PERMANENT INTERSTATE COMMITTEE FOR DROUGHT CONTROL IN THE SAHEL (CILSS)

COMMON REGULATION FOR THE REGISTRATION OF PESTICIDES IN CILSS MEMBER STATES

Revised version

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MALI – MAURITANIA – NIGER – SENEGAL

INTRODUCTION

Agricultural intensification in the SAHEL, required to achieve food security for its populations, may increase the use of chemical inputs such as pesticides. To ensure that pesticides used in the different countries in the Sahel are effective, of suitable quality and of low hazard to man and the environment, the CILSS Member States signed in 1992 the "Common Regulation for the Registration of Pesticides in CILSS Member States''.

The main objective of this Common Regulation was to combine the expertise on pesticide evaluation and management of all CILSS Member States for pesticides registration. The Sahelian Pesticide Committee (CSP[1]), the common pesticide registration body, became operational in 1994. It assesses registration dossiers submitted by the agro-chemical industry and grants sales permits valid for all its Member States.

During the years that followed the signature of the Common Regulation, CILSS Member States have modified their national phytosanitary legislation, or are in the process of doing so, in order to take into account pesticide registration by the CSP as well as the implementation of pre- and post-registration activities such as pesticide efficacy evaluation, control of pesticide import and use, and the monitoring of ecological and health effects.

This close cooperation between countries for pesticides registration and management is cited as an almost unique example in the world.

The current revision of the Regulation was elaborated to take into account these various developments in pesticide management and legislation in the CILSS Member States, as well the experiences obtained by the CSP since its creation with respect to the registration process. It is expected to improve the reliability and the transparency of the decisions taken by the CSP and to give better insurance that pesticides used in the Sahel are effective and have acceptable hazards for man and the environment.

This revision has been adopted by the 34th session of the CILSS Council of Ministers, held in N'Djamena, Republic of Chad, as Resolution N° 8/34/CM/99.

The CILSS Coordinating Minister

[1] : The French acronym for the Sahelian Pesticide Committee, CSP, is maintained troughout the text.

PREAMBLE

The Member States of the Permanent Interstate Committee for Drought Control in the Sahel (CILSS),

- Taking into account Resolution N° 7/27/CM/92 of the 27th ordinary session of the CILSS Council of Ministers regarding phytosanitary control and pesticide registration, which adopted the Regulations on phytosanitary control and registration of pesticides, and more particularly the Common Regulation for the Registration of Pesticides in CILSS Member States,

- Taking into account Resolution N° 10/29/CM/94 of the 29th ordinary session of the CILSS Council of Ministers regarding the enforcement of the Common Regulation for the Registration of Pesticides,

- Taking into consideration the FAO International Code of Conduct on the Distribution and Use of Pesticides,

- Taking into consideration the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade,

- Aware of the potential hazards of the use of pesticides for Sahelian populations and the environment,

- Emphasizing the willingness for cooperation between States within CILSS,

- Recognizing the need to re-examine the existing text in the perspective of developments and experiences gained in the field of pesticide registration by CILSS Member States,

- Taking into account the national legislation put into place, or being elaborated, since the adoption of Resolution N° 7/27/CM/92 cited above,

Have agreed as follows:

CHAPTER I: OBJECTIVE

Article 1

1.1 The current revision of the Common Regulation for the Registration of Pesticides in CILSS Member States (hereafter called "the Common Regulation") concerns the authorization, the placing on the market, the use and the control of active ingredients and formulated products of pesticides in the CILSS Member States (hereafter called "the Member States").

1.2 The objective of the Common Regulation is to combine the experience and expertise of Member States with respect to the evaluation and registration of pesticides in order to ensure their rational and judicious use, as well as the protection of human health and the environment .

CHAPTER II: DEFINITIONS

Article 2

For the purpose of the current Common Regulation the following definitions are applicable:

Provisional registration: Temporary registration of a pesticide in order to allow the collection of further data needed for a full registration.

Biopesticide: Biological control agent, generally a pathogen, formulated and applied in a manner similar to a chemical pesticide.

Packaging: The container together with the protective wrapping used to carry pesticide products via wholesale or retail distribution to users.

Sahelian Pesticide Committee (CSP): Committee in charge of the evaluation and registration of pesticides, composed of experts of Member States as well as of external experts to these Member States.

Manufacturer: An entity in the public or private sector engaged in the business or function, whether directly or through an agent or through an entity controlled by or under contract with it, of manufacturing a pesticide active ingredient or preparing its formulation or product.

Formulation: The combination of various ingredients designed to render the product useful and effective for the purpose claimed; the form of the pesticide as purchased by users.

Registration: The process whereby the responsible authority approves the sale and use of a pesticide following the evaluation of comprehensive scientific data demonstrating that the product is effective for the purpose intended and not unduly hazardous to human or animal health or the environment.

