

Bill No. 57 of 2013

THE BIOTECHNOLOGY REGULATORY AUTHORITY OF INDIA BILL, 2013

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SCHEDULE II

AS INTRODUCED IN LOK SABHA

Bill No. 57 of 2013

THE BIOTECHNOLOGY REGULATORY AUTHORITY OF INDIA
BILL, 2013

A

BILL

to promote the safe use of modern biotechnology by enhancing the effectiveness and efficiency of regulatory procedures and provide for establishment of the Biotechnology Regulatory Authority of India to regulate the research, transport, import, manufacture and use of organisms and products of modern biotechnology and for matters connected therewith or incidental thereto.

WHEREAS the modern biotechnology offers opportunities to address important needs related to agriculture, health, food production and environment;

AND WHEREAS India is a party to the United Nations Convention on Biological Diversity signed at Rio de Janeiro on the 5th day of June, 1992 which came into force on the 29th December, 1993; and Cartagena Protocol on Biosafety to the Convention which was adopted in Montreal on the 29th September, 2000 and came into force on the 11th September, 2003;

AND WHEREAS the aforesaid Convention and the Protocol provide that each Contracting Party shall, as far as possible and as appropriate, establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from modern biotechnology;

AND WHEREAS the Protocol provides that the Parties to the Protocol shall ensure that the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account the risks involved to human health;

AND WHEREAS it is considered necessary to take measures for the safe and responsible use of biotechnology for safeguarding the health and safety of the people of India and to protect the environment and consolidate regulatory policies, rules and services under statutory and autonomous regulatory authority and also to strengthen the implementation of the aforesaid Convention and Protocol.

BE it enacted by Parliament in the Sixty-fourth Year of the Republic of India as follows:—

CHAPTER I
PRELIMINARY

| | | |
|--|---|----------------------------|
| Short title, extent and commencement. | <p>1. (1) This Act may be called the Biotechnology Regulatory Authority of India Act, 2013.</p> <p>(2) It extends to the whole of India.</p> <p>(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 provision to the commencement of this Act shall be construed as a reference to the coming into force of that provision.</p> <p>(4) Any reference in this Act to a law which is not in force in the State of Jammu and Kashmir shall in relation to that State be construed as a reference to the corresponding law, if any, in that State.</p> | 5 10 |
| Declaration as to expediency of control by Union. | <p>2. It is hereby declared that it is expedient in the public interest that the Union should take under its control the regulation of organisms, products and processes of modern biotechnology industry.</p> | 15 |
| Definitions. | <p>3. In this Act, unless the context otherwise requires,—</p> <p>(a) “animal clones” means animals derived through somatic cell nuclear transfer techniques excluding humans;</p> <p>(b) “Appellate Tribunal” means the Biotechnology Regulatory Appellate Tribunal established under section 44;</p> <p>(c) “Authority” means the Biotechnology Regulatory Authority of India established under sub-section (1) of section 4;</p> <p>(d) “biotechnology” means modern biotechnology as defined under clause (r);</p> <p>(e) “Chairperson” means the Chairperson of the Authority appointed under section 5;</p> <p>(f) “Chief Regulatory Officer” means the head of a Division of the Authority under sub-section (3) of section 21;</p> <p>(g) “clinical trial” means systematic study of any new organism or product specified in Schedule I in human for the purpose of generating data for discovering or verifying its clinical, pharmacological (including pharmacodynamic and pharmacokinetic) biological, or, adverse effects with the objective of determining safety, efficacy or tolerance of that organism or product;</p> <p>(h) “confidential commercial information” means,—</p> <p>(i) a trade secret or any other information which has a commercial or other value which would be, or could reasonably be expected to be, destroyed or diminished if such information was disclosed; or</p> <p>(ii) such other information which relates to lawful commercial or financial affairs of a person, organisation or undertaking dealing with organisms or products specified under Part I or Part II or Part III of Schedule I which, if disclosed, could adversely affect such person, organisation or undertaking;</p> | 20 25 30 35 40 |

(i) “conjugation” means the union of gametes or unicellular organisms during fertilisation;

5 (j) “containment” means measures and protocols applied to limit contact of genetically engineered organisms or products with the environment external to the containment facility;

(k) “containment facility” means an enclosed structure with walls, floor and ceiling, or an area within such building, where containment is in accordance with the physical and operational requirements specified and regulated under clause (d) of sub-section (2) of section 18;

10 (l) “environment” shall have the meaning assigned to it in clause (a) of section 2
29 of 1986.

(m) “environmental release” means the use of genetically engineered organisms into the environment outside of any containment;

15 (n) “field trials” means a field experiment of growing a genetically engineered organism in the environment under specified terms and conditions which are intended to mitigate the establishment and spread of the organism;

(o) “import” means to bring into India the organisms and products of modern biotechnology by land, sea or air;

20 (p) “manufacture” means and includes the preparation, compounding, propagation, processing, or fabrication of any organism or product regulated under this Act;

(q) “Member” means a whole-time Member or part-time Member of the Authority appointed under section 5 and includes the Chairperson;

25 (r) “modern biotechnology” means the application of *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid 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 but does not include tissue culture of unmodified plant cells; animal cell culture of unmodified gametes; and
30 natural processes such as conjugation, transduction, transformation; polyploidy induction; and mutation breeding;

(s) “Monitoring Officer” means a person appointed as such under sub-section (1) of section 38;

35 (t) “mutation breeding” means a process which involves the use of ionizing radiation or chemical mutagenesis to induce mutations in the genome;

(u) “notification” means a notification published in the Official Gazette and the expression “notify” shall be construed accordingly;

40 (v) “organism” means any genetically engineered organism or living modified organism or genetically modified organism excluding humans, which is a product of modern biotechnology;

(w) “polyploidy induction” means the induction of a cell to have more than twice the basic or haploid number of chromosomes;

(x) “premises” means a building or structure or part of a building or structure or land;

45 (y) “prescribed” means prescribed by rules made by the Central Government under this Act;

(z) “regulations” means regulations made by the Authority under this Act;

(za) “Schedule” means Schedules I and II to this Act;

(zb) “State Government in relation to a Union territory” means the Administrator of that Union territory appointed by the President under article 239 of the Constitution;

(zc) “transduction” means natural transfer by means of a viral vector of a deoxyribonucleic acid sequence from one cell to another; 5

(zd) “transformation” means any reference to the natural transfer of genetic material from the donor to the recipient;

(ze) “University Grants Commission” means the University Grants Commission established under section 4 of the University Grants Commission Act, 1956; 3 of 1956.

(zf) “use” means authorisation of an organism or product regulated under this Act as safe for its intended purpose and such authorisation shall be subject to all other laws for the time being in force and rules and regulations made thereunder. 10

CHAPTER II

BIOTECHNOLOGY REGULATORY AUTHORITY OF INDIA

Establishment of Biotechnology Regulatory Authority of India. 4. (1) **The Central Government shall, by notification, establish an Authority to be known as the Biotechnology Regulatory Authority of India to exercise the powers conferred on it and to perform the functions assigned to it under this Act.** 15

(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. 20

(3) The head office of the Authority shall be in the National Capital Region.

(4) The Authority may, with the prior approval of the Central Government, establish its offices at any other place in India.

Composition of Authority. 5. The Authority shall consist of a Chairperson and two whole-time Members and two part-time Members to be appointed by the Central Government. 25

Qualifications for appointment of Chairperson and Members. 6. (1) The Chairperson of the Authority shall be a person of ability, integrity and outstanding scientific calibre with a doctorate degree or equivalent degree in the field of biological sciences or a postgraduate degree in medical sciences from a university recognised by the University Grants Commission or a university or institute established by law for the time being in force, and having not less than twenty years experience in a leadership role in a scientific organisation, scientific institution or scientific agency, or similar organisation or institution or agency, out of which at least five years should be as head of the organisation or institution or agency or unit or division, as the case may be. 30

(2) A Member, shall be a person of ability, integrity and outstanding scientific calibre with a doctorate degree or equivalent degree in the field of biological sciences or a postgraduate degree in medical sciences from a university recognised by the University Grants Commission or a university or institute established by law for the time being in force, and having not less than fifteen years experience in a leadership role in a scientific organisation, scientific institution or scientific agency or unit or division: 35

Provided that the Central Government shall, while appointing the Members, ensure that one such Member has requisite knowledge and experience in the fields of molecular biology, health care, agriculture or environment biotechnology and areas connected therewith respectively. 40

(3) The Chairperson and whole-time Members of the Authority shall be appointed on the recommendation of the Selection Committee constituted under sub-section (1) of section 7. 45

(4) The Chairperson or the whole-time Member of the Authority shall not hold any other office during the period of holding his office as such.

(5) The Central Government shall, within a period of two months from the date of occurrence of any vacancy in the office of the Chairperson or Member, by reason of death, resignation or removal of the Chairperson or a Member and six months before the superannuation or completion of the term of office of the Chairperson or a Member, make a reference to the Selection Committee constituted under section 7 for filling up of such vacancy.

7. (1) The Central Government shall, for the purpose of selection of the Chairperson and Members, constitute a Selection Committee consisting of—

Selection
Committee
for selection
of
Chairperson
and Members.

- (a) Cabinet Secretary – Chairperson of the Selection Committee;
- 10 (b) Secretary-in-charge of the Ministry or Department of the Central Government dealing with health research–Member;
- (c) Secretary-in-charge of the Ministry or Department of the Central Government dealing with Agriculture–Member;
- 15 (d) Secretary-in-charge of the Ministry or Department of the Central Government dealing with Biotechnology–Member;
- (e) Secretary-in-charge of the Ministry or Department of the Central Government dealing with Environment–Member;.
- (f) Secretary-in-charge of the Ministry or Department of the Central Government dealing with Personnel–Member;
- 20 (g) two eminent biotechnologists to be nominated by the Central Government—Members.

(2) A scientist not below the rank of Grade ‘G’ in the Department of Biotechnology in the Ministry of Science and Technology shall be the convenor of the meetings of the Selection Committee.

25 (3) The Selection Committee shall finalise the selection of the Chairperson and Members of the Authority within two months from the date on which the reference is made to it under sub-section (5) of section 6.

(4) The Selection Committee shall recommend a panel of two names for every vacancy referred to it.

30 (5) Before recommending any person for appointment as a Chairperson or a Member of the Authority, the Selection Committee shall satisfy itself that such person does not have any financial or other conflict of interest, which is likely to affect prejudicially his functions as Chairperson or Member, as the case may be.

35 (6) No appointment of the Chairperson or Member of the Authority shall be invalid merely by reason of any vacancy in the Selection Committee.

(7) Subject to the provisions of sub-sections (1) to (6), the Selection Committee may regulate its own procedure.

40 8. (1) The Chairperson shall have powers of general superintendence and direction in the conduct of the affairs of the Authority (including all its decisions, risk assessment units Environment Appraisal Panel and Product Ruling Committees) and he shall, in addition to presiding over the meetings of the Authority, and without prejudice to any of the provisions of this Act, exercise and discharge such powers and functions of the Authority as may be prescribed.

Functions of
Chairperson.

(2) The Chairperson shall be responsible for—

- 45 (a) the day-to-day administration of the Authority;
- (b) implementing the work programmes and the decisions of the Authority;
- (c) the preparation of the statement of revenue and expenditure and the execution of the budget of the Authority;

(d) submission of the annual report of the Authority in the form and manner as specified under section 74.

(3) Without prejudice to the provisions contained in sub-sections (1) and (2), the Chairperson shall be the chief executive of the Authority and shall exercise such powers and discharge such functions as chief executive of the Authority as may be prescribed. 5

(4) The Chairperson, or whole-time Member or an officer of the Authority if so authorised by the Chairperson, shall approve all financial expenditures of the Authority.

Term of office and other conditions of service of Chairperson and Members.

9. (1) The Chairperson and other Members shall hold office for a term of three years from the date on which they enter upon their offices, and shall be eligible for re-appointment for a further period of three years: 10

Provided that the Chairperson or a Member shall not hold office as such after he has attained the age of sixty-five years.

(2) The Chairperson and every Member shall, before entering upon his office make and subscribe, to an oath of office and of secrecy, in such form and in such manner and before such authority as may be prescribed. 15

(3) Any person holding any office (whether as an employee or an officer or a director or managing director or secretary or manager or in any other capacity) under the Central Government or State Government or in a company (including a Government Company referred to in section 617 of the Companies Act, 1956) or in any other institution, organisation, society or University or Board, shall, on his selection as the Chairperson or a whole-time Member, be required to seek retirement or resign from the services of such Central or State Government or company or institution or organisation or society or University or Board, as the case may be, before accepting the employment as the Chairperson or whole-time Member. 1 of 1956. 20

(4) The salaries and allowances payable to, and the other terms and conditions of service of, the Chairperson and whole-time Members and allowances payable to part-time Members shall be such as may be prescribed: 25

Provided that the salary, allowances and other terms and conditions of service of the Chairperson or a whole-time Member shall not be varied to his disadvantage after his appointment.

(5) Notwithstanding anything contained in sub-section (1), the Chairperson or a Member may— 30

(a) relinquish his office by giving in writing to the Central Government a notice of not less than three months; or

(b) be removed from his office in accordance with the provisions of section 11.

Restriction on Chairperson or Members on employment after cessation of office.

10. (1) The Chairperson or a Member, ceasing to hold office as such, shall not— 35

(a) for a period of two years from the date on which they cease to hold office, accept any employment in, or connected with the management or administration of, any person which has been associated with or granted authorisation for research, transport or import of organisms or products or manufacture or use of organisms and products under this Act: 40

Provided that nothing contained in this section shall apply to any employment under the Central Government or a State Government or local authority or in any statutory authority or any corporation established by or under any Central, State or Provincial Act or a Government company as defined in section 617 of the Companies Act, 1956; or 45 1 of 1956.

(b) act for, or on behalf of, any person or organisation in connection with any specific proceeding or transaction or negotiation or a case to which the Authority is a party and with respect to which the Chairperson or such Member before cessation of his office had acted for, or provided advice to, the Authority; or

(c) give advice to any person (including his client, business associate or employer) using information which was obtained in his capacity as the Chairperson or a Member and being not available or cannot be made available to the public; or

5 (d) for a period of two years from his last day in office, enter into a contract of service with, or accept an appointment to a board of directors of, or accept an offer of employment with, an entity with which he had direct and significant official dealings during his term of office as such without the due approval of the Central Government.

10 (2) The Chairperson and Members shall not communicate or reveal to any person any matter which has been brought under his consideration or known to him while acting as such.

11. (1) Notwithstanding anything contained in sub-section (5) of section 9, the Central Government may, by order, remove from office, the Chairperson or any Member, if he — Removal of
Chairperson
and Members.

(a) has been adjudged an insolvent; or

15 (b) has been convicted of an offence which, in the opinion of the Central Government, involves moral turpitude; or

(c) has become physically or mentally incapable of acting as Chairperson or Member; or

(d) has acquired such financial or other interests as is likely to affect prejudicially his functions; or

20 (e) has so abused his position as to render his continuance in office prejudicial to the public interest.

(2) The Chairperson or any Member shall not be removed under clauses (d) and (e) of sub-section (1) unless he has been given a reasonable opportunity of being heard in the matter.

25 12. (1) The Authority shall meet at such times and places, and observe such rules of procedure in regard to the transaction of business at its meetings (including quorum at such meeting) as may be specified by regulations. Meetings of
Authority.

(2) The Chairperson, if for any reason, is unable to attend a meeting of the Authority, the senior-most Member shall preside at the meeting.

30 (3) All questions which come up before any meeting of the Authority shall be decided by a majority of votes of the Members present and voting, and in the event of an equality of votes, the Chairperson or in his absence, the Member presiding, shall have a second or casting vote.

13. No act or proceeding of the Authority shall be invalidated merely by reason of—

35 (a) any vacancy in, or any defect in the constitution of, the Authority; or Vacancies,
etc., not to
invalidate
proceedings of
Authority.

(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.

40 14. (1) The Authority may appoint, such number of, Chief Regulatory Officers and other officers and such other employees as it considers necessary for the efficient discharge of its functions and exercise of its powers under this Act. Chief
Regulatory
Officers and
other
employees of
Authority.

(2) **The salaries, allowances and pensions payable to, and other terms and conditions of service of, the Chief Regulatory Officers and other officers and employees of the Authority, shall be such as may be prescribed.**

CHAPTER III

INTER-MINISTERIAL GOVERNING BOARD AND BIOTECHNOLOGY ADVISORY COUNCIL

Constitution
of Inter-
Ministerial
Governing
Board.

