THE ENVIRONMENT (PROTECTION) ACT, 1986

MINISTRY OF ENVIRONMENT & FORESTS
DEPARTMENT OF ENVIRONMENT, FORESTS & WILDLIFE
GOVERNMENT OF INDIA
NEW DELHI

The Environment (Protection) Act, 1986

No. 29 OF 1986

[*23rd May, 1986*]

An Act to Provide for the Protection and Improvement of Environment and for Matters Connected therewith.

WHEREAS decisions were taken at the United Nations Conference on the Human Environment held at Stockholm in June, 1972, in which India participated, to take appropriate steps for the protection and improvement of human environment;

AND WHEREAS it is considered necessary further to implement the decisions aforesaid in so far as they relate to the protection and improvement of environment and the prevention of hazards to human beings, other living creatures, plants and property;

BE it enacted by Parliament in the Thirty-seventh Year of the Republic of India as follows:

CHAPTER I

PRELIMINARY

Short title, extent and commencement.

1. (1) This Act may be called the Environment (Protection) Act, 86.

(2) It extends to the whole of India.

(3) It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint and different dates may be appointed for different provisions of this Act and for different areas.

Definitions.

2. In this Act, unless the context otherwise requires: –

(a) "environment" includes water, air and land and the inter-relationship which exists among and between water, air and land, and human beings, other living creatures, plants, micro-organism and property;

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

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

(d) "handling", in relation to any substance, means the manufacture, processing, treatment, package, storage, transporation, use, collection, destruction, conversion, offering for sale, transfer or the like of such substance;

(e) "hazardous substance" means any substance or preparation which, by reason of its chemical or physico-chemical properties or handling, is liable to cause harm to human beings, other living creatures, plants, micro-organism, property or the environment;

(f) "occupier", in relation to any factory or premises, means a person who has control over the affairs of the factory or the premises and includes, in relation to any substance, the person in possession of the substance;

(g) "prescribed" means prescribed by rules made under this Act.

CHAPTER II

General Powers of the Central Government

Power of Central Government to take measures to –

3. (1) Subject to the provisions of this Act, the Central Government shall have the power to take all such measures as it deems necessary or expedient for the purpose of protecting and improving the quality of the environment and preventing, controlling and abating environmental pollution.

protect and improve environment.

(2) In particular, and without prejudice to the generality of the provisions of sub-section (i), such measures may include measures with respect to all or any of the following matters, namely: —

(i) co-ordination of actions by the State Governments, officers and other authorities: —

(a) under this Act, or the rules made thereunder; or

(b) under any other law for the time being in force which is relatable to the objects of this Act;

(ii) planning and execution of a nation-wide programme for the prevention, control and abatement of environmental pollution;

(iii) laying down standards for the quality of environment in its various aspects;

(iv) laying down standards for emission or discharge of environmental pollutants from various sources whatsoever;

Provided that different standards for emission or discharge may be laid down under this clause from different sources having regard to the quality or composition of the emission or discharge of environmental pollutants from such sources;

(v) restriction of areas in which any industries, operations, or processes or class of industries, operations or processes shall not be carried out or shall be carried out subject to certain safeguards;

(vi) laying down procedures and safeguards for the prevention of accidents which may cause environmental pollution and remedial measures for such accidents;

(vii) laying down procedures and safeguards for the handling of hazardous substances;

(viii) examination of such manufacturing processes, materials and substances as are likely to cause environmental pollution;

(ix) carrying out and sponsoring investigations and research relating to problems of environmental pollution;

(x) inspection of any premises, plant, equipment, machinery manufacturing or other processes, materials or substances and giving, by order, of such directions to such authorities, officers or persons as it may consider necessary to take steps for the prevention, control and abatement of environmental pollution;

(xi) establishment or recognition of environmental laboratories and institutes to carry out the functions entrusted to such environmental laboratories and institutes under this Act;

(xii) collection and dissemination of information in respect of matters relating to environmental pollution;

(xiii) preparation of manuals, codes or guides relating to the prevention, control and abatement of environmental pollution;

(xiv) such other matters as the Central Government deems necessary or expedient for the purpose of securing the effective implementation of the provisions of this Act.

(3) The Central Government may, if it considers it necessary or expedient so to do for the purposes of this Act, by order, published in the Official Gazette, constitute an authority or authorities by such name or names as may be specified in the order for the purpose of exercising and performing such of the powers and functions (including the power to issue directions under section 5) of the Central Government under this Act and for taking measures with respect to such of the matters referred to in sub-section (2) as may be mentioned in the order and subject to the supervision and control of the Central Government and the provisions of such order, such authority or authorities may exercise the powers or perform the functions or take the measures so mentioned in the order as if such authority or authorities had been empowered by this Act to exercise those powers or perform those functions or take such measures.

Appointment of officers and their powers and functions.

4. (1) Without prejudice to the provisions of sub-section (3) of section 3, the Central Government may appoint officers with such designations as it thinks fit for the purposes of this Act and may entrust to them such of the powers and functions under this Act as it may deem fit.

(2) The officers appointed under sub-section (1) shall be subject to the general control and direction of the Central Government or, if so directed by that Government, also of the authority or authorities, if any, constituted under sub-section (3) of section 3 or of any other authority or officer.

Power to give directions

5. Notwithstanding anything contained in any other law but subject to the provisions of this Act, the Central Government may, in the exercise of its powers and performance of its functions under this Act, issue directions in writing to any person, officer or any authority and such person, officer or authority shall be bound to comply with such directions.

Explanation:—For the avoidance of doubts, it is hereby declared that the power to issue directions under this section includes the power to direct:—

(a) the closure, prohibition or regulation of any industry, operation or process; or

(b) stoppage or regulation of the supply of electricity or water or any other service.

Rules to regulate environmental pollution.

6. (1) The Central Government may, by notification in the Official Gazette, make rules in respect of all or any of the matters referred to in section 3.

(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) the standards of quality of air, water or soil for various areas and purposes;

(b) the maximum allowable limits of concentration of various environmental pollutants (including noise) for different areas;

(c) the procedures and safeguards for the handling of hazardous substances;

(d) the prohibition and restrictions on the handling of hazardous substances in different areas;

(e) the prohibition and restrictions on the location of industries and the carrying on of processes and operations in different areas;

(f) the procedures and safeguards for the prevention of accidents which may cause environmental pollution and for providing for remedial measures for such accidents.

CHAPTER III

PREVENTION, CONTROL AND ABATEMENT OF ENVIRONMENTAL POLLUTION

Persons carrying on industry operation, etc., not to allow emission or discharge of environmental pollutants in excess of the standards.

7. No person carrying on any industry, operation or process shall discharge or emit or permit to be discharged or emitted any environmental pollutant in excess of such standards as may be prescribed.

Persons handling hazardous substances to comply with procedural safeguards.

8. No person shall handle or cause to be handled any hazardous substance except in accordance with such procedure and after complying with such safeguards as may be prescribed.

Furnishing of information to authorities and agencies in certain cases.

9. (1) Where the discharge of any environmental pollutant in excess of the prescribed standards occurs or is apprehended to occur due to any accident or other unforeseen act or event, the person responsible for such discharge and the person in charge of the place at which such discharge occurs or is apprehended to occur shall be bound to prevent or mitigate the environmental pollution caused as a result of such discharge and shall also forthwith: –

(a) intimate the fact of such occurrence or apprehension of such occurrence; and

(b) be bound, if called upon, to render all assistance, to such authorities or agencies as may be prescribed.

(2) On receipt of information with respect to the fact or apprehension of any occurrence of the nature referred to in sub-section (1), whether through intimation under that sub-section or otherwise, the authorities or agencies referred to in sub-section (1) shall, as early as practicable, cause such remedial measures to be taken as are necessary to prevent or mitigate the environmental pollution.

(3) The expenses, if any, incurred by any authority or agency with respect to the remedial measures referred to in sub-section (2), together with interest (at such reasonable rate as the Government may, by order, fix) from the date when a demand for the expenses is made until it is paid may be recovered by such authority or agency from the person concerned as arrears of land revenue or of public demand.

Powers of entry and inspection.

10. (1) Subject to the provisions of this section, any person empowered by the Central Government in this behalf shall have a right to enter, at all reasonable times with such assistance as he considers necessary, any place: –

(a) for the purpose of performing any of the functions of the Central Government entrusted to him;

(b) for the purpose of determining whether and if so in what manner, any such functions are to be performed or whether any provisions of this Act or the rules made thereunder or any notice, order, direction or authorisation served, made, given or granted under this Act is being or has been complied with;

(c) for the purpose of examining and testing any equipment, industrial plant, record, register, document or any other material object or for conducting a search of any building in which he has reason to believe that an offence under this Act or the rules made thereunder has been or is being or is about to be committed and for seizing any such equipment, industrial plant, record, register, document or other material object if he has reasons to believe that it may furnish evidence of the commission of an offence punishable under this Act or the rules made thereunder or that such seizure is necessary to prevent or mitigate environmental pollution.

