(Legislative Supplement No. 61)

LEGAL NOTICE NO. 130

THE PEST CONTROL PRODUCTS ACT

(Cap. 346*)*

THE PEST CONTROL PRODUCTS (REGISTRATION) REGULATIONS, 2024

ARRANGEMENT OF REGULATIONS

Regulation

THE PEST CONTROL PRODUCTS ACT
(Cap. 346)

IN EXERCISE of the powers conferred by section 15 of the Pest Control Products Act, the Cabinet Secretary for Agriculture and Livestock Development, after consultation with the Pest Control Products Board, makes the following Regulations—

THE PEST CONTROL PRODUCTS (REGISTRATION) REGULATIONS, 2024

Citation.

1. These Regulations may be cited as the Pest Control Products (Registration) Regulations, 2024.

Interpretation.

2. In these Regulations, unless the context otherwise requires—

"adjuvant" means a compound or substance that enhances or modifies or is intended to enhance or modify the physical or chemical characteristics of a pest control product to which it is added;

"banned pest control product" means a pest control product where all uses have been prohibited by the Board through a regulatory action;

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

"confidential business information" means information that discloses the—

(a) manufacturing or quality control processes and 5-batch analysis;

(b) methods for testing and measuring the quantity of deliberately added inert ingredients and impurities; and

(c) identity or percentage quantity of deliberately added inert ingredients in the technical grade or formulated product;

"conventional pest control product" means a synthetic chemical pesticides;

"designated competent persons" 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, physicochemical studies, toxicological, ecotoxicological and residue studies;

"device" means any article, instrument, apparatus, contrivance or gadget that by itself or in conjunction with a pest control product is used as a means to control pests directly or indirectly;

"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, efficacy trials and other studies prior to consideration for registration;

"local agent" means a person or company that has been appointed to act on behalf of a registrant in accordance with regulation 11(2);

"macrobial biopesticide" means a pest control product of naturally occurring macro-organisms or macro-biological agents such as predators, parasitoids, entomopathogenic nematodes, or genetically modified living macro- organism, intended for the control of invertebrate pests, weeds, pathogens of crops and pests of public health and to which effects of the pest control products or active agent are attributed;

"maximum residue limit" means the maximum concentration of a residue that is legally permitted or recognized as acceptable in or on a food, agricultural commodity or feedstuff;

"microbial biopesticide" means a pest control product of naturally occurring micro-organisms or microbiological agents such as viruses and rickettsia, bacteria, protozoa, fungi, or genetically modified living micro-organism, intended for the control of invertebrate pests, weeds, pathogens of crops and pests of public health and to which effects of the pest control products or active agent are attributed;

"national collection number" means the unique code given to a culture or an isolate by the National Museums of Kenya or any other institution recognized by the Board;

"parallel registration" means a registration of a trade name based on a registered product from the same manufacturer and source and with authorization from the registrant; and

"registrant" means the owner of technical information submitted for the purposes of registration of a pest control product or person authorized in writing by such owner.

Object of the Regulations.

3. (1) The object of these Regulations is to provide a framework for the registration of pest control products.

(2) Without prejudice to the generality of sub-regulation (1), the object of these Regulations is to provide for the—

(a) procedures, requirements and conditions for the registration of pest control products; and

(b) risk assessment and evaluation of pest control products.

General requirements on registration of pest control products.

4. (1) A person who intends to register a pest control product shall apply to the Board using the respective application form set out in the First Schedule.

(2) An application under sub-regulation (1) shall—

(a) be submitted in triplicate;

(b) comply with the requirements set out in the First Schedule;

(c) contain a checklist and an index to ensure that the applicant has supplied the relevant data required in the First Schedule;

(d) include a certificate of registration from the country of origin, where the product is sourced outside Kenya; and

(e) be accompanied by a copy of the label for the pest control product and the proposed trade name of the product.

(3) Where a pest control product is sourced from a non-English speaking country, the applicant shall provide a translated copy of the certificate of registration.

(4) Where an applicant who intends to register a pest control product is sourced from a non-English speaking country submits wrongly translated registration certificate under sub-regulation (3), the applicant shall be required to—

(a) submit a new application;

(b) pay a resubmission fee; and

(c) conduct another efficacy trial for the pest control product.

(5) An applicant who intends to import into or export out of Kenya live organisms shall provide to the Board proof of compliance with any other written law governing such organisms.

(6) An applicant who intends to introduce genetically modified organisms and living modified organisms as microbial biopesticides shall provide to the Board proof of compliance with any other written laws governing such organisms or requisite approvals from the relevant government agency.

Application for registration of a conventional pest control products.

5. (1) A person who intends to register a conventional pest control product shall apply to the Board in Form A1 as set out in the First Schedule.

(2) The application under sub-regulation (1) shall be accompanied by a copy of the summary dossier in the manner set out in Form B as set out in the First Schedule.

Application for registration of a biopesticide or biocontrol agent.

6. (1) A person who intends to register a biopesticide or a biocontrol agent shall apply to the Board in Form A2 as set out in the First Schedule.

(2) For purposes of sub-regulation (1), the applicant shall—

(a) provide information in support of the request for registration, both published and unpublished, fully cited, in the form of a summary data sheet in Form A2 set out in the First Schedule; and

(b) attach a copy of the summary dossier for biochemical pest control products in Form B3 as set out the First Schedule.

(3) An applicant intending to introduce a microbial or macrobial biopesticide shall—

(a) submit evidence of collection and culture reference number where culture is deposited;

(b) provide a sample of the technical grade of the biopesticide's active agent to the Board;

(c) submit a copy of a summary dossier—

(i) for microbial pest control products, in Form B1 as set out in the First Schedule; or

(ii) for macrobial pest control products, in Form B2 as set out in the First Schedule.

Application for registration of a generic pest control product or equivalent.

7. A person who intends to register a generic pest control product equivalent to a registered pest control product shall apply to the Board in Form A3 as set in the First Schedule.

Small pack labels display panel.

8. (1) A person who intends to register a spray adjuvant shall apply to the Board in Form A4 as set out in the First Schedule.

(2) The application under sub-regulation (1) shall be accompanied by a copy of the summary dossier in Form B4 as set out in the First Schedule.

Application for registration for use in paint for in-can and film preservatives.

9. (1) A person who intends to register a pest control product for use in paint for in-can and film preservatives shall apply to the Board in Form A5 as set out in the First Schedule.

(2) The application under sub-regulation (1) shall be accompanied by a copy of the summary dossier in Form B5 as set out in the First Schedule.

Application for registration of a plant growth regulator.

10. (1) A person who intends to register a plant growth regulator and post-harvest product for flowers and ornamentals shall make an application to the Board in Form A6 set out in the First Schedule.

(2) The application under sub-regulation (1) shall be accompanied by a copy of the summary dossier in Form B6 set out in the First Schedule.

Efficacy trials.

11. (1) For purposes of regulations 5, 6, 7, 8, 9 and 10, local efficacy trials shall be conducted following the requirements on generating and reporting of pest control products for plants and the national efficacy trial requirements for public health products, respectively.

(2) Efficacy and other pre-registration trials shall be conducted in a recognized institution approved in accordance with the technical criteria for designating efficacy trial centres as provided for in the First Schedule.

(3) For purposes of regulations 5, 6, 7, 8, 9 and 10—

(a) local efficacy data shall be generated in accordance with the data extrapolation requirements set out in the First Schedule;

(b) residue data for edible crops shall be generated and submitted in accordance with the requirements for the conduct of supervised pesticide residue field trials on crops as set out in the First Schedule; and

(c) residue data for edible crops shall be submitted or generated for an individual crop or indicator crop in accordance with

the data extrapolation requirements as set out in the First Schedule.

Waiver of data requirements.

12. (1) A person may apply to the Board for determination of the technical equivalence of the active ingredient in the pest control product in Form A3 as set out in the First Schedule.

(2) Where the Board determines that the active ingredient of the pest control product under sub-regulation (1) is equivalent to an active ingredient of a pest control product registered in accordance with these Regulations, the Board may waive any of the data requirements for the active ingredient and register the pest control product upon submission of data for the formulated pest control product.

Registration of a parallel pest control product.

13. (1) The Board shall register a parallel pest control product where the applicant—

(a) submits to the Board an application in Form A7 as set out in the First Schedule;

(b) pays the prescribed fee;

(c) provides a letter of access from the registrant;

(d) provides a letter of no objection from the local agent; and

(e) uses the approved label of the original registered pest control product and only changes the trade name of the product.

(2) The Board shall not require a new dossier for the registration of a parallel pest control product.

(3) The Board shall register a parallel pest control product if the —

(a) original registered product and the parallel pest control product originate from the same source; and

(b) number of the registered parallel pest control product does not exceed five parallel pest control products in respect to one original pest control product.

(4) The Board shall, upon registration of a parallel pest control product, issue the applicant with a Parallel Registration Certificate.

(5) The registration number of the certificate issued under sub-regulation (4) shall be linked to the original registered pest control product by indicating the original registered product number on the Parallel Registration Certificate.

(6) A parallel pest control product registered under this regulation shall be exempt from local efficacy trials where the intended use is identical to that of the original registered pest control product.

(7) Where the use of a parallel pest control product is different from that of the original registered pest control product, efficacy trials shall be conducted.

(8) A person shall not use the registration requirements of a parallel pest control product to register another pest control product.

(9) The use for which an original pest control product is registered may change without affecting the parallel registration and may transfer access of the original dossier.

Experimental label.

14. The Board may extend the use of a registered pest control product through a label extension where the applicant shall submit—

(a) successful two-season efficacy trial data on the respective area of use including crop or pest combination in accordance with the efficacy requirements set out in the First Schedule;

(b) residue data based on the Good Agriculture Practice in the efficacy trial, if the new use is on edible crops in accordance with the residue requirements set out in the First Schedule;

(c) a copy of the previously approved label;

(d) a revised commercial label with the proposed new uses, rates, pre-harvest interval and re-entry interval and the final commercial version label; and

(e) proposed maximum residue limits and pre- harvest intervals for edible commodities and re-entry interval for greenhouse use.

Application by non-residents.

15. (1) For purposes of these Regulations, a person not resident in Kenya who intends to register a pest control product under these Regulations shall appoint a local agent for purposes of registration of the pest control product.

(2) A local agent appointed under sub-regulation (1) shall—

(a) be a permanent resident of Kenya;

(b) possess at least an undergraduate degree in chemistry, crop protection, toxicology, environmental science or any other relevant science;

(c) engage a person with technical expertise in pesticide management where the local agent does not have expertise in pesticide management;

(d) facilitate registration, renewal and payment, importation, exportation, and product stewardship; and

(e) be the contact person to whom any notice or correspondence relating to the pest control product may be sent.

(3) Despite sub-regulation (2)(c), the Board may directly engage with the registrant, manufacturer, exporter or formulator of a pest control product on matters relating to the product.

(4) The applicant under this regulation shall deposit with the Board a binding agreement with a clear duration of contract entered into with the agent appointed under sub-regulation (1).

(5) The Board may consider the terms of the agreement deposited under sub-regulation (4) and any other relevant documents to make a determination under these Regulations.

(6) The applicant under this regulation shall submit to the Board an application for registration of a local agent in Form C1 as set out in the First Schedule.

(7) Where there is a change in appointment of the local agent, the applicant shall submit to the Board an application for registration of a change of agent in Form C2 as set out in the First Schedule.

(8) Where the registrant or local agent intends to terminate or replace the agency agreement, either party shall issue a six month notice to the other party and the Board.

(9) A person who fails to comply with the provisions of this regulation commits an offence.

Change of trade name.

16. A person who intends to change the trade name of a pest control product submitted under regulation 4(2)(e) shall apply to the Board in Form C3 as set out in the First Schedule

Technical information required.

17. (1) A person who intends to introduce a pest control product for efficacy testing and other trials in Kenya shall submit to the Board the requisite information including regulatory data and confidential business information.

(2) The Board shall evaluate the data provided under sub-regulation (1) and if satisfied that the application merits approval, issue a Pest Control Experimental Permit to the applicant.

(3) The Pest Control Experimental Permit shall be in Form D as set out in the First Schedule.

(4) The Board shall provide the applicant, with information relating to existing designated competent persons in the field of trial or study whom the applicant may work with.

(5) When the efficacy trials or other studies have been completed, the designated competent persons shall submit reports thereon to the Board.

Confidential business information.

18. (1) An application for registration of a pest control product under these Regulations shall be accompanied by detailed confidential business information as prescribed in Form E1 as set out in the First Schedule.

(2) The applicant shall ensure that confidential business information is packaged and submitted to the Board in a sealed envelope or file, separate from any other regulatory data, and clearly marked as "Confidential Business Information".

(3) A local agent submitting the confidential business information to the Board shall sign the confidential declaration set out in Form E2 as set out in the First Schedule at the time of submitting the dossier.

(4) An officer of the Board receiving confidential business information shall record the confidential business information data submitted in Form E1 as set out in the First Schedule.

(5) The confidential business information data shall not be copied by any person unless authorised by the Board.

(6) The Board shall store the confidential business information in a secure place and such information may only be accessed by a person authorised by the Board in that regard.

(7) An authorisation by the Board to make copies of confidential business information shall contain the—

(a) name of the recipient of the copy;

(b) intended purpose for which the copy is to be used; and

(c) manner in which the copy is to be disposed of after use.

(8) Save as provided in these Regulations, no person shall disclose confidential business information obtained under these Regulations.

(9) A person may be required to reveal confidential business information to the Board, judicial hearings or in findings of fact issued by the Board, formulas of products, even if confidential, to carry out other functions of the Board.

(10) The Board, the applicant and the local agent shall protect confidential business information obtained under these Regulations and shall not disclose such information.

(11) The requirements for protection of confidential business information shall be as set out in Form E1 of the First Schedule.

(12) A person who discloses confidential business information contrary to this regulation commits an offence.

Submission of samples.

19. (1) An applicant shall, when requested to do so by the Board, provide—

(a) a sample of the pest control product;

(b) a sample of the technical grade of the pest control product active ingredient;

(c) a sample of the analytical standard of pest control product active ingredient; and

(d) any other sample as may be required by the Board.

(2) The samples under sub-regulation (1) shall be submitted to the Board in Form F as set out in the First Schedule.

Denaturation.

20. Where the physical properties of a pest control product are such that the presence of the pest control product may not be recognized when it is used, and is likely to expose a person or domestic animal to a severe health risk, the pest control product shall be denatured by means of colour, odour or such other means as the Board may approve to provide signal or warning of its presence.

Fees for application for registration.

21. An applicant shall pay the prescribed fees for the registration of a pest control product.

Revocation. Sub-Leg.

22. The Board may terminate the process of registration of a pest control product at any stage where—

(a) new information has become available that indicates that the product is unsafe to human health and environment; or

(b) the use of the active ingredient has been withdrawn for use or banned from use in Kenya or globally.

Issuance of certificate of registration.

23. (1) The Board shall, if satisfied with the quality, safety, efficacy and economic value of a pest control product, issue a notification of approval of registration of the pest control product.

(2) Upon receipt of the notice under sub-regulation (1), the applicant shall, within ninety days from the date of receipt of the notice—

(a) submit a sample of the pest control product;

(b) submit the final commercial label for the pest control product;

(c) pay the prescribed registration fee; and

(d) fulfil any other condition imposed by the Board.

(3) An applicant who fails to meet the timeline set out in sub-regulation (2) shall be liable to a penalty as prescribed by the Board.

(4) Where the applicant meets the conditions set out in sub-regulation (2), the Board shall register the pest control product and issue a certificate of registration in Form G as set out in the First Schedule.

(5) Where the Board is not satisfied with the safety, efficacy, quality or economic value of the pest control product, the Board may defer the registration of the pest control product and communicate the reasons for the deferment to the applicant, in writing.

(6) Where the Board is satisfied that the reasons for deferment of registration under sub-regulation (5) have been addressed by the applicant, the Board shall approve the application and issue a notification in writing.

(7) A person to whom a certificate of registration has been issued shall not transfer the certificate to any other person without the approval of the Board.

(8) The approval of the Board shall be endorsed on the Certificate of Registration.

Duration and renewal of certificate of registration.

24. (1) A certificate of registration issued under these Regulations shall, unless suspended or revoked, be valid for a period of five years from the date of issue and may thereafter be renewed for a period not exceeding three years at any one time.

(2) An applicant shall pay the prescribed fee for the renewal of a certificate of registration and the application for renewal shall be accompanied by three copies of the current label for the pest control product.

(3) A holder of a certificate of registration who does not apply for renewal within three months after expiry of the validity period of the certificate shall pay a penalty as prescribed under the Regulations made under the Act.

(4) A holder of a certificate of registration who does not apply for renewal within six months after expiry of the validity period shall have the pest control product removed from the list of registered products and from the distribution chain.

(5) A holder of a certificate of registration issued under these Regulations shall give a notice to the Board in writing at least three months before the expiry of the registration, of any intention to keep the product registration in abeyance for a period not exceeding five years and the notice shall—

(a) give reasons for temporary withdrawal; and

(b) show the record of all quantities of the pest control product in stock, manufactured and sold by the holder of certificate of registration in the preceding two years.

(6) The Board shall consider the notification under sub-regulation (5) and if satisfied with the reasons for temporary withdrawal, the Board shall suspend the registration of the pest control product for a period not exceeding five years.

(7) A person whose certificate of registration has expired shall give a notice to the Board in writing of any intention to reintroduce the product for registration and the notice shall—

(a) give reasons for reintroduction;

(b) be accompanied by a fee for the renewal of a certificate of registration which fee shall include the fees payable for the period that the product was in abeyance had the certificate of registration been renewed; and

(c) be accompanied by three copies of the label that conforms with these Regulations.

(8) A holder of a certificate of registration who does not apply for renewal within five years in accordance with sub-regulation (2) shall —

(a) have the registration cancelled;

(b) submit a fresh application; and

(c) supply any further information which may be requested by the Board in writing.

Temporary registration.

25. (1) The Board may, on payment of the prescribed fee, register a pest control product for a period of one year where the applicant agrees to produce additional scientific or technical information in relation to the use for which the pest control product is to be sold.

(2) The terms and conditions specified by the Board under sub-regulation (1) shall be contained in the temporary certificate of registration.

(3) The temporary registration of the pest control product issued under this regulation may be renewed for a maximum period of two years.

Emergency Registration.

26. (1) The Board may register a pest control product for managing invasive and exotic pests for a period of one year where there is localized, confined or nationwide invasion, or infection, or an emergency situation that can potentially affect plants or public health.

(2) A person who wishes to apply for an emergency use registration under sub-regulation (1) shall submit the following documents to the Board—

(a) a duly filled application form;

(b) proof of payment for the application of emergency use application;

(c) supporting technical data on pest control product;

(d) a pest control product label;

(e) proof of registration of the pest control product in another country; and

(f) any other additional information that the Board may, in writing, request for.

(3) The requirements for emergency registration of pest control products for use in plants or public health shall be as specified in Form H as set out in the First Schedule.

(4) A pest control product registered under this regulation shall only be sold for emergency control of infestations that are seriously detrimental to public health, animals, crops, agricultural produce or natural resources.

(5) The Board may cancel an emergency use registration where the registrant contravenes the registration conditions of the pest control product.

Registration of pest control Products for export and re-exports.

27. The Board may, upon payment of the prescribed fee, register a pest control product for export or re-export if the safety data sheet and certificate of analysis provided by the applicant meets the requirement prescribed by the Board.

Risk assessment.

28. The Board shall conduct a hazard and risk assessment on a pest control product and where applicable provide mitigation measures on the associated hazard or risk.

Sources of registered pest control products.

29. (1) Where a certificate of registration for a pest control product is issued under these Regulations, the product shall be obtained from the declared source at the time of registration.

(2) An application for change of source or additional source for the product shall be submitted to the Board in Form I as set out in the First Schedule.

Exemption from registration.

30. A pest control product shall be exempt from registration under these Regulations if the pest control product is—

(a) for use by a person for research purposes on the approval of the Board;

(b) a classical biological control agent for release by an authorized Government agency; or

(c) a type or kind set out in the Second Schedule and meets the conditions relevant to that substance as set out in the Second Schedule.

Refusal to register pest control product.

31. The Board may refuse to register a pest control product where the—

(a) application for registration or the label for the pest control product does not comply with the provisions of the Act and these Regulations;

(b) information provided to the Board by the applicant is insufficient to enable the pest control product to be assessed or evaluated;

(c) applicant fails to establish that the pest control product has merit or value for the purpose claimed when the pest control product is used in accordance with its label directions; or

(d) use of the pest control product would lead to an unacceptable risk or harm to—

(i) things on or in relation to which the pest control product in intended to be used; or

(ii) public health, plants, animals or the environment.

Suspension of certificate of registration.

32. (1) The Board may suspend a certificate of registration issued under these Regulations where—

(a) the quality of the product does not meet the specifications declared during the registration process; or

(b) the registrant has not renewed the certificate of registration for the pest product.

(2) The suspension of a registration certificate under sub-regulation (1) shall not exceed a period of six months.

Revocation of certificate of registration.

33. (1) The Board may revoke a certificate of registration issued under these Regulations where—

(a) the information provided in the application for registration was false;

(b) new scientific information has become available to the Board which indicates that pest control product is unsafe or dangerous to use according to label instructions;

(c) new information has become available to the Board indicating that the pest control product is sourced from a manufacturer, formulator or any facility other than that specified in the application form and dossier for registration for the respective pest control product or sources authorised by the Board;

(d) the principal or registrant withdraws the technical support to the local agent or distributor on the basis of which a pest control product was registered, in writing; or

(e) the timeframe of six months under suspension in regulation 32 has lapsed and no corrective action has been undertaken by the principal or registrant.

(2) The Board shall revoke the parallel registration of a pest control product when the registrant withdraws the letter of access.

(3) The Board shall cancel the registration of a parallel pest control product where the registrant of an original pest control product requests, in writing, the cancellation the registration of the pest control product.

Notice to holder of certificate of registration.

34. Where the Board—

(a) refuses to register a pest control product; or

(b) intends to revoke the certificate of registration,

the Board shall issue the applicant or the holder of the Certificate of Registration, as the case may be, with a notice through any recognized means of communication, notifying the applicant or holder of the refusal or revocation and the reasons thereof.

Appeals.

35. An applicant or holder of a Certificate of Registration who has received a notice under regulation 34 may, within thirty days from the date of receipt of the notice, appeal to the Cabinet Secretary.

Register of Pest Control Products.

36. The Board shall maintain an up-to-date database of the registered pest control products.

Records.

37. A holder of a certificate of registration issued under these Regulations shall keep a record of all the quantities of the pest control products stored, manufactured or sold by the holder and that record shall—

(a) be maintained for five years from the time the record is made; and

(b) be availed to the Board at such times and in much manner as the Board may require.

General penalty.

38. A person who contravenes these Regulations commits an offence and shall be liable upon conviction to the penalties specified under section 12A of the Act.

Revocation. Sub. Leg.

39. The Pest Control Products (Registration) Regulations are revoked.

SCHEDULES

THE PEST CONTROL PRODUCTS (REGISTRATION) REGULATIONS, 2024

FIRST SCHEDULE

FORMS

FORM A1 *(r 5(1)*

THE PEST CONTROL PRODUCTS BOARD

APPLICATION FOR THE REGISTRATION OF CONVENTIONAL CHEMICAL PESTICIDES

Data Requirements

INTRODUCTION

Data requirements are listed in two parts: Part I for data required on the active ingredient(s); and Part II for data required on the formulated product. If the product contains more than one active ingredient a separate dossier for part I should be submitted for each active ingredient.

Part III of the requirements contains the application form for registration of a conventional chemical pesticide.

The data requirements below are structured as follows:

Number = Data point number. Applicants should follow the numbering in these requirements when constituting their dossier.

Data = Description of the data or study required

Use pattern = The pesticide use patterns for which the data are required

- All: all uses
- Food uses: use of the pesticide on human food, or when food may be exposed to the pesticide (e.g. crops, stored products, livestock)
- Feed uses: use of the pesticide on animal feed, or when feed may be exposed to the pesticide (e.g. grazing land, fodder, feed crops)
- Outdoor uses: all outdoor uses of the pesticide (e.g. terrestrial fields, aquatic use (e.g. irrigated rice), forestry, gardens)
- Indoor uses: all indoor uses of the pesticide (e.g. glasshouse, store)

Conditions = R = always required; CR = conditionally required (conditions are specified in the remarks column)

Remarks = Details about the studies to be conducted, conditions under which these are required, etc.

Endpoint of study = The resulting value(s) or outcome(s) of a study. These are specified when relevant

Level of detail = The level of detail of the information or data to be provided is specified, when needed:

- endpoint = only the endpoint(s) of the study needs to be provided;
- summary = a summary of the study needs to be provided, describing – as a minimum – the title page, signed declaration page, materials and methods, main observations and outcomes of the study, the endpoint(s) of the study
- report = the full report of the study needs to be provided.

In ALL CASES, the source/reference of the data or study should be provided, as well as the method used to generate the data. Internationally accepted testing methods should be used, whenever possible (e.g. OECD, CIPAC, ASTM, EC)

List of abbreviations

ADI	Acceptable Daily Intake
a.i.	active ingredient
AOEL	Acceptable Operator Exposure Level
ARfD	Acute Reference Dose
bw	body weight
CAS	Chemical Abstracts Service
CBI	Confidential Business Information
CIPAC	Collaborative International Pesticides Analytical Council
CR	Conditionally required
DT_{50}	Half-life (dissipation)
$DegT_{50}$	Half-life (degradation)
GAP	Good Agricultural Practice
GLP	Good Laboratory Practice
ISO	International Standards Organization
IUPAC	International Union of Pure and Applied Chemistry
K_{ow}	Octanol-water partition coefficient
K_{oc}	Adsoption coefficient (organic carbon)
K_{om}	Adsoption coefficient (organic matter)

LD_{50}	Median lethal dose
LC_{50}	Median lethal concentration
MRL	Maximum Residue Limit
NOAEL	No Observed Adverse Effect Level
NOEC	No Observed Effect Concentration
Pa	Pascal
pK_a	Acid dissociation constant
R	Required

DATA TO BE PROVIDED ON THE ACTIVE INGREDIENT

	Data	*Use pattern*	*Conditions*	*Remarks*	*Endpoint of study*	*Level of detail*
1	DESIGNATION / IDENTITY					
1.1	Common name (ISO) of the active ingredient (a.i.)	All	R	According to the International Organization for Standardization (ISO) common name, or proposed ISO common name		
1.2	Applicant name and address	All	R	To be provided on the application form		
1.3	Name and address of manufacturer of the a.i.	All	R			
1.4	Name and address of toll manufacturer of the a.i. (i.e. secondary contract manufacturer) (if applicable)	All	R			
1.5	Name and address of manufacturing plant(s) of the a.i.	All	R			
1.6	Manufacturer or development code of the a.i.	All	R			
1.7	Methods of manufacture (synthesis pathway), including starting materials, pathways, by-products, impurities	All	R	To be treated as Confidential Business Information (CBI)		Summary
1.8	Purity of the active ingredient	All	R	Minimum content of pure active ingredient in the technical material used for production of	In g/kg	

	Data	*Use pattern*	*Conditions*	*Remarks*	*Endpoint of study*	*Level of detail*
				the pesticide		
1.9	Identity, content, structural formula of isomers, impurities, and additives	All	R	If the active ingredient is a mixture of isomers, the ratio of the content of isomers should be specified Minimum and maximum content in g/kg of each impurity and additive To be treated as CBI; relevant impurities will not be considered as CBI	In g/kg	
1.10	Batch analysis data	All	R	At least five analytical profiles of representative batches from current industrial scale production of the a.i. needs to be provided. They should include the content (in g/kg) of pure a.i., impurities, additives and other components, as appropriate. Representative batches shall, in principle, be within the last five years of manufacture. All components present in	Analytical profiles. Contents in g/kg	Report

	Data	*Use pattern*	*Conditions*	*Remarks*	*Endpoint of study*	*Level of detail*
				quantities of 1 g/kg or more should be analysed and the total of all components should account for at least 980 g/kg of the material analysed. To be treated as CBI		
1.11	Chemical name (IUPAC)	All	R	According to the International Union of Pure and Applied Chemistry (IUPAC)		
1.12	Chemical group	All	R			
1.13	Structural formula	All	R			
1.14	Empirical formula	All	R			
1.15	Patent status	All	R	Name of patent holder; expiry date of patent		
1.16	Molecular mass	All	R			
1.17	CAS Number, CIPAC number	All	R	Chemical Abstracts Service (CAS) and Collaborative International Pesticides Analytical Council (CIPAC) numbers of the a.i., where they exist		
2	PHYSICAL AND CHEMICAL PROPERTIES					
2.1	Physical state	All	R	Solid, liquid etc.		Endpoint
2.2	Colour	All	R			Endpoint

	Data	*Use pattern*	*Conditions*	*Remarks*	*Endpoint of study*	*Level of detail*
2.3	Odour	All	R			Endpoint
2.4	Density	All	R	At 20 °C		Endpoint
2.5	Vapour pressure	All	R	At 20 or 25 °C.	In Pa	Endpoint
2.6	Volatility	All	R	If the a.i. is a solid or liquid, the volatility (Henry's law constant) of the purified a.i. needs to be determined or calculated.	In Pa × m^3 × mol^{-1}	Endpoint
2.7	Solubility in water	All	R	At 20 °C, in neutral pH range. If the pK_a (acid dissociation constant) is between 2 and 12, water solubility also needs to be determined in the acidic range (pH 4–5) and in the alkaline range (pH 9–10). If the solubility in water cannot be determined due to instability of the a.i., this should be justified.	g/L	Endpoint
2.8	Solubility in organic solvents	All	R	Provide for relevant solvents. Temperature should be specified.	g/L	Endpoint
2.9	N-octanol/water partition coefficient (K_{ow} or	All	R	At 20 or 25 °C		Endpoint

	Data	*Use pattern*	*Conditions*	*Remarks*	*Endpoint of study*	*Level of detail*
	log P_{ow})					
2.10	Boiling point	All	R		In °C	Endpoint
2.11	Melting point	All	R		In °C	Endpoint
2.12	Decomposition temperature	All	R		In °C	Endpoint
2.13	Stability in water	All	R			Endpoint
2.14	Stability in organic solvents used in formulation	All	R			Endpoint
2.15	Thermal stability, identity of breakdown product	All	R			Endpoint
2.16	Flammability	All	R			Endpoint
2.17	Flash point	All	R	If the a.i. as manufactured has a melting point below 40 °C		Endpoint
2.18	Explosive properties	All	R			Endpoint
2.19	Oxidizing properties	All	R			Endpoint
2.20	Absorption spectra	All	R	Ultraviolet/visible (UV/VIS), infrared (IR), nuclear magnetic resonance (NMR) and mass spectra (MS)		Endpoint
2.21	Reactivity towards container material	All	R			Endpoint
3	ANALYTICAL METHODS					
3.1	Methods for analysis of the active substance as manufactured	All	R	Provide methods for the determination of: pure active substance in the a.i.as		Summary or Full method (to be determine

	Data	*Use pattern*	*Conditions*	*Remarks*	*Endpoint of study*	*Level of detail*
				manufactured significant and relevant impurities and additives (such as stabilisers) in the a.i. as manufactured. Refer to CIPAC methods, where applicable		d by the national authority)
3.2	Analytical methods for the determination of residues to enable compliance with MRLs or to determine dislodgeable residues	Food uses	R	For all components of the residue definition		
		Non-food uses	CR	If dislodgeable residues need to be determined (e.g. for risk assessment of harvesting)		
3.3	Description of methods for analysis in the environment of the parent compound and metabolites of toxicological, ecotoxicological or environmental concern	All	CR	For environmental components (soil, water, organisms …), as relevant, depending on the proposed use pattern of the product		
4	TOXICOLOGY					
4.1	Toxicological reference values	All	R	Acceptable DailyIntake (ADI) Acute Reference Dose (ARfD) Acceptable Operator Exposure Level (AOEL) Specify source.	mg a.i./kg body weight	Summary

	Data	*Use pattern*	*Conditions*	*Remarks*	*Endpoint of study*	*Level of detail*
4.2	Acute oral toxicity	All	R	Not required if test material is a gas or a highly volatile liquid. Study normally conducted in rat.	LD_{50} (mg a.i./kg bw)	Summary
4.3	Acute dermal toxicity	All	R	Not required if test material is a gas or a highly volatile liquid. Not required if the test material is corrosive to skin or has a pH of < 2 or > 11.5. Study normally conducted in rat, rabbit or guinea pig	LD_{50} (mg a.i./kg bw)	Summary
4.4	Inhalation toxicity	All	R	Required if the product consists of, or under conditions of use will result in, a respirable material (e.g. gas, vapour, aerosol or particulate). Study normally conducted in rat.	LC_{50} (mg a.i./L)	Summary
4.5	Skin irritation	All	R	Not required if test material is a gas or a highly volatile liquid. Not required if the test material is corrosive to skin or has a pH of < 2 or > 11.5. Study normally conducted in rabbit; alternatively,	Categories for erythema/eschar formation, oedema formation, inflam-mation, reversibility of skin lesions	Summary

	Data	*Use pattern*	*Conditions*	*Remarks*	*Endpoint of study*	*Level of detail*
				studies with skin disks of the rat or human skin models can be used		
4.6	Eye irritation	All	R	Not required if the test material is corrosive to skin or has a pH of < 2 or > 11.5. Study normally conducted in rabbit; alternatively, corneas from cattle eyes, or chicken eyes can be used.	Categories for corneal opacity, iritis, conjuctival redness or oedema (chemosis), reversibility of eye lesions	Summary
4.7	Skin sensitization	All	R	Not required if the test material is corrosive to skin or has a pH of < 2 or > 11.5. Required if repeated dermal exposure is likely to occur under conditions of use. Conventional study normally conducted in guinea pig; local lymph node assay (LLNA) in mice	Conventional test: skin reaction (e.g. erythema) LLNA: proliferation of lymphocytes in the lymph nodes	Summary
4.8	Sub-chronic oral toxicity (90 day)	All	R	Study normally conducted in rat. Additional studies in a non-rodent species, or through dermal or inhalation exposure, may	NOAEL (mg a.i./kg bw/day)	Summary

	Data	*Use pattern*	*Conditions*	*Remarks*	*Endpoint of study*	*Level of detail*
				be required by the registration authority		
4.9	Chronic oral toxicity	Food uses	R	Study normally conducted in rat. May be combined with the carcinogenicity study.	NOAEL (mg a.i./kg bw/day)	Summary
		Non-food uses	CR	Required if oral exposure could occur.		
4.10	Carcinogenicity	All	CR	Study normally conducted in two rodent species, rat and mouse. Required if: the use of the pesticide is likely to result in significant human exposure over a considerable portion of the human lifespan which is significant in terms of either frequency, duration or magnitude of exposure; or the use requires a maximum residue limit or an exemption from the requirement of a maximum residue limit; or the active ingredient, metabolite,	NOAEL (mg a.i./kg bw/day)	Summary

	Data	*Use pattern*	*Conditions*	*Remarks*	*Endpoint of study*	*Level of detail*
				degradate, or impurity (a) is structurally related to a recognized carcinogen, or (b) causes mutagenic effects as demonstrated by in vitro or in vivo testing, or (c) produces a morphologic effect in any organ (e.g. hyperplasia, metaplasia) in sub-chronic studies that may lead to a neoplastic change.		
4.11	Acute neurotoxicity	All	R	Study normally conducted in rat.	NOAEL (mg a.i./kg bw/day)	Summary
4.12	Sub-chronic neurotoxicity (90 days)	All	R	Study normally conducted in rat. May be adapted to be combined with the sub-chronic oral toxicity study	NOAEL (mg a.i./kg bw/day)	Summary
4.13	Delayed neurotoxicity following acute exposure	All	CR	Required if the pesticide is an organophosphorus substance or is structurally related to other substances that may cause the delayed neurotoxicity. Study normally conducted in hen.	Toxic response, including mortality	Summary

	Data	*Use pattern*	*Conditions*	*Remarks*	*Endpoint of study*	*Level of detail*
4.14	Teratogenicity	Food uses	R	Study normally conducted in two species: rat and rabbit.	NOAEL (mg a.i./kg bw/day)	Summary
		Non-food uses	CR	Required if use of the pesticide is likely to result in significant human exposure over a portion of the human lifespan in terms of frequency, magnitude or duration of exposure.		
4.15	Reproduction toxicity (two-generation study)	Food uses	R	Study normally conducted in rats	NOAEL (mg a.i./kg bw/day)	Summary
		Non-food uses	CR	Required if use of the pesticide is likely to result in significant human exposure over a portion of the human lifespan in terms of frequency, magnitude or duration of exposure.		
4.16	Mutagenicity / Genotoxicity	All	R	Both in vitro and in vivo cytogentics studies are required. At a minimum, an initial battery of mutagenicity tests with possible confirmatory testing is needed.		Summary
4.17	Metabolism – Absorption, distribution,	Food uses	R	Study normally conducted in rats		Summary

	Data	*Use pattern*	*Conditions*	*Remarks*	*Endpoint of study*	*Level of detail*
	excretion and metabolism in mammals, with special reference to differences between laboratory animals and humans, kinetics, accumulation and half-lives	Non-food uses	CR	Required when chronic or carcinogenicity studies are recommended. May be recommended if significant adverse effects are seen in available toxicology studies and these effects can be further elucidated by metabolism studies.		
4.18	Other studies	All	CR	As required by the registration authority		Summary
5	ECOTOXICOLOGY					
5.1	Birds – oral toxicity	Outdoor uses	R	Studies should be conducted on two relevant species: one passerine species and either one waterfowl species or one terrestrial bird species. Generally not required for pesticide products in the form of a gas, a highly volatile liquid, a highly reactive solid, or a highly corrosive material.	LD_{50} (mg a.i./kg bw) NOAEL (mg a.i./kg bw/day)	Summary

	Data	*Use pattern*	*Conditions*	*Remarks*	*Endpoint of study*	*Level of detail*
		Indoor uses	CR	Required if exposure of birds may occur (e.g. open-sided greenhouses) Waterfowl or terrestrial bird species are preferred.		
5.2	Birds – reproduction toxicity	Outdoor uses	R	Studies should be conducted on two relevant species: waterfowl and terrestrial bird species are preferred. Generally not required for pesticide products in the form of a gas, a highly volatile liquid, a highly reactive solid, or a highly corrosive material. Not required for indoor uses.	NOAEL (mg a.i./kg bw/day)	Summary
5.3	Fish – acute toxicity	Outdoor uses	R	Studies should be conducted on two relevant fish species. If the pesticide is to be used in coastal areas, data on one marine/estuarine fish species should be provided.	LC_{50} (mg a.i./L)	Summary
		Indoor uses	CR	Required if exposure of waterways may occur (e.g.		

