COMITE PERMANENT INTER-ETATS DE LUTTE CONTRE LA SECHERESSE DANS LE SAHEL
PERMANENT INTERSTATE COMMITTEE FOR DROUGHT CONTROL IN THE SAHEL

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Composition of the Registration Dossier for bio-pesticides in the Sahel region

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This document relates to the registration of microbial products to control harmful organisms, all these microbial products are referred to here as "bio-pesticides".

I Definitions

The following definitions apply in this document:

Biological ingredient (b.i): in this document, is any microorganism (bacterium, fungus, virus or protozoon) biologically active and present in the formulation of a biopesticide (USEPA, 1996).

Active ingredient, pure: active ingredient without manufacturing impurities, contaminants or additives (USEPA, 1996)

Technical quality active ingredient: active ingredient including manufacturing impurities. It is used for the production of the formulated product and in various tests (USEPA, 1996).

Provisional authorization of sale (APV): temporary registration of a pesticide, made in order to allow the necessary supplementary data acquisition necessary for establishing a final registration to be generated (CSP 2000).

Parasite: organism which lives with or depends on another organism which can contribute to limiting the population of its host. It includes the parasites, the parasitoides, the predators and pathogens (FAO 1990).

Biopesticide: biological control agent formulated and applied in a way similar to a chemical pesticide (RC 1999) whose active ingredient is a microorganism such as fungi, bacteria, viruses and protozoa. Biochemical products, nematodes, pheromones, hormones, growth regulators, genetically modified organisms and plant extracts are excluded (FAO 1990; CSP 1999).

Exotic species and indigenous species: indigenous species "natives" are those found naturally in the area of the CILSS. Non indigenous species, known as "exotics" are those originating elsewhere (CSP 2000).

Infection: penetration and invasion of the body by a pathogenic micro organism and reaction of tissues invaded to its presence. It refers to the multiplication of the organism in mammals as measured by the presence of its vegetative stages in tissues or by the collection of a number of them from the living organism at the time (Siegel and Shaduck, 1990). (to be re-examined).

Infectivity: ability to penetrate a body by overcoming its defense mechanisms thereby allowing a pathogen to enter its tissues (Siegel and Shaduck, 1990). Capacity of the pathogen to cross the natural barriers of the host thereby infecting it (USEPA, 1996). (to be re-examined)

Parasitoid: an arthropod which only parasitises in the immature stages of its life cycle which is destroyed by its host during its development and which lives independently once it is an adult (FAO, 1990).

Pathogenic: microorganism which causes a disease.

Pathogenicity: ability of the organism to cause the disease in the host once the host is infected (Siegel and Shaduck, 1990).
Persistence: survival of the pathogenic microorganism in a dormant state in host tissues (Siegel and Shaduck, 1990.

Pathogenic capacity: capacity of an organism to cause a disease either by virulence or by the production of toxins (Medical Encyclopaedia).

Formulated product: pesticide in the form in which it is packaged and sold (CSP, 2000). The synonyms are: commercial speciality or commercial product.

II Information required for registration of bio-pesticides

The application file for registration of bio-pesticides in the Sahel should contain the following information:

1) a request for registration of the formulated product duly completed, dated and signed by the applicant;
2) a summary of the information presented in the file;
3) a summary identifying the formulated product
4) a statement identifying the biological agent
5) a statement demonstrating the efficacy of the product
6) a statement on the Toxicology of the product
7) an environmental assessment of the product
8) a sample of the container and the label;
9) a sample of the product

The whole set documents referred to in points 1 to 9 to be provided in two copies in French or English.

III Confidential data protection

The CSP encourages applicants to publish any relevant trial data relating to their products in order to promote its use. (to be removed)

Confidentiality of the information submitted is provided for through the data protection Regulation of the Member States of the CILSS on the registration of pesticides in its articles 16 and 17 as follows:

The data provided by the applicant in a file for seeking the registration of pesticides in the Sahel may not be used for the benefit of other applicants without the written approval of the original applicant.

The applicant, by submitting the registration dossier can indicate the parts of the file which, from

its point of view, constitute or contain industrial or commercial secrets. The CSP and Member States will ensure that such information remains confidential.

