



agriculture, forestry & fisheries

Department:
Agriculture, forestry & fisheries
REPUBLIC OF SOUTH AFRICA

GUIDELINES ON THE DATA AND DOCUMENTS REQUIRED FOR REGISTRATION OF FARM FEEDS IN SOUTH AFRICA

Issued by the Registrar: Act No. 36 of 1947

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SECTION A: REGISTRATION PROCESS

1. INTRODUCTION

The Department of Agriculture, Forestry and Fisheries (DAFF) through the Directorate of Agriculture Inputs Control (DAIC) under the authority of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947), regulates the importation, manufacture, acquisition, distribution, sales, use, advertisement and disposal of farm feeds.

Farm Feeds is defined in the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act (Act No. 36 of 1947), as -

- a) (i) any substance obtained by a process of crushing, gristing or grinding, or by the addition to any substance or the removal therefrom of any ingredient; or
- (ii) any condimental food, vitamin or mineral substance or other substance which possesses or is alleged to possess nutritive properties; or
- (iii) any bone product, intended or sold for the feeding of domestic animals or livestock; or
- b) any stock lick or substance which can be and is used as a stock lick, whether or not such stock lick or substance possesses medicinal properties,

but does not include straw, chaff, unground hay, silage, any cereal in the grain or any substance which would otherwise be a farm feed but has been ground, crushed, gristed or prepared for any person, in accordance with his directions for his own use, unless the Minister has by notice in the *Gazette* declared such substance a farm feed for the purposes of this Act.

Animal Feeds has the same meaning.

Persons who wish to manufacture, import, acquire, sell and advertise animal feeds in South Africa must submit detailed information and data for assessment to the Registrar of Act No. 36 of 1947. Section 3 of Act No. 36 of 1947 requires that applicants must submit data generated from scientific studies for assessment of safety, efficacy and quality of products. Data must be generated from studies carried out according to acceptable local and international standards such as SANS, EC, EFSA, OECD, etc. (see a non-exhaustive list of standards listed in Annexure 2). It should be noted that the DAIC does not conduct its own tests when evaluating animal feeds, but conducts a scientific review of the data submitted by the applicants.

The DAIC performs a full assessment and does not consider approval by another regulatory authority as criteria for registration. DAIC has the responsibility to ensure that animal feed registered for use in South Africa is:

- safe to the target animal, the user, the general public and the environment;
- efficacious – that means, a product is capable of producing the intended results;
- suitably formulated using ingredients allowed in animal feed; and
- properly labelled.

1.1. CLASSES OF FARM FEEDS

The following feeds must be registered **prior to importation, manufacture or sale** in South Africa. Refer to (Annexure I) for forms to be used for the registration of farm feeds.

1.1.1 Raw material

- Source of macro mineral
- Raw material of plant origin
- Raw material of animal origin

1.1.2 Feed additive

- Nutritional additive
- Technological additive
- Zootechnical additive
- Sensory additive
- Nutritional additives premixes

1.1.3 Livestock feed

- Complete feed
- Concentrate
- Supplement

1.1.4 Pet food

- Complete Dog or Cat food (including Raw pet food)
- Complete miscellaneous pet food (Horse, Rabbits, Hamster, Mice, Fish, Birds and other minor species)
- Complementary pet food (including Raw Pet Food)
- Pet nutraceuticals
- Herbal supplements
- Seed and Grain mixture
- Nutritional supplements for pets

Feeds for the following species are regulated under the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947:

Dogs, cats, cattle, horses, sheep, goats, swine, poultry (chickens, turkeys, ducks, geese, ostrich), fish, crocodile, game, rabbits, chinchillas, mice, rats and cage birds.

2. AIM

The purpose of this document is to outline the procedures for applying to the Registrar of Act No. 36 of 1947 (DAIC) for registration of animal feeds. The ultimate goal is to ensure that the submission management process is efficient, effective and predictable for applicants, registration holders and the DAIC registration officers. Detailed guidance on the category under which an application must be

made, and data requirements for that application are set out in the “Technical data requirements” section.

3. TYPES OF SERVICES THAT MAY BE APPLIED FOR

This document pertains to all applications for:

- New registrations
 - Daughter registrations
 - Parallel registrations
- Renewal of registrations
- Cancellation of registrations
- Re-instatement of registrations
- Transfer of registrations
- Amendments
 - Label amendments
 - Technical amendments
 - Additional manufacturer / source
 - Change of registration holder / company name
 - Change of product name
 - Additional pack size
- Free Sale Certificate
- Import permits
- Advertisement

4. WHO CAN APPLY TO REGISTER ANIMAL FEED

The applicant may be an individual or a registered company. It must be a person residing in the Republic of South Africa, or in the case of a juristic person, it must be a person who has a registered company in the Republic of South Africa.

4.1. APPLICANT AND REGISTRATION HOLDER

The applicant is the individual or company who/which will become the registration holder of the approved or registered product should the application be successful. In the case where the application is for any changes to be made to an approved current registration, the applicant will be the registration holder.

All individual representative applicants must reside in South Africa or in the case of a company, the company must have a registered office in South Africa. If the applicant is an individual, a copy of an Identity Document must be provided. If the applicant is a registered company, a copy of the company registration certificate from the Registrar of companies must be provided. The company must nominate an authorized/approved contact person.

4.2 APPROVED CONTACT PERSON

An approved person is an individual, company representative or third party representative who is resident in South Africa and who will take responsibility for the application. In relation to an application, generally the approved person is responsible for:

- giving consent to the Registrar to alter the application form
- providing extra information or changing information previously given to the Registrar
- giving the Registrar written notice to withdraw the application.

An applicant may appoint a third party (a company or an individual outside their company but residing in South Africa). When an applicant wishes to make use of a third party representative, they must send a letter of authority to the Registrar. The letter of authority must specify:

- i) which of the regulatory matters the approved person is authorised to conduct, i.e. all aspects of the application or only specified functions.
- ii) the duration of the agreements, i.e. The same person will also be responsible for only the application process or if they will also be responsible for the post-registration matters.

If an applicant appoints a different approved person for any one or more of the regulatory matters, they must send separate letters to the Registrar for each different approved person. The individual signing the application form must be qualified to do so and authorized by the company.

An applicant can withdraw the appointment of an approved person at any time by writing to the Registrar. An applicant may also vary the authority or responsibilities of an approved person. Should an applicant wish to change aspects relating to the approved person, these changes must be submitted to the Registrar in writing, clearly detailing the required changes.

5. WHAT TO INCLUDE IN A FARM FEED REGISTRATION APPLICATION

5.1. SERVICE REQUEST FORM

It is important to include a Service Request Form clearly outlining the intent of the submission. A standard Service Request Form for farm feed registration applications (Application Form Ref: FF/SRF_01) has been designed to enable applicants to indicate the services they require from the Registrar's office. This form should be used in the place of a cover letter. The form is available for download on the Department of Agriculture Forestry and Fisheries website (<http://www.daff.gov.za/daffweb3/Branches/Agricultural-Production-Health-Food-Safety/Agriculture-Inputs-Control/Forms>); it can also be obtained from the Registrar's office. An additional motivational cover letter may be submitted with the application documents where necessary.

5.2. APPLICATION FORM

Applicants seeking registration must submit a duly completed Farm Feed Application Form (Application Form Ref: FF/FF_01). The application form must be signed by the Commissioner of

Oaths. Application forms are available for download on the Department of Agriculture Forestry and Fisheries website (<http://www.daff.gov.za/daffweb3/Branches/Agricultural-Production-Health-Food-Safety/Agriculture-Inputs-Control/Forms>); they can also be obtained from the Registrar's office. Please ensure that the forms are duly completed and signed by the Commissioner of Oaths. All application forms must be submitted in **duplicate**. Accompanying documents must be enclosed as per technical requirements of the specific product. The technical data requirements are outlined in the technical data requirements section.

5.3. CONTACT DETAILS FORM

The Contact Details form (Form C) (Application Form Ref: FF/Contact_01) should be completed by new applicants, when applying for renewal of registrations and when the contact details of the company have changed. The contact details form must be submitted. It is available for download on the Department of Agriculture Forestry and Fisheries website (<http://www.daff.gov.za/daffweb3/Branches/Agricultural-Production-Health-Food-Safety/Agriculture-Inputs-Control/Forms>); and can also be obtained from the Registrar's office.

5.4. PRODUCT LABEL

A proposed product label must be submitted **in duplicate** and it must contain at least the following information:

- a) The name of the product.
- b) Class of the product. (e.g. Complete feed for broilers or Raw material)
- c) The phrase "Reg. No. V _____ Act No. 36 of 1947" (to indicate where the registration number will be displayed).
- d) The ingredient list.
- e) Guaranteed analysis, e.g.
 - Crude protein (minimum)
 - Moisture (maximum)
 - Crude fat (minimum)
 - Crude fibre (maximum)
 - Calcium (maximum)
 - Phosphorus (minimum)
- f) Package size. (e.g. Mass 50 kg).
- g) Directions for use or Feeding recommendations.
- h) The contact details (postal address and telephone numbers etc.) of the applicant.
- i) Batch number.
- j) Indication of shelf life (expiry date or best before date).

Further details of the various guaranteed analysis on the different types of feed may be found in Regulations 21 and 22 of the Farm Feeds Regulations No. R. 1087.