	Data	*Use pattern*	*Conditions*	*Remarks*	*Endpoint of study*	*Level of detail*
				drainage of contaminated irrigation water from greenhouses) Studies should be conducted on one fish species.		
5.4	Fish – early-life stage	Outdoor uses	R	Studies should be conducted on one relevant fish species. If the pesticide is to be used in coastal areas, data on one additional marine/estuarine fish species should be provided. Not required for indoor uses.	NOEC (mg a.i./L)	Summary
5.5	Fish – life-cycle test	Outdoor uses	CR	Required if the pesticide is to be applied to water, and the results of the early-life stage test indicate that fish are sensitive to the pesticide. Not required for indoor uses.	NOEC (mg a.i./L)	Summary
5.6	Fish – bioconcentration	Outdoor uses	CR	Required if log K_{ow} > 3 and the pesticide is stable in water (i.e. < 90% loss by hydrolysis in 24 hours)	BCF	Summary
5.7	Daphnia – acute toxicity	Outdoor uses	R	If the pesticide is to be used in coastal areas, data on one	LC_{50} (mg a.i./L)	Summary

	Data	*Use pattern*	*Conditions*	*Remarks*	*Endpoint of study*	*Level of detail*
				additional marine/estuarine invertebrate species should be provided.		
		Indoor uses	CR	Required if exposure of waterways may occur (e.g. drainage of contaminated irrigation water from greenhouses)		
5.8	Daphnia – life cycle study	Outdoor uses	R	If the pesticide is to be used in coastal areas, data on one additional marine/estuarine invertebrate species should be provided. Not required for indoor uses.	NOEC (mg a.i./L)	Summary
5.9	Algae	Outdoor uses	R	Studies should be conducted on one species of green algae. For phytotoxicants (e.g. herbicides), a second algal species, from a different taxonomic group, should be tested.	NOEC (mg a.i./L)	Summary
		Indoor uses	CR	Required if exposure of waterways may occur (e.g. drainage of contaminated irrigation water from greenhouses)		

	Data	*Use pattern*	*Conditions*	*Remarks*	*Endpoint of study*	*Level of detail*
5.10	Honey bees – acute oral and contact toxicity	Outdoor uses	R		LD_{50} (µg a.i./bee)	Summary
		Indoor uses	CR	Required if exposure of bees may occur (e.g. open-sided greenhouses, indoor pollination by bumblebees)		
5.11	Honey bee – toxicity of residues on foliage	Outdoor uses	CR	Required if acute contact LD_{50} is < 11 µg/bee	RT_{25} (hours)	Summary
5.12	Bee brood-feeding tests	Outdoor uses	CR	Required for pesticides that may have sublethal effects on growth or development	NOEC (mg a.i./kg food)	Summary
5.13	Non-target terrestrial arthropods	Outdoor uses and greenhouses	CR	Data on relevant predators, parasitoids and other beneficials are required if the pesticide is intended to be used in Integrated Pest Management (IPM).	Depends on test	Summary
5.14	Earthworms	Outdoor uses, except aquatic uses	R	Studies on other soil organisms may be required, in particular if the pesticide is intended to be used in semi-arid conditions	NOEC (mg a.i./kg soil)	Summary
5.15	Soil micro-organisms	Outdoor uses, except aquatic uses	R		NOEC (mg a.i./kg soil)	Summary

	Data	*Use pattern*	*Conditions*	*Remarks*	*Endpoint of study*	*Level of detail*
5.16	Terrestrial plants – screening data	Outdoor uses	R	Screening data can be used to show that the pesticide does not have herbicidal or plant growth regulatory activity. Screening should be done on at least 6 plant species from 6 different families		Summary
5.17	Terrestrial plants – toxicity tests	Outdoor uses	CR	Toxicity tests on terrestrial plants are required if the pesticide has herbicidal or plant growth regulatory activity. Studies on vegetative vigour and seedling emergence should be conducted	ER_{50} (g a.i./ha)	Summary
5.18	Other studies	All	CR	Other ecotoxicological studies (e.g., semi-field studies, micro-/mesocosms) may be required by the registration authority		
6	BEHAVIOUR IN ENVIRONMENT					
6.1	Behaviour, ways of degradation, degradation products in soil:					

	Data	*Use pattern*	*Conditions*	*Remarks*	*Endpoint of study*	*Level of detail*
6.1.1	Behaviour, ways of degradation, degradation products in soil – aerobic	Outdoor and greenho use uses	R	Required, unless exposure of aerobic soils is unlikely to occur (e.g. indoor treatment of stored products)	Soil degradation pathways (schematic), major metabolites, $DegT_{50}$ (days)	Summary
6.1.2	Behaviour, ways of degradation, degradation products in soil – anaerobic	Outdoor uses	R	Required, unless it is unlikely that the pesticide will be exposed to anaerobic soil conditions	Soil degradation pathways (schematic), major metabolites, $DegT_{50}$ (days)	Summary
6.1.3	Mobility – adsorption/desorption studies of the a.i.	Outdoor and greenho use uses	R	Required, unless exposure of soils is unlikely to occur (e.g. indoor treatment of stored products)	K_{oc} , K_{om}	Summary
6.1.4	Mobility – adsorption/desorption studies of the metabolites	Outdoor and greenho use uses	R	Required if metabolites account for more than 5% of the active ingredient in the soil degradation studies	K_{oc}, K_{om}	Summary
6.2	Behaviour, ways of degradation, degradation products in water:					
6.2.1	Hydrolysis	Outdoor and greenho use uses	R		Major metabolites, $DegT_{50}$ (days)	Summary
6.2.2	Photolysis	Outdoor uses	R		Major metabolites, $DegT_{50}$ (days)	Summary
6.2.3	Water-sediment studies	Outdoor uses	R		Major metabolites, $DegT_{50}$ (days), DT_{50} (days)	Summary

	Data	*Use pattern*	*Conditions*	*Remarks*	*Endpoint of study*	*Level of detail*
6.3	Behaviour, ways of degradation, degradation products in air	All	CR	Required for fumigants and other volatile products		
7	MODE OF ACTION					
7.1	Function (e.g. herbicide, insecticide)	All	R			Endpoint
7.2	Mode of action of the active ingredient	All	R			Summary
8	RESIDUES					
8.1	Storage stability of residues	Food uses	R			Summary
8.2	Metabolism and behaviour of residues					
8.2.1	Nature and chemical identity of the residue in plants, including major metabolites	Food uses (crops, stored products)	R	Also required for green tobacco. Depending on the level of residues found on the green tobacco, additional data may be required on cured or dried tobacco and pyrolysis products.	Include schematic diagramme of the metabolic pathways in plants	Summary
8.2.2	Nature and chemical identity of the residue in animal products, including major metabolites	Food use (animals)	CR	Required if the pesticide use is directly applied to livestock. Required if pesticide residues are present in or on livestock feed items or intentionally added to drinking-water,	Include schematic diagramme of the metabolic pathways in animals	Summary

	Data	*Use pattern*	*Conditions*	*Remarks*	*Endpoint of study*	*Level of detail*
				unless livestock metabolism studies indicate negligible transfer of the pesticide residues of concern to tissues, milk and eggs from animals exposed at the maximum expected level.		
8.2.3	Nature and chemical identity of the residue in fish, including major metabolites	Aquatic food use	R	Required if the pesticide is applied directly to water inhabited, or to be inhabited, by fish that may be caught or harvested for human consumption.	Include schematic diagramme of the metabolic pathways in animals	Summary
8.3	Residue trials	Residue trials in Kenya are required, unless: - A Codex MRL has been established, and the proposed GAP of the pesticide to be registered is similar to the Codex GAP (i.e. ±25% of the reference GAP), and no specific dietary concerns exist; or - An MRL has been established by the EU, the USA, Australia, New Zealand, Japan, Canada or Brazil, and the proposed GAP of the pesticide to be registered is similar to the reference GAP, and no specific dietary concerns exist. or - If residue data extrapolation is possible base on Codex crop grouping. Residue trials conducted in other countries may be submitted, if				

	Data	*Use pattern*	*Conditions*	*Remarks*	*Endpoint of study*	*Level of detail*
		conducted under comparable agronomic practices for crop/pesticide combinations and following a similar GAP. Such studies should be conducted by GLP certified institutions and follow internationally accepted requirements. For further details on the number and design of residue trials, the applicant should refer to the Requirements for the Conduct of Supervised Residue Field Trials on Crops				
8.3.1	Residue trials for crops or plant product used as food or feed on which use is proposed or from which residues from soil can be taken up (crop field trials)	Food use (crops)	R	Also required if indoor use could result in pesticide residues in or on food or feed.		Summary Full reports for trials conducted
8.3.2	Livestock feeding studies on the nature of the residue in livestock	Feed use	CR	Required if a pesticide is to be applied directly to livestock, to livestock premises, to livestock drinking-water, or to crops used for livestock feed. If the results of the plant metabolism study show differing metabolites in plants and animals, an additional livestock metabolism study involving		Summary Full reports for trials conducted

	Data	*Use pattern*	*Conditions*	*Remarks*	*Endpoint of study*	*Level of detail*
				dosing with the plant metabolite(s) may also be needed.		
8.3.3	Effects of industrial processing and/or household preparation on the nature of the residue, distribution of the residue, and residue levels	Food and feed use.	CR	Required if residues could potentially concentrate during processing thus requiring the establishment of a separate MRL higher than that of the raw agricultural commodity.		Summary Full reports for trials conducted
8.3.4	Residues in succeeding crop (rotational crops)	Food and feed use.	CR	Required if it is reasonably foreseeable that a food or feed crop could subsequently be planted on the site of pesticide application after harvest or failure of the treated crop. Not required for pesticide uses in permanent food crops (e.g. various tree crops, vines) or semi-permanent crops (e.g. asparagus, pineapples) or for greenhouse crops if the substrate is replaced.		Summary Full reports for trials conducted
8.4	National or regional residue definition and	Food and feed	R	Required if use could result in pesticide		Summary

	Data	*Use pattern*	*Conditions*	*Remarks*	*Endpoint of study*	*Level of detail*
	MRL (if established), or proposed national residue definition and MRL. (incl. associated GAP)	use		residues in or on food or feed.		
8.5	Residue definition and MRL by the Codex Alimentarius (if established) and by other relevant authorities (e.g. European Union, US-EPA, countries to which treated commodities are likely to be exported). (incl. associated GAP)	Food and feed use	R	Required if use could result in pesticide residues in or on food or feed.		Summary
8.6	Proposed pre-harvest intervals, withholding periods in case of post-harvest use.	Food and feed use	R	Required if use could result in pesticide residues in or on food or feed.		Summary

II. DATA TO BE PROVIDED ON THE FORMULATED PRODUCT

For terminology and the list of abbreviations, see the Part I – Active Ingredient

	Data	*Use pattern*	*Conditions*	*Remarks*	*Endpoint*	*Level of detail*
1	IDENTITY					
1.1	Trade or commercial or brand name	All	R	Trade name of the pesticide product should be unique in Kenya; identical trade names for the different products are not allowed.		
1.2(a)	Type and code of formulation	All	R	According to the latest Catalogue of pesticide formulation types and international coding system of CropLife International		
1.2(b)	Type of Registration Applied for. Tick as Necessary Full Registration Temporary Registration					

1.3	Detailed quantitative and qualitative information on the composition of the formulation, including: −content of technical active substance and formulants −certified limits of each compound −salt, ester, anion or cation present for each active substance −for each formulant, or component of formulants: chemical name, structure or structural formula, CAS or CIPAC numbers, trade name, specification of formulation, function of each formulant −description of formulation process and discussion of the formation of impurities of toxicological concern	All	R	To be treated as Confidential Business Information (CBI)		Complete recipe

1.4	Certificate of analysis	All	R	Certificate should be from a GLP laboratory Contact details of the laboratory should be provided		
2	PHYSICAL AND CHEMICAL PROPERTIES					
2.1	Physical state/formulation type	All	R	Solid, liquid etc.		Endpoint
2.2	Colour	All	R			Endpoint
2.3	Odour	All	R			Endpoint
2.4	Storage stability	All	R	Indicate the stability of the preparation after storing at 54°C for 14 days. Other durations and/or other temperatures (e.g. 8 weeks at 40°C, 18 weeks at 30°C) if the preparation is thermo-sensitive.		Endpoint(s)
2.5	Shelf-life	All	R	The shelf-life of the product at room temperatures (30°C) is given in years if it is more than two years and in months if it is less than two years. The appropriate temperature specifications must be given.		Endpoint
2.6	Relative density	All	CR	Required for liquids		Endpoint
2.7	Bulk density	All	CR	Required for solids, after compression		Endpoint

2.8	Flammability	All	R			Endpoint
2.9	Flash point	All	R			Endpoint
2.10	Compatibility/in-compatibility with other pesticides	All	R	Indicate types of pesticides that the product is incompatible with. Explain the hazards or adverse effects		Summary
2.11	pH range	All	R	State the effect of pH on stability and effectiveness.		Summary
2.12	pH of 1% aqueous dilution	All	R	Required for products to be diluted in water		Endpoint
2.13	Oxidizing properties	All	R	Indicate materials that can be damaged by oxidizing properties of the formulation.		Endpoint
2.14	Corrosiveness	All	R	Specify effect on containers, equipment, skin etc.		Endpoint
2.15	Water content	All	R	Indicate the maximum water content when it has an influence on the quality of the product		Endpoint
2.16	Degree of dissolution and/or solution stability	All	CR	Required for water soluble formulations.		Endpoint
2.17	Wettability	All	CR	Required for solid formulations to be dispersed or dissolved in water.		Endpoint

2.18	Persistent foaming	All	CR	Required for formulations intended for dilution with water before use.		Endpoint
2.19	Particle size	All	CR	Required for formulations containing particles		Endpoint
2.20	Nominal size range	All	CR	Required for granular formulations		Endpoint
2.21	Dustiness	All	CR	Required for granular formulations		Endpoint
2.22	Attrition resistance & tablet integrity	All	CR	Required for granular and tablet formulations		Endpoint
2.23	Suspensibility	All	CR	Required for wettable powders (WP), suspension concentrates (SC), flowable concentrate for seed treatment (FS) which are diluted for use, capsule suspensions (CS), water dispersible granules (WG) and water dispersible tablets (WT)		Endpoint
2.24	Dispersibility and spontaneity of dispersion	All	CR	Required for suspension concentrates (SC), aqueous capsule suspensions (CS) and water dispersible granules (WG)		Endpoint

2.25	Wet sieve test	All	CR	Required for wettable powders (WP); suspension concentrates including those for seed treatment and oil-based (SC, FS and OD); water dispersible granules (WG) and water dispersible powder for slurry seed treatment (WS) ; aqueous capsule suspensions (CS); dispersible concentrates (DC); suspo-emulsions (SE); water-soluble and dispersible tablets (ST and WT); and emulsifiable granules and powders (EG and EP)		Endpoint
2.26	Dry sieve test	All	CR	Required for powders and granules intended for direct application and seed treatment		Endpoint
2.27	Emulsion stability	All	CR	Required for emulsifiable concentrates (EC), emulsions, oil in water (EW) and microemulsions (ME)		Endpoint

2.28	Flowability	All	CR	Required for water dispersible granules (WG), water soluble granules (SG), granules (GR) and emulsifiable granules (EG)		Endpoint
2.29	Pourability	All	CR	Required for suspension concentrates (SC, FS and OD), aqueous capsule suspensions (CS), suspo-emulsions (SE) oil-in-water emulsions (EW) and similarly viscous formulations, but may also be applied to formulations in solution, such as soluble concentrates (SL) and emulsifiable concentrates (EC)		Endpoint
2.30	Dispersion stability	All	CR	Required for suspo-emulsions (SE), emulsifiable granules (EG), emulsifiable powders (EP), dispersible concentrates (DC) and oil-based suspension concentrates (OD)		Endpoint

2.31	Miscibility with hydrocarbon oil	All	CR	Required for any formulation intended to be diluted with oil before use (e.g. OL)		Endpoint
2.32	Volatility	All	CR	Required for ultra-low volume liquids (UL)		Endpoint
2.33	Viscosity	All	CR	Required for formulations to be used at very low volume		Endpoint
2.34	Adhesion to seeds	All	CR	Required for seed treatment formulations		Endpoint
2.35	Dissolution of water soluble bags	All	CR	Required for formulations packaged in water soluble bags		Endpoint
3	METHODS OF ANALYSIS					
3.1	Methods of analysis	All	R	Analytical methods for the determination of the active ingredient, impurities of toxicological concern and formulants in the formulated product . Refer to CIPAC methods, where applicable		Summary or Full method (depending on the presence of a pesticide analytical laboratory in the country)
4	TOXICOLOGY					
4.1	Acute oral toxicity	All	R	Not required if the product is a gas or a highly volatile liquid.	LD_{50} (mg a.i./kg bw)	Summary

4.2	Acute dermal toxicity	All	R	Not required if the product is a gas or a highly volatile liquid. Not recommended if the test material is corrosive to skin or has a pH of < 2 or > 11.5.	LD_{50} (mg a.i./kg bw)	Summary
4.3	Inhalation toxicity	All	R	Required if the product consists of, or under conditions of use will result in, a respirable material (e.g. gas, vapour, aerosol or particulate).	LC_{50} (mg a.i./L)	Summary
4.4	Skin irritation	All	R	Not required if the product is corrosive to skin or has a pH of < 2 or > 11.5.	Categories for erythema/ eschar formation, oedema formation, inflam-mation, reversibility of skin lesions	Summary
4.5	Eye irritation	All	R	Not required if the product is a gas or a highly volatile liquid. Not required if the product is corrosive to skin or has a pH of < 2 or > 11.5.	Categories for corneal opacity, iritis, conjunctival redness or oedema (chemosis), reversibility of eye lesions	Summary

4.6	Skin sensitization	All	R	Not required if the product is corrosive to skin or has a pH of < 2 or > 11.5. Required if repeated dermal exposure is likely under conditions of use.	Conventional test: skin reaction (e.g. erythema) LLNA: proliferation of lymphocytes in the lymph nodes	Summary
4.7	Dermal absorption.	All	CR	Dermal absorption data of the formulation may be provided when dermal exposure is a significant exposure route, and default absorption values result in no acceptable risk.		Summary
4.8	Other toxicity studies	All	CR	Additional toxicological studies with the formulated product may be required by the registration authority.		Summary
5	EFFICACY					
5.1	Efficacy data, demonstrating efficacy for the crops/pests for which a registration has been requested	All	R	Efficacy requirements should be used		Full report

5.2	Adverse effects (e.g. phytotoxicity, effects on succeeding or adjacent crops, development of resistance)	All	R	Observations to be included in the efficacy trials under 5.1, whenever possible. Specify any contraindications with respect to follow-up crops, adjacent crops etc		Full report
5.3	Good Agricultural Practices (GAP) table for all uses/crops/pests for which a registration has been requested, including:	All	R	Use OECD format for GAP table, or similar.		Table
5.3.1	Crop/area of use			The common name of the crop on which the product is aimed at should be clearly specified. When the product is not aimed at a crop, indicate the areas of use, e.g. livestock, public health, post-harvest		
5.3.2	Target organism			The target organisms should be identified by common and scientific name.		

5.3.3	Nature of effects on the target organisms			Nature of effects of the pesticide should be specified; e.g. contact action, whether the active ingredient is trans-located inside the organism, etc.)		
5.3.4	Application rate			The rate of application must be indicated on the basis area treated or volume used e.g. l/ha, g/ha, l/m^3 etc.		
5.3.5	Application frequency			Specify the minimum and maximum number of treatments per year or per growing season		
5.3.6	Method of application			Specify the methods(s) of application of the product that are recommended to be used		
5.3.7	Stage of treatment			Specify the stage of the crop or target organism at which application must be made		
5.3.8	Pre-harvest interval or waiting period			Minimum time needed between the last treatment and harvest, re-entry of livestock, entry of workers, etc.		

5.4	Data on efficacy, as well as on effects on beneficial organisms, of the use of the pesticide within IPM/IVM	All	CR	Required in case a claim of compatibility within IPM/IVM is made		Full report
6	OTHER INFORMATION					
6.1	Material Safety Data Sheet (MSDS)	All	R			
6.2	Hazard classification (WHO)	All	R	Provide the hazard classification of the formulated product according to the WHO classification of pesticides by hazard		
6.3	Hazard classification (GHS)	All	R	Provide the complete hazard classification of the formulated product according to the Globally Harmonized System of classification and labelling of chemicals (GHS). This includes physical hazards, health hazards and environmental hazards, as far they product triggers a hazard classification		

6.4	Emergency measures in case of exposure or poisoning	All	R	Include information on treatment of poisoning and antidotes (if relevant)		
6.5	Emergency measures in case of spillage or fire	All	R	Include decontamination procedures and neutralizing chemicals (if relevant), and information of combustion products likely to be generated in case of fire		
6.6	Type of packaging, pack size(s) and (in-)compatibility with the formulation	All	R			
6.7	Procedures for cleaning application equipment	All	R			
6.8	Risk statements and precautionary statements	All	R	Statement of risks arising from the recommended methods, and precautions and handling procedures to minimize those risks, including: storage; transport; protective clothing; procedures to minimize generation of waste		

6.9	Pyrolytic behaviour	All	R	Pyrolytic behaviour of the active substance under controlled conditions at 800 °C, and the content of polyhalogenated dibenzo-p-dioxins in the products of pyrolysis		
6.10	Disposal procedures for the pesticide	All	R	Provide realistic safe disposal method of the product		
6.11	Proposed label	All	R	Provide a realistic mock-up of the proposed label, as required by respective member state pesticide laws.		

6.12	Registration of the product in other countries	All	R	Provide a complete list of registrations of the formulated product in other countries. Specify for which uses the product has been registered, as well as national or regional registration numbers and expiry dates. Indicate whether the product is registered in the country of formulation and/or manufacture; if the product is not registered, indicate why this is the case.		

7	DECLARATION	
	For and on behalf of …… I hereby certify that the above mentioned information, as well as the data provided in the technical dossier, in support of this application are true, correct and complete.	
	…… *Name in full (print)*	…… *Signature*
	…… *Official title*	…… *Date*
	Official stamp of applicant/company	
8	FOR OFFICIAL USE	
	Application No: …	
	Reception date: …	
	Fees received: □ Yes □ No	

SUMMARY DOSSIER

FORM B *(r.5(2))*

PEST CONTROL PRODUCTS BOARD
P.O. BOX 13794-00800, NAIROBI, WAIYAKI WAY
Tel 020 4446115 or 020 4450242 Fax 020 4449072
E-MAIL: info@pcpb.go.ke/md@pcpb.go.ke
WEBSITE ADDRESS: https://www.pcpb.go.ke/

Summary of the data submitted to the PCPB for registration of a Conventional Pest Control Product.

PART I

Trade Name…….....

The Name and Address of Formulator…….. .....

.....

Common Name of the active ingredient(s), and concentration .....

.....

.....

Source(s) of a.i.(s) .....

Source(s) of formulation(s) .....

Chemical Name .....

.....

Formulation type .....

Proposed Uses .....

.....

Packaging/Containers (Material size .....

.....

Registrant (Name, Address, Status .....

.....

Agents/Distributors in Kenya .....

.....

Premises (License No., Date of issue .....

.....

PART II

CHEMISTRY DATA

(a) Physical /Chemical Properties of the a.i .....

.....

.....

(b) Physical/Chemical properties of the technical grade material.....

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.....

.....

(c) Composition of the technical product (purity%, nature and content of impurities, isomers, by-products)

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(d) Physical/Chemical Properties of the Formulated Product

.....

.....

.....

(e) Composition of the Formulated Product .....

.....

.....

(f) Method of analysis for determination of the a.i. in technical and formulated products

.....

.....

PART III

BIOLOGICAL(EFFICACY) DATA

(a) Summarize the efficacy trial including the testing institution, number of seasons, period of testing…….....

……..……

(b) Target Pest(s), Diseases(s), Host(s). Complete the efficacy GAP table below, in accordance with local efficacy data

GAP Table for Efficacy

1	3	4	5	6	7		8	10		11	12	13	14
Use-No.	Crop and /or situation (crop destination / purpose of crop)	Fungicide /Herbicide /Insecticide /Others (specify)	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest Group, where necessary [e.g. larvae, adults])	Application				Application rate				PHI (days)	Remarks:
				Method / Kind	Timing / Growth stage of crop & season	Max. number of applications a) per use b) per crop or season	Min. interval between applications	L. product / ha a) max. rate per appl. b) max. total rate per crop/ season	g/kg a.i/haa) max. rate per appl. b) max. total rate per crop or season	g/kg of a.i. per hL min. -- max.	Water L/ Hamin/ max		
1	Indicator crop: (e.g. Tomato)	e.g. Fungicide	*Indicator pest(s):* *e.g.* *Phytophthor ainfestans* (late blight)	Foliar spray	Upon infestation	1 – 2 per season	7 days	2.0 kg 4.0 kg	1.6 kg 3.2 kg	1.6 – 2g	600 – 1000 L	14 days	
2	To be extrapolated to: Potato	F	*Phytophthor ainfestans*(late blight	Foliar spray	Upon infestation	1 – 2 per season	7 days	2.0 kg 4.0 kg	1.6 kg 3.2 kg	1.6 – 2g	600 – 1000 L	14 days	

(c) Complete the crop safety GAP table below:

Crop safety assessment results

1		3	6	7			8	10		11	12	13	14
Use-No.	Formulation details (a.i/ L or Kg and formulation type)	Crop and/or situation (crop destination / purpose of crop)	Application									Crop response	Remarks
			Method / Kind	Timing / Growth stage of crop	Growing conditions (e.g. protected vs. outdoor)	Number of applications per season	Interval of applications	Product rate/ ha	g/kg a.i/ha	g/kg of a.i. per hL min. -- max.	Water L/ha		
1		Representative commodity: (e.g.Tomato)	Foliar spray	Flowering		3	7 days	2.0 kg 4.0 kg	1.6 kg 3.2 kg	1.6 – 2g	600 – 1000 L		

d) Recommendations for use in Kenya

.....

e) Recommendations for use by authorized bodies outside Kenya .....

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PART IV

Toxicological data

a) Acute Toxicological Data of the active ingredient(s)

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b) Acute toxicity data of the formulated product:..

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c) Short term toxicity studies .....

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d) Other toxicological studies:

1) Reproduction studies .....

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2) Teratological studies.....

.....

3) Neurotoxicity studies .....

.....

4) Mutagenecity studies .....

.....

5) Long term toxicity/carcinogenicity studies .....

.....

6) Accumulation of compound in tissues .....
……...…
……...……
7) Metabolic studies ……..……
.....
.....
8) Effects on livestock, poultry ……
……..…
……..……
9) Toxicity Data on impurities ……..…
……..…
……..…
10) Toxicity Data on metabolites ……..…
……...…
……...……
11) Human toxicology and medical aspects:
1)Hazards to humans ……..……...…
.....
……...….
2) Symptoms of poisoning……...……

……..……

3) Antidote……

……..

4) Treatment ……

……

5) First Aid Measures……...…

……..……..

……..…..

6) Safety Precautions/Restrictions……...……

……..…..
……...

PART V – RESIDUE DATA

a) Principal Residues……

……..

……...……

b) Disappearance and fate of residues……

……...……

……...……

c) Method(s) of analysis (crops, soil, water, feedstuffs etc.)……

……

……

d) Summary of results of supervised residue trials (Complete the GAP table for residues below. Use a different table for each crop group listed in the efficacy GAP table)

GAP table for residues

1	2	3	4	6	7		8	10		11	12	13	14	
Use/ No.	Country	Formulation details (a.i/L or Kg and formulation type)	Crop and/or situation (crop destination / purpose of crop)	Application								PHI (days) (days after last application)	Results (mg a.i/kg)	Codex /EU MRL
				Method / Kind	Timing / Growth stage of crop	Number of applications per season	Interval of applications	Product rate / ha	g/kg a.i/ha	g/kg of a.i. per hL min. -- max.	Water L/ha min / max			
1			Representative commodity: (e.g. Tomato)	Foliar spray	Flowering	3	7 days	2.0 kg 4.0 kg	1.6 kg 3.2 kg	1.6 – 2g	600 – 1000 L	14 days		
			Trial 1											
			Trial 2											
			Trial 3											
			Trial 4											

PART VI

Environment and wildlife hazards

a) Degradation and mobility studies (soil,water, air) ……...……...…

b) Toxicity to birds ……..……...…..

c) Toxicity to fish……

d) Toxicity to honeybees/beneficial insects ……...……

e) Toxicity to earthworms, other soil invertebrates ……...……

f) Changes in soil ecology……..……

PART VII

Information on Approvals/Registrations in other countries ……..…….……..

……..……

PART VIII

Draft of local label

……..

PART IX

Brief prepared by:……...……

Signature:……..……

Official stamp

Date……..

PART X

Decision of the PCPB registration Sub-Committee

Recommended/Not Recommended for registration

Reasons:-

……...

Date……

FORM A2 *(r6(1)(2)(a)*

REQUIREMENTS FOR THE REGISTRATION OF BIOPESTICIDES AND BIOCONTROL AGENTS FOR PLANT PROTECTION

ABBREVIATIONS

BCF-	Bio Concentration Factor
CAS-	Chemical Abstracts Service
CFU-	Colony Forming Unit
CRISPR-	Clustered regularly interspaced short palindromic repeats
DNA-	Deoxyribonucleic acid
EC-	European Commission
FAO-	Food and Agriculture Organization of the United Nation
GMOs-	Genetically modified organisms
GV-	Granulosis virus
ICIPE-	International Centre of Insect Physiology and Ecology
IPM-	Integrated Pest Management
IPPC-	International Plant Protection Convention
ISO-	The International Organization for Standardization
ISPM-	International Standards for Phytosanitary Measures
IU-	International Unit: a standardised measure of dosage for Bt product
IUPAC-	The International Union of Pure and Applied Chemistry
NOEL	'No observable effect level' in testing toxicity and other undesired effects of a pesticide.
NPV-	Nuclear Polyhedrosis Virus
OECD-	Organisation for economic cooperation and development
POB-	Polyhedral Occlusion Body
RNA-	Ribonucleic Acid
SCLPs-	straight chain lepidopteran pheromones
TGAI:	Technical grade active ingredient.
WHO-	Word Health Organization

1. INTRODUCTION

Kenya needs to intensify agricultural production to ensure achievement of food security and increased incomes through trade of agricultural produce that is necessary to support their economies. Currently, plant protection is heavily dependent on the use of conventional pesticides whose excessive use may adversely impact human health and environment. The development and use of alternative plant protection approaches such as Biopesticides is recommended to augment existing Integrated Pest Management (IPM) system. Biopesticides are a potential tool in integrated pest management as they generally pose minimal health or environment risk and can have good compatibility with many beneficial invertebrates used in IPM.

The registration of biopesticides and biocontrol agents should take into account the special biological properties of the natural agents and requires expertise in microbial ecology, bacteriology, virology and protozoology in order to understand the biology of the particular agents and evaluate key issues of safety and environmental impact.

1.1. OBJECTIVES

These requirements aim at providing data requirements, evaluations and decision making with regard to registration of Biopesticides and biocontrol agents in order to provide an acceptable level of protection for human and animal health and the environment.

1.1.1. OVERALL OBJECTIVE

Provide farmers with a sustainable access to safer and effective biopesticides and Biocontrol agents for pest control.

1.2. GENERAL PROVISIONS

1.2.1. PCPB shall ensure that all new Biopesticides and biocontrol agents or new uses of existing products are subjected to a thorough efficacy evaluation before they are authorized for any use.

1.2.2. All efficacy trials involving Biopesticides and biocontrol agents shall be approved by PCPB.

1.2.3. Applicants intending to register Biopesticides or biocontrol agents shall ensure the protocols are compiled with.

1.2.4. The cost of conducting efficacy trials of biopesticides or biocontrol agents authorized by the regulatory authority will be incurred by the applicant.

1.2.5. All applicants intending to import/export live organisms into or out of tthe country should seek clearance from the National Plant Protection Organization.

1.3. SCOPE

These Requirements covers:

(i) Microorganisms (bacteria, fungi, viruses, protozoa)

(ii) Macro-organisms (Predators and Parasitoids, insects and mites)

(iii) Biochemical pesticides (Botanicals and Semiochemicals).

These requirements shall not cover biochemical pesticides and any other products that may pose adverse effects on human, non-target organisms and environment. Therefore, in this case, such products shall not be considered as bio pesticides and shall

be evaluated as conventional pesticides. In some cases, waivers will be granted where there is sufficient evidence that there are no safety concerns.

Microbial, macrobial, botanical and semiochemical bio pesticides derived from or based on genetically modified organisms (GMOs) and pest control agents based on "RNA interference" technology or on "clustered regularly interspaced short palindromic repeats (CRISPR)" or other gene editing techniques and microbial agents for control of vertebrate pests e.g rodents are not covered.