The confidentiality does not apply to:

i. the concentration and content of the active ingredients nor to the formulation of the commercial product;
ii. the names of the other ingredients considered as dangerous to humans, animals, plants or the environment;
iii. the physicochemical data concerning the active ingredient its important degradation products relating to the (eco) toxicology of the product;
iv. antidotes to the active ingredient in the commercial product;
v. the summary of the results of the tests intended to establish the effectiveness of the product and its harmlessness to humans, animals, plants and the environment;
vi. the methods and precautions recommended to reduce the risks during handling, storage, or transport;
vii. the methods of analysis of active ingredients and their post application residues, as well as metabolites or other components considered important from the ecotoxicological point of view;
viii. the methods of disposal of the product and its containers;
ix. decontamination measures to be taken in the event of accidental contact or spillage;
x. first aid and medical treatment to apply in the event of accidental exposure or ingestion.

SUMMARY

The purpose of the summary is to provide to the Sahelian Pesticide Committee with relevant information on the product to be approved. The data provided will allow, not only the members of the CSP to have a quick overview of the product but will also be used later to educate the users and in the production of a Plant Health Index for the Sahel.

It is requested that the applicant should provide the following information in this summary. This should comprise only the essential information and if possible in the form of key words or of standard sentences.

Index of summary

Name and addresses of the applicant:
Commercial name of the product:

Identification of the product

Commercial name
Scientific name of the biological ingredients
Form in which the active ingredient is multiplied

Physico-chemical properties

Physical state, smell and colour
Storage stability
Incompatibilities
Other important properties of the product according to the applicant

Biological efficacy

Type of the product
Organism
Recommended rates
Periods and frequencies of application

Toxicological information

For the active agents

Eye Irritation

Skin Irritation

Allergies

For the formulated product

Eye Irritation

Skin Irritation

Allergies

Symptoms of poisoning

Ecotoxicological information

Toxicity of the product to birds

Toxicity of the product to fish

Toxicity of the product to bees

Toxicity towards the soil organisms (termites, ants and worms)

List of countries where the product is already registered

Safety measures

Precautions to be taken in transport of the product

Precautions to be taken in storage

Precautions to be taken for destruction of expired products and empty packaging

Recommendations for cleaning of application equipment and protective clothing

Precautions to be taken before, during and after the application of the product

Date summary compiled……Signature of the applicant…….

1.0 The Application for Registration

Must include:

a. Name and addresses of the applicant;
b. Name and addresses of the owner of the trademark;
c. Name and addresses of the producer of the biological agent and the place of production;
d. Name and addresses of the manufacturer of the active ingredient and the place of manufacture.
e. When the manufacturer of the formulated product is not the owner of the intellectual property incorporated in the biological agent he must provide an original letter of agreement granting the use of the ingredient by the owner of the intellectual property as part of the registration application.
f. Common name of the biological agent
g. Commercial name of the formulated product;
h. List ingredients of the formulated product: their names and quantities in the product
i. Formulation;
j. Smell and colour of the formulated product.

1.2 Recommended uses

1.2.1 Type of biopesticide (e.g. insecticide, herbicide, etc…)
1.2.2 Suggested uses (e.g. leaf-eating insects of cotton plant, insects of rice);
1.2.3 List of the countries where the bio-pesticide is already approved and the recommendations for use in these countries;

3.0 REFERENCE FILE

The reference file must include:

- identity of the biological ingredients and
- identity of the formulated product;

3.1 Identity of the ingredient or the biological ingredients

The applicant must provide information on the taxonomy of the agent or the biological agents:

- common name or traditional name;
- family;
- genus;
- species;
- serotype, stock, pathotype;
- relation to other species;
- any other suitable classification

Must provide information on:

- the biology of the biological ingredient (rate of multiplication);
- the ecology of the biological ingredient (geographical distribution, agro-ecological zones);
- the mode of action of the biological ingredients e.g. biochemical, physiological;

Must provide a description of the mode of action e.g. repulsion, ingestion, inhalation, contact, systemic;

