

**GOVERNMENT OF THE PEOPLE'S REPUBLIC OF BANGLADESH  
MINISTRY OF AGRICULTURE**

**Section II  
NOTIFICATION**

**Dhaka, the 16<sup>th</sup> November 1985**

**No. S.R.O. 479-L/85.**—In exercise of the powers conferred to it under section 29 of the Pesticides Ordinance, 1971 (II of 1971), the Government is, in consultation with the Pesticide Technical Advisory Committee, pleased to make the following rules, the same having been previously published as required by sub-section (1) of the said section 29, namely:—

**THE PESTICIDE RULES, 1985**

**CHAPTER I**

**PRELIMINARY**

1. **Short title.**—These rules may be called The Pesticide Rules, 1985.
2. **Definition.**—In these rules, unless there is anything repugnant in the subject or context,—
  - (a) “Advisory Committee” means the Pesticide Technical Advisory Committee constituted under section 12;
  - (b) “Antidote” means a substance intended to counteract the poisonous effects of pesticides;
  - (c) “Director” means the administrative head of the pesticide laboratory by whatever name called and includes any other officer as the Director may authorise in writing for the purposes of these rules;
  - (d) “Form” means a form appended to these rules;
  - (e) “Laboratory” means the pesticide laboratory set up under section 13;
  - (f) “Licensing authority” means the Director, Plant Protection Wing of the Department of Agricultural Extension and includes any person authorized by him in writing;
  - (g) “Ordinance” means the Pesticides Ordinance, 1971 (II of 1971);
  - (h) “Pest control operation” means operation to control pest in crops, hotels, ware-houses, godowns and in such other places;
  - (i) “Registration authority” means the Director of Plant Protection Wing of the Department of Agricultural Extension and includes any person authorized by him in writing;
  - (j) “Repacking” means repacking of pesticides from a bulk container into small container;

- (k) “Schedule” means a Schedule appended to these rules; and
- (l) “Section” means a section of the Ordinance.

## CHAPTER II

### REGISTRATION OF PESTICIDES

3. **Application for registration of pesticides.**—An application in triplicate for registration of a brand of pesticide under sub-section (1) of section 5 shall be made to the Registration Authority in Form 1.

4. **Registration of pesticide.**—(1) On receipt of an application for registration of a brand of pesticide, the Registration Authority shall send the application together with a sample of pesticide to the laboratory for test or analysis and to ascertain whether the sample is in accordance with the information provided along with the application.

(2) On receipt of the result of the test or analysis under sub-rule (1), the Registration Authority shall forward the same to the Advisory Committee to conduct, in direct association with the applicant for the registration of pesticide, such biological test and trial under field condition as may be required.

(3) On receipt of a report from the Advisory Committee under sub-rule (2), the Registration Authority, if he is of the opinion that the brand of pesticide conforms to the requirements of the Ordinance and these rules, give registration to the brand of pesticide in Form 2 on such conditions as may be specified in the certificate and assign to the certificate a registration number.

(4) A certificate of registration granted under sub-rule (3) shall apply only to the pesticide described in the application to which the certificate relates.

(5) Pesticides registered, as aforesaid, shall be published by the Registration Authority in the official Gazette within thirty days from the date of granting registration certificate.

5. **Rejection of application for registration.**—(1) If it appears to the Registration Authority that the result of the test or analysis under provisions of these rules do not corroborate with the information supplied by the applicant or the labels and containers intended to be used do not conform to the requirements in this behalf, he may reject the application for registration and shall inform the applicant of the reasons for the rejection and supply him full particulars of the tests.

(2) The rejection of an application for registration of an application for registration of a pesticide shall, however, not debar the applicant from making a fresh application for registration.

6. **Renewal of registration certificate.**—(1) An application in duplicate for renewal of registration shall be made in Form 3 to the Registration Authority before expiry of the date of its effectiveness.

(2) A certificate of renewal of registration shall be issued in Form 4.

7. **Fees.**—(1) A fee of two thousand taka shall be paid with each application for a certificate or renewal of a certificate of registration which shall, in no case, be refunded to the applicant.

(2) A fee of taka one hundred shall be paid for a duplicate copy of the registration certificate if the original one is defaced, destroyed or lost.

8. **Cancellation of the certificate of registration.**—Cancellation of the certificate of registration of a brand of pesticide shall be published in any leading daily newspaper and in the journal of the Agriculture Information Service.

9. **Discontinuation of manufacture or formulation etc.**—If the manufacture, formulation or repacking of a pesticide is discontinued, the manufacturer, formulator, repacker or his agent shall within three months from the date of such discontinuation, give notice of such discontinuation to the Registration Authority.

### CHAPTER III

10. **Conditions to be fulfilled after registration of pesticide for manufacture and formulation, etc.**—A person who intends to manufacture and formulate pesticides registered under these rules shall—

- (a) provide and maintain adequately qualified staff and suitable premises and plant for the proper manufacture, formulation, repacking or storage of pesticide in respect of which the certificate of registration has been granted;
- (b) maintain a laboratory for carrying out quality control tests of the pesticide;
- (c) keep records of the details of manufacture and formulation of each batch of the pesticide which is issued for sale or distribution;
- (d) allow any person authorized by the Government in this behalf to enter into any premises where the manufacture, formulation or packing of pesticide is being carried on;
- (e) allow to inspect the premises and the means employed for testing of pesticides;
- (f) from time to time, report to the Government any change in the expert staff responsible for manufacture, formulation or repacking of pesticides;
- (g) observe the conditions for the storage of pesticides as laid down in these rules;
- (h) provide such protective clothing, as may be required, to the workers and take all necessary precautions for their health as may be specified by these rules or by the Registration Authority; and
- (i) arrange medical check up of the workers as often as required or at least twice a year, and provide medical treatment free of cost.

## CHAPTER IV

11. **Import of pesticides.**—(1) No pesticide shall be imported into Bangladesh unless—

- (a) it has been registered and it complies strictly with the application for registration;
- (b) it is packed and labeled in conformity with these rules;
- (c) the importer has proper facilities for its storage.

(2) No pesticide shall be imported through a route other than the recognised custom frontier stations of Bangladesh.

(3) These rules shall not apply in case of pesticides imported for experimental or research purposes in reasonable quantity.

## CHAPTER V

### LICENCES

12. **Licence for manufacture/formulation, stock, repacking, sale, etc., of pesticides.**—(1) Application for grant of licence of pesticides for the purposes specified below shall be made to the licensing authority in the Form specified against each purpose:—

- |     |  |     |     |     |     |     |     |     |         |
|-----|--|-----|-----|-----|-----|-----|-----|-----|---------|
| (a) | import                                     | ... | ... | ... | ... | ... | ... | ... | Form 5  |
| (b) | manufacture or formulation                 |     |     |     |     |     |     |     | Form 6  |
| (c) | holding in stock for wholesale             |     |     |     |     |     |     |     | Form 7  |
| (d) | retail sale                                | ... | ... | ... | ... | ... | ... | ... | Form 8  |
| (e) | re-packing                                 | ... | ... | ... | ... | ... | ... | ... | Form 9  |
| (f) | pest control operation on commercial basis |     |     |     |     |     |     |     | Form 10 |
| (g) | advertisement                              | ... | ... | ... | ... | ... | ... | ... | Form 11 |

(2) Licences for the purposes mentioned in sub-rule (1) shall be made by the licensing authority in Form 12, Form 13, Form 14, Form 15, Form 16, Form 17, Form 18 respectively.

(3) An application for grant of licence and renewal thereof under this rule shall be accompanied by a fee specified below :

		Licence fee Taka	Renewal fee Taka
(a)	import	One hundred	One hundred
(b)	manufacture or formulation	Three Thousand	Five hundred
(c)	holding in stock for wholesale	Three hundred	One hundred
(d)	retail sale	Seventy-five	Twenty-five
(e)	repacking	Two hundred	Two hundred
(f)	pest control operation on commercial basis	Five hundred	Two hundred
(g)	advertisement	Two hundred	One hundred

(4) Licences issued under this rule shall be subject to the conditions specified on the face of the licence.

(5) If any pesticide is proposed to be manufactured, stocked, sold, formulated, repacked or operated on commercial basis at more than one place, separate application shall be made for each such place and separate licence shall be issued in respect of every such place.

13. **Refusal to grant licence.**—The licensing authority may, after giving reasonable opportunity of being heard to the applicant for a licence, refuse to grant or renew any licence under this chapter and on such refusal the fee paid shall be refunded to the applicant.

14. **Duplicate licence.**—A fee of Tk. 25 (twenty-five) shall be paid for duplicate copy of a licence issued under this chapter if the original one is defaced, damaged or lost.

15. **Duration of licences.**—(1) Any licence issued or renewed under this chapter shall, unless sooner suspended or cancelled, be in force for a period of two years from the date of issue or from the date of renewal, as the case may be.

(2) An application for the renewal of a licence shall be made before its expiry and if such application is made within 30 days of such expiry, a penalty of taka fifty shall accompany the application along with usual renewal fee.

(3) The licence shall continue to be in force until it is renewed accordance with these rules, suspended or revoked or, where an appeal preferred until the appeal is disposed of.

16. **Appeal.**—(1) An appeal against the decision for refusal to grant renew a licence or against/suspension or cancellation of a licence shall preferred to the Secretary, Ministry of Agriculture within sixty days from the decision or order.

(2) The appeal shall be in writing and shall set out concisely and under distinct heads of the grounds on which appeal is preferred.

(3) A fee of taka twenty shall be deposited under the Head of Account “৪৫-কৃষিপ্রাপ্তি-অনিষ্টকারী পোকা-মাকড়, রোগ-বালাই ব্যবস্থাপনা ও বিবিধ খাতে আয়” and treasury chalan showing the deposit shall accompany the application for appeal.

17. **Conditions of Licence.**—(1) Subject to such conditions as are contained in the licence, a licence shall not be granted to any person under this chapter unless the licensing authority is satisfied that the premises in respect of which a licence is to be granted are adequate and equipped with proper storage accommodation for avoiding any hazard and for preserving the property pesticides in respect of which licence is granted.

(2) In granting a licence, the licensing authority shall have regard, among other things, to—

- (a) the number of licences granted in the locality during any year; and
- (b) the occupation, trade or business carried on by the applicant.

18. **Amending a licence.**—The licensing authority may, either on an application made by the licensee or if he is satisfied that the conditions under which a licensee has been granted under this chapter have been changed that it is so necessary to do, amend a licence after giving an opportunity of being heard to the person holding the licence.

19. **Transfer of licence.**—(1) The holder of a licence may, at any time before expiry of the licence apply for permission to transfer the licence to any other person.

(2) The application under sub-rule (1) shall be accompanied by a fee which shall be the half of the original licence fee.

(3) The licensing authority may, after such inquiry as he thinks fit, accord permission to transfer the licence and on such permission being given, an endorsement to that effect shall be made in the licence.

20. **Procedure on disability of licensee.**—(1) If any person in whose name a licence has been issued under this chapter dies or is incapable of carrying on the business for which licence is given, his legal representative interested in carrying on the business may apply in accordance with the provisions of these rules to the licensing authority for transfer of the licence in his name.

(2) If an application is made under sub-rule (1) for the transfer of licence, it shall be lawful for the applicant to carry on the business of the licence until it is refused by the licensing authority.

## CHAPTER VI

### ADVISORY COMMITTEE AND PESTICIDE LABORATORY

21. **Functions of the Advisory Committee.**—In addition to the functions assigned to it by the Ordinance, the Advisory Committee shall advise the Government on—

- (a) general policy relating to pesticides and pest management;
- (b) the indigenous manufacture and formulation of pesticides;
- (c) the large scale use of pesticides;
- (d) the classification of pesticides on the basis of their toxicity as well as their being suitable for aerial application;
- (e) such other matters as the Government may refer to it from time to time.

22. **Functions of the Laboratory.**—The functions of the laboratory shall be as follows—

- (a) to analyse such samples of pesticides as sent to it by any officer or authority authorized by the Government and submit certificate of analysis to the concerned authority;
- (b) to carry out such investigations as may be necessary for the purpose of ensuring the conditions of registration of pesticides;
- (c) to analyse samples of materials for residue analysis;
- (d) to determine the efficacy and toxicity of pesticides;
- (e) to carry out such other functions as may be entrusted to it by the Government after consultation with the Committee.

**23. Despatch of samples for test or analysis to the Laboratory.**—(1) Samples of pesticides shall be sent to the Laboratory by registered post or by special messenger in sealed packet together with a memorandum in Form 19 in an outer cover addressed to the Director.

(2) The sealed packet as well as the outer cover referred to in sub-rule (1), shall have distinguished mark or number.

(3) A copy of the memorandum and a specimen impression of the seal used to seal the packet shall be sent separately by registered post or by special messenger to the Director.

(4) On receipt of the packet, it shall be opened by the Director.

**24. Report of result of test or analysis.**—(1) After test or analysis, the report of the result of test or analysis together with full particulars of the test applied, shall be supplied to the sender in Form 20 within four weeks from the date of receipt of the samples.

(2) The report of the test or analysis shall be signed by the Director.

**25. Access to information.**—No person, other than officer of the laboratory authorized in writing by the Director, shall have access to the information deposited in the laboratory.

**26. Destruction of information.**—The formula deposited in the laboratory shall be destroyed by the Director if the application for registration is rejected or if the certificate of registration is cancelled.

**27. Disclosure of information.**—No person on the staff of the laboratory shall disclose to any person any information in relation to the composition the particular pesticide acquired in the course of his duties in the laboratory. Provided that the Director may with the previous approval of the Government, disclose any information so acquired to the extent necessary for the purpose of prosecution under the Ordinance.

**28. Method to be followed by Laboratory.**—The pesticide laboratory shall follow the following methods, in the order as they are given, for the formulation and residue analysis of pesticides, namely:—

- (a) methods of Association of Official Agricultural Chemists (AOAC) of United States of America;
- (b) methods of Collaborative International Pesticides Analytical Council (CIPAC);
- (c) methods of formulation panel of the Pesticide Analytical Committee (PAC) of the Ministry of Agriculture, Fisheries and Food, Government of the United Kingdom;

- (d) methods of WHO specification of pesticides;
- (e) methods published in the periodicals from time to time;
- (f) methods of Federal Drugs Administration (FDA) of the U.S.A.; and
- (g) methods given by the firm.

29. **Limit of variability to be allowed.**—The pesticide laboratory shall follow the limit of variability to be allowed in the analytical results, that is tolerance in the contents of active ingredients in pesticide consignments in the light of Appendix V to the “Manual on the use of FAO Specifications for Plant Protection Product.”

## **CHAPTER VII**

### **PACKAGING AND LABELLING**

30. **Prohibition of sale or distribution unless packed and labelled.**—No person shall stock or exhibit for sale or distribute any pesticide unless it is packed and labelled in accordance with the provisions of this Chapter.

31. **Packing of pesticides.**—Every package containing pesticides shall be of a type approved by the Director and a sample container in which the pesticide is proposed to be packed shall be supplied to the Director separately.

32. **Leaflet to be contained in a package.**—The manufacturer, formulator or distributor shall provide wholesale and retail dealers with leaflet of every pesticide which shall be affixed or attached to the package or repacking containing the following details, namely:—

- (a) the plant pests for which the pesticide is to be applied, the adequate direction including the manner in which the pesticide is to be used at the time of application;
- (b) particulars regarding chemicals harmful to human beings, animals and wild life;
- (c) warning and cautionary statements including the symptoms of poisoning, suitable and adequate safety measure and emergency first aid treatment, where necessary;
- (d) caution regarding storage;
- (e) instructions concerning the decontamination or safe disposal of used containers;
- (f) statement showing the antidote for the poison shall be included in the leaflet and the label;
- (g) if the pesticide is irritating to the skin, nose, throat or eyes, a statement shall be included to that effect.

33. **Manner of labeling.**—(1) The following particulars shall be either printed or written in indelible ink on the label of the innermost container of any pesticide and on the outermost covering in which the container is packed or repacked—

- (a) name of the manufacturer, formulator or repacker (if the manufacturer, formulator or repacker is not the person in whose name the pesticide is registered, the relationship between the person in whose name the pesticide has been registered and the person who manufactures, formulates or packs or repacks, distributes or sells shall be stated);
- (b) name of the pesticide (brand name or trade mark under which the pesticide is sold);
- (c) registration number of the pesticide;
- (d) net content of volume (the net content shall exclusive of wrapper or other materials);
- (e) batch number or lot number;
- (f) expiry date, i.e. up to the date the pesticide will retain its efficacy and safety;
- (g) Antidote statement.

(2) The label shall so affixed to the container that it cannot be ordinarily removed.

(3) The label shall contain in a prominent place and occupying not less than the one-sixteenth of the total area of the face of the label, and square set at an angle of 45° (diamond shape). The dimension of the said square shall depend on the size of the package on which the label is to be fixed. The said square shall be divided by horizontal lines into two equal parts. The upper part shall contain the symbol and signal word specified in sub-rule (4) and the lower part shall contain the colour specified in the sub-rule (5).

(4) The upper part of the square referred to in sub-rule (3) shall contain the following symbol and warning statement, namely :—

- (i) pesticide belonging to category I (highly toxic) contain a symbol of a skull and cross bones and the word “POISON” printed in red;
- (ii) the words “KEEP OUT OF THE REACH OF CHILDREN” shall appear on the label at suitable place outside the square;
- (iii) pesticides in category II (moderately toxic) shall bear the word “Poison” “DANGER” and the statement “KEEP OUT OF THE REACH OF CHILDREN” shall appear on the label at suitable place outside the square;
- (iv) pesticides in category III (slightly toxic) shall bear the word “Poison” “CAUTION” and the statement “KEEP OUT OF THE REACH OF CHILDREN” shall appear on the label at suitable place outside the square.

(5) The lower part of the square referred to in sub-rule (3) shall contain the colour specified in column 5. of the Table below depending on the classification of the pesticide specified in the corresponding entry in column (1):

**TABLE**

Classification of the pesticide	Median Lethal dose by the oral rout (acute toxicity) LD 50 mg/kg of body weight of the test animal.	Median Lethal dose dermal rout (dermal toxicity) LD 50 mg/kg of body weight of the test animal.	Median Lethal dose by inhalation (inhalation toxicity) LD 50 mg/kg litre of air.	Colour of identification band on the label.
1	2	3	4	5
1. Highly toxic	51-500	201-2000	0.2-2	Bright red
2. Moderately toxic	501-5000	2001-20000	2-20	Bright yellow
3. Slightly toxic	More than 5000	More than 20000	More than 20	Bright green

(6) The label, leaflets affixed or attached to the package or repacking containing pesticides shall be printed in Bengali.

