BUENOS AIRES,

HAVING REGARD TO Docket File No. S01:0451266/2010 from the Record of the MINISTRY OF AGRICULTURE, LIVESTOCK AND FISHERIES, Act No. 18284, Executive Decree No. 7845 of October 8, 1964, Decrees No. 4238 of July 19, 1968, No. 2126 of June 30, 1971, No. 1585 of December 19, 1996 and No. 825 of June 10, 2010; Resolutions No. 76 of October 8, 1998 and No. 60 of January 25, 2001, both from the former SECRETARIAT OF AGRICULTURE, LIVESTOCK, FISHERIES AND FOOD; No. 447 of April 16, 2004 and No. 1389 of December 29, 2004, both of the former SECRETARIAT OF AGRICULTURE, LIVESTOCK, FISHERIES AND FOOD; No. 38 of February 3, 2012 of the MINISTRY OF AGRICULTURE, LIVESTOCK AND FISHERIES; No. 69 of January 13, 1993, No. 248 of May 12, 1995, No. 253 of May 12, 1995 and No. 117 of September 7, 1995; all from the former NATIONAL SERVICE FOR ANIMAL HEALTH; No. 354 of April 26, 1999, No. 238 of February 9, 2001, No. 508 of November 9, 2001, No. 525 of November 26, 2001, No. 341 of July 24, 2003, No. 656 of September 22, 2006, No. 440 of June 5, 2009, No. 818 of November 10, 2011, No. 206 of May 15, 2014, No. 359 of August 13, 2014; all from the NATIONAL SERVICE FOR AGRI-FOOD HEALTH AND QUALITY; Dispositions No. 1 of January 5, 2007 and No. 115 of September 5, 2008 of the former National Directorate for Agri-Food Surveillance of the abovementioned National Service; No. 30 of June 7, 2012 of the National Directorate for Agri-Food Safety and Quality of the abovementioned National Service, and

WHEREAS, THAT:

The Resolutions mentioned in the foregoing paragraph established the hygienic-sanitary conditions and the assurance levels in the Regulatory Framework for manufacturing, fractioning, distributing, importing or exporting establishments and firms of products intended for animal feed, as well as the products they manufacture and/or commercialize.

Experience in performance of registration, authorization, verification and control actions of manufacture, fractioning, storage, distribution, import and export of products intended for animal feed has favored the development of greater knowledge about the operation of the different activities above, generating thus the need to introduce changes and advances in the design of systems and programs to achieve greater efficiency in their application.

In view of the concept of food chain, it is necessary to bear in mind the criteria established in the "Argentine Food Code."

In view of the advances in manufacture processes, management systems, certification procedures, and dynamics in the supply and demand of products intended for animal feed which have generated an increase in the variety of ingredients and raw materials used to manufacture those products, it is necessary to adjust registration and authorization requirements and demands to ensure controls to animal feed manufacturing and fractioning plants and to products manufactured and distributed for animal feed, in order to ensure and improve better safety conditions of obtained feed.

Furthermore, establishments of manufacture, fractioning, storage, distribution, imports and exports of food intended for animal feed are mainly responsible for ensuring that their products do not represent a risk for animal health and the safety of products intended for animal feed, and therefore, they shall perform the necessary actions to minimize risk of possible contamination of products commercialized. So, it corresponds to clearly establish primary responsibilities regarding safety to be assigned to all agents in the agri-food chain in relation to the activity they perform.

Changes in production systems of the different agri-food chains have generated a growing participation of livestock producers that manufacture feedstuffs intended for their own animals, so it corresponds to establish responsibilities and minimum compliance criteria based on good manufacture practices, yet without obligation to register said feedstuffs.

Health reasons turn it necessary to tend to optimize controls on raw materials forming the feedstuffs intended for animal feed and, especially, those administered to bovine, goat and other ruminant species.

Minimum conditions shall be established to be complied with by establishments that manufacture, fraction, store or deposit products intended for animal feed, as well as those transporting them.

In view of feedstuff manufacture practices, as an exception, and due to specific and seasonal nurture reasons, in limited volumes and non-permanently, at the request of producers that use it for their own animals, it corresponds to determine the minimum obligations to be complied by intervening parts and to assign responsibilities to each.

The REPUBLIC OF ARGENTINA is an agri-food exporting country. Many of agri-food products are intended for animal feed. The country is also importer of ingredients, raw materials, or feedstuffs. Therefore, certification conditions and procedures shall be established for such activities.

In order to ensure controls to manufacturing and fractioning establishments of animal feed and to products manufactured, fractioned, and distributed for animal feed, the Technical Standard hereby approved, contemplates the registration of firms that manufacture, fraction, store, export or import products for animal feed; the registration and authorization of establishments engaged in activities of manufacture, fractioning, or storage of said products; and the registration and authorization of use and trade of products intended for animal feed, therefore, conditions, requirements and procedures shall be established to obtain registration, authorization and licensing of applicant firms.

Products intended for animal feed may contain undesirable substances that may harm animal health or, that due to their presence in products derived from animals, may harm human health. Therefore, it is necessary to consider the advances made within *Codex Alimentarius* and the FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS (FAO), as well as the data

obtained nationally to set maximum permitted limits for contaminants in feedstuffs, to ensure animal health and safety of food derived from them.

Besides, relevant restrictions should be established to safeguard animal and human health by prohibiting the use of substances, practices, or ingredients and/or raw materials considered of risk for animal feed and for their subsequent human consumption.

Advances in the understanding of the issue of antimicrobial resistance make it necessary to adopt prevention measures to avoid practices that may derive in selecting bacterial strains resistant to antimicrobials; and, bearing in mind that registered veterinary products are approved to be administered at the time of their use, being feedstuffs only a vehicle for such administration, specific requirements should be determined for feedstuffs with drugs.

In order to establish a set of obligations, regulations, processes, procedures, records, hygiene and safety conditions and levels of assurance to be complied and enforced in the territory of the ARGENTINE REPUBLIC by all firms and establishments that manufacture, fraction, store, distribute, commercialize, transport, import or export products intended or that may be intended for animal feed and by all products intended or that may be intended for animal feed, by means of a single and obligatory regulatory framework for firms and establishments to perform their activities uniformly and homogeneously complying with the conditions above, it is necessary to issue a technical standard containing all obligations to be complied with and shaping the current legal basis on the subject matter.

Animal feed is an essential part of several agri-food chains with both plant and animal origin, therefore, it is transversal to all strategic axis and SENASA thematic areas, on health and food, so, it is appropriate to create the Advisory Committee formed by representatives of all chains, with responsibilities and understanding about the subject matter.

The complexity that animal feed has acquired at a regional, national and international level, as a consequence, among other reasons, of the diversity of identified and potentially emergent hazards, makes it necessary to conduct a risk analysis within the ambit of the Directorate for Hygiene

and Safety of Plant Products and Feedstuffs of SENASA National Directorate for Agri-Food Safety and Quality, in order to comply with the first stage of the risk analysis process through a specialized technical entity.

As a consequence of the previous existence of standards and procedures that have provided for the hygienic-sanitary conditions and requirements to be met by establishments and firms that manufacture, fraction, distribute, import or export products intended for animal feed, as well as by products manufactured and/or commercialized, it is appropriate to set deadlines for the transition of firms and establishments in operation at the time of this Resolution to adjust to the new requirements.

The Directorate for Legal Affairs has issued its opinion and found no legal objections to make.

This Resolution is issued in compliance with the powers conferred by Section 8, paragraph f) Decree No. 1585 of December 19, 1996, substituted by its similar No. 825 of June 10, 2010.

Therefore,

THE PRESIDENT OF THE NATIONAL SERVICE FOR

AGRI-FOOD HEALTH AND QUALITY

RESOLVES AS FOLLOWS:

SECTION 1.- Technical Standard on Feedstuffs of the REPUBLIC OF ARGENTINA; Approval: the Technical Standard on Feedstuffs of the REPUBLIC OF ARGENTINA is hereby approved as a consolidated and integral regulatory framework about food intended for animal feed, which forms part of this Resolution as Annex I.

SECTION 2.- Application for Registration of Feedstuffs; Approval: the form of “Application for Registration of Feedstuffs” is hereby approved, which forms part of this Resolution as Sub-Annex I.

SECTION 3.- Application for Registration of Additives, Vitamin Supplements, Minerals, Vitamin and Mineral Compounds and Additive Premixes; Approval: the form of "Application for Registration of Additives, Vitamin Supplements, Minerals, Vitamin and Mineral Compounds and Additive Premixes" is hereby approved, which forms part of this Resolution as Sub-Annex II.

SECTION 4.- Application for Registration of By-Products of Plant Origin Intended for Animal Feed; Approval: the form of "Application for Registration of By-Products of Plant Origin Intended for Animal Feed" is hereby approved, which forms part of this Resolution as Sub-Annex III.

SECTION 5.- Technical Directors; Approval: the "Profile of Technical Directors for Animal Feed" is hereby approved, to govern the activities of Technical Directors for Animal Feed, which forms part of this Resolution as Annex II.

SECTION 6.- Risk Assessment: risk assessment of feedstuffs shall be conducted within the ambit of the Directorate for Hygiene and Safety of Plant Products and Feedstuffs of SENASA National Directorate for Agri-Food Safety and Quality, for the purposes of:

Subsection a) Identifying existing and emerging hazards, related to raw materials and products intended for animal feed.

Subsection b) Developing risk profiles for raw materials and products intended for animal feed at the request of SENASA National Directorate for Agri-Food Safety and Quality.

Subsection c) Recommending measures to mitigate risk on raw materials and products intended for animal feed, based on identified hazards and characterized risks.

Subsection d) Creating a list of ingredients exempted from registration of feedstuffs due to be considered generally recognized as safe (GRAS) or to be approved for human consumption by the competent official entity, whenever they do not present specific restrictions for use and they are not commercialized as such.

SECTION 7.- Ad-Honorem Technical Advisory Committee: the Technical Advisory Committee for Feedstuffs is hereby created, which shall operate within the scope of SENASA National Directorate

for Agri-Food Safety and Quality. This Committee shall be integrated by representatives of SENASA areas involved in animal feed issues, representatives of government organizations, scientific institutions, and representatives of public and private agents that are part of agri-food chains engaged in animal feed. The decisions, conclusions and advice shall not be binding and shall be provided only for advisory purposes. All activities shall be performed ad-honorem.

SECTION 8.- Assessment: the Directorate for Hygiene and Safety of Plant Products and Feedstuffs shall periodically conduct an assessment of all actions and activities related to the enforcement of the Technical Standard approved by means of Section 1, to establish general and homogeneous enforcement criteria. Criteria established shall be periodically informed to the Directorates for Regional Centers for enforcement purposes.

SECTION 9.- Good Manufacture Practices (GMP); Implementation Schedules: Good Manufacture Practices, based on hazard identification and risk analysis, shall be obligatorily implemented within the following schedule applicable as from the date of entry into force of this Resolution, and SENASA shall verify their gradual and progressive implementation:

Subsection a) Establishments authorized after the entry into force of this Resolution shall demonstrate implementation and compliance with the GMP manual, with auditable records, within a maximum period of TWELVE (12) months after authorization.

Subsection b) Establishments that manufacture or fraction feedstuffs for ruminant and non-ruminant animals using prohibited proteins of animal origin, and that are authorized by the date of this Resolution are obliged to implement and comply with the GMP Manual within a period of TWELVE (12) months following the entry into force of this Resolution.

Subsection c) Establishments that manufacture or fraction feedstuffs using veterinary drugs, which are authorized by the date of this Resolution, are obliged to implement and comply with the GMP Manual within a period of TWELVE (12) months following the entry into force of this Resolution.

Subsection d) Establishments that manufacture or fraction feedstuffs for ruminants that do not use proteins of animal origin and that are authorized by the date of this Resolution are obliged to implement and comply with the GMP Manual within a maximum period of EIGHTEEN (18) months following the entry into force of this Resolution.

Subsection e) The rest of the establishments that manufacture or fraction feedstuffs are obliged to implement and comply with the GMP Manual within a maximum period of TWENTY-FOUR (24) months following the entry into force of this Resolution.

Subsection f) Feedstuff warehouses are obliged to implement and comply with the GMP Manual within a maximum period of TWENTY-FOUR (24) months following the entry into force of this Resolution.

SECTION 10.- Hazard Analysis and Critical Control Points (HACCP): Hazard Analysis and Critical Control Points (HACCP) shall be implemented in the establishments stated in Section 5, within the schedule established by the National Directorate for Agri-Food Safety and Quality, based on the production risk, from the safety point of view.

SECTION 11.- Expiry of registrations: firms and establishments that by the date of this Resolution have been registered and authorized for more than TEN (10) years with the National Registry of Products for Animal Feed shall renew such registration and authorization within the period of ONE (1) year as from the date of validity of this Resolution.

SECTION 12.- Feedstuff with drugs; validity: the schedule to comply with the requirements and validity of registrations are as follows:

Subsection a) Valid registrations of feedstuffs: firms holding valid registration of feedstuffs with antibiotics, antiparasitics or coccidiostats shall present a duly completed form of “Application for Registration of Feedstuffs”, which forms part of this Resolution as Sub-Annex I to Annex I, within a maximum period of ONE (1) year as from the entry into force of this Resolution.

Subsection b) New applications for registration of products: products applied for registration within the year of entry into force of this Resolution shall present, with points 20.5, 20.6 and 20.7 duly completed, a form of “Application for Registration of Feedstuffs”, which forms part of this Resolution as Sub-Annex I to Annex I, within a maximum period of ONE (1) year as from the entry into force of this Resolution.

Subsection c) SENASA National Registry of Products for Animal Feed shall not accept applications for registration of feedstuffs with antibiotics, antiparasitics or coccidiostats as from July 1, 2017.

Subsection d) As from January 2, 2019 registrations and certificates for use and commercialization of feedstuffs with antibiotics, antiparasitics or coccidiostats shall automatically be annulled, notwithstanding the obligations to comply with other terms provided for by standards on the subject matter. The shorter term shall apply.

Subsection e) Firms holding registration of feedstuffs with antibiotics, antiparasitics or coccidiostats shall have a term of THIRTY (30) days as from the annulment of the certificates of authorization for use and commercialization to declare, by means of an affidavit, before SENASA National Registry of Products for Animal Feed about the remains of products and packages, stating the location where they are stored under their responsibility.

Subsection f) SENASA National Registry of Products for Animal Feed shall inform the firm about the final destination to be assigned to remains declared pursuant to Subsection d) of this Section within a period of THIRTY (30) days after receiving the affidavit.

SECTION 13.- Obligation to have a Technical Direction: forms registering products with SENASA National Registry of Products for Animal Feed shall have at least ONE (1) Technical Director for the Product. Establishments engaged in activities included in this Resolution shall have at least ONE (1) Technical Director for the Establishment.

SECTION 14.- Powers: the National Directorate for Agri-Food Safety and Quality from the NATIONAL SERVICE FOR AGRI-FOOD HEALTH AND QUALITY is hereby empowered to modify the terms set forth in this Resolution, as well as any other terms not covered by it.

SECTION 15.- Good Practices Guidelines by Chain: the National Directorate for Agri-Food Safety and Quality from the NATIONAL SERVICE FOR AGRI-FOOD HEALTH AND QUALITY is hereby empowered to establish Good Practices Guidelines specific for each link of the Agri-Food chain of integral manufacturer and self-consumption manufacturers of animal feedstuffs.

SECTION 16.- Penalties: failure to comply with this Resolution shall result in the penalties provided for by Section 18 of Decree No. 1585 of December 19, 1996, notwithstanding the preventive measures set forth in Resolution No. 38 of February 3, 2012 of the MINISTRY OF AGRICULTURE, LIVESTOCK AND FISHERIES.

SECTION 17.- Incorporation: this Resolution is hereby incorporated to Book III, First Part, Title III, Chapter II of the LEGAL DIGEST of the NATIONAL SERVICE FOF AGRI-FOOD HEALTH AND QUALITY, approved by Resolution No. 800 of November 9, 2010 and its supplementary No. 445 of October 2, 2014.

SECTION 18.- Repeal: the following legislation is hereby repealed: Resolutions No. 354 of August 31, 1999 of the former SECRETARIAT OF AGRICULTURE, LIVESTOCK, FISHERIES AND FOOD; No. 1389 of December 29, 2004 of the former SECRETARIAT OF AGRICULTURE, LIVESTOCK, FISHERIES AND FOOD; No. 117 of September 17, 1995 of the former NATIONAL SERVICE FOR ANIMAL HEALTH; No. 525 of November 26, 2001, No. 341 of July 24, 2003, No. 656 of September 22, 2006 and No. 440 of June 5, 2009, all from the NATIONAL SERVICE FOR AGRI-FOOD HEALTH AND QUALITY; Dispositions No. 1 of January 5, 2007 and No. 115 of September 5, 2008 of the former National Directorate for Agri-Food Surveillance of the abovementioned National Service.

SECTION 19.- Validity: this Resolution shall enter into force as from the day following its publication in the Official Bulletin.

SECTION 20.- Have it communicated, published and given to the National Directorate for Official Record and filed.

RESOLUTION No.

TECHNICAL STANDARD ON FEEDSTUFFS OF THE ARGENTINE REPUBLIC

PRELIMINARY PROVISIONS

1.- GENERAL PROVISIONS

1.1.- Scope of application. The Technical Standard on Feedstuffs is of obligatory application throughout the territory of the ARGENTINE REPUBLIC by all firms and establishments manufacturing, fractioning, storing, distributing, commercializing, transporting, importing, or exporting products intended, or that may be intended, for animal feed and to all national or imported products intended, or that may be intended, for animal feed, pursuant to the provisions of Decree Act No. 7845 of October 8, 1964, and Decree No. 1585 of December 19, 1996.

1.2.- Purpose. The purpose of the Technical Standard on Feedstuffs is to establish a set of obligations, regulations, processes, procedures, registries, hygiene and safety conditions, and assurance levels that shall be enforced within the scope of application of this standard, by means of a single and obligatory legal framework, and shall be complied with by firms and establishments manufacturing, fractioning, storing, transporting, commercializing, exporting, and importing products for animal feed, and performing their activities in uniform and homogeneous compliance with this standard.

1.3.- Safety of Products for Animal Feed. Firms performing some or all of the activities regulated by this Technical Standard shall ensure the safety and health of products intended for animal feed along the entire food chain, from primary production to animal feeding, regarding those activities under their control.

1.4.- Compliance with conditions. Registration, licensing and authorization processes are conditional upon verifying compliance with the provisions of this Technical Standard.

1.5.- Registries. The following Single and Obligatory National Registries are hereby created and are managed by the Directorate for Hygiene and Safety of Plant Products and Feedstuffs

under the National Directorate for Agri-Food Safety and Quality of the NATIONAL SERVICE FOR AGRI-FOOD HEALTH AND QUALITY:

1.5.1.- National Registry of Firms Manufacturing Feedstuffs.
1.5.2.- National Registry of Establishments Manufacturing Feedstuffs.
1.5.3.- National Registry of Products for Animal Feed.

1.6.- Firm registration and establishment licensing. Firms and establishments shall be pertinently registered, licensed or authorized in order to perform all or some of the activities mentioned in this Technical Standard.

1.7.- Product registration and authorization. Commercialized products, as well as the ingredients requiring a certain degree of industrialization, shall be registered with and authorized by SENASA, according to the provisions of this Technical Standard, except for the following:
1.7.1.- Products on demand. Even though these products are not to be registered, they shall be manufactured pursuant to the provisions of this Technical Standard.
1.7.2.- Low-risk products. These products shall be exempted from compulsory registration after performing a risk assessment.
1.7.3.- Products for on-farm consumption. These products are manufactured by a manufacturer of feed for on-farm consumption. Even though they are not to be registered, they shall be manufactured pursuant to the provisions of this Technical Standard.

1.8.- Registration in previous registries. Registrations made in registries created by SENASA Resolutions No. 354 of April 26, 1999, and 341 of July 24, 2003, are automatically included to the registries created in this Technical Standard.

1.9.- Obligatory Technical Directorate.
1.9.1.- Technical Director of the Establishment. All establishments performing all or some of the activities provided for in this Technical Standard shall have a Technical Director of the

Establishment that complies with the conditions stated in the applicable current specific regulations.

1.9.1.1.- Responsibilities. The Technical Director of the Establishment is responsible for overseeing that processes, technical health procedures and good manufacturing practices are implemented within the establishment according to the provisions of this Technical Standard.

1.9.1.2.- Exceptions to having a Technical Director of the Establishment.

The following are exempted from having a Technical Director:

1.9.1.2.1.- Establishments manufacturing feed for on-farm consumption, unless any other SENASA specific standard regulating said activity states otherwise.

1.9.1.2.2.- Warehouses. Establishments licensed only as warehouses, in which:

1.9.1.2.2.1.- No activity implying direct contact with products for animal feed is performed; no manufacturing or fractioning of feedstuffs stored therein is performed; no toxic products are stored, such as insecticides, agrochemicals, fertilizers, etc., that may pose a risk to human, animal, plant, or environmental health, or any other drug that may contaminate feedstuffs stored therein.

1.9.1.2.2.2.- Regular pest controls shall be performed.

1.9.1.3.- Sworn Statement. The firms responsible for the establishments shall submit a sworn statement to the pertinent Directorate for Regional Centers stating compliance with all the conditions established in numeral 1.9.1.2.

1.9.1.3.1.- Administrative act authorizing the exception. Once the sworn statement is presented, an administrative act authorizing and accrediting the exception shall be issued.

1.9.2.- Technical Director of Products. In order to be registered and to obtain the certification of use and commercialization, products shall compulsorily have a Technical Director of Products that complies with the conditions required by this Technical Standard and with SENASA specific standards.

1.9.2.1.- Responsibilities. Said Technical Director is responsible for product registration, including the design of every technical aspect and the required product records.

1.9.3.- Performance of both duties. The duties of the Technical Director of Products and of the Technical Director for the Establishment can be performed by the same professional.

1.10.- Good Manufacturing Practices (GMP). The implementation of Good Manufacturing Practices based on hazard identification and risk analysis shall be compulsory in establishments performing all or some of the activities provided for in this Technical Standard.

1.11.- Traceability. Firms are responsible for establishing and ensuring a traceability system in all stages of the activities under their control to allow identifying the origin and the destination of every product, substance, ingredient and raw material used in the manufacturing, fractioning, storage, transport, export and import of products intended, or that may be intended, for animal feed.

1.12.- Risk analysis. When deemed pertinent, SENASA shall implement the principles of risk analysis established or to be established by the *Codex Alimentarius* and by multilateral organizations of reference.

