REGISTRATION OF BIOCIDAL PRODUCTS

GUIDELINES FOR SUBMISSION OF APPLICATIONS

VETERINARY MEDICINES DIRECTORATE	DOCUMENT NO:	VERSION:

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Note: This is a controlled document and shall not be amended or revised without authorization.

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LIST OF ABBREVIATIONS

AI	Active Ingredient
CAS	Chemical Abstract Service
GMP	Good Manufacturing Practices
IUPAC	International Union of Pure and Applied Chemistry
POP	Persistent Organic Pollutants
VMD	Veterinary Medicines Directorate

1. INTRODUCTION

These guidelines applies only to registration of biocidals and provides recommendations for applicants preparing application for submission to Veterinary Medicines Directorate (VMD).

The guidelines lay down rules for the regulation and labelling of biocidals in order to provide the basis for the assurance of a high level of protection of human health, animal health and welfare and environment.

Biocidal products are necessary for the control of organisms that are harmful to human or animal health and for the control of organisms that cause damage to natural or manufactured materials. However, biocidal products can pose risks to humans, animals and the environment due to their intrinsic properties and associated use patterns.

Biocidal products shall neither be made available on the market nor used unless authorised in accordance with these guidelines.

These guidelines are underpinned by the precautionary principle to ensure that the manufacturing and making available on the market of active substances and biocidal products do not result in harmful effects on human or animal health or unacceptable effects on the environment.

These guidelines apply to biocidal products that, in the form in which they are supplied to the user, consist of, contain or generate one or more active substances.

In the light of the diversity of both active substances and biocidal products, the data and test requirements should suit the individual circumstances and allow an overall risk assessment. Therefore, an applicant should meet the data requirements, as appropriate, including request the waiving of data requirements which are not necessary or are impossible to submit in view of the nature or the proposed uses of the product. Applicants should provide appropriate technical and scientific justification to support their requests.

When authorising biocidal products the Authority will ensure that, when properly used for the purpose intended, they are sufficiently effective and have no unacceptable effect on the target organisms such as resistance, or, in the case of vertebrates, unnecessary suffering and pain. Furthermore, they may not have, in the light of current scientific and technical knowledge, any unacceptable effect on human health, animal health or on the environment. Where appropriate, maximum residue limits for food and feed should be established with respect to active substances contained in a biocidal product to protect human and animal health. When these requirements are not met, biocidal products shall not be authorised unless their authorisation is justified because of

the disproportionate negative impact for society of not authorising them when compared to the risks arising from their use.

1.1 Scope

This guideline applies to biocidal products for veterinary hygiene. The product-types are as follows;

(a) Products used for veterinary hygiene purposes such as disinfectants, disinfecting soaps, oral or corporal hygiene products or with anti-microbial function.

(b) Products used to disinfect the materials and surfaces associated with the housing or transportation of animals.

(c) Antifouling products (Products used to control the growth and settlement of fouling organisms)

1.2 Definition of Terms

For the purposes of these guidelines, the following definitions shall apply:

Biocidal product means

— any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action,

— any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.

Micro-organism means any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, including lower fungi, viruses, bacteria, yeasts, moulds, algae, protozoa and microscopic parasitic helminths;

Active substance means a substance or a micro-organism that has an action on or against harmful organisms;

Substance of concern means any substance, other than the active substance, which has an inherent capacity to cause an adverse effect, immediately or in the more distant future, on humans, in particular vulnerable groups, animals or the environment and is present or is produced in a biocidal product in sufficient concentration to present risks of such an effect.
Such a substance would, unless there are other grounds for concern, normally be:
— a substance classified as dangerous or that meets the criteria to be classified as dangerous.
— a substance classified as hazardous
— a substance which meets the criteria for being a persistent organic pollutant (POP)

Harmful organism means an organism, including pathogenic agents, which has an unwanted presence or a detrimental effect on humans, their activities or the products they use or produce, on animals or the environment;

Residue means a substance present in or on products of plant or animal origin, water resources, drinking water, food, feed or elsewhere in the environment and resulting from the use of a biocidal product, including such a substance's metabolites, breakdown or reaction products;
Making available on the market means any supply of a biocidal product for distribution or use in the course of a commercial activity, whether in return for payment or free of charge;