15. (1) The Central Government shall, by notification, constitute an Inter-Ministerial Governing Board to promote Inter-Ministerial or Departmental co-operation required for effective discharge of functions and performance of the Authority for the purposes of this Act. 5
- (2) The Inter-Ministerial Governing Board shall consist of members representing following Ministries, Departments, Councils, Directorate, authorities and officers of the Central Government or under its control or established under the Central Acts, namely:—
- (a) the Ministry of Commerce and Industry; 10
 - (b) the Ministry of Food Processing Industries;
 - (c) the Ministry of Environment and Forests;
 - (d) the Ministry of Health and Family Welfare;
 - (e) the Ministry of External Affairs;
 - (f) the Department of Agriculture and Co-operation, Ministry of Agriculture; 15
 - (g) the Department of Animal Husbandary, Dairying and Fisheries, Ministry of Agriculture;
 - (h) the Department of Biotechnology, Ministry of Science and Technology;
 - (i) the Department of Science and Technology, Ministry of Science and Technology; 20
 - (j) the Indian Council of Agricultural Research, Ministry of Agriculture, being society registered under the Societies Registration Act, 1860; 21 of 1860.
 - (k) the Indian Council of Medical Research, Ministry of Health and Family Welfare, being society registered under the Societies Registration Act, 1860; 21 of 1860.
 - (l) the Council of Scientific and Industrial Research, Ministry of Science and Technology, being society registered under the Societies Registration Act, 1860; 25
21 of 1860.
 - (m) the office of the Drug Controller General of India or office of any other authority regulating the manufacture or sale of drugs;
 - (n) the Directorate of Plant Protection, Quarantine and Storage, Ministry of Agriculture; 30
 - (o) the Food Safety and Standards Authority of India established under the Food Safety and Standards Act, 2006; 34 of 2006.
 - (p) the Biotechnology Regulatory Authority of India, established under this Act;
 - (q) such other officer of the Central Government as may be specified, by notification, by the Central Government. 35
- (3) No Ministries, Departments, Councils, Directorate, authorities and offices referred to in clauses (a) to (q) of sub-section (2) shall nominate any person below the rank of an Additional Secretary to the Government of India or equivalent rank to represent such Ministries, Departments, Councils, Directorate, authorities and offices in the Inter-Ministerial Governing Board. 40
- (4) The Secretary, in the Department of Science and Technology, Ministry of Science and Technology shall be the Chairperson of the Inter-Ministerial Governing Board.
- (5) One of the Members of the Authority, as may be nominated by the Chairperson of the Authority, shall be the convener of meetings of the Inter-Ministerial Governing Board. 45

(6) The functions of the Inter-Ministerial Governing Board shall be to ensure co-ordination amongst various Ministries, Departments, Councils, Directorate, authorities and offices on the matters of discharge of duties and performance of the functions of the Authority and regulatory policy, standards and protocols relating to organisms and products of modern biotechnology and discharge such other functions as may be prescribed.

(7) The expenses for attending the meetings of the Inter-Ministerial Governing Board (including travel expenses or any other allowances) shall be borne by the respective Ministries, Departments, Councils, Directorate, authorities and offices whom they represent under clauses (a) to (q) of sub-section (2).

10 **16.** (1) The Central Government shall, by notification, constitute a Biotechnology Advisory Council to render strategic advice to the Authority on the matters relating to developments in modern biotechnology and their implications in India.

Constitution of Biotechnology Advisory Council.

(2) The Biotechnology Advisory Council shall consist of a Presiding Officer and members not exceeding fifteen comprising from the following, namely:—

- 15 (a) Chairperson of the Authority – Presiding Officer;
 (b) plant scientist (from public or private sector);
 (c) animal or veterinary scientist (from public or private sector);
 (d) industrial or environmental scientist (from public or private sector);
 (e) medical or pharmaceutical scientist (from public or private sector);
 20 (f) nutritionist or community health specialist;
 (g) representative from consumer affairs organisation;
 (h) representative from farmer organisation;
 (i) economist;
 (j) ethicist;
 25 (k) legal expert;
 (l) any other person not falling under clauses (a) to (k).

(3) The members of Biotechnology Advisory Council referred to in clauses (b) to (l) shall be appointed, on the recommendations of the Inter-Ministerial Governing Board, by the Central Government in such manner as may be prescribed so as to secure the highest standards of competence, relevant expertise, and the broadest possible geographic representation within the country.

(4) One of the Members of the Authority, as may be nominated by the Chairperson of the Authority, shall be the convenor of the meetings of the Biotechnology Advisory Council.

35 (5) The members of the Biotechnology Advisory Council shall hold office as such for a term of three years from the date on which they enter upon their office and shall be eligible for re-appointment for a further period of three years.

(6) The functions of the Biotechnology Advisory Council shall be to advise the Authority on the relevant practices on the matters relating to modern biotechnology and its products, their uses, safety and effects and discharge such other functions, as may be prescribed.

(7) The expenses for attending the meetings of the Biotechnology Advisory Council (including travel expenses and sitting fee) or any other allowances incurred by the members shall be borne by the Authority.

45 **17.** The Inter-Ministerial Governing Board and the Biotechnology Advisory Council shall meet at such times and places, and shall observe such procedures in regard to the transaction of business at their meetings (including the quorum), as may be prescribed.

Meetings of Inter-Ministerial Governing Board and Biotechnology Advisory Council.

CHAPTER IV

FUNCTIONS AND POWERS OF AUTHORITY

Functions and
powers of
Authority.

- 18.** (1) It shall be the duty of the Authority to regulate the research, transport, import, manufacture and use of organisms and products as specified in Schedule I so as to ensure the safety to human health, animal health and the environment. 5
- (2) Without prejudice to the provisions of sub-section (1), the Authority may by regulations specify measures to regulate,—
- (a) the import of organisms and products specified under Parts I and III of Schedule I;
 - (b) the import of organisms and products for research and development specified under Part II of Schedule I; 10
 - (c) the transport of organisms and products specified under Parts I, II and III of Schedule I;
 - (d) the containment of organisms and products specified under Parts I, II and III of Schedule I; 15
 - (e) the research including field trials of organisms specified under Parts I and III of Schedule I;
 - (f) the research including pre-clinical evaluation of organisms and products specified under Part II of Schedule I;
 - (g) the environmental release of organisms and products specified under Parts I, II and III of Schedule I; 20
 - (h) the procedures and standards to be followed by the laboratories or research institutions notified under section 41 or by other laboratories or research institutions for undertaking research on organisms and products specified under Parts I, II and III of Schedule I; 25
 - (i) all processes and other new products of modern biotechnology;
 - (j) the amounts of fees and other charges to be levied under this Act; and
 - (k) any other measures necessary for the purpose of giving effect to the purposes of this Act.
- (3) Without prejudice to the provisions contained in sub-sections (1) and (2), the Authority shall,— 30
- (a) provide scientific advice and technical support to the Central Government and State Governments in matters of framing the policy and rules in areas which have a direct or indirect bearing on the safety of products and processes regulated under this Act; 35
 - (b) provide technical support to the agencies in India which deal with international activities related to establishing and implementing policies which have impact on the regulation of modern biotechnology;
 - (c) monitor, review and analyse national and international policies which may affect priorities in relation to the modern biotechnology sector; 40
 - (d) develop and implement guidelines for safety assessment methodologies for products and processes regulated under this Act;
 - (e) monitor and forward information relating to the safety of modern biotechnology products and processes regulated under this Act to the Central Government and State Governments; 45
 - (f) provide scientific and technical advice and assistance to the Central Government and State Governments regarding risk management procedures with

regard to the safety of modern biotechnology products and processes regulated under this Act;

5 (g) establish a network of organisations to facilitate scientific co-operation, the exchange of information, the development and implementation of projects, the exchange of expertise and best practices followed in areas relating to modern biotechnology under this Act;

(h) ensure that the process and criteria for safety assessment and decision making in relation to modern biotechnology become accessible and understandable;

10 (i) inform the public of all applications for field trials and all regulatory decisions made by the Authority under this Act;

(j) organise workshops, conferences and such other programmes to inform the public about the mandate, programmes and policies of the Authority;

15 (k) commit to a process of continual quality improvement and professional development in all programmes, policies and activities of the Authority to ensure that the scientific and management capacity within the Authority remain up to date and consistent with best practices adopted internationally;

(l) provide training opportunities to State-level personnel and other stakeholders, who are entrusted with responsibilities related to the regulation of organisms and products of modern biotechnology;

20 (m) serve as the nodal agency for co-ordination for work on standards and guidance related to regulation of organisms and products of modern biotechnology, with the international, governmental and non-governmental organisations;

25 (n) promote consistency between international technical standards and technical standards in India related to regulation of organisms and products of modern biotechnology while ensuring that the level of protection adopted in India is not reduced;

(o) discharge in case, it considers so necessary, any other functions in relation to organisms, products and processes of modern biotechnology.

30 **19.** (1) Where the Authority considers it expedient so to do, it may, by order in writing,—

35 (a) call upon any person, who had submitted application under sub-section (1) of section 24 or under sub-section (1) of section 27 or who has been granted authorisation under sub-section (1) of section 24, or under sub-section (1) of section 27, or from any person engaged in activities relating to modern biotechnology, at any time to furnish in writing such information or explanation relating to its affairs as the Authority may require; or

(b) appoint one or more persons to make an inquiry in relation to the affairs of any person referred to in clause (a); and

40 (c) direct any of its officers or employees to inspect the books of account or other documents of any person referred to in clause (a).

(2) Where any inquiry in relation to the affairs of any person referred to in clause (a) of sub-section (1) has been undertaken under that sub-section,—

(a) every director, manager, secretary or other officer, if such person referred to in clause (a) of sub-section (1) is a company; or

45 (b) every partner, manager, secretary or other officer, if such person referred to in clause (a) of sub-section (1) is a firm; or

Powers of Authority to call for information, conduct investigations, etc.

(c) every other person or body of persons who has had dealings in the course of business with any of the persons mentioned in clauses (a) and (b) of sub-section (1), shall be bound to produce before the Authority making the inquiry, all such books of account or other documents in his custody or power relating to, or having a bearing on the subject-matter of such inquiry and also to furnish to the Authority with any such statement or information relating thereto, as the case may be, required of him within such time as may be specified. 5

(3) Every person referred to in clause (a) of sub-section (1) shall maintain such books of account or other documents as may be prescribed.

Power of Authority to issue directions.

20. The Authority shall have the power to issue such directions to any person referred to in clause (a) of sub-section (1) of section 19 as it may consider necessary for proper safety of products or processes of modern biotechnology or which may be necessary for proper discharge of its functions or exercise of its powers under this Act. 10

CHAPTER V

DIVISIONS, UNITS AND PRODUCT RULINGS COMMITTEE OF AUTHORITY 15

Regulatory Divisions of Authority.

21. (1) The Authority shall have at least three Regulatory Divisions, namely:—

(i) a division, dealing with agriculture, forests and fisheries, and, responsible for regulating in accordance with the provisions of this Act, and rules and regulations made thereunder, the organisms and products as specified in Part I of Schedule I;

(ii) a division dealing with human health and veterinary and responsible for regulating in accordance with the provisions of this Act, and the rules and regulations made thereunder, the organisms and products as specified in Part II of Schedule I; and 20

(iii) a division dealing with industrial and environmental applications and responsible for regulating in accordance with the provisions of this Act, and the rules and regulations made thereunder, the organisms and products as specified in Part III of Schedule I. 25

(2) Without prejudice to the provisions contained in sub-section (1), the Authority may establish such other divisions as may be necessary, from time to time, to discharge its functions under the Act. 30

(3) Each division of the Authority, referred to in sub-sections (1) and (2), shall be headed by a Chief Regulatory Officer, who shall be a scientist of outstanding scientific calibre with a doctorate degree in biological or post graduate degree in Medicine or equivalent degree from a university recognised by the University Grants Commission or a university or institute established under any law for the time being in force, in a scientific discipline relevant to the Division and has not less than fifteen years experience in relevant discipline and other qualifications as may be specified by regulations. 35

(4) The duties and functions of the Chief Regulatory Officer shall be such as may be specified by regulations.

(5) Every Chief Regulatory Officer shall, before entering upon his office, make and subscribe to an oath of office and of secrecy in such form and in such manner and before such authority as may be prescribed. 40

(6) Every Chief Regulatory Officer shall be appointed on whole-time basis and not take up any employment, business or profession while acting as such and not communicate or reveal to any person or persons any matter which has been brought under his consideration or known to him while acting as such. 45

(7) Any Chief Regulatory Officer, ceasing to hold office, in the Authority, shall not—

(a) act for, or on behalf of, any person or organisation in connection with any specific proceeding, transaction, negotiation or case to which the Authority is a party

and with respect to which such Chief Regulatory Officer had acted for, or provided advice to, the Authority;

5 (b) render advice to his client, business associate or employer using information which was obtained in his capacity as a Chief Regulatory Officer and the same is not available to the public;

(c) for a period of two years from his last day in office, enter into a contract of service with, or accept an appointment to a board of directors of, or accept an offer of employment with, an entity with which he had direct and significant official dealings during his term of office without the prior approval of the Authority.

10 (8) Each regulatory division shall maintain a roster of qualified scientific experts in such manner as may be specified by regulations.

22. The Authority shall constitute a Risk Assessment Unit comprising of scientific officers possessing such qualifications, as may be specified by regulations, and to undertake science-based safety assessments in such manner as may be specified by regulations. Risk Assessment Unit.

15 23. (1) The Authority shall constitute an Enforcement Unit consisting of Monitoring Officers appointed under sub-section (1) of section 38, for enforcing the decisions of the Authority in such manner as may be specified by regulations. Other Units.

(2) Without prejudice to the provisions contained in sub-section (1), the Authority may establish such other units, as may be necessary from time to time, to discharge its functions. 20

24. (1) Every person shall obtain authorisation under sub-section (3), for the purpose of the research, transport or import of organisms and products as specified in Parts I, II and III of Schedule I, and submit for the said purpose an application to the Authority, in such form and manner, along with such fee and accompanied by such documents and information, as may be specified by regulations. 25

(2) On receipt of the application under sub-section (1) for the purpose of the research, transport or import of organisms and products as specified in Parts I, II and III of Schedule I, the Authority shall forward the application to the Risk Assessment Unit which shall undertake a science-based evaluation of the application and submit a clear assessment as to the safety of the proposed research, transport or import of such organisms or products to the Authority. 30

(3) The Authority shall, on receipt of the clear assessment under sub-section (2), as to the safety of research, transport or import of organisms and products, referred to in sub-section (1), consider all other relevant matters, in addition to the assessment submitted to it, and — 35

(a) if it is of the opinion that the proposed research, transport or import of such organism or product referred to in sub-section (1) is safe, it may, in writing, authorise, with or without conditions, such research, transport or import of organisms and products, as the case may be;

40 (b) if it is of the opinion that the proposed research, transport or import of organism and product is not safe to human health, animal health or the environment, it may, in writing, refuse to grant authorisation for the research, transport or import, as the case may be;

45 (c) if the Authority has reasonable grounds to believe that the applicant may not comply with the conditions which may be imposed under clause (a) in respect of the authorisation for the research, transport or import referred to in sub-section (1), it may in writing refuse to grant authorisation for the research, transport or import, as the case may be.

50 (4) Where the Authority refuses to grant authorisation, referred to in clause (c) of sub-section (3), it shall record the reasons for such refusal and shall furnish a copy thereof to the applicant.

(5) The decisions of the Authority taken under sub-section (3) shall be communicated in writing to the applicant and be made available to public, within ten working days of the decision being taken by it.

(6) The Authority, may, by notice given in writing to the applicant, may suspend or cancel the authorisation,—

(a) if it is of the opinion that any condition of the authorisation has been violated; or

(b) the authorisation was obtained improperly; or

(c) any new risks have emerged for continuation of the activity.

Product
Rulings
Committee.

25. (1) The Authority shall constitute a Product Rulings Committee, in such manner as may be specified by the regulations, for the purpose of making recommendations to the Authority for manufacture or use of organisms and products specified under Part I, Part II and Part III of Schedule I.

(2) The Product Rulings Committee referred to in sub-section (1) shall consists of —

(a) one of the Member of the Authority to be nominated by the Chairperson— Presiding Officer;

(b) all the Chief Regulatory Officers of their Regulatory Divisions — *ex officio* members;

(c) one representative from the Central Drugs Standard Control Organisation to be nominated by the Ministry of Health of the Central Government—member;

(d) at least three and not exceeding five members, whose names appear as qualified scientific experts in the roster of experts maintained under sub-section (8) of section 21, to be appointed by the Authority — members:

Provided that one of the experts shall be nominated by the Ministry of Environment and Forests of the Central Government from the roster of experts prepared for this purpose by the Authority in consultation with that Ministry.

(3) The Chief Regulatory Officer dealing with the organisms and products specified under Part I, Part II or Part III of Schedule I shall be the convenor of the Product Rulings Committee constituted for making recommendations for the manufacture or use of the same organisms or products dealt by the said Chief Regulatory Officer.

(4) The fee and allowances payable to the qualified scientific experts in the roster of experts maintained under sub-section (8) of section 21, shall be such as may be specified by regulations.

(5) The Product Rulings Committee shall meet at least once in every three weeks or within such period as may be decided by the Authority.

(6) The Product Rulings Committee shall observe such procedures in regard to the transaction of business at their meetings, including the quorum, as may be specified by the regulations.

Environment
Appraisal
Panel or
application of
law relating to
protection of
environment.

26. (1) The Authority shall constitute, in consultation with the Union Ministry of Environment and Forests, a panel to be known as the Environment Appraisal Panel, consisting of—

(a) a chairperson to be nominated by the Ministry of Environment and Forests of the Central Government;

(b) such members not exceeding five; and

(c) a Member-Secretary to be nominated in the Ministry of Environment and Forests of the Central Government,

having such qualifications and experience as may be prescribed.

(2) The Environment Appraisal Panel may regulate its own procedure for the purpose of conducting its meeting (including quorum) and making recommendations under sub-section (1).

(3) The Environment Appraisal Panel shall make recommendations on environmental safety of organisms and products on such matter covered under section 6 and procedure under section 8 of the Environment (Protection) Act, 1986 as may be referred to it by the Authority under sub-section (4) of section 27.

27. (1) Every person shall obtain authorisation under clause (a) of sub-section (6), for the purpose of manufacture or use, of organisms and products specified in Parts I, II [except products covered under drug as defined under clause (b) of section 3 of the Drugs and Cosmetics Act, 1940] and III of Schedule I, and submit for the said purpose an application in the form and manner, along with such fees and accompanied by such documents and information as may be specified by regulations.

Procedure for grant of authorisation for manufacture or use of organisms and products.