1.13.- Product recall. Firms that perform all or some of the activities provided for in this Technical Standard shall compulsorily recall the products determined by SENASA, whenever this Service deems so, at its sole discretion and after providing due grounds that a probable or known risk to human or animal health exists, by notifying the assessed risk and the motives behind the implemented measure.

1.13.1.- Firms may recall products on their own initiative when a risk is identified, even before notifying SENASA of said situation. The recalled product shall be intervened by SENASA and placed at its disposal, and shall not be used, disposed of, handled, or destroyed, until this Service decides on its final destination.

1.14.- Obligation to Report. The individual responsible for the establishment and the Establishment Technical Director shall compulsorily report SENASA about any situation or circumstance that poses or may pose a risk to safety due to non-compliances with the current standards.

1.15.- Export conditions. The firms of establishments manufacturing products intended for export shall be aware of and comply with the conditions established by destination countries regarding products, processes and further requirements.

1.16.- Import conditions. The importing firm is responsible for the following tasks:
1.16.1.- Official controls. SENASA is empowered to implement audit, control and monitoring systems and procedures in order to verify compliance from responsible firms with this Technical Standard.
1.16.2.- Cooperating with authorities. Firms shall compulsorily cooperate with SENASA in control activities, and shall provide the information and documents said authority requires.

1.17.- Fees, expenses and tariffs. The firm and the Technical Directors shall pay for any fees, tariffs, costs and expenses established in current standards that stem from bureaucratic procedures, general procedures, inspections, registrations, establishment licensing, and further activities established in this Technical Standard.

1.18.- Classified information. The proceedings by which ingredients, raw materials, products intended for animal feed, firms, and establishments are registered remain classified pursuant to Section 38 of Decree No. 1759 dated April 3, 1972 (O.T. 1991), as they contain information on composition and manufacturing processes. Their review is reserved only to the staff and assistants of the Competent Authority concerned with the registration procedure, to designated technicians, and to individuals duly authorized by the firm requesting the registration.

1.19.- Scientific documents. Language. All technical-scientific documents shall be presented in Spanish or shall be translated by a Sworn Translator, and shall bear the signature of the Technical Director on every page of both the original document and its translation.

2.- DEFINITIONS

For the purposes of implementing this Technical Standard, the following terms are hereby defined:

2.1.- Feed additive: any ingredient deliberately added during manufacture that is not usually consumed as feedstuff, with or without nutritional value, and that affects the characteristics of feedstuffs or animal products. This definition includes microorganisms, enzymes, acidity regulators, trace elements, vitamins, and other products, depending on their intended use and the administration method. Ingredients intended for disease prevention and/or treatment purposes are excluded from this definition.

2.2.- Complete balanced feedstuff: it covers by itself the nutritional requirements for animals of a certain species, category, and physiological condition for which it is intended.

2.3.- Feedstuff: any product, whether industrialized or not, consumed by animals that contributes to their nutrition by promoting their development, maintenance, breeding, and/or productivity or to their adjustment to a better health status.

2.4.- Feedstuff with drugs: product that, apart from having nutritional characteristics, also contains veterinary drugs registered with SENASA.

2.5.- Adulterated feedstuff, supplement, ingredient or feed additive: see Argentine Food Code, Section 6, Point 7.

2.6.- Altered feedstuff, supplement, ingredient or feed additive: see Argentine Food Code, Section 6, Point 5.

2.7.- Contaminated feedstuff, supplement, ingredient or feed additive: see Argentine Food Code, Section 6, Point 6.

2.8.- Counterfeit feedstuff, supplement, ingredient or feed additive: see Argentine Food Code, Section 6, Point 8.

2.9.- Animals for slaughter: those animals that are or may be placed in the market as a product or by-product for food production intended for human consumption.

2.10.- Notice of departure: compulsory document that certifies that the product is registered and fit for export.

2. 11.- Notice of arrival: compulsory document that certifies the registration of the products with SENASA National Registry of Products for Animal Feed and authorizes their entry into the country.

2.12.- Bone ashes (BA): see Decree No. 4238 of July 19, 1968, Chapter XXIV, numeral 24.6.16.

2.13.- Concentrate: any ingredient or mix of ingredients with a high proportion of energy and protein substrates, and which should be added to other ingredients in order to obtain balanced feed or a feed ration.

2.14.- Energy concentrate: any ingredient or mix of ingredients containing less than EIGHT-EEN PER CENT (18 %) of crude fibers and proteins, and more than THIRTY-FIVE PER CENT (35 %) of dry matter, as the amount of energy they provide is comparatively higher than the amount of protein.

2.15.- Protein concentrate: any ingredient or mix of ingredients in which protein ingredients have a proportion of THIRTY PER CENT (30 %) or MORE THAN THIRTY PER CENT (30 %) of crude protein, and which shall be added to other ingredients in order to obtain balanced feed or a feed portion.

2.16.- Cross-Contamination (CC): the introduction or presence of foreign substances in food-stuff during production processes and further activities of the chain.

2.17.- Commercial name: name with which a product is commercialized and that may include or not a trademark registered with official entities for trademarks and patents.

2.18.- Export dispatch: *idem* Notice of departure.

2.19.- Double line - Separated lines: production lines that do not share processes within manufacturing plants. Separated lines are those in which all stages of production are separated, from the stage prior to the first identified Critical Control Point (CCP) through all subsequent stages, in order to prevent cross-contamination.

2.20.- Technical Director of the Establishment: a professional at an establishment who is responsible for the processes, technical-sanitary procedures and good manufacturing practices established in this Technical Standard.

2.21.- Technical Director of Products: the professional responsible for product design and for the compliance with product approval and registration procedures, according to the provisions of this Technical Standard.

2.22.- Manufacturer of feed for on-farm consumption: an individual or entity that manufactures products to feed only animals under his/her responsibility. Said manufacturing process is performed at the premises where all or part of the animals are located.

2.23.- Company: see Firm.

2.24.- Establishment: physical, fixed facilities intended for manufacturing, fractioning and/or storing products intended for animal feed and/or to perform any of the activities established in this Technical Standard.

2.25.- Third-Party establishments: authorized establishments under the responsibility of a registered firm where another registered firm manufactures, fractionates, and stores products intended for animal feed.

2.26.- Integrated establishment: an establishment that receives animals, feedstuff, and health assistance from the integrator.

2.27.- Integrating manufacturing establishment: establishment of an integrating firm where feedstuff is manufactured and distributed to integrated establishments.

2.28.- Flow chart: systematic representation of the sequence of stages or operations performed during the production or manufacture of a specific food product.

2.29.- Firm: any individual or legal entity responsible for and/or exercising control over manufacturing, fractioning, storage, distribution, transport, commercialization, import and/or export activities of products intended for animal feed. It may also perform any other activity established in this Technical Standard.

2.30.- Firms owning an establishment: those firms that perform activities in establishments under their responsibility.

2.31.- Firms performing activities in third-party establishments: those firms that perform activities in authorized establishments under the responsibility of another firm, prior agreement between them.

2.32.- Assurance: quantification of formulation values of the approved product.

2.33.- Ingredient: see the Argentine Food Code, section 6, amended by Resolution of the MINISTRY OF PUBLIC HEALTH AND SOCIAL ACTION of January 3, 1995.

2.34.- Integrator: individual or entity that provides animals for breeding and fattening processes, feedstuff, and health assistance, retaining ownership or responsibility over the animals.

2.35.- Production line: integrated manufacturing process performed at an establishment, which comprises from the implemented system for raw material reception until the obtainment of the finished product. It includes the pertinent storage of raw materials and finished products.

2.36.- Batch: see Labeling – Argentine Food Code, Joint Resolutions No. 149 of the SECRETARIAT FOR POLICIES, REGULATIONS AND HEALTH RELATIONS, and No. 683 of the former SECRETARIAT OF AGRICULTURE, LIVESTOCK, FISHERIES AND FOODSTUFF of September 8, 2005, numeral 2.11.

2.37.- Raw material: see Ingredient.

2.38.- Nucleus: any concentrated ingredient or mix of ingredients added to a final mix that contains substances usually absent in feed or that can be present in smaller quantities below optimum.

2.39.- Hazard: biological, physical, or chemical agent present in feedstuff that may have a detrimental effect on health.

2.40.- Feed for animals: see Feedstuff.

2.41.- Premix: any nucleus that decreases in concentration due to the addition of other ingredients with the purpose of placing said addition into the feed.

2.42.- Product: see Product intended for animal feed.

2.43.- Product intended for animal feed: any food, additive, ingredient, concentrate, premix, supplement, or any other industrialized, processed substance that is or may be used in animal feed.

2.44.- Veterinary drug: see Veterinary product.

2.45.- Veterinary product: any chemical, biological, or bio-technological substance or manufactured preparation individually or collectively administered, directly or mixed with foodstuff, with the purpose of preventing, diagnosing, healing, or treating animal diseases, including additives, supplements, promoters, improvers of animal production, disinfectant antiseptics for equipment or environmental use, pesticides, and any product that, used in animals and their habitat, protects, restores, or modifies their organic and physiological functions. It also includes products intended for animal embellishment.

2.46.- Critical Point: any stage in the production line that is highly susceptible or prone to retain hazards.

2.47.- Critical Control Point (CCP): stage in which control may be applied and which is essential to prevent or remove any hazards from food safety for the purpose of reducing it to an acceptable level.

2.48.- Risk: probability of occurrence of an adverse effect on health due to a hazard present in foodstuff.

2.49.- Label: see Labeling – Argentine Food Code, Joint Resolutions No. 149 of the SECRETARIAT FOR POLICIES, REGULATIONS AND HEALTH RELATIONS, and No. 683 of the former SECRETARIAT OF AGRICULTURE, LIVESTOCK, FISHERIES AND FOOD of September 8, 2005, numeral 2.1.

2.50.- Supplement: ingredient or mix of ingredients capable of providing nutrients to animal feed, which is added to the ration.

2.51.- ACRONYMS AND ABBREVIATIONS

A.A.F.C.O.: ASSOCIATION OF AMERICAN FEED CONTROL OFFICIALS, INC.

C.F.R.: CODE OF FEDERAL REGULATIONS

CODEX: *CODEX ALIMENTARIUS*

DHIPOVYP: SENASA DIRECTORATE FOR HYGIENE AND SAFETY OF PRODUCTS OF PLANT ORIGIN AND FEED

DILACOT: SENASA GENERAL DIRECTORATE FOR LABORATORIES AND TECHNICAL CONTROL

DIPOA: SENASA DIRECTORATE FOR PRODUCTS OF ANIMAL ORIGIN

DNICA: SENASA NATIONAL DIRECTORATE FOR AGRI-FOOD SAFETY AND QUALITY

DNPV: SENASA NATIONAL DIRECTORATE FOR PLANT PROTECTION

DNSA: SENASA NATIONAL DIRECTORATE FOR ANIMAL HEALTH

DTI: SENASA DIRECTORATE FOR INTERNATIONAL MOVEMENTS OF GOODS AND ANIMALS

TSE: TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES

F.D.A.: FOOD AND DRUG ADMINISTRATION

N.R.C.: NATIONAL RESEARCH COUNCIL

RENSPA: SENASA NATIONAL HEALTH REGISTRY FOR LIVESTOCK AND AGRICULTURAL PRODUCERS

SAGPYA: SECRETARIAT OF AGRICULTURE, LIVESTOCK, FISHERIES AND FOOD

SIGFITO: SENASA SYSTEM FOR PHYTOSANITARY MANAGEMENT

SIGSA: SENASA SYSTEM FOR ANIMAL HEALTH MANAGEMENT

SENASA: NATIONAL SERVICE FOR AGRI-FOOD HEALTH AND QUALITY

SPRYRS: SECRETARIAT FOR POLICIES, REGULATIONS AND HEALTH RELATIONS

USDA: UNITED STATES DEPARTAMENT OF AGRICULTURE

FIRMS AND ESTABLISHMENTS

3.- GENERAL PRINCIPLES FOR FIRM AND ESTABLISHMENT REGISTRATION, LICENSING AND AUTHORIZATION

3.1.- Scope of firm registrations. Firms may be registered under any of the following categories: manufacturer, fractionator, warehouse, distributor, importer, and/or exporter of products intended, or that may be intended, for animal feed.

3.1.1.- Method for firm registration. In order to be registered with the Registry, firms shall declare all their establishments, both their own or from third parties, where activities are performed. A firm shall not be registered unless it declares an establishment.

3.2.- Scope of establishment licenses. Establishments may be licensed under any of the following categories: manufacturer, fractionator, and warehouse of products intended, or that may be intended, for animal feed.

3.3.- Responsibility over establishments. Every establishment shall be under the responsibility of a firm previously registered with the National Registry of Firms and Establishments Manufacturing Feedstuff and Establishments, which shall confirm tenure over the building in which the establishment is established.

3.4.- License holder. The firm responsible for the establishment shall be the license holder.

3.5.- Validity period of registrations and licenses. Firm registrations and establishment licenses have a validity period of TEN (10) years, beginning from the date the registration or license was granted. Once said period has expired, they shall be renewed.

3.6.- Provisional registrations and licenses. Provisional registrations and licenses may be issued once under exceptional circumstances, which shall be duly grounded, for a one-year period and only for administrative or documentary purposes.

3.7.- Incomplete or observed documents. In case the required documents are incomplete at the time of presentation, or if the assessing technical area observes said documentation, the firm shall be requested to submit the missing documents within a specified period of time. If the required documents are not presented before said period expires, the procedure shall be abandoned and proceedings shall be filed.

3.8.- Original or certified documents. All documents required by this Technical Standard shall be presented in original or duly certified copy.

3.9.- Information update. Firms shall update the information opportunely provided to SENASA whenever this Service requires so. Said request shall be duly grounded.

3.10.- Special address. Firms shall state a special address in their first presentation, where all notifications associated with the activities regulated by this Technical Standard shall be served.

3.11.- Municipal licenses. Firms responsible for establishments shall present an updated certificate of the pertinent municipal license authorizing the performance of the activities mentioned in this Technical Standard within a specific establishment, or, otherwise, a certificate that said municipality has no jurisdiction to grant said license.

3.11.1.- The form and scope of the aforementioned licenses is under exclusive jurisdiction of competent local entities. The final or provisional nature of said licenses, as well as any other circumstance mentioned therein, shall not condition this procedure, provided that the authorization to perform the required tasks stems from said license.

3.12.- Provincial legislation. The granting of a municipal license denotes compliance with the provincial legislation associated with the activities applied for.

3.13.- Changes and modifications in registration and licensing conditions. Firms that wish to make changes regarding registration and licensing conditions shall previously notify it to SENASA. Any changes shall be previously approved and authorized by SENASA prior to their implementation.

3.13.1.- The approval of said changes undergoes the same procedure established in this Technical Standard for registrations and licenses.

3.14.- Registration and license renewal. Firms and establishments that have been registered or licensed for TEN (10) years with the National Registry of Firms and Establishments Manufacturing Feedstuffs after this Technical Standard enters into force shall renew said registrations and licenses within ONE (1) year from the date the TEN (10)-year registration or license period is completed.

3.15.- Withdrawal from the Registry. Withdrawal from the registries implies the permanent exclusion of registrations and licenses.

Withdrawal may stem from the request of an interested firm, as the consequence of a penalty applied by SENASA as conclusion to a summary proceeding due to the violation of current standards.

3.15.1.- Withdrawal implementation. Registered products. In order to cancel the registration of the firm or establishment, it should be previously verified that the firm does not have any product registered under its name with the Registry of Products or any debt with the Service. If so, any product registration shall be transferred or cancelled as a necessary condition to give effect to the withdrawal and to cancel the debt, if any.

3.16.- Category extension and/or modifications to registration and license conditions. The extension of categories and/or modifications to registration and license conditions shall be processed by means of the establishment licensing or firm registration procedure, as applicable, maintaining registration and license numbers. Modifications to firm or establishment data shall be notified to SENASA within, at least, THIRTY (30) days after the introduction of said modifications.

4.- PROCEDURES FOR REGISTRATION, LICENSING AND AUTHORIZATION OF FIRMS AND ESTABLISHMENTS

4.1.- Firm registration.

4.1.1.- Required documentation for the registration of a firm: the following documents shall be presented to register a firm:

4.1.1.1.- Application for Firm Registration, duly completed.

4.1.1.2.- Corporate contract certified by a notary public, for legal entities.

4.1.1.3.- Certificate of registration with bodies and/or authorities that register legal entities.

4.1.1.4.- Documents confirming the appointment of current corporate authorities.

4.1.1.5.- Documents confirming the legal capacity of those individuals acting on behalf of the firm.

4.1.1.6.- Tax Payer I.D. (CUIT, for its acronym in Spanish) Certificate

4.1.1.7.- In case of a sole proprietorship, a certified copy of the National Identification Document (DNI, for its acronym in Spanish) and of the CUIT number.

4.1.1.8.- Legal certification of the address issued by a competent authority.

4.1.1.9.- In the case of *de facto* business organizations, the engagement letter of the members, the certified copies of their DNI and the legal certification of their address issued by a competent authority, and the CUIT of the company and of the partners.

4.1.1.10.- Document for manufacturing in a third-party establishment, if applicable.

4.1.2.- Legal Representative. The firm shall inform, by means of a letter, about who exercises the duties of legal representative, who shall be appointed in the corporate contract. In case of sole proprietorships, the owner is the legal representative.

4.1.3.- Agent. Firms may appoint an agent, who shall be empowered by means of a public document.

4.1.4.- Authorized individual. The firm may appoint one or many individuals to complete bureaucratic procedures before SENASA, except those exclusively corresponding to the Technical Director. The appointment shall be performed by the legal representative or agent bearing sufficient power by means of a letter bearing a certified signature. The authorized individual is only empowered to complete mere bureaucratic procedures.

4.1.5.- Registration procedure. The firm registration procedure may be initiated in the office of the Directorate for Hygiene and Safety of Products of Plant Origin and Feedstuffs or in the local offices of the Regional Centers. Said procedure shall be performed and completed in the office where the documents were presented. However, if the documents were first submitted to the Directorate of a Regional Center, the docket file shall be forwarded to the Directorate for Hygiene and Safety of Products of Plant Origin and Feedstuffs to remain there once the procedure is completed, as it is the office responsible for managing the Registry of Firms and Establishments.

4.1.5.1.- Simultaneous procedure – Separate docket files. The procedures for firm registration and establishment licensing may be simultaneously initiated but shall be processed in separate docket files. The registering administrative act shall be issued independently from the licensing one.

4.2.- Establishment licensing.

4.2.1.- Required documentation for licensing of an establishment. In order to license an establishment, the following documents shall be submitted to the Directorate for Regional Centers:

4.2.1.1.- Certificate of registration of the firm responsible for the establishment.

4.2.1.2.- Document proving tenancy of the establishment by the responsible firm that shall perform the tasks, such as the pertinent property title or agreement.

4.2.1.3.- Application for Establishment Licensing, duly completed.

4.2.1.4.- Certificate of the municipal license authorizing the activity to be performed.

4.2.1.5.- Blueprint on a scale of ONE IN TWO THOUSAND (1:2000) of the plot wherein the space occupied by the establishment, its access roads and main neighboring buildings shall be marked.

4.2.1.6.- Blueprint on a scale of ONE IN ONE THOUSAND (1:1000) of each sector, indicating facilities and equipment, as well as the entry/exit flow of staff, raw materials and products.

4.2.1.7.- Two blueprints on a scale of ONE IN ONE HUNDRED (1:100) approved by the Municipality, if applicable.

4.2.1.8.- Diagram coinciding with the blueprint that indicates offices, fixed equipment, and facilities.

4.2.1.9.- Physical and building specification statement.

4.2.1.10.- Operational flow chart.

4.2.1.11.- Protocol for physicochemical and bacteriological analyses of water, except for storage.

4.2.1.12.- State if product quality controls are conducted in a laboratory owned by the establishment and/or by third parties.

4.2.1.13.- State if the establishment performs any other activity apart from feed manufacture (specify).

4.2.1.14.- State what type of food, raw materials, additives, and ingredients shall be used for the activities to be developed, and the species and destinations to which they are intended.

4.2.1.15.- Appointment and approval of the Technical Director.

4.2.2.- Previous inspection. Once the documents are analyzed, the staff of the Regional Center in charge shall visit the establishment for inspection purposes in order to verify compliance with the requirements established in this Technical Standard. Inspections shall be conducted according to the model of the Reference Record for Establishment Licensing (which is available on SENASA website), which shall be completed according to the verifications performed.

4.2.3.- Assessment and inspection reports. After completing the inspection, SENASA staff shall assess the verifications performed and their attached documents in order to determine if the requirements demanded by this Technical Standard are complied with, and shall issue a technical report with the results of said assessment. The technical reports shall be signed by the Coordinator of the area and shall be forwarded to the Director of Regional Centers.

4.2.4.- Compliance with the requirements. If the establishment complies with the established requirements, a technical report recommending its licensing shall be issued.

4.2.5.- Minor non-compliances. When officials detect minor inconsistencies and shortcomings, which do not hinder the performance of activities under the conditions established by this Technical Standard, but require work and improvements towards their solution, a technical report recommending the licensing of the establishment and indicating this circumstance shall be issued.

4.2.5.1.- Notification. The firm shall be notified of the obligation to perform the indicated work and improvements within a certain period established by SENASA. Failure to complete the work and improvements in due time and manner constitutes a breach to this Technical Standard.

4.2.6.- Non-compliance with the requirements. If the officials in charge consider that the establishment does not meet the requirements laid down by this Technical Standard, which, from a technical and sanitary point of view, enable the performance of the required activity, they shall issue a technical report detailing the circumstances and events by which the establishment licensing is not appropriate.

4.2.6.1.- Notification. The firm shall receive a notification stating that the verified circumstances do not meet the requirements demanded to license the establishment, detailing said circumstances and ordering the firm to comply with missing requirements within a period established by the officials, under penalty of considering the procedure abandoned and of filing all related documents. The granted period shall be in line with the time required to correct or comply with the missing requirements.

4.2.6.2.- Notification of prohibition. The same notification shall state that the performance of any activity mentioned in this Technical Standard is prohibited until the establishment is licensed.

4.2.7.- Legal opinion. Prior to the issuance of the administrative act granting the license, the pertinent legal opinion shall be requested to the Directorate for Legal Affairs regarding the conditions to issue the administrative act.

4.2.8.- Administrative act. Once the registration number is granted by the Directorate for Hygiene and Safety of Products of Plant Origin and Feedstuff, the Regional Director shall issue an Order licensing the establishment and registering it with the National Registry of Establishments Manufacturing Feedstuffs under the assigned number. In addition, firms shall be duly notified according to the formalities laid down in the National Act on Administrative Procedures No. 19549, Regulatory Decree No. 1759/72 (o.t. Dec. 1883/91).