Placing on the market means the first making available on the market of a biocidal product or of a treated article;

Use means all operations carried out with a biocidal product, including storage, handling, mixing and application, except any such operation carried out with a view to exporting the biocidal product or the treated article outside the Union;

Authorisation holder means the person established who is responsible for the placing on the market of a biocidal product in a particular Kenya and specified in the authorisation;

Product-type means one of the product-types specified in Annex 1;

Letter of access means an original document, signed by the data owner or its representative, which states that the data may be used for the Authority for the purposes of this registration;

Technical equivalence means similarity, as regards the chemical composition and hazard profile, of a substance produced either from a source different to the reference source, or from the reference source but following a change to the manufacturing process and/or manufacturing location, compared to the substance of the reference source in respect of which the initial risk assessment was carried out.

Authority means the Veterinary Medicines Directorate

Advertisement means a means of promoting the sale or use of biocidal products by printed, electronic or other media;

Composition
Means the ingredients including additives/excipients of which it consists, proportions, quality and purity in which those ingredients are contained.

Container
Means a bottle, jar, box, packet, sachet or other receptacle which contains or is to contain in it, and where any such receptacle is or is to be contained in another receptacle, includes the former but does not include the latter receptacle.

Country of origin
Means a country in which the nutrient and borderline product has been manufactured or produced.

Ingredient

Means any substance used in the manufacture or preparation of nutritional supplement and present in the finished product in its original or in a modified form.

Label

Means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embossed or impressed on or attached to a packaging material of any nutrient or borderline product.

Manufacture

Means and includes all operations involved in the production preparation, processing, compounding, formulating, filling, refilling, transforming, packaging, re-packaging and labelling of nutrient or borderline product.

Manufacturer

Means a person or firm that is engaged in the manufacture or processing of nutrient or borderline product.

Placing on the market means the initial placing on the Kenyan market of an additive after its manufacture, the import of an additive, or, where an additive has been incorporated into feed without being placed on the market, the first placing on the market of that feed.

2. GENERAL REQUIREMENTS

2.1 Applicants are required to carefully read this guideline, fill in application form, prepare information and submit them in one (1) hard-copy as well as an electronic copy (on a CD-ROM or memory stick) which should be cross-referenced to the hard copy by clearly indicating the title and section number of all the supporting documents. All areas in the application form are to be filled out by the applicant EXCEPT where indicated for “Official Use Only”!

2.2 In order to avoid unnecessary delays, applicants are strongly urged to read these guidelines carefully to enable them prepare and submit acceptable applications. Submission of an application contrary to the requirements prescribed in this guidelines may result in delays, queries or rejection of the application.

2.3 The conditions for labelling set out in Annex III.

2.4 The conditions for authorization are set out in Annex II.

2.6 Applicant

2.6.1 An application for registration of biocidals shall only be made either by the patent holder, the manufacturer or a distributor/local representative authorized by the manufacturer or patent holder.

2.6.2 The applicant shall be accountable for the product and all information submitted in support of the application for registration of the product and alteration thereof.

2.6.3 Applicant shall monitor the quality and safety of the product marketed in Kenya and inform the Authority in case of product defects and safety issues.

2.6.4 Applicant shall effect product recalls whenever necessary.

2.7 Application

2.7.1 Any person seeking an authorisation to place a biocidal in the Kenyan market shall submit an application in accordance with the application form attached to Annex I.

2.8 Language

All applications and supporting documents shall be in English and legible. Where material is not originally in English, a copy in the original language and a full translation should be submitted, the accuracy of which is the responsibility of the applicant. Authentication of the translation has to be done at the nearest Kenyan Embassy or by the national drug regulatory authority of the country from where the document originates. Information submitted only in a language other than English will not be accepted.

