

GOVERNMENT OF ZAMBIA

STATUTORY INSTRUMENT NO. OF 2023

**The Environmental Management Act
(Act No. 12 of 2011)**

**The Environmental Management,
(General) Regulations, 2023**

IN EXERCISE of the powers contained in sections 43, 65A and 134 of the Environmental Management Act, 2011, the following Regulations are hereby made:

PART I

PRELIMINARY PROVISIONS

Title

1.

These Regulations, may be cited as the Environmental Management (General) Regulations, 2022.

Definitions

2.

In these Regulations, unless the context otherwise requires-

“”

PART II

PESTICIDE REGISTRATION

Division 1- Preliminary Provisions

Definitions under

3.

In this Part, unless the context otherwise requires- part

“active ingredient” means a part of a pesticide product that provides the pesticidal action;

“amendment” means an amendment to a

certificate of registration of a pesticide which does not affect the details of the inherent properties of the pesticide.

“appropriate efficacy report” means an efficacy report containing results and protocols of trials conducted in accordance with the guidelines issued by the Agency for purposes of registration of a pesticide; or containing results of trials done in climatic conditions similar to Zambia and in accordance with trials and protocols similar to the ones in Zambia.

“banned pesticide” means a pesticide for which all registered uses have been prohibited under the Act;

“biopesticide” means a pesticide whose active ingredient is derived from nature;

“chemical pesticide” means a pesticide other than a biopesticide;

“disposal” means any operation to recycle, neutralize, destroy or isolate a pesticide, an expired pesticide, spillage of a pesticide, a left-over pesticide or material contaminated by a pesticide;

“distribution” means the process by which

pesticides are supplied through trade channels to local or international markets;

“formulation” means a combination of various ingredients designed to render a pesticide useful and effective for the purpose claimed and for the envisaged mode of application;

“hazard” means the inherent property of a substance, agent or pesticide having the potential to cause adverse effects;

“maximum residue limit” means the maximum concentration of a pesticide residue that -

a) is legally permitted under a written law as acceptable in or on food or animal feed stuff; or

b) the Agency or appropriate Authority classifies as acceptable in or on food or animal feed stuff;

“pesticide” has the meaning assigned to the word in the Act; “quality” means the degree of conformity to established standards set by the Zambia Bureau of Standards or

international standards accepted for use in Zambia;

“relevant research institution” means a higher education institution, research institution or any other training institution with expertise in pesticides management;

“restricted pesticide” means a pesticide restricted under the Act;

“risk” is the likelihood of an adverse effect occurring as a result of exposure to a pesticide;

“severely restricted pesticide” means a pesticide severely restricted under the Act; and

“trade name” means the name under which a pesticide is, registered, or licensed under the Act.

Division 2- Registration of Pesticides

Requirement for registration

4. (1)

A person shall not, possess, import or manufacture a pesticide that is not registered under these Regulations.

(2)

The Agency shall not register a pesticide unless the efficacy, safety, quality and technical specifications of the pesticide have been assessed in accordance with Regulation 5.

5. (1) A person who intends to possess, import or manufacture a pesticide shall apply to the Agency for registration of the pesticide in Form I of the First Schedule on payment of a fee set out in the Second Schedule.
- (2) An application under subregulation (1) shall be-
- a) accompanied by an efficacy report, other documents set out in Form I of the First Schedule and any other information requested by the Agency; and
 - b) in either of the following formats:
 - i) five hard copies; or
 - ii) an electronic copy.
- (3) Despite sub regulation (2), the Agency shall-
- a) where it determines that an efficacy report is not appropriate, direct the applicant to engage a relevant research institution recommended by the Agency to conduct local trials on the respective pesticide.; and
 - b) where it determines that information in an appendix to the application under sub regulation (1) is unsatisfactory, request the applicant to resubmit a revised appendix with the information requested by the Agency.
- (4) A relevant research institution engaged

