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Report Name: Specifications for the Regulation of Products for Animal Use or Consumption

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Report Category: Livestock and Products, Poultry and Products, Sanitary/Phytosanitary/Food Safety, Grain and Feed

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Report Highlights:

On November 6, 2023, Mexico's Secretariat of Agriculture (SADER) published Official Mexican Standard NOM-012-SAG/ZOO-2020: Specifications for the Regulation of Products for Animal Use or Consumption. The standard outlines specifications for the production, storage, distribution, marketing, quality control, and verification of products for animal use or consumption for nutritional purposes and disease management.

On November 6, 2023, Mexico's Secretariat of Agriculture (SADER) published Official Mexican Standard NOM-012-SAG/ZOO-2020: Specifications for the Regulation of Products for Animal Use or Consumption in the official gazette. The Official Mexican Standard (NOM) replaces NOM-012-ZOO-1993: Specifications for the Regulation of Chemical, Pharmaceutical, Biological, and Food Products for Use in Animals or Consumption.

NOM-012-SAG/ZOO-2020 updates the specifications for the production, storage, distribution, marketing, quality control, and verification of products for animal use or consumption for use in nutrition and disease prevention, diagnosis, control, and treatment. The NOM's enforcement agency is the National Service for Agricultural Health, Food Safety and Agri-food Quality (SENASICA).

The NOM enters into force 180 days after the day of publication. This report provides an unofficial English translation of the standard.

Key Points

- Controls must be established to ensure that proteins of ruminant origin are not used in the production of ruminant feed. It is mandatory to keep records of the sale and purchase of meals used as raw materials in the production of feed products for at least five years.
- Establishments must guarantee the quality of each imported batch of raw material or finished product by presenting analysis or manufacturing company quality control documentation carried out under internationally recognized analytical techniques.
- Products under this regulation must include the label "for veterinary use." For feed products, this label may be changed to "Feed for …" stating the intended species.
- Labels of biological products must include "consult a veterinarian" and "purchase only with a veterinary prescription."
- The verification file of biological products based on genetic engineering must include the complete sequence of their construction.
- Products for animal use or consumption registered or authorized by SADER, through SENASICA, may only be imported by the product owner.
- In the case of imported raw materials for production of products for animal use or consumption, the country of origin must be identified for traceability purposes.
- Feed products, balanced feed, milk substitutes, dairy supplements and all foods which include pharmaceutical products, or include active ingredients of pharmaceutical products in their formulation, for therapeutic use in animals, must include the label "medicated food."

Begin Unofficial Translation

Official Mexican Standard NOM-012-SAG/ZOO-2020, Specifications for the regulation of products for animal use or consumption.

On the margin a seal with the National Shield, which says: United Mexican States. - AGRICULTURE. - Secretariat of Agriculture and Rural Development.

JOSÉ EDUARDO ESPINOSA DE LOS MONTEROS AVIÑA, General Director of Agri-Food Standardization of the Secretariat of Agriculture and Rural Development, based on the provisions of articles 12 and 35 sections IV and XXIV of the Organic Law of the Federal Public Administration; 4 of the Federal Law of Administrative Procedure; 38, sections II and IX, 39, 40, section I, II and III, 41, 46 and 47 of the Federal Law on Metrology and Standardization; 28 and 34 of the Regulations of the Federal Law on Metrology and Standardization; Transitory Fourth of the Quality Infrastructure Law; 1, 6, fractions I, II, V, IX, XIII, XIV, LI and LII; 32, 95, sections I and III, 99, 104, 105, sections V and VI of the Federal Animal Health Law; 150, 151, 152, 153, 171 and 212 of the Regulations of the Federal Animal Health Law; 1 and 2 first paragraph, letter A, section XIII and letter B, section V, 21, section I and 52 of the Internal Regulations of the Secretariat of Agriculture and Rural Development; 1, 3, 11, section IX and 14, section XXI of the Internal Regulations of the National Agri-Food Health, Safety and Quality Service, and

CONSIDERING

That the National Development Plan establishes as a higher objective "The general well-being of the population" which seeks to promote production through the construction of a regulation that allows healthy competition, based on updating and deregulating the framework. regulations of the agri-food sector.

That it is the power of the Secretariat of Agriculture and Rural Development (AGRICULTURE) to determine the characteristics and specifications of products for animal use or consumption and their raw materials, as well as recommendations for their prescription, application, use and consumption by animals.

That products registered or authorized for animal use or consumption are used to strengthen animal health and food safety, for nutritional, preventive, diagnosis, control, and treatment of diseases, thus contributing to the increase in national livestock production.

That the use of products prepared and handled in accordance with the manufacturer's instructions and specifications contribute to the strengthening of animal health, as well as the reduction of animal health risks and the promotion of food safety.

That good control in the production process of products registered and authorized by the Secretariat through SENASICA for animal use or consumption, as well as the raw materials that make them up, is an important factor that helps guarantee the effectiveness and safety of the products.

That quality control of products must be carried out during their production and storage.

That the correct application of products for animal use or consumption, their prudent use and observance of the withdrawal time of these in animals, will reduce the risk they represent for animal and human health.

That the information provided on the product labeling must guarantee its proper use and handling.

That the regulation of national products and imported supports guaranteeing the effectiveness and safety of products marketed in the national territory.