Must provide information on the biophysical properties;

Must provide information on the range of hosts and indicate any alternate hosts

3.2 Identity of the formulated product

The applicant must provide the following information:

- The name of the formulated product;

- The composition of the formulated product: names and proportions
    - of the biological ingredient or ingredients;
    - additives;
    - inert compounds;
- The type of formulation;
- WHO Toxicological classification of the formulation
- physicochemical properties (color, smell, etc…);
- *in vitro* stability;
- storage stability (to indicate the shelf life of the product in its commercial packing);
- incompatibilities between the formulated product and other chemicals
- other important information which the applicant considers useful to make available to the CSP

3.3 Identity of the technical quality active ingredient:

The applicant must provide information requested in 3.1 and the following information on:
- the physical state, the color and odor;
- possible variations in the composition: maximum and minimum purity

4.0 IDENTIFICATION FILE

The identification file must include:

- criteria and methods for identification of the biological ingredients and the formulated product;
- results of these identification tests and quantification;

4.1 Biological ingredient

4.2 Formulated product

- criteria and methods of identification;
- results of the identification tests;
- methods of identification and quantification of the biological ingredient;
- results of the identification tests and quantification of the biological ingredient.

5.0 THE BIOLOGICAL EFFICACY FILE

The tests of biological effectiveness are shown to have been conducted on the formulated product. They aim at providing sufficient data to allow an evaluation of the level, duration and uniformity of control, protection or other expected effects of the formulated product by comparison with suitable reference products if there are any.

For these tests the objectives must be specified, the materials and methods used, the results obtained as well as the references of the institutions that carried out the tests.

The results arising from these tests must be sufficient to allow an evaluation of the biological effectiveness of the formulated product.

The biological effectiveness file must include:

5.1 A synthesis of the:

Methods of use

- a description of the applications of the formulated product (e.g. field, greenhouse, garden, crop storage or livestock);
- a specification of each application (e.g. for use in the field: vegetables, cotton, cereals, horticultural etc);
- a description of the target organisms and the range of possible hosts (e.g. insects, fungi, nematodes, bacteria, with a specification of the family, genus, species);
- a precise specification of the rates of application, periods, stages and frequencies of application;
- the application procedures recommended for the product;
- indication of the use limits to ensure safety for crops, animals, the treated organisms, the operators and consumers;
- information on the actual or possible development of resistance and a resurgence of the pests;

- latency time and the rate of effectiveness expected.

5.2 Reports on the tests of effectiveness

5.2.1 Requirements of tests

In theory, a test must relate to three objects:

- the product tested;
- the reference product;
- an untreated control

The tests must demonstrate the degree of effectiveness of the formulated product on the target organisms for which the registration request is presented.

The formulated product must be tested under conditions where it is shown that the harmful organism is present at a level causing harmful effects to the output, quality etc.

For each formulated product presented for registration the applicant must have the results of trials in one or more countries of the CILSS and covering, as appropriate, the following ecological zones:

- Sahelian zone;
- Sudano sahelian zone;
- North Guinean zone.

The numbers and the types of trials must be as follows:

- first year: one (1) test on station;
- second year: one (1) test on station and one (1) test on farm;
- third year: one (1) test on farm;
- fourth year: one (1) test on farm;

If the organisms targeted by the product presented for registration constitute a problem in all three (3) ecological zones, the trials must cover all of them. On the other hand, if the harmful organisms are only in one or two zones, the applicant only has to provide results from these specific zones.

With specific regard to locust control, the Sahelian-Saharan zone must be taken into account in the evaluation of biological effectiveness.

The CSP can decide to grant an APV based on reliable results obtained during the first two years of the trials. Moreover, in certain cases, replication in space could replace replication of independent trials in time.

On the other hand, for the purposes or registration the applicant must have the results of trials run over at least four (4) years, in one or more countries of the CILSS and covering, depending on the circumstances, the ecological zones concerned.

5.2.2 Content of the reports

The reports of the studies of biological effectiveness of the formulated product proposed for registration must be presented in conformity with the Protocols Frameworks (PF) and Specific Protocols (SP) of the CSP. In the absence of these, the applicant may refer to international experimental Protocols on the subject.

