#### LEGAL NOTICE NO. 123

# THE PEST CONTROL PRODUCTS ACT (Cap. 346)

IN EXERCISE of the powers conferred by section 15 of the Pest Control Products Act, the Minister for Agriculture, makes the following Regulations:—

### THE PEST CONTROL PRODUCTS (REGISTRATION) (AMENDMENT) REGULATIONS, 2006

1. These Regulations may be cited as the Pest Control Products (Registration) (Amendment) Regulations, 2006.

#### L.N. 46/1984. L.N.109/1984.

2.The Pest Control Products (Registration) regulations, 1984 (hereinafter referred as the "principal Regulations") are amended in Regulation 2 by inserting the following new definitions in their alphabetical sequence—

"accredited scientists/institution" means a person or an institution that has been officially recognized by the Board as having the capacity and competence to undertake biological efficacy trials.

"biochemical pesticide" means a pest control product whose active ingredient constitutes a chemical derived from naturally occurring plant or animal intended to control invertebrate pests.

"experimental permit" means a permit issued by the Board for small quantity of a pest control product imported or produced locally for purposes of research and efficacy trials prior to consideration for registration.

"microbial and macrobial biopesticide" means a pest control product of naturally occurring micro-organisms (microbiological agents viruses and rickettsia; bacteria, protozoa, fungi,) and macro-organisms (macro biological agents such as predators, parasitoids and entomopathogenic nematodes), respectively intended for the control of invertebrate pests weeds, pathogens of crops, and pests of livestock and public health and to which effects of the pest control products or active agent are attributed but does not include a component that by itself is not primarily responsible for the control effect of the pest control product or genetically modified living microorganism and macro-organism.

3. The Pest Control Products (Registration), Regulations herein referred to as principal Regulations are amended in Regulation 3 by inserting a new regulation 3A-

"3A 1. Every person desiring to introduce a pest control product for efficacy testing shall—

- (a)make application to the Board for an experimental permit in Form C set out in the Second Schedule;
- (b)provide all the details required in the form;
- (c)on request supply any further information which may be required by the Board; and
- (d)pay the prescribed application fees determined by the Board from time to time therefor.
- 2 (a) The Board shall evaluate the data provided and if satisfied that the application merits approval, shall issue an experimental permit in the prescribed Form D in the Second Schedule;
- (b) The Board shall, in addition, give the applicant information relating to the existing accredited scientists or institutions in the field of trial whom the applicant will work with;
- 3. When the efficacy trials are complete the accredited scientist or institution shall submit efficacy reports to the Board."
- 4.Regulation 4 (1) of the principal Regulations is amended by deleting the word 'Form A' and substituting therefor the words 'either Forms A, Al, A2 or A3;'
- 5.Regulation 4 of the principal Regulations is amended by inserting the following sub-regulation (4) after sub-regulation (3)-
- "(4) An applicant who is not resident in Kenya shall be required to deposit with the Board a binding agreement entered with the agent permanently resident in Kenya".
- 6. Principal Regulations are amended by inserting the following sub-regulations 4 (1) A-
- "4 (1) A. (a) The application for registration of a synthetic or conventional pest control product under Regulation 4 (1) shall be in the prescribed Form A completed by the applicant or duly authorized person and submitted in triplicate.
- (b) The Board shall supply the applicant with check lists and an index to ensure that the applicant has supplied the relevant data required in Form A in the Second Schedule.
- (B) (a) The application for registration of microbia' biopesticide shall be in the prescribed Form Al.
- (b) Information in support of a request for registration, both published and unpublished (fully cited) sha be supplied in the form of a summary data sheet required in Form Al.
- (c)Pre-registration consultations between the applicant and the registration authority shall he undertaken after the application has been made.

- (d)All applicants intending to import/export live organisms into or out of the country shall comply with any other existing laws governing such organisms.
- (d) All applicants intending to import/export live organisms into or out of the country shall comply with any other existing laws governing such organisms.
- (e)The use of genetically modified organisms and living modified organisms as microbial biopesticides shall comply with any other existing laws governing such organisms before an application is made to the Board.
- (f)the Board shall supply check lists and an index to ensure that the applicant has provided all relevant data and cited material.
- (C) (a) The application form for registration of macrobial biopesticide shall be as set out in Form A2.
- (b) Information in support of a request for registration, both published and unpublished (fully cited) shall be supplied in the form of a summary data sheet laid out according to the format given in Form A2.
- (c) Pre-registration consultations between the applicant and the registration authority shall be undertaken after the application has been made.
- (d) The applicant shall be required to :-
- (i)submit a sample of the pest control product with National Museums of Kenya or National Collection Number obtained if already in collection;
- (ii)provide a sample of the technical grade of its active agent;
- (iii)send an additional sample to the National Agricultural Research Laboratories [NARL], Biological Control Unit, Muguga (Kenya Agricultural Research Institute), and Kenya Plant Health Inspectorate Service.
- (iv)supply any other sample as may be requested by the Board.
- (e) All applicants intending to import/export live organisms into or out of the country shall comply with any other existing laws governing such organisms.
- (f)The use of genetically modified organisms and living modified organisms as macrobial hiopesticides shall comply with any other existing laws governing such organisms before an application is made to the Board.
- (g)the Board shall supply check lists and an index to ensure that the applicant has provided all relevant data and all cited material.