That for the reasons indicated above and prior legal procedures, on January 17, 1995, the Official Mexican Standard NOM-012-ZOO-1993, Specifications for the regulation of chemical, pharmaceutical, and pharmaceutical products, was published in the Official Gazette of the Federation. biological and nutritional products for use in animals or consumption by them.

That based on article 51 of the Federal Law on Metrology and Standardization, on June 3, 1998, the modification to the Official Mexican Standard NOM-012-ZOO-1993, Specifications for the regulation of chemical, pharmaceutical, biological and nutritional products for use in animals or consumption by them at the point corresponding to the maquila.

That by virtue of the proposal of various sectors involved, on January 27, 2004, the Modification to the Official Mexican Standard NOM-012-ZOO-1993, Specifications for the regulation of chemical, pharmaceutical, biological and food products for use in animals or consumption by them, with the aim of making it clearer and more precise.

That on June 26, 2018, the Draft Modification to the Official Mexican Standard NOM-012-ZOO-1993, Specifications for the regulation of chemical, pharmaceutical, biological and food products for use in animals or consumption by them, to become the Official Mexican Standard NOM-012-SAG/ZOO-2020, Specifications for the regulation of products for animal use or consumption, so that within the next 60 calendar days, interested parties will present their comments. to the National Advisory Committee for Agri-Food Standardization, in accordance with the provisions of article 47 of the Federal Law on Metrology and Standardization.

That, as a result of the aforementioned legal procedure, the various points of the project that were appropriate were modified, and therefore, the Official Mexican Standard NOM-012-ZOO-1993, Specifications for chemical, pharmaceutical, biological products, was modified and foodstuffs for use in animals or consumption by them.

That in order to comply with the provisions of articles 68, last paragraph, and 78 of the General Law of Regulatory Improvement, the Secretariat, in order to reduce compliance costs for individuals, through the issuance of: 1) Agreement by which municipalities are declared zones free of the large avocado pit borer (Heilipus Lauri), the small avocado pit borer (Conotrachelus Aguacatae and C. perseae) and the pit borer moth (Stenoma Catenifer). from Morelia, Zitácuaro, Tzintzuntzan and Morelos of the State of Michoacán de Ocampo; as well as, the Miahuatlán agroecological zone of the Municipality of Ixtapan del Oro, the Loma-Cruz de Piedra Agroecological Zone of the Municipality of Coatepec Harinas and the Cruz Verde-Los Berros Cuentla Agroecological Zone of the Municipality of San Simón de Guerrero of the State of Mexico; 2) Agreement declaring zones free of the large avocado pit borer (Heilipus Lauri), the small avocado pit borer (Conotrachelus Aguacatae and C. perseae) and the pit-boring moth (Stenoma Catenifer), the municipalities of Charo, Nuevo Urecho and Tangancícuaro in the state of Michoacán de Ocampo, the municipality of Quitupán in the state of Jalisco, the municipalities of Atlixco, Huaquechula and Ocoyucan in the state of Puebla, as well as the Duarte agroecological zone that includes the communities of Cuesta Blanca, Duarte and the red ones of the municipality of León in the state of Guanajuato; 3) Agreement by which the municipalities of Áporo, Senguio and Lagunillas of the State of Michoacán de Ocampo; Chiquilistlán and Tepatitlán de Morelos of the State of Jalisco; Ahuacatlán and Ixtlán del Río of the State of Nayarit, and Taxco de Alarcón of the State of Guerrero; 4) the Agreement by which the federal entities of Baja California, Chihuahua, Coahuila de Zaragoza, Durango and Sonora are declared free zones of the pink cotton bollworm (Pectinophora gossypiella), published in the Official

Gazette of the Federation on the 19th. July 2021, generating savings due to: a reduction in trapping activity; 5) regarding the simplification made to the SENASICA-01-020 procedure. Modifications to the characteristics of products registered or authorized for animal use or consumption, derived from the application of the Agreement that modifies the similar one that specifies non-medicated products for animal use or consumption that are deregulated, published in the Official Gazette of the Federation on November 29, 2010 and, of those generated by numerals 6.3.2., 6.3.4, 7.2.4.3, 7.4.4 and 9. of this Official Mexican Standard NOM-012-SAG/ ZOO-2020, Specifications for the regulation of products for animal use or consumption.

That this modification was approved as final in the First Extraordinary Session of the Animal Health Protection Subcommittee, held on April 11, 2023 and was subsequently approved in the Second Ordinary Session of the National Consultative Committee for Agri-Food Standardization of the Secretariat of Agriculture and Rural Development, held on June 15, 2023.

That due to the above and in exercise of the powers conferred in article 21, section I of the Internal Regulations of the Secretariat of Agriculture and Rural Development, published in the Official Gazette of the Federation on May 3, 2021, I have had to well issue this:

OFFICIAL MEXICAN STANDARD NOM-012-SAG/ZOO-2020, SPECIFICATIONS FOR THE REGULATION OF PRODUCTS FOR ANIMAL USE OR CONSUMPTION

INDEX

1. Objective and field of application

1.1. This Standard is mandatory throughout the national territory and aims to establish the specifications for production, storage, distribution, marketing, quality control and verification, which products for animal use or consumption must comply with, in accordance with the Law. Federal Animal Health and its Regulations.