NB: The Provisional registration or the Registration will be issued for the specific harmful organisms for which the results show the product to be satisfactorily effective.

6.0 THE TOXICOLOGICAL FILE

It must include:

- primary toxicological data of the biological ingredient and the formulated product;
- additional toxicological data;
- safety measures.

6.1 Primary toxicological data

6.1.1 Active ingredient

Pathogenic capacity: It is recommended that pathogenicity be tested on rats or mice, according to recognised standard methods, in order to determine any chronic side effects and any behaviour. The data generated must be according to good laboratory practice as necessary for any exotic organism.

Acute oral toxicity: The study is made by administration of a single amount. The applicant must specify the animal species and the references used.

Acute toxicity by inhalation: The study is to be carried out on rats, mice, rabbits, etc. according to recognised standard methods.

Acute skin toxicity: The study on skin irritation is to be carried out on rats, mice, rabbits, etc, according to recognised standard methods.

Acute intravenous toxicity: The study is to be carried out on rats, mice, rabbits, etc, according to standard recognised methods.

Acute gut toxicity: The study is to be carried out on rats, mice, rabbits, etc. according to recognised standard methods

Eye Irritation: The study is to be carried out on rats, mice, rabbits, etc. according to recognised standard methods.

Allergies

Allergy: The allergy studies are to be carried out according to recognised standard methods.

Hyper sensitivity: in the event of allergy the study of hyper-sensitivity must be carried out unless the biological ingredient is known not to be hyper allergenic. The study must be carried out according to recognised standard methods.

Genotoxicity: Studies of genotoxicity are required if the active ingredient is a virus.

Mutagenicity: The studies of *in vitro* mutagenicity are required if the active ingredient produces toxins. It must be carried out according to recognized standard methods.

6.1.2 Formulated product

Acute oral toxicity: The study is done by administration of a single dose. The applicant will specify the animal species and the references used.

Acute toxicity by inhalation: The study is carried out on rats, mice, rabbits, etc. according to recognized standard methods.

Acute skin toxicity: The study of skin irritation is to be carried out on rats, mice, rabbits, etc, according to recognized standard methods.

Acute intravenous toxicity: The study is to be carried out on rats, mice, rabbits, etc. according to the recognized standard methods.

Acute gut toxicity: The study is to be carried out on mice and rats, according to recognized standard methods.

Eye Irritation: The study is to be carried out on mice and rats, according to the recognised standard methods.

Allergies

- **Allergy:** The Allergy studies are to be carried out according to recognised standard methods.
- **Hyper sensitivity:** in the event of allergies the study of hyper sensitivity must be carried unless the biological ingredient is known not to be hyper sensitive. It is to be carried out according to recognised standard methods.

6.1.3 Additional toxicological data

Additional toxicological tests can be requested when the primary toxicological data are not sufficient to guarantee the safety of the biological ingredient and if it produces a toxin.

One 21 day study is necessary to detect the chronic side effects and 90 days to evaluate the chronic effects. One can thus determine the nature of the side effects, their reversibility or irreversibility and establish the quantity which can be absorbed without observable effects (DSEO).

6.1.4 Safety precautions

The recommendations must include the following elements:

- Precautions to be taken in transport;
- Precautions to be taken in storage;
- Precautions to be taken for the decontamination and safe disposal of empty containers;
- Precautions to be taken in the event of spillage or accidental discharge;
- Recommendations for the decontamination of application equipment, protective clothing and equipment;
- instructions to be printed on the label;
- nature of the risks. Precautions to be taken before, during and after the application for the safe use of the bio-pesticide

7.0 THE ENVIRONMENTAL FILE

The environmental study requirements depend primarily on the following factors:

- the field and methods of use;
- risks to the non target organisms and the environment;
- results of previous studies.

The CSP recommends two levels of toxicological trials in the evaluation of a biopesticide.

Level 1 corresponds to the evaluation of the toxicological effects of the "Maximum acceptable dose", the recommended amount. If there are no significant effects, the product is authorised. If there are significant effects, the CSP requires thorough tests corresponding to level 2.