4.2.9.- Report and database. Once the administrative act is issued, the Regional Center shall forward a certified copy of said document and all the necessary information to the Directorate for Hygiene and Safety of Products of Plant Origin and Feedstuffs in order to enter the data of the firm or establishment in the software, or to enter said data directly in the aforementioned software.

4.3.- Renewal of registrations and licenses. In order to renew registrations and licenses, the procedure provided by this Technical Standard for initial registration and licensing of firms and establishments shall be followed.

4.4.- Firms and establishments that are already registered and licensed in other SENASA areas and apply to perform activities mentioned in this Technical Resolution.

4.4.1.- Every firm and establishment already registered with certain SENASA registries, different from those mentioned in this Resolution, and that wish to perform all or some of the activities established in this Technical Standard shall request the pertinent Regional Center a

category extension and comply with all the conditions laid down in this Technical Standard in order to obtain the pertinent registrations and licenses to perform the requested activities.

4.4.1.1.- Firm registration. The firm responsible for the establishment shall be registered with the Registry of Firms of this Technical Standard according to the established procedure, for which the documentation provided in the first docket file may be used, if applicable to said purpose.

4.4.2.- License extension. Activity extension shall be done according to the procedure laid down in point 4.2. of this Technical Standard regarding establishment licensing, which shall be adjusted to the specific characteristics of the existing license.

4.4.3.- Granting of extension. The extension of the requested activities shall be granted with the official number provided by the area of primary intervention once all the conditions demanded by this Technical Standard are met and all the expected fees, rates and contributions established by current standards are paid.

4.4.4.- Control. The control of activities included in the category extension covered by this Technical Standard shall be conducted by the Directorate for Hygiene and Safety of Products of Plant Origin and Feedstuffs.

4.5.- Establishment conditions to export to a certain destination.

4.5.1.- Compliance certification. In order to certify compliance with the requirements of destination countries, the firm of the establishment manufacturing the product shall request SENASA, by means of a letter, to verify compliance with said requirements.

4.5.2.- If there is no agreement between the health authorities of the Argentine Republic and the ones of the destination country, the exporting firm shall duly notify, by means of a Sworn Statement, the requirements demanded by the destination country.

4.5.3.- If there is a bilateral agreement between health authorities, SENASA shall verify compliance of the establishment and/or the product to be exported with the conditions and requirements laid down in said agreement.

5. - SYSTEMS FOR GOOD MANUFACTURING PRACTICES (GMP)

5.1.- General conditions of Good Manufacturing Practices:

5.1.1.- Manufacturers of feedstuff for on-farm consumption and integrators. Establishments manufacturing feedstuff for on-farm consumption shall only comply with the Good Manufacturing Practices established in Numeral 18 of this Technical Standard.

5.1.2.- Commercializing establishments. The minimum criteria that the registered and licensed establishments commercializing products shall meet in order to implement Good Manufacturing Practices along the entire chain are the following:

5.2.- Manual on Good Manufacturing Practices.

5.2.1.- Drawing up of the Manual. All establishments shall have a Manual on Good Manufacturing Practices. The manual shall state the principles and criteria established in this Technical Standard and in the Code of Practice on Good Animal Feeding CAC/RCP 54-2004 of the *Codex Alimentarius*.

5.2.2.- Individuals responsible for the Manual. The manual shall be signed by the individual responsible for the firm and by the Technical Director of the Establishment, and shall be available at the establishment at all times for SENASA.

5.2.3.- Obligatory nature of the Manual on Good Manufacturing Practices. The manual shall be compulsorily implemented within the establishment with auditable systems. All activities shall be performed in compliance with said manual.

5.2.3.1.- Period for implementation of the Manual on Good Manufacturing Practices. Establishments requesting licenses and registrations upon the entry into force of this Technical Standard shall implement the Manual on Good Manufacturing Practices within a period not exceeding the TWELVE (12) months after licensing.

5.2.4.- Controls on Manual implementation. When deemed necessary, SENASA is empowered to verify the existence of the Manual, its adjustment to the principles and concepts established in this Technical Standard, and its implementation within the establishment with auditable systems.

5.2.5.- Minute book. The establishment shall have a minute book used exclusively by the Service, who shall authorize and number it, where the established requirements and the new information arising from audits based on surveillance or monitoring programs shall be registered.

5.2.6.- Prevention from contamination.

5.2.6.1.- The manufacture and storage of products intended for animal feed shall be performed in such manner that prevents contamination risks.

5.2.6.2.- Manufacture, fractioning and storage of products in the open is hereby prohibited.

5.2.7.- Separated manufacturing lines. Establishments that manufacture feedstuff for ruminants and for non-ruminants and that use prohibited proteins for ruminants shall have separate production lines.

5.2.8.- Filing documents. Manufacturers shall keep the documents on the inputs used during product manufacture filed for a minimum period of SIX (6) months beginning from the expiry date of the product. If the inputs are animal products, by-products or derivatives, the obligatory period for keeping the documents is SEVEN (7) years.

5.2.9.- Minimum contents of the Manual on Good Manufacturing Practices. The Manual on Good Manufacturing Practices shall at least contain the following information:

5.2.9.1.- Purpose.

5.2.9.2.- Scope.

5.2.9.3.- Introductory chapter (brief monograph) where the product(s) to be manufactured, the manufacturing methods/techniques, and the machines to be used are clearly specified.

5.2.9.4.- Responsibilities. An organizational chart indicating functions and responsibilities shall be provided.

5.2.9.5.- Scope of the contents.

5.2.9.5.1.- Documents.

5.2.9.5.2.- Facilities. It shall describe manufacturing lines, entry area, raw materials, drug storage facility, processing area, storage area, maintenance, boiler room, staff area, limits of the premises, staff circulation, lighting, others.

5.2.9.5.3.- Equipment. Calibration and maintenance procedures, among others, shall be included.

5.2.9.5.4.- Staff: functions and responsibilities shall be specified.

5.2.9.5.5.- Controls: including controls on production processes, flow charts, the internal circuit with a description of the manufacturing process flow and the installation of equipment and machines.

5.2.9.5.6.- Procedures that, at least, entail the following stages:

5.2.9.5.6.1.- Reception and storage of raw materials. If applicable, supplier selection. It shall also include a specific procedure in case of storing drugs or products susceptible to environmental effects.

5.2.9.5.6.2.- Description of production batch(es). It shall describe the criterion for batch creation and/or assignment for each manufacturing consignment.

5.2.9.5.6.3.- Processing, formulation and mixing. It shall describe how production orders are generated, who is responsible for them, how raw materials are selected, how ingredients are mixed, and how weighing and measuring equipment is calibrated.

5.2.9.5.6.4.- Storage and transport of finished products.

5.2.9.5.6.5.- Quality controls.

5.2.9.5.6.5.1.- Self-controls: including practices, procedures, and analytical tests conducted at an own or external laboratory, which are necessary to maintain the system under control and which are evidenced by auditable records.

5.2.9.5.6.5.2.- Supplier development.

5.2.9.5.6.5.3.- Records.

5.2.9.5.6.5.4.- Traceability.

5.2.9.5.6.6.- Alert system: to identify raw materials nearing expiry date.

5.2.9.5.6.7.- Storage of finished products.

5.2.9.5.6.8.- Packing, packaging, and tagging: labeling.

5.2.9.5.6.8.1.- In bulk.

5.2.9.5.6.8.2.- Packaging.

5.2.9.5.6.9.- Final residue disposal and flushing.

5.2.9.5.6.10 Product recall. Complaints.

5.2.9.5.6.11.- Traceability.

5.2.9.5.6.12.- Staff training.

5.2.9.5.6.13.- Documentation and Records. Auditable records. There shall be a documentary system that allows a clear identification and registration of all stages of manufacturing and commercialization processes. The recordkeeping periods are the following: for manufacturers of ruminant feedstuff using raw materials of animal origin, SEVEN (7) years; for manufactur-

ers using veterinary drugs, TWO (2) years; for products and raw materials not specifically covered, TWO (2) years.

5.2.9.5.6.14.- Annexed procedures. Only if applicable; for instance, for cross-contamination in manufacturing processes using veterinary drugs; for ruminant and non-ruminant manufacturers.

5.2.9.5.6.15.- SSOPs. Describe the set of health, operational and pre-operational measures implemented to preserve hygiene conditions in the various stages. Maintenance. Include individuals, equipment and facilities. Authorized own and third-party procedures.

5.2.9.5.6.16.- Pest and rodent controls (insects, rodents, birds).

5.2.9.5.6.17.- Transport.

5.2.9.5.6.18.- Official verifications. Controls on inspections and SENASA visits. Book for SENASA exclusive use.

5.3.- Basic principles for the implementation of Good Manufacturing Practices.

5.3.1.- Quality control.

5.3.1.1.- A Quality Manager of the company shall be appointed for the implementation of Good Manufacturing Practices.

5.3.1.2.- Companies shall have access to a laboratory (internal and/or external) to conduct the necessary analytical tests within the framework of Good Manufacturing Practices. Said laboratories shall have trained staff and the necessary equipment to conduct the required assays.

5.3.1.3.- Actions intended to keep the process under control shall be drawn up and implemented, including sampling procedures and their frequency, analysis methods, compliance with specifications (as well as product destination in case of non-compliance), from processed materials to finished products.

5.3.1.4.- Firms manufacturing and fractionating products for animal feed shall ensure that the various stages of production are performed pursuant to the procedures and instructions previously established in writing with the purpose of defining, verifying and maintaining under control the critical points of the manufacturing process.

5.3.1.5.- All the necessary documents shall be kept in order to ensure traceability. Documents shall be available to the competent authorities. In addition, samples shall be collected and preserved of the batches of manufactured and commercialized products or of each specific

fraction of product (in case of continuous production), according to the procedure previously established by the manufacturer. Samples shall be sealed and labeled in such a manner that they are easily identified.

5.3.2.- Staff.

5.3.2.1.- General considerations:

The companies shall have sufficient staff with necessary competences and qualifications in order to manufacture the products involved. Functions and responsibilities shall be clearly stated in writing to the entire staff, especially when modifications are made.

5.3.2.2.- Responsibility.

The individual responsible for the establishment shall provide the Permanent Staff with all the necessary elements to perform their tasks, including regular training courses and practices, and shall keep specific records on said performances.

Said individual shall ensure that the different stages of production, fractioning, or any handling or transport of feedstuff are performed pursuant to the procedures and instructions previously established in writing in order to determine, verify and keep the processes performed under control.

5.3.2.3.- Individual responsible for the processes.

It is the individual responsible for implementing technical or organizational measures.

Said individual shall supervise the absence of prohibited products, undesired substances and further contaminants that may affect animal and human health, and shall develop control strategies that reduce risks to a minimum.

Said individual shall provide simple and reliable information to ensure product traceability.

5.3.2.4.- Permanent Staff.

They are in charge of performing tasks according to the auditable procedure established by the company. Said staff shall be regularly trained.

5.3.3.- Raw material receipt and storage.

5.3.3.1.- Raw materials shall be stored under the right conditions and in an orderly manner to enable batch separation and inventory rotation, following the “first in, first out” or “first expired, first out” principles.

5.3.3.2. Raw materials shall be identified and analyzed according to their compliance with the established specifications; they shall be approved or rejected, and stored, identified and released for use according to the written procedures established by the firm.

5.3.3.2.1.- If a supplier delivers raw materials in different batches, each batch shall be individually sampled, analyzed and released.

5.3.3.2.2.-. Stored raw materials shall be identified and shall provide sufficient information for traceability purposes.

5.3.3.2.3.- Raw materials that may be considered dangerous for handling operations or for certain destination species shall be collected pursuant to the applicable SENASA standards and hygiene and safety regulations.

5.3.3.2.4.- The following raw materials are considered to be under Conditional Reception:

5.3.3.2.4.1.- Those that do not bear legible labels;

5.3.3.2.4.2.- Those which container shows visible signs of breakage or content leakage;

5.3.3.2.4.3.- Those not showing documentary receipt evidence identifying their origin (Delivery notes and/or entries in Plant Records);

5.3.3.2.4.4.- Those not complying with the minimum tolerance parameters according to specifications[*sic*].

5.3.3.2.5.- Storage.

To ensure that raw materials and/or ingredients are separately stored from manufactured foods, without exception.

5.3.4.- Production.

5.3.4.1.- A qualified individual shall be designated to be in charge of production.

5.3.4.2.- Technical or organizational measures shall be implemented in order to prevent or reduce to a minimum, as required, cross-contamination and shortcomings. Sufficient and adequate resources shall be available to perform controls during manufacture.

5.3.4.3.- Residues and materials that are not fit for consumption shall be isolated and identified.

5.3.5.- Facilities and equipment.

5.3.5.1.- Facilities, equipment, containers, packaging and vehicles used in processing and storage of feedstuff, as well as their immediate surroundings, shall be maintained clean. In addition, efficient pest control programs shall be adopted.

5.3.5.2.- The layout, design, construction and dimensions of facilities and pieces of equipment shall:

5.3.5.2.1.- Enable their adequate cleaning and disinfection, for which detergent solutions and/or disinfectants approved by SENASA shall be used.

5.3.5.2.2.- Reduce the risk of shortcomings to a minimum and prevent contamination, including cross-contamination, and any harmful effects to product safety and quality in general. Machinery in contact with feedstuff shall be dried after a wet cleaning process is conducted.

5.3.5.3.- Facilities and equipment used in mixing and manufacturing processes shall be regularly subjected to the appropriate controls, pursuant to the written procedures previously established for products by the manufacturer.

5.3.5.3.1.- All scales and measuring devices used during the manufacture of products for animal feed shall be adequate for the range of weights and volumes that shall be measured and shall be regularly subjected to tests to ensure their accuracy.

5.3.5.3.2.- All mixing devices used in the manufacture of products for animal feed shall be adequate for the range of weights and volumes that shall be mixed and capable of manufacturing ideal homogeneous mixes and dilutes. Manufacturers shall prove the efficiency of mixers regarding homogeneity.

5.3.5.4.- Facilities shall have adequate natural and/or artificial lighting and shall comply with the applicable hygiene, safety and lighting standards.

5.3.5.5.- Waste pipes shall be adequate for the intended purposes and shall be designed and made in such a manner that prevents any contamination risks.

5.3.5.6.- The water used in the manufacture of products for animal feed shall be fit for animals, and water pipes shall be made of materials that do not affect safety conditions required for water. A chemical analysis shall be annually performed on water, as well as a bacteriological analysis every six months.

5.3.5.7.- Drainage of waste and rain water shall be performed in such a manner that does not affect the equipment nor the safety and quality of products.

5.3.5.8.- Windows and any other openings shall be efficient for pest control.

5.3.5.9.- If necessary, ceilings and roof trusses shall be designed, constructed and finished in such a manner that prevents dirt buildup and reduces condensation, undesired mold formations and the shedding of particles that may affect product safety and quality.

5.3.5.10.- Drug storage facilities for veterinary products allowed under usage recommendations.

A place intended for products allowed under usage recommendations shall be determined, which shall have minimum organizational and recording criteria, according to the following points:

5.3.5.10.1.- Access to the place shall be restricted; thus, only previously authorized Operational Managers are allowed. All products therein shall be correctly labeled and their containers shall be appropriately closed.

5.3.5.10.2.- A Record shall be kept on product entries and exits, dates, and volumes of each operation, and shall provide a description of the food for which the product is intended.

5.3.6.- Sanitation Standard Operating Procedures (SSOPs). These are the standard operating procedures that describe sanitation tasks, which are performed before, during and after operations.

The following shall be considered:

5.3.6.1.- Descriptive and operational building blueprints of common areas and Operational Units (posts). Written documents describing facilities (water supply, ventilation, restrooms, storage of chemical products, tools used, etc.).

5.3.6.2.- Written documents of procedures describing the tasks to be performed, including frequencies and levels of application.

5.3.6.3.- Daily Record Sheets (or any other fixed frequency, not exceeding a month, according to the designer) on tasks to be performed and verified within the Establishment, providing date, name and signature of the staff. Findings and recommendations.

5.3.7.- Cleaning procedures.

The design of the manufacturing lines shall enable a regular cleaning and the due verification of said tasks at Control Points, in order to ensure hygiene and health quality of the products manufactured therein.

5.3.7.1.- Pre-operational cleaning. A regular Pre-Operational Cleaning shall be established in the Procedural Manual, stating the frequency (weekly, fortnightly, etc.) in which empty facilities are cleaned using the appropriate physical means (brushing, ventilation, etc.), which shall ensure the sweeping of dangerous substances and, therefore, prevent cross-contamination.

5.3.7.2.- Operational cleaning in production lines. Dangerous ingredients are swept by using a safe ingredient acting as "flushing" material. Prior to beginning a new feedstuff manufacturing process for a specific species and animal category, whether medicated or not, intended for various animal categories or other species, a material not containing hazardous ingredients shall circulate around the production line for flushing purposes. The volume used of said material shall ensure the sweeping of hazardous substances and prevent cross-contamination. The total volume to be used may be measured by sampling manufactured products by means of analytical procedures.

5.3.7.3.- Destination of products used as "flushing" material.

In the case of "flushing" materials, they shall be used for the following purposes:

5.3.7.3.1.- Perform a re-processing procedure to include a new feedstuff for non-ruminants.

5.3.7.3.2.-. Divert its use due to the condition in which it is found and intend it for feeding other species, when applicable.

5.3.7.3.3.- Regarding numerals 5.3.7.3.2 and 5.3.7.3.3, there shall be auditable records documenting the destination of said products. Thus, authorized delivery notes from consignment receivers informing restriction of use of feedstuff for non-ruminant animal species shall be filed. Said restriction shall be evidenced, for instance, with a seal expressly indicating the following caption: "*Banned for use in bovines, sheep, goats or other ruminants*".

5.3.8.-. Planned production and control on manufacture procedures.

Planned Production shall be arranged on a major-to-minor risk scale in order to facilitate cleaning processes and further control of cross-contamination. Thus, at least the following Planning Basic Criteria are considered, going from minor to major risk and complexity:

5.3.8.1.- Feedstuff medicated with minimum risk VP, preceding those of maximum risk, which sequence determination is under the responsibility of the Veterinary Technical Director.

5.3.8.2.- Feedstuff without nucleus, before those containing it.

5.3.8.3.- If the manufacturing plant produces both for itself and for a third party, this shall be included in the Production Plan by conveniently registering its addition to the Program. If the Planned Production needs interruption due to market requirements or *force majeur*, additional preventive measures, which are under the responsibility of the Individual Responsible for Processes, shall be taken in cleaning procedures once said accidental production is finished.

5.3.8.4.- General feedstuff and feedstuff with drugs. The manufacturing establishment shall validate the official copies of scientific papers by means of the signature of the Technical Director of the Plant. Said documents shall be available at the request of SENASA inspection staff. The registration number of the authorized feedstuff, the veterinary product content (percentage), the logo of the Service, the name and registration number of the manufacturing establishment, the relevant usage recommendations and restrictions, including the withdrawal period shall be verified in scientific papers on feedstuff with drugs approved by SENASA.

5.3.8.5.- Formulations. The planned formulations for the manufacture of feedstuff with drugs shall match those stated in registered scientific papers that were approved by SENASA.

5.3.8.6.- Veterinary drugs. The registration number of the product, the name and registration number of the manufacturing Laboratory authorized by SENASA, the logo of the Service, the information on active ingredient content, the animal species and category for which it is intended, the allowed dose, the corresponding usage recommendations, and, specially, the withdrawal period shall be verified.

5.3.8.7.- Products on demand. They shall comply with the provisions of this Technical Standard.

5.3.9.- Storage and transport of finished products.

5.3.9.1.- Storage.

5.3.9.1.1.- Products for animal feed shall be separated from non-processed raw materials and from additives in order to prevent any cross-contamination in products.

5.3.9.1.2.- Products for animal feed shall be stored in places designed, arranged and maintained in such a manner that ensures that storage conditions guarantee safety conditions. Only the staff authorized by the company shall have access to said products.

5.3.9.1.3.- Products for animal feed shall be stored and transported in such a manner that enables easy identification in order to avoid any confusion or cross-contamination and to prevent their deterioration.

5.3.9.1.4.- Containers and equipment used in transportation, storage, carriage, handling, and weighing operations shall be kept clean.

5.3.9.1.5.- Any type of deterioration shall be reduced to a minimum and kept under control in order to curb pest proliferation.

5.3.9.1.6.- When applicable, storage temperatures shall be maintained within the parameters established by the company, which shall ensure the preservation of the characteristics and the safety of the product to be stored.

5.3.9.2.- Product identification.

In the case of bag packaged feedstuff, identification systems easily identifiable by operators shall be maintained.

Regarding in-bulk storage, there shall also be highly-visible signs.

5.3.10.- Transport within the establishment.

Containers and equipment used in transportation, storage, carriage, handling, and weighing operations of feedstuff shall be kept clean. Cleaning programs shall be adopted.

5.3.11.- Waste management.

Waste management shall be performed in compliance with the conditions established in this Technical Standard. Classification and destination according to the type of waste shall be determined after considering, at least, the following points:

5.3.11.1.- Waste from feedstuff manufactured with prohibited proteins for ruminants: non-ruminant feed with auditable documents.

5.3.11.2.- Waste from non-standard feedstuff manufactured without prohibited proteins: ruminant and non-ruminant feed, with auditable documents.

5.3.11.3.- Waste from feedstuff manufactured with drugs: destruction and final disposal, with auditable documents.

5.3.11.4.- Other waste: final disposal with non-feeding purposes with auditable documents.

5.3.11.5.- For points 5.3.11.1 and 5.3.11.2, the firm responsible for the establishment shall ensure waste traceability, destination RENSPA, and that transport complies with the conditions established in this Technical Standard.

5.3.12.- Documents associated with waste transport (delivery note or its equivalent) shall be recorded and filed.

5.3.13.- Complaints and product recall.

5.3.13.1.- Firms manufacturing products for animal feed shall have a system for recording and processing complaints.

5.3.13.2.- In addition, a quick recall system of products present in the distribution circuit shall be established, if applicable. The destination of the recalled products shall be determined by means of a written procedure and said products shall be subjected to a new quality control before being released back into circulation.

5.3.14.- Documentary records.

5.3.14.1.- All documents and records shall be available, at all times, for the staff SENASA appoints for control and verification operations. Each plant shall have, at least, the following records:

5.3.14.1.1.- Sheet on Weekly Plan: per products and dates.