2.0 DEFINITIONS

Active agent: A living component in a bio pesticide to which pest control activity is attributed.

Active ingredient: The biologically active part of the bio pesticide such as microbials or phytochemicals, extracted with solvent chemicals.

Acute dermal LD50: A statistically derived estimate of the single dermal dose of a substance that would cause 50 percent mortality to the test population under specified conditions.

Acute inhalation LC50: A statistically derived estimate of the inhaled concentration of a substance that would cause 50 percent mortality to the test population under specified conditions.

Acute oral LD50: A statistically derived estimate of the single oral dose of a substance that would cause 50 percent mortality to the test population under specified conditions.

Antagonism: refers to the action of any organisms that suppress or interfere the normal growth and activity of a plant pathogen, such as the main parts of bacteria or fungi.

Baculoviruses: a member of a family of DNA viruses infecting only invertebrate animals. Some have a very specific insect host, and may be used in biological pest control.

Bioassay: Procedure or method of testing potency of a substance by its effect on living cells or tissues.

Biocontrol: A pest control strategy that uses living natural enemies, antagonists or competitors of the organism being protected and other self-replicating biotic entities.

Biological control agent: A natural enemy, antagonist or competitor, and other self-replicating biotic entity used for pest management.

Biopesticide: A generic term generally applied to a substance derived from nature, such as a microorganism or botanical or semiochemical that may be formulated and applied in a manner similar to a conventional chemical pesticide and that is normally used for short-term pest control.

Botanical: Natural (unmodified) plant extracts.

Botanical pesticides: Formulations of pesticides that originate from plants as phytochemicals and eliciting toxic effects on insects and mites.

Colony Forming Unit: An estimate of viable bacterial or fungal cells.

Efficacy (of a biological control agent): The ability to cause a statistically significant reduction with regard to the number of pest organisms, direct and indirect crop damage, or yield loss.

Endotoxin: a toxin present inside a bacterial cell that is released when it disintegrates.

Entomopathogenic: is the ability to act as a parasite of insects and kills or seriously disables them.

Entomotoxic: Any substance that is toxic to insects

Environmental Fate: The destiny of pesticides after release into the environment.

Formulated product: The pesticide active ingredient(s) and other components, in the form in which it is packaged and sold.

Formulation: means the combination of various ingredients designed to render the product useful and effective for the purpose claimed; the form of the biopesticides ready to use products) as purchased by users.

Human health exposure: Degree of likelihood that one or more exposures to a biopesticides may have damaged or will damage the health of the exposed person(s).

Immunology assay: biochemical test that measures the presence of concentration or a macromolecule or a small molecule in a solution through the use of an antibody (usually) or an antigen (sometimes).

Inert ingredient: means any substance (or group of structurally similar substances if designated by Generalist.

Infectivity: The ability of a microorganism to invade and persist in a viable state or to multiply within or on an organism, with or without disease manifestation.

Integrated Pest Management (IPM): The careful consideration of all available pest control techniques and subsequent integration of appropriate measures that discourage the development of pest populations and keep biopesticides and other interventions to levels that are economically justified and reduce or minimize risks to human and animal health and/or the environment.

Macrobials: An invertebrate natural enemy used for pest management.

Macroorganisms: Are organisms large enough to be seen by the normal unaided human eye.

Metabolites: are breakdown products that form when a biopesticide is used in the environment and mixes with air, water, soil or living organisms.

Microbial: relating to or characteristic of a microorganism, especially a bacterium causing disease or fermentation.

Microorganism: Living organism (such as a bacteria, fungi, viruses) too small to be seen with naked eye but visible under a microscope.

Mode of action: it describes a functional or anatomical change, at the cellular level, resulting from the exposure of a living organism to a substance.

Monophagous: An organism that attacks only one host species and is species specific.

Non-target organism: Living organisms other than the one against which the biopesticide is applied.

Oligophagous: An organism that attacks a limited group of related hosts.

Parasite: An organism which lives on or in a larger organism, feeding upon it.

Parasitoid: An insect parasitic only in its immature stages, killing its host in the process of its development, and free living as an adult.

Pathogenicity: The ability of a microorganism to inflict injury and damaging the host after infection.

Polyphagous: An organism that attacks a wide range of hosts from different subfamilies.

Predator: A natural enemy that preys and feeds on other animal organisms, more than one of which are killed during its lifetime.

Regulatory authority: The government agency or agencies responsible for the registration and management of pesticides/biopesticides for manufacturing, distribution, stock and sale in Kenya.

Residue: means any specified substances in or on food, agricultural commodities or animal feed resulting from the use of a pesticide.

Semiochemicals: Substances or mixtures of substances emitted by plants, animals, and other organisms that evoke a behavioural or physiological response in other individuals of the same or other species.

Shelf life: the length of time in the approved label for which a formulated biopesticide remains stable and fit for use.

Technical grade: The technical material used to manufacture the biopesticide product.

3.0 CATEGORIES OF BIOPESTICIDES

For the purpose of these requirements, biopesticides fall into three categories:

i. Microbial pesticides (Bacteria, fungi, viruses)

ii. Biochemical pesticides (Botanicals and Semiochemicals)

iii. Macroorganisms (Predators and Parasitoids)

3.1. Major registration categories of Biopesticides and biocontrol agents

In the following sections the data requirements for each category of Biopesticides and biocontrol agents are described. The data requirements will apply equally whether the application is for:

3.1.1. Experimental use permit: means status granted (bearing experimental Permit number) allowing experimental use prior to submitting application for full registration.

3.1.2. Full registration: Granted when all registration requirements have been met and the registration authority has granted approval for Biopesticides and biocontrol agents according to the conditions laid down in the certificate of registration.

3.1.3. Temporary/Emergency registration: means registration status granted to a microbial biopesticide (with temporary registration number) after pre-submission consultation and approval has been given for full submission, but not allowing the Biopesticides and biocontrol agents to be used.

3.1.4. Provisional registration: means registration status granted to Biopesticides and biocontrol agents (bearing provisional registration number) pending supply of further data required by the registration authority. (Black, 2013).

3.2. MICROBIAL PESTICIDES

Microbial pesticides are microorganisms that produce a pesticidal effect. They have pesticidal modes of action that often include competition or inhibition, toxicity and even use of the target pest as a growth substrate. Microbial pesticides can control many different kinds of pests, although each separate active agent is relatively specific for its target pest (s).

3.2.1. Data requirements for microbial pesticides registration

3.2.1. Biological and Chemical Characteristics

Microbial biopesticide products covered under this guideline shall meet the criteria summarized in Table 1.

3.2.1.1 Systematic name

The systematic names, consisting of genus and species names, of microbial shall be given. (example: *Bacillus thuringiensis, Trichoderma harzianum*).

3.2.1.2 Strain or isolate of microbials

The strain or isolate of microbial shall be stated clearly. (Example: *Bacillus thuringiensis* subsp. *kurstaki*, strain ABTS-351; *Metarhizium Anisopliae ICIPE 69 strain*)

3.2.1.3. Source or origin, host range, and mode of action

The source or origin of microbial shall be indicated including country, where its isolated from, ecological habitat. The host range of microbial should be clearly indicated. Reports from any reliable and reputable publication journal are accepted. The mode of action of microbial should be indicated clearly (example: infection of target, competitive or antagonistic behaviour, etc).

3.2.1.4. Biological properties

History and geographical distribution of active agent

Life cycle

Mode of action

Relationship to known plant animal or human pathogens

Host range

Dispersal

Colonizing ability

Information on production of metabolites

Genetic stability

3.2.1.5. Specification of active agent (Technical grade) and Composition of the product

Specification of the active agent shall include names, and amount af the active agent, concentration and contaminants. Microbial active agent needs to be specified in relevant unit of activity. The example unit of activity for each microbial are as follows:

(a) Entomotoxic bacteria in endotoxin content (IU/mg or ml);

(b) Baculoviruses (Nuclear Polyhedrosis Virus (NPV) and Granulosis virus (GV)) in viral unit (Polyhedral Occlusion Body (POB)/capsul count/ml or mg);

(c) Entomopathogenic fungi and antagonistic bacteria (Colony Forming Unit (cfu)/g or ml) product.

The Composition of active and inert ingredients in % w/w and purpose in formulation shall be stated.

3.2.1.6 Impurities and contaminants

The technical grade and formulation product shall be free from biological contaminants especially plant, human and animal pathogenic contaminants such as *Salmonella typhi*, *Salmonella paratyphi* A, B, and C, *Salmonella sendai*, *Salmonella cholera-suis*, *Shigella dysenteriae*, *Escherichia coli* and *Vibrio cholerae*. The technical grade shall be free from the contaminants. (Other microbial contaminants should not exceed 1 x 10^4 count/ml or g of formulation (FAO, 2012, 2018). The microbial contaminants shall be determined throughout the process of production. The method used shall be mentioned and the result attached in product specification sheet.

3.2.1.7. Physical chemical properties of formulated product

Physical chemical properties Specification of the product include appearance, physical state, colour, pH, persistent foaming, solubility or suspendability, particle size, viscosity (liquids) and density. Type and test method used shall be indicated clearly.

3.2.1.8. Production process and quality control

The production process shall be stated clearly;

(a) The name and address of the production plant shall be provided

(b) Flowchart of the production process shall be submitted with the application. All raw materials used shall be stated.

(c) The quality control procedure shall be described

3.2.1.9. Test procedure and criteria for identification

Test procedure and criteria for identification for each microbial shall be stated clearly. The robust methods of bioassays and identification shall be used:

a) Entomotoxic bacteria; immunology assays: Elisa/Dot Blot assay test or potency of product by bioassay method (LC50) on target larvae (*Trichoplusia ni*/*Helocoverpa armigera*) and potency against a reference using artificial diet or leaf disc method or in the water for mosquito larvae.

b) Baculoviruses; biological assay for determining the LC50/LD50 of the formulation. Bioassay for Nuclear Polyhedrosis Virus (NPV) by the diet surface contamination method and Granulosis virus (GV) using bioassay against *Chilo infuscatellus*, *Plutella xylostella* or *Acheae janata*.

c) Entomopathogenic fungi; pathogenicity test on a relevant insect and bioassay procedure shall be provided

Test procedure other than the above may also be used for consideration.

The identification and bioassay shall be carried out in a laboratory accredited

and/or recognized by the regulatory authority

3.2.1.10. Shelf life claim

Applicants shall provide storage stability studies and shelf life in the proposed packaging to support specific shelf life claim

3.2.1.11. Quality verification report

The verification report from a laboratory accredited and/or recognized by the regulatory authority shall be provided to confirm that the content of active agent is the same as the composition declared.

3.2.1.12. Bioefficacy

The recommended product use on crops shall be obtained from local bioefficacy trials. Efficacy trials shall be carried out in accordance with the requirements for evaluating and reporting the efficacy of pest control products for plants.

3.2.1.13. Laboratory studies

Additional laboratory study reports may be submitted depending on proposed uses.

3.2.1.14. Packaging and labelling

3.2.1.14.1. Packaging material

The type of packing material used shall be stated. The packaging material shall maintain the quality, integrity and the properties of the product without leakages.

3.2.1.14.2. Labels and leaflets

A draft label shall be submitted to the PCPB for evaluation.

3.2.1.14.3. Infectivity and pathogenicity or toxicity to test animals

Toxicological data may be waived where there is sufficient evidence that the product is safe. This would be based on results of medical surveillance, actual

studies or published data. Where no evidence is provided or where there is insufficient evidence, toxicological studies have to be conducted as indicated under TIER 1 in the first instance. TIER 2 is applied when, in the absence of evidence of pathogenicity, either toxicity of infectivity is observed in TIER 1.

TIER 3 is applied when there are issues of known or suspected subchronic toxicity and human pathogenicity and tests for effects following long-term exposure and particular adverse effects of intra-cellular parasites of mammalian cells. Report on infectivity and pathogenicity or toxicity on test animals for the technical material of the microbial shall be submitted to PCPB. Acute studies (six pack for formulated product shall be submitted to PCPB

3.2.1.15. Human health hazard/assessment, environmental fate and effects

3.2.1.15.1. Human health hazard

Data on animal tests are required to facilitate risk assessment. Specific studies on the active agent and formulated product as indicated in the summary of data requirements for microbial registration shall be submitted. Peer reviewed Reports from scientific journals on human health based on the active agent may be submitted where there is sufficient evidence that the active agent is safe and has been in use for many years.

3.2.1.15.2. Ecotoxicological and Environmental fate

Waivers may be granted on presentation of evidence that exposure to the particular non target organisms will not occur, or where effects of exposure are already documented. TIER 1 studies should report any observed pathogenicity/infectivity to the test species. TIER 2 studies are required on representative non target species if acute studies indicate that adverse effects will occur during routine application. Data on the effect on birds, aquatic organisms, algae and bees shall be submitted for evaluation. Data on the fate and behavior of the microbials in the environment shall be provided.

3.2.1.15.3. Residues

Data shall be submitted if microbes are suspected to produce any residue of concern on food or feed items. Inert ingredients used in formulated products must not produce residues of concern on food or feed items. Where applicable, residue data shall be provided as per the PCPB requirements for the conduct of supervised residue field trials.

Table 1: Summary of data requirements for the registration of microbial

No.	Status of data requirements	Active agent (A.A.)	Formulation Formulated product
	Type of Registration Applied for. Tick as Necessary Full Registration Temporary Registration	R	R
A: Biological and Chemical Characteristics			
1	Systematic name	R	
2	Strain or isolate of microbials	R	
3	Common name (if available)	R	
4	Source or origin (country, where its isolated from, ecological habitat)	R	
5	Physical chemical properties of the product physical colour pH persistent foaming suspendability particle size viscosity		R

	density test method		
6	Biological properties History and geographical distribution of active agent Life cycle Mode of action Relationship to known plant animal or human pathogens Host range Dispersal Colonizing ability Information on production of metabolites Genetic stability	R	
7	Composition of the product	R	R
8	Production process and quality control Name and address of manufacturer Name and address of Formulator flowchart of production process	R	R
9	Test Procedure and criteria for identification	R	
10	Impurities and contaminants	R	
11	Shelf life claim		R
12	Quality Verification report		R
B. Bioefficacy			
13	Field efficacy studies on proposed use		R
14	Laboratory studies for Bioassays	CR	
C. Packaging and Labelling			
15	Packaging material		R
16	Labels and leaflets		R
D. Human Health, Infectivity and Pathogenicity or Toxicity to test animals			
17	Infectivity and pathogenicity TIER 1 Studies Medical surveillance data for	R	

	manufacturing plants and Agricultural workers (Such as occurrence of hypersensitivity/allergies) Acute Oral LD_{50} mg/kg LC_{50} (rat/rabbit) Acute dermal Inhalation LC_{50} mg/4 hours (rat/rabbit) Dermal irritation Eye irritation Skin sensitazition Intra-peritoneal (Fungi and protozoa)/Intravenous (others) injection for infectivity TIER 2 Studies Subchronic toxicity 28 day NOEL mg/kg/day TIER 3 Studies Chronic toxicity/Carcinogenicity NOEL mg/kg/day (mouse/rat) Neurotoxicity NOEL mg/kg/day Teratogenicity NOEL mg/kg/day Reproduction (rat/rabbit) Mutagenicity		
	Acute Toxicity studies Acute Oral LD50 mg/kg LC50 (rat/rabbit) Acute dermal Inhalation LC50 mg/4 hours (rat/rabbit) Dermal irritation Eye irritation Skin sensitization		R
E. Ecotoxicology and Environmental Fate			
18	Ecotoxicology fate TIER 1 (Acute studies) Birds (2 species) Aquatic organisms (2 species)	R	

	Aquatic invertebrates Algae Bees Representative natural enemies Earthworms Soil Micro organisms Representative non target plant TIER 2 Birds (1 specie) Reproduction and NOEL Aquatic organisms (2 species) Reproduction, BCF & NOEL		
	Environmental fate – Behaviour in the soil, surface & ground water Persistence of active agent, Mobility ofactive agent, Major metabolites where appropriate		
	F. Residue		
19	Residue data	CR	
20.	Clearance from National Plant Protection Organization (NPPO) authorizing import or export.	R	R
21.	Procedure for destruction and decontamination		R

Abbreviation: R= required CR=Conditionally Required

3.3. BIOCHEMICAL PESTICIDES

Biochemical pesticides means a pest control product whose active ingredient derived from naturally occurring plants, animals, or other organisms intended to control plant pests. For the purpose of these requirements, Biochemical pesticides include Botanicals and Semiochemicals.

3.3.1. BOTANICAL/ PLANT EXTRACTS

Botanical active substance: It consists of one or more components found in plants and obtained by subjecting plants or parts of plants of the same species to a process such as pressing, milling, crushing, distillation and/or other methods of extractions. Botanical products covered under this guideline shall meet the criteria summarized in Table 2.

3.3.2. Data requirements for registration of botanical/plant extract

3.3.2.1. Nomenclature

The systematic and common names the plant shall be provided. The active ingredient (s) of the plant extracts shall be provided if available.

3.3.2.2. Source or origin

The source or origin of botanical/plant extract shall be indicated including country, where its extracted from, plant part, and ecological habitat. The applicant shall provide information on registration status of the product in the country of origin.

3.3.2.3. Physical chemical properties of active ingredient and formulated product.

Information of Color, physical state, odour, storage stability, corrosion characteristics, UV-light absorption, water solubility and vapor pressure for the plant extracts and formulated products shall be submitted. The specification of the technical grade and the formulated product shall conform to, FAO specifications whenever such specifications are available.

3.3.2.4. Composition of the product

Composition of active and inert in % w/w or w/v and purpose in formulation shall be provided. If available, the following information shall be submitted: IUPAC and CAS chemical names and numbers, and structural formula.

3.3.2.5. Manufacturing process

The Extraction process shall be stated clearly and the following information shall be provided;

a) The name and address of the manufacturing plant.

b) A description of the quality control procedures and equipment shall be provided to assure consistency of the composition of substance produced.

c) Information on substances used in the manufacturing process (example: identity of any extraction solvent, enzymes, stabilizers such as antioxidants), and any special precautions such as control of light, humidity and temperature.

d) Flowchart of the process of extraction of active ingredient and the manufacture of formulated product shall be submitted.

3.3.2.6. Test procedures and criteria for identification

The applicant shall provide test procedures for the plant extracts and or a validated analytical method for the active ingredients.

3.3.2.7. Impurities

The applicant shall provide information on the identity and quantity of the impurities in the plant extracts.

3.3.2.8. Storage stability

The applicant shall specify the shelf life of the products based on test conducted under the following conditions:

a) FAO Accelerated Storage Test Procedures is performed at 54 ± 2 °C for 14 days or at 45 ± 2 °C for 6 weeks or at 40 ± 2 °C for 8 weeks or at 35 ± 2 °C for 12 weeks or at 30 ± 2 °C for 18 weeks when applicable.

b) Two- Year Storage Stability (Ambient testing) to demonstrate the storage stability of a formulation under true storage conditions usually over a period of 2 years. The test shall be conducted at ambient temperature or, 20 °C, 25 °C or 30 °C dependent on the final area of use.

c) The packaging used in the study shall be based upon that in which the product is sold.

3.3.2.9. Verification report

The applicant shall provide a verification report base on a five batch analysis of the plant extracts and formulated products to ensure that content of active ingredient is the same as in composition declared. A report from own or third party independent laboratory is accepted.

3.3.2.10. Packaging and labelling

3.3.2.10.1. Packaging material

The type of packing material used shall be stated. The packaging material shall maintain the quality, integrity and the properties of the product without leakages.

3.3.2.10.2. Labels and leaflets

A draft label shall be submitted to PCPB for evaluation.

3.3.2.11. Human health hazard/assessment, environmental fate and effects

3.3.2.11.1. Human health hazard

Data on animal tests are required to facilitate risk assessment. Specific studies on the active ingredient and formulated product for registration of botanical products shall be submitted. Peer reviewed reports from scientific journals on human health based on the plant extract or active ingredient may be submitted where there is sufficient evidence that the plant extract or active ingredient is safe and has been in use for many years.

3.3.2.11.2. Ecotoxicological and Environmental fate

Waivers may be granted on presentation of sufficient evidence that exposure to the particular non target organisms will not occur, or where effects of exposure are already documented. TIER 1 studies should report any acute effects on non-target species. TIER

2 studies are required on non-target species if acute studies indicate that adverse effects will occur during routine application.

Data on the effect on birds, aquatic organisms, algae and bees shall be submitted for evaluation. Data on the fate and behavior of the plant extracts and the active ingredient in the environment shall be provided.

3.3.2.11.3. Efficacy and laboratory studies

Efficacy data requirements for botanical/plant extract are similar to those for conventional agriculture products. Required field and laboratory studies will depend on purpose of uses.

3.3.2.11.4. Residues

Data shall be submitted if plant extracts are suspected to produce any residue of concern on food or feed items. Inert ingredients used in formulated products must not produce residues of concern on food or feed items. Where applicable, residue data shall be provided as per the PCPB requirements for the conduct of supervised residue field trials.

Table 2: Summary of data requirements for registration of botanicals

No.	Status of data requirements	Active agent (A.I.)	Formulation
Type of Registration Applied for. Tick as Necessary Full Registration Temporary Registration		R	R
	A: Physical and Chemical Characteristics		
1	Systematic name	R	
2	Common name (if available)	R	
3	Source or origin	R	
4	Specification of the product physical state colour Odour Storage stability Corrosion characteristics UV-light absorption Water pressure Vapor pressure	R	R
5	Composition of the product	R	R
6	Manufacturing process and quality control	R	R

	manufacturer name and address flowchart of manufacturing process		
7	Test Procedure and criteria for identification	R	R
8	Impurities	R	
9	Verification report	R	R
10	Packaging and labelling		R
	B. Toxicology Evaluation		
11	TIER 1 Studies Acute Oral LD_{50} mg/kg LC_{50} (rat/rabbit) Acute dermal Inhalation LC_{50} mg/4 hours (rat/rabbit) Dermal irritation Eye irritation Skin sensitazition TIER 2 Studies Subchronic toxicity 28 day NOEL mg/kg/day TIER 3 Studies Chronic toxicity/Carcinogenicity NOEL mg/kg/day (mouse/rat) Neurotoxicity NOEL mg/kg/day Teratogenicity NOEL mg/kg/day Reproduction (rat/rabbit) Mutagenicity	R	
12	Acute Toxicity studies Acute Oral LD50 mg/kg LC50 (rat/rabbit) Acute dermal Inhalation LC50 mg/4 hours (rat/rabbit) Dermal irritation Eye irritation Skin sensitization		R
13	Ecotoxicology and Environmental Fate	R	
	Ecotoxicology fate		

	TIER 1 (Acute studies) Birds (2 species) Aquatic organisms (2 species) Aquatic invertebrates Algae Bees Representative natural enemies Earthworms Soil Micro organisms Representative non target plant TIER 2 Birds (1 specie) Reproduction and NOEL Aquatic organisms (2 species) Reproduction, BCF & NOEL		
	Environmental fate – Behaviour in the soil, surface & ground water Persistence of active agent, Mobility ofactive agent, Major metabolites where appropriate	R	
	C. Efficacy		
14	Field and laboratory study		R
	D. Residue		
15	Residue data	CR	

Abbreviations: R = Required CR = Conditionally Required

3.4. SEMIOCHEMICALS

Semiochemicals are active substances used in plant protection and public health products and have a non-toxic, target specific, mode of action and are of natural occurrence. They are generally effective at very low rates, often comparable to levels that occur naturally. They may be volatile and can dissipate and/or degrade rapidly in the environment. These chemicals pose low risk to human health and the environment. Different types of semiochemicals are:

i. Allelochemicals produced by individuals of one species that modify the behaviour of individuals of a different species (i.e. an interspecific effect). They include allomones (emitting species benefits), kairomones (receiving species benefits) and synomones (both species benefit).

ii. Pheromones produced by individuals of a species that modify the behaviour of other individuals of the same species (i.e. an intraspecific effect).

iii. Straight-chained lepidopteran pheromones (SCLPs) are a group of pheromones consisting of unbranched aliphatics having a chain of 9 to 18 carbons, containing up to three double bonds, ending in an alcohol, acetate or aldehyde functional group.

3.4.2. Data requirements for registration of Semiochemicals

i. Common name proposed/accepted by ISO or others standard of international organizations, (if any)

ii. Trade name or manufacturer's code number

iii. The composition of the semiochemical and its formulated products

iv. Chemical and technical information of the semiochemicals and its intended use (Pheromones, mating disruption or kairomones).

v. Production process and quality control

vi. Content (%) and nature of components included in the formulation and appearance.

vii. Analytical method for active ingredient

viii. Validated laboratory report of five batch analysis

ix. Information about packaging and labeling

x. Peer reviewed reports from the scientific journal may be accepted.

xi. On case by case basis other information may be required by the regulatory authority.

Disclaimer: The above requirements shall be applicable only for a pure formulation of a semiochemical. Where a semiochemical is combined with;

(a) a conventional insecticide in a formulation, the requirements for the registration for conventional pesticides shall be required.

(b) a microbial in a formulation the requirements for the registration for semiochemical and microbials shall be required.

Table 3: Summary of data requirements for registration of Semiochemicals

(Pheromones, disrupting hormones and other semiochemicals)

No.	Status of data requirements	A.I.	Formulation
	A: Physical and Chemical Characteristics		
1	Systematic name	R	
2	Common name (if available)	R	
3	Trade name		R
4	Chemical and technical information	R	R
5	Source or origin	R	
6	Physical properties: (Specification of the product) Colour, odour, physical state, stability (temperature, metals). solubility in water and other solvents UV/visible absorption Volatility (Henry's law constant) Octanol/water partition coefficient Submission of analytical standards (samples). Corrosion characteristics Water pressure Vapor pressure	R	R
7	Composition of the product -g/kg or g/L of TGAI - g/kg or g/L of all ingredients exceeding 1g/kg	R	R
8	Content (%) and nature of components		R
9	Production process and quality control Description of starting materials, production process and potential impurities manufacturer name and address flowchart of manufacturing process	R	R
10	Test Procedure and criteria for identification Identity by spectral confirmation, including one or more of UV/IR/NMR/MS.	R	R
11	Impurities	R	
	Analytical method for active ingredient Analytical data and methodology (including spectral confirmation of identity) Analytical methodology and data for impurities of toxicological concern.	R	
12	Validated laboratory report of five batch analysis	R	R

13	Packaging and labeling		R
	C. Efficacy		
14	Field and laboratory study Efficacy Summary Description of pest problem and AI's mode of action (May be addressed by qualitative description). Efficacy trials of product, used as directed on label, including reportin Sustainability considerations (compatibility with integrated pest management; contribution to risk reduction)g of adverse effects to site (e.g., phytotoxicity) (May be addressed by qualitative description).		R
	D. Residue		
15	Residue data and Analytical method for residues.	CR	

Abbreviations: R = Required CR = Conditionally Required

3.5. MACROBIALS

These requirements cover registration of:

(i) predators

(ii) parasitoids

3.5.1. Required information on predators and parasitoids

(a) The following information shall be required by the regulatory authority for the registration of predators and parasitoids:

(b) Taxonomic identity along with classification (e.g. phylum, class, order, family, genus, species), including common names and history of any recorded name change; with accession number of voucher specimen deposited in recognized museum or culture collection.

(c) Information on physical characteristics: morphology, appearance, sexual dimorphism, height, length, weight and size, winged/wingless.

(d) Bionomics and lifecycle of the organism, including behavioural characteristics such as predator/prey relationships, life history and life cycle information; for example, mode of reproduction, seasonal pattern of reproduction; reproductive potential (number of eggs, young, generations), and longevity.

(e) Information on the efficacy is important to prevent the introduction and release of ineffective biocontrol agents. A biological control agent is considered effective if it can cause a statistically significant reduction of at least 10 percent in the number of pest organisms, of direct and indirect crop damage, or of yield loss. All relevant information to judge the efficacy of a biocontrol agent shall be provided. Summary of the information on crop, against pest, and conditions the agent is shown to be effective, the role and strength of the agent would be in IPM programmes.

(f) Host range. Available information on host/prey range of biocontrol agents shall be provided. Monophagous and oligophagous biocontrol agents are expected to pose no or very limited potential risks to non-target organisms, whereas polyphagous biocontrol agents may affect them directly and indirectly.

(g) Intra-guild predation. Provide available information on negative intraguild predation effects for specific or related natural enemy species, or determine from the biology of the natural enemy whether negative effects are likely.

(h) Information on competition and displacement shall be summited to the regulatory authority.

(i) Potential for hybridisation with indigenous strains or biotypes. Provide available information on hybridisation of the natural enemy with indigenous strains or biotypes of the same or very closely related natural enemy species.

(j) Effects on plants: Effects of natural enemy on plants shall be provided if the biological control agent is potentially a facultative herbivore and if there is a potential for phytotoxic effects.

(k) Available information on the potential for establishment and dispersal shall be provided.

Potential for establishment. In case of movement of biological control agents from one area to another, it is important to know if the agent can be established. If the agent cannot be established, less information may be required.

Key factors that need to be considered include:

— abiotic factors: The matching of climates of the area of origin and area of release.

— biotic factors: availability of non-target species suitable for reproduction, temporal and/or spatial matching of non-target organisms and biocontrol agent, diapause capabilities, dry season survival; and combined biotic and abiotic factors: availability of other resources for survival and reproduction.

Potential for dispersal: The probability of a temporal and spatial encounter between the biological control agent and non-target species to determine the potential for dispersal of the biocontrol agent.

(l) Available information on possible indirect effects – report of any known indirect effects or discuss potential indirect effects on individual species and/or ecosystem.

(m) Available information on environmental benefits – information on the benefical effects of release of biological control agents compared to current or alternative pest management methods. Information for assessment of any potential environmental risks.

(n) Information for assessment of efficacy of biological control agent

Methods for the evaluation of quality and purity (quality control) of biological control agents.

Benefits of use of biological control agents.

Summary of assessment of efficacy.

(o) For native or established natural enemies and on biological control agents, long use, substantially reduced information requirements may be appropriate

(p) Assessment of safety and effects on human health

Safety and effects on human health in manufacturing, market handling, and storage in commercial warehouses and farms as well as application in farms shall be provided to the regulatory authority. Peer reviewed report from the scientific journals may be accepted.

(q) Packaging and labelling

Packaging material

The type of packing material used shall be stated. The packaging material shall maintain the quality, integrity and the properties of the product without leakages.

Labels and leaflets

A draft label shall be submitted to PCPB for evaluation.

3.5.2. Data requirements for registration of macrobial pest control products

The dossier accompanying the application must provide full details of the information requested in this list. If the product contains more than one active agent, a separate dossier for each active agent should be provided.

Table 4: Summary of data requirements for registration of a Macrobials

Pest control product

(a) Designation / identity

NO.	STATUS OF DATA REQUIREMENTS	Active agent	Formulated product
	Common name	R	
1.2	Full taxonomic name including isolate, strain or subspecies (where appropriate)	R	
	Full taxonomic classification	R	
	Methods of identification and enumeration	R	R
	Manufacturer or Development Code	R	
1.6	Source, Name and Address of manufacturer /formulator and address and location of manufacturing plants.	R	R
	Methods of production, substrates and quality control	R	R
1.8	Collection and culture reference number where culture is deposited.	R	
1.9	Formulation type and Code		R
1.10	Source and specifications for components included in the formulation		R
1.11	Evidence of registration/approval in other countries		R
1.12	Validated laboratory report of five batch analysis	R	R
	C. Efficacy		
1.13	Efficacy Summary of Field and laboratory study		R

(b). biological/physical properties of the macrobial agents

NO.	Status of data requirements	Active agent	Formulated product
2.1	History of the macro-organism and its uses. Natural occurrence and geographical distribution	R	
2.2	Description of the target organism(s) and mode of action	R	

2.3	Host specificity range and effects on species other than the target harmful organism	R	
2.4	Development stages/life cycle of the macro-organism	R	
2.5	Invasiveness, dispersal and colonisation ability	R	
2.6	Effect of environmental parameters on stability and survival (UV, temperature, soil pH, humidity, etc.) of macrobial agents	R	
2.7	Relationships to known plant, animal or human parasites/pests and any known hyper parasite of macrobial	R	
2.8	Genetic stability of macrobial agent	R	
2.9	Information on the production of metabolites (relevant to entomopathogenic nematodes)	CR	
2.10	Biological function in the control of insects, mites, ticks, nematodes, weeds, molluscs, etc	R	
2.11	Information on the occurrence or potential development of resistance of the target organism(s) and resistance management strategy.	R	
2.12	Methods to prevent loss of predation or parasitic properties of the seed stock of the macro-organism	R	
2.13	Recommended methods and precautions concerning handling, storage, or transport	R	
2.14	Procedures for destruction or decontamination	R	R
2.15	Physical state (solid, liquid etc)		R
2.16	Colour		R
2.17	Storage stability in proposed packaging		R
2.18	Shelf life		R
2.20	Water content (Humidity)		R
2.21	Type and size of packaging		R
2.22	labeling		R

(c) Biosafety

Hazard data may be waived where there is sufficient evidence that there are no safety concerns. This would be based on results of medical surveillance and published data

NO.	Status of data requirements	Active agent	Formulated product
3.1	Medical surveillance data for manufacturing plant and agricultural workers (such as occurrence of hypersensitivity / allergies)	R	R
3.2	Discussion of the effects of repeated human exposure	R	R

(d) Environmental safety

Waivers may be granted on presentation of evidence that exposure to the particular non-target organism will not occur, or where effects of exposure are already documented.

NO.	Status of data requirements	Active agent	Formulated product
4.1	Aquatic organisms	CR	
4.2	Aquatic invertebrate	CR	
4.3	Bees	CR	
4.4	Representative natural enemies	CR	
4.5	Persistence of active agent (days)	R	
4.6	Mobility of active agent	R	

Abbreviations: R = Required CR = Conditionally Required

4. REFERENCES

Black, R. (2013). A guide to the development of regulatory frameworks for microbial biopesticides in Sub-Saharan Africa.

FAO. (2012). GUIDANCE FOR HARMONIZING PESTICIDE REGULATORY MANAGEMENT IN SOUTHEAST ASIA. *Electronic Publishing Policy and Support Branch Communication Division*.

FAO. (2018). *International code of conduct on pesticide management: requirements for the registration of microbial, botanical and semiochemical pest control agents for plant protection and public health uses*: Food & Agriculture Org.

https://croplife-r9qnrxt3qxgjra4.netdna-ssl.com/wp-content/uploads/2017/04/Technical-Monograph

Pest control products board (2003). Application for the registration of a microbial pest control product, Form A2 PCPB, Nairobi, Kenya

FORM A2

APPENDIX 1: Application Form for the Registration of a Biopesticide Product

Information for applicants

1. The applicant is the natural or legal person that manufactures the pest control product and/or places it on the market. After approval of the registration, the applicant will become the registration holder of the product.

2. The applicant shall be a legal entity in Kenya or be represented by a local agent who is a permanent resident in Kenya and duly recognized by PCPB.

3. The application form shall be completed by a person duly authorized by the applicant.

4. The application shall be submitted in triplicate to PCPB

5. Every application must be accompanied by:

   (a) proof of payment of the application fee as prescribed by the national pesticide registration authority;

   (b) three (3) copies of the draft label

   (c) three (3) copies of the technical dossier as per the data requirements detailed in List I (active ingredient) and List II (formulated product).