Consideration
of application
for registration

- under sub regulation 3 shall conduct the efficacy trials in accordance with guidelines issued by the Agency.
- (5) The applicant shall be responsible for any cost relating to registration of a pesticide.
- 6.** (1) The Agency may within seven days of receipt of a complete application under Regulation 5, transmit a single copy of the dossier to a relevant appropriate authority or research institution, for comments.
- (2) The applicant under subregulation (1) shall be responsible for any cost and other requirements necessary for the consideration of the dossier by the relevant appropriate authority or research institution.
- (3) Where a relevant appropriate authority or research institution fails to make comments within the period specified under subregulation (3), the Agency may proceed to consider the dossier.
- (4) The Agency shall, within ninety days of receipt of the application under sub regulation (1) consider the application and make a decision to either-
- a) grant the registration
 - b) reject the registration; or
 - c) defer the registration, where information provided is insufficient to make a decision.

(5) The Agency shall where it grants an application for registration of a pesticide, issue a certificate of registration in Form II of the First Schedule to the applicant and register the respective pesticide subject to conditions which the Agency may determine.

(6) The Agency shall reject an application for registration of a pesticide if the-

- a) application does not meet the requirements of the Act and these Regulations;
- b) pesticide poses unacceptable risk to human health or the environment under the conditions of use;
- c) pesticide is not effective for the intended purpose;
- d) pesticide is banned under the Act; or
- e) registration of the pesticide would be in contravention of the conditions under which the pesticide is restricted or severely restricted under the Act.

(8) The Agency shall where it rejects an application under this Regulation inform the applicant of the rejection in Form III of the First Schedule.

Validity of registration and renewal

7. (1) A certificate of registration shall be valid for six years and subject to renewal for a like period.

(2) A holder of a certificate of registration may

apply for renewal of the registration of a pesticide in Form IV set out in the First Schedule.

(3) An application for the renewal of the registration of a pesticide shall be made not less than six months before the expiry of the registration of the pesticide.

(4) The Agency shall, prior to the expiration of the period of registration of a pesticide, grant the application to renew the registration of the pesticide if the application meets the requirements of the Act and these Regulations.

(5) The Agency shall, where it grants an application for renewal of registration of a pesticide, issue the applicant with a new certificate of registration in Form II of the First Schedule.

(6) The Agency shall reject an application for renewal of registration of a pesticide if the application does not meet the requirements of the Act and these Regulations.

(7) The Agency shall where it rejects an application for renewal under this Regulation inform the applicant of the rejection in Form III of the First Schedule.

Transfer of
certificate of
registration

8. (1)

A holder of a certificate of registration shall not transfer the certificate of registration to a third party without the prior approval of

the Agency.

- (2) An application for approval to transfer a certificate of registration shall be made in Form V set out in the First Schedule and shall be-
- a) made by the transferor not less than six months before the expiry of the registration of the pesticide; and
 - b) accompanied by the original certificate of registration and a letter of commitment to adhere to the conditions pertaining to the certificate of registration by the prospective transferee.
- (3) The Agency shall, within thirty days of receipt of an application under subregulation (2), grant the application if the transferor and transferee meet the requirements of the Act and these Regulations.
- (4) The Agency shall, where it grants an application for transfer of a certificate of registration, issue the applicant with a new certificate of registration in Form II of the First Schedule.

(5) The Agency shall reject an application for transfer of a certificate of registration of a pesticide if the application does not meet the requirements of the Act and these Regulations.

Replacement of
certificate of
registration

9. (1) A holder of a certificate of registration may apply for replacement of a certificate of registration in writing and on payment of a fee set out in the Second Schedule.

(2) An application under subregulation (1) shall be accompanied by -

- a) a Report from the Police Service, detailing the circumstances that have necessitated the replacement; and
- b) Proof of payment of the application fee set out in the Second Schedule.

(3) The Agency shall within thirty days of receipt of an application under subregulation (1) and where the applicant meets the requirements under subregulation (2), issue a replacement certificate of registration.

Amendment of
registration

10. (1) An application for an amendment to a certificate of registration shall be made to the Agency in Form VI set out in the First Schedule.

(2) The Agency shall where an application under this Regulation is granted, issue the applicant with an amended certificate of

registration.