5.5. CERTIFICATE OF ANALYSIS

Certificates of analyses are required for new registrations, technical amendments and registration renewals. The certificates shall be authenticated and shall not be more than one year old at the time of application. The analysis must be performed by an accredited laboratory.

5.6. PROOF OF PAYMENT

The application fee is determined according to the type of product and type of application lodged. The tariffs are published in the government gazette at the beginning of each financial year and are also posted on the DAFF website, www.daff.gov.za. DAFF accepts payments in a form of a cheque, cash deposits into the bank account, cash payment at Finance Division of DAFF and Electronic Funds Transfers (EFT). Payment should be made to the Director-General: Department of Agriculture, Forestry and Fisheries into the following bank account:

Account name:	NDA-Act 36 of 1947
Account number:	011203102
Reference:	11F1 and Name of Company/Name of applicant
Branch code:	010845
Branch name:	Arcadia
Bank name:	Standard Bank

6. HOW TO ALTER AN APPLICATION DOSSIER

An approved person may request the Registrar to alter aspects of their application or give the Registrar additional or different information, by submitting a written request and authorization in this regard. The request will be processed, provided that the technical screening and assessment process of the applicable application has not yet been completed. If the request for alteration is received after the application has been finalized, the applicant will be notified that their request was unsuccessful and that an application for amendment needs to be submitted.

7. HOW TO WITHDRAW AN APPLICATION

At any stage of a registration process, an applicant or approved person may request the Registrar to withdraw their application by sending written authorization. When an applicant voluntarily withdraws an application before the assessment process has commenced, the Registrar may refund the full amount to the applicant in a form of credit for future application(s). If the application has passed technical screening and technical assessment has commenced, withdrawal of application will be regarded as a rejection of the application and thus final processing of the application and a rejection letter will be issued to the applicant. No refunds will be made.

8. FORMAT OF AN APPLICATION

8.1. LANGUAGE

All applications and accompanying data submitted to the Registrar of Act No. 36 of 1947 must be in English. If an applicant wishes to submit material in another language, they must supply an authorized English translation done by a sworn translator, and clearly identify it as such. The Registrar may request the original foreign language document.

8.2. CONFIDENTIAL BUSINESS INFORMATION or TRADE SECRETS

The officials of DAFF are required to handle Confidential Business Information (CBI) submitted by applicants. Data that falls under CBI is protected for an unlimited time period. Confidential Business Information relating to an application for a new or existing farm feeds registration or as a constituent of a farm feed refers to:

- technical and formulation specifications, including confidential statement on formula, and certificate of composition documents;
- description of manufacturing process;
- analytical methods on “non-relevant” impurities of the manufacturing process; and
- other specific documents which are commercially sensitive; for example: market share information, names and addresses of scientists.

8.3. PHOTOCOPIES AND GRAPHIC IMAGES

Applicants must ensure that all photocopies are legible with adequate margins on both edges of the page. The Registrar will return any unreadable, unclear or incomplete copies and ask the applicant to replace them. All graphic images (including photos) must be of high quality that will enable replication. Original prints are preferred. Photocopies of photographs will only be accepted if they are of good quality and clearly illustrate the subject.

8.4. REFERENCES AND TESTIMONIALS

If specific references are cited in an application, applicants must include a legible copy of the whole article with the application. Applicants must indicate which part of the reference is applicable to the application. For generally accepted scientific information, full references will not usually be required. However, in some instances the DAIC may require a copy of a reference. Testimonials and other forms of anecdotal evidence are not acceptable, and will be disregarded.

8.5. PRESENTATION, BINDING AND PAGINATION

All documents submitted must be legible and printed on A4 paper. Applicants may print pages on both sides if legibility is not affected. Margins must be wide enough to enable the material to be read when bound and/or placed on file. The material must be presented in a systematic order. If the entire

dossier submission contains more than 10 pages of data, applicants must separate the different data (e.g. efficacy data, safety data, toxicology data and so forth) using a separator slide with a section title on it. If a section comprises a series of studies, a concise summary (abstract) must be provided at the front of each study. Within each section, similar studies must be grouped together to facilitate assessment. The full name of each study must be listed in the table of contents along with referenced species.

The application submission must be bound and the documents on the submission file must be page numbered and cross-referenced to the table of contents. Lever arch files are preferred for large dossiers. The use of plastic or paper folders should be limited to smaller dossiers. The cover page for bound dossiers must contain a list of contents to enable assessors to easily identify and access documents. If the dossier is more than one volume, applicants must label the cover of each volume. The following information must be clearly identified on the cover page:

- Name of the applicant
- Common name of the product
- Trade name of the product
- Registration number (if registered)
- Type of application or category
- Volume numbers and total number of volumes in the application
- Date of application.

Pages must be numbered systematically so that assessors can easily and accurately locate documents. Pages may be sequentially numbered from start to finish or, if an application is in several volumes, sequentially numbered within each volume, for example; Volume 1: Pages 1.1, 1.2, 1.3 and so on, and Volume 2: Pages 2.1, 2.2, 2.3 and so on. Any system for numbering the pages of an application may be used, if it is consistent throughout the application and is accurately reflected in the table of contents. Applicants do not need to erase page numbers on copies of other documents included in an application unless those page numbers could be confused with the page numbers of the application form.

9. THE REGISTRATION PROCESS

The following section provides a step-by-step description of the submission review process which can be divided into 4 categories; verification, technical screening, assessment and approval.

9.1. VERIFICATION (ADMINISTRATIVE SCREENING)

Administrative screening of applications take place within 14 calendar days of receipt of the documents to ensure that non-data elements including the Service Request Form, the appropriate application form and the proof of payment have been provided. Applications that meet all the administrative requirements are then accepted and sent for technical screening and assessment.

Applicants are then provided with a letter acknowledging receipt of the application and also indicating the estimated time for completion of the registration process.

If an application fails the administrative screening, the Registrar will inform the applicant (via an e-mail or facsimile), outlining the deficiency and indicating a timeframe of 30 calendar days within which the deficiency must be rectified and re-submitted. Once the deficiency has been rectified and re-submitted the application will progress to technical advisors for technical screening and assessment.

9.2. TECHNICAL SCREENING

In the technical section, the data submitted are screened against the data requirements outlined in this guideline. Deficiencies are communicated to the applicant and should be rectified within 30 calendar days. If the requested information is not supplied within the specified period, the application will be rejected.

9.3. ASSESSMENT

Once an application passes the screening process, it is allocated for scientific evaluation. During the process of evaluation, the applicant may be contacted for clarity or if data is missing. If the information is not supplied by the applicant within the specified period, the application will be rejected.

9.4. APPROVAL

Once the product evaluation process has been completed, the technical advisor submits an evaluation report and recommendations to the registrar. Registration officers prepare documents on the application for submission to Registrar. The applicant is informed in writing about the decision of the Registrar, and issued with the relevant documentation. A registration is valid for a term of three years and is subject to renewal.

10. APPEAL PROCESS

If the application for registration has been rejected or has been approved with conditions that the applicant is not satisfied with, section 6 of the Act provides for an appeal to the Minister against the decision of the Registrar. The Minister will then follow the process available to him/her.

11. REGISTRATION/APPROVAL TIME FRAMES

Applications are reviewed according to the date of submission and categories of the different applications. Depending on the type of application, the registration process timeframes vary between 7 to 120 calendar days. Please note that the time during which an application is waiting for outstanding information is not included in the 7 to 120 calendar days.

The time frames for specific processes and categories can be summarized as follows:

Table1: Timeframes according to type of applications and registration processes

Type of application	Registration Period
New applications	4 months
Renewal of registration	4 months
Re-instatement of registration	3 months
Cancellation of registration	2 months
Label amendments	2 months
Technical amendments	2 months
Additional supplier / manufacturer	2 months
Amendment of registration holder/company name	2 months
Free sale certificate	1 week
Addition of Packaging size	2 months
Import permits	2 weeks
Advertisement	2 weeks

12. REGISTRATION PERIOD

Farm feed registrations are valid for three years and expire on 31 March, three years after the date of registration. An application for renewal of farm feed can be made to the Registrar before the expiry date is reached.

13. WHERE TO SEND AN APPLICATION

All applications must be submitted in hard copy and delivered to:

The Registrar: Act No. 36 of 1947

Directorate Agriculture Inputs Control

Agriculture Place, Room number LB-FF-09 or LB-FF-10,

20 Steve Biko Road, Arcadia

Pretoria, 0002

Appointments must be made prior to the delivery of any applications. Appointments can be made through AICHelpdesk@daff.gov.za or Tel. 012 – 319 7847 / 7103

or sent by post to:

The Registrar: Act No. 36 of 1947

Directorate Agriculture Inputs Control

Department of Agriculture, Forestry and Fisheries

Private Bag X343

Pretoria, 0001

15. ENQUIRIES

All enquiries must be directed to the DAIC Help Desk.