6. The applicant may be required to submit:

   (a) Registration authorization letter: In case the applicant is not the owner of the TGAI/product, provide a letter in which the owner of the TGAI/product authorizes the applicant to apply for registration;

   (b) sample of the pest control product, for bio efficacy trial purposes;

   (c) a sample of the pest control product for residue trial purposes (where applicable);

   (d) a sample of the technical grade of its active ingredient(s)/ agent(s);

   (e) a sample of the analytical standard of its active ingredient(s) (Applicable for only Biochemicals);

   (f) any other sample as may be required by the pesticide registration authority

1	PRODUCT	
1.1	Product name (brand name)	
1.2	Type of formulation (CropLife code)	
1.3	Active ingredient(s)/Agent (s) (common name)	
1.4	Active ingredient/Agent (s) concentration(s)	
1.5	Patent status and expiry date (if applicable)	
1.6	Quick Response (QR) code (if available)	
2	APPLICANT	
2.1	Applicant name (corporate name of company)	
2.2	Status	□ manufacturer □ formulator □ other: ….
2.3	Business registration number	
2.4	Physical address	
2.5	Postal address	
2.6	Telephone number	
2.7	E-mail address	
2.8	Web site	
2.9	Contact person at applicant company	
2.10	Contact person telephone number	
3	LOCAL AGENT	
3.1	Local agent name (corporate name of company) (if different from applicant)	
3.2	Status	□ formulator □ importer □ distributor □ other: ….
3.3	Business registration number	
3.4	Physical address	
3.5	Postal address	
3.6	Telephone number	
3.7	E-mail address	
3.8	Contact person at local agent	
3.9	Contact person telephone number	

4	PURPOSE OF APPLICATION			
A	New pest control product containing a new active ingredient (a.i.)/Agent			
B	New pest control product containing an active ingredient/Agent already registered in the country			
C	New source of active ingredient/Agent and/or formulation of an existing registration			
D	Amendment or extension to an existing registration			
E	Registration transfer (between registrants)			
F	Other (specify):	…		
5	INTENDED USE			
5.1	Function/category of product (more functions/categories possible)	Insecticide	Fungicide	Herbicide
		Acaricide	Rodenticide	Molluscicide
		Bactericide	Defoliant	Plant growth regulator
		Semio Chemical		
		Other (specify):	…	
5.2	Type of use (more types possible)	Agriculture	Veterinary	Public health
		Household	Forestry	Industrial
		Other (specify):	…	
5.3	Category of Biopesticide	Microbial	Macrobial	
		Botanicals	Semio chemicals	
5.4	Target pest(s)/disease(s) and crop(s)/use(s)	1	…	
		2	…	
		3	…	
		…		
6	HAZARD CLASSIFICATION (FOR BIOCHEMICALS)			
6.1	WHO Hazard Class of the formulated product	Class Ia	Class Ib	Class II
		Class III	Class U	
6.2	GHS classification of the formulated product (list all classifiable hazards)			
	Physical hazards	…		
	Health hazards	…		
	Environmental hazards	…		

	DECLARATION
	For and on behalf of ……. I hereby certify that the above mentioned information, as well as the data provided in the technical dossier, in support of this application

	are true, correct and complete.	
	..... *Name in full (print)*	..... *Signature*
	..... *Official title*	..... *Date*
	Official stamp of applicant/company	
8	*FOR OFFICIAL USE*	
	Application No: …	*Remarks:* ....
	Reception date: …	
	Fees received: Yes No	
	Amount paid:	
	Status of application:	*Approved* *Rejected* *Pending*

Complete the GAP Table for Efficacy Appendix xxx

GAP table for

		GAP rev. 1, date:
Product name Active ingredient(s)	Kuvu 80WP Mancozeb	Formulation type: WP Conc. of a.i: 800g/Kg
Applicant:	XYZ Agrochemicals	

1	3	4	5	6	7		8	10		11	12	13	14
Use/ No.	Crop and/ or situation (crop destination / purpose of crop/ growth habitat e.g indoor or outdoor)	Fungicide/Herbicide/Insecticide/Others (specify)	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest Group, where necessary [e.g. larvae, adults])	Application				Application rate				PHI (days)	Remarks:
				Method / Kind	Timing / Growth stage of crop & season	Max. number of applications per crop or season	Min. interval between applications	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g/kg a.i/ha a) max. rate per appl. b) max. total rate per crop or season	g/kg of a.i. per hL min. -- max.	Water L/ha min / max		
1	Indicator crop: (e.g. Tomato)	e.g. Fungicide	Indicator pest(s): e.g. Phytophthorainfestans(late blight)	Foliar spray	Upon infestation	1 – 2 per season	7 days	2.0 kg 4.0 kg	1.6 kg 3.2 kg	160 – 200g	600 – 1000 L	14 days	
2	To be extrapolated to: Potato	F	Phytophthorainfestans(late blight	Foliar spray	Upon infestation	1 – 2 per season	7 days	2.0 kg 4.0 kg	1.6 kg 3.2 kg	160 – 200g	600 – 1000 L	14 days	

FORM B3 *(r. 6 (2)(b)*

PEST CONTROL PRODUCTS BOARD

P.O. BOX 13794-00800, NAIROBI, WAIYAKI WAY
Tel: 254-020 4446115/4450242 Fax: 254-020 4449072
E-MAIL: info@pcpb.go.ke/md@pcpb.go.ke
WEBSITE ADDRESS: https://www.pcpb.go.ke/

SUMMARY OF THE DATA SUBMITTED TO THE BOARD FOR REGISTRATION OF A BIOCHEMICAL PEST CONTROL PRODUCT.

PART I

Trade Name……

The Name and Address of manufacturer……...……

The Name and Address of Formulator……..

……...……

Common Name of the active ingredient(s)……

Concentration of active ingredient(s)……..…..……

Source of active ingredient(s)…….……..……..

Chemical Name…….……

Formulation type…….……...……

Proposed Uses…….……..

…….……

Packaging/Containers (Material size)……..…..……...

Registrant (Name, Address, Status)……..……

Agents/Distributors in Kenya……...…….……

Premises (Reg.No. Date of issue)…….…….……

PART II

CHEMISTRY DATA

(a) Physical /Chemical Properties of the a.i……..…….……

(b) Physical/Chemical properties of the technical grade material…….……
……..……..

(c) Composition of the technical product (purity%, nature and content of impurities, isomers, by-products – other details should be provided in the dossier)
……

……...……

(d) Physical/Chemical Properties of the Formulated Product

……

……

(e) Composition of the Formulated Product (Concentration of a.i. in the formulation. other details should be provided in the dossier) .....

(f) Method of analysis for determination of the a.i. in technical and formulated products

……

PART III

Biological (efficacy) Data

a) Target Pest(s), Diseases(s), Host(s). ……..……..

b) Mode of action…….……

c) Method, Rate, Frequency of application……

……..

d) Recommendations for use in Kenya ……...……

e) Recommendations for use by authorized bodies outside Kenya…….……

……..……

PART IV

Toxicological data

a) Acute Toxicological Data of the active ingredient(s)

…….

…….

b) Acute toxicity data of the formulated product:

…….

…….

c) Short term toxicity studies……

……..……

d) Other toxicological studies:

1) Reproduction studies ……..

2) Teratological studies……..

……..

3) Neurotoxicity studies…….…….....

……..

4) Mutagenecity studies…….……..

……

5) Long term toxicity/carcinogenicity studies……..…….……

……...…….……

6) Accumulation of compound in tissues…….……

……..……

7) Metabolic studies……..……

…….……

8) Effects on livestock, poultry…….……

…….……

9) Toxicity Data on impurities…….……

…….……

10) Toxicity Data on metabolites……

……

11) Human toxicology and medical aspects:

(a) Hazards to humans……..…

(b) Symptoms of poisoning……..

(c) Antidote……

(d) Treatment ……

(e) First Aid Measures……

(f) Safety Precautions/Restrictions……

PART V – RESIDUE DATA

a) Principal Residues……

b) Disappearance and fate of residues……

c) Method(s) of analysis (crops, soil, water, feedstuffs etc.)……

PART VI

Environment and wildlife hazards

a) Degradation and mobility studies (soil,water, air) ……..

……

b) Toxicity to birds……

……

c)Toxicity to fish……..

……

d)Toxicity to honeybees/beneficial insects……..

……

e) Toxicity to earthworms, other soil invertebrates……..

……

f) Changes in soil ecology……

……

PART VII

Information on Approvals/Registrations in other countries (Attach copies of certificates)

……

PART VIII

Draft of local label……

PART IX

Brief prepared by……..

Signature……

Official stamp ……...…

Date……

PART X

Decision of the PCPB registration Sub-Committee

……..

Recommended/Not Recommended for registration

……...…

Reasons:-

……..……..……

Date……

FORM B1 *(r6(3)(c)(i))*

PEST CONTROL PRODUCTS BOARD
P.O. BOX 13794-00800, NAIROBI, WAIYAKI WAY
Tel: 254-020 4446115/4450242 Fax: 254-020 4449072
E-MAIL: info@pcpb.go.ke/md@pcpb.go.ke
WEBSITE ADDRESS: https://www.pcpb.go.ke/

SUMMARY OF THE DATA SUBMITTED TO THE PCPB FOR REGISTRATION OF A MICROBIAL PEST CONTROL PRODUCT.

PART I

Trade Name……

Name of the manufacturer and address……..……

The Name and Address of Formulator……..

Common Name of the active Agent (s) ……

Concentration of active ingredient(s) ……..……..……

Source of active ingredient(s) ……..……..……

Scientific name of the microbial Agent…….....

Formulation type……..……

Proposed Uses……

Packaging/Containers (Material size)…….……..

Agents/Distributors in Kenya……...……

Premises (Reg.No. Date of issue) ...…….……

PART II

PHYSICAL/CHEMICAL PROPERTY OF THE ACTIVE AGENT

(a) Physical /Chemical Properties of the active agent……..

……..……..……

(b) Physical/Chemical properties of the technical grade material add (incase different from point a) above) ……..……

……...…

(c) Composition of the technical product (purity%, nature and content of impurities/ contaminants, by-products – other details should be provided in the dossier)

……...…..…

(d) Physical/Chemical Properties of the Formulated Product

……...……

(e) Concentration of active agents. in the formulation. (Other details should be provided in the dossier) ……..……

……...……

(f) Method of Identification, Enumeration and Bioassay

…….…….....

……...……

PART III

BIOLOGICAL PROPERTIES OF THE MICROOGANISM

(a) Origin of microorganisms and its uses……..……

(b) Effect in the non-target organisms……...……

(c) Life cycle of the microorganisms……...……..

(d) Infectivity (plants and animals)……...……

(e) Dispersal and colonization……...……

(f) Effect of environmental parameters (UV, temperature, soil pH, humidity, nutrition requirements, etc.) on stability and survival

(g) Relationships to known plant, animal or human pathogens…….……

(h) Genetic stability and factors affecting it(potential mutant)…….……

(i) Information on the production of metabolites (especially toxins) …….……

(j) Show antibiotics and other anti-microbial properties……...……

PART IV

BIOLOGICAL (EFFICACY) DATA

(a) Target Pest(s), Diseases(s), Host(s)……..…..…….……

(b) Mode of action of the microorganism ……..……..……..……

(c) Method, Rate, Frequency of application……..……..……

(d) Recommendations for use in Kenya ……..……

(e) Recommendations for use by authorized bodies outside Kenya……..……..

PART V

TOXICOLOGICAL DATA

(a) Acute Toxicological/Infectivity Data of the active agent(s)

……..…….

(b) Acute toxicity data of the formulated product:

……..……..

(c) Short term toxicity studies (if there is concern under Tier 1 studies)……

……..……

(d) Other toxicological studies(if concerns on Tier 1 and 2)……..……

(1) Reproduction studies

……..……..

……...……

(2) Teratological studies……..……

……...

(3) Neurotoxicity studies……..……...

……...

(4) Long term toxicity/carcinogenicity studies……...……

……...……

6) Metabolic studies (if microorganism organism is known to produce metabolites) …...

……...

……...……

(7) Effects on livestock, poultry (if exposure is expected)……

……...……

……...……

(8) Toxicity information on impurities/contaminants if pathogenic significant

……...…

……...……

(9) Toxicity Data on metabolites (if applicable) ……

(10) Human toxicology and medical aspects:

(a) Hazards to humans……...

(b) Symptoms of poisoning or allergic reactions……...……..

(c) Antidote……

(d) Treatment ……

(e) First Aid Measures……

(f) Safety Precautions/Restrictions……

PART VI

RESIDUE DATA

(Data is required if the microorganism produces metabolites)

(a) Principal Residues……..……

……...……

(a) Disappearance and fate of residues……

……...……

(c) Method(s) of analysis (crops, soil, water, feedstuffs etc.)……..……

……..……...……

PART VII

ENVIRONMENT AND WILDLIFE HAZARDS

(a) Degradation and mobility studies (soil, water, air) ……..……..

(b) Toxicity to birds……..……

(c) Toxicity to fish……..……

(d) Effects on aquatic invertebrates……..……

(e) Toxicity to honeybees/beneficial insects……..……..

(f) Toxicity to earthworms, other soil invertebrates……

(g) Effect on other soil microorganisms……

PART VIII

(a) Information on Approvals by local phytosanitary authorities……

(b) Registrations in other countries (Attach copies of certificates)

……...……

(b) Information on approval by national bio-safety Board if GMO's……

……...……

……...……

PART IX

Draft of local label (as per Legal Notice No.89/1984).

……...……

……...……

PART X

Brief prepared by……...……

Signature……

Official stamp ……..……

Date……

PART XI

Decision of the PCPB Technical and registration Committee

Recommended/Not Recommended for registration

Reasons:-

……

……

Date……

FORM B2 *(r.6 (3)(c)(ii)*

PEST CONTROL PRODUCTS BOARD

P.O. BOX 13794-00800, NAIROBI, WAIYAKI WAY
Tel: 254-020 4446115/4450242 Fax: 254-020 4449072
E-MAIL: md@pcpb.go.ke
WEBSITE ADDRESS: https://www.pcpb.go.ke/

SUMMARY OF THE DATA SUBMITTED TO THE PCPB FOR REGISTRATION OF A MACROBIAL PEST CONTROL PRODUCT.

PART I

Trade Name……

Collection Number (National museum of Kenya)……..……

The Name and Address of Formulator……...……..

……...……

Common Name of the active agent(s)

Description of unit……

Counts of active agent(s) per unit ……..……

Source of active agent ……..……..……..……

Scientific name of the agent……..…….……

……..…….……

Form of presentation (stage of development, carrier material……..…….……

Proposed Uses……..……..

……..……

Packaging/Containers (Material ,size)……...

……..……

Registrant (Name, Address, Status)……...……

……..……..

Agents/Distributors in Kenya……..……...……

……..……..

Premises (Reg.No. Date of issue)……..……

……..……..

PART II

BIOLOGICAL DATA

(a) Description of the agent as presented (stage, colour)

(b) Taxonomy

(c) Descriptive identification of the agent

(d) Natural occurrence and geographical distribution…..

(e) Host specificity range and effects on non-target species…(including invasiveness, dispersal, colonization ability)

(f) Development stages/life cycle

(g) Genetic stability.

(h) Stability in proposed packaging

(i) Method of quantification

PART III

EFFICACY DATA

(a) Target Pest(s), Diseases(s), Host(s). ……..

b) Mode of action……

b) Method, Rate, Frequency of application……

c) Recommendations for use in Kenya ……

d) Recommendations for use by authorized bodies outside Kenya……..

PART IV

BIOSAFETY DATA

(a) Bio-Surveillance data available ……

(b) Relationships to known plant, animals or human parasites…….……..……..

(c) Hazards to humans…….……

(d) Safety precautions/Restrictions……..

(e) Recommended methods and precautions concerning handling, storage, or storage ……...

(f) Procedures for destruction…..……

(g) Measures in case of an accident ……

PART VI

ENVIRONMENTAL DATA

(a) Effects of environmental parameters on stability and survival (UV, temperature, soil, pH, Humidity, etc) ……..……

PART VII

(a) Clearance by Phytosanitary Board

(b) Registrations in other countries (Attach copies of certificates)

……..…..

PART VIII

Draft of local label

……..……..

……..……

PART IX

Brief prepared by……..…..……

Signature……..…..……

Official stamp …….……

Date……..……..

PART X

Decision of the PCPB registration Sub-Committee

Recommended/Not Recommended for registration

Reasons:—

……...

……...

Date……

PEST CONTROL PRODUCTS ACT

FORM A3 *(r7, 12(1)*

APPLICATION FOR THE REGISTRATION OF A PEST CONTROL PRODUCT (GENERIC)

Introduction

These requirements are for registration of identical products that are manufactured after the expiry of the patent of an original/proprietary registered product. These identical products are generally referred to as generics and will include conventional and biochemical pesticides. A pre-registration consultation between the applicant and the registration Board is strongly recommended.

TRADE NAME:……

Information for Applicants

1. The application form must be completed by a duly authorized person.
2. The application must be submitted in triplicate to:

   The Managing Director/Secretary

   Pest Control Products Board (PCPB)

   P.O. Box 13794 - 00800 Nairobi.

   E-mail address: info@pcpb.go.ke.ke/md@pcpb.go.ke

   Tel: 254— 020 — 8021846/7/8 Fax: 254- 020- 8021865

   Website: https://www.pcpb.go.ke/
3. Every application must be accompanied by: -
   (a) application fee as prescribed (Registration fee is payable upon approval by the Board).
   (b) 3 copies of the draft label as per PCPB requirements.
4. The applicant may be required to submit: -
   (a) a sample of the pest control product;
   (b) a sample of the technical grade of its active ingredient;
   (c) a sample of the laboratory standard of its active ingredient;
   (d) any other sample as may be required by the Board.
5. List I and II are supplied as a check list and an index to ensure that the applicant has provided the relevant data.
6. The application must be accompanied by a technical dossier as per PCPB data requirements (Lists I and II).
7. An applicant who is not a resident in Kenya must appoint an agent permanently resident in Kenya and duly recognized by the Pest Control Products Board.

PURPOSE OF APPLICATION
(*tick/fill as appropriate*)

(a) Pest control product containing a generic active ingredient (i) Date of expiry of patent…….. (ii) Name of former patent holder……..…..……
(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.g inerts, source of technical material e.t.c) ☐
(e). Type of Registration Applied for. Tick as Necessary Full Registration Temporary Registration
(f) Other (Explain) …….. ……..…… ……..……
(g) Will the product be marketed under own label? Yes ☐ No ☐ If no specify……
Proposed date of marketing……

1. APPLICANT	
1.1 Identification	
Name of applicant/Corporate name of company	
Business Registration No.:	
Name of registration holder	
1.2 Status: (manufacturer / formulator/ other)	
1.3 Physical Address	
1.4 Postal Address:	
1.5 Telephone: (and area code)	
1.6 Fax: (and area code)	
1.7 e-Mail:	

2. Name of local agent in country: (if different from registration holder)	
Business Registration No.:	
2.1 Status: (Importer/formulator/distributor)	
2.2 Physical Address	
2.3 Postal Address:	
2.4 Telephone:(and area code)	
2.5 Fax:(and area code)	
2.6 e-mail:	
3 PRODUCT	
3.1 Designation (Description of product)	Trade name: Trade mark: Trade mark holder:
3.2 Function of product: (eg. Insecticide, herbicide etc.)	
3.3 Intended use: (Public health, industrial, agriculture, forestry, etc.	
3.4 Application for (a) Single crop/pest combination (b) Multiple uses (using the extrapolation tool) (c) If YES under (b) above, refer to the crop grouping and data extrapolation requirements to identify the relevant indicator pest and crop for efficacy.	Yes ☐ NO ☐ Yes ☐ No ☐

<table>
<tr><td>3.5 Indicator pest(s)
3.6 Indicator host crop (s)</td><td><table><tr><td>Indicator pest (Common and scientific name)</td><td>Indicator crop (Common and scientific name)</td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr></table></td></tr>
<tr><td>3.7 Requested extrapolation pests and crops</td><td><table><tr><td>Pest (Common and scientific name)</td><td>Crop (Common and scientific name)</td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr></table></td></tr>
<tr><td>3.8 Method, dosage rates and frequency of application:</td><td>Complete the GAP Table for Efficacy Appendix xxx</td></tr>
<tr><td>3.9 Type of formulation: (eg. EC, WP, etc.)</td><td><table><tr><td>Crop Life International(CLI*)
Code (if available)</td></tr></table></td></tr>
<tr><td>3.10 a) Is the product registered in country of manufacture?

b) Is the product registered in the country of formulation?</td><td>Yes ☐ No ☐
If no, give reasons ……
……
Yes ☐ No ☐
If no, give reasons ……
……..</td></tr>
<tr><td>3.11 Proof of registration in SEARCH** country/ies: (names)</td><td></td></tr>
<tr><td>3.12 Proof of registration in other countries.</td><td></td></tr>
</table>

3.13 Customs Tariff Code: (Brussels Tarrif Nomenclature)	

4 COMPOSITION OF ACTIVE INGREDIENT (S) (Technical grade) (Information on a.i may be attached in sealed envelope)			
Active ingredient(s): (Common name/s)	Manufacturer: (Name and address)	Minimum a.i. % purity	a.i. Range %

5. FORMULATION			
5.1 Formulator: (Name) Postal Address: Physical address:			
5.2 Internal code:			
5.3 Composition (Information on composition may be attached in sealed envelope)			
Ingredients and Function:	g/L	g/Kg	Range

6. TOXICOLOGY (formulated product)					
6.1 Rat:	Acute Oral (LD_{50} mg/Kg)	Acute Dermal (LD_{50} mg/Kg)	Inhalation LC_{50} (mg/L/4 hour)		
	Experimental	Experimental	Experimental		
6.2 Rabbit:	Skin irritation	Eye irritation			
None					
Mild					
Moderate					
Severe					
6.3 Skin Sensitization in guinea pig: (tick)		None ☐	Mild ☐	Moderate ☐	Severe ☐
6.4	Ia	Ib	II	III	Table V

6.5 Summary of other mammalian toxicological studies: eg. Livestock, wildlife, poultry, pets

7 Summary of environmental effects	
7.1 Toxicity to bees:	
7.2 Toxicity to fish and other aquatic organisms:	
7.3 Toxicity to birds:	
7.4 Toxicity to earthworms and soil micro-organisms:	
7.5 Toxicity to other non-target organisms:	
7.6 Persistence in environment:	
7.7 Other effects: Specify	

8. PACKAGING	
8.1 Packaging material / container:	
8.2 Pack size(s):	
8.3 Disposal of empty container(s):	

9. OTHER SPECIFIC REQUIREMENTS
9.1 Operator exposure
9.1.1 Dermal absorption.
9.1.2 Likely operator exposure under field conditions
9.2 Available toxicological data relating to other ingredients in formulation (non-active additives in formulation).

10. DECLARATION	
For and on behalf of …… I hereby certify that the above mentioned information 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*

Official Stamp of Applicant / Company	FOR OFFICIAL USE Remarks ……..……..… ……..…..…..……... ……...……...……..……..… ……..….. *Signed:* …… *Date:*

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

FORM A3, LIST I

ACTIVE INGREDIENT: DOSSIER INDEX

The dossier accompanying the application must provide full details (as applicable) of the information requested in this list. I.e., details of the methods used, results of toxicological and ecotoxicological studies, methods of analysis, etc. Applicants are advised to use CIPAC methods for physical and chemical properties. Numbering used in the dossier must correspond to that used in the application form. If the product contains more than one active ingredient, compile a separate dossier for each active ingredient.

ACTIVE INGREDIENT (a.i)	Annex No. in dossier if study included	Official use only
1. DESIGNATION/IDENTITY OF a.i.		
1.1 Common name (ISO)		
1.2 Manufacturer or Development code		
1.3 Source, Name and Address of manufacturer and address and location of manufacturing plants.		
1.4 Methods of manufacture (synthesis Pathways) to include relevant impurities i.e. manufacturing impurities, water content &insolubles may be sent direct to PCPB.		
1.5 Specifications of purity supported by random ”5” batch analysis from GLP certified laboratory.		
1.6 Active ingredient content supported by random “5” batch analysis from GLP certified laboratory.		
1.7 Chemical name (IUPAC)		
1.8 Chemical group		
1.9 Structural formula		
1.10 Empirical formula		
1.11 Molecular mass		
1.12 CAS Number		
1.13 Expiry of patent		

2. PHYSICAL AND CHEMICAL PROPERTIES

The applicant must provide original information specific to the generic product (technical grade)

2.1 Physical state		
2.2 Colour		
2.3 Odour		
2.4 Density at 20°C		
2.5 Vapour pressure at 20/25°C		
2.6 Volatility		
2.7 Hydrolysis DT_{50} ….. Days …… ^{0}C …… pH		
2.8 Photolysis		
2.9 Solubility in water ……^{0}C ……. pH		
2.10 Solubility in organic solvents		
2.11 n-octanol/water partition coefficient		
2.12 Boiling point ^{0}C		
2.13 Melting point ^{0}C		
2.14 Decomposition temperature ^{0}C		
2.15 Method of Analysis and Impurities		
2.16 Stability in water, hydrolysis rate, effect of light, identity of breakdown products		
2.17 Stability in organic solvents used in formulation		
2.18 Stability in air; effect of light, identity of breakdown Products		
2.19 Thermal stabilty, identity of breakdown products.		
2.20 Flammability		
2.21 Flash point		
2.22 Explosive properties		
2.23 Oxidizing properties		
2.24 Absorption spectra – UV/Visible, infra-red, IMR, MS		
2.25 Reactivity towards container material		
2.26 Technical Equivalence (if applicable)		

3. [1]Technical equivalence – refer to dossier index

TOXICOLOGY

Where technical equivalence is proven, provide studies from 3.1 to 3.3 specific to the technical grade material. Information required from 3.4 to 6.4 may be sourced from published literature.

Where technical equivalence is not proven then all the studies specific to the technical grade material from 3.1 to 6.4 must be provided.

Where an impurity is present at a concentration greater than 1g/Kg or is known or suspected to be of toxicological significance then its toxicological profile must be submitted.

3.1 ADI		
3.2 Acute oral LD_{50} mg/Kg rat/rabbit		
3.3 Acute dermal LD_{50} mg/Kg (rat)		
3.4 Inhalation LC_{50} mg/L hour (rat)		
3.5 Skin irritation (rabbit)		
3.6 Eye irritation (rabbit)		
3.7 Skin sensitization (guinea pig)		
3.8 Reproduction (specify species)		
3.9 Subchronic toxicity 90 day NOEL mg/Kg/day		
3.10 Chronic toxicity NOEL mg./Kg/day		
3.11 Carcinogenicity (life time) NOEL mg/Kg/day		
3.12 Neurotoxicity NOEL mg/Kg/day		
3.13 Teratogenicity NOEL mg/Kg/day		
3.14 Mutagenicity /Genotoxicity		
3.15 Metabolism (rat)		
3.16 Other studies		

4. ACTIVE INGREDIENT

ECO-TOXICOLOGY (Active ingredient – technical grade	Annex No. in dossier if study included	Official use only
4.1 Birds (2 species)		
LD_{50} mg/Kg		
NOEL		
Reproduction		

LD_{50} mg/Kg		
NOEL		
Reproduction		
4.2 Fish (2 species)		
LD_{50} mg/Kg		
NOEL		
Reproduction		
BCF		
LD_{50} mg/Kg		
NOEL		
Reproduction		
BCF		
4.3 Daphnia		
LC_{50} mg/L		
NOEL		
4.4 Algae		
EC_{50} mg/L (96 hours)		
4.5 Bees		
LD_{50}		
ì g/bee		
4.6 Earthworms		
LC_{50} mg/Kg		
4.7 Soil micro-organisms		

5. BEHAVIOUR IN ENVIRONMENT

5.1Behaviour, ways of degradation, degradation products in soil:		
5.1.1 Major metabolites		
5.1.2 DT_{50} (days)		
5.1.3 Mobility of a.i.		
5.1.4 Adsorption / desorption		
5.1.5 Mobility of metabolites		
5.2 Behaviour, ways of degradation, degradation products in water		
5.2.1 Major Metabolites		

5.2.2 DT_{50} (days)		
5.2.3 Surface water		
5.2.4 Ground water		
5.3 Behaviour, ways of degradation, degradation products in air. Rate and route of degradation in air (for fumigants and other volatile products).		

6. RESIDUES		
6.1 Major metabolites		
6.2 Metabolism		
6.3 Behaviour of residues		
6.4 MRL codex or other certified sources		
6.5 Method of residue analysis		

7. MODE OF ACTION		
8. OTHER SPECIFIC REQUIREMENTS		
8.1 Residue data from a GLP certified laboratory.		
8.2 Proposed pre-harvest intervals, withholding Periods in case of post-harvest use.		
8.3 Effect on taint, odour, taste, or other quality aspects due to residues in or on fresh or processed products.		
8.4 Effects on industrial processing and/or household preparation on the nature and magnitude of residues.		
8.5 Residue data in succeeding or rotational crops where presence of residues might be expected.		

FORM A3, LIST II

FORMULATED PRODUCT: DOSSIER INDEX

The dossier accompanying the form should provide more details of the information requested in this list. Applicants are advised to use Collaborative International Pesticides Analytical Council (CIPAC) methods for Physical/Chemical properties.

Summaries of the methods used and the results of toxicological and ecotoxicological studies, methods of analysis etc. should be given.

Numbering used in the dossier must correspond with that used in Form A3.

FORMULATED PRODUCT		
1. PHYSICAL AND CHEMICAL PROPERTIES	Annex No. in dossier if study included	Official use only
1.1 Source, Name and Address of formulator and address and location of formulation plant.		
1.2 Source, MSDS and specifications for components included in the formulation		
1.3 Physical state / formulation type		
1.4 Colour		
1.5 Odour		
1.6 Effects of light, air, temperature, water on technical characteristics of the formulation		
1.7 Storage stability in proposed packaging		
1.8 Shelf life		
1.9 Density		
1.10 Bulk density		
1.11 Flammability		
1.12 Flash point		
1.13 Explosivity		
1.14 In-compatibility with other pest control Products		
1.15 pH		
1.16 pH of 1% aqueous dilution		
1.17 Oxidizing properties		
1.18 Corrosiveness		
1.19 Water content		

1.20 Wettability		
1.21 Solubility in water		
1.22 Persistent foaming		
1.23 Particle size		
1.24 Suspensibility / emulsifiability		
1.25 Emulsion stability		
1.26 Volatility		
1.27 Viscosity		
1.28 Wet sieve test		
1.29 Dry sieve test		
1.30 Methods of Analysis		
1.31 Detailed composition supported by analytical evidence from GLP certified laboratory		
1.32 Other properties (where applicable)		

2. TOXICOLOGY		
2.1 Rat Acute oral LD_{50} mg/Kg		
2.2 Acute dermal LD_{50} mg/Kg		
2.3 Inhalation LC_{50} mg/L / 4hours		
2.4 Rabbit Skin irritation		
2.5 Eye irritation		
2.6 Skin Sensitization in guinea pig or Local lymph node assay (LLNA)		
2.7 WHO classification		
2.8 Other studies		

Detailed studies in 2.1 to 2.6 MUST be original and specific to the formulation. The studies should be conducted in GLP certified laboratories.

	Annex No. in dossier if study included	Official use only
3. EMERGENCY PROCEDURES IN CASE OF ACCIDENTAL EXPOSURE OR POISONING		
3.1 Symptoms of human poisoning		
3.2 Mode of action in man		
3.3 First aid treatment		
3.4 Skin contact		

3.5 Eye contact		
3.6 Inhalation		
3.7 Ingestion		
3.8 Antidote		
3.9 Note to physician		

4. EMERGENCY PROCEDURES IN CASE OF FIRE/SPILLAGE		
4.1 Fire-fighting measures		
4.2 Procedures in case of spillage		

5. BIOEFFICACY/USES (New label claims with this application)		
	Annex No. in dossier if study included	Official use only
5.1 Crop/public health etc		
5.2 Target organism		
5.3 Rate		
5.4 Stage of treatment		
5.5 Directions for use		
5.6 Residue data and pre-harvest interval; Refer to section 6 in the requirements		
5.7 Provide Efficacy data from similar climatic zones		
5.8 Phytotoxicity/Crop safety Refer to section 5.7 in the guideline		
5.9 Contraindications		

6. MINIMUM LABEL REQUIREMENTS –See PCPB label requirements (provided separately).

7. OTHER SPECIFIC REQUIREMENTS		
7.1 Medical surveillance, on manufacturing plant personnel		
7.2 Health records of occupationally exposed personnel, - industry, agriculture, forestry etc.		
7.3 Proposed packaging Type of packaging in which the product is imported		

Type of packaging for distribution in Kenya Packaging material Sizes of individual packaging		
7.4 Procedures of destruction and decontamination of pest control product and its packaging - Possibility of neutralization - Controlled discharge - Controlled incineration - Water purification - Procedures of cleaning application equipment - Recommended methods and precautions concerning handling, storage, display or transport.		

THE PEST CONTROL PRODUCTS ACT

FORM A4 *(r 8(1)*

APPLICATION FOR THE REGISTRATION OF A PEST CONTROL PRODUCT (SPRAY ADJUVANT)

A Spray adjuvant: Is a compound or substance that enhances or modifies or is intended to enhance or modify the physical or chemical characteristics of a pest control product to which it is added.

TRADE NAME:…….

Information for Applicants

1. The application form must be completed by a duly authorized person.

2. The application must be submitted in triplicate to:

The Managing Director/Secretary

Pest Control Products Board (PCPB)

P.O. Box 13794 - 00800 Nairobi.

E-mail address: *info@pcpb.go.ke/md@pcpb.go.ke*

Tel: 254 – 020 – 8021846/7/8 Fax: 254 – 020 – 8021865

Website*:https://www.pcpb.go.ke/*

3. Every application must be accompanied by: —

   (a) application fee as prescribed (Registration fee is payable upon approval by the Board.

   (b) copies of the draft label as per PCPB requirements.

4. The applicant may be required to submit: —

   (a) a sample of the pest control product;

   (b) a sample of the laboratory standard of its active ingredient;

   (c) any other sample as may be required by the Board.

5. List I is supplied as a check list and an index to ensure that the applicant has provided the relevant data.

6. The application must be accompanied by a technical dossier as per PCPB data requirements (Dossier index).

7. An applicant who is not a resident in Kenya must appoint an agent permanently resident in Kenya and duly recognized by the Pest Control Products Board.