(2) On receipt of the application under sub-section (1) for the manufacture or use of organisms and products specified under Parts I, II [except products covered under drug as defined under clause (b) of section 3 of the Drugs and Cosmetics Act, 1940] and III of Schedule I, the Authority shall forward the application to the Risk Assessment Unit which shall undertake a science-based evaluation of the application and submit its risk assessment report as to the safety of the proposed manufacture and use of organisms or products to the Authority.

(3) The Authority, on receipt of the risk assessment report under sub-section (2), as to the safety for manufacture or use of organisms and products, shall forward the risk assessment report of the Risk Assessment Unit to the Product Rulings Committee for giving its recommendations thereon, as to the safety of organisms and products.

(4) The Authority shall obtain the opinion of the Environmental Appraisal Panel in case of organisms and products having environmental impact as may be referred by the Authority:

Provided that in case of difference of opinion between the Environmental Appraisal Panel and the Authority, the Authority shall pass an order giving its reason in this regard.

(5) Without prejudice to the provisions contained in sub-sections (1), (2), (3) and (4), the Authority shall obtain the objections or suggestions from the public in case of organisms and products.

(6) The Authority, on receipt of the recommendations under sub-section (3), as to the safety for manufacture or use of organisms and products, shall consider all other relevant matters, in addition to the risk assessment report submitted to it by the Risk Assessment Unit and—

(a) if it is of the opinion that the proposed manufacture or use of organisms and products is safe it may, in writing authorise, with or without conditions, such manufacture or use of organisms and products, as the case may be;

(b) if it is of the opinion that the proposed manufacture or use of organisms and products is not safe to human health or animal health or the environment, it may, in writing refuse to grant authorisation for the manufacture or use of organisms and products, as the case may be;

(c) if the Authority has reasonable grounds to believe that the person may not comply with the conditions which may be imposed under clause (a) in respect of the authorisation, it may in writing refuse to grant authorisation for the manufacture or use of organisms and products, as the case may be.

(7) Where the Authority refuses to grant authorisation referred to in clause (c) of sub-section (6), it shall record the reasons for such decision and furnish a copy thereof to the applicant.

(8) The decisions of the Authority taken under clause (a) or clause (b) or clause (c) of sub-section (6) shall be communicated in writing to the applicant and be made available to public, within ten working days of the decision being taken by it.

(9) The Authority may, by notice given in writing to the applicant, suspend or cancel the authorisation—

(a) if it is of the opinion that any condition of the authorisation has been violated; or

(b) the authorisation was obtained improperly; or

(c) any new risks have emerged for continuation of the activity.

(10) The Authority may develop a prompt and effective product recall system of organisms and products in circumstances as specified.

Disclosure of confidential commercial information.

28. (1) In case an application to be submitted under sub-section (1) of section 24 or sub-section (1) of section 27 requires the disclosure of confidential commercial information, such information shall, notwithstanding anything contained in the Right to Information Act, 2005, be retained as confidential by the Authority and not be disclosed to any other party.

(2) If the Authority is satisfied that the public interest outweighs the disclosure of confidential commercial information or such disclosure shall not cause harm to any person, it may refuse to retain that information as confidential commercial information.

Scientific Advisory Panels and Roster of Experts.

29. The Authority may constitute one or more Scientific Advisory Panels, from the roster of experts referred to in sub-section (8) of section 21 in such manner as may be specified by the regulations, to provide scientific advice, information and recommendations to the Authority under this Act on biotechnology issues which may, result from regulatory actions of the Authority, and, would have an impact on the safety of human health, animal health and the environment.

Seeking advice from Scientific Advisory Panels and roster of experts.

30. The Authority may, for the purpose of obtaining scientific advice and technical support on any issue relating to modern biotechnology, without prejudice to the other provisions of this Act, may seek advice from any member of the Scientific Advisory Panel referred to in section 29 in such manner as may be specified by the regulations.

Authentication of decisions or orders, etc.

31. All orders and decisions of the Authority shall be authenticated by the signature of the Chairperson or any other officer of the Authority so authorised by the Chairperson.

Delegation.

32. The Authority may, by general or special order in writing, delegate to the Chairperson or any member or any 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 regulations under section 83) as it may consider necessary.

CHAPTER VI

PROVISIONS RELATING TO IMPORT OF ORGANISMS AND PRODUCTS AS SPECIFIED IN SCHEDULE I

Application of law relating to customs and powers of Customs officers.

33. (1) The law for the time being in force relating to the customs and goods, the import of which is prohibited under the Customs Act, 1962 or any other law for the time being in force shall, subject to the provisions of section 27 of this Act, apply in respect of organisms and products specified under Part I, Part II [except products covered under drug as defined under clause (b) of section 3 of the Drugs and Cosmetics Act, 1940] and Part III

62 of 1962. of Schedule I, the import of which requires the authorisation by the Authority under Chapter V, and officers of Customs and officers empowered under the Customs Act, 1962 or any other law for the time being in force, to perform the duties imposed thereby on a Commissioner of Customs and other officers of Customs, shall have the same powers in
5 respect of such organisms and products as they have for the time being in respect of such goods as aforesaid.

(2) Without prejudice to the provisions of sub-section (1), the Commissioner of Customs or any officer of the Government authorised by the Central Government in this behalf, may detain any imported package which he suspects to contain any organisms and
10 products specified under Part I, Part II and Part III of Schedule I and the import of which requires the approval of the Authority under Chapter V, and shall forthwith report such detention to the Authority, and, if necessary, forward, with the approval of the Authority, the package or sample of any suspected organisms and products found therein to the laboratory notified or research institution accredited under this Act.

15

CHAPTER VII

FIELD TRIALS OR CLINICAL TRIAL

34. (1) No person shall conduct field trials in respect of any organisms or products specified in Part I and Part III of Schedule I: Field trials or clinical trials.

20 Provided that the Authority may having regard to the development of modern biotechnology permit field trials in respect to any organisms or products specified in Part I and Part III of Schedule I with such safeguards as it may consider necessary and which may be specified by the regulations.

(2) The Authority may evaluate and recommend clinical trials of organisms and products specified in Part II of Schedule I on the application forwarded by the Central
25 Drugs Standard Control Organisation under the provisions of the Drugs and Cosmetics Act, 1940 and the rules and regulations made thereunder.
23 of 1940.

Explanation.—For the removal of doubts, it is hereby declared that the Authority shall not grant any permission or authorisation to conduct any clinical trial in respect of organisms and products specified in Part II of Schedule I but nothing shall prevent the
30 Authority to authorise any trial in laboratory or in containment for pre-clinical testing preceding the clinical trial.

CHAPTER VIII

STATE BIOTECHNOLOGY REGULATORY ADVISORY COMMITTEE

35. (1) Every State Government shall, for the purposes of discharging its functions under sub-section (6), constitute a committee to be called as the “..... (Name of the State) Biotechnology Regulatory Advisory Committee”. State Biotechnology Regulatory Advisory Committee.

(2) Every State Biotechnology Regulatory Advisory Committee shall consist of,—

(a) a representative not below the rank of Director from the Ministry or Department dealing with health;

40 (b) a representative not below the rank of Director from the Ministry or Department dealing with environment;

(c) a representative not below the rank of Director from the Ministry or Department dealing with agriculture;

(d) a representative not below the rank of Director from the Ministry or Department dealing with Industry;

(e) two members, having technical expertise in healthcare and allied fields, agriculture and allied fields or environmental or industrial sciences and allied fields, to be nominated by the Authority;

(f) two other members, having adequate knowledge of, and experience in, the field of biotechnology to be nominated by the Secretary or Commissioner or head referred to in sub-section (3), as the case may be, who presides over the State Biotechnology Regulatory Advisory Committees referred to in that sub-section.

(3) Every State Biotechnology Regulatory Advisory Committee shall be convened by the Secretary or head or Commissioner of State Department of Biotechnology or Biotechnology Commission, as the case may be, where no State Department of Biotechnology or Biotechnology Commission exists, by the Secretary or head of the State Department of Science and Technology.

(4) The Secretary or head or Commissioner referred to in sub-section (3) shall preside over the meetings of the State Biotechnology Regulatory Advisory Committee.

(5) The State Biotechnology Regulatory Advisory Committee shall observe such procedures in regard to transaction of business at its meetings (including the quorum and the intervals at which the meeting may be held) and pay such fee and allowances to its members as may be specified by the State Government.

(6) The functions of a State Biotechnology Regulatory Advisory Committee shall be to,—

(a) act as the nodal agency for inter-action between the State Government and the Authority in respect of matters related to the regulation of modern biotechnology under this Act and the rules and regulations made thereunder;

(b) facilitate inter-departmental co-ordination within the State for regulation of modern biotechnology;

(c) identify state-specific needs related to the regulation of modern biotechnology and apprise the same to the Authority;

(d) collaborate with the Authority for undertaking capacity building and information sharing activities relating to biotechnology within the State;

(e) ensure that information relating to activities and programmes of the Authority are made available to the public in a transparent and accessible manner within the State.

(7) The Authority shall provide technical or financial assistance or such other assistance as it may consider necessary, for the establishment of the State Biotechnology Regulatory Advisory Committee and discharge of its functions, in such manner as may be prescribed.

(8) Every State Biotechnology Regulatory Advisory Committee shall prepare and publish an annual report and make the same available to the State, the Authority and the public.

Convening of meetings of State Biotechnology Regulatory Advisory Committees.

36. The Chairperson of the Authority shall convene an annual meeting of State Biotechnology Regulatory Advisory Committees of all the States, in such manner as may be specified by the regulations, with a view to identify priority issues and activities which the State Governments may include in their programmes and operations related to the regulation of modern biotechnology.

CHAPTER IX

ENFORCEMENT OF PROVISIONS OF ACT

37. The Authority shall be responsible for enforcement of the provisions of this Act and regulations made thereunder.

Authority responsible for enforcement of Act.

5 38. (1) The Authority may, by notification, appoint such number of persons, including the officers of the Authority, any State Governments or any other authority, as Monitoring Officers in its Enforcement Unit referred to in sub-section (1) of section 23, as it may deem fit, for the purpose of exercising powers or performing functions under this Act.

Monitoring Officers.

(2) The persons appointed as Monitoring Officers, under sub-section (1), shall possess such qualifications and experience relating to modern biotechnology as may be specified by the regulations.

(3) The Authority shall establish such mechanisms, in consultation with the concerned State Governments, State Biotechnology Regulatory Advisory Committees or any other authority, as may be considered necessary to facilitate enforcement of the provisions of this Act, the rules and regulations made thereunder.

39. (1) Every Monitoring Officer shall undertake such activities, as may be directed by the Authority, to ensure compliance with the provisions of this Act and the rules and regulations made thereunder and such activities include,—

Functions of Monitoring Officers.

(a) enforcement of the regulations made under sub-section (2) of section 18 under this Act; and

(b) enforcement of compliance of refusal of authorisation under clause (c) of sub-section (6) of section 27.

(2) In exercising the powers or performing the functions as a Monitoring Officer, the Monitoring Officer shall comply with such directions of the Authority, as it may issue to such Monitoring Officers.

40. (1) The Monitoring Officer may, for the purpose of discharging his functions under this Act, and if so authorised by the Authority, —

Powers of Monitoring Officers.

(a) enter and inspect any premises where products and processes regulated under this Act may be found;

(b) inspect, examine, take measurements of, or conduct tests on, or take samples of, anything on the premises which relates to products and processes regulated under this Act;

(c) take photographs, make video or audio recordings of the premises or anything on the premises on which products and processes regulated under this Act have been found;

(d) inspect any book, record or document on the premises referred to in clause (a);

(e) take to the premises referred to in clause (a), such equipment and materials as the Monitoring Officer may require for the purpose of exercising his powers and discharging his functions in relation to products or processes regulated under this Act.

(2) The Monitoring Officer shall, in exercising the powers of entry upon, and inspection of any place under this section, follow, as far as may be, the provisions of the Code of Criminal Procedure, 1973 relating to the search or inspection of a place by a police officer executing a search warrant under that Code.

(3) A Monitoring Officer shall not enter any premises except with the consent of the occupant of the premises or under the authority of a warrant.

Explanation.— For the purpose of sub-section (3) “warrant” means a warrant issued by the Judicial Magistrate of the first class or the Metropolitan Magistrate, as the case may be, within whose jurisdiction the place, where the warrant is to be executed, is situated. 5

CHAPTER X

NOTIFICATION OF LABORATORIES

Notification of accredited laboratories and research institutions.

41. The Authority may, notify, for the purposes of this Act, such laboratories or research institutions which have been accredited by such agencies as may be specified by the regulations: 10

Provided that the Authority may, if it considers so necessary, having regard to emerging nature of modern biotechnology and facilities and equipment available in laboratories, (other than accredited laboratories) may, notify for the purposes of this Act, such laboratories or research institutions which had not been accredited by such agencies, as laboratories or research institutions for the purposes of this Act. 15

Designation of certain organisation or agency as auditor.

42. (1) The Authority may designate one or more organisations or agencies as an auditor for the purpose of auditing notified laboratories and research institutions to ensure compliance with activities, relating to safety of modern biotechnology, as may be specified by regulations.

(2) An organisation or agency shall not be qualified for designation as auditor under sub-section (1), unless such organisation or agency fulfils such criteria as may be specified by regulations. 20

(3) Every person authorised by an organisation or agency referred to in sub-section (1) shall, for the purpose of auditing laboratories and research institutions notified under section 41, have a right on all working days to access such notified laboratories and research institutions in respect of which such organisation or agency had been designated as an auditor and be entitled to require from the officers of such notified laboratories and research institutions, such information or document as the auditor may consider necessary for the performance of his duties as an auditor. 25

(4) The auditor referred to in sub-section (1) shall, within such time as may be specified by the Authority, make a report in writing to the Authority, including therein the specific areas or issues or standards or procedures, directed by it to be audited, as may be specified by it in this regard. 30

CHAPTER XI

BIOTECHNOLOGY REGULATORY APPELLATE TRIBUNAL 35

Appeal to Appellate Tribunal.

43. (1) Any person aggrieved by a decision or order or directions of the Authority under this Act, may, within a period of thirty days from the date on which the decision or order or direction is communicated to him, file an appeal to the Biotechnology Regulatory Appellate Tribunal.

(2) Every such appeal shall be preferred in such form and manner along with such fees and contain such particulars as may be prescribed. 40

Establishment of Appellate Tribunal.

44. **The Central Government shall, by notification, establish with effect from such date as may be specified therein, an Appellate Tribunal to be known as the Biotechnology Regulatory Appellate Tribunal to exercise the jurisdiction, powers and authority conferred on such Tribunal by or under this Act.** 45

- 45.** (1) The Appellate Tribunal shall consist of—
- (a) a full-time Chairperson;
- (b) part-time expert Members not exceeding five, as the Central Government may notify.
- 5 (2) The Chairperson of the Appellate Tribunal may, if considered necessary, direct any one or more person having specialised knowledge and experience in a particular case before the Appellate Tribunal to assist the Appellate Tribunal in that case.
- (3) The Appellate Tribunal shall sit at such place or places, as the Central Government may, by notification, specify.
- 10 (4) The Central Government may, in consultation with the Chairperson of the Appellate Tribunal, make rules regulating generally the practices and procedure of the Appellate Tribunal including —
- (a) rules as to the persons who would be entitled to appear before the Appellate Tribunal;
- 15 (b) rules as to the procedure for hearing appeals and other matters pertaining to the appeals;
- (c) the minimum number of members who would hear the applications and appeals in respect of any class or classes of appeals.
- 46.** (1) A person shall not be qualified for appointment as the Chairperson of the Appellate Tribunal unless he is, or has been, a Judge of the Supreme Court of India or the Chief Justice of a High Court.
- 20 (2) A person shall not be qualified for appointment as part-time expert Member, unless he is a person who is an eminent scientist in the field of biological sciences or biotechnology related to healthcare or agriculture or environmental or industrial activities and possesses an experience of at least twenty years in the field, or who has held the post in the Central Government or a State Government dealing with biological sciences or biotechnology related to healthcare or agriculture or environmental or industrial activities equivalent to the Joint Secretary to the Government of India for at least three years and possesses special knowledge in the field.
- 25 (3) The Chairperson and part-time expert Members of the Appellate Tribunal shall not hold any other office during their tenure as such.
- 47.** (1) Subject to the provisions of sub-sections (2) and (3), the Chairperson and part-time expert Members of the Appellate Tribunal shall be appointed by the Central Government.
- 30 (2) The Chairperson shall be appointed by the Central Government in consultation with the Chief Justice of India.
- (3) The part-time expert Members of the Appellate Tribunal shall be appointed on the recommendations of such Selection Committee and in such manner as may be prescribed.
- 48.** The Chairperson and part time expert Members of the Appellate Tribunal shall hold office as such for a term of three years from the date on which they enter upon their office, but shall not be eligible for re-appointment:
- 40 Provided that no Chairperson shall hold office as such after he has attained the age of seventy years:
- Provided further that no part-time expert Member shall hold office after he has attained
- 45 the age of sixty-five years.

Composition
of Appellate
Tribunal.

Qualifications
for appoint-
ment of
Chairperson
and part-time
expert
Members.

Appointment
of Chairper-
son and part-
time expert
Members.

Term of office
and other
conditions of
service of
Chairperson
and part-time
expert
Members.