Banned: Is said of a pesticide for which all registered uses have been prohibited by final regulatory action, or for which all requests for registration or equivalent action for all uses have, for health or environmental reasons, not been granted.

Active ingredient: The biologically active part of the pesticide present in a formulation.

Common name: The name assigned to a pesticide active ingredient by the International Standards Organization or adopted by national standards authorities to be used as a generic or non proprietary name for that particular active ingredient only.

Trade name: The name under which the pesticide is labelled, registered and promoted by the manufacturer and which, if protected under national legislation, can be used exclusively by the manufacturer to distinguish the product from other pesticides containing the same active ingredient.

Pesticide: Any substance or mixture of substances intended :
- for preventing, destroying or controlling any pest, 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 commodities, wood and wood products or animal feedstuffs,
- to be administered to animals for the control of insects, arachnids or other pests in or on their bodies,
- for use as a plant growth regulator, defoliant, desiccant, or agent for thinning fruit or preventing the premature fall of fruit.

Product: The pesticide in the form in which it is packaged and sold.

Residue: Any specific substance in foods, agricultural commodities, or animal feed resulting from the use of a pesticide. The term includes any derivatives of a pesticide, such as conversion products, metabolites, reaction products, and impurities considered to be of toxicological significance. The term "pesticides residue" includes residues from unknown or unavoidable sources (e.g. environmental), as well as known uses of the chemical.

Severely restricted: A limited ban – is said of a pesticide for which virtually all registered uses have been prohibited by final regulatory action but certain specific registered use or uses remain authorized.

CHAPTER III: SCOPE AND AREA OF COMPETENCE

Article 3

The Common Regulation concerns the authorization, placing on the market, use and control of the active ingredients and formulated products of pesticides in the Member States. The Common Regulation is also applicable to the authorization, placing on the market, use and control of biopesticides.

Article 4

The Common Regulation is applicable to the classification, labelling, packing and packaging of pesticide formulations.

Article 5

5.1 Evaluation and registration of active ingredients and formulated products falls within the competence of CILSS. It is carried out for all Member States. The registration procedures and conditions are described in this Common Regulation.

5.2 The control of import, export, placing on the market, use and destruction of pesticides registered under this Common Regulation falls within the competence of the

responsible authorities of the Member States. The regulation of advertising with respect to pesticides are part of this control.

Article 6

6.1 The present Common Regulation is applicable while taking into account the *Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade*, as well as the obligations of Member States having ratified this Convention.

6.2 The CSP will evaluate all notifications and Decision Guidance Documents (DGD) regarding the Rotterdam Convention and will provide advice to Member States on import decisions for implementation.

CHAPTER IV: THE SAHELIAN PESTICIDE COMMITTEE

Article 7

7.1 A specialized body, the Sahelian Pesticide Committee (CSP) is created to execute the Common Regulation. The composition and duties of the CSP are described in Article 26.

7.2 The CSP is placed under the direct institutional supervision of the Institut du Sahel (INSAH). The offices of the CSP are located at the Institut du Sahel in Bamako. They can be transferred to any other CILSS Member State.

7.3 A Permanent Secretariat is created to manage the daily activities of the CSP. The composition and duties of the Permanent Secretariat are determined by the CILSS Executive Secretary on the proposal of the CSP.

CHAPTER V: GENERAL PROVISIONS

Article 8

8.1 Member States shall stipulate that pesticides cannot be placed on the market and be used in their territory except after registration of the product in question in accordance with the present Common Regulation, except where the intended use is in accordance with Articles 21 or 23.

8.2 Member States retain the right not to authorize the placing on the national market of a pesticide that is registered or provisionally registered by the CSP if:

i the use pattern for which the pesticide has been registered do(es) not exist in the country,
ii it is impossible to satisfy the conditions and/or the restrictions related to the registered use of the pesticide,
iii the ecological conditions in the country are substantially different from those used in the evaluation of environmental risks by the CSP,
iv the placing on the market or the use of the pesticide contradicts national policies in agriculture, environment or in public health.

The Member State which does not authorize the placing on the national market of a pesticide registered of provisionally registered by the CSP immediately informs the CSP of that decision and provides the arguments that led to it.

Article 9

Member States shall stipulate that the pesticides must be used properly. Proper use shall include compliance with the conditions listed in Articles 10 and 11, with the principles of good plant protection, veterinary practice or vector control, as well as with the principles of integrated pest management, whenever possible.

CHAPTER VI: REGISTRATION CONDITIONS

Article 10

10.1 A list of registered products shall be established by the CSP.

10.2 A pesticide shall be registered for a specific use. Only the registered use shall be authorized in the Member States.