2.9 Presentation of the application documents

All data shall be presented on A4 and 80g/m2 paper with readily readable letters of 12 font sizes. Every page shall be numbered sequentially and state the exact location (Annex number) of any appended documents in the relevant sections of the form. Provide all requested information before submitting the completed application form. Tables, diagrams and other supporting documents shall as far as possible be of the same size, well annotated, numbered and appropriately cross-referenced. Acronyms and abbreviations should be defined the first time they are used in each part. Every page should be numbered. Different sections of the document shall be distinctly marked and page numbered and have a table of contents indicating the sections and page numbers. All parts must be bound and arranged sequentially. The left-hand margin should be sufficiently large that information is not obscured by the method of binding. The covers shall be made of a material which is thick and hard enough not to collapse in standing position.

2.10 Submission of Application

The application should be submitted to the following address:

The Chief Executive Officer
Veterinary Medicines Directorate
P. O. Box 66171-00800,
NAIROBI, KENYA
Email: vmd@kilimo.go.ke

For purposes of submission to VMD, an application for registration of food supplement shall include:

I. One duly filled application form and an electronic copy on a CD-ROM or memory stick including their supporting documents - see Annex I
II. Three (3) samples of the smallest commercial pack(s) from one batch with batch certificates of analysis.
III. Nonrefundable application fee for registration of biocidal products.
IV. GMP certificate of the manufacturing site

2.11 Payment of Fees

Every application shall be accompanied by appropriate fees at the time of application. Any application that will not be accompanied by appropriate fees will not be accepted. Application fees for registration of feed additives are as follows:

I. Products imported into Kenya US$ 500
II. Locally manufactured in Kenya US$ 250
III. Annual retention for products imported into Kenya US$ 150
IV. Annual retention for locally manufactured in Kenya US$ 150
V. Penalty for late retention (after 30th January) US$ 100
VI. Replacement of a Certificate: A fee of KSH 1,000 shall be paid for a replacement copy of a Certificate, if the original is defaced, damaged or lost. The copy shall be titled ―duplicate copy.
VII. Appeal fee: With respect to an appeal to an original application, a fee of US$ 300 must be paid at the time of appeal. Any appeal that will not be accompanied by appropriate fees will not be accepted.
VIII. Other Charges: The VMD may, at its own discretion, charge an applicant such costs as it may incur for carrying out any laboratory investigations prior to the registration of a product.

Verification of compliance to current Good Manufacturing Practices (cGMP): VMD may conduct inspection of the site or use other means to verify whether the facility complies with current Good Manufacturing Practices Regulations before a product is registered or in case of quality issues with the product in the market.

2.12 Timelines

I. Fast-tracked registration (Locally manufactured and Priority products only), Post Approval Variation and Renewal of registration will be processed within 90 days of receiving the application including evaluation of documentation and consideration by the council.
II. Applications for imported products will be processed within 6 months of receipt of the application.
III. VMD shall give an opinion within two months of receipt of a valid application. This time limit shall be extended whenever VMD seeks supplementary information from the applicant.

IV. VMD may, where appropriate, request the applicant to supplement the particulars accompanying the application within a specified time limit after consultation with the applicant.

2.13 Withdrawal of an application

When the applicant fails to submit written responses to queries within 3 months from the date of their issuance, it will be deemed that the applicant has withdrawn the application or if the queries have been reissued for a second time and the applicant provides unsatisfactory responses, the product will be disqualified and the application will be rejected. The applicant will be required to apply afresh.

2.14 Validity of registration

The registration of feed additives shall be valid for five (5) years unless suspended or revoked by VMD or withdrawn by applicant. The council will give reasons in writing when it suspends or revokes, or amends conditions of registration.

2.15 Notification of change/Variation

If for any reason the registration holder changes any matter related to a registered feed additive (e.g. change of composition, packaging, labelling etc) shall before marketing the changed product, notify the alteration along with justification and obtain an approval.

3. TECHNICAL REQUIREMENTS

3.1. APPLICANT

3.1.1. Name and address, etc.

3.1.2. Contact person

3.1.3. Manufacturer and formulator of the biocidal product and the active substance(s) (names, addresses, including location of plant(s)

3.1.4. A full visual description of the product. This shall include color, size, shape and other relevant features.

3.1.5. Commercial pack sizes of the product.

This shall include a list all pack sizes intended for marketing in Kenya.