(7) Labelling of pesticides must not bear any unwarranted claims for the safety, efficacy of the pesticide or its ingredients like “safe”, “non-injurious”, “non- poisonous”, etc.

34. **Prohibition against alteration in label.**—No person shall alter, obliterate or deface any inscription or mark made or wrapper of any pesticide: Provided that nothing in this rule shall apply to any alterations or mark made on the containers, label or wrapper of any pesticide at the instance direction or permission of the Director.

## CHAPTER VIII

### GOVERNMENT ANALYST AND INSPECTOR

35. **Qualification of Government Analyst.**—A person shall be eligible for appointment as a Government Analyst under the Ordinance only if he possesses the following qualifications, namely :—

- (a) Master degree in Agricultural Chemistry or Chemistry from a recognized University; and
- (b) At least five years' experience in pesticide formulation analysis in a reputed laboratory.

36. **Powers of Government Analyst.**—The Government Analyst shall have the power to call for such information or particulars or do anything as may be necessary for the proper examination of the samples sent to him.

37. **Duties of Government Analyst.**—(1) The Government Analyst shall analyse or cause to be analysed or test or cause to be tested such samples of pesticides as may be sent to him by the Inspector under the provisions of Ordinance and shall furnish reports or results of such tests or analysis.

(2) The Government Analyst shall, from time to time, forward to the Government reports giving the result of analytical work and investigation with a view to their publication at the discretion of the Government.

**38. Procedure on receipt of sample.**—(1) On receipt of a package from a Inspector containing a sample for test or analysis, the Government Analyst shall compare the seal on the packet with the specimen impression received separately and shall note the condition of the seals on the packet.

(2) In making the test or analysis of pesticide, the Government Analyst shall follow the method of examination of sample adopted or approved by the Standard Institution of the country. The sample should be analysed in such a way as to determine the pesticide-properties and whether the ingredients as stated on the label are present and whether the pesticides contain any adulterations. If necessary, laboratory or field tests shall be made to determine the effectiveness, laboratory or field tests shall be made to determine the effectiveness of the pesticides as contained in the label.

(3) After the test or analysis has been carried out under sub-rule (2), the Government Analyst shall forthwith supply to the Inspector a report in triplicate in Form 21 of the result of test or analysis.

**39. Report of results of test or analysis.**—An application from a purchaser for test or analysis of pesticide under section 20 shall be made in triplicate in Form 22 and the report of the test or analysis of the pesticide made shall be supplied to the applicant in Form 23.

**40. Fees payable for testing or analysis.**—(1) The fees payable for testing or analysing pesticides shall be those as specified in the Schedule 1.

(2) No fee shall be charged for routine test or rechecking of samples carried out at the instance of Inspector.

(3) Fee realized under this rule shall be deposited with the Director of Plant Protection under the Head of Account. “৪৫-কৃষি-প্রাণ্ডি-অনিষ্টকারী পোকা-মাকড়, রোগ-বালাই ব্যবস্থাপনা ও বিবিধ খাতে আয়।”

**41. Duties of Inspector.**—Subject to the provisions of section 16, an Inspector may, within the local limits of the area for which he is appointed,—

- (a) inspect any premises wherein any pesticides is being manufactured or formulated, repacked, the means employed for quality control and testing of pesticides and all record and registers relation thereto;
- (b) inspect any premises wherein any pesticide is being sold or stocked or exhibited for sale or wherefrom any pesticide is being distributed;
- (c) take samples of any pesticide which is being manufactured or formulated or being sold or stocked or exhibited for sale or is being distributed and forward them for test or analysis in accordance with these rules provided that a sample shall not exceed two pounds (one kilogram) in quantity;
- (d) enter and search, at all reasonable times, with such assistance, if any, as he considers necessary, any building, vessel or place in which he has reason to believe from personal knowledge or from information given by any person and taken down in writing that an offence under the ordinance or these rules has been or is being committed;

(e) seize such pesticide and all materials used in the manufacture thereof and all other articles including registers, cash memos, invoices, bills which he has reason to believe may furnish evidence of the commission of an offence punishable under the Ordinance or these rules.

42. **Prohibition of disclosure of information.**—Except for the purpose of official business or when required by a court of law, an Inspector shall not disclose to any person any information acquired by him in the performance of his official duties.

43. **Order of Inspector not to dispose of stock.**—An order by the Inspector requiring a person not to dispose of any stock in his possession shall be in Form 24.

44. **Seized pesticide.**—A report by an Inspector for the stock of any pesticide seized shall be in Form 25.

45. **Intimation for purpose of taking samples.**—Where an Inspector takes a sample of a pesticide for the purpose of test or analysis; he shall issue a receipt thereof in Form 26.

46. **Procedure for despatch of sample of pesticide to Government Analyst.**—(1) The portion of the sample of the container to be sent by Inspector to the Government Analyst for test or analysis under the Ordinance shall be sent by registered post or by hand in a sealed packed with a memorandum in Form 27 in an outer cover.

(2) A copy of the memorandum and specimen impression of the seal used to seal the packet shall be sent to the Government Analyst separately by registered post or by hand.

## CHAPTER IX

### TRANSPORT AND STORAGE OF PESTICIDE BY RAIL ROAD OR WATER

47. **Manner or packing and storage while in transit by rail.**—(1) Packages containing pesticides, offered for transport by rail, shall be packed in accordance with the conditions specified by the Railway Authority in Red Tariff.

(2) No pesticide shall be transported or stored in such a way as to come in direct contact with foodstuff or animal feeds.

(3) No foodstuff or animal feeds which got mixed up with pesticides as a result of damages to the package containing pesticides during transport or storage shall be released to the consignee unless it has been examined for possible contamination by competent authority as may be notified by the Government.

(4) If any pesticide is found to have leaked out in transport or storage, it shall be the responsibility of the transport agency or the storage owner to take such measures urgently to prevent Poisoning and pollution of soil or water, if any.

48. **Conditions for storage of pesticides.**—(1) The packages containing pesticides shall be stored in separate rooms or premises away from the rooms or premises used for storing other articles or shall be kept in separate room under lock and key depending upon the quantity and nature of the pesticides.

(2) The rooms or premises meant for storing pesticides shall be well built, dry, well lit and ventilated and of sufficient dimension.

**CHAPTER X**  
**PROVISIONS REGARDING FACILITIES DURING MANUFACTURE, ETC. OF**  
**PESTICIDES**

49. **Medical Examination.**—(1) The persons who will be engaged in the work of handling pesticides during its manufacture, formulation, repacking, transport, distribution or application, shall be medically examined before their employment and shall also be examined periodically while in service by a competent physician who is aware of the risks to which such persons will be exposed.

(2) Any person showing symptoms of poisoning shall be immediately examined and given proper treatment.

50. **First aid measures.**—In all cases of poisoning, first aid treatment shall be given before the physician is called. The guide for handling cases of pesticide poisoning shall be consulted for such first aid treatment in addition to any other books on the subject.

51. **Protective clothing.**—(1) Persons handling pesticide during its manufacture, formulation, repacking, transport, distribution or application shall be adequately protected with appropriate clothing and appliances.

(2) The protective clothing shall be used, whenever necessary, in conjunction with respiratory devices as laid down in these rules.

(3) The protective clothing's shall be made of materials which prevent or resist the penetration of any form of pesticide formulations. The materials shall also be washable so that the toxic elements may be removed after each use.

(4) A complete suit of protective clothing shall consist of the following dresses, namely:

- (a) protective outer garments, overalls, hood and hat;
- (b) rubber gloves or such other protective gloves extending half way up to the fore-arm, made of materials impervious to liquids;
- (c) dust-proof goggles; and
- (d) boots.

52. **Respiratory Devices.**—For preventing of toxic dusts, vapours or gases the workers shall use any of the following types of respirators or gas-mask suitable for the purpose, namely :—

- (a) chemical-cartridge respirator;
- (b) supplied-air respirator;
- (c) demand flow type respirator; or
- (d) full face or half face gas mask with canister.

In no case shall the concentrates of pesticides in the air where the pesticides are mixed exceed the maximum permissible values.

**53. The manufacturer, etc., to keep sufficient quantities of antidotes and first aid medicines.**—The manufacturers and distributors of pesticides and persons who undertake to spray pesticides on commercial basis (hereafter in these rules referred to as “pest control operation”) shall keep sufficient stocks of such first aid tools, equipments, antidotes, injections and medicines, as may be required to prevent poisoning cases arising from inhalation, skin contamination, eye contamination and swallowing.

**54. Training of workers.**—The manufacturers, formulators, repackers and distributors of pesticides and operators shall arrange for suitable training of the workers in observing safety precautions and handling safety equipment provided to them.

**55. Age of workers.**—The manufacturers, formulators, repackers or distributors of pesticide shall not employ a worker of below 18 and over 60 years of age for working with pesticides.

**56. Disposal of used packages, condemned and surplus materials, etc.**—(1) It shall be the duty of manufacturers, formulators, repackers of pesticides and operators to dispose of packages, condemned or surplus materials and washing in a safe manner so as to prevent air, soil, water or other environmental pollution.

(2) The used package shall not be left outside to prevent their re-use.

(3) The packages shall be broken, burnt, incinerated and buried away from habitation and water ways.

## CHAPTER XI

### SAFETY PRECAUTIONS

**57. Standard precautions.**—The following precautions shall be observed while working with any kind of pesticide, namely:—

- (a) read the “label” carefully, especially the safety precautions before handling any pesticides;
- (b) do not eat, drink or smoke;
- (c) when opening the container or while transferring, overalls, respirators goggles as the case may be;
- (d) wash hands and exposed skin before drinking or smoking;
- (e) avoid breathing pesticides;
- (f) avoid contaminating clothing;
- (g) avoid spilling and splashing;
- (h) wash and flush off pesticides from skins and eyes immediately;
- (i) remove heavily contaminated clothing and footwear immediately;
- (j) wash thoroughly protective clothing, gloves, etc.

58. **Safety precautions for the health of worker.**—Every employer shall observe the following precautions against poisoning by pesticides, namely—

- (a) ensure that workers are thoroughly trained in the precautions to be observed and are being adequately supervised by qualified supervisors;
- (b) not to permit a worker on job unless he is using standard protective clothing or devices;
- (c) ensure that a worker does not eat, drink or smoke unless he has removed all his protective clothing and has washed his hands and face and has left the area of work;
- (d) ensure that the overall and boots are washed at least once in a week.

## CHAPTER XII

59. **Nomenclature of Plant and Animal life.**—The plant and animal life, the nomenclature of which are specified in schedule II, shall be deemed to be insects, fungi and other plant or pests etc.

60. **Pesticides to be labelled poison.**—The pesticides specified in schedule III shall be labeled “Poison”.

61. **Symptoms of poisoning, first aid and antidotes of pesticides.**—The symptom of poisoning from various pesticides, first aid that should be given and the antidotes of each such pesticides are set out in Schedule IV.

## SCHEDULE I

(see rule 40)

### Fees for Test or Analysis of Pesticides

	<b>Taka</b>
1. Test or analysis of physical and chemical properties	1,000.00 (One thousand)
2. Test or analysis of active ingredient	500.00 (five hundred)
3. Suspending /emulsion	50.00 (fifty)
4. Acidity or alkalinity	50.00 (fifty)
5. Sieve test	50.00 (fifty)
6. Storage stability test	600.00 (six hundred)
7. Flash point test	50.00 (fifty)
8. Cold storage test	50.00 (fifty)
9. Residue test or analysis of pesticides	2,000.00 (two thousand for each sample)

**FORM- 1**

**(SEE RULE-3)**

**APPLICATION FOR REGISTRATION OF PESTICIDES**

1.	Name and address of the applicant	:	
2.	Name of the pesticide (Brand Name / Trade name)	:	
3.	Name and address of the manufacturer/ formulator	:	
4.	Common Name / Descriptive name	:	
5.	Chemical Name (IUPAC nomenclature)	:	
6.	Structural formula	:	
7.	Empirical formula and molecular weight	:	
8.	Manufacturer's development code number(s)	:	
9.	<b>Active ingredient (certified percentage of active material)</b>	:	
	(a) Physical state	:	
	(b) Colour / Appearance	:	
	(c) Odour	:	
	(d) Refractive index	:	
	(e) Melting point	:	
	(f) Decomposition point	:	
	(g) Viscosity	:	
	(h) Boiling point	:	
	(i) <b>Vapour pressure</b> : Figures should be given at a stated temperature preferably in the range of (20°—25°C)	:	
	(j) Flash point	:	
	(k) Specific gravity / Density (for liquids only)	:	
	(l) Hydrolysis rates under stated relevant conditions	:	
	(m) Surface tension	:	
	(n) Stability	:	
	(o) Solubility	:	

	(p) Compatibility	:	
	(q) Photolysis	:	
	(r) Absorptions spectra, <i>e.g.</i> , ultraviolet, visible and infrared, etc.	:	
	(s) Any other relevant properties	:	
	(t) Acidity, Alkalinity/P <sup>H</sup> value	:	
10	<b>Technical grade material</b>		
	(a) <b>Source:</b> Name and address of manufacturer and address where manufactured	:	
	(b) Physical state	:	
	(c) Colour	:	
	(d) Odour	:	
	(e) Acidity/Alkalinity or P <sup>H</sup> value	:	
	(f) Specific gravity	:	
	(g) Viscosity	:	
	(h) Flash point	:	
	(i) Minimum and Maximum) active ingredient content in % w/w	:	
	(j) Identity and amount of isomers, impurities and other by-products together with information on their possible range expressed as % w/w	:	
	(k) Storage stability (Low and high temp. storage stability)	:	
11	<b>Formulated Product</b>		
	(1) Identity / Appearance (color)	:	
	(2) Odour	:	
	(3) Type of formulation	:	
	(4) Content of active ingredient(s)	:	
	(5) Content and nature (Identity if possible of other components included in the formulation, <i>e.g.</i> , technical grade, adjuvants and inert ingredient)	:	
	(6) Water content/Moisture	:	

(7) Specific Gravity	:	
(8) Viscosity	:	
(9) Low and high temp .storage stability (In respect to composition and physical properties related to use)	:	
(10) Impurities	:	
(11) Flammability a. <b>Liquid</b> : Flash Point b. <b>Solids</b> : A statement must be made as to weather the product in flammable	:	
(12) Acidity (as H <sub>2</sub> SO <sub>4</sub> )	:	
(13) Alkalinity (as NaOH)	:	
(14) P <sup>H</sup> value	:	
(15) Other properties may in certain cases need evaluation	:	
(16) Carrier materials	:	
(17) Wet ability (for dispersible powders)	:	
(18) Persistent foam (for formulation applied in water)	:	
(19) Suspensibility (For dispersible powders and suspension concentrates)	:	
(20) Particle size	:	
(21) Wet sieve test (For dispersible powder & suspension concentration)	:	
(22) Dry sieve test (For Granules, Dust)	:	
(23) Emulsion stability (For emulsifiable Concentration)	:	
(24) Bulk density	:	
(25) Corrosiveness (when necessary)	:	
(26) Flowability	:	
(27) In case of Tablet/Pellets a. Weight b. Thickness/Height c. Diameter d. Colour Appearance e. Percentage of active ingredients and other related standard specification	:	

	(28) Known incompatibilities with other products	:	
	(29) Application with dosage rate	:	
12	Rate of release of active ingredient	:	
13	<b>Efficacy :</b> Primary evaluation data using, harmonized method and reported in a systematically presented complete dossier	:	
14	<b>Toxicology data :</b>		
	(a) Acute Oral toxicity and Dermal toxicity	:	
	(b) Acute Percentaneous toxicity	:	
	(c) Acute Inhalation	:	
	(d) Acute Other routes, e.g., in traperitoneal	:	
	(e) Skin irritation	:	
	(f) Eye irritation	:	
	(g) Short term Oral administration	:	
	(h) Short term Sensitizing effects	:	
	(i) Toxic effects of metabolizes, breakdown products or impurities	:	
	(j) Metabolic-studies	:	
	(k) Long-term toxicity, including carcinogenicity	:	
	(l) Neurotoxicity	:	
	(m) Reproduction studies	:	
	(n) Embryotoxicity, including teratogenicity	:	
	(o) Mutagenicity	:	
	(p) Potentiality	:	
	(q) Direct observations, e.g., clinical cases	:	
	(r) Health records, both from industry and agriculture	:	
	(s) Treatment of poisoning	:	
	(t) First aid measure	:	
	(u) Supplementary treatment	:	
	(v) Waiting period (Last application to harvesting)	:	

15	<b>Residue studies :</b>		
	(a) Primary physical, chemical and biological data	:	
	(b) Identification of residue-design of analytical method	:	
	(c) Reliable residue data from supervised trials.	:	
	(d) Estimation of maximum residue level at harvest	:	
	(e) Data on further disappearance on storage, transport etc.	:	
	(f) Estimation of residue level in commodity on sale	:	
	(g) Data on disappearance on food preparation, cooking or processing.	:	
	(h) Prediction of potential consumer intake, actual intake studies.	:	
	(i) Assessment of actual consumer intake	:	
	(j) Persistence of the product	:	
16	<b>Prediction of Environment effect :</b>		
	(a) Fate and mobility studies of toxicant	:	
	(b) Method of application of pesticide	:	
	(c) Time of application	:	
	(d) Rate of application	:	
	(e) Scale of use (number of application etc.)	:	
	(f) Climate and geographical locality	:	
	(g) Volatility of product	:	
	(h) Water solubility	:	
	(i) Octanol / water partition coefficient	:	
	(j) Absorption	:	
	(k) Desorption	:	
	(l) Degradation	:	
	(m) Persistence	:	
	(n) Effects on birds	:	
	(o) Effects on fish	:	

	(p) Effects on fish food species	:	
	(q) Effects on honey bees	:	
	(r) Degradation product in soil	:	
	(s) Possibilities of accumulation, with stable lipophilic compounds.	:	
	(t) Effects on local aquatic species	:	
	(u) Effects on soil organism	:	
	(v) Disposal of used, condemned and surplus pesticides and pesticides containers.	:	
	(w) Proposal for labeling and directions for use	:	
17	<b>Packaging</b>		
	(a) State weight (or for liquids, volumes) and the sizes of package in which the products is to be marked and for each size, the type of package, for instance i.e. 1 kg in cans with screw plug and 50 kg in iron drums. (Please note that the product must be sold in package size and type notified to the plant Protection Wing Dept. of Agric. Extension and for which the label is approved.)	:	
	(b) Classification during transport	:	
18	<b>Method of analysis</b>		
	(a) Methods to determine the active ingredients of the product (the accuracy of the method of determination should be stand)	:	
	(b) Methods to determine the amount of isomers, impurities and other by-product.	:	
19	<b>Labeled samples for analysis :</b>		
	(a) Analytical reference standard 2—5g.	:	
	(b) Technical grade material 0.5—1.0 kg	:	
	(c) Formulated product 5 kg/lit. for each formulation.	:	

20. **Registration Fee** : Taka 2000 (taka two thousand) to be deposited in Treasury Challan payable under Head of Account “৪৫-কৃষি প্রাপ্তি- অনিষ্টকারী পোকা-মাকড়, রোগ-বালাই ব্যবস্থাপনা ও বিবিধ খাতে আয়”।

I do hereby apply for registration of the pesticides particulars of which are given above and hereby certify that these particulars are to the best of my knowledge true and correct.