Article 11

A pesticide can be registered as far as the formulation presents the following characteristics:

If it is established, after the examination of the registration dossier described in Annex 2, and when used in accordance with Article 9, considering all normal conditions under which it can be used, as well as its consequences:

it is sufficiently effective against the targeted organism,

it is not phytotoxic under normal conditions of use in the Sahel,

it is not harmful to man or non-target fauna under normal conditions of use in the Sahel,

it has no unacceptable effects on the Sahelian environment.

ii. If the results of trials, conducted in the Member States, show that the product has an acceptable biological efficacy.

iii. If the active ingredient(s), the impurities and the residues of the pesticide can be determined by officially recognized analytical methods.

iv. If, for agricultural commodities concerned by the registration and intended for human consumption, Maximum Residue Limits have been established by the Member States or by other national or international competent authorities.

Article 12

The registration criteria with respect to biological effectiveness, the quality of formulations placed on the market, the toxicity and the risk of the product for man, as well as harmful effects and the risk of the product to environment, are set out in Annex 3.

Article 13

13.1 *Registration*

A full registration is granted if all conditions listed in *Article 11* are satisfied. A registration is valid for five (5) years and is renewable for the same period. A registration may be granted with specific use restrictions.

13.2 *Provisional Registration*
A provisional registration is granted if most of the data required to evaluate the conditions listed in Article 11 are provided, but where further information is considered necessary in order to comply with these conditions in a satisfactory manner. This type of information mainly concerns data which cannot be provided unless the pesticide has been applied on a larger scale and in a real conditions of use in the Sahel.

A provisional registration has a limited validity of three (3) years and is renewable once for the same period. It can be granted with specific use restrictions.

13.3 *Maintaining under assessment*
A registration request is maintained under assessment if the dossier is not sufficiently complete to evaluate whether the conditions listed in Article 11 are satisfied. The CSP requires further information from the applicant.

13.4 *Denial of registration*
Registration can be denied if the conditions listed in Article 11 cannot, or with difficulty, be satisfied in real conditions of use of the pesticide in the Member States.

13.5 A registration or a provisional registration can be reexamined, modified or cancelled at any time:

i. if one of the requirements for it being granted is no longer satisfied,
ii. if false or misleading information has been provided on the basis of which it was granted,
iii. if, taking in account the evolution of scientific and technical knowledge, its use pattern and the dose rates applied can be modified,
iv. if, taking in account the evolution of scientific and technical knowledge, the methods of evaluation of the data provided in the registration dossier, as specified in Annex 2 and 3, have changed.

CHAPTER VII: REGISTRATION PROCEDURE OF A FORMULATION

Article 14

14.1 The request for a registration of a product is deposited at the Permanent Secretariat of the CSP, accompanied by a complete dossier in accordance with Annex 2. Technical, and more specific, guidelines on the different data to be submitted will be published by the CSP. In order to ensure optimal evaluation of the dossier, the applicant shall strictly, and in chronological order, follow each parameter of the composition of the registration dossier.

14.2 The registration of a product is based on the decisions taken by the CSP, as described in Annex 1.

Article 15

It is desirable that the applicant for a registration of a product has a permanent office or a representation in an Member State fo the Economic Community of West African States (ECOWAS).

CHAPTER VIII: PROTECTION OF CONFIDENTIAL DATA

Article 16

The data provided by the applicant, in accordance with the registration dossier for pesticides in the Sahel, cannot be used to the benefit of another applicant, unless the first applicant agrees with this other applicant that the information may be used.

Article 17

17.1 The applicant, in submitting the registration dossier, can mark the parts of the dossier which, in his opinion, represent or contain industrial or commercial secrets. The CSP and the Member States ensure that such information, considered as industrial or commercial secrets, remains confidential.

17.2 This confidentiality does not apply:

1. to the name(s) or the concentration of the active ingredient(s) nor to the name of the commercial product,
ii. to the names of other substances considered as hazardous to man and the environment,
iii. to the physico-chemical data of the active ingredient, the degradation products or metabolites of (eco)toxicological importance, and the commercial product,
iv. to the measures used to make the active ingredient or the commercial product harmless,

to the summary of the results of the trials intended to establish the efficacy of the product and its innocuousness for man, animals, plants and the environment,

vi. to the methods and precautions recommended to reduce risks during handling, storage, transport or other,
vii. to the methods of analysis of the active ingredient(s) and its residues after application, as well as the metabolites or other components considered important from an (eco)toxicological point of view,
viii. to the methods of destruction of the product and its packaging,
ix. to the decontamination measures to be taken in the case of accidental application or leakage,

22. to the first aid and medical treatment to conduct in the case of accidental exposure or poisoning.

CHAPTER IX: INFORMATION

Article 18

18.1 The CSP shall inform the applicant of its decision to grant a provisional registration or a registration within 2 months after the meeting in which the dossier has been evaluated.

18.2 The registrations and provisional registrations granted by the CSP shall be signed by the CILSS Coordinating Minister. An original copy of each registration or provisional registration shall be sent to the applicant, to the Executive Secretariat of CILSS and to the CSP. A certified copy is sent to all Member States as soon as possible after the CSP meeting during which the registration or provisional registration has been granted.

