DRAFT
NATIONAL BIOTECHNOLOGY REGULATORY BILL, 2008

An Act to establish the National Biotechnology Regulatory Authority of India and to regulate the research, manufacture, importation and use of products of modern biotechnology.

WHEREAS the Government of India recognises that modern biotechnology offers opportunities to address important needs related to health, agriculture and food production, environmental protection, climate change and sustainable development that will have profound impact on society and the economy, and that modern biotechnology should be developed in a responsible way in harmony with ecological and ethical values and goals;

AND WHEREAS the Government seeks to safeguard the health and safety of the people of India and to protect the environment by identifying potential risks posed by, or as a result of, modern biotechnology, and managing those risks through regulating the safe development and deployment of biotechnology products and processes;

AND WHEREAS the Government of India wishes to promote the safe and responsible use of biotechnology by enhancing the effectiveness and efficiency of regulatory procedures and through the provision of the requisite services, infrastructure and enabling resources;

AND WHEREAS the consolidation of regulatory policies, rules and services under a single biotechnology regulatory authority will facilitate a more uniform and consistent approach to address the safety of biotechnology products and processes in a scientific and transparent manner;

BE it enacted by Parliament in the Sixtieth Year of the Republic of India as follows:

	CHAPTER I **PRELIMINARY**	
Short title, extent and commencement	**1**. (*1*) This Act may be called the National Biotechnology Regulatory Act, 2008. (*2*) It extends to the whole of India. (*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 the coming into force of that provision.	
Definitions	**2**. In this Act, unless the context otherwise requires— (a) "Authority" means the National Biotechnology Regulatory Authority established under section **3**; (b) "Biotechnology" means modern biotechnology as defined under this Act; (c) "Chairperson" means the Chairperson of the National	

	Biotechnology Regulatory Authority; (d) "Chief Regulatory Officer" means the Officer responsible for a specified regulatory branch of the Authority under sub-section (*4*) of section **9** under this Act; (e) "Containment" means measures and protocols applied to limit contact of genetically engineered organisms with the environment external to the containment facility; (f) "Containment facility" means an enclosed structure with walls, floor and ceiling, or an area within such a building, where containment is in accordance with the physical and operational requirements under sub-section (*2*)(b) of section (**9**) under this Act. (g) "Environment" includes water, air and land and the interrelationship which exists among and between water, air and land, and human beings, other living creatures, plants, micro-organism and property; (h) "Genetically engineered organism" means any organism, excluding humans, that is a product of modern biotechnology; (i) "Import" means to bring into India by land, sea or air; (j) "Monitoring Officer" means a person designated as a monitoring officer under subsection (*1*) of section **13** of this Act; (k) "Modern biotechnology" means the application of *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection. It excludes: *in vitro* fertilisation; natural processes such as conjugation, transduction, transformation; polyploidy induction; and accelerated mutagenesis; (l) "Notification" means a notification published in the Official Gazette; (m) "Premises" means a building or structure or part of a building or structure or land. (n) "Rules" means the rules made by the Authority under this Act; (o) "Tribunal" means the National Biotechnology Regulatory Authority Appellate Tribunal.	

	CHAPTER II **NATIONAL BIOTECHNOLOGY REGULATORY AUTHORITY**	
Establishment of the National Biotechnology Regulatory Authority of India	**3**. (*1*) The Central Government shall, by notification in the Official Gazette, establish an Authority to be known as the National Biotechnology Regulatory Authority of India to exercise the powers conferred on, and to perform the functions assigned to, it under this Act. (*2*) The Authority shall be a body corporate by the name aforesaid, having perpetual succession and a common seal with power to acquire, hold and dispose of properties, both movable and immovable, and to contract, and shall, by the said name, sue or be sued. (*3*) The head office of the Authority shall be at Delhi. (*4*) The Authority may establish branch offices at any other place in India.	
Composition of the National Biotechnology Regulatory Authority	**4**. (*1*) The Authority shall consist of— (a) The Chairperson; (b) Chief Regulatory Officers; (c) Regulatory Branches (d) Risk Assessment Unit (d) Cross-Sectoral Offices (*2*) The Chairperson will be supported by: (a) The Inter-Ministerial Advisory Board; and (b) The National Biotechnology Advisory Council.	
Chairperson to be Chief Executive Functions of the Chairperson	**5**. (*1*) The Chairperson shall be the Chief Executive of the Authority and shall exercise such powers and perform such duties as may be prescribed in rules under this Act. (*2*) The Chairperson shall be the legal representative of the Authority and shall be responsible for— (a) the day-to-day administration of the Authority; (b) implementing the work programmes and the decisions adopted by the Authority; (c) ensuring the provision of appropriate scientific, technical and administrative support for the Authority; (d) ensuring that the Authority carries out its tasks in	[to be elaborated in rules]