- (D) (1) The application form for the registration of a biochemical pesticide shall be in Form A3 in the Second Schedule.
- (ii)Information in support of a request for registration, both published and unpublished shall be supplied in form of a summary data sheet laid out according to the format given in Form A3.
- (iii)Pre-registration consultation between the applicant and the registration authority shall be undertaken".
- 7.The principal Regulations are amended in regulation 6 by deleting the words "two thousand five hundred shillings" and substituting the words "the prescribed fees determined by the Board from time to time" therefor.
- 8.The principal Regulations are amended in regulation 8 (2) by deleting the words "two thousand shillings" and inserting the words "the prescribed fees determined by the Board from time to time" therefor.
- 9. The principal Regulations are amended in regulation 8 by inserting the following new sub-regulation 8 (3) to (8)-
- 8 (3) A holder of a certificate of registration issued under these Regulations shall give a notice to the Board in writing at least 3 months before the expiry of the registration of any intentions to keep the product registration in abeyance for a period not exceeding 5 years and the notice shall-
- (a) give reasons for temporary withdrawal; and
- (b)show the records of all quantities of the pest control product in stock, manufactured or sold by him.
- (4)The Board shall consider the notification under sub-regulation (3) and if it is satisfied with the reasons for temporary withdrawal shall suspend the registration of the pest control product for a period not exceeding 5 years.
- (5) The information on suspended registration under sub-regulation (4) shall be made known to the holder in writing and the general public by gazette notice.
- (6) A person whose certificate of registration has been suspended under sub-regulation (4) shall withdraw the product from the market within a period of 3 months from the date of expiry of registration.
- (7) A person whose certificate of registration has been suspended under these regulations shall give a notice to the Board in writing of any intentions to re-introduce the product registration and the notice shall—
- (a) give reasons for reintroduction,

- (b)be accompanied by a fee for the renewal of a certificate of registration for the preceding two years and the current year,
- (c)be accompanied by five copies of the current label for the pest control product.
- (8) A holder of a certificate of registration issued under these Regulations whose product registration has been suspended for a period exceeding five years shall apply for registration afresh and shall, on request supply any further information, which may be required by the Board".
- 10. The principal Regulations are amended in regulation 9 (1) by deleting the words "a fee of one thousand shillings" and inserting the words "prescribed fee determined by the Board from time to time" therefor.
- 11. The principal Regulations are amended in regulation 11(2) by inserting the following new paragraph 11(2)d –
- "11 (2) (d) that the holder of a certificate of registration has given a notice to the Board in writing of any intentions to suspend product registration for a period not exceeding 5 years".

#### SECOND SCHEDULE

# FORM A —APPLICATION FOR REGISTRATION OF A PEST CONTROL PRODUCT (CONVENTIONAL)

| TRADE NAME OF THE PRODUCT                     |                |
|---|----------------|
| PURPOSE OF APPLICATION (tick as appropri      | ate)           |
| a. Pest control product containing a new act  | ive ingredient |
| b. Pest control product where source of       |                |
| active and/or formulation is not              |                |
| identical to that of a registered product     |                |
| c. Registration transfer                      |                |
| d. Amendments to existing registration        |                |
| e. Other (Explain)                            |                |
| Will the product he marketed under own label? | Yes □ No □     |
| If no, specify                                |                |
| Proposed date of marketing                    |                |
| 1.APPLICANT                                   |                |

| 1.1 Identification  |   |                            |                       |
|---|---|----------------------------|-----------------------|
| Name of applicant / Cor   | rporate name of                         |                            |                       |
| company   |   |                            |                       |
| Business Reg No.  |   |                            |                       |
| Name of registration ho   | lder                                    |                            |                       |
| Name of local agent in  | country:                                |                            |                       |
| (if different from registr  |   |                            |                       |
| 1.2 Status:   | ,                                       |                            |                       |
| (Importer/formulator/di   | stributor)                              |                            |                       |
| Business Registration N   |   |                            |                       |
| 1.3 Physical Address  |   |                            |                       |
| 1.4 Postal Address:   |   |                            |                       |
| 1.5 Telephone: (and are   | a code)                                 |                            |                       |
| 1.6 Fax: (and area code)  |   |                            |                       |
| 1.7 e-Mail:   | ,                                       |                            |                       |
| 2.PRODUCT   |   |                            |                       |
| 2.1 Designation (Descri   | ntion of product)                       | Trade name:                |                       |
| 2.1 Designation (Descri   | ption of product)                       | Trade mark:                |                       |
|   |   | Trade mark holder:         |                       |
| 2.2. Function of produc   | t. (eg. Insecticide                     | Trade mark norder.         |                       |
| herbicide etc.)   | i. (eg. msecuciae,                      |                            |                       |
|   | rinary public health                    |                            |                       |
| 2.3 Intended use: (Veterinary, public health, industrial, agriculture, forestry, etc. |   |                            |                       |
| 2.4 Target pest(s) and h  | •                                       |                            |                       |
|   |   |                            |                       |
| 2.5 Method, dosage rates and frequency of application:                                |   |                            |                       |
| 2.6 Type of formulation   | r (eg FC WP etc.)                       |                            | Crop Life             |
| 2.0 Type of formulation   | i. (cg. LC, WI, ctc.)                   |                            | International(CLI*)   |
|   |   |                            | Code (if available)   |
| 2.7 a) Is the product reg   | istered in country of                   | Yes□ No □                  | Code (ii available)   |
| manufacture?  | istered in country of                   | If no, give reasons        |                       |
| manaractare.  |   | in no, give reasons        |                       |
|   |   | Yes□ No □                  |                       |
| b) Is the product registe   | red in the country of                   | If no, give reasons        |                       |
| formulation?  | rea in the country of                   | in no, give reasons        |                       |
|   |   |                            |                       |
| 2.8 Registration in SEA   | RCH* country(ies):                      |                            |                       |
| (names)   | (103).                                  |                            |                       |
| 2.9 Existing registration   | No(s) and country(s).                   |                            |                       |
| 2.10 Customs Tariff Co  | • |                            |                       |
| Nomenclature)   | ac. (Diassels Tailii                    |                            |                       |
|   | ACTIVE INGREDIENT                       | (S) (Technical grade) (Int | formation on a.i. mav |
| be attached in sealed en  |   | (-, (1000) (111)           |                       |
| Active ingredient(s):   | Manufacturer: (Name                     | Minimum a.i.% purity       | a.i. Range %          |
| (Common name/s)   | and address)                            | r                          |                       |

| 4.FORMULATION   |     |      |           |
|---|-----|------|-----------|
| 4.1 Formulator: (Name)  |     |      |           |
| Postal Address:   |     |      |           |
| Physical address:   |     |      |           |
| 4.2 Internal code:  |     |      |           |
| 4.3 Composition (Information on composition may he attached in sealed envelope) |     |      | envelope) |
| Ingredients and   | g/l | g/kg | Range     |
| Function:   |     |      |           |
|   |     |      |           |