5.3.14.1.2.- Sheet on the Entry of Raw Materials: date, entry authorization, volume entered, stock balance (weekly); records on raw materials of risk shall be kept separately from other food ingredients: meat and bone meals (MBM) and veterinary products (VP).

5.3.14.1.3.- Sheet on Dosing and Grinding Operations: date, batch No., product reference, Registration or Order No. with formula (if applicable), and the volume of each ingredient.

5.3.14.1.4.- Sheet on Manufacturing Controls: date, batch No., product reference, description of controlled parameters.

5.3.14.1.5.- Sheet on Packaging or In-bulk Storage.

5.3.14.1.6.- Sheet on Dispatch: volume, No. of delivery note, addressee, receipt approval (delivery note approved at destination and forwarded back to the Plant to be filed for, at least, 1 year).

5.3.14.1.7.- Sheet on Waste Destination: delivery note, destination, volume, transport, and receipt approved by the individual responsible for receipt at destination.

5.3.14.1.8.- Record Sheet on the Cleaning of Facilities and Manufacturing Lines.

5.3.14.1.9.- Sheet on SSOP implementation.

5.3.14.1.10.- Sheet on Permanent Staff Training.

5.3.14.2.- Establishment documents.

Documents that shall be available within the plant for official inspectors:

5.3.14.2.1.- Certificate of Firm Registration: original copy or photocopy signed by the Technical Director of the Establishment.

5.3.14.2.2.- Certificate of Plant Licensing: original copy or photocopy signed by the Technical Director of the Establishment.

5.3.14.2.3.- Fee Pay Slip (updated) or photocopy signed by the Technical Director of the Establishment.

5.3.14.2.4.- Certificate of Product Approval: original copy or photocopy signed by the Technical Director of the Establishment.

5.3.14.2.5.- Blueprint of the company with coinciding machinery layout.

5.3.14.2.6.- Manufacturing contract with third parties or photocopy signed by the Technical Director of the Establishment or the Individual Legally Responsible for the firm.

5.3.14.2.7.- Folder with official supervision procedures: in chronological order and in which, at least, the following information must be provided:

5.3.14.2.7.1.- Results of analyses performed.

5.3.14.2.7.2.- Reference Record of Inspection and/or Establishment Licensing (copy).

5.3.14.2.7.3.- Records of Notices/Notifications.

5.3.14.2.7.4.- Book of signatures of area managers (technical director, individual responsible for quality control, individual responsible for storage, etc., as applicable).

5.3.14.2.7.5.- Official Certificates on the origin of animal raw materials.

5.3.14.2.7.6.- Book on SENASA inspection news. Minutes Book: hard covered, numbered and sealed by SENASA.

6. FACILITIES

6.1.- Building structure and equipment.

6.1.1.- All establishments shall have facilities and equipment to comply with production, quality control, hygiene and safety standards. Their design shall minimize the risk of errors to a minimum and enable an effective cleaning and maintenance, so as to prevent cross-contamination, dust accumulation, dirt and any adverse effect that may alter the product.

6.1.2.- Auditable procedures on facility maintenance shall be established.

6.1.3.- The size of rooms or areas shall be adequate for the volume and type of products to be manufactured, fractionated and/or stored.

6.1.4.- All openings connecting to the exterior shall be protected against pests (insects, birds, rodents, etc.).

6.1.5.- All areas of the building shall be located on high grounds not prone to flooding or, otherwise, provide the necessary structures to reduce the effect of possible floods or waterlogging.

6.1.6.- Areas of access and neighboring zones shall be constructed in such a manner that allows the entry of staff without inconvenience and prevent water and waste accumulation.

6.1.7.- All establishments shall have a perimeter fence preventing the entry to the establishment of foreign animals and individuals.

6.1.8.- Accesses within the establishment shall be paved or consolidated, and shall have adequate areas for loading and unloading operations.

6.1.9.- Product manufacture shall be isolated from the presence of animals and from objects foreign to production.

6.1.10.- The manufacturing plant shall be located no further than 500 (FIVE HUNDRED) meters from any farm or collection center or, otherwise, it

shall take the necessary measures to reduce the risks arising from said situation.

6.1.11.- In the case of integrating establishments, SENASA shall perform a risk analysis to determine the distance of the manufacturing plant from the farm or collection center.

6.1.12.- The establishments shall have divided areas for the different activities performed therein.

6.1.13.- Waste and rain waters and general waste shall be disposed of in such a manner that ensures the non-contamination of equipment, ingredients and products.

6.2.- Auxiliary areas

6.2.1.- Dressing rooms, washrooms and restrooms shall comply with the applicable hygiene and safety standards according to the number of users. Restrooms shall not be directly connected to production and storage areas.

6.2.2.- In the case of resting rooms or canteens, these shall be separated from the rest of the areas.

6.2.3.- Maintenance areas shall be located in zones separated from production areas.

6.2.4.- Tools and further pieces of the production area shall be kept in places intended for that purpose.

6.2.5.- If the establishment has a boiler room, it shall be isolated from the rest of the production sectors and shall be connected to the exterior. In addition, it shall have adequate security and temperature display systems, and shall comply with the standards regulating its operation.

6.3.- Storage area.

6.3.1.- Storage areas shall have sufficient capacity to orderly store different types of materials and products, in individual and separated sectors, such as: raw materials, packaging materials, intermediate materials, materials in bulk, finished products, officially interdicted products and returned or recalled products. There shall be a procedure in place to re-enter the returned or recalled products into the market and their final destination shall be approved

by the quality manager after a risk assessment is performed for each particular case.

6.3.2.- Drug storage facility. Veterinary drugs shall be stored somewhere isolated and with restricted access, separated from the rest of the products and ingredients, and shall be duly identified.

6.3.3.- Phytosanitary products and fertilizers. Phytosanitary products and fertilizers shall be stored in a completely independent and isolated place, with restricted access, and separated from the rest of the products and ingredients, and shall be duly identified.

6.3.4.- They shall be designed in such a manner that ensures the right conditions for storage; thus, materials or objects that enable floor isolation shall be used. These areas shall be clean and dry, and the limits set by the company for temperature and humidity shall be respected in order to ensure characteristic preservation and safety of stored materials.

6.3.5.- If specific conditions on temperature and humidity should be demanded for storage purposes, these shall be followed, monitored and registered.

6.3.6.- Reception areas shall be designed and equipped respecting the limits set by the company in order to ensure characteristic preservation and safety of stored materials.

6.3.7.- Substances prone to provoke fire or explosions shall be stored in isolated, safe and ventilated areas.

6.4.- Manufacturing area.

6.4.1.- Facilities shall be located in such a manner that manufacturing processes can be performed in a logical order, coinciding with the sequence of production operations. In addition, all the pertinent hygiene and health conditions shall be met.

6.4.2 The layout of the working area shall allow the logical and organized arrangement of equipment and materials in order to reduce the risk of contamination to a minimum.

6.4.3.- Pipes, lighting, ventilation points and other services shall be designed and located in such a manner that prevents the existence of spots that are difficult to clean,

6.4.4.- The ventilation of the manufacturing area shall ensure compliance with the provisions of the current standards regulating said activity.

6.5.- Hygiene and Health Conditions.

6.5.1.- All activities performed at an establishment shall meet hygiene conditions.

6.5.2.- The establishment and manufacturing equipment shall be in perfect hygiene and health conditions, and maintenance of said conditions shall be ensured at the beginning and at the end of daily work.

6.5.3.- A plan ensuring efficient pest control by means of blueprints, procedural manuals, safety data sheets of the products used and auditable records shall be implemented.

6.5.4.- Each production area shall respect the limits set by the company to temperature and humidity levels in order to ensure the characteristics and safety of stored materials and, thus, prevent mold and toxin formation and propagation.

6.5.5.- Should the results of a risk analysis determine so, the company shall order the cleaning of machines and equipment before initiating production of a new batch of products, in order to reduce cross-contamination occurrence.

6.5.6.- The clothes worn by operators shall be clean and shall meet conditions ensuring personal safety and non-contamination of finished products.

6.5.7.- Smoking, drinking, eating, or keeping food, drinks, cigarettes and personal medication in manufacturing, laboratory, quality control and storage areas, or in any other areas wherein said actions may adversely alter the quality of the product, are hereby prohibited.

6.6.- Self-controls.

6.6.1.- If the establishment has a laboratory for quality control, it shall be separated from the production area, shall be fully equipped, and shall have properly trained staff capable of conducting all required analyses.

6.6.2.- Establishments not owning a laboratory shall designate a third-party laboratory for the performance of necessary controls on finished products and raw materials.

6.6.3.- Documents on quality controls performed to products and raw materials shall be filed.

6.6.4.- A sample of each batch of manufactured products shall be kept until its expiry date.

7.- TRANSPORT OF PRODUCTS FOR ANIMAL FEED

7.1.- Obligation. All products intended for animal feed shall be transported in compliance with the conditions and requirements established in this numeral 7, regardless of the compliance with the requirements established in other applicable standards on this matter.

7.2.- Methods for product transport.

7.2.1.- Registered products and products on demand. Registered products and products manufactured on demand can be transported in bulk or in packages.

7.2.2.- Bone ashes and meat meals. Prohibition. Transport in bulk of bone ashes and meals containing proteins of animal origin as a sole ingredient or mixed with other products are exempted from in the provisions of point 7.2.1, as they shall be exclusively transported as a finished product, duly packaged and labeled according to numeral 19.7.

7.2.3.- Products for pets. Products for dogs and cats and other pets shall be transported in packages.

7.3.- General conditions for product transport. Vehicles transporting products shall be in perfect hygiene and cleaning conditions, free from any remains of the previous load, covered, closed, and not exposed to the exterior. If a canvas is used, it shall be in perfect conditions, clean and dry.

7.4.- Transport in bulk.

7.4.1.- Should products be transported in bulk, the appropriate vehicles shall be used to preserve their technical, physical and chemical characteristics.

7.4.2.- When different products are transported in bulk in the same vehicle, each product shall be conditioned in compartments that prevent contact among them.

7.4.3.- The transport of products in bulk is prohibited in vehicles containing the following materials: inorganic matter, scrap metal, treated wood, crystal, glass, inert waste, fats of animal and plant origin, products and by-products of animal origin, inorganic substances (clay, minerals, toxic oxide materials, etc.), organic substances (household waste and wastewaters), organic chemical substances (phytosanitary products, fertilizers, diesel) and any other substance different from the original composition of the product.

7.5.- Transfer.

7.5.1.- When products are transported to a warehouse and are forwarded therefrom to another destination, said warehouse shall be registered with and authorized by SENASA, and product transport shall comply with the provisions of this numeral during its itinerary.

7.5.2.- When feedstuff is transferred from one vehicle to another, transport conditions established in this Technical Standard shall be complied with at all times.

7.6.- Obligatory documentation for transport.

7.6.1.- Documents for products manufactured on demand. When products manufactured on demand are transported in bulk or in packages, the load shall be supported by the original copy and duplicated copies of the duly completed Document for On-Demand Manufacture. A copy of the document shall remain with the establishment during product transportation.

7.6.2.- Product delivery. When a product is delivered, the requesting party shall confirm reception by signing the original copy, which shall be filed by the manufacturing establishment for a period of two years. The requesting party shall keep a duplicated copy and file it as well for a period of TWO (2) years.

7.7.- Documents for registered products.

7.7.1.- In bulk. Each consignment of products in bulk shall be accompanied by a copy of the final label approved under the docket file of product registration, which is signed by the Technical Director of the Establishment.

7.7.1.1.- Delivery note. SENASA product registration number and the batch number shall appear in the delivery note or similar document accompanying the product.

7.7.2.- Packaged. When registered products are transported in packages, each package shall contain the label approved for said product. Big bag is considered a package.

7.7.2.1.- Delivery note. SENASA product registration number and the batch number shall appear in the delivery note or similar document accompanying the product.

7.8.- Scope and methods of the requested documents.

7.8.1.- Documents supporting product transport shall travel in the same vehicle where the product is transported during the entire itinerary and shall be shown to authorities requiring so.

7.8.2.- The information provided in the documents shall precisely match the actual load being transported and the destination mentioned in said documents.

7.8.3.- If the vehicle transports different types of products, each one of them shall have its pertinent documents.

7.8.4.- If the same vehicle transports products to different destinations, each product shall have its corresponding documents.

7.9 Rejection of transport. SENASA may reject and return the vehicle containing the load to its place of origin, or take any other health measure, if it confirms that the transport does not meet the conditions established by this Technical Standard.

7.10.- Responsibilities.

7.10.1.- The product sender and its carrier are jointly responsible for complying with the provisions of this chapter regarding the activities under their control and with the requirements provided by other standards covering the

transport of products and raw materials intended, or that may be intended, for animal feed.

7.10.2.- The firm sending the product is responsible for providing the documents to the carrier. The latter is responsible for transporting the product with its pertinent documents during the entire itinerary.

7.10.3.- The carrier is solely responsible for ensuring that no product contamination occurs during transport, from loading until final destination.

7.10.4.- The carrier is responsible of ensuring that the vehicle driver complies with the provisions of this Technical Standard.

PRODUCTS FOR ANIMAL FEED

8.- GENERAL PRODUCT REQUIREMENTS

8.1.- Authorization and registration. Products intended for animal feed to be commercialized, stored, used or consumed shall be authorized and registered with the Registry of Products established in this Technical Standard.

8.1.1.- Exception. The following products are exempted from the obligation established in point 8.1: products manufactured on demand, products obtained from manufacturers of feed for on-farm consumption, non-industrialized raw materials of plant origin and the ingredients indicated by DNICA as results from the risk assessment established in this Technical Standard.

8.1.2.- Only products manufactured at an establishment registered and licensed by SENASA can be registered.

8.1.3.- In order to register a product with the Registry of Products, firms shall have a Technical Director of Products registered with the Registry of Technical Directors.

8.2.- Products approved for human consumption. Products approved for human consumption by the competent national body are authorized as ingredients and are exempted from the obligations established in numeral 8.1, provided that no specific

restrictions are imposed on their use in animal feed and that they are not commercialized as such.

8.3.- By-products and derivatives of animal origin. By-products and derivatives of animal origin used in products for animal feed shall be registered with and authorized by SENASA and shall originate in establishments registered with and licensed by said National Service.

8.4.- Classification. Products are classified in the following manner:

8.4.1.- Complete Balanced Feed

8.4.2.- Complete Balanced Feed with Drugs

8.4.3.- Diet-Correcting Complete Balanced Feed

8.4.4.- Nutritional Additive

8.4.5.- Non-Nutritional Additive

8.4.6.- Food Supplement

8.4.7.- Food Supplement with Drugs

8.4.8.- Vitamin Supplement

8.4.9.- Vitamin Supplement with Drugs

8.4.10.- Mineral Supplement

8.4.11.- Mineral Supplement with Drugs

8.4.12.- Mineral and Vitamin Supplement

8.4.13.- Mineral and Vitamin Supplement with Drugs

8.4.14.- Protein Concentrate

8.4.15.- Protein Concentrate with Drugs

8.4.16.- Energy Concentrate

8.4.17.- Energy Concentrate with Drugs

8.4.18.- Nucleus

8.4.19.- Nucleus with Drugs

8.4.20.- Premix

8.4.21.- Premix with Drugs

8.5.- Commercialization, storage and transport.

8.5.1.- Products may be commercialized, stored and transported in bulk or in packages pursuant to the provisions of this Technical Standard.

8.5.2.- Products for dogs and cats shall be commercialized in packages.

8.5.3.- Bone ashes and meat meals. Prohibition. Transport, commercialization and storage in bulk of bone ashes and of meals containing proteins of animal origin as a sole ingredient or mixed with other products are hereby prohibited. They shall only be transported, commercialized and stored as a finished product, duly packaged and labeled, according to the provisions of numeral 19.7.

8.6.- Individual responsible for safety and quality operations. The holder of the certificate of use and commercialization, along with the firm owning the establishment manufacturing the product, are jointly responsible for safety and quality operations, and their assurance levels, and shall ensure compliance with what was duly approved.

8.7.- Prohibitions.

8.7.1.- Drugs. The manufacturing, fractioning, import, transport, storage, distribution, commercialization, use and possession of products for animal feed containing in its formulation pharmacological products neither registered nor approved with SENASA Registry of Pharmacological Products is hereby prohibited for use in animal feed.

8.7.2.- Poultry bedding. The use of poultry beddings and/or waste deriving from poultry rearing is hereby prohibited throughout the entire Territory of the ARGENTINE REPUBLIC for use in animal feed.

9.- REQUIREMENTS FOR SPECIFIC PRODUCTS

9.1.- Milk and milk substitutes intended for animal feed.

9.1.1.- Milk and milk substitutes used and/or intended for animal feed shall be registered and authorized for use according to the provisions of this Technical Standard on Feedstuff and shall originate in establishments registered with and licensed by SENASA.

9.1.2.- Milk and milk substitutes used or intended for animal feed, whether manufactured in the country or imported, shall contain a registered colorant that turns the product red, blue or green. Said colorant shall be added at the manufacturing plant of origin.

9.1.3.- Only the following colorants can be added to ready-to-eat products in the concentration levels specified below.

Coloring substances	Identification	Concentration level
Crimson, carminic acid, cochineal	INS 120	100 mg/kg as carminic acid
Azorubine	INS 122	50 mg/kg
Ponceau 4R	INS 124	50 mg/kg
40 Red, Allura Red AC	INS 129	50 mg/kg
Patent Blue V	INS 131	50 mg/kg
Indigotine, Indigo Carmine	INS 132	50 mg/kg
Brilliant Blue FCF	INS 133	50 mg/Kg
Copper Chlorophylla	INS 141	50 mg/kg
Copper Chlorophylla	INS 142	50 mg/kg
Food Green, Fast Green	INS 143	50 mg/kg

9.1.4.- The amount of colorant used shall meet the provisions of the Argentine Food Code, the International *Codex Alimentarius*, or other directives established by the FAO of the WHO.

9.2.- Industrial by-products intended for animal feed.

9.2.1.- By-products of the food industry. By-products of the food industry and by-products or storage discards of collection centers intended for animal feed shall originate in establishments licensed by competent authorities for the activities performed therein.

9.2.2.- By-products of the non-food industry. By-products from the non-food industry shall be registered with and authorized by the Registry of Products established in this Technical Standard.

9.2.3.- Requirements for industrial by-products. Industrial by-products shall not contain the following:

9.2.3.1.- Excrements, animal secretions, animal remains, inorganic materials, metal, scrap, plastic, wood, crystal, glass, inert waste.

9.2.3.2.- Industrial fats, inorganic and organic substances such as diesel, clay, toxic oxide materials, household waste and wastewaters.

9.2.3.3.- Minerals in concentrations exceeding the ones allowed for the species and categories for which they are intended.

9.2.3.4.- Phytosanitary products and fertilizers.

9.2.3.5.- Pathogenic microbiological contaminants, or those that may produce toxins.

9.2.3.6.- Vegetative material or seeds that may be toxic to animals.

9.2.3.7.- Any other substance identified as expressly prohibited or contaminant that exceeds the maximum levels allowed for products intended for animal feed.

9.2.4.- Responsible individuals. Livestock producers using by-products from the food industry and from collection centers for animal feed shall be responsible for the safety conditions of said by-products and shall confirm their traceability in an auditable manner, according to the provisions of this Technical Standard.

10. GENERAL CONDITIONS FOR PRODUCT REGISTRATION AND AUTHORIZATION

10.1.- Application for registration. In order to apply for a product registration, the firm responsible for said product and the pertinent establishment shall be registered and licensed with the Registry of Firms and the Registry of Establishments, and shall have a Technical Director of Products.

10.2.- Documents. All documents presented for product registration shall bear the signature of the Technical Director of Products on all pages.

10.3.- Registration procedure. The application for product registration shall be performed pursuant to the procedure established in numeral 11 of this Technical Standard.

10.3.1.- Status and review of docket file. In order to request information on the status of the docket file or its review, SIXTY (60) calendar days shall elapse since the submission of the procedure.

10.4.- Use and Commercialization Certification. All authorized and registered products, both national and imported, are granted the pertinent Use and Commercialization Certificate supporting their free sale throughout the national territory.

10.4.1.- Validity period of the certificate. The Use and Commercialization Certificate has a validity period of TEN (10) years, after which the product shall be re-registered.

10.5.- Re-registration.

10.5.1.- Re-registration shall be requested at least ONE HUNDRED AND TWENTY (120) calendar days prior to the expiry date.

10.5.2.- If the application for re-registration is presented less than ONE HUNDRED AND TWENTY (120) calendar days prior to the expiry date, the product shall not be commercialized as from said date unless the validity period was renewed prior to said date.

10.5.3.- If no application for re-registration is presented after SIX (6) months of the expiry date, the product shall be automatically deleted from the National Registry of Products for Animal Feed and its docket file shall be permanently filed without notifying the interested parties on both circumstances.

10.5.4.- When a product corresponding to an extension of the Use and Commercialization Certificate is to be re-registered, said re-registration shall be jointly requested by the holder of the original registration and the holder of the certificate extension.

10.6.- Period expiry. Once the period expires and re-registration is not completed, the product shall not be manufactured nor commercialized under any circumstance.

10.7.- Product transfer. The registration of products may be transferred only to another firm registered with the registries of this Technical Standard, after presenting a letter requesting said transfer and its acceptance.

10.7.1.- Transfer procedure. Transfer shall be requested by the registration holder, authorized by the firm to which it is transferred and completed by issuing the pertinent administrative act.

10.7.2.- Change of name. It is not obligatory to change the name of the product during transfer.

10.8.- Extension of the certificate of use and commercialization. The registration holder of a product may only extend the certificate of use and commercialization of said product to other registered firm/s, which shall be authorized by means of the pertinent administrative act.

10.8.1.- Requirements. The extension request shall be performed by means of a letter signed by the representative of the firm owning the product and by the representative of the firm to which the certificate is extended.

10.8.1.1.- Previous extension. The extension request shall expressly state that the product does not have pending extensions of use and commercialization.

10.8.2.- Change of name. Obligatory nature. If a product certificate is extended, changing the name of said product is obligatory in order for it to be used by the firm to which the certificate is extended.

10.8.3.- Expiry date. The extension lasts until the expiry date of the original product certificate, unless a shorter period is established.

10.8.4.- Withdrawal. The product holder or the firm to which the certificate was extended can request withdrawal from the extension prior to the expiry date of product registration and after notifying the other party.

10.8.5.- New extension. No new extensions can be requested if a previous extension procedure has not been completed. The firm owning the product may cancel the pending extension request in order to initiate a new one.

