**No. R. 101** **19 February 2010**

## FERTILIZERS, FARM FEEDS, AGRICULTURAL REMEDIES AND STOCK REMEDIES ACT, 1947 (ACT NO. 36 OF 1947)

## REGULATIONS RELATING TO FERTILIZERS, FARM FEEDS, AGRICULTURAL REMEDIES AND STOCKREMEDIES, STERILIZING PLANTS AND PEST CONTROL OPERATORS, APPEALS AND IMPORTS: PROPOSED AMENDMENTS

I, Tina Joemat-Pettersson, Minister for Agriculture, Forestry and Fisheries acting, acting under Section 23 of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947), hereby-

i. make known that I intend to make regulation in the schedule; and

ii. invite interested persons to submit any objections to or representations concerning the proposed regulation in writing to the Registrar: Fertilizer, Farm Feeds, Agricultural Remedies and Stock Remedies, Private bag X 343, Pretoria, 0001, within four weeks from date of publication hereof.

T. Joemat-Pettersson
Minister for Agriculture, Forestry and Fisheries

## FERTILIZERS, FARM FEEDS, AGRICULTURAL REMEDIES AND STOCK REMEDIES ACT, 1947 (ACT NO. 36 OF 1947)

## AGRICULTURAL REMEDIES: PROPOSED AMENDMENT

The Minister for Agriculture, Forestry and Fisheries has under Section 23 of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947), made the regulations in the Schedule.

### SHEDULE

Definition

1. In this schedule "the regulations" means the regulations published by government notice No. R1017 of 3 November 2006.

**Addition of Regulation 1**

2. The regulations are hereby amended by the addition in regulation 1 of the following definition;

"**SANAS**" means South African National Accreditation System;

**Substitution of Regulation 3(1)**

3. The regulations are hereby amended by the substitution of regulation 3(1) by the following regulation;

3. (1) Subject to the provisions of Sections 4 and 4A of the Act, an animal feed registration in terms of Section 3 of the Act shall be valid up to 30 September of a three year registration cycle;

**Addition of Regulation 11(7)**

4. The regulations are hereby amended by the addition of regulation 11(7) in the regulations as follows;

11. (7) Subject to the provisions of Section 16 of the Act, no one shall import farm feed into the Republic for use in the manufacture of livestock feed or pet food, or for use as farm feed unless it is registered in terms Sections 3 of the Act;

**Substitution of Regulation 21(2) (b)**

5. The regulations are hereby amended by the substitution of regulation 21(2) (b) by the following regulation;

21. (2) (b). The particulars required in terms of paragraph (a) shall appear on the label (as required) expressed as percentages or gram per kilogram for macronutrients, milligrams or micrograms per kilogram for micronutrients, International unit per kilogram for vitamin A, D and E, as activity unit per gram or activity unit per milliliter for enzymes and their preparations, as colony forming units per gram for micro-organisms and their preparations in the following order –

(i) Crude protein (minimum)
(ii) Equivalent crude protein from non-protein nitrogen (maximum)
(iii) Amino acids (minimum)

(iv) Moisture (maximum)
(v) Crude fat (minimum and/or maximum)
(vi) Crude fibre (minimum and/or maximum)
(vii) Calcium (minimum and/or maximum)
(viii) Phosphorus (minimum)
(ix) Other mineral guarantees
(x) Vitamins (minimum)
(xi) Total sugar as invert (minimum)
(xii) Viable micro-organisms producing lactic acid (minimum)
(xiii) Other guarantees (minimum)

**Substitution of Regulation 22(1) (g)**

6. The regulations are hereby amended by the substitution of regulation 22(1) (g) by the following regulation;

22. (1) (g). The information that is required to appear in the "Average analysis" or "analysis" shall be listed in the following order-

(i) Crude protein
(ii) Moisture
(iii) Crude fat/oil
(iv) Crude fibre
(v) Crude Ash
(vi) Calcium (optional)
(vii) Phosphorus (optional)

**Substitution of Regulation 22(1) (h)**

7. The regulations are hereby amended by the substitution of regulation 22(1) (h) by the following regulation;

22. (1) (h). The average analysis shall be expressed in terms of percentages or gram per kilogram for macro-nutrients, milligrams or micrograms per kilogram 9mg/kg or µg/kg) for micro-nutrients and international units per kilogram (IU/kg) for vitamin A and D. All guarantees shall be expressed on an as fed basis. Vitamin inclusion levels shall be those in the pet food at the "best before" date;

**Substitution of Regulation 22(2) (a)**

8. The regulations are hereby amended by the substitution of regulation 22(2) (a) by the following regulation;

22. (2) (a). A vignette, graphic, or pictorial presentation of a product on a pet food shall not misinterpret the contents of the package. When a graphic or picture of animal protein, vegetables, cereals and grains is used on the label it shall be used subject to the following rules-

(i) Where a label shows graphics or pictorial of vegetables, fish, milk and eggs it shall mean that there is at least a 4%, of the ingredient appearing in the picture or graphic in the final product;

(ii) Where a label shows graphics or pictorial of cereals and/or grains, it shall mean that there is at least a 14%, of the ingredient appearing in the picture or graphic in the final product; and

(iii) Where a label shows graphics or pictorial of meat, it shall mean that there is at least a 26%, of the ingredient appearing in the picture or graphic in the final product.

**Substitution of Regulation 22(2) (m) (iv)**

9. The regulations are hereby amended by the substitution of regulation 22(2) (m) (iv) by the following regulation;

22. (2) (m) (iv) in the case of nutrients, the minimum content, expressed as set out in regulation 22(1)(g) above, shall clearly be indicated as part of the average analysis and shall follow the mandatory guarantees;

**Substitution of Regulation 22(2) (m) (vi)**

10. The regulations are hereby amended by the substitution of regulation 22(2) (m) (vi) by the following regulation;

22. (2) (m) (vi) if particular attention is drawn to an inclusion as an optimum ratio then the inclusion ratio shall be shown in the analysis on the label;

**Substitution of Regulation 22(2) (q)**

11. The regulations are hereby amended by the substitution of regulation 22(2) (q) by the following regulation;

22. (2) (q) Statements of energy content shall only be permitted on the label if they are substantiated. Where a statement(s) that make reference to weight control or obesity is claimed on the label it shall be accompanied by a declaration of product energy content;

**Substitution of Regulation 22(2) (u)**

12. The regulations are hereby amended by the substitution of regulation 22(2) (u) by the following regulation;

22. (2) (u) A reference to quality, nature, form, or other attributes of an ingredient shall not be made unless such reference is accurate and unless the ingredient imparts a distinctive characteristic to the pet food because it possesses that attribute. Reference to poor, low, inferior, undesirable ingredient(s) quality shall not be permitted on pet food label;

**Substitution of Regulation 22(7)**

13. The regulations are hereby amended by the substitution of regulation 22(7) by the following regulation;

22. (7) Not withstanding the provisions of subregulation (1) and subregulation (2) the Registrar may, on written request of the applicant grant certain exemptions from the stipulations of these subregulations under certain conditions;

**Substitution of Regulation 24(3) (b)**

14. The regulations are hereby amended by the substitution of regulation 24(3) (b) by the following regulation;

24. (3) (b) be accompanied by two copies of a typed version of the advertisement in English and, if applicable, two copies of illustrations to be used in connection with that advertisement; and

**Substitution of Regulation 26**

15. The Regulations are hereby amended by the substitution of regulation 26 by the following regulation;

26. (1) The site where the manufacturing facility is located shall be maintained so as to prevent contamination and enable the production of safe feed, such that -

(a) measures necessary to protect the site from any potential undesirable contaminants shall be in place and periodically reviewed to ensure they continue to be effective; and

(b) the site boundaries shall be clearly defined.

26. (2) All grounds within the site shall be finished and maintained to an appropriate standard, such that -

(a) where natural drainage is inadequate, additional drainage shall be installed to avoid the risk of contamination of feedingstuffs;

(b) where external storage is necessary, items shall be protected from contamination and deterioration;

(c) wherever possible, all buildings shall be surrounded by a clear space. All immediate surrounding areas shall be kept clean, and effective pest control programs shall be implemented; and

(d) waste collection shall take place in a well-defined area.

26. (3) Premises and plant shall be designed, constructed and maintained to control the risk of product contamination, such that -

(a) the production process from reception to dispatch, shall be designed to permit adequate cleaning and/or disinfection in order to prevent personnel, product, facilities and equipment contamination and cross-contamination;

(b) premises shall allow sufficient working space and storage to enable all operations to be carried out properly under safe and hygienic conditions;

(c) the systems of working shall, where appropriate, be such as to reduce any potential physical, chemical or microbiological contamination risks;

(d) there shall be an appropriate segregation between unprocessed and processed materials to minimise the risk of product cross-contamination;

(e) segregation shall take into account the product flow, nature of materials, equipment, personnel, waste management, airflow, and air quality and services provision; and

(f) manufacturing plants shall have adequate facilities for disposing of unused animal by-products remaining after the production of the products. Alternatively this material shall be sent to a processing plant or to an incineration or co-incineration plant.