Telephone No.: 012 – 319 7847 / 7103

Facsimile No.: 012 – 319 7179

Email: AICHelpdesk@daff.gov.za

SECTION B: TECHNICAL SECTION DATA REQUIREMENTS

1. GENERAL TECHNICAL INFORMATION

1.1. PROHIBITED SUBSTANCES

- 1 The use of the ingredients in regulation 11(4)(d) of the Farm Feeds Regulations No. R. 1087 is prohibited in animal feeds.
- 2 A product shall not be registered as an animal feed if -
 - (a) it contains any feed ingredient of such nature or in such quantities that it could cause an interaction leading to the loss of one or more of the nutrients in that product such as to be below the intended nutritional requirement for that product.
 - (b) it consists of or contains any substance of animal origin, including excreta or other by-products, which has not been sterilised beforehand to such an extent that the infection or contamination of such product with *Bacillus anthracis*, organisms of the gas-gangrene type, other pathogenic or putrefactive organisms of viable micro-organisms or substances has been reduced to the level where such organisms or substances will be harmful to or endanger the health or detrimentally affect the productive capacity of animals to which such product is fed.
 - (c) it contains any scheduled substance under the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) unless it is exempted to be registered as animal feed in terms of the provisions of Act No. 101 of 1965.

1.2. LIMITED SUBSTANCES

- 1 The use of mammalian derived protein and by-products is limited to non-ruminant animal feeds and pet food.
- 2 An exemption is required for the use of blood meal in non-ruminant animal feed. The procedure for applying for an exemption is as follows:
 - (a) The applicant must obtain the prescribed application form from the Registrar;
 - (b) The form must be accompanied by an exemption letter which was granted by the Director: Animal Health according to Regulation 24 of the Animal diseases Act, 1984 (Act No. 35 of 1984);
 - (c) The application must be accompanied by the prescribed administrative fee.

1.3. UNDESIRABLE SUBSTANCES

Subject to the provisions of regulation 11(3) of the Farm Feeds Regulations No. R. 1087; feed ingredients for use in animal feeds cannot be considered as sound, genuine and of merchantable quality if the level of undesirable substances in the product is higher than the maximum levels fixed in the regulation.

1.4. EXEMPTIONS

1.4.1. Unprocessed whole grains and oilseeds are exempt from registration.

1.4.2. Custom mixed feeds are exempt from registration. "Custom mix" means a mixture compiled on the written advice of a qualified person for a specific client or a mixture of registered ingredients mixed at the written request of an end user. Prescription mixture has a corresponding meaning.

The manufacturer must keep -

- i) a reference sample for at least 3 months.
- ii) records of the following:
 - a) Results of quality checks on additives used.
 - b) Records of each sale (include customer and quantity sold).
 - c) Name and address of customer.
 - d) Composition and mixing instructions, as well as the purpose for which it is needed.
 - e) The quantity mixed.
 - f) The signature of and date on which the person submitted a request.

1.4.3. Pet chews and toys and exercisers made of raw hide, wood or any man-made material, hooves, ears, bones and ligaments, whether flavour coated or unflavoured are exempt from registration unless any nutritional value or benefit to the animal is claimed on the label or labelling of the product (example: digestibility, tartar control, etc).

2. RAW MATERIALS OF PLANT ORIGIN

- i) Raw materials of plant origin must conform with and comply with the definitions as set out in the Farm Feeds General Guidelines. The guidelines are available for download on the Department of Agriculture Forestry and Fisheries website (<http://www.daff.gov.za/daffweb3/Branches/Agricultural-Production-Health-Food-Safety/Agriculture-Inputs-Control/Forms>); and can also be obtained from the Registrar's office.
- ii) Novel raw materials must be clearly described to allow proper classification of the product in the Farm Feeds General Guidelines.
- iii) All raw materials must be marked and labeled according to marking and labelling regulations in the Farm Feeds Regulations No. R. 1087.
- iv) Applications to register raw materials shall be accompanied by:
- a) A Service Request Form (Application Form Ref: FF/SRF_01);
 - b) Farm Feeds Application Form **in duplicate** - (Application Form Reference: FF/FF_01);
 - c) Contact details form should be completed by new applicants. Form C (Contact details) – (Application Form Ref: FF/Contact_01);
 - d) Proposed product label **in duplicate** (See guaranteed analysis requirements below);
 - e) Certificate of nutritional Analysis (See requirements below) and
 - f) Proof of payment.

Application forms are available for download on the Department of Agriculture Forestry and Fisheries website (<http://www.daff.gov.za/daffweb3/Branches/Agricultural-Production-Health-Food-Safety/Agriculture-Inputs-Control/Forms>); and can also be obtained from the Registrar's office.

2.1 Alfalfa/Lucerne Products, Cereal Grain products, Barley Products, Oat Products, Rice Products and Wheat Products

- 1.1.1 The product must be analysed for protein, moisture and fibre.
- 1.1.2 The label shall include guarantees for protein (minimum), moisture (maximum), fibre (minimum) and (maximum) for high-fibre products.
- 1.1.3 The maximum moisture should not exceed 120 g/kg.

2.2 Brewers Products

- 1.2.1 The product must be analysed for protein, moisture and fibre.
- 1.2.2 The label shall include guarantees for protein (min), moisture (max), fibre (min) and (max).
- 1.2.3 The maximum moisture should not exceed 120 g/kg.
- 1.2.4 The product may contain pulverised dried spent hops in a quantity not exceeding 30 g/kg, evenly distributed.

2.3 Citrus Products

- 1.3.1 The product must be analysed for protein, moisture and fibre.
- 1.3.2 The label shall include guarantees for protein (min), moisture (max) and fibre (max).
- 1.3.3 The maximum moisture for dehydrated products must not exceed 120 g/kg.
- 1.3.4 If calcium oxide or calcium hydroxide is added as an aid in processing, the maximum quantity (g/kg) present, expressed as calcium (Ca), must be declared.
- 1.3.5 If it bears a name descriptive of its kind or origin, it must correspond thereto.

2.4 Distillers' Products

- 1.4.1 The product must be analysed for protein, moisture and fibre.
- 1.4.2 The label shall include guarantees for protein (min), moisture (max), fibre (min) and (max).
- 1.4.3 The maximum moisture should not exceed 120 g/kg in dried/dehydrated products.
- 1.4.4 The maximum moisture should be declared in wet products.

2.5 Grain Sorghums

- 1.5.1 The maximum moisture must not exceed 120 g/kg.
- 1.5.2 The product shall be analysed for protein, moisture, fibre.
- 1.5.3 Sorghum and its by-products shall also be analysed for tannin.
- 1.5.4 The label shall include guarantees for protein (min), moisture (max), fibre (max) and tannin (max)
- 1.5.5 Grain sorghum mill feed (see definition in the Farm Feeds General Guidelines) must contain a minimum of 50 g/kg crude fat and a maximum of 60 g/kg crude fibre.

2.6 Maize products

- 1.6.1 The product must be analysed for protein, moisture and fibre.
- 1.6.2 The label shall include guarantees for protein (min), moisture (max), fibre (min) and fibre (max) for maize products rich in fibre.
- 1.6.3 The maximum moisture should not exceed 120 g/kg.
- 1.6.4 The maximum moisture in Hominy chop should not exceed 130 g/kg.

2.7 Fats and Oils (from plant origins and animal origins)

- 1.7.1 The product must be analysed for total fatty acids, free fatty acids, moisture, unsaponifiable matter and insoluble impurities.
- 1.7.2 The label shall include guarantees for total fatty acids (minimum), free fatty acids (maximum), moisture (maximum), unsaponifiable matter (maximum) and insoluble impurities (maximum). Refer to Farm Feeds General Guidelines for acceptable minimum and maximum levels according to type of oil and fat.
- 1.7.3 The use of the term "feed grade" requires that the specific type of product be adequately tested to prove its safety for feeding purposes.
- 1.7.4 Any mixture of two or more fats or fat derivatives must be identified by listing each component:

e.g, "animal fat and hydrolysed vegetable oil."

1.7.5 Fats or fat derivatives must come from acceptable animal feed sources. **Use of fats from mammalian origins is restricted to non-ruminants.**

1.7.6 An anti-oxidant that is generally regarded as safe must be added in accordance with good manufacturing practices.

1.7.7 The following warning must be displayed on the label of animal fats: **This product has a limited shelf-life and must not be stored for long periods.**

1.7.8 The maximum gossypol level must be declared in Cottonseed oil.

1.7.9 The maximum lipid not bound in the calcium and long-chain fatty acids of vegetable origin should be 200 g/kg in Calcium salts of long-chain fatty acids.

2.8 Marine Products

1.8.1 The product must be analysed for crude protein, moisture, crude fat, crude ash, phosphorus (P), calcium (Ca) and sodium.

1.8.2 The label must include guarantees for crude protein (minimum), moisture (maximum), crude fat (minimum and maximum), crude ash (maximum), phosphorus (minimum), calcium (maximum) and sodium (maximum).

1.8.3 Products with a fat content exceeding 80 g/kg must contain an approved anti-oxidant added in accordance with good manufacturing practice.

2.9 Milk Products

1.9.1 The product must be analysed for crude protein, moisture, minimum milk fat, minimum phosphorus (P), maximum calcium (Ca).

1.9.2 Dried (dry) whey must also be analysed for lactose.

1.9.3 The label must include guarantees for minimum crude protein, maximum moisture, minimum milk fat, minimum phosphorus (P), maximum calcium and lactose (minimum) (applicable to Dry whey).

1.9.4 Products with a fat content exceeding 80 g/kg must contain an approved anti – oxidant in accordance with Good Manufacturing Practice.

2.10 Mineral Products

1.10.1 Mineral products that are a source of macro minerals are classified as raw materials. Refer to requirements for nutritional additives for technical data required for registration.

i) The analyses to be conducted on sources of macro minerals depend on the minerals contained. Refer to the Farm Feeds General Guidelines for specific information.