Date.....

.....

Signature of applicant

## NOTES

### **Direction of completion and submission of application. (In Triplicate)**

1. The application must be accompanied by:
  - (a) General literature of the product including toxicological and efficacy data.
  - (b) Standard specification of technical product and formulation of the product.
  - (c) Standard of ingredients (active and inert materials to be enclosed separately in a sealed and confidential cover).
2. Certified true copy of the contract / agreement made between the manufacturer / Principal and the local agent authenticated by the competent agency of the country for import and marketing the product in Bangladesh.
3. (a) In case of renewal of an existing registration, the previous certificate of registration; and  
(b) A suitable sample of the pesticide sufficient for test and analysis (Physical and Chemical properties).
4. Treasury challan of Taka two thousand evidencing payment shall be deposited under the receipt head: “৪৫-কৃষি শ্রাণ্ডি- অনিষ্টকারী পোকা-মাকড়, রোগ-বালাই ব্যবস্থাপনা ও বিবিধ খাতে আয়”।
5. Submission of application in a sealed covers and marked, “Confidential”.

**FORM-2**

[see rule 4(3)]

**Certificate of Registration of Pesticide**

Certified that the Pesticide has been registered in the name of undertaking whose Particulars are specified below:

1. Name of the undertaking :
2. Address :
3. Registration No. :
4. Name of the Pesticide (Common name, brand name or trade name, descriptive name of the pesticide, details thereof regarding its composition, etc.) :
5. Name and address of the manufacturer :

DHAKA:

The.....201....

Signature of the Registration Authority.  
Seal

Conditions:

**FORM—3**

**[see rule 6(1)]**

**(To be rendered in duplicate)**

**Application for renewal of a certificate of Registration of Pesticides.**

1. Full name of the applicant :
2. Address :
3. Common, descriptive, chemical, brand or trade name :
4. Previous Registration No. :
5. Change, if any made since the original registration. :

I do hereby apply for the renewal of a certificate of registration in terms of section 8 of the Pesticide Ordinance, 1971 (II of 1971) and for which the particulars are given above and I do hereby inform that no change has been made since the original registration except as indicated above.

Date:

FORM—4

[see rule 6(2)]

(In duplicate)

Certificate of Renewal of Registration of Pesticide

Name of the undertaking

.....

I do hereby:

(a) Certify that the brand of Pesticide (name of Pesticide) referred to in application  
No.....dated.....has been renewed for registration  
No .....and

(b) Certify that the following change(s) from the original registration have been accepted.

No .....

DHAKA;

The.....201.....

Signature of the Registration Authority.  
(Seal)

**FORM—5**  
**[see rule 12(1)]**

(In duplicate)

**Application for licence or renewal of licence to import Pesticides.**

To  
The Licensing Authority

.....

1. Full name and address of the applicant/ undertaking :
2. Name of the brand of Pesticide(s) and ingredients of pesticides :
3. Descriptive name of the pesticide(s) :
4. Name and address of the manufacturer :
5. Purpose of import :
6. Use of pesticide in agriculture/storage/public health/veterinary of any other field
7. Quantities of pesticide(s) to be imported
8. Previous licence to be enclosed in the case of renewal
9. Profession of the applicant
10. Licence fee of Taka .....credited to

the Government under head of account “৪৫-কৃষি শ্রাণ্ডি-অনিষ্টকারী পোকা-মাকড়, রোগ-বালাই ব্যবস্থাপনা ও বিবিধ খাতে আয়”। (Challan No .....dated.....)

I/We..... of.....hereby apply for the grant of a licence to import pesticide mentioned above and to be stored on the premises situated at.....

Date:

Signature of the Applicant

**Note :** For experimental or research purposes, import licence shall not be required.

**FORM—6**

[see rule 12(1)]

(In duplicate)

**Application for the grant or renewal of licence for manufacturer or formulation of Pesticide.**

To  
The Licensing Authority

1. I/We.....of.....hereby apply for the grant of a licence to manufacture/formulate on the premises situated at .....the undermentioned pesticide(s) ..... Name of the pesticide(s) (each pesticide to be separately specified).

2. The names, qualifications and experience of the expert staff actually connected with the manufacture/formulation and testing of the specified products in the manufacturing/formulation premises .....

3. I/We enclose—

(a) A certified true copy of a letter from the manufacturing concern whose manufacturing capacity is intended to be utilized by me/us.

(b) A certified true copy of a letter from the manufacturing concern that they agree to lend the services of their expert staff, equipment and premises for the manufacture/formulation of each pesticide required by me/us and that they will analyse every batch of finished product and maintain the registers of the materials, finished products and reports of the analysis separately in this behalf or inspection by the authorised agency.

(c) Specimens of labels, cartons of the products proposed to be manufactured/ formulated.

4. Previous licence to be enclosed in the case of renewal of licence.

5. A fee of Tk.....has been credited to the Government under the head of account “৪৫-কৃষি প্রাপ্তি-অনিষ্টকারী পোকা-মাকড়, রোগ-বালাই ব্যবস্থাপনা ও বিবিধ খাতে আয়”। (Challan No ..... dated.....).

Date:

Signature.

Date:

(1) In the case of application for manufacturer’s licence, the word formulation shall be deleted and vice versa.

(2) If there is any change in the details of manufacturer/formulation including of condition of licence subject to which the licence is required to be renewed, the same be indicated here.

**FORM—7**

[see rule 12(1)]

(In duplicate)

**Application for the grant or renewal of licence to hold in stock for wholesale.**

To

The Licensing Authority,

1. Full name and address of the applicant :
2. Is the applicant a new comer? :
3. If yes, the name of the Principals, if any, whom he represents. :
4. If the applicant has been— :
  - (i) In the trade, give full particulars of the names of pesticides handled in the period and the places at which the trade was carried on (and the Principals whom he represented) and
  - (ii) Give the quantities handled during the past two calendar years:
    - (a)
    - (b)
5. Situation of the premises where the pesticides will be stored for sale, distribution, etc. :
6. Names of the pesticide for which the applicant desires to carry on business.
7. Quantities of each brand of pesticide to be stocked for sale or distribution.
8. Previous Licence to be enclosed in the case of renewal.
9. I/We have deposited the licence fee of Tk.....under the head of account “৪৫-কৃষি প্রাঙ্গি-অনিষ্টকারী পোকা-মাকড়, রোগ-বালাই ব্যবস্থাপনা ও বিবিধ খাতে আয়”। (Challan No ..... dated.....)
10. **Declarations:**
  - (a) I/We declare that the information given above is true to my/our knowledge and belief and no part there of is false.
  - (b) I/We carefully have read the terms and conditions of the licence and agree to abide by them.

Date :

Signature of the applicant.

**NOTE :** The application shall be accompanied by certificates issued by the Principal(s) whom the applicant represents.

**FORM—8**

[see rule 12(1)]

(In duplicate)

**Application for grant or renewal of retail licence for pesticide.**

To  
The Licensing Authority.

1. Full name and address of the applicant :
2. Source or sources from which pesticide will be obtained. :
3. Quantities of pesticide (s) to be stocked for sale. :
4. Situations of the dealer's premises where the pesticide will be (a) stored and (b) sold. :
5. The name(s) of the pesticide(s) in which applicant desires to carry on the business. :
6. Previous licence to be enclosed in the case of renewal of licence. :
7. Licence fee of Taka ..... is credited to the Government under head of account "৪৫-কৃষি প্রাপ্তি-অনিষ্টকারী পোকা-মাকড়, রোগ-বালাই ব্যবস্থাপনা ও বিবিধ খাতে আয়"। (Challan No ..... dated.....)

**8. Declarations:**

- (a) I declare that the information given above is true to my knowledge and belief and no part thereof is false.
- (b) I carefully have read the terms and conditions of the licence and agree to abide by them

Place.....

Date.....

Signature of the Applicant.

**FORM—9**  
**[see rule 12(1)]**

(In duplicate)

**Application for a licence or renewal of licence for repacking of pesticides.**

To  
The Licensing Authority.

1. I/We..... hereby apply for a licence or renewal of licence for re-packing pesticides situated at .....
2. Name(s) of the brand of pesticides(s) to be re-packed with the name(s) of the manufacturer/formulators, etc. :
3. Quantities to be repacked in a year :
4. Name(s), qualification and technical experience of the expert staff to be employed for the direction and supervision of repacking:  
(1).....  
(2).....
5. A fee of Taka .....is credited to the Government under the head of account “৪৫-কৃষি শ্রাণ্ডি-অনিষ্টকারী পোকা-মাকড়, রোগ-বলাই ব্যবস্থাপনা ও বিবিধ খাতে আয়”। (Challan No ..... dated.....)
6. Full name of the applicant in block letters with address. :
7. Previous licence to be enclosed in the case of renewal. :

Signature of the applicant.

**NOTE :** The application to be accompanied by a sketch plan of the premises.

**FORM—10**  
**[see rule 12(1)]**

(In duplicate)

**Application for grant of Pest Control Operation Licence on Commercial basis or  
renewal thereof.**

To  
The Licensing Authority.

1. Full name and address of the applicant (in block letters) :
  2. Is the applicant a new comer? :
  3. If the applicant has been in the trade, give full particulars of pesticides handled and pest control operation undertaken. :
  4. Quantities of Pesticides handled during the last two calendar years for pest control operation to be specified. :
  5. Situation of the Premises where the implements will be housed and pesticides stored. :
  6. Name to the place(s), crops and infested places in which applicant desires to carry on business. :
  7. Pesticide stockist licence, if any. :
  8. Previous licence to be enclosed in the case of renewal of licence. :
  9. Names, qualifications and experience of persons (trained in pest control operation) to be employed for direction and supervision. :
10. Licence fee of Taka 500 has been credited to the Government under the head of account “কৃষি প্রাপ্তি-অনিষ্টকারী পোকা-মাকড়, রোগ-বালাই ব্যবস্থাপনা বিবিধ খাতে আয়”। in treasury challan No.....-1-4331-0000-2043, dated.....

**11. Declaration:**

- (a) I/We declare that the information given above is true to my/our knowledge and belief and no part thereof is false.
- (b) I/We carefully have read the terms and conditions of licences and agree to abide by them.

Date: .....

Signature of the applicant (s)

**Note:** Application to be accompanied by a sketch plan of premises.



**FORM 12**  
**[see rule 12(2)]**

(In duplicate)

**Licence to Import pesticide (s).**

M/S ..... is hereby granted  
licence to import the following brand of pesticide (s) :—

- (a) Brand name of pesticide(s) with registration No. :
- (b) Descriptive name of pesticides :
- (c) Name of Ingredients of pesticide :
- 2. Name of the manufacturer :
- 3. Quantities to be imported :
- 4. The licence shall be in force for a period of two years from the date of issue.

Licence No.....

Date.....

Licensing Authority.  
(Seal)

**Conditions**

- 1. The licence shall be displayed in a prominent place of the office premises.
- 2. The licensee shall comply with the provision of the Pesticide Ordinance, 1971 and the rules made thereunder for the time being in force, provided that the condition shall not apply to import any pesticide for experimental or research purposes.
- 3. Renewal.

**FORM 13**

[see rule 12(2)]

**Licence for manufacture/formulation of pesticides.**

Licence No .....,  
date.....

M/s .....of.....is  
hereby granted licence to manufacture/formulate the pesticides on the premises situated at  
..... under the direction  
of the following expert staff:

- (a) Expert staff (names) : Qualification
- (b) Names of pesticide(s) :

- 2. The licence shall be in force for a period of two years from the date of issue.
- 3. The licence is subject to the conditions stated below and to such conditions as are specified in the rules for the time being in force under the Pesticide Ordinance, 1971.

Date :

Signature

Licensing Authority

(Seal)

**Conditions**

- 1. This shall be kept on the approved premises and shall be produced for inspection at the request of an authorised officer under the Pesticide Ordinance, 1971 and rules thereunder.
- 2. Any change in the expert staff named in the licence shall forthwith be reported to the licensing authority.
- 3. If the licensee wants to undertake during the currency of the licence to manufacture/ formulate for sale additional pesticide, he should apply to the licensing authority with the licence.
- 4. Renewal.

**FORM 14**

[see rule 12(2)]

**Licence to hold in stock for wholesale of pesticides.**

Licence No.....,  
date.....

Mr/M/s..... is hereby granted licence to hold in stock for wholesale of pesticides on the premises situated at ..... subject to the conditions specified below and to the provisions of the Pesticide Ordinance, 1971 and the rules made thereunder.

2. Licence shall be in force for a period of two years from the date of issue.
3. Categories of pesticides to be hold in stock.
4. Total quantity of pesticides to be stocked.

Date:

Licensing Authority

(Seal).

**Conditions**

1. The licence shall be displayed in a prominent place in the part of the premises open to the public.
2. The licence shall comply with the provisions of the Pesticide Ordinance, 1971 and the rules made thereunder for the time being in force.
3. No sale of pesticide shall be made to a person not holding a retail licence to sell pesticide, provided that this condition shall not apply to the sale of any pesticide to an officer or authority purchasing on behalf of Government.
4. The licence shall not be allowed to take wholesale commission for sale of pesticide exceeding the rate fixed by the Government.
5. Renewal.

**FORM 15**

[see rule 12(2)]

**Licence for retail sale of pesticide**

M/s..... is hereby granted licence to sell pesticide(s) by retail sale on the premises situated at ..... subject to the conditions specified below and to the provision of the Pesticide Ordinance, 1971 (No. 11 of 1971) and the rules made thereunder.

2. Licence shall be in force for a period of two years from the date of issue.

3. Pesticides to be sold :

Licence No.....

Date.....

Licensing Authority

(Seal).

**Conditions**

1. The licence shall be displayed in a prominent place in any part of the premises open to the public.
2. The licensee shall comply with the provisions of the Pesticide Ordinance, 1971 and the rules made thereunder.
3. The licensee shall not be allowed to take commission for retail sale of pesticides exceeding the rate fixed by the Government.
4. Renewal.

**FORM 16**

[see rule 12(2)]

**Licence to repack pesticides.**

M/s ..... is hereby granted licence for re-packing pesticide(s) at the premises situated at ..... under the direction and supervision of the following expert staff:

(a) Name ..... Qualification  
.....

(b) Name ..... Qualification  
.....

2. The licence authorises the licensee for re-packing the brand of pesticide(s) mentioned in the application as stated below.
3. The licence shall be in force for a period of two years from the date of issue.
4. Type of re-packing(s).
5. Quantity to be re-packed in a year:

Licence No .....

Date .....

Licensing Authority

(Seal)

**Conditions**

1. The licence shall be displayed in a prominent place in the part of the premises open to the public.
2. The licensee shall comply with the provisions of the Pesticide Ordinance, 1971 and the rules made thereunder.
3. Renewal.

**FORM 19**

**(see rule 23)**

**Memorandum to Director, Pesticide Laboratory.**

To  
The Director, Pesticide Laboratory, Dhaka

I (full name of Inspector) ..... do hereby  
certify that accompanying is a sample of pesticide taken by me on  
..... at ..... (specify full address)  
from stock in charge of .....(state name and address of  
Importers/stockist/manufacturer/formulator/repacker/seller).....  
..... in presence of .....  
..... (state names and address of witness).

The following further particulars are given in connection with the samples:

1. Name of the brand of Pesticide.
2. Descriptive name of Pesticide.
3. Marks or number on samples.
4. Information given on container from which sample was taken.
5. Approximate quantity of pesticide represented by the sample.
6. Other particulars.

Signature of Witness  
Place  
Date

Signature of Inspector  
(Seal)

**Note:** A copy of the memorandum shall be handed over or forwarded to the owner of the pesticide or to his agent. A copy shall be retained by the Inspector.

**FORM 20**

**[(see rule 24 (1))]**

**Report of Test or Analysis by Pesticide Laboratory.**

It is certified:

- (1) that on ..... the sample of .....  
was received from ..... in the  
Pesticide Laboratory, Dhaka for test and/or analysis,
- (2) that the sample was labelled, sealed and marked .....,  
and
- (3) that the sample was tested and/or analysed and found that (Specify details of the  
results of test/or analysis).

Date:

Signature of Director,  
Pesticide Laboratory,  
Dhaka.

**FORM 21**

**[(see rule 38 (3))]**

(In triplicate)

**Report of results of analysis of test of sample of pesticide by Government Analyst**

I (full name) ....., a duly appointed Government Analyst in terms of section 14 of Pesticide Ordinance, 1971, do hereby make oath and state.....

1. that on ..... received a sample of ..... from (full name of Inspector) ..... for analysis and/or test,
2. that the sample was labelled, sealed and market .....,
3. that I have analysed and/or tested the sample and found that (specify the details of results of analysis and/or test with protocols of test applied).

