REGISTRATION OF ADDITIVES FOR USE IN ANIMAL NUTRITION

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

FAO	Food and Agriculture Organization
GMP	Good Manufacturing Practices
HACCP	Hazard Analysis Critical Control Points
VMD	Veterinary Medicines Directorate
WHO	World Health Organization
BMR	Batch Manufacturing Records

1. INTRODUCTION

These guidelines applies only to registration of feed additives 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 feed additives and premixtures in order to provide the basis for the assurance of a high level of protection of human health, animal health and welfare and environment.

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"!

1.1 Definition of Terms

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

Feed (or 'feeding stuff') means any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals

Feed additives means substances, micro-organisms or preparations, other than feed material and premixtures, which are intentionally added to feed or water in order to perform, in particular, one or more of the following functions

1. Favourably affect the characteristics of feed
2. Favourably affect the characteristics of animal products
3. Favourably affect the colour of ornamental fish and birds
4. Satisfy the nutritional needs of animals
5. Favourably affect the environmental consequences of animal production
6. Favourably affect animal production, performance or welfare, particularly by affecting the gastro-intestinal flora or digestibility of feeding stuffs
7. Have a coccidiostatic or histomonostatic effect

Feed materials means various products of vegetable or animal origin, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, whether or not containing additives, which are intended for use in oral animal feeding either directly as such, or after processing, in the preparation of compound feeding stuffs or as carriers of premixtures

Premixtures means mixtures of feed additives or mixtures of one or more feed additives with feed materials or water used as carriers, not intended for direct feeding to animals

Antimicrobials means substances produced either synthetically or naturally, used to kill or inhibit the growth of micro-organisms, including bacteria, viruses or fungi, or of parasites, in particular protozoa;

Antibiotic means antimicrobials produced by, or derived from, a micro-organism, which destroys or inhibits the growth of other micro-organisms;

Coccidiostats and **Histomonostats** means substances intended to kill or inhibit protozoa

Batch

Means defined quantity of any nutritional supplement processed in a single process or series of processes such that it can reasonably be expected to be uniform in character and quality. Batch also means lot.

Certification of GMP or HACCP Compliance

Means a certificate or warranty accompanying an application for registration of nutritional supplements to be imported into Kenya issued by competent authority certifying that the manufacturing premises comply with GMP or HACCP.

Codex

Means the Codex Alimentarius Commission responsible for execution of the joint FAO/WHO food standards programme for the purpose of protecting the health of food consumers and ensuring fair practices in the international food trade.

Competent Authority

Means an authority responsible for regulation of the quality and safety of nutrients and borderline products.

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 No product shall be placed on the market, processed or used a feed additive unless it has been given market authorization in accordance with VMD Regulations.

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 use of authorized feed additives are set out in Annex II.

2.4 The conditions for labelling set out in Annex III.

2.5 Unless otherwise specified, the mixing of additives to be sold directly to the end-user shall be allowed, subject to compliance with the conditions for use laid down in the authorisation for each single additive.

2.6 Applicant

2.6.1 An application for registration of nutritional supplement 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 VMD 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 feed additive 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

Note 1: 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 nutrients and borderline 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$ 100
II. Locally manufactured in Kenya US$ 50
III. Annual retention for products imported into Kenya US$ 30
IV. Annual retention for locally manufactured in Kenya US$ 30
V. Penalty for late retention (after 30th January) US$ 10

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.

Note 2: 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 Identification of the feed additive

3.1.1 All feed additives shall be notified as per their proprietary Name. The Proprietary Name should not be derived from INN name and should not have an INN stem.

3.1.2 If derived from Generic Name should not be similar to the Generic Name.

3.1.3 Each Name used should be distinctive in sound and in writing not to be confused with Names of other Products.

3.1.4 The Name should not be misleading e.g. use Protavit for product not containing implied micro or macronutrient. Names which lead to self-diagnosis in conditions requiring professional diagnosis will be considered as misleading.

3.1.5 Any phrase that implies superiority, speed or better performance over other products shall not be allowed.

3.1.6 Meaning of abbreviations, symbols, alpha-numerals must be explained in a covering letter.

3.1.7 A proprietary name should not carry prescription information unless otherwise backed with a strong scientifically proven report that support the connotation.

3.1.8 When the Name being applied for is identical or very close to already registered Name, applicant shall be advised to change to another Name.

3.1.9 Proprietary Names shall not be reserved for applications that have not been yet received.

3.2 Approved / INN / generic name (where applicable).

This is the internationally recognized non-proprietary name of the active ingredient of the additive

3.3 Category of additive

A proposal for its classification by category and functional group under Annex IV, and its specifications, including, where applicable, purity criteria

3.4 Strength.

This shall be given per unit dosage form or per specified quantity: e.g. mg per tablet, mg per capsule, mg/mL, mg per G, etc.