18.3 The CSP shall update the list of registrations and provisional registrations after each meeting. The updated list is sent to each Member State and is published in an official journal of CILSS.

CHAPTER X: LABELLING AND PACKAGING

Article 19

19.1 Information for users shall be provided by the labels and the enclosed directions for use, according to the specifications in force. The minimum of information to appear on the label and/or the enclosed directions for use is given in Annex 4. The labels and/or the directions for use enclosed with the product must be written in the official language(s) of the country where the product is commercialized, as given in Annex 5.

19.2 Pictograms must complement the text, particularly for the precautions to take during handling. The colours required on the labels are those related to the risks of poisoning in accordance with the World Health Organization (WHO) classification.

Article 20

The packaging characteristics will be in conformity with the guidelines for pesticide registration and control of the Food and Agriculture Organization of the United Nations (FAO). They shall be in accordance with the standards that are internationally applied for the transport of dangerous chemical goods by air, sea, railroad or road.

CHAPTER XI: EXPERIMENTATION

Article 21

Trials or experiments conducted in the Member States for the purpose of research or development and involving the release in the environment of an pesticide not authorised by the CSP, can take place only if an authorisation is delivered by the Competent Authority of the Member State in which the trial or experiment is carried out, and according to the national legislation in force.

Article 22

22.1 Biological efficacy trials for the purpose of registration shall be conducted by public or private institutions selected by the CSP. Trials will be carried out according to the protocols elaborated by the CSP.

22.2 The specific technical guidelines referred to in Article 14.1 contain detailed instructions with respect to the protocols and experimental methods required for registration.

CHAPTER XII: EMERGENCY SITUATIONS

Article 23

23.1 The use of a pesticide which has not been registered or provisionally registered by the CSP can be accepted, as an exception, in the case of a phytosanitary, veterinary or sanitary emergency, such as the unforeseen outbreak of a pest or the unexpected appearance of vector disease.

23.2 The use of a pesticide which has not been registered or provisionally registered shall only be accepted if no alternative management option of the pest organism is available, and shall be of limited scale and duration.

23.3 A pesticide which has not been registered or provisionally registered shall only be used after the explicit authorisation by the Competent Authority of the Member State concerned.

23.4 The Member State wishing to use, for reasons of an emergency, a pesticide which has not been registered or provisionally registered, will immediately inform the CSP of its decision and will submit a dossier with the argumentation which has led to this decision.

23.5 The CSP shall set out the conditions under which the use of a pesticide which has not been registered or provisionally registered is acceptable for emergency reasons.

CHAPTER XIII: CONTROL

Article 24

24.1 Member States shall take the necessary measures to ensure post-registration control of the distribution and use of pesticides, and provide the human, material and financial means for that purpose.

24.2 Pesticides which have been registered or provisionally registered shall be subject to health monitoring by appropriate institutions in the Member States.

Article 25

Member States regulations shall enforce the conditions required by this Common Regulation, notably :

i. the quality of formulations placed on the market,
ii. the authorized areas of use and the restrictions as specified on the provisional registrations and registrations,
iii. the standards and use indications shown on the labels,

iv. the use of the commercialized pesticides according to the indications as specified on the labels,
v. the effects of the pesticides on the environment.

CHAPTER XIV: COMPOSITION, ATTRIBUTES AND FUNCTIONS OF THE SAHELIAN PESTICIDE COMMITTEE

Article 26

26.1 The Sahelian Pesticide Committee (CSP) is composed of :

i. two experts of each Member State: *ordinary member*
ii. three toxicologists working in the Sahel: *ordinary member*
iii. the Permanent Secretary of the CSP: *ordinary member*
iv. the Technical Director of OCLALAV: *associate member*
v. one representative of ECOWAS: *associate member*
vi. one representative of the Inter-African Phytosanitary Council of the Organisation of African Unity (IPC/OAU): *associate member*
vii. one representative of the AGRHYMET Centre: *associate member*
viii. one representative of FAO: *observer*
ix. one representative of WHO: *observer*
x. one representative of the pesticide registration system of West and Central Africa: *observer*

26.2 The experts of the Sahelian countries shall be specialists in different sectors of plant protection, toxicology, ecotoxicology or chemistry.

26.3 Based on the nomination by their Ministry, ordinary members of the CSP are appointed, by decree, by the CILSS Coordinating Minister. They are the only ones having the power of decision.

26.4 The CSP can call on any resource person according to his/her qualifications

26.5 The CSP shall be chaired by a Chair Person in accordance with the indications contained in its Internal Rules of Procedure.