1.2. This standard is applicable to establishments dedicated to the production, import, export, packaging, storage, distribution, and marketing of products for animal use or consumption, including mobile establishments, and all those that represent a zoo sanitary risk, in accordance with the Law. Federal Animal Health and its Regulations.

1.3. The application and monitoring of this Standard correspond to the Secretariat of Agriculture and Rural Development, through the National Service of Health, Safety and Agri-Food Quality, as well as its General Directorates, Regional and State Representations, within the scope of their respective powers. and territorial constituencies.

2. References

For the correct application of this Standard, the following Official Mexican Standards and Agreements must be consulted:

2.1. NOM-008-SCFI-2002, General System of Measurement Units, published in the Official Gazette of the Federation on November 27, 2002.

2.2. NOM-130-SSA1-1995, Goods and services. Food packaged in airtight containers and subjected to heat treatment. Sanitary provisions and specifications, published in the Official Gazette of the Federation on December 27, 2012.

23. NOM-073-SSA1-2015, Stability of drugs and medications, as well as herbal remedies, published in the Official Gazette of the Federation on June 7, 2016.

2.4. NOM-060-SAG/ZOO-2020, Zoo sanitary specifications for the transformation of animal offal and its use in animal feed, published in the Official Gazette of the Federation on September 8, 2022.

2.5. NOM-064-ZOO-2000, "Guidelines for the classification and prescription of veterinary pharmaceutical products by the level of risk of their active ingredients", published in the Official Gazette of the Federation on January 27, 2003.

2.6. Agreement that modifies the agreement that establishes the classification and prescription of veterinary pharmaceutical products by risk level, published in the Official Gazette of the Federation on March 5, 2012.

2.7. Agreement specifying non-medicated products for animal use or consumption that are deregulated, published in the Official Gazette of the Federation on November 29, 2010.

2.8. Agreement that modifies the similar one that specifies non-medicated products for animal use or consumption that are deregulated, published on November 29, 2010, published in the Official Gazette of the Federation on August 14, 2018.

2.9. Agreement by which the list of substances or products prohibited for use or consumption in animals destined for supply is announced, published in the Official Gazette of the Federation on July 13, 2018.

2.10 Quality Infrastructure Law, published in the Official Gazette of the Federation on July 1, 2020.

3. Definitions

In addition to the definitions contained in the Federal Animal Health Law and its Regulations, for the purposes of this Standard, it is understood as:

3.1 Conditioning: operations to which a bulk product must undergo until it is presented as a finished product. Primary packaging is that which is in direct contact with the chemical, pharmaceutical or

biological product, and secondary packaging is that which includes the product in its primary packaging, including its labeling.

3.2. Concentrated food: this category includes those food products that require mixing with either cereal grains or protein supplements, to be a finished food ready for consumption.

3.3. Medicated balanced food: this category includes those food products composed of a mixture of foods and pharmaceutical products, ready for marketing and intended for animals.

3.4. Food for self-consumption: this category includes balanced or concentrated food products, prepared, and consumed in the same facility, property or production unit or in its integrated establishments, who, according to the nature of their activities, have complied with the obligation, as appropriate, to notify operation and certify good practices in livestock production and product manufacturing before SENASICA. Food for self-consumption should not be sold or donated.

3.5. Antigen: molecule or substance foreign to the body that induces an immune response.

3.6. Biologicals with activated agents: those that, when inoculated into susceptible animal species, can replicate or reproduce within the host without causing the disease.

3.7. Biologicals with inactivated agents: products formulated from microorganisms, which have been inactivated through physical or chemical processes, which when inoculated into susceptible animal species do not replicate within the host and do not cause the disease.

3.8. Quality: set of characteristics that give a product the ability to satisfy the needs for which it was created.

3.9. Verification: procedure by which the Secretariat, through SENASICA, or official, approved or authorized laboratory, verifies that products for animal use or consumption comply with the specifications presented by the producer or importer as a requirement to be registered or authorized, in the case of biological products will be requested only from SENASICA.

3.10. Guaranteed composition: it is the expression of the quantity of the active components in their recognized and determinable forms.

3.11. Net content: quantity of corresponding packaged product after all tare deductions have been made where applicable.

3.12. Quality control: set of techniques and activities carried out to guarantee compliance with a product's specifications.

3.13. Product quarantine: animal health measure consisting of the restriction of the mobilization of products for animal use or consumption, raw materials, or packaging materials, for a certain period, in order to verify that they comply with the requirements established in this Standard.

3.14. Viable count: A quality control test to determine the number of colony-forming units present in a product.

3.15. Dose: amount of product expressed on the label to be administered to the animal.

3.16. Packaging: material that wraps, contains, and protects finished products, to facilitate their handling and conservation in storage and transportation operations.

3.17. Manufacturing company: national or foreign establishment dedicated to the production of products for animal use or consumption, which complies with current regulations and, where applicable, has manufacturing authorization in the country of origin.

3.18. Packaging: elements or containers that are in direct contact with the product to protect and preserve it.

3.19. Specification: list of detailed requirements that the products or materials used or obtained during its production must meet.

3.20. Stability: quality of a product for animal use or consumption contained in a primary packaging to maintain, during the time of storage and use, the established quality specifications.