3.4 Dosage form.

This is the form in which the nutrient or borderline products is presented, e.g. solution, suspension, Tablet, emulsion, Capsules, Sachet, etc.

3.5 A full visual description of the additive

This shall include color, size, shape and other relevant features.

3.6 Commercial pack sizes of the product.

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

3.7 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.

3.8 Particulars of the manufacturer(s) and activity

The name, physical address, telephone number, fax number, and e-mail address of the manufacturer shall be provided. Where different activities of manufacture of a given product are carried out at different manufacturing sites, the above particulars shall be provided for each site and the activity carried out at the particular site shall be stated.

3.9 Intended uses and volumes of use of the product

For a product to qualify as a nutrient or borderline product it should conform to the definitions given in this guideline and in addition should meet the following requirements;

I. Should not have any medicinal or therapeutic claims in relation to use of the product for treatment or averting of a disease condition.
II. Should not contain any substance of known pharmacological activity.

3.10 Raw material specifications

Applications shall include comprehensive specifications of each ingredient used in the product describing the limits or criteria of acceptance or rejection of raw materials.

Copies of the supplier's or manufacturer's Certificates of Analysis shall be submitted for each raw material as proof of conformance to all declared specifications.

3.11 Manufacture

A description of the method of production, manufacturing of the feed additive, the method of analysis of the additive in feed according to its intended use and, where appropriate, of the method of analysis for the determination of the level of residues of the feed additive, or its metabolites, in food from animal origin.

3.12 Safety

Studies which have been carried out and any other material which is available to demonstrate that the feed additive meets the highest levels of safety.

3.13 Post Market Monitoring

For additives which do not belong to either category (a) or category (b) referred to in Annex IV, and for additives containing or produced from GMOs, a proposal for post-market monitoring

3.14 Finished Product Specifications

Summarized specifications of the final product shall be given, i.e. the acceptable limits of the physical, chemical, biological and (where applicable) microbiological parameters. A full

description of analytical and other control procedures carried out to ascertain the final product specifications stated above shall be given.

The Finished product specification should include but not limited to the following tests;

I. Description, Identity (test method should be specific for active ingredient(s), Assay (test method should be specific and stability indicating for active ingredient(s) and Impurity limits - to determine the level of degradation products of active ingredients, and active ingredient-excipient interaction impurities.

II. For oral liquids, the following additional tests for oral liquids shall be required
    a) PH
    b) Microbial limits
    c) Antimicrobial preservative content/ preservative efficacy test
    d) Antioxidant preservative content
    e) Effects of the primary container on the product
    f) Alcohol content
    g) Dissolution of suspensions
    h) Particle size distribution
    i) Re-dispersibility
    j) Specific gravity
    k) Water content

All tests should be performed unless development pharmaceutics studies or process validation prove that they are unnecessary. Such proof should be provided by the applicant.

3.15 Specifications of the packaging material

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.

3.16 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.

3.17 Conditions for Authorisation

I. No feed additive shall be authorised unless the applicant for such authorisation has adequately and sufficiently demonstrated in accordance with the implementing measures referred to in Article 7 that, when used in accordance with conditions to be set out in the Regulation authorising the use of the additive, it satisfies the requirements of paragraph 2, and has at least one of the characteristics set out in paragraph 3.

II. The feed additive shall not:

(a) have an adverse effect on animal health, human health or the environment,

(b) be presented in a manner which may mislead the user,

(c) harm the consumer by impairing the distinctive features of animal products or mislead the consumer with regard to the distinctive features of animal products.

III. The feed additive shall:

(a) favourably affect the characteristics of feed,

(b) favourably affect the characteristics of animal products,

(c) favourably affect the colour of ornamental fish and birds,

(d) satisfy the nutritional needs of animals,

(e) favourably affect the environmental consequences of animal production,

(f) favourably affect animal production, performance or welfare, particularly by affecting the gastro-intestinal flora or digestibility of feedingstuffs,

(g) have a coccidiostatic or histomonostatic effect.

IV. Antibiotics, other than coccidiostats or histomonostats, shall not be authorised as feed additives.

4. POST MARKET SURVEILLANCE

4.1 Each consignment of feed additives that is imported into KENYA shall be inspected at the port of entry by VMD Inspectors for physical attributes and only registered products shall be accepted.

4.2 Each batch of every consignment shall be accompanied by an authenticated certificate of analysis.

4.3 The inspector at the port of entry shall ensure that feed additives are properly labelled with the following minimum labelling requirements according to these guidelines.