- (3) The Agency shall where it rejects an application for the amendment of a certificate of registration, inform the applicant of the rejection in writing stating the reasons for such rejection.

Re-registration

11.

A holder of a certificate of registration issued under these Regulations shall where the holder seeks to change the formulation, active ingredient, concentration of the pesticide, apply to the Agency for re-registration of the pesticide under the procedure set out in Regulation 5 and the Agency shall consider the application in the manner set out in Regulation 6.

12.

The Agency shall initiate a review of a registered pesticide if it-

- (a) considers that in the period since the pesticide was registered, there has been a change in the information required to evaluate the pesticide or in the procedures needed to properly evaluate the human, animal or plant health hazards, environmental hazards, efficacy or quality of the pesticide; or
- (b) has reasonable grounds to believe that the human, animal or plant health hazards or environmental hazards linked to the pesticide are now unacceptable and likely to cause adverse effects.

13.

There is established a register of pesticides which shall be maintained by the Agency.

The register of pesticides shall be in manual or electronic form and shall include the following information: -

- (a) product registration number;
- (b) the trade name and product number;
- (c) the active ingredient and concentration of the active ingredient;
- (d) name and contact details of the registration holder;
- (e) name and details of authorised local representative;
- (f) name and contact details of local

distributor;

- (g) the expiration date of the registration;
- (h) the uses for which it is registered;
- (i) any restriction to the use of the pesticides;
- (j) the signal word of the pesticide;
- (k) the hazard classification of the pesticide; and (l) the list of hazardous co-formulants.

Suspension or
cancellation of
registration

14. (1)

Subject to the provisions of the Act and these Regulations, the Agency may suspend or cancel the registration of a pesticide if:-

- (a) the holder of a certificate of registration obtained the registration certificate by fraud or deliberate negligent submission of false information or statement;
- (b) the holder of the certificate of registration contravenes the terms and conditions issued by the Agency under the Act;
- (c) if upon review of the pesticide, the Agency determines that the pesticide is likely to cause an unacceptable risk to human health or the environment under the conditions of use or is no longer effective for its intended purpose; or
- (d) the Agency considers it necessary to

protect human health and the environment.

- (2) The Agency shall prior to suspending or cancelling a certificate of registration under this Regulation give notice to the holder thereof, of its intention to suspend or cancel the certificate of registration in Form VII set out in the First Schedule.
- (3) The Agency shall not suspend or cancel a certificate of registration under this Regulation if the holder of the certificate takes remedial measures to the satisfaction of the Agency within the period specified in the notice referred to in subregulation (2).
- (4) The Agency shall suspend or cancel a certificate of registration and notify the holder of the suspension or cancellation in Form VIII of the First Schedule if the holder-
 - a) fails to show cause to the satisfaction of the Agency why the certificate should neither be suspended nor cancelled; or
 - b) does not take remedial measures within the time specified in the notice issued under subregulation (2).
- (5) Suspension or cancellation of a certificate of registration shall be effective upon the Agency's indication of the said suspension or

cancellation of registration in the register of pesticides.

A person whose certificate of registration is cancelled may apply for re-registration of the pesticide if-

- a) more than one-year elapses since the cancellation; and
- b) the person takes remedial measures to the satisfaction of the Agency.

Recall

15. (1)

The Agency shall where it cancels the registration of a pesticide, recall the pesticide, where necessary in order to protect human health or the environment.

(2)

A holder of a certificate of registration of a pesticide, a person in possession of a recalled pesticide or a dealer in a recalled pesticide shall within 15 days of the recall order in subregulation (1), notify the Agency of the location of the recalled pesticide, for purposes of disposal.

(3)

The holder of a certificate of registration of a pesticide shall be responsible for the cost of collection and disposal of a recalled pesticide in accordance with the provisions of the Act.

Publication of cancellation or recall

16. (1)

The Agency shall, upon cancellation of a certificate of registration or recall of a pesticide under these Regulations, publish the suspension, cancellation or recall in the *Gazette*.

- (2) The Agency shall within seven days of the publication of the cancellation or recall under subregulation (1), cause to be published in a newspaper of general circulation in Zambia and in electronic media of wide coverage, of the cancellation or recall.