	accordance with the requirements of its users, in particular with regard to the adequacy of the services provided and the time taken; (e) the preparation of the statement of revenue and expenditure and the execution of the budget of the Authority; and (f) developing and maintaining contact with the Central Government and various stakeholders, for ensuring a regular dialogue through its relevant committees. (*3*) The Chairperson shall be responsible for submission of the Annual Report of the Authority in the form and manner as prescribed in section **23**. (*4*) The Chairperson shall approve all financial expenditures of the Authority. (*5*) The Chairperson shall have administrative control over the officers and other employees of the Authority.	
Establishment of Inter-Ministerial Advisory Board	**6**. (*1*) The Inter-Ministerial Advisory Board shall be established as specified in rules under this Act to promote Central Government cooperation as regards the implementation of India's national biotechnology regulatory system.	[to be elaborated in rules]
Establishment of National Biotechnology Advisory Council	(*2*) The National Biotechnology Advisory Council shall be established as specified in rules under this Act to provide the Authority with independent, strategic advice from various stakeholders on developments in modern biotechnology and their implications for Indian society. (*3*) The Inter-Ministerial Advisory Board and the National Biotechnology Advisory Council will have no authority to intervene on product-specific decisions made by the NBRA.	[to be elaborated in rules]
Officers and other employees of National Biotechnology Regulatory Authority	**7**. (*1*) The Authority shall appoint such other officers and employees as it considers necessary for the efficient discharge of its functions and exercise of its powers under this Act. (*2*) The salaries, allowances and pensions payable to, and other conditions of service of, the Chairperson of the Authority, officers and other employees of the Authority, shall be such as may be determined by the rules under this Act with the approval of the Central Government. **8**. No act or proceeding of the Authority shall be invalidated merely by reason of— (a) any vacancy in, or any defect in the constitution of, the Authority;	[to be elaborated in rules]

	(b) any defect in the appointment of a person as a member of the Authority; or (c) any irregularity in the procedure of the Authority not affecting the merits of the case.	
	CHAPTER III **RESPONSIBILITIES OF THE NATIONAL BIOTECHNOLOGY REGULATORY AUTHORITY**	
Responsibility of National Biotechnology Regulatory Authority Duties and functions of the National Biotechnology Regulatory Authority	**9**. (*1*) It shall be the responsibility of the Authority to regulate the research, manufacture, importation and use of genetically engineered organisms and products derived thereof as indicated in the First Schedule of this Act. (*2*) Without prejudice to the provisions of sub-section (*1*), the Authority may by rules specify— (a) measures to regulate the importation of genetically engineered organisms into India; (b) measures to regulate the containment of genetically engineered organisms in India; (c) measures to regulate clinical studies of genetically engineered organisms and derived medicines in India; (d) measures to regulate the environmental release of genetically engineered organisms in India; (e) measures to regulate the use of genetically engineered organisms and products derived thereof as, or in, food and use in human or animal health, agriculture or other applications in India; (f) procedures and standards in relation to the accreditation and notification of facilities undertaking research with genetically engineered organisms; (g) amounts of fees and other charges payable under this Act; and (h) any other measures for the purpose of giving effect to the provisions of this Act. (*3*) The Authority shall also as provided in rules under this Act: - (a) provide scientific advice and technical support to the Central Government and the State Governments in matters of framing the policy and rules in areas which have a direct	[to be elaborated in rules] [to be elaborated in rules]