Article 27

The CSP is charged with:

- the examination and follow-up of registration applications,

ii. the preparation of a list of public institutions authorized to carry out trials,
iii. the preparation of a list of laboratories authorized to carry out analyses for second assessments,
iv. the definition of methods for the control of the composition and the quality of products and their evaluation with respect to man, animals and to the environment,

the definition of technical guidelines on the data to be provided and the studies to be conducted for the registration by the applicant,

vi. the updating of a register of registrations and authorizations,
vii. the establishment of an inventory of pesticides used or sold in the CILSS Member States.

viii. the preparation of a list of pesticides which use is banned or severely restricted in the CILSS Member States,
ix. maintaining relations with the National Pesticide Management Committees (NPMCs) in the CILSS Member States.

Article 28

28.1 The CSP shall meet twice a year. Extraordinary sessions can be convened by its Chair Person.

28.2 The functioning of the CSP is described by its Internal Rules of Procedure, defined by Executive Secretary of CILSS, on the proposal of the CSP.

CHAPTER XV: APPEALS

Article 29

29.1 The applicant has the right to a re-examination of a decision taken by the CSP with respect to the denial of a registration as defined in Article 13.4, or the modification or cancellation of a provisional registration or a registration as defined in Article 13.5.

29.2 After being informed of the CSP decision, in accordance with Article 18.1, the applicant may request, by registered mail sent to the Permanent Secretary of the CSP, a re- examination of the decisions listed in Article 29.1, within three months following this decision. A detailed justification must be joined to this request.

29.3 The Permanent Secretary of the CSP shall acknowledge receipt within a month after reception of the re-examination request by the applicant.

29.4 An Appeals Committee responsible for examining this request shall be appointed by the Director General of the Institut du Sahel and shall be composed of three CSP members representing different CILSS Member States.

29.5 The Appeals Committee shall examine the arguments justifying the re-examination request, and will take a decision within six months after the reception of the request at the Permanent Secretariat of the CSP. The applicant may be invited to defend his re-examination request before the Appeals Committee.

29.6 The decision by the Appeals Committee is final. It will be circulated in the Member States as soon as possible.

CHAPTER XVI: SPECIFIC PROVISIONS

Article 30

The examination fees of the registration dossiers are to be paid by the applicant. The amount of these fees is determined by the CSP.

Article 31

31.1 The Annexes to this document provide more detailed information on certain articles of the Common Regulation. They are an integral part of this Common Regulation.

31.2 Technical guidelines with respect to the data to be provided by the applicant of a registration, the studies to be executed, as well as the registration criteria, will be elaborated by the CSP, provided they are consistent with the provisions of this Common Regulation.

Article 32

32.1 The registration criteria to which reference is made in *Article 12* will be proposed and elaborated by the CSP, after wide consultation in the Member States.

32.2 The registration criteria will be moved by the Executive Secretariat of CILSS before the Council of Ministers for adoption within two (2) years after entry into force of this Revision of the Common Regulation. They will be added to the Common Regulation as Annex 3.

CHAPTER XVII: AMENDMENTS

Article 33

33.1 The present Common Regulation can only be amended by a decision of the CILSS Council of Ministers, on the proposal of the Executive Secretary or one of the Member States.

33.2 The Annexes to the Common Regulation can be provisionally amended by decision of the CILSS Executive Secretary, on the proposal of the CSP. The Executive Secretary shall immediately report to the CILSS Coordinating Minister concerning any change made to the annexes of this common Regulation. These amendments are valid until next meeting of the Council of Ministers, when they must be approved.

CHAPTER XVIII: RATIFICATION

Article 34

34.1 The present Common Regulation shall be subject to ratification by the CILSS Member States. Ratification shall be carried out in accordance with the legal procedures in force in each Member State.

34.2 It shall remain possible, for each CILSS Member State, to adhere to this Common Regulation after it has come into force.

34.3 The instruments of ratification and adhesion shall be deposited with the Depositary.

CHAPTER XIX: ENTRY INTO FORCE

Article 35

35.1 This revision of the Common Regulation shall enter into force as soon as it is ratified by the fifth (5^{th}) Member State.

35.2 Member States shall modify, after ratification, their national legislation in order to comply with this revision of the Common Regulation.

35.3 After this revision of the Common Regulation has entered into force, only the Member States that will have ratified it will retain the right to hold a seat as ordinary members in the CSP.

35.4 Member States that have not yet ratified the Common Regulation at the time it enters into force, may participate in the meetings of the CSP as observers.

CHAPTER XX: TEMPORARY PROVISIONS

Article 36

The present revision of the Common Regulation is without prejudice to the decisions on pesticides taken by the CSP before its entry into force.

CHAPTER XXI: SANCTIONS

Article 37

Each member State that will have ratified the Common Regulation shall adopt legislation that lays out financial and/or criminal sanctions for offenders, in case of non-compliance with the present Regulation.

CHAPTER XXII: RESERVATIONS

Article 38

No reservations can be made to this Common Regulation.