3.1.6 Applicant should provide a registration certificate or authorization to market the product as an additive in the country of manufacture. (If a product is not registered in country of manufacture, a valid explanation must be given) A copy of the manufacturing license of the manufacturer shall be provided.

3.2. IDENTITY OF THE BIOCIDAL PRODUCT

3.2.1. Trade name or proposed trade name

3.2.2. Manufacturer's development code and number of the product, if appropriate

3.2.3. Complete quantitative (g/kg, g/l or % w/w (v/v)) composition of the biocidal product, i.e. declaration of all active substances and non-active substances, which are intentionally added to the biocidal product (formulation) as well as detailed quantitative and qualitative information on the composition of the active substance(s) contained in the biocidal product. For non-active substances, a safety data sheet has to be provided.

In addition, all relevant information on individual ingredients, their function and, in the case of a reaction mixture, the final composition of the biocidal product shall be given

3.2.4. Formulation type and nature of the biocidal product, e.g. emulsifiable concentrate, wettable powder, solution e.t.c.

3.2.5. Shelf life and storage conditions.

All applications must include stability data supporting the proposed shelf life of the finished product.

The applicant shall submit stability studies report for at least three batches of the finished product which shall include the study design (protocol), including test conditions (humidity and temperature), type of container, results and conclusions. Testing must be conducted using containers and closures intended for marketing of product and the test condition must mimic climatic conditions of Kenya for real-time and accelerated studies. Data for accelerated stability testing must be at least for six months.

The stability data must be sufficient to demonstrate, or indicate with a high probability that the product intended for market will remain safe, of consistent quality and efficacious throughout the product's shelf life. Attributes (parameters) to be tested should be those susceptible to change and are likely to influence the quality and safety of the finished product and they shall at least cover appearance for all product forms, levels of nutrients, physicochemical properties such as pH, dissolution, disintegration and microbial limits. The stability data will form the basis for setting a shelf life and recommended storage conditions for the product.

While applicants may choose the format for the presentation of stability data, the following headings are recommended: study design; test methods; commentary on the results obtained in the studies for individual parameters (including any trends); conclusions and summary of claims.

3.3. PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES

3.3.1. Appearance (at 20 °C and 101,3 kPa)

-Physical state (at 20 °C and 101,3 kPa)

- Colour (at 20 °C and 101,3 kPa)

- Odour (at 20 °C and 101,3 kPa)

3.3.2. Acidity/alkalinity

The test is applicable when the pH of the biocidal product or its dispersion in water (1 %) is outside the pH range 4-10

3.3.3. Relative density (liquids) and bulk, tap density (solids)

3.3.4. Storage stability, stability and shelf-life

a) Storage stability tests

- Accelerated storage test

- Long term storage test at ambient temperature

- Low temperature stability test (liquids)

b) Effects on content of the active substance and technical characteristics of the biocidal product

- Light
- Temperature and humidity
- Reactivity towards container material

3.3.5. Technical characteristics of the biocidal product

-Wettability

-Suspensibility, spontaneity and dispersion stability

-Wet sieve analysis and dry sieve test

-Emulsifiability, re-emulsifiability and emulsion stability

- Disintegration time
- Particle size distribution, content of dust/fines, attrition, friability
- Persistent foaming

-Flowability/Pourability/Dustability

-Burning rate - smoke generators

- Burning completeness — smoke generators
- Composition of smoke — smoke generators
- Spraying pattern — aerosols

-Other technical characteristics

3.3.6. Physical and chemical compatibility with other products including other biocidal products with which its use is to be authorised