	or indirect bearing on the safety of modern biotechnology products and processes regulated under this Act; (b) serve as the national point of contact for international activities related to establishing and implementing policies that impact the regulation of biotechnology and will monitor, review and analyse national and international policies that may affect Government of India priorities for the biotechnology sector; (c) develop and implement guidelines for risk assessment methodologies and monitor and conduct and forward messages about the safety of modern biotechnology products and processes to the Central Government and State Governments; (d) provide scientific and technical advice and assistance to the Central Government and the State Governments in implementation of crisis management procedures with regard to the safety of modern biotechnology products and processes; (e) establish a network of organisations with the aim to facilitate scientific co-operation through the co-ordination of activities, the exchange of information, the development and implementation of joint projects, the exchange of expertise and best practices in the fields within the Authority's responsibility; (f) ensure that the process and criteria for risk assessment and risk management are easily accessible so that product developers, stakeholders, and the public can be confident that the biotechnology regulatory system is both credible and predictable; (g) be responsible for notifying the public of all applications for field and clinical trials and of all regulatory decisions made by the Authority; (h) implement public outreach programs to inform the public about the mandate and programs of the Authority; (i) commit to a process of continual quality improvement and professional development in all programs and operations to ensure that its scientific, risk assessment and risk management capacity remains current and consistent with the best practices internationally; (j) provide training opportunities for state-level personnel who are tasked with responsibilities related to the regulation	

	of biotechnology as well as other stakeholders where capacity building needs have been identified; (k) undertake any other task assigned to it by the Central Government to carry out the objects of this Act; (l) contribute to the development of international technical standards for the safety assessment of biotechnology products and processes; (m) serve as the national point of co-ordination for work on standards and guidance related to the regulation of biotechnology products and processes undertaken by international governmental and non-governmental organisations; and (n) promote consistency between international technical standards and domestic standards related to the regulation of biotechnology products and processes while ensuring that the level of protection adopted in the country is not reduced.	
Regulatory Branches of the National Biotechnology Regulatory Authority	(*4*) The Authority shall have at least three regulatory branches, namely (a) Agriculture, Forest and Fisheries Branch, responsible for regulating biotechnology products and processes used in agriculture, forestry and fisheries, including aquaculture, as indicated in the First Schedule; (b) Human and Animal Health Branch, responsible for regulating biotechnology products and processes with applications in human and veterinary health as indicated in the First Schedule; and (c) Industrial and Environmental Applications Branch, responsible for regulating biotechnology products and processes used in industrial manufacturing and in environmental applications as indicated in the First Schedule.	
	(5) Other regulatory branches may be established as required for meeting specific needs and enhancing efficiency to regulate biotechnology products and processes.	
Chief Regulatory Officer	(*6*) Each branch shall be headed by a Chief Regulatory Officer, an eminent scientist with subject matter expertise relevant to the Branch, appointed at the rank of Additional Secretary to the Government of India.	
Risk Assessment Unit	(*7*) The Authority shall constitute a Risk Assessment Unit to be comprised of scientific officers employed by the Authority to	[to be elaborated in rules]

	undertake science-based risk assessments in accordance with rules specified under this Act.	
Scientific Advisory Panels	(*8*) The Authority shall convene Scientific Advisory Panels on an as needed basis and in accordance with rules specified under this Act to provide scientific advice, information and recommendations to the Authority on biotechnology issues that may result from regulatory actions that could impact on human and animal health, and the environment.	[to be elaborated in rules]
Roster of Experts	(a) Each regulatory branch shall establish a roster of qualified scientific experts in accordance with rules specified under the Act.	
	(b) Members of Scientific Advisory Panels will be selected by the Authority from the roster of experts in sub-section (*7*)(a) in accordance with rules specified under this Act.	[to be elaborated in rules]
Authentication of orders etc. of the National Biotechnology Regulatory Authority	(*9*) All orders and decisions of the Authority shall be authenticated by the signature of the Chairperson or any other member authorized by the Chairperson on his behalf.	
Delegation	(*10*) The Authority may, by general or special order in writing, delegate to the Chairperson, any member or officer of the Authority subject to such conditions or limitations, if any, as may be specified in the order, such of its powers and functions (except the power to make rules under section **30** under this Act) as it may deem necessary.	
	CHAPTER IV **GENERAL PROVISIONS AS TO GENETICALLY ENGINEERED ORGANISMS**	
Restrictions on import, development, manufacturing and use of genetically engineered organisms	**10**. (*1*) No person shall undertake to research, import, manufacture and use a genetically engineered organism or product derived thereof, unless: (a) application to research, import, manufacture and/or use the subject genetically engineered organism or product derived thereof has been provided in writing to the Chairperson, accompanied by all of the information required under rules to this Act; and (b) the Chairperson has authorized the research, importation, manufacture and/or use of the subject genetically engineered organism and product derived thereof in accordance with the requirements of this Act. (*2*) Sub-section (*1*) applies to the genetically engineered	