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|--|--|------------------------------------|
| Resignation. | <p>49. The Chairperson or part-time expert Member of the Appellate Tribunal may, by notice in writing under their hand addressed to the Central Government, resign from their office.</p> | |
| Salaries, allowances and other terms and conditions of service. | <p>50. The salaries and allowances payable to, and the other terms and conditions of service (including pension, gratuity and other retirement benefits) of, the Chairperson and allowances and fee payable to part-time expert Members of the Appellate Tribunal shall be such as may be prescribed:</p> <p style="padding-left: 40px;">Provided that neither the salary and allowances nor the other terms and conditions of service of the Chairperson shall be varied to their disadvantage after his appointment.</p> | 5 |
| Restriction on Chairperson or Members on employment after cessation of office. | <p>51. The Chairperson or a Member of the Appellate Tribunal, ceasing to hold office as such, shall not —</p> <p style="padding-left: 40px;">(a) for a period of one year from the date on which they cease to hold office, accept any employment in, or connected with the management or administration of, any person which has been a party to a proceeding before the Appellate Tribunal under this Act:</p> <p style="padding-left: 40px;">Provided that nothing contained in this section shall apply to any employment under the Central Government or a State Government or local authority or in any statutory authority or any corporation established by or under any Central, State or Provincial Act or a Government company as defined in section 617 of the Companies Act, 1956;</p> <p style="padding-left: 40px;">(b) act, for or on behalf of any person or organisation in connection with any specific proceeding, transaction, negotiation or a case to which the Authority is a party or whose matter had been before such Chairperson or Member.</p> <p style="padding-left: 40px;">(c) give advice to any person (including his client, business associate or employer) using information which was obtained in his capacity as the Chairperson or a Member and being not available or cannot be made available to the public.</p> <p style="padding-left: 40px;">(d) for a period of two years from his last day in office, enter into a contract of service with, or accept an appointment to a board of directors of, or accept an offer of employment with, an entity with which he had direct and significant official dealings during his term of office or whose matter had been before such Chairperson or Member as such without the approval of the Central Government.</p> | 10 15 20 25 30 |
| Removal and suspension of Chairperson and part-time expert Member. | <p>52. (1) The Central Government may, in consultation with the Chief Justice of India, remove from office of the Chairperson of the Appellate Tribunal, who,—</p> <p style="padding-left: 40px;">(a) has been adjudged an insolvent; or</p> <p style="padding-left: 40px;">(b) has been convicted of an offence which, in the opinion of the Central Government, involves moral turpitude; or</p> <p style="padding-left: 40px;">(c) has become physically or mentally incapable; or</p> <p style="padding-left: 40px;">(d) has acquired such financial or other interest as is likely to affect prejudicially his functions; or</p> <p style="padding-left: 40px;">(e) has so abused his position as to render his continuance in office prejudicial to the public interest.</p> <p>(2) The Chairperson shall not be removed from his office except by an order made by the Central Government, after an inquiry made by a Judge of the Supreme Court in which such Chairperson has been informed of the charges against him and given a reasonable opportunity of being heard in respect of those charges.</p> <p>(3) The Central Government may suspend from office the Chairperson in respect of whom a reference of conducting an inquiry has been made to the Judge of the Supreme Court under sub-section (2), until the Central Government passes an order on receipt of the report of inquiry made by the Judge of the Supreme Court on such reference.</p> | 20 1 of 1956. 35 40 45 |

(4) The Central Government may, by rules, regulate the procedure for inquiry referred to in sub-section (2).

(5) The part-time expert Member may be removed from his office by an order of the Central Government on the grounds specified in sub-section (1):

5 Provided that the part-time expert Member shall not be removed unless he has been given an opportunity of being heard in the matter.

10 **53.** In the event of the occurrence of any vacancy in the office of the Chairperson of the Appellate Tribunal, by reason of his death, resignation or otherwise, such part-time expert Member of the Appellate Tribunal, as the Central Government may, by notification, authorise in this behalf, shall act as the Chairperson until the date on which a new Chairperson is appointed in accordance with the provisions of this Act.

To act as Chairperson of Appellate Tribunal or to discharge his functions in certain circumstances.

54. (1) The Central Government shall determine the nature and categories of the officers and other employees required to assist the Appellate Tribunal in the discharge of its functions.

Staff of Appellate Tribunal.

15 (2) The recruitment of the officers and other employees of the Appellate Tribunal shall be made by the Chairperson in such manner as may be prescribed.

(3) The officers and other employees of the Appellate Tribunal shall discharge their functions under the general superintendence of the Chairperson of the Appellate Tribunal.

20 **(4) The salaries and allowances payable to, and the other terms and conditions of service of, the officers and other employees of the Appellate Tribunal shall be such as may be prescribed.**

55. The Chairperson of the Appellate Tribunal shall exercise such financial and administrative powers as may be vested in him under the rules made by the Central Government:

Financial and administrative powers of Chairperson.

25 Provided that the Chairperson shall have the authority to delegate such of his financial and administrative powers, as he may think fit, to any part-time expert Member or officer of the Appellate Tribunal subject to the condition that the Member or such officer, while exercising such delegated power, continues to act under the direction, control and supervision of the Chairperson.

30 **56.** (1) The Appellate Tribunal shall have the jurisdiction over all civil cases where a substantial question relating to modern biotechnology is involved and such question arises out of the safety and use of organisms, products and processes specified under Part I or Part II or Part III of Schedule I and hear appeals from the decisions or orders of the Authority.

Appellate Tribunal to settle disputes.

35 (2) The Appellate Tribunal shall hear the appeals referred to in sub-section (1) and dispose of such appeals and pass order thereon.

(3) No application for deciding substantial question relating to modern biotechnology under this section shall be entertained by the Appellate Tribunal unless it is made within a period of two years from the date on which the cause of action for such question first arose:

40 Provided that the Appellate Tribunal may, if it is satisfied that the applicant was prevented by sufficient cause from filing the application within the said period, allow it to be filed within a further period not exceeding sixty days.

45 (4) The application, or as the case may be, the appeal filed before the Appellate Tribunal under sub-section (1) or sub-section (3) shall be dealt with by it as expeditiously as possible and endeavour shall be made by it to dispose of the application, or, as the case may be, the appeal, finally within six months from the date of filing of the application, or as the case may be, the appeal, after providing the parties concerned an opportunity to be heard.

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| Procedure and powers of Appellate Tribunal. | <p>57. (1) The Appellate Tribunal shall not be bound by the procedure laid down by the Code of Civil Procedure, 1908 but shall be guided by the principles of natural justice.</p> <p>(2) Subject to the provisions of this Act, the Appellate Tribunal shall have power to regulate its own procedure.</p> <p>(3) The Appellate Tribunal shall also not be bound by the rules of evidence contained in the Indian Evidence Act, 1872.</p> <p>(4) The Appellate Tribunal shall have, for the purposes of discharging its functions under this Act, the same powers as are vested in a civil court under the Code of Civil Procedure, 1908, while trying a suit, in respect of the following matters, namely:—</p> <p>(a) summoning and enforcing the attendance of any person and examining him on oath;</p> <p>(b) requiring the discovery and production of documents;</p> <p>(c) receiving evidence on affidavits;</p> <p>(d) subject to the provisions of sections 123 and 124 of the Indian Evidence Act, 1872, requisitioning any public record or document or copy of such record or document from any office;</p> <p>(e) issuing commissions for the examination of witnesses or documents;</p> <p>(f) reviewing its decision;</p> <p>(g) dismissing an application for default or deciding it <i>ex parte</i>;</p> <p>(h) setting aside any order of dismissal of any application for default or any order passed by it <i>ex parte</i>;</p> <p>(i) pass an interim order (including granting an injunction or stay) after providing the parties concerned an opportunity of being heard, on any application made or appeal filed under this Act;</p> <p>(j) any other matter which may be prescribed.</p> <p>(5) All proceedings before the Appellate Tribunal shall be deemed to be judicial proceedings within the meaning of sections 193, 219 and 228 for the purposes of section 196 of the Indian Penal Code, and the Appellate Tribunal shall be deemed to be a civil court for the purposes of section 195 and Chapter XXVI of the Code of Criminal Procedure, 1973.</p> | <p>5 of 1908.</p> <p>5</p> <p>1 of 1872.</p> <p>5 of 1908.</p> <p>10</p> <p>15</p> <p>1 of 1872.</p> <p>20</p> <p>25</p> <p>45 of 1860. 2 of 1974.</p> |
| Decision to be taken by majority. | <p>58. The decision of the Appellate Tribunal by majority of members shall be binding.</p> | <p>30</p> |
| Cost. | <p>59. While disposing of an application or an appeal under this Act, the Appellate Tribunal shall have power to make such order as to costs as it may consider necessary.</p> | |
| Execution of award or order of Appellate Tribunal. | <p>60. An award or order or decision of the Appellate Tribunal under this Act shall be executable by the Appellate Tribunal as a decree of a civil court, and for this purpose, the Appellate Tribunal shall have all the powers of a civil court.</p> | <p>35</p> |
| Appeal to Supreme Court. | <p>61. (1) Notwithstanding anything contained in the Code of Civil Procedure, 1908 or in any other law for the time being force, an appeal shall lie against any order, (not being an interlocutory order) of the Appellate Tribunal to the Supreme Court on one or more of the grounds specified in section 100 of that Code.</p> <p>(2) No appeal shall lie against any decision or order made by the Appellate Tribunal with the consent of the parties.</p> <p>(3) Every appeal under this section shall be preferred within a period of ninety days from the date of the decision or order appealed against:</p> | <p>5 of 1908.</p> <p>40</p> |

Provided that the Supreme Court may entertain the appeal after the expiry of the said period of ninety days, if it is satisfied that the appellant was prevented by sufficient cause from preferring the appeal in time.

CHAPTER XII

5

OFFENCES AND PENALTIES

62. If a person, in connection with a requirement or direction under this Act, provides any information or produces any document that the person knows is false or misleading, he shall be punishable with imprisonment for a term which may extend to three months and also with fine which may extend to five lakh rupees.

Punishment for false information.

63. (1) Whoever, himself or by any other person on his behalf, conducts field trials with organisms or products specified in Part I or Part III of Schedule I, in contravention of section 34 shall be punished with imprisonment for a term which shall not be less than six months but which may extend to one year and with fine which may extend to two lakh rupees.

Punishment for conduct of unapproved field trial.

(2) Whoever, having been convicted of an offence under sub-section (1), is again convicted of an offence under that sub-section, shall be punished with imprisonment for a term which shall not be less than two years but which may extend to four years and with fine which may extend to four lakh rupees.

64. If a person, without reasonable excuse, resists, obstructs, or attempts to obstruct, impersonate, threaten, intimidate or assault an officer of the Authority or any person assigned to discharge any function under this Act, or in exercising his functions under this Act, he shall be punishable with imprisonment for a term which may extend to three months and also with fine which may extend to five lakh rupees.

Punishment for obstructing or impersonating an officer of Authority.

65. If any auditor's report is made, which is false or otherwise than in conformity with the specific areas or issues or standards or procedures directed to be audited by the Authority under sub-section (4) of section 42, the auditor concerned and the person, if any, other than the auditor who signs the report or signs or authenticates the document, shall, if the default is wilful, be punishable with imprisonment which may extend to three years or with fine which may extend to five thousand rupees or with both.

Punishment in relation to audit report.

66. If any person contravenes or attempts to contravene or abets the contravention of the provisions of this Act or of any rules or regulations made thereunder, for which no punishment is provided elsewhere in this Act, he shall be punishable with imprisonment for a term which may extend to two years and also with fine which may extend to ten lakh rupees.

General provisions relating to offences and fine.

67. (1) Where an offence under this Act has been committed by a company, every person who at the time the offence was committed was in charge of, and was responsible to, the company for the conduct of the business of the company, as well as the company, shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly:

Offences by companies.

Provided that nothing contained in this sub-section shall render any such person liable to any punishment provided in this Act, if he proves that the offence was committed without his knowledge or that he has exercised all due diligence to prevent the commission of such offence.

(2) Notwithstanding anything contained in sub-section (1), where an offence under this Act has been committed by a company and it is proved that the offence has been committed with the consent or connivance of, or is attributable to, any neglect on the part of any director, manager, secretary or other officer of the company, such director, manager, secretary or other officer shall also be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly.

Explanation.—For the purposes of this section,—

(a) “company” means any body corporate and includes a firm or other association of individuals; and

(b) “director”, in relation to a firm, means a partner in the firm.

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Offences by society, trust or university. **68. (1)** Where an offence under this Act has been committed by a society or trust or university, every person who at the time the offence was committed was in charge of, and was responsible to, the society or trust or university for the conduct of the business of the society or trust or university, as well as the society or trust or university, shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly: 5

Provided that nothing contained in this sub-section shall render any such person liable to any punishment provided in this Act, if he proves that the offence was committed without his knowledge or that he has exercised all due diligence to prevent the commission of such offence.

(2) Notwithstanding anything contained in sub-section (1), where an offence under this Act has been committed by a society or trust or university and it is proved that the offence has been committed with the consent or connivance of, or is attributable to, any neglect on the part of any governors, vice-chancellor, directors, committee, trustees, registrar or other officer, such governors, vice-chancellor, directors, committee, trustees, registrar or other officer shall also be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly. 10 15

Offences by Government Departments. **69. (1)** Where an offence under this Act has been committed by any Department of Government, the Head of the Department shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly unless he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent the commission of such offence. 20

(2) Notwithstanding anything contained in sub-section (1), where an offence under this Act has been committed by a Department of Government and it is proved that the offence has been committed with the consent or connivance of, or is attributable to any neglect on the part of, any officer, other than the Head of the Department, such officer shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly. 25

Cognizance of offences. **70. (1)** No court shall take cognizance of any offence punishable under this Act or the rules or regulations made thereunder, save on a complaint made by the Authority or any officer or person authorised by it. 30

(2) No court inferior to that of a Chief Metropolitan Magistrate or a Chief Judicial Magistrate shall try any offence punishable under this Act.

CHAPTER XIII

FINANCE, ACCOUNTS, AUDITS AND REPORTS

Grants by Central Government. **71. 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 the Central Government may think fit for being utilised for the purposes of this Act.** 35

Other fees and revenue. **72. The fees or revenue collected by the Authority shall be credited to the Consolidated Fund of India and the entire amount so credited may, after due appropriation made by Parliament by law in this behalf, be transferred to the Authority.** 40

Budget, accounts and audit. **73. (1)** The Authority shall prepare a budget, maintain proper accounts and other 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. 45

(2) The accounts of the Authority shall be audited by the Comptroller and Auditor-General of India at such intervals as may be specified by him and any expenditure incurred in connection with such audit shall be payable by the Authority to the Comptroller and Auditor-General of India.

(3) The Comptroller and Auditor-General of India 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 of India generally has in connection with the audit of Government 50

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.

(4) The accounts of the Authority, as certified by the Comptroller and Auditor-General of India 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.

74. (1) The Authority shall prepare once in every year, in such form and at such time as may be prescribed by the Central Government, an annual report giving,— Annual report.

(a) a description of all the activities of the Authority for the previous year;

(b) the annual accounts for the previous year; and

(c) the programmes of work 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 XIV

MISCELLANEOUS

75. (1) Without prejudice to the foregoing provisions of this Act, the Authority shall, in exercise of its powers or the performance of its functions under this Act, be bound by such directions on question 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: Power of Central Government to issue directions.

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) The decision of the Central Government, whether a question is one of policy or not, shall be final.

76. (1) If, at any time the Central Government is of the opinion,—

(a) that, on account of circumstances beyond the control of the Authority, it is unable to discharge the functions or perform the duties imposed on it by or under the provisions of this Act; or Power of Central Government to supersede Authority.

(b) that the Authority has persistently defaulted in complying with any direction given by the Central Government under this Act or in the discharge of the functions or performance of the duties imposed on it by or under the provisions of this Act and as a result of such default the financial position of the Authority or the administration of the Authority has suffered; or

(c) that circumstances exist which render it necessary in the public interest so to do,

the Central Government may, by notification, supersede the Authority for such period, not exceeding six months, as may be specified in the notification and appoint a person or persons as the President may direct to exercise powers and discharge functions under this Act:

Provided that before issuing any such notification, the Central Government shall give a reasonable opportunity to the Authority to make representations against the proposed supersession and shall consider the representations, if any, of the Authority.

(2) Upon the publication of a notification under sub-section (1) superseding the Authority,—

(a) the Chairperson and other members shall, as from the date of supersession, vacate their offices as such;

(b) all the powers, functions and duties which may, by or under the provisions of this Act, be exercised or discharged by or on behalf of the Authority shall, until the Authority is reconstituted under sub-section (3), be exercised and discharged by the person or persons referred to in sub-section (1); and

(c) all properties owned or controlled by the Authority shall, until the Authority is reconstituted under sub-section (3), vest in the Central Government.

(3) On or before the expiration of the period of supersession specified in the notification issued under sub-section (1), the Central Government shall reconstitute the Authority by a fresh appointment of its Chairperson and other members and in such case any person who had vacated his office under clause (a) of sub-section (2) shall not be deemed to be disqualified for re-appointment. 5

(4) The Central Government shall cause a copy of the notification issued under sub-section (1) and a full report of any action taken under this section and the circumstances leading to such action to be laid before each House of Parliament at the earliest.

Bar of jurisdiction.

77. No civil court shall have jurisdiction in respect of any matter which the Appellate Tribunal is empowered by or under this Act to determine and no injunction shall be granted by any court or other authority in respect of any action taken or to be taken in pursuance of any power conferred by or under this Act. 10

Members and staff of Authority to be public servants.

78. The Chairperson, Members, Chief Regulatory Officers, other officers and other employees 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. 15

45 of 1860.

Protection of action taken in good faith.

79. 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, Chief Regulatory Officers and other officers or other employees 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 or regulations made thereunder. 20

Provisions of this Act not to apply to the Drugs and Cosmetics Act, 1940 and the Food Safety and Standards Act, 2006.

80. Nothing contained in this Act shall apply to the clinical trials of drug as defined under clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 or food or food additive or any material or thing which is covered under the Food Safety and Standards Act, 2006. 23 of 1940. 25 24 of 2006.

Act to have overriding effect.