4.4 The manufacturer shall be liable to ensure the quality and safety of their products in the Kenyan market

ANNEX 1: APPLICATION FORM

APPLICATION FOR REGISTRATION OF FEED ADDITIVES

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	Trade Name
1.2	International Non-proprietary Name (INN) of the Active Ingredients (AI)
1.3	Proposed Category
1.4	Strength of Active Ingredients (AI) per unit dosage
1.5	CAS Number
1.6	Other Names
1.7	Molecular formula for each active ingredient
1.8	Molecular weight for each active ingredient
1.9	intended use or indications of the product
1.10	Dosage forms

1.11	Dosages
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) 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	**DETAILS OF THE PROCEDURES INVOLVED IN THE VARIOUS STAGES OF MANUFACTURE** (A description of the method of production, manufacturing of the feed additive, the method of analysis of the additive in feed according to its intended

	use and, where appropriate, of the method of analysis for the determination of the level of residues of the feed additive, or its metabolites, in food from animal origin)

5. INGREDIENTS			
No.	Name	Proportion (e.g. %, ppm, units)	Purpose of use

6. ADDITIVES			
No.	Name	Proportion (e.g. %, ppm, units)	Purpose of use

7	**RAW MATERIALS SPECIFICATIONS** (limits or criteria of acceptance or rejection of raw materials). *Attach Certificates of Analysis from an accredited laboratory as proof of conformance to all declared specifications.*

8	**FINISHED PRODUCT SPECIFICATIONS** (acceptable limits of the physical, chemical, biological and microbiological parameters). *Attach Certificates of Analysis from an accredited laboratory as proof of conformance to all declared specifications*.

9	**SAFETY AND SAFETY MANAGEMENT INFORMATION** (provide references)

9	**PROPOSAL FOR POST MARKETING MONITORING (**For additives which do not belong to either category (a) or category (b) referred to in Annex IV, and for additives containing or produced from GMOs)

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 OF USE

I. The quantity of additives that also exists in the natural state in certain feed materials shall be calculated so that the total of the elements added and the elements present naturally does not exceed the maximum level provided for in the authorisation Regulation.

II. Mixing of additives shall be permitted only in premixtures and feeding stuffs where there is physico-chemical and biological compatibility between the components of the mixture in relation to the effects desired.

III. Supplementary feeding stuffs, diluted as specified, may not contain levels of the additives which exceed those fixed for complete feeding stuffs.

IV. In the case of premixtures containing silage additives the words ‘of silage additives’ must clearly be added on the label after ‘PREMIXTURE’.

V. Technological additives or other substances or products contained in additives consisting of preparations shall only modify the physico-chemical characteristics of the active substance of the preparation and shall be used in accordance with their conditions of authorisation where such provisions are provided for. Physico-chemical and biological compatibility between the components of the preparation shall be ensured in relation to the effects desired.

ANNEX III: LABELLING AND PACKAGING OF FEED ADDITIVES AND PREMIXTURES

General Requirements

I. No product shall be placed on the market as a feed additive or a premixture of additives unless its packaging or container is labelled under the responsibility of a producer, packer, importer, seller or distributor registered in Kenya and bears the following information, in a conspicuous, clearly legible and indelible manner, in English;

(a) the specific name given to the additives upon authorisation, preceded by the name of the functional group as mentioned in the authorisation

(b) the name or business name and the address or registered place of business of the person responsible for the particulars in the authorization

(c) the net weight or, in the case of liquid additives and premixtures, either the net volume or the net weight

(d) where appropriate, the approval number of the establishment manufacturing or placing on the market the feed additive or the premixture

(e) directions for use, and any safety recommendations regarding the use and, where applicable, the specific requirements mentioned in the authorisation, including animal species and categories for which the additive or premixture of additives is intended

(f) the batch reference number and date of manufacture

(g) In the case of premixtures, points (b), (d), (e) and (g) shall not apply to the incorporated feed additives.

II. For flavouring compounds, the list of additives may be replaced by the words ‘mixture of flavouring compounds’. This shall not apply to flavouring compounds subject to a quantitative limitation when used in feed and drinking water.

III. In the case of premixtures, the word ‘premixture’ shall appear on the label.

IV. Additives and premixtures shall be marketed only in closed packages or closed containers which must be closed in such a way that the fastener is damaged on opening and cannot be re-used.

Specific Requirements

(a) Zootechnical additives, coccidiostats and histomonostats:

- The expiry date of the guarantee or the storage life from the date of manufacture,
- The directions for use, and
- The concentration.