-Physical compatibility

-Chemical compatibility

3.3.7. Degree of dissolution and dilution stability

3.3.8. Surface tension

3.3.9. Viscosity

3.4. PHYSICAL HAZARDS AND RESPECTIVE CHARACTERISTICS

3.4.1. Explosives

3.4.2. Flammable gases

3.4.3. Flammable aerosols

3.4.4. Oxidising gases

3.4.5. Gases under pressure

3.4.6. Flammable liquids

3.4.7. Flammable solids

3.4.8. Self-reactive substances and mixtures

3.4.9. Pyrophoric liquids

3.4.10. Pyrophoric solids

3.4.11. Self-heating substances and mixtures

3.4.12. Substances and mixtures which in contact with water emit flammable gases

3.4.13. Oxidising liquids

3.4.14. Oxidising solids

3.4.15. Organic peroxides

3.4.16. Corrosive to metals

3.4.17. Additional physical indications of hazard

- Auto-ignition temperatures of products (liquids and gases)
- Relative self-ignition temperature for solids
- Dust explosion hazard

3.5. METHODS OF DETECTION AND IDENTIFICATION

3.5.1. Analytical method including validation parameters for determining the concentration of the active substance(s), residues, relevant impurities and substances of concern in the biocidal product

3.5.2. Analytical methods for monitoring purposes including recovery rates and the limits of determination of relevant components of the biocidal product and/or residues thereof, where relevant in or on the following:

- Soil
- Air
- Water (including drinking water) and sediment
- Animal and human body fluids and tissues

3.5.3. Analytical methods for monitoring purposes including recovery rates and the limit of quantification and detection for the active substance, and for residues thereof, in/on food of plant and animal origin or feeding stuffs and other products where relevant (not necessary if neither the

active substance nor the material treated with it come into contact with food- producing animals, food of plant and animal origin or feeding stuffs)

3.6. EFFECTIVENESS AGAINST TARGET ORGANISMS

3.6.1. Function, e.g. fungicide, rodenticide, insecticide, bactericide

Mode of control e.g. attracting, killing, inhibiting

3.6.2. Representative organism(s) to be controlled and products, organisms or objects to be protected

3.6.3. Effects on representative target organisms

3.6.4. Likely concentration at which the active substance will be used

3.6.5. Mode of action (including time delay)

3.6.6. The proposed label claims for the product and, where label claims are made, for treated articles

3.6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant

3.6.8. Any known limitations on efficacy

Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies

Observations on undesirable or unintended side effects e.g. on beneficial and other non-target organisms

3.6.9. Summary and evaluation

3.7. INTENDED USES AND EXPOSURE

3.7.1. Field(s) of use envisaged for biocidal products and, where appropriate, treated articles

3.7.2. Product-type

3.7.3. Detailed description of intended use pattern(s) for biocidal products and, where appropriate, treated articles

3.7.4. User e.g. industrial, trained professional, professional or general public (non-professional)

3.7.5. Likely tonnage to be placed on the market per year and, where relevant, for different use categories

3.7.6. Method of application and a description of this method

3.7.7. Application rate and, if appropriate, the final concentration of the biocidal product and active substance in a treated article or in the system in which the product is to be used, e.g. cooling water, surface water, water used for heating purposes

3.7.8. Number and timing of applications, and where relevant, any particular information relating to geographical location or climatic variations including necessary waiting periods, clearance times, withdrawal periods or other precautions to protect human health, animal health and the environment

3.7.9. Proposed instructions for use

7.10. Exposure data;

a) Information on human exposure associated with production and formulation, proposed/expected uses and disposal

b) Information on environmental exposure associated

c) With production and formulation, proposed/expected uses and disposal

d) Information on exposure from treated articles including leaching data (either laboratory studies or model data)

e) Information regarding other products that the product is likely to be used together with, in particular the identity of the active substances in these products, if relevant, and the likelihood of any interactions

3.8. TOXICOLOGICAL PROFILE FOR HUMANS AND ANIMALS

3.8.1. Skin corrosion or skin irritation

3.8.2. Eye irritation

3.8.3. Skin sensitization. The assessment of this endpoint shall comprise the following consecutive steps; an assessment of the available human, animal and alternative data

; in vivo testing

The Murine Local Lymph Node Assay (LLNA) including, where appropriate, the reduced variant of the assay, is the first-choice method for in vivo testing. If another skin sensitisation test is used justification shall be provided

3.8.4. Respiratory sensitisation

3.8.5. Acute toxicity

• By oral route

• By inhalation

• By dermal route

For biocidal products that are intended to be authorised for use with other biocidal products, the risks to human health, animal health and the environment arising from the use of these product combinations shall be assessed. As an alternative to acute toxicity studies, calculations can be used.