1.10.2 Mineral products that are a source of micro/trace minerals are classified as Nutritional feed additives. Refer to requirements for feed additives.

Note: Use of mineral products from mammalian origins as sources of minerals is restricted to non-ruminant feeds.

2.11. Miscellaneous Products

Miscellaneous raw materials are products such as dried apple pomace, bagasse, dried bakery products and cereal food fines; to name a few.

- 1.11.1 The product must be analysed for protein, moisture, fibre. Refer to the Farm Feeds General Guidelines for specific information on more analyses to be conducted.
- 1.11.2 The maximum moisture must not exceed 120 g/kg for dried products.
- 1.11.3 The label must include guarantees for protein (minimum), moisture (maximum), fibre (minimum) and fibre (maximum) for high-fibre products. Refer to Farm Feeds General Guidelines for specific nutrients to be declared on individual product.

2.12 Molasses

- 1.12.1 The product must be analysed for protein, moisture, total sugar and density.
- 1.12.2 The label must have guarantees for protein (min), moisture (max), total sugar (min) expressed as invert and density expressed as Brix.

2.13 Oilseed Products

- 1.13.1 The product must be analysed for protein, moisture, fat and fibre. Refer to the Farm Feeds General Guidelines for specific information per product.
- 1.13.2 The maximum moisture for dehydrated products must not exceed 120g/kg.
- 1.13.3 The label shall include guarantees for crude protein (minimum), moisture (maximum), crude fat (minimum) and crude fibre (minimum) and (maximum) for high-fibre products.
- 1.13.4 The maximum gossypol level must be declared in Cottonseed oil.
- 1.13.5 Products with a fat content exceeding 80 g/kg must contain an anti-oxidant that is generally regarded as safe, added in accordance with good manufacturing practice.

3. RAW MATERIALS OF ANIMAL ORIGIN

3.1. Animal Products

- 3.1.1 The products must be analysed for protein, moisture, fat, ash, calcium and phosphorus.
- 3.1.2 The products must also be analysed for pathogenic organisms including *Clostridium perfringens*, *Enterobacteriaceae*, *Salmonella*, *Escherichia Coli* and Coliform.
- 3.1.3 The maximum moisture content of dehydrated rendered meals must not exceed 100g/kg moisture.
- 3.1.4 Products with a fat content exceeding 80 g/kg must contain an approved anti-oxidant added in accordance with good manufacturing practice.
- 3.1.5 The label shall include guarantees for protein (minimum), moisture (maximum), fat (maximum), ash (maximum), calcium (minimum and maximum) and phosphorus (minimum).
- 3.1.6 Rendered products must be manufactured in registered sterilizing plants in accordance with good manufacturing practices, regulations and guidelines applicable thereto.
- 3.1.7 **Use of animal products from mammalian origins is restricted to non-ruminants.** The label

shall have the following warning, in bold face type: **“NOT TO BE USED IN RUMINANT FEEDS OR FEEDING”**.

3.2. Recycled Animal Waste Products

Recycled animal waste products include products such as sterilized animal manure.

3.2.1 The application must be accompanied by the following information:

- a) All sources of raw materials and date acquired, including information on drug and pesticide usage.
- b) All production output, including a code or other method to identify the date of production.
- c) All sales and distribution, including the name and address of the purchaser or to whom distributed, date, quantity and product code.
- d) Sample and assay records of testing specified above.

3.2.2 The application must also be accompanied by Certificates of Analyses for:

- a) Drugs suspected or known to be used in the feed or as a therapeutic treatment of source animals.
- b) Pesticides used on the source animal, facility, and wastes for pest control.
- c) Pathogenic organisms, at least to include *Salmonella* and *E. coli*.
- d) Heavy metals: arsenic, cadmium, copper, lead, mercury and selenium, at least.
- e) Parasitic larva or ova.
- f) Mycotoxins, such as aflatoxins.

3.2.3 If a product contains drug residue, then the label shall contain the following statement in bold face type:

"WARNING: THIS PRODUCT CONTAINS DRUG RESIDUE. DO NOT USE WITHIN 15 DAYS OF SLAUGHTER AND DO NOT USE 15 DAYS PRIOR TO OR DURING THE FOOD PRODUCTION PERIOD OF DAIRY ANIMALS AND LAYING HENS."

3.2.4 If the product contains 25 ppm or greater of copper, a maximum guarantee of copper and the following statement in bold face type is required:

"WARNING: CONTAINS HIGH LEVELS OF COPPER: DO NOT FEED TO SHEEP".

3.2.5 If the product contains NPN, labels must contain prescribed NPN warnings in accordance with Farm Feeds Regulations No. R. 1087.

3.2.6 Processed animal waste products as a class, offered for sale or distributed for sale, shall not contain extraneous materials such as, but not limited to, metal, glass, nails or other harmful matter.

4. PREMIXTURES

A product containing a mixture of additives or mixtures of one or more additives with substances used as carriers **intended for the manufacture of animal feeds** and contains nutrients and/or other ingredient in quantities and such ratios that it will supply the prescribed requirements for animals may be registered as a nutritional feed additive.

4.1. Applications to register premixtures shall be accompanied by:

- a) A Service Request Form (Application Form Ref: FF/SRF_01);
- b) Farm Feeds Application Form **in duplicate** (Application Form Reference: FF/FF_01);
- c) Contact details form should be completed by new applicants. Form C (Contact details) – (Application Form Ref: FF/Contact_01);
- d) Proposed product label **in duplicate**;
- e) Certificate of Analysis of either the premix or the constituents of the premix;
- f) Free Sale Certificate (imported products);
- g) Proof of compliance with local legislation in country of origin (imported products);
- h) Proof of registration in terms of Act No. 27 of 2003 (SACNASP);
- i) Proof of quality management system (e.g. GPM, ISO 9001, ISO 22000, FEMI QS, GMP+, etc) and
- j) Proof of payment.

Application forms are available for download on the Department of Agriculture Forestry and Fisheries website (<http://www.daff.gov.za/daffweb3/Branches/Agricultural-Production-Health-Food-Safety/Agriculture-Inputs-Control/Forms>); and can also be obtained from the Registrar's office.

5. LIVESTOCK FEED

5.1. A product which consists of a mixture of different ingredients, whether or not containing additives, and which contains nutrients and other ingredients in such quantities and such ratios that it will supply the nutritional requirements of the target animal may be registered as **complete animal feed**.

5.2. **Complementary, supplementary and concentrated animal feed** is feed which contains any feedstuff in excess of the maximum content specified for that feeds in relation to the complete animal feed for the target animal. The instruction for use shall state, according to the species and age of the animal, the maximum quantity in grams or kilograms of the animal feed to be given per animal per day, and shall be so formulated that, when they are correctly followed, the final content of the animal feed does not exceed the maximum specified. This guideline shall not apply to products delivered to manufacturers of complete animal feeds or to their suppliers.

5.3. Applications to register livestock feed shall be accompanied by:

- a) A Service Request Form (Application Form Ref: FF/SRF_01);
- b) Farm Feeds Application Form **in duplicate** (Application Form Ref: FF/FF_01)
- c) Contact details form should be completed by new applicants. Form C (Contact details) – (Application Form Ref: FF/Contact_01);
- d) Product label **in duplicate**;
- e) Certificate of analysis of the final product or the formulation of the product;
- f) Proof of payment;
- g) Free Sale Certificate (imported products);
- h) Proof of compliance with local legislation in country of origin (imported products);
- i) Proof of registration in terms of Act No. 27 of 2003 (SACNASP) and
- j) Proof of quality management system.

Application forms are available for download on the Department of Agriculture Forestry and Fisheries website (<http://www.daff.gov.za/daffweb3/Branches/Agricultural-Production-Health-Food-Safety/Agriculture-Inputs-Control/Forms>); and can also be obtained from the Registrar's office.

The label must include guarantees for -

- i. **Milk replacers fed to calves:** crude protein (minimum), lysine (maximum), moisture (maximum), crude fat (minimum), crude fibre (maximum), calcium (minimum and maximum), phosphorus (minimum), Ph (minimum) for acidified milk replacers, starch (maximum).
- ii. **Dairy cattle feed:** crude protein (minimum), non-protein nitrogen (maximum) if added and protein ex NPN % (maximum), moisture (maximum), crude fat (maximum), crude fibre (maximum), calcium (minimum and maximum), phosphorus (minimum).
- iii. **Dairy cattle, beef cattle, sheep, goat, game and horses - fed mineral supplement:** calcium (minimum and maximum), phosphorus (minimum), salt (minimum and maximum), magnesium