(2) Every person carrying on any industry, operation or process or handling any hazardous substance shall be bound to render all assistance to the person empowered by the Central Government under sub-section (1) for carrying out the functions under that sub-section and if he fails to do so without any reasonable cause or excuse, he shall be guilty of an offence under this Act.

(3) If any person wilfully delays or obstructs any person empowered by the Central Government under sub-section (1) in the performance of his functions, he shall be guilty of an offence under this Act.

2 of 1974.

(4) The provisions of the Code of Criminal Procedure, 1973, or, in relation to the State of Jammu and Kashmir, or any area in which that Code is not in force, the provisions of any corresponding law in force in that State or area shall, so far as may be, apply to any search or seizure under this section as they apply to any search or seizure made under the authority of a warrant issued under section 94 of the said Code or, as the case may be, under the corresponding provision of the said law.

Power to take sample and procedure to be followed in connection therewith

11. (1) The Central Government or any officer empowered by it in this behalf, shall have power to take, for the purpose of analysis, samples of air, water, soil or other substance from any factory, premises or other place in such manner as may be prescribed.

(2) The result of any analysis of a sample taken under sub-section (1) shall not be admissible in evidence in any legal proceeding unless the provisions of the sub-sections (3) and (4) are complied with.

(3) Subject to the provisions of sub-section (4), the person taking the sample under sub-section (1) shall:—

(a) serve on the occupier or his agent or person in charge of the place, a notice, then and there, in such form as may be prescribed, of his intention to have it so analysed;

(b) in the presence of the occupier or his agent or person, collect a sample for analysis.

(c) cause the sample to be placed in a container or containers which shall be marked and sealed and shall also be signed both by the person taking the sample and the occupier or his agent or person;

(d) send without delay, the container or the containers to the laboratory established or recognised by the Central Government under section 12.

(4) When a sample is taken for analysis under sub-section (1) and the person taking the sample serves on the occupier or his agent or person, a notice under clause (a) of sub-section (3), then:—

(a) in a case where the occupier, his agent or person wilfully absents himself, the person taking the sample shall collect the sample for analysis to be placed in a container or containers which shall be marked and sealed and shall also be signed by the person taking the sample, and

(b) in a case where the occupier or his agent or person present at the time of taking the sample refuses to sign the marked and sealed container or containers of the sample as required under clause (c) of sub-section (3), the marked and sealed container or containers shall be signed by the person taking the samples,

and the container or containers shall be sent without delay by the person taking the sample for analysis to the laboratory established or recognised under section 12 and such person shall inform the Government Analyst appointed or recognised under section 13 in writing, about the wilful absence of the occupier or his agent or person, or, as the case may be, his refusal to sign the container or containers.

Environmental laboratories.

12. (1) The Central Government may, by notification in the Official Gazette: –

(a) establish one or more environmental laboratories;

(b) recognise one or more laboratories or institutes as environmental laboratories to carry out the functions entrusted to an environmental laboratory under this Act.

(2) The Central Government may, by notification in the Official Gazette, make rules specifying:—

(a) the functions of the environmental laboratory;

(b) the procedure for the submission to the said laboratory of samples of air, water, soil or other substance for analysis or tests, the form of the laboratory report thereon and the fees payable for such report;

(c) such other matters as may be necessary or expedient to enable that laboratory to carry out its functions.

Government Analysts.

13. The Central Government may by notification in the Official Gazette, appoint or recognise such persons as it thinks fit and having the prescribed qualifications to be Government Analysts for the purpose of analysis of samples of air, water, soil or other substance sent for analysis to any environmental laboratory established or recognised under sub-section (1) of section **12**.

Reports of Government Analysts.

14. Any document purporting to be a report signed by a Government analyst may be used as evidence of the facts stated therein in any proceeding under this Act.

Penalty for contravention of the provisions of the Act and the rules, orders and directions.

15. (1) Whoever fails to comply with or contravenes any of the provisions of this Act, or the rules made or orders or directions issued thereunder, shall, in respect of each such failure or contravention, be punishable with imprisonment for a term which may extend to five years or with fine which may extend to one lakh rupees, or with both, and in case the failure or contravention continues, with additional fine which may extend to five thousand rupees for every day during which such failure or contravention continues after the conviction for the first such failure or contravention.

(2) If the failure or contravention referred to in sub-section (1) continues beyond a period of one year after the date of conviction, the offender shall be punishable with imprisonment for a term which may extend to seven years.

Offences by companies.

16. (1) Where any offence under this Act has been committed by a company, every person who, at the time the offence was committed,

was directly 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:

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 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 deemed to be guilty of that 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;

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

Offences by Government Departments.

17. (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:

Provided that nothing contained in this section shall render such Head of the Department liable to any punishment if he proves that the offence was committed without his knowledge or that he 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 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.

CHAPTER IV

MISCELLANEOUS

Protection of action taken in good faith.

18. No suit, prosecution or other legal proceeding shall lie against the Government or any officer or other employee of the Government or any authority constituted under this Act or any member, officer or other employee of such authority in respect of anything which is done or intended to be done in good faith in pursuance of this Act or the rules made or orders or directions issued thereunder.

Cognizance of offences.

19. No court shall take cognizance of any offence under this Act except on a complaint made by:—

(a) the Central Government or any authority or officer authorised in this behalf by that Government; or

(b) any person who has given notice of not less than sixty days, in the manner prescribed, of the alleged offence and of his intention to make a complaint, to the Central Government or the authority or officer authorised as aforesaid.

Information, reports or returns

20. The Central Government may, in relation to its functions under this Act, from time to time, require any person, officer, State Government or other authority to furnish to it or any prescribed authority or officer any reports, returns, statistics, accounts and other information and such person, officer, State Government or other authority shall be bound to do so.

Members, officers and employees of the authority constituted under section 3 to be public servants.

21. All the members of the authority, constituted, if any, under section 3 and all officers and other employees of such authority when acting or purporting to act in pursuance of any provisions of this Act or the rules made or orders or directions issued thereunder shall be deemed to be public servants within the meaning of section 21 of the Indian Penal Code.

Bar of jurisdiction.

22. No civil court shall have jurisdiction to entertain any suit or proceeding in respect of anything done, action taken or order or direction issued by the Central Government or any other authority or

officer in pursuance of any power conferred by or in relation to its or his functions under this Act.

Power to delegate.

23. Without prejudice to the provisions of sub-section (3) of section 3, the Central Government may, by notification in the Official Gazette, delegate, subject to such conditions and limitations as may be specified in the notification, such of its powers and functions under this Act, [except the power to constitute an authority under sub-section (3) of section 3 and to make rules under section 25] as it may deem necessary or expedient, to any officer, State Government or other authority.

Effect of other laws

24. (1) Subject to the provisions of sub-section (2), the provisions of this Act and the rules or orders made there in shall have effect notwithstanding anything inconsistent therewith contained in any enactment other than this Act.

(2) Where any act or omission constitutes an offence punishable under this Act and also under any other Act then the offender found guilty of such offence shall be liable to be punished under the other Act and not under this Act.

Power to make rules.

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

(2) In particular, and without prejudice to the generality of the foregoing power, such rules may provide for all or any of the following matters, namely: –

(a) the standards in excess of which environmental pollutants shall not be discharged or emitted under section 7;

(b) the procedure in accordance with and the safeguards in compliance with which hazardous substances shall be handled or cause to be handled under section 8;

(c) the authorities or agencies to which intimation of the fact of occurrence or apprehension of occurrence of the discharge of any environmental pollutant in excess of the prescribed standards shall be given and to whom all assistance shall be bound to be rendered under sub-section (1) of section 9;

(d) the manner in which samples of air, water, soil or other substance for the purpose of analysis shall be taken under sub-section (1) of section **11**;

(e) the form in which notice of intention to have a sample analysed shall be served under clause (a) of sub-section (3) of section **11**;

(f) the functions of the environmental laboratories, the procedure for the submission to such laboratories of samples of air, water, soil and other substances for analysis or test; the form of laboratory report; the fees payable for such report and other matters to enable such laboratories to carry out their functions under sub-section (2) of section **12**;

(g) the qualifications of Government Analyst appointed or recognised for the purpose of analysis of samples of air, water, soil or other substances under section **13**;

(h) the manner in which notice of the offence and of the intention to make a complaint to the Central Government shall be given under clause (b) of section **19**;

(i) the authority or officer to whom any reports, returns, statistics, accounts and other information shall be furnished under section **20**;

(j) any other matter which is required to be, or may be, prescribed.

Rules made under this Act to be laid before Parliament.