	organisms and derived products identified in the First Schedule.	
Product Rulings Committee	**11**. (*1*) The Authority will constitute a Product Rulings Committee which will be comprised of the Chairperson and the Chief Regulatory Officers of the regulatory branches.	
Members of Product Rulings Committee	(*2*) Additional members of the Product Rulings Committee shall be appointed for applications provided under section **10**, sub-section (*1*)(a) for research, manufacture and/or use of biotechnology products for various applications as indicated in the First Schedule to this Act. Three additional members shall be appointed from the roster of experts established by the respective regulatory Branch under sub-section (*6*) of section **9**. Their appointment and service on the Product Rulings Committee shall be in accordance with rules specified under the Act.	[to be elaborated in rules]
Meetings of Product Rulings Committee	(*3*) The Product Rulings Committee will meet regularly and no less than once every two weeks.	
	(*4*) Subject to sub-section (*5*), on receiving the application provided under section **10**, sub-section (*1*)(a), the Risk Assessment Unit of the Authority shall undertake a science-based evaluation of the information required under rules to this Act and will subsequently submit an opinion as to the safety of the proposed undertaking to the Product Rulings Committee.	[to be elaborated in rules]
Decisions of Product Rulings Committee	(*5*) The Product Rulings Committee shall consider all relevant matters, including the results of sub-section (*4*), and shall:	
	(a) authorize the proposed undertaking and may, where necessary in order to minimize the risk human health, animal health or the environment, impose conditions for the management of the risk; or	[to be elaborated in rules]
	(b) refuse to authorize the proposed undertaking where the proposed undertaking poses an unacceptable risk to human health, animal health or the environment.	
	(*6*) The Product Rulings Committee may decide not to grant an authorization to a person under sub-section (*5*)(a) if the Product Rulings Committee has reasonable grounds for believing that the person may not comply with the conditions that would be imposed under that sub-section in respect of the authorization.	
Publication of decisions	(*7*) Decisions taken under sub-section (*5*) will be communicated in writing to the applicant and will be made public by the Authority.	[to be elaborated in rules]

	CHAPTER V **ENFORCEMENT OF THE ACT**	
Authority responsible for enforcement of Act	**12**. The Authority shall be responsible for enforcement of this Act.	
Monitoring Officers	**13**. (*1*) The Authority may, by notification, appoint such persons as it chooses, having the qualifications prescribed by the Authority, as Monitoring Officers for the purpose of exercising powers or performing functions under this Act and the rules made thereunder.	[to be elaborated in rules]
	(*2*) The Authority may establish cooperative mechanisms with state governments and panchayati raj institutions as required to facilitate enforcement of this Act and the rules made thereunder.	
	CHAPTER VI **NOTIFICATION OF LABORATORIES**	
Notification of accredited laboratories and research institutions	**14**. The Authority may notify any laboratory and research institutions accredited by any agency as per the Authority's choosing to carry out activities as may be specified in rules under this Act.	[to be elaborated in rules]
Recognition of auditors	**15**. The Authority may recognise any organisation or agency for the purpose of auditing notified laboratories and research institutions to ensure compliance with activities as may be specified in rules under this Act.	[to be elaborated in rules]
	CHAPTER VII **OFFENCES AND PENALTIES**	
General provisions relating to offences and penalties	**16**. Any person who knowingly fails to comply with the requirements of this Act or the rules issued thereunder shall be guilty of an offence.	
	17. Any person, in connection with a requirement or direction under this Act, who provides any information or produces any document that he knows is false or misleading, shall be guilty of an offence.	
	18. Any person who, without reasonable excuse, resists, obstructs, or attempts to obstruct, impersonate, threaten, intimidate or assault an Officer of the Authority in exercising his functions under this Act, shall be guilty of an offence.	
	19. Penalties for offences are as specified in rules under this Act.	[to be elaborated in rules]