3.21. Integrated establishment: one that receives food for self-consumption, from the integrating establishment.

3.22. Integrating establishment: one belonging to a consortium, where food is produced and distributed to its integrated establishments.

3.23. Sterility: quality control testing and verification to ensure that a product is free of viable contaminating microorganisms.

3.24. Commercial sterility: condition that allows the food to be free of viable forms of potentially harmful microorganisms, both for animal or human health, and for the conservation of the product under normal storage and distribution conditions.

3.25. Label: set of drawings, figures, legends, and specific indications, engraved or printed on containers and packaging.

3.26. Expiry date: is the one that indicates the end of the period of use or consumption of raw materials or finished products.

3.27. Pharmaceutical form: it is the product of the transformation of an active ingredient through technical procedures with characteristics in its presentation that facilitate its administration.

3.28. Ingredient: any substance or mixture of substances involved in the formulation.

3.29. Immunogenicity: Quantitative test to ensure that the finished product stimulates an immune response, when inoculated into an animal.

3.30. Internal quality control laboratory: these are the company's own facilities and equipment where the necessary tests are carried out to guarantee that the product characteristics meet current specifications.

3.31. Raw materials: are materials extracted from nature or obtained synthetically and that are transformed to produce consumer goods or finished products.

3.32. Maquila: action that a manufacturing establishment carries out for another establishment and that consists of executing one, several or all the operations in the manufacturing process of a product for animal use or consumption.

3.33. Analytical method: it is the technique to follow to control raw materials or finished products, in order to verify that the established specifications are met.

3.34. Batch number: any combination of letters, numbers, or symbols, which serve to identify a batch and under which all documents relating to its manufacturing and control are covered.

3.35. Potency: quality control test or verification, to ensure that a biological product can produce an immune response, which will be expressed in international units or percentage of protection according to what is established in the product quality specifications. For the purposes of chemical and

pharmaceutical products, it is understood as the activity of the product expressed in terms of international units, compared with a standard or reference substance.

3.36. Product: result of a specific process.

3.37. Pharmaceutical product: one made with raw materials of natural or synthetic origin with therapeutic or preventive effect on animals.

3.38. Released product is one that has been completed, has satisfactorily passed quality control tests, and is ready for distribution or marketing.

3.39. Finished product: the one that is packaged, labeled, and packaged.

3.40. Production protocol: document that contains the steps to follow during all stages of production and quality control of a product.

3.41. Purity: is the degree to which raw materials, bulks, and finished products are free of materials or microorganisms that are not typical of their formulation; also referring to a quality control test or verification for biological products.

3.42. Jointly responsible: natural or legal person who shares the obligation to comply with this standard and other complementary provisions, therefore, is subject to what is appropriate in the event of non-compliance by the owner of the product for animal use or consumption.

3.43. Secretariat: The Ministry of Agriculture and Rural Development.

3.44. Safety: verification test or microbiological quality control to ensure that a product does not cause unfavorable reactions attributable to it.

3.45. Master seed: microorganism identified, selected, and permanently stored at a specific passage level, used to produce a biological.

3.46. SENASICA: National Agri-Food Health, Safety and Quality Service.

3.47. Fresh by-products of animal origin: clean, unprocessed parts, include lung, spleen, kidney, brain, liver, blood, heart, skin, bone, adipose tissue, stomach, and intestines free of their fecal contents and foreign matter. Does not include hair, feathers, teeth, beaks, cartilage, nails, and hooves.

3.48. Dairy supplement: product made mostly with milk or its industrial derivatives, with or without the addition of other ingredients that complete the guaranteed composition, and which are used in the nutrition of animals during their lactation period.

3.49. Milk substitute: homogeneous mixture of mainly dairy ingredients, which can be added with others of animal or plant origin, essential to fully cover the daily nutritional needs for maintenance and growth of animals during their lactation period.

3.50. Titration: quality control test or verification to ensure that a product has the amount of antigen established in the product specifications.

3.51. Vaccine: suspension of biological agents, live attenuated or inactivated, their fractions or derivatives of biotechnology, which are applied to individuals with the aim of inducing protective immunity against the corresponding infectious disease.

3.52. Autogenous vaccine: inactivated biological product designed to stimulate the active immunization of animals, prepared from the isolation of a microorganism originating from an endemic disease focus in a Production Unit in Mexico, which may be applied locally or regionally that maintains an epidemiological relationship.

3.53. Validation: documentary evidence generated through the scientific collection and evaluation of the data obtained in the qualification and specific tests, throughout the entire life cycle of a product, the purpose of which is to demonstrate the functionality, consistency and robustness of a process given in terms of its ability to deliver a quality product.

For the purposes of this Standard, each of the points indicated include the general concepts related to chemical, pharmaceutical, biological and food products for animal use or consumption, and a particular mention is only made when there are some differences.

4. Storage

4.1. General considerations.

All products and raw materials used in the production that enter the establishment's warehouse must have the analysis or quality control granted by the supplier, which guarantees at least the specifications established for this purpose.