PURPOSE OF APPLICATION (*tick as appropriate*)

(a) A pest control product which is an adjuvant	☐
(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) Type of Registration Applied for. (*Tick as Necessary)* Full Registration ☐ Temporary Registration ☐	
(f) Other (*Explain*)	
Will the product be marketed under own label? Yes ☐ No ☐ If No specify……	
Proposed date of marketing……	

1. APPLICANT	
1.1 Identification	
Name of applicant/Corporate Name of company	
Business Registration No.:	
Name of registration holder	
1.14 Status: (*manufacturer / formulator/ other*)	
1.15 Physical Address	
1.16 Postal Address:	
1.17 Telephone:(*and area code*)	
1.18 Fax: (*and area code*)	
1.19 E-Mail:	

2. Name of local agent in country: (if different from registration holder)	
Business Registration No.:	
3.1 Status: (Importer/formulator/distributor)	
3.2 Physical Address	
Postal Address:	
3.4 Telephone: (and area code)	
3.5 Fax: (and area code)	
3.6 E-mail:	

3. PRODUCT	
3.1 Designation (Description of product)	Trade name:
	Trade mark:
	Trade mark holder:
3.2. Spray adjuvant function: (wetter, surfactant, etc)	
3.3 Intended use: (Public health, industrial, agriculture, forestry, etc.	
3.4 Application for (a) Single crop/Pest combination (b) Multiple uses (using the extrapolation tool) (c) If YES under (b) above, refer to the crop grouping and data extrapolation requirements to identify the relevant indicator pest and crop for efficacy.	Yes _____ NO_____ Yes ☐ No ☐

<table>
<tr><td>3.5 Target use e.g product and crop/animal
3.6 Indicator pest (s)
3.7 Indicator host crop (s)</td><td><table><tr><td>Indicator pest (Common and scientific name)</td><td>Indicator crop (Common and Scientific name)</td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr></table></td></tr>
<tr><td>3.8 Requested extrapolation pests and crops</td><td><table><tr><td>Pest (Common and scientific name)</td><td>Crop (Common and Scientific name)</td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr></table></td></tr>
<tr><td>3.9 Method, dosage rates and frequency of application:</td><td>Complete the GAP Table for Efficacy Appendix xxx</td></tr>
<tr><td>3.10 Type of formulation: (e.g. EC, WP, etc.)</td><td><table><tr><td></td><td>CropLife International (CLI[1*]) Code (if available)</td><td></td></tr></table></td></tr>
<tr><td>3.11 a) Is the product registered in country of manufacture?

b) is the product registered in the country of formulation?</td><td>Yes ☐ No ☐
If no, give reasons

Yes ☐ No ☐
If no, give reasons</td></tr>
<tr><td>3.12 Registration in SEARCH[2**] Country/ies: (names)</td><td></td></tr>
<tr><td>3.13 Proof of existing registration in other country(ies)</td><td></td></tr>
<tr><td>3.14 Customs Tariff Code: (Brussels Tarrif Nomenclature)</td><td></td></tr>
</table>

[4*] CLI – CropLife International formerly Global Crop Protection Federation (GCPF)

[5**] SEARCH: Southern and Eastern African Regulatory Committee on Harmonisation of Pesticide Registration

4. SPRAY ADJUVANT FORMULA (attach confidential formula)			
Active ingredient(s): (Common name/s)	Manufacturer: (Name and address)	Spray adjuvant function	Percentage

5. FORMULATION			
5.1 Formulator: (Name) Postal Address: Physical address:			
5.2 Internal code:			
5.3 Composition (Information on composition formula may be attached in sealed			
Ingredients	g/L	g/Kg	Range

* *SEARCH — Southern and Eastern African Regulation Committee on Harmonisation of Pesticide Registration*

6. TOXICOLOGY (*formulated product*)			
6.1 Rat:	Acute Oral (LD_{50} mg/kg)	Acute Dermal (LD_{50} mg/kg)	Inhalation LC_{50} (mg/l/hour)
	Experimental	Experimental	Experimental
	Calculated	Calculated	Calculated
6.2 Rabbit:	Skin irritation	Eye irritation	
None			
Mild			
Moderate			
Severe			
6.3 Skin Sensitization in Guinea pig: (tick)	None ☐	Mild ☐	Moderate ☐ Severe ☐
6.4 WHO Classiffication:	Ia	Ib	II III
6.5 Summary of other toxicological studies: eg. wildlife, poultry, pets			

7.	SUMMARY OF ENVIRONMENTAL EFFECTS (*where applicable e.g. sensitive areas*)	
7.1	Toxicity to bees:	
7.2	Toxicity to fish and other aquatic organisms:	
7.3	Toxicity to birds:	
7.4	Toxicity to earthworms and soil micro-organisms:	
7.5	Toxicity to other non-target organisms:	
7.6	Persistence in environment:	
7.7	Other effects: Specify……	

8	PACKAGING	
8.1	Packaging material / container:	
8.2	Pack size(s):	
8.3	Disposal of empty container(s):	

9.	OTHER SPECIFIC REQUIREMENTS
9.1	Operator exposure
9.1.1	Dermal absorption.
9.1.2	Likely operator exposure under field conditions
9.2	Available toxicological data relating to other ingredients in formulation (non-active additives in formulation).

10. DECLARATION	
For and on behalf of ……..…… I hereby certify that the above mentioned information 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*
Official Stamp of Applicant / Company	FOR OFFICIAL USE Remarks ……...… ……..…… ……...…… …….. …… *Signed:* *Date*:

FORMULATED PRODUCT/ SPRAY ADJUVANT: DOSSIER INDEX

The dossier accompanying the form should provide more details of the information requested in this list. Applicants are advised to use Collaborative International Pesticides Analytical Council Limited (CIPAC) methods for Physical/Chemical properties. Summaries of the methods used and the results of toxicological and methods of analysis etc. should be given. Numbering used in the dossier must correspond with that used in Form A4.

FORMULATED PRODUCT/Spray adjuvant		
1. PHYSICAL AND CHEMICAL PROPERTIES	Annex No. in dossier if study included	Official use only
1.1 Source, Name and Address of formulator and address and location of formulation plant.		
1.2 Source, MSDS and specifications for components included in the formulation		
1.3 Physical state / formulation type		
1.4 Colour		

1.5	Odour		
1.6	Effects of light, air, temperature, water on technical characteristics of the formulation		
1.7	Storage stability in proposed packaging		
1.8	Shelf life		
1.9	Density		
1.10	Bulk density		
1.11	Flammability		
1.12	Flash point		
1.13	Explosivity		
1.14	Incompatibility with other pest control Products		
1.15	pH		
1.16	pH of 1% aqueous dilution		
1.17	Oxidizing properties		
1.18	Corrosiveness		
1.19	Water content		
1.20	Wettability		
1.21	Solubility in water		
1.22	Persistent foaming		
1.23	Particle size		
1.24	Suspensibility / emulsifiability		
1.25	Emulsion stability		
1.26	Volatility		
1.27	Viscosity		
1.28	Surface tension (where applicable)		
1.29	Adhesion		
1.30	Methods of Analysis		
1.31	Detailed composition supported by analytical evidence from certified laboratory		
1.32	Other properties (where applicable e.g penetration)		

2.	TOXICOLOGY	Annex No. in dossier if study included	Official use only
2.1	Acute oral LD_{50} mg/Kg (Rat)		

2.2 Acute dermal LD_{50} mg/Kg		
2.3 Inhalation LC_{50} mg/L / 4hours		
2.4 Skin irritation (Rabbit)		
2.5 Eye irritation		
2.6 Skin Sensitization in guinea pig or Local lymph node assay (LLNA)		
2.7 WHO classification		
2.8 Other studies		

Detailed studies in 2.1 to 2.6 MUST be original and specific to the formulation.

The studies should be conducted in GLP certified laboratories.

3. EMERGENCY PROCEDURES IN CASE OF ACCIDENTAL EXPOSURE OR POISONING		
	Annex No. in dossier if study included	Official use only
3.1 Symptoms of human poisoning		
3.2 Mode of action in man		
3.3 First aid treatment		
3.4 Skin contact		
3.5 Eye contact		
3.6 Inhalation		
3.7 Ingestion		
3.8 Antidote		
3.9 Note to physician		

4. EMERGENCY PROCEDURES IN CASE OF FIRE/SPILLAGE		
4.1 Fire fighting measures		
4.2 Procedures in case of spillage		

5. BIOEFFICACY/USES		
SPRAY ADJUVANT	Annex No. in dossier if study included	Official use only
5.1 Product and Crop/public health etc		
5.2 Spray adjuvant function		
5.3 Adjuvant Rates		
5.4 Spray carrier		

5.5 Stage of treatment		
5.6 Directions for use		
5.7 Residue data and pre-harvest interval Refer to section 8 in the requirements		
5.8 Provide Efficacy data from similar climatic zones		
5.9 Phytotoxicity/ Crop safety Refer to section 5.7 in the guideline		

6. MINIMUM LABEL REQUIREMENTS –See PCPB label requirements (provided separately).

7. BEHAVIOUR IN ENVIRONMENT

Where used in environmentally sensitive areas e.g aquatic systems, information on environmental impact potential should be submitted.

7.1 BEHAVIOUR, WAYS OF DEGRADATION, DEGRADATION PRODUCTS IN SOIL:		
7.1.1 Major metabolites		
7.1.2 DT_{50} (days)		
7.1.3 Mobility of a.i.		
7.1.4 Adsorption / desorption		
7.1.5 Mobility of metabolites		
7.2 Behaviour, ways of degradation, degradation products in water		
7.2.1 Major Metabolites		
7.2.2 DT_{50} (days)		
7.2.3 Surface water		
7.2.4 Ground water		
7.3 Behaviour, ways of degradation, degradation products in air. Rate and route of degradation in air (for fumigants and other volatile products).		

8. RESIDUES (where applicable in food crops/animals)		
8.1 Major metabolites		
8.2 Metabolism		
8.3 Behaviour of residues		
8.4 MRL codex or other certified sources		
8.5 Method of residue analysis		
8.6 Residue data from a GLP certified laboratory.		

8.7	Proposed pre-harvest intervals /withholding periods in case of post-harvest use.		
8.8	Effect on taint, odour, taste, or other quality aspects due to residues in or on fresh or processed products.		
8.9	Effects on industrial processing and/or household preparation on the nature and magnitude of residues.		
8.10	Residue data in succeeding or rotational crops where presence of residues might be expected.		

9 MODE OF ACTION

FORM B4 *(r.8 (2)*

PEST CONTROL PRODUCTS BOARD

P.O. BOX 13794-00800, NAIROBI, WAIYAKI WAY
Tel: 254-020 4446115/4450242 Fax: 254-020 4449072
E-MAIL: info@pcpb.go.ke/md@pcpb.go.ke
WEBSITE ADDRESS: https://www.pcpb.go.ke/

SUMMARY OF THE DATA SUBMITTED TO THE BOARD FOR REGISTRATION OF A SEMIOCHEMICAL PEST CONTROL PRODUCT

PART I

1. Trade Name……
2. The Name and Address of Formulator……...……
3. Common Name of the active ingredient(s)……..…
4. Concentration of active ingredient(s)……...……..…
5. Source of a.i. (natural or synthetic)……...……
6. Name and Location of producer ofa.i……
7. Chemical Name……..……
8a. Formulation type……..……..…
8b. Associated Device……...……
9. Proposed Uses……
……...……
10. Packaging/Containers (Material, size)……...
……..……...
11. Registrant (Name, Address,)……..……...
……..……..
12. Agent/Distributors in Kenya……...…….…….
……..…….…….
13. Premises (Registration No. Date of issue:)……..…..……..
……

PART II

CHEMISTRY DATA

14 a) Physical/Chemical properties of the technical grade material……..…
……..……..……

b) Composition of the technical product (purity %, natures and identity of impurities — other details should be provided in the dossier).
……

c) Physical/Chemical Properties of the Formulated Product
……

d) Composition of the Formulated Product (Concentration of a.i. in the formulation. Other details should be provided in the dossier)……
……...……

e) Method of analysis for determination of the a.i. in technical and formulated products (State all the methods for different components)
……...

PART III

BIOLOGICAL EFFICACY DATA

a) Target Pest(s), Host(s). ……..……
……..…...

b) Mode of action……

c) Method, Rate, Frequency of application……
……

d) Recommendations from local biological efficacy trials for use in Kenya
……

e) Recommendations for use by authorized bodies outside Kenya ……...
..……...……..…

PART IV
TOXICOLOGICAL DATA

A) TECHNICAL GRADE ACTIVE INGREDIENT(S)
TIER I Requirements:

a) Acute Toxicological Data of the Technical grade active ingredient(s) Straight-Chain Lepidopteran Pheromones (SCLPs) are exempt from all toxicological data requirements. The following studies are required for non- SCLPs

Acute oral LD_{50}……..……
Acute dermal LD50……..…..
Inhalation LC_{50} ……..
……

b) Short term toxicity studies……..……..…

c) Mutagenecity studies

TIER II Requirements: (Information is required if concerns are triggered by TIER I studies.

1) Reproduction studies ……...…….
……

2) Teratological studies……..……
……...

3) Neurotoxicity studies……...……...
……...

4) Additional mutagenicity studies……

……..……

5) Carcinogenicity studies……..…..…..…..

……..…

6) Chronic toxicity……..……..……..

……

7) Hypersensitivity/allergies in human or any other human exposure data

……

8) Metabolic studies……

……

B) ACUTE TOXICITY DATA OF THE FORMULATED PRODUCT:

SCLPs are exempt provided the co-formulants are not of toxicological concern (MSDS must be provided). The Acute toxicity studies will be provided for non-SCLPs if any of the co-formulants are of toxicological concern.

……..……

……..……

PART V

EMERGENCY PROCEDURES IN CASE OF ACCIDENTAL EXPOSURE OR POISONING

a) Hazards to humans……..……

……

b) Symptoms of poisoning……..

……

c) Antidote……..……

……

d) Treatment……

e) First Aid Measures……..……

……

f) Safety Precautions/Restrictions……..

……

PART VI

ECO-TOXICOLOGY

a) Toxicity to birds (Required if the product could be ingested by birds, e.g. a granular formulation) ……..……

……

b) Toxicity to fish (Required if product is applied by air, or directly to water or at a rate exceeding natural background levels) ……..

c) Freshwater invertebrates (Required if product is applied by aircraft, or directly to water or at a rate exceeding natural background levels ……

d) Algae (Waived for products in affixed dispensers and if exposure is unlikely to exceed natural background levels) ……..……..

……..……..……..

e) Toxicity to bees (Information/discussion, to address whether behaviou0r or reproduction would be affected, is required if exposure is likely to exceed natural background levels) ……..……

……

f) Toxicity to earthworms (Required if product is applied to soil and can accumulate in soil. Required if exposure exceeds natural background levels) …….....

……

PART VII

Information on Approvals/Registrations in other countries (Attach copies of certificates) ……

…..……..

……

PART VIII

Draft of local label ..……..……

PART IX

Brief prepared by……...……

Signature……

Official stamp ……..……

Date……

PART X (FOR OFFICIAL USE ONLY)

Decision of the PCPB registration Sub-Committee

Recommended/Not Recommended for registration

Reasons: ……..…..……

Date……

PEST CONTROL PRODUCTS ACT

FORM A5 *(r.9(1)*

APPLICATION FOR THE REGISTRATION OF A PEST CONTROL PRODUCT FOR USE IN PAINT FOR IN-CAN AND FILM PRESERVATIVES

INFORMATION FOR APPLICANTS

1. The application form must be completed by a duly authorized person.
2. The application must be submitted in triplicate to:

   The Secretary, Pest Control Products Board (PCPB)

   P.O. Box 13794—00800 Nairobi,

   E-mail address: -info@pcpb.go.ke/md@pcpb.go.ke

   Tel.254-2-8021846/7/8,

   Fax 254-2-8021865
3. Every application must be accompanied by: -
   (a) Application fee as prescribed (Registration fee is payable upon approval by the Board.
   (b) copies of the draft label as per PCPB requirements.
4. The applicant may be required to submit: -
   (a) a sample of the pest control product;
   (b) a sample of the technical grade of its active ingredient;
   (c) a sample of the laboratory standard of its active ingredient;
   (d) any other sample as may be required by the Board.
5. List I and II are supplied as a check list and an index to ensure that the applicant has provided the relevant data.
6. The application must be accompanied by a technical dossier as per PCPB data requirements (Lists I and II attached).
7. An applicant who is not a resident in Kenya must appoint an agent permanently resident in Kenya and duly recognized by the Pest Control Products Board.

TRADE NAME ……..……

PURPOSE OF APPLICATION (tick as appropriate)

(a) Pest control product containing a new active 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) Type of Registration Applied for. *Tick as Necessary* Full Registration Temporary Registration	☐ ☐
(f) Other (Explain) ……..…… ……..…… ……..……	

Will the product be marketed under own label?	Yes	☐	No ☐
If No specify……			
Proposed date of marketing ……			

1.	APPLICANT	
1.1	Identification	
	Name of applicant / Corporate name of company	
	Business Reg No.:	
	Name of registration holder	
	Name of local agent in country: (*if different from registration holder)*	
1.14	Status: (Importer/formulator/distributor)	
	Business Registration No.:	
1.15	Physical Address	
1.16	Postal Address:	
1.17	Telephone: (*and area code*)	

1.18 Fax: (*and area code*)		
1.19 e-Mail:		
2. PRODUCT		
2.1 Designation (Description of product)	Trade name:	
	Trade mark:	
	Trade mark holder:	
2.2. Function of product: (eg. Insecticide, herbicide etc.)		
2.3 Intended use: (Public health, industrial, agriculture, forestry, etc.		
2.4 Target pest(s) and host(s)		
2.5 Method, dosage rates and frequency of application:		
2.6 Type of formulation: (eg. EC, WP, etc.)	Crop Life International(CLI*) Code (if available)	
2.7 a) Is the product registered in country of manufacture?	Yes ☐ No ☐ If Yes, attach a copy of certificate, If no, give reasons	
b) Is the product registered in the country of formulation?	Yes ☐ No ☐ If Yes, attach a copy of certificate, If no, give reasons	
2.8 Registration in SEARCH* country/ies: (names)		
2.9 Existing registration No(s) and country(s).		
2.10 Customs Tariff Code: (Brussels Tarrif Nomenclature)		

3. COMPOSITION OF ACTIVE INGREDIENT(S) (Technical grade) *(Information on a.i may be attached in sealed envelope)*			
Active ingredient(s): (Common name/s)	Manufacturer: (Name and address)	Minimum a.i.% purity	a.i. Range %

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

* Formerly GCPF

* SEARCH — Southern and Eastern African Regulation Committee on Harmonisation of Pesticide Registration

5. TOXICOLOGY (formulated product)				
5.1 Rat:	Acute Oral (LD_{50} mg/kg)	Acute Dermal (LD_{50} mg/kg)		Inhalation LC_{50} (mg/l/hour)
	Experimental	Experimental		Experimental
	Calculated	Calculated		Calculated
5.2 Rabbit:	Skin irritation	Eye irritation		
None				
Mild				
Moderate				
Severe				
5.3 Skin Sensitization in guinea pig: (tick)		None ☐ Mild ☐ Moderate ☐ Severe ☐		
5.4 WHO classiffication:	Ia	Ib	II	III
5.5. Summary of other toxicological studies: eg. wildlife, poultry, pets				

5.6 SUMMARY OF ENVIRONMENTAL EFFECTS	
5.6.1 Toxicity to bees:	
5.6.2 Toxicity to fish and other aquatic organisms:	
5.6.3 Toxicity to birds:	
5.6.4 Toxicity to earthworms and soil micro-organisms:	
5.6.5 Toxicity to other non-target organisms:	

5.6.6 Persistence in environment:	
5.6.7 Other effects: Specify	
6 PACKAGING	
6.1 Packaging material / container:	
6.2 Pack size(s):	
6.3 Disposal of empty container(s):	
7 OTHER SPECIFIC REQUIREMENTS	
7.1 Operator exposure	
(a). Dermal absorption.	
(b). Likely operator 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 …… I hereby certify that the above mentioned information 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*
Official Stamp of Applicant / Company	FOR OFFICIAL USE Remarks ……...…… … ……..……..…… … ……...…… … …….. …… *Signed:* *Date*:

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

FORM A5, LIST I

ACTIVE INGREDIENT: DOSSIER INDEX

The dossier accompanying the application must provide full details (as applicable) of the information requested in this list. i.e., details of the methods used, results of toxicological and ecotoxicological studies, methods of analysis, etc. Applicants are advised to use CIPAC methods for physical and chemical properties. Numbering used in the dossier must correspond to that used in the application form. If the product contains more than one active ingredient, compile a separate dossier for each active ingredient.

ACTIVE INGREDIENT (a.i)	Annex No. in dossier if study included	Official use only
1. DESIGNATION/IDENTITY OF a.i.		
1.1 Common name (ISO)		
1.2 Manufacturer or Development code		
1.3 Source, Name and Address of manufacturer and address and location of manufacturing plants.		
1.4 Methods of manufacture (synthesis pathways), may be sent direct to PCPB.		
1.5 Chemical name (IUPAC)		
1.6 Chemical group		
1.7 Structural formula		
1.8 Empirical formula		
1.9 Patent status		
Is the a.i. under patent?		
Who is patent holder		
Expiry date		
1.10 Molecular mass		
1.10 CAS Number		

2. PHYSICAL AND CHEMICAL PROPERTIES

2.1 Physical state		
2.2 Colour		
2.3 Odour		
2.4 Density at 20°C		

2.5 Vapour pressure at 20/25ºC		
2.6 Volatility		
2.7 Hydrolysis DT_{50} ….. Days …… ^{0}C …… pH		
2.8 Photolysis		
2.9 Solubility in water ……^{0}C …….. pH		
2.10 Solubility in organic solvents		
2.11 n-octanol/water partition coefficient		
2.12 Boiling point ^{0}C		
2.13 Melting point ^{0}C		
2.14 Decomposition temperature ^{0}C		
2.15 Method of Analysis and Impurities		
2.16 Stability in water, hydrolysis rate, effect of light, identity of breakdown products		
2.17 Stability in organic solvents used in formulation		
2.18 Stability in air; effect of light, identity of breakdown Products		
2.19 Thermal stabilty, identity of breakdown product.		
2.20 Flammability		
2.21 Flash point		
2.22 Explosive properties		
2.23 Oxidizing properties		
ACTIVE INGREDIENT	Annex No. in dossier if study included	Official use only
2.24 Absorption spectra – UV/Visible, infra-red, NMR MS		
2.25 Reactivity towards container material		

3. TOXICOLOGY

3.1 Acute oral LD_{50} mg/kg rat/rabbit		
3.2 Acute dermal LD_{50} mg/kg (rat)		
3.3 Inhalation LC_{50} mg/l hour (rat)		
3.4 Skin irritation (rabbit)		
3.5 Eye irritation (rabbit)		

3.6 Skin sensitisation (guinea pig)		
3.7 Reproduction (specify species)		
3.8 Subchronic toxicity 90 day NOEL mg/kg/day		
3.9 Chronic toxicity NOEL mg./kg/day		
3.10 Carcinogenicity (life time) NOEL mg/kg/day		
3.11 Neurotoxicity NOEL mg/kg/day		
3.12 Teratogenicity NOEL mg/kg/day		
3.13 Mutagenicity /Genotoxicity		
3.14 Metabolism (rat)		
3.15 Other studies		

Notes:- For long term studies individual studies or published literature may be acceptable.

4. ACTIVE INGREDIENT

ECO-TOXICOLOGY (Active ingredient – technical grade	Annex No. in dossier if study included	Official use only
4.1 Birds (2 species)	LD_{50} mg/kg	
	NOEL	
	LD_{50} mg/kg	
	NOEL	
	Reproduction	
4.2 Fish (2 species)	LD_{50} mg/kg	
	NOEL	
	LD_{50} mg/kg	
	NOEL	
	Reproduction	
	BCF	
4.3 Daphnia	LC_{50} mg/l	
	NOEL	
4.4 Algae	LC_{50} mg/l	
	NOEL	
4.5 Bees	LD_{50} ì g/bee	
	NOEL	
4.6 Earthworms	LC_{50} mg/kg	
4.7 Soil micro-organisms		

5. BEHAVIOUR IN ENVIRONMENT

5.1 Behaviour, ways of degradation, degradation products in soil:		
5.11 Major metabolites		
5.12 DT_{50} (days)		

5.13 Mobility of a.i.		
5.14 Adsorption / desorption		
5.15 Mobility of metabolites		
	Annex No. in dossier if study included.	For official use only.
5.2 Behaviour, ways of degradation, degradation products in water		
5.21 Major Metabolites		
5.22 DT_{50} (days)		
5.23 Surface		
5.24 Ground		
5.3 Behaviour, ways of degradation, degradation products in air. Rate and route of degradation in air (for fumigants and other volatile products).		
6. MODE OF ACTION		

FORM B6,

LIST II

FORMULATED PRODUCT: DOSSIER INDEX

The dossier accompanying the form should provide more details of the information requested in this list. Applicants are advised to use CIPAC methods for Physical/Chemical properties. Summaries of the methods used and the results of toxicological and ecotoxicological studies, methods of analysis etc. should be given. Numbering used in the dossier must correspond with that used in Form A5.

FORMULATED PRODUCT		
1. PHYSICAL AND CHEMICAL PROPERTIES	ANNEX NO. IN DOSSIER IF STUDY INCLUDED	OFFICIAL USE ONLY
1.1 Source, Name and Address of formulator and address and location of formulation plant.		
1.2 Source and specifications for components included in the formulation		
1.3 Physical state / formulation type		
1.4 Colour		
1.5 Odour		
1.6 Effects of light, air, temperature, water on technical characteristics of the formulation		
1.7 Storage stability in proposed packaging		
1.8 Shelf life		
1.9 Density		
1.10 Bulk density		

1.11 Flammability		
1.12 Flash point		
1.13 Explosivity		
1.14 In-compatibility with other pest control Products		
1.15 pH		
1.16 pH of 1% aqueous dilution		
1.17 Oxidizing properties		
1.18 Corrosiveness		
1.19 Water content		
1.20 Wettability		
1.21 Solubility in water		
1.22 Persistent foaming		
1.23 Particle size		
1.24 Suspensibility / emulsifiability		
1.25 Emulsion stability		
1.26 Volatility		
1.27 Viscosity		
1.28 Other properties (where applicable)		
1.29 Methods of Analysis		

TOXICOLOGY:

Food grade & Generally Regarded as Safe (GRAS) data waivers admissible; Published literature/studies should be submitted; but where there are coformulants of toxicological concern the toxicological studies for the end use product should be provided. For non-food grade and Non GRAS Toxicological studies should be provided.

2. TOXICOLOGY	ANNEX NO. IN DOSSIER IF STUDY INCLUDED	OFFICIAL USE ONLY
2.1 Rat Acute oral LD_{50} mg/kg		
2.2 Acute dermal LD_{50} mg/kg		
2.3 Inhalation LD_{50} mg/l /hour		
2.4 Rabbit Skin irritation		
2.5 Eye irritation		
2.6 Sensitisation in guinea pig		
2.7 WHO classification		
2.8 Other studies		

	ANNEX NO. IN DOSSIER IF STUDY INCLUDED	OFFICIAL USE ONLY
3. EMERGENCY PROCEDURES IN CASE OF ACCIDENTAL EXPOSURE OR POISONING		
3.1 Symptoms of human poisoning		
3.2 Mode of action in man		
3.3 First aid treatment		
3.4 Skin contact		
3.5 Eye contact		
3.6 Inhalation		

3.7 Ingestion		
3.8 Antidote		
3.9 Note to physician		
4. EMERGENCY PROCEDURES IN CASE OF FIRE/SPILLAGE		
4.1 Fire-fighting measures		
4.2 Procedures in case of spillage		

5. USES (New label claims with this application)		
FORMULATED PRODUCT	Annex No. in dossier if study included	Official use only
5.1 area of use		
5.2 Target organism		
5.3 Dosage		
5.4 Stage of treatment		
5.5 Directions for use		
5.8 Contraindications		
6. MINIMUM LABEL REQUIREMENTS –See PCPB label requirements (provided separately).		
7. OTHER SPECIFIC REQUIREMENTS		
7.1 Medical surveillance, on manufacturing plant personnel		
7.2 Health records of occupationally exposed personnel, - industry..etc.		
7.3 Proposed packaging. Type of packaging in which the product is imported. Type of packaging for distribution in Kenya. Packaging material. Sizes of individual packaging		
7.4 Procedures of destruction and decontamination of pest control product and its packaging. Possibility of neutralization. Controlled discharge. Controlled incineration. Water purification. Procedures of cleaning application Equipment. Recommended methods and precautions concerning handling, storage, display or transport.		

FORM B6 *(r.10 (2)*

PEST CONTROL PRODUCTS BOARD

P.O. Box 13794 — 00800, Nairobi
E-mail address: info@pcpb.go.ke/md@pcpb.go.ke
Tel: 254- 020 – 8021846/7/8 Fax: 254- 020- 8021865
WEBSITE ADDRESS:
https://www.pcpb.go.ke/

SUMMARY OF THE DATA SUBMITTED TO THE BOARD FOR REGISTRATION OF PLANT GROWTH REGULATORS AND POST HARVEST PRODUCTS FOR FLOWERS AND ORNAMENTALS

PART I

1. Trade Name……
2. The Name and Address of Formulator……...……
……...…..…
3. Common Name of the active ingredient(s)…….……
4. Concentration of active ingredient(s)……..…
5. Name & Location of manufacturer of technical grade active ingredient……...
7. Chemical Name…….……..…..……..
8. Formulation type…….……..……
9. Proposed Uses…….……..……..
…….……..……..……
10. Packaging/Containers (Material, size)……..……...
…….……...……
11. Registrant (Name, Address, Status)……...……
12. Agents/Distributors in Kenya……..……...……
……..……..
13. Premises (Reg.No. Date of issue)……..…….……
…….……..……..

PART II

CHEMISTRY DATA

14. Physical /Chemical Properties of the a.i……
……
……..……...

(b) Physical/Chemical properties of the technical grade material……...…..……

…….……

……...……

(c) Composition of the technical product (purity %, natures and identity of impurities — other details should be provided in the dossier)

……...……

……

(d) Physical/Chemical Properties of the Formulated Product

……..…

(e) Composition of the Formulated Product (Concentration of a.i. in the formulation. other details should be provided in the dossier)……

……

(f) Method of analysis for determination of the a.i. in technical and formulated products (State all the methods for different components) ……...……

……...……

PART III

Biological (efficacy) Data

(a) Area of use/Target Organism (if any), flower type(s).

……..…..

(b) Mode of action…….

(c Method, Rate, Frequency of application……

……..……...

(d) Recommendations for use in Kenya …….……

……..……...

(e) Recommendations for use by authorized bodies outside Kenya…….…….…..

……...

PART IV

Toxicological data

Food grade & Generally Regarded as Safe (GRAS) data waivers admissible; include summaries from Published literature or studies.

For non food grade and Non GRAS provide acute toxicological study summaries. For long term study summaries from peer reviewed literature should be included

(a) Acute Toxicological Data of the active ingredient(s)

……..

(b) Acute toxicity data of the formulated product:..

……..

(c) Short term toxicity studies……..……

……

(d) Other toxicological studies:

(1) Reproduction studies ……...……..

……

(2) Teratological studies……...……

……..…...

(3) Neurotoxicity studies……..……...

……..……...

(4) Mutagenecity studies……..

……..……

(5) Long term toxicity/carcinogenicity studies……...……

……..……

(6) Accumulation of compound in tissues…….……...…

……..……

.....

7) Metabolic studies .....

.....

(8) Effects on livestock, poultry……...……

.....

(9) Toxicity Data on impurities ……...……..……..

.....

10) Toxicity Data on metabolites…….……

.....

(11) Human toxicology and medical aspects:

(i) Hazards to humans .....

(ii) Symptoms of poisoning .....

(iii) Antidote .....

(iv) Treatment .....

(v) First Aid Measures .....

(vi) Safety Precautions/Restrictions.....

PART V:

ENVIRONMENT AND WILDLIFE HAZARDS

Summaries from published literature or studies should be included to address individual requirements

(a) Degradation and mobility studies (soil, water, air) .....

……

(b) Toxicity to birds .....

.....

(c) Toxicity to fish ……..……...……...……

…….……

(d) Toxicity to honeybees/beneficial insects……

…….……

(e) Toxicity to earthworms, other soil invertebrates……

……...…...

(f) Changes in soil ecology……

……

PART VI

Information on Approvals/ Registrations in other countries (*attach copy of certificate of Registration)*

PART VII

Draft of local label .

……..

PART VIII

Brief prepared by……

Signature……

Official stamp ……

Date……..

PART IX

Decision of the PCPB registration Sub-Committee

Recommended/Not Recommended for registration

Reasons:—

……...……

Date……

FORM A7 (*r13(1)*

APPLICATION FORM FOR THE REGISTRATION OF PARALLEL PEST CONTROL PRODUCT

INFORMATION FOR APPLICANTS

1. The application form shall be completed by a person duly authorized by the applicant. and submitted to The Chief Executive Officer, PCPB.

2. The applicant shall be required to: —

   (a) Pay the prescribed fee;

   (b) Provide an original letter of access from the registrant;

   (c) Provide an original letter of no objection from the local agent;

   (d) Use approved label of the original registered product and only changes the trade name to prepare a product label.

   (e) Provide three (3) copies of the Proposed label

   (f) Conduct efficacy trials where the proposed use of a parallel pest control product is different from that of the original registered pest control product.

   (g) Provide any other information as may be required by the Board

1	PROPOSED PRODUCT	
1.1	Proposed Product name (brand name)	
2	ORIGINAL PRODUCT DETAILS	
2.1	Original Product Brand Name	
2.2	Type of formulation (Crop Life code[3])	
2.3	Active ingredient(s)/Agent (s) (common name)	
2.4	Active ingredient/Agent (s) concentration(s)	
2.5	Name of Manufacturer, Physical address, Email address and Telephone	
2.6	Name of Formulator, Physical address, Email address and Telephone	
2.7	Registrant, Physical address, Email address and Telephone	
2.8	Local agent, Physical address, Email address and Telephone	
3.	APPLICANT	

3.1	Applicant name (corporate name of company)			
3.2	Status in Kenya	□ Manufacturer □ Formulator □ Distributor □ Other: ….		
3.3	PCPB Premise License Number and date of issue			
3.4	Business Registration Number			
3.5	Physical Address			
3.6	Postal Address			
3.7	Telephone Number			
3.8	E-mail Address			
3.9	Web site			
3.10	Contact person at applicant company			
3.11	Contact person telephone number			
3	LOCAL AGENT OF THE ORIGINAL REGISTERED PRODUCT			
4	PURPOSE OF APPLICATION			
A	□ Application for Parallel registration of a pest control product for the same uses as the original registered			
B	□ Application for Parallel registration of a pest control product for different uses from the Original registered product			
C	□ Other (specify):	…		
5	INTENDED USE			
5.1	Function/Category of product (more functions/ categories possible)	□ Insecticide	□ Fungicide	□ Herbicide
		□ Miticide	□Rodenticide	□ Molluscicide
		□ Bactericide	□ Defoliant	□ Plant growth regulator
		□ Semio Chemical		
		□ Other (specify): ……..		
5.2	Type of use (more types possible)	□ Agriculture	□ Veterinary	□ Public health
		□ Household	□ Forestry	□ Industrial
		□ Other (specify):	…	
5.4	Target pest(s)/ disease(s) and crop(s)/ use(s) (if different from the registered uses of the original product)	1	.....	
		2	.....	
		3	.....	
		4	.....	

	DECLARATION	
	For and on behalf of ……..… I hereby certify that the above mentioned information, as well as the data provided in the technical dossier, in support of this application are true, correct and complete.	
	..... *Name in full (print)*	..... *Signature*
	..... *Official title*	..... *Date*
	Official stamp of applicant/company	
8	FOR OFFICIAL USE	
	Application No: ……..…	Remarks:
	Reception date: ……..…	……
	Fees received: □ Yes □ No	……
	Amount paid:	……...
	Status of application:	□ Approved □ Rejected □ Pending

FORM C1 *(r.15 (6)*

APPLICATION FOR REGISTRATION AS A LOCAL AGENT

INFORMATION FOR APPLICANTS

1. "Agent" means a person or company who has/that has been appointed to act on behalf of a registrant in accordance with regulation 4(2) of the Pest Control Products (Registration) Regulations.
2. The application form must be completed by a duly authorized person.
3. The application must be submitted to:

The Managing Director/ Secretary
Pest Control Products Board (PCPB)
P.O. Box 13794 — 00800 Nairobi.
E-mail address:
info@pcpb.go.ke/md@pcpb.go.ke
Tel: 254— 020 — 8021846/7/8 Fax: 254— 020— 8021865
Website:
https://www.pcpb.go.ke/

4. Every application must be accompanied by:—
   (a) An original letter from the registrant,
   (b) A binding agreement entered between the registrant and the agent,

PRODUCT DETAILS

(a) Trade Name……...
(b) Name of Manufacturer……
(c) Name of Formulator……...……
(d) Name of Registrant……..……...…
(e) Name of Agent……...……..……
(f) Period for which agent has been appointed……...…

....
Signature of applicant (local agent) *Date*

....
Signature of Registrant *Date*

.....
Official Stamps of Applicant and Registrant

FORM C2 *(r.15 (7)*

APPLICATION FOR CHANGE OF AGENCY

INFORMATION FOR APPLICANTS

1. "Agent" means a person or company who has/that has been appointed to act on behalf of a registrant in accordance with regulation 4(2) of the Pest Control Products (Registration) Regulations.
2. The application form must be completed by a duly authorized person.
3. The application must be submitted to:

The Managing Director/Secretary
Pest Control Products Board (PCPB)
P.O. Box 13794 — 00800 Nairobi
E-mail address:
info@pcpb.go.ke/md@pcpb.go.ke
Tel: 254- 020 — 8021846/7/8 Fax: 254— 020— 8021865
Website:— https://www.pcpb.go.ke/

4. Every application must be accompanied by:—
   (a) An original letter from the registrant,
   (b) A binding agreement entered between the registrant and the agent,
   (c) An original letter of no objection from the former agent,
   (d) Application fee of KSh. 20,000 per product (change of agency fee is payable upon approval by PCPB after meeting the other requirements),
   (e) A copy of the draft label as per PCPB requirements,
   (f) Proof of licensing of the new agent by PCPB.