CHAPTER VIII
NATIONAL BIOTECHNOLOGY REGULATORY APPELLATE TRIBUNAL

Establishment of National Biotechnology Regulatory Appellate Tribunal	**20**. (*1*) The Central Government may by notification of the Official Gazette, establish a Tribunal to be known as the National Biotechnology Regulatory Appellate Tribunal to exercise the jurisdiction, powers and authority conferred on it by this Act or rules thereunder.	[to be elaborated in rules]
Composition of Tribunal Competencies of Tribunal Members	(*2*) The Tribunal shall consist of one Judicial Member and two Technical Members to be appointed by the Central Government for a term of three years in accordance with rules under this Act. One Technical Member shall be from healthcare and allied fields and one Technical Member shall be from agriculture and allied fields.	[to be elaborated in rules]
	(*3*) The Central Government shall appoint the Judicial Member of the Tribunal to be the Chairperson thereof.	
	(*4*) Any person aggrieved by a decision of the Authority under sub-section (*5*) of section **11** may, within 30 days from the date on which the decision is communicated to the applicant, submit a written request for the National Biotechnology Regulatory Appellate Tribunal to be convened.	
Appeal to Tribunal	(*5*) An Appeal of a decision includes reference to— (a) Making, suspending, revoking or refusing to make a decision; (b) Issuing, suspending, revoking or refusing to issue a decision; (c) Imposing a condition or restriction as part of a decision.	
	(*6*) The Tribunal shall, after giving both Parties to the appeal an opportunity of being heard, pass such orders thereon as it thinks fit.	
	(*7*) In every appeal, the Tribunal may, where it is possible, hear and decide such appeal within a period of six months from the date of filing of the appeal.	
Orders of Tribunal	(*8*) The Tribunal shall send a copy of any order passed under this section to the Chairperson of the Authority.	
	(*9*) Any orders of the Tribunal under this Act shall be executable as a decree of a civil court.	

CHAPTER IX
FINANCE, ACCOUNTS, AUDITS AND REPORTS

Grants by Central Government

21. (*1*) The Central Government may, after due appropriation made by Parliament by law in this behalf, make to the Authority grants of such sums of money as are required by it.

National Biotechnology Regulatory Authority Fund

(*2*) There shall be constituted a Fund to be called the National Biotechnology Regulatory Authority Fund and there shall be credited thereto—

(a) all grants, fees and charges received by the Authority under this Act; and

(b) all sums received by the Authority from such other sources as may be determined by the Central Government.

(*3*) The Fund may be applied for meeting the salaries, allowances and other expenses necessary to carry out the objects and purposes of this Act.

Accounts and Audit

22. (*1*) The Authority shall maintain proper accounts and relevant records and prepare an annual statement of accounts in such form as may be prescribed by the Central Government in consultation with the Comptroller and Auditor-General of India.

(*2*) The Comptroller and Auditor-General and any person appointed by him in connection with the audit of the accounts of the Authority under this Act shall have the same rights and privileges and authority in connection with such audit as the Comptroller and Auditor-General generally has in connection with the audit of Government accounts and, in particular, shall have the right to demand the production of books, accounts, connected vouchers and other documents and papers, and to inspect any of the offices of the Authority.

(*3*) The accounts of the Authority, as certified by the Comptroller and Auditor-General or any other person appointed by him in this behalf, together with the audit report thereon shall be forwarded annually to the Central Government by the Authority and the Central Government shall cause the audit report to be laid, as soon as may be after it is received, before each House of Parliament.

Annual report

23. (*1*) The Authority shall prepare once every year, in such form and at such time as may be prescribed in rules under this Act, an annual report giving— [elaborated in rules]