- (minimum), potassium (minimum), sulphur (minimum), specific trace minerals (minimum), Vitamins (minimum) if added.
- iv. **Beef cattle:** crude protein (minimum), non-protein nitrogen (maximum) if added and protein ex NPN %, moisture (maximum), crude fat (minimum and maximum), crude fibre (minimum and maximum), calcium (minimum and maximum), phosphorus (minimum).
 - v. **Sheep, goat and game feed:** crude protein (minimum), non-protein nitrogen (maximum) if added and protein ex NPN %, moisture (maximum), crude fat (minimum and maximum), crude fibre (minimum and maximum), calcium (minimum and maximum), phosphorus (minimum), copper (maximum mg/kg) if it exceeds 22.5 ppm.
 - vi. **Horse feed:** crude protein (minimum), moisture (maximum), crude fat (minimum), crude fibre (minimum and maximum), calcium (minimum and maximum), phosphorus (minimum).
 - vii. **Ostrich feed:** crude protein (minimum), lysine (minimum), moisture (maximum), crude fat (minimum), crude fibre (maximum), calcium (minimum and maximum), phosphorus (minimum).
 - viii. **Fish (all), crocodile, pigeon, parrot, mice and rat:** crude protein (minimum), moisture (maximum), crude fat (minimum), crude fibre (maximum), calcium (maximum), phosphorus (minimum).
 - ix. **Rabbits and chinchillas:** crude protein (minimum), moisture (maximum), crude fat (minimum), crude fibre (minimum and maximum), calcium (maximum), phosphorus (minimum).
 - x. **Grain mixtures for pigeons, birds and poultry:** grain (minimum and maximum), protein seeds (minimum and maximum) or crude protein (minimum), moisture (maximum), crude fat (minimum), crude fibre (maximum), calcium (maximum), phosphorus (minimum).
 - xi. **Race and breed mixtures and Maintenance mixtures:** grain (minimum and maximum), protein seeds (minimum and maximum) or crude protein (minimum), moisture (maximum), crude fat (minimum), crude fibre (maximum), calcium (maximum), phosphorus (minimum).
 - xii. **Bird seed:** seeds (minimum and maximum).
 - xiii. **Mixed poultry grain:** grain (maximum).
 - xiv. **Duck and geese:** crude protein (minimum), moisture (maximum), crude fat (minimum), crude fibre (maximum), calcium (minimum and maximum), phosphorus (minimum), salt (maximum) if added.
 - xv. **Pigs:** crude protein (minimum), lysine (minimum), methionine (minimum), moisture (maximum), crude fat (minimum), crude fibre (maximum), calcium (minimum and maximum), phosphorus (minimum), salt (maximum) if added.
 - xvi. **Chicken and other poultry:** crude protein (minimum), lysine (minimum), methionine (minimum), moisture (maximum), crude fat (minimum), crude fibre (maximum), calcium (minimum and maximum), phosphorus (minimum), salt (maximum) if added.
 - xvii. **Mineral supplement feeds:** calcium (minimum and maximum) if present, salt (maximum) if added, fluoride (maximum) if present, other minerals (minimum) if present in significant amounts, vitamins (minimum) if added.

6. PET FOOD

- 6.1. A product which consist of a mixture of different ingredients, whether or not containing additives, and which contains nutrients and other ingredients in such quantities and such ratios that it will supply minimum and maximum nutrients as specified in column 3 and 4 of Table 5 in the regulations for dog food and Table 6 in the Farm Feeds Regulations No. R. 1087 for cat food shall be registered as a complete pet food of which the name is indicated by the kind of animal if it meets the nutrient contents so specified in the applicable columns of the applicable tables.
- 6.2. Where the digestibility of a complete pet food is higher than 65% on which the Tables referred to above are based, the corresponding corrections shall be made and evidence of the higher digestibility provided to the Registrar.
- 6.3. Marking and labelling of pet food shall conform to regulation 22 of the Farm Feeds Regulations No. R. 1087. The label must include guarantees for protein (minimum), moisture (maximum), crude fat (minimum), crude fibre (maximum) and crude ash (maximum) or calcium (maximum) and phosphorus (minimum).
- 6.4. Applications to register complete pet food shall be accompanied by:
- a) A Service Request Form (Application Form Ref: FF/SRF_01);
 - b) Farm Feeds Application Form **in duplicate** - (Application Form Ref: FF/FF_01);
 - c) Contact details form should be completed by new applicants. Form C (Contact details) – (Application Form Ref: FF/Contact_01);
 - d) Product label with artwork **in duplicate**;
 - e) Certificate of analysis for microbiological analysis for pet food that is not extruded or sterilized;
 - f) Data attesting to the nutritional adequacy of the complete pet food. This shall be established by at least one of the following methods –
 - (i) submission of the full details of the nutritional profile of all relevant nutrients as specified in Tables 5 (dog food) and Table 6 (cat food) in the regulations. All nutrients shall be corrected for moisture, energy and processing losses. Alternatively, a product formulation can be submitted;
 - (ii) submission of the scientific results of a feeding trial using the latest American Association of Feed Control Officials (AAFCO) testing procedures; or
 - (iii) submission of the full results of a chemical analysis of the finished pet food product. The data shall include at least an analysis of those elements with asterisks in Table 7 in the regulations. Applicants shall be at liberty to submit more comprehensive data if they so desire. The Registrar shall reserve the right to require the analysis of further elements in the Table without asterisks in the event that he or she is of the opinion that such analysis is necessary in order to substantiate nutritional adequacy of a particular product;

- g) Data attesting to label claims that require substantiation;
- h) Proof of payment;
- i) Free Sale Certificate (imported products);
- j) Proof of compliance with local legislation in country of origin (imported products);
- k) Proof of registration in terms of Act No. 27 of 2003 (SACNASP) and
- l) Proof of quality management system.

Application forms are available for download on the Department of Agriculture Forestry and Fisheries website (<http://www.daff.gov.za/daffweb3/Branches/Agricultural-Production-Health-Food-Safety/Agriculture-Inputs-Control/Forms>); and can also be obtained from the Registrar's office.

6.5. Despite method (i), (ii) or (iii) under (f) above that is used to substantiate nutritional adequacy, the application shall be accompanied by an affidavit sworn by an approved person attesting to the nutritional adequacy of the pet food.

6.6. Dry pet foods

6.6.1 Dry pet food with moisture content of more than 100 g/kg, the applicant shall provide the Registrar with additional stability data to prove that the product in question is stable enough to be stored and sold bearing in mind the weather conditions in the Republic of South Africa.

6.6.2 Dry pet food containers must carry a "best before" date which is up to 12 months from date of manufacture and information in support of the shelf life must be supplied to the Registrar with the application for registration.

6.7. Semi-moist pet food

6.7.1 With regard to registration applications for all semi-moist products the applicant shall provide the Registrar with additional stability data to prove that the product in question is stable enough to be stored for the proposed shelf-life, bearing in mind the weather conditions in the Republic of South Africa.

6.8. Wet pet food

6.8.1 With regard to registration applications for wet pet foods with moisture content of more than 820 g/kg, the Registrar shall be entitled to request from the applicant supporting documentation and evidence attesting to the nutritional adequacy of the product in question in order to satisfy himself that the product should be registered.

6.8.2 Wet pet food containers must carry a "use by" date which is up to 24 months from date of manufacture and information in support of the shelf life must be supplied to the Registrar with the application for registration.

6.9. Dietetic pet food

6.9.1 Applications for the registration of pet foods for a particular nutritional purpose must satisfy the following requirements-

- a) Where an applicant is seeking to register a pet food for a particular nutritional purpose, they shall submit to the Registrar appropriate substantiation demonstrating that the precise use, i.e. the particular nutritional purpose which they intend to attribute to the product, is in fact appropriate.

6.10. Complementary pet food

6.10.1 No specific nutritional adequacy validation procedure shall be required for treats or complementary pet foods.

6.10.2 Complementary pet foods and treats with a nutritional value must show a guaranteed analysis on the label, as well as an ingredient statement, as per complete pet foods.

6.10.3 Pet food that is not sterilized that contains meat must also be analysed for pathogenic organisms including *Clostridium perfringens*, *Enterobacteriaceae*, *Salmonella*, *Escherichia Coli* and Coliform.

7. FEED ADDITIVES

7.1 TYPES OF FEED ADDITIVES

Feed additives that can be registered as animal feed in the Republic of South Africa belong to four categories namely:

a) Technological additives

A technological additive is any substance which favourably affects the characteristics of feed.

Functional groups:

- i) Preservatives
- ii) Antioxidants
- iii) Emulsifiers
- iv) Stabilizers
- v) Thickeners
- vi) Gelling agents
- vii) Binders
- viii) Substances for the control of radionucleid contamination
- ix) Anticaking agents
- x) Acidity regulators
- xi) Silage additives
- xii) Denaturants
- xiii) Substances for reduction of the contamination of feed by mycotoxins

b) Sensory additives

A sensory additive is any substance, the addition of which to feed improves or changes the organoleptic properties of the feed, or the visual characteristics of the food derived from animals.

Functional groups:

- i) Colourants
- ii) Flavouring agents
- iii) Aroma enhancing agents

c) Nutritional additives

A nutritional additive is any substance added to feed to satisfy the nutritional needs of animals.

Functional groups:

- i) Vitamins, pro-vitamins and chemically well-defined substances having similar effect.
- ii) Compounds of trace elements.
- iii) Amino acids, their salts and analogues.
- iv) Urea and its derivatives.

d) Zootechnical additives

A zootechnical additive is any additive used to affect favourably the performance of animals in good health or used to affect favourably the environment.

Functional groups:

- i) Digestibility enhancers
- ii) Gut flora stabilizers
- iii) Substances which favourably affect the environment
- iv) Other zootechnical additives

7.1.1 Applications to register additives shall be accompanied by:

- a) A Service Request Form (Application Form Ref: FF/SRF_01);
- b) Farm Feeds Application Form **in duplicate** (Application Form Reference: FF/FF_01);
- c) Contact details form should be completed by new applicants. Form C (Contact details) – (Application Form Ref: FF/Contact_01);
- d) Product label **in duplicate**;
- e) Certificate of analysis;
- f) Product specification sheet;
- g) Data on efficacy, safety and toxicity (as outlined in 7.3 to 7.12 below), including attestation to label claims that require substantiation;
- h) Proof of payment;
- i) Free Sale Certificate (imported products);
- j) Proof of compliance with local legislation in country of origin (imported products);
- k) Proof of registration in terms of Act No. 27 of 2003 (SACNASP) and
- l) Proof of quality management system.

