

COMITÉ PERMANENT INTER-ÉTATS DE LUTTE
CONTRE LA SÉCHERESSE DANS LE SAHEL



PERMANENT INTERSTATE COMMITTEE
FOR DROUGHT CONTROL IN THE SAHEL

CILSS

SAHEL INSTITUTE
Sahelian Pesticide Comittee

Composition of Pesticides Registration Dossier in the Sahel

Revised Version
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The Composition of the Dossier for Pesticides Registration in the Sahel is organised as followed:

1. Application form for formulated product dully filled, signed and dated by the applicant;
2. A summary of all submitted **Dossier**;
3. A physico-chemical **Dossier**;
4. A biological efficacy **Dossier**;
5. An analytical **Dossier** ;
6. A toxicological **Dossier** ;
7. A **Dossier** on environnement
8. A **Dossier** on residues;
9. A **Dossier** on container and labelling;
10. An attestation or a registration certificate of the product from the country of origin if available;
11. a sample to analyse the pure active substance, active technical substance, some standards for analysis of characteristic metabolites and other components included in the residues and if possible, some samples of reference substances of impurities contained in the formulated product (upon request by the Sahelian Pesticides Committee);
12. A sample of formulated product (upon request by the Sahelian Pesticides Committee).

All the documents listed in points 1 to 10 will be submitted in two copies written in French (or otherwise in English). The samples referred in points 11 and 12 will be sent to the Sahelian Pesticides Committee only on specific request.

The following definitions will be applicable to this document:

pesticide: any substance or mixture of substances intended:

- for preventing, destroying or controlling any pests including vectors of human or animal disease unwanted species of plants or animals causing harm during or otherwise interfering with the production, processing, storage, transport or marketing of food, agricultural product, wood and woody products or animal feedstuffs;

- to be administered to animals for the control of insects, arachnids or other pests in or on their bodies;
- to be used as plant growth regulator, defoliant, desiccant, or agent for thinning or preventing the premature falling of fruit;

formulated product: pesticide *under appearance* in which it is formulated and sold.

Synonyms are commercial speciality or commercial product.

active ingredient (a..i) or substance : the biologically active part of pesticide contained in the formulation

- **pure active substance:** active substance without impurities
- **active technical substance:** active substance comprising production impurities. It is used for formulated product and others tests ;

When the formulation manufacturer is not the active substance manufacturer, a letter of original agreement will be added to the file. It will be mentioned in the agreement that the active substance developer to make reference to the data requested by the applicant.

The confidentiality arrangements of the files are described in articles 16 and 17 of the Common Regulation to CILLS countries for pesticide registration (revised version, December, 1999) whose content is:

Article 16

The data submitted by an applicant in a pesticide registration file in the Sahel cannot be used by other applicants unless the first applicant has agreed for their use.

Article 17

17.1 the applicant, while submitting the registration dossier can indicate part of the dossier which from his point of view are or comprise industrial or commercial secret. The CSP and the members states will ensure that that information considered as industrial or commercial secret are kept confidential.

17.2 Confidentiality does not apply to:

- names or content of the active substances and name of commercial product ;
- names of other substances considered to be hazardous to human and environment;
- physico-chemical data on active substance, degradation substances or eco-toxicologically important metabolites, and commercial product;
- the means used to make the substance active or the commercial product non hazardous ;
- summary of tests results aimed to establish product efficacy and product safety on humans, animals and environment.
- recommended methods and precautions to reduce risks during handling, storage, transport, or other operations;
- analytical methods of one or more active substances and their residues after application, and metabolites or other components considered important from the eco-toxicological point of view ;
- Methods of disposal of product and its container;

- ix. decontamination measures to be taken during application or in the event of accidental leakage;
- x. first aid and medical treatment to apply in case of accidental exposure or poisoning.

1.

APPLICATION FOR REGISTRATION

It must comprise:

1.1 administrative information

1.1.1 address of the applicant;

1.1.2 name and address of the owner of the trade-mark;

1.1.3 name and address of the manufacturer of the product and place of manufacture;

1.1.4 name and address of manufacturer of one or more active substances and place of manufacture;

1.2 Identity of the formulation

1.2.1 name of the formulation ;

1.2.2 composition of the formulated product : name and contents

- active substance(s) ;
- adjuvants ;
- inert materials ;

1.2.3 type of formulation (see annexe II) ;

1.2.4 WHO toxicological classification of the formulation.

1.3 Identity of the active substance (s)

1.3.1 international common name (ISO);

1.3.2 *purities*;

1.3.3 identity and proportion of additives and impurities.

1.4 Propose use

1.4.1 type of pesticide
(ex : insecticide, herbicide)

1.4.2 *field of use*
(ex. cotton leaf miners, rice weeds);

1.4.3 list of countries (with similar ecology) where formulation is registered and authorisation for use is obtained in those countries ;

The objective of the summary is to submit to the Sahilian Pesticide Committee relevant information on the product to be registered. Data submitted will allow SPC members to have overview knowledge on the product to be registered. Data will be used later to inform product users and for development Phytosanitary Index for the Sahel.

The applicant should fill the following form for this reason. He will mention only what is essential and if possible key words or phrases.

Summary form

Name and address of applicant

Commercial Name of product

<i>Product identification</i>		
Commercial Name		
Common Name of active substances		
Type of Formulation	Content of active substances	
<i>Physico-chemical properties</i>		
Melting point	Boiling point	Relative density
Vapour pressure	pH	flammability
Solubility in water		
Solubility in organic solvents		
Appearance, odour et colour		
Stability at storage		
Incompatibility		
Other important properties of product according to the applicant		
<i>Biological efficacy</i>		
Proposed use of product		
Pest Organism(s)		
Recommended application rate		
Périods and number of application		
re-entry and pre-harvest period		
<i>toxicological Informations</i>		
<i>For active technical substance</i>		
LD50 oral	LD50 dermal	LC50 inhalation
Eye irritation	Skin irritation	Sensitization
Carcinogenicity	Teratogenicity	Embryotoxicity
Neurotoxicity	Effect on reproduction	
WHO Classification		
For formulation	LD50dermal	LC50 inhalation
WHO Classification	Skin irritation	<i>Sensitization</i>
Eye Irritation		
Manifestations and symptoms of exposure		
Symptoms of poisoning		

Summary form (continues)

Name and address of applicant
Commercial Name of the product

First aid measures in case of poisoning
Therapy and antidotes
<i>Security Measures</i>
Precautions during transport
Precautions during storage
Precautions in case of fire and explosion
Precautions for surplus product and containers disposal
Recommandations for decontamination of application materials, protective clothings and equipment,
Precautions before, during, after application of product for a good use minimising risk
Effect of product on environnement
Fate and behaviour of product in soil TD50
Fate and behaviour of product in water TD50
Maximum residue limits in food
Toxicity of product to birds LD 50 oral
Toxicity of product to fish LC50
Toxicity of product to bees LD 50 oral
Toxicity of product to soil organisms LC50

Date of summary
Signature of applicant

It must comprise:

3.1 For Formulation:

3.1.1 Commercial name

3.1.2 type of formulation

3.1.3 Appearance, colour and odour

3.1.4 chemical nature of different constituents of the formulation and their quantities

Quantities are expressed in gramme per kilogramme for solid substances or in grammes per liter at 20°C for liquids:

- active substances ;
- inert materials ;
- diluants ;
- solvents ;
- emulsifiers;
- colorants ;
- different adjuvants.