CHAPTER XXIII: WITHDRAWAL

Article 39

39.1 A State that is Party to this Common Regulation may withdraw at anytime from the Common Regulation by giving written notification to the Depositary.

39.2 Any such withdrawal shall take effect upon expiry of one year from the date of receipt by the Depositary of the notification of withdrawal.

CHAPTER XXIV: DEPOSITARY

Article 40

The Executive Secretariat of CILSS shall be the Depositary of the present Common Regulation and shall register it with the United Nations and the Organization of the African Unity. The Executive Secretariat shall notify the Member States of the dates of deposit of the instruments of ratification or adhesion.

CHAPTER XXV: AUTHENTIC TEXTS

Article 41

The original of the present Common Regulation, elaborated in French, shall be deposited with the Depositary. Translations in English and in Portuguese shall be made of the original text. Certified copies of the Common Regulation shall be provided to all Member States.

In witness whereof the undersigned being duly authorized to that effect, have signed this Common Regulation.

Done at N'Djamena on this sixteen day of December, two thousand.

On behalf of BURKINA FASO

The Minister of Agriculture

On behalf of the Republic of CAPE VERDE

The Minister of Agriculture, Food and Environment

On behalf of the Republic of GAMBIA

The Secretary of State for Agriculture

On behalf of the Republic of GUINEA BISSAU

The Minister of Agriculture, Fisheries and Natural Resources

On behalf of the Republic of MALI

The Minister of Rural Development

On behalf of the Republic of MAURITANIA

The Minister of Rural Development and Environment

On behalf of the Republic of NIGER

The Minister of Rural Development

On behalf of the Republic of SENEGAL

The Minister of Agriculture

On behalf of the Republic of CHAD

The Minister of Agriculture

Common procedure for pesticide registration in CILSS Member States

First step

1] The applicant sends a complete dossier required for the registration request to the Permanent Secretariat of the Sahelian Pesticide Committee (CSP), at Institut du Sahel in Bamako, Mali. For this purpose, the Permanent Secretariat of the CSP has available for each applicant the model registration dossier.

2] The Permanent Secretariat of the CSP registers the dossier and acknowledges receipt to the applicant.

3] The applicant pays the examination fees.

4] The Permanent Secretariat of the CSP verifies the completeness of the dossier and, if essential information is missing, instructs the applicant to complete the dossier.

5] The Permanent Secretariat submits the dossier to the experts of the CSP.

Second step

6] The CSP examines the dossier and may either:

- decide to fully register the pesticide in the Sahel for five (5) years,
- deliver a provisional registration for a duration of three (3) years while waiting for additional studies,
- maintain a dossier under assessment, awaiting additional information,
- deny registration of the pesticide.

The registered or provisionally registered pesticide bears a single number for all the CILSS Member States.

Third step

7] The Permanent Secretariat of the CSP informs the applicant and the Member States of the decisions by the CSP.

8] The Permanent Secretariat publishes the list of registrations and provisional registrations in a CILSS publication.

Composition of the dossier to be submitted for pesticide registration

The dossier to be submitted shall include the necessary information to allow evaluation of the efficacy of the pesticide and the potential risks that it may represent for man, non-targeted animals and for the Sahelian environment. It includes all information on the identification and the physico-chemical properties of the product and the active ingredient, on the toxicology, on the impact on the environment, fauna and flora, on the residues as well as on anything that concerns the safety connected with the use of the product.

The dossier for a request for pesticide registration in the Sahel is composed as follows:

1) A request for registration of the product,
2) A descriptive file,
3) A technical file,
4) An analytical file,
5) A toxicological file,
6) The original label or its model,
7) A reference sample of the active ingredient(s) included in the product and a sample of the commercial product,
8) An attestation or a certificate of registration in the country of origin.

All documents provided shall be written in French or in English, preferably the former.

Complete study reports being very voluminous, the registration dossier shall rather include the summaries of these studies. The complete study reports will, however, be available at the request of the CSP.

The dossier must include an impartial report providing an acceptable justification to the CSP in the case that the provision of certain data or specific information does not seem to be necessary. This may be the case due to the nature of the product or the proposed use patterns, or when it is not considered scientifically necessary or technically possible to provide the information or data.

Part 1: Request for the registration of the product.