26. Every rule made under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.

This Act of Parliament received the assent of the President of India on the 23rd May, 1986: —

THE NOISE POLLUTION (REGULATION AND CONTROL) RULES, 2000

(AS AMENDED TO DATE)

THE NOISE POLLUTION (REGULATION AND CONTROL) RULES, 2000

MINISTRY OF ENVIRONMENT & FORESTS

NOTIFICATION

[1][S.O.123(E)] – Whereas, the increasing ambient noise level in public places from various sources, inter-alia, industrial activity, construction activity, [2][fire crackers, sound producing instruments], generator sets, loud speakers, public address systems, music systems, vehicular horns and other mechanical devices have deleterious effects on human health and the psychological well being of the people; it is considered necessary to regulate and control of noise producing and generating sources with the objective of maintaining the ambient air quality standards in respect of noise;

Whereas, a draft of Noise Pollution (Regulation and Control) Rule, 1999 was published under the notification of the Government of India in the Ministry of Environment and Forests vide number S.O.528 (E), dated the 28th June, 1999 inviting objections and suggestions from all the persons likely to be affected thereby, before the expiry of the period of sixty days from the date on which the copies of the Gazette containing the said notification are made available to the public;

And, whereas, copies of the said Gazette were made available to the public on the 1st day of July, 1999;

And, whereas the objections and suggestions received from the public in respect of the said draft rules have been duly considered by the Central Government;

Now, therefore, in exercise of the powers conferred by clause (ii) of sub-section (2) of section 3, sub-section (1) and clause (b) of sub-section (2) of section 6 and section 25 of the Environment (Protection) Act, 1986 (29 of 1986) read with Rule 5 of the Environment (Protection) Rules, 1986, the Central Government hereby makes the following rules for the regulation and control of noise producing and generating sources, namely:-

The Noise Pollution (Regulation and Control) Rules, 2000.

---

1 As published in the Gazette of India, Extraordinary, Part II- Section 3(i), vide S.O. 1246(E), dated 14.11.2000 and amended by the Noise Pollution (Regulation and Control) (Amendment) Rules, 2000 notified vide S.O. 1046(E), dated 22.11.2000.

2 Inserted by Rule 2 of the Noise Pollution (Regulation and Control) (Amendment) Rules, 2010 notified vide S.O.50 (E), dated 11.01.2010.

1. SHORT-TITLE AND COMMENCEMENT.-

(1) These rules may be called the Noise Pollution (Regulation and Control) Rules, 2000.

(2) They shall come into force on the date of their publication in the Official Gazette.

2. DEFINITIONS.-

In these rules, unless the context otherwise requires,-

(a) "Act" means the Environment (Protection) Act, 1986 (29 of 1986) ;

(b) "area/zone" means all areas which fall in either of the four categories given in the Schedule annexed to these rules;

[1][(c) "authority" means and includes any authority or officer authorized by the Central Government, or as the case may be, the State Government in accordance with the laws in force and includes a District Magistrate, Police Commissioner, or any other officer not below the rank of the Deputy Superintendent of Police designated for the maintenance of the ambient air quality standards in respect of noise under any law for the time being in force];

[2][(d) "court" means a governmental body consisting of one or more judges who sit to adjudicate disputes and administer justice and includes any court of law presided over by judge, judges or a magistrate and acting as a tribunal in civil, taxation and criminal cases;

(e) "educational institution" means a school, seminary, college, university, professional academies, training institutes or other educational establishment, not necessarily a chartered institution and includes not only buildings, but also all grounds necessary for the accomplishment of the full scope of educational instruction, including those things essential to mental, moral and physical development;

---

1 Substituted by Rule 2(i) of the Noise Pollution (Regulation and Control) Amendment Rules, 2000 notified vide S.O. 1036(E) dated 22.11.2000, w.e.f. 22.11.2000

2 Inserted by Rule 2(ii), of the Noise Pollution (Regulation and Control) Amendment Rules, 2000 notified vide S.O. 1036(E) dated 22.11.2000, w.e.f. 22.11.2000)

(f) "hospital" means an institution for the reception and care of sick, wounded, infirm or aged persons, and includes government or private hospitals, nursing homes and clinics;]

[1][(g) "person" shall include any company or association or body of individuals, whether incorporated or not;]

[2][(h) "State Government" in relation to a Union territory means the Administrator thereof appointed under article 239 of the Constitution;]

[3][(i) "public place" means any place to which the public have access, whether as of right or not, and includes auditorium, hotels, public waiting rooms, convention centres, public offices, shopping malls, cinema halls, educational institutions, libraries, open grounds and the like which are visited by general public; and

(j) "night time" means the period between 10.00 p.m. and 6.00 a.m.]

3. AMBIENT AIR QUALITY STANDARDS IN RESPECT OF NOISE FOR DIFFERENT AREAS/ZONES.-

(1) The ambient air quality standards in respect of Noise for different areas/zones shall be such as specified in the Schedule annexed to these rules.

(2) The State Government [4][shall categorize] the areas into industrial, commercial, residential or silence areas/zones for the purpose of implementation of noise standards for different areas.

(3) The State Government shall take measures for abatement of noise including noise emanating from vehicular movements, [5][blowing of horns, bursting of sound emitting fire crackers, use of loud speakers or public address system and sound producing instruments] and ensure that the existing noise levels do not exceed the ambient air quality standards specified under these rules.

(4) All development authorities, local bodies and other concerned authorities while planning developmental activity or carrying out functions relating to town

---

1 Re-numbered and substituted by Rule 2(ii) of the Noise Pollution (Regulation and Control) (Amendment) Rules, 2000 notified vide S.O.1046(E), dated 22.11.2000, w.e.f. 22.11.2000.

2 Renumbered by Rule 2(iii), ibid.

3 Inserted by Rule 3 of the Noise Pollution (Regulation and Control) (Amendment) Rules, 2010 notified vide S.O. 50 (E), dated 11.01.2010.

4 Substituted by Rule 3 of the Noise Pollution (Regulation and Control) (Amendment) Rules, 2000 notified vide S.O.1046(E), dated 22.11.2000, w.e.f. 22.11.2000.

5 Inserted by Rule 4 of the Noise Pollution (Regulation and Control) (Amendment) Rules, 2010 notified vide S.O. 50 (E), dated 11.01.2010.

and country planning shall take into consideration all aspects of noise pollution as a parameter of quality of life to avoid noise menace and to achieve the objective of maintaining the ambient air quality standards in respect of noise.

(5) An area comprising not less than 100 meters around hospitals, educational institutions and courts may be declared as silence area/zone for the purpose of these rules.

4. RESPONSIBILITY AS TO ENFORCEMENT OF NOISE POLLUTION CONTROL MEASURES.-

(1) The noise levels in any area/zone shall not exceed the ambient air quality standards in respect of noise as specified in the Schedule.

(2) The authority shall be responsible for the enforcement of noise pollution control measures and the due compliance of the ambient air quality standards in respect of noise.

[1][(3) The respective State Pollution Control Boards or Pollution Control Committees in consultation with the Central Pollution Control Board shall collect, compile and publish technical and statistical data relating to noise pollution and measures devised for its effective prevention, control and abatement.]

5. RESTRICTIONS ON THE USE OF LOUD SPEAKERS/PUBLIC ADDRESS SYSTEM [2][AND SOUND PRODUCING INSTRUMENTS].-

(1) A loud speaker or a public address system shall not be used except after obtaining written permission from the authority.

[3][(2) A loud speaker or a public address system or any sound producing instrument or a musical instrument or a sound amplifier shall not be used at night time except in closed premises for communication within, like auditoria, conference rooms, community halls, banquet halls or during a public emergency.]

---

1 Inserted by Rule 2 (i) of the Noise Pollution (Regulation and Control) Amendment Rules, 2006 notified vide S.O.1569(E), dated 19.9.2006

2 Inserted by Rule 5(i) of the Noise Pollution (Regulation and Control) (Amendment) Rules, 2010 notified vide S.O.50 (E), dated 11.01.2010

3 Substituted by Rule 5(ii) of the Noise Pollution (Regulation and Control) (Amendment) Rules, 2010 notified vide S.O.50 (E), dated 11.01.2010

[1][(3) Notwithstanding anything contained in sub-rule (2), the State Government may subject to such terms and conditions as are necessary to reduce noise pollution, permit use of loud speakers or [2][public address systems and the like during night hours] (between 10.00 p.m. to 12.00 midnight) on or during any cultural or religious festive occasion of a limited duration not exceeding fifteen days in all during a calendar year.] [3][The Concerned State Government shall generally specify in advance, the number and particulars of the days on which such exemption would be operative].

[4][(4) The noise level at the boundary of the public place, where loudspeaker or public address system or any other noise source is being used shall not exceed 10 dB(A) above the ambient noise standards for the area or 75 dB(A) whichever is lower.