CSP requires local tests and data but will also take into account data generated elsewhere than in CILSS as long as they arise under similar conditions and the use of recognised standard methods.

The environmental file must include:

- studies of the ecological effects of the biopesticide.
- data on the residues in the environment.

7.1 Studies of the ecological effects of the biopesticide

7.1.1 Studies of the effect of the bio-pesticides on the non target organisms

Toxicity to birds
Level 1: Acute oral toxicity
Technical Grade Biological ingredient
Acute oral toxicity studies are necessary for uses, except for products intended specifically for the treatment of closed spaces such as greenhouses and stores for food products.

Acute effects (mortality, side effects) must be given for at least one species of birds.

Domestic or laboratory tests are acceptable. For example a Sahelian species, the Indian Silverbill (*Lonchura malabarica*) is acceptable. The species studied will be selected by taking account of their eating habits and their risks of exposure. The use of the young birds (of 2 or 3 weeks of age) is preferable because they are often more insectivorous than their parents (EPA, 1996 885.4000, p19).

If the target animals are used as food, the acute effects arising from consumption by a Sahelian species can be used instead of an oral test. Such tests make it possible to have data on the ages at risk.

Formulated product

Testing the acute oral toxicity of the formulated product is required if the product is in forms which can be directly consumed (treatment of seeds, the pellets, granules, etc.) which can be used in the field.

Tier 2: Lethal amount and sub-chronic test

If the studies at level 1 reveal mortality due to the technical grade biological ingredient or the formulated product, acute tests are required in order to determine the lethal or pathogenic amount level. A sub-chronic test is necessary to determine if there is any adverse effect following repeated exposure to recommended amounts.

Toxicity to reptiles

If the bio-pesticides are intended against insects which are used as food by lizards, acute ingestion tests are required on an indigenous species in the Sahel. The tests will consist of giving lizards infected insects and evaluating the effects on the lizards.

NOTE: Since standardized protocols do not exist yet for these tests, the laboratory data and tests on the reptiles will not, at present, be required.

Toxicity to fish

Tier 1

Technical grade biological ingredient

The data required vary according to the field of application and possibility of contamination of surface water.

A sub-chronic exposure over 21 days is necessary in order to measure the effects on fish. The test will be run on at least two suitable fish species. One will use standard methodologies on at least one tropical species (e.g. *Siluris glanis*, or carp). The Sahelian species *Oreochromis niloticus* "tilapia" is preferred.

Formulated product

Laboratory studies of the formulation to be approved are required if one cannot predict the risk from the biopesticide on the basis of information provided about the biological ingredient. This can be for formulations containing ingredients capable of increasing the toxicity of the biological ingredient (e.g. certain solvents, dispersants etc) or oils which can cover the surface of water.

Studies on the formulated product are always required for products intended for application directly to water or to aquatic environments like the rice paddies and irrigation canals. These studies are also required if there is significant risk of contamination of surface water.

Tier 2

If the tier 1sub-chronic tests on the technical grade biological ingredient and the formulated product show signs of raised toxicity or pathogenicity, the following Tier 2 tests are required:

Acute test with a single dose on at least one Sahelian species to determine the median effective amount of the biological ingredient or formulated product which causes mortality or pathogenicity.

If the active ingredient enters an aquatic environment: If the former studies indicate pathogenicity

of the biological ingredient above the recommended environmental minimum, then studies on it becoming an active biological agent in aquatic environments are required.

Toxicity to aquatic invertebrates

Tier 1

Acute toxicity

Technical grade biological ingredient

These studies are obligatory for all biological ingredients except if they are not exposed to aquatic environments.

In the event of direct exposure of water to the biological ingredient, a study on at least one species of each of the following three groups of invertebrates is required:

- Insects;
- Crustaceans;
- Molluscs.

A maximum single-dose test is necessary on at least one suitable species of organism. The study must be carried out on the standard species *Daphnia magna*, or with one of the Sahelian species *Caridina africana* (crustacean), *Streptocephalus sudanicus* (crustacean) or *Anisops sardeus* (aquatic insect).