4.1.2. Warehouses must have:

4.1.2.1 Facilities and equipment according to the nature of their activities in accordance with applicable regulations.

4.1.2.2. Identified and delimited sites, at least for the reception, sampling and storage of:

4.1.2.2.1. Raw Materials;

4.1.2.2.2. Materials;

4.1.2.2.3. Product on process;

4.1.2.2.4. Finished product;

4.1.2.2.5. Products in quarantine and

4.1.2.2.6. Approved products.

4.1.2.3. Identification of the sites where products in process, quarantine and approved are stored.

4.1.2.4. Site intended for weighing.

4.1.2.5. Entry and exit controls.

4.1.2.6. Materials, products and packaging must be stored in such a way as to prevent any possibility of contamination, cross contamination or deterioration.

4.2. Storage of raw materials and materials.

The raw materials and materials used for the production and distribution of the products referred to in this Standard must be identified, inventoried, and stored according to their nature, under appropriate conditions and in the corresponding locations.

4.3. Storage of in-process, quarantine, and finished product.

4.3.1. The products must be stored in places designated for each of these purposes, physically separated from each other, complying with the temperature and humidity conditions required by the type of product.

4.3.2. Biological products and all those that by their nature require it, must be stored in refrigerators equipped with thermographic or equivalent, calibrated or verified systems. as appropriate, ensuring a regulated temperature of 2 to 8º C, except for those that by their nature require another temperature.

4.3.3. Bulk food products, before packaging, must be placed in containers, containers, or hoppers for preservation.

5. Raw materials.

The quality control analysis document must be available for all raw materials used in the production of finished products, as well as for those that will be imported and marketed in national territory. Document that can be issued by the manufacturing or marketing company, which must be verified by the manufacturing or maquiladora company, without prejudice to what is established in other complementary provisions.

5.1. In the case of food products for animal consumption, under no circumstances should the substances established in the Agreement announcing the list of substances or products prohibited for use or consumption in animals intended for food be used, nor the following raw materials:

5.1.1. Melamine.

5.1.2. Nitrofurans.

6. Production

6.1. General considerations.

6.1.1. The production area must be physically isolated from the outside environment, constructed in such a way as to facilitate its disinfection and cleaning according to the nature of the product.

6.1.2. Staff must dress in clean clothing, according to the activities designated to produce the product.

6.1.3. In chemical, pharmaceutical, and biological production areas that require sterile conditions, there must be sites subject to microbiological control, as well as locks for the entry and exit of personnel and materials, in order to reduce the risks of contamination.

6.2. Preparation protocol and other documents.

6.2.1. For each type of product there must be a production protocol and for each manufacturing batch a production order or equivalent documents.

Each batch of product must be identified and controlled in such a way that allows the traceability and traceability of the raw materials and finished product.

For the purposes of this section, production order will be understood as the individualized control that contains all the information necessary to execute the production of a batch of a product.

6.2.2. The preparation protocol must describe at least:

6.2.2.1. The raw materials used in the production of the product, specifying the common name, quantity of each one, as well as its potency when applicable.

6.2.2.2. The stages of its preparation until completing the finished product.

6.2.2.3. The equipment used in the process.

6.2.2.4. The stage of production in which samples are obtained to carry out quality control tests.

6.2.2.5. Labeling, packaging, and storage.

6.2.2.6. Indications for washing, sterilizing equipment, and containers, when applicable.

6.3. Product assembly.

Each batch of product must be identified and controlled in such a way that allows the traceability and traceability of the raw materials and finished product.

6.3.1. Establishments that produce products for animal use or consumption that provide total or partial maquila services must comply with the provisions of this Standard and notify the maquila agreements to the Secretariat through SENASICA.

6.3.2. The agreements or contracts entered for the product manufacturing process must establish the responsibility of the contracting parties, in the sense of maintaining records of sales and distribution channels for at least five years; the list of products that are the reason for the agreement or contract; its validity and the conditions of its termination.

6.3.3. Natural or legal persons who enter maquila agreements or contracts will be jointly and severally liable.

6.3.4. In maquila agreements or contracts for the production of food products for consumption by ruminants, which contain proteins of animal origin, in addition to what is indicated in the previous paragraph, controls will be established to ensure that proteins of ruminant origin are not used in accordance with the provisions of the Official Mexican Standard NOM-060-SAG/ZOO-2020, Zoo sanitary specifications for the transformation of animal offal and its use in animal feed; and the responsibility of both parties to keep records of the sale and purchase of flour used as raw material in the production of food products, at least for five years, without prejudice to other zoo sanitary provisions on the matter.

6.3.5. Establishments involved in the manufacturing of chemical, pharmaceutical, and biological products through maquila must be processors.

6.3.6. The maquiladora establishment that intervenes in the manufacturing of food products must be a processor.

7. Quality control and verification

7.1. General considerations.

7.1.1. Each batch of finished product intended to be marketed in Mexico must be analyzed in the quality control laboratory, in accordance with the provisions of article 171 of the Regulations of the Federal Animal Health Law.

7.1.2. Establishments must guarantee the quality of each imported batch of raw material or finished product by presenting the analysis or quality control document of the manufacturing company, carried out under internationally recognized analytical techniques or the analytical methods preferably described in the latest edition of the Pharmacopoeia. from the United Mexican States (FEUM) and/or supplements; If the analytical method is not described in this document, pharmacopoeias from other countries or regions of the world may be used, or, where applicable, for imported products, validated internal methods.