81. Save as otherwise provided, 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.

82. (1) The Central Government may, by notification in the Official Gazette, make rules for carrying out the provisions of this Act. 30

(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 Authority which may be exercised and discharged by the Chairperson under sub-section (1) of section 8;

(b) powers and functions which may be exercised and discharged by the Chairperson as the chief executive of the Authority under sub-section (3) of section 8; 35

(c) the form and the manner in which, and the authority before whom, the oath of office and of secrecy to be subscribed by the Chairperson and every Member under sub-section (2) of section 9;

(d) the salaries and allowances payable to, and the other terms and conditions of service of, the Chairperson and Members under sub-section (4) of section 9; 40

(e) the salaries, allowances and pensions payable to, and other conditions of service of the Chief Regulatory Officers, other officers and employees of the Authority, under sub-section (2) of section 14;

(f) the other functions of the Inter-Ministerial Governing Board under sub-section (6) of section 15; 45

(g) the manner in which members of the Biotechnology Advisory Council referred to in clauses (b) to (l) of sub-section (2) of section 16 shall be appointed under sub-section (3) of that section;

5 (h) the other functions of the Biotechnology Advisory Council to be specified under sub-section (6) of section 16;

(i) the times and places at which the meetings of the Inter-Ministerial Governing Board and the Biotechnology Advisory Council to be held and procedures to be observed in regard to the transaction of business at its meetings, (including the quorum) under section 17;

10 (j) the books of account and other documents which the persons referred to in clause (a) of sub-section (1) of section 19 shall maintain under sub-section (3) of that section;

15 (k) the form and manner in which and the authority before whom the oath of office and of secrecy to be subscribed by every Chief Regulatory Officer under sub-section (5) of section 21;

(l) the members of the Environment Appraisal Panel, their qualifications and experience under sub-section (1) of section 26;

20 (m) the manner in which the Authority shall provide technical or financial assistance or such other assistance as may be necessary, for the establishment of State Biotechnology Regulatory Advisory Committee, and, discharge of its functions, under sub-section (7) of section 35;

(n) the form and manner in which, and the fees along with which, the appeal shall be preferred and the particulars which such appeal shall contain, under sub-section (2) of section 43;

25 (o) the rules regulating generally the practices and procedure of the Appellate Tribunal in respect of matters specified under clauses (a) to (c) of sub-section (4) of section 45;

30 (p) the manner in which the part-time expert Members of the Appellate Tribunal on the recommendations of the Selection Committee shall be appointed under sub-section (3) of section 47;

(q) the salaries and allowances payable to, and the other terms and conditions of service (including pension, gratuity and other retirement benefits) of, the Chairperson and allowance and fee payable to part-time expert Member of the Appellate Tribunal under section 50;

35 (r) the procedure for inquiry, for removal of the Chairperson of the Appellate Tribunal, under sub-section (4) of section 52;

(s) the manner in which the recruitment of the officers and other employees of the Appellate Tribunal shall be made under sub-section (2) of section 54;

40 (t) the salaries and allowances and other terms and conditions of service of the officers and employees of the Appellate Tribunal under sub-section (4) of section 54;

(u) the financial and administrative powers of the Chairperson of the Appellate Tribunal as may be vested in him under section 55;

45 (v) such other matters in respect of which the Appellate Tribunal shall have power, for the purposes of discharging its functions under this Act, under clause (j) of sub-section (4) of section 57;

(w) the form in which the Authority shall prepare a budget, maintain proper accounts and other relevant records and prepare an annual statement of accounts under sub-section (1) of section 73;

50 (x) the form in which and time at which the Authority shall prepare an annual report under sub-section (1) of section 74;

(y) 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
make
regulations.

83. (1) The Authority may, by notification, make regulations in consistent with this Act and the rules made thereunder to carry out the purposes 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:—

- (a) the times and places of meetings of the Authority and the rules of procedure to be observed by the Authority in regard to the transaction of business at its meetings (including quorum at such meeting) under sub-section (1) of section 12; 5
- (b) measures to regulate the research, transport, import, manufacture and use of organisms and products referred to in clauses (a) to (k) of sub-section (2) of section 18;
- (c) the other qualifications of the Chief Regulatory Officer under sub-section (3) of section 21; 10
- (d) the duties and functions of the Chief Regulatory Officer under sub-section (4) of section 21;
- (e) the manner of maintenance of roster of qualified scientific experts in each regulatory division under sub-section (8) of section 21; 15
- (f) the qualifications of the scientific officers of the Risk Assessment Unit and the manner of undertaking science based safety assessment under section 22;
- (g) the manner of constitution of Enforcement Unit for enforcing the decision of the Authority under sub-section (1) of section 23;
- (h) the form and manner for submission of application for the purpose of obtaining authorisation for research, transport or import of organisms and products, the fee payable therewith and the documents and information to be accompanied with such applications under sub-section (1) of section 24; 20
- (i) the manner of constitution of a Product Rulings Committee under sub-section (1) of section 25; 25
- (j) the fee and allowances payable to the qualified scientific experts in the roster of experts under sub-section (4) of section 25;
- (k) the procedure to be observed by the Product Rulings Committee in regard to transaction of business at the meetings, including the quorum, under sub-section (6) of section 25; 30
- (l) the form and manner for submission of application for the purpose of obtaining authorisation for the manufacture or use of organisms and products, the fee payable therewith and the documents and information to be accompanied with such applications under sub-section (1) of section 27;
- (m) the manner of constitution of one or more Scientific Advisory Panels under section 29; 35
- (n) the manner of seeking advise from any Member of Scientific Advisory Panel from the roster of experts under section 30;
- (o) the safeguards subject to which the Authority may permit clinical trials or field trials of organisms and products under section 34; 40
- (p) the manner of convening by the Chairperson of the Authority, the annual meeting of a State Biotechnology Regulatory Advisory Committee under section 36;
- (q) the qualifications and experience of Monitoring Officers under sub-section (2) of section 38;
- (r) the agencies which may accredit the laboratories or research institutions under section 41; 45
- (s) the organisations or the agencies to be designated by the Authority, and the activities relating to safety of modern biotechnology, the compliance of, which shall be ensured for the purposes of auditing notified laboratories or research institutions under sub-section (1) of section 42; 50
- (t) the criteria which an organisation or agency shall fulfil, to be designated as auditor, under sub-section (2) of section 42;

(u) 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.

84. The Central Government, after consultation with the Authority 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 Schedule I of this Act for the purposes of this Act and thereupon the said Schedule shall be deemed to be amended accordingly.

Power to amend Schedule I.

85. Every rule and every regulation made under this Act and every notification issued under section 84, shall be laid, as soon as may be after it is made, or issued, 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 regulation or notification or both Houses agree that the rule or regulation or notification should not be made or issued, the rule or regulation or notification 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 or regulation or notification.

Rules, regulations and notifications to be laid before Parliament.

86. The provisions of this Act shall be in addition to, and not in derogation of, any other law for the time being in force.

Application of other laws not barred.

87. (1) The enactments specified in Parts I and II of the Schedule II to this Act shall be amended in the manner specified therein and such amendments shall take effect from such date as the Central Government may, by notification, specify and such amendments shall not affect—

Amendment of certain enactments and savings.

(a) the previous operations of the enactment 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 or orders; or

(c) any penalty, forfeiture or punishment incurred in respect of any offences committed against the enactment; 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 enactment specified under sub-section (2), 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.

88. (1) If any difficulty arises in giving effect to the provisions of this Act, the Central Government may, by order, published in the Official Gazette, make such provisions not inconsistent with the provisions of this Act as may appear to be necessary for removing the difficulty:

Power to remove difficulties.

Provided that no order shall be made under this section after the expiry of two years from the date of commencement of this Act.

(2) Every order made under this section shall be laid, as soon as may be after it is made, before each House of Parliament.

SCHEDULE I
(See section 18)

PART I

1. Organisms and products mentioned under sub-paragraphs (a) to (d) of this Part which shall be regulated by the Authority— 5

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

(b) any genetically engineered plant, animal, micro-organism, virus or other animate organism used as food; 10

(c) any animal clones that may have application in agriculture, fisheries or food production;

(d) genetically modified or engineered food and foods containing such ingredients.

PART II 15

2. Organisms and products mentioned under sub-paragraphs (a) to (j) of this Part which shall be regulated by the Authority—

(a) recombinant proteins and combinations thereof;

(b) DNA vaccines intended to induce or increase an antigen specific immune response for prophylactic or therapeutic immunisation, regardless of the composition or method of manufacture; 20

(c) vaccines for use in humans or animals that contain living genetically engineered organisms;

(d) cellular products, including products composed of human, bacterial or animal cells (such as pancreatic islet cells for transplantation), or from physical parts of those cells (such as whole cells, cell fragments, or other components intended for use as preventative or therapeutic vaccines); 25

(e) recombinant gene therapy products including nucleic acids, viruses, or genetically engineered micro-organisms that mediate their effect by transcription and/or translation of the transferred genetic material, and/or by integrating into the host genome and 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; 30

(f) transgenic blood or plasma derived products;

(g) stem cell based products; 35

(h) RNA interference (RNAi) based products;

(i) products of synthetic biology for human or animal use;

(j) any products that include as a component of a product from categories (a) to (i) above.

PART III 40

3. Organisms and products mentioned under this Part which shall be regulated by the Authority.

Any genetically engineered plant, animal, micro-organism, virus or other animate organism that may be released into the environment, excluding the provisions of Parts I and II of this Schedule, or have application in industrial production or manufacturing processes. 45

SCHEDULE II
(See section 87)

PART I

AMENDMENTS TO THE DRUGS AND COSMETICS ACT, 1940
(23 OF 1940)

5

After section 37, the following section shall be inserted, namely:—

Insertion of
new section
37A.

“37A. Nothing contained in this Act shall apply to the genetically modified or engineered organisms or any matter or thing connected with it to which are covered under the Biotechnology Regulatory Authority of India Act, 2013.”

Provisions of
this Act not to
apply to
genetically
modified or
engineered
organisms.

10

PART II

AMENDMENTS TO THE FOOD SAFETY AND STANDARDS ACT, 2006
(34 OF 2006)

1. In section 3, in sub-section (1), in clause (j), after the proviso, the following *Explanation* shall be substituted, namely:—

Amendment of
section 3.

15

‘*Explanation.*— For the purposes of this clause “genetically modified or engineered food or food containing such ingredients” means food and food ingredients composed of, or containing, or produced from but not containing genetically modified or engineered organism obtained through modern biotechnology and approved to be safe for human consumption by the Biotechnology Regulatory Authority of India under the provisions of the Biotechnology Regulatory Authority of India Act, 2013.’

20

2. In section 13, in sub-section (3), clause (c) shall be omitted.

Amendment of
section 13.

3. In section 22, in the *Explanation*, for clause (2) the following clause shall be substituted, namely:—

Amendment of
section 22.

25

‘(2) “Genetically modified or engineered food or food containing such ingredients” means food and food ingredients composed of, or containing, or produced from but not containing, genetically modified or engineered organism obtained through modern biotechnology and approved to be safe for human consumption by the Biotechnology Regulatory Authority of India under the provisions of the Biotechnology Regulatory Authority of India Act, 2013.’

30

4. After section 98, the following section shall be inserted, namely:—

Insertion of
new section
98A.

“98A. Nothing contained in this Act shall apply to the genetically modified or engineered organisms or any matter or thing connected with it to which are covered under the Biotechnology Regulatory Authority of India Act, 2013.”

Provisions of
this Act not to
apply to
genetically
modified or
engineered
organisms.

STATEMENT OF OBJECTS AND REASONS

Modern biotechnology is recognised globally as a rapidly advancing science wherein advanced molecular techniques and processes are employed to develop useful products, processes and services in areas of agriculture, human and animal healthcare, environment management and industry. There are large number of biotech products already in the market and many more of such products are in the pipeline *viz.* therapeutic biotech drugs; vaccines; genetically modified crops with resistance to pests and diseases, drought and salinity and with enhanced nutritional factors. Biotechnology industry in India has been growing at an average annual rate of twenty to thirty per cent. during the last five years and its turnover during 2011-12 exceeded Rs. 20,440.00 crores approximately. The potential of biotechnology with respect to food security, public health, employment generation, intellectual wealth creation, expanding entrepreneurial opportunities and augmenting industrial growth warrants a focused approach towards innovation, regulation and commercialisation.

2. There are public concerns in respect of organisms and products derived from modern biotechnology on human, animal and environmental safety. Various countries have developed regulatory mechanisms to ensure safe and responsible use of biotechnology organisms and products. In India, activities and processes involving the genetically engineered organisms and products thereof, are at present, broadly regulated under the rules titled as “Rules for Manufacture, Use/Import/Export and Storage of hazardous Microorganisms/Genetically Engineered Organisms or Cells, 1989” notified under the Environment (Protection) Act, 1986 and the guidelines published by the Department of Biotechnology in the Ministry of Science and Technology.

3. Subsequent to making of aforesaid rules and publication of guidelines biotechnology regulatory system in India has experienced a number of challenges. The Task Force on the Application of Agriculture Biotechnology constituted by the Ministry of Agriculture in 2003 recommended the establishment of an “autonomous, statutory and professionally-led National Biotechnology Regulatory Authority” for generating the necessary public, political, professional and commercial confidence in the science-based regulatory mechanism. Subsequently, the other Task Force constituted by Ministry of Environment and Forests in 2004 on recombinant pharma also supported the establishment of the Biotechnology Regulatory Authority.

4. India is a party to the United Nations Convention on Biological Diversity signed at Rio de Janeiro on the 5th day of June, 1992 which came into force on the 29th December, 1993; and Cartagena Protocol on Biosafety to the Convention which was adopted in Montreal on the 29th September, 2000 and came into force on the 11th September, 2003.

5. In order to implement the recommendations of the aforesaid Task Forces, and to give effect to certain provisions of the aforesaid Convention and Protocol, it has been decided to establish an independent statutory regulator to regulate the research, transport, import, manufacture and use of organisms and products of modern biotechnology so as to keep pace in regulatory measures with the rapid technology advancement in the field of modern biotechnology and at the same time ensure safety to human and animal health and the environment.

6. The proposed statutory independent regulator that is the Biotechnology Regulatory Authority of India (BRAI) would be a nodal agency of the Government of India to ensure comprehensive safety assessment of organisms and products of modern biotechnology. Commercialisation of biotechnology products in agriculture and healthcare would be subject to all other laws whether Central or State, for the time being in force and the rules and regulations made thereunder. The organisational plan of the Authority also provides collaborative arrangements, co-ordination and mechanisms with other existing regulatory agencies. The Biotechnology Regulatory Authority of India proposed to be established under the proposed legislation would regulate the trials preceding the clinical trials in the health sector and present mechanism for regulating clinical trials would continue.

7. The Biotechnology Regulatory Authority of India Bill, 2013, *inter alia*, provides for the following, namely:—

(a) establishment of the Biotechnology Regulatory Authority of India to regulate the research, transport, import, manufacture and use of organisms and products of modern biotechnology;

(b) constitution of Inter-Ministerial Governing Board to oversee the performance of the Authority;

(c) constitution of Biotechnology Advisory Council to render strategic advice to the Authority on the matters relating to developments in modern biotechnology and their implications in India;

(d) providing for Regulatory Divisions of the Authority dealing with agriculture, forest and fisheries, human health and veterinary products and industrial and environmental applications for implementation of safety assessment procedures and processes;

(e) constitution of Risk Assessment Unit comprising of scientific officers, product rulings committee and environmental appraisal panel for elaborate risk assessment process involving scientific experts and representatives of concerned Ministries including a special public review system for evaluation of applications before final approvals;

(f) constitution of the State Biotechnology Regulatory Advisory Committee to act as nodal agency between the State Government and the Authority in respect of matters related to the regulation of modern biotechnology;

(g) provides for notification by the Authority of accredited laboratories and research institutions by the Authority for the purposes of proposed legislation;

(h) provides for Biotechnology Regulatory Appellate Tribunal consisting of full-time Chairperson who has been a Judge of the Supreme Court of India or a Chief Justice of a High Court and part-time expert members not exceeding five to hear the appeals against the decision or order or direction of the Authority;

(i) provides for offences and penalties for contravening the provisions of the proposed legislation;

(j) empower the Central Government to supersede the Authority in certain circumstances.

8. The notes on clauses explain in detail various provisions in the Bill.

9. The Bill seeks to achieve the above objectives.

NEW DELHI;

S. JAIPAL REDDY

The 11th March, 2013.

Notes on clauses

Clause 1.—This clause provides for short title, extent and commencement. It provides that the proposed legislation will extend to whole of India. It further provides that any reference made in the proposed legislation, to a law which is not in force in the State of Jammu and Kashmir, shall in relation to that State be construed as a reference to the corresponding law, if any, in that State.

It is also proposed to empower the Central Government to bring it into force on such date as it may appoint by notification in the Official Gazette and the Central Government may notify different dates for different provisions of the proposed legislation.

Clause 2.—This clause makes the Declaration as to expediency of control by Union. It proposes to declare that it is expedient in the public interest that the Union should take under its control the regulation of organisms, products and processes of modern biotechnology industry.

Clause 3.—This clause seeks to define certain expressions used in the proposed legislation. These definitions *inter alia*, include “animal clones”, “Biotechnology”, “clinical trial”, “conjugation”, “environmental release”, “modern biotechnology”, “mutation breeding”, “organism”, “polyploidy induction”, “transduction”, “use”, etc.

Clause 4.—This clause provides for the establishment of Biotechnology Regulatory Authority of India which shall be a body corporate and having its headquarters in the National Capital Region. It further provides for establishing branch offices at any other place in India with prior approval of the Central Government.