Formulated product

The studies on the formulated product are always required for products are intended to be directly applied to water. These studies are also required if there is a significant risk of contamination of surface water.

Laboratory studies on the product are required if one cannot reasonably estimate the risks from the bio-pesticide from the studies carried out on the biological ingredient. This can be for

formulations containing substances capable of increasing the toxicity of the active ingredient (e.g. Solvents, surfactants etc.) or oils which cover the surface of water.

Tier 2

A chronic study with a suitable species of aquatic invertebrates is required:

- for every product applied directly to water, or very near to surface water, as in certain anti-vectoral treatments (e.g. Mosquitoes, *Simulidae*, anti bird treatment, e.g. *Quelea*) and if the $DT_{50} > 2$ days;
- if the results of the acute toxicity studies dictate such a study.

The studies will be carried out on Sahelian species such as *Caridina africana* or *Streptocephalus sudanicus*.). One may also determine the EC_{50} and CSEO for at least one suitable species of aquatic invertebrates, preferably *Daphnia magna*.

Toxicity to aquatic algae

The tests on algae are required for the bioherbicides and all other products containing recognised phytotoxic ingredients.

Effects on growth

Technical grade biological ingredient

Determination of the EC_{50} and the CSEO on the growth of algae is required. In general the study is made on a green algae (e.g. *Scenedesmus subspicatus* or *Selenastrum capricornutum*).

These studies are obligatory for the following uses:

- ground treatment;
- full field treatment (terrestrial or air);
- external domestic treatments;
- water treatment.

Such studies are also required for any other application if exposure of water to the biological

ingredient is possible.

In the case of a bioherbicide, a study on at least a second species of another group of algae (e.g. blue-green diatoms or algae) is also required.

Formulated product

Studies on the formulated product are always required for products intended for direct application to water. These studies are also required if there is a significant risk of contamination of surface water.

Laboratory studies of the product are required if one cannot predict the risk arising from the bio-pesticide from the studies on the biological ingredient. This can be for formulations containing the substances capable of increasing the toxicity of the active ingredient (e.g. solvents, surfactants etc.).

Other studies on aquatic organisms

Tests on species of organisms other than the studied species may be required on a case-by-case basis.

Toxicity to bees

Tier 1

Acute toxicity

Formulated product

This study is required for all applications, except if bees are not exposed. An acute toxicity test to a "challenge maximum" level, according to the mode of action, is required, as a minimum.

Tier 2

Toxicity of the residues

Formulated product

Tests on residues are not required except if the tests at tier 1 show serious risks. If this is the case laboratory or 'in the wild' study on the effects of the residues is required.

Toxicity to larvae

Formulated product

Larvae are generally not exposed; the young adults are more commonly exposed. Such tests could be required on a case-by-case basis by the CSP.

Toxicity to the natural enemies of the target pests (auxiliary)

Formulated product

Data on toxicity of the product are required on a species of parasitoids or the predators of the vermin. At least one Sahelian species must be tested.

If the product is intended for use within an integrated pest management framework of Sahelian pests, the tests must be carried out on Sahelian species.

Toxicity to the soil invertebrates

Tier 1

Acute toxicity

Formulated product

The determination of the acute toxicity level of the product on non targeted worms, termites and ants is necessary to evaluate the risk from the bio-pesticide to soil living organisms according to the method of application:

- For products intended to be used mainly in the semi-arid zones (e.g. locust control), the study must be made on termites. Test protocols currently exist for *Psammotermes* and *Odontotermes*.
- For products intended to be used in the wetter zones, the worm must be studied. The local species are acceptable in this case.

A study of acute toxicity is required for all applications, except if soil living invertebrates will not be exposed to the product.

Tier 2

A study the sub effects on soil are required when the results of the acute toxicity tests indicate a long term risk.

7.1.2 Study of the impact and residual products on the soil

These data are required on a case-by-case basis to determine the impact and residues of a bio-pesticide on the soil, it is necessary to supply sufficient information on the origin, the properties, the survival and the residual metabolites of the microorganism.