It shall include:

1. Name and address of the applicant,
2. Name and address of the manufacturer of the product,
3. Name and address of the owner of the trade-mark,
4. Name of the product,
5. Form under which the product is marketed,
6. Detailed chemical composition of the product (or, if need be, its biological

composition),

7. Nature of the mode of action and the proposed use patterns,
8. Directions for use,
9. Application rates and concentrations of use,
10. A summary of information appearing in the toxicological dossier related to the acute toxicity of the formulated product and of the active ingredient(s),
11. Hazard class of the formulation (according to the WHO classification),
12. Acceptable Daily Intake (ADI), Maximum Residue Limit(s) (MRL) and the proposed pre-harvest intervals and withholding periods for the Sahel,
13. Precautions to be taken by the users before, during and after the application of the product,
14. Symptoms of poisoning in animals and, when data are available, in man,
15. Measures to be taken in case of poisoning,
16. Nature, content and dimensions of the packaging,
17. Precautions to be taken for the storage of the product,
18. Shelf life of the product,
19. Recommendations for the destruction of obsolete products and packaging,
20. List of countries with similar ecologies where the formulation is registered and the authorisations for use in these countries,
21. when required, a sufficient quantity of formulated product for carrying out experimental trials in the Sahel.

Part 2: Descriptive file

It shall include :

1 For the formulated product:

1.1 Trade name,
1.2 Name and address of the manufacturer of the product,
1.3 Type of formulation,
1.4 Appearance,
1.5 Composition,
1.6 Minimum and maximum concentrations of the active ingredient(s),
1.7 Real or apparent density,
1.8 Flammability,
1.9 Corrosiveness,
1.10 Acidity or alkalinity,
1.11 Water content,
1.12 Wettability,
1.13 Suspension concentration,
1.14 Emulsion stability,
1.15 Particle size range,

1.16 Flowability,
1.17 Viscosity,
1.18 Miscibility with hydrocarbons,
1.19 Known incompatibilities of the product,
1.20 Nature, size and contents of packaging as well as the description of the closing mechanism(s)
1.21 Storage stability.

2. For the technical quality product(s):

2.1 Origin : name and address of the manufacturer and its location,
2.2 Appearance,
2.3 Density,
2.4 Minimal purity,
2.5 Possible variations in the composition

3. For the active ingredients(s)

3.1 International common name and synonyms,
3.2 Chemical name according to international nomenclature,
3.3 Empirical chemical formula, structural chemical formula, as well as molecular weight,
3.4 Appearance,
3.5 Density,
3.6 Melting point, boiling point, and decomposition temperature,
3.7 Vapour pressure,
3.8 Volatility or Henry's law constant,
3.9 Sulfonation index and distillation characteristics,
3.10 Solubility in water and organic solvents,
3.11 Partition coefficient between water and an appropriate non-miscible solvent,
3.12 Absorption spectra: ultra-violet, visible and infra-red,
3.13 Chemical stability,
3.14 Identity of metabolite(s) originating from the active ingredient(s) after application. It should be noted whether they are toxic or phytotoxic,
3.15 Any other relevant properties.

In case the formulation consists of several active ingredients, the above information must be provided for each active ingredient separately.

Part 3: Technical file

It shall include:

22. A description of the mode of action of the active ingredient(s),

23. A study of the activity of the commercial product submitted for registration, its persistence of action, its phytoxicity, its selectivity, and its potential undesirable

side effects,

24. The direction for use. The following shall be described: dose rates, periods, plant stages and frequencies of application,

25. Limits to use of the product. The following shall be described: limit to use to ensure no hazard to the crop, the animal or the treated substrate, as well as to the users, the consumers, or to the next crop rotation,

26. A statement of known incompatibilities of the product with other pesticides.

Part 4: Analytical file

It shall include:

27. Methods of extraction, identification and analysis of the active ingredient(s) contained in the commercial product,

28. Methods of extraction and analysis of the residues of the active ingredient(s) and its (their) metabolite(s) which are part of the definition of the residues,

29. Method of evaluation of residues in plants and commodities which are susceptible to be contaminated,

30. A study on the pathways of degradation of the active ingredient(s) in the plant or the commodity treated,

31. A study regarding the fate and behaviour of the active ingredient(s) and its (their) metabolites in soil and water.

Part 5: The toxicological file

It shall include:

32. Toxicity studies with the formulated product

1.1 Acute toxicity:
- 1.1.1 Oral LD_{50},
- 1.1.2 Dermal LD_{50},
- 1.1.3 Inhalation LC_{50},

1.2 Skin irritation,

1.3 Eye irritation,

33. Toxicity studies with the active ingredient(s)

2.1 Acute toxicity:
- 2.1.1 Oral LD_{50},
- 2.1.2 Dermal LD_{50},
- 2.1.3 Inhalation LC_{50}

2.2 Skin irritation,

2.3 Eye irritation,

2.4 Sensitization,
2.5 Subchronic toxicity:
2.5.1 Dietary toxicity,
2.6 Chronic dietary toxicity,
2.7 Mutagenicity and effects on DNA:
2.7.1 In vitro,
2.7.2 In vivo,
2.8 Carcinogenicity,
2.9 Teratogenicity and embryotoxicity,
2.10 Effects on reproduction,
2.11 Neurotoxicity,
2.12 Other studies: Other studies may be asked for if the results of the toxicity tests, or the structure and the properties of the chemical substance, justify them,
2.13 Animal metabolism.