\* SEARCH - Southern and Eastern African Regulation Committee on Harmonization of Pesticide Registration.

| 5. TOXICOLOGY                            | (formu                  | ılated product |                         |                 |                       |
|--|-------------------------|----------------|-------------------------|-----------------|-----------------------|
| 5.1 Rat:                                 | `                       | e Oral<br>0    | Acute Dermal (LD mg/kg) |                 | ation LC50<br>I/hour) |
|  |                         |                | T 1                     |                 | 1                     |
|  | Experimental Calculated |                | Experimental            |                 | rimental              |
| 5 2 D 11 1                               |                         |                | Calculated              | Calci           | ılated                |
| 5.2 Rabbit:                              | Skin                    | irritation     | Eye irritation          |                 |                       |
| None                                     |                         |                |                         |                 |                       |
| Mild                                     |                         |                |                         |                 |                       |
| Moderate                                 |                         |                |                         |                 |                       |
| Severe                                   | <b>&gt;</b> T           | ,              | 6'11 I                  | . —             | <u> </u>              |
| 5.3 Skin                                 | None                    | L N            | ⁄Iild□ Mode             | rate $\square$  | Severe □              |
| Sensitization in                         |                         |                |                         |                 |                       |
| guinea pig: (tick)                       |                         | TI             | TT                      | TTT             | 0.1                   |
| 5.4 WHO Ia                               |                         | Ib             | II                      | III             | Others                |
| classification:                          | 1                       |                | 1:11:                   | 1:41:1-         | 11:6144               |
| •  |                         |                | cological studies: eg   | . Hvestock, who | ilite, poultry, pets  |
| 5.6 Summary of en                        |                         | ientai effects | <u> </u>                |                 |                       |
| 5.6.1 Toxicity to be                     |                         | - 41           |                         |                 |                       |
| 5.6.2 Toxicity to fis                    | sn and                  | otner          |                         |                 |                       |
| aquatic organisms:                       | mda.                    |                |                         |                 |                       |
| 5.6.3 Toxicity to bi                     |                         | ms and soil    |                         |                 |                       |
| 5.6.4 Toxicity to ea                     | ıuıwoı                  | ms and som     |                         |                 |                       |
| micro-organisms: 5.6.5 Toxicity to other | hor no                  | n target       |                         |                 |                       |
| organisms:                               | 1161 1101               | n-iai get      |                         |                 |                       |
| 5.6.6 Persistence in                     | enviro                  | nment:         |                         |                 |                       |
| 5.6.7 Other effects:                     |                         |                |                         |                 |                       |
| 6.PACKAGING                              | Т - /                   | •              | <u> </u>                |                 |                       |

<sup>\*</sup> Formerly GCPF

| 6.1 Packaging material / container:      |   |
|--|---|
| 6.2 Pack size(s):                        |   |
| 6.3 Disposal of empty container(s):      |   |
| 7.OTHER SPECIFIC REQUIREMENT             | TS  |
| 7.1 Human exposure                       |   |
| (a) Dermal absorption.                   |   |
| (b) Likely human exposure under          |   |
| field conditions                         |   |
| (c) Available toxicological data         |   |
| relating to other ingredients in         |   |
| formulation (non-active                  |   |
| additives in formulation).               |   |
| 8.DECLARATION                            |   |
| For and on behalf of                     |   |
| 1  | ed information and data provided in support of this |
| application are to the best of my knowle | edge true, correct and complete.                    |
|  | ~   |
|  | Signature   |
| Name in full (printed)                   |   |
|  | D /   |
|  | Date  |
| Official Title                           |   |
| Official Stamp of Applicant /            | FOR OFFICIAL USE                                    |
| Company                                  | TOR OTTIONE COE                                     |
| r · J                                    | Remarks   |
|  |   |
|  |   |
|  |   |
|  |   |
|  |   |
|  |   |
|  |   |
|  | Signed: Date  |
|  |   |

NOTE: The format of this application is recognized by all SEARCH countries.

FORM Al-

APPLICATION FOR REGISTRATION OF A MICROBIAL BIOPESTICIDE (PEST CONTROL PRODUCTS — MICROBIAL AGENT)

TRADE NAME OF THE PRODUCT.....