10.8.6.- Cancellation of extension. SENASA may cancel the extension during the validity period of the Use and Commercialization Certificate when technical or legal grounds require so, and shall justify said grounds.

10.9.- Modifications. All modifications introduced to a registered product, whether to its formulation, ingredients, labeling, etc., shall be notified to the Registry of Products prior to its manufacture and commercialization in order to assess and approve it or, if applicable, to register it as a new product.

10.10.- New product. A new product is that differing from the one opportunely registered:

10.10.1.- Intended for animals for slaughter. In feedstuff intended for animals that will be consumed by humans:

a) When the values of the formula constituents originally stated are modified, which determines changes in product destination and/or in its usage indication and/or classification, or any other relevant change proving that it is a different product.

b) When the modifications introduced do not comply with the minimum requirements of the stated category, according to the standards established by international bodies of reference (AAFCO, CFR, NRC, FDA, and others).

c) When drugs or medicinal substances are added to or removed from a product.

10.10.2.- For animals not intended for human consumption. In feedstuff intended for animals that will not be consumed by humans:

a) When the values of the formula constituents originally stated are modified, which determines changes in product destination and/or in its usage indication and/or its classification, or any other relevant change proving that it is a different product.

b) When the modifications introduced do not comply with the minimum requirements of the stated category, according to the standards established by international bodies of reference.

10.11.- Registration of a new product. A product considered new shall initiate a new registration procedure.

10.12.- Expiry of the certificate of use. When the Use and Commercialization Certificate of the product expires and is renewed, an updated list of ingredients and their suppliers shall be presented if the holder declares that no modifications have been made to the composition of the product. The pertinent authorization certificate issued by the competent official body, the commercial packaging and any other information required by SENASA shall be presented as well.

10.12.1.- Imported products. Regarding imported products, a certificate of free sale issued by the health authority of the country of origin, which shall not exceed its first year of issuance, shall be presented, along with its qualitative and quantitative formulation and the list of ingredients, and shall be either certified by Apostille or legalized by the Consulate, as applicable.

10.13.- Contaminant levels. The levels of contaminants, residues or deleterious substances present in products intended for animal feed shall not exceed the allowed maximum levels and types established by the competent authority of this Technical Standard. The parameters established by the *Codex Alimentarius* shall be considered as reference.

10.14.- Veterinary products. Use. If veterinary products are used in product manufacturing, these shall be registered pursuant to the Legal Framework for Veterinary Products, its supplementary regulations, and current standards on that matter.

11.- PROCEDURES FOR REGISTERING PRODUCTS FOR ANIMAL FEED

11.1.- Required documents.

11.1.1.- New national products.

11.1.1.1.- Registration. In order to register products, firms shall comply with all the corresponding applications (which are available on SENASA website), attaching the specific documents requested for each case.

11.1.1.2.- Substances with pharmacological activity. All products containing in their list of ingredients substances with pharmacological activity (antimicrobial agents, anticoccidial agents and other antiparasitics, dietary supplements, antitympanic agents) shall state the No. of the Use and Commercialization Certificate of such substances granted by the appropriate area, indicating the active ingredient.

11.1.2.- New imported products.

In order to register imported products, firms shall comply with all registration applications, as appropriate (which are available on SENASA website). The following documents shall be presented as well:

11.1.2.1.- Free Sale or Manufacture Certificate of the country of origin, either certified by Apostille or legalized by the Consulate and translated by a sworn translator. It shall not be more than one year old.

11.1.2.2.- Original final package not containing the product to be registered.

11.1.3.- For export-only products.

In order to register export-only products, firms shall comply with registration applications, as appropriate, which are available on SENASA website.

11.2.- Registration procedures.

11.2.1.- New National Product.

In order to register a new national product, the following steps shall be complied with:

11.2.1.1.- Presenting required documents to the Registry of Products.

11.2.1.2.- Verifying the presented documents.

11.2.1.3.- Presenting documents for the payment of fees and expenses.

11.2.1.4.- Opening a Docket File once fees and expenses have been paid.

11.2.1.5.- Issuing a Technical Report by means of the technical area of the Registry of Products and notifying the interested party.

11.2.1.6.- Should there be objections, these shall be mentioned in the Technical Report. The procedure shall be pending an answer on such objections.

11.2.1.7.- Should the product meet the necessary conditions for its registration, it shall be stated in the report and the Technical Director or Agent shall be notified of this. The notification can be served by e-mail.

11.2.1.7.1.- The certificate of free debt is optional for the firm.

11.2.1.8.- Passing it to the Administrative Area for the continuation of the procedure.

11.2.1.9.- Drawing up a project of the product's Administrative Registration Act.

11.2.1.10.-Forwarding the Docket File for the signing of the Administrative Act.

11.2.1.11.- Once the Administrative Act has been signed, the Docket File returns to the Coordination Office for Registration of Feedstuff in order to notify the Act.

11.2.1.12.- Optionally, the firm can present the final label or package corresponding to that of lower net weight or volume. It shall state the registration number granted to the product and its final classification, as well as any other information required by this Technical Standard. Also, a Sworn Statement shall be presented, indicating that the label submitted is identical to those of higher weight or volume for assessment. This shall happen

prior to the delivery of the Use and Commercialization Certificate, once the submitted label has been approved.

11.2.1.13.- If the firm opts against presenting the final label or package for assessment as a condition prior to the delivery of the Use and Commercialization Certificate, it shall have a period of SIXTY (60) calendar days from the collection of the Certificate to present the final label or package corresponding to that of lower net weight or volume. It shall state the registration number of the product and its final classification, as well as any other information required by this Technical Standard. Also, a Sworn Statement shall be presented, indicating that the label submitted is identical to those of higher weight or volume.

11.2.1.14.- The non-compliance with numeral 11.2.1.13 shall result in the suspension of the Use and Commercialization Certificate, pending the compliance with such requirement.

11.2.2.- New Imported Product.

11.2.2.1.- The procedure shall be the same as that for a new national product.

11.2.2.2.- Upon order from the Coordination Office for Registry, the Directorate for Quarantine Standards of the National Directorate for Animal Health shall be intervene to authorize the analyzed product to enter the country and to establish the health requirements that said product has to comply in order to enter. The “Declaration of Ingredients of Animal Origin in Imported Products” shall be filled in (it is available on SENASA website).

11.2.2.3.- The Directorate for Animal Quarantine submits the Docket File to the Registry, where the interested party is notified of the is-

sued report, together with the Report drafted by the Technical Area of the Registry.

11.2.2.4.- Should there be any objections, the Technical Report shall be issued indicating such objections. The procedure shall remain pending their adjustment.

11.3 Request for product transfer.

11.3.1. Product transfer can only be performed done TWO (2) registered firms.

11.3.2. Changing the name of the product is not obligatory during transfer.

11.3.3 The validity of the certificate corresponds to the original certificate.

11.3.4. Required documents.

11.3.4.1.- Letter of the current holder of the Use and Commercialization Certificate referring to the Docket File of the product, stating name and certificate number of the product and a request for its transfer to another registered firm, which shall be identified with name, and registration and authorization number (if appropriate).

11.3.4.2.- Letter of the firm to which the Use and Commercialization Certificate is transferred, referring to the Docket File of the product, stating the name and certificate number of said product, the acceptance for its transfer, and the ratification or rectification of the fantasy name with which it shall be commercialized.

11.3.4.3.- Draft printouts with the necessary amendments in the information on the manufacturer and any other corresponding data. Information on the Technical Director shall be optional.

11.3.4.4.- Debt free for both firms (optional).

11.4.- Application for Extension of a Registered Product Certificate.

This procedure can only be performed between two registered firms. The following documents shall be presented:

11.4.1.- Letter of the current holder of the Use and Commercialization Certificate referred to the Docket File of the product, stating name and certificate number of the product and a request for the extension of the Use and Commercialization Certificate in favor of the other registered firm, identified by its name and registration number.

11.4.2.- Letter of the registered firm accepting the requested extension, referred to the Docket File of the product, stating the fantasy name with which it shall be commercialized.

11.4.3.- Draft printouts stating all the information indicated in the printout of the original product, modifying only the following information:

11.4.3.1.- The new name.

11.4.3.2.- Information on the new distributor.

11.4.3.3.- The caption “Certificate No.” shall be replaced by “Extension of Certificate No.”.

11.5.- Certificate for Product Registration: It is granted when a product is registered but not commercialized within the country. It is issued with the purpose of being submitted to third countries and according to the procedure stated in numeral 14.3 for requesting the Free Sale Certificate.

11.6.- Monograph certification: It is granted in order to certify all or some of the stages of the manufacturing process and any other characteristic of the product to be presented in third countries. In order to apply for this, the firm shall present a letter signed by the agent or by the Technical Director of the Product. letter note shall inform certificate number, Docket file number, and the detail of the product to be certified.

12. LABELS AND CONTAINERS OF THE PRODUCTS

12.1.- Condition of containers. Products commercialized in containers shall be prepared in containers of first use, perfectly clean, dry, labeled and closed in such a way that their inviolability is ensured.

12.2.- Container material. Containers shall be manufactured with materials that maintain the organoleptic properties of the product, that protect such product from humidity and that prevent its modification without evidences of it.

12.3.- Out-of-use containers: Out-of-use containers and packaging materials shall be immediately withdrawn from the stock and such activity shall be duly registered by means of auditable records.

12.4.- Label language: The information stated in the label can be written in other languages different from Spanish.

12.5.- Denominating ingredient: It constitutes the product in such a proportion that it is included in the commercial name. Internationally recognized standards are referenced with the purpose of its assessment (AAFCO, FDA, CFR, NRC, USDA).

12.6.- Product for export: The information stated in the label of the product that is exported but not commercialized in the country can be written on the container only in the language of the destination country. The project of the label in Spanish shall be presented in the registration file of the product. The label in the language of the destination country shall match the project of the approved Spanish label.

12.7.- Small containers: Cans and small containers prepared in boxes shall indicate at least product denomination, series or batch number, expiry date, registration number of the product, owner of the product and authorization number of the manufacturing establishment.

12.7.1.- Container box: A leaflet stating the information of the complete and approved label shall be attached to container boxes.

12.8.- Advertising: No advertisement or product name that lead the buyer to a misinterpretation of the benefits of the product shall be stated in the label.

12.9.- Captions on containers.

12.9.1.- Labels: Labels shall be in accordance with the approved set of printouts, it shall be firmly attached to the package and they shall state, at least, the following information:

12.9.1.1.- Name and registration number of the owner of the product.

12.9.1.2.- SENASA registration number of the product.

12.9.1.3.- Authorization number(s) of the manufacturing establishment(s).

12.9.1.4.- Registered trademark of the product: If any, the intention to incorporate it to the commercial name in the draft label shall be expressly indicated. Should this happen, the trademark shall compose the commercial name and it shall be incorporated to it by the responsible firm. Should said intention not be expressly stated, the commercial name shall be conformed without the registered trademark.

12.9.1.5.- Commercial name.

12.9.1.6.- Feedstuff classification granted by the Registry of Products.

12.9.1.7.- Species and categories for which it is intended.

12.9.1.8.- .Full list of possible ingredients.

12.9.1.9.- Indication of assurance levels (centesimal composition, active ingredient, etc.).

12.9.1.10.- Instructions for use.

12.9.1.11.- Manufacture date and suitability period and/or expiry date.

12.9.1.12.- Product for animal feed only.

12.9.1.13.- Argentine industry or manufacturing country.

12.9.1.14.- Number of batch, series or item.

12.9.1.15.- Preservation conditions for the product.

12.9.1.16.- Restrictions, side-effects, precautions, warnings and withdrawal or pre-slaughter period, if appropriate.

12.9.1.17.- Net weight expressed in kilograms (kg) for products prepared in containers weighting ONE (1) kilogram or more and in grams (g) for products weighting less than ONE (1) kilogram. For liquid products both weight and volume units are accepted.

12.9.1.18.- Caption for export. For export-only products, the following caption shall be compulsorily added in Spanish: “Export-only

product" or "Product registered to be exclusively commercialized outside the Argentine territory".

12.9.1.19.- SENASA logo.

12.9.1.20.- Caption for ruminants. Products containing proteins of animal origin that are commercialized as such, as well as supplements that contain them as ingredients, intended for non-ruminant species feeding shall compulsorily state the following highlighted caption "BANNED FOR FEEDING CATTLE, SHEEP, GOATS OR OTHER RUMINANTS".

12.9.1.21.- Ingredient denomination. Ingredients shall be stated in the label with common or usual names and in decreasing order of quantity intervening in the final product. When appropriate, the active ingredients shall be stated instead of its commercial name.

12.10.- Layout of information for the purposes of official control. The information referred in numerals 12.9.1.1; 12.9.1.2; 12.9.1.3; 12.9.1.5; 12.9.1.6; 12.9.1.7; 12.9.1.8 and 12.9.1.19 shall be visibly presented in a box with a white background and black letters in a legible size.

12.10. 1.- Non-compulsory information. Any added technical information that is not compulsory and that the firm wishes to incorporate to the label shall be incorporated in such a way that it is part neither of the centesimal composition nor of the list of ingredients.

12.10.2.- Labels of products in bulk

The label of the products in bulk corresponds to the set of printouts of the label approved in the Docket file.

13.- PRODUCT ASSURANCES

13.1.- Specifications. Every product registered with the Registry for Products shall have full specifications for assurance levels.

13.2.- Composition. Composition or nutritional assurance levels shall conform to formulation approved by the Registry of Products.

13.2.1.- In case of a feedstuff containing a drug, the amount expressed as concentration of active ingredient provided by the veterinary product shall be listed in the composition stated in the label.

13.3.- Indicating assurance levels. Products shall obligatory indicate ―either on a wet basis or as they are presented— the percentages of the following assurance levels:

CRUDE PROTEIN..... (MINIMUM)
CRUDE FIBER……. (MAXIMUM)
ETHER EXTRACT…….. (MINIMUM)
HUMIDITY..... (MAXIMUM)
TOTAL ASHES AND MINERALS..... (MAXIMUM)
CALCIUM..... ……. (MINIMUM AND MAXIMUM)
PHOSPHORUS..... (MINIMUM AND MAXIMUM)

13.3.1.- For additives, processing aids, supplements, vitamin and/or mineral nuclei the percentage of product constituents shall be listed, in decreasing order, indicating the purity of each one of them.

13.3.2.- Digestible and/or metabolizable energy expressed in kilocalories/kilograms of total digestible nutrients (TDN), acid detergent fiber (ADF) and/or neutral detergent fiber (NDF) can be included in assurance levels.

13.3.3.- Products containing non-protein nitrogen shall include its maximum percentage in their assurance levels.

13.3.4.- For products containing crude protein assurance, added non-protein nitrogen (NPN) shall be indicated in the maximum protein equivalent.

13.3.5.- Other intended products shall indicate nutritional assurance levels of their active ingredients per kilogram, complying with the following specifications:

13.3.5.1.- Mineral macroelements: expressed in grams (g).

13.3.5.2.- Mineral microelements: expressed in milligrams (mg).

13.3.5.3.- Vitamins A and D: expressed in International Units (IU).

13.3.5.4.- Vitamin B12: expressed in micrograms.

13.3.5.5.- Vitamin E: expressed in milligrams (mg).

13.3.5.6.- Choline: expressed in grams (g).

13.3.5.7.- Other vitamins: expressed in milligrams (mg) or in International Units (IU).

13.3.5.8.- Amino acids as ingredients: expressed in percentage (%).

13.3.5.9.- Methionine and lysine: expressed in grams (g).

13.3.5.10.- The remaining amino acids expressed in milligrams (mg).

14.- PRODUCT COMMERCIALIZATION

14.1.- Use and Commercialization Certificate. Product commercialization shall be determined by the approval of the product by means of the corresponding administrative act and submission of the Use and Commercialization Certificate.

14.2.- Imported products. If a registered firm wishes to commercialize within national territory imported products intended for animal feed, such products shall be registered and shall comply with the same requirements and conditions established for national products.

14.2.1.- Exemption from registration. Samples without commercial value. Products imported as samples without commercial value are exempted from registration; nevertheless, they shall comply with conditions stated in this Technical Standard.

14.3.- Free Sale Certificate. Together with the corresponding application for registration and the original container, the “Free Sale Certificate for Products Intended for Animal Feed” shall be submitted, issued by the competent official body of the country of origin, either in Spanish or translated by a Sworn Translator and certified by Apostille or legalized by the Consulate, as appropriate.

15.- EXPORTS AND IMPORTS OF PRODUCTS

15.1.- General provisions. Every export and import of products intended for animal feed shall comply with both procedures provided for in numeral 15 and current standards on this subject. Any situation not mentioned by this numeral shall be consulted with SENASA.

15.2.- Commercial certifications. SENASA does not issue health documents requested to comply with trade patterns established between private entities.

15.3.- Exports

15.3.1.- Requirements. The applicant firm shall comply with requirements established by SENASA Resolution No. 492, of November 6, 2001, and with this Technical Standard. The manufacturing establishment shall comply with requirements provided for in this Technical Standard.

15.3.2.- Export procedure for registered products, non-registered products and samples.

15.3.2.1.- Notice of Departure. In the light of a Notice of Departure, the following documents shall be presented to the Registry for Products:

15.3.2.1.1.- A letter requesting the export of the products.

15.3.2.1.2.- "Notice of Departure. Authorization to Export." (Available on SENASA website.) It shall be duly filled out and signed either by the responsible individual or by the agent of the importing firm, in accordance with the Guide of Procedures approved by means of SENASA Resolution No. 206/2014.

15.3.2.1.3.- Proforma invoice.

15.3.2.2.- Comments. Should a comment be made, SENASA shall communicate it to the interested party for it to respond.

15.3.2.3.- Free Sale Certificate. Firms that wish to obtain a free sale certificate shall submit a duly filled out "Free Sale Certificate for Products Intended for Animal Feed" (that is available on

SENASA website). Its viability shall be verified by the Registry of Products and, if appropriate, it shall be issued.

15.3.2.4.- Obligatory nature of the Notice of Departure. The free sale certificate does not replace the notice of departure, which is obligatory to obtain authorization to export.

15.3.2.5.- Export-only products. Information stated in the label of products that are exported and not commercialized within the country can be written on the container, only in the language of the destination country.

15.3.2.6.- Draft label. The draft label approved in Spanish shall be attached to the documents supporting the consignment.

15.3.3.- Exports of products exclusively of plant origin.

15.3.3.1.- Requirements. In order to export products exclusively of plant origin, numeral 15.3.2 of this Technical Standard shall be complied with, as well as SENASA Resolution No. 260/2014 (by means of the computer system SIGFITO and the Official Health Certificate ―OHC—when appropriate) and any other standard establishing specific procedures for products or raw materials of plant origin. Moreover, demands established by the Health Authority of the destination country shall also be complied with.

15.3.3.2.- Description of constituents. For the purposes of export certification, the exporter shall submit a Sworn Statement signed by the agent of the firm responsible for the manufacturing establishment or by its Technical Director, describing the proportion of the constituents of the product that are of plant origin, and assuring that such composition complies with the nutritional levels approved for that product.

15.3.4.- Export of products intended for animal feed containing constituents of animal origin.

15.3.4.1.- Requirements. In order to export products containing constituents of animal origin, the procedure established by the DNICA Directorate for International Movement of Goods and Animals shall be complied with, in accordance with the Final Procedure Manual for Export and with any other standard establishing specific procedures for products or raw materials of animal origin, as well as with demands of the Health Authority of the destination country.

15.3.4.2.- Official Health Certificate for country status or animal health status. The country status certificate accredits the animal health status regarding certain diseases of animal origin. It is issued only upon official request of the Health Authority of the destination country. The country status certificate is issued by means of Certification Offices, according to current standards.

15.4.- Imports.

15.4.1.- Prior authorization. If products contain products or by-products of animal or plant origin (without processing) which import requires prior authorization, the requesting firm shall comply with requirements established by SENASA Resolutions No. 492 of November 6, 2001, and No. 816 of October 4, 2002, and with any other applicable standards.

15.4.1.1.- Import procedure for registered products.

For every request for import, the following documents shall be presented to the Registry of Products:

15.4.1.1.1.-A letter requesting the import of products.

15.4.1.1.2.- A “Notice of Import Arrival” (available on SENASA website) duly filled out and signed either by the individual responsible for the importing firm or by its agent.

15.4.1.1.3.- A Free Sale Certificate of the country of origin issued by the competent official health authority, containing the qualitative and quantitative composition and ingredients. Said certificate shall be considered as valid for FIVE (5) years from the registration date of the product. After such period, a new certificate shall be presented.

15.4.1.1.4.- Proforma invoice.

15.4.1.2. New Free Sale Certificate of the country of origin. After FIVE (5) years of the registration of the imported product, a new Free Sale Certificate of the country of origin shall be submitted in order to continue importing such product.

15.4.2.- Non-registered products. Samples without commercial value. The import of products intended for animal feed that are not registered in the ARGENTINE REPUBLIC may be authorized at the request of a legal individual or entity registered with the corresponding National Registry, as samples without commercial value and for the purposes of being used in experimental trials or for laboratory testing.

15.4.2.1.- Import procedure for samples without commercial value.

For every request for import, the following documents shall be submitted to the Registry of Products:

15.4.2.1.1.- A Free Sale Certificate of the country of origin signed by the competent official health authority, containing the qualitative and quantitative composition and ingredients; or

15.4.2.1.2.- a Manufacture Certificate signed by the competent official authority, stating the qualitative and quantitative formulation and the ingredients of the product; and

15.4.2.1.3.- a Sworn Statement signed by the individual responsible for the firm, stating the amount of product, the purpose of the sample, the warehouse location and the disposal of remnants.

15.4.2.1.4.- Should samples enter intended for animal testing, a Sworn Statement signed by the individual responsible for the test shall also be presented, stating testing place, amount of animals, daily consumption and final purpose of the animals used in such test.

15.4.3.- Import without right to use.

15.4.3.1.- Upon labeling mistakes without health implications, the DHIPOVyP can authorize the import of products without right to use as interdicted products.

15.4.3.2.- The following documents shall be presented to the DHIPOVyP:

A letter as a sworn statement stating type and amount of product to be imported, final purpose of such product and warehouse location. Said letter shall be signed by the agent of the importing firm, who shall be the legal depositary of the stated product and who shall bear the responsibilities granted as such according to the provisions of Sections 254, 255 and 263 of the Criminal Code. This shall be expressly stated in the interdiction record.

15.4.3.3.- The DHIPOVyP shall both establish safeguard measures and conduct the procedure with the purpose of verifying the interdicted status and, if appropriate, the final arrangements for the products.