Date:

Signature of Government Analyst  
(Official seal).

**FORM 22**

**(see rule 39)**

(In triplicate)

**Application for the testing of a pesticide by the purchaser**

1. Name of the applicant :
2. Address of the applicant :
3. Name of pesticide or brand :
4. Name of the manufacturer/ formulator/ dealer/  
vendor :
5. Registration No :
6. Requirement of test :
7. Purpose of purchase :

**Specification Limit.**

- (i)
- (ii)
- (iii)

I do hereby apply for the testing in terms of section 20 of the Pesticide Ordinance, 1971 of the pesticide, the particulars of which are given above. A fee of Taka ..... is being submitted herewith as per Schedule I.

Date:

Signature of applicant.

**FORM 23**

**(see rule 39)**

**Report of the test or analysis for purchaser.**

1. Name of persons from whom sample received :
2. Date of receipt :
3. Name of pesticide or brand :
4. Percentage of active ingredient :
5. Opinion of the Government Analyst :
6. The sample referred to above is/is not of  
standard quality as specified :

Date:

Signature of the Government Analyst

(Official seal).

**FORM 24**

**(see rule 43)**

**Order not to dispose of any stock.**

Whereas I have reason to believe that the stock of.....  
Pesticide(s) in your Possession, detailed below, is being distributed, sold, used or disposed  
of in contraventions of the provisions of section .....  
the Pesticide Ordinance, 1971 and the Pesticide Rules, 1985 thereunder.

I hereby require you under section 24(1) of the said Ordinance not to dispose of the said  
stock.

Is of stock of pesticide:

- 1.
- 2.
- 3.
- 4.

Date:

Inspector  
(Official seal).

**FORM 25**

**(see rule 44)**

**Receipt for stock of pesticides seized.**

The stock of pesticides detailed below has this day been seized by me under the provision of section 24(1) of the Pesticide Ordinance, 1971 from the premises of .....  
..... situated at .....  
.....

Details of pesticide(s) seized giving full inventory of the materials with quantities of each:

- 1.
- 2.
- 3.
- 4.
- 5.

Date:

Signature of Inspector.

(Official seal).

**FORM 26**

**(see rule 45)**

To  
I have this day (date ..... and time.....) taken from  
the premises of ..... situated at  
..... samples of the pesticides as specified below  
for the purpose of test or analysis.

Details of sample taken.

Date :

Signature of Inspector  
(Seal)

**FORM 27**

**(see rule 46)**

Memorandum to Government Analyst.

To  
The Government Analyst,

The portion of sample of the container described below is sent herewith for test or analysis under the rule 46 of the Pesticide Ordinance, 1971.

The portion of sample of the container has been marked by me with the following mark:

Details of portion of sample of the contain with the name of Pesticide which it imports to contain.

Signature of Inspector

(Official seal)

কৃষি মন্ত্রণালয়

সেকশন ৬

প্রজ্ঞাপন

তারিখ, ১৪ শ্রাবণ ১৪১৭/২৯ জুলাই ২০১০ খ্রিস্টাব্দ

নং এস, আর, ও ২৮২-আইন/২০১০—যেহেতু সরকার The Pesticides Ordinance, 1971 (II of 1971) এর Section 29 (1)-এ প্রদত্ত ক্ষমতাবলে সরকার কর্তৃক Pesticides Technical Advisory Committee এর সাথে পরামর্শক্রমে THE PESTICIDE RULES, 1985 নিম্নরূপভাবে সংশোধনের প্রস্তাব করিয়া প্রস্তাবিত সংশোধনীর ফলে প্রভাবিত বা ক্ষতিগ্রস্ত হইতে পারেন এমন সকল ব্যক্তিদের অবগতি এবং তাহাদের নিকট হইতে আপত্তি বা পরামর্শ আহ্বান করিয়া প্রস্তাবিত সংশোধনী গেজেটে প্রকাশের তারিখ হইতে ৩০ (ত্রিশ) দিনের সময়সীমা উল্লেখ উক্ত 29 (1) এর বিধান অনুযায়ী বাংলাদেশ গেজেটের অতিরিক্ত সংখ্যা ২৬ বৈশাখ, ১৪১৭ বঙ্গাব্দ মোতাবেক ৯ মে ২০১০ খ্রিস্টাব্দ তারিখে প্রাক-প্রকাশ করিয়াছিল; এবং

যেহেতু, জারীকৃত প্রজ্ঞাপনের প্রেক্ষিতে কাহারও নিকট হইতে কোন আপত্তি বা পরামর্শ পাওয়া যায় নাই;

সেহেতু The Pesticides Ordinance, 1971 (Ordinance No. II of 1971) এর Section 29 (1)-এ প্রদত্ত ক্ষমতাবলে সরকার Pesticides Technical Advisory Committee এর সাথে পরামর্শক্রমে The Pesticide Rules, 1985 এর নিম্নরূপ সংশোধন করিল, যথাঃ—

উপরিউক্ত Rules এর—

(১) Rules 2 এর clause (1) এর প্রান্তস্থিত (.) ফুল স্টপের পরিবর্তে (;) সেমিকোলন প্রতিস্থাপিত হইবে এবং অতঃপর নিম্নরূপ নতুন clause (m), (n), (o), (p), (q), (r), এবং (s) সংযোজিত হইবে, যথাঃ—

**m. “Active ingredient:”** means the biologically active part of the pesticide present in a formulation.

**n “Agricultural pesticide :”** means the pesticides which are intended for use against agricultural pests.

**o “Biopesticide:”** According the FAO, “Biopesticides” are naturally occurring substances or their synthetic analogues that are distinguished from conventional chemical pesticides by their unique modes of action, low use volume, and target species specificity.

**p “Government:”** means Secretary, Ministry of Agriculture or any government official as may be authorized and duly notified by the Secretary, Ministry of Agriculture for the purpose of these rules.

**q “Inert ingredient:”** means an ingredient in a formulated pesticide product which will not prevent, Destroy, repel or mitigate any pest and is intentionally included in

the product. This includes ingredient such as solvents, emulsifiers, wetting agents, carriers, diluents, conditioning agents etc.

**r “Manufacturer:”** means a corporation or other entity in the public or private sector or any individual engaged in the business or function (whether directly or through an agent or through an entity controlled by or under contract with it) of manufacturing a pesticide active ingredient or preparing its formulation or product.

**s “Public health pesticide:”** means the pesticides which are intended for use against public health concern.

**t “Person”** means importer, manufacturer, formulator, repacker, vendor or stockholder, wholesaler and retailer of Pesticides but does not include farmer or enduser.

৩. **Rule 3** এর পরিবর্তে নিম্নরূপ **rule 3** প্রতিস্থাপিত হইবে, যথা ঃ—

“3. **Application for registration of pesticides,**—(1) An application in triplicate for registration of a brand of pesticide under sub-section (1) of section 5 of the Ordinance shall be made to the Registration Authority in Form- I. a. for Conventional Chemical pesticides, Form-1b for Biochemical pesticides and Form-1c for Microbial pesticides.

(2) Where the person, making application under sub-section (1) of section 5 of the Pesticides Ordinance, 1971 (II of 1971), is not domiciled in Bangladesh the application shall, besides such person, be signed by his agent or representative in Bangladesh”.

8. **Rule 4** এর—

(ক) sub-rule (2), (3) ও (4) এর পরিবর্তে নিম্নরূপ sub-rule (2) (3) (4) ও (5) প্রতিস্থাপিত হইবেঃ

“ (2) On receipt of the result of the test or analysis under sub-rule (1) the Registration Authority shall submit the result to the sub-committee for approval. After approval of sub-committee the registration authority shall send the sample of the pesticide to the respective specialized institutes/organization authorized by the Advisory Committee to conduct biological test and trial for both the new molecule and Me-too product under field condition as may be required. Both for Me-too Product & New Molecule, 2 (two) different locations and 2(two) crop season trials are required. After field trial, report should be made available within 1(one) month. The respective specialized institutes/ organization shall conduct such biological and field efficacy tests following standard Bio-efficacy Test Protocols either available with the respective specialized institutes/organization or prescribed by the Advisory Committee.

(3) The specialized institute/organization will send the test result to the Registration Authority. On receipt of the test result, the Registration Authority will send the result to the next meeting of the sub-Committee of the Advisory Committee.

(4) The Sub-Committee will examine the test result with the list of protocols and shall send its recommendations to the Registration Authority within 15(fifteen) days on receipt of the result.

(5) On receipt of the recommendation of the Sub-committee of Advisory committee under sub-rule (4) the Registration Authority will forward the recommendation of the sub-Committee to the advisory committee. If advisory committee approved and recommend that the brand of pesticide conforms to the requirement of the ordinance and rules then the registration authority give registration to the brand of pesticide in Form-2 in such condition as may be specified in the registration certificate.”

**(খ) Sub-rule (5) এর পরে নিম্নরূপ নূতন sub-rules (6) (7) (8) ও (9) সংযোজিত হইবে, যথা ঃ—**

“(6) A certificate of registration granted under sub-rule (5) shall apply only to the pesticide described in the application to which the certificate relates.

(7) The registration authority shall issue the registration certificate within 15(fifteen) working days of Advisory Committee approval.

(8) Pesticides registered as aforesaid shall be published by the Registration Authority in the official Gazette within 30(thirty) days from the date of granting registration certificate.

(9) The registration of a brand of pesticide shall be effective from the date of its registration until the thirtieth day of June of the third year following the year of registration.”

**৫। Rule 6 এর পরিবর্তে নিম্নরূপ rule 6 প্রতিস্থাপিত হইবে, যথা ঃ—**

“(1) An application in duplicate for renewal of registration shall be made in Form-3 to the Registration authority at least 30 (thirty) days before its expiry.

(2) The registration of a pesticide shall be deemed to have been cancelled if not applied under sub-rule (1).

(3) A certificate of renewal of registration shall be issued in Form 4 within 90(ninety) days after receiving the application.

(4) On receipt of application with fee the Registration authority can approve by himself the changes in address and country of origin of a registered brand of a pesticide.

(5) In case of change of country of origin, the sample of the product should be tested and should comply with the original product.”

৬। **Rule 7** এর **sub-rule (1)** এর পরিবর্তে নিম্নরূপ sub-rule(1) ও (2) প্রতিস্থাপিত হইবে, যথা ঃ—

“(1) A fee of TK. 20,000.00 (Taka Twenty thousand) shall be paid with each application for a Registration Certificate and a fee of TK. 5,000.00 (Taka five thousand) for renewal of certificate of registration, which shall, in no case, be refunded to the applicant.

(2) A fee of TK. 2000.00 (Taka two thousand) shall be paid for a duplicate copy of the registration certificate if the original one is defaced, destroyed or lost.”

৭। **Rule 8** এ “service” শব্দের পর “and in the official Gazette” শব্দসমূহ সংযোজিত হইবে।

৮। **Rule 9** এ “**Authority**” শব্দের পর “and the registration authority will cancel the registration” শব্দসমূহ সংযোজিত হইবে।

৯। **Rule 11** এর sub-rule (3) পরে নিম্নরূপ sub-rule (4) সংযোজিত হইবে, যথাঃ—

“(4) **Pesticide shall be importable only from the manufacturer/formulator as mentioned in the Registration Certificate.**”

১০। **Rule 12** “ এর

(ক) sub-rule (2) এ “ Form 12,” এর পর “ Form 12 (a)” শব্দগুলি, সংখ্যা ও কমা সন্নিবেশিত হইবে;

(খ) sub-rule (3) এর পরিবর্তে নিম্নরূপ sub-rule (3) প্রতিস্থাপিত হইবে, যথা ঃ—

“(3) An application for grant of licence and renewal thereof under this rule will be accompanied by a fee specified below :

	<u>Licence fee Taka</u>	<u>Renewal fee Taka</u>
(a) import	Two thousand	One thousand
(b) manufacture or formulation	Five thousand	One thousand
(c) holding in stock for wholesale	One thousand	Five thousand
(d) retail sale	Three thousand	Two thousand
(e) repacking	Two thousand	One thousand
(f) pest control operation on commercial	Two thousand	Five thousand
(g) Advertisement	One thousand	Five thousand

(গ) **Sub-rule (5)** এর পরে নিম্নরূপ **sub-rule (6)** সংযোজিত হইবে, যথা ঃ—

“(6) Environmental certificate is required from Department of Environment for Pesticide repacker, Formulation factory or manufacturer following Environmental conservation Act 1995 and Environmental Conservation Rules 1997.”

১১। **Rule 14** এর পরিবর্তে নিম্নরূপ rule 14 প্রতিস্থাপিত হইবে, যথা ঃ—“14 A fee of TK 100 (one hundred) shall be paid for duplicate copy of a licence issued under this chapter if the original one is defaced, damaged or lost.

১২। **Rule 15** এর sub-rule (2) এর পরিবর্তে নিম্নরূপ sub-rule (2) প্রতিস্থাপিত হইবে, যথা ঃ—

“(2) An application in duplicate for renewal of license shall be made to the Registration authority within 30 (thirty) days of such expiry of the date of its effectiveness and if the application is not made so, a penalty of TK. 300.00 (three hundred) for each month up to 3(three) months from the date of expiry, shall accompany the application along with usual renewal fee. The license of a pesticide shall be deemed to, have been cancelled if the renewal is not applied for within 90 (ninety) days from the date of expiry.”

১৩। **Sub-rule (3)** এ “45- কৃষি প্রাপ্তি- অনিষ্টকারী পোকা-মাকড়, রোগ-বালাই ব্যবস্থাপনা ও বিবিধ খাতে আয়” শব্দসমূহের পরিবর্তে “1-4331-0000-2043” শব্দসমূহ প্রতিস্থাপিত হইবে।

১৪। **Rule 19** এর **sub-rule (3)** এর পরিবর্তে নিম্নরূপ sub-rule (3) প্রতিস্থাপিত হইবে, যথা ঃ—

“(3) The licensing authority may after such inspection finds all terms and conditions paid down under Rule 17 and/ or which is applicable or fulfilled by the person to whom the license is proposed to be transferred, accord permission to transfer the license and on such permission being given, an endorsement to the that effect shall be made in the license.”

১৫। **Rule 21** এর—

(ক) Clause (e) তে “pesticides” শব্দটির পরিবর্তে “Agricultural and Public Health pesticides” শব্দসমূহ; এবং

(খ) Clause (d) তে “as well as they are being suitable for aerial application” শব্দসমূহের পরিবর্তে “based on formulation as well as they are being suitable for ground and aerial application” শব্দসমূহ প্রতিস্থাপিত হইবে।

১৬। **Rule 28** এর clause (d) তে “WHO” শব্দের পরে and “FAO” শব্দগুলি সংযোজিত হইবে।

১৭। **Rule 32** এর—

(ক) “leaflet” শব্দের পরে “of every pesticide which shall be affixed” or attached to the package or repacking” শব্দগুলি বিলুপ্তি হইবে ; এবং

(খ) clause (d) “storage” শব্দটির পরে “shall be exclusive” শব্দগুলি সন্নিবেশিত হইবে।

১৮। **Rule 33** এর sub-rule (4) এ—

- (ক) Clause (i) এ “category 1 (highly toxic)” শব্দগুলির পরিবর্তে “ 1a and 1b (extremely and highly hazardous)” শব্দসমূহ প্রতিস্থাপিত হইবে ;
- (খ) Clause (iii) এ “ (moderately toxic) shall bear the word “Poison” “DANGER” and the statement “ KEEP OUT OF THE REACH OF CHILDREN” shall appear on the label at suitable place outside the square” শব্দগুলির পরিবর্তে “(moderately hazardous) shall bear the word “Poison” “DANGER” printed in bright yellow; and” শব্দসমূহ ও কমা প্রতিস্থাপিত হইবে; এবং the statement “keep out of the reach of children” shall appear on the label at suitable out side the square.
- (গ) Clause (iv) এর পরিবর্তে নিম্নোক্ত clause (iv) প্রতিস্থাপিত হবে, যথাঃ—  
“(iv) pesticides in category III (slightly hazardous) shall bear the word “Poison” “ CAUTION” and the word “CAUTION” printed in bright green and the statement “KEEP OUT OF THE REACH OF CHILDREN” shall appear on the label at suitable place outside the square.”
- (ঘ) Sub-rule (5) এ TABLE এর পরিবর্তে নিম্নরূপ TABLE প্রতিস্থাপিত হইবে, যথা ঃ—

**“ TABLE”**

Class		LD 50 for the rat (mg/kg body weight) based on formulations				Color of identification band on the label
		Oral		Dermal		
		Solid	Liquids	Solids	Liquids	
1a	Extremely hazardous	5 or less	20 or less	10 or less	40 or less	Red
1b	Highly hazardous	5-50	20-200	10-100	40-400	Red
II	Moderately hazardous	50-500	200-2000	100-1000	400-4000	Bright yellow
III	Slightly hazardous	Over 500	Over 2000	Over 1000	Over 4000	Bright green

The terms “Solids” and “Liquids” refer to the physical state of the active ingredient being classified.”

১৯। **Rule 38** এর sub-rule (2) এ “country” শব্দের পরে “ and FAO, WHO, ISO, CIPAC specification” শব্দসমূহ ও কমা সংযোজিত হইবে।

২০। **Rule 40** এর sub-rule (3) এ ৪৫-কৃষিপ্রাপ্তি অনিষ্টকারী পোকা-মাকড়, রোগ-বালাই ব্যবস্থাপনা ও বিবিধ খাতে আয় শব্দসমূহের পরিবর্তে “1-4331-0000-2043” সংখ্যা ও চিহ্নসমূহ প্রতিস্থাপিত হইবে।

২১। **Rule 41** এর clause (c) এ “shall not exceed two pounds (one kilogram)” শব্দসমূহের পরিবর্তে “ shall be maximum 125ml for liquid, 500gms for granules and powder” শব্দসমূহ প্রতিস্থাপিত হইবে।

২২। **Rule 58** এর clause (d) এর পর নিম্নরূপ clause (e) নূতন সংযোজিত হইবে, যথাঃ—

“(e) ensure periodic (monthly blood cholinesterase test for the workers and removing the worker from the plant, whose blood cholinesterase level has been depressed below WHO limits.”