### POSE OF APPLICATION (tick as appropriate)

| a. Biopesticides containing a new active ag        |                  |  |           |
|--|------------------|--|-----------|
| b. Biopesticides where source of active and        | or formulation i | s not identical to                             | that of a |
| registered product                                 |                  |  |           |
| c. Registration transfer                           |                  |  |           |
| d. Amendments to existing registration             |                  |  |           |
| e. Other (Explain)                                 |                  |  |           |
| Will the product be marketed under own la—1?       | Yes $\square$    | No   |           |
|  |                  |  |           |
| If No, specify                                     |                  |  |           |
|  |                  |  |           |
| 1 ADDITO ANT                                       |                  |  |           |
| 1. APPLICANT                                       | <u> </u>         |  |           |
| Name of applicant                                  |                  |  |           |
| Corporate name of company                          |                  |  |           |
| Reg No   |                  |  |           |
| Name of registration holder.                       |                  |  |           |
| Name of local agent in country: (if different      |                  |  |           |
| from registration holder)                          |                  |  |           |
| Status: (Importer / formulator / distributor etc.) |                  |  |           |
| Physical Address                                   |                  |  |           |
| Postal Address:                                    |                  |  |           |
| Telephone (and area code):                         |                  |  |           |
| Fax (and area code):                               |                  |  |           |
| E-Mail:  |                  |  |           |
| 2. PRODUCT   | 1                |  |           |
| 2.1 Identity and stage(s) of active agent and      |                  |  |           |
| culture collection code                            |                  |  |           |
| 2.2 Concentration of active agent in technical     |                  |  |           |
| material.  |                  |  |           |
| 2.3 Designation (Description of product)           | Trade name:      |  |           |
|  | Trade mark:      |  |           |
|  | Trade mark hol   | der:   |           |
|  | Internal code:   |  |           |
| 2.4 Function of product: (e.g. Insecticide,        |                  |  |           |
| herbicide <i>etc.</i> )                            |                  |  |           |
| 2.5 Intended use: (Veterinary, horticultural,      |                  |  |           |
| public health, industrial, agriculture, forestry,  |                  |  |           |
| etc).  |                  |  |           |
| 2.6 Target pest(s) and host(s)                     |                  |  |           |
| 2.7 Method, dosage rates and frequency of          |                  |  |           |
| application:                                       |                  | <u>,                                      </u> |           |
| 2.8 Type of formulation: (e.g. Suspension, WP,     |                  |  |           |
| etc.)  |                  |  |           |
| 2.9 Is the product registered in country of        | Yes              |  |           |

|                                       |                            | If no, specify            |               |
|---------------------------------------|----------------------------|---------------------------|---------------|
| a) origin                             |                            |                           |               |
| b) manufacture:                       |                            | Yes $\square$             |               |
| c) formulation:                       |                            | If no, specify            |               |
|                                       |                            |                           |               |
| 2.10 Registration in SE.              | ARCH country/ies:          |                           |               |
| (country names, produc                | t name and registration    |                           |               |
| number)                               |                            |                           |               |
| 2.11 Registration in oth              | er country/ies,            |                           |               |
| particularly OECD cour                | ntries: (country name,     |                           |               |
| product name and registration number) |                            |                           |               |
| 2.12 Customs Tariff Co                | de: (Brussels Tariff       |                           |               |
| Nomenclature)                         |                            |                           |               |
|                                       |                            |                           |               |
| 3.IDENTIFICATION                      |                            |                           |               |
| 3.1 Identification of Mi              | cro- organism              | Life stage (spore, hypha  | ne etc)       |
|                                       |                            |                           |               |
| 3.2 Identification                    |                            | Genus Species             | Sub species   |
|                                       |                            |                           |               |
| Scientific. name                      |                            |                           |               |
|                                       |                            |                           |               |
| Common name(s)                        |                            |                           |               |
|                                       | ***                        |                           |               |
| 3.23 Contents.(number                 | · ·                        | AMEDICAL A CENTERON (E.   | 1 ' 1 1 \     |
|                                       |                            | NTROL AGENT(S) (Tec       | hnical grade) |
|                                       | agent may be attached in   |                           | · <b>P</b> 0/ |
| Active agent(s):                      | Manufacturer: (Name        | Minimum a.i.% purity      | a.i. Range %  |
| (Common name/s)                       | and address)               |                           |               |
| 5 CODMIN ATION                        |                            |                           |               |
| 5.FORMULATION                         |                            | Dootel Address.           |               |
| 5.1 Formulator: (Name)                |                            | Postal Address:           |               |
| Internal code:                        |                            | Physical address:         |               |
| (8) Composition (Inform               |                            |                           |               |
| may be attached in seal               |                            | Huita (a. a. afr. an HID) | Danas         |
| Ingredients and                       | Units (w/w, w/v etc.)      | Units (e.g. cfu or IUP)   | Range         |
| Function:                             |                            |                           |               |
|                                       |                            |                           |               |
| 6 DIOLOGICAL DDOD                     | LERTIES OF ACTIVE A        | CENT                      |               |
|                                       |                            | UENI                      |               |
| 6.1 History and geograp               | micai distribution of      |                           |               |
| active agent                          | host range                 |                           |               |
| 6.2 Mode of action and                | nost range                 |                           |               |
| 6.3 Life cycle                        | l and aclonicing abilities |                           |               |
| 6.4 Infectivity, dispersa             |                            |                           |               |
| 6.5 Relationships to kno              | own plant, animal or       |                           |               |
| human pathogens                       |                            | 1                         |               |