(5) The peripheral noise level of a privately owned sound system or a sound producing instrument shall not, at the boundary of the private place, exceed by more than 5 dB(A) the ambient noise standards specified for the area in which it is used].

[5]**[5A.RESTRICTIONS ON THE USE OF HORNS, SOUND EMITTING CONSTRUCTION EQUIPMENTS AND BURSTING OF FIRE CRACKERS.-**

(1) No horn shall be used in silence zones or during night time in residential areas except during a public emergency.

(2) Sound emitting fire crackers shall not be burst in silence zone or during night time.

(3) Sound emitting construction equipments shall not be used or operated during night time in residential areas and silence zones.]

---

1 Inserted by Rule 2 of the Noise Pollution (Regulation and Control) Amendment Rules, 2002 notified vide Notification S.O. 1088(E), dated 11.10.2002

2 Substituted by Rule 5(iii)(a) of the Noise Pollution (Regulation and Control) (Amendment) Rules, 2010 notified vide S.O.50 (E), dated 11.01.2010

3 Inserted by Rule 5(iii)(b) of the Noise Pollution (Regulation and Control) (Amendment) Rules, 2010 notified vide S.O.50 (E), dated 11.01.2010

4 Inserted by Rule 5(iv) of the Noise Pollution (Regulation and Control) (Amendment) Rules, 2010 notified vide S.O.50 (E), dated 11.01.2010

5 Inserted by Rule 6 of the Noise Pollution (Regulation and Control) (Amendment) Rules, 2010 notified vide S.O.50 (E), dated 11.01.2010

6. CONSEQUENCES OF ANY VIOLATION IN SILENCE ZONE/AREA.-

Whoever, in any place covered under the silence zone/area commits any of the following offence, he shall be liable for penalty under the provisions of the Act:-

(i) whoever, plays any music or uses any sound amplifiers,

(ii) whoever, beats a drum or tom-tom or blows a horn either musical or pressure, or trumpet or beats or sounds any instrument,

(iii) whoever, exhibits any mimetic, musical or other performances of a nature to attract crowds,

[1][(iv) whoever, bursts sound emitting fire crackers; or

(v) whoever, uses a loud speaker or a public address system.]

7. COMPLAINTS TO BE MADE TO THE AUTHORITY.-

(1) A person may, if the noise level exceeds the ambient noise standards by 10 dB(A) or more given in the corresponding columns against any area/zone [2][or, if there is a violation of any provision of these rules regarding restrictions imposed during night time], make a complaint to the authority.

(2) The authority shall act on the complaint and take action against the violator in accordance with the provisions of these rules and any other law in force.

8. POWER TO PROHIBIT ETC. CONTINUANCE OF MUSIC SOUND OR NOISE.-

(1) If the authority is satisfied from the report of an officer incharge of a police station or other information received by him [3][including from the complainant] that it is necessary to do so in order to prevent annoyance, disturbance, discomfort or injury or risk person who dwell or occupy property on the vicinity, he may, by a written order issue such directions as he may consider necessary to any person for preventing, prohibiting, controlling or regulating :-

---

1 Inserted by Rule 7 of the Noise Pollution (Regulation and Control) (Amendment) Rules, 2010 notified vide S.O.50(E), dated 11.01.2010

2 Inserted by Rule 8 of the Noise Pollution (Regulation and Control) (Amendment) Rules, 2010 notified vide S.O.50(E), dated 11.01.2010

3 Inserted by Rule 2(ii)(a) of the Noise Pollution (Regulation and Control) Amendment Rules, 2006 notified vide S.O.1569 (E), dated 19.9.2006.

(a) The incidence or continuance in or upon, any premises of –

(i) Any vocal or instrumental music,

(ii) sounds caused by playing, beating, clashing, blowing or use in any manner whatsoever of any instrument including loudspeakers, [1][public address systems, horn, construction equipment, appliance or apparatus] or contrivance which is capable of producing or re-producing sound,

[2][(iii) sound caused by bursting of sound emitting fire crackers, or]

(b) The carrying on in or upon, any premises of any trade, a vocation or operation or process resulting in or attended with noise.

(2) The authority empowered under sub-rule (1) may, either on its own motion, or on the application of any person aggrieved by an order made under sub-rule (1), either rescind, modify or alter any such order:

provided that before any such application is disposed of, the said authority shall afford to the applicant [3][and to the original complainant, as the case may be] an opportunity of appearing before it either in person or by a person representing him and showing cause against the order and shall, if it rejects any such application either wholly or in part, record its reasons for such rejection.

---

1 Substituted by Rule 9(i) of the Noise Pollution (Regulation and Control) (Amendment) Rules, 2010 notified vide S.O.50(E) dated 11.01.2010

2 Inserted by Rule 9(ii) of the Noise Pollution (Regulation and Control) (Amendment) Rules, 2010 notified vide S.O.50(E), dated 11.01.2010

3 Inserted vide Rule 2(ii)(b) of the Noise Pollution (Regulation and Control) Amendment Rules, 2006 notified vide S.O.1569 (E) dated 19.9.2006.

SCHEDULE

see rule 3(1) and 4(1)

Ambient Air Quality Standards in respect of Noise

Area Code	Category of Area/Zone	Limits in dB(A) Leq*	
		Day Time	Night Time
(A)	Industrial area	75	70
(B)	Commercial area	65	55
(C)	Residential area	55	45
(D)	Silence Zone	50	40

Note:- 1. Day time shall mean from 6.00 a.m. to 10.00 p.m.

2. Night time shall mean from 10.00 p.m. to 6.00 a.m.

[1][3. Silence zone is an area comprising not less than 100 metres around hospitals, educational institutions, courts, religious places or any other area which is declared as such by the competent authority].

4. Mixed categories of areas may be declared as one of the four above mentioned categories by the competent authority.

*dB(A) Leq denotes the time weighted average of the level of sound in decibels on scale A which is relatable to human hearing.

A "decibel" is a unit in which noise is measured.

"A", in dB(A) Leq, denotes the frequency weighting in the measurement of noise and corresponds to frequency response characteristics of the human ear.

Leq: It is an energy mean of the noise level over a specific period.

Note: The principal rules were published in the Gazette of India vide number, S.O.123(E), dated 14th February, 2000 and subsequently amended vide S.O.1046(E), dated 22nd November, 2000, S.O. 1088(E), dated 11th October, 2002, S.O. 1569(E), dated the 19th September, 2006 and S.O.50(E), dated 11th January, 2010.

Substituted by Rules 4 of the Noise Pollution (Regulation and Control) (Amendment) Rules, 2000 notified vide S.O. 1046 (E), dated 22.11.2000

THE MANUFACTURE, STORAGE AND IMPORT OF HAZARDOUS CHEMICAL RULES, 1989

MINISTRY OF ENVIRONMENT & FORESTS

(Department of Environment, Forests and Wildlife)

NOTIFICATION

(New Delhi, the 27th November 1989)

***S.O.966(E)** - In exercise of the powers conferred by Section 6, 8 and 25 of the Environment (Protection) Act, 1986 (29 of 1986), the Central Government hereby makes the following rules, namely :

3. DUTIES OF AUTHORITIES –

The concerned authority shall, -

(a) inspect the industrial activity at least once in a calendar year;

(b) except where such authority is the Ministry of Environment and Forests, annually report on the compliance of the rules by the occupiers to the Ministry of Environment and Forests through appropriate channel ;

(c) subject to the other provisions of these rules, perform the duties specified in column 3 of Schedule 5.]

4. GENERAL RESPONSIBILITY OF THE OCCUPIER DURING INDUSTRIAL ACTIVITY -

(1) these rules shall apply to, -

(a) an industrial activity in which a hazardous chemical, which satisfies any of the criteria laid down in Part I of Schedule 1 [1][or listed] in Column 2 of Part II of this Schedule is, or may be, involved; and

[2][(b) isolated storage of a hazardous chemical listed in Schedule 2 in a quantity equal to or more than the threshold quantity specified in Column 3, thereof.]

---

1 Substituted by Rule 3(i) of the MSIHC (Amendment) Rules, 1994 notified vide S.O.2882, dated 3.10.1994.

2 Substituted by Rule 3(ii), ibid.

(2) An occupier who has control of an industrial activity in terms of sub-rule (1) shall provide evidence to show that he has, -

(a) identified the major accident hazards; and

(b) taken adequate steps to -

(i) prevent such major accidents and to limit their consequences to persons and the environment;

(ii) provide to the persons working on the site with the information, training and equipment including antidotes necessary to ensure their safety.

4. NOTIFICATION OF MAJOR ACCIDENT -

(1) Where a major accident occurs on a site or in a pipe line, the occupier shall [1][within 48 hours notify] the concerned authority as identified in Schedule 5 of that accident, and furnish thereafter to the concerned authority a report relating to the accidents in installments, if necessary, in Schedule 6.