3.8.6. Information on dermal absorption

Information on dermal absorption when exposure occurs to the biocidal product. The assessment of this endpoint shall proceed using a tiered approach

3.8.7. Available toxicological data relating to:

— non-active substance(s) (i.e. substance(s) of concern), or

— a mixture that a substance(s) of concern is a component of

If insufficient data are available for a non-active substance(s) and cannot be inferred through read-across or other accepted non-testing approaches, targeted test(s) shall be carried out for the substance(s) of concern or a mixture that a substance(s) of concern is a component of

3.8.8. Food and feeding stuffs studies; If residues of the biocidal product remain in or on feeding stuffs for a significant period of time, then feeding and metabolism studies in livestock shall be required to permit evaluation of residues in food of animal origin

3.8.9. Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the biocidal product

3.8.10. Other test(s) related to the exposure to humans

Suitable test(s) and a reasoned case will be required for the biocidal product.

In addition, for certain biocides which are applied directly or around livestock (including horses) residue studies might be needed.

3.9. ECOTOXICOLOGICAL STUDIES

3.9.1. Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required;

3.9.2. Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk

3.9.3. Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated

3.10. ENVIRONMENTAL FATE AND BEHAVIOUR

The test requirements in this section are applicable only to the relevant components of the biocidal product

3.10.1. Foreseeable routes of entry into the environment on the basis of the use envisaged

3.10.2. Further studies on fate and behaviour in the environment

Further studies relevant components of the biocidal product or the biocidal product itself may be required.

For products that are used outside, with direct emission to soil, water or surfaces, the components in the product may influence the fate and behaviour (and ecotoxicity) of the active substance. Data are required unless it is scientifically justified that the fate of the components in the product is covered by the data provided for the active substance and other identified substances of concern

3.10.3. Leaching behaviour

3.10.4. Testing for distribution and dissipation in the following: Soil

Water and sediment Air

3.10.5. If the biocidal product is to be sprayed near to surface waters, then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions

10.6. If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given, then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions

3.11. MEASURES TO BE ADOPTED TO PROTECT HUMANS, ANIMALS AND THE ENVIRONMENT

3.11.1. Recommended methods and precautions concerning handling, use, storage, disposal, transport or fire

3.11.2. Identity of relevant combustion products in cases of fire

3.11.3. Specific treatment in case of an accident, e.g. first- aid measures, antidotes, medical treatment if available; emergency measures to protect the environment

3.11.4. Possibility of destruction or decontamination following release in or on the following: Air, Water, including drinking water, Soil

3.11.5. Procedures for waste management of the biocidal product and its packaging for industrial use, use by trained professionals, professional users and non- professional users (e.g. possibility of reuse or recycling, neutralisation, conditions for controlled discharge, and incineration)

3.11.6. Procedures for cleaning application equipment where relevant

3.11.7. Specify any repellents or poison control measures included in the product that are present to prevent action against non-target organisms

3.12. CLASSIFICATION, LABELLING, AND PACKAGING

3.12.1. Labelling information shall be given according to annex III.

3.12.2. Hazard classification

3.12.3. Hazard pictogram

3.12.4. Signal word

3.12.5. Hazard statements

3.12.6. Precautionary statements including prevention, response, storage and disposal

3.12.7. Proposals for safety-data sheets should be provided, where appropriate

3.12.8. Packaging (type, materials, size, etc.), compatibility of the product with proposed packaging materials to be included. The products shall be packed in containers which safeguard hygienic and other qualities. The containers, including packaging material, shall be made only of substances which are safe and suitable for their intended use. The following information shall be provided:

I. A general description of the container and closure system including primary (inner) and secondary (outer) packaging materials used.
II. Specifications for primary (immediate) packaging components such as: glass containers, plastic containers, rubber closures.
III. Evidence of suitability of the container and closure system for the finished product and proof of compatibility of primary packaging components with finished product.