PRODUCT DETAILS

Trade name……..…….
Registration Number (If registered)……Status of registration ……
Name of Manufacturer……...……...……
Name of formulator……..
Period of which agent has been appointed…….……...
Name of Registrant……..……..……

Signature …… Date ……..……..……
Official Stamp
Name of former agent……
Signature ……..…… Date……..…….

Official Stamp.

Name of new agent……

Signature …….……Date…….……..

Official Stamp

FOR OFFICIAL USE ONLY

Please check whether the following documents have been provided:

REGISTRATION DEPARTMENT:

1. Has an original letter from the registrant been provided? Yes ☐ No ☐
2. Has an original letter of no objection from the former agent been provided?

   Yes ☐ No ☐
3. Has the applicant attached a copy of the draft label?

   Yes ☐ No ☐

INSPECTION DEPARTMENT:

4. Is the applicant licensed as a pesticide dealer/agent with PCPB in the current year? Yes…….. No……
5. If yes indicate licence No. ……

ACCOUNTS:

6. Has the applicant paid the change of agency fee.

   Yes…….. No……

Indicate Receipt Number…….. Date……

7. Has the applicant paid the dealers/agency license fee? Yes…… No……...…

Indicate Receipt Number……..….. Date……

Recommended	Not Recommended	Recommended	Not Recommended	Recommended	Not Recommended
Date……		Date……		Date……	
…… Registration Officer		…… Inspector		…… Accountant	

…… ……

Approved by Managing Director *Date*
Pest Control Products Board

Changes effected by (IT Officer) …… Date ……

FORM C3 *(r16)*

THE PEST CONTROL PRODUCTS ACT

APPLICATION FOR CHANGE OF TRADE NAME FOR A PEST CONTROL PRODUCT

INFORMATION FOR APPLICANTS

1. The application form must be completed by a duly authorized person/Agent
2. The application must be submitted to:

The Managing Director,
Pest Control Products Board (PCPB)
P.O. Box 13794— 00800 Nairobi.
E-mail address:
info@pcpb.go.ke/md@pcpb.go.ke
Tel: 254— 020 - 4446115/4450242 Fax: 254— 020— 4449072.

3. Every application must be accompanied by:—
   (a) An original consent letter from the manufacturer/principal
   (b) A copy of the draft label as per PCPB requirements,
   (c) Proof of licensing as a dealer with Pest Control Products by PCPB
4. The applicant shall be required to submit a sample of the pest control product;
5. The applicant may be required to submit:
   (e) A sample of the technical grade of its active ingredient;
   (f) A sample of the laboratory standard of its active ingredient;
   (g) Any other information as may be required by the Board.
6. Evidence from Kenya Intellectual Property Institute (KIPI) that the new trade name is available for use.

PRODUCT DETAILS

Current Trade Name .....

Proposed Trade Name .....

Reason for change .....

Stage of registration

(i) Registered (indicate registration No.)……

(Trade name to be in use 6 (six) months after approval to allow exhaustion of old stock)

(ii) Undergoing trials (State institution carrying out trials and permit No.)

(iii) Other (indicate)

Name of Manufacturer……..…...……

Name of Registrant (Proprietary owner of Technical information)

……..

Name of agent……..…

Signature of applicant …… Date……

Official Stamp of Applicant / Company

FOR OFFICIAL USE ONLY

Please check whether the following documents have been provided:

Registration Department:

8. Has an original letter from the registrant been provided? Yes ☐ No ☐
9. Has the applicant attached a copy of the draft label? Yes ☐ No ☐
10. Has KIPI confirmed availability of new trade name? Yes ☐ No ☐
11. Has the applicant submitted a sample of the pest control product? Yes ☐ No ☐

INSPECTION DEPARTMENT:

12. Is the applicant licensed as a pesticide dealer/agent with PCPB in the current year?

Yes ☐ . No… ☐ If yes indicate licence No……..

Accounts:

13. Has the applicant paid the dealers/agency license fee? Yes..☐ No… ☐

Indicate Receipt Number……..…….. Date……

14. Departmental recommendations

RECOMMENDED	NOT RECOMMENDED	RECOMMENDED	NOT RECOMMENDED	RECOMMENDED	NOT RECOMMENDED
Date……		Date……		Date……	
…… *Registration Officer*		…… *Inspector*		…… *Accountant*	

15. Recommendation of the Technical and Registration Committee of the Board

Recommended ☐ Not Recommended ☐ Date……

16. Decision by the Board of Management

Approved ☐ Not Approved ☐ Date……

17. Changes effected on List of Products and data base by (IT Officer)

Signature……..…..…..… *Date* ……..……

FORM D *(r.17 (3)*

PEST CONTROL PRODUCTS BOARD
THE PEST CONTROL PRODUCTS ACT CAP 346
EXPERIMENTAL PERMIT

Date……

Accredited testing institution

Address

Tel: ……

Email: ……

PERMIT FOR EFFICACY TRIALS OF NEW PEST CONTROL PRODUCTS

This is to inform you that your organization has been identified to carry out efficacy trials of the newly introduced pest control product (s) as indicated below:-

Pest Control Product(s) (Trade name)	Common name and concentration of a.i	Crop(s)/Commodity (ies)/ Use(s)	Target Pest(s)

You are required to inform the Pest Control Products Board the commencement of the experiment/efficacy trials and submit to the Board progress reports. The trials should be carried out using the Pest Control Products Board approved trial protocol. At the conclusion of the experiment/efficacy trials, a confidential report on the performance of the product and recommendations for its use should be submitted to the Board quoting the above reference and date.

It will be appreciated if trials are completed as soon as possible. Local agent will provide you with the required materials and financial resources for the trials. *All companies must apply for an import license for the trial sample which should be submitted directly to the Board for onward transmission to the researchers. The trial samples should neither be sold nor used elsewhere without Board from PCPB.*

Local agent is advised to liaise closely with you and PCPB to ensure that the tests are carried out in accordance with the approved trial protocol.

CHIEF EXECUTIVE OFFICER /SECRETARY

cc. Local agent

Address

Note:—All applicants are expected to submit the Pre-harvest interval (PHI) and Maximum Residue Levels (MRLs) for all edible crops.

FORM E1 (*r 18(1)(4)(11)*

PEST CONTROL PRODUCTS BOARD

REQUIREMENTS FOR THE PROTECTION OF CONFIDENTIAL BUSINESS INFORMATION SUBMITTED FOR PESTICIDE REGISTRATION ACTIONS IN KENYA

INTRODUCTION

In submitting data or information required by the Board for the initial registration or experimental use permit or a temporary/emergency registration or a provisional registration of a pesticide product or any other related regulatory action thereof, applicants (registrants) may claim certain data or information as 'Confidential Business Information' or CBI. This will eventually facilitate trade in Kenya

These Requirements define what constitutes CBI, list the requirements and procedures for submission and designation of CBI, and describe the responsibilities of the Applicant and the Board to protect CBI from unlawful or unintended disclosure.

Definition and Scope of Confidential Business Information

The following data or information required by the Board and shall be claimed by the applicant (registrant) as CBI:

1. Information that discloses the identity or percentage quantity of deliberately added inert ingredients in the technical grade of the active ingredient or in the formulated products (except those considered to have health and environmental risks/concerns). For example, specifications of the technical grade (active ingredient), composition of the product formulation, the process of formation of impurities.

2. Information that discloses the processes of manufacturing or the formulation process, quality control and testing of batch analysis of a pesticide product. For example, the method of manufacture.

3. Commercial or financial information relating to trade secrets, production, distribution, sales, inventories or other privileged trade information provided for the purposes of registration.

4. There are several other data requirements that do not constitute CBI. For example, the molecular formula of the active ingredient, the characterization or summaries of publicly-available risk evaluations where the risk assessment has been conducted by a governmental organization.

5. As a general rule, CBI shall not be disclosed to the public.

6. In exceptional cases such as in the public interest, the Board may disclose CBI to Board Committees or in Court Proceedings/Legal Hearings in compliance with other legal authorities or when public health or environmental safety is at risk leading to cancellation or suspension hearings.

7. For a more detailed list of what constitutes CBI, see First Schedule Form A.

GENERAL PROCEDURES

The Board and the applicant (registrant), and their local representatives shall implement measures to protect CBI.

Responsibilities of the Applicant (Registrant) or its local representative shall be to:

1. Ensure that all CBI is submitted to the Board in a secure manner and by a responsible person, authorized by the applicant.
2. Submit the CBI in a separate sealed envelope or a separate electronic storage device clearly marked or identified as "CONFIDENTIAL BUSINESS INFORMATION."
3. Provide justification at the time of submission why additional information may be claimed as CBI. In such case a Justification for Additional CBI Protection) may be required to be submitted.

RESPONSIBILITIES OF THE BOARD SHALL BE TO:

1. Designate the regulatory officials that will receive, review, record and store CBI submitted by the applicant (registrant).
2. Establish mechanisms for regular training (minimum of one per year) of the designated regulatory officials in the PCPB Protection of CBI Requirements and its implementation.
3. Institute adequate measures to protect CBI, such as the reception place, the secure storage area (office), and limiting the access to CBI to only authorized personnel.
4. Ensure that the storage area is secured with access to only authorized personnel and contains a locked storage unit (e.g. locked cabinet, or a separate laptop or computer).
5. Maintain a record in the form of a log, that indicates the name of applicant, date of reception, dates of any internal disclosures, the person or committee to whom disclosure was made, and a description of the information disclosed.
6. Designate a regulatory officer who shall receive the CBI, record the list of CBI data or information, and store the CBI in the secure storage area and the secure storage unit.
7. Allow only access to authorized and trained persons.
8. Review and validate the information submitted as CBI and may ask for additional clarification from the applicant to make the determination whether such information constitutes CBI.
9. Make an official notification of CBI determination to the applicant by certified mail, return receipt requested, or by personal delivery. Where there is no response of this official notification, the determination of the CBI shall suffice as the official record of what constitutes CBI.
10. Inform the applicant of disclosure and justification for disclosure in cases when PCPB may be required to disclose CBI by Board Committees or in Court Proceedings/Legal Hearings.
11. Not copy any information submitted and marked by the applicant as CBI unless authorized by the Board. The authorization to make copies of CBI must contain the following information:

- The name of the recipient of the copy.
- The intended purpose for which the copy is to be used.
- The manner in which the copy is to be disposed of after use.

12. Not disclose CBI in its custody or submitted by the applicant, to other pesticide applicants or other local representatives.
13. Not disclose CBI to a similar authority in a different region or country or jurisdiction for the purposes of facilitating registration for a pesticide product, unless the applicant has consented in writing, in advance, to such disclosure.
14. Implement a sufficiently deterrent penalty or fine system applicable to regulators or other, third parties who intentionally and unlawfully disclose CBI for personal financial or other gains in accordance with their national laws and regulations.

DISPUTE RESOLUTION

In the event of an unauthorized disclosure of CBI, PCPB shall conduct an internal investigation to determine the facts of the unauthorized disclosure, to assess culpability for such disclosure, and serve as the basis for any penalty or fine for such disclosure to be assessed under the applicable national law(s).

CONFIDENTIAL BUSINESS INFORMATION SUBMISSION/RECEIPT FORM

		Provided		Remarks
		Yes	No	
1	Method of manufacture (e.g. synthesis pathway)			
2	Specifications of the technical grade (active ingredient)			
3	Composition of the formulation			
4	Method of analysis for impurities			
5	'5-batch' analysis; including chromatographs			
6	Any other information			

Date received	
Trade name of the Product	
Active ingredient(s)	
Registrant	
Manufacturer(s) of active ingredient	
Formulator	

Exporter	
Local agent	
Submitted by (Full Name and signature)*	
Received by: Officer's name and signature	
Handed over to the Head of department. Signature:	

** Confidential business information received as it is subject to technical evaluation*

FORM E2 *(r.18 (3)*

CONFIDENTIALITY DECLARATION

I……from……..(*company oflocal agent, representative*) declare that I shall maintain confidentiality of all Confidential Business information (CBI) as provided for under the Pest Control Products Act and Regulations made thereunder.

Signature……..

Name of agent/representative

Designation

Date…….

FORM F *(r.19 (3)*

THE PEST CONTROL PRODUCTS ACT CAP 346

SUBMISSION OF SAMPLE (S) FOR EFFICACY TESTING

This form should be filled in duplicate: Part I and II to be filled by the Applicant

I) PRODUCT DETAILS

Trade name……

Formulation type……

Active ingredient (s) ……..……

Concentration of active ingredient(s)……

Quantity of sample (Liters or grams)……

Number of packages……..……

REF: (Permit No. and date)……...……

Name of Applicant (Local agent)……..

II) SUBMISSION DETAILS

Submitted by:

Name…… Signature…… Date……..……..

III) DELIVERY DETAILS

Received on behalf of PCPB by:

Name……Signature……Date……..

Institution(s) of destination……..……

Means of delivery:

A. PCPB PERSONNEL

Name of Person delivering……..……...……

Date of delivery……...……..

Received by……..……

Signature……

Official stamp……...……

B. COURIER SERVICE

Name of company……..……

Contact person……..……...……

Charges (Attach receipt)……...……

Date of delivery……...…….……...……

Official stamp…….……...…..……

Receiving Institution ……...…..……

Date of receipt…….……...……

Person receiving…….……...……

Signature……*Date*……...……

Official Stamp…….……...….

FORM G *(r. 23(4)*

PEST CONTROL PRODUCTS BOARD

(Statutory Organization of Government of Kenya)

THE PEST CONTROL PRODUCTS ACT

CERTIFICATE OF REGISTRATION OF A PEST CONTROL PRODUCT

Number ……..……

It is hereby certified that the pest control product described herein has been registered under the Pest Control Product Act and is subject to conditions indicated-

1. Approved common name ……..
2. Trade name under which marketed in Kenya ……...……

……...……

4. Active ingredient(s) ……..

……

4. Formulation ……..……..
5. Condition(s) under which pest control product is registered ……

……

6. Registration No. ……
7. Registration in the name of ……

Address…… Email Adress……...……

Tel. No.:……

8. Date of registration ……
9. Expiry date of registration ……

……..……

CHIEF EXECUTIVE OFFICER

Pest Control Products Board

FORM H (*r.26(3)*

PEST CONTROL PRODUCTS BOARD

PEST CONTROL PRODUCTS ACT

REQUIREMENTS FOR APPROVING EMERGENCY USES OF PEST CONTROL PRODUCTS FOR MANAGING AGRICULTURAL AND PUBLIC HEALTH PESTS IN KENYA

PREAMBLE

These requirements shall be used to address the regulatory approach for approving pest control products in Kenya in the event of pest emergency situations where:

- An invasive or exotic pest has been properly identified.
- No specific pest control products are registered for controlling the pest emergency.
- Registered pest control products are no longer effective for controlling the pest emergency; and
- There is valid scientific information of the potential economic damage to agricultural production and public health.

1.0 INTRODUCTION

The transboundary movement of agricultural pests and resurgence of existing (endemic) agricultural and public health pests are occurring with increased frequency due to several interacting forces, such as globalization, expansion and intensification of agricultural production, emergence of pest resistance to common pest control measures, and climate change.

Invasive pests typically invade new ecosystems without the specific natural predators that keep them in check in their native environment. Unimpeded increase in invasive pest populations cause significant economic losses and crop damage until effective integrated pest control measures are developed, adopted, and deployed.

Since early 2016, Kenya has been confronted by severe infestations of invasive agricultural pests such as, the Fall Armyworm (*Spodoptera frugiperda*), *Drosophila Suzukii*, Golden apple snails, the African desert locust (*Schistocerca gregaria*) among others, which have posed significant economic damage to key agricultural crops and public health. Whether an invasive or an outbreak of a pest occurs, its unabated control poses special problems for farmers and pest control regulators.

The African desert locust is an example of a devastating transboundary, endemic, and recurring agricultural pest. Agronomic (development of pest resistance to intensive use of registered pest control products and environmental factors are known to create conditions that enable endemic pests to become more damaging and virulent over time.

These scenarios justify the need for an effective regulatory instrument capable of responding to pest emergency situations to minimize the potential economic damage to agricultural production and public health.

2.0 OBJECTIVES

To facilitate PCPB to expedite approval of pest control products during emergency situations for purpose of mitigating the impact of pest emergency situations.

3.0 SCOPE OF THE REQUIREMENTS

The requirements laid out in this document shall be used to regulate the approval of plant and public health pest control products in Kenya in a pest emergency situation.

4.0 PROCESS OF APPROVING PEST CONTROL PRODUCTS FOR EMERGENCY USES

4.1 Identification of the pest threat (pest emergency)

The relevant agency shall be required to identify and recommend to the minister to declare a pest as an emergency pest by:

(a) Acquiring scientifically validated information on taxonomic identification, or genotyping, or breeding/cultivation.

(b) Understanding the nature of the pest threat and determining the potential to affect an agricultural production and public health.

(c) Estimating the potential crop losses in tonnage or financial terms, or the serious threat to food security or risk to public health if the pest emergency remains unchallenged or uncontrolled.

4.2 Determination of potential or actual 'Significant Yield Loss' and 'Significant Economic Impact'

A key factor to properly classify an invasive or critical agricultural/public health pest as a pest emergency is the determination of what constitutes a 'significant' yield loss and a 'significant' economic impact to be caused by the said pest.

This will be determined by the relevant government agencies in agriculture (for agricultural pests) and public health (for public health pests).

4.3 Scenarios of a Pesticide Emergency Use Situation

The requirements shall be applicable where there is:

(a) Localized or confined invasion/infection- for pest emergency situations that potentially affect agricultural production and public health in a confined area and that can be managed locally,

(b) Nationwide invasion/ infection – for pest emergency situations that potentially affect all agricultural areas and

(c) Regional crisis – for agricultural pest emergencies that potentially affect neighboring countries.

4.4 Process of Approval of a Pesticide Emergency Use Registration

4.4.1 Official declaration of a pest emergency and the need for the emergency use registration of a pest control product(s)

If the criteria in 4.3 above are met, the responsible institution shall in consultations with other relevant government departments and agencies officially declare a pest emergency and the need for the emergency use of a pest control product.

4.4.2 Notification of a pest emergency

Once, the need for an emergency use registration of a pest control product is declared, the Pest Control Products Board will prepare an official notification of an emergency pest situation which shall include information on:

- The nature of the pest emergency,
- The affected crops and farmers, area or public health,
- Determination that no registered pest control products are available,
- The extent of the potential yield losses, economic impact, and risks to public health, and
- The need to mitigate the pest emergency.

In preparing the notification, the PCPB shall solicit comments and the engagement with and the cooperation of appropriate stakeholders (e.g., farmer groups, government agencies, pesticide industry, international organizations, any other relevant stakeholders) to identify candidate pest control products.

The official notification shall be published on the PCPB website and/or any other available means of communication to inform registration holders and other key stakeholders of the need to cooperate and participate in identifying and applying for emergency use registration for pest control products to manage the pest emergency situation.

4.4.3 Identification of candidate pest control products for the management of the pest emergency

The PCPB shall engage local representatives of the registered pesticides or the pesticide industry to collectively identify those pest control products that are potential candidates for emergency use registration to manage the pest emergency based on:

(i) Demonstrated efficacy and safety of registered pest control products for biologically similar pests in the affected agricultural crop or public health in Kenya,

(ii) Demonstrated efficacy and safety of pest control products on the pest in the same or similar agricultural crops and public health in other countries with established pesticide regulatory systems, *(Demonstrated efficacy on the pest from other countries means information extrapolated from scientifically verified efficacy data from other countries).*

(iii) Priority shall be given to:

- Effective and safe product formulations containing active ingredients (conventional chemicals or biopesticides) already approved for use in recognized regulatory jurisdiction with strong pesticide regulatory framework,
- Effective biocontrol product or conventional chemicals already approved for use in Kenya,
- In the event, that a new unregistered active ingredient or formulated product or biocontrol product is identified as needed, the applicant shall be required to provide evidence through scientific data that the pest control products are effective and will not cause unacceptable adverse effects on human health and the environment.

Upon approval of a pesticide emergency use and where the use is on a food crop, the applicant shall be required to provide scientific evidence that the potential residues on food do not pose an unreasonable adverse dietary risk.

4.4.4 Application for a pest control products emergency use registration

PCPB may prior to arrival of an invasive pest of concern approve emergency registration of pest control products once by evaluating data on pest monitoring and early pest warning system from responsible national and international organization in consultation with relevant stakeholders.

Once a pest control product candidate (s) is/are identified, the local representative of an existing approved pesticide or the company that owns an unregistered pest control product candidate must formally apply for an emergency use registration to the PCPB, with the following documentation:

(i) A completed Emergency use application form available from the PCPB *website* https://www.pcpb.go.ke

(ii) Proof of payment of applicable fees for application of an emergency use registration as determined by the Board from time to time.

(iii) Supporting technical data on the pest control product:

- Physical/chemical properties,
- Toxicity (human health, environmental fate and ecotoxicological),
- Efficacy,
- Potential residues on affected agricultural crops, evidence of established pesticide maximum residue limits (MRLs) for the active ingredient in/on affected crops (e.g., Codex Alimentarius or established MRLs from other countries where the MRLs were established under scientific criteria). And for biopesticides, evidence of MRLs exemptions.
- A supplemental label, specific to address the pest emergency use situation. The supplemental label shall clearly state that the pest control product can only be used for the pest emergency. The supplemental label shall have an expiration date of one year from the product approval date. The supplemental label shall also contain basic label information (such as, product composition, registrant information, directions for use, Date of manufacture, expiry date, batch number, declaration of the shelf life, health and environmental warning, proper product disposal, product warranty, first aid statement, etc.).
- For an unregistered pest control product, proof of registration details and technical information from any foreign country where such a product may already be registered (if applicable).
- For an unregistered pest control product, a plan for managing unused stocks of the product at the end of pest emergency.
- Any additional and pertinent information, such as letters from grower associations or other government agencies in support of the application.

4.4.5 Granting a pest control products emergency use registration.

After a thorough evaluation of the pest control product emergency use application, the PCPB shall grant a pesticide emergency use registration if the application meets the

minimum requirements. The pesticide emergency use registration shall be for a 12-month period.

This can be renewed once, if the pest emergency continues and no other effective integrated pest control measure exists, or no duly registered pesticide has been approved for controlling the pest.

Once an emergency use registration has been granted the second time, the local representative of the pesticide emergency use registration shall commit to submit data to fulfill all the requirements for a formal registration of the product.

4.4.6 *Additional requirements for approved pest control product emergency uses.*

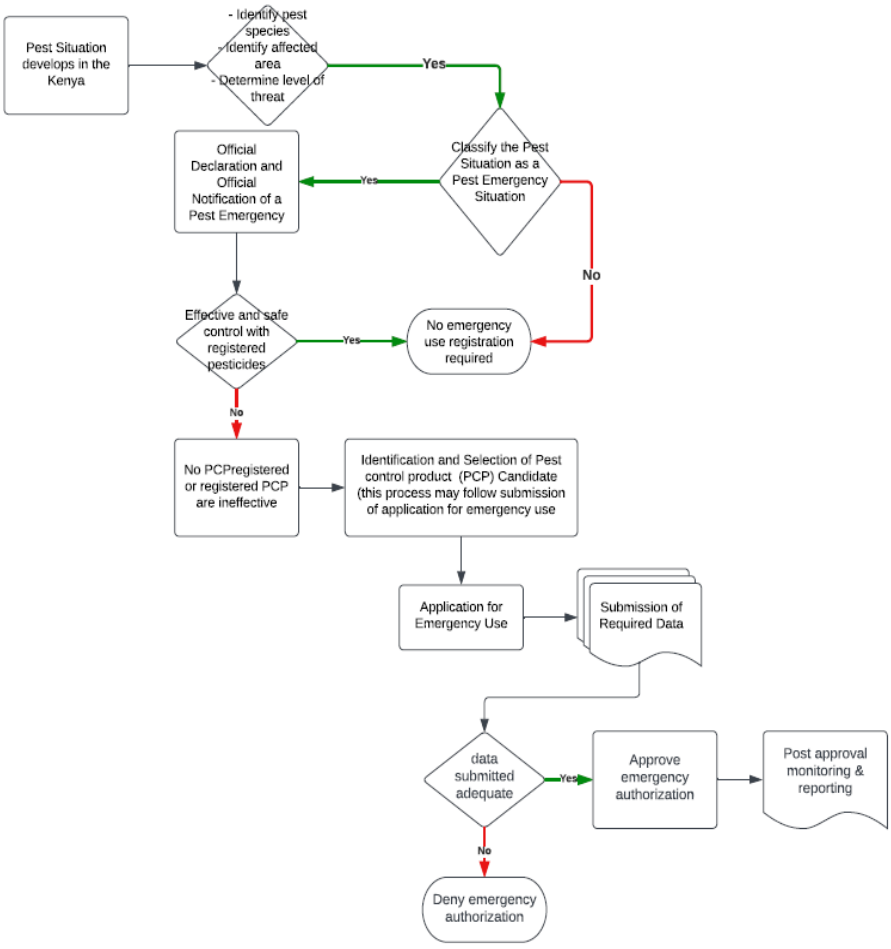
In approving the pest control product emergency use, the holder of the registration shall commit to submit an annual report to the PCPB detailing:

- The quantity of products that were imported, produced and or sold to users,
- Actual field information on product performance as claimed in the application for the pest emergency,
- Information that the use of the product has not resulted in undue risks to human health and the environment.
- Evidence that residues on treated food crops do not exceed the maximum residue limits for the active ingredient(s); and
- At any time during the pest emergency situation, should the local representative of the pest control product emergency use applicant become aware of problems with the efficacy, exceedance of maximum residue limits or undue risk to human health and the environment; the holder of the pest control product emergency use registration shall immediately inform the PCPB in writing of such situations upon which the PCPB shall institute appropriate remedial action.

4.5 Cancellation of emergency use registration

The PCPB shall cause cancellation of an emergency use registration when it is established beyond reasonable doubt that there was a contravention in one or more conditions for granting the said approval.

Figure 1: Flowchart for the process of approving a Pest Control product emergency Use



FORM I *(r29(2)*

PEST CONTROL PRODUCTS BOARD

CHANGE OF SOURCE

PRODUCT INFORMATION

1. Trade Name:……...……
2. Common name of active ingredient(s) and Concentration:……
3. PCPB Registration No:……...……
4. Technical Grade Active Ingredient (Current source)
   (a) Name of basic manufacturer:……..……
   (b) Physical Location of basic manufacturer:……...……
   (c) Address:
      (i) Postal Address:……..……
      (ii) Telephone No:……..……..
      (iii) E-Mail……
      (iv) Fax No:……..
      (v) Street/Road:……...……
   (d) Specifications (Certificate of composition)
   (e) Relationships with Registrant, if different
5. Technical Grade Active Ingredient (New source)
   (a) Name of basic manufacturer:……
   (b) Physical Location of basic manufacturer:……..……
   (c) Address:
      (i) Postal Address:……
      (ii) Telephone No:……..……..
      (iii) E-Mail Address:……
      (iv) Fax No:……..
      (v) Street/Road:……..……..……
   (d) Specifications (with analytical proof-5 batch analysis)
   (e) Relationships with Registrant, if different

6. Formulated Product

(a) Name of Formulator:……..……

(b) Physical Location:……..……

(c) Address

(i) Postal Address: ……

(ii) Telephone No: ……

(iii) Fax No:……...……..……

(iv) E-Mail Address: ……..……

(v) Street/Road: ……

(d) COMPOSITION (with analytical proof)

(e) Relationship with the registrant

7. Reason for change of manufacturer/Formulator.

NB: *Fill separate form for each basic manufacturer/formulator, if more than one.*

r6(1)

REQUIREMENTS FOR EVALUATING AND REPORTING THE EFFICACY OF PEST CONTROL PRODUCTS FOR

PROCEDURES FOR EVALUATING & REPORTING THE EFFICACY OF PEST CONTROL PRODUCTS FOR PLANTS

1. INTRODUCTION

Efficacy evaluation of a pest control product is important because it enables the registration authorities to evaluate the benefits to be gained from new pest control products or new uses of existing pest control products to weigh their benefits against potential hazards due to their introduction.

Reports of efficacy trials in the region are not uniform. These requirements have been developed for trial managers carrying out the efficacy trials with a view to harmonizing the procedure of conducting and reporting of efficacy trials. This will improve the evaluation process for the registration of new pest control products in the region.

All trials must be authorized by the Board. The trial manager is obliged to liaise closely with the Board throughout the trial period.

2 GENERAL PROVISIONS

The Board shall ensure that all new pest control products or new uses of existing pest control products are subjected to a thorough efficacy evaluation before they are authorized for any use.

All efficacy trials involving pesticides shall be approved by the Board.

2.1 Samples of the pest control product must be sent to the Board for forwarding to the testing institution.

2.2 (a) All trials must be carried out by institutions and/or individuals accredited by the Board.

The criteria for accreditation shall be clearly indicated to guarantee standards of efficacy trials.

2.3 Applicant intending to register product(s) in Kenya shall ensure that a common crop/ pest specific study plan is developed in line with this guideline and the efficacy trial protocol approved by the Board in consultation with the testing institutions. The applicant shall ensure the study plans are complied with.

2.4 The efficacy test report should be submitted in hard (duplicate) and soft copies to the Board, with a copy to the applicant.

2.5 The cost of trial authorized by the Board will be incurred by the applicant

2.6 Where the provisions of the European and Mediterranean Plant Protection Organization (EPPO) requirements conflict with these requirements, the provision of these guideline shall prevail.

3 SCOPE

The procedures laid out in this document shall be applied to, pest control products used to control harmful organisms (insects, pathogens, weeds etc.) on plants, plant products, products applied to soil and regulated articles. The procedures shall also be applied to plant growth regulators. This guideline covers all plants.

4 CONDUCTING EFFICACY TRIALS

The procedures outlined below shall be employed when setting up efficacy trials.

Objectives of the trials

The pest control product to be evaluated and the target crop/plant, the target pest(s) and other objectives must be stated clearly.

5 MATERIALS AND METHODS

The trial manager should refer to this guideline when conducting efficacy trials. If details are not available, internationally acceptable requirements should be used, e.g. the EPPO standards that are freely available on the EPPO website *(http://archives.eppo.int/EPPOStandards/efficacy.htm)*

5.2.1. Trial site selection

The sites should be as uniform as possible and representative of the conditions where commercial use is anticipated. Sites with irregular soil conditions should be avoided or experiments should be designed to accommodate the minor differences.

The disease, insects, weeds, etc. which forms the object of the efficacy trial should occur in a uniform pattern over the site or should be expected to become uniformly present during the trial period. Before trials are carried out, it is important to assess the infestation levels.

When selecting a site, the history of the site should be considered such as the preceding crop situation and previous infestations. A single preceding crop, on which only uniform treatments were applied, should have been grown over the whole area of the site.

As a general rule, sites at field edges, or near ditches, trees, hedges or other obstacles should be avoided, as they are subject to interfering "edge" effects from those obstacles.

The experiment should be sited away from the edges of a normal commercial crop. If the crop has to be treated with a pest control product which may interfere with those under study in the experiment, then a sufficient margin of untreated crop should be left in the immediate vicinity of the experiment. If the trial consists of repeated blocks which follow each other in the direction of drilling, spraying or other treatments of the crop, it may be helpful to have a gap between the blocks to allow for turning on and off the supply of the pest control product, and as well to align the apparatus with the next plot or sub-plot.

5.2.2. Trials on plants grown under protection

Efficacy trials on plants grown under protection should be conducted under conditions comparable to those used in practice. If products with high vapor pressure, fumigants, aerosols or fogs are tested, separate glasshouses or glasshouse compartments should be used for each treatment.

5.2.3 Post harvest pest control products

Post-harvest products should be tested in the laboratory (bioassay) and field facilities that simulates supply chain/storage conditions. Laboratory tests should be based on reference or known test population of the appropriate pest.

Storage duration of the grain before application (or in the case of fresh produce, cold storage conditions) should be specified to establish if there is a relationship between time in storage and prevalence in pest population/disease severity/incidence, and subsequent influence to the trial.

5.2.4. Trial lay-out

The design of a trial intended for efficacy evaluation should permit a statistical evaluation. It should however be simple and compatible with the immediate objective of the test.

A randomized complete block design is usually adequate. A very unique design may be used with prior approval by the Board.

5.2.5. The non-treated control plot

It is a requirement to include non-treated control plots in efficacy trials.

It is important to note that in some situations, the layout of non-treated plots within the randomized blocks may give rise to disadvantages due to extensive interference between non-treated and treated plots. Examples are efficacy trials for fungicides with "preventive" action on susceptible cultivars of potatoes, or apples for the control of late blight and apple scab, respectively. In order to avoid heavy losses in both the current and subsequent crops, it may sometimes be necessary to discard the non-treated plots from the experiment shortly after the occurrence of the disease becomes obvious. The initial non-treated plots should be sprayed, taking due care to avoid drift into treated plots. Alternatively, excluded controls, i.e. control plots located outside the trial area but in an area where conditions are comparable to the trial area, can be used where interference with treated plots is expected. Excluded controls provide information on the level of pest infestation but cannot be included in the statistical analysis.

5.2.6. Choice of reference product

The reference product is sometimes referred to as a standard or positive control. The reference product must have been registered and in use in the country where test is being done for use on the pest and target crop, where possible, the positive control should have the same mode of action as the test product. The reference product should preferably be a product registered in Kenya.

In case no product is registered with the same active ingredient or a similar mode of action, the trial manager should liaise with the Board for guidance.

5.2.7. Plot size and shape

This should be determined by the crop-pest combination in question. In narrow row (broadcast sown) crops, minimum net plot size (the part of the plot used for assessment and harvest) should be between 10 and 20 m^2 depending on plant density. Higher density allows for smaller plot size). In row crops net plot size should be two (2) to four (4) rows of 8-10 m depending on plant density. In tree crop trials, it is desirable to have 4-6 trees per net plot to allow for variability between trees. The minimum plot size in uniform vegetable or flower crops may be smaller, if internal interferences can be avoided. The

plot size should be sufficiently large to allow application of treatments, sampling and evaluation of the crop yield at harvest.

In some situations, the plot size and separation distance may be required to be larger in order to reduce interferences between treatments e.g. trials on pheromones.

5.2.8. Number of treatments

Efficacy trials on the new product should have a maximum of five treatments distributed as follows: manufacturer recommended rate; rates slightly higher than recommended and slightly lower than recommended for the new product; reference standard at the registered rate; and untreated control. (Lower and higher treatment should not be more than 25% variation above or below the manufactures´ recommended rate). There may be exceptional circumstances where more than five treatments may be required, such as where the test product has more than one active ingredient with different modes of action and >1 positive control may be necessary.