26 (4) The fabric of the site, buildings and facilities shall be suitable for the intended purpose. The use of glass shall be avoided where necessary. The -

(a) walls shall be designed, constructed, finished and maintained to prevent the accumulation of dirt, to reduce condensation and mould growth and to facilitate cleaning;

(b) wall/floor junctions and corners shall be covered to facilitate cleaning and disinfection; cavities in the surface of walls shall be avoided, where necessary, to prevent debris from accumulating and pest harbourage;

(c) drainage shall not compromise product safety and shall flow away from high-risk areas;

(d) drainage facilities shall be adequate for the purpose intended and shall be designed and maintained to minimise risk of product contamination;

(e) floors shall be designed to meet the demands of the process, and withstand cleaning materials and methods; they shall be impervious and maintained in good conditions;

(f) floors shall have adequate falls to cope with the flow of any water or effluent towards suitable drainage;
(g) careful consideration to the sitting of machinery; suitable drainage shall be provided so that any discharge or overspill from processing goes directly into a drain rather than on the floor;
(h) use of false ceilings shall be accompanied by adequate access to the void in order to facilitate cleaning, maintenance of services and inspection for pest activity;
(i) ceilings and overhead fixtures, where necessary, shall be designed, constructed, finished and maintained to prevent the accumulation of dirt, to reduce condensation, minimise mould growth and to prevent the accumulation of dust that can affect the safety and quality of livestock or pet food;
(j) use of glass close to production machinery shall be avoided and wherever necessary it shall be protected against breakage;
(k) windows hall be designed to be opened for ventilation purposes, they shall, where necessary, be adequately screened to prevent the ingress of pests;
(l) doors shall be kept closed at all times, when not in use;
(m) doors shall be close-fitting and proofed against pests when closed;
(n) external doors to raw material handling, processing, packaging and storage areas when kept open, suitable precautions shall be taken to prevent the ingress of pests;
(o) facilities shall have adequate natural and/or artificial lighting;
(p) shatterproof plastic diffusers or sleeve covers shall protect all bulbs and strip lights, including those on electric fly killer units, where they constitute a risk to the product; for high temperature lights, where plastic covers are not viable, a fine mesh metal screen shall be fitted; where full protection cannot be provided, the glass management system shall take this into account;
(q) equipment used for the purpose of screening or filtering air shall be adequately maintained;
(r) dust extraction equipment for dry powder handling areas shall be installed;
(s) compressed air in contact with products shall be filtered;
(t) water supplies used for cleaning shall, where appropriate, be potable, either being drawn from mains supply or suitably treated according to its source;
(u) water used in livestock feed or Pet food manufacture shall be of suitable quality for animals; all piping etc. shall be of inert nature;
(v) quality of water, steam or ice that comes in contact with livestock feed or pet food shall be regularly monitored and shall present no risk to product safety; and
(w) water supply systems shall be properly labelled and segregated between potable and non-potable supplies.

26. (5) Equipment shall be suitably designed for the intended purpose and shall be used so as to minimise the risk of product contamination, such that -

(a) equipment shall be designed, so as to minimise the risk of error and to avoid contamination, cross-contamination and any adverse affect, generally on the safety and quality of the products; when appropriate, machinery coming into contact with feed shall be dried following any wet cleaning process;
(b) equipment shall be positioned so as to allow easy access for cleaning and/or disinfection and servicing;

(c) all equipment shall be properly specified prior to commissioning, and shall be adequately maintained, serviced and operated to allow for the production of safe and quality compliant feed;
(d) all equipment surfaces coming into contact with the product shall be impervious and non-reactive;
(e) all equipment shall be designed so that it does not in itself contaminate the product due to leaking seals, lubrication or through subsequent modification; and
(f) all feed or food contact lubricants shall be of food grade quality.

26. (6) A system of planned maintenance shall be in place covering all items of equipment, which are critical to product safety and quality, such that-
(a) equipment shall undergo appropriate and regular maintenance, in accordance with written procedures pre-established by the equipment manufacturer;
(b) the manufacturer shall ensure that the safety and quality of product is not jeopardised during and after maintenance operations; particular attention shall be drawn to the risk of foreign body contamination;
(c) third party contractors and all engineers shall be aware of and adhere to the manufacturer's hygiene standards, with particular focus on both high and low risk areas; and
(d) cleaning or replacing light fittings and glass shall be done in a manner as to minimise the potential of product contamination.

26. (7) Staff facilities shall be designed, and used to minimise the risk of product contamination, such that-
(a) where specific work-wear is required, changing facilities shall be provided for all personnel, whether staff, visitor or contractor, prior to entry to production or packing areas, and where appropriate, prior to entry to storage areas;
(b) where appropriate, suitable and sufficient hand washing facilities shall be provided;
(c) toilets doors shall not open directly into production, packing or storage areas;
(d) smoking shall only be permitted in appropriate designated areas;
(e) where catering facilities are provided, these shall be suitably controlled to prevent contamination of product;
(f) where appropriate, changing facilities shall be located to allow personnel direct access to the packing or storage area , without first passing through areas external to the factory buildings;
(g) suitable provisions shall be made for the storage of food brought onto the premises by staff;
(h) outdoor clothing and other personal items shall be stored separately from work-wear within the changing facilities; and
(i) where appropriate, the use of work-wear shall be restricted to the work premises.

26. (8) Appropriate facilities and procedures shall be in place to control the risk of physical or chemical product contamination, such that-
(a) the manufacturer shall adopt all measures to comply with the maximum permitted levels of physicochemical residues;
(b) appropriate storage facilities shall be provided for the control and storage of any hazardous chemicals;
(c) written procedures for handling glass and hard clear plastic breakages in raw material handling, preparation, processing, packing and storage areas shall be in place to ensure the necessary precautions are taken; these procedures shall form part of a formal glass policy; and

(d) the use of wood within raw material handling, preparation, processing, packing and storage areas shall, be minimised.

26. (9) Appropriate standards of hygiene and housekeeping shall be maintained at all times, such that-

(a) cleaning and/or disinfection programmes shall be implemented and effective in order to minimise the risk of contamination; programme shall be documented;
(b) all cleaning staff shall be trained and competent to perform the required tasks;
(c) the effectiveness of the cleaning and sanitation procedures in processing areas shall be verified; and
(d) only approved food grade cleaning agents shall be used.

26. (10) There shall be adequate systems for the collation, collection and disposal of waste material, such that -

(a) sewage, waste and rain water shall be disposed of in a manner which ensures that the safety and quality of feed is not affected; spoilage and dust shall be controlled to prevent pest invasion;
(b) waste and materials not suitable as feed shall be isolated and identified; any such materials containing hazardous levels of veterinary drugs, contaminants or other hazards shall be disposed of in an appropriate way and not used as feed;
(c) systems shall be in place to minimise the accumulation of waste in production areas, and shall prevent the use of unfit materials; defined waste areas shall be established;
(d) waste disposal shall meet legislative requirements and, where appropriate, removed by licensed contractors;
(e) external waste collection containers and compactors shall be closed and/or covered; and
(f) all waste containers shall be clearly marked and designated for that purpose only.

26. (11) The Manufacturer shall be responsible for minimising the risk of pest infestation on the site, such that -

(a) pest control programmes are implemented.
(b) the manufacturer either contract the services to a competent registered pest control operator, or shall have trained personnel, for the regular inspection and treatment of premises to stop and eradicate pest infestation; where the services of a pest control contractor are employed, the service contracted shall be clearly defined and reflect the activities of the site;
(c) detailed records of the pest control inspections, recommendations and necessary action undertaken shall be kept;
(d) where appropriate, permanently operational electric fly killers shall be provided and correctly positioned;
(e) drains shall be fitted with screens and traps to prevent pest entry;
(f) where appropriate, incoming raw materials shall be thoroughly checked on arrival for the absence of pests;
(g) raw materials, packaging and finished products shall be stored so as to minimise the risk of pest infestation; where stored, product may attract pests, appropriate measures shall be included in the control programme;
(h) documentation shall provide detailed information on the safe use and application of baits; and
(i) the location of all pest control measures shall be identified on a plan/diagram of the site.

26. (12) The Manufacturer shall ensure that all employees are adequately trained, instructed and supervised, commensurate with their activity, such that -

(a) all employees involved in the production of animal feed, including storage and transport, be aware (e.g. clearly informed in writing of their duties, responsibilities and powers) that they contribute to the quality and safety of the finished products;

(b) all personnel, including temporary personnel and contractors, shall be in sufficient number, possess the skills and qualifications necessary for the manufacturing process and be appropriately trained prior to commencing work; they shall be adequately supervised throughout the working period;

(c) the staff shall be adequately trained for quality management; the person responsible for supervising quality control shall furthermore be in a position to carry out his/her tasks independently and to take the appropriate decisions; and

(d) the manufacturer shall have full training programmes and records.

26. (13) The Manufacturer's personal hygiene standards shall be documented and adopted by all personnel, including contractors and visitors to the factory. These standards shall be designed with due regard to the risk of product contamination, such that-

(a) jewellery and watches shall not be worn unless in exceptional circumstances when there is no risk of product contamination and with the exception of a plain wedding ring and sleeper earrings;

(b) all cuts and grazes on exposed skin shall be covered (e.g. by a detectable blue metal strip plaster, that is Pet food manufacturer-issued);

(c) smoking, eating and drinking shall only be permitted in designated areas;

(d) hand cleaning shall be performed in an appropriate manner and frequency;

(e) medical screening procedures shall be implemented, where appropriate, in particular for staff working in areas where product safety could be compromised; and

(f) personnel known, or suspected, to be suffering from a disease likely to be transmitted to livestock feed or pet food, shall not be allowed to enter any feed handling area where there is a likelihood of contaminating the feed, posing a risk to the safety of the product, the target animal and to humans handling the feed.