Clause 5.—This clause contains provision for composition of Authority. It provides that the Authority shall consist of a Chairperson, two whole-time members and two part-time members to be appointed by the Central Government.

Clause 6.—This clause provides for qualifications for appointment of Chairperson and Members. It provides that the Chairperson of the Authority shall be a person of ability, integrity and outstanding scientific calibre with a doctorate degree or equivalent degree in the field of biological sciences or a postgraduate degree in medical sciences from a university recognised by the University Grants Commission or a university or institute established by law for the time being in force, and having not less than twenty years experience in a leadership role in a scientific organisation, scientific institution or scientific agency, or similar organisation or institution or agency, out of which at least five years should be as head of the organisation or institution or agency or unit or division.

It further provides that a Member, shall be a person of ability, integrity and outstanding scientific calibre with a doctorate degree or equivalent degree in the field of biological sciences or a postgraduate degree in medical sciences from a university recognised by the University Grants Commission or established by law for the time being in force, and having not less than fifteen years experience in a leadership role in a scientific organisation, scientific institution or scientific agency or unit or division and the Central Government shall, while appointing the Members, ensure that one such Member has requisite knowledge and experience in the fields of molecular biology, health care, agriculture and environment biotechnology and areas connected therewith respectively.

It further provides that the Chairperson and Members of the Authority shall be appointed on the recommendation of the Selection Committee constituted under sub-clause (1) of clause 7 and the Chairperson or the whole-time Member of the Authority shall not hold any other office during the period of holding his office as such.

It also provides that the Central Government shall, within a period of two months from the date of occurrence of any vacancy in the office of the Chairperson or Member, by reason of death, resignation or removal of the Chairperson or a Member and six months before the superannuation or completion of the term of office of the Chairperson or a Member, make

a reference to the Selection Committee constituted under clause 7 for filling up of such vacancy.

Clause 7.—This clause provides for constitution of Selection Committee for selection of Chairperson and Members. It provides that the Central Government shall, for the purpose of selection of the Chairperson and Members, constitute a Selection Committee consisting of Cabinet Secretary as Chairperson of the Selection Committee; Secretaries-in-charge of each Ministry or the Department of the Central Government dealing with health research, Agriculture, Bio-technology, Environment, Personnel and two eminent biotechnologists nominated by the Central Government as its Members. It further provides that a scientist not below the rank of Grade 'G' in the Department of Biotechnology in the Ministry of Science and Technology as convenor of the meetings of the Selection Committee.

It further provides that the Selection Committee shall finalise the selection of the Chairperson and Members of the Authority within two months from the date on which the reference is made to it under sub-clause (5) of clause 6 and the Selection Committee shall recommend a panel of two names for every vacancy referred to it.

It further provides that before recommending any person for appointment as a Chairperson or a Member of the Authority, the Selection Committee shall satisfy itself that such person does not have any financial or other conflict of interest, which is likely to affect prejudicially his functions as Chairperson or Member and also provides that no appointment of the Chairperson or Member of the Authority shall be invalid merely by reason of any vacancy in the Selection Committee.

Clause 8.—This clause lays down the functions of the Chairperson. It provides that the Chairperson shall be the Chief Executive of the Authority and empowered to exercise all powers and do all acts and things to be exercised or done by the Authority. Various responsibilities of the Chairperson *inter alia* include day to day administration of the authority, implementing work programmes and decisions, preparing the statement of revenue and expenditure, approving financial expenditure and submission of the annual report of the Authority.

Clause 9.—This clause provides for the term of office and other conditions of service of Chairperson and Members. It provides that the Chairperson and other Members shall hold office for a term of three years from the date on which they enter upon their offices, and shall be eligible for re-appointment for a further period of three years and provides that the Chairperson or a Member shall not hold office as such after he has attained the age of sixty-five years.

It further provides that the Chairperson and every Member shall, before entering upon their office make and subscribe, to an oath of office and of secrecy, in such form and in such manner and before such authority as may be prescribed.

It further provides that any person holding any office (whether as an employee or an officer or a director or managing director or secretary or manager or in any other capacity) under the Central Government or State Government or in a company (including a Government Company referred to in section 617 of the Companies Act, 1956) or in any other institution, organisation, society or University or Board, shall, on his selection as the Chairperson or a whole-time Member, be required to seek retirement or resign from the services of such Central or State Government or company or institution or organisation or society or University or Board, as the case may be, before accepting the employment as the Chairperson or whole-time Member.

It further provides that the salaries and allowances payable to, and the other terms and conditions of service of, the Chairperson and whole-time Members and allowances payable to part-time Members shall be such as may be prescribed by the Central Government but neither the salary and allowances nor the other terms and conditions of service of the

Chairperson or a whole-time Member shall be varied to their disadvantage after their appointment.

It also provide that the Chairperson or Member may relinquish their office by giving in writing to the Central Government a notice of not less than three months or be removed from their office in accordance with the provisions of clause 11.

Clause 10.—This clause lays down restriction on Chairperson or Members on employment after cessation of office. It lays down that the Chairperson or a Member, ceasing to hold office as such, shall not, for a period of two years from the date on which they cease to hold office, accept any employment in, or connected with management or administration of, any person which has been associated with or granted authorisation for research, transport or import of organisms or products or manufacture or use of organisms and products under the proposed legislation.

It further lays down that nothing contained in this clause shall apply to, any employment under the Central Government or a State Government or local authority or in any Statutory authority or any corporation established by or under any Central, State or Provincial Act or a Government company as defined in section 617 of the Companies Act, 1956; act, for or on behalf of any person or organisation in connection with any specific proceeding or transaction or negotiation or a case to which the Authority is a party and with respect to which the Chairperson or such Member before cessation of their office had acted for, or provided advice to, the Authority; or, give advice to any person (including his client, business associate or employer) using information which was obtained in their capacity as the Chairperson or a Member and being not available or cannot be made available to the public; or, for a period of two years from their last day in office, enter into a contract of service with, accept an appointment to a board of directors of, or accept an offer of employment with, an entity with which they had direct and significant official dealings during their term of office as such without the due approval of the Central Government.

It also lays down that the Chairperson and Members shall not communicate or reveal to any person any matter which has been brought under their consideration or known to them while acting as such.

Clause 11.—This clause contains the provisions relating to the removal of the Chairperson or a Member. It provides that the Central Government may, by order, remove from office, the Chairperson or a Member, in case he has been adjudged as insolvent, convicted of an offence or involved in moral turpitude or has become physically or mentally incapable or acquired financial or other interest likely to affect prejudicially his functions or abused his position prejudicially to the public. It also provides for giving a reasonable opportunity to Chairperson or Member before his removal.

Clause 12.—This clause provides for the procedures for meetings of the Authority. It provides for an alternate senior-most Member to preside at the meetings in case the Chairperson is unable to attend a meeting of the Authority. It makes provision for decisions to be made in the meeting of Authority by a majority vote of the Members present and voting. In the event of an equality of votes, the Chairperson or in his absence, the person presiding, shall have a second or casting vote. The Authority would observe such rules of procedure in regard to transaction of business which may be provided in the rules made by the Central Government.

Clause 13.—This clause provides that vacancies, etc., in the Authority will not invalidate proceedings of Authority. It provides that proceedings of the Authority shall not be invalidated merely because of reasons such as any vacancy in, or any defect in the constitution of the Authority or appointment of a person as a Member of the Authority or any irregularity in the procedure of the Authority not affecting the merits of the case.

Clause 14.—This clause contains provisions for Chief Regulatory Officers and other employees of the Authority. It provides for appointment of Chief Regulatory Officers, other officers and employees by the Authority. It further provides that the salaries, allowances,

pensions, conditions of services of the Chief Regulatory Officers and other officers and employees of the Authority shall be provided by the rules made by the Central Government.

Clause 15.—This clause provides for constitution of Inter-Ministerial Governing Board. It provides that the Central Government shall, by notification, constitute an Inter-Ministerial Governing Board to promote Inter-Ministerial or Departmental co-operation required for the effective discharge of functions and performance of the Authority for the purposes of the proposed legislation. It further provides for composition of Inter-Ministerial Governing Board which would *inter alia* consist of concerned (a) Ministries and Departments of the Central Government, (b) research bodies such as Indian Council of Agricultural Research (ICAR), Indian Council of Medical Research (ICMR) and Council of Scientific and Industrial Research (CSIR), (c) other regulatory authorities such as the Drug Controller General of India; the Directorate of Plant Protection, Quarantine and Storage; the Food Safety and Standards Authority; and the Biotechnology Regulatory Authority of India. It further provides that no person below the rank of Additional Secretary to the Government of India or equivalent rank shall be appointed as a Member of the Inter-Ministerial Governing Board. It also provides that the Secretary, Department of Science and Technology shall be the Chairperson and one of the Members of the Authority shall be the convener of the Inter-Ministerial Governing Board.

Clause 16.—This clause provides for constitution of the Biotechnology Advisory Council. It provides that the Central Government shall, by notification, constitute a Biotechnology Advisory Council to render strategic advice to the Authority on the matters relating to developments in modern biotechnology and their implications in India. It provides that the Biotechnology Advisory Council shall consist of a Presiding Officer and members not exceeding fifteen representing, *inter alia*, the scientific experts in various disciplines from public and private sectors, consumer affairs organisations, farmers organisations, economist, ethicist, and legal experts. It further seeks to provide that members to the Biotechnology Advisory Council shall be appointed on the recommendations of the Inter-Ministerial Governing Board according to specific criteria such as expertise, knowledge, and experience, so as to secure the highest standards of competence, relevant expertise, and the broadest possible geographic representation within the country. It further provides that the Chairperson of the Authority would be the Presiding Officer of the Biotechnology Advisory Council and one of the Members of the Authority shall be the convener and appointment of the members shall be for a term of three years with eligibility for re-appointment for a further period of three years.

It also provides that the expenses for attending the meetings of the Biotechnology Advisory Council (including travel expenses and sitting fee) or any other allowances incurred by the members would be borne by the Authority.

Clause 17.—This clause deals with the provisions of meetings of Inter-Ministerial Governing Board and Biotechnology Advisory Council. It provides that the Inter-Ministerial Governing Board and the Biotechnology Advisory Council shall meet at such times and places, and shall observe such procedures in regard to the transaction of business at their meetings, (including the quorum), as may be prescribed by rules.

Clause 18.—This clause provides for the functions and powers of Authority. It *inter alia* provides that it shall be the duty of the Authority to regulate the research, transport, import, manufacture and use of organisms and products as specified in Schedule I so as to ensure the safety to human health, animal health and the environment. It further provides that the Authority shall provide scientific advice and technical support to the Central Government and State Governments in matters of framing the policy, develop and implement guidelines for safety assessment, establish a network of organisations to facilitate scientific co-operation, organise workshops and training programmes for State level personnel and other stakeholders, inform the public of all applications for field trials and all regulatory decisions made by the Authority, etc.

It also provides for the Authority to serve as a nodal agency for coordination of work on standards and guidance related to regulation of organisms and products of modern biotechnology and to promote consistency with international technical standards.

Clause 19.—This clause provides for the powers of the Authority to call for information, conduct investigation, etc. It, *inter alia*, states that where the Authority considers it expedient so to do, it may by order in writing call upon any person, who had submitted application under sub-section (1) of section 24 or under sub-section (1) of section 27 or who has been granted authorisation under sub-section (1) of section 24, or under sub-section (1) of section 27, or from any person engaged in activities relating to modern biotechnology, at any time to furnish in writing such information or explanation relating to its affairs as the Authority may require or appoint one or more persons to make an inquiry in relation to the affairs of any person, etc.

Clause 20.—This clause empowers the Authority to issue directions. It provides that the Authority shall have the power to issue directions to any person referred to in clause (a) of sub-clause (1) of clause 19 for proper safety of products or processes of modern biotechnology or which may be necessary for proper discharge of its functions or exercise of its powers under the proposed legislation.

Clause 21.—This clause relates to Regulatory Divisions of the Authority. It provides that the Authority shall have at least three Regulatory Divisions of the Authority with each division dealing with, (i) Agriculture, Forest and Fisheries; (ii) Human Health and Veterinary; and (iii) Industrial and Environmental Applications. It further provides that each division shall be headed by a Chief Regulatory Officer, who shall be a scientist of outstanding scientific calibre in relevant discipline. It further provides that the Chief Regulatory Officer shall not enter into a contract of service with, accept an appointment to a board of directors of, or accept an offer of employment with, an entity with which he had direct and significant official dealings during his term of office without the due approval of the Central Government for a period of two years from his last day in office. This clause also provides for maintaining a roster of qualified scientific experts in such manner as may be specified by regulations.

Clause 22.—This clause seeks for constitution of Risk Assessment Unit. It provides that the Authority shall constitute a Risk Assessment Unit comprising of scientific officers possessing such qualifications, and to undertake science-based safety assessments in such manner, as may be specified by regulations.

Clause 23.—This clause provides for constitution of other Units by the Authority. It provides for constitution of an Enforcement Unit consisting of Monitoring Officers for enforcing the decisions of the Authority. It also provides for setting up of such other units as may be necessary from time to time.

Clause 24.—This clause provides for the procedure by Risk Assessment Unit for research, transport, or import of organisms or products. Sub-clause (1) of this clause provides that every person shall obtain authorisation under sub-clause (3) for other purpose of research, transport or import of organisms and products as specified in Schedule I and submit for the said purpose an application to the Authority. Sub-clause (2) of this clause provides that on receipt of the application under sub-section (1), the Authority shall forward the application to the Risk Assessment Unit for science-based evaluation of the application and submit a clear assessment as to the safety of the proposed research, transport or import of such organisms or products to the Authority for giving authorisation with or without conditions. It further empowers the Authority to suspend or cancel the authorisation if it is of the opinion that any condition of the authorisation has been violated, or the authorisation was obtained improperly or any new risks have emerged for continuation of the activity.

Clause 25.—This clause, *inter alia*, provides for the constitution of a Product Rulings Committee. It provides for constitution of a Product Rulings Committee for the purpose of making recommendations for manufacture or use of organisms and products as specified in

Schedule I to the proposed legislation. It further provides that the Product Rulings Committee shall be comprised of (i) one of the Members nominated by the Authority as its Chairperson (ii) all the Chief Regulatory Officers of the Regulatory Divisions (iii) one representative from the Central Drugs Standards Control Organisation to be nominated by the Ministry of Health; and (iv) at least three and not exceeding five experts to be appointed by the Authority, whose names appear as qualified scientific experts in the roster of experts maintained under sub-clause (8) of clause 21. It further provides for meetings of the Product Rulings Committee at least once in every three weeks.

Clause 26.—This clause provides for constitution of Environment Appraisal Panel or application of law relating to protection of environment. It provides that the Authority shall constitute, in consultation with the Union Ministry of Environment and Forests, a panel to be known as the Environment Appraisal Panel, consisting of a Chairperson to be nominated by Ministry of Environment and Forests; other members not exceeding five and a Member Secretary to be nominated by the Ministry of Environment and Forests having such qualifications and experience as may be prescribed. It further provides that the said Appraisal Panel would regulate its own procedure for the purpose of conducting its meeting (including quorum) and making recommendations relating to environmental safety of organisms and products as may be referred to it by the Authority.

Clause 27.—This clause lays down the procedure for grant of authorisation for manufacture or use of organisms and products. It provides that every person shall obtain authorisation for the purpose of manufacture or use of organisms and products specified in Parts I, II (except products covered under drug as defined under clause (b) of section (3) of the Drugs and Cosmetics Act, 1940) and III of Schedule I, and submit for the said purpose an application in the form and manner, along with such fee and accompanied by such documents and information as may be specified by regulations.

It further provides that on receipt of the application for the manufacture or use of organisms and products specified under Parts I, II (except products covered under drug as defined under clause (b) of section (3) of the Drugs and Cosmetics Act, 1940) and III of Schedule I, the Authority shall forward the application to the Risk Assessment Unit which shall undertake a science-based evaluation of the application and submit its risk assessment report as to the safety of the proposed manufacture and use of organisms or products to the Authority.

It further provides that the Authority, on receipt of the risk assessment report, as to the safety for manufacture or use of organisms and products, shall forward the said risk assessment report of the Risk Assessment Unit to the Product Rulings Committee for giving its recommendations thereon, as to the safety of organisms and products.

It also provides that the Authority shall consider the recommendations of Product Rulings Committee and all relevant matters in addition to the risk assessment report submitted by Risk Assessment Unit before authorising the manufacture or use with or without conditions.

Clause 28.—This clause relates to disclosure of confidential commercial information. It seeks to provide for retaining confidential commercial information submitted by the applicant by not disclosing to any other party. This clause also confers power upon the Authority to refuse to retain the information referred above as confidential commercial information, if the Authority is satisfied that the public interest outweighs the disclosure or such disclosure shall not cause harm to any person.

Clause 29.—This clause provides for constitution of Scientific Advisory Panels and Roster of Experts. It provides that the Authority may constitute one or more Scientific Advisory Panels, from the roster of experts referred to in sub-clause (8) of clause 21 in such manner as may be specified by regulations, to provide scientific advice, information and recommendations to the Authority under the proposed legislation on biotechnology issues which may result from regulatory actions of the Authority and would have an impact on the safety of human health, animal health and the environment.

Clause 30.—This clause contains provisions for seeking advice from Scientific Advisory Panels and Roster of Experts. It provides that the Authority may, for the purpose of obtaining scientific advice and technical support on any issue relating to modern biotechnology, without prejudice to the other provisions of the proposed legislation, may seek advice from any member of Scientific Advisory Panel in such manner as may be specified by regulations.

Clause 31.—This clause contains provisions for authentication of decisions or orders. It provides for authentication of orders, etc., of the Authority by the signature of the Chairperson or any other officer of the Authority so authorised by the Chairperson.