২৩। **Rule 59** এর পরিবর্তে নিম্নরূপ **rule 59** প্রতিস্থাপিত হইবে, যথা ঃ—

“A List of the plant and animal life, the nomenclature of which are specified in Schedule II shall be maintained at PPW and shall be updated from time to time by the Director, PPW as per approval of the Advisory Committee.”

২৪। **Rule 60** এর পরিবর্তে নিম্নরূপ **rule 60** প্রতিস্থাপিত হইবে, যথা ঃ—

“60(1) The pesticides which get registration shall be specified in Schedule III and shall be labeled “Poison” as per the provision of rule 33.

(2) Director, PPW shall update the list from time to time.”

২৫। Form-1, এর ১৪ নং কলামে বর্ণিত “Toxicological data” শব্দটির পরিবর্তে “Toxicological data of Technical Grade Active Ingredient (TGAI) and Formulated Product (FP)” শব্দসমূহ প্রতিস্থাপিত হইবে।

২৬। বর্তমান Form-1, Form-1 (a) for Chemical pesticides দ্বারা প্রতিস্থাপিত হইবে।

Form 1(a) এর পরে Form 1 (b) for Biochemical Pesticides এবং Form 1 (c) for Microbial Pesticides নতুনভাবে সংযোজিত হইবে।

## FORM 1 (a): For Chemical Pesticides

(See rule 3)

### APPLICATION FOR REGISTRATION OF CHEMICAL PESTICIDES

1. Name and address of the applicant :
2. Name of the pesticide :
3. Name and address of the manufacturer :
4. Common Name/Descriptive Name :
5. Chemical Name (IUPAC nomenclature) :
6. Structural formula :
7. Empirical formula and molecular weight :
8. Manufacturer's development code number(s) :
9. Active ingredient (certified percentage of active material) :
  - (a) Physical state :
  - (b) Colour/Appearance :
  - (c) Odour :
  - (d) Refractive index :
  - (e) Melting point :
  - (f) Decomposition point :
  - (g) Viscosity :
  - (h) Boiling point :
  - (i) Vapour pressure (Figures should be given at a stated temperature preferably is the range of (20-25°C). :
  - (j) Flash point :
  - (k) Specific gravity/Density (for liquids only) :
  - (l) Hydrolysis rate under stated relevant conditions :

- (m) Surface tension :
- (n) Stability :
- (o) Solubility :
- (p) Compatibility :
- (q) Photolysis :
- (r) Absorption spectra, e.g. ultra-violet and infra red, :
- (s) Any other relevant properties :
- (t) Acidity/Alkalinity/pH value :

**10. Technical grade material :**

- (a) **Source** : name and address of manufacturer and address where manufactured :
- (b) Physical state :
- (c) Colour :
- (e) Acidity/Alkalinity/P<sup>H</sup> value :
- (f) Specific gravity :
- (g) Viscosity :
- (h) Flash Point :
- (i) Minimum (and maximum) active ingredient content in % w/w :
- (j) Identity and amount of isomers, impurities and other by products together with information on their possible range expressed as % W/W :
- (k) Storage stability (Low and High temperature storage stability) :

**11. Formulated product**

- (1) Identity/appearance (colour) :
- (2) Odour :
- (3) Type of formulation :
- (4) Contents of active ingredient (s) :

- (5) Content and nature (identity, if possible, of other components included in the formulation, e.g., technical grade, adjuvants and inert ingredient). :
- (6) Water content/Moisture (above relevant) :
- (7) Specific gravity :
- (8) Viscosity :
- (9) Low & High temperature storage stability ( in respect to composition and physical properties related to use. :
- (10) Impurities :
- (11) **Flammability** :
  - (a) **Liquids** : Flash point :
  - (b) **Solids** : A statement must be made as to whether the product is flammable Non solid :
- (12) Acidity :
- (13) Alkalinity :
- (14) pH Value :
- (15) Other properties may in certain cases need evaluation :
- (16) Carrier materials :
- (17) Wettability (for dispersible powders) :
- (18) Persistent foam (for formulation applied in water) :
- (19) Suspensibility (for dispersible powders and suspension concentrates) :
- (20) Particle size :
- (21) Wet sieve test (for dispersible powders and suspension concentrates) :
- (22) Dry sieve test (for granules, dusts) :
- (23) Emulsion Stability ( for emulsifiable concentrate ) :
- (24) Bulk density : :
- (25) Corrosiveness (when necessary) :
- (26) Flow ability :

- (27) **In case tablet/pellets :** :
- (a) Weight :
- (b) Thickness/height :
- (c) Diameter :
- (d) Colour/Appearance :
- (e) Percentage of active ingredients and other related standard specifications :
- (28) Known incompatibility with other products, e.g., pesticides, fertilizers :
- (29) Application with dosage rate :
- 12. Rate of release of active ingredient (granules, dust, etc.) :**
- 13. Efficacy :**  
Primary evaluation data using harmonized method and reported in a systematically presented complete dossier
- 14. Toxicological data of Technical Grade Active Ingredient (TGAI ) and Formulated Product (FP)" :**
- (a) Acute Oral toxicity and Dermal toxicity :
- (b) Acute percentaneous toxicity :
- (c) Acute inhalation toxicity :
- (d) Acute other routes e.g., intraperitoneal :
- (e) Skin irritation :
- (f) Eye irritation :
- (g) Short-term oral administration :
- (h) Short-term sensitizing effects :
- (i) Toxic effects of metabolites :
- (j) Metabolic studies :
- (k) Long-term toxicity including carcinogenicity :
- (l) Neurotoxicity :
- (m) Reproduction studies :
- (n) Embryotoxicity, including teratogenicity. :

- (o) Mutagenicity :
- (p) Potentiation :
- (q) Direct observations, e.g., clinical cases :
- (r) Health records, both from industry and agriculture. :
- (s) Treatment of poisoning :
- (t) First aid measure :
- (u) Supplementary treatment :
- (j) Waiting period (last application to harvesting) :

**15. Residue studies :**

- (a) Primary physical, chemical and biological data. :
- (b) Identification of residue design of analytical method :
- (c) Reliable residue data from supervised trials :
- (d) Estimations of maximum residue :
- (e) Data on further disappearance on storage, transport, etc. :
- (f) Estimation of residue level in commodity on sale :
- (g) Data on disappearance on food preparation cooking or processing :
- (h) Prediction of potential consumer intake, actual intake studies. :
- (i) Assessment of actual consumer intake :
- (j) Persistence of the product :

**16. Prediction of Environment effects :**

- (a) Fate and mobility studies of toxicant :
- (b) Method of application of pesticide :
- (c) Time of application :
- (d) Rate of application :
- (e) Scale of use (number of application (etc.) :
- (f) Climatic and geographical locality :

- (g) Volatility of product :
- (h) Water solubility :
- (i) Octanol water partition coefficient :
- (j) Absorption :
- (k) Desorption :
- (l) Degradation :
- (m) Persistence :
- (n) Effect on birds :
- (o) Effect on fish :
- (p) Effect on fish food species :
- (q) Effect on honey bee :
- (r) Degradation product in soil :
- (s) Possibilities of accumulation with stable lipophilic compound :
- (t) Effect on local aquatic species :
- (u) Effect on soil organism :
- (v) Disposal of used, condemned and surplus pesticides and pesticides containers. :
- (w) Proposal for labelling and direction for use as per pesticide rule 1985. :

**17. Packaging :**

- (a) State weight (or for liquid volume) and the sizes of package in which the products are to be marketed and for each size, the type of package, for instance i.e. 1 kg in cans with screw plug and 50 kg in iron drums. (please note that the product must be sold only in the package size and type notified to the Plant Protection Wing, Department of Agricultural Extension and for which the label is approved. :
- (b) Classification during transport :

**18. Method of analysis :**

- (a) Methods to determine the active ingredients of the product (the accuracy of the method of determination should be stated both instrumental and chemical) :
- (b) Methods to determine the amount of isomers, impurities and other by products :

**19. Labelled samples for analysis :**

- (a) Analytical reference standard 2—5 g :
- (b) Technical grade material 0.5—1.0 Kg :
- (c) Formulated product 1 kg/lit for each formulation :

**20. Registration fee :**

Taka ..... (Taka ..... thousand) deposited in Treasury Challan No. dated (original Treasury Challan enclosed) under Head of Account " 1-4331-0000-2043"

I do hereby apply for registration of the pesticide, particulars of which are given above, and hereby certify that these particulars are, to the best of my knowledge, true and correct.

**Explanation :** In this Form. "Active ingredient" means an ingredient capable in itself of preventing, destroying, repelling or mitigating insects, fungi, bacteria, nematodes viruses, rodents, weeds or other pests when used in the same manner and for the same purpose and those for which it is intended but is not antagonistic to the activity of any other active ingredient in the same formulation.

Date.....

.....  
Signature of applicant

**Notes**

**Directions for completion and submission of application. (in triplicate)**

**1. The application must be accompanied by :**

- a. General literature of the product including toxicological and efficacy data.
- b. Standard specification of technical product and formulation of the product.
- c. Statement of ingredients (active and inert materials to be enclosed separately in a sealed and confidential cover).
- d. Composition of formulation in details with percentage.

2. Certified true copy of the contract/agreement made between the manufacturer and the local agent authenticated by the competent agency of the country for import and marketing the product in Bangladesh.
3. (a) In case of renewal of an existing registration, the previous certificate of registration and  
 (b) A suitable sample of the pesticide sufficient for test and analysis (physical and chemical properties).
4. Treasury challan of Taka ..... thousand evidencing payment in the head of account: “1-4331-0000-2043” shall be submitted.
5. Submission of application in a sealed cover marked “Confidential”.

**FORM 1 (b): For Biochemical Pesticide**

(See rule 3)

**APPLICATION FOR REGISTRATION OF BIOCHEMICAL PESTICIDES<sup>1</sup>**

1. Name and address of the applicant :
  2. Name of the pesticide :
  3. Name and address of the manufacturer :
  4. Common Name/Descriptive Name :
  5. Active Ingredient
- I. Chemistry and other relevant particulars :**
- a. Type (Pheromone/Allomone/Kairomone/Synomone/Hormone/NPR/IGR/Botanical)<sup>2</sup> :
  - b. Natural or Synthetic
  - c. Identity of Natural Source :
  - d. Chemical Abstract Name :
  - e. IUPAC nomenclature :
  - f. Structural formula :
  - g. Empirical formula and molecular weight :
  - h. Manufacturer's development code number(s) :
  - i. Manufacturing Process (Attach details) :
  - j. Certified percentage (Purity %) (Attach detailed method of purity identification by GC/SP techniques) :

- k. **Physical and Chemical properties :**
- (i). Colour/Appearance :
  - (ii) Odour :
  - (iii) Refractive index :
  - (iv) Melting point :
  - (v) Decomposition point :
  - (vi) Viscosity :
  - (vii) Boiling point :
  - (viii) Vapour pressure (Figures should be given at a stated temperature preferably in the range of (20—25°C). :
  - (ix) Flash point :
  - (x) Specific gravity/Density (for liquids only) :
  - (xi) Hydrolysis rate :
  - (xii) Surface tension :
  - (xiii) Stability :
  - (xiv) Storage condition with range of temperature :
  - (xv) Solubility :
  - (xvi) Compatibility (Required only in case its use in combination with other pesticides or agrochemicals is recommended) :
  - (xvii) Photolysis :
  - (xviii) Absorption spectra, e.g., ultra-violet and infra red, etc. :
  - (xix) Any other relevant properties :
  - (xx) Acidity/Alkalinity/p<sup>H</sup> value :

**II. Biological Properties :**

- (a) Mode of action :
- (b) Degree of specificity :
- (c) Target pest (s) :
- (d) Target crop (s) :
- Dosage rate (g/acre/year of a,i.) :

**6. Technical grade material :**

- (a) **Source** : name and address of manufacturer and address where manufactured :
- (b) Physical and chemical properties :
  - (i) Colour :
  - (ii) Acidity/Alkalinity/p<sup>H</sup> value :
  - (iii) Specific gravity :
  - (iv) Viscosity :

- (v) Flash Point :
- (vi) Minimum (and maximum) active ingredient content in g/Kg or g/L :
- (vii) Identity and amount of isomers, impurities and other by products together with information on their possible range expressed in g/Kg or g/L :
- (viii) Description of starting materials, production process and potential impurities :
- (ix) Storage stability (Low and High temperature storage stability) :

**7. Formulated product:** :

- (1) Type of formulation :
- (2) Contents of active ingredient (s) g/Kg or g/L :
- (3) Content and nature (identity if possible) of other components included in the formulation, e.g. technical grade, adjuvants and inert ingredient) in g/Kg or g/L :
- (4) Physical and chemical properties :
  - (i) Identity/appearance (colour) :
  - (ii) Odour :
  - (iii) Water content/Moisture (above relevant) :
  - (iv) Specific gravity :
  - (v) Viscosity :
  - (vi) Low & High temperature storage stability (in respect to composition and physical properties related to use. :
  - (vii) Impurities :
  - (viii) Flammability :
- (a) **Liquids** : Flash point
- (b) **Solids** : A statement must be made as to whether the product is flammable
  - (ix) Acidity :
  - (x) Alkalinity :
  - (xi) pH Value :
  - (xii) Other properties may, in certain cases, need evaluation :
  - (xiii) Carrier materials :

- (xiv) Wettability (for dispersible powders) :
- (xv) Persistent foam (for formulation applied in water) :
- (xvi) Suspensibility (for dispersible powders and suspension concentrates) :
- (xvii) Particle size (for dispersible powders) :
- (xviii) Wet sieve test (for dispersible powders and suspension concentrates) :
- (xix) Dry sieve test (for granules, dusts) :
- (xx) Emulsion Stability (for emulsifiable concentrate ) :
- (xxi) Bulk density :
- (xxii) Corrosiveness (when necessary) :
- (xxiii) Flowability (for dust) :
- (xxiv) Following information for special formulations (tablet/pellets/microcapsule/ lures/traps) (must comply with standard specification–Annexure 1) :
- (a) Type
- (b) Percentage of active ingredients and other related standard specifications
- (c) Weight :
- (d) Thickness/height :
- (e) Diameter/size :
- (f) Appearance/shape :
- (g) release rate :
- (xxv) Known incompatibility with other products, e. g., pesticides, fertilizers :

**8. Toxicology Data of Technical Grade Active Ingredient (TGA) and Formulated product (FP) :**

- (a) Acute oral toxicity in rats and mice Oral toxicity and Dermal toxicity :
- (b) Acute dermal toxicity :
- (c) Acute inhalation toxicity :
- (d) Skin irritation :
- (e) Irritation to mucous membrane :

- (f) Eye irritation :
- (g) Short-term (90 days) oral feeding effect only for TGAI (1 species)<sup>3,4</sup> :
- (h) Short-term (90 days) dermal toxicity for TGAI only (1 species)<sup>3,4</sup> :
- (i) Metabolic studies in animals<sup>3,4</sup> :
- (j) Cellular immune response/Immunotoxicity<sup>3</sup> :
- (k) Reproduction studies<sup>3,4</sup> only for TGAI :
- (l) Embryotoxicity, including teratogenicity<sup>3</sup> only for TGAI. :
- (m) Mutagenicity<sup>3</sup> only for TGAI :
- (n) Long-term toxicity including carcinogenicity<sup>4</sup> :
- (p) Potentiation :
- (q) Direct observations, e.g. clinical cases :
- (r) Health records, both from industry and agriculture. :
- (s) Treatment of poisoning :
- (t) First aid measure :
- (u) Supplementary treatment :
- (v) Waiting period (last application to harvesting) for FP :
- 9. Rate of release of active ingredient :**
- 10. Bio-Efficacy of FP**
- I. Laboratory Test**
- (a) Effectiveness of Lure/dispenser manufactured from the TGAI (Effectiveness of Lure/ dispenser manufactured from the TGAI should be tested by using Wind Tunnel and should demonstrate at least 50% efficacy) :
- II. Field test**
- (a) The data on bio-efficacy based on two seasons field trials conducted following proper design and standard method under local agroclimatic conditions under the supervision of recognized national organization and presented in the form of authentic/published report. :

### III. Application

- (a) Purpose of application :
- (b) Target pest (s) :
- (c) Target crop (s) :
- (d) Time of application :
- (e) Method of application :
- (f) Rate of application (g/acre/year) :
- (g) Limitation (s) of use :

### 11. Residue studies<sup>5</sup> :

- (a) Chemical identity of residues :
- (b) Nature of residues in plants, commodity and livestock :
- (c) Reliable residue data from supervised trials :
- (d) Estimations of maximum residue :
- (e) Proposed Maximum Residue Limit (If expected concentration greatly exceed levels from naturally occurring substance) :
- (f) Estimation of residue level in commodity on sale :
- (g) Data on disappearance on food preparation cooking or processing :
- (h) Prediction of potential consumer intake, actual intake studies. :
- (i) Assessment of actual consumer intake :
- (j) Persistence of the product :

### 12. Prediction of Environmental effects :

- (a) Concentration of naturally occurring substance :
- (b) Rate of use (gm/acre/year) :
- (c) Desorption :
- (d) Degradation :
- (e) Persistence :
- (f) Effect on birds :
- (g) Effect on fish :

- (h) Effect on fish food species :
- (i) Effect on honey bee :
- (j) Degradation product in soil :
- (k) Possibilities of accumulation with stable lipophilic compound :
- (l) Effect on local aquatic species :
- (m) Effect on soil organism :
- (n) Disposal of used, condemned and surplus pesticides and pesticides containers. :
- (o) Proposal for labelling and direction for use as per pesticide rule 1985 :

**13. Packaging :**

- (a) State weight (or for liquid volume) and the sizes of package in which the products are to be marketed and for each size, the type of package, for instance i.e. 1 kg in cans with screw plug and 50 kg in iron drums. (Please note that the product must be sold only in the package size and type notified to the Plant Protection Wing, Department of Agricultural Extension and for which the label is approved. :
- (b) Classification during transport :

**14. Method of analysis :**

- (a) Methods to determine the active ingredient of the TG and FP (the accuracy of the method of determination should be stated) both instrumental and chemical :
- (b) Methods to determine the amount of isomers, impurities and other by products :

**15. Labelled samples for analysis :**

- (a) Analytical reference standard: 10—50g :
- (b) Technical grade material : 50—200g :
- (c) Formulated product 200—500g for each formulation :

**16. Registration fee :**

Taka -----) deposited in Treasury :  
Challan No. dated (original Treasury Challan enclosed)  
under Head of Account " 1- 4331-0000-2043.