3.1.5 minimum and maximum quantities of active ingredients

3.1.6 real density for liquids or mass for solids

Expressed in mass per volume unit at 20°C (ex. g/l)

3.1.7 volatility

3.1.8 flammability

- for liquids :give decomposition temperature in degree centigrade and indicate the method used;
- for solids: mention with precision if product is flammable and indicate conditions of flammability ;

NB. If product is flammable, represent it with a flame pictogram on the label

3.1.9 acidity/ alkalinity/ pH

- acidity : expressed in g/kg of H₂SO₄ ;
- alkalinity: expressed in g/kg of NaOH ;
- pH: expressed for a dilution at 1% of formulations to be diluted in water .
Mention precisely compatible limits for a good stability of product.

3.1.10 Corrosion properties

Indicate corrosive effects of product on materials to be used for containers and on materials which may be in contact with the product when used.

3.1.11 Stability during storage

Indicate the warranty period of product stability in its commercial container and precise conditions:

- Give accelerated stability test results done during 2 weeks at 54°C;
- Give also long period stability test result done during 12 weeks at 45°C, or 52 weeks at 37°C. Indicate method used.

3.1.12 Presentation on formulation incompatibilities

Indicate incompatibilities with material with which it can be in contact during storage, manipulation or application.

3.1.13 Stability of emulsion and its capacity to become emulsion again

To be determined for emulsifiable concentrates. Indicate method used.

3.1.14 Behaviour while in suspension

To determine for wettable powder and for suspension *concentrates*. Indicate method used.

3.1.15 Water content

Indicate maximum tolerable quantity and method used.

3.1.16 Solubility

To be determined for wettable powders in water. Indicate method used.

3.1.17 Fineness of particules

To be determined for granules, dusts, wettable powders and for suspensions concentrates. Indicate method used

3.1.18 fluence

To be determined for wettable powders. Indicate method used

Cinematic viscosity

Express in centistocks (or mm^2/s) at 25, 30 and 40°C, for formulations intended for ULV spray. Indicate method used

3.1.19 miscibility with hydrocarbons

Particularly with kerosene and "Solvesso" 200 (or an aromatic solvent of same characteristics) To be determined for liquids intended for ULV spray. Indicate method used

3.2 For active technical substance:

3.2.1 Appearance, colour, odour

3.2.2 real density (to determinate for liquids or mass (to determine for solids)

It is expressed mass per volume unit at 20°C (ex. g/l).

3.2.3 possible variations of the composition : minimum and maximum purity

3.2.4 melting point

3.2.5 Boiling point

3.2.6 decomposition point

3.3 For pure active substances :

3.3.1 International common name

Proposed or accepted by ISO and synonyms

3.3.2 Chemical name (IUCPA)

3.3.3 Chemical name (CA)

3.3.4 structural formula

3.3.5 molecular mass

3.3.6 Appearance, colour, odour

3.2.3 3.3.7 real density (to be determined for liquids) or mass (to be determined for solids)

It is expressed in mass per volume unit at 20°C (ex. g/l).

3.3.8 melting point

3.3.9 Boiling point

3.3.10 decomposition point

3.3.11 Vapour pressure

It is expressed in millibars.

3.3.12 indice of sulfonation and distillation characteristics

To be determined for mineral oils.

3.3.13 solubility in water and organic solvents

At a specified temperature, preferably between 20 and 25 °C interval.

3.3.14 Separation coefficient

Between water and an appropriate non miscible.

3.3.15 absorption spectrum:

- Ultra-violet ;
- visible ;
- infra-red ;
- Nuclea magnetic resonance (NMR) ;
- mass spectrometry (MS).

3.3.16 Chiminal stability :

- Hydrolysis and photolysis in relevant specified conditions ;
- Half-life according pH in *water solution* at 20°C or in a mixture of isopropanol / water in 1:1 proportion.

In case the formulation has more than one active substance, all information will be given for each active substance.

Biological Efficacy trials are conducted with formulated product. They are meant to give sufficient data to allow an assessment of level, period and uniformity of control, protection or expected effects of formulated product in comparison with appropriate reference products if available.

For these trials, it is required to give details on objectives, materials and methods used, results of trials and also references of institutions having done the trials.

The results from trials must be sufficient to allow an assessment of biological efficacy of formulation.

Biological efficacy dossier must comprise:

4.1 Reports of efficacy trials

4.1.1 Trial Requirements

In principle, a trial must have 3 treatments:

- Test product;
- Reference product ;
- untreated.

It must show efficacy effect of formulation on targeted pest organism for which application for registration is made.

Formulation must be tested in conditions where it is proved that pest organism is present at a level causing negative effects on yield, quality and so on...

For any formulation submitted for registration, applicant must present trial results conducted in one or more CILSS member countries and including depending on case, the following ecological zones.

- Sahelian zone :
- Sudanian zone:
- northern-guinean zone:

Number and types of trials are distributed as follow:

- Year one : one (1) trial on research station ;
- Year two :one (1) trial on research station and one (1) trial in field conditions ;
- Year three : one (1) trial in field conditions;
- Year four : one (1) trial in field conditions;

If the targeted pests for formulation constitute pest problem in the 3 ecological zones, trials must be done in all 3. However, if pest organisms are only a

problem in one or two zones, applicant will only present results of specific zones of pest prevalence.

With regard to grasshopper and locust control, a sahelo-saharian zone must be considered in biological efficacy assessment.

SPC can decide to give a Provisional Authorisation of sell (PAS) based on reliable results collected during two first years of sequential trials. More over, in some cases, spatial replication can replace independent trial replications in time.

For registration, the applicant must present at least four (4) years trial results conducted in one or more CILSS member countries, and covering accordingly, concerned ecological zones.

4.1.2 Reports Content

Reports on biological efficacy studies of formulation submitted for registration must be presented according to « Protocols Format PC » and Specific Protocols of CSP. In case of non availability of these protocols for a given combination (crop/organism pest), reports will comply with OEPP Directives on biological efficacy data required for pesticide registration.

4.2 A summary recalling:

4.2.1 mode of action of the active substance (s)

Ex. biochemical, physiological

4.2.2 A description of mode of action

Ex. repellent, ingestion, inhalation, contact, systemic

4.2.3 method used

4.2.3a description of field use of formulation

Ex. field crops, green house, garden, store food or animal products

4.2.3b a specification of each situation of application

Ex. for field crop: garden crop, cotton crop, cereal crop, horticultural crop.

4.2.3c a description of target organism

Eg. insects, weeds, fungus, nematodes, bacteria, with family, group, and genus.

4.2.3d a precision of doses, periods, stages and number of application

Mention application practices recommended for the product.

4.2.3e a precision on application of formulation effects on yield, quality of crops, crop products or animals.

Organoleptic, commercial quality, *aptitude* to storage, to processing and transport.

4.2.4 Use limitations

4.2.4a A use limitation indication in order to ensure safety for:

- crop ;
- animal ;
- treated *substrat* ;
- users ;
- consumers .