5.2.9 Number of replications

This will be determined by the likely magnitude of experimental variance and the number of treatments. The fewer the treatments, the more the replications needed to give an acceptable estimate of variance and to give the necessary degrees of freedom. Four to five replications are usually sufficient to give a reasonable estimate of the variation.

5.2.10. Number of seasons

(a) Where an applicant submits an application to the Board for registration of a product not registered in Kenya according to this guideline, the product shall be subjected to two (2) successful cropping seasons trials at two sites in different agro-ecological zones. Where a commercial crop is only grown in one agro-ecological zone, data from that one zone will suffice.

(b) Where an application is for a label extension two season's trial shall be conducted

(c) The above conditions for label extension apply to specific crop and pest combinations but may be adopted in the context of crop grouping and data extrapolation

5.2.11. Application of the pest control products

The type of equipment used should be stated. It should, as much as possible, be similar to that currently used in practice, and should give an even distribution of the pest control product over the plot. Other relevant information such as type of nozzles, operating pressure in kilopascal (Kpa) should be provided.

The type (foliar, soil incorporated, seed dressing.etc.), method of application (e.g. drench, spray, etc.), time, dosage and frequency of the pest control products application will be as recommended by the applicant and they should be recorded. Where deviations occur, records should be maintained. Precautions should be taken to ensure minimum interference with the adjacent plots (avoid drift).

5.2.12 Other pest control products used

Information on other pest control products used in the trial plots should be provided by the scientist involved in the trial.

5.2.13 Growth stage of the crop and variety used

The growth stage of the crop at the time of application should be indicated. The last application (pre-harvest interval) should be linked with harvesting time. The variety of the crop in use should be specified. The most susceptible variety should be considered for the worst case scenario, among the available commercial varieties.

5.2.14 Meteorological and edaphic data

Before, during and after the time of application, precipitation (type and daily amount of rainfall in mm), temperature (daily average, maximum and minimum in ºC), insolation should be recorded on the field trial site or obtained from a nearby meteorological station. Extreme weather conditions such as severe and prolonged drought, storms, hail, etc, which are likely to influence the effect of the product(s) should also be recorded. For pest control products applied to the soil, soil organic matter, texture and moisture should be recorded. For plants grown under protected environment (glass houses) or grains stored in fumigation sheets or silos, temperature and humidity should be recorded throughout the trial period.

5.2.15 Assessment of efficacy and yield

An assessment of the level of infestation/infection should always be made prior to treatment. The number of assessments after treatment depends on the type of the plant, pest and the growth stage of the plant. Assessment should always be made in the net plot. Objective methods of assessment such as counting, weighing, measuring should be used rather than subjective methods such as visual assessment except for diseases where severity or incidence is the commonly agreed method of assessment. Parameters that demonstrate direct effects should be measured e.g. disease severity. Where internationally acceptable assessment methods exist, they should be adopted. Time of assessment and sampling method should be recorded.

Yield data should be recorded in all the efficacy trials. However, in some crops like pineapples and sugarcane, yield data may be waived due to duration of the cropping season.

Raw data and analyzed data should be maintained by the testing institutions and should be readily available to the regulatory authority whenever required.

5.2.16 Phyto-toxicity and other side effects

The type and extent of phyto-toxicity should be described and, where appropriate, recorded according to a recognized scale. Any detrimental effects on wildlife and/or beneficial organisms shall also be recorded. For high value crops such as roses and other flowers, varietal phytotoxicity tests should be carried out on a number of representative varieties.

For herbicide and plant growth regulators, data should always be provided from trials on crops/plants where double of the normal dose is applied.

5.2.17 Residual effects

The effect of the pest control product on subsequent crop should be documented. This is particularly important for herbicides. Information on effects on succeeding crops may be obtained from trials conducted outside Kenya, including published data. For further information on the assessment of the risk of effects on succeeding crops consult PCPB testing protocol and/or EPPO Standard on Effects on succeeding crops. These data are not required for perennial crops such as sugarcane, pineapple, coffee, etc.

5.2.18 Monitoring of efficacy trials

The testing institution should send to the Board the study plan and schedule of activities showing critical milestones, including the initiation of the trials, treatment application, data collection and expected date of completion for each season. The Board shall ensure that a representative sample of trials being conducted in Kenya in accordance with these requirements, are monitored for compliance. Evidence of peer review should be provided.

5.2.19 Statistical analysis of data

The generated data should be subjected to statistical analysis to establish statistical significance. The statistical method(s) used should be indicated. The raw and statistically analyzed data should be held by the trial manager for submission to the Board on request. All data and information should be filed appropriately by the testing institution for easy retrieval. Further information on statistical analysis of efficacy trials may be obtained from PCPB testing protocol and/or EPPO Standard: *Design and analysis of efficacy evaluation trials*.

6.0 REPORTING

A progress report should be submitted at the end of each season. The report should undergo internal peer review before being submitted by the head of the institute to the Board. The report should be submitted in both hard copy and electronically. The final report should summarize the results and should be compiled in the following format. More information on reporting efficacy trials may be obtained from the Boardreporting standard and/or EPPO Standard: *Conduct and reporting of efficacy trials including good experimental practice*.

6.1 Title

The title should reflect the content of the report.

6.2 Summary

It should summarize the content of the report and the main findings

6.3 Introduction

It should contain a brief literature review and objectives of carrying out the study.

6.4 Materials and methods

It should give a description of methods used and citations of relevant reference methods. The information should include the common and trade names of the candidate product, source of product, formulation, concentration of the active ingredient, test crop/commodity, target pests, experimental design and methods of statistical analysis.

6.5 Results

The results should be fully described in relation to the stated objective. Tables should contain summaries of statistically analyzed results showing: means, minimum and maximum values for each treatment, coefficient of variation (CV), levels of significance, appropriate mean separation etc. The report should summarize results obtained from all the test seasons and describe variations or consistence among seasons.

6.6 Discussions

(a) State main findings

(b) How the findings relate to stated objectives

(c) Any inferences made

(d) Explain any variations or factors that may have influenced the performance of the product under investigation

(e) Relate results to previous findings

6.7 Recommendations and Conclusions

(a) State clearly whether the product is suitable for registration for the stated use based on the findings.

(b) The trial manager should clearly recommend: -

(i) Application rates expressed as amount per ha, amount of active ingredient per ha, amount of product per 20 L of water.

(ii) Time of application (also in relation to harvesting)

(iii) Number of applications per season

(iv) Frequency of application

(v) Spray volume

(vi) Any other observations

(c) State clearly whether the data met the 2/3 consecutive season criteria.

6.8 Acknowledgement

Pertinent acknowledgement should be included.

6.9 References

A list of references should be included with author, date of publication, title of article, name of journal/source, volume and the first and last page of the document.

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REQUIREMENTS FOR THE CONDUCT OF SUPERVISED PESTICIDE RESIDUE FIELD TRIALS ON CROPS

ABBREVIATIONS:

ADI	Acceptable Daily Intake
BBCH	"Biologische Bundesanstalt, Bundessortenamt und CHemischeIndustrie": Scale used to identify the phenological development stages of a plant
CAC	Codex Alimentarius Commission
CCPR	Committee on Pesticide Residues
DP	Dustable powder
EC	Emulsifiable Concentrate
GR	Granules
JMPR	FAO/WHO Joint Meeting on Pesticide Residues
SC	Suspension concentrates
SL	Soluble concentrates
WG	Water dispersible granules
WP	Wettable powder

1. DEFINITIONS

ACTIVE INGREDIENT: means the part of the product that provides the pesticidal action [1].

ADJUVANT refers to any product added to the spray tank for the purpose of improving the performance of the test substance/active ingredient. Adjuvants can be characterized for example as wetting agents, spreader-stickers, compatibility agents, buffering agents, de-foamers, non-ionic surfactants, crop oil concentrates, etc. [2].

APPLICANT refers to a company and/or person who applies for a registration, amended registration, reregistration or MRL. Also see *Manufacturer*

APPLICATION EQUIPMENT means any technical aid, equipment, implement or machinery which is used for the application of pesticides [1].

Commodity group: Commodities within a group based on similar residue characteristics and which are deemed to be suitable for setting group MRLs are said to belong to a Commodity group, also known as a Crop group. Commodity groups (e.g., pome fruits, cereal grains) within the Codex Classification for Foods and Feeds are suitable for establishing group MRLs.

CONTROL PLOT: The plot that is not applied/treated with the test substance, or a substance that has similar chemistry or belongs to the same pesticide class and is part of crop field trials, which could interfere with the trial. The use of other products may be necessary to maintain the health of the treated and untreated (control) plants. In that case, only those pesticides that do not interfere with the residue analysis may be used. The additional products used should be noted and, where possible, advice from the analyst should be sought before use.

CROP FIELD TRIAL – see "SUPERVISED FIELD TRIAL"; these terms are considered synonymous for purposes of this guideline.

CROP FIELD TRIAL SITE is a geographically defined address/location within a country/region/state of a field, space, greenhouse or other area in/on which a pesticide field trial is conducted. A site may consist of several *plots* (areas with defined boundaries on which a crop is grown), including control and one or more treated plots, each of which receives a specific pesticide application regimen. The trial location for a post-harvest application is defined as the location where the post-harvest treatment takes place (for example treatment room or storage location). Additionally, the trial location for a seed treatment crop field trial is defined as the location where the seed is planted or sown.[2]

CROP GROUP refers to a group of crops in which the expected residues on the commodities are likely to be similar (from treatment under similar GAP) and where the group or subgroup MRLs can be considered. Crop grouping is based on similarities in appearance, harvestable commodity, edible portions and/or growth habits etc. [2]

END-USE PRODUCT is a product containing *active ingredient(s)* and usually formulants that has been manufactured, packaged, and labelled with instructions for direct pest control use or application in a form that is usable by the consumer.

EXTRAPOLATION refers to a system projection of data from one system to another system. In this sense, data received from one formulation can be extrapolated to another formulation under certain circumstances. In some instances, extrapolation of field trial data obtained from one commodity are used to predict the residue behaviour of another similar commodity under described circumstances and thus proposing the same MRLs for both commodities. [2].

Formulation means the combination of various ingredients designed to render the product useful and effective for the purpose claimed and for the envisaged mode of application. [1]

GOOD AGRICULTURAL PRACTICE in the use of pesticides includes the officially recommended or nationally authorized uses of pesticides under actual conditions necessary for effective and reliable pest control. It encompasses a range of levels of pesticide applications up to the highest authorized use, applied in a manner which leaves a residue which is the smallest amount practicable [1].

CRITICAL GOOD AGRICULTURAL PRACTICE (*c*GAP) is the GAP selected to represent the worst-case use scenario within the context of national, regional, or global uses that will be producing the highest possible field residues on crop commodities. It usually includes the maximum use-rate and number of applications and the minimum re-treatment and pre-harvest intervals.

GOOD EXPERIMENTAL FIELD PRACTICE is the formalized process for designing and recording the practices used in the performance of field investigations with pesticides, and which assure the reliability and integrity of the data [3].

GOOD LABORATORY PRACTICE (GLP) is the formalized process and conditions under which laboratory studies on pesticides are planned, performed, monitored, recorded, reported and audited. Studies performed under GLP are based on the national regulations of a country and are designed to assure the reliability and integrity of the studies and associated data. The U.S. Environmental Protection Agency GLP definition also covers field experiments [3].

HIGHEST RESIDUE – The Highest residue (HR) level (expressed as mg/kg) in a composite sample of the edible portion of a food commodity when a pesticide has been used according to the maximum GAP conditions. The HR is estimated as the highest of the residue values (typically, one from each trial) from supervised trials conducted according to maximum GAP conditions, and includes residue components defined by the Joint Meeting on Pesticide Residues (JMPR) for estimation of dietary intake. [4]

IMPORT TOLERANCE is a MRL set for to facilitate the importation of products to meet the needs of international trade where (a) the use of the active substance in a plant protection product on a given product is not authorised in Kenya for reasons other than public health reasons for the specific product and specific use; or (b) a different level is appropriate because the existing MRL was set for reasons other than public health reasons for the specific product and specific use.

LIMIT OF DETECTION (LOD) The LOD is the lowest concentration of a pesticide residue or contaminant that can be identified and quantitatively measured in a specified food, agricultural commodity or animal feed with an acceptable degree of certainty by a regulatory method of analysis. (Codex Alimentarius, Vol. 2A), [4]. LIMIT OF QUANTITATION (LOQ) The LOQ is the smallest concentration of the analyte that can be quantified. It is commonly defined as the minimum concentration of analyte in the test sample that can be determined with acceptable precision (repeatability) and accuracy under the stated conditions of the test. [5] See Explanatory note

MANUFACTURER means a corporation or other entity in the public or private sector (including an individual) engaged in the business or function (whether directly or through an agent or entity controlled by or under contract with it) of manufacturing a pesticide active ingredient or preparing its formulation or product [1].

[8] Limit of quantification' and 'limit of quantitation' are used synonymously and are abbreviated to LOQ. The FAO Panel estimates the LOQ of an analytical method for residues in specified substrates as being the lowest level where satisfactory recoveries

MAJOR CROPS *SEE MINOR CROPS*

CODEX MAXIMUM LIMIT FOR PESTICIDE RESIDUES (MRL) is the maximum concentration of a pesticide residue (expressed as mg/kg), recommended by the Codex Alimentarius Commission to be legally permitted in or on food commodities and animal feeds. MRLs are based on GAP data and foods derived from commodities that comply with the respective MRLs are intended to be toxicologically acceptable. Codex MRLs, which are primarily intended to apply in international trade, are derived from estimations made by the JMPR following:

(a) toxicological assessment of the pesticide and its residue; and

(b) review of residue data from supervised trials and supervised uses including those reflecting national good agricultural practices.

Data from supervised trials conducted at the highest nationally recommended, authorized or registered uses are included in the review. In order to accommodate variations in national pest control requirements, Codex MRLs take into account the higher levels shown to arise in such supervised trials, which are considered to represent effective pest control practices. Consideration of the various dietary residue intake estimates and determinations both at the national and international level in comparison with the ADI, should indicate that foods complying with Codex MRLs are safe for human consumption. [6]

The MAXIMUM RESIDUE LEVEL is estimated by the JMPR as the maximum concentration of residues (expressed as mg/kg) which may occur in a food or feed commodity following Good Agricultural Practices. The estimated maximum residue level is considered by the JMPR to be suitable for establishing Codex MRLs.[4]

MINOR CROPS are crops for which a use of a pesticide or constituent would not produce sufficient economic return to an applicant for registration of the pesticide to meet the cost of registration of the product. [7]. Major crops would generally be the converse of minor crops. PESTICIDE RESIDUE means any specified substance in food, agricultural commodities, or animal feed resulting from the use of a pesticide. The term includes any derivatives of a pesticide, such a conversion products, metabolites, reaction products, and impurities considered to be of toxicological significance. [6]

PRE HARVEST INTERVAL (PHI) is the time interval in days between the last application of a pesticide to a crop and harvest to meet the relevant *maximum residue limits* for a particular crop. [3]

PRODUCT (or pesticide product) means the formulated product (pesticide active ingredient(s) and co- formulants), in the form in which it is packaged and sold. [1]

POST HARVEST Treatment refers to a pesticide application to the harvested crop, which may occur before or during storage.

RAW AGRICULTURAL COMMODITY (RAC) means the product in or nearly in its natural state intended for sale or consumption without further processing, or for processing into food for sale to the consumer. It includes irradiated primary food commodities and products after removal of certain parts of the plant or parts of animal tissue. The term “raw agricultural commodity (RAC)” means the same as "primary food commodity”. [4]

RESPONSIBLE AUTHORITY: Means the government agency or agencies responsible for regulating pesticides and more generally for implementing pesticide legislation [1].

Responsible authority also refers to the regulatory authority responsible for the registration of pesticides

REPRESENTATIVE COMMODITIES are those designated commodities from which extrapolations of residue levels and resulting MRLs can be made to one or more related commodities or to an entire group of commodities ('crops').

SAMPLE is a defined representative amount of individual raw agricultural commodity unit(s) (e.g. specific number of fruits or tubers, a set +weight of grain, etc.) randomly selected from a plot which may be composited for pesticide analysis.

SEED TREATMENT application is made to the seeds of crops prior to planting or sowing, which may occur at a seed treatment facility or in the field immediately prior to planting or sowing. [2] SUPERVISED FIELD TRIALS are residue field trials conducted on crops, typically according to the principles of Good Laboratory Practice (GLP), in order to assess the magnitude of the residues under the conditions of the critical Good Agricultural Practice(cGAP).

SUPERVISED TRIALS MEDIAN RESIDUE (STMR) is the expected residue level (expressed as mg/kg) in the edible portion of a food commodity when a pesticide has been used according to Maximum Good Agricultural Practice conditions. The STMR is estimated as the median of the residue values (one from each trial) from supervised trials conducted according to maximum Good Agricultural Practice conditions [8].

TEST SUBSTANCE is the product or formulation used in a crop field trial for the purpose of generating residue data for a specific crop or commodity [4].

2. GENERAL PROVISIONS

The Board will ensure that all new pest control products or new uses of existing pest control products are subjected to supervised residue field trials where the JMPR data or such data is unavailable from another region before they are authorized for use or where new information from exposure assessment is received that may require a change in the use pattern.

2.1 The manufacturer shall prepare the study protocol for submission to the responsible authority for approval. Upon approval, the study protocol shall be submitted to the authorized testing institution to conduct the supervised residue field trials.

2.2 The testing institution shall conduct the supervised residue field trials in accordance with the provisions laid out in the study protocol and in general accordance with provisions of GLP.

2.3 Samples of the test substance must be provided by the manufacturer to the testing institution upon approval by the responsible authority for pesticides.

2.4 All trials must be authorized by PCPB. It is recommended that the responsible authority liaise closely with the trial scientist/testing institution and the applicant throughout the trial period.

2.5 Field residue trials and laboratory analysis must be carried out by institutions that are officially recognized by the PCPB. In case there is absence of recognized laboratory, the PCPB shall recommend to accredited reference laboratory.

2.6 The report shall be submitted in hard and soft copies to PCPB

3 RESIDUE TRIAL REQUIREMENTS

In designing a residue trial, early consideration must be given to the intended use of the residue data to be obtained and to the sampling programme and analytical work that this entails. The trials should reflect the proposed use with respect to the rate and mode of application, number and timing of applications, and formulations proposed.

3.1 Design of residue trials

Trials should be designed to cover a range of representative field conditions, typical periods of the year, cropping and farming practices which are commonly encountered. If data are sought to support establishment of a maximum residue limit, results from a number of trials in several geographical areas or during typical periods of the year and farming practices are required. When a product is applied to a crop near maturity, studies on residue disappearance with time are usually needed to determine acceptable pre-harvest intervals. Such considerations markedly influence the location of the test plots. The size and number of samples that must be taken from each plot determines the size of the experimental plots.

Since climatic conditions may have an important influence on the persistence and performance of a chemical, trials shall be carried out in those areas where the product is to be finally used.

3.1.1 Zoning

The FAO/WHO Joint Meeting on Pesticide Residues agreed with the conclusion that the impact of climatic zones on pesticide residues is small, and residue data derived from similar use patterns and growing conditions may be compared regardless of the of the geographical location of the trials [9].

3.1.2 Selection of sites

Trials should be carried out in major areas of cultivation or production and should be sited to cover the range of relevant representative conditions including different bioclimatic regions, seasons of production, soil characteristics, cropping system, farming practices, cultivars etc.) likely to be met for the intended use of the pesticide.

3.1.3 Number of sites and replication

The number of sites needed depends upon the range of conditions to be covered, the uniformity of crops, variation in agricultural practices, and the data already available. Since the variations in residue levels between replicates at individual sites are small compared with those found in data from different sites, it is usually not necessary to replicate treatments at individual sites [10].

As a general rule, a minimum of five trials (for major crops) or a minimum of four trials (for minor crops) are required. The trials sites should be at least thirty five (35) kilometres apart to be deemed independent.

3.1.4 Plots

Residue data should not be generated from plots which are too small to be representative. The size of the individual plots will vary from crop to crop but should be large enough generally at least 10 m^2 for row crops and typically four trees or eight vines for orchard and vineyard crops respectively; in order:

(i) to apply the pesticide in an accurate and realistic manner, preferably under the same conditions as in normal local commercial/production practice; and

(ii) to provide representative crop samples.

A control plot for the supply of untreated samples is necessary to provide the analyst with a sample known to be free from residues of the pesticide under investigation. Where treated and control plots are in close proximity, measures should be taken to avoid contamination (e.g., covering or shielding crop if necessary). It is also important to ensure that plots are adequately buffered or separated. There is no minimum distance between plots which ensures adequate buffering, however prevailing wind, slope and distance between plots should all be considered prior to designing the field trial.

Control samples are needed:

(i) to ascertain that no artefact in the crop derived from local conditions could give rise to interference in the analysis;

(ii) to establish the recovery level of the pesticide from the crop or soil by the analytical method;

(iii) in the case of a new crop or pesticide, to investigate the storage stability of any residue.

The control plot should be large enough to satisfy these requirements and should be located close enough to secure identical growing and climatic conditions.

Specific trial protocols (procedures) shall be prepared for specific pesticide / crop combinations based on the type of trials to be conducted.

3.1.5 Crop Variety/Cultivars

The type or variety of crop and the way in which it is grown may influence the residue pattern. Data should be generated on the most commonly used type or variety and on the factor or combination of factors most likely to result in the highest residue levels. If more than one variety of crops is commonly grown, then more than one variety should be used in the trials.

3.1.6 Number and Timing of Applications and additional pesticides

The number of treatments and the intervals between applications should reflect the latest and maximum use of the product to be recommended.

No pesticide in addition to those to be analyzed should be applied to the control or experimental plots before or during the trial period. However, since it is of primary importance that both the untreated and treated plants be healthy, the use of other pesticides may be necessary. In this case only those pesticides that will not interfere with the analysis of the residues of the test compound may be used.

3.1.7 Number of seasons

Residue data from only one season are considered sufficient provided that crop field trials are located in the typical crop production areas such that a variety of climatic conditions is taken into account. However, if a particular crop is mainly produced commercially in one geographic locality/ climatic area, then trial sites should be situated at least thirty five (35) kilometres apart. If this is not possible, trials should be separated by time e.g. done over a minimum of two seasons.

3.1.8 Application rates

Supervised residue field trials should be carried out according to the typical commercial practice(s) in regard to spray volume ensuring that the range of volumes utilized is captured. For all applications, the application rate should be expressed in terms of amount of product and/or active ingredient per unit area (e.g., kg a.i. per hectare or per

acre) and where appropriate, the concentration (e.g., kg a.i. /100 liters or) at which it is applied. Due consideration should be made for foliar application of "tall" crops, (e.g., orchard and vine crops, greenhouse tomatoes), where flat boom spraying is not common practice and (air assisted) mist blowing equipment is often used. Spray concentration and spray volume should be considered and reported when conducting SRFT. Application rates for seed and seedling treatments are expressed as concentration per unit of seed weight or seedling rate.

For dip or drench of fruit, concentration of the active ingredient in solution should be recorded ((e.g., kg a.i. /100 liters) as well as the amount of fruit treated per volume and contact time in seconds. Where dips are replenished to maintain the active ingredient concentration during treatment (i.e., where residue stripping occurs), the additional 'top-up' treatments should also be recorded. The application rate for gases and aerosols used in fumigation should be expressed as amount per unit volume of treated bulk good.

The maximum label rate or maximum proposed label rate of the active ingredient (according to the *c*GAP) should be used when applying the test substance for crop field trials. The maximum number of applications and minimum re-treatment interval for use of the test substance under evaluation should reflect the *c*GAP. It is important to indicate the types of crop varieties included in a trial in order to evaluate an appropriate range of pre- (PHIs) (e.g., shorter and longer intervals from planting to maturity in the case of pre-emergence application to an annual crop). Basically in all trials both the growth stage at application (preferably as BBCH code) and PHI should be recorded.

3.1.9 Equipment and Mode of application:

Applications should preferably be made with equipment similar to that used in normal commercial practice for application to that crop. Other forms of applicators may be used, provided the deposition and coverage achieved are similar to what would occur in normal practice. Consideration should also be given to selection of appropriate nozzles in crop field trials. Ensure that the application is appropriate to the anticipated use of the pesticide, as indicated in the product label. Care should be taken to avoid contamination of neighbouring plots.

3.1.10 Equipment calibration

Before application of the test substance, the application equipment must be calibrated for the intended delivery, such as discharge and application speed calibration. To ensure correct usage rates and uniformity of application the operation should be carried out under the supervision of qualified personnel.

3.2 Other general considerations:

Other considerations to take into account include:

(a) Adequate separation between plots should be provided to avoid contamination especially during sampling.

(b) Adequate buffering should be provided between plots, however, sites at field edges, or near ditches, trees, hedges or other obstacles should be avoided, as they are subject to interfering "edge" effects from those obstacles.

(c) Selection of crop variety should be taken into account to ensure that varieties of commercial importance, size variation and time of maturity of the varieties. The tests should be carried out in plots with the same edaphic homogeneity.

(d) Crop protection measures in the trial plot should be chosen in such a way that they do not affect or interfere with the residue analysis of the pesticide and metabolites under trial

(e) Soil types should be reported in all field sites.

(f) Trials can be conducted under complete protected conditions; the type of protection should be stated in the planning of the trial.

(g) Appropriate care should be made to minimize drift especially into water bodies such as lakes and rivers.

3.3 Decline studies:

Residue decline data are necessary for uses where the pesticide is applied when the edible portion of the crop has formed or it is expected that residues may occur on the food or feed commodities at, or close to, the earliest harvest time. Residue decline data are used in residue evaluation for purposes such as:

(a) Determining if residues are higher at longer PHIs than requested;

(b) Estimating the half-life of the residues;

(c) Determining whether alteration of the PHI to levels represented in the decline trials around the GAP PHI affects the residue levels;

(d) Allowing for a degree of interpolation to support use patterns, including PHIs, not directly equivalent to those used in the trials on a case-by-case basis;

(e) Determining the profile of the residue over time to add to the understanding of metabolism of the pesticide under conditions more applicable to GAP and to assist in appropriate selection of residue definitions; and

(f) Determining the time interval to reach maximum residues for a systemic compound applied to crops such as potatoes or peanuts.

When residue decline data are necessary, up to 50% of the residue trials should be decline studies to demonstrate the behavior of the active ingredient and relevant metabolites close to harvest.

When decline data is generated, sampling of more than one commodity or matrix per crop may be needed. This will be the case whenever different commodities are used as food or feed at different growth stages of the crop (e.g., cereal forage, cereal fodder, cereal grain and straw). This will result in two or more sets of sampling dates within one residue decline trial.

The design of *residue decline studies* should include 3 to 5 sampling intervals in addition to the target PHI (if practical, include 0-day sampling). These sampling intervals should be spaced somewhat equally and, where possible, sampling should occur at shorter and longer time points relative to the target PHI, when such is permitted by the window of commercial maturity. When multiple applications are involved, a sampling point immediately prior to the final application is desirable to determine the contribution of earlier applications and the effect on residual half-life

3.4 NUMBER OF CROP FIELD TRIALS

In the Kenya, trials should be conducted to represent the typical growing areas of crops. The number of crop field trials conducted at the critical GAP should be in line with international provision taking into account the following:

(a) Crop production regions, often defined or identified by the crop production practices (e.g., irrigation - beneath crop canopy vs. overhead sprinkler; planting densities of fruit trees) and the soils and climatic properties of the region.

(b) Significance of the crop in the country of production, most often determined by the production area (acres or hectares) or production quantity(tons).

(c) The importance of the crop in the national diet.

A minor use crop may be defined as a crop that is grown on a small area and therefore uses amounts of pesticides that are too small to justify standard pesticide registration. A crop may be considered a minor crop based on the description provided in the Guidance to facilitate the establishment of MRLs for pesticides for minor crops [10].

For major crops in Kenya, the minimum total number of trials in a complete (comprehensive) submission is eight but ideally at least fifteen (15).

A complete (comprehensive) data set in the context of the Crop Field Trials Test Guideline is the number of supervised field trials matching the critical GAP (cGAP) which are required for setting an appropriate MRL and/or obtaining a new registration or new use (i.e. plant protection product in/on a crop). A reduced data set on the other hand refers to a reduced number of supervised field trials matching the cGAP which may be adequate to obtain a new or amended registration and/or MRL for a plant protection product in/on a specific crop. A reduced data set may be sufficient when conducting trials in cases where no residues are anticipated at or above the limit of quantitation.

To qualify for this comprehensive submission approach, all crop field trials should meet the following criteria[1]:

(i) Field trials are conducted according to the (*c*GAP) (within ± 25% of the application rate, number of applications or PHI). At least 50% of the trials should be conducted at or above, but within 25% of the cGAP. Trials whose intended application rates match the cGAP but actual rates fall up to 10% below the cGAP (e.g., due to the normal variability in preparing spray solutions) are considered acceptable. In addition, at least 50% of the trials need to be decline studies.

(ii) The trials span a range of representative crop production practices for each crop including those likely to lead to the highest residues (e.g., irrigated vs. non-irrigated, trellis vs. non-trellis production, fall-planted vs. spring-planted, etc.).

For minor crops Kenya shall adopt the decision from the 47thSession of the CCPR which decided that the minimum number of four and five independent supervised field trials would be conducted, reflecting the respective good agricultural practice for Category 2 and 3 respectively [11]. For minor crops in Category 1, fewer trials (four) may be acceptable on a case by case basis. Crops would be assigned to the Categories defined using the methodology described in the guidance document.

3.4.1 Requirements for independent supervised residue trials

The following trial conditions are usually recorded and are taken into consideration in defining an independent supervised residue trial:

(a) Geographical location and site – trials at different geographic locations are considered independent;

(b) Dates of planting (annual crops) and treatments - trials involving different planting dates or treatment dates (> 30 days apart) are considered independent;

(c) Formulations – comparability or independence of trials with different formulations should to be assessed;

(d) Types of treatment, e.g., foliar, seed treatment, directed application – different types of treatment on different plots at the same site are considered as separate trials;

(e) Addition of surfactants – a trial with the addition of surfactant may constitute sufficient difference to be treated as independent, provided the relevant label does not prescribe the use of adjuvant;

(f) Application rates and spray concentrations – trials conducted at the same location with significantly different application rates and spray concentrations are not independent; the principle of proportionality may be applied to select the trial which leads to the highest residues;

(g) Crop varieties – different varieties at a single site may not be 'independent'; some varieties may be sufficiently different (different morphology etc.) to influence the residue;

(h) Treatment operations – trials at the same site treated in the same spray operation are not counted as separate trials;

(i) Application equipment – trials at the same site treated by different equipment, other things being equal, are not counted as separate trials.

4 TEST SUBSTANCE

The test substance(s) (pesticide) should be stored under appropriate conditions for the study duration and applied soon after preparation or mixing. If residue data is generated for a single active ingredient, there are no additional data requirements for tank mix, pre-mix or other types of combinations with other active ingredients as long as there is no evidence of synergism associated with the combination(s) and as long as the cGAP for the active ingredient is not exceeded with any of the combinations.

Active ingredients may be applied in combination (i.e., tank mix, pre-mix or sequential) in crop field trials to a single treated plot as long as there is clear analytical separation (i.e., no analytical interference) of active ingredients and any relevant metabolites. A single sample may then be collected from the treated plot and prepared for residue analysis for two or more active ingredients.

4.1 Formulations

The formulation tested in crop field trials should be as close as possible to the intended enduse product for the crop or commodity. The requirements in this guideline in regard to a complete data set (the number of crop field trials matching the cGAP which are required) are generally based upon only one formulation type being requested for use on a specific crop. The decision will be based upon how similar the formulations are in composition and physical form, the mode of application, and the timing of the application. Controlled release formulations (e.g., certain microencapsulated products) normally require a complete data set tailored to that particular use. Granules (GR) and dusts (DP) are the most common examples of the latter. Granular formulations applied intact will generally require a complete data set regardless of what data are already available for other formulation types.

The most common formulation types which are diluted in water prior to application include Emulsifiable Concentrates (EC), Wetable Powders (WP), Water dispersible Granules (WG), Suspension Concentrates (SC)(also called flowable concentrates), and Soluble Concentrates (SL). Experience from trials demonstrates that these formulations lead to similar residues. Residue data may be translated among these formulation types for applications that are made to seeds, prior to crop emergence, i.e., pre-plant, at-plant, and pre-emergence applications, just after crop emergence or directed to the soil, such as row middle or post-directed applications (as opposed to foliar treatments). Most of the remaining types of formulations can be divided into two groups—those that are diluted with water prior to application and those which are applied intact.

In many situations different formulations would cause no more variation than other factors, and data derived with different formulations would be considered comparable.

5 BRIDGING STUDIES:

Bridging studies are an essential extrapolation tool to make the best use of existing data to support minor changes or variations to existing uses. A bridging study normally involves a comparison of different formulations or application methods for the purpose of data extrapolation, but may or may not involve side-by-side comparisons.

For late season foliar applications of formulations diluted in water, the decision on the need for additional data depends upon two factors:

5.1.1 the presence of organic solvents or oils in the product and

5.1.2 the pre-harvest interval.

Wider extrapolation of data will generally be permitted for formulations that do not contain organic solvents or oils.

Some active ingredients, e.g., phenoxy herbicides, can be applied as one or more salts and/or esters. Different salts of an active ingredient may be considered equivalent for residue purposes in most cases regardless of the timing of the application. However, examples for which additional data may be needed for a new salt include the presence of counter ions that impart surfactant properties, significantly change the degree of dissociation, or chelate with the active ingredient ion. If the PHI is less than or equal to 7 days, the different esters are considered as new formulations of that active ingredient for the purposes of determining data needs, and bridging studies would be required as for different formulations.

If bridging trials are deemed necessary and a pesticide is used on a wide range of crops, data should be generated for at least three major crop groups (one crop per crop group), e.g., a leafy crop, a root crop, a tree fruit, a cereal grain, an oilseed with a minimum of four trials per crop. The trials should be carried out on crops that would be expected to show high levels of residue (often those with applications at or near harvest). If a bridging study is conducted and residues are significantly higher with a new formulation or different application method, or the combined residue data set obtained with different formulations would lead to a higher MRL, generation of a complete new data set may be necessary.

6 GENERAL GUIDANCE ON CROP GROUPS AND EXTRAPOLATION

6.1 Extrapolation and principles of representative commodities

Residue extrapolation is the process by which the residue levels on representative commodities are utilized to estimate residue levels on related commodities in the same commodity group or subgroup for which trials have not been conducted.

The establishment of commodity group MRLs as opposed to MRLs for individual commodities has long been considered an acceptable procedure since economics may not justify residue trials on all of the individual crops in a group. In principle the approach recognizes that adequate data for the major crop commodities of a group may be sufficient to estimate maximum residue levels for the whole group. Since some pesticides may behave differently in different circumstances. Consequently, it is not possible to define precisely those commodities on which trials will always provide data that can lead to a group MRL. Extrapolation is possible if the GAP of the minor crop is similar to that of a relevant major crop (e.g. in the same crop grouping).

Preconditions for extrapolation of residues

Extrapolation of residue data for different crops presumes that the following are comparable:

(i) conditions of use with regard to the amount of active substance applied,

(ii) the time of application,

(iii) the number of applications,

(iv) the interval between applications,

(v) application methods,

(vi) formulation used, and

(vii) climatic conditions.

The following are the principles of selection of representative commodity within groups as agreed by the Codex Committee on Pesticide Residues (CCPR) [12]. A representative commodity is:

- most likely to contain the highest residues.
- likely to be major in terms of production and/or consumption.
- is most likely similar in morphology, growth habit, pest problems and edible portion to the related commodities within a group or subgroup.