26. (14) feed handlers, visitors, and contractors working in, or entering the feed handling areas, shall wear suitable feed manufacturer-issued protective clothing, such that-

(a) where appropriate, all hair shall be fully covered to prevent product contamination;

(b) suitable safety footwear shall be worn within the factory environment;

(c) all protective clothing shall be laundered effectively on a regular basis; and

(d) gloves, if worn, shall be subject to adequate control to avoid product contamination.

**Substitution of Regulation 27**

16. The Regulations are hereby amended by the substitution of regulation 27 by the following regulation;

27. (1) Clear responsibilities and procedures for the production process shall be in place, such that-

(a) a qualified employee shall be designated as the person responsible for the production process;

(b) the manufacturer shall ensure that the different production stages are carried out in accordance with written procedures and instructions; in order to obtain the desired quality of feed, these procedures shall define the critical points of the manufacturing process; and

(c) measures shall be taken to avoid contamination, cross contamination and human error to maintain the hygiene and safety standards.

27. (2) Weighing and metering equipment, both for bulk and hand tipped ingredients, is essential and shall be accurately done in order for the production of a safe feed, such that-

(a) all scales and metering devices used in the manufacture of feed shall be appropriate for the range of weights or volumes to be measured and a regular programme of calibration and testing of weighing and metering equipment shall be implemented; guidance from equipment manufacturers shall be taken in developing written procedures for calibration and testing; and

(b) a regular maintenance programme shall also be in place in order to ensure that weighing equipment is kept clean and that worn parts are replaced when necessary.

27. (3) A homogenous mixture is essential for nutritional balance and feed safety. The accuracy of mixing shall be assured and verified, such that-

(a) all mixers used in the manufacture of feed shall be appropriate for the range of weights or volumes being mixed, and shall be capable of manufacturing homogeneous mixes or homogenous solutions;

(b) the mixer shall be cleaned to ensure efficacy and feed safety;

(c) written maintenance schedules shall exist for examination of the mixer to ensure that worn equipment parts do not lead to the build up of residues when the mixer is emptied;

(d) the mixers shall operate for a pre-set time, determined by pre-production trials to ensure homogenous mixes and/or solutions;

(e) The efficiency of the mixing process shall be regularly checked to ensure that additives are evenly dispersed throughout the mix;

(f) an unacceptable carry over of additives, veterinary medical substances or any other undesirable substance shall be prevented; and

(g) operators shall demonstrate the effectiveness of mixers with regard to homogeneity.

27. (4) A Quality Control Plan shall be drawn up and implemented for the use of raw materials, pre-mixtures and finished products. The Manufacturer shall undertake or sub-contract analysis, critical to product safety and quality, using appropriate procedures and facilities, such that -

(a) the Quality Control Plan shall identify checks on critical control points in the manufacturing process, sampling procedures as well as determine the frequency of these checks and sampling procedures; the plan shall also specify which methods of analysis are to be used and how frequently; the quality control plan shall mention actions to be taken in case of non-compliance with the specifications;

(b) the manufacturer shall, based on risk assessment (including HACCP), determine what level of analytical testing (microbiological, physical or chemical) needs to be performed to verify that the food safety management system is under control;

(c) pet food and dog chews made from animal by-products, random samples shall be taken during production and/or finished products (before dispatching) to verify compliance with the following standards: Salmonella (absence in 25g, n=5, c=0, M=0); and Enterobacteriaceae (n=5, c=2, m=10, M=300 in 1g); however, for canned pet food and other

hermetically sealed heat treated containers that has undergone heat treatment described in the production section (temperature), sampling and testing for Salmonella and Enterobacteriaceae may not be necessary;

(d) procedures shall be in place to ensure reliability of test results;

(e) personnel undertaking analyses shall be suitably qualified, and/or trained and shall be competent to carry out the analyses required; and

(f) where the feed manufacturer undertakes or sub-contracts analyses critical to product safety or legal compositional verification, the laboratory shall be independently accredited by SANAS or ILAC.

27. (5) The Manufacturer shall be able to demonstrate effective control of all operations undertaken. Where temperature control of the raw materials, intermediate or finished product, process and/or environment is critical to product safety and quality, this shall be adequately controlled, monitored and recorded, such that -

(a) in circumstances where temperature and/or time control is critical to product safety and quality (e.g. thermal processing, freezing or chilling), temperature and/or time recording equipment, linked to a suitable failure alarm system, shall be used to monitor at an appropriate frequency, the process status;

(b) canned pet food and other hermetically sealed heat treated containers shall be subject to heat treatment to a minimum Fc value of 3;

(c) processed pet food other than canned pet food or other hermetically sealed heat treated containers shall be subject to a heat treatment of at least 90°C throughout its substance; after treatment, every precaution shall be taken to ensure that the product is not exposed to contamination; the product shall be packed in new packaging; and

(d) dog chews shall be subject to a heat treatment during processing sufficient to destroy pathogenic organisms (including salmonella); after treatment, every precaution shall be taken to ensure that the product is not exposed to contamination; the product shall be packed in new packaging.

27. (6) The Manufacturer shall ensure that all necessary steps are taken to identify, avoid, eliminate or minimise the risk of metal or other foreign body contamination, such that -

(a) the manufacturer shall use hazard analysis and determine the critical control points to avoid foreign body contamination. When necessary, metal or other foreign body detection equipment shall be installed;

(b) where a metal or foreign body detector is required, the manufacturer shall establish and apply the best practice critical limits for detection, having due regard to the nature of the feed, the location of the detector and any other factors influencing the sensitivity of the detector;

(c) the manufacturer shall establish and implement procedures for the operation, routine monitoring and testing of the metal and other foreign body detectors; and

(d) the manufacturer shall establish and implement corrective action and reporting procedures, in the event of the monitoring and testing procedure identifying any failure of the metal or foreign body detector; these will include the isolation, quarantining and re-inspection of all products since the last acceptance test of the metal or other foreign body detector.

27. (7) The Manufacturer shall ensure that the product is not released before all the procedures have been followed, such that -

(a) The manufacturer shall ensure that the product is only released by authorised personnel in line with release procedures ensuring product safety.

27. (8) The Manufacturer shall ensure all out-of-specification raw materials and semi- or finished products are clearly identified, labelled and quarantined, such that -

(a) clear procedures for the control of non-conforming material, including rejection, acceptance by concession, or agreement to use for another purpose, shall be in place and understood by all authorised personnel;

(b) corrective actions shall be implemented to avoid recurrence of non-conformance and adequate records of the action taken; and

(c) all non-conforming products shall be handled or disposed of according to the nature of the problem and/or specific requirements.

27. (9) Checks shall be carried out to demonstrate that a package conforms with the Trade Metrology Act, 1973 (Act 77 of 1973) legal requirements and with any additional recognised industry sector codes/guides, such that -

(a) The frequency and methodology of quantity checking shall meet the minimum requirements of legislation pertaining to quantity verification, irrespective of the nature of the pre-packaged material (e.g. average quantity, weight/volume); and

(b) all equipment used for quantity measurement shall be legally acceptable and regularly calibrated.

27. (10) The Manufacturer shall operate procedures that verify that the process and equipment employed are capable of producing consistent safe products with the desired quality characteristics, such that -

(a) in the event of changes to product formulation, processing methods, equipment or packaging, the manufacturer shall, where appropriate, re-establish process characteristics and validate product data, to ensure product safety and quality; and

(b) in the case of equipment failure or process deviation, procedures shall be in place to establish the safety status of the product, prior to release.

27. (11) Equipment used to monitor critical control points and product compliance shall be calibrated and traceable, such that -

(a) where necessary, equipments shall:

(i) be calibrated or verified at specified intervals or prior to use and the basis used for calibration or verification shall be recorded;

(ii) be adjusted or re-adjusted as necessary;

(iii) be identified to enable the calibration status to be determined;

(iv) be safeguarded from adjustments that would invalidate the measurement results; and

(v) be protected from damage and deterioration.

(b) records of the results of calibration and verification shall be maintained.

27. (12) Where materials require special handling procedures, these shall be in place to ensure that product safety and quality are maintained, such that -

(a) where packaging materials (e.g. glass containers) pose a risk to the product safety, special handling procedures shall be in place to prevent product contamination or spoilage; records of failures and corrective actions taken shall be maintained; and

(b) where re-processing is used, or reworking operations carried out, procedures shall be implemented to ensure the safety and quality of the finished product.

27. (13) Product packaging shall be appropriate for the intended use and stored under proper conditions to minimise the risk of contamination and deterioration, such that-

(a) proper packaging materials shall be used;
(b) procedures shall be in place to confirm that product packaging conforms to specification;
(c) where staples or other items likely to cause damage or contamination in packaging are used, appropriate precautions shall be taken to minimise the risk of product contamination;
(d) any packaging material surplus to a specific production run shall be protected before being returned to storage; and
(e) packaging material shall be stored apart from raw materials to avoid cross-contamination.