ANNEX 1: APPLICATION FORM

APPLICATION FOR REGISTRATION OF BIOCIDAL PRODUCTS

The Chief Executive Officer,
Veterinary Medicines Directorate,
P.O. Box 66171-00800,
Westlands, Nairobi
Telephone: +254743795395
Email: VMD@kilimo.go.ke

1	**PARTICULARS OF THE PRODUCT**
1.1	Common name proposed or accepted by ISO and synonyms (usual name, trade name, abbreviation)
1.2	Other Names
1.3	Chemical name (IUPAC and CA nomenclature or other international chemical name(s))
1.4	CAS Number
1.5	Strength of Active Ingredients (AI) per unit dosage
1.6	Molecular and structural formula
1.7	Molecular weight for each active ingredient
1.8	Specification of purity of the active substance as manufactured in g/kg, g/l or %w/w (v/v) as appropriate, providing inclusively the upper and lower limit
1.9	Intended use or indications of the product
1.10	The identity of any impurities and additives including by-products of synthesis, optical isomers, degradation products (if the substance is unstable) un-reacted and end-groups etc. of polymers and un-reacted starting materials of UVC-substances
1.11	Instructions for use

1.12	Proposed shelf life, shelf life after opening of container and shelf life after reconstitution (Attach stability data)
1.13	Country of origin and release (Attach a registration certificate or authorization to market the product as nutrient and borderline products in the country of manufacture and in other countries)
1.14	Brief description of the physical characteristics of the product (color, size, shape and other relevant features)
1.15	Type of materials for the packaging/container (Attach specifications of the primary container and artworks for labelling and or information leaflets)
1.16	Type of closure system for package or container
1.17	Packaging unit(s)/Pack sizes intended for marketing (Provide 3 samples for every unit)

2. PARTICULARS OF THE APPLICANT (SHOULD BE THE LOCAL TECHNICAL REPRESENTATIVE)	
Name	
Postal Address	
Country	
Physical Address (plot/block	

No./street/Village/district/region)	
Telephone number	
Email	

Note: If the applicant is not the LTR, explain and provide evidence of the relationship with manufacturer.

3. PARTICULARS OF MANUFACTURER OF FINISHED PRODUCT	
Name	
Postal Address	
Country	
Physical Address (plot/block No./street/Village/district/region)	
Telephone number	
Email	
Good Manufacturing Practice (GMP) status (Attach certificate)	

4	**TECHNICAL INFORMATION** (Detailed description of the technical information required in sections 3.3 to 3.12 of the guidelines)

Declaration by an applicant

I,……the……
……..(position in the company) and a dully authorized representative of …… (the company) declare that all the information filled in this form and all the accompanying documents are true and correct and confirm that the information referred to in this application is available for verification.

Signature……

Date…….

Official Stamp/Seal……

ANNEX II: GENERAL CONDITIONS FOR GRANTING AUTHORIZATION

1. A biocidal product shall be authorised provided the following conditions are met:

(a) The active substances are approved for the relevant product- type and any conditions specified for those active substances are met;

(b) It is established, according to the common principles for the evaluation of dossiers for biocidal, that the biocidal product, when used as authorised, fulfils the following criteria:

(i) The biocidal product is sufficiently effective;

(ii) The biocidal product has no unacceptable effects on the target organisms, in particular unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates;

(iii) the biocidal product has no immediate or delayed unacceptable effects itself, or as a result of its residues, on the health of humans, including that of vulnerable groups, or animals, directly or through drinking water, food, feed, air, or through other indirect effects;

(iv) The biocidal product has no unacceptable effects itself, or as a result of its residues, on the environment, having particular regard to the following considerations:

— The fate and distribution of the biocidal product in the environment,

— Contamination of surface waters (including estuarial and seawater), groundwater and drinking water, air and soil, taking into account locations distant from its use following long-range environmental transportation,

— The impact of the biocidal product on non-target organisms,

— The impact of the biocidal product on biodiversity and the ecosystem;

(c) The chemical identity, quantity and technical equivalence of active substances in the biocidal product and, where appropriate, any toxicologically or ecotoxicologically significant and relevant impurities and non-active substances, and its residues of toxicological or environmental significance, which result from uses to be authorised, can be determined.