Clause 32.—This clause relates to the delegation of powers. It provides for delegation of specified powers and function to the Chairperson or any Member or any officer of the Authority (except the power to make regulations under clause 83 under the proposed legislation) as the Authority may consider necessary.

Clause 33.—This clause provides for application of law relating to customs and powers of Custom Officers. It provides that the Commissioner of Customs or any officer of the Government authorised by the Central Government in this behalf, may detain any imported package which he suspects to contain any organisms and products specified under Part I, Part II [except products covered under drug as defined under clause (b) of section 3 of the Drugs and Cosmetics Act, 1940] and Part III of Schedule I and the import of which requires the approval of the Authority under Chapter V, and shall forthwith report such detention to the Authority, and, if necessary, forward, with the approval of the Authority, the package or sample of any suspected organisms and products found therein to the laboratory notified or research institution accredited under this Act.

Clause 34.—This clause seeks to provide for field trials. It provides that no person shall conduct field trials in respect of any organisms or products specified in Part I and Part III of Schedule I to the Bill, unless permitted by the Authority.

Clause 35.—This clause relates to the establishment of State Biotechnology Regulatory Advisory Committees. It enumerates the composition and functions of State Biotechnology Regulatory Advisory Committees. It provides that every State Biotechnology Regulatory Advisory Committee shall be convened by the State Department of Biotechnology or Biotechnology Commission or the State Department of Science and Technology, in case there is no State Department of Biotechnology or Biotechnology Commission exists and the Secretary or Commissioner or head of such Department or Commission shall preside over such State Biotechnology Regulatory Advisory Committees.

It further provides that State Biotechnology Regulatory Advisory Committee shall act as the nodal agency for interactions between the State Government and the Authority in respect of matters related to the regulation of modern biotechnology under the provisions of the proposed legislation and the rules proposed thereunder and also facilitate inter-departmental co-ordination in respect of biotechnology regulation within the State.

It further provides that the State Biotechnology Regulatory Advisory Committee will also identify state-specific needs related to the regulation of modern biotechnology and communicate the same to the Authority and it will collaborate with the Authority for undertaking capacity building and information sharing activities relating to biotechnology to ensure that information relating to activities and programmes of the Authority are communicated in a transparent and accessible fashion within the State.

It also provides for technical and financial support by the Authority for the establishment of the State Biotechnology Regulatory Advisory Committee in each State and also provides that every State Biotechnology Regulatory Advisory Committee prepare and publish an annual report which it would make available to the State, the Authority and the public.

Clause 36.—This clause provides for the convening of meetings of State Biotechnology Regulatory Advisory Committees. It provides that an annual meeting of State Biotechnology

Advisory Committees would be convened by the Chairperson of the Authority to identify priority issues and activities which the State Governments which may include programs and operations related to the regulation of modern biotechnology.

Clause 37.—This clause makes the Authority responsible for enforcement of the provisions of the proposed legislation and the regulations made thereunder.

Clause 38.—This clause contains provisions relating to Monitoring Officers. It provides for appointment of the Monitoring Officers, with such qualifications and experience relating to biotechnology as may be specified by regulations, for the purpose of exercising powers or performing functions under the proposed legislation. This clause also provides for establishing mechanisms in consultation with the concerned State Biotechnology Advisory Committees to facilitate enforcement of the proposed legislation and the rules made thereunder.

Clause 39.—This clause lays down for the functions of the Monitoring Officers. It provides that the Monitoring Officers shall undertake activities as directed by the Authority to ensure compliance of the provisions of the proposed legislation and rules and regulations made thereunder.

Clause 40.—This clause empowers the Monitoring Officers. It provides that the Monitoring Officer, for the purpose of discharging his functions under the proposed legislation, and if authorised by the Authority, in relation to products or processes regulated under the proposed legislation, will, enter and inspect any premises where such products and processes may be found; inspect, examine, take measurements of, or conduct tests on, or take samples of, any thing on the premises which relates to products and processes; take photographs, make video or audio recordings of the premises or any thing on the premises on which products and processes have been found and inspect any book, record or document on the premises.

It further empowers the Monitoring Officer to make entry upon, and inspect any place, except with the consent of the occupant of the premises or under the authority of a warrant, and, while doing so, he shall follow the procedure provided under the provisions of the Code of Criminal Procedure, 1973 relating to the search or inspection of a place by a police officer executing a search warrant under that Code.

Clause 41.—This clause relates to the notification of accredited laboratories and research institutions. It provides for notification of laboratories or research institutions for the purposes of the proposed legislation including those accredited by other agencies.

Clause 42.—This clause empowers the Authority to designate any organisation or agency as auditor. It provides that the Authority may designate one or more organisations or agencies as an auditor for the purpose of auditing notified laboratories and research institutions to ensure compliance with activities, relating to safety of modern biotechnology, as may be specified by regulations. It further provides that every person authorised by an organisation or agency recognised for the purpose of auditing, shall have a right of access on all working days to such notified laboratories and shall be entitled to obtain necessary information the auditor may consider necessary for the performance of his duties as auditor.

Clause 43.—This clause makes provision for filing appeal to the Appellate Tribunal. It provides that any person aggrieved by a decision or order or direction of the Authority may prefer an appeal against such order or decision to the Biotechnology Regulatory Appellate Tribunal within a period of thirty days from the date of the decision or order or direction is communicated to him, in such form and manner along with such fees and such particulars as may be prescribed by the Central Government.

Clause 44.—This clause makes provision for the establishment of the Appellate Tribunal. It provides that the Central Government shall, by notification, establish an Appellate Tribunal to be known as the "Biotechnology Regulatory Appellate Tribunal" to exercise the jurisdiction, powers and authority conferred upon it under the provisions of the proposed legislation.

Clause 45.—This clause provides for the composition of Appellate Tribunal. It provides that the Appellate Tribunal shall consist of a full-time Chairperson and part-time expert Members not exceeding five as notified by the Central Government. It further provides that any one or more person having specialised knowledge and experience in a particular case can be directed to assist the Appellate Tribunal in that case.

It further provides for the sitting of the Appellate Tribunal at such place or places, as specified by the Central Government. It also provides that the Central Government may, in consultation with the Chairperson of the Appellate Tribunal, make rules regulating generally the practices and procedure of the Appellate Tribunal including, rules as to the persons who would be entitled to appear before the Appellate Tribunal, rules as to the procedure for hearing appeals and other matters pertaining to the appeals; and the minimum number of members who would hear the applications and appeals in respect of any class or classes of appeals.

Clause 46.—This clause lays down the qualifications for appointment of Chairperson and part-time expert Members. It provides that a person shall be qualified for appointment as the Chairperson of the Appellate Tribunal, if such person is, or has been, a Judge of the Supreme Court of India or the Chief Justice of a High Court.

It further provides that a person shall be qualified for appointment as part-time expert Member, if such person is an eminent scientist in the field of biological or biotechnology related to healthcare or agriculture or environmental or industrial activities and possesses an experience of at least twenty years in the field, or who has held the post in the Central Government or a State Government dealing with biological or biotechnology related to healthcare or agriculture or environmental or industrial activities equivalent to the Joint Secretary to the Government of India for at least three years and possesses special knowledge in the field.

It also provides that the Chairperson and part-time expert Members of the Appellate Tribunal would not hold any other office during their tenure as such.

Clause 47.—This clause provides for appointment of Chairperson and part-time expert Members. It provides that the Central Government shall appoint the Chairperson in consultation with the Chief Justice of India and part-time expert Members on the recommendations of the Selection Committee in the manner as may be prescribed by rules.

Clause 48.—This clause provides for term of office and other conditions of service of Chairperson and part-time expert Members. It provides that the Chairperson and part-time expert Member of the Appellate Tribunal shall hold office as such for a term of three years from the date on which they enter upon their office and shall not be eligible for re-appointment.

It further provides that the Chairperson and the part-time expert Members shall not hold office as such after they attained the age of seventy years and sixty-five years, respectively.

Clause 49.—This clause provides for resignation. It provides that the Chairperson or part-time expert Member or of the Appellate Tribunal may, by notice in writing under their hand addressed to the Central Government, resign from their office.

Clause 50.—This clause makes provisions for salaries, allowances and other terms and conditions of service of Chairperson and Members. It provides that the salaries and allowances payable to, and the other terms and conditions of service (including pension, gratuity and other retirement benefits) of, the Chairperson and allowances and fee payable to part-time expert Members of the Appellate Tribunal shall be such as may be prescribed.

It further provides that neither the salary and allowances nor the other terms and conditions of service of the Chairperson shall be varied to their disadvantage after their appointment.

Clause 51.—This clause lays down the restriction on Chairperson or Members on employment after cessation of office as Chairperson or Member of the Appellate Tribunal. It provides that the Chairperson or a Member of the Appellate Tribunal, ceasing to hold office

shall not hold office for a period of one year from the date on which they cease to hold office, accept any employment in, or connected with the management or administration of, any person which has been a party to a proceeding before the Appellate Tribunal under the proposed legislation. It further provides that the above said restriction shall not apply to any employment under the Central Government, State Government, local authority, any statutory authority or any corporation or a Government company.

It also provides for restrictions with respect to acting for, or, on behalf of persons or organisations in connection with any specific proceeding, transaction, negotiation or a case to which the Authority is a party or whose matter had been before such Chairperson or Member before cessation of his office.

It also contains provisions regarding restrictions on giving advice to any person using information obtained in the capacity as the Chairperson or a Member that is not publicly available and entering into a contract of service or accept an appointment to a board of directors of, or accept an offer of employment with, an entity whose matter had been before such Chairperson or Member without the due approval of the Central Government for a period of two years from his last day in office.

Clause 52.—This clause deals with the provisions relating to removal and suspension of Chairperson and part-time expert Member. It provides that the Central Government may, in consultation with the Chief Justice of India, remove from office, the Chairperson or a Member, in case he has been adjudged an insolvent, convicted of an offence or involved in moral turpitude or has become physically or mentally incapable or acquired financial or other interest likely to affect prejudicially his functions or abused his position prejudicially to the public.

It further provides for giving a reasonable opportunity to the Chairperson and part-time members before their removal and the Chairperson shall be removed from his office only after an inquiry made by a Judge of the Supreme Court.

Clause 53.—This clause provides for the part-time expert Member of the Appellate Tribunal to act as Chairperson of Appellate Tribunal and to discharge his functions in certain circumstances. It provides that in the event of the occurrence of any vacancy in the office of the Chairperson of the Appellate Tribunal by reason of his death or resignation or otherwise, the part-time expert Member of the Appellate Tribunal shall act as the Chairperson of the Tribunal until the date on which a new Chairperson is appointed in accordance with the provisions of the proposed legislation.

Clause 54.—This clause makes provision for staff of the Appellate Tribunal and their salaries and allowances. It provides that the Central Government shall determine the nature and categories of the officers and other employees required to assist the Appellate Tribunal in the discharge of its functions.

It further provides that the recruitment of the officers and other employees of the Appellate Tribunal shall be made by the Chairperson in such manner as may be prescribed by the Central Government.

It further provides that the officers and other employees of the Appellate Tribunal shall discharge their functions under the general superintendence of the Chairperson of such Appellate Tribunal and their salaries and allowances payable to, and the other terms and conditions of service of, the officers and other employees of the Appellate Tribunal shall be such as may be prescribed by the Central Government.

Clause 55.—This clause provides for financial and administrative powers of Chairperson of the Appellate Tribunal. It provides that the Chairperson of the Appellate Tribunal shall exercise financial and administrative powers as are vested in him under the rules made by the Central Government and it also contains provisions regarding delegation of financial and administrative powers by the Chairperson to any part-time expert Member or officer of the Appellate Tribunal.

Clause 56.—This clause makes provision to settle disputes by the Appellate Tribunal. It provides that the Appellate Tribunal shall have the jurisdiction over all civil cases where a substantial question relating to modern biotechnology is involved and questions arising out of the safety and use of organisms and products and processes specified under Schedule I and to hear appeals from the decisions or orders of the Authority.

It further provides that no application for deciding substantial question relating to modern biotechnology under this section shall be entertained by the Appellate Tribunal unless it is made within a period of two years from the date on which the cause of action for such question first arose.

It also provides that if it is satisfied that the applicant was prevented by sufficient cause from filing the application within the said period, the Appellate Tribunal may allow it to be filed within a further period not exceeding sixty days and such application or appeal shall be dealt with expeditiously and disposed of finally within six months from the date of filing of the application.

Clause 57.—This clause provides for the procedure and powers of the Appellate Tribunal. It provides that the Appellate Tribunal shall be guided by the principles of natural justice and not bound by the procedure laid down by the Code of Civil Procedure, 1908 or the rules of evidence contained in the Indian Evidence Act, 1872.

It further provides that the Appellate Tribunal shall have the same powers as are vested in a civil court under the Code of Civil Procedure, 1908, in respect of the matters such as, summoning and enforcing the attendance of any person and examining him on oath; requiring the discovery and production of documents; receiving evidence on affidavits subject to the provisions of sections 123 and 124 of the Indian Evidence Act, 1872; requisitioning any public record or document or copy of such record or document from any office; issuing commissions for the examination of witnesses or documents, reviewing its decision, dismissing an application for default or deciding it *ex parte*; setting aside any order of dismissal of any application for default or any order passed by it *ex parte*; pass an interim order (including granting an injunction or stay) after providing the parties concerned an opportunity of being heard, on any application made or appeal filed under the proposed legislation; and any other matter which may be prescribed.

It also provides that all proceedings before the Appellate Tribunal shall be deemed to be judicial proceedings within the meaning of sections 193, 219 and 228 for the purposes of section 196 of the Indian Penal Code, 1860 and the Appellate Tribunal shall be deemed to be a civil court for the purposes of section 195 and Chapter XXVI of the Code of Criminal Procedure, 1973.

Clause 58.—This clause provides for the binding of majority decision of the Appellate Authority. It provides that the decision of the Appellate Tribunal by majority of members shall be binding.

Clause 59.—This clause contains provisions regarding cost. It provides that while disposing of an application or an appeal under the proposed legislation, the Appellate Tribunal shall have power to make order as to costs as it may consider necessary.

Clause 60.—This clause provides for the execution of award or order of Appellate Tribunal. It provides that an award or order or decision of the Appellate Tribunal under the proposed legislation shall be executable by the Appellate Tribunal as a decree of a civil court, and for this purpose, the Appellate Tribunal shall have all the powers of a civil court.

Clause 61.—This clause makes provisions for appeal against any order of the Appellate Tribunal to the Supreme Court. It provides that notwithstanding anything contained in the Code of Civil Procedure, 1908 or in any other law, an appeal shall lie against any order, not being an interlocutory order, of the Appellate Tribunal to the Supreme Court on one or more of the grounds specified in section 100 of the Code. It further provides that no appeal shall lie against any decision or order made by the Appellate Tribunal with the consent of the

parties. It also provides that every appeal under this section shall be preferred within a period of ninety days from the date of the decision or order appealed against, however the Supreme Court may entertain an appeal after the expiry of the said period of ninety days, if it is satisfied that the appellant was prevented by sufficient cause from preferring the appeal in time.

Clause 62.—This clause provides for punishment for false information. It provides that, if any person provides any information or produces any document knowing it as a false or misleading, in connection with a requirement or direction under the proposed legislation, he shall be punishable with imprisonment for a term which may extend to three months and also with fine which may extend to five lakh rupees.

Clause 63.—This clause provides for punishment for conduct of unapproved field trials. Sub-clause (1) of this clause provides that whoever, himself or by any other person on his behalf, conducts field trials with organisms or products specified in part I or part III of Schedule I, in contravention of section 34 shall be punishable with imprisonment for a term which shall not less than six months but which may extend to one year and with fine which may extend to two lakh rupees. Sub-clause (2) of this clause provides that whoever, having been convicted of an offence under sub-clause (1), is again convicted of an offence under that sub-section, shall be punishable with imprisonment for a term which shall not be less than two years but which may extend to four years and with fine which may extend to four lakh rupees.

Clause 64.—This clause provides for punishment for obstructing or impersonating an officer of Authority. It provides that if a person, without reasonable excuse, resists, obstructs, or attempts to obstruct, impersonate, threaten, intimidate or assault an officer of the Authority or any person assigned to discharge any function or in exercising his functions under the proposed legislation, shall be punishable with imprisonment for a term which may extend to three months and also with fine which may extend to five lakh rupees.

Clause 65.—This clause provides for punishment in relation to audit report. It provides that if any auditor's report which is false or otherwise than in conformity with the specific areas or issues or standards or procedures directed to be audited by the Authority, the auditor concerned and the person, if any, other than the auditor who signs the report or signs or authenticates the documents, he shall, be punishable with imprisonment which may extend to three years or with fine which may extend to five thousand rupees or with both.

Clause 66.—This clause deals with the general provisions relating to offences and fine. It provides that if any person who contravenes or attempts to contravene or abets the contravention of the provision of the proposed legislation or of any rules or regulations made thereunder, for which no punishment is provided elsewhere in the proposed legislation, shall be punishable with imprisonment for a term which may extend to two years and also with fine which may extend to ten lakh rupees.

Clause 67.—This clause contains provisions for offences by companies. It provides that where an offence under the proposed legislation has been committed by a company, every person directly in charge of, and responsible to, the company for the conduct of its business at the time of commission of offence shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly unless he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent the commission of such offence. It also provides that where any offence under the proposed legislation has been committed with the consent or connivance of, or attributable to any neglect on the part of, any director, manager, secretary or other officer of the company, such director, manager, secretary or other officer shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly. The *Explanation* to the clause seeks to define the terms "company" and "director".