4.2.4b indication of period to be observed between last application of products and:

- Sowing or crop planting;
- Sowing or crop planting following in crop rotation ;
- Workers entry in treated plots ;
- Animals entry to treated zones.

4.2.5 Product compatibilities with other pesticides

4.2.6 information on *resistance appearance* or it's eventual development

Nota Bene **Provisional Authorisation for sale or Registration can be delivered for the purpose of use and pest organisms for which biological efficacy trials have been satisfactory.**

It must contain:

5.1 Formulated product

Extraction methods, identification, and dosage of active substance (s) contained in commercial product.

5.2 Residues

5.2.1 methods of extraction, identification, and dosage of residues of their metabolites as of residues definition .

5.2.2 Study methods of residues in plants and food which can be contaminated (eg: meat, fat, milk, eggs, stored food, food products).

It must contain:

- 1 a toxicity study of active substance (s);
- 2 toxicological study of formulation;
- 3 a synthetic report of observations on formulation toxicity to human ;
- 4 recommendations concerning therapy and precautions.

For these studies, it is required to give precisions on objectives, materials and methods used, results and references.

6.1 toxicity study of active technical substance(s)

Summaries of studies must be *comforted* with references and test reports mentioning explicitly methods used and *the mean* through which toxic substance was administered. Study should be conducted separately for each active substance present in the product composition

6.1.1 acute toxicity

Study will deal with the following points:

6.1.1a LD₅₀ oral

On two species of animals where one is a rodent male and female after a single dose.

6.1.1b LD₅₀ dermal

On rabbit or rat after a single dose;

6.1.1c LC₅₀ inhalation

It must be conducted when active substance:

- is a gas, but packed in pressure tank or bottle ;
- must be use as fumigant ;
- must be incorporated in a fumigant preparation ;
- is an aerosol ;
- has a vapour pressure $>1 \times 10^{-2}$ Pa and must be incorporated in preparations to be used indoors like stores or green houses;
- must be incorporated in dust preparations containing a significant proportion of particles of <50 M diameter ($>1\%$ on weight basis) ;
- must be incorporated in preparations to be applied according to procedures producing a significant part of particles or droplets of <50 M diameter ($>1\%$ on weight basis) ;

6.1.2 Skin irritation

It will be conducted on rabbit using recognised standard methods.

6.1.3 Eye irritation

It will be conducted on rabbit using recognised standard methods.

6.1.4 Sensitizing

Test must be conducted in all circumstances except where sensitizing element is known. It will be conducted using existing standard methods and results must clearly indicate if active substance is sensitizing or not.

6.1.5 Oral toxicity by administration

In all cases, give precision on species of animal used. Test duration (28 to 90 days) must allow to determine nature of secondary effects, their reversibility, and to establish dose whose effect is not observable.(DSEO).

6.1.6 Toxicity by reiterated administration by other routes

Some supplementary toxicity tests, dermal or by inhalation can be required for applicator exposure assessment.

6.1.7 Carcinogenicity

Carcinogenicity study must give at least the results of trials at each step. It is recommended that studies are carried out *in vivo* on somatic cells and *in vivo* on germinal cells. Other tests to conduct depend on results interpretation at each step.

6.1.7a In-vitro Studies

Mutagenic tests in-vitro must always be conducted (bacterial test related to genetic mutation, clastogenetical test in mammal cells and test of genetic mutation in mammal cells)

The following tests could be used :

- Ames test on *Salmonella typhimurium* and /or *Escherichia coli*, with or without activation by microsomal enzymes of hepatic cells;
- Punctual mutation test on lymphomatic cells of mices or chinese hamster with or without activation by microsomal enzymes of hepatic cells;
- test on human fibroblastes ;
- test on rat hepatocytes to see a possible synthesis of DNA without *programmation*
- test on *Saccharomyces cerevisiae* substrat on mitotic crossing and genetic conversion
- "Pol-A1" test on DNA deterioration with *Escherichia coli* mutants with or without activation by liver microsomal enzymes;
- "Rec-Assay" tests: on *Bacillus subtilis* to detect an eventual *nocive* effect on DNA.

6.1.7b In-vivo Studies (somatic cells)

Following tests could be used:

- Metaphase analysis of spinal cord of rodents ;
- Micronucleus test in rodents ;
- No *programmation* DNA synthesis;
- spot test on rats.

6.1.7c In-vivo Studies (germinal cells)

Following test could be used:

- dominant lethality test for rats ;

- test on hamster (cytogenetic study of *spermatogonies*) ;
- test on chinese hamster (study on sister chromatids exchange and chromosomic abnormalities) ;
- lethal recessive mutation test on *Drosophila melanogaster* ;

6.1.8 Chronic toxicity / Carcinogenicity

Chronic toxicity and Carcinogenicity of any active substance must be determined. If in certain exceptionnal cases it is declared that such tests are not necessary , these declarations must be fully justified.

Chronic studies conducted and reported, considered with other data and important information on active substance must be sufficient to show resulting effect from successive exposures to the active substance and must also be sufficient for negative effects from exposure to the active substance, for target organism identification, to establish the response dose, to identify changes occurred in toxicity signals and manifestations and set up a non observable effect dose.

In the same way, Carcinogenic studies result added to other data and relevant informations must be sufficient for human hazard assessment after repetitive exposures to active substance and particularly be sufficient to identify carcinogenetic effects from exposure to active substance, to determine kind and specificity of *inducted* tumours, to establish response dose, and for non genotoxic carcinogenicity, identify maximum dose with non negative effect.

6.1.9 Teratogenicity and embryotoxicity

Studies are conducted on two species of animals of which rabbit. Product is administered by oral route during a well established period of organogenesis.

6.1.10 Effects on reproduction

Studies are conducted at least on two generations, with one mating preferably on rats. Observations will also be on reproductive fertility (male and female), pre and post natal on young rats and sensitizing development during the two generations. Administered doses *repartition* will be made *in sort of* at least one dose will have an effect according to other toxicity studies.

6.1.11 Delayed neurotoxicity

Studies will give sufficient data to show if active substance can induce a delayed neurotoxicity after an acute exposure. These studies must be conducted for active substance with similar or related structure to those susceptible to induce a delayed neurotoxicity (ex: organophosphates).

6.1.12 toxicocinetic studies

Studies will be conducted on rats (single dose for two concentrations and repetitive doses of one single concentration) on adsorption, distribution and accumulation in body, biotransformation, elimination, and others of tested active substance and its metabolites.

6.1.13 Other Studies

Other studies can be required if toxicity test results or chemical structure and active substance justify it:

- studies on immunotoxicological potential
- studies of active substance(s) on different animal species already referred to;
- Studies on eye abnormalities (*cataract*) conducted on duckling ;
- Studies on cholinesterase inhibition (plasma, erythrocytes, brain) ;
- Studies on toxicity of isomers, solvents, inert substance, adjuvants, impurities and other derivative products contained in formulation ;

6.2 Toxicity study on formulated product

Toxicity studies should allow to indicate the classification on formulated product according to WHO.

Studies summary must be supported with references, tests report mentioning clearly methods used and material used to administer the toxic substance.