(d) The physical and chemical properties of the biocidal product have been determined and deemed acceptable for the purposes of the appropriate use and transport of the product;

(e) Where appropriate, maximum residue limits for food and feed have been established with respect to active substances contained in a biocidal product

(f) Where nanomaterials are used in that product, the risk to human health, animal health and the environment has been assessed separately.

2. The evaluation of whether a biocidal product fulfils the criteria set out in point (b) of paragraph 1 shall take into account the following factors:

(a) Realistic worst case conditions under which the biocidal product may be used;

(b) The way in which treated articles treated with the biocidal product or containing the biocidal product may be used;

(c) The consequences of use and disposal of the biocidal product;

(d) Cumulative effects;

(e) Synergistic effects.

3. A biocidal product shall only be authorised for uses for which the application was made.

4. A biocidal product shall not be authorised for making available on the market for use by the general public where:

(a) It is classified as;

— Toxic or very toxic,

— A category 1 or 2 carcinogen,

— A category 1 or 2 mutagen, or

— Toxic for reproduction category 1 or 2;

(b) It is classified as:

— Acute oral toxicity category 1 or 2 or 3,

— Acute dermal toxicity category 1 or 2 or 3,

— Acute inhalation toxicity (gases and dust/mist) category 1 or 2 or 3,

— Acute inhalation toxicity (vapours) category 1 or 2,

— A category 1A or 1B carcinogen,

— A category 1A or 1B mutagen, or

— Toxic for reproduction category 1A or 1B

(c) It meets the criteria for being PBT or vPvB

(d) It has endocrine-disrupting properties

(e) It has developmental neurotoxic or immunotoxic effects.

5. Where appropriate, the applicant shall establish maximum residue limits (MRL) with respect to active substances contained in a biocidal product.

ANNEX III: LABELLING

General Requirements

1. Authorisation holders shall ensure that biocidal products are classified, packaged and labelled in accordance with the approved summary of biocidal product characteristics including the hazard statements and the precautionary statements,

In addition, products which may be mistaken for food, including drink, or feed shall be packaged to minimise the likelihood of such a mistake being made. If they are available to the general public, they shall contain components to discourage their consumption and, in particular, shall not be attractive to children.

2. In addition to compliance with paragraph 1, authorisation holders shall ensure that labels are not misleading in respect of the risks from the product to human health, animal health or the environment or its efficacy and, in any case, do not mention the indications 'low-risk biocidal product', 'non-toxic', 'harmless', 'natural', 'environmentally friendly', 'animal friendly' or similar indications. In addition, the label must show clearly and indelibly the following information:

(a) The identity of every active substance and its concentration in metric units;

(b) The nanomaterials contained in the product, if any, and any specific related risks, and, following each reference to nanomaterials, the word 'nano' in brackets;

(c) The authorisation number allocated to the biocidal product issued by the Authority;

(d) The name and address of the authorisation holder;

(e) The type of formulation;

(f) The uses for which the biocidal product is authorised;

(g) Directions for use, frequency of application and dose rate, expressed in metric units, in a manner which is meaningful and comprehensible to the user, for each use provided for under the terms of the authorisation;

(h) Particulars of likely direct or indirect adverse side effects and any directions for first aid;

(i) If accompanied by a leaflet, the sentence 'Read attached instructions before use' and, where applicable, warnings for vulnerable groups;

(j) Directions for the safe disposal of the biocidal product and its packaging, including, where relevant, any prohibition on the reuse of packaging;

(k) The formulation batch number or designation and the expiry date relevant to normal conditions of storage;

(l) where applicable, the period of time needed for the biocidal effect, the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during use and transport;

(m) Where applicable, the categories of users to which the biocidal product is restricted;

(n) Where applicable, information on any specific danger to the environment particularly concerning protection of non- target organisms and avoidance of contamination of water;

(o) Date of manufacture and date of expiry

Where necessary because of the size or the function of the biocidal product, the information referred to in points (e), (g), (h), (j), (k), (l) and (n) may be indicated on the packaging or on an accompanying leaflet integral to the packaging.