(a) a description of all the activities of the Authority for

	the previous year; (b) the annual accounts for the previous year; (c) the programmes of work for the coming year; and (d) the budget for the coming year. (*2*) A copy of the report received under sub-section (*1*) shall be laid, as soon as may be after it is received, before each House of Parliament.	
	CHAPTER X **MISCELLANEOUS**	
Power of Central Government to give directions	**24**. (*1*) Without prejudice to the foregoing provisions of this Act, the Authority shall, in exercise of its powers and in performance of its functions under this Act, be bound by such directions on questions of policy, other than those relating to technical and administrative matters, as the Central Government may give in writing to it from time to time: Provided that the Authority shall, as far as practicable, be given an opportunity to express its views before any direction is given under this sub-section. (*2*) If any dispute arises between the Central Government and the Authority as to whether a question is or is not a question of policy, the decision of the Central Government thereon shall be final. (*3*) The Authority shall furnish to the Central Government such returns or other information with respect to its activities as the Central Government may, from time to time, require.	
Power to remove difficulties	**25**. The Central Government may give such directions, as it may deem necessary, to a State Government for carrying out all or any of the provisions of this Act and the State Government shall comply with such directions.	
Bar of jurisdiction	**26**. With effect from the date of establishment of the Authority, no civil court or other authority shall have jurisdiction to entertain any appeal in respect of any matter with which the Authority is so empowered by or under this Act.	
Members and staff of Authority to be public servants	**27**. Officers of the Authority shall be deemed, when acting or purporting to act in pursuance of any of the provisions of this Act, to be public servants within the meaning of section 21 of the Indian Penal Code.	

Protection of action taken in good faith	**28**. No suit, prosecution or other legal proceedings shall lie against the Central Government, the Authority and other bodies constituted under this Act or any officer of the Central Government, or any member, officer or other employee of such Authority and bodies or any other officer acting under this Act for anything which is in good faith done or intended to be done under this Act or the rules made thereunder.	
Act to have overriding effect	**29**. 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.	
Power to make rules	**30**.(*1*) The Central Government may, by notification in the Official Gazette, 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— (a) powers and functions of the Chairperson of the Authority under section **5**; (b) establishment and functions of the Interministerial Advisory Board under sub-section (*1*) of section **6**; (c) establishment and functions of the National Biotechnology Advisory Council under sub-section (*2*) of section **6**; (d) salaries and other conditions of service of officers and other employees of the Authority under sub-section (*2*) of section **7**; (e) regulatory and administrative measures in relation to biotechnology products and processes under sub-section (*2*) of section **9**; (f) other functions of the Authority under sub-section (*3*) of section **9**; (g) procedures of the Risk Assessment Unit under sub-section (*7*) of section **9**; (h) procedures of Scientific Advisory Panels under sub-section (*8*) of section **9**; (i) procedures of the Product Rulings Committee under sub-section (*2*) and sub-section (*4*) of section **11**; (j) qualifications, powers and functions of Monitoring	

	Officers under sub-section (*1*) of section **13**; (k) activities to be undertaken by notified laboratories and research institutions under section **14**; (l) activities to be undertaken by auditors under section **15**; (m) penalties for offences specified in sections **16**-**18**. (n) establishment, jurisdiction, powers and authority of the National Biotechnology Regulatory Appellate Tribunal under section **20**; (o) financial rules to be adopted by the Authority in drawing up its budget under sub-section (*1*) of section **23**; and (p) any other matter which is required to be, or may be, specified by rules or in respect of which provision is to be made by rules.	
Power to amend First Schedule	**31**. The Central Government, after recommendation by the Chairperson and after giving, by notification in the Official Gazette, not less than three months notice of its intention to do so, may, by like notification, add to or otherwise amend the First Schedule of this Act for the purposes of the Act and thereupon the said Schedule shall be deemed to be amended accordingly.	
Rules to be laid before Parliament	**32**. Every rule made under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.	
Repeal and savings	**33**. (*1*) With effect from such date as the Central Government may appoint in this behalf, the enactment and orders specified in the Second Schedule shall stand repealed provided that such repeal shall not affect— (a) the previous operations of the enactment and orders under repeal or anything duly done or suffered thereunder; or (b) any right, privilege, obligation or liability acquired,	