7.1.3. Companies that import raw materials that are not freely marketed in the country of origin, prior to importation, must have express authorization from the Secretariat, and present at the time of import, the export certificate and certificate of origin issued by the competent authority and the quality control certificate, for each batch, carried out in an internal quality control laboratory of the manufacturing company in the country of origin, carried out under internationally recognized analytical techniques.

7.1.4. All chemical, pharmaceutical, and biological products must have stability testing during the development phase; Likewise, food products that have a moisture content greater than 12 percent (%) must have stability tests. Such tests must be based on scientifically verifiable preservation methods.

7.1.5. Food products packaged in hermetically sealed containers or subjected to heat treatment are exempt from compliance with section 7.1.4., if commercial sterility tests have been carried out, in which the validity is up to 24 months, based on the "Official Mexican Standard NOM-130-SSA1-1995, Goods

and services. Food packaged in hermetically sealed containers and subjected to heat treatment. Sanitary provisions and specifications", in its test methods section, as well as food products that demonstrate, through laboratory analysis, a moisture content of less than 12 percent (%).

7.1.6. In the case of self-consumption food products, stability tests will be established in accordance with what is indicated in the technical guides referred to in section 7.2.4.8 of this Standard.

7.1.7. Companies must have procedures for the final disposal of raw materials and finished products, outside of specifications, that prevent their distribution, marketing, use or consumption. In cases where reconditioning and/or reprocessing is intended, the holder of the registration or authorization must comply with the internal procedure for products out of specification, established by each manufacturing establishment.

7.1.8. Under no circumstances should expired products be imported, distributed, or marketed. Establishments must have procedures that guarantee the correct withdrawal, storage, immobilization, and final disposal, avoiding its distribution, commercialization, use or animal consumption.

7.2. Quality control and verification tests

7.2.1 . The tests of the products to be regulated must be carried out in verification and internal quality control laboratories approved and/or authorized by the Secretariat through SENASICA.

7.2.2. For chemical and pharmaceutical products.

7.2.2.1. The active ingredients of the various pharmaceutical forms will be quantified according to the analytical methods described in the latest edition of the Pharmacopeia of the United Mexican States (FEUM) or supplements; If the analytical method is not described in it, any other international pharmacopoeia may be used, or those analytical techniques validated and authorized by the interested party in obtaining its regulation.

7.2.2.2. The analytical results will be reviewed and endorsed by a professional authorized by the Secretariat through SENASICA, and must have records of the calculations, observations and results obtained.

7.2.2.3. According to the physical presentation or pharmaceutical form of the finished products, they must be subjected to the tests indicated below:

a) Tests for solids

	Globule tablet, pill	**Capsule**	**Powder to reconstitute for oral use, crushed**	**Powder to reconstitute for parenteral use**	**Topical use powder**	**Powder for inhalation**
Appearance/ Description/ Appearance	*	*	*	*	*	*
Valuation	*	*	*	*	*	*
pH	NA	NA	2	2	NA	NA
Disintegration	3,	3	NA	NA	NA	NA
Dissolution	2,	2	NA	NA	NA	NA
Humidity	NA	2	*	*	*	*

Time for reconstitution	NA	NA	2	*	NA	NA
Limit microbial	5	2	*	NA	*	*
Sterility/Pyrogens or bacterial endotoxins	NA	NA	NA	*	NA	NA
Identity	6	6	6	NA	6	NA

Note:

N/A= Not applicable

*= Yes, you have to take the test

1. When the capsule is made of soft gelatin and the content is liquid
2. When applicable
3. When dissolution is not required
4. Except blood cells
5. Only for herbal remedies and medicines
6. Only for herbal remedies

b) Tests for semisolids.

	Suppository and suppository	**Gel, cream, topical ointment, jelly**	**Gel, cream and ointment otic, ophthalmic or intramammary**
Appearance/Description/Appearance (including consistency)	*	*	*
Valuation and identity	*	*	*
pH	NA	1	1
particulate matter	NA	NA	*
Goo	NA	1 (except ointment)	1 (except ointment)
Sterility	NA	NA	*
Limit microbial	*	*	NA
Identity	NA	2	NA

Note:

N/A= Not applicable

*= Yes you have to take the test

1. When applicable
2. Only for herbal remedies

c) Tests for liquids .

	Oral, topical and nasal solution, syrup, elixir, herbal tea, tinctures and extracts	**Solution, ophthalmic, otic and parenteral, eye drops**	**Oral and topical emulsion, liniments, lotions**	**parenteral emulsion**	**Oral, topical and nasal suspension**	**Ophthalmic and parenteral suspension**
Appearance/ Description/ Appearance	*	*	*	*	*	*
pH	*	*	*	*	*	*
Assessment	*	*	*	*	*	*
Limit microbial	*	NA	*	NA	*	NA
Sterility	NA	*	NA	*	NA	*
Pyrogens or endotoxins bacterial	NA	*	NA	*	NA	*
Identity	2	NA	2	NA	2	NA

Note:

N/A= Not applicable

*= Yes you have to take the test

1. When applicable

2. Only for herbal remedies

d) Other special cases of pharmaceutical forms or considerations of use.