Clause 68.—This clause contains provisions for offences by society, trust and university. It provides that where an offence under the proposed legislation has been committed by a society or trust or university, every person directly in charge of, and was responsible to, the society or trust or university for the conduct of its business at the time of commission of offence shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly unless he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent the commission of such offence. It also provides that where any offence under the proposed legislation has been committed with the consent or connivance of, or attributable to any neglect on the part of, any governors, vice-chancellor, directors, committee, trustees, registrar or other officer of the society or trust or university, such governors, vice-chancellor, directors, committee, trustees, registrar or other officer shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

Clause 69.—This clause contains provisions for offences by Government Departments. It provides that where an offence under the proposed legislation has been committed by any Department of the Government, the Head of the Department shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly, in accordance with the provisions of the said clause unless he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent the commission of such offence. It also provides that where any offence under the proposed legislation has been committed with the consent or connivance of, or attributable to any neglect on the part of, any officer, other than the Head of the Department, such officer shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

Clause 70.—This clause contains provisions for cognizance of offences and provides that no court inferior to that of a Chief Metropolitan Magistrate or a Chief Judicial Magistrate shall try any offence under the proposed legislation and that cognizance of such offence shall be taken only on a complaint made by the Central Government or any authority or officer authorised by it.

Clause 71.—This clause provides for grants by the Central Government. It provides that 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 the Central Government may think fit for being utilised for the purposes of the proposed legislation.

Clause 72.—This clause provides for other fees and revenues. It provides that the fees or revenue collected by the Authority shall be credited to the Consolidated Fund of India and the entire amount so deposited may, after due appropriation made by Parliament by law in this behalf, be transferred to the Authority.

Clause 73.— This clause provides for usual provisions regarding budget, accounts and audit. It provides that the Authority shall prepare a budget, maintain proper accounts and other relevant records and prepare an annual statement of accounts as may be prescribed by the Central Government. It further provides that the accounts of the Authority shall be audited and certified by the Comptroller and Auditor-General of India, which would be laid before Parliament by the Central Government.

Clause 74.—This clause provides for furnishing of annual report to the Central Government. It provides that the Authority would prepare once in every year, in such form and at such time as may be prescribed by the Central Government, an annual report and a copy of the same is required to be laid, as soon as may be after it is received, before each House of Parliament.

Clause 75.— This clause confers powers upon the Central Government to issue directions. It provides that the Authority shall, in exercise of its powers or the performance of its functions under the proposed legislation, be bound by such directions on question 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. However, the Authority shall be given an opportunity to express its views before any such direction is given and the decision of the Central Government, whether a question is one of policy or not, shall be final.

Clause 76.—This clause confers power on the Central Government to supersede the Authority. It provides that if, at any time the Central Government is of the opinion, that, on account of circumstances beyond the control of the Authority, it is unable to discharge the functions or perform the duties imposed on it; or that the Authority has persistently defaulted in complying with any direction given by the Central Government and in discharging the functions or performance of the duties imposed on it by or under the provisions of the proposed legislation and as a result of such default the financial position of the Authority or the administration of the Authority has suffered; or that circumstances exist which render it necessary in the public interest so to do, the Central Government may, by notification, supersede the Authority for such period, not exceeding six months and appoint a person or persons as the President may direct to exercise powers and discharge functions under the proposed legislation.

It further provides that before issuing any such notification, the Central Government shall give a reasonable opportunity to the Authority to make representations against the proposed supersession and shall consider the representations, if any, of the Authority.

It further provides that upon the decision of the Central Government to supersede the Authority, the Chairperson and other members shall, from the date of supersession, vacate their offices; all the powers, functions and duties which may, by or under the provisions of proposed legislation, be exercised or discharge by or on behalf of the Authority shall, until the Authority is reconstituted, be exercised and discharged by the person or persons appointed for the said purpose, and all properties owned or controlled by the Authority shall, until the Authority is reconstituted, vest in the Central Government.

It also provides that, on or before the expiration of the period of supersession specified in the notification, the Central Government shall reconstitute the Authority by a fresh appointment of its Chairperson and other members and in such case persons who had vacated their office shall not to be deemed be disqualified for re-appointment.

It also provides that the Central Government shall cause a copy of the notification of superseding the Authority and a full report of action taken and the circumstances leading to such action to be laid before each House of Parliament.

Clause 77.— This clause provides for exclusion of jurisdiction of civil courts. It provides that no civil court shall have jurisdiction in respect of any matter which the Appellate Tribunal is empowered by or under the proposed legislation to determine and no injunction shall be granted by any court or other authority in respect of any action taken or to be taken in pursuance of any power conferred by or under the proposed legislation.

Clause 78.— This clause specifies the Members and staff of Authority as public servants. It provides that the Chairperson, Members, Chief Regulatory Officers, other officers and other employees of the Authority shall be deemed to be public servants within the meaning of section 21 of the Indian Penal Code.

Clause 79.— This clause provides for protection of action taken in good faith. It provides that no suit, prosecution or other legal proceedings shall lie against, the Central Government, the Authority and other bodies constituted; any officer of the Central Government, or any Member, Chief Regulatory Officers and other officers or other employees of such Authority and bodies or any other officer, as the case may be, for anything which is in good faith done or intended to be done in pursuance of the proposed legislation or the rules made thereunder in discharge of their duties.

Clause 80.— This clause provides for non-application of provisions of the proposed legislation to the Drugs and Cosmetics Act, 1940 and the Food Safety and Standards Act, 2006. It provides that nothing contained in the proposed legislation shall apply to the food or food additive or any material or thing which is covered under the Food Safety and Standards Act, 2006 or clinical trials of a drug as defined under clause (b) of section 3 of the Drugs and Cosmetics Act, 1940.

Clause 81.— This clause lays down the provisions for overriding effect of the proposed legislation. It provides that the provisions of the proposed legislation shall have overriding 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 the proposed legislation.

Clause 82.— This clause confers on the Central Government the power to make rules. It provides that the Central Government may, by notification in the Official Gazette, make rules for carrying out the provisions of the proposed legislation. Sub-clause (2) specifies matters for which such rules may be made by the Central Government.

Clause 83.— This clause empowers the Authority to make regulations. It provides that the Authority may, by notification, make regulations consistent with the provisions of the proposed legislation and the rules made thereunder to carry out the provisions of the proposed legislation. Sub-clause (2) specifies matters for which such regulations may be made by the Authority.

Clause 84.— This clause empowers the Central Government to amend the Schedule I which contains the list of certain organisms and products specified therein. It provides that the Central Government, after consultation with the Authority 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 Schedule I of the proposed legislation and thereupon the said Schedule shall be deemed to be amended accordingly.

Clause 85.— This clause provides for laying of rules, regulations and notifications before Parliament. It provides that every rule made and every notification issued by the Central Government and every regulation made by the Authority under the proposed legislation shall be required to be laid before each House of Parliament.

Clause 86.— This clause provides for application of certain laws. It provides that the provisions of the proposed legislation shall be in addition to and not in derogation of any other law for the time being in force.

Clause 87.— This clause lays down the provisions for amendment of certain enactments and savings. It provides that the enactments specified in Parts I and II of the Schedule II to the proposed legislation shall be amended in the manner specified therein and such amendments shall take effect from such date as the Central Government may by notification, specify and that such amendments shall not, affect, the previous operations of the enactment under repeal or anything duly done or suffered thereunder; any right, privilege, obligation or liability acquired, accrued or incurred under any of the enactment or orders; any penalty, forfeiture or punishment incurred in respect of any offences committed against the enactment; or 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 the proposed legislation had not been passed.

It further provides that if there is any other law for the time being in force in any State corresponding to the proposed legislation, the same shall upon the commencement of the proposed legislation, 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.

It also provides that notwithstanding the repeal of enactment specified under sub-clause (2), the licences issued under any such enactment or order, which are in force on the

date of commencement of the proposed legislation, 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 the proposed legislation or the rules made thereunder.

Clause 88.—This clause makes provisions for removal of difficulties. It empowers the Central Government to make, by order published in the Official Gazette, provisions for removal of difficulties in giving effect to the provisions of the proposed legislation. Such orders could be made only within two years from the commencement of the proposed legislation. Sub-clause (3) provides that every order issued under this clause is required to be laid before each House of Parliament.

Schedule I.—It specifies the organisms and products proposed to be regulated by the Authority.

Schedule II.—It proposes to make certain amendments in the Drugs and Cosmetics Act, 1940 and the Food Safety and Standards Act, 2006.

FINANCIAL MEMORANDUM

Sub-clause (1) of clause 4 of the Bill provides that the Central Government shall establish a body to be known as the Biotechnology Regulatory Authority of India to exercise the powers conferred on, and to perform the functions assigned to it, under the Bill. Sub-clause (4) of clause 9 of the Bill provides that the Central Government shall prescribe the salary, allowances and other terms and conditions of the services of the Chairperson and the Members of the Authority. Sub-clause (2) of clause 14 provides that the salary, allowances and other terms and conditions of service of Chief Regulatory Officers and other employees of the Authority shall be prescribed by the Central Government. Sub-clause (7) of clause 35 provides that the Authority shall provide technical or financial support for establishment of the State Biotechnology Regulatory Advisory Committee in each State.

2. Clause 44 of the Bill provides for establishment of an Appellate Tribunal to be known as the Biotechnology Regulatory Appellate Tribunal. Clause 50 provides that the Central Government shall prescribe the salaries, fees, allowances and other terms and conditions of service of the Chairperson and part-time expert members of the Biotechnology Regulatory Appellate Tribunal. Sub-clause (4) of clause 54 provides that the salary, allowances and other terms of conditions of service of officers and employees of the Appellate Tribunal shall be as prescribed by the Central Government.

3. Clause 71 of the Bill provides that 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 the Central Government may think fit for being utilised for the purposes of this Act. Clause 72 provides that the fees or revenue collected by the Authority shall be credited to the Consolidated Fund of India and the entire amount so credited will be transferred to the Authority.

4. The manpower requirements and the total financial implication in terms of recurring and non-recurring expenditure involved would be as per the set up of the proposed Biotechnology Regulatory Authority of India, Appellate Tribunal and the various State Biotechnology Regulatory Advisory Committees. It is difficult to estimate the exact expenditure, both recurring and non-recurring at this stage. On a representative basis, it is estimated that the recurring annual expenditure of the Authority shall be approximately in the range of Rs. 20.00 crores and the one time capital investment is estimated to be Rs. 25.00 crores for the establishment of the Biotechnology Regulatory Authority of India, Appellate Tribunal and the various State Biotechnology Regulatory Advisory Committees to be borne by the Central Government.

MEMORANDUM REGARDING DELEGATED LEGISLATION

Sub-clause (1) of clause 82 empowers the Central Government to make, by notification in the Official Gazette, rules for carrying out the provisions of the proposed legislation. Sub-clause (2) enumerates the matters in respect of which such rules may be made. These matters, *inter alia* specifies the power and functions of the Authority which may be exercised and discharged by the Chairperson as the Chief executive of the Authority under clause 8; the form and the manner in which, and the Authority before whom, the oath of office and of secrecy to be subscribed by the Chairperson and every Member and salaries and allowances payable to, and the other terms and conditions of service of, the Chairperson and Members under clause 9; the salaries, allowances and pensions payable to, and other conditions of service of the Chief Regulatory Officers, other officers and employees of the Authority, under sub-clause (2) of clause 14; the other functions of the Inter-Ministerial Governing Board under sub-clause (6) of clause 15; the manner in which members of the Biotechnology Advisory Council appointed and the other functions of the Biotechnology Advisory Council to be specified under clause 16; the times and places at which the meetings of the Inter-Ministerial Governing Board and the Biotechnology Advisory Council to be held and procedures to be observed in regard to the transaction of business at its meetings under clause 17; the qualifications and experience of the members of the Environment Appraisal Panel under clause 26; the manner in which the Authority shall provide technical or financial assistance or such other assistance, for the establishment of State Biotechnology Regulatory Advisory Committee, and, discharge of its functions, under sub-clause (7) of clause 35; the form and manner in which, and the fees along with which, the appeal shall be preferred and the particulars which such appeal shall contain under clause 43; the rules regulating generally the practices and procedure of the Appellate Tribunal under clause 45; the manner in which the part-time expert Members of the Appellate Tribunal are appointed under sub-clause (3) of clause 47; the salaries and allowances payable to, and the other terms and conditions of service of, the Chairperson and allowance and fee payable to part-time expert Member of the Appellate Tribunal under clause 50; the procedure for inquiry and removal of the Chairperson of the Appellate Tribunal, under sub-clause (4) of clause 52; the financial and administrative powers of the Chairperson of the Appellate Tribunal as may be vested in him under clause 55; the form in which the Authority shall prepare a budget, maintain proper accounts and other relevant records and prepare an annual statement of accounts under sub-clause (1) of clause 73; the form in which and time at which the Authority shall prepare an annual report under sub-clause (1) of clause 74.

2. Sub-clause (1) of clause 83 of the proposed legislation empowers the Biotechnology Regulatory Authority of India to make, by notification in the Official Gazette, regulations, for carrying out the provisions of the proposed legislation. Sub-clause (2) enumerates the matters in respect of which such regulations may be made. These matters, *inter alia* specify the times and places of meetings of the Authority and the rules of procedure to be observed by the Authority in regard to the transaction of business at its meetings under sub-clause (1) of clause 12; measures to regulate the research, transport, import manufacture and use of organisms and products referred to in clause 18; the other qualifications and duties and functions of the Chief Regulatory Officer under clause 21; the qualifications of the scientific officers of the Risk Assessment Unit and the manner of undertaking science-based safety assessment under clause 22; the manner of constitution of the Enforcement Unit for enforcing the decision of the Authority under sub-clause (1) of clause 23; the form and manner for submission of application for the purpose of obtaining authorisation for research, transport or import of organisms and products, the fee payable and the documents and information to be accompanied with such applications under clause 24; the manner of constitution of a Product Rulings Committee, the fee and allowances payable to the qualified scientific experts in the roster of experts and the procedure to be observed by the Product Rulings Committee

in regard to transaction of business at the meetings, including the quorum under clause 25; the form and manner for submission of application for the purpose of obtaining authorisation for the manufacture or use of organisms and products, the fee payable and the documents and information to be accompanied with such applications under clause 27; the manner of constitution of one or more Scientific Advisory Panels under clause 29; the safeguards subject to which the Authority may permit clinical trials or field trials of organisms and products under the proviso to clause 34; the manner of convening of the annual meeting of a State Biotechnology Regulatory Advisory Committee, by the Chairperson of the Authority, under clause 36; the qualifications and experience of Monitoring Officers under sub-clause (2) of clause 38; the agencies which may accredit the laboratories or research institutions under clause 41; the organisations or the agencies to be designated by the Authority, and the activities relating to safety of modern biotechnology, the compliance of which shall be ensured for the purposes of auditing notified laboratories or research institutions and the criteria which an organisation or agency shall fulfil, to be designated as auditor, under clause 42.

3. Clause 85 provides that every rule made and every notification issued by the Central Government and every regulation made by the Authority is required to be laid before each House of Parliament.

4. The matters in respect of which rules and regulations may be made are matters of procedures or administrative detail and it is not practicable to provide for them in the Bill itself. The delegation of legislative power is, therefore, of a normal character.

ANNEXURE

EXTRACTS FROM THE FOOD SAFETY AND STANDARDS ACT, 2006

(34 OF 2006)

* * * * *

13. (1)* * * * * *

Scientific Panels.

(3) Without prejudice to the provisions of sub-section (1), the Food Authority may establish as many Scientific Panels as it considers necessary in addition to the Panels on:

* * * * *

(c) genetically modified organisms and foods;

* * * * *

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

Genetically modified foods, organic foods, functional foods, proprietary foods, etc.

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;

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to promote the safe use of modern biotechnology by enhancing the effectiveness and efficiency of regulatory procedures and provide for establishment of the Biotechnology Regulatory Authority of India to regulate the research, transport, import, manufacture and use of organisms and products of modern biotechnology and for matters connected therewith or incidental thereto.

(Shri S. Jaipal Reddy, Minister of Science and Technology and Earth Sciences)

LOK SABHA

CORRIGENDA

to

THE BIOTECHNOLOGY REGULATORY AUTHORITY OF INDIA BILL, 2013

[To be/As introduced in Lok Sabha]

1. Page (ii), in the Arrangement of Clauses, in heading under CHAPTER VII,-
for "CLINICAL TRIAL"
read "CLINICAL TRIALS"
2. Page (iii), in the Arrangement of Clauses, in heading under CHAPTER XIII,-
for "AUDITS"
read "AUDIT"
3. Page 5, line 40, -
for "Environment Appraisal"
read "Environment Appraisal"
4. Page 14, line 20,-
for "Ministry of Health"
read "Ministry of Health and Family Welfare"
5. Page 17, in marginal citation against line 2, -
for "62 of 1962 "
read "52 of 1962"
6. Page 17, line 16, -
for "CLINICAL TRIAL"
read "CLINICAL TRIALS"
7. Page 19, line 25, -
for "Monitoring Officers."
read " Monitoring Officer."

P.T.O.

8. Page 22, line 9, -
for "to their disadvantage"
read " to his disadvantage"
9. Page 25, line 12, -
for "shall be punished with"
read " shall be punishable with"
10. Page 25, line 15, -
for "shall be punished with"
read " shall be punishable with"
11. Page 25, line 27, -
for "imprisonment which"
read "imprisonment for a term which"
12. Page 26, line 34, -
for "AUDITS"
read "AUDIT"
13. Page 41, line 4, -
for "Ministry of Health"
read "Ministry of Health and Family Welfare,"
14. Page 44, line 5 from the bottom, -
for "to their disadvantage after their"
read " to his disadvantage after his"

NEW DELHI;

March 18, 2013
Phalgun 27, 1934 (Saka)