	accrued or incurred under any of the enactment orders under repeal; or (c) any penalty, forfeiture or punishment incurred in respect of any offences committed against the enactment and orders under repeal ; or (d) any investigation or remedy in respect of any such penalty, forfeiture or punishment, and any such investigation, legal proceedings or remedy may be instituted, continued or enforced and any such penalty, forfeiture or punishment may be imposed, as if this Act had not been passed. (*2*) If there is any other law for the time being in force in any State corresponding to this Act, the same shall upon the commencement of this Act, stand repealed and in such case, the provisions of section 6 of the General Clauses Act, 1897 shall apply as if such provisions of the State law had been repealed. (*3*) Notwithstanding the repeal of the aforesaid enactment and orders, the licences issued under any such enactment or order, which are in force on the date of commencement of this Act, shall continue to be in force till the date of their expiry for all purposes, as if they had been issued under the provisions of this Act or the rules made thereunder. (*4*) Notwithstanding anything contained in any other law for the time being in force, no court shall take cognizance of an offence under the repealed Act or orders after the expiry of a period of three years from the date of the commencement of this Act. **34**. (*1*) Notwithstanding the repeal of the enactment and Orders specified in the Second Schedule the standards, safety requirements and other provisions of the Act and the rules made thereunder and Orders listed in that Schedule shall continue to be in force and operate till new standards are specified under this Act or rules made thereunder: (*2*) Provided that anything done or any action taken under the enactment and Orders under repeal shall be deemed to have been done or taken under the corresponding provisions of this Act and shall continue in force accordingly unless and until superseded by anything done or by any action taken under this Act.	

FIRST SCHEDULE

(1) Products to be regulated by the Agriculture, Fisheries and Forestry Branch, NBRA

(a) Any genetically engineered plant, animal, micro-organism, virus or other animate organism or product(s) derived thereof that may have application in agriculture, fisheries (including aquaculture), forestry or food production; and

(b) Any cloned animals that may have application in agriculture, including products derived thereof that may be used as, or in, food, or in food manufacturing.

(2) Products to be regulated by the Human and Animal Health Branch

(a) DNA vaccines intended to induce or increase an antigen specific immune response for prophylactic or therapeutic immunization, regardless of the composition or method of manufacture;

(b) Vaccines for use in humans or animals that contain living genetically engineered organisms;

(b) Recombinant gene therapy products including nucleic acids, viruses, or genetically engineered microorganisms that mediate their effect by transcription and/or translation of the transferred genetic material, and/or by integrating into the host genome. Cells may be modified in these ways *ex vivo* for subsequent administration to the recipient, or altered *in vivo* by gene therapy products administered directly to the recipient;

(c) Recombinant blood and plasma derived products.

(3) Products to be regulated by the Industrial and Environmental Applications Branch

(a) Any genetically engineered plant, animal, micro-organism, virus or other animate organism or product(s) derived thereof that may be released into the environment, excluding the provisions of sections **1** and **2** of this schedule, or have application in industrial production or manufacturing processes.

(**4) Combination Products**

Combination products comprised of a genetically engineered, biological product component with a drug component will be assigned to an authority for review and regulation in accordance with the products' primary mode of action. When a product's primary mode of action is attributable to a type of biological product assigned to NBRA, the product will be assigned to the NBRA.

Combination products that include characteristics that may be trigger oversight by more than one regulatory branch of the NBRA will be co-operatively regulated by the relevant branches.

SECOND SCHEDULE

1. Rules for the manufacture, use, import, export & storage of hazardous micro-organisms, genetically engineered organisms or cells, 1989 issued under Environment (Protection) Act, 1986: To be amended to exclude genetically engineered organisms or cells from the mandate/scope of the Rules.

2. Food Safety and Standards Act, 2006:

(a) Section 13(3)(c): The Scientific Panel may be established for genetically modified foods. Genetically modified organisms to be taken out of the mandate of FSSA.

(b) Section 22(2): The definition of genetically engineered or modified food to be amended to exclude foods and food ingredients composed of or containing genetically modified or genetically engineered organisms.

3. Drugs and Cosmetics Act, 8th Amendment:

(a) The definition of recombinant drug to include all therapeutic proteins derived from recombinant organisms, but exclude recombinant biologics (*e.g*., DNA vaccines, gene therapy products etc.).

4. The Drugs and Cosmetics (Amendment) Bill, 2007

(a) To exclude clinical trials, pre commercial safety assessment, product approval and post release monitoring of recombinant biologics.

5. The Seed Bill, 2004:

(a) Section 15 on Special provision for registration of transgenic varieties: In clause 1 Environment (Protection) Act, 1986 to be replaced with National Biotechnology Regulatory Act.

6. Proposed Plant Quarantine Bill

(a) Section 6(2)(o): Regulating the import of transgenic materials, to be modified as "regulating the import of transgenic material subject to the approval of the National Biotechnology Regulatory Authority".