Application forms are available for download on the Department of Agriculture Forestry and Fisheries website (<http://www.daff.gov.za/daffweb3/Branches/Agricultural-Production-Health-Food-Safety/Agriculture-Inputs-Control/Forms>); and can also be obtained from the Registrar's office.

7.2 GENERAL DATA REQUIREMENTS

This section sets out the requirements for establishing the list and the characteristics of studies and information on substances, micro-organisms and preparations to be submitted with dossiers for applications for new registrations and technical amendments to registered feed additives.

The dossiers must enable an assessment to be made of additives based on the current state of knowledge and permit verification of the compliance of these additives with the fundamental principles for compliance, which are laid down in Farm Feeds Regulations No. R. 1087.

7.3 APPLICATION OVERVIEW

7.3.1 Product rational

The applicant shall give an overview of the purpose of the product and reasons behind the decisions made when developing the product.

7.3.2 Active substance(s)

Description

A qualitative description of the active substance or agent shall be given. This shall include purity and origin of the substance or agent, plus any other relevant characteristics.

7.3.2.1 Chemical substances

(a) Chemically well-defined substances shall be described by generic name, chemical name according to IUPAC (International Union of Pure and Applied Chemistry) nomenclature, other generic international names and abbreviations and/or Chemical Abstract Service Number (CAS). The structural and molecular formula and molecular weight must be included.

(b) For chemically defined compound used as flavourings, the EU Flavour Information System number (FLAVIS) in connection with relevant chemical group shall be included. For plant extracts the phytochemical markers must be included. Mixtures in which the constituents cannot be described by a single chemical formula and/or not all of them can be identified shall be characterised by constituent(s) contributing to its activity and/or typical major constituent(s). Marker compound shall be identified to allow stability to be assessed and to provide a means of traceability.

(c) For enzyme and enzyme preparations, the number and systematic name proposed by the International Union of Biochemistry (IUB) in the most recent edition of 'Enzyme Nomenclature' shall be given for each declared activity. For activities not yet included, a systematic name consistent with the IUB rules of nomenclature shall be used. Trivial names are acceptable provided that they are unambiguous and used consistently throughout the dossier, and they can be clearly related to the systematic name and IUB number at their first mention. The biological origin of each enzyme activity must be given.

(d) The microbial origin of chemical substances produced by fermentation shall also be described.

7.3.2.2 Micro-organisms

For all micro-organisms, whether used as product or as production strain, the origin shall be provided. For micro-organisms used as a product or as production strain, any history of modification shall be indicated. The name and taxonomic classification of each micro-organism shall be provided, according to the latest published information in the International Codes of Nomenclature (ICN). In addition, all relevant morphological, physiological and molecular characteristics necessary to provide the unique identification of the strain and the means to confirm its genetic stability shall be described.

For GMOs the description of the genetic modifications shall be given and they shall comply with the Genetically Modified Organisms Act of 1997 (GMO Act No. 15 of 1997).

7.4 CHEMISTRY AND MANUFACTURE

7.4.1 Identity of Additive

- (a) Proposed propriety name(s)
- (b) Type of additive according to its main function
- (c) Qualitative and quantitative composition (active substance, other components, impurities)
- (d) Physical state, particle size
- (e) Manufacturing process including any specific processing process

7.4.2. Specifications concerning active substance

- (a) Name according to main active as described by IUB/IUPAC, EINECS and CAS Number
- (b) The biological origin, the activities towards relevant chemically pure model substrates and other physico-chemical characteristics.
- (c) Purity (checking the level of contaminating microorganisms, heavy metals, absence of toxins relevant to the source organism as shown by suitable method, absence of antibiotic activity at feed concentration level as determined by a suitable method, and composition of the non-active components (i.e. Total Organic Solids).
- (d) Optimal pH, purification process and media used.

7.4.3 Physico-Chemical, Technological & Biological Properties of the Additive

- (a) Stability on exposure to environmental conditions such as light, temperature, pH, moisture, and oxygen.
- (b) Stability during the preparation of premixtures and feed, in particular stability to heat, pressure and moisture. Determine possible decomposition product.
- (c) Stability during the storage of premixtures under defined conditions (Storage time under defined conditions) for shelf life.
- (d) Other appropriate physico-chemical, technological or biological properties such as stability to obtain homogenous mixtures in premixtures and feed, dust-forming properties, assessment of resistance to degradation or loss of biological activity in the digestive tract or by system of stimulation in vitro.
- (e) Physico-chemical or biological incompatibilities or interactions (e.g. with feeds, other approved additives or medicinal products).

7.4.4 Control Methods

- 7.4.4.1 Description of the methods used for the determination of the criteria listed under items 7.1.4(c), 7.4.2(c), 7.4.2(d), 7.4.3(a-d)

7.4.4.2 Description of the qualitative and quantitative analytical methods for routine control of the additive in premixtures and feeds.

7.5 TOXICOLOGY

7.5.1 Studies on laboratory animals

When the active substance is a non-photogenic micro-organism found naturally, these types of studies may not be necessary.

7.5.2 Acute Toxicity

7.5.2.1 Acute inhalation toxicity

- (a) Evidence shall be provided that airborne levels of dust or mist of the additive will not constitute a hazard to the health of users/workers. This evidence shall include, where necessary:
- inhalation tests in laboratory animals.
 - published epidemiological data and/or the applicants own data on its work plant and/or irritancy.
 - respiratory system sensitization tests.
- (b) Acute inhalation toxicity studies shall be performed if particles or droplets with a diameter of less than 50 µm constitute more than 1 % on a weight basis of the product.
- (c) Protocols for acute inhalation toxicity studies should be in line with OECD Guideline 403. If sub-chronic toxicity studies are considered necessary, they can follow OECD Guidelines 412 (Repeated Dose Inhalation Toxicity: 28-day or 14-day study) or 413 (Sub-chronic Inhalation Toxicity: 90-day study).

7.5.2.2 Skin and eye irritancy

- (a) Where available, direct evidence of absence of irritancy and/or sensitisation shall be provided from known human situations. This shall be supplemented by findings from validated animal tests for skin and eye irritation, and for sensitisation potential using the appropriate additive. Allergic potential in sensitisation potential shall also be assessed. Protocols for these studies should be in line with OECD Guidelines 404 (Dermal Irritation/Corrosion), 405 (Eye Irritation/Corrosion), 406 (Skin Sensitisation), 429 (Skin Sensitisation — local lymph-node assay).
- (b) If corrosive properties are known, either from published data or specific in vitro tests, then further in vivo tests shall not be performed.
- (c) Dermal toxicity must be considered, if the additive is toxic by inhalation. Studies should be in line with OECD Guideline 402 (Acute Dermal Toxicity).

7.5.3 Mutagenicity

7.5.3.1 Ames/Salmonella test; and

7.5.3.2 Chromosomal aberration test

- (a) To identify active substances and, if appropriate, their metabolites and degradation products with mutagenic and genotoxic properties, a selected combination of different genotoxicity tests must be carried out. If appropriate the tests shall be performed without and with mammalian metabolic activation and the compatibility of the test material with the test system shall be taken into account.

- (b) The core set comprises the following tests:
 - i) induction of gene mutations in bacteria and/or in mammalian cells (preferably the mouse lymphoma assay).
 - ii) induction of chromosomal aberrations in mammalian cells.
 - iii) in vivo test in mammalian species.

- (c) Additional tests may be needed depending on the outcome of the above mentioned tests and taking into consideration the whole toxicity profile of the substance, as well as its intended use.

- (d) Protocols should be in line with OECD Guideline 471 (Salmonella typhimurium Reverse Mutation Test), 472 (Escherichia coli Reverse Mutation Test), 473 (in vitro Mammalian Chromosomal Aberration Test), 474 (Mammalian Erythrocyte Micronucleus Test), 475 (Mammalian Bone Marrow Chromosomal Aberration Test), 476 (in vitro Mammalian Cell Gene Mutation Test) or 482 (Unscheduled DNA Synthesis in Mammalian Cells in vitro), as well as other relevant OECD Guidelines for in vitro and in vivo assays.

7.5.4 Pharmacokinetic Aspects

The purpose of this essay is to examine the disposition of a chemical substance. The tests give information on its absorption, distribution, biotransformation (i.e. metabolism) and excretion and they also aid in understanding its mechanism of toxicity. The protocol should be in line with OECD guideline 417 (Toxicokinetics).

7.5.5 Subchronic Toxicity

The data derived from subchronic inhalation toxicity studies can be used for quantitative risk assessments and for the selection of concentrations for chronic studies. This study should be conducted in line with OECD guideline 413.

7.5.6. Chronic Toxicity/Carcinogenicity

These tests can be conducted according to the combined chronic toxicity/carcinogenicity studies guideline 453 of the OECD.

7.5.7 Reproductive Toxicity

7.5.7.1 Depending on the active substance tested, a summary of the reproductive toxicity can be done in accordance with OECD guideline 421 (Reproduction/Developmental toxicity screening test). This test is designed to generate limited information concerning the effects of a test substance on male and female reproductive performance such as gonadal function, mating behaviour, conception, development of the conceptus and parturition.