15.4.4.- Products containing constituents of animal origin. Firms importing products and samples of products containing constituents of animal origin shall comply with SENASA Resolutions No. 238/01 and No. 816/02.

15.4.5.- Quarantine. Upon entry, the firm shall submit to the DTI, if appropriate, the documents required by SENASA Directorate for Quarantine Standards of the National Directorate for Animal Health.

15.4.6.- Milk and imported milk replacers intended for animal feed.

15.4.6.1.- Milk and imported milk replacers intended for animal feed shall have a free sale certificate or a manufacture certificate of the country of origin, stating the coloring substance that complies with the provisions of numeral 9.1.3 and which can be identified by means of an internationally recognized code. The submission of such certificate is essential for registering and authorizing the aforementioned products.

15.4.6.2.- Milk and imported milk replacers shall be labeled in Spanish, stating its name, chemical composition and/or the appropriate chemical analysis, origin, manufacture date, use and use restrictions.

15.4.7.- Inspections at establishments of origin.

SENASA may arrange inspection visits on the manufacturing establishment whenever it considers that health, safety or risk circumstances merit so.

SPECIFIC METHODS FOR THE PRODUCTION OF FEEDSTUFF

16.- MANUFACTURING, FRACTIONING AND STORAGE IN THIRD-PARTY ESTABLISHMENTS

16.1.- Responsibilities. The firm ordering the performance of activities in third-party establishments and the firm in charge of the establishment where the activities are performed are jointly and severally liable for the compliance with this Technical Standard regarding activities under their control.

16.2.- Registration procedure.

16.2.1.- Required documents. The firm requesting the manufacture in third-party establishments shall submit, together with other required documents, the

Document for Manufacturing in a Third-Party Establishment (which is available on SENASA website), in quadruplicate. Such document shall be signed by the legal representative or agent of the applicant firm and by the legal representative or agent of the firm responsible for the establishment where products are manufactured.

16.3.-Registration act. Upon submission of documents, SENASA shall analyze the information provided and, should it be satisfactory, it shall issue the corresponding document for the registration of the firm with the National Registry of Firms and Establishments Manufacturing Feedstuff as third-party manufacturer.

17. PRODUCTS MANUFACTURED ON DEMAND.

17.1.- Products manufactured on demand. Definition. Products manufactured on demand are products manufactured at an authorized establishment on specific demand of a producer or registered firm.

17.1.1.- Prohibition. Products manufactured on demand can be neither commercialized nor donated.

17.2.- Exception. On-demand products are not manufactured permanently but exceptionally and in limited volumes due to specific nutritional and seasonal reasons.

17.3.- Manufacture ordered by a Producer.

17.3.1.- Ordering Producer. The producer ordering the manufacture shall be registered with RENSPA, according to the provisions of SENASA Resolution No. 423/2014.

17.3.2.- Intended purpose of the product. The product ordered by the Producer can only be used to feed animals under the responsibility of said producer.

17.3.3.- Used as ingredient of other commercial products. Products ordered by a producer cannot be used as ingredients for the manufacture of other commercialized products or products intended to be commercialized.

17.4.- Manufacture ordered by a firm.

17.4.1.- Ordering firm. The firm requesting the product on demand shall be registered in the registries established in this Technical Standard.

17.4.2.- Intended purpose of the product. The product ordered by the firm can only be used as an ingredient of a registered product.

17.4.3.- Used as ingredients of other on-demand products. The product manufactured on demand for the ordering firm shall not be an ingredient in other product manufactured on demand.

17.5.- Establishments manufacturing on-demand products.

17.5.1.- Registration and authorization. The establishment manufacturing products on demand shall be registered and authorized in accordance with the provisions of this Technical Standard. It shall be authorized to manufacture for the requested species as well.

17.5.2.- Commercialization with the requestor. The establishment manufacturing a product on demand shall commercialize it only with the requestor.

17.5.3.- Manufacture of the product ordered on demand in third-party establishments. The firm to which the on-demand product is ordered can order its manufacture to another establishment, in compliance with numeral 16 of this Technical Standard.

17.6.- Registration and authorization of products ordered on demand. Products ordered on demand are not required to be registered with the National Registry of Products for Animal Feed.

17.7. Veterinary drug products. Should the ordered product contain veterinary products, they shall be approved by and registered with SENASA. They shall be used in accordance with indications stated in the label of such veterinary product. The order shall be prescribed by the veterinary doctor. Usage restrictions and indications shall be transcribed in the “Document for On-Demand Manufacture” and their use shall comply with current standards on the matter.

17.8.- Procedure for manufacturing products on demand.

17.8.1.- Order. The requestor shall submit the Order for On-demand Products (which is available on SENASA website) to the manufacturing establishment.

17.8.3.1.- Ordering producer. Should the manufacture be ordered by a producer, the order shall be signed by the producer and by the professional responsible for the nutrition and health of the animals of the requestor. Should the ordered product contain veterinary products, such order shall be signed by a veterinary doctor.

17.8.3.2.- Ordering firm. Should the manufacture be ordered by a firm, the order shall be signed by the Technical Director of the Establishment under responsibility of such firm.

17.8.3.- Manufacture according to order. The establishment shall manufacture the product according to what is stated in the Order for On-Demand Products.

17.8.4.- Document for manufacturing products on demand. Codes. For each manufacture on demand, the firm responsible for the establishment shall print the "Document for On-Demand Manufacture" (which is available on SENASA website). On such document, an alphanumeric code with the following format shall be printed: NNNNN/LL/AAAA/MM/DD/XXXXX; in which NNNNN is the establishment's official number, LL are the letters included in said number, AAAA is the manufacturing year, MM is the manufacturing month, DD is the manufacturing day and XXXXX is a serial number that shall start in 00001.

The document shall be filled in with specific information stated in the order, and both documents shall be filed jointly.

17.8.5.- Computer system. SENASA may implement a computer system for the preparation of the Manufacturing Document with the corresponding identification number, and for the obligatory implementation and compliance by the firms and establishments.

17.8.6.- Signing of the document. The "Document for On-Demand Manufacture" shall be complied with and it shall be signed by the Technical Director of the manufacturing establishment with the validity of a Sworn Statement.

17.8.7.- Amount of documents to be issued. The Document shall be issued in duplicate. The original document shall be submitted to the manufacturing establishment and the duplicate to the requestor.

17.9.- Document file. Documents related with the manufacture of products on demand shall be filed in the manufacturing establishment for TWO (2) years and they shall be available at the request of SENASA.

17.10.- Prohibition to manufacture without the Document. It is hereby prohibited to manufacture on demand without the corresponding "Document for On-Demand Manufacture" (which is available on SENASA website), duly drafted, and with the corresponding alphanumeric code for current authorization. The document without the corresponding alphanumeric code shall be fit for neither authorizing nor supporting the on-demand manufacture.

18.- INTEGRATING MANUFACTURERS AND MANUFACTURERS OF FEED FOR ON-FARM CONSUMPTION

18.1.- INTEGRATING MANUFACTURERS

18.1.1.- Integrating establishments. Integrating establishments are not considered to be manufacturers of feed for on-farm consumption.

18.1.2.- Registration and authorization. Integrating establishments shall be registered and authorized in accordance with numeral 4. They shall also have a Technical Director of the Establishment, as provided for in numeral 1.9.1.

18.1.3.- Products.

18.1.3.1.- Registration. Products manufactured by integrating establishments shall not be registered with the National Registry of Products for Animal Feed.

18.1.3.2.- Feedstuff destination. The manufactured feedstuff shall only be delivered to an integrated facility to be consumed by animals in such facility that are owned or that are under responsibility of the integrator.

18.1.3.3.- Commercialization. Donation. The feedstuff produced by the integrator can be neither commercialized nor donated.

18.1.4.- Feedstuff movement. The feedstuff can only be moved to another integrated facility to be consumed only by animals of that facility.

18.1.4.1.- Feedstuff movement. The movement of feedstuff manufactured by integrators shall be covered by a delivery note stating the following information: “Movement document for feed for on-farm consumption”, which is available on SENASA website.

18.1.5.- Integrated facilities. The integrator shall keep an auditable and updated record of integrated facilities. Said record shall be available at the request of SENASA.

18.1.6.- Responsibility. Integrators are responsible for complying with and for implementing the provisions of numeral 18.1. They are also responsible for hygienic and sanitary conditions of the products that they manufacture.

18.1.7.- Ingredients. Industrialized and processed ingredients, including nuclei, vitamins, minerals and additives, as well as therapeutic products used by integrators shall be registered with and approved by SENASA, or other official competent body (except for on-demand products, which shall comply with numeral 17).

18.1.8.- Traceability and tracking. Integrators shall ensure the traceability and tracking of products manufactured by them. The origin of raw materials shall be registered and production batches shall be identified, as well as product destination. All the activities shall be duly registered so as to be verified by SENASA.

18.1.9.- GOOD MANUFACTURING PRACTICES FOR INTEGRATING ESTABLISHMENTS

18.1.9.1.- Purpose. The purpose of this guidance is to establish hygiene and safety conditions for products manufactured in integrating establishments.

18.1.9.2.- Ingredients. Industrialized and processed ingredients, including nuclei, vitamins, minerals and additives, as well as veterinary products used shall be registered with and approved by SENASA, or other official competent body.

18.1.9.3.- Raw materials of plant origin.

18.1.9.3.1.- Industrialized. Industrialized raw materials of plant origin shall originate in establishments authorized by SENASA.

18.1.9.3.2.- Non-industrialized. Should they directly proceed from agricultural producers, they shall be registered in RENSPA. Registration shall be accredited by means of the appropriate commercial documents (delivery note, bill of lading, etc.) or otherwise evidence of said registration shall be demanded. Documents shall be filed for TWO (2) years.

18.1.9.4.- Adding Veterinary Products to Feedstuff. Veterinary products administered with feedstuff shall be approved by and registered with SENASA; their use shall be adjusted to what is stated in their labels or instructions for use. Whenever specific instructions for administration and/or a withdrawal period for use prior to slaughter are required, the staff administering feedstuff shall be duly notified.

18.1.9.4.1.- Particular attention shall be paid to the veterinary product’s restriction period for use prior to the slaughter of the animal(s) that consumed it. The dates of last feeding and delivery for slaughter shall be clearly registered.

18.1.9.4.2.- Drugs shall remain closed, identified and isolated, and their access shall be restricted to authorized staff.

18.1.9.5.- Facilities, Equipment and Components for Manufacture.

18.1.9.5.1.- Facilities, equipment and components shall be regularly cleaned, preventing the accumulation of dust, dirt, feed or raw materials spilled on floors within the building and around it, over the machines, on the ceilings, walls, roof structures, holes and projections.

18.1.9.5.2.- There shall be adequate ventilation.

18.1.9.5.3.- Residues of raw materials and ingredients produced during manufacture shall be daily removed from the manufacture site.

18.1.9.6.- Storage

18.1.9.6.1.- Raw materials, ingredients and finished feedstuff stored either packed or in bulk shall be adequately identified and separated.

18.1.9.6.2.- Adequate containers shall be used allowing the reduction of physical, chemical and biological contamination risks to a minimum.

18.1.9.6.3.- Bags. The storing area for bagged material shall be big enough so as to allow adequate separation between various materials and stock rotation.

18.1.9.7.- Pest control. In order to avoid pests, particularly birds, rodents and insects, adequate treatments and controls shall be performed. These tasks may be performed by own staff, supervised by a responsible professional, or by hired external staff.

18.1.9.8.- Grinding Machines / Mixers.

18.1.9.8.1.- Weighing scales shall be regularly maintained and controlled by means of auditable records.

18.1.9.8.2.- Machines shall be maintained by means of a preventive program for lubricating and registering

breakages so as to perform timely technical service.

18.1.9.8.3.- Equipment or machines that can be easily washed or cleaned shall be used in order to avoid cross-contamination.

18.1.9.8.4.- According to the type of food to be manufactured, adequate equipment for dust extraction and/or sieves shall be available for removing foreign material (for example: non-ferrous material).

18.1.9.9.- Staff manufacturing feedstuff

18.1.9.9.1.- All the staff involved in the manufacture, storage and handling of fodder and feed ingredients shall be duly trained and shall be aware of their role and responsibility regarding food safety.

18.1.9.9.2.- Workers shall know and apply Good Manufacturing Practices.

18.1.9.10.- Handling of raw materials

18.1.9.10.1.- Records on origin, receipt dates and batch identification and quantities of all the raw materials used shall be kept.

18.1.9.10.2.- Safety and quality instructions for each raw material used shall be submitted to suppliers, regarding used raw materials with such specifications.

18.1.9.10.3.- Raw materials shall be assessed at the moment of delivery, before unloading, with the purpose of avoiding re-loading in case of rejection.

18.1.9.10.4.- Before unloading, a quick visual, olfactory and physical examination shall be performed on raw

materials so as to observe contaminants such as insects or odors.

18.1.9.10.5.-Raw materials sampled at entry and pending quality control results shall be identified, so as to avoid their use before approval.

18.1.9.10.6.- Rejected and duly identified raw materials shall be immediately returned to the supplier.

18.1.9.11.- Feed formulation

18.1.9.11.1.- The Technical Director of the Establishment is responsible for the safety and quality of the manufactured product.

18.1.9.11.2.- Each manufactured feedstuff shall display its written formula, clearly indicating ingredients and quantitative relationships.

18.1.9.11.3.- Feedstuff formulae shall be kept filed at the manufacturing establishment for TWO (2) years.

18.1.9.12.- Mixing. Products shall be mixed in such a way that contamination possibilities are minimized between products or ingredients that may affect their safety.

18.1.9.13.- Records for Manufactured Products

18.1.9.13.1.- Records on manufacture procedures for products shall be kept.

18.1.9.13.2.- Records on product manufacture shall be kept per formula, identifying animal species and category.

18.1.9.13.3.- A record shall be kept on which animal species and category receives each manufactured feed and the time during which said feed was administered.

18.2.- MANUFACTURERS OF FEED FOR ON-FARM CONSUMPTION

18.2.1.- Feedstuff manufacture and destination. Feed for on-farm consumption shall be manufactured in the same establishment where all the animals, or some, for which the feed is intended are.

18.2.2.- Prohibition to commercialize. The feed for on-farm consumption can be neither commercialized nor donated.

18.2.3.- Feedstuff movement. Feedstuff can only be moved to another establishment manufacturing feed for on-farm consumption to be consumed only by animals under responsibility of said establishment.

18.2.4.- Animals fit for consuming said feedstuff. Said feedstuff can only be administered for consumption to animals under responsibility of the manufacturer of feed for on-farm consumption.

18.2.5.- Responsibility. Manufacturers of feed for on-farm consumption are responsible for complying with and for implementing the provisions of this numeral 18. They are also responsible for hygiene and health conditions of the products that they manufacture.

18.2.6.- Identification in RENSPA. Manufacturers of feed for on-farm consumption are compelled to state before SIGSA whether they manufacture all or a part of the feed that they administer to their animals.

18.2.7.- Feedstuff movement. The movement of feed for on-farm consumption shall be covered by the “Movement Document for Feed for On-Farm Consumption”, which is available on SENASA website.

18.2.8.- Ingredients. Industrialized and processed ingredients, including nuclei, vitamins, minerals and additives, as well as therapeutic products used, shall be registered with and approved by SENASA, or other official competent body, except for on-demand products, which shall comply with numeral 17.

18.2.9.- Traceability and tracking. Manufacturers of feed for on-farm consumption shall ensure the traceability and tracking of products manufactured by them. The origin of raw materials shall be registered and production

batches shall be identified, as well as product destination. All the activities shall be duly registered so as to be verified by SENASA.

18.2.10.- Good Manufacturing Practices for Establishments Manufacturing Feed for On-Farm Consumption. Obligatory nature. The Guidance for Good Manufacturing Practices established in numeral 18.2.11 is obligatory for establishments manufacturing feed for on-farm consumption. Said guidance shall be implemented according to the specific features of each establishment.

18.2.11.- GOOD MANUFACTURING PRACTICES GUIDANCE FOR ESTABLISHMENTS MANUFACTURING FEED FOR ON-FARM CONSUMPTION

18.2.11.1.- Purpose. The purpose of this guidance is to establish hygiene and safety conditions for products manufactured for on-farm consumption.

18.2.11.2.- Raw materials

18.2.11.2.1.- Raw materials of plant origin

18.2.11.2.1.1.- Industrialized. Industrialized raw materials of plant origin shall both originate from establishments authorized by SENASA and comply with this standard as well.

18.2.11.2.1.2.- Non-industrialized. Should they directly proceed from agricultural producers, they shall be registered in RENSPA. Registration shall be accredited by means of the appropriate commercial documents (deliv-

ery note, bill of lading, etc.) or otherwise evidence of said registration shall be demanded. Documents shall be kept filed for TWO (2) years.

18.2.11.2.2.- Raw materials of animal origin. Raw materials of animal origin shall both originate in establishments authorized by SENASA and comply with this standard.

18.2.11.3.- Adding Veterinary Products to Feedstuff. Veterinary products administered with feedstuff shall be approved by and registered with SENASA; their use shall be adjusted to what is stated in their labels or instructions for use. Whenever specific instructions for administration and/or a withdrawal period for use prior to slaughter are required, the staff administering feedstuff shall be duly notified.

18.2.11.3.1.- Particular attention shall be paid to the product's withdrawal period for use prior to the slaughter of the animal(s) that consumed it. The dates of last feeding and delivery for slaughter shall be clearly registered.

18.2.11.3.2.- Drugs shall remain closed, identified and isolated, and access to them shall be restricted to authorized staff.

18.2.11.4.- Application of Veterinary Products. Upon application and use of veterinary products on feed manufactured for on-farm consumption, the Book for Treatments of Livestock Establishments Producing Animals for Human Consumption shall be implemented, laid down in SENASA Resolution No. 666 of September 2, 2011.

18.2.11.5.- Feed for Ruminants (cattle, sheep, goat and others). Feed for ruminants shall be manufactured in accordance with numeral 19 of this Technical Standard.

18.2.11.6.- Facilities, Equipment and Components for Manufacture.

18.2.11.6.1.- Permanent facilities.

18.2.11.6.1.1.- Facilities, equipment and components shall be regularly cleaned, preventing the accumulation of dust, dirt, feed or raw materials spilled on floors within the building and around it, over machines, on the ceilings, walls, roof structures, holes and projections.

18.2.11.6.1.2.- Raw materials shall be separated from fertilizers and phytosanitary products, veterinary products, fuels, lubricants and cleaning products.

18.2.11.6.1.3.- Operations continuity shall be ensured in case of rain.

18.2.11.6.1.4.- Facilities shall be adequately ventilated.

18.2.11.6.1.5.- There shall be no animals at the manufacturing site, warehouse and loading and unloading areas.

18.2.11.6.1.6.- Residues of raw materials and ingredients produced during manufacture shall be daily

withdrawn from the manufacture site.

18.2.11.6.2.- Mobile facilities

18.2.11.6.2.1.- Equipment and components shall be regularly cleaned, preventing the accumulation of dust, dirt, feed or raw materials spilled around the machines.

18.2.11.7.- Storage

18.2.11.7.1.- Raw materials, ingredients and finished feedstuff stored either packed or in bulk shall be separated from other ingredients and finished feedstuff, identified and protected from severe weather.

18.2.11.7.2.- Measures shall be implemented, allowing to reduce the risk of physical, chemical and biological contamination to a minimum.

18.2.11.7.3.- Bags. The storing area for bagged material shall be big enough so as to allow adequate separation between various materials and stock rotation. It shall be performed on the basis of “first in, first out”; this is achieved by labeling batches or by means of numerated bags of which records shall be kept.

18.2.11.8.- Pest control. In order to avoid pests, particularly birds, rodents and insects, adequate treatments and controls shall be performed. These tasks may be performed by own staff, supervised by a responsible professional, or by outsourced staff.

18.2.11.9.- Grinding Machines / Mixers

18.2.11.9.1.- Machines used shall be fit for that purpose, paying attention to manufacturer recommendations on operating capacity, methods and time.

18.2.11.9.2.- Weighing scales shall be regularly maintained and controlled by means of auditable records.

18.2.11.9.3.- Machines shall be maintained by means of a preventive program for lubricating, registering breakages, etc., so as to perform timely technical service.

18.2.11.9.4.- The equipment and machines used shall be easy to wash or clean so as to avoid cross-contamination.

18.2.11.10.- Workers manufacturing feedstuff

18.2.11.10.1.- All the staff involved in the manufacture, storage and handling of fodder and feed ingredients shall be duly trained and shall be aware of their role and responsibility regarding food safety.

18.2.11.10.2.- Workers shall know and apply Good Manufacturing Practices.

18.2.11.11.- Handling of raw materials

18.2.11.11.1.- General provisions

18.2.11.11.2.- A “Receipt Record” shall be kept for all the raw materials used. It shall state origin, receipt date, description of the ingredient and batch amount and identification.

18.2.11.11.3.- Raw materials shall be assessed at the moment of delivery, before unloading, with the purpose of avoiding re-loading in case of rejection.

18.2.11.11.4.- Before unloading, a quick visual, olfactory and physical examination shall be performed on raw materials so as to observe contaminants such as insects or odors.

18.2.11.12.- Mixing

Products shall be mixed in such a way that contamination possibilities are minimized, achieving a homogeneous product.

18.2.11.13.- Records for Manufactured Products. Records on product manufacture procedures shall be kept.

19.- FEED FOR RUMINANTS. GENERAL PROVISIONS FOR FEED FOR RUMINANTS

19.1.- Prohibition. The use of proteins of animal origin is hereby prohibited throughout the National Territory, either as sole ingredient or mixed with other products for administration with feeding or supplementary purposes for ruminants.

19.2.- Definition. For the purposes of this Technical Standard, “prohibited proteins of animal origin” are meat-and-bone meal, meat meal, bone meal, blood meal, dried plasma or other blood derivatives, organ meal, hoof meal, horn meal, dried greaves, debris meal or poultry offal meal or other derivatives, and any other product containing such meals.

19.2.1.- Poultry litter. The use of poultry litter and/or debris resulting from poultry breeding is hereby prohibited in animal feed throughout all the National Territory.

19.3.- Exemptions. Dairy proteins, fish meal, egg meal and feather meal in which the absence of proteins that are not inherent to the product is ensured by means of analytical techniques recognized by SENASA and of auditable documents shall be exempted from the prohibition stated in numeral 19.1.

19.4.- Bone ashes. Bone ashes manufactured in accordance with procedures authorized by SENASA, in which the absence of total proteins is ensured and verifiable by means of analytical techniques recognized by such Service and of auditable documents are hereby authorized as supplement for ruminant feed, as supply of minerals of animal origin (phosphorus and calcium).