6.2.1 Acute toxicity

Study will have following components :

6.2.1a Oral LD₅₀

On rat or male and female mice after a single dose administration.

6.2.1b Dermal LD₅₀

On rabbit or rat after a single dose application.

6.2.1c LC₅₀ by inhalation

For some formulations after a single exposure of animal according to recognised standard methods. The preferred animal to be used for this test is rat. This test can be conducted on any animal recorded in the recognised standard methods

Formulations for which LC₅₀ is required are:

- A gas, packed in pressure container;
- A fumigant preparation ;
- An aerosol ;
- A dust with significant proportion of particles of diameter <50 M (>1% based on weight)
- a formulation sprayed by plane in case inhalation exposure is relevant ;
- a formulation due to contain active substance whose vapour pressure is <1x10⁻² Pa and must be used indoor such as stores and green houses ;
- a formulation due to be applied according to a process producing significant proportion of particles or droplets of diameter <50 M (>1% on weight basis).

6.2.2 Skin Irritation

Study will be conducted on rabbit according to recognised standard methods. This test will not be necessary if *corrositivity* of product is established.

6.2.3 Eye irritation

Study will be conducted on rabbit according to recognised standard methods. This test will not be necessary if product give a strong skin irritation.

6.2.4 Sensitizing

Study will be conducted on rabbit according to recognised standard methods and results must indicate if product is allergic or not.

6.2.5 Data relative on exposure

These are data dealing with workers protection against product exposure hazards

6.2.5a Estimation and measure of operator exposure

Exposure estimation of operator, under proposed conditions of application must be done by using an appropriate calculation model. Estimation will be done knowing operator does not use any individual protective equipment and another estimation where operator uses an efficient protective equipment available on the market.

Effective data on exposure on main routes of exposure must be given if risk assessment indicates that a risk limit value on health is too high.

6.2.5.b Exposure estimation and *measure* of people present

People present can be exposed during product application. Exposure estimation of people present must be done for each application method of product. Estimation will be done when people don't wear any individual protective equipment. Measures against exposure for people present can be required when estimation reveal a serious situation.

6.2.5c Exposure estimation and measure for workers

Workers can be exposed after product application by entering in crop fields or indoors treated or by manipulating plants or parts of plants on which product residues persist.

Sufficient back ground data must be given for selection of appropriate protective *disposition* including entrance and non entrance to treated places.

In case skin exposure is the main route of exposure, a skin adsorption test can if not already done, be a good replacement to improve estimation.

6.2.5d Skin adsorption

It must be done when skin exposure is a significant route of exposure and when risk assessment indicates that a risk limit value on health is too high.

6.2.5e Available toxicological data concerning non active substances

A guideline for specific information system related to non active substances which can be hazardous will be set up. The applicant will submit maximum information available on the subject.

6.3 Synthesis of observations on toxicity to human of formulated product

Studies will mention if available, synthesis of observations done on product toxicity to humans, taking into account health dossier of workers manipulating the product, direct clinic observation in case of intended or accidental poisoning and cases of hypersensitisation. If data are available, give metabolite nature for human. Estimation of *hazardous* dose will be made for humans based on all these data.

Indication will be on:

- Signal and symptoms of poisoning for human ;
- Emergency measures and warning in case of emergency and or sickness ;
- Therapy and antidote and emergency treatment ;
- Security measures for storage and transport;
- Decontamination process.

- **6.4 Recommendations concerning therapy and precautions**

Recommendations will have following elements:

6.4.1 Diagnosis and symptoms of poisoning

6.4.2 first aid measures in case of poisoning and warning

6.4.3 therapy and antidotes

Description of treatment by medical doctor, antidotes and mode of use and warning will be made;

6.4.4 Security measures

6.4.4a Precautions during transport;

6.4.4b Precautions during storage;

6.4.4c Precautions in case of fire;

6.4.4d Precautions during handling of container;

6.4.4e Precautions during leakage or accidental leak;

6.4.4f Recommendations for decontamination of material, protective clothing and equipment use for application

6.4.4g Instructions and or proposal to be found on container and type of risk. Precautions before, during and after application of pesticides in minimizing risk

7.

ENVIRONNEMENTAL DOSSIER

It must contain:

- 1 studies on behaviour and fate of pesticide in the environment
- 2 studies on the effects of pesticide on non target organisms.

These studies take a lot of space and pages, so applicant will present only detailed summaries (study objective, material and methods used, results obtained and study references) so to allow good comprehension. Supplementary reports of some studies can however be requested by SPC.

The requirements to conduct environmental studies depend on many factors: intended use, mode of application of product, possible exposure of part of the environment or non target organisms and results of studies conducted before. Some fundamental studies will always be requested and further studies will be requested if risk assessments from fundamental studies indicate the necessity.

Tests must be conducted according to protocols or internationally recognised directives, like those of *OCDE*, *UE*, or *SETAC*. *For each study, reference will be made (in the dossier) to protocols and/or to applied directives.*

Studies required in this chapter comprise the minimum requirement for APV and registration. However, applicant can give information and /or supplementary study results describing environmental effects of product submitted for registration.

7.1 Behavior and fate of pesticide in environment

7.1.1 Fate and behaviour in soil

7.1.1a Degradation routes in soil

Laboratoy studies

Laboratory tests must be done to identify processes involve (chemical and biological degradation), relevant elements of products present in the soil (active substance, metabolites, products derived from reactions and extractible and non extractible residues. Tests must be conducted at least on a representative soil of the Sahel. Results obtained must be presented as a diagram.

Description of anaerobic degradation route is only required in case of anaerobic conditions (ex: treatment of surface water, irrigation zones or drainage...)

Photodegration route must always be described unless possibility of product contamination on soil surface is excluded(ex : treatment of indoors, treatment of food store house, domestic use of pesticide and veterinary products).

Tests are conducted with actual active technical substance. Tests can also be conducted with exact formulation to be registered if extrapolation of results from active substance is not possible (ex: for formulation with slow *liberation*)

Field tests

Field tests are not generally required.

7.1.1b Degradation rate in the soil

Laboratoy tests

Aerobic degradation rate in soil must be estimated in 3 types of soil of the Sahel (fine sand, *limon sand with limon* (2-5% organic matter) and clay soil. Tests will lead to TD50 determination and TD50 for each type of soil

Degradation rate must always be estimated excepted when possibility of soil contamination is excluded (ex. Indoors treatment, food storage treatment, domestic use and veterinary products).

Description of anaerobic degradation route is only required in anerobic conditions (ex.treatment of surface water, irrigation zones, or drainage). Tets is conducted on same soil for degradation study(see 7.1.1.a).

Tests are conducted with active technical substance. Tests can also be conducted with the actual formulation to be registered if extrapolation of results from active substance is not possible (ex: for formulation with slow liberation)

Standard test are done at 20°C and are acceptable. However, since degradation speed can be higher in Sahel because of hot temperatures, supplemental tests at 25-30° are suggested for a better assessment of temperature effect on pesticide degradation.

Field study

Dissipation

Dissipation study in soil TD₅₀, TD₉₀ is always required unless possibility of soil contamination is excluded (ex. Indoors treatment, food storage treatment, domestic use, and veterinary products).