(b) Enzymes, in addition to the abovementioned indications:

- The specific name of the active component or components in accordance with their enzyme activities, in conformity with the authorisation given,
- The International Union of Biochemistry identification number, and
- Instead of concentration: units of activity (units of activity per gram or units of activity per millilitre).

(c) Micro-organisms:

- The expiry date of the guarantee or the storage life from the date of manufacture, directions for use,
- The strain identification number, and
- The number of colony-forming units per gram.

(d) Nutritional additives:

- The active-substance level, and
- The expiry date of the guarantee of that level or storage life from the date of manufacture.

(e) Technological and sensory additives with the exception of flavouring compounds:

- The active substance level.

(f) Flavouring compounds:

- The incorporation rate in premixtures.

Additional labelling and information requirements for certain additives consisting of preparations and premixtures containing such preparations.

(a) Additives belonging to the categories (a), (b) and (c) and consisting of preparations:

i. The indication on the packaging or container of the specific name, the identification number and the level of any technological additive contained in the preparation for which maximum levels are set in the corresponding authorisation;

ii. The following information via any written medium or accompanying the preparation: the specific name and the identification number of any technological additive contained in the preparation, and the name of any other substance or product contained in the preparation, indicated in descending order by weight.

(b) Premixtures containing additives belonging to the categories (a), (b) and (c) and consisting of preparations:

i. If appropriate, the indication on the packaging or container that the premixture contains technological additives included in additive preparations, for which maximum levels are set in the corresponding authorisation

ii. Upon request from the purchaser or the user, information on the specific name, the identification number and an indication of the level of technological additives referred to in point (i) of this paragraph included in the additive preparations.

ANNEX IV: ADDITIVE CATEGORIES

I. In the category 'technological additives', the following functional groups are included:

(a) preservatives: substances or, when applicable, micro-organisms which protect feed against deterioration caused by micro-organisms or their metabolites;

(b) antioxidants: substances prolonging the storage life of feeding stuffs and feed materials by protecting them against deterioration caused by oxidation;

(c) emulsifiers: substances that make it possible to form or maintain a homogeneous mixture of two or more immiscible phases in feeding stuffs;

(d) stabilisers: substances which make it possible to maintain the physico- chemical state of feeding stuffs;

(e) thickeners: substances which increase the viscosity of feeding stuffs;

(f) gelling agents: substances which give a feeding stuff texture through the formation of a gel;

(g) binders: substances which increase the tendency of particles of feeding stuffs to adhere;

(h) substances for control of radionucleide contamination: substances that suppress absorption of radionucleides or promote their excretion;

(i) anticaking agents: substances that reduce the tendency of individual particles of a feeding stuff to adhere;

(j) acidity regulators: substances which adjust the pH of feeding stuffs;

(k) silage additives: substances, including enzymes or micro-organisms, intended to be incorporated into feed to improve the production of silage;

(l) denaturants: substances which, when used for the manufacture of processed feeding stuffs, allow the identification of the origin of specific food or feed materials;

(m) substances for reduction of the contamination of feed by mycotoxins: substances that can suppress or reduce the absorption, promote the excretion of mycotoxins or modify their mode of action;

(n) hygiene condition enhancers: substances or, when applicable, microorganisms which favourably affect the hygienic characteristics of feed by reducing a specific microbiological contamination;

(o) other technological additives: substances or, when applicable, microorganisms added to feed for a technological purpose and which favourably affect the characteristics of the feed.

II. In the category 'sensory additives', the following functional groups are included:

(a) colourants:

(i) substances that add or restore colour in feeding stuffs;

(ii) substances which, when fed to animals, add colours to food of animal origin;

(iii) substances which favourably affect the colour of ornamental fish or birds;

(b) flavouring compounds: substances the inclusion of which in feeding stuffs increases feed smell or palatability.

III. In the category 'nutritional additives', the following functional groups are included:

(a) vitamins, pro-vitamins and chemically well-defined substances having similar effect;

(b) compounds of trace elements;

(c) amino acids, their salts and analogues;

(d) urea and its derivatives.

IV. In the category 'zootechnical additives', the following functional groups are included:

(a) digestibility enhancers: substances which, when fed to animals, increase the digestibility of the diet, through action on target feed materials;

(b) gut flora stabilisers: micro-organisms or other chemically defined substances, which, when fed to animals, have a positive effect on the gut flora;

(c) substances which favourably affect the environment;

(d) other zootechnical additives;

(e) physiological condition stabilisers: substances or, when applicable microorganisms, which, when fed to animals in good health, favourably affect their physiological condition, including their resilience to stress factors.