| 6.6 Genetic stability                |                           |                      |                     |                             |       |                  |         |            |
|--------------------------------------|---------------------------|----------------------|---------------------|-----------------------------|-------|------------------|---------|------------|
| 6.7 Information on the               | e production of           |                      |                     |                             |       |                  |         |            |
|                                      | y antibiotics and toxins  |                      |                     |                             |       |                  |         |            |
| 7.TOXICOLOGY (ac                     |                           |                      |                     |                             |       |                  |         |            |
| 7.1 Rat:                             | Acute Oral (LD50          | Inhalatio            | on LC <sub>50</sub> | Intra                       | a-per | itoneal i        | niectio | n          |
|                                      | mg/kg)                    | (mg/4/ho             |                     |                             | _     | tivity (L        | •       |            |
|                                      | Experimental              | Experim              |                     |                             | erim  |                  | 200     | <i>O</i> / |
|                                      | Calculated                | Calculated Calcu     |                     | Calculated                  |       |                  |         |            |
| Hypersensitivity/                    |                           |                      |                     |                             |       |                  |         |            |
| allergies in humans                  |                           |                      |                     |                             |       |                  |         |            |
| 8.TOXICOLOGY (for                    | rmulated product)         |                      |                     | l                           |       |                  |         |            |
|                                      | Acute Oral                | Acute D              | ermal               | Inhalation LC <sub>50</sub> |       | .C <sub>50</sub> |         |            |
|                                      | $(LD_{50} \text{ mg/kg})$ | (LD <sub>50</sub> g/ |                     |                             |       | g/4/hour         |         |            |
|                                      | (== 308/                  | ( 30 &               | 6)                  |                             | (2    | , ., ,,          | •       |            |
|                                      | Experimental              | Experim              | ental               |                             | Exp   | eriment          | al      |            |
|                                      | Calculated                | Calculat             |                     |                             | _     | culated          |         |            |
|                                      |                           |                      |                     |                             |       |                  |         |            |
| 8.2 Rabbit:                          | Skin irritation           | Eye irrit            | ation               |                             |       |                  |         |            |
| None                                 |                           | J                    |                     |                             |       |                  |         |            |
| Mild                                 |                           |                      |                     |                             |       |                  |         |            |
| Moderate                             |                           |                      |                     |                             |       |                  |         |            |
| Severe                               |                           |                      |                     |                             |       |                  |         |            |
| 8.3 Skin Sensitization               | in guinea pig: (tick)     | None                 | Mild                |                             | Mo    | derate           | Sever   | e          |
| 8.4 WHO classification               |                           | Ia                   | Ib                  | II                          | 1,10  | III              |         | hers       |
| or ward dimensional                  | ( ) .                     |                      |                     |                             |       |                  |         |            |
| 8.5 Summary of other                 | mammalian                 |                      | 1                   | I                           |       |                  | I       |            |
|                                      | e.g. livestock, wildlife, |                      |                     |                             |       |                  |         |            |
| poultry, pets                        |                           |                      |                     |                             |       |                  |         |            |
| 9.ECOTOXICOLOGY                      | Y                         | l                    |                     |                             |       |                  |         |            |
| 9.1 Toxicity to bees:                |                           |                      |                     |                             |       |                  |         |            |
| 9.2 Toxicity to fish an              | d other aquatic           |                      |                     |                             |       |                  |         |            |
| organisms:                           | 1                         |                      |                     |                             |       |                  |         |            |
| 9.3 Toxicity to birds:               |                           |                      |                     |                             |       |                  |         |            |
| 9.4 Toxicity to earthw               | orms or other soil        |                      |                     |                             |       |                  |         |            |
| invertebrates. and soil              | micro-organisms:          |                      |                     |                             |       |                  |         |            |
| 9.5 Toxicity to other n              | on-target organisms:      |                      |                     |                             |       |                  |         |            |
| 9.6 Persistence in envi              |                           |                      |                     |                             |       |                  |         |            |
| 9.7 Available toxicolo               | gical data relating to    |                      |                     |                             |       |                  |         |            |
| other ingredients in fo              | rmulation (non-active     |                      |                     |                             |       |                  |         |            |
| additives in formulation             | on).                      |                      |                     |                             |       |                  |         |            |
| 9.8 Other effects: Spec              |                           |                      |                     |                             |       |                  |         |            |
| 10. PACKAGING                        |                           |                      |                     |                             |       |                  |         |            |
| 10.1 Packaging materi                | ial / container:          |                      |                     |                             |       |                  |         |            |
| 10.2 Pack size(s):                   |                           |                      |                     |                             |       |                  |         |            |
| 10.3 Disposal of empty container(s): |                           |                      |                     |                             |       |                  |         |            |

| 11. OTHER SPECIFIC REQUIREMENTS                   |  |
|---|--|
| 11.1 Operator exposure                            |  |
| 11.2 Sanitary and phytosanitary measures          |  |
| 11.3 Has the product been cleared by the          |  |
| phytosanitary authorities? (tick):                | Yes□                                       |
|   | (provide evidence)                         |
| a. in the country of origin                       |  |
|   | No □                                       |
| b. the recipient country                          | (give reasons)                             |
|   |  |
| 12. DECLARATION                                   |  |
| For and on behalf of                              |  |
| I hereby certify that the above mentioned inform  | ation and data provided in support of this |
| application are to the best of my knowledge true, | , correct and complete.                    |
|   | -  |
|   |  |
|   |  |
| Name in full (printed)                            | Signature                                  |
|   |  |
|   |  |
| Official Title                                    | Date                                       |
|   |  |
| a. Biopesticides containing a new active          |  |
| agent   |  |
| b. Biopesticides where source of active           |  |
| and/or formulation is not identical to that       |  |
| of a registered product                           |  |
| c. Registration transfer                          |  |
| d. Amendments to existing registration            |  |
| e. Other (Explain)                                |  |
| Will the product be marketed under own label?     | Yes □ No □                                 |
| product of managed ander own Idoor.               |  |
| If No, specify                                    |  |
| Proposed date of marketing                        |  |
| . I   |  |
|   |  |