Tests are conducted with active technical substance. Tests can also be conducted with exact formulation to be registered if extrapolation of results from active substance is not possible (ex: for formulation with slow liberation)

Residues

A study can be required to determine residue content at harvesting period, planting or establishment of the subsequent crop. It is generally required when TD50 (lab) is superior than 1/3 period from application to harvest and when residue adsorption by crop is possible.

Tests are conducted with technical active substance in Sahel or in similar environmental conditions. Tests can also be conducted with exact formulation to be registered if extrapolation of results from active substance is not possible (ex: for formulation with slow liberation)

Accumulation

Accumulation test of active substance and metabolites in soil can be required if the product has ($TD_{90} > 12$ months) and repetitions are scheduled.

Tests are conducted with technical active substance in the sahel or in similar environmental conditions. Tests can also be conducted with exact formulation to be registered if results extrapolation from active substance is not possible (ex: for formulation with slow liberation)

7.1.1c Adsorption / desorption in soil

Laboratory studies

Data submitted must be sufficient to determine adsorption coefficient of active substance, metabolites and degradation products and reactions, having toxicological and environmental effects or representing more than 10% of original active substance. Assessment of importance of related residues must done.

Study must be conducted in at least 3 representative types of soil *for the Sahel*.

Adsorption and desorption effect must be estimated unless possibility of soil contamination is excluded (eg : treatment of indoors, treatment of food store house, domestic use of pesticide and veterinary products).

Tests are conducted with active technical substance.

Field Studies

Field studies are not generally required.

7.1.1d Mobility in soil

Laboratory studies

Data submitted should be sufficient for assessment of mobility and active lixiviation of active substance and if possible metabolites from degradation and reaction products with toxicological and environmental effects or representing more than 10% of original active substance.

Study is conducted in at least 3 types of soil representative for the sahel.

Soil mobility must always be estimated unless if it is possible to do it from adsorption /desorption data or if possibility of soil contamination is excluded (eg: treatment of indoors, treatment of food stores, domestic use of pesticide and veterinary products).

Tests are conducted with active technical substance. However, tests must be also done with exact formulation to be registered when extrapolation of results from active substance is not possible (ex: for formulation with slow liberation)

Field studies

Mobility test can be required if it is not possible to extrapolate above laboratory results (ex: for formulation with slow liberation).

Study is done with formulated product in Sahel or in similar environmental conditions.

7.1.1e Estimation of expected concentrations in soil

Estimation of expected concentration in soil must be submitted. It must correspond at a single application of the product, at highest dose for which registration is applied. Moreover, estimation of concentration is done for a maximum number of applications at highest dose during a cropping season.

Estimations are done for each type of soil tested. Estimations also comprise beside active substance concentration, metabolites and reaction product from degradation and having a toxicological and environmental effects.

7.1.2 Fate and behaviour in water

7.1.2a Degradation route in water

Laboratory studies

laboratory studies must be conducted to identify relevant components of product present in water, in sediments and suspension matters (active substance, metabolites, reaction products...) and also processes put in place (hydrolysis, photochemical and biological degradation). Results obtained must be presented in a diagram.

Degradation routes in aquatic environment must always be described except if water contamination is excluded (eg : indoor treatment, treatment of food stores, domestic use of pesticide and veterinary products).

Tests are conducted with active technical substance.

Field studies

Field studies are not generally required.

7.1.2b Degradation rate in aquatic environment

Laboratory studies

Laboratory studies must be done in order to estimate rate of degradation of active substance. Tests on rate of hydrolysis, photochemical and biological degradation must be done.

Rate of degradation in aquatic environment must always be described except if water contamination is excluded (ex: indoor treatment, treatment of food stores and domestic use of pesticide and veterinary products).

Tests are conducted with active technical substance

Field studies

Field studies can be required if extrapolation of results from above laboratory results cannot be made. They will be done with formulated product in the Sahel or in similar environmental conditions.

7.1.2c Estimation of expected concentrations

Estimations of expected concentrations in surface water and ground water must be submitted. They must meet highest application dose and the maximum numbers of application for which registration is applied.

After concentration of active substance, estimations must comprise concentration of metabolites, reaction and degradation products having toxicological and environmental effect.

7.1.3 Fate and behavior in air

Nowadays, there are no specific requirements for assessment of fate and behaviour of pesticide in the air.

7.1.4 Définition of residue

It is important to propose a definition of residue in soil, taking into account their levels and toxicological and environmental effects. Definition of residue will help in monitoring environment and toxicovigilance.

7.2 Effects of pesticide on non target organisms

7.2.1 Toxicity to birds

7.2.1a Acute oral Toxicity

Of active technical substance

The acute oral LD₅₀ of active technical substance will be determined for at least two species of birds. The appropriate species are pigeon, japanese quail, duck, chaffinch *Bengalius*. As sahelian species, *the silver beak (Lonchura malabarica)* is acceptable. Tested species will be selected according to their food eating behaviour and risk exposure. Studies are required for all types of products, except for products intended specifically for domestic use (eg: bomb aerosol, coils) and products used for indoors and food stores).

Of formulation

An acute oral toxicity study with formulated product is required if TERA¹ or TERst² of active substance goes from 10 to 100. Moreover, a test study with formulated product is required if product contains many active substances and that toxicity results on mammals show that formulation is more toxic than the expected because of separate additive toxicity of active substances.

Study is done with the most sensitive shown during active substances study.

7.2.1b Starvation / acute oral toxicity

Appetence study will be conducted with granules formulation, pastilles, baits and treated seeds. Moreover, study must be done (with appropriate food) for all formulations that have TERA < 10.

In case of ingestion, acute oral LD₅₀ will be determined for at least one bird species. Appropriate type of birds can be provided from the list 7.2.1a, considering their dietary behaviour and the treated substance.

Study will be conducted with formulated product.

7.2.1c Sub acute dietary Toxicity

Of active technical substance

Acute LC₅₀ and CSEO will be determined for at least one bird species. Selected species are in considered according to dietary behaviour and exposure risk.

¹TERa (acute ratio toxicity / exposure) = LD₅₀ (mg m.a./kg body weight) / ETE (estimated theoretical exposure) (mg .a.i /kg body weight).

²TERst (acute ratio dietary toxicity exposure) = LC₅₀ (mg m.a./kg diet) / ETE (estimated theoretical exposure (mg a.i./kg diet).

Species mentioned in 7.2.1a are generally accepted for study.

Studies are required for all type of products, except for products intended specially for domestic use (ex: bomb aerosol, coils) and products used for indoors and stored food).

Dietary toxicity is done with active technical substance

Of formulation

A study test with formulated product is required if product comprises many active substances and that toxicity results on mammals show that formulation is more toxic than the expected because of separate additive toxicity of active substances.

In case of consumption of formulation in a starvation test (see 7.2.1b), acute toxicity is required for granules, *pastilles*, baits or treated seeds.

7.2.1d Sub-chronic Toxicity and / or reproductive toxicity

Will be necessary if there is long term exposure risk because of

- method and frequency of application of the formulation;
- if there is indication of accumulation of the substance;
- if damaging effects are expected considering results of studies done with similar products or acute and chronic toxicity of active substance;
- if predictions cannot be made on long term effects of active substance, due to lack of knowledge on relation between chemical structure and its toxicity;

Subchronic and / or reproductive toxicity studies are done with active substance technical

7.2.1e Indoor or field studies

Studies must allow to assess nature and impact of product application risk in real conditions of the Sahel.