	Aerosol for inhalation	**Patches, earrings, necklaces**	**Medicinal gases**	**Nasal spray: solution or suspension**	**Topical spray**	**application implants, vaginal and intrauterine drug-releasing devices**
Appearance / Description /	*	*	NA	*	*	*

Appearance						
Assessment	*	*	*	*	*	*
Adhesiveness	NA	NA earrings and necklaces	NA	NA	NA	NA
Microbial limit	*	1	NA	*	*	1
Sterility	NA	NA	NA	NA	NA	1
Identity	NA	2	NA	NA	NA	NA

Note:

N/A= Not applicable

*= Yes you have to take the test

1. When applicable.

2. Only for herbal remedy.

7.2.2.4. For medicated shampoos and medicated premixes, the tests to which they must be subjected are indicated in "Appendix A" (Normative) of this legal instrument.

7.2.3. For organic products.

7.2.3.1. Batches of biological products must be subjected to the corresponding tests described in the quality control and verification protocol established in Appendices B or C (Normative) of this Standard.

7.2.3.2. When immunogenicity is ensured in the master seed and the finished product based on the content of microorganisms, through "in vitro" methods, potency tests must be replaced by titration, viable count, or serology techniques.

7.2.3.3. Where appropriate, nationally and/or internationally recognized challenge “strains” and standardized biologics should be used in potency testing performed “in vivo” or “in vitro.”

7.2.3.4. Polyvalent products composed of two or more immunogenic fractions must be evaluated by tests applicable to each fraction and the entire construction, so that their effectiveness is demonstrated in a particular and total way.

7.2.3.5. Each batch that is intended to be marketed must satisfactorily comply with all the quality control tests indicated in its corresponding protocol at the time of its release and during its validity.

7.2.3.6 The analytical results of products manufactured in Mexico will be reviewed and endorsed by a professional authorized by the Secretariat through SENASICA, and must have records of the calculations, observations and results obtained.

7.2.3.7. Biological products based on genetic engineering must completely sequence their construction, as part of their verification file.

7.2.3.8. For biological products that may represent a risk of interference in epidemiological surveillance or any official strategy, they must document the serological tests used to differentiate vaccine antibodies from antibodies produced by field viruses, DIVA (Differentiating Infected from Vaccinated Individuals)., as part of your verification file.

7.2.4. For food products.

7.2.4.1. The analytical techniques authorized for quality control and verification of food products must be those recognized by national and international organizations.

7.2.4.2. Quality control and verification of food products should include, as required; the proximal chemical analysis, quantitative determination of active pharmaceutical ingredients, additives, determination of other necessary nutrients, as well as the other tests described in the manufacturing protocol.

7.2.4.3. Manufacturers, as well as importers of finished food products, must carry out or have quality control documents that support the results obtained by determining the levels of aflatoxins in their raw materials to which the risk is applicable, which They must be kept in the company's custody for 6 months.

7.2.4.4. The analytical results will be issued by approved or authorized laboratories which must be reviewed and endorsed by handwritten signature and seal of the professional authorized by the Secretariat through SENASICA, and must have records of the calculations, observations and results obtained.

7.2.4.5. Prior to the regulation of finished products, the manufacturer or importer must carry out the verification in an official, approved or authorized laboratory. by SENASICA. In cases in which the regulation corresponds to national products subject to authorization, if the manufacturing company has an authorized or approved internal quality control laboratory to carry out the corresponding analytical techniques on the product, it is exempt from the verification.

7.2.4.6. Prior to the regulation of food products packaged in hermetically sealed containers or subjected to heat treatment packaged aseptically, commercial sterility tests must be carried out as established in the "Official Mexican Standard NOM-130-SSA1-1995, Goods and services. Packaged foods in hermetically sealed containers and subjected to heat treatment. Sanitary provisions and specifications" without prejudice to other complementary provisions.

7.2.4.7. The marketing, in the national territory, of foods that contain products or by-products, viscera or fresh offal of animal origin, must comply with the provisions of this standard, and its preparation, storage, marketing, distribution will be subject to the official provisions, without prejudice to other provisions on the matter.

7.2.4.8. The Secretariat, in accordance with the provisions of Article 92 of the Federal Animal Health Law, will establish and disseminate in the Official Gazette of the Federation the technical information guides for the registration or authorization of food products produced by natural or legal persons who are destined for "self-consumption" or "on request", based on the risk to animal health, public health, agri-food safety and traceability.

7.2.4.9. When national or imported food products seek authorization or registration containing two or more pharmaceutical products with different registration numbers, they must scientifically justify and in therapeutic or preventive terms, the need to mix the active ingredients, through the following studies or tests as applicable. to the product.

7.2.4.9.1. Sensitivity studies against reference microorganisms, indicating the corresponding minimum inhibitory concentrations (MIC), when applicable.

7.2.4.9.2. Pharmacokinetic studies of the active ingredients in combination, for each of the species for which the product will be intended, in accordance with the conditions under which the pharmaceutical products to be used in the formulation were registered.

7.2.4.9.3. Tests of compatibility, synergy, or antagonism, or those that justify their combination.

7.2.4.9.4. Tests to corroborate withdrawal time of the food to be regulated; requirement that applies to products intended for species that produce food of animal origin for human consumption and must be executed in accordance with the provisions of national or international organizations that are experts in the matter.

7.2.4.9.5. Tests to corroborate maximum residue limits; requirement that applies to products intended for species that produce food of animal origin for human consumption and must be executed in accordance with the provisions of national or international organizations that are experts in the matter.