(2) The concerned authority shall on receipt of the report in accordance with sub-rule 1 of this rule, shall undertake a full analysis of the major accident and sent the [2][requisite information within 90 days to the Ministry] of Environment and Forests through appropriate channel.

[3][(3) An occupier shall notify to the concerned Authority, steps taken to avoid any repetition of such occurrence on a site.]

[4][(4) The concerned Authority shall compile information regarding major accidents and make available a copy of the same to the Ministry of Environment & Forests through appropriate channel.

(5) The concerned Authority shall in writing inform the occupier, of any lacunae which in its opinion needs to be rectified to avoid major accidents.]

6. INDUSTRIAL ACTIVITY TO WHICH RULES 7 TO 15 APPLY -

---

1 Substituted by Rule 3(a) of the MSIHC (Amendment) Rules, 1994 notified vide S.O.2882, dated 3.10.1994.

2 Substituted by Rule 3(b) ibid.

3 Substituted by Rule 3(c) of the Manufacture, Storage and Import of Hazardous Chemical (Amendment) Rules, 1994 notified vide S.O. No.2882, dated 3.10.1994.

4 Inserted by Rule 3(d); ibid.

(1) Rules 7 to 15 shall apply to, -

(a) an industrial activity in which there is involved a quantity of hazardous chemical listed in Column 2 of Schedule 3 which is equal to or more than the quantity specified in the entry for that chemical in Column 3 & 4 (Rules 10-12 only for Column 4); and

(b) isolated storage in which there is involved a quantity of a hazardous chemical listed in Column 2 of Schedule 2 which is equal to or more than the quantity specified in the entry for that chemical in Column [1][3 & 4 (rules 10-12 only for column 4).]

(2) For the purpose of rules 7 to 15,

(a) "new industrial activity" means an industrial activity which, –

(i) commences after the date of coming into operation of these rules; or

(ii) if commenced before that date, is an industrial activity in which a modification has been made which is likely to cover major accident hazards, and that activity shall be deemed to have commenced on the date on which the modification was made;

(b) an "existing industrial activity" means an industrial activity which is not a new industrial activity.

7. [2][APPROVAL AND] NOTIFICATION OF SITES -

(1) An occupier shall not undertake any industrial activity [3][unless he has been granted an approval for undertaking such an activity and has submitted] a written report to the concerned authority containing the particulars specified in Schedule 7 at least 3 months before commencing that activity or before such shorter time as the concerned authority may agree and for the purpose of this paragraph, an activity in which subsequently there is or is liable to be a threshold

---

1 Substituted by Rule 4; ibid.

2 Substituted by Rule 5 of the MSIHC (Amendment) Rules, 2000 notified vide S.O.57(E), dated 19.1.2000.

3 Substituted by Rule 4 (a) of MSIHC (Amendment) Rules, 1994 notified vide S.O.2882, dated 3.10.1994.

quantity or more of an additional hazardous chemical shall be deemed to be a different activity and shall be notified accordingly.

[1][(2) The concerned Authority within 60 days from the date of receipt of the report shall approve the report submitted and on consideration of the report if it is of the opinion that contravention of the provisions of the Act or the rules made thereunder has taken place, it shall issue notice under rule 19].

13. PREPARATION TO ON-SITE EMERGENCY PLAN BY THE OCCUPIER -

(1) An occupier shall prepare and keep up-to-date [2][an on-site emergency plan containing details specified in Schedule II and detailing] how major accidents will be dealt with on the site on which the industrial activity is carried on and that plan shall include the name of the person who is responsible for safety on the site and the names of those who are authorized to take action in accordance with the plan in case of an emergency.

(2) The occupier shall ensure that the emergency plan prepared in accordance with sub-rule (1) takes into account any modification made in the industrial activity and that every person on the site who is affected by the plan is informed of its relevant provisions.

(3) The occupier shall prepare the emergency plan required under sub-rule (1),-

(a) in the case of a new industrial activity, before that activity is commenced;

(b) in the case of an existing industrial activity within 90 days of commencing into operation of these rules.

[3][(4) The occupier shall ensure that a mock drill of the on-site emergency plan is conducted every six months;

---

1 Substituted by Rule 4(b), ibid.

2 Substituted by Rule 8(a), ibid.

3 Inserted by Rule 8(b) of the MSIHC (Amendment) Rules, 1994 notified vide S.O.2882, dated 3.10.1994.

(5) A detailed report of the mock drill conducted under sub-rule (4) shall be made immediately available to the concerned Authority.]

14. PREPARATION OF OFF-SITE EMERGENCY PLAN BY THE AUTHORITY -

(1) It shall be the duty of the concerned authority as identified in Column 2 of Schedule 5 to prepare and keep up-to-date [1][an adequate off-site emergency plan containing particulars specified in Schedule 12 and detailing] how emergencies relating to a possible major accident on that site will be dealt with and in preparing that plan the concerned authority shall consult the occupier, and such other persons as it may deem necessary.

(2) For the purpose of enabling the concerned authority to prepare the emergency plan required under sub-rule (1), the occupier shall provide the concerned authority with such information relating to the industrial activity under his control as the concerned authority may require, including the nature, extent and likely effects off-site of possible major accidents and the authority shall provide the occupier with any information from the off-site emergency plan which relates to his duties under rule 13.

(3) The concerned authority shall prepare its emergency plan required under sub-rule (1),-

(a) In the case of a new industrial activity, before that activity is commenced;

(b) In the case of an existing industrial activity, within six months of coming into operation to these rules.

[2][(4) The concerned authority shall ensure that a rehearsal of the off-site emergency plan is conducted at least once in a calendar year.]

18. IMPORT OF HAZARDOUS CHEMICALS -

---

1 Substituted by Rule 9 (a), ibid.

2 Inserted by Rule 9(b) of the MSIHC (Amendment) Rules, 1994 notified vide S.O.2882, dated 3.10.1994.

(1) This rule shall apply to a chemical which satisfies any of the criteria laid down in Part I of Schedule 1 [1][or listed] in Column 2 of Part II of this Schedule.

(2) Any person responsible for importing hazardous chemicals in India shall provide [2][before 30 days or as reasonably possible but not later than] the date of import to the concerned authorities as identified in Column 2 of Schedule 5 the information pertaining to, -

(i) the name and address of the person receiving the consignment in India;

(ii) the port of entry in India;

(iii) mode of transport from the exporting country to India;

(iv) the quantity of chemical (s) being imported; and

(v) complete product safety information.

(3) If the Concerned Authority of the State is satisfied that the chemical being imported is likely to cause major accidents, it may direct the importer to take such safety measures as the concerned Authority of the State may deem appropriate.]

[(3A) In case the concerned Authority of the State is of the opinion that the chemical should not be imported on safety or on environmental considerations, such Authority may direct stoppage of such import.]

(4) The concerned Authority at the State shall simultaneously inform the concerned Port Authority to take appropriate steps regarding safe handling and storage of hazardous chemicals while off-loading the consignment within the port premises.

(5) Any person importing hazardous chemicals shall maintain the records of the hazardous chemicals imported as specified in Schedule 10 and the records so maintained shall be open for inspection by the concerned authority at the State or the Ministry of Environment and Forests or any officer appointed by them in this behalf.

---

1 Substituted by Rule 8(a), ibid.

2 Substituted by Rule 10(a) of the MSIHC (Amendment) Rules, 1994 notified vide S.O.2882, dated 3.10.1994.

(6) The importer of the hazardous chemical or a person working on his behalf shall ensure that transport of hazardous chemicals from port of entry to the ultimate destination is in accordance with the Central Motor Vehicles Rules, 1989 framed under the provisions of the Motor Vehicles Act, 1988.

1. Subs by MSIHC (Amendment) Rules, 1994 (w.e.f. 22.10.1994)
2. Subs. by S.O. 57(E), dated 19th January, 2000 (w.e.f. 19.1.2000)

[1][SCHEDULE 1]

[See rule 2e (i), 4 (1)(a), 4(2), 17 and 18]

[Part -I]

(a) ***Toxic Chemicals***: Chemicals having the following values of acute toxicity and which owing to their physical and chemical properties, are capable of producing major accident hazards:

S.No.	Toxicity	Oral toxicity LD_{50}(mg/kg)	Dermal toxicity LD_{50}(mg/kg)	Inhalation toxicity LC_{50}(mg/l)
1.	Extremely toxic	>5	<40	<0.5
2.	Highly toxic	>5-50	>40-200	<0.5-2.0
3.	Toxic	>50-200	>200-1000	>2-10

(b) ***Flammable Chemicals :***

(i) flammable gases: Gases which at 20^{o}C and at standard pressure of 101.3KPa are :-

(a) ignitable when in a mixture of 13 percent or less by volume with air, or ;

(b) have a flammable range with air of at least 12 percentage points regardless of the lower flammable limits.