27. (14) All vehicles or warehouses used for the transportation or storage of raw materials (including packaging), intermediates/semi-processed products and finished product, shall be suitable for the intended purpose, and be maintained in good repair and in a hygienic condition, such that-

(a) the manufacturer shall make sure that, the goods delivered match with those ordered, the feed is properly labelled in accordance with legal requirements; and that all measures have been taken to ensure the quality and safety of the feed delivered;
(b) all containers used for transporting or warehouses used for storing raw materials and finished products shall be kept free of potential contaminants, whether chemical, odour, pests (e.g. microorganisms, rodents, insects, birds) and domestic animals;
(c) only persons authorised by the manufacturer shall have access to the storage facilities;
(d) the name and the address of the carrier shall be registered;
(e) raw materials, packaging materials and finished products shall be stored and transported in such a way as to make them easily identifiable (product name, number, date and time of manufacture) and to prevent cross-contamination and deterioration;
(f) refrigerated transport or storage shall be capable of maintaining product/raw material temperature within specification, under maximum load, and whilst the product/raw material is stored on the vehicle or in the warehouse;
(g) procedures shall, where appropriate, be in place in the case of equipment failure (e.g. refrigeration); these procedures shall ensure product safety and quality;
(h) where the raw material, packaging materials or finished product transported is susceptible to damage by the weather, vehicles shall be weather proofed and shall be loaded and unloaded in covered bays to protect the material.
(i) animal by-products and processed products shall be collected and transported in sealed new packaging or covered leak-proof containers or vehicles;
(j) vehicles and reusable containers and all reusable items of equipment or appliances that come into contact with animal by products or processed products, shall be: cleaned, washed and disinfected after each use; maintained in a clean condition; and clean and dried before use;
(k) re-usable containers shall be dedicated to the carriage of a particular product in order to avoid cross contamination;

(l) unprocessed animal by-products that are fit for human consumption destined for the production of feed material or pet food shall be transported chilled or frozen, unless processed within 24 hours of the time at which it was generated; and

(m) Packaging material shall be incinerated or disposed of in accordance with relevant legislation (s).

27. (15) Storage segregation procedures shall be in place to prevent the cross-contamination of finished products, packaging and raw materials, such that-

(a) processed feed and packaging material shall be separated from unprocessed feed materials and additives, in order to avoid any cross-contamination of the processed feed and/or of the packaging material.

27. (16) Procedures shall be in place to ensure that materials and products are used in the correct order and within the allocated shelf life, such that -

(a) receipt documents and/or product labelling shall facilitate correct stock rotation (F.I.F.O. - first in first out).

27. (17) The basis of the Pet food manufacturer's food safety system shall be a HACCP Plan which shall be systematic, comprehensive and thorough and shall be based on the Codex Alimentarius HACCP principles, such that -

(a) the Pet food manufacturer shall use the Codex HACCP principles to:
  (i) conduct a hazard analysis;
  (ii) determine the Critical Control Points (CCP);
  (iii) establish the Critical Limits;
  (iv) establish a system to monitor control of the CCP;
  (v) establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control;
  (vi) establish procedures of verification to confirm that a HACCP System is working effectively; and
  (vii) establish documentation concerning all procedures and records appropriate to these principles and their applications.

(b) the HACCP study shall be based on an assessment of risk, and shall identify which hazards are of such a nature that their elimination or reduction to acceptable levels is essential to the correct production of pet food; in conducting the hazard analysis, wherever possible, the following shall be included:
  (i) the likely occurrence of hazards and severity of their adverse health effects;
  (ii) the qualitative and/or quantitative evaluation of the presence of hazards;
  (iii) survival and multiplication of micro-organisms of concern;
  (iv) production and persistence in pet foods of toxins, chemical or physical agents; and
  (v) conditions leading to the above.

(c) HACCP shall have Senior Management commitment and shall be implemented through the Pet food manufacturer's quality management system;

(d) the HACCP team leader or nominated team representative shall be able to demonstrate competence in the understanding of HACCP principles and their application;

(e) key personnel identified as HACCP Team members shall have adequate training and experience;

(f) the HACCP system shall be specific to the application, practical to implement and effective in controlling the associated hazards of the operation;

(g) all existing and new products shall be covered by the HACCP system, which shall be reviewed on a regular basis (at least once a year) and shall be validated;

(h) Critical Control Points, identified in relation to the operation, shall be controlled and monitored within predetermined Critical Limits; records of conformance and effective corrective action resulting from non-conformance shall be maintained;

(i) the food safety management system shall consist of both a validated and verified prerequisite programme and a HACCP system, and through these, the pet food manufacturer shall be able to demonstrate effective food safety control of all operations undertaken; and

(j) the HACCP study shall be carried out by a multi-disciplinary team.

27. (18) Traceability shall be applied and be the responsibility of each operator of the entire animal feed and pet food chain ("from farm to fork / from farm to feeding bowl").
The Manufacturer shall adequately identify all materials used in the livestock feed or pet food production (raw materials, additives, packaging, packaging materials), including the finished product, and be able to trace what occurred in all phases of production, and up to the distribution to the customer, such that-

(a) the manufacturer shall work with a system of documentation designed to ensure an adequate level of traceability; traceability is the capability to be able to identify any person from whom they have been supplied with feed materials, additives, packaging material or any substance intended to be, or expected to be, used for the production of feed; the manufacturer shall record and keep the following information for at least two years, or five years if the product contains GMOs, in order to ensure product traceability:

(i) the name and address of the suppliers (e.g. raw materials, additives/pre-mixtures, and packaging) and the sources of these raw materials/packaging, including the batch number, quantity and delivery date;

(ii) the raw material registration number of the suppliers;

(iii) the nature, formulation and quantity of the finished products manufactured, along with the manufacturing date and batch number; Samples and records of each batch shall be retained in accordance with these regulations; and

(iv) the name and address of the site where the batch of semi-finished or finished products are delivered.

(b) where rework or any reworking operation is performed, traceability shall be maintained.

27. (19) The Manufacturer shall identify each individual sales unit, such that-

(a) the manufacturer shall establish and maintain documented procedures for identifying materials from reception through production to finished products; finished products shall be labelled to ensure traceability to batch.

27. (20) The Manufacturer shall have an effective product recall procedure for all products in the distribution network, such that-

(a) the manufacturer shall implement a system for the prompt recall of products in the distribution network;

(b) should a product be delivered, which does not meet the food safety requirements, the manufacturer has to recall these products from the distribution network; the manufacturer has to take care that the products will not be put back into circulation unless they have undergone a risk assessment and, if required, treated in an appropriate way; the

manufacturer, therefore, shall have a recall procedure implemented; a Rapid Alert System shall be in place, which is the obligation to inform the Registrar, in case a product recall is necessary;

(c) the procedure shall be: appropriate; formalised; capable of being operated at any time within four hours; the procedure shall be regularly reviewed and revised as appropriate; and

(d) the procedure shall be regularly tested in a manner that is appropriate to ensure its effective operation.

27. (21) A hazard analysis study (HACCP) shall be undertaken during the design/development phase of the product, packaging and process to identify and assess all potential safety hazards (Codex Alimentarius, 1997 (II)), such that-

(a) the feed shall be designed to produce a safe feed and meet the nutritional requirements of the animal;

(b) the manufacturer shall, where appropriate, undertake factory trials and carry out testing to verify if product formulation and manufacturing processes are capable of producing a nutritionally well balanced and safe product;

(c) shelf life shall be established, taking into account the product formulation, production process, packaging process and packaging and subsequent storage conditions; and

(d) packaging, process and the material used in the manufacture shall assure feed safety.

27. (22) Feed materials have to be mixed to produce a safe feed, such that-

(a) the presence of prohibited feed materials, undesirable substances, prohibited substances and pathogens in relation to animal or human health shall be monitored and appropriate control strategies to minimise the risk shall be in place;

(b) this regulation establishes a list of products whose use as feed materials is prohibited; the manufacturer shall make sure that the products included on the list of prohibited products are not used; certain feed materials and additives are subject to restriction for use in certain species; the manufacturer shall make sure that they are used accordingly and that the risks of accidental contamination are controlled/eliminated; and

(c) only permitted additives can be used and mixed in appropriate quantities and homogeneously with the feeding materials, in order to ensure that they are only present in non-toxic quantities.

27. (23) The Manufacturer shall operate procedures for approval and monitoring of its suppliers, including finished and semi-finished products manufactured by third parties, such that-

(a) a Vendor/Supplier Assurance (VA) programme shall exist to control the purchase of raw materials and packaging materials from approved suppliers; this programme shall document all standards and monitoring procedures dealing with primary production, inbound raw material and packaging and transport;

(b) specifications, based on risk assessment, for raw materials, semi-processed products (where supplied to other factories) and packaging materials shall be documented and implemented; the specification may include detail on analytical, nutritional requirements as well as food safety and hygiene requirements; there shall be a list of approved suppliers;

(c) appropriate methods of assessment/inspection of suppliers shall be performed with the frequency and type of audit being determined by risk assessment; assessment may take the form of monitoring performance

through in-house checks, certificates of analysis or extend to supplier inspection, as appropriate;

(d) supplier assessment shall include the suppliers' ability to trace back to their supplier, evaluation of HACCP systems, product safety information and legal requirements; the methods and frequency of assessment shall be based on formal risk assessment; and

(e) the procedures shall define how materials of unknown origin are handled.