<sup>1</sup> *Biochemical pesticides are naturally-occurring substances or chemical synthesized by man, which must be structurally identical to a naturally occurring chemical and that must exhibit mode of action other than direct toxicity in the target pest (for example, growth regulation, mating disruption, attraction). For a synthetic chemical to be identical in chemical structure to a naturally occurring chemical, the molecular structure of the major component of the synthetic chemical must be the same as the molecular structure of the naturally occurring analog. (For details see Enclosure I).*

<sup>2</sup> ***Pheromones** are substances emitted by individuals of one species, which modify the behaviour of others within the same species. **Allomonones** are chemicals emitted by one species, which modify the behaviour of a different species, to the benefit of the emitting species. **Kairomones** are chemicals emitted by one species, which modify the behaviour of a different species to the benefit of the receptor species. **Synomonones** are chemicals emitted by one species, which modify the behaviour of a different species to the benefit of both the species. **Hormones** are biochemical agents that are synthesized in one part of an organism and translocated to another where they have controlling, behavioural or regulating effects. **Natural plant regulators (NPR)** are chemicals produced by plants that have inhibitory, stimulatory, or other modifying effects on the same or other species of plants. Some of these are termed "plant hormones" or "phytohormones". **Insect growth regulators (IGR)** are chemicals that have toxic, inhibitory, stimulatory, or other modifying effects on the insect growth cycle. Botanical will include only Azadirachtin based formulation.  
(For details see Enclosure I)*

<sup>3</sup> *Pheromones used in solid matrix, dispenses and having low annual use rates (less than 150 gms/acre/year) can be waived of these data.*

<sup>4</sup> *Naturally occurring short-chained lepidopteran pheromones having low annual use rates (less than 150 gms/acre/year) can be waived of these data.*

<sup>5</sup> *All information are not mandatory; whatever data are available from published source will be acceptable.*

I do hereby apply for registration of the pesticide, particulars of which are given above, and hereby certify that these particulars are, to the best of my knowledge, true and correct.

**Explanation** – In this Form. "Active ingredient" means an ingredient capable in itself of preventing, destroying, repelling or mitigating insects, fungi, bacteria, nematodes viruses, rodents, weeds or other pests when used in the same manner and for the same purpose and those for which it is intended but is not antagonistic to the activity of any other active ingredient in the same formulation.

Date.....

.....

Signature of applicant

## Notes

### Directions for completion and submission of application. (in triplicate)

1. **The application must be accompanied by** : General literature of the product including toxicological and efficacy data. Standard specification of technical product and formulation of the product. Statement of ingredients (active and inert materials to be enclosed separately in a sealed and confidential cover). Composition of formulation in details with percentage.
2. Certified true copy of the contract/agreement made between the manufacturer and the local agent authenticated by the competent agency of the country for import and marketing the product in Bangladesh.
3. (a) In case of renewal of an existing registration, the previous certificate of registration; and  
(b) A suitable sample of the pesticide sufficient for test and analysis (physical and chemical properties).
4. Treasury challan of Taka ..... thousand evidencing payment in the head of account: "1-4333-0000-2043" shall be submitted.
5. Submission of application in a sealed cover marked "Confidential".

## FORM 1 (c): For Microbial Pesticides

(See rule 3)

### APPLICATION FOR REGISTRATION OF MICROBIAL PESTICIDES<sup>1</sup>

1. Name and address of the applicant :
2. Name of the pesticide :
3. Name and address of the manufacturer :
4. Common Name :
5. Technical Grade Active Agent :
- I. Systematics and other relevant particulars.* :
  - a. Type (Bacteria/Virus/Fungus/Protozoa) :
  - b. Systematic/Scientific name :
    - (i) Genus (if applicable) :
    - (ii) Species (if applicable) : :
    - (iii) Serotype (if applicable) :
    - (iv) Strain (if applicable) :
  - c. Natural occurrence/Source and Origin :
  - d. Manufacturer's development code number(s) :
  - e. Manufacturing Process (The cultures are multiplied by liquid solid fermentation. Information pertaining to user of entire mycelial mats with spores separated should be provided<sup>2</sup>) :
  - f. Specifications (Must comply with the recommended standard available from PPW for each type of pesticide) :
    - (i) Form/Appearance :
    - (ii) Moisture content :
    - (iii) pH :
    - (iv) Particle size :
    - (v) Suspensibility :
    - (vi) Miscibility :

- g. Composition :

  - (i) Delta Endotoxin content<sup>3</sup> :
  - (ii) Beta Exotoxin content<sup>3</sup> :
  - (iii) Viable spore count<sup>3</sup> :
  - (iv) Adjuvants
  - (v) Human pathogens/pathogenic contaminants :  
(Attach culture method)
  - (vi) Other microbial contaminants (not more than :  
10/gm)
  - (vii) Other unintentional ingredients, their nature :  
and identity, and quantity

- h. Test procedures and criteria used for identification, :  
morphology, biochemistry, serology/immunology<sup>3</sup>

  - (1) Morphology description, particle size, heat :  
resistant spore count<sup>3</sup>
  - (2). Immunology assays (Elisa/Dot Blot assay test)<sup>3</sup> :  
(Appendix VI)
  - (3). Routine test:<sup>3</sup> (Appendix I & IV) :

    - (i) Level of toxin by Housefly Bioassay method :  
relevant conditions
    - (ii) Potency of product by Bioassay method :

  - (4). Test methods/analysis :

    - (i) Bioassay method<sup>3</sup> (Appendix I, II & IV) :

      - LC<sub>50</sub> on target larvae and potency against :  
a reference using artificial diet or leaf disc  
method or in water for mosquito
      - Housefly Bioassay method for Beta :  
exotoxin (for Bt) and chemical contaminants

    - (ii) Dual culture for antagonistic fungi/bacteria :
    - (iii) Pathogenicity test on insect in case of :  
tomopathogenic fungi
    - (iv) Qualitative analysis<sup>2</sup>

      - (a) CFU on selective medium :
      - (b) Test for gram negative bacterial :  
contaminants
      - (c) Test for moisture content :

- (v) Test procedure/Method of analysis<sup>4</sup> :
- (a) An appropriate test procedure and criteria used for identification by Restriction Enzymes analysis test :
- (b) Method of analysis (standard counting method attached as Appendix VII should be followed) :
- (c) Biological assays (Bioassay tests by Diet Surface Contamination method against second instar host insect should be generated for determining the LC<sub>50</sub> of the formulation as against standards) (Appendix VIII). :
- (5). Viable Spore counts<sup>3</sup> (Appendix V) :
- (6). Toxin content by dot blot/Elisa assay<sup>3</sup> (Appendix VI) :
- (7). Technique for separation and purification of crystals<sup>3</sup> (Appendix III) :
- i. Shelf life claim :
- (a) Data on storage stability as per shelf lime claims; and additional two months data for six months claim, three months additional data for one year's claim at two different locations at ambient temperature along with meteorological data.<sup>2, 4</sup> :

**II. Toxicology Data<sup>3</sup> :**

- a. Single exposure studies :
- (i) Oral toxicity/Pathogenicity/Infectivity :
- (ii) Dermal toxicity/Pathogenicity/Infectivity :
- (iii) Inhalation toxicity/Pathogenicity/Infectivity :
- (iv) Primary Skin irritation :
- (v) Irritation to mucous membrane :
- (vi) Eye irritation :
- (vii) Allergy/sensitization/immuno-suppression :

### III. Bio-efficacy<sup>3</sup>

Laboratory test: LC<sub>50</sub> values for each insect species under laboratory condition generated at least at two recognized national organization :

### 6. Formulated Product (FP) :

#### I. *Systematics and other relevant particulars* :

a. Type (Bacteria/Virus/Fungus/Protozoa) :

b. Systematic/Scientific name :

(i) Genus (if applicable) :

(ii) Species (if applicable) : :

(iii) Serotype (if applicable) :

(iv) Strain (if applicable) :

c. Natural occurrence :

d. Manufacturer's development code number(s) :

e. Manufacturing Process (The cultures are multiplied by liquid solid fermentation. Information pertaining to user of entire mycelial mats with spores separated should be provided<sup>2</sup>) :

f. Specifications (Must comply with the recommended standard available from PPW for each type of pesticide) :

(i) Form/Appearance :

(ii) Moisture content :

(iii) pH :

(iv) Particle size :

(v) Suspensibility :

(vi) Miscibility :

g. Composition :

(i) Delta Endotoxin content<sup>3</sup> :

(ii) Beta Exotoxin content<sup>3</sup> :

(iii) Viable spore count<sup>3</sup> :

- (iv) Adjuvants :
  - (v) Human pathogens/pathogenic contaminants :  
(Attach culture method)
  - (vi) Other microbial contaminants (not more than 10/gm) :
  - (vii) Other unintentional ingredients, their nature and identity, and quantity :
- h. Test procedures and criteria used for identification, morphology, biochemistry, serology/immunology<sup>3</sup> :
- (1) Morphology description, particle size, heat resistant spore count<sup>3</sup> :
  - (2). Immunology assays (Elisa/Dot Blot assay test)<sup>3</sup> :
  - (3). Routine test: <sup>3</sup> :
  - (i) Level of toxin by Housefly Bioassay method and relevant conditions :
  - (ii) Potency of product by Bioassay method :
  - (4). Test methods/analysis :
  - (i) Bioassay method<sup>3</sup> :
  - LC<sub>50</sub> on target larvae and potency against a reference using artificial diet or leaf disc method or in water for mosquito :
  - Housefly Bioassay method for Beta exotoxin (for Bt) and chemical contaminants :
  - (ii) Dual culture for antagonistic fungi/bacteria :
  - (iii) Pathogenicity test on insect in case of entomopathogenic fungi :
  - (iv) Qualitative analysis<sup>2</sup> :
  - (a) CFU on selective medium :
  - (b) Test for gram negative bacterial contaminants :
  - (c) Test for moisture content :

- (v) Test procedure/Method of analysis<sup>4</sup> :
- (a) An appropriate test procedure and criteria used for identification by Restriction Enzymes analysis test
  - (b) Method of analysis (standard counting : method attached as Appendix 1 should be followed)
  - (c) Biological assays (Bioassay tests by Diet : Surface Contamination method against second instar host insect should be generated for determining the LC<sub>50</sub> of the formulation as against standards).
- (5) Viable Spore counts<sup>3</sup> :
- (6) Toxin content by dot blot/Elisa assay<sup>3</sup> :
- (7) Technique for separation and purification of crystals<sup>3</sup> :
- i. Shelf life claim :
- (a) Data on storage stability as per shelf life claims; and additional two months data for six months claim, three months additional data for one year's claim at two different locations at ambient temperature along with meteorological data.<sup>2,4</sup>
- II. *Toxicology Data of Formulated Product (FP) and Primary Culture* :
- a. Single exposure studies (for formulations only) :
  - (i) Oral toxicity/Pathogenicity/Infectivity :
    - (ii) Dermal toxicity/Pathogenicity/Infectivity :
    - (iii) Intravenous toxicity/Pathogenicity/Infectivity<sup>2,4</sup> :
    - (iv) Inhalation toxicity/Pathogenicity/Infectivity :
    - (v) Primary Skin irritation :
    - (vi) Irritation to mucous membrane :
    - (vii) Primary Eye irritation :
    - (viii) Allergy/sensitization/immuno-suppression :

- (ix) Pulmonary toxicity/Pathogenicity/Infectivity :  
Infectivity<sup>2,4</sup> (Intra-tracheal preferred)<sup>2,4</sup>
- (x) Human safety records (Effect or lack of effects)<sup>2,4</sup> :
- (xi) Cell culture<sup>2,4</sup> (Appendix IX) :
- b. Eco-toxicity (for formulations only)<sup>3</sup> :
- (i) Toxicity to birds :
- (ii) Toxicity to fish :
- (iii) Toxicity to honey bee :
- (iv) Toxicity to silkworm :
- c. For Primary Culture<sup>2,4</sup> :
- (i) Single dose (rats and mouse) :
- (ii) Single dose pulmonary :
- (iii) Single dose intravenous :
- (iv) Cell culture<sup>4</sup> (Appendix IX) :
- (v) Human safety records :
- d. Environmental Safety Testing (for formulations :  
only)<sup>2,4</sup>
- (i) Non-target vertebrates (information on infection :  
and pathogenicity in mammals from mammalian  
safety testing)
- (ii) Birds (information on infection and :  
pathogenicity due to single dose-oral in  
bobwhite, quail, Japanese quail, mallard/  
pigeon and chicken)
- (iii) Fresh water fish (information on infection and :  
pathogenicity due to single dose-oral in rainbow  
trout, blue gill sunfish, Tialpia)
- (iv) Terrestrial invertebrates (Information on :  
mortality of honey bee and silkworm) (not  
required for *Trichoderma* and *Pseudomonas*)
- (v) Information on mortality of earthworm or :  
organism of similar habitat and nature ((not  
required for *Trichoderma* and *Pseudomonas*)

- III. Bio-efficacy** :
- a. Laboratory test: LC<sub>50</sub> values for each insect species under laboratory condition generated at least at two recognized national organization<sup>3</sup> :
  - b. Field test: :
    - (i) Efficacy of field trials conducted at least in two seasons under supervision of recognized national research organizations and presented in the form of authentic/published report. :
    - (ii) Phyto-toxicity data :  
Effect on non-target organisms (predators/parasites) at least in two seasons :
- 7. Packaging and Labeling** :
- (a) State weight (or for liquid volume) and the sizes of package in which the products are to be marketed and for each size, the type of package, for instance *i.e.* 1 kg in cans with screw plug and 50 kg in iron drums. (Please note that the product must be sold only in the package size and type notified to the Plant Protection Wing, Department of Agricultural Extension and for which the label is approved. :
  - (b) Classification during transport :
- 8. Methods (cite methods mentioned above or alternate authentic methods best fit)**
- (1) Culture method for human pathogens<sup>3</sup> :
  - (2) Procedure for morphology description, particle size, heat resistant spore count<sup>3</sup> :
  - (3) Immunology assays (Elisa/Dot Blot assay test)<sup>3</sup> :
  - (4) Routine test<sup>3</sup>: :
    - (i) Housefly Bioassay method for Level of toxin :
    - (ii) Bioassay method for Potency of product :

- (5) Method of analysis<sup>3</sup> :
- (i) Bioassay method :
- LC<sub>50</sub> on target larvae and potency against a reference using artificial diet or leaf disc method or in water for mosquito :
  - Housefly Bioassay method for Beta exotoxin and chemical contaminant :
- (6) Method for Viable Spore counts :
- (7). Dot blot/Elisa assay for Toxin content<sup>3</sup> :
- (8) Technique for separation and purification of crystals<sup>3</sup> :
- (9) Dual culture for antagonistic fungi/bacteria :
- (10) Pathogenicity test on insect in case of entomopathogenic fungi :
- (11) Qualitative analysis<sup>2</sup>
- (a) CFU on selective medium :
  - (b) Test for gram negative bacterial contaminants :
  - (c) Test for moisture content :
9. **Labelled samples for analysis** :
- (a) Primary reference standard 0.5 to 1g :
  - (b) Technical grade material 100 to 200g :
  - (c) Formulated product 200 to 500 g or equivalent for each formulation :
10. **Registration fee** :
- Taka ..... (Taka ..... thousand) deposited in Treasury Challan No. dated (Original Treasury Challan enclosed) under Head of Account " 1-4331-0000- 2043 :

<sup>1</sup> Microbial pesticides consist of a naturally occurring microorganism (*e.g.*, a bacterium, fungus, virus or protozoan) as the active ingredient. In case of bacterium and fungus also mention if it is antagonistic and in case of fungus also mention if it is entomogenous

<sup>2</sup>Applicable only for Antagonistic bacteria/fungi and entomogenous fungi.

<sup>3</sup> For *Bacillus spp.*

<sup>4</sup> Applicable for Virus (NPV, BV and GV)

I do hereby apply for registration of the pesticide, particulars of which are given above, and hereby certify that these particulars are, to the best of my knowledge, true and correct.

*Explanation*—In this Form. “Active agent” means an organism capable in itself of preventing, destroying, repelling or mitigating insects, fungi, bacteria, nematodes viruses, rodents, weeds or other pests when used in the same manner and for the same purpose and those for which it is intended but is not antagonistic to the activity of any other active ingredient in the same formulation.

Date.....

.....

Signature of applicant

### Notes

#### Directions for completion and submission of application. (in triplicate)

1. The application must be accompanied by :  
General literature of the product including toxicological and efficacy data. Standard specification of technical product and formulation of the product. Statement of ingredients (active and inert materials to be enclosed separately in a sealed and confidential cover). Composition of formulation in details with percentage.
2. Certified true copy of the contract/agreement made between the manufacturer and the local agent authenticated by the competent agency of the country for import and marketing the product in Bangladesh.
3. (a) In case of renewal of an existing registration, the previous certificate of registration; and  
(b) A suitable sample of the pesticide sufficient for test and analysis (physical and chemical properties).
4. Treasury challan of Taka ..... thousand evidencing payment in the head of account: “1-4333-0000-2043” shall be submitted.
5. Submission of application in a sealed cover marked “Confidential”.