Note : The flammability shall be determined by tests or by calculation in accordance with methods adopted by International Standards Organization ISO Number 10156 of 1990 or by Bureau of Indian Standard ISI Number 1446 of 1985.

(ii) ***extremely flammable liquids*** : chemicals which have flash point lower than or equal to 23^{o}C and boiling point less than 35^{o}C.

---

[1] Substituted by Rule 9 of the MSIHC (Amendment) Rules, 2000 notified vide S.O.57(E), dated 19.1.2000.

(iii) ***very highly flammable liquids*** : chemicals which have a flash point lower than or equal to 23°C and initial boiling point higher than 35°C.

(iv) ***highly flammable liquids*** : chemicals which have a flash point lower than or equal to 60°C but higher than 23°C.

(v) ***flammable liquids*** : chemicals which have a flash point higher than 60°C but lower than 90°C.

(c) ***Explosives*** : explosives mean a solid or liquid or pyrotechnic substance (or a mixture of substances) or an article.

(a) which is in itself capable by chemical reaction of producing gas at such a temperature and pressure and at such a speed as to cause damage to the surroundings ;

(b) which is designed to produce an effect by heat, light, sound, gas or smoke or a combination of these as the result of non-detonative self sustaining exothermic chemical reaction.

MINISTRY OF ENVIRONMENT & FORESTS

NOTIFICATION

New Delhi, the 5th December, 1989

RULES FOR THE MANUFACTURE, USE, IMPORT, EXPORT AND STORAGE OF HAZARDOUS MICRO ORGANISMS GENETICALLY ENGINEERED ORGANISMS OR CELLS

(To be notified under the EP Act, 1986)

G.S.R. 1037(E).-In exercise of the powers conferred by sections 6, 8 and 25 of the Environment (Protection) Act, 1986 (29 of 1986) and with a view to protecting the environment, nature and hea11h, in connection with the application of genetechnology and micro-organisms, the Central Government hereby makes the following rules, namely:-

1. Short title, extent and commencement

(1) These rules may be called the Rules for the Manufacture, Use, Import, Export and Storage of Hazardous micro-organisms Genetically engineered organisms or cells.

(2) These rules shall come into operation on the date to be notified for this purpose in the Official Gazette.

2. Application

(1) These rules are applicable to the manufacture import and storage of micro-organisms and Gene-Technological products.

(2) These shall apply to genetically engineered organisms micro-organisms and cells and correspondingly to any substances and products and food stuffs, etc. of which such cells, organisms or tissues hereof form part.

(3) These rules shall also apply to new genetechnologies apart from those referred to in clauses (ii) and (iv) of rule 3 and these rules shall apply to organisms/micro-organisms and cells generated by the

utilisation of such other gene-technologies and to substances and products of which such organisms and cells form part.

(4) These rules shall be applicable in the following specific cases;

(a) sale, offers for sale, storage for the purpose of sale, offers and any kind of handling over with or without a consideration;

(b) exportation and importation of genetically engineered cells or organisms;

(c) production, manufacturing, processing, storage, import, drawing off, packaging and repacking of the Genetically Engineered Products;

(d) Production, manufacture etc. of drugs and pharmaceuticals and food stuffs distilleries and tanneries, etc. which make use of micro-organisms genetically engineered micro-organisms one way or the other.

(5) These rules shall be applicable to the whole of India.

3. Definition

In these rules unless the context requires,

(i) "Biotechnology" means the application of scientific and engineering principles to the processing of materials by biological agents to produce goods and services;

(ii) "Cell hybridisation" means the formation of live cells with new combinations of genetic material through the fusion of two or more cells by means of methods which do not occur naturally;

(iii) "Gene Technology" means the application of the gene technique called genetic engineering, include self-cloning and deletion as well as cell hybridisation;

(iv) "Genetic engineering" means the technique by which heritable material, which does not usually occur or will not occur

naturally in the organism or cell concerned, generated outside the organism or the cell is inserted into said cell or organism. It shall also mean the formation of new combinations of genetic material by incorporation of a cell into a host cell, where they occur naturally (self cloning) as well as modification of an organism or in a cell by deletion and removal of parts of the heritable material;

(v) "microorganisms" shall include all the bacteria, viruses, fungi, mycoplasma, cells lines, algae, protodones and nematotes indicated in the schedule and those that have not been presently known to exist in the country or not have been discovered so far.

4. Competant Authorities

(1) Recombinant DNA Advisory Committee (IXDAC)

This committee shall review developments in Biotechnology al national and international levels and shall recommend suitable and-appropriate safety regulations for India in recombinant research, use and applications from time to time. The committee shall function in the Department of Biotechnology.

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

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

(e) other experts in their individual capacity. Review Committee on Genetic Manipulation may appoint sub groups.

It shall bring out Manuals of guidelines specifying procedure for regulatory process with respect to activities involving genetically engineered organisms in research use and applications including industry with a view to ensure environmental safety. All ongoing projects

involving high risk category and controlled field experiments shall be reviewed to ensure that adequate precautions and containment conditions are followed as per the guidelines.

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

(3) Institutional Biosafety Committee (IBSC).

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

(4) Genetic Engineering Approval Committee (GE.AC)

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

The composition of the Committee shall be

(i) Chairman-Additional Secretary Department of Environment Forests and Wild life

Co-Chairman Representative of Department of Bio-technology

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

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

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

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

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

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

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

```
(i)     Chief Secretary                                    -
Chairman
(ii)    Secretary, Department of Environment               -
Member Secretary
(iii)   Secretary, Department of Health                    -
Member
```

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

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

(6) District Level Committee (DLC)

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

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

The District Level Committee shall comprise of:-

(i) District Collector - Chairman
(ii) Factory Inspector - Member
(iii) A representative of the Pollution Control Board - Member
(iv) Chief Medical Officer (District Health Officer) - Member
(v) District Agricultural Officer - Member
(vi) A representative of the Public Health Engineering Department - Member
(vii) District Microbiologists/Pathologist (technical expert) - Member
(viii) Commissioner Municipal Corporation - Member

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

5. Classification of microorganisms or genetically engineered product

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

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

6. Microorganisms laid down in the Schedule are divided into the following:-

(i) Bacterial Agents;
(ii) Fungal Agents;
(iii) Parasitic Agents;
(iv) Viral, Rickettsial and Chlamydial Agents;
(v) Special Category.

15. Penalties

(1) If an order is not complied with, the District Level Committee or State Biotechnology Co-ordination Committee may take measures at the expense of the person who is responsible.

(2) In case where immediate intervention is required in order to prevent any damage to the environment, nature or health, the District level Committee or State Biotechnology Coordination Committee may take the necessary steps without issuing any order or notice. The expenses incurred for this purpose will be repayable by the person responsible for such damage.

(3) The State Biotechnology Co-ordination Committee/District Level Committee may take samples for a more detailed examination of organisms and cells.

(4) The State Biotechnology Co-ordination Committee/District Level Committee shall be competent to ask for assistance from any other government authority to carry out its instructions.

The Bio-Medical Waste (Management and Handling) Rules, 1998

MINISTRY OF ENVIRONMENT & FORESTS

NOTIFICATION

New Delhi, 20th July, 1998

S.O. 630 (E).-Whereas a notification in exercise of the powers conferred by Sections 6, 8 and 25 of the Environment (Protection) Act, 1986 (29 of 1986) was published in the Gazette vide S.O. 746 (E) dated 16 October, 1997 inviting objections from the public within 60 days from the date of the publication of the said notification on the Bio-Medical Waste (Management and Handling) Rules, 1998 and whereas all objections received were duly considered..

Now, therefore, in exercise of the powers conferred by section 6, 8 and 25 of the Environment (Protection) Act, 1986 the Central Government hereby notifies the rules for the management and handling of bio-medical waste.

4. DUTY OF OCCUPIER:

It shall be the duty of every occupier of an institution generating bio-medical waste which includes a hospital, nursing home, clinic, dispensary, veterinary institution, animal house, pathological laboratory, blood bank by whatever name called to take all steps to ensure that such

waste is handled without any adverse effect to human health and the environment.

5. TREATMENT AND DISPOSAL

(1) Bio-medical waste shall be treated and disposed of in accordance with Schedule I, and in compliance with the standards prescribed in Schedule V.

(2) Every occupier, where required, shall set up in accordance with the time-schedule in Schedule VI, requisite bio-medical waste treatment facilities like incinerator, autoclave, microwave system for the treatment of waste, or, ensure requisite treatment of waste at a common waste treatment facility or any other waste treatment facility.

6. SEGREGATION, PACKAGING, TRANSPORTATION AND STORAGE

(1) Bio-medical waste shall not be mixed with other wastes.

(2) Bio-medical waste shall be segregated into containers/bags at the point of generation in accordance with Schedule II prior to its storage, transportation, treatment and disposal. The containers shall be labeled according to Schedule III.