27. (24) The Manufacturer shall operate procedures for monitoring the quality and safety of raw material at delivery, such that -

(a) each feed material, additive and packaging material shall have a written specification which is regularly updated; in addition to the nutritional and analytical characteristics of the feed material, this written specification shall include a list of approved origins and sources, details of any processing that the material has undergone, types of feedstuffs in which its use is approved, notes on any hazards or limitations on its use and any special characteristics of the feed material;

(b) Monitoring at delivery shall ensure that the feed materials and additives are traceable, conform to quality and safety specifications, delivered by an approved or registered supplier, when the products are covered by an approval or registration procedure;

(c) a record shall be kept of the origin of each feed material and additive delivered;

(d) suppliers delivering animal by-products shall meet specific registration, production process and analytical requirements; and

(e) a raw material/packaging acceptance procedure shall exist and each material shall be checked (against the specification) following a schedule of examination that takes into account its critical importance, as identified by risk assessment, in the final product, for example using certificates of analysis, sampling of the material on arrival.

**Substitution of Regulation 28**

17. The Regulations are hereby amended by the substitution of regulation 28 by the following regulation;

28. (1). The Manufacturer shall have a clearly defined and documented quality policy statement and quality objectives, such that -

(a) the policy shall state the manufacturer's intentions to meet its obligations to produce safe products, and its responsibility to its customers; the policy shall also include the commitment of continuously improving the effectiveness of the quality management system;

(b) quality objectives shall be established, implemented and reviewed; targets shall be defined and quality indicators shall be monitored in order to follow quality performance and trends; a regular evaluation of the data shall be a critical tool for continuous improvement of products and services which are delivered to the customer;

(c) the manufacturer's Directors and Senior Management shall demonstrate commitment to the implementation of the manufacturer Quality Policy; and

(d) the policy and the objectives, as well as the actual quality performance/trends shall be communicated throughout the company, and regularly reviewed.

28. (2) The Manufacturer shall have a Quality Manual which states the manufacturer's commitment to quality and which covers the requirements to Good Practice, such that-

(a) the Quality Manual shall contain an outline of working methods and practices that meet the requirements of these regulations; and

(b) the requirements specified within the Quality Manual shall be fully implemented.

28. (3) The Manufacturer shall have an organisational structure, clearly defined and documented, reflecting the effectiveness of all the required tasks and detailing personal responsibility and reporting relationships of the staff involved in the production process; in particular those activities affecting product safety and quality, such that-

(a) the manufacturer's Directors shall be responsible for manufacturer policy and objectives, and shall provide adequate resources and investment to ensure product safety and quality; a qualified person responsible for quality and feed safety shall be designated;

(b) the manufacturer's Directors shall ensure that all employees are aware of their responsibilities and mechanisms are in place either to monitor the effectiveness of their operation and/or to trigger corrective actions;

(c) the manufacturer shall ensure that levels of responsibility and accountability are clearly defined for key staff involved with the production process, product safety, legality and quality systems; to this end, job descriptions and an organisation chart setting out qualifications and responsibilities of the supervisory staff shall be drawn up and made available to the Registrar for inspection; a qualified person responsible for production shall be designated; there shall be appropriate arrangements in place to cover for the absence of key staff;

(d) the manufacturer shall have a system in place to ensure that it is kept informed of all relevant legislation, food safety issues as well as, legislative, scientific and technical developments; and

(e) the manufacturer shall ensure that adequate resources are available for training all employees, in particular new employees.

28. (4) The Management shall review the quality management system on a regular basis, such that-

(a) senior management shall review the organisation's quality management system, at planned intervals, to ensure its continuing adequacy and effectiveness; this review shall include an assessment of any opportunity for improvement, as well as an assessment of the need to change the quality management system, including the quality policy and quality objectives.

28. (5) The Manufacturer shall have, and operate in accordance with written detailed procedures, instructions, and reference documents to cover all relevant aspects of product safety and quality, such that -

(a) documents shall be clearly legible, unambiguous and sufficiently detailed to enable effective use by appropriate personnel, and shall be readily accessible at all times.

28. (6) The Manufacturer shall ensure that all documents, records and data critical to the management of product safety and quality, are in place and effectively controlled, such that-

(a) the Manufacturer shall keep in a register, relevant data comprising details of purchase, transport, production and sales for effective tracing from receipt to delivery;

(b) the documentation relating to the manufacturing process shall be designed to define and control the critical points in the manufacturing process and to establish and implement a quality control plan;

(c) the commercial documents and health certificates shall be kept for a period of at least 2 years for presentation to the registrar; and
(d) all documents in use shall be properly authorised and be the versions as issued by the manufacturer.

28. (7) The Manufacturer shall maintain records to demonstrate the effective control of product safety and quality. These records shall include product samples as appropriate, such that-

(a) the manufacturer shall have access to a laboratory with adequate staff and equipment;
(b) a quality control plan shall be drawn up in writing and implemented, to include, in particular, checks on the critical points, sampling procedures and frequencies, methods of analysis and their frequency, compliance with the specifications;
(c) The manufacturer shall operate procedures for collation, review, maintenance, storage and retrieval of all records appertaining to product safety and quality; and
(d) the records shall be retained in good condition, for an appropriate defined period, but not less than two years.

28. (8) The Manufacturer shall have in place a procedure to inform, as appropriate, the Registrar in case of hazards related to the product, such that-

(a) the manufacturer processing animal by-products shall inform the Registrar, should the laboratory examination of samples or any other information available reveal the existence of a serious animal health or public health hazard;
(b) the manufacturer processing stock remedies into feed shall inform the Registrar, should the laboratory examination of samples or any other information available reveal the existence of a serious animal health or public health hazard;
(c) the manufacturer processing contaminated animal feed shall inform the Registrar, should the laboratory examination of samples or any other information available reveal the existence of a serious animal health or public health hazard; and
(d) the manufacturer processing animal containing undesirable substances shall inform the Registrar, should the laboratory examination of samples or any other information available reveal the existence of a serious animal health or public health hazard.

28. (9) The Manufacturer shall ensure that appropriate specifications exist for-

(a) raw materials;
(b) packaging materials;
(c) processing;
(d) finished products;
(e) intermediate/semi-processed products (where appropriate);
(f) transport & Warehouse;

28. (10) The Manufacturer shall ensure that specifications according to regulation 27(9) shall be adequate, accurate, and shall ensure compliance with Occupational Health and Safety Act, 1993 (Act No. 85 of 1993) and Trade Metrology Act, 1973 (Act 77 of 1973).

28. (11) The Manufacturer shall monitor information relating to customer perception, such as whether the customer requirements have been met or not, such that -

(a) a method for obtaining information on customer satisfaction and how to use the information shall be determined by the manufacturer; and

(b) key performance indicators (KPI) on customer satisfaction are used as an important tool for continuous improvement of the product and service delivered; such KPIs shall be developed in agreement with the customer, whenever possible.

28. (12) The Manufacturer shall audit those systems and procedures, which are critical to product safety and quality, to ensure they are in place, appropriate and complied with, such that-

(a) internal audits shall be carried out by competent auditors, who shall be independent of the area of operation being assessed; and

(b) documentary results of the internal audit shall be brought to the attention of the personnel responsible for the activity audited; corrective actions and time-scales for their implementation shall be agreed.

28. (13) The Manufacturer shall, when necessary, put in place investigation on processes to assess the cause of significant non-conformity with standards, specifications and procedures, which are relevant to product safety (according to HACCP principles and procedures) and quality, such that-

(a) causes of problems, when clearly identified, shall be used to re-engineer processes and/or procedures to avoid recurrence of the non-conformity; this information shall also, whenever possible, be used to predict potential problems and to amend working practices to ensure that problems do not occur;

(b) corrective actions shall be undertaken in a timely manner to prevent a re-occurrence of the non-conformity;

(c) corrective actions shall be accurately documented, assigning responsibility and accountability;

(d) HACCP is the recommended tool when taking preventive actions; a careful and detailed assessment of hazards from the product development stage up to consumption shall be performed for all products; and

(e) changes in existing or new production lines, equipment or products, shall be based on HACCP study/review.

28. (14) The Manufacturer shall have a system in place for the registration and management of product complaints, such that-

(a) the manufacturer shall implement a system for registering and processing complaints and a system for the prompt recall of products in the distribution network; recalled products shall only be put back into circulation after undergoing a quality-control reassessment;

(b) appropriate actions to the seriousness and frequency of the problems identified, shall be carried out promptly and effectively;

(c) complaint records and data shall, where appropriate, be used to improve the product safety and quality, and seek to avoid a reoccurrence;

(d) Pet Food safety complaints shall be evaluated in the light of the current HACCP plan and the defined Critical Control Points; the evaluation may lead to a review of the HACCP plan; and

(e) livestock feeds complains shall be evaluated in light of good manufacturing practices.

28. (15) The Manufacturer shall continuously improve the quality management system, such that-

(a) the Manufacturer shall continuously improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions, management review and maintaining up to date documentation.

