged food shall be permitted unless they have been certified and labelled to be "GM free", by the exporting country.

(v) The customs authorities as well port authorities across the State are directed to ensure strict compliance of the above mentioned directions.

(vi) The constitutional challenge given to Rule 6(7) of the Rules of 2011 fails and therefore, the Rule 6(7) of the Rules of 2011 is upheld.

64. Ordered accordingly. No order as to costs.

(SANJEET PUROHIT),J **(SANJEEV PRAKASH SHARMA),ACTING CJ**

TN/