The absence of this data does not constitute a breach of the APV.

7.1.3 Residue Data

If the micro-organisms excrete toxins, the applicant must provide information on the identity and the methods of analysis of the toxic residue levels found in crop products, following the application of the product.

8.0 THE PACKING AND LABEL FILE

This must include:

8.1 Packing

The packing must retain all its characteristics during the storage period of the biopesticide.
The material selected must suit the physicochemical properties of the contents according to the local storage conditions, in particular to avoid any corrosion.
If the contents are to be used with very small quantities of liquid products, in particular, the provision of a measuring cap is an additional guarantee of good measurement and safety.
The unit volume of packing must, if possible, suit the unit area to be treated by the entire contents if used in one go.
Outer packaging, cardboard in particular, must be the strongest available to facilitate safe transport and storage. Transport instructions are to be printed on the packing and outer packing in accordance with international symbols adopted for air, marine, railway and road transport.

The applicant must specify:

- the nature of the packing materials;
- capacity;
- dimensions of packing in particular the diameter of the openings and the closure;
- recommendations for the disposal of out-of-date products and packing;

8.2 Sample Label

The label is intended as a means of high level communication between the supplier and the purchaser and/or the user. It must state, in clear and concise terms, the fundamental information about the safe use of the product and how to obtain effectiveness through its use.

Any request for registration must be accompanied by a sample label or a model of it. In the event that a model is submitted the manufacturer must state what measures will be employed to ensure

that the label is indelible, clearly visible and easy to read.

The model label must conform to the FAO Directives on the labelling of the pesticides.

The label must include the following data:

8.2.1 Description of the contents

- commercial name of the bio-pesticide;
- name and content of biological ingredient;
- type of pesticide (insecticide, herbicide, etc.);
- formulation;
- net quantity expressed in international measuring units

8.2.2 a very clear indication of the risk level of the product shown by a colored band around the bottom of the label and a toxicity symbol in accordance with the WHO classification of pesticides.

8.2.3 concise recommendations on safety precautions to be taken in handling and judiciously use of the bio-pesticide.

8.2.4 concise recommendations on first aid in the event of poisoning

8.2.5 recommendations on correct use of the contents: how, when and where to use the product. Specify the pests, vermin and the stages in their life cycles for treatment

8.2.6 contra indications to use. e.g. “do not treat during flowering”

8.2.7 precise details of the pre harvest interval; last treatment before harvest, consumption.

8.2.8 the name and the address of the Manufacturer (“Pesticide manufactured by »)

8.2.9 the place of manufacture of the product (Country)

8.2.10 the name and the address of the national or regional distributor if applicable ("Pesticide distributed by »)

8.2.11 registration number

8.2.12 the date of manufacture or formulation (« Manufactured »)

8.2.13 batch number

8.2.14 expiry date (« To use before »)

8.2.15 stability of the product

8.2.16 warnings

8.2.17 indication of the legal responsibilities

8.2.18 compatibility and incompatibility with other pesticides.

The manufacturer must use labels with internationally approved symbols and pictograms, in addition to written instructions and warnings. It is essential that the label is perfectly attached to the packing, if possible impermeable and perfectly legible when ever it is used. The label must be marked: "Please read the label carefully before use".

8.3 Labels for small packs

For small packs whose volume is less than or equal to 100 ml for liquids and less than or equal to 100g for solids, the applicant is required to provide an insert note. This note must contain the whole requirements of the model label.

The label on this packing will carry the following data:

8.3.1 Description of the contents:

- commercial name of the pesticide
- name and content of active ingredient
- type of pesticide e.g. insecticide, herbicide
- formulation
- net volume expressed in international measuring units

8.3.2 a very prominent indication of the risk level by a colored band around the bottom of the label in accordance with the WHO classification of pesticides

8.3.3 recommendations on correct use of the contents

8.3.4 name and the address of the Manufacturer (« Pesticide manufactured by »

8.2.5 the Registration number

8.2.6 batch number

8.2.7 date of manufacture or formulation

8.2.8 the expiry date (« Use before»)

8.2.9 the message: «Please read the label carefully before use”