When TERa and TERst >100 and when Sub-chronic / or reproductive toxicity studies with active substance did not reveal any risk, it is not necessary to do indoor or field Studies.

For any different case, specialist opinion is requested to make a decision whether or not to conduct indoor or field tests in the Sahel.

As an indication, SPC will normally require studies when:

- TERa and TERst <10 or TERIt³ <5 (unless assessment is possible from starvation study);
- For products intended for aerial spray or ground spray on large scale (ex: locust control, anti vectorial control), unless it can be concluded from the above studies the risk on birds is negligible.

Indoors and field studies are done with formulated product.

Results obtained in other ecological regions and/ or under similar climate can replace in some cases a test to be conducted in Sahel.

7.2.2 Toxicity on reptiles

NOTE : *Knowing that standard protocols for such studies are not available, laboratory data on reptiles will not be required.*

7.2.2a Acute toxicity

LD₅₀ oral (and eventually dermal) will be determined for at least one reptile.

Studies will be required for soil, field, ground, aerial and water treatment.

7.2.2b Dietary Toxicity

Acute Dietary LC₅₀ will be determined for at least one species of reptile..

7.2.2c Sub-chronic and / or reproductive toxicity

Sub-chronic and / or reproductive toxicity data will be necessary when:

- There is long term exposure risks because of method and number of application of formulation.
- if there is indication of accumulation of substance;
- if damaging effects are expected considering results of studies done with similar products or acute and chronic toxicity of active substance;
- if predictions cannot be made on long term effects of active substance, due to lack of knowledge on relation between chemical structure and its toxicity;

Studies could be required for products intended for soil, open field, ground, aerial and water treatment.

³ **TERIt** (ratio dietary toxicity long-term/exposure) = CSEO (mg ai./kg food) / ETE (estimated theoretic exposure) (mg .ai./kg food).

7.2.3 Other Studies on terrestrial vertebrates

Studies on secondary poisoning, tests with other species of vertebrates or other necessary studies on risk assessment of product for vertebrates can be requested by SPC, to deliver PAS or registration certification

7.2.4 Toxicity on fish

7.2.4a Acute Toxicity

Of active substance

LC₅₀ after 96 hours will be determined for at least two appropriate species of fish. Recommended species by standard methodologies will be used of which at least from tropical climate (ex: catfish, carp). The sahelian species *Oreochromis niloticus* (“tilapia”) can also be used.

Studies must be conducted for the following type of use of pesticides: Treatment of soil, open field, ground, aerial, outdoor domestic use and water treatments or use of rodenticides.

Studies can be required for any other intended use of product if exposure to water is possible.

Test will be done with active technical substance.

Of formulation

Studies in laboratory on fish must be conducted with formulation to be registered if one cannot predict pesticide risk from studies with active substance. This can be the case for formulations containing more than one active substance or formulations containing substances which can increase toxicity of active substance (ex: some solvents, dispersants ...)

Studies with formulation must always be conducted for products intended to be applied directly in surface water. Those studies must be conducted if there is a big risk of surface water contamination.

If one of the three groups of organisms evaluated in 7.2.4 to 7.2.6 is much more sensitive than others to the active substance (*factor 100* or above), studies with formulation must be done only with the most sensitive species. Otherwise, study must be conducted with at least one species of each group of aquatic organisms (fish, invertebrates and algae).

7.2.4b Chronic Toxicity

Study is done in order to determine EC50 and CSEO for at least one appropriate species of fish.

A chronic study with one appropriate species of fish is required :

- for any product applied directly on water, near to surface water (ex : aquatic herbicides, treatment in rice field with water, antivectorial treatment ‘mosquitos, simuliidae’, antilocust control) if TD50>2days ;
- if there is indication of accumulation of active substance;
- If short-term toxicity study results imply such a study is necessary.

Test will be done with active technical substance.

7.2.4c Bio-accumulation

When it is suspected that a product is bioaccumulable (Log P_{ow} >3) a bioaccumulation study on fish is required when formulated product is intended to be used for the following purposes: soil treatment, open field treatment (on ground or aerial), water treatment and use of rodenticides.

Studies can be requested for other treatment purposes if exposure to water is possible.

Given this study results, supplementary tests can be required on bioaccumulation.

Test will be done with active technical substance.

7.2.5 Toxicity to aquatic invertebrates

7.2.5a Acute Toxicity

Of active substance

Acute EC50 determination for at least one appropriate organism is required. Test can be done with standard species *Daphnia magna* or one of sahelian species *Caridina africana* (crustacea), *Streptocephalus sudanicus* (crustacea) or *Anisops sardeus* (aquatic insect).

The studies are obligatory for the following purposes of use of pesticides: treatment of ground, treatment in open field (terrestrial or air), outdoor domestic use, water treatment, rodenticides. They can be required for any other field of application if the exposure of water with the product is possible.

In the case of direct exposure of water with the pesticide, a study on at least a species of each of the three groups of the following invertebrates is required: aquatic insects, aquatic mollusc..

Test will be done with active technical substance

Of formulation

Studies in laboratory on fish must be conducted with formulation to be registered if one cannot predict pesticide risk from studies with active substance. This can be the case for formulations containing more than one active substance or formulations containing substances which can increase toxicity of active substance (ex: some solvents, *dispersants* ...)

The studies with the formulation are always required for products intended to be applied directly in water. In this case, a study on at least one species from the following three groups of invertebrates is required: aquatic insects, aquatic crustaceans, and aquatic molluscs. These studies can also be required if there is a great risk of contamination of surface water.

If one of the three groups of organisms evaluated into 7.2.4 to 7.2.6 is much more sensitive than the others to the active substance (a *factor of 100*, or more), the studies with the formulation must be only done with the most sensitive species. If necessary, the studies are made with at least one species of each of the three groups of aquatic organisms (fish, invertebrate, algae).

7.2.5b Chronic Toxicity

Determine EC50 and CSEO for at least one appropriate aquatic invertebrate species preferably *Daphnia magna*.

After development of the standard protocols for the chronic tests, the study can also be carried out with one sahelian species like Caridina africana or Streptocephalus sudanicus).

A chronic study with a suitable species of aquatic invertebrate is required for any product applied directly on water, or very near to surface water, (e.g. aquatic herbicides, treatment of rice in water, some anti-vectorial treatments {e.g. mosquitos, Simuliidae}, anti-locust treatment), if TD50 > 2 days; if short term toxicity studies results indicates such study is necessary.

Test will be done with active technical substance

7.2.6 Toxicity on aquatic algae

7.2.6a Effects on growth

Of active substance

The determination of the EC50 and the CSEO for the growth of the algae is required. In general the study is done with a green alga (for example *Scenedesmus subspicatus* or *Selenastrum capricornutum*).