19.5.- Meal. Meal of animal origin, as well as bone ashes intended for animal feed can be commercialized only when they originate in manufacturing establishments authorized by SENASA.

19.6.- Authorizations. Manufacture procedures covered by the scope of this numeral 19, including meals of animal origin, shall be authorized by SENASA in accordance with current standards and with documents auditable by that Service.

19.7.- Transport. It is hereby prohibited to transport and commercialize in-bulk bone ashes, as well as meal containing proteins of animal origin as sole ingredient or mixed with other products. It is hereby established that they shall be commercialized only as a duly packaged and labeled finished product.

19.8.- Caption. Labels and delivery notes of containers of proteins of animal origin commercialized as such, as well as labels and delivery notes of feeds or supplements containing said proteins as ingredients, and which are intended for feeding

ruminant species shall obligatory state and highlight the following caption: "BANNED FOR FEEDING CATTLE, SHEEP, GOATS AND OTHER RUMINANTS." The following alternatives are accepted for imported products "BANNED FOR FEEDING RUMINANT ANIMALS" and "BANNED FOR RUMINANT FEED".

19.9.- Manufacturers of feed for on-farm consumption. Manufacturers of ruminant feed for on-farm consumption shall only use animal bone ashes, originating from establishments authorized by SENASA. The evidence supporting that such products originate in an establishment authorized by SENASA shall be filed for SEVEN (7) years.

19.10.- Analytical determinations. Official analytical determinations shall be performed at the Official Laboratory of the NATIONAL SERVICE FOR AGRI-FOOD HEALTH AND QUALITY or at third-party laboratories authorized by such National Service. This shall be performed under procedures established by SENASA Directorate for Laboratories and Technical Control.

19.11.- Self-controls. Manufacturing establishments covered by this Technical Standard, including manufacturers of bone ashes and ruminant feed, shall perform the analytical self-control of their products. This shall be done in order to ensure that such products do not contain banned proteins of animal origin. The self-control system and the amount of samples to be analyzed are suggested by the manufacturer and validated and audited by the NATIONAL SERVICE FOR AGRI-FOOD HEALTH AND QUALITY, according to the volume of production.

19.12.- Separated lines. The establishments shall have separated manufacture lines when using proteins banned for ruminants and manufacturing ruminant feed and non-ruminant feed.

19.13.- Exemption for separated lines. Those establishments stating that they do not use proteins banned by numeral 19.1 in the manufacture of their products are exempted from separating manufacture lines where such products are manufactured.

19.14.- Document file. The people responsible for establishments covered by this Technical Standard shall keep at the manufacturing establishment for SEVEN (7) years the list of products manufactured by them, with their corresponding monographs and labels. They shall also keep for said period the details of raw materials of animal origin and formulae used in feed and products manufactured on demand.

20.- PROCEDURES TO BE APPLIED UPON POSITIVE TEST RESULTS OF BANNED ANIMAL PROTEINS ON RUMINANT FEED

20.1.- Positive result. Whenever DILACOT notifies DHIPOVyP a positive or presumed positive result of banned animal proteins on feed intended for ruminants, it shall submit the original analysis protocol to DHIPOVyP of the National Directorate for Agri-Food Safety and Quality (DNICA). The corresponding Docket File shall be initiated and the aforementioned protocol and the original or authenticated copy of the Sample Collection Record shall be attached thereto.

20.1.1.- Notification to the TSE Program. Once the notification mentioned in item 20.1 is served, the DHIPOVyP shall notify SENASA DNSA Transmissible Spongiform Encephalopathies Program. A copy of such notification shall be added to the Docket File.

20.1.2.- Notification to DIPOA. Once the notification mentioned in numeral 20.1 is served, the DHIPOVyP shall notify, when appropriate, SENASA DNICA's DIPOA. A copy of such notification shall be added to the Docket File.

20.2.- Service order

The DHIPOVyP shall issue a service instruction for the Regional Thematic Coordinator who shall urgently order the movement of the staff to the establishment where the result test was detected, due to an alleged breach of numeral 19.1 and for the purposes of performing the corresponding actions according to the following procedure:

20.3.- Notifications

20.3.1.- The result of the analysis performed shall be notified to the individual of higher hierarchy responsible for the establishment (manager or plant manager, technical director, etc.) that is present at the moment of said notification.

Notification shall be performed by means of the corresponding Act of Notification / Intervention or interdiction expressly indicating that an alleged breach of numeral 19 has occurred. The responsible individual has the right to request the analysis of the counter sample in its possession, should it be of its interest.

The request for counter-sample analysis shall be issued within FIVE (5) working days from notification date. Should the request not be issued within such period, this Service shall confirm the positive test.

20.3.2.- The people responsible for the establishment shall be notified of the intervention of such establishment. From that moment on, the establishment shall enter an audit phase that implies monitoring and controlling the manufacturing process for feed and ingredients intended for ruminants.

Interdicted ruminant feed batches, or batches manufactured during the intervention period can only be commercialized upon negative results to tests of the analyses performed previously on such batches. The aforementioned analyses shall be performed at DILACOT.

20.3.3.- The manufacturing establishment shall be notified that, in accordance with numeral 20.3.2, finished feed intended for ruminants that are at the establishment at the moment of the notification shall remain preventively interdicted in said establishment, in accordance with MINAGRI Resolution No. 38/2012.

20.3.4.- The individual responsible for the establishment shall be notified. This individual shall notify within TEN (10) business days from the notification date the corresponding Regional Center Directorate of the disclaimers and evidences within his/her rights.

20.3.5.- Should counter samples analyses tested negative, the preventive measures adopted shall be withdrawn.

20.4.- Intervention procedure

20.4.1.- The intervention of the manufacturing establishment shall be performed drafting the corresponding acts.

20.4.2.- The acting SENASA officer shall collect FIVE (5) consecutive samples of ruminant feed manufactured during the intervention period of the establishment and from various batches.

20.4.3.- Samples shall be submitted to the official laboratory with the purpose of determining the compliance with numeral 19.

20.4.4.- Results shall be communicated by the official laboratory to DHIPOVyP. Should FIVE (5) consecutive negative tests results be obtained from new batches of manufactured products, the acting official shall lift the intervention of that establishment.

20.4.5.- The establishment can commercialize ruminant feed upon obtaining a negative test result from each batch monitored by the intervening officer.

20.5.- Interdiction procedure

20.5.1.- All ruminant feed and supplement either stored at the establishment or in process of manufacture shall be immediately identified and interdicted.

20.5.2.- In order to implement the interdiction, the Act of Notification/Intervention/Interdiction shall be used.

20.5.3.- The individual of higher hierarchy responsible for the establishment (manager or plant manager, technical director, etc.) that is present at the moment of the interdiction shall be legal depositary of the intervened products and shall bear the responsibilities stated in Sections 254, 255 and 263 of the Argentine Criminal Code.

20.5.4.- The name of the legal depositary and the responsibilities granted as such according to the provisions of Sections 254, 255 and 263 of the Argentine Criminal Code shall be expressly stated in the interdiction record.

20.5.5.- Should the positive test result be confirmed, the batch(es) involved shall be seized and destroyed. According to paragraph 20.6.5, the possibility of giving a different destination of use under official control of the products that tested positive can be assessed.

20.6.- Procedure for releasing batches interdicted and/or produced during intervention

20.6.1.- Before releasing the batch or consignment of interdicted feed, it shall be previously analyzed by SENASA laboratory or by other laboratory composing the Network of Laboratories authorized by this National Service. SENASA staff shall proceed to collect a sample from each identified feed batch, in accordance with "Procedure PG7" established by former-SAGPyA Resolution No. 370 of June 4, 1997. Samples shall be submitted to the corresponding laboratory in the order determined by the individual responsible for the plant and depending of the commercial commitments assumed.

In labels identified as ML, CM1 and CM2 of the aforementioned samples, the following caption shall state in capital letters and in a font size no smaller than ONE CENTIMETER (1 cm): "INTERDICTED BATCH. ANIMAL PROTEINS IN RUMINANT FEED. ANALYZE URGENTLY."

20.6.2.- Whenever SENASA laboratory performs the corresponding analyses regarding the compliance with numeral 19 and issues the pertinent protocols, the original documents shall be submitted to the DHIPOVyP, who shall communicate the results to the acting Regional Center Directorate in order for it to proceed accordingly.

20.6.3.- Should one or several analyzed batches tested negative, the batch(es) involved shall be released.

20.6.4.- Whenever one of the analyzed batches tested positive, the interested party has the right to proceed in accordance with the provisions of numeral 20.3. Should one positive test result be confirmed, the batch(es) involved shall be seized and destroyed. According to paragraph 20.6.5, the

possibility to give a different destination of use under official control of the products that tested positive can be assessed.

20.6.5.- In accordance with numerals 20.5.5 and 20.6.4, the interested party may request authorization to the acting officer to intend the product composing the batch(es) that tested positive to a use other than ruminant feed. The local acting officer shall assess the feasibility of ensuring the effective requested different destination of use and, if authorized, an official follow up of the operations performed, drafting the corresponding records.

20.6.6.- A manufacturing establishment shall be no longer under health surveillance by SENASA when it adopts the corresponding corrective measures and when FIVE (5) consecutive negative tests results are obtained from new batches of ruminant feed manufactured during the intervention.

20.6.7.- The costs resulting from the performance of all and each one of the procedures established in this Resolution shall be borne by the individual responsible for the inspected establishment.

20.7.- Handling documents.

Upon initiation of the docket file in DHIPOVyP, this Coordination office shall issue a service instruction to be performed by the corresponding Regional Center Directorate.

Once the instruction has been performed, the corresponding actions have been complied with, and the establishment at issue has regularized its situation and performed all the necessary health measures, the Regional Center Directorate shall submit all the original documents to the DHIPOVyP, in order for it to become acquainted with the actions and continue with the administrative procedure.

21. INSPECTION AND VERIFICATION PROCEDURES TO BE APPLIED UPON DETECTION OF A POSITIVE TEST RESULT OF PROTEINS OF ANIMAL ORIGIN THAT ARE BANNED IN RUMINANT FEED

21.1.- Single manufacturing line. Inspection of the manufacturing process upon a positive test in establishments with a single manufacturing line.

21.1.1.- The compliance with the Sworn Statement performed in the "Application for Establishment Authorization" (which is available in SENASA website) shall be verified. The individual responsible for the establishment states therein that Banned Animal Proteins (BAP) are not used, and informs the animal species for which the feed produced in said establishment is intended.

21.1.2.- The existence of procedures in the Good Manufacturing Practices Manual shall be verified.

21.1.3.- The following documents and information shall be requested to establish the origin of the ingredients used in the manufacturing process:

21.1.3.1.- Records for entry/exit movements of ingredients that may contain animal proteins, as well as of the rest of the ingredients.

21.1.3.2.- Delivery notes for every entry/exit movement in the last month.

21.1.3.3.- Details of the use given to ingredients established by means of the manufacturing records of the feedstuff that are available at the establishment, considering stock in the plant.

21.1.3.4.- Manufacturing forms for production lines, in order to verify that no feedstuff containing banned animal proteins has been produced.

21.1.3.5.- The Inspections Book established by this Technical Standard to register that an audit/inspection has been performed due to aforementioned reasons and to detail therein the observations made.

21.1.3.6.- Certificates of origin issued by SENASA, corresponding to ingredients used in the manufacturing process.

21.1.4.- The individual responsible for the firm shall state in writing the reasons for the presence of Banned Animal Proteins (BAP).

21.2.- Separated manufacturing lines

21.2.1.- Inspection of the manufacturing process upon a positive test result in establishments with separated production lines.

21.2.1.1.- The existence of procedures in the Good Manufacturing Practices Manual shall be verified.

21.2.1.2.- The following documents and information shall be requested to establish the origin of the ingredients used in the manufacturing process:

21.2.1.2.1.- Records of entry/exit movements of ingredients that may contain animal proteins, as well as of the rest of ingredients.

21.2.1.2.2.- Delivery notes for every entry/exit movement in the last month.

21.2.1.2.3.- Manufacturing forms for the ruminant line, in order to verify that NO feedstuff containing banned animal proteins has been produced.

21.2.1.2.4.- The Inspection Book established by this Technical Standard to state that an audit/inspection has been performed due to aforementioned reasons and to detail therein the observations made.

21.2.1.2.5.- Certificates of origin issued by SENASA, corresponding to ingredients used in the manufacturing process.

21.2.1.3.- In order to avoid cross-contamination, a revalidation of control points at the production line shall be requested to the firm.

21.2.1.4.- The individual responsible for the firm shall state in writing the reasons for the presence of Banned Animal Proteins (BAP).

APPLICATION FOR REGISTRATION OF FEEDSTUFFS

Place and date:…….

1.- Feedstuff classification (do not complete; reserved for official use):

2.- Brand (should it be stated, it shall be incorporated to the commercial name):

3.- Commercial name:

4.- Intended Species and category:

5.- Applicant firm

5.1.- Company name or business name:

5.2.- Registration No.:

5.3.-Address for notification:

5.4.- E-Mail:

5.5.- Telephone:

5.6.- Taxpayer ID Number (CUIT):

5.7.- TECHNICAL DIRECTOR OF THE PRODUCT

5.7.1.- Name and surname:

5.7.2.- SENASA Registration No.:

5.7.3.- E-Mail:

5.7.4.- Telephone:

6.- MANUFACTURING ESTABLISHMENT(S)

6.1.- Official Authorization No.:

6.2.- Firm responsible for the establishment:

6.3.- Address for notification:

6.4.- E-Mail:

6.5.- Telephone:

7.- IMPORTING FIRM

7.1.- Company name or business name:

7.2.- Address for notification:

7.3.- E-Mail:

7.4.- Telephone:

7.5.- Manufactured by:

8.- PRODUCT CLASSIFICATION

Select the appropriate option:

8.1.- Balanced feed ( )

8.2.- Feed supplement ( )

9.- PHYSICAL FEATURES: (for example: liquid, meal, pellets, extruded feed, powder, granulated feed, wet feed, or other).

10.- USE. Define the product, indicating the following information:

10.1.- Its features or properties.

10.2.- Age and/or weight, productive capacity, physiological status, breeding conditions or management of the species consuming such feedstuff.

11.- LIST OF INGREDIENTS THAT ARE LIKELY TO BE USED IN MANUFACTURE: (For all stated industrialized ingredients, the supplier and the certificate number granted to the product when registered with the competent official body shall be indicated.)

11.1.- For national products:

11.1.1.- Raw materials and/or by-products of plant origin.

11.1.2.- Raw materials and/or by-products of animal origin.

11.1.3.- List of additives to be used in the product. Said additives shall be previously registered, as well as their name(s) and certificate numbers.

11.1.4.- List of raw material suppliers.

11.2.- For imported products:

The Free Sale Certificate or Free Manufacture Certificate stating the list of ingredients shall be submitted, issued or supported by the health authority of the country of origin.

Note: Without these documents, the procedure for product registration shall not be initiated.

12.- PRODUCT CENTESIMAL COMPOSITION: indicate the following values, if appropriate, or other centesimal composition, in accordance with the product involved.

OVER SUBSTANCE AS IT STANDS IN PERCENTAGE (%) w/w

Minimum crude protein content

Minimum ethereal extract content

Maximum crude fiber content

Maximum total minerals content

Maximum humidity content

Calcium content: minimum, maximum

Phosphorus content: minimum, maximum

Note: In the case of feedstuff intended for poultry, the available phosphorous value shall be stated. When it contains urea, state the maximum protein equivalent.

13.- ENERGY VALUE: Express it as digestible or metabolisable energy per kilogram of dry product.

14.- ADDITIVE CONCENTRATION (Only added products, expressed as active ingredients)

14.1.- MINERALS: Express macroelements % w/w in feedstuff and trace elements in ppm, calculated over the active ingredient as it stands.

14.2.- VITAMINS: Express as I. U., mg or mcg, as appropriate, per kg of feed, calculated over the substance as it stands.

14.3.- AMINO ACIDS: Express amino acids quantity per kg of feed, calculated over the substance as it stands.

14.4.- OTHER ADDITIVES (flavoring and coloring substances, etc.): Express as the amount of each additive per kilogram of finished product.

15.- INSTRUCTIONS FOR PRODUCT USE: The method for product administration shall be clearly explained (AMOUNT, FREQUENCY, ETC.).

16.- PRESERVATION PERIOD AND CONDITIONS: Indicate the appropriate conditions for product storage and their expiry date.

17.- COMMERCIAL PRESENTATIONS FOR FEEDSTUFF: Indicate if the product is commercialized either in bulk or packaged and the characteristics of its container, specifying the various commercial presentations (depending on container and net weight).

18.- MONOGRAPH ON THE MANUFACTURING PROCESS: Brief description of the manufacturing process. For products that are subjected to a thermal treatment, temperature and retention time shall be indicated.

19.- CONTROL METHODS: Methods to be performed on the finished product (as appropriate), in order to verify the qualitative and quantitative content of the various components, specifying used techniques and indicating AOAC methods or otherwise other internationally recognized.

19.1.- Biological method

19.2.- Microbiological method

19.3.- Chemical method

19.4.- Physical method

19.5.- Physico-Chemical method

20.- DRUGS: Indicate (if appropriate) the list of active ingredients with pharmacological effects that will be incorporated to product composition. Include their corresponding commercial name(s) and certificate number.

20.1.- Amount of product registered per kg of feed

20.2.- Use restrictions and side effects

20.3.- Withdrawal period

20.4.- Precautions and warnings

20.5.- A stability test attached to its results. It shall ensure that the concentration of the active ingredient in the drug to the feedstuff expiry date has not broken down and that manufacturing processes or recommended storing conditions have not caused it to break down.

20.6.- Submit the analytical results for the quantitative content of the active ingredient in the drug. These results shall be taken from five different batches for testing development to the suggested feedstuff expiry or due date, indicating the methods used.

20.7.- Technical justification explaining the presence of other components of the feedstuff (such as fat or humidity level) that do not produce structural alterations in the drug that may impede its appropriate therapeutic action.

20.8.- Photocopy of the label or leaflet of the drug, stating the approval registration number.

21.- THE SET OF PRINTOUTS shall indicate the following information:

a) For national products:

1.- Commercializing firm, place of business

2.- Registered trademark (when stated, it shall be incorporated to the product's commercial name)

3.- Commercial name

4.- Type of feedstuff (extruded feed, pellets, mix, etc.)

5.- SENASA classification for the product

6.- Species and category for which it is intended

7.- List of ingredients

8.- Centesimal composition

9.- Directions for use

10.- Expiry date

a) In the event of containing a drug, should the lifespan of the drug be shorter than that of the finished product, the lifespan of the drug shall be considered as the expiry date of the finished product.

b) Note: The information to be stated varies according to the following:

Date and month for products lasting no more than three months.

Month and year for products lasting more than THREE (3) months.

11.- Manufacturing Establishment License No.

12.- SENASA Registration No. for the product

13.- Product to be used only for animal feed

14.- Argentine Industry

15.- Net weight

16.- Series or batch No.

17.- Preservation conditions for the product

18.- Restrictions, side effects, precautions, warnings and withdrawal period (if appropriate)

19.- SENASA logo

20.- All captions, graphs, documents or images stated in the final label.

b) For imported products: (either an information leaflet or a label may be used depending on container and size)

1.- Manufacturing firm

2.- Registered trademark of the product

3.- Commercial name

4.- Type of feedstuff (extruded feed, pellets, mix, etc.)

5.- SENASA classification for the product

6.- Intended species and category

7.- List of ingredients

8.- Centesimal composition

9.- Instructions for use

10.- Expiry date

a) Note: The information to be stated varies according to the following:

Date and month for products lasting no more than three months.

Month and year for products lasting more than three months.

11.- Importing and/or commercializing firm: name, place of business, and official registration No.

12.- SENASA Registration No. for the product

13.- Product to be used only in animal feed

14.- Net weight

15.- Series or batch No.

16.- Preservation conditions for the product

17.- Restrictions, side effects, precautions, warnings and pre-slaughter period (if appropriate)

18.- SENASA logo

19.- All captions, graphs, documents or images stated in the final label.

Note: The firm shall submit additional information, should the Registration Area deem it necessary.

IMPORTANT:

For imported products, the following information shall be submitted:

A) A Free Sale Certificate issued by the official competent authority in the country of origin, which shall include the centesimal composition and a list of ingredients. It shall be either certified by Apostille or legalized by the Consulate and translated to the national language by a Sworn Translator.

B) For ingredients of animal origin, the animal species and the country of origin of such animals shall be stated, and it shall be supported by the competent Health Authority. It shall be either certified by Apostille or legalized by the Consulate and translated to the national language.

Full instructions of products and by-products of animal origin.

A) Containers or final labels.

When requesting re-registration

A) A Free Sale Certificate issued by the official competent authority in the country of origin, which shall include the centesimal composition and a list of ingredients. It shall be either certified by Apostille or legalized by the Consulate and translated to the national language by a Sworn Translator.

B) For ingredients of animal origin, the animal species and the country of origin of such animals shall be stated, and it shall be supported by the competent Health Authority. It shall be either certified by Apostille or legalized by the Consulate and translated to the national language by a Sworn Translator.

C) Final containers or labels shall be attached to such document.

D) A copy of use and commercialization certificates granted in due course shall also be attached to such document.

Raw materials of plant and/or animal origin used in the manufacture of feedstuff shall only be those adjusted to quality parameters stated for those purposes.

SWORN STATEMENT

All the pages composing the application shall be signed by the Technical Director of the Product.

.....

Signature and type or print name of the Technical Director of the Product.

APPLICATION FOR REGISTRATION OF ADDITIVES, VITAMIN SUPPLEMENTS, MINERALS, VITAMIN AND MINERAL COMPOUNDS AND ADDITIVE PREMIXES

Place and date ……..

1.- FEEDSTUFF CLASSIFICATION OR TYPE(Reserved for official use):

2.- BRAND (should it be stated, it shall be incorporated to the commercial name):

3.- COMMERCIAL NAME:

4.- SPECIES AND CATEGORY FOR WHICH IT IS INTENDED:

5.- APPLICANT FIRM

5.1.- Company name or business name:

5.2.- Official Registration No.:

5.3.- Taxpayer ID Number (CUIT):

5.4.- Address for notification:

5.5.- Telephone:

5.6.- E-Mail:

6.- TECHNICAL DIRECTOR OF THE PRODUCT

6.1.- Name and surname:

6.2.- Technical Director SENASA Registration No.:

6.3.- E-Mail:

6.4.- Telephone:

7.- MANUFACTURING ESTABLISHMENT

7.1.- Company name or business name:

7.2.- Official Authorization No.:

7.3.- E-Mail:

7.4.- Telephone:

8.- IMPORTING FIRM

8.1.- Company name or business name:

8.2.- Manufactured by:

8.3.- Importing Firm Registration No.:

8.3.- Taxpayer ID Number (CUIT):

8.4.- E-Mail:

8.5.- Telephone:

9.- PRODUCT FEATURES:

a) Indicate product nature and origin.

b) Organoleptic and physico-chemical properties of the product.

c) Purpose of the product in the feedstuff.