#### (২৬) FORM 2 এ

item 5. এর পরিবর্তে নিম্নরূপ item 5. এবং item 6. প্রতিস্থাপিত হইবে, যথা ঃ—

5. Name and address of the manufacturer

(a) Formulated product :

(b) Technical grade material :

6. Name and address of the local manufacturer:

*Dhaka:*

*The.....201*

*Signature of the Registration Authority  
Seal*

#### Conditions:

The registration of a brand of pesticide shall be effective from the date of its registration until the thirtieth day of June of the third year following the year (fiscal) of registration

- (২৭) **FORM 3** এর item 5 এ “registration” শব্দের পরে “(Except guarantee or ingredients)” শব্দগুলি ও বন্ধনী সংযোজিত হইবে।
- (২৮) **FORM 4** এর item (b) এর পর নিম্নরূপ নূতন item (b) প্রতিস্থাপিত হইবে, যথা ঃ—  
 (b) certify that except guarantee and ingredients the following change(s) from the original registration have been accepted”;  
 (খ) “-----১৯৮----- “-----20-----”  
 ডটগুলি ও সংখ্যাটি প্রতিস্থাপিত হইবে।
- (২৯) **Form 5** এর item 10 এ “৪৫-কৃষিপ্রাপ্তি-অনিষ্টকারী পোকা-মাকড়, রোগ-বালাই ব্যবস্থাপনা ও বিবিধ খাতে আয়” শব্দসমূহের পরিবর্তে “1-4331-0000-2043” শব্দসমূহ প্রতিস্থাপিত হইবে।
- (৩০) **FORM 6** এর—  
 (ক) item 1 এর “ Name of the pesticide (s) (each pesticide to be separately specified) ” শব্দসমূহের পরিবর্তে নিম্নরূপ শব্দগুলি, বন্ধনীগুলি এবং বন্ধনীসহ বর্ণটি এবং কোলনগুলি প্রতিস্থাপিত হইবে, যথা ঃ—  
 “Name of the pesticide(s) (each pesticide to be separately specified);”  
 Brand name:  
 Common name.”  
 (খ) item 5 এ “৪৫-কৃষিপ্রাপ্তি-অনিষ্টকারী পোকা-মাকড়, রোগ-বালাই ব্যবস্থাপনা ও বিবিধ খাতে আয়” শব্দসমূহের পরিবর্তে “1-4331-0000-2043” শব্দসমূহ প্রতিস্থাপিত হইবে।
- (৩১) **FORM 7** এর item 9 এ “৪৫-কৃষিপ্রাপ্তি-অনিষ্টকারী পোকা-মাকড়, রোগ-বালাই ব্যবস্থাপনা ও বিবিধ খাতে আয়” শব্দসমূহের পরিবর্তে “1-4331-0000-2043” শব্দসমূহ প্রতিস্থাপিত হইবে।
- (৩২) **FORM 8** এর item 7 এ “৪৫-কৃষিপ্রাপ্তি-অনিষ্টকারী পোকা-মাকড়, রোগ-বালাই ব্যবস্থাপনা ও বিবিধ খাতে আয়” শব্দসমূহের পরিবর্তে “1-4331-0000-2043” শব্দসমূহ প্রতিস্থাপিত হইবে।
- (৩৩) **FORM 9** এর—  
 (ক) item 2 এ “manufacturer/formulators” শব্দসমূহের পরিবর্তে “manufacturer” শব্দটি প্রতিস্থাপিত হইবে।  
 (খ) item 5 এ “৪৫-কৃষিপ্রাপ্তি-অনিষ্টকারী পোকা-মাকড়, রোগ-বালাই ব্যবস্থাপনা ও বিবিধ খাতে আয়” শব্দসমূহের পরিবর্তে “1-4331-0000-2043” শব্দসমূহ প্রতিস্থাপিত হইবে।
- (৩৪) **FORM 10** এর item10 এ “৪৫-কৃষিপ্রাপ্তি-অনিষ্টকারী পোকা-মাকড়, রোগ-বালাই ব্যবস্থাপনা ও বিবিধ খাতে আয়” শব্দসমূহের পরিবর্তে “1-4331-0000-2043” শব্দসমূহ প্রতিস্থাপিত হইবে।
- (৩৫) **FORM 11** এর note 2 এ “৪৫-কৃষিপ্রাপ্তি-অনিষ্টকারী পোকা-মাকড়, রোগ-বালাই ব্যবস্থাপনা ও বিবিধ খাতে আয়” শব্দসমূহের পরিবর্তে “1-4331-0000-2043” শব্দসমূহ প্রতিস্থাপিত হইবে।
- (৩৬) **FORM 12** এর পর নূতন **FORM 12 (a)** প্রতিস্থাপিত হইবে।

FORM 12 (a)

[See rule 12(2)]

**Licence to import pesticide (s) (Technical grade material)**

1. M/s.....is hereby granted licence to import the following technical grade material  
(a) Name of technical to the imported  
(b) Brand name of pesticide(s) with registration No.
2. Name of manufacturer of technical grade material
3. Quantities to be imported :
4. The licence shall be in force for a period of two years from the date of issue.

Licence No.....

Date.....

*Licensing Authority.*

*Seal.*

**Conditions**

1. The licence shall be displayed in a prominent place of the office premises.
2. The licensee shall comply with the provision of the Pesticide Ordinance, 1971 and the rules made there under for the time being in force, provided that the condition shall not apply to import any pesticide for experimental or research purposes.
3. Renewal.

(৩৭) FORM 19 এর পর নিরূপ নূতন Enclosure সংযোজিত হইবে, যথা ঃ—

ENCLOSURE

**DEFINITIONS, SALIENT FEATURES AND CLASSIFICATION OF BIOPESTICIDES, AND THEIR DATA REQUIREMENTS FOR REGISTRATION**

**1.0 DEFINITION OF BIOPESTICIDE:**

According to EPA, biopesticides are certain types of pesticides derived from such natural materials as animals, plants, bacteria, and certain minerals. According to FAO, biopesticides are naturally occurring substances or their synthetic analogues or genetically modified agents that are distinguished from conventional chemical pesticides by their unique mode of action, low use volume, and target species specificity.

## 2.0 CLASSIFICATION OF BIOPESTICIDES

Biopesticides fall into following three major classes:

- (i) Biochemical pesticides
- (ii) Microbial pesticides
- (iii) Plant-incorporated protectants (PIPs)

### 2.1 Biochemical pesticides :

Biochemical pesticides are naturally occurring substances that control pests by a mode of action other than direct toxicity in the target pest. A chemical must meet the following two criteria in order to be classified as a biochemical pesticide and to be subject to the data requirements for this class of compounds:

- The chemical must exhibit a mode of action other than direct toxicity in the target pest (*e.g.* growth regulation, mating disruption, attraction). Pesticides such as **strychnine, rotenone, nicotine, and pyrethrin**, which exhibit direct toxicity, are not considered biochemical pesticides; and
- A biochemical pesticide must be naturally occurring, or if the chemical is synthesized by man, then it must be structurally identical to a naturally occurring chemical. For a synthetic chemical to be identical in chemical structure to a naturally occurring chemical, the molecular structure of the major component of the synthetic chemical must be the same as the molecular structure of the naturally occurring analogy. Minor differences between the stereochemical isomer ratios (found in the naturally occurring compound compared to the synthetic compound) will normally not rule out a chemical being classified as a biochemical pest control agent unless an isomer is found to have significantly different toxicological properties than another isomer.

There are situations where a candidate chemical possesses many characteristics of a biological pesticide, but does not technically meet the two criteria established for defining biochemical pesticides. The Sub-technical Committee formed by PTAC should evaluate such chemicals on a case-by-case basis to determine whether it should be classified as a biochemical pesticide or a conventional pesticide. For example, a case-by-case evaluation would be required if the exact molecular structure of the naturally occurring compound is unknown, or if the synthetic chemical is closely related to but not identical in structure to the naturally occurring compound, or if the mode of action is different in the target, compared to non-target organisms.

In these case-by-case situations, the criteria to be used to determine whether the chemical is a biochemical pesticide, include:

- the chemical and toxicological significance of the differences in chemical structure;

- the mode of action of the synthetic analog in the target species as compared to the mode of action of the naturally occurring compound;
- differences in toxicity between the naturally occurring chemical and the synthetic analog.

### **Sub-classes of Biochemical pesticides:**

Biochemical pesticides fall into four general biologically functional classes such as Semiochemicals, Hormones, Natural plant regulators and insect growth regulators, and Enzymes. Brief description of each subclass is given below:

#### **2.1.1 Semiochemicals**

Semiochemicals (SC) are chemicals emitted by plants, animals, and other organisms, and synthetic analogues of such substances that evoke a behavioural or physiological response in individuals of the same or other species. They include pheromones and allelochemicals. Pheromones are substances emitted by individuals of one species, which modify the behaviour of others within the same species. Allelochemicals are semiochemicals produced by individuals of one species that modify the behaviour of individuals of a different species. Allelochemicals include allomones, kairomones and synomones. Allomones are chemicals emitted by one species, which modify the behaviour of a different species, to the benefit of the emitting species. Kairomones are chemicals emitted by one species, which modify the behaviour of a different species to the benefit of the receptor species. Synomones are chemicals emitted by one species, which modify the behaviour of a different species to the benefit of both the species.

#### **2.1.2 Hormones**

Hormones are biochemical agents that are synthesized in one part of an organism and translocated to another where they have controlling, behavioural or regulating effects.

#### **2.1.3 Natural plant regulators and insect growth regulators**

Natural plant regulators are chemicals produced by plants that have inhibitory, stimulatory, or other modifying effects on the same or other species of plants. Some of these are termed "plant hormones" or "phytohormones". Insect growth regulators are chemicals that have toxic, inhibitory, stimulatory, or other modifying effects on the insect growth cycle.

#### **2.1.4 Enzymes**

Enzymes are defined as protein molecules that are the instruments for expression of gene action and that catalyze chemical reactions.

### 2.1.5 Botanicals

Although not covered by FAO definition, Azadirachtin, a naturally occurring component of Neem, which controls a number of pests through non-toxic mechanism of action such as molting disruption, antifeedance, desiccation etc., may be considered as biochemical pesticide.

### 2.2 Microbial pesticides

Microbial pesticides consist of a microorganism (e.g., a bacterium, fungus, virus or protozoan) as the active ingredient. The microbial pesticides include naturally occurring agents such as bacteria, fungi, viruses, and protozoa, or genetically modified such microorganisms.

### 2.3 Plant-incorporated protectants (PIPs)

Plant-incorporated Protectants (PIPs) are pesticidal substances that plants produce from genetic material that has been added to the plant. For example, scientists can take the gene for the Bt pesticidal protein, and introduce the gene into the plant's own genetic material. Then the plant, instead of the Bt bacterium, manufactures the substance that destroys the pest. In this case the protein and its genetic material, but not the plant itself, are to be regulated. PIPs will not be considered at present because GMOs are not still covered under national policy.

(৪৩) Enclosure এর পর নিম্নরূপ নতুন Annexures সংযোজিত হইবে, যথা ঃ—

## ANNEXURES

### Annexure 1

#### SPECIFICATIONS FOR PHEROMONE TRAPS AND LURES

The pheromone trap and lure should comply with the following specifications or specifications mentioned in the application as per bio-efficacy test:

1. **Funnel shaped or any other standard trap** : Funnel shaped trap generally used for trapping the moths of *Helicoverpa armigera*, *Spodoptera litura*, *Earias* spp. etc. or any other standard type developed for the purpose.

(I) **Colour** : Any colour other than Black

(II) **Structure** : The funnel trap may have three parts (1) canopy (2) tunnel shaped "trap base" and (3) a collection device. Or, the standard trap having the requisite parts for effective use.

(1) Canopy Dia: 120 -160 mm  
Thickness: 1.0 -3.0mm  
(There should be provision for fixing the canopy to the "trap base" and also the (pheromone lure)

- (2) Trap base :
- Dia of the mouth : 75-120mm
  - Height of funnel : 45-190 mm
  - Dia of the bottom hole: 20-30 mm
  - Should possess a "L" or "T" shaped handle or any other device by which the "trap" may be fixed to the support.
  - The "Trap base" may be provided with 2 to 4 stalks for fixing the canopy to the "trap base". The canopy should be firmly rest on stalks so that the canopy is not dislodged due to wind.
- (3) **Collection device** : It should be made of polythene or any other suitable material. It should withstand wind, temperature and rain water.
- Should be fixed to the "trap base" in such a way that the device remains attached to the trap under field condition.

2. Sticky trap (for pink bollworm etc.):
- Corrugated DVC, plastic laminated cardboard, tin or any other suitable material that should be water-proof.
  - The sticky glue should be non-drying.
  - The outer surface of trap should be water-proof.
  - The colour may be except black.
  - There should be provision for fixing the trap for support.
3. Fly trap (For fruit/vegetable flies) :
- Material construction as described in sticky/funnel trap.
  - Any colour except black.
  - Should withstand rainfall, heat/temperature and wind.
  - Should be structured in such a way that the trap is escape proof.

**Specification of Lures:**

1. Lure made of sulphur free rubber/polypropylene/PVC impregnated with specific pheromone blends.
2. Field efficacy should be minimum for 15 days after application.
3. Impregnated lures should be packed singly in individual tri-laminated pouches with 30 MI Aluminum foil.
4. Shelf-life of Lure in original pack should be minimum 6 months at room temperature.
5. Lures should attract target insect species only, with 50% insect attractancy by pheromone/lure/dispenser by using wind tunnel method.

#### Other specifications of Semiochemicals:

- For potential effects on non-target insects (predators, parasites, honeybee/pollinators), a discussion of available information may be sufficient.
- Aquatic testing will not be required for fixed point dispensers applied over land.
- Aquatic invertebrate and fish toxicity data are required for direct application to aquatic sites

#### Annexure II

##### SPECIFICATION FOR ANTAGONISTIC BACTERIA/FUNGI AND ENTOMOGENOUS FUNGI

1. **CFU counts :** *Trichoderma* 2x10<sup>6</sup> CFU/ml or g  
Entomopathogenic fungi 1x10<sup>9</sup> CFU/ml or g
2. **Contaminants :** *Salmonella*, *Shigella* or *Vibro* should be absent. Other microbial contaminants should not exceed 1X10<sup>4</sup> count/ml or g
3. **Method of analysis :**
  - (a) CFU counts by serial dilution and examination under phase contrast microscope
  - (b) Plating for contaminants on specific media
  - (c) Antagonistic capability on target microbe by bioassay on plates or
  - (d) Entomopathogenic capability on target insect by bioassays.
4. An undertaking should be submitted that the strain is indigenous, naturally occurring and not exotic and not genetically modified.

#### Annexure III

##### SPECIFICATIONS FOR BACULOVIRUS

1. **Viral Unit :** NPV-1x10<sup>9</sup> POB/ml or gm  
1x10<sup>8</sup> POB/ml or gm  
GV-5x10<sup>9</sup> Capsules/ml or g  
(POB - Polyhedral occlusion body)
2. **Contaminations :** *Salmonella*, *Shigella* or *Vibro* should be absent. Other microbial contaminants should not exceed 1X10<sup>4</sup> count/ml or g
3. Identification of *Baculovirus* by restriction enzyme analysis and Southern blot.

4. An undertaking should be submitted that the strain is indigenous, naturally occurring and not exotic and not genetically modified.
5. **Method of analysis :**  
 Counting for POB /Capsule as per Appendix-I  
**Viral Unit :** NPV- $1 \times 10^9$  POB/ml or gm  
 $1 \times 10^8$  POB/ml or gm  
 GV- $5 \times 10^9$  Capsules/ml or g

**Note:**

1. In case of NPVS, POB count should be taken with haemocytometer and phase contrast microscope. In case of GVs shallow depth (0.01mm) counting chamber under dark field illumination will be used.
2. **Biological assay:** Results of bio-efficacy tests by diet surface contamination method against second instars target should be generated for determining the LC<sub>50</sub> of the formulation as against Standards as per enclosed procedure (Appendix II)
3. Plating for contaminants on specific media

(৪৩) Annexure এর পর নিরূপ নূতন Appendixes সংযোজিত হইবে, যথা ঃ—

## APPENDICES

### Appendix I

#### BIOASSAY METHOD FOR BACILLUS

The following procedure (or any other authentic alternate procedure) should be carried out:

- (i) **Test insects:** 2-3 instars larvae of target insects
- (ii) **Procedure:**

1 gm of Bacillus preparation is mixed with 40 ml. of distilled water and blended at 12000 rpm for one minute. Dilution will depend upon the nature of test sample or standard preparation. 10 gm. of artificial diet/9.5ml tap water and 0.5 ml of diluted sample are mixed thoroughly. The diet/ tap water incorporated sample food, the leaf discs of uniform size are dipped for 30 seconds in different dilutions of *Bacillus* and dried under fan. Thirty larvae (10 larvae X 3 dishes) are used for each dilution of the sample or standard preparation. The larvae are incubated for 1-3 days test period. Mortalities recorded in 3-5 dilutions are recorded and plotted on log-probability paper. If more than 3 out of control larvae die, the results are discarded.

(iii) **Calculation of results :**

The potency of the sample is calculated by the following formula :

Potency of sample = LC 50 of standard (mg/ml) X IU /mg of standard  
LC 50 of sample (mg/ml)

- (iv) Each registrant should prepare a "Self Reference" and should deposit it with the Registering authority. Each self-reference will be expressed as IU/mg using International Standard.

## Appendix II

### **Blot assay of *Bacillus thuringiensis* (B.t) toxin protein as alternate of Bioassay (or Follow any other authentic alternate method)**

- (1) B.T grown till sporulation in shake flask or in fermenter vessel and let the cells lyse and release spore/crystals into the medium.
- (2) Cells are harvested by centrifugation at 10k for 15 minutes.
- (3) Wash the pellet with 1M NaCl to remove the B.T. associated seine/ metallo proteases and washed twice with sterile distilled water.
- (4) Pellet re-suspended in 50 MM NaOH to solublize the toxin protein for 2 hours at R.T. with slow shaking and centrifuged again at 10K for 15 Minutes.
- (5) Supernatant was adjusted to P<sup>H</sup> 8.0 with the HCl P<sup>H</sup> 8.0.
- (6) Protein contents estimated by Lowry's protocol.
- (7) To fold serial dilutions of test protein were made in PBS and known amount at protein applying on NCP using S&S or Biorad Dot Blot manifold apparatus and applying water vacuum for 30 minutes.
- (8) NCP was carefully removed from Dot Blot set and soaked in excess of 3% Skim milk in PBS for blocking the remaining acetic sites on NCP for 2-3 hours at R.T/O/N at 4<sup>0</sup>C.
- (9) Wash the NCP with excess PBS with 0.01% Tween 20.3-4 times and then finally with PBS.
- (10) Polyclonal antiserum raised against total crystal protein was suitably diluted in PBS and added to the "seal a meal" containing NCP and incubated for 1-2 hours with shaking.
- (11) Remove the NCP from the bag and wash several times (as in step 9).
- (12) Anti-rabbit antibodies conjugated with HRPO/Alkaline Phosphate was diluted as per the suppliers instruction and incubated NCP (as in step 10).
- (13) Wash as in step 11

14. For HRPO :

(a) Diaminobenzeden (4mg/10ml PBS/4-Chloro-1-Naphthol (4ma/10ml 20% Alcohol) were dissolved and 10 ml of 30% of H<sub>2</sub>O<sub>2</sub> per 10 ul substrate solution was added and colour reaction developed in dark for 5-10 mins (DAB gives brick red colour. 40N gives blue colour).