The application of the three principles is based on the assumption that all commodities of the respective group or subgroup are treated according to a similar use pattern or GAP. To facilitate the global use of the commodity groups for MRLs, alternative representative commodities may be selected giving flexibility for use of residue research conducted in different countries or regions that may vary due to regional differences in dietary consumption and/or areas of production for certain commodities.

6.2 WIDER EXTRAPOLATIONS

The term ‘wider extrapolations’ (also referred to as ‘cross group extrapolations’) is used in this context for extrapolations that go beyond the bounds of a crop group or subgroup. Such extrapolations may be possible in special circumstances, on the basis of residue data. Consideration on a case-by-case basis may be given to commodities with very similar shapes, volumes, and weights. For example, in Australia, apple, peach, and nectarine may be extrapolated to persimmon.

Wider extrapolations may also be considered, on a case-by-case basis, for:

(a) Situations where residues are expected to be <LOQ (e. g. pre-emergence herbicide uses, pre-flower treatments);

(b) Situations where the active substance is used early in the growing season (last application before consumable parts of the crop have started to form). (This kind of extrapolation should be used with caution since for some crops the edible part of the crop is always present either as a food or a feed item.);

(c) Seed treatments, if data from treatment of several different 'representative' seed types all report no detectable residues in the commodities from crops grown from the treated seed;

(d) Post-harvest treatments for non-systemic pesticides to commodities of similar size and morphology on the basis of the same treatment regimens; and

(e) Soil treatments with granules (depending on extent of residue uptake and distribution in the plant as evidenced by data from different crop types including a root crop).

A representative commodity should meet at least two (2) of the principles stated in 10.1 above. More details on the selection of representative commodities can be found in Principles and Guidance on the Selection of Representative Commodities for the Extrapolation of Maximum Residue Limits for Pesticides to Commodity Groups (CAC/GL 84-2012).

It may not always fit well with the growth habits or pest problems of morphology within one group or subgroup. In such situations, extrapolations beyond the members of a commodity group may be appropriate. These can be considered on a case-by-case basis when commodities (with similar GAPs) have similar size, shape and surface area. Examples of these possible wider extrapolations include:

(a) Translation of certain stone or pome fruit MRLs to a tropical fruit;

(b) Where residues are all <LOQ for pre-emergent herbicide uses and

(c) Seed treatments for non-systemic pesticides.

7 FIELD SAMPLING

For raw agricultural commodities (RAC), samples should be taken of the commodity as it is traded. . The detailed sampling procedures are outlined in the FAO Manual [13].

Below are general provisions for sampling:

7.1 Sample handling

Care should be taken not to remove surface residues during handling, packing or preparation.

(i) Avoid any damage to or deterioration of the sample which might affect residue levels.

(ii) To provide a representative sample of the raw commodity, adhering soil may have to be removed from some crops, such as root crops. This may be done by brushing and, if necessary, gentle rinsing with cold running water.

(iii) Sample untreated control plots before treated plots

7.2 Contamination

It is essential to avoid any contamination with the pesticide under study or with other chemicals during sampling, transportation or subsequent operations. Special attention should, therefore, be paid to the following:

(i) Ensure that sampling tools and bags are clean. To avoid contamination, use new bags and containers of suitable size and adequate strength. The bags or containers should be made of materials which will not interfere with the analysis.

(ii) Avoid contamination of the sample by hands and clothes which may have been in contact with pesticides.

(iii) Do not allow the samples to come into contact with containers or equipment (including vehicles) that have been used for transporting or storing pesticides.

(iv) Avoid sampling at the plot borders because the residue deposit may not be representative.

(v) Take special care to avoid contamination when commercial mechanical harvesting practices are used

(vi) Avoid cross-contamination of crop and soil samples.

(vii) Sampling should proceed from the control to the lowest treatment and so on to the highest treatment.

7.3 Control samples

Control samples (samples taken from the untreated plot) are in every way as important as samples from test plots. The quality of control samples should be similar to that of the test samples, e.g., maturity of fruit, type of foliage, etc. Always take control samples. In decline studies of up to 14 days' duration, control samples from the start and from the end of the study may suffice.

7.4 Sampling in decline studies

The first sampling in a decline study may take place on the day of application. These samples should be taken immediately after application, or in the case of spray application, immediately after the spray has dried (approximately 1-2 hours). Care should be taken to avoid contamination and samples should be taken to be representative of the average size or weight of crop on the plot.

7.5 Sampling at normal harvest time

(i) Take samples so as to be representative of typical harvesting practice.

(ii) Avoid taking diseased or undersized crop parts or commodities at a stage when they would not normally be harvested.

8 DETAILED SAMPLING PROCEDURES

The requirements give a detail on the number of samples to take per site for both treated and untreated controls; and the number of composite samples to be taken and the minimum field sample size (by weight and number of samples).

Details of the sampling procedures are described in detail in the FAO Manual [13] Recommended sampling methods for supervised residue field trials; as follows.

(a) Table V.1 Sampling of fruits

(b) Table V.2 Sampling of bulb, root and tuber vegetables

(c) Table V.3 Sampling of other vegetables

(d) Table V.4 Sampling of cereals

(e) Table V.5 Sampling of forage crops and animal feed

(f) Table V.6. Sampling of herbs, spices; tea leaves; hops and beer

8.1 Sample transportation

Proper labelling of samples is of utmost importance. Sample labels must indicate crop, variety, trial site, active ingredient, pesticide formulation, dosage rate, date of sampling, time of sampling and name of sampler. Samples should be frozen as soon as possible following collection to avoid sample deterioration and decomposition of the residue(s). It is not advisable to allow samples to thaw once frozen; therefore, shipment of frozen samples should be either by freezer truck or packed in dry ice. It is acceptable to ship samples overnight, with coolant such as "blue ice", to the sample preparation facility as long as they are "peeled" or "pitted", or otherwise prepared for analyses and frozen immediately upon arrival.

8.2 Sample reception and handling

Samples should be transported immediately to the laboratory and upon arrival the pesticide residue laboratory personnel should verify the following:

- Sampling record is included with the samples, and the sample details should match the sampling record
- Check and report the conditions of the samples upon arrival
- Accuracy of the sampling record especially rate and interval data
- Completeness of information

If there are any deviations of any consequence, or the Sampling Report is not received or is incomplete, the samples should be stored in the simplest form that will preserve the residue and the crop. The trial organizer should then be contacted immediately to determine how to proceed.

Once the samples are packed and labelled, they may be stored or preferably immediately sent to the residue laboratory according to the nature of the sample. The mode of shipping (e.g. deep-frozen or at ambient temperature shall be selected taking into account the stability of the residue and the kind of study undertaken. It is important that packing and shipment are carried out in such a way that the samples arrive as soon as possible (normally within 24–36 hours) after being taken and without change of any kind, e.g., deterioration, physical damage, contamination, loss of residue, or change in moisture content. Storage and shipping should always be under deep-frozen conditions. Mixing of samples and sample size reduction at the field site is not recommended and should be avoided.

8.3 Sub-sampling and processing

The laboratory samples should be prepared for analysis following the instructions of the Codex Standard on Portion of commodity to which MRLs apply and which is analyzed [14].

It is acceptable to subsample large commodities (e.g., head cabbage, melons, etc.) with procedures such as quartering and collecting opposing quarters. However, this should be done in a laboratory environment to avoid contamination or degradation of pesticide residues. If analyses are planned on matrices such as pulp and peel (e.g., for dietary risk assessment refinement), the whole commodity should be shipped to the analysis lab to avoid cross contamination of peel and pulp.

Shelling, removing seeds or beans from pods, etc. should be undertaken in the pesticide residue laboratory to ensure minimum contamination e.g. through using clean tools and changing gloves between plot samples. In cases where commodities such as peel and pulp or stone and pulp are separated for analyses, weights should be determined for each commodity

Apart from superficial cleansing i.e., removal of any extraneous matter such as soil, no intrusive cleaning should be attempted. In the case of root crops recovered with soil, where light brushing is not sufficient to remove soil, gentle minimal rinsing under cold running water may be used.

8.4 Sample size reduction

The Codex guideline on the Portion of Commodities to Which Codex Maximum Residue Limits Apply and Which is Analyzed [14] provides a table to guide on the part of the raw agricultural commodity to which the maximum residue limit applies and which is to be prepared as the analytical sample for the determination of pesticide residues.

8.5 Storage

Samples should be analyzed as quickly as possible after collection before physical and chemical changes occur. If prolonged storage is unavoidable, store the samples at a low temperature, preferably at or below –20 °C.. Do not store samples (whole or homogenised) for analysis unless an adequate check has been made on the stability of the residue. Fumigant residue samples need special attention and ideally should be analyzed immediately on receipt at the laboratory.

9 RESIDUE ANALYSIS

Residue analysis consists of a chain of procedures, done in accordance with the principles of pesticide residue analysis and the requirements of Analytical Quality Assurance (AQA) systems such as ISO 17025 (2005) [15].

Pesticide residue laboratories should use the requirements on good laboratory practice in pesticide residue analysis (CAC/GL 40-1993) [16]. Further, the Guidance Document on pesticide residue analytical methods", 2007 published by the OECD; should be used in providing guidance on the residue analytical methods used to generate the data for establishing Maximum Residue Limits (MRLs) and to determine processing factors [17]. Method validation should be undertaken in accordance with principles set out in the said requirements.

10 DATA REPORTING

The data obtained from the supervised residue field trials shall be reported using internationally harmonized formats.

The reporting of supervised trials are assisted with the attached electronic versions of the Excel templates and spreadsheets to the Manual that can be downloaded from the FAO Homepage [18].

Detailed outline of how to organize the data is described in the FAO Manual on the Submission and evaluation of pesticide residue data for the estimation of maximum residue levels in food and feed [19, Appendix VII: Standardized Format for Organizing the Data Directory (Index) of Information to be Submitted for Evaluation]. A summary of the data layout in table form is also described in the FAO Manual [20, Appendix XI: "Table and Spreadsheet Examples].

The following information shall be provided:

1. Summary

(a) Study ID, Title, Author(s), Publication date, Report No., Study dates

(b) Testing Laboratory

(c) Test Guideline, including deviations

(d) Purpose of studies

(e) Description and rationale for the total number of field trials and the locations chosen (countries/regions)

(f) Results (including explanations for apparently aberrant or atypical values, discussion of geographical representation (major growing areas), seasonal variation (summer/winter, wet/dry, etc.) and representative nature of types and varieties of the raw agricultural commodity).

(g) Field procedures

(h) Analytical procedures/instrumentation

(i) Method recovery and validation data

(j) Storage stability / Storage period for samples should be compared to those utilized in storage stability study.

(k) Discussion (including Quality Control measures taken; GLP compliance; statistical treatments of data; and information on the levels of the components of the residue definition in or on the RAC (specific plant parts) arising from the use of the pesticide formulated product on the test crop under specific use conditions and storage stability).

(l) Conclusions

2. The following information shall be provided on the data tables and other graphical representations:

(a) Summary map of crop field study sites (by crop)

(b) Summary tables of residue results of individual field trials

(c) Graphic representations (e.g., residue decline, figures, flowcharts, etc.)

(d) Summary tables of recovery data via the analytical methodology

(e) Summary tables of storage stability validation data

(f) Chromatograms (as applicable)

3. Raw data on individual field trials (specifically, each individual field trial report should include the following information):

(A) Reporting of Test substance(pesticide).

(i) Identification of the test pesticide active ingredient (a.i.), including CAS and IUPAC chemical name, common name (e.g., BSI, ISO), and company developmental or experimental name.

(ii) Identification of the pesticide formulated products used in the field trial, including trade name, type (EC, WP, G, etc.), and amount of active ingredient per gallon, pound, liter, kg, etc., and manufacturer.

(iii) Information on other relevant parameters, as pertinent, (e.g., tank mates, spray additives, carrier (encapsulating polymer, etc.)).

(iv) Other. Any and all additional information the applicant considers appropriate and relevant to provide a complete and thorough description of the test substance.

(B) Test commodity(RAC).

(i) Identification of the RAC, including type/variety.

(ii) Identification of specific crop parts harvested; used in residue analytical methodology validations; and subjected to residue analysis for a determination of the components of the residue definition.

(iii) The developmental stages, general condition (immature/mature, green/ripe, fresh/dry, etc.) and sizes of the RAC at time of pesticide application(s) and at harvestings.

(iv) Any other information that may be considered appropriate and relevant to provide a complete and thorough description of the RAC.

4. Reporting test procedures.

(A) A detailed description of the experimental design and procedures followed in the growing of the RAC, applications of the pesticide formulated products, and harvestings of samples. The information provided, which should be presented on standardized field sheets, should include (in addition to a description of the test substance and test commodity):

(i) Trial identification number.

(ii) Cooperator (name, address), test location (e.g., state, country) and year.

(iii) Field trial lay-out (e.g., size and number of control and experimental plots; number of plants per plot/unit area, number of rows per plot, length of rows and row spacing).

(iv) Cultural treatments — farming practice (cultivation, irrigation, etc.) and cropping system.

(v) Soil characteristics (name/designation of the soil type). If application rate of the pesticide is dependent on any soil properties such as percent of organic matter, these should also be described.

(vi) Methods of application (air or ground) of the pesticide formulated products, description of the application equipment, type of application (band/broadcast, soil/foliar/ directed, ULV/concentrate/dilute, other), and calibration of pesticide application equipment, including methods and dates.

(vii) Application rates (amount of active ingredient and formulated product per acre, row, volume, etc.) and spray volumes per acre or hectare.

(viii) Number and timing of applications (total number, during dormancy, pre-plant, pre-emergence, pre-bloom, etc., between-application-intervals, and treatment-to-sampling intervals (pre-harvest intervals =PHI)).

(ix) Other pesticides applied (identity (name and type of formulated products, active ingredients), rates, dates, purpose of use, indicate whether applied separately or mixed with active ingredient of interest in trials).

(x) Climatological data (record of temperature and rainfall during the growing season from the nearest weather station, and wind speed during application).

(xi) Dates (planting/sowing/transplanting, as applicable, other significant dates in the growing of the crop (e.g., husk split for tree crops), pesticide applications, harvests).

(xii) Harvest procedures (method of harvesting (mechanical/hand, from the plant/ground/flotation, etc.), type equipment used, number/weight of samples collected per replication and number of replications per treatment level, statistical nature of sampling (e.g., fruit taken from upper, middle, and lower portions of tree exterior and interior), sample coding (cross-referenced to sample history), etc.).

(xiii) Quality control (control measures/precautions followed to ensure the fidelity of the crop field test).

(xiv) Other. Any and all additional information the applicant considers appropriate and relevant to provide a complete and thorough description of the growing of the RAC, applications of the pesticide formulated products, and harvesting of samples.

(B) A detailed description of the handling, pre-shipping storage, and shipping procedures for harvested RAC samples. The information provided, which shall be presented on a standardized form, should include (in addition to a description of the test substance and the test commodity):

(i) Sample identification (means of labeling/coding).

(ii) Conditions (temperatures, container types/sizes, sample sizes, form (e.g., whole commodity; chopped), etc.) and duration of storage before shipping.

(iii) Methods of packaging for shipment (container types/sizes, sample sizes, ambient/iced, labeling/coding, etc.).

(iv) Means of transport from the field to the laboratory.

(v) Dates (harvest, pre-shipping storage, shipping, and receipt in the laboratory).

(vi) Quality control (control measures/precautions followed to ensure the integrity of harvested samples during handling, pre-shipping storage, and shipping operations).

(vii) Other: All additional information the applicant considers appropriate and relevant to provide a complete and thorough description of the handling, pre-shipping storage, and shipping procedures for harvested samples.

(C) A detailed description of the conditions and length of storage of harvested RAC samples following their receipt in the laboratory.

(D) A detailed description of the residue analyses used in determining the components of the residue definition in field trial RAC and storage stability samples. If the specified information is provided elsewhere within the overall data submission package, it need not be reiterated here. In that case, a reference to the relevant analytical methodology would be sufficient.

(E) Method recovery validation studies should be run concurrently with the residue analyses of crop field trial samples from each individual field trial in order to provide information on the recovery levels of the test compounds from the test substrates at various fortification levels using the residue analytical methods, and to establish a validated limit of quantification. The following information specific to the method validations, which may be presented on a standardized form, should include:

(i) Experimental design: Identity of test substrates (specific plant parts) and test compounds (parent/specific metabolites). Number and magnitude of fortification levels, number of replicate samples per test compound per fortification level, sample coding, control samples, etc.

(ii) Fortification procedure: Detail the preparation of the test compounds and test substrates and the manner in which the test compounds were introduced to the test substrates.

(iii) Dates: Test sample preparation (maceration/extraction/etc.), test compounds preparation (standard solutions of known concentration), residue analyses.

(iv) Residue results: Raw data, ppm or mg/kg found uncorrected (corrected values may also be reported but the basis of correction should be explained), procedures for calculating percent recoveries, recovery levels (range), and limits of quantitation and detection.

(v) Other. Any and all additional information the applicant considers appropriate and relevant to provide a complete and thorough description of analytical methodology validation procedures.

5. Organization of data tables and forms.

(A) Tables of residue assay data for specific plant parts analyzed. Residue levels should be reported uncorrected. Corrected values may also be presented but the procedure needs to be explained with sample calculations.

(B) Tables on residue recovery values.

(C) Graphs, as pertinent (e.g., residue decline).

(D) Forms containing field trial history information.

(E) Forms containing harvesting, shipping, storage information.

(F) Tables of weather data if unusual conditions claimed to result in aberrant residues.

(6) Trial Information

(A) Geographic Location (Trial Specific information – should be provided for all trial locations)

(i) Trial ID No (Trial Specific, unequivocal identification code (e.g., Company Internal Code)

(a) Trial Deviation (List any deviations which may impact the trial results or study conclusions)

(ii) Year (the year in which the first GLP data are collected in trial)

(iii) Country

(iv) Geographic Region (e.g., lowland, coastal, high altitude and mid altitude or stating agroecological zone)

(v) Province/Country (e.g.,Kwale/Kenya)

(vi) County

(vii) GPS Coordinates (if possible)

(viii) Describe the agricultural practice of producing this crop in this region

(ix) Crop Grouping

(x) Crop

(a) Crop Variety (e.g., Apple mango)

(xii) Crop Code

Codes can be obtained from FAO/WHO. 1993. Codex Classification of Foods and Animal Feeds in Codex Alimentarius, 2nd ed., Volume 2. Pesticide Residues, Section 2 Joint FAO/WHO Food Standard Programme. FAO, Rome. Note: the CCPR currently is working on the revision of classification of commodities. The implementer is advised to check which groups have been finalised and enforced By the Committee/Codex Alimentarius Commission

(xiii) Soil Characterization (e.g., sandy loam, sandy clay loam, etc.)

(B) Plot (Information should be provided for all plots)

(i) Plot ID (Unequivocal Plot Identification; e.g., consecutive number). Numerical field or combination

(ii) Control Plot (yes or no)

(iii) Plot Description - Describe plot specific information: e.g., plot size or area, row spacing, plant spacing, plants/area, crop height, seeding rates, number of seeds/area, exaggerated application rate, type of protection in case of a protected crop scenario, in case of a storage protection use give type, size and volume of store, also type and size of package of stored products (e.g., bulk, paper, plastic bag) etc.

(iv) Environmental Conditions

Describe abnormal weather conditions, if applicable, soil properties, any other environmental effect that might have had an impact on the results observed in this study; for storage protection or glasshouse application give room/glasshouse temperatures/humidities

(v) Describe crop maintenance on the plot, e.g., all procedures used in planting, maintenance, and harvest, including irrigation, application of fertilizers and other maintenance chemicals

(vi) Date of planting/sowing (for permanent crops year of planting is sufficient); in case of seed treatment give date of seed treatment and date of sowing, beginning and end of flowering, beginning and end of commercial harvest

(vii) Application

(a) Application No (e.g. 1, 2, ...)

Consecutive numbers of the applications. i.e., 1st application = 1, 2nd application = 2. In the case of seed treatment, the sowing of the seeds is the first application.

(b) Growth stage at application, height of plants at application in case of "tall crops" (e.g., vines) and both height and crown height of plants in case of tree crops

(c) Date of Application (indicate format e.g.:dd/mm/yyyy)

In case of seed treatment, state the date of sowing, in case of post-harvest dip, state the date of dip. In case of storage treatment give beginning and end of treatment together with beginning and end of ventilation

(d) Method of Application

(e) Seeding Rate (Used in conjunction with seed treatment. Using this, combined with no. seeds/ Unit, one can determine TGW (Thousand Grain Weight), etc.)

— Number of seeds/unit (no. seeds/kg)

(f) Test Item (Pesticide(s) tested in this study)

— Description of Test Item; information regarding tested Pesticide Product, End-Use Product, formulation, treated/dressed seed, etc. used in the test item applied to the trial plot, crop, and/or the harvested commodity

— Test Item Formulation Type

— Test Item Trade Name

— Test Item Active Ingredient Code/unique identifier (e.g., Company Internal Code)

— Test Item Active ingredient name(s)

— Test Item Nominal active ingredient content (e.g., grams a.i./liter)

(g) Test Item actual amount active ingredient applied (e.g., grams a.i./ha); for storage protection uses: application rate (e.g., kg a.i./m^3), duration of treatment (h), duration of ventilation

(h) Test Item actual amount active ingredient/seed if seed treatment (e.g., g a.i./100 kg seed)

(h) Test Item cumulative amount applied

(i) Adjuvant Added, Adjuvant Type, Adjuvant Name, Adjuvant amount in Spray Volume (%)

(j) Amount of water used in spray application(actual)

(viii) Sampling

(a) Sampling No.

Consecutive numbering of sampling events

(b) Sample ID – Unique sample identification code

(c) Sampling Timing: Provide any information regarding the timing of the sampling, e.g., relation to application events, days after last application, etc.

PHI – pre-harvest interval

DALA — Days after last application Days Before Harvest

(d) Growth Stage at sampling

(e) Date of Sampling(dd/mm/yyyy)

(f) Sampling Information:

Description of sampling method, special remarks (e.g., cabbage was harvested according to agricultural practice, 1st set of outer leaves were removed), sample handling (e.g., samples were frozen within 24 hours)

(g) Sampled Material/Commodity (Field RAC Sample)

(k) Analysis Sample (Description of Analysis sample)

Field Sample should be separated into several analysis samples, e.g., whole mango may be separated into a peel sample and a flesh sample for analysis (in that case also give weights of peel and pulp).

(l) Analysis Sample ID

(m) Analysis Sample Description

(n) Analyte measured

(o) Analyte ID.

(p) Extraction Date(dd/mm/yyyy)

(q) Actual date of extraction

(r) Analysis Date(dd/mm/yyyy)

(s) Actual date of analysis

(t) Method ID

(u) Recovery

(v) Residue Level (e.g., mg/kg). The value should not be corrected for recovery and rely on the measured level of the analyte. Additionally, give calculated residue if appropriate (e.g., residue xy calculated/expressed as yz or acid calculated/expressed as carboxylic ester, sum of a.i. and metabolites x and y, expressed as a.i.…)

(w) Number of analytical replicates

(7) Analytical Methodology: Describe basic principle of analytical method(s) and their LOQ(s),

Method ID or cross-reference to relevant method template

(A) analytical Method Information

(B) Fortification Level

(C) Recovery (%)

(8) References

List of references used should also be included in the Report.

R6(1)

TECHNICAL CRITERIA FOR DESIGNATING EFFICACY TRIAL CENTERS

Introduction

This document prescribes the technical requirements for private or public institutions for designation as Efficacy Trial Centers for conducting efficacy studies that support or are intended to support applications for registration of pesticides in Kenya. It is intended to ensure the quality and integrity of efficacy study results that are submitted Kenya in support of pesticides registration or an extension of uses.

Definitions

Batch —	means a specific quantity of the control and test substance.
Carrier —	means any material (e.g. water, soil, nutrient media, e.t.c) combined with test substance.
Control substance –	means any chemical substance or mixture, or any other substance (e.g. microbials) other than the test substance and used for comparison with the test substance.
Efficacy Trial Center —	means a private or public institution that meets the technical criteria and so designated by the Government of Kenya.
Experimental start date —	means the 1st date that the test substance is applied in the study.
Experimental end date —	means the last date on which data is collected from the study.
Quality assurance —	means compliance with quality assurance of the studies.
Quality registration control —	means the internal process for designated Center to ensure all steps in the study protocols are followed.
Raw data —	means all original information collected from the study and necessary for the evaluation of study results.
Specimen —	means any study subject (target pest) intended for examination and analysis.
Sponsor —	means the applicant (registration) that financially supports the study.
Study —	means the efficacy trial conducted in a laboratory, greenhouse, or in the field at one or more sites in which the test substance is applied.

Study Director —	means the individual responsible for the overall conduct of the study.
Study Personnel —	means all individuals involved in the efficacy study.
Study Protocol —	means all processes and steps required for testing the test substance and all documentation that is required by the study.
Test substance —	means any chemical substance or mixture, or any other substance which is the subject of the efficacy study.

Application Process

Private or public institutions shall formally apply for designation as Kenya Designated Efficacy Trial Centre s. Application form attached (Annex A) shall be submitted to PCPB and provide the technical information required by the criteria as explained below. PCPB shall accredit a public or private institution to conduct the trials. The duration for which accreditation is valid should be specified.

Inspection of Efficacy Trial Centre

A prospective or Designated Efficacy Trial Centre shall permit an authorized official of PCPB at reasonable times and in a reasonable manner, to conduct physical verification of the information provided through an inspection. Assessment criteria of institutions involved/ to be involved in carrying out efficacy trials on Pest Control Products is attached (Form B).

A. Testing Institution

The Testing Institution shall ensure that:

(1) A Study Director is assigned to oversee the execution of an efficacy trial. The Study Director shall be a scientist or a professional with the required education, training, and experience. The Study Director shall have overall responsibility of conducting the trial, ensuring that all steps in the protocol are followed; trained personnel implement the trial; and appropriate tools are available for data collection and documentation.

(2) There is a Quality Assurance/Quality Control (QA/QC) Unit, independent of the Study Director. The QA/QC Unit shall be responsible for inspecting and ensuring the quality and integrity of the efficacy trial. It shall periodically inspect the trial steps and report to the institution management. It shall also review all documentation and the final report to ensure that the reported results accurately reflect the raw data of the study.

(3) Quality Assurance/Quality Control Unit communicate any deviations or problems to the Study Director and ensure corrective actions are taken.

(4) Evaluation of test substances against the control for identity, amount, stability, and effectiveness in accordance with the submitted pesticide label is carried out.

(5) They provide personnel, resources, facilities, equipment, materials, and protocols (and methodologies) before commencement of the experiment.

(5) personnel have been properly trained and can perform the functions they are to perform in the study.

B. Testing Centre Facility

The Testing Centre shall have:

(a) Shall Standard Operating Procedures (SOP) for conducting efficacy trials.

(b) Adequate space and infrastructure for effective conduct of the efficacy trial.

(c) Indoor, greenhouse or outdoor facilities. Studies conducted in outdoor facilities must be located in suitable locations.

(d) Proper isolation of trial sites to prevent drift or contamination on the efficacy trial.

(e) Adequate space for storing and handling of samples and equipment and collection facilities for pesticide waste.

C. Efficacy Trial Personnel

The personnel to engage in the efficacy trials shall

(1) Have the minimum professional competence required to conduct efficacy trial.

2) be knowledgeable of the Study Protocol.

3) be properly trained in the safe use and application of pesticides.

D. Records and Documentation

The Testing Center Facility shall demonstrate the ability to maintain all raw data, protocols, and final reports resulting from the efficacy trials.

Other Criteria

1) Previous experience in conducting pesticide efficacy trials.

2) International accreditations obtained by the Center.

ANNEXES

Form A—Application Form

Form B—Inspection Form

APPLICATION FORM FOR INSTITUTIONS INVOLVED/ TO BE INVOLVED IN CARRYING OUT EFFICACY TRIALS ON PEST CONTROL PRODUCTS

1. INFORMATION FOR APPLICANTS

a. The Application Form shall be completed by a duly authorized person.

b. The application shall be submitted in triplicate to PCPB:

c. Every Application shall be accompanied by application fee as prescribed

d. The Application shall be accompanied by the evidence as per the specific data requirements

2. DETAILS OF APPLICANT

a) Name and Address of institution/researcher: .....

b) Contact person:……

c) Tel No: ……

d) Email Address: .....

e) Signature: …….……..

f) Date:…….……...

3. AREAS FOR ACCREDITATION

a) Pest Control Products Category (e.g. Herbicides, Insecticides, Fungicides, et):

b) Crops: ……

4. SPECIFIC REQUIREMENTS

During the visit the following items shall be evaluated: Please indicate level of compliance

		Comments on Level of Compliance
A	GENERAL	
	Physical facilities	
	Office space	
	Location/accessibility	
	Availability of Transport	
	Equipment maintenance	
	Cost of doing trials	
	Procedures of keeping records and for how long (archiving)	
	Awareness/utilization of PCPB trial protocol	
B	IMPORTANT	
	Facilities: particularly chemical store, equipment store, other relevant on and off-site facilities)	
	Disposal consideration after testing	
	Workers' safety	
	Mode of assessment (type, time and frequency of assessment, phytotoxicity).	
	Proposed System of reporting – Individual reports for each season submitted? Subjected to internal Peer Review Committee? Submission by Head of Department?	
C	CRITICAL	
	Availability of land/green houses	
	Availability of crops/animals for trials	
	Staff management – (structure and responsibilities)	

		Comments on Level of Compliance
D	VERY CRITICAL	
	Human Resources: Qualifications Experience in carrying out efficacy trials	
E	ADDED ADVANTAGE	
	Any specific internationally recognized testing requirements to be followed	
	Copies of study plans (Trial Protocols for specific trials)	
	Testing organization accreditation for any other work	
	Standard Operating Procedures	
	Any other uniqueness of the institution/comment	

NOTE:

METHODOLOGY OF ASSESSMENT

Actual visit to the institutions and private researchers shall be undertaken to inspect the facilities and interview staff involved in efficacy trials.

Date .....

FINAL MARKS AWARDED……

ASSESSMENT CRITERIA OF INSTITUTIONS INVOLVED/ TO BE INVOLVED IN CARRYING OUT EFFICACY TRIALS ON PEST CONTROL PRODUCTS

SCORE SHEET AND CRITERIA

1. OBJECTIVES OF THE VISIT

a) To assess the capacity of private/public institutions to carry out efficacy trials on pest control products for registration purposes.

b) To assess the safety of workers involved in efficacy trials and the concerns to the environment.

c) Make recommendations to the Regulatory Authority based on the findings.

2. METHOD OF WORK

Actual visit to the institutions and private researchers, inspecting the facilities and interviewing staff involved in efficacy trials.

a) Name and Address of institution/researcher: .....

b) Contact person:……

Tel. No: ……..……..

Email Address: .....

3. SPECIFIC INSPECTION REQUIREMENTS

During the visit the following items shall be evaluated: Insert the score for each criteria as indicated below

	Item	Requirements	Evaluator 1	Evaluator 2	Evaluator 3	Evaluator 4	Evaluator 5	Total Marks	Recommended / Harmonized marks
A	GENERAL							Possible by Individual assessor	
1	Physical facilities								
	Office space	Should have computer, telephone, internet services						1	
	Location/ accessibility	Should be easy to locate						1	
	Availability of Transport	Evidence of transport for easy access to trial sites						1	
	Equipment maintenance	Maintenance schedule should be shown (is it reasonable)						1	
	Cost of doing trials	Approximate costs for various categories should be given						1	
	Procedures of keeping records and for how long (archiving)	Records must be shown						1	
	Awareness/ utilization of PCPB trial protocol	Evidence should be provided for inspection						10	

	Item	Requirements	Evaluator 1	Evaluator 2	Evaluator 3	Evaluator 4	Evaluator 5	Total Marks	Recommended / Harmonized marks
	Remarks							Total (16)	
B	IMPORTANT								
	Facilities: particularly chemical store, equipment store, other relevant on and off-site facilities)	Should be shown						5	
	Disposal consideration after testing							5	
	Workers' safety	Personal protective Equipment must be shown						5	
	Mode of assessment (type, time and frequency of assessment, phytotoxicity).							5	
	Proposed System of reporting – Individual reports for each season submitted? Subjected to internal Peer Review Committee? Submission by Head of Department?	Evidence of structured reporting system must be provided for inspection						5	
	Remarks							Total (25)	
C	CRITICAL								
	Availability of land/green houses	If leased documentary proof required						10	

	Item	Requirements	Evaluator 1	Evaluator 2	Evaluator 3	Evaluator 4	Evaluator 5	Total Marks	Recommended / Harmonized marks
	Availability of crops for trials	Evidence should be shown or lease agreement, as applicable						10	
	Labaratory facilities							5	
	Staff management – (structure and responsibilities)	Responsible officer must be clearly identified						10	
	Remarks							Total (35)	
D	VERY CRITICAL								
	Human Resources: Qualifications Experience in carrying out efficacy trials	Lead researcher must have minimum of a relevant M.Sc degree *(Masters 10 &PhD 15)* Lead researcher must have practical experience on relevant crop/pest						15 5	
	Remarks							(Total 20)	
E	ADDED ADVANTAGE								
	Any specific internationally recognized testing requirements to be followed.							1	
	Copies of study plans (Trial Protocols for specific trials)	Must be provided for inspection						1	

	Item	Requirements	Evaluator 1	Evaluator 2	Evaluator 3	Evaluator 4	Evaluator 5	Total Marks	Recommended / Harmonized marks
	Testing organization accredited for any other work?							1	
	Standard Operating Procedures	SOP's should be provided for inspection						1	
	Remarks								
	Sub-total							4)	
	TOTAL MARKS							100	
	Recommendation								

Pass Mark = 70% but part D is mandatory

Name of Assessor:— .....

Final Recommendation: Recommended ☐

for .....

General remarks: .....

.....

Not Recommended ☐

Marks shall be awarded according to the criteria, where the Maximum possible mark is indicated. The categories are as indicated below

GENERAL *(where max awarded for each = 1*	IMPORTANT *Where max awarded for each = 5*	CRITICAL *Where max awarded for each = 10*	*VERY CRITICAL Where max awarded for each = 10*	ADDED ADVANTAGE *max for each = 1*
Office space	Chemical store	Land/Greenhouse/ Lease agreement	Human resource	Standard operating procedures
Availability of transport	Disposal consideration	Crops		Study plans
Location	Workers safety	Protocol awareness		Other internationally recognized protocols
Procedures of keeping records	Assessment mode	Staff management structure		Other accreditation
Costs of trials	System of reporting			Other trial sites
Maintenance of equipment				
SUB-TOTAL = 16	SUB-TOTAL = 25	SUB-TOTAL = 35	SUB-TOTAL = 20	SUB-TOTAL = 04

Any other observations —

SECOND SCHEDULE *(r.30(2))*

ITEMS EXEMPTED FROM REGISTRATION

1. Garment bags, cabinets or chests that are manufactured, represented or sold as a means to protect clothing or fabrics from pests.
2. Electronic apparatus that is manufactured, represented or sold as a means to attract or destroy flying insects.
3. Devices of products that are manufactured, represented or sold to repel birds and other pests by causing physical discomfort by means of sound or touch.
4. Devices of attachment to garden watering hoses that are manufactured, represented or sold as pest control product.
5. Devices that are manufactured, represented or sold as a means of providing the automatic or unattended application of a pest control product.
6. Devices that are sold for use with chemical products containing cyanide as a means to control animal pests.
7. Devices that are meant to control any pest through physical or mechanical means provided that there are no known environmental hazards expected from the use of the device.

Made on the 22nd May, 2024.

MITHIKA LINTURI,
Cabinet Secretary for Agriculture and Livestock Development.

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