| 1. APPLICANT                                      |                    |
|---|--------------------|
| 1.1 Name of applicant                             |                    |
| 1.2 Corporate name of company                     |                    |
| 1.3 Reg. No. of the company                       |                    |
| 1.4 Name of registration holder                   |                    |
| 1.5 Name of local agent in country: (if           |                    |
| different from registration holder)               |                    |
| 1.6 Status: (Importer / formulator / distributor  |                    |
| etc.)   |                    |
| 1.7 Physical Address                              | 1 2                |
| 1.8 Postal Address:                               | 1 2                |
| 1.9 Telephone (and area code):                    | 1 2                |
| Fax (and area code):                              | 1 2                |
| E-Mail:   | 1 2                |
| 2. PRODUCT  |                    |
| 2.1 Identity and stage(s) of active agent and     |                    |
| culture collection code                           |                    |
| 2.2 Concentration of active agent in technical    |                    |
| material.   |                    |
| 2.3 Description of product                        | Trade name:        |
|   | Trade mark:        |
|   | Trade mark holder: |
|   | Internal code:     |
| 2.4 Function of the product: (e.g. predator,      |                    |
| parasitoid,                                       |                    |
| entomopathogenic nematode)                        |                    |
| 2.5 Intended use: (veterinary, horticultural,     |                    |
| public health, industrial, agriculture, forestry, |                    |
| etc).   |                    |
| 2.6 Target pest(s) and host(s)                    |                    |
| 2.7 Method, dosage rates and frequency of         |                    |
| application:                                      |                    |
| 2.8 Type of formulation: (if any)                 |                    |
| 2.9 Is the product registered in country          |                    |
| of:   | Yes□ No□ □□        |
|   | If no, specify     |
| a) origin   |                    |
|   |                    |
| b) manufacture:                                   | Yes □ No □         |
|   | If no, specify     |
| c) formulation:                                   |                    |
|   | N D N D            |
|   | Yes □ No □         |
|   | If no, specify     |
|   |                    |
|   | 1                  |

| 2.10 Registration in SEARCH country(ies):       |                 |                   |               |
|---|-----------------|-------------------|---------------|
| (country names, product name and registration   |                 |                   |               |
| number)   |                 |                   |               |
| 2.11 Registration in other country(ies),        |                 |                   |               |
| particularly OECD countries: (country names,    |                 |                   |               |
| product name and registration number)           |                 |                   |               |
| 2.12 Customs Tariff Code: (Brussels Tariff      |                 |                   |               |
| Nomenclature)                                   |                 |                   |               |
| 3.IDENTIFICATION                                | <b>!</b>        |                   |               |
| Identification of Macrobiological agent         | Life stage (egg | /adult/larva etc) |               |
|   |                 | ,                 |               |
| 3.1 Identification                              | Genus           | Species           | Sub species   |
|   |                 | 1                 | 1             |
| Scientific name                                 |                 |                   |               |
|   |                 |                   |               |
| Common name(s)                                  |                 |                   |               |
| <b>,</b>  |                 |                   |               |
| 3.2 Contents (number per Unit)                  |                 |                   |               |
| 4.SOURCE  | <b>!</b>        |                   |               |
| Source (original isolation)                     |                 |                   |               |
| 5. FORMULATION                                  |                 |                   |               |
| 5.1 Formulator: (Name)                          | Postal Address  | •                 |               |
| 5.2 Internal code:                              |                 |                   |               |
|   | Physical addres | ss:               |               |
| 5.3 Composition (information on composition m   |                 |                   |               |
| Ingredients and Function:                       | Units           | Range             |               |
|   |                 |                   |               |
| 6.SUMMARY OF ENVIRONMENTAL EFFEC                | TS (BIOSAFET    | Y)                |               |
| 6.1 Risk assessment for replacement of indigeno | `               |                   | niche (exotic |
| macrobials only)                                | 6               | · · · · · ·       | (1)           |
| 6.2 Risk to bees:                               |                 |                   |               |
| 6.3 Risk to fish and other aquatic organisms:   |                 |                   |               |
| 6.4 Risk to birds:                              |                 |                   |               |
| 6.5 Risk to earthworms and soil micro-          |                 |                   |               |
| organisms:                                      |                 |                   |               |
| 6.6 Risk to other non-target organisms          |                 |                   |               |
| 6.7 Other effects: specify (human health        |                 |                   |               |
| problems)                                       |                 |                   |               |
| 7.PACKAGING                                     |                 |                   |               |
| 7.1 Packaging material/container:               |                 |                   |               |
| 7.2 Pack size(s)                                |                 |                   |               |
| 8. OTHER SPECIFIC REQUIREMENTS                  |                 |                   |               |
| 8.1 operator exposure                           |                 |                   |               |
| 8.2 Likely operator exposure under field        |                 |                   |               |
| conditions                                      |                 |                   |               |
| CONGREGATIO                                     | Ī               |                   |               |

| 8.3 Sanitary and phytosanitary measures  |   |  |
|--|---|--|
| 8.4 Has the product been cleared by the  |   |  |
| phytosanitary authorities?   | Yes □ No □  |  |
| 9. DECLARATION   |   |  |
| For and on behalf of   | I hereby certify that the above                           |  |
| mentioned information and data provided in sup   |   |  |
| knowledge true, correct and complete   | port of this application are to the best of my            |  |
| knowledge true, correct and complete   |   |  |
|  |   |  |
| Name in full (minted)  | Cionatura   |  |
| Name in full (printed)   | Signature   |  |
|  |   |  |
| O.C. 1 T. 1  | D /   |  |
| Official Title   | Date  |  |
| NOTE: The format of this application form is red   | cognized by all SEARCH countries.                         |  |
| FORM A3  |   |  |
|  | OF A BIOCHEMICAL PESTICIDE (PEST<br>SIOCHEMICAL PRODUCTS) |  |
| PRODUCT TRADE NAME   |   |  |
| PURPOSE OF APPLICATION (tick as appropri   | iate)   |  |
| a. Biochemical pesticides containing a new   | active ingredient $\square$                               |  |
| b. Biochemical pesticides where source of active and/or formulation is not identical to that |   |  |
| of a registered product  |   |  |
| c. Registration transfer □   |   |  |
| d. Amendments to existing registration   |   |  |
| e. Other (Explain)   |   |  |
| e. Other (Explain)   |   |  |
|  |   |  |
|  |   |  |
| Will the product he morketed under own lobel.  | Vos 🗆 No 🖂  |  |
| Will the product be marketed under own label   |   |  |
| If no, specify   |   |  |