(3) If a container is transported from the premises where bio-medical waste is generated to any waste treatment facility outside the premises, the container shall, apart from the label prescribed in Schedule III, also carry information prescribed in Schedule IV.

(4) Notwithstanding anything contained in the Motor Vehicles Act, 1988, or rules thereunder, untreated biomedical waste shall be transported only in such vehicle as may be authorised for the purpose by the competent authority as specified by the government.

(5) No untreated bio-medical waste shall be kept stored beyond a period of 48 hours

Provided that if for any reason it becomes necessary to store the waste beyond such period, the authorised person must take permission of the prescribed authority and take measures to ensure that the waste does not adversely affect human health and the environment.

7. PRESCRIBED AUTHORITY

(1) The Government of every State and Union Territory shall establish a prescribed authority with such members as may be specified for granting authorisation and implementing these rules. If the prescribed authority comprises of more than one member, a chairperson for the authority shall be designated.

(2) The prescribed authority for the State or Union Territory shall be appointed within one month of the coming into force of these rules.

(3) The prescribed authority shall function under the supervision and control of the respective Government of the State or Union Territory.

(4) The prescribed authority shall on receipt of Form 1 make such enquiry as it deems fit and if it is satisfied that the applicant possesses the necessary capacity to handle bio-medical waste in accordance with these rules, grant or renew an authorisation as the case may be.

(5) An authorisation shall be granted for a period of three years, including an initial trial period of one year from the date of issue. Thereafter, an application shall be made by the occupier/operator for renewal. All such subsequent authorisation shall be for a period of three years. A provisional authorisation will be granted for the trial period, to enable the occupier/operator to demonstrate the capacity of the facility.

(6) The prescribed authority may after giving reasonable opportunity of being heard to the applicant and for reasons thereof to be recorded in writing, refuse to grant or renew authorisation.

(7) Every application for authorisation shall be disposed of by the prescribed authority within ninety days from the date of receipt of the application.

(8) The prescribed authority may cancel or suspend an authorisation, if for reasons, to be recorded in writing, the occupier/operator has failed to comply with any provision of the Act or these rules :

Provided that no authorisation shall be cancelled or suspended without giving a reasonable opportunity to the occupier/operator of being heard.

8. AUTHORISATION

(1) Every occupier of an institution generating, collecting, receiving, storing, transporting, treating, disposing and/or handling bio-medical waste in any other manner, except such occupier of clinics, dispensaries, pathological laboratories, blood banks providing treatment/service to less than 1000 (one thousand) patients per month, shall make an application in Form 1 to the prescribed authority for grant of authorisation.

(2) Every operator of a bio-medical waste facility shall make an application in Form 1 to the prescribed authority for grant of authorisation.

(3) Every application in Form 1 for grant of authorisation shall be accompanied by a fee as may be prescribed by the Government of the State or Union Territory.

9. ADVISORY COMMITTEE

The Government of every State/Union Territory shall constitute an advisory committee. The committee will include experts in the

field of medical and health, animal husbandry and veterinary sciences, environmental management, municipal administration, and any other related department or organisation including non-governmental organisations. The State Pollution Control Board/Pollution Control Committee shall be represented. As and when required, the committee shall advise the Government of the State/Union Territory and the prescribed authority about matters related to the implementation of these rules.

10. ANNUAL REPORT

Every occupier/operator shall submit an annual report to the prescribed authority in Form 11 by 31 January every year, to include information about the categories and quantities of bio-medical wastes handled during the preceding year. The prescribed authority shall send this information in a compiled form to the Central Pollution Control Board by 31 March every year.

11. MAINTENANCE OF RECORDS

(1) Every authorised person shall maintain records related to the generation, collect ' ion, reception, storage, transporation, treatment, disposal and/or any form of handling of bio-medical waste in accordance with these rules and any guidelines issued.

(2) All records shall be subject to inspection and verification by the prescribed authority at any time.

12. ACCIDENT REPORTING

When any accident occurs at any institution or facility or any other site where bio-medical waste is handled or during transportation of such waste, the authorised person shall report the accident in Form Ill to the prescribed authority forthwith.

13. APPEAL

Any person aggrieved by an order made by the prescribed authority under these rules may, within thirty days from the date

on which the order is communicated to him, prefer an appeal to such authority as the Government of State/Union Territory may think fit to constitute :

Provided that the authority may entertain the appeal after the expiry of the said period of thirty days if it is satisfied that the appellant was prevented by sufficient cause from filing the appeal in time.

SCHEDULE I

(See Rule 5)

CATEGORIES OF BIO-MEDICAL WASTE

Option	Waste Category	
Category No. I	**Human Anatomical Waste** (human tissues, organs, body parts)	
Category No. 2	**Animal Waste** (animal tissues, organs, body parts carcasses, bleeding parts, fluid, blood and experimental animals used in research, waste generated by veterinary hospitals colleges, discharge from hospitals, animal houses)	incineration@/deep burial*
Category No 3	**Microbiology & Biotechnology Waste** (wastes from laboratory cultures, stocks or specimens of micro-organisms live or attenuated vaccines, human and animal cell culture used in research and infectious agents from research and industrial laboratories, wastes from production of biologicals, toxins, dishes and devices used for transfer of cultures)	local autoclaving/micro-waving/incineration@
Category No 4	**Waste sharps** (needles, syringes, scalpels, blades, glass, etc. that may cause puncture and cuts. This includes both used and unused sharps)	disinfection (chemical treatment@01/auto claving/micro-

Category No 5	**Discarded Medicines and Cytotoxic drugs** (wastes comprising of outdated, contaminated and discarded medicines)	inc ineratio n@/destruct ion and
Category No 6	**Solid Waste** (Items contaminated with blood, and body fluids including cotton, dressings, soiled plaster casts, lines, beddings, other material contaminated with blood)	incineration@
Category No. 7	**Solid Waste** (wastes generated from disposable items other than the waste shaprs such as tubings, catheters, intravenous sets etc).	disinfection by chemical
Category No. 8	**Liquid Waste** (waste generated from laboratory and washing, cleaning, house-keeping and disinfecting activities)	disinfection by chemical
Category No. 9	**Incineration Ash** (ash from incineration of any bio-medical waste)	
Category No. 10	**Chemical Waste** (chemicals used in production of biologicals, chemicals used in disinfection, as insecticides, etc.)	chemical treatment@@ and

---

@@ Chemicals treatment using at least 1% hypochlorite solution or any other equivalent chemical reagent. It must be ensured that chemical treatment ensures disinfection.

Multilation/shredding must be such so as to prevent unauthorised reuse.

@ There will be no chemical pretreatment before incineration. Chlorinated plastics shall not be incinerated.

* Deep burial shall be an option available only in towns with population less than five lakhs and in rural areas.

A NOTE ON SALIENT PROVISIONS UNDER THE DRUGS AND COSMETICS ACT, 1940 TO CHECK THE PRODUCTIONS AND EXPORT OF SPURIOUS AND SUBSTANDARD MEDICINE AND MEDICAL DEVICES.

The manufacture and sale of drugs is a licensed activity under the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945. The licensees are required to comply with the provisions of the Act, Rules and the condition of the licence granted to them by the licensing authorities for manufacture and sale of drugs.

The Drugs and Cosmetics Act, 1940 have elaborate provisions to check the production of spurious and substandard drugs in the country. The Act provides elaborate definitions of the terms spurious, adulterated and misbranded drugs for the purpose of taking penal actions against the offenders. The terms have been defined as under.

'**Spurious drugs -** For the purposes of this Chapter, a drug shall be deemed to be spurious,-

(a) if it is manufactured under a name which belongs to another drug; or

(b) if it is an imitation of, or is a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon its label or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug; or

(c) if the label or container bears the name of an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious or does not exist; or

(d) if it has been substituted wholly or in part by another drug or substance; or

(e) if it purpose to be the product of a manufacturer of whom it is not truly a product.'

'**Adulterated drugs -** For the purposes of this Chapter, a drug shall be deemed to be adulterated,-

(a) if it consists in whole or in part, of any filthy, putrid or decomposed substance; or

(b) if it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health; or

(c) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(d) if it bears or contains, for purposes of colouring only, a colour other than one which is prescribed; or

(e) if it contains any harmful or toxic substance which may render it injurious to health; or

(f) if any substance has been mixed therewith so as to reduce its quality or strength.'

'Misbranded drugs - For the purposes of this Chapter, a drug shall be deemed to be misbranded,-

(a) if it is so coloured, coated, powdered or polished that damage is concealed or if it is made to appear of better or greater therapeutic value than it really is; or

(b) if it is not labelled in the prescribed manner; or

(c) if its label or container or anything accompanying the drug bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular.'

Drugs and Cosmetics (Amendment) Act, 2008

The Drugs and Cosmetics Act, 1940, has been recently amended under the Drugs and Cosmetics (Amendment) Act, 2008 providing very strict penalties for manufacture of spurious and adulterated drugs.