The studies are obligatory for the following purposes of use of pesticides: treatment of ground, treatment in open field (terrestrial or aerial), water, outdoor domestic treatments and use of rodenticides. They can be required for any other field of application if the exposure of water with the product is possible

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

Test will be done with active technical substance

Of the formulation

Laboratory studies on fish must be conducted with formulation to be registered if one cannot predict pesticide risk from studies with active substance. This can be the case for formulations containing more than one active substance or formulations containing substances which can increase the toxicity of active substance (eg: some solvents, *dispersants* ...)

The studies with the formulation are always required for products intended use is direct application on water. These studies can also be required if there is a great risk of contamination of surface water.

If one of the three groups of organisms evaluated into 7.2.4 to 7.2.6 is much more sensitive than the others to the active substance (a factor of 100, or more), the studies with the formulation must be only done with the most sensitive species. If necessary, the studies are conducted with at least one species of each of the three groups of aquatic organisms (fish, invertebrate, algae).

7.2.7 Other studies on aquatic organisms

Studies with other species of aquatic organisms, with juvenile fish, microcosm / mesocosm tests, or field studies, can be required by the SPC, either for the delivery of a PAS, or for registration. Expert opinion is generally necessary to determine the need.

The studies which will be normally required by the SPC are:

For any herbicide studies on aquatic plants will be required;

In case of real risk of contamination of estuaries or marine zones studies on aquatic estuarine species will be required;

In case of real risk of persistence of the product in the sediments, studies on the soil living organism will be required.

7.2.8 Toxicity on bees

7.2.8a Acute Toxicity

At least a test of acute oral toxicity and a test of acute toxicity by contact for the bees are required. The study is required for all the purposes of application, except if the exposure of the bees can be excluded. This is the case for seed and soil treatments with non-systemic products, the treatment of indoor spaces, stored food products, indoor domestic, rodenticides and veterinary use.

The study is generally carried out with the formulated product, but the one from active substance technical can also be accepted. In case of formulation containing more than one active substance, the study must always be made with the formulated product.

7.2.8b Residual toxicity

A study in laboratory or in cages on the toxicity of the residues on crops can be required when the QHC > 50. Expert opinion is necessary to decide a need for such evaluation.

Test will be done with formulation.

7.2.8c Toxicity on larva

A food test on the hives of bees can be necessary in order to evaluate the toxicity of the product on larvae.

This study is always required when the active substance can act like insects growth regulator.

The study is generally carried out with the formulated product, but the one from active technical substance can also be accepted. In case of formulation containing more than one active substance, the study must always be made with the formulated product.

7.2.8d Tests in cage, *tunnel* or field

Tests in cage, tunnel or field can be required in order to evaluate the risk of the product under relatively natural conditions.

This study can be required when the QHC and the QHO⁴ > 50. Expert opinion is necessary to decide a need for such evaluation.

Test will be done with the formulation.

7.2.9 Toxicity on beneficial organisms

Data on toxicity of the product will be required on 4 species of parasitoids or pest predators. In principle, tests are carried out on a species representing each of the four large groups of beneficial organism: predators living on/in the soil, predator living on plants, predator on arachnids and parasitoids. At least one of these species must be sahelian; the other data can come from moderate or tropical climate.

If the product is intended to be used in IPM in the Sahel, all tests must be carried out with sahelian species.

The studies are required for all fields of application, except if the exposure of beneficial organism is excluded (e.g. treatment of seeds with non-systemic product, rodenticides, indoor domestic and veterinary use).

The study is generally carried out with the formulated product, but if done with active technical substance it can also be accepted. In the event of the formulation containing more than one active substance, the study must always be made with the formulated product.

7.2.10 Toxicity on soil invertebrates

7.2.10a Acute Toxicity

⁴ QHO (Oral hazard quotient) = application dose (kg/ha) /acute oral LD₅₀ (µg a.i./bees)

The determination of the acute toxicity of the product for earth worms or non target termites can be necessary to evaluate the risk of the pesticide on soil organisms.

For products intended to be used mainly in semi - arid zones (e.g. locust control), the study should be done with termites. Tests protocols of tests currently exist for *Psammotermes* and *Odontotermes*. For products intended to be used in the wet zones, the study should be done with the earthworm. The species from moderate climate are acceptable in this case.

The study is required for all purposes of application, except if the exposure of soil invertebrates is excluded. This is the case for indoor and stored food products treatment, indoor domestic use, rodenticides and veterinary use.

The studies are made with the active technical substance or with the formulation. They are required with the formulation when it is impossible to extrapolate from results obtained with the active substance (e.g. for formulations with slow release and those containing more than one active substance).

7.2.10b Other Studies

Other studies with soil invertebrates (sub-lethal effects or field tests) can be required when the results of the tests of acute toxicity indicate a long term risk. This can be the case for the relatively persistent products (e.g. TD90 > 90 days).

7.2.11 Toxicity on non target soil micro-organismes

The studies are carried out in order to evaluate the effect of pesticide on soil respiration and nitrogen conversion. In case of pesticides intended for soil sterilization, the studies must have objective to determine rates of soil recovery after treatment. The study is required for all purposes of application, except if the exposure of **micro-organisms** is excluded. This is case for indoor and stored food products treatment, indoor domestic use, rodenticides and veterinary use.

Test will be done with active substance or formulation.

It must contain:

1. Studies relative to metabolism and residues transformation
2. Studies relative to content of residues
3. Studies relative to consumer exposure

8.1 Studies relative to metabolism and residue transformation

8.1.1 Residue metabolism in plants

The studies must relate to crop or crop groups of on which the pesticide to be registered will be used in the Sahel. They can be carried out in the Sahel, but the data coming from other climatic zones are also acceptable, provided that the categories of studied plants are the same or very similar to those which will be sprayed in the Sahel.

The studies of the metabolism in the plant are required on a minimum of three crops, except if it can be justified that a different metabolism is less probable, or if the registration of the pesticide is applied for less than three crops.

In case registration is applied for diverse categories of crops, studies must be representative as of these categories. Five principal categories of crop are recognized for this purpose:

- root and tubers;
- leafy vegetables;
- fruits;
- leguminous plants and oily plant;
- Cereals.

If the results show that the metabolism of the pesticide can be variable, studies on more than three categories of plants can be required.

Studies are carried out with the active technical substance.

Studies are always required, except if it is possible to prove that no residue remains on the crops or agricultural products intended for human or animal consumption. However, the studies are not required if it can be proven that crop to be treated is not for human or animal consumption.

The SPC encourages presentation of studies summaries on metabolism in the plants already evaluated and accepted by the international agencies like the “WHO/FAO Joint Meeting on Pesticide Residues (JMPR)” or the “Commission of the European Communities”.

8.1.2 Residue studies on metabolism in livestock

These studies are carried out with ruminants in lactation (e.g. the cow, the goat or the camel) or poultry in period of egg-laying.

They can be carried out in the Sahel, but data coming from other climatic zones are also acceptable, provided that the categories of studied animals are the same or very similar to those which will be exposed to the pesticide in the Sahel.

Test will be done with active technical substance.

These studies must be carried out if the pesticide is applied directly to the animals or houses sheltering them. Moreover, they are required if significant residues are found in animal feed. A residue of pesticide is considered to be significant when its level of concentration is higher than 1 mg/kg in animal feed.