| 1.7 Physical Address                          |                    |
|---|--------------------|
| 1.8 Postal Address:                           |                    |
| 1.9 Telephone                                 |                    |
| (and area code)                               |                    |
| 1.10 Fax                                      |                    |
| (and area code)                               |                    |
| 1.11 E-mail                                   |                    |
| 2. PEST CONTROL PRODUCTS                      |                    |
| 2.1 Identity                                  |                    |
| 2.2 Concentration of a.i.                     |                    |
| 2.3 Designation                               | Trade name:        |
| ( Description of pi (duct)                    | Trade mark:        |
|   | Trade mark holder: |
|   | Internal code:     |
| 2.4 Function of product: (e.g. Insecticide,   |                    |
| herbicide etc.)                               |                    |
| 2.5 Intended use: (Veterinary, public health, |                    |
| industrial, agriculture, forestry, etc.       |                    |
| 2.6 Target pest(s) and host(s)                |                    |
| 2.7 Method, dosage rates and frequency of     |                    |
| application:                                  |                    |
| 2.8 Type of formulation: (e.g. EC, WP, etc.)  |                    |
| 2.9 Is the product registered in country of   |                    |
|   |                    |
| a) origin                                     | Yes□ No□ □□        |
|   | If no, specify     |
|   |                    |
| b) manufacture:                               | Yes□ No□ □□        |
|   | If no, specify     |
|   |                    |
| c) formulation:                               | Yes□ No□ □□        |
|   | If no, specify     |
| 2.10 Registration in SEARCH** country/ies:    |                    |
| (names)                                       |                    |
| 2.11 Registration in other country/ies,       |                    |
| especially OECD countries: (names)            |                    |
| 2.12 Customs Tariff Code: (Brussels Tariff    |                    |
| Nomenclature)                                 |                    |
|   |                    |

\*\*SEARCH — Southern and Eastern African Regulatory Committee on Harmonization of Pesticide
Registration

<sup>\*</sup>Formerly GCPF.

| attached in sealed envelope)  |                 |  |                                |                 |                              |
|---|-----------------|--|--------------------------------|-----------------|------------------------------|
|   | Manufact        |  | Minimum a.i.%                  |                 | purity                       |
| Active ingredient(s):   | (Name an        | d address)                                 |                                |                 | a.i. Range %                 |
| (Common name/s)   |                 |  |                                |                 |                              |
|   |                 |  |                                |                 |                              |
| A TOWIGOLOGY OF   | <b>A</b> O      | 1 /I D                                     | A . 1                          | 1/10            | T 1 1 4                      |
| 4. TOXICOLOGY OF  | Acute Ora       | $\mathrm{II}\left(\mathrm{LD}_{50}\right)$ | Acute dermal (LD <sub>50</sub> |                 | Inhalation                   |
| ACTIVE INGREDIENTS  | mg/kg)          |  | mg/kg)                         |                 | LC <sub>50</sub> (mg/I/hour) |
| (Technical grade)   |                 |  |                                |                 |                              |
|   | Experime        | ntal                                       | Experime                       | ental           | Experimental                 |
|   | Calculated      |  | Calculated                     |                 | Calculated                   |
|   |                 |  |                                |                 |                              |
| 5.FORMULATION   |                 |  |                                |                 |                              |
| 5.1 Formulator: (Name)  | l               |  | Postal Address:                |                 |                              |
| 5.2 Internal code:  |                 |  | Physical                       | address:        |                              |
| 5.3 Composition (Information  | on compos       | sition may l                               | e attached                     | l in sealed env | elope)                       |
| Ingredients and Function:   | units           |  | Units                          |                 | Range                        |
|   |                 |  |                                |                 |                              |
| 6. TOXICOLOGY (formulate  | d product)      |  |                                |                 |                              |
| 6.1 Rat:  | Acute Ora       | al (LD <sub>50</sub>                       | Acute Dermal (LD <sub>50</sub> |                 | Inhalation LC <sub>50</sub>  |
|   | mg/kg)          |  | g/kg)                          |                 | (mg/I/hour)                  |
|   | Experimental    |  | Experimental                   |                 | Experimental                 |
|   | Calculated      |  | Calculated                     |                 | Calculated                   |
| 6.2 Rabbit:   | Skin irritation |  | Eye irritation                 |                 |                              |
| None  |                 |  |                                |                 |                              |
| Mild  |                 |  |                                |                 |                              |
| Moderate  |                 |  |                                |                 |                              |
| Severe  |                 |  |                                | 1               |                              |
| 6.3 Skin Sensitization in   | None            |  | Mild                           | Moderate        | Severe                       |
| guinea pig  |                 |  |                                |                 |                              |
| (tick)  |                 | 71   | **                             | ***             | 0.1                          |
| 6.4 WHO classification:   | Ia              | Ib   | Н                              | III             | Others                       |
| 6.5 Summary of other mamma  | alian toxico    | logical info                               | rmation m                      | av he required  | 1                            |
| 6.5 Summary of other mammalian toxicological information may he required 6.6 Summary of environmental effects |                 |  |                                |                 |                              |
| 6.6.1 Toxicity to bees:   |                 |  |                                |                 |                              |
| 6.6.2 Toxicity to fish and other aquatic organisms:   |                 |  |                                |                 |                              |
| 6.6.3 Toxicity to birds:  |                 |  |                                |                 |                              |
| 6.6.4 Toxicity to earthworms  |                 |  |                                |                 |                              |
| 6.6.5 Toxicity to other non-tar   |                 |  |                                |                 |                              |
| 6.6.6 Persistence in environme  |                 |  |                                |                 |                              |
| 6.6.7 Other effects: Specify  |                 |  |                                |                 |                              |
| 7.PACKAGING   |                 |  |                                |                 |                              |
| 7.1 Packaging material / conta  | iner:           |  |                                |                 |                              |