**Substitution of Regulation 36(2)**

18. The Regulations are hereby amended by the substitution of regulation 36(2) by the following regulation

36. (2) Laboratories performing such analyses shall be accredited by South African Accreditation System (SANAS) to perform such specific analyses or be accredited by an organisation that is a member of the International Laboratory Accreditation Cooperation (ILAC) to perform such specific analyses.

**Substitution of Regulation 39(2)**

19. The Regulations are hereby amended by the substitution of regulation 39(2) by the following regulation;

39. (2) Any fee payable in terms of these regulations shall be paid by means of a cheque, postal order, money order in favour of the Director-General: Agriculture, Reference: Farm Feeds; if such payment is delivered by hand, they may be paid in cash in which case a receipt shall be issued, and if such fees are paid electronically through an Electronic Transfer Account payment shall be made as follows;

Account name: NDA-ACT36 of 1947
Account number: 11203102
Reference: 11F1
Branch code: 010845
Branch name: Arcadia
**Bank name: Standard Bank**

*Substitution of Table 3 of the Regulations*
**13. The Regulations are hereby amended by the substitution of Table 3 with the following table;**

**TABLE 3**
**PROHIBITED INGREDIENTS**
**[REG. 11(4) (d)]**

| |
|---|
| 1. Faeces, urine as well as separated digestive tract content resulting from the emptying of or removal of the digestive tract. |
| 2. Processed hide and hide treated with tanning substances, including its waste. |
| 3. Seeds and other plant propagating materials which, after harvest, have undergone specific treatment with plant protection products for their intended use (propagation), and any derived by-products. |
| 4. Wood, sawdust and other materials derived from wood treated with wood protection products. |
| 5. Sludge from sewage plants treating waste waters. |
| 6. Solid urban waste, such as household waste. |
| 7. Untreated waste from eating places. |
| 8. The packaging and parts of packaging or the use of products from the agri-food industry. |
| 9. Untreated or unsterilized poultry litter |
| 10 Processed hair and its by-product |

*Substitution of Table 5 of the Regulations*
**14. The Regulations are hereby amended by the substitution of Table 5 with the following table;**

**TABLE 5**
**NUTRIENT REQUIRMENTS FOR COMPLETE DOG FOOD –UNITS PER 100g DRY MATTER (DM)**
**(Based on ≥ 70% digestibility)**
**(REG. 17)**

| Nutrient | UNIT | Adult | Early Growth (<14 weeks) & reproduction | Late Growth (≥ 14 weeks) | Maximum limit |
|---|---|---|---|---|---|
| **Protein*** | **g** | **18.00** | **22.50** | **22.00** | **-** |
| Arginine* | g | 0.52 | 0.79 | 0.71 | |
| Histidine* | g | 0.23 | 0.39 | 0.25 | - |
| Isoleucine | g | 0.46 | 0.65 | 0.50 | - |
| Leucine | g | 0.82 | 1.29 | 0.80 | - |
| Lysine* | g | 0.42 | 0.88[max 2.80] | 0.7[max 2.80] | - |
| Methionine* | g | 0.31 | 0.35 | 0.26 | - |
| Methionine-cystine* | g | 0.62 | 0.70 | 0.53 | - |
| Phenylalanine | g | 0.54 | 0.65 | 0.50 | - |
| Phenylalanine-tyrosine* | g | 0.89 | 1.30 | 1.00 | - |
| Threonine | g | 0.52 | 0.81 | 0.64 | - |
| Tryptophan | g | 0.17 | 0.23 | 0.21 | - |
| Valine | g | 0.59 | 0.68 | 0.56 | - |
| **Fat*** | **g** | **5.5** | **8.50** | **8.50** | **-** |
| Linoleic acid n-6 | g | 1.32 | 1.30[max 6.50] | 1.30 | - |
| Arachidonic acid | mg | - | 30.00 | 30.00 | - |
| Alpha-linoleic acid* | g | - | 0.08 | 0.08 | - |
| EPA + DHA* | g | - | 0.05 | 0.05 | - |
| **Fibre** | **g** | - | - | - | **5** |
| **Minerals** | - | - | - | - | - |
| Calcium* | g | 0.50[max 2.5] | 1.00[max 1.6] | 0.80[max 1.8] | - |
| Phosphorus | g | 0.40[max 1.60] | 0.90 | 0.70 | - |
| Ca / P ratio | | 1/1-2/1 | 1/1-1.5/1 | 1/1-1.5/1 | - |
| Potassium | g | 0.50 | 0.44 | 0.6 | - |
| Sodium* | g | 0.10[max 1.8] | 0.22 | 0.22 | - |
| Chloride | g | 0.15[max 2.25] | 0.29 | 0.33 | - |
| Magnesium | g | 0.07 | 0.04 | 0.04 | - |
| **Trace elements*** | - | - | - | - | - |
| Copper* | mg | 0.72 | 1.10 | 1.10 | 2.8 |
| Iodine* | mg | 0.11 | 0.09 | 0.15 | 1.1 |
| Iron* | mg | 3.60 | 8.80 | 8.80 | 142 |
| Manganese | mg | 0.58 | 0.56 | 0.56 | 17.0 |
| Selenium* | mg | 30.0 | 35.00 | 35.00 | 56.8 |
| Zinc* | mg | 7.2 | 10.0[max 100] | 10.0[max 100] | 28.4 |
| **Vitamins** | - | - | - | - | - |
| Vitamin A | IU | 500[max 40,000] | 500[max 40,000] | 500[max 40,000] | - |
| Vitamin D | IU | 50.0[max 320] | 55.2[max 320] | 50.0[max 320] | 227 |
| Vitamin E | IU | 3.60 | 3.00 | 5.00 | - |
| Thiamine | mg | 0.23 | 0.14 | 0.14 | - |
| Riboflavin* | mg | 0.60 | 0.53 | 0.53 | - |
| Pantothenic acid | mg | 1.00 | 1.50 | 1.50 | - |
| Vitamin B6 (pyridoxine) | mg | 0.15 | 0.15 | 0.15 | - |
| Vitamin B12 | µg | 2.20 | 3.50 | 3.5 | - |
| Niacin | mg | 1.10 | 1.70 | 1.7 | - |
| Folic Acid | µg | 18.00 | 27.0 | 27.0 | - |

| | | | | | |
|---|---|---|---|---|---|
| Biotin* | µg | - | - | - | - |
| Choline | mg | 120 | 170 | 170 | - |
| Vitamin K* | µg | - | - | - | - |

**Table 5 (continued – explanations)**
**Substantiation of nutrient recommendations for dogs**

**- How to read the tables -**

Values are expressed as follows: recommended value [nutritional maximum]
The maximum levels of nutrients are listed in a separate column (right column), because they apply to all life stages. For commercial dog food it is recommended that the nutrient levels are at or above the levels listed in the table and do not exceed the nutritional or maximum limit.

***Conversion factors:***
units/1000kcal ← x 2.5 units/100g DM x 0.598 → Units/MJ
units/100g DM ← x 0.4 units/1000kcal x 0.239 → Units/MJ
units/100g DM ← x 1.6736 Units/MJ x 4.184 → units/1000kcal

These conversions assume an energy density of 16.7kJ (4.0kcal) ME/g DM. For foods with energy densities different from this value, the recommendations shall be corrected for energy density. Specific recommendations for nutrient intake during reproduction are only available for a few nutrients. Hence, until more data becomes available, recommendations in the tables combine early growth and reproduction for dogs.

**GENERAL**
1. Amino acids, trace elements, vitamins (Adult dogs): Unless indicated with an * and substantiated hereafter, the values recommended for adult dogs are the levels recommended by NRC 2006 increased by 20% to compensate for the lower energy requirement of household dogs compared to the energy intake assumed by NRC.

**PROTEIN Total protein**
1 Total protein (Adult dogs): NRC-2006 RA of 25g/1000kcal for adult dogs is based on Sanderson *et al.* (2001).However the diet in this study had a high protein digestibility and the energy intake was around 130kcal/KgBW0.75. FEDIAF has adjusted the protein value to take into account a digestibility of 75% and added a further 20% to account for lower energy intakes for pet dogs, giving a FEDIAF RA of 40g/1000kcal. This value has been increased to 45g/1000kcal to cover requirements of older dogs. This is equivalent to 18g per 100g DM (10.8 g/MJ). If formulating below 18g protein/100g it is particularly important to ensure that the amino acid profile meets FEDIAF guidelines for adult maintenance.

**Arginine**
1. Arginine (All life stages): The arginine requirement increases with increased protein content owing to its role as an intermediate in the urea cycle. For every gram of crude protein above the stated values, an additional 0.01g of arginine is required

**Lysine**
1. Lysine (nutritional maximum for puppies): Czarnecki *et al.* (1985) a showed that excess dietary lysine (4.91% DM [basal diet 0.91% + 4% from a supplement]) decreases weight gain in puppies but not 2.91 % DM (basal diet + 2% from a supplement). It was concluded that the highest no-effect-level of lysine for puppies was 2.91% DM (energy density 4156 kcal/kg). This is equivalent to 7.0 g/1000 kcal or 2.8% DM (at 4 kcal/g DM) and this is therefore the FEDIAF maximum for puppy growth.