(b) For Alkaline Phosphatase Buffer:  
Alkaline Phosphatase Buffer:

1M Tris pH 8.8	-10 ml/
4M NaCl	-2.5ml/make up 100 ml
1M MgCl <sub>2</sub>	-2 - 0.5ml/

For 10 ml of above buffer add NBT-66 µl and BCIP-33 µl and develop and colour reaction

(15) Stop the reaction by removing the substrate and washing with PBS

(16) Keep on filter paper and dry.

### DEFFERENT PROTEIN CONCENTRATION

10µg 5µg 2.5µg 512.5ng 256.25ng 128ng 64ng 32ng 16ng 8ng 4ng  
of different samples

#### Determination of cell dry weight

- Take a known volume of Bacterial culture spin down at 4R for min.
- Wash the Pellet in minimal distilled water.
- Transfer to a pre weighed container.
- Incubate at 80 C for 16-18 hours till become dry and weight becomes constant.

### Appendix-III

#### **PURIFICATION OF CRYSTALS BY GELATIN METHOD (OR FOLLOW ANY AUTHENTIC METHOD)**

- Centrifuge the sporulated material and wash pallet twice with 1M NaCl.
- Add 200 ml. of 0.5% Gelatin, stir and remove all froth completely.
- Dilute with sterile water and centrifuge.

- Take debris and stir with 20 ml. of 1.5 M sucrose. Further add 50 ml of 1.5 M sucrose.
- Stir and centrifuge at 3000RPM for 2 hours.
- Remove supernatant and purified crystals are harvested.

#### Appendix IV

#### BETA-EXOTOXIN DETERMINATION BY HOUSE FLY BIOASSAY METHOD (OR FOLLOW ANY OTHER AUTHENTIC ALTERNATE METHOD).

Fly Assay Diet condition		Laboratory
Agar-	16g	Temp. 25 C +2C
Milk powder	100g	R.H. +70%
Yeast	100g	Test Insect -2 days
	old Hot	
Methyl Paraben - 2.1 g		fly larvae.
Water-	1000ml	
		No. of replications = 2

#### Procedure:

- 1g sample thoroughly mixed with 9ml. of sterile saline. This solution is heat treated at 65<sup>0</sup>C (water bath) for 45 minutes and incubate at rotary shaker for 2hrs. at room temp.
- Then centrifuge this sample at 12,000 RPM for 10minutes.
- This suspension is serially diluted (1:10) to 10 dilutions.
- Liquid diet 200g for each replicate is placed in trays/beakers.
- 5ml. of heat-treated culture supernatant (10<sup>-6</sup>) is poured on diet. Let it solidify at room temp. For control, use 5 ml. of sterile water :
- 2 days old House fly larvae (50) in each replicate i.e. two replicate each for sample and control & cover with wire mesh/ clot.
- Incubate the trays at 25<sup>0</sup> C + 2<sup>0</sup>C till emergence.
- After 24 hrs. just put 5 g wheat bran in each tray on the top (On 8th to 10th day). On adult emergence freeze the trays for 2 hrs. to count the adults and % mortality may be calculated as:—  
Mortality + (100—Number of Normal Adults)

**DETERMINATION OF HEAT RESISTANT VIABLE SPORE COUNT OF BACILLUS SPP. (OR FOLLOW ANY OTHER AUTHENTIC ALTERNATE METHOD) :**

**Materials required:**

- (i) Beaker/flasks
- (ii) Sterile Water
- (iii) Test Tubes
- (iv) Micropipettes
- (v) Water bath
- (vi) Petri plates
- (vii) Nutrient Agar
- (viii) p<sup>H</sup> meter

**Method:**

- (i) Weight 1g or 1ml of the Bt formulation.
- (ii) Transfer it in a sterile 250 ml corneal flask with 100 ml sterile water.
- (iii) Mix it gently to form a uniform suspension.
- (iv) Heat this material in a preheated water bath at 80°C for 15 minutes ensure that the vegetable cells of BT and all other microorganisms are killed except the Bt spores.
- (v) Add 9 ml of sterile water in each in 10 sterile test tubes number form 1 to 10.
- (vi) Add 1 ml of heat-treated Bt suspension to test tube no. 1
- (vii) Shake well and transfer 1ml of the suspension from test tube 1 to be labeled 2.
- (viii) Repeat the procedure till the last test tube to give the dilution of 1/100 1/1000, 1/10000 i.e. 10<sup>1</sup> , 10<sup>2</sup>, 10<sup>3</sup> ..... 10<sup>10</sup> and the corresponding dilute factor ins 10, 100, 1000 ..... respectively.
- (ix) Dispense 50ml of diluted sample suspension from 5th to 10th dilute in triplicate in the plates with 15-20 ml Nutrient Agar medium Nutrient Agar plates should be prepared the previous day and must observed for any possible contamination.
- (x) Spread the sample suspension on the agar medium thoroughly with glass spreader.
- (xi) Incubate the plates at 30°C for 24 hours and count the number of colonies.

**Calculation:**

No. of viable spores/gm or ml. = Nx Dx 2x10<sup>3</sup>

N—no. of colonies in plate (Average of three plates)

D—Dilution factor

**QUANTIFICATION OF BT ENDOTOXIN USING ELISA TECHNIQUE (OR FOLLOW ANY OTHER AUTHENTIC ALTERNATE METHOD):**

## 1. Material required:

Micropipette            1000 µl ,                            20µl,                            20µl.  
 Microtips  
 Microtitre Plates  
 Measuring Cylinder  
 Electronic balance  
 Beaker/Flask  
 Petridish  
 Tissue paper or Blotting Paper  
 Primary antisera (Antibody raised in rabbit against *Bacillus* Spp. antigen (crystal proteins)  
 Secondary antibody (Goat-anti rabbit 1gG - aP conjugate)  
 ELISA Reader with 405 nm filter.  
 P<sup>H</sup> meter

## 2. Reagents:

Phosphate Buffered saline (PBS), p<sup>H</sup> 7.4 95 X conc.) :

NaCl                            40.0 g

K<sub>2</sub>HPO<sub>4</sub>                        1.4g

Na<sub>2</sub> HPO<sub>4</sub> 12 H<sub>2</sub>O        14.5g

KCL                            1.0g

Make up to 1 litre and stored at 4°C

Make it 100 mM, take 200 ml of PBS and make 1 litre with water.

Blocking solution:

Skimmed Milk Powder 3% in PBS

PBST

PBS (5x) 200ml

10% Tween 20 5 ml

Make up to 1 Litre.

Coating Buffer:

Na Co                        1.59g

NaHCo                      2.93 g

Make up to 1 litre

Substrate buffer for Alkaline Phosphatase: (Prepare freshly)

Diethanolamine            97 ml

Water                        800 ml

Adjust the pH to 9.8 with HCL

Make up to 1 Litre.

Substrate for Alkaline Phosphatase

NitroPhenyl Phosphate (NPP) 0.5mg/ml in substrate buffer.

### 3. Method

#### Preparation of antigens:

- (i) Weigh 1mg of biopesticides and add 1ml of 100 mM Sodium Carbonate (P<sup>H</sup> 10)
- (ii) Incubate for 2 hrs at 37°C at 100 rph in an incubator shaker.
- (iii) Make two fold dilution of the test protein and the pure toxin protein separately in different rows.

#### Two fold dilution making:

- (i) Add 100 µl of 1000 mM sodium carbonate buffer in Columns 4 to 10 microtitre plate.
- (ii) Add 200 µl (containing 16 µg) of the pure crystal toxin in column 3.
- (iii) Add 100 µl of aliquots from column 3 to column 4 and mix well by gentle pipetting.
- (iv) Similarly do from 4 to 5, 5 to 6 ..... 9 to 10.
- (v) Discard 100 µl from 10 .
- (vi) Coat the test antigens in sodium carbonate buffer and incubate the plate overnight at 4°C
- (vii) Use 2 to 3 replications for each sample.
- (viii) Record the sample data in the record chart.

#### **ALLOW THE ELISA PLATE TO DRY AT ANY STAGE**

Remove the solutions in the ELISA Plate by inverting it and gentle tapping on a tissue paper or blotting paper.

Wash the microtitre ELISA plate once with 150 µl of PBS

Add the Blocking solution to each well till the brim.

Incubate the plate at 37°C for 1 hr.

Add 100 µl of Primary antibody (1:1000) dilution in PBS to each well.

Incubate the plate at 37°C for 1 hr.

Wash the microtitre ELISA plate twice with PBS:

Add 100 µl of Secondary antibody conjugate (1:2000) dilution in PBS to each well.

(Secondary Antibody is Goat - anti Rabbit 1gG-AP conjugate)

Incubate the plate at 37°C for 1 hr.

Wash the microtitre ELISA plate thrice with PBST.

Wash the Microtitre ELISA plate once with the substrate buffer.

Add 100 µl of substrate solution to each well.

Incubate the plate for 15 to 30 minutes at room temperature until colour develops.

Read the absorbance in an ELISA reader at 405 nm.

Using the standard curve determine the concentration of the Bt toxin unknown test samples.

## Appendix VII

### **COUNTING NPV (POB) USING IMPROVED NEUBAUER HAEMOCYTOMETER OR COUNTING CHAMBER (OR FOLLOW ANY OTHER AUTHENTIC ALTERNATE METHOD) :**

A haemocytometer is an essential tool used for estimating the number of microorganisms in a capsule. The Improved Neubauer haemocytometer comprised a thick glass slide with a shallow depression in the central section divided into two halves. On each side, the base of the depression has a fine ruled grid of squares, which is visible under a microscope. The dimensions of this grid are defined. With a thickened cover slip placed over the depression a chamber is created of fixed depth. A small volume of test suspension is introduced to both halves of the slide chamber from a pipette and 2-5 minutes allowed for particles to sediment to the chamber floor.

Either dark field or phase contrast microscopy is used to identify and count polyhedra (POB) with the counting chamber under the microscope. The number of Polyhedra/ capsules in a given number of grid squares can be counted. Each count consists of a tally of the number of polyhedra completely contained within a square plus the number of touching the left and upper sides. Polyhedra touching the bottom and right sides are not counted. Since both the depth of the chamber and the grid dimensions are known. It is then a straightforward calculation to determine the number of particles per ml of test suspension.

$$\text{Number of polyhedra (POB) per ml/gm} = \frac{D \times X}{N \times K}$$

Where

D= Dilution factor

X= total number of polyhedra counted

N= Number of squares counted

K= volume above one small square in cm

Area of each small square is  $1/400 \text{ mm}^2 = 0.0025 \text{ mm}^2$ . Depth of chamber is 0.1mm. Volume of liquid above a single small square is  $0.0025 \text{ mm}^2 \times 0.1 \text{ mm} = 0.00025 \text{ mm}^3$ . To convert to  $\text{cm}^3$  multiply by  $1/1000$  to get a volume of  $2.5 \times 10^{-7} \text{ cm}^3$  above 1 small square.

#### **Example**

Suppose in a sample diluted by a factor of 1000 we count 535 polyhedra in 160 small square then:

$$D = 1000$$

$$X = 535$$

$$N = 160$$

$$K = 2.5 \times 10^{-7} \text{ cm}^3$$

$$\text{Thus POB count} = \frac{1000 \times 535}{160 \times 2.5 \times 10^{-7}} \times \frac{5.35 \times 10^3}{4 \times 10^5} = 1.33 \times 10^3 \text{ Polyhedra/ml undiluted sample}$$

Usually this procedure is repeated 3 times and average taken to get a more accurate estimate.

### Appendix VIII

#### **PROCEDURE FOR ESTIMATION OF LC<sub>50</sub> OF NPV BY THE STANDARD DIET SURFACE CONTAMINATION METHOD (OR FOLLOW ANY OTHER AUTHENTIC ALTERNATE METHOD):**

- (i) **Diet to be used:** The standard chickpea-based diet without formaline.
- (ii) **Bioassay bottles:** 5ml vials with a diameter of 18 mm (255 mm surface area)
- (iii) **Doses of NPV to be tested:**

POB/ml	POB/mm <sup>2</sup>
(a) 5x10 <sup>4</sup>	19.6
(b) 1x10 <sup>4</sup>	3.9
(c) 2x10 <sup>3</sup>	0.78
(d) 0.8x10 <sup>2</sup>	0.16
(e) 0.16x10 <sup>2</sup>	0.03
(f) 1.6x10 <sup>4</sup>	0.006
- (iv) **Method of dosing :** Dispense 10 Microlitre aliquots into each vial and spread uniformly over the entire diet surface using a polished rounded lip of a 4 mm glass rod and allow to dry off under hood for 10 min.
- (v) **No. of Larvae/dose:** 50 (maintain 50 larvae without virus inoculation for control)
- (vi) **Stage of larvae:** 2nd instar larvae (preferably 4 days old) Release one larva/ vial and plug mouth with sterile absorbent cotton. Incubate at 25 + 1° C for 7 days.
- (vii) Record mortality in different doses on the 7th day.
- (viii) Apply Abbott's correction.
- (ix) **Subject the dose:** Morality response to probit analysis using a statistical soft ware in a computer.
- (x) Express LC<sub>50</sub> as POB/mm<sup>2</sup> of diet surface.

<u>Expected standards for NPV for 2nd instars larvae</u>	
Species	LC <sub>50</sub> POB/mm <sup>2</sup>
1. <i>Helicoverpa armigera</i>	0.5
2. <i>Spodoptera litura</i>	20.0

**TOXICITY/PATHOGENICITY STUDY BY CELL CULTURE METHOD (IN VITRO)  
(OR FOLLOW ANY OTHER AUTHENTIC ALTERNATE METHOD)  
(APPLICATION FOR VIRUS BASED BIOPESTICIDES)**

**1.0 Cell Culture**

**A. Rationale:**

Viral agents may have toxic potential and or may be infectious to mammalian cells. The purpose of the following test is to assess the capability of viral pest control agent for infection and toxicity. The applicant should submit information and /or data addressing the above two aspects. If the results indicate toxicity or pathogenicity then data on additional cell line from other species shall be required.

**B. Protocols:**

**(1) Substance to be tested:**

The most infective forma of the viruses should be used for the test. The virus titer should be tittered using standard method and should be devoid of defective viral particles. For virus titration, the most susceptible host system should be used.

**(2) Methods of Virus Preparation:**

The process of virus manufacture should be noted with reference to cell culture method, operation, medium used and stock virus used to generate the virus product.

**(3) Cell Culture:**

For testing the toxicity and infectivity of the virus product an established human cell line (such as WI 38) or any other primate continuous cell line such as monkey CV-1 should be used. The source, genetic stability and the passage number of each cell lines used should be provided. Sub-confluent culture (containing approximately 200 cells on 25 cm sq. dish) of each cell lines should be used for the test.

**2.1 Toxicity Evaluation:**

Approximately 200 cells on 25 cms sq dish are plated in petri dishes in suitable medium. Twenty-four hours after planting, virus based biopesticides (about 10 POB/MI) are introduced into the plate. After 1 hr, colonies (an aggregation of minimum 25 cells) were counted , stained and morphological evolutions are done for Cytopathic Effects (CPE) Result from the cultures of minimum of 6 plates along with the concurrent three controls to be provided.

**2.2 Infectivity Evaluation :**

Approximately  $2 \times 10^6$  cells on 25cms sq dish in the media were exposed to virus-based biopesticides at  $1 \times 10^6$  POB/ml in petri plates. Cultures were quantitatively assayed for the virus concentration and infectivity at 1,2,5,7, 14 and 21 days if required after inoculation. Results of the cultures from 6 plates along with three concurrent controls to be provided.

### **2.3 Test Evaluation**

Both toxicity and infectivity studies should be compared with proper control experiments. Inactivated virus of same dose can be used as negative control and permissive cell line or host organism as positive control. The results of culture from 3 plates each from negative and positive controls should be presented and reported. Any cytopathic effect and /or viral infection observed in tissue culture should be described.

The following definitions apply to this protocol:

#### **Cytopathic Effects (CPE) :**

Cytopathic effects (CPE) are any host cell damage or injury resulting from infection of the cell by a virus. These effects can be morphological or biochemical, and include but are not limited to cell growth, attachment morphology, nucleus size and shape, and cellular processes such as macromolecular synthesis.

The results of CPE can be classified as follows:

- (A) 1+ = Suggestive of virus-included morphologic changes.
- (B) 2+ = definitive morphologic changes.
- (C) 3+= more than 50 per cents cell degeneration
- (D) 4+= complete cell destruction

#### **Most Infectious Form (MIF) :**

Most infectious form (MIF) is the form or preparation of virus that gives optimal infection in the susceptible cell culture or organism. For occluded viruses (e.g. baculoviruses, cytoplasmic polyhedroses viruses, entomopox viruses) the IMF for cell culture or injection into an organism is extracellular virus found in cell culture medium or in infectious hemolymph. The IMF for susceptible insect host for infection by natural routes (feeding) is the viral occlusion body.

#### **Viral Infectivity:**

Viral infectivity is the ability of viral genes to become established in a host cell genome, or the ability of viral genes to be expressed in a host cell (resulting in the production of virus-encoded nucleic acids). The results of the viral infectivity should be reported as titration value of virus during entire period of incubation time.

**Viral Toxicity:**

Viral toxicity is the ability of a virus to inflict injury or damage to a host cell. Where infection by, and/or replication of the virus are not necessarily required. Toxicity can also be the ability of non-viral components or a preparation to inflict injury or damage to a host cell.

**Report Preparation:**

The report should contain:

1. Cell line and source
2. Cell culture method
3. Virus genotype and host
4. CTE-Data from positive and negative control and treatment group (results of individual plates to be provided on infectivity and toxicity).