5.7.7.2 Where necessary, reproductive toxicity should be tested in different stages, i.e. prenatal development toxicity study which is designed to provide general information concerning the effects of prenatal exposure on the pregnant test animal and on the developing organism. The test can be done according to OECD guideline 414.

5.7.7.3 One-generation reproductive toxicity which is designed to provide general information concerning the effects of a test substance (Solid, liquid, gas or vapour) on male and female reproductive performance. This test should be in line with OECD guideline 415.

5.7.7.4 Two-generation reproductive toxicity which is designed to provide general information concerning the effects of a test substance on the integrity and performance of the male and female reproductive systems, and on the growth and development of the offspring. The test should be done in line with OECD guideline 416.

7.6 METABOLISM AND TOXICOKINETICS

Metabolism in Livestock studies are used to determine the qualitative and quantitative metabolism and/or degradation of the active ingredient resulting from pesticide use in feed ingredients among other situations. The studies provide an estimate of total residues in the edible livestock commodities, as well as the excreta; identify the major components of the terminal residue in the edible tissues; elucidate a metabolic pathway for the pesticide in ruminants and poultry; provide evidence whether or not a residue should be classified as fat soluble. The protocol should be in line with OECD guideline 503 (Metabolism in livestock).

7.7 RESIDUES

The residues in Livestock studies are conducted in order to quantify levels of residues in meat, milk, eggs and edible meat by-products following the use of a pesticide product. The situations to which such studies apply include application of a pesticide to raw materials and the feed that are consumed by livestock among other situations. The primary purposes of the Residues in Livestock study are to provide: the basis for establishing maximum residue limits (MRLs) and for conducting dietary intake assessments for consumer safety. The protocol should be in line with OECD guideline 505 (Residues in livestock).

7.8 REGULATORY STATUS IN OTHER COUNTRIES

The applicant must list all the countries in which the additive is registered.

7.9 OCCUPATIONAL HEALTH AND SAFETY

A material safety data sheet must be provided. If necessary, measures for the prevention of occupational risks and means of protection during manufacture, handling, use and disposal shall be proposed.

7.10 ENVIRONMENTAL STUDIES

Consideration of the environmental impact of additives is important since administration of additives typically occurs over long periods, often involves large groups of animals and the active substance(s) may be excreted to a considerable extent either as the parent compound or its metabolites.

7.11 EFFICACY AND SAFETY

7.11.1 Studies concerning the efficacy of the additive

- (a) Broiler trials
- (b) Layer hen trials
- (c) Turkey trials
- (d) Piglet trials
- (e) Fattening pig trials
- (f) Sow trials
- (g) Ruminant trials
- (h) Other relevant trials

7.11.2 Studies concerning the safety of the target animal

- (a) Chicken for fattening
- (b) Laying hens
- (c) Turkey for fattening
- (d) Piglets
- (e) Sows
- (f) Ruminant trials
- (g) Other relevant trials

7.12 OTHER TRADE ASPECTS

7.12.1 Studies concerning the quality of the animal produce

The aim is to evaluate the safety of the additive for the consumer and to establish potential residues of the additive or its metabolites in food derived from animals given feed or water containing or treated with the additive.

8. OTHER TYPES OF APPLICATIONS

8.1. DAUGHTER REGISTRATION

Daughter registration is the registration of a registered product by another (different) company or applicant under a different product name. The registration number (V-number) allocated will be different from that of the current registration holder (mother registration holder). The mother company must give approval in a form of a contract to a daughter applicant. The composition of the product must be the same in all respects. When the mother registration is cancelled or lapses then the daughter registration automatically lapses.

8.1.1 The following documents must be submitted:

- a) A Service Request Form (Application Form Ref: FF/SRF_01);
- b) Copy of contract;
- c) Farm Feeds Application Form **in duplicate** (Application Form Ref: FF/FF_01)
- d) Product label **in duplicate** (with contact details of the applicant).
- e) Proof of payment.

8.2. PARALLEL REGISTRATION

Parallel registration is the registration of a registered product by the same registration holder under a different product name. The registration number (V-number) allocated will be different from that of the product already registered. The composition of the product must be the same in all respects.

8.2.1 The following documents must be submitted:

- a) A Service Request Form (Application Form Ref: FF/SRF_01);
- b) Farm Feeds Application Form **in duplicate** (Application Form Ref: FF/FF_01);
- c) Product label **in duplicate**;
- d) Proof of payment.

8.3. FREE SALE CERTIFICATE

The free sale certificate is issued to a registration holder who intends to export a registered product to other countries for sale.

The application must be accompanied by the following:

- a) A Service Request Form (Application Form Ref: FF/SRF_01);
- b) Proof of payment.

8.4. IMPORT PERMIT

Import permits are issued for products that are imported for:

- Trial purposes.
- Laboratory analysis.
- Own use by individuals.

8.4.1 Application must be accompanied by:

- a) A Service Request Form (Application Form Ref: FF/SRF_01);
- b) An application letter stating:
 - (i) The reason for the importation.
 - (ii) Type of product(s).
 - (iii) Quantities of the product(s).
 - (iv) The country of origin of the products.
 - (v) Port of entry into the Republic of South Africa.
- c) Product label.
- d) Product specification sheet.
- e) Certificate of analysis.
- f) Free Sale Certificate (imported feed, premixes and additives).
- g) Proof of payment.

Note: The permit is valid for only one (1) consignment per product.

8.5. ADVERTISEMENT

The application must be made by the registration holder. The registration numbers of the products being advertised must be indicated on the advertisement.

8.5.1 The following documents must be submitted:

- a) A Service Request Form (Application Form Ref: FF/SRF_01);
- b) A copy of the advertisement;
- c) Proof of payment.

Note: The approval is valid for one year and it is renewable.

9. AMENDMENT OF REGISTERED PRODUCTS

Note: Application to renew or amend a registration can only be lodged by the registration holder.

Note: The application for amendment can only be processed, reviewed and approved if the registration is still valid.

Note: No amendments will be accepted during product registration renewal or re-instatement. Applicants must lodge applications for approval of amendments prior to or after registration renewals or re-instatement.

9.1 TRANSFER OF REGISTRATIONS

The Registrar should be notified in writing of the change in registration holder on or before the effective date of owner transfer. Registrations can be transferred to another company or individual on request when the company changes management or when the business is sold to another company.

9.1.1 The following documents must be submitted:

- a) A Service Request Form (Application Form Ref: FF/SRF_01);
- b) Farm Feed Application Form **in duplicate** (Application Form Ref: FF/FF_01);
- c) Sworn affidavit that serves as an agreement between two companies stating the registrations to be transferred from Company A to Company B;
- d) Proposed labels **in duplicate** with the contact details of the new registration holder;
- e) Original registration certificates from the current registration holder;
- f) Proof of payment.

9.1.2 The new registration holder (company B) shall keep the registration numbers that were allocated to the previous registration holder.

9.1.3 If the transfer is done at the time of renewal, the fee is **in addition** to the renewal fee.

9.2 RE-INSTATEMENT OF REGISTRATION

The application must be made by the former registration holder of the product. The registration of a product can be re-instated if its registration had been cancelled or the registration has lapsed.

9.2.1 The following documents must be submitted:

- a) A Service Request Form (Application Form Ref: FF/SRF_01);
- b) Farm Feed Application Form **in duplicate** (Application Form Ref: FF/FF_01);
- c) Product label **in duplicate**;
- d) Certificate of analysis;
- e) Proof of payment.

9.3 RENEWAL OF A REGISTRATION

The office of the Registrar sends reminders for renewals three (3) months before the end of March each year to registration holders whose registrations are about to expire. It is advisable not to wait for the reminders and apply to renew registrations at least three (3) months prior to the expiry date to ensure continuous registration. Applications for registration renewals must be submitted to the office of the Registrar not later than the 31st of March. Applications submitted after this date but before the 30th of April are liable for a late renewal penalty fee that is payable in addition to the renewal fee. The registration of an application that is submitted after the 30th of April in the year of its expiry is considered to have lapsed and must be re-instated.

9.3.1 The following documents must be submitted:

- a) Renewal form Farm Feed: Form A – (Application Form Ref: FF/Renew_01) listing names and registration numbers of products whose registrations need to be renewed.
- b) Contact details of applicant and manufacturer form: Form C – (Application Form Ref: FF/Contact_01)
- c) Proof of payment.
- d) Certificate of Analysis when required by the Registrar.
- e) Product label in duplicate when required by the Registrar.

9.4 CANCELLATION OF A REGISTRATION

The registration of a product can be cancelled by the registration holder. In some instances, it can be cancelled by the Registrar in terms of section 4 of Act No. 36 of 1947. The registration holder must return the original registration certificate to the Registrar within 14 of the product registration cancellation.

9.4.1 The following documents must be submitted to cancel a registration:

- a) Cancellation form: Form B – (Application Form Ref: FF/Cancel_01) listing product names and registration numbers whose registrations should be cancelled.

9.5 LABEL AMENDMENT

A label amendment includes change in the design of the label or change in the packaging material used. The application must be made by the registration holder.

9.5.1 The following documents must be submitted:

- a) A Service Request Form (Application Form Ref: FF/SRF_01);
- b) Application form for registration of farm feed **in duplicate** (Application Form Ref: FF/FF_01);
- c) Proposed label **in duplicate** (with proposed changes);
- d) Copy of approved label;
- e) Proof of payment;
- f) Two samples of 100g or 100 ml each (when required by Registrar).