10.- LIST OF PROBABLE INGREDIENTS, INDICATING ITS SALTS

11.- QUALITATIVE AND QUANTITATIVE COMPOSITION:

The percentages of product constituents shall be indicated in decreasing order, as well as the purity and minimum amount of each one of them.

In the case of additives premix, each active ingredient shall be stated, indicating the following information:

- Product(s), Registration Certificate(s) and doses
- Active ingredient; minimum amount; doses
- SENASA Certificate No. for each one of them, if appropriate

12.- MANUFACTURING PROCESS:

Describe the product manufacturing process; indicating the periods and temperatures used in each stage of said process.

13.- INSTRUCTIONS FOR PRODUCT USE

Clearly explain which method and proportions shall be used for the product, according to the intended consumer species, age, productive capacity, body weight, production stage, physiological status, type of handling and habitat.

14.- PRODUCT DOSAGE

For each one of the intended consumer species and categories (expressed in the appropriate units), both for additives and premixes:

a) Indicate the minimum amount of additive per unit of feedstuff weight that is necessary for reaching the desired effect.

b) If appropriate, indicate the maximum acceptable doses for the intended consumer species.

c) Use recommendations for use in drinking water, if appropriate.

15.- PRODUCT KINETICS:

In the event of additives only, indicate distribution and elimination channels of the product in the animal.

16.- UNDESIRABLE EFFECTS:

Indicate existing incompatibilities with other products or ingredients that may be used in animal feed, as well as side or detrimental effects, when appropriate.

17.- GENERAL PRECAUTIONS:

17.1.- For additives:

a) Indicate courses of action for intoxication or overdose in intended consumer animals.

17.2.- For additives, premixes, supplements and nuclei

a) Indicate courses of action for appropriately and safely product handling.

b) Indicate, when appropriate, use restrictions and withdrawal period for indicated species.

18.- CONTROL METHODS:

Methods to be performed on the finished product (as appropriate), in order to verify the qualitative and quantitative content of the various constituents, specifying used techniques and indicating AOAC methods or others internationally recognized.

1.- Biological method

2.- Microbiological method

3.- Chemical method

4.- Physical method

5.- Physico-Chemical method

19.- PRESERVATION PERIOD AND CONDITIONS:

a) Indicate the appropriate conditions for product storage (temperature, humidity, etc.) and expiry date.

20.- COMMERCIAL PRESENTATIONS FOR FEEDSTUFF

Indicate container characteristics (materials used, capacity, net weight, etc.).

21.- LABELS AND LEAFLETS:

The set of printouts for the final label shall be adjusted and attached to the following specifications:

a) For national products:

1.- Commercializing firm, address

2.- Brand

3.- Commercial name

4.- Type of feedstuff

5.- SENASA classification for the product

6.- Intended species and category

7.- Qualitative and quantitative composition of the product:

7.1.- Additives:

Expressed as active ingredient (in I. U., g, mg, or mcg) for every ONE HUNDRED (100) g of products.

7.2.- Premixes:

Expressed as active ingredient (in I. U., g, mg, or mcg) for every kg of product.

8.- Instructions for use

9.- Dosage

10.- Preservation conditions

11.- Expiry date

12.- SENASA Manufacturing Establishment Authorization No.

13.- SENASA Registration No. for the product

14.- Product to be used only in animal feed

15.- Argentine Industry

16.- Net weight

17.- Series, item or batch No.

18.- Restrictions, side effects, precautions, warnings and pre-slaughter period (if appropriate)

19.- SENASA logo

20.- All captions, graphs, documents or images stated in the final label.

b) For imported products:

1.- Manufacturing company, place of business

2.- Brand

3.- Commercial name

4.- Type of feedstuff

5.- SENASA classification for the product

6.- Intended species and category

7.- Qualitative and quantitative composition

7.1.- Additives:

Expressed as active ingredient (in I. U., g, mg, or mcg) for every ONE HUNDRED (100) g of products.

7.2.- Supplements and nuclei

Expressed as active ingredient (in I. U., g, mg, or mcg) for every kg of product.

8.- Instructions for use

9.- Dosage

10.- Expiry date

11.- Importing and/or commercializing firm: name or business name, address, and official registration No.

12.- SENASA Registration No. for the product

13.- Product to be used only in animal feed

14.- Preservation conditions for the product

15.- Net weight

16.- Series, item, or batch No.

17.- Restrictions, side effects, precautions, warnings and withdrawal period (if appropriate)

18.- SENASA logo

19.- All captions, graphs, documents or images stated in the final label.

22.- BIBLIOGRAPHY, SCIENTIFIC PAPERS AND/OR MONOGRAPHS RELATED TO THE PRODUCT

The aforementioned information shall be submitted in national language whenever the Official Agency requires doing so. The application shall be technically grounded.

In the case of premixes, a copy of the approval certificates for the ingredients composing such mix shall be attached.

23.- FREE SALE CERTIFICATES IN THE COUNTRY OF ORIGIN

For an imported product, a Free Sale Certificate issued by the official competent authority in the country of origin shall be presented. Said certificate shall include a detailed qualitative and quantitative composition. It shall be either certified by Apostille or legalized by the Consulate and translated to the national language by a Sworn Translator.

All the pages composing the application shall be signed by the Technical Director for the product.

THIS SHALL BE A SWORN STATEMENT

....

Signature and type or print name of the Technical Director of the product.

APPLICATION FOR REGISTRATION OF BY-PRODUCTS OF PLANT ORIGIN INTENDED FOR ANIMAL FEED

Place and date …….

1.- FEEDSTUFF CLASSIFICATION (do not complete; official use):

2. BRAND (should it be stated, it shall be incorporated to the commercial name):

3.- COMMERCIAL NAME:

4.- SPECIES AND CATEGORY FOR WHICH IT IS INTENDED:

5.- APPLICANT FIRM

5.1.- Company name or business name:

5.2.- Registration No.:

5.3.- Taxpayer ID Number (CUIT):

5.4.- Address for notification:

5.5.- E-Mail:

5.6.- Telephone:

6.- TECHNICAL DIRECTOR OF THE PRODUCT

6.1.- Name and surname:

6.2.- Technical Director SENASA Registration No.:

6.3.- E-Mail:

6.4.- Telephone:

7.- MANUFACTURING ESTABLISHMENT(S)

7.1.- Company name or business name:

7.2.- Official Authorization No.:

7.3.- Address for notification:

7.4.- E-Mail:

7.5.- Telephone:

8.- IMPORTING FIRM

8.1.- Company name or business name:

8.2.- Address for notification:

8.3.- Taxpayer ID Number (CUIT):

8.4.- Importing Firm Registration No.:

8.5.- E-Mail:

8.6.- Telephone:

8.7.- Manufactured by:

9.- RAW MATERIALS:

9.1.- Storage (handling of grains and/or by-products of plant origin) (humidity percentage in grains, monitoring, silo cleaning, etc.).

9.2.- Botanical name(s)

9.3.- Part of the product or by-product that is used – ripening – quality – Specific features (including in the raw material the plant species from where it originates, additives, agglutinative and coloring substances, etc.).

10.- INFORMATION ABOUT THE FINISHED PRODUCT:

10.1.- Physical features: (for example: liquid, meal, pellets, extruded feed, powder, granulated feed, wet feed, or other).

Instructions for product use

10.2.- LIST OF INGREDIENTS THAT ARE LIKELY TO BE USED IN MANUFACTURE:

(For all stated industrialized ingredients, the supplier and the certificate number granted to the product when registered with the competent official body shall be indicated.)

10.3.- MONOGRAPH ON THE MANUFACTURING PROCESS: Brief description of the manufacturing process. For products that are subjected to a thermal treatment, temperature and retention time shall be indicated.

10.4.- PRODUCT CENTESIMAL COMPOSITION: indicate the following values, if appropriate, or other centesimal composition, in accordance with the product at issue.

OVER SUBSTANCE AS IN PERCENTAGE (%) w/w

Minimum crude protein content

Minimum ethereal extract content

Maximum crude fiber content

Maximum total minerals content

Maximum humidity content

Calcium content: minimum, maximum

Phosphorus content: minimum, maximum

10.5.- ENERGY VALUE: Express it as digestible or metabolisable energy per kilogram of dry product.

10.6.- ADDITIVE CONCENTRATION (Only added products, expressed as active ingredients)

10.7.- CONTROL METHODS: Methods to be performed on the finished product (as appropriate), in order to verify the qualitative and quantitative content of the various ingredients, specifying used techniques and indicating AOAC methods or other internationally recognized.

1) Biological method
2) Microbiological method
3) Chemical method
4) Physical method
5) Physico-Chemical method

10.8.- PRESERVATION PERIODS AND CONDITIONS FOR FINISHED PRODUCTS: Indicate the appropriate conditions for product storage and expiry date.

10.9.- COMMERCIAL PRESENTATIONS FOR FEEDSTUFF: Indicate if the product is commercialized either in bulk or packaged and the characteristics of its container, specifying the various commercial presentations (depending on container and net weight).

10.10.- The SET OF PRINTOUTS OF THE FINAL LABEL: shall indicate the following information:

a) For national products:

1.- Commercializing firm, place of business

2.- Registered trademark (when stated, it shall be incorporated to the product commercial name)

3.- Commercial name

4.- Type of feedstuff (extruded feed, pellets, mix, etc.)

5.- SENASA classification for the product

6.- Intended species and category

7.- List of ingredients

8.- Centesimal composition

9.- Instructions for use

10.- Expiry date

a) Note: The information to be stated varies according to the following:

Date and month for products lasting no more than three months.

Month and year for products lasting more than THREE (3) months.

11.- Manufacturing Establishment Authorization No.

12.- SENASA Registration No. for the product

13.- Product to be used only in animal feed

14.- Argentine Industry

15.- Net weight

16.- Series or batch No.

17.- Preservation conditions for the product

18.- Restrictions, side effects, precautions, warnings and withdrawal period (if appropriate)

19.- SENASA logo

20.- All captions, graphs, documents or images stated in the final label.

b) For imported products: (either an information pamphlet or a label may be used depending on container and size)

1.- Manufacturing firm

2.- Registered trademark

3.- Commercial name

4.- Type of feedstuff

5.- SENASA classification for the product

6.- Intended species and category

7.- List of ingredients

8.- Centesimal composition

9.- Instructions for use

10.- Expiry date

a) Note: The information to be stated varies according to the following outline:

Date and month for products lasting no more than three months.

Month and year for products lasting more than three months.

11.- Importing and/or commercializing company: name, place of business, and official registration No.

12.- SENASA Registration No. for the product

13.- Product to be used only in animal feed
14.- Net weight
15.- Series or item No.
16.- Preservation conditions for the product
17.- Restrictions, side effects, precautions, warnings and withdrawal period (if appropriate)
18.- SENASA logo
19.- All captions, graphs, documents or images stated in the final label.

Note: The firm shall submit additional information, should the Registration Area deem it necessary. The application or request shall be technically substantiated.

IMPORTANT:

For imported products, the following documents shall be presented:

A) A Free Sale Certificate issued by the official competent authority in the country of origin, which shall include the centesimal composition and a list of ingredients. It shall be either certified by Apostille or legalized by the Consulate and translated to the national language by a Sworn Translator.
B) Containers or final labels.

When requesting the re-registration

C) A Free Sale Certificate issued by the official competent authority in the country of origin, which shall include the centesimal composition and a list of ingredients. It shall be either certified by Apostille or legalized by the Consulate and translated to the national language by a Sworn Translator.
D) Final containers or labels shall be attached to such document.
E) A copy of use and commercialization certificates granted in due course shall also be attached to such document.

RAW MATERIALS OF PLANT AND/OR ANIMAL ORIGIN USED IN THE MANUFACTURE OF FEEDSTUFF SHALL ONLY BE THOSE ADJUSTED TO QUALITY PARAMETERS STATED FOR THOSE PURPOSES.

THE MANUFACTURER STATES KNOWING HEALTH AND HYGIENE STANDARDS ESTABLISHED ON THE MANUFACTURE OF THE PRESENTED PRODUCT, AND THAT BOTH THE ADDITIVES COMPOSING IT AND THE RAW MATERIALS USED FOR PACKAGING AND LABELING SHALL ALWAYS BE AUTHORIZED AND NEW.

All the pages composing the application shall be signed by the Technical Director of the product.

SWORN STATEMENT

....

Signature and type or print name of the Technical Director for the product.

ANNEX II

PROFILE OF TECHNICAL DIRECTORS FOR ANIMAL FEED

1.- TECHNICAL DIRECTORS FOR ANIMAL FEED

1.1.- Authorized professionals. The role of Technical Director shall only be performed by Veterinary Doctors, Agricultural Engineers or other professional graduated with a university decree related to the activities covered by this Regulation.

1.1.1.- Related decrees. The Directorate for Hygiene of Products of Plant Origin and Feed, which is an area within the scope of SENASA National Directorate for Agri-Food Safety and Quality, shall resolve if a related university decree complies with demands and activities established in the Technical Standard for Feedstuff.

1.2.- Obligation to register in the Registry for Technical Directors. In order to perform the activities proper to a Technical Director, professionals must be registered with the National Registry for Technical Directors for Animal Feed, henceforth referred to as the Registry.

1.3.- Employment. In order to be registered with the Registry and to maintain such registration, it is not necessary for the professional to have an employment relationship with a firm or establishment.

1.4.- Registration validity. The registration of the Technical Director in the Registry shall be valid for two years; therefore, it shall be renewed after such period. Should registration not be renewed, SENASA shall be empowered to remove the Technical Director from the Registry, prior warning for renewal.

1.5.- Number of establishments. The Technical Director can have up to three establishments under its direction.

1.6.- Professional License. In order to be registered and to maintain such registration, the Technical Director must have a professional license granted by one of the Professional Bodies that administer licenses for his/her profession. It is not compulsory for the Technical Director to be licensed in a Professional Body corresponding to the jurisdiction in which the establishment or firm that s/he consults is located. The purpose of demanding a professional license is to accredit that the professional actively practices the profession.

1.7.- Obligations of the Technical Directors.

1.7.1.- Obligations of the Technical Director of the Establishment:

1.7.1.1.- Ensuring that the composition and/or nutritional assurances of products manufactured in said establishment correspond to the product registered or authorized by SENASA.

1.7.1.2.- Complying with storing conditions stated in the Technical Standard for Animal Feed regarding products stored in such establishment.

1.7.1.3.- Ensuring that processes, technical and health procedures, and good manufacturing practices are implemented in accordance with the provisions of the Technical Standard for Animal Feed.

1.7.1.4.- Signing the Good Manufacturing Practices Manual jointly with the individual responsible for signing on behalf of the establishment.

1.7.1.5.- Ensuring that the establishment implements the Good Manufacturing Practices Manual.

1.7.1.6.- Signing documents supporting the manufacture of on-demand products.

1.7.1.7.- Being present in scheduled inspections performed by SENASA in the establishment where said Director exercises its functions.

1.7.1.8.- Communicating suspensions or cancellations of professional licenses to SENASA area responsible for the Registry for Technical Directors.

1.7.2. Obligations of the Technical Director of the Product:

1.7.2.1.- Designing and technically supporting, by means of its signature, monographs and any other documents referred to products registered with the Registry.

1.7.2.2.- Participating in changes, procedures and documents referred to the product registered for which s/he is Technical Director.

1.7.2.3.- Communicating suspensions or cancellations of professional licenses to SENASA area responsible for the Registry of Technical Directors.

1.8.- Incompatibilities. The performance of duties is incompatible with the performance of official duties proper to responsibilities stated in the Technical Standard for Animal Feed, notwithstanding other incompatible causes that may arise from existing legislation.

1.9.- Responsibilities.

The Technical Director is responsible for the compliance with obligations established in the Technical Standard for Animal Feed.

1.10.- Extension of liability of the Technical Director of the Establishment. The responsibility of the leaving Technical Director shall be extended up to the last batch or series manufactured and fractioned during its administration.

1.11.- Responsibilities of manufacturing in third-party establishments. When performing activities in third-party establishments, the Technical Director of the manufacturing establishment shall be responsible for the compliance of obligations provided for in this Resolution.

1.12.- Impossibility to perform activities without a Technical Director of the Establishment. Should the Technical Director of the Establishment be at a standstill or interruption of activities, the firm for which it works cannot manufacture nor fractionate until a new Technical Director is appointed.

1.13.- Annual update of information on the Technical Director of the Establishment.

SENASA shall have updated information on the technical direction of the establishments; therefore, firms are compelled to annually inform data on their current Technical Directors.

1.14.- Training activities.

1.14.1.- The enforcement authority shall provide for the performance of training activities for Technical Directors and it may also declare said activities to be compulsory. The purpose of such activities is to instruct and perfect said professionals on areas proper to their duties and on their knowledge regarding the Technical Standard for Animal Feed.

1.14.2.- If the enforcement authority declares training activities to be obligatory, the compliance with them shall be necessary and exclusionary to maintain the registration status and to perform functions proper to Technical Directors.

1.14.3.- Training activities for accrediting continuity in the registry can be imparted either exclusively by SENASA; by SENASA jointly with public or private entities, or performed in external institutions or entities and validated by SENASA as fit for complying with training activities required to maintain said registration status.

1.14.4.- In all cases, such activities shall be arranged and authorized by DHIPOVyP as fit for compliance with required training needs so as to accredit continuity in the Registry for Technical Directors.

1.14.5.- The DHIPOVyP can notify the schedule of compulsory activities by means of an e-mail to the address stated by the professional, or by whatever means it deems convenient, such as SENASA website.

1.14.6.- Professionals attending training activities shall be awarded the corresponding certificates accrediting both their attendance and, if appropriate, the passing of such activities.

1.14.7.- Failure to comply with training activities established by the enforcement authority shall empower said authority to either suspend or definitely remove the professional at issue form the Registry. In that case, it shall not be necessary for the enforcement authority to perform any prior administrative procedure for such measure.

1.14.8.- SENASA staff involved in the activities established in this Regulation may participate on training activities, prior DHIPOVyP authorization.

1.15.- Specialization. Upon development of training activities, the Registry for Technical Directors shall establish specialization categories referred to specific activities developed by such professionals that shall constitute an obligatory condition for task fulfillment.

1.16.- Suspension of the registration. Any action, behavior, or situation in which the Technical Director may be involved and that SENASA considers to be an alleged breach to this Regulation, or an alleged health risk that affects or may affect the process of products, empowers the Service to either preventively suspend or cancel the registration of the professional at issue in SENASA National Registry for Technical Directors for Animal Feed. This shall be implemented for the length of the measure, notwithstanding the initiation of the corresponding administrative procedure so as to establish the existence of breaches of current regulations.

1.17.- Penalties

1.17.1.- The suspension or cancellation of the registration shall be applied upon verification of liability on the part of the Technical Director due to breaches of the provisions of this Regulation.

1.17.2.- The suspension or cancellation of the registration shall impede the professional to perform functions proper to a Technical Director of any establishment and regarding all the products under its scope of Technical Director.

1.17.3.- Should SENASA cancel or suspend the registration of a Technical Director, said professional shall be duly informed about such situation, as well as the firm where s/he performed professional functions.

2. REGISTRATION WITH THE NATIONAL REGISTRY FOR TECHNICAL DIRECTORS

2.1.- Required documents. The interested professional shall submit to the Regional Center or to the DHIPOVyP the following documents:

2.1.1.- Duly filled in application for registration in the Registry for Technical Directors (which is available at SENASA website). Such application shall state an address for service to which all notifications shall be sent, regarding the accreditation and registration processes as Technical Director, as well as every notification proper to the duties performed by a Technical Director.

2.1.2.- Copy of the university certificate. It shall be reduced and certified.

2.1.3.- Professional license. Professional license in force, issued by the corresponding board or body.

2.1.4.- Curriculum vitae

2.1.5.- Tax Payer ID number (CUIT).

2.2.- Related decrees.

2.2.1.- Additional documents. When a university professional of related decrees requests registration and accreditation, said professional shall submit the documents stated in numeral 2.1, as well as the following documents:

2.2.1.1.- Responsibilities. Professional responsibilities stated in the Professional Duties Act.

2.2.1.2.- Background. Resume, including curricular contents obtained during the university career.

2.3.- Documents submitted to the Regional Center. If the documents stated in numerals 2.1 and 2.2. have been submitted to the Regional Center, such Center shall submit those documents to the DHIPOVyP. The DHIPOVyP shall assess the documents and issue an opinion, which is stated in numeral 2.4.1.

2.4.- Registration.

2.4.1.- Document analysis. The DHIPOVyP shall analyze the submitted documents and, according to results arising therefrom, it shall issue a technical decision stating if the professional is eligible for registration or not.

2.4.2.- Registration rejection. Should the decision establish that the professional is not eligible for registration, s/he shall be notified of it.

2.4.3.- Registration approval. Administrative act. Should the decision recommend the registration of the professional at issue, it shall be submitted to DNICA, which shall issue the corresponding administrative act registering the professional in the Registry for Technical Directors.

2.5.- Updating information on the Technical Director

The update shall be performed within THIRTY (30) calendar days after registration and it shall be ratified at the moment of re-registration with the Registry.

2.6.- Termination of duties as Technical Director of the Establishment.

2.6.1.- Whenever the Technical Director terminates its duties for a certain establishment, it shall be duly notified either to the Regional Center or directly to the Registry. If the notification was served to the Regional Center, it shall communicate such notification to the corresponding Registry, within no more than 48 hours after the termination.

2.6.2.- The document communicating the termination shall be signed either by the professional himself or by the agent of the firm for which the professional worked.

2.6.2.1.- Whenever the termination is submitted by the Technical Director, an evidence that s/he communicated such termination to the firm for which s/he worked shall be submitted as well.

2.6.3.- The duties of the Technical Director shall terminate at the moment of submitting or receiving the document stating said termination between the professional and the firm or establishment.

2.6.4.- The Regional Center shall submit to the DHIPOVyP an authenticated copy of the document by means of which the termination was communicated, in order to register it in the National Registry for Establishments and, if appropriate, to register the withdrawal from the System for Firms and Establishments.