Exemption of registration requirements for research, trial purposes or emergencies

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- 17.** (1) Despite the other provisions of these Regulations, the Agency may grant an exemption for the registration of a pesticide for purposes of conducting research or trials on a pesticide.

- (2) The Agency may, in the event of an emergency and where no other available alternative exists, permit importation and distribution of an unregistered pesticide for such time, use and in such quantities as may be specified in a gazette notice issued by the Minister.

- (3) An application for exemption under subregulations 1 and 2 shall be made in Form IX of the First Schedule.

- (4) The Agency shall on receipt of an application under subregulation (3)-
- a) waive the requirement for registration of a pesticide, with conditions; or
 - b) reject the application, with reasons.

PART III
REGISTRATION OF ENVIRONMENTAL ASSESSMENT EXPERT

Prohibition
on
conducting
Environmental
Assessment
without
Registration

18. (1)

A person shall not conduct an Environmental Assessment or prepare an environmental assessment report unless the person is registered with the Agency and holds a valid certificate of registration.

- a) An environmental assessment report prepared by a person not registered by the Agency shall be void and will not be considered by the Agency.
- b) A person who contravenes subregulation (1) commits an offence and is liable to a fine not exceeding five hundred thousand penalty units or to imprisonment for a term not exceeding five years or to both.

Registration
of
Experts

19. (1)

An application for registration as an environmental assessment expert shall be made to the Agency in Form IX set out in the First Schedule on payment of a fee prescribed in the Second schedule.

(2)

A person shall not be registered as an environmental assessment expert unless the person meets the requirements set out in the Third Schedule.

(3)

The Agency shall within thirty days of receipt of an application under sub regulation (1);

- a) grant the application;
- b) reject the application; or
- c) request the applicant to submit

additional information.

- (4) The Agency shall, where the Agency grants an application under sub regulation (3), register the applicant and issue a certificate of registration in form X set out in First schedule.
- (5) The Agency shall reject an application for registration if the applicant;
- a) has not met the requirements set out in the third schedule;
 - b) fraudulently or negligently provides false or misleading information to the Agency;
 - c) was convicted or fined for an offence under the Act within two years preceding the application for registration; and
 - d) is an undischarged bankrupt.

(6) The Agency shall, where the Agency rejects an application under sub regulation (3), inform the applicant in form XI set out in first schedule.

(7) An application under subregulation (1) shall be deemed to have been granted where the Agency fails to inform the applicant within the period specified under subregulation (3).

Validity of certificate

20. (1)

A certificate of registration issued under these Regulations shall be valid for a period of three years and may be registration

renewed for like period.

- (2) An application for renewal of a Certificate of Registration shall be made to the Agency at least sixty days before the expiry of the Certificate of Registration in Form XII set out in the first schedule on payment of a prescribed fee set out in the second schedule.
- (3) The Agency shall, within thirty days of receipt of an application under subregulation 1, consider the application and reject or grant the application.
- (4) An application under subregulation (2) shall be deemed to have been granted where the Agency fails to inform the applicant of its decision within the period specified under subregulation (3).

Unauthorized disclosure of information

- 21.**
- (1) An Environmental Assessment expert shall not, without the prior consent of the proponent or developer, communicate information which has come to their knowledge in the course of duty.
 - (2) A person who contravenes sub regulation (1), commits an offence and is liable upon conviction to a fine not exceeding two hundred thousand penalty units or to imprisonment for a term not exceeding two years or to both.

Independence of Environmental Assessment expert

22.

An Environmental Assessment expert shall:-

- a) exercise independent judgment at all times;
- b) perform work in an objective manner, even if this results in views and findings that are not favorable to the proponent or developer;
- c) avoid conflict of interest;
- d) comply with the Act, these Regulations and any other written law; and
- e) subject to Regulation 22, disclose to the Proponent, developer and the Agency all material information in the possession of the Environmental Assessment expert relating to the Environmental Assessment process.