It is provided that any drug deemed to be adulterated or spurious when used by any person for or in the diagnosis, treatment, mitigation, or prevention of any disease or disorder is likely to cause his death or is likely to cause such harm on his body as would amount to grievous shall be punishable with imprisonment for a term which shall not be less than ten years but which may extend to imprisonment for life and shall also be liable to fine which shall not be less than ten lakh rupees or three times value of the drugs confiscated, whichever is more. The fines realized in such cases will be paid to the relative of the deceased or the aggrieved person.

Any drug deemed to be spurious but not being a drug referred to above shall be punishable with imprisonment of a term which shall not be less than 7 years but which may extend to imprisonment for life and with fine which shall not be less than 3 lakh rupees or three times the value of the drugs confiscated, which ever is more.

Offences relating to sale and manufacture of spurious and adulterated drugs have now been made cognizable and non bailable.

It has been provided that besides an Inspector appointed under the Act, the person aggrieved or consumer associations, a gazetted officer authorised by the Government have also been authorised to launched prosecution under the Act.

A provision has been made for especially designated courts for trial of offences under the act.

A provision for compounding of minor offences has also been introduced.

Regulatory control over the manufacture and sale of drugs

Regulatory control over the manufacture and sale of drugs is exercised by the State Licensing Authorities appointed by the State Governments which are responsible for monitoring the quality

of drugs moving in the market. As a part of their function, the Inspectors appointed by the State carry out market surveillance by drawing samples from the sales establishments, hospitals and manufacturers and get them tested at governments' laboratories. Wherever a drug is declared as spurious or adulterated or not of standard quality, prosecutions are launched against offenders in the court of law by the concerned regulatory authorities depending upon the merits of the case. Being an undercover activity, it is difficult to detect the manufacture or movement of spurious drugs except by continuous surveillance by the State Drug Control Organization and active cooperation from the law and order Enforcement machinery in the State and other stakeholders like drug manufacturers associations and voluntary associations.

A Drug Inspector appointed by the respective Governments is required to inspect not less than once a year all establishment licensed for manufacture or sale within the area assigned to him and to satisfy himself that the conditions of license are being observed. He may draw samples of a drugs or cosmetics from the manufacturing or sale premises, where he has reason to doubt the quality of drug, in a prescribed manner and send them for test and analysis to the Government analyst to check the quality.

The manufacturer is also required to allow an inspector to inspect all registers and records maintained by him and to take samples of manufactured products, if required, and provides such information as required for the purpose of ascertaining whether the provisions of the Act and Rules thereunder have been observed. The inspection may be conducted by one or more inspectors to examine the premises, plant, appliances and process of manufacture, professional qualifications of technical staff and capability of the manufacturer to comply with the requirements of Good Manufacturing Practices and requirements of plant and equipment before a license is granted.

Quality controls at manufacturers level

The manufacturer is required to ensure that the drugs manufactured and marketed by him are of standard quality and tested before release. The provisions of the Drugs and Cosmetics Rules provides for in process controls over the quality of drugs manufactured by the licensed manufacturers.

Schedule M to the Drugs and Cosmetics Rules provides requirements for Good Manufacturing Practices and requirements of plant and equipment for manufacture of drugs. It specify in detail the requirements of premises, surroundings, personnel, sanitation, storage of raw materials, documentation and records, self inspections and quality control systems and site master files etc. The manufacturer is required to comply with the requirements of Schedule M under the conditions of the license.

The manufacturer is required to provide and maintain adequate staff, premises, plant and machinery for manufacture of drugs under the conditions of license for manufacture of drugs. He is also required to maintain records of manufacture including the testing of raw material and finished products. Each batch of the product is required to be tested by the manufacturer either in his own laboratory or any laboratory approved by the Licensing Authority before releasing the product into market.

Media reports about spurious drugs

The prevalence of spurious drugs is a public health concern and an emotive issue. Unverified and unsupported figures are being reported in the media regarding large-scale production and trading of spurious drugs in India. The media had been projecting problem of spurious drugs in the country in a manner which does not provide a balanced perspectives and has, therefore,

caused serious apprehensions. The figures quoted by media range from 10% to 25% of drugs in the country being spurious drugs. These are totally unsubstantiated reports. For example, on the basis of an alleged WHO report, the media frequently reports that 35% of fake drugs produced in the world come from India. However, when enquired, the WHO has categorically denied its authenticity. Further 80% of total production of drugs in the country is by the large and medium units in the organized sector which strictly follow GMPs, in process controls etc. The figures quoted by the media therefore, looked more on the basis of hearsay. Similarly certain figures were published by ASSOCHEM about spurious drug in the year 2009. On enquiry it was revealed that the report was based on the fall in sale of specific drugs and not on the basis of any survey conducted on the availability of spurious drugs.

Extent of Spurious Drugs

It has been observed from the reports of the drug samples tested all over the country in last three years as received from State Drug Controllers, that about 0.3% to 0.4% of around 40,000 samples per annum fall within the category of spurious drugs.

Country wide survey on Spurious Drugs

A survey to assess the extent of spurious drugs in the country was conducted in the year 2009 by the Ministry of Health, through CDSCO. Statistical principles were provided by Indian Statistical Institute (ISI), Hyderabad. Under this survey 24,136 samples of 61 brands of drugs belonging to 9 therapeutic categories of 29 manufacturers from over 100 different Pharmacy outlets in different regions of the country and located in each stratum viz. metros, big cities, district, towns and villages were collected. The survey has revealed that the extent of drugs found spurious was 0.045% only.

Initiative taken by the Government to Enforce Drugs And Cosmetics Act More Effectively

i. Whistle blower scheme

Whistle Blower Scheme has been announced by Government of India to encourage vigilant public participation in the detection of movement of spurious drugs in the country. Under this policy the informers would be suitably rewarded for providing concrete information in respect of movement of spurious drugs to the regulatory authorities.

ii. Guidelines for taking action on test reports in the light of enhanced penalties

In the 40th meeting of Drugs Consultative Committee (DCC) consisting of the DCGI and all State Drug Controllers held on 29.6.2009, guidelines for taking action on samples of drugs declared spurious or not of standard quality in the light of enhanced penalties under the Drugs & Cosmetics (Amendment) Act, 2008 were adopted for the purpose of uniform implementation of the Drugs and Cosmetic Act in the country. The guidelines with approval of the Ministry of Health were forwarded to the State Drugs Controllers for information and compliance. The guidelines have also been placed on the web site of CDSCO (www.cdsco.nic.in).

iii. Strengthening of drug testing laboratories

Under a Capacity Building Project through World Bank, assistance was provided to upgrade testing facilities and to establish new drug testing laboratories in the country so as to enhance the capacity of the laboratories to test large number of samples. Under this project 23 States and 6 Central Drug laboratories have been strengthened through renovations, extensions and equipments.

It is expected to increase the number of samples tested in the country from about 36,000 samples to 1,00,000 samples per year and to reduce the reporting time to less than a month as against the present period from 3 to 6 months.

iv. Good manufacturing practices

Schedule M to the Drugs and Cosmetics Rules, 1945, pertaining to Good Manufacturing+ Practices was amended to make it at par with the international standards and it is mandatory for the manufacturers of drugs to comply with the requirements of this Schedule for quality control of the drugs manufactured by them.

v. **Other Measures**

a. To take care of the quality of import/export consignments of drugs which are presently kept along with food stuff, meat and other general cargo, it has been decided to set up exclusive pharmaceutical zones with dedicated area for storage of drugs meant for export/import at Delhi, Hyderabad and Mumbai Airport.' CDSCO is involved in negotiation/consultation with the port authorities in the matter.

b. To take care of increased traffic of import and export of drugs, two SubZonal offices at Hyderabad and Ahmadabad airport have been converted into Zonal offices. A new Sub-Zonal office at Bangalore airport has also been set up to cope up the situation of increased traffic of import and export of drugs in that region. It has also been decided to set up a sub zonal office at Chandigarh as northern India has become a major Pharma hub due to setting up of large no. of drug manufacturing units in the excise free zones.

c. Detailed guidelines have been issued to the State Govts. to undertake focused surveillance over possible movement of spurious drugs.

d. Training programme for regulatory officials of State Govts. on logistics of intelligence, surveillance, prosecutions, etc. has been conducted with the assistance of FDA, Maharashtra.

e. Pharma industry and traders has been motivated to fight menace of spurious drugs as a

shared responsibility. No. Of cases could be successfully detected through the initiative taken by Pharma industry involving hiring of retired intelligence officers.

Medical Devices

Only a limited number of notified medical devices (14 in number) are being regulated under the said Act at present. These devices are regulated under the provisions applicable for drugs. The proposal to regulate quality of medical devices in general is under consideration of the Government of India.