34. A summary of observations on the toxicity of the product to humans.

4. Studies of the effects of the product on the environment

4.1 Toxicity to birds:
4.1.1 Acute toxicity,
4.1.2 Dietary toxicity,
4.1.3 Effects on reproduction,
4.2 Toxicity to reptiles:
4.2.1 Acute toxicity,
4.2.2 Chronic toxicity,
4.3 Toxicity to aquatic organisms:
4.3.1 Toxicity to fish:
4.3.1.1 Acute toxicity,
4.3.1.2 Chronic toxicity,
4.3.2 Toxicity towards invertebrates,
4.3.3 Toxicity to algae:
4.3.3.1 Acute toxicity,
4.3.3.2 Additional studies,
4.4 Toxicity to beneficial arthropods:
4.4.1 Toxicity to honey bees:
4.4.1.1 Acute oral toxicity,
4.4.1.2 Acute contact toxicity,
4.4.2 Toxicity for natural enemies of invertebrate pests,
4.5 Toxicity to soil organisms,
4.6 Fate and behaviour in the environment:
4.6.1 Fate and behaviour in the soil:
4.6.1.1 Rate and pathways of degradation,
4.6.1.2 Adsorption and desorption,
4.6.1.3 Mobility,
4.6.1.4 Importance and nature of bound residues,
4.6.2 Fate and behaviour in water and air:

4.6.2.1 Rate and pathways of degradation,
4.6.2.2 Adsorption and desorption.

35. Studies on the bioaccumulation of the active ingredient(s).

36. Recommendations regarding the precautions for use and the treatment of poisoning

6.1 Diagnostics and symptoms of poisoning,
6.2 First aid and emergency measures in case of poisoning and precautions for treatment,
6.3 Therapy and antidotes,
6.4 Security measures:
- 6.4.1 Precautions to be taken for transport,
- 6.4.2 Precautions to be taken for storage,
- 6.4.3 Measures to be taken in case of fire,
- 6.4.4 Precautions to be taken for handling packaging,
- 6.4.5 Measures to be taken in case of leakage or accidental spillage,
- 6.4.6 Recommendations for decontamination of application material, protective clothing and equipment,
- 6.4.7 Instructions and/or measures which have to appear on the packaging.

6.5 Recommendations on the elimination of obsolete products and their packaging materials.

Part 6: Original label or its model

See Annex 4

Part 7: A reference sample of the active ingredient(s) included in the product and a sample of the commercial product.

Part 8: An attestation or a certificate of registration in the country of origin.

Criteria for the registration of pesticides in the Sahel

To be included in the Common Regulation at a later stage (see *Article 32*)

Labelling of pesticides

The label should be conceived so as to ensure optimal communication between the supplier and the buyer and/or user. Therefore, it should effectively show, during all of its lifetime, in clear and concise terms the basic information for use of the pesticide with minimum risk.

The information shall be provided by the manufacturer using one or several of the official languages of the CILSS Member States (see Annex 5), in indelible ink, clearly visible and easy to read.

The label shall include the following information:

1. A description of the contents:
   - 1.1 Trade name of the pesticide,
   - 1.2 Name and concentration of the active ingredient(s),
   - 1.3 Type of the formulation,
   - 1.4 Net content expressed in legal units of measure.

37. A highly visible indication of the risk, using a coloured band on the bottom of the label in accordance with the WHO classification of pesticides. In addition, concise indications are given on the precautions to be taken during handling and use of the pesticide, with minimum risk, as well as on first-aid measures,

3. Indications on the appropriate use of the contents:
   - 3.1 How, when and where to use the product, and on which crops, plant stages and against which pests,
   - 3.2 When not to use the product,
   - 3.3 Description of pre-harvest intervals and withholding periods,

4. Name and address of the manufacturer,
5. Place of manufacturing,
6. Name and address of the national or regional distributor,
7. Registration number ("Sahel number"),
8. Physico-chemical incompatibilities with other pesticides,

Date of manufacturing or formulation, the expiry date of use and instructions on stability conditions and written warnings.

Given that the information to be provided on the label cannot be too detailed, manufacturers shall put at the disposal of distributors and extension personnel, a brochure or technical note, of a maximum of one to four pages, which supplements the information on physico-chemical identity of the active ingredient(s), and the formulation, toxicological data, detailed information on the directions for use and the precautions to be taken, including instructions for the destruction of empty packaging, if available. Furthermore, it is recommended to provide a specific information brochure intended for physicians, hospital services or anti-poisoning centres, specifying the treatment recommended in case of poisoning.

Official languages within CILSS Member States, for labelling purpose (see Annex 4)

Burkina Faso	French
Cape Verde	Portuguese
Gambia	English
Guinea Bissau	Portuguese
Mali	French
Mauritania	French, Arabic
Niger	French
Senegal	French
Chad	French