Cancellation or suspension of certificate of registration

23. (1)

Subject to subregulation (2) the Agency may suspend or suspension of cancel the Certificate of Registration issued under these certificate of Regulations where the Agency is satisfied that the registration Environmental Assessment expert;

- a) obtained the Certificate of Registration by fraud or mistake;
- b) fraudulently or negligently provides false or misleading information to the Agency;
- c) makes a false declaration
- d) fraudulently alters an Environmental Assessment Report;

- e) is convicted or fined for an offence under this Act;
- f) is an undischarged bankrupt; or
- g) Has been found guilty of professional misconduct by the relevant professional body.

(2) The Agency shall, before suspending or cancelling a Certificate of Registration in accordance with sub-regulation (1), give notice to the holder thereof of its intention to suspend or cancel the Certificate of Registration in Form XIII set out in the First Schedule

(3) The Agency shall not suspend or cancel a Certificate of Registration under this regulation if the holder takes remedial measures to the satisfaction of the Agency within the period specified in the notice referred to in sub-regulation (2).

(4) Where a holder of a Certificate of Registration who is notified under subregulation (2) fails to show cause to the satisfaction of the Agency or does not take any remedial measures within the time specified in the notice, the Agency shall suspend or cancel the Certificate of

Registration and notify the holder in Form XIV set out in the First Schedule.

- (5) Where a Certificate of Registration is cancelled, the holder of the Certificate of Registration shall return it to the Agency and the Agency shall cancel the licence and record accordingly.
- (6) Subject to sub-regulation (7), a person whose Certificate of registration is cancelled may re-apply for registration in the relevant form set out in the First Schedule if that person takes remedial measures to the satisfaction of the Agency.
- (7) An application for a new Certificate of Registration may be made after one year from the date of the cancellation of the Certificate of Registration.

Failure to
declare
interest

24. (1)

A registered environmental expert who is an employee of an appropriate authority or consultation body and has participated in conducting an environmental assessment or preparing an environmental assessment or audit report which is under consideration by the Agency shall declare interest to the appropriate authority.

(2)

A person who fails to declare interest in accordance with subregulation (1) shall have their certificate of registration suspended or cancelled.

PART IV
GENERAL PROVISIONS

Offences and Penalties

25. (1)

A person shall not –

- a) in the practice as an environmental assessment expert, fail to abide by the provisions of Part III of these Regulations;
- b) fail to comply with the conditions of the Certificate of Registration of a Pesticide; or
- c) fail to comply with a provision of these Regulations.

(2)

A person who contravenes subregulation (1) commits an offence and is liable, on conviction, to a fine not exceeding five hundred thousand penalty units, or to imprisonment for a period not exceeding five years, or to both

Registers

26. (1)

The Agency shall maintain a register of Environmental Assessment experts registered under these regulations.

(2)

The Register referred to under sub regulation (1) shall be kept by the Director General and shall be open for inspection in both electronic and hard copy form by Members of the Public.

Guidelines

27. (1)

The Agency may issue guidelines to give effect to a regulation or provision in these Regulations.

- (2) Despite the generality of subregulation (1), the Agency shall issue guidelines pertaining to-
- a) assessment of trials conducted to determine the efficacy of a pesticide;
 - b) requirements for review of pesticide dossiers;
 - c) the criteria for appointment of relevant appropriate authorities or research institutions for purposes of Pesticide registration; or
 - d) further registration requirements for Environmental Assessment experts;

Transitional Provisions

28. (1) A person shall not be required to apply for registration of a pesticide prior to the Agency's issuance of a pesticide licence, where-

- a) at the commencement of these Regulations, the person has already applied to the Agency for a pesticide licence or renewal of a pesticide licence; or
- b) at the commencement of these Regulations, the person is a holder of a valid pesticide licence

(2) A holder of a pesticide licence issued under subregulation (1) shall on the expiration of the said licence and where the holder of the licence intends to hold another pesticide licence, ensure that pesticides under the

licence are registered in accordance with these Regulations.

- (3) An environmental expert shall within twelve months of the commencement of these regulations, comply with the requirements of these Regulations

Fees

29.

The fees set out in the Second Schedule are payable in respect of the matters specified in that Schedule

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