| 7.2 Pack size(s):                                      |                            |   |
|--|----------------------------|---|
| 7.3 Disposal of empty container(s):                    |                            |   |
| 8.OTHER SPECIFIC REQUIREMENTS                          |                            |   |
| 8.1 Operator exposure                                  |                            |   |
| 8.2 Dermal absorption.                                 |                            |   |
| 8.3 Likely operator exposure under field conditions    |                            |   |
| 8.4 Available toxicological data relating to other ing | redients in formulation (1 | non- active                             |
| additives in formulation).                             |                            |   |
| 9. DECLARATION   |                            |   |
| For and on behalf of                                   |                            |   |
| above mentioned information and data provided in s     | upport of this application | are to the best of                      |
| my knowledge true, correct and complete.               |                            |   |
|  |                            |   |
|  | •••••                      | • |
| Name in full (printed)                                 | Signature                  |   |
|  |                            |   |
| 0.00 1.1 77.1  |                            |   |
| Official Title   | Date                       | -                                       |
|  | FOR OFFIC                  | IAL USE                                 |
|  | D 1                        |   |
| 000 110  | Remarks                    | • |
| Official Stamp   |                            |   |
| of Applicant / Company                                 |                            |   |
|  |                            |   |
|  |                            | D /                                     |
|  | Signed:                    | Date:                                   |

NOTE: The format of this application form is recognized by all SEARCH countries.

FORM C

# THE PEST CONTROL PRODUCTS ACT (Cap. 346)

THE PEST CONTROL PRODUCTS (REGISTRATION) REGULATIONS, 2006

APPLICATION FOR THE INTRODUCTION OF NEW PEST CONTROL PRODUCT (To be Completed and Submitted in Triplicate)

To: The Managing Director
Pest Control Products Board
P.O. Box 13794-00800
Westlands, Nairobi

| • • • • • • |   |
|-------------|---|
|             | Fax No  |
|             | JS OF APPLICANT (Manufacturer, agent etc)                     |
|             |   |
| • • • • • • |   |
|             |   |
| 1.          | Approved Common Name(s)                                       |
|             |   |
| 2.          | Chemical Name   |
|             |   |
| 3.          | Chemical formula  |
|             |   |
| 4.          | Chemical Structure.   |
|             |   |
| 5.          | Trade Name(s)   |
|             |   |
| 6.          | Proposed Kenyan Name(s  |
|             |   |
| 7.          | Formulation Type (W.P., E.C., Dust etc                        |
|             |   |
| 8.          | Concentration of Each Active                                  |
|             | Ingredients   |
| 9.          | Quantity required for testing                                 |
|             |   |
| 10.         | Proposed Uses (Agricultural, Health, Veterinary, Forestry etc |
|             |   |

| 12     | . Target pest(s) Host(s) or Area of Application                                      |
|--------|--|
| 13     | . Mode of action   |
| 14     | . Toxicity of the product to test animals (Acute Oral and Dermal LD50 Inhalation etc |
| 15. T  | ne effects of the product on the environment: -                                      |
|        | Toxicity to bees   |
| (b)    | Toxicity to fish   |
| (c)    | Toxicity to birds  |
| (d)    | Toxicity to soil micro-organisms   |
|        | roposed precautions to users   |
| 17. Aı | ntidote, Treatment of poisoning  |
| 18. Sh | elf life of the product  |
| 19. Co | ountry of Origin of the  |
| -      | ame and Address of manufacturer  |
|        | ame and address of formulator  |
|        |  |
|        | ountries where tested and registered   |

| 23. Ownership of data (name. address)   |
|---|
| 24. Patent sit (lilt ion/patent holder  |
| Confirm that the information contained herein is true to the best of by knowledge and belief.                                   |
| Date of application Signature of applicant  |
| Name  |
| Note:   |
| Every application must be accompanied by:   |
| 1. Supporting data and information which should include:-   |
| (a) Chemistry specifications, composition of the product, and the technical a.i. method of analysis for the a.i. determination; |
| (b) information on biological activity on the product, directions for use;  |
| (c) Metabolism. Residues, methods of analysis for residues:   |
| (d) Toxicological data on the technical and formulated product(s);  |
| (e) Environmental toxicity.   |
| 2. Experimental labels (typed).   |
| 3. Analytical standards (approximate 100% a.i.) — 1.0 gram.   |
| Form D  |
| THE PEST CONTROL PRODUCTS ACT (Cap. 346)  |
| TI IF PEST CONTROL PROUDCTS (REGISTRATION) REGULATIONS 2006   |
| Date:   |
| REF: PERMIT NO.   |

# PERMIT FOR EXPERIMENTAL AND EFFICACY TRIALS OF NEW PEST CONTROL PRODUCTS

This is to grant permission as requested for your Centre/Organization to carry out efficacy trials of the new pest control product(s) as indicated below:-

Pest Control Product(s)

Crop(s)/Commodity(ies)/Use(s)

Target Pest(s)

You are requested to inform the Pest Control Products Board of the commencement of the experimental/efficacy trials and also periodically submit to the Board progress reports. The trial should he carried out using a Pest Control Products Board approved trial protocol. At the conclusion of the experimental/efficacy trials, a detailed confidential report on the performance of the candidate pesticide and recommendations for its use shall he submitted to the Board quoting the above reference and date.

It would he highly appreciated if trials are completed as quickly as possible to avoid delays in introducing suitable products in the market. The company will provide you with the required trial samples/materials but the Board shall not meet expenses for the trials.

It is the responsibility of the applicant to ensure that the efficacy trials are carried out to the satisfaction of the Board.

Managing Director, Pest Control Products Board.

Made on the 6<sup>th</sup> September, 2006.

KIPRUTO A RAP KIRWA, Minister for Agriculture.