**Methionine-cystine**
1. Methionine-cystine (Adult dogs): The recommended values are based on a dog food containing a very low taurine content, i.e. <100 mg/kg dry matter a. For products containing higher levels of taurine the RA for sulphur amino acids can be lower than the values quoted in the table.

**Tyrosine**
1. Tyrosine (All life stages): For maximisation of black hair colour, the tyrosine content may need to be 1.5 to 2 times higher than the amount stated.

**FAT Total fat**
1 Total fat (All life stages): Dogs fed foods containing normal levels of protein tolerate very high levels of fat (e.g. sled dogs). However, very high fat foods with very low protein content have been linked with adverse effects in dogs.

**Omega 3 and 6 fatty acids**
1. Omega-3 and Omega-6 polyunsaturated long chain fatty acids (Growth & Reproduction) DHA are the preferred substrate for retinal uptake in early development when the demand for DHA is greatest. For neural development arachidonic acid (AA) is also important. Supplementation with α-linolenic acid and linoleic acid during gestation and lactation is an ineffective means of increasing the milk content of DHA and AA respectively to supply enough for neonatal nutritional modifications but, it is thus preferable to have small amounts of DHA and/or EPA, as well as AA in foods for growth and reproduction a Bauer *et al.* Retinal functions of young dogs are improved and maternal plasma phospholipids are altered with diets containing long-chain n-3 PUFA during gestation, lactation and after weaning.

**MINERALS**
**Calcium**
1. Calcium (Adult dogs): As the calcium level approaches the stated nutritional maximum, it may be necessary to increase the levels of certain trace elements such as zinc and copper.

2. Calcium (RA for puppies): A calcium level of 0.8g/100gDM has been shown to be adequate for growing dogs. However, this level has been reported to be marginal for some breeds particularly during the fast growing phase (particularly breeds with lower energy requirements). Therefore FEDIAF recommends a level of 1.0g/100g DM for early growth and 0.8g/100g DM for later growth.

3. Calcium (Maximum for puppies): High intake of calcium has an adverse effect on skeletal development in large breed dogs, particularly during the early growth phase. Therefore a strict nutritional maximum is recommended for foods intended for large breed puppies. Weber *et al.* showed that when feeding a balanced food, a calcium level of 1.6 % DM from 9 weeks of age does not cause side effects. During later growth up to 1.8% DM can be fed to all breed dogs including giant breeds with the exception of great Danes. This breed may be more susceptible and it is preferable to continue.

**Sodium**
1. Sodium (Adult dogs): Studies in dogs have demonstrated that 45.4 mg / MJ (0.19g / 1000kcal) sodium is adequate for all life stages

2. Sodium (Adult dogs): Studies in dogs have demonstrated that foods containing 2% of sodium (DM) may result in negative potassium balance, it is reasonable to set the safe nutritional maximum at 1.8% DM.

**TRACE ELEMENTS**

**General**

1. General Manufacturers are reminded that the bioavailability of trace-elements is reduced by a high content of certain minerals (e.g. calcium), the level of other trace elements (e.g. high zinc decreases copper absorption) and sources of phytic acid (e.g. some soy products).

**Copper**

1. Copper (General): Owing to its low availability copper oxide shall not be considered as a copper source.

**Iodine**

1. Iodine: From studies by Castillo *et al.* A low nutritional maximum for iodine in dogs (0.4mg/100gDM) was recommended. However in these studies puppies were significantly overfed (approx. 75% above energy requirement) which resulted in a substantially increased intake of iodine. Furthermore the food was deficient in a number of key nutrients, e.g. Ca, P and K, and therefore inappropriate for puppies. Consequently, these results are irrelevant for normal commercial nutritionally balanced foods, and the existing legal maximum is safe for all dogs.

**Iron**

1. Iron: Because of very poor availability, iron from oxide or carbonate salts that are added to the diet shall not be considered sources contributing to the minimum nutrient level.

**Selenium**

1. Selenium (Adult dogs): There are no data available about the exact requirements for selenium of adult dogs. However, according to experts the availability of and requirement for selenium in dogs are similar to those in the cat. Therefore, the recommended allowance for cats is used for dogs until more information becomes available.

**Zinc**

1. Zinc (Growth): A pet food containing 5 mg zinc per 100g DM is sufficient to meet the requirements for growing puppies.

**VITAMINS**

**Vitamin A**

1. Vitamin A: The FEDIAF maximum is based on the studies reported by Hathcock *et al.*, Goldy *et al.* and Cline *et al.* in adult dogs. The value is 80% of the dose that Goldy *et al.* identified "as may be approaching a level that challenges the dog's ability to maintain normal vitamin A homeostasis" and about 45% of the no adverse-effect intake established by Cline *et al.* over one year (no detrimental effects on bone health). Furthermore Hathcock *et al.* reported an intake at least three times the FEDIAF nutritional maximum as safe in adult dogs fed for ten months (body growth and haematological indices unaffected). In view of these data the FEDIAF maximum is considered appropriate for all life stages.

2. Vitamin A

(Puppies): There is no evidence so far that the nutritional maximum for puppies shall be different from the current nutritional maximum for adults. This value has been used in this guide for at least 10 years and has never given rise to any problems in growing dogs. Nevertheless, the industry is actively investigating whether puppies behave similarly to adult dogs with regard to vitamin A metabolism.

**Vitamin D**

1. Vitamin D: Studies in Great Dane puppies showed that a dietary vitamin D level of 435 IU/100g DM can affect Ca absorption and may stimulate endochondral ossification disturbances. a, b. Therefore, 320 IU per 100g DM shall be the nutritional maximum for growing giant breed dogs. Based on differences in cholecalciferol metabolism between giant breed and small breed puppies

puppies, 425 IU/100g DM can be considered a safe nutritional maximum for small breed puppies. Since there is no information on maximum safe intakes for adult dogs and breeding bitches, FEDIAF recommends the same nutritional maximum for other life stages as those indicated for puppies.

**Vitamin K**

1. Vitamin K: does not need to be added unless diet contains antimicrobial or anti-vitamin compounds.

**Riboflavin**

1. Riboflavin: Based on erythrocyte glutathione reductase activity coefficient (EGRAC) Cline *et al.* determined that the riboflavin requirement for the adult dog at maintenance is 66.8µg/kg BW per day, when feeding a semi-purified diet. This corresponds with about 0.6 mg/100g DM for practical pet foods by including a safety margin of 25%.

*Substitution of Table 6 of the Regulations*

**15. The Regulations are hereby amended by the substitution of Table 6 with the following table;**

**TABLE 6**
**NUTRIENT REQUIRMENTS FOR COMPLETE CAT FOOD PER 100g DRY MATTER (DM)**
**(Based on ≥ 70 % digestibility)**
**(REG. 17)**

| Nutrient | UNIT | Adult | Growth & reproduction | Maximum limit |
|---|---|---|---|---|
| **Protein*** | **g** | **62.50** | **70.00/75.00** | - |
| Arginine* | g | 2.50 | 2.68/2.78[max kittens 8.75] | |
| Histidine | g | 0.75 | 0.83 | - |
| Isoleucine | g | 1.24 | 1.35 | - |
| Leucine | g | 2.93 | 3.20 | - |
| Lysine | g | 0.98 | 2.13 | - |
| Methionine* | g | 0.49 | 1.10[max kittens 3.25] | - |
| Methionine-cystine* | g | 0.98 | 2.20 | - |
| Phenylalanine | g | 1.15 | 1.25 | - |
| Phenylalanine-tyrosine* | g | 4.40 | 4.78 | - |
| Threonine | g | 1.50 | 1.63 | - |
| Tryptophan* | g | 0.37 | 0.40[max kittens 4.25] | - |
| Valine | g | 1.47 | 1.60 | - |
| Taurine (canned pet food)* | g | 0.50 | 0.63 | |
| Taurine (dry pet food)* | g | 0.25 | 0.25 | |
| **Fat*** | **g** | **22.50** | **22.50** | - |
| Linoleic acid n-6 | g | 1.25 | 1.38 | - |
| Arachidonic acid | mg | 15.00 | 50.00 | - |
| Alpha-linoleic acid* | g | - | 0.05 | - |
| EPA + DHA* | g | - | 0.03 | - |
| **Fibre** | **g** | - | | **4.5** |
| **Minerals** | | | | - |
| Calcium* | g | 1.48 | 2.50 | - |
| Phosphorus | g | 1.25 | 2.10 | - |
| Ca / P ratio* | | 0.65-2 | 0.65-1.5 | - |
| Potassium | g | 1.50 | 1.50 | - |
| Sodium* | g | 0.19[max 4.5] | 0.40 | - |

| | | | | |
|---|---|---|---|---|
| Chloride | g | 0.26 | 0.75 | - |
| Magnesium | g | 0.10 | 0.13 | - |
| **Trace elements*** | - | | | - |
| Copper* | mg | 1.25 | 2.50 | 7.1 |
| Iodine* | mg | 0.15 | 0.45 | 2.8 |
| Iron* | mg | 20.00 | 20.00 | 355 |
| Manganese | mg | 1.25 | 2.50 | 42.6 |
| Selenium | mg | 75.00 | 75.00 | 142 |
| Zinc | mg | 18.75[max 150] | 18.75 | 71.0 |
| **Vitamins** | - | | | - |
| Vitamin A* | IU | 833.3[max 100,000] | 2250.0[max 100,000/83,333] | - |
| Vitamin D* | IU | 62.50[max 7500] | 187.5[max 7500] | 568 |
| Vitamin E* | IU | 9.50 | 9.50 | - |
| Thiamine | mg | 1.40 | 1.38 | - |
| Riboflavin | mg | 1.00 | 1.00 | - |
| Pantothenic acid | mg | 1.44 | 1.43 | - |
| Vitamin B6 (pyridoxine)* | mg | 0.63 | 1.00 | - |
| Vitamin B12* | µg | 5.63 | 5.00 | - |
| Niacin | mg | 10.00 | 10.00 | - |
| Folic Acid | µg | 187.5 | 200.0 | - |
| Biotin | µg | 18.75 | 17.50 | - |
| Choline | mg | 600.0 | 600.0 | - |
| Vitamin K* | µg | 25.00 | 25.00 | - |

**Table 6 (continued – explanations)**
**Substantiation of nutrient recommendations for cats**

**- How to read the tables -**

Values are expressed as follows: recommended value [nutritional maximum]
The maximum levels of nutrients are listed in a separate column (right column), because they apply to all life stages. For commercial cat food it is recommended that the nutrient levels are at or above the levels listed in the table and do not exceed the nutritional or maximum limit.