The SPC encourages presentation of summaries of studies on metabolism in the plants already evaluated and accepted by the international agencies like the “WHO/FAO Joint Meeting on Pesticide Residues (JMPR)” or the “Commission of the European Communities”.

8.1.3 Studies on industrial and/or domestic food processing

The studies on processing must simulate commercial or domestic practices as much as possible. In general, a study is necessary for at least each group of agricultural products. However, if the agricultural product represents a large portion of diet, several studies may be required.

Studies are not necessary in the following cases:

- if any significant residue is found in the plant or the agricultural product; except if acute toxicity is high or the ADI is low. A pesticide residue is considered to be significant when its level of concentration is higher than 0.1 mg/kg in food intended for human consumption;
- if the agricultural product is consumed fresh.

Test will be done with formulated product.

8.2 Studies relative to residue content

8.2.1 Estimation of maximum content of residue in plants

Tests must be carried out according to recommended or proposed good agricultural practices, meaning respect of dose, number and methods of treatment identical or very similar to those proposed for registration. Minimum information which must appear for each test is those required by FAO as mentioned in *Codex Alimentarius*.

Studies must be done on crops or groups of crops on which the pesticide to be registered will be used in the Sahel. They can be carried out in the Sahel, but the data from other similar climatic zones are also acceptable, provided that the categories of studied plants are the same or very similar to those which will be treated in the Sahel.

The studies must always be conducted when the pesticide is intended to be applied to crops or crop products used like food or animal feed or if residues contained in soil or other substrates can be absorbed by these plants.

Results of a minimum of 6 relevant tests must be provided for each group of crop for which registration is applied. For the agricultural product intended for export, a minimum of 3 tests must always be carried out in the Sahel.

The list of the export agricultural products is available with the Permanent Secretary of the SPC

The studies are carried out with the formulated product.

The SPC encourages presentation of the summaries of studies on metabolism in agricultural products or food already evaluated and accepted by the international agencies like the “WHO/FAO Joint Meeting on Pesticide Residues (JMPR)” or the “Commission of the European Communities”.

8.2.2 Residue Studies on subsequent Crops in the rotation

For the beginning, a theoretical estimate of residue content of crop to be evaluated as the subsequent crop in rotation is sufficient. If the probability to find residues in the following crop cannot be excluded, metabolism and distribution studies may be required, eventually in field.

If it is shown that significant concentrations of residues (> 10% of the quantity of active substance applied) remain in the soil or in the crop products (e.g. straw) up to sowing period or planting of the **subsequent** crop, it is then necessary to study the residues in this **subsequent** crop.

8.2.3 Dictionary of the maximum residue limit

A list of Maximum Residue Limit (MRL) already set by other organisations or in other countries must be provided for the crop and agricultural products concerned with the application for registration or eventually for similar agricultural products. The MRL of the *Codex Alimentarius* and European Commission must always be given.

A specific MRL for the Sahel can be proposed, with detailed justifications

8.3 Studies relative to Consumer exposure

8.3.1 Withdrawal periods

Proposed Withdrawal periods between the last treatment and harvest or between the last application of product and the consumption of stored food products must always be provided. They must be entirely justified.

8.3.2 Estimation of Exposure

An estimation of potential or real exposure to residues caused by food diet or other causes must be provided. It is based on a realistic forecast of ingestion according to food diet or animal feed.

9. CONTAINER AND PACKAGING DOSSIER

It must contain:

9.1 Container

Container must preserve all its qualities during storage period of the pesticide. The selected material must be perfectly adapted to the physicochemical properties of contained product according to the local conditions of storage, in particular to avoid any corrosion.

If the contents were to be used with very low dose for liquid products in particular, presence of measuring cap is an additional guarantee of good dosage and safety use.

The unit volume of container must, if possible, be adapted to unit of area to be sprayed, for a total use of product in container at once.

Over containers, particularly paperboards must be as strong as possible to facilitate transport and storage. Transport notices are put on *over* containers and large containers in compliance with the international symbols adopted for air, sea, railway and roads.

The applicant must specify:

- the nature of *constitutive* materials of container;
- Container capacity;
- Container size: in particular the diameter of the openings and the closing method;
- Recommendations for disposal of obsolete products and containers;

9.2 Type of label

Label is designed like a mean to achieve a good level of communication between the provider and buyer and or the user. It must comprise, in clear and concise words, fundamental information for safe use of product with efficiency guarantee during product life time.

All registration applications must have an original label model attached to them. Label information must be written by the manufacturer in indelible characters, clearly visible and easy to read.

The model label will have to comply with FAO Directives for pesticide good labelling procedures.

Label must contain the following information:

9.2.1 A description of product content:

9.2.1a commercial name of the pesticide

9.2.1b name and content of active substances

9.2.1c type of pesticide
(insecticide, herbicide,)

9.2.1d type of formulation

9.2.1e net content expressed in international measuring units

9.2.2 very visible indication of hazard

By a colored band at the bottom of the label and a toxicity symbol in compliance with WHO pesticide classification.

9.2.3 Concise indications for precautions to observe

For a judicious handling and use of the pesticide.

9.2.4 Concise indications first aid in case of poisoning

9.2.5 Indications on use of product:

9.2.5a How, when, where to use the product

Precise crop, pest organisms and period of treatment

9.2.5b Warning phrases

Eg. « *do not spray during flowering period* »

9.2.5c Precisions on re-entry or pre-harvest interval

Last treatment before harvest, before consumption.

9.2.6 name and address of manufacturer

(« *Pesticide formulated by* »)

9.2.7 Place of product formulation (country)

9.2.8 Name and address of national or regional distributor agent

(« *Pesticide distributed by* »)

9.2.9 Registration number (« *Registration N°* »)

9.2.10 Formulation date (« *Formulated the* »)

9.2.11 Batch number

9.2.12 Expiry date (“to use before”)

9.2.13 Stability conditions

9.2.14 Warning statements

9.2.15 Indication of legal responsibilities

The manufacturer must use labels which carry as much as possible of the symbols and pictograms approved internationally, in addition to the written instructions and warning statements.

It is essential that label be perfectly adherent to container, if possible impermeable and perfectly readable, whatever the period of use.

It must be marked on the label: "Before using product, read the label"

9.3 Labels for small packages

Labels for small **packages** whose size is less or equal to 100 ml for the liquids and less or equal to 100 g for solids), the applicant must submit a leaflet. This leaflet must contain all requirements of a label leaflet

The label on this packing will carry the following data:

9.3.1 A description of product content:

- 9.3.1a pesticide commercial name**
- 9.3.1b name and content of active substances**
- 9.3.1c type of pesticide**
(Insecticide, herbicide ...)
- 9.3.1d type of formulation**
- 9.2.1e net content expressed in international measuring units**

9.2.4 Very visible indication of hazard

By a colored band down bellow on the label and a toxicity symbol in compliance with WHO pesticide classification.

9.3.3 Indications on appropriate use of product

9.3.4 Name and address of Manufacturer (« *Pesticide formulated by* »)

9.3.5 Registration number (« *Registration N°* »)

9.3.6 batch number

9.3.7 formulation date (« *Formulated the* »)

9.3.8 expiry date (“to use before”)

9.3.9 Inscription on label: "Before using product, read the label"