- g) Stability data may be required, depending on the type of product.

9.6 MANUFACTURING FACILITY AMENDMENT

This application is lodged if the manufacturing site changes/relocates; ownership of the manufacturing facility changes (if not owned by registration holder) or the manufacturing facility is modified. Such application can also be lodged when a manufacturing or bagging facility is added to a product registration.

9.6.1 The following documents must be submitted:

- a) A Service Request Form (Application Form Ref: FF/SRF_01);
- b) Application form for registration of farm feed **in duplicate** (Application Form Ref: FF/FF_01);
- c) Copy of approved label;
- d) Certificate of analysis;
- e) Proof of quality management system;
- f) Proof of payment.

9.7 AMENDMENT OF REGISTRATION HOLDER OR COMPANY NAME

This application is lodged when a company changes ownership or the name of the company changes. The Registrar must be notified in writing within two months of the change. The application must be made by the registration holder. A request to retain the current registration number must be included in the Service Request Form.

9.7.1 The following documents must be submitted:

- a) A Service Request Form (Application Form Ref: FF/SRF_01);
- b) Application for registration of farm feed (Application Form Ref: FF/FF_01);
- c) Copy of registration certificate of a new company (issued by the Registrar of Companies);
- d) Proposed labels **in duplicate** with new contact details;
- e) Copy of approved label;
- f) Proof of payment.

9.8 AMENDMENT OF PRODUCT NAME

Such an application is lodged when only the name of a product changes and no other changes to the product or its information.

9.8.1 The following documents must be submitted:

- a) A Service Request Form (Application Form Ref: FF/SRF_01);
- b) Application form for registration of farm feed **in duplicate** (Application Form Ref: FF/FF_01);
- c) Product label **in duplicate** (with proposed name);
- d) Copy of approved label;

- e) Proof of payment.

9.9 AMENDMENT OF PACKAGING SIZE

This application is lodged when the registration holder wishes to add different package sizes to those declared when the product was being registered.

9.9.1 The following documents must be submitted:

- a) A Service Request Form (Application Form Ref: FF/SRF_01);
- b) Farm Feed Application Form **in duplicate** (Application Form Ref: FF/FF_01);
- c) Product label **in duplicate** (with new or additional pack size);
- d) Copy of approved label;
- e) Proof of payment.

9.10 TECHNICAL AMENDMENT

This application is lodged when the registration holder wishes to change the nutritional composition of the product, ingredients used, feeding recommendations, target species, shelf life of the product and add new claims on the label.

9.10.1. Change in nutritional composition

9.10.1.1. The following documents must be submitted:

- f) A Service Request Form (Application Form Ref: FF/SRF_01);
- g) Farm Feed Application Form **in duplicate** (Application Form Ref: FF/FF_01);
- h) Product label **in duplicate** (with new information);
- i) Copy of the approved label;
- j) Certificate of analysis;
- k) Proof that product is still suitable for purpose (Data required will depend on product type);
- l) Proof of payment.

9.10.2. Change of ingredients

9.10.2.1. The following documents must be submitted:

- a) A Service Request Form (Application Form Ref: FF/SRF_01);
- b) Farm Feed Application Form **in duplicate** (Application Form Ref: FF/FF_01);
- c) Product label **in duplicate** (with new information);
- d) Copy of the approved label;
- e) Certificate of analysis;
- f) Proof that product is still suitable for purpose (Data required will depend on product type);
- g) Proof of payment.

9.10.3. Change of feeding recommendations

9.10.3.1. The following documents must be submitted:

- a) A Service Request Form (Application Form Ref: FF/SRF_01);

- b) Farm Feed Application Form **in duplicate** (Application Form Ref: FF/FF_01);
- c) Product label in duplicate (with new information);
- d) Copy of the approved label;
- e) Justification for new feeding recommendation (data required will depend on product type);
- f) Proof of payment.

9.10.4. Change of target species

9.10.4.1. The following documents must be submitted:

- a) A Service Request Form (Application Form Ref: FF/SRF_01);
- b) Farm Feed Application Form **in duplicate** (Application Form Ref: FF/FF_01);
- c) Product label **in duplicate** (with new information);
- d) Copy of the approved label;
- e) Efficacy and safety data on new species;
- f) Proof of payment.

9.10.5. Change of shelf life

9.10.5.1. The following documents must be submitted:

- a) A Service Request Form (Application Form Ref: FF/SRF_01);
- b) Farm Feed Application Form **in duplicate** (Application Form Ref: FF/FF_01);
- c) Product label **in duplicate** (with new information);
- d) Copy of the approved label;
- e) Certificate of analysis;
- f) Shelf life study data;
- g) Proof of payment.

9.10.6. Change or additional claims

9.10.6.1. The following documents must be submitted:

- a) A Service Request Form (Application Form Ref: FF/SRF_01);
- b) Farm Feed Application Form **in duplicate** (Application Form Ref: FF/FF_01);
- c) Product label **in duplicate** (with new information);
- d) Copy of the approved label;
- e) Certificate of analysis;
- f) Data attesting to new claims;
- g) Proof of payment.

10. REFERENCES

1. Fertilizers, farm feeds, agricultural remedies and stock Remedies Act 36 of 1947. Department of Agriculture, Forestry and Fisheries. South Africa. [www.daff.gov.za/agricultural production, health & food safety branch/feeds, stock remedies, pesticides and fertilizers.](http://www.daff.gov.za/agricultural_production_health_and_food_safety_branch/feeds_stock_remedies_pesticides_and_fertilizers)
2. Farm Feeds Regulations No. R. 1087. [www.daff.gov.za/agricultural production, health & food safety branch/feeds, stock remedies, pesticides and fertilizers.](http://www.daff.gov.za/agricultural_production_health_and_food_safety_branch/feeds_stock_remedies_pesticides_and_fertilizers)
3. Farm Feeds General Guidelines. [www.daff.gov.za/agricultural production, health & food safety branch/feeds, stock remedies, pesticides and fertilizers.](http://www.daff.gov.za/agricultural_production_health_and_food_safety_branch/feeds_stock_remedies_pesticides_and_fertilizers)
4. Guidelines on the data and documents required for registration of agricultural remedies in South Africa. 2013. Registrar: Act No. 36 of 1947, Agriculture, Forestry and Fisheries. South Africa. [www.daff.gov.za/agricultural production, health & food safety branch/feeds, stock remedies, pesticides and fertilizers.](http://www.daff.gov.za/agricultural_production_health_and_food_safety_branch/feeds_stock_remedies_pesticides_and_fertilizers)
5. Commission Regulation (EC) No 429/2008. Official Journal of the European Union L133, 22.5.2008.
6. OECD (Organisation for Economic Co-operation and Development) Guidelines for testing of chemicals. www.oecd.org.

ANNEXURE 1

Application Forms for the registration of Farm Feeds

The following application forms are available for the respective registration applications. The forms can be downloaded from the DAFF website at:

<http://www.daff.gov.za/daffweb3/Branches/Agricultural-Production-Health-Food-Safety/Agriculture-Inputs-Control/Forms>). They can also be obtained from the Registrar's office.

- Service Request Form - (Service Request Form Ref: FF/SRF_01)
- Farm Feed Application Form - (Application Form Ref: FF/FF_01)
- Renewal Farm Feed Form: Form A – (Application Form Ref: FF/Renew_01)
- Cancellation Form: Form B – (Application Form Ref: FF/Cancel_01)
- Contact details of applicant and manufacturer: Form C – (Application Form Ref: FF/Contact_01)

ANNEXURE 2

The following list of OECD Guidelines is referenced in this Guideline document and may be downloaded from the OECD website at:

http://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals-section-4-health-effects_20745788

OECD Guidelines 402 - Acute Dermal Toxicity
OECD Guidelines 403 - Acute inhalation toxicity
OECD Guidelines 404 - Dermal Irritation/Corrosion
OECD Guidelines 405 - Eye Irritation/Corrosion
OECD Guidelines 406 - Skin Sensitisation
OECD Guidelines 412 - Repeated Dose Inhalation Toxicity: 28-day or 14-day study
OECD Guidelines 413 - Sub-chronic Inhalation Toxicity: 90-day study
OECD Guidelines 414 - Parental Development Toxicity study
OECD Guidelines 415 - One-generation reproduction toxicity testing
OECD Guidelines 416 - Two-generation reproduction toxicity testing
OECD Guidelines 417 - Toxicokinetics
OECD Guidelines 421 - Reproduction/Developmental toxicity screening test
OECD Guidelines 429 - Skin Sensitisation — local lymph-node assay
OECD Guidelines 453 - Combined Chronic toxicity/carcinogenicity studies
OECD Guidelines 471 - Salmonella typhimurium Reverse Mutation test
OECD Guidelines 472 - Escherichia coli Reverse Mutation test
OECD Guidelines 473 - in vitro Mammalian Chromosomal Aberration test
OECD Guidelines 474 - Mammalian Erythrocyte Micronucleus test
OECD Guidelines 475 - Mammalian Bone Marrow Chromosomal Aberration test
OECD Guidelines 476 - in vitro Mammalian Cell Gene Mutation test
OECD Guidelines 482 - Unscheduled DNA Synthesis in Mammalian Cells in vitro
OECD Guidelines 503 - Metabolism in livestock
OECD Guidelines 505 - Residues in livestock