7.2.4.9.6. The tests listed do not need to be carried out in official, approved, or authorized laboratories. The laboratory that executes them must have facilities, equipment and methodology validated by the establishment's quality control laboratory.

7.2.4.10. In the formulation of feed for ruminants, it is allowed to include chicken manure or poultry manure previously subjected to a thermal process.

7.2.4.11. Dairy supplements, including milk substitutes used in animal feed, both domestic and imported, must be pigmented with non-toxic colorants approved in the country of origin for marketing, in such a way that allows them to be identified and differentiated. or not be pigmented, if their traceability and use in the target species are guaranteed through their logs.

7.2.4.12. The importation for marketing purposes of dairy supplements and non-pigmented milk substitutes will be subject to the presentation of a certificate issued by SENASICA through the State Representation in the corresponding federal entity, which will be issued at the request of the party, in which indicates that it will supervise the use of the product in animal feed, said certificate must indicate the quantity to be imported.

7.2.4.13. In the case of probiotic additives, made with lactic acid-producing microorganisms or similar, prior to their regulation, verification must be carried out to determine the genus and species used, as well as specify the concentration of viable microorganisms expressed in Colony Forming Units per milliliter. (CFU/ml) or gram of finished product.

7.3. Sampling

To carry out quality control tests on each batch that is intended to be marketed, representative samples of the finished product and/or raw material must be taken.

7.3.1. The sampling must have the following characteristics:

7.3.1.1. It must be carried out by qualified personnel, in a random and representative manner.

7.3.1.2. The procedures used must avoid any risk of contamination by being carried out with clean, inert and, where appropriate, sterile utensils.

7.3.1.3. The material of the containers to place the samples must be appropriate to the type of sample and analysis being carried out.

7.3.1.4. The containers or containers where the samples are placed must be identified with at least the following data: name of the product or ingredient, lot number, number that identifies the sample, quantity, name of the person who sampled and date of sampling.

7.4. Retention samples.

7.4.1. Each batch of active ingredient and finished product must have retention samples that must be stored in a specifically designated location, under pre-established environmental conditions, for proper conservation. Must have records that support the procedure.

7.4.2. The number of samples must be sufficient to carry out at least two complete analyses.

7.4.3. Retention samples of biological products must be kept for at least three months after the validity period.

7.4.4. For chemical and pharmaceutical products, as well as the raw materials used in their production, retention samples must be kept for a period of one year after expiration.

7.4.5. For finished food products, retention samples must be retained for a minimum of six months from the date of manufacture or until expiration, whichever occurs first. Raw materials must be kept for the same period, starting from their receipt.

7.5. Product released.

Each batch of finished product must be released and ready for distribution or marketing, once it has satisfactorily passed all the tests established in the quality control protocol.

8. Containers, packaging, and labeling.

8.1. Containers and packaging.

The containers must be inert, easy to clean and, when required, sterilized, of sufficient size, so that they provide adequate protection to the product against external factors that could cause its deterioration, contamination, or leak.

8.2. Labeling of finished product.

8.2.1. General characteristics.

8.2.1.1. The texts and legends on the labeling of the containers of domestically produced and imported products for animal use or consumption that are intended to be marketed must be printed in Spanish.

8.2.1.2. The necessary labeling legends, graphic representations or designs must appear clearly visible and legible and must not use any type of images or legends that confuse or induce misuse of the product.

8.2.1.3. The ink, paper or glue used must be made of materials that avoid alterations caused by the usual manipulations of storage and transportation.

8.2.1.4. The language must be clear, simple, and free of ideas that lead to the possible exaggeration of the real quality of the product; prohibiting terms or phrases that cause exaggeration or characteristics not typical of the products such as: "etc., certain, almost all, the majority" or favorable ones such as "the only thing, the best."

8.2.1.5. The magnitudes must be represented in the International System of Units according to with NOM-008-SCOFI-2002, General System of Measurement Units.

8.2.1.6. When the size of the label is reduced or additional information is required and there is not enough space for the required information, instructions must be used, which can be printed or digital.

8.2.1.7. For food products, the total of the information indicated in points 8.2.2., 8.2.3. and 8.2.4. It must be placed on the main faces of the packaging and adapted in the order that best suits the presentation of the product.

8.2.2. The following information must be placed on the label, in the main box or side faces, product packaging and boxes, as appropriate:

8.2.2.1 . Net content of the product, which must be expressed in units of the decimal metric system or recognized international units, in accordance with the authorized or registered presentation.

8.2.2.2. Commercial name of the product.

8.2.2.3. Regulation number of the product before the Secretariat, except those that the current regulations or the Secretariat itself establishes as exempt from regulation or deregulated.

8.2.2.4. Logo.

8.2.2.5. The legend "veterinary use."

8.2.2.5.1. In food products, it may be replaced by the legend "Food for", indicating the species for which it is intended.

8.2.2.5.2. Biological products must include the legends: "consult the veterinarian" and "sale requires a prescription."

8.2.2.6. If the product is national, the legend "Made in Mexico by" must be printed, indicating the name of the company and address.

8.2.2.7. If the product is imported, the legend "Manufactured by" and "Imported and distributed by" must be indicated