***Conversion factors:***
units/1000kcal ← x 2.5 units/100g DM x 0.598 → Units/MJ
units/100g DM ← x 0.4 units/1000kcal x 0.239 → Units/MJ
units/100g DM ← x 1.6736 Units/MJ x 4.184 → units/1000kcal

These conversions assume an energy density of 16.7kJ (4.0kcal) ME/g DM. For foods with energy densities different from this value, the recommendations shall be corrected for energy density. Specific recommendations for nutrient intake during reproduction are only available for a few nutrients. Hence, until more data become available, recommendations in the tables combine early growth and reproduction for cats.

**GENERAL**
1. Amino acids, trace elements, vitamins (Adult cats): Unless indicated with an * and substantiated hereafter, the values recommended for adult cats are the levels recommended by NRC 2006 increased by 20% to compensate for the lower energy requirement of household cats compared to the energy intake assumed by NRC.

**PROTEIN**

**Arginine**

1. Arginine (All life stages): The arginine requirement increases with increased protein content owing to its role.

2. Arginine (Kittens): Taylor (1995) found that 45 g/kg diet (470 kcal/100 g) was associated with a small decrease in growth rate. NRC therefore set a prudent maximum of 3.5 g/100 g DM (400 kcal/100 g

**Lysine**

1. Lysine (Adult cats): The recommended values are based on a study by Burger and Smith showing that adult cats need 0.16 g lysine per MJ ME to maintain a positive N-balance. After adding a safety margin of 20% this corresponds to 0.34% DM or 0.85g per 1000 kcal ME.

**Methionine-cystine**

1. Methionine-cystine (Adult cats): The recommended values are based on a study by Burger and Smith showing that adult cats need 0.16 g methionine (without cystine) per MJ ME to maintain a positive N-balance. After adding a safety margin of 20% this corresponds to 0.34% DM or 0.85g per 1000 kcal ME methionine + cystine.

**Tryptophan**

1. Tryptophan (kittens): Taylor *et al.* (1998) fed 15 g/kg in a diet containing 450 kcal/100 g with no ill effects. Herwill (1994) fed levels up to 60 g/kg in a diet containing 470 kcal/100 g. 20g/kg was satisfactory but food intake decreased at 40 g/kg; much more severe effects were observed at 60 g/kg. Therefore the maximum can be set at 2 g per 470 kcal or 1.7g per 100g DM (400 kcal/100g).

**Phenylalanine-tyrosine**

1. Phenylalaninetyrosine (All life stages): Diets with a moderate level of phenylalanine + tyrosine but higher than the minimum requirement for growth may cause discolouring of black hair in kittens. This is corrected by feeding a food containing ≥1.8% DM of phenylalanine or a combination of tyrosine and phenylalanine. To maximise black hair colour, the tyrosine level shall be equal or higher than that of phenylalanine.

**Taurine**

1. Taurine Studies have shown that the bioavailability is lower when cats are fed a heated-processed canned food. To maintain adequate taurine status, a heat-processed wet cat food needs to contain approximately 2 to 2.5 times more taurine than a dry extruded food; the latter shall contain 0.1% DM taurine.

**FAT**

**Omega 3 and 6 fatty acids**

1. Omega 3 fatty acids (Growth & Reproduction): The study by Pawlosky *et al.* suggests that juvenile felines it is important that the status of DHA in the nervous system is maintained for optimal retinal function. However, young felines have a low synthetic capacity to produce DHA. Therefore it is recommended to have a small amounts of DHA and/or EPA in foods for growth and reproduction.

1. Omega 3 fatty acids (Adult cats): Although there is increasing evidence of beneficial effects of omega-3 fatty acids, the current information is insufficient to recommend a specific level of omega-3 fatty acids for adult cats.

**MINERALS**

**Calcium**
1. Calcium FEDIAF value is higher than NRC including a safety margin to take into account the bioavailability of raw materials used.

2. Calcium-to phosphorus ratio (Growth): A calcium-to-phosphorus ratio of ≥ 0.65 is appropriate for growing kittens, provided that the calcium and phosphorus levels in the food are at least 0.5% and 0.63% respectively.

**Sodium**
1. Sodium (Adult cats): Based on plasma aldosterone concentration, Yu and Morris concluded that the minimum requirement of sodium for maintenance of a Yu S, Morris JG. Sodium requirement of adult cats for maintenance based on plasma aldosterone concentration. In adult cat it is 0.08 % DM at 5.258 kcal ME/g (22kJ). This corresponds with 0.076% at 4 kcal ME/g after adding a safety margin of about 25%.

2. Sodium (Adult cats): In one study with healthy adult cats, no adverse effects were seen when feeding a food with 1.5 % of sodium (DM). The nutritional maximum shall be set at 1.8% DM.

1. Sodium (Growth): Based on plasma aldosterone concentration, Yu and Morris recommended that food for kittens shall contain a minimum of 0.16% DM of sodium at 5.258 kcal ME/g (22kJ). This corresponds with 0.16% at 4 kcal ME/g after adding a safety margin of about 30%.

**Magnesium**
1. Magnesium: Studies have demonstrated that 10mg/MJ will maintain adult cats. This value has been doubled to accommodate interactions with other dietary factors.

**TRACE ELEMENTS**
**General**
1. General Manufacturers are reminded that the bioavailability of trace-elements is reduced by a high content of certain minerals (e.g. calcium), the level of other trace elements (e.g. high zinc decreases copper absorption) and sources of phytic acid (e.g. some soy products).

**Copper**
1 Copper (General): Owing to its low availability copper oxide shall not be considered as a copper source.

**Iodine**
1. Iodine: Based on the Tc99m thyroid to salivary ratio, Wedekind *et al.* (2005) have shown that the minimum requirement of iodine for the cat is 0.51 mg/kg DM a. The recommended allowance, therefore, can be set at 0.61 mg/kg DM taking into account a safety margin of about 20%.

**Iron**
1. Iron: Because of very poor availability, iron from oxide or carbonate salts that are added to the diet shall not be considered sources a NRC absorption and bioavailability of dietary iron in dogs and cats

**VITAMINS**

**Vitamin A**
1 Vitamin A (Adult cats): The FEDIAF maximum is based on the study reported by Seawright *et al.* in kittens. The FEDIAF maximum of 40,000 IU/100g DM is about 50% of the maximum NOAEL reported by Sea Seawright *et al.* in kittens from 6 to 8 weeks of age fed for 41 weeks. Since kittens are at least equally vulnerable as adults to hypervitaminosis A, this level shall also be safe for adult cats.

2. Vitamin A (Growth and reproduction): Seawright *et al.* reported no adverse effects in kittens from 6 to 8 weeks of age fed for 41weeks on a vitamin A intake of 50,000 IU/kg BW corresponding to about 90,000 IU per 100g DM. Therefore, FEDIAF's maximum of 40,000 IU/100g DM can be considered safe for growing kittens. Freytag *et al* reported that feeding food with 100,000 IU/100g DM to pregnant queens caused fatal malformations in kittens. The next lowest value of 2000 IU/100g DM caused no adverse effects. From these data NRC 2006 recommended not to exceed 33,330 IU/100g DM in feeding stuffs intended for reproduction. In view of these data, FEDIAF recommends a maximum vitamin A level of 33,330 IU/100g DM for products designed for reproducing queens.

**Vitamin D**

1. Vitamin D: Based on the study of Sih *et al.* (2001), a nutritional maximum of 3000 IU/100 DM (7500 IU/1000 kcal) can be considered safe for cats of all life stages.

**Vitamin E**

1. Vitamin E: 10 IU of Vitamin E shall be added above the level recommended in the table per gram of fish oil per kilogram of diet.

**Vitamin K**

1. Vitamin K: does not need to be added unless the diet contains anti-microbial or anti-vitamin compounds, or contains more than 25% fish on a DM basis.

**Vitamin B6 (Pyridoxine)**

1 Vitamin B6 (All life stages): Requirements of vitamin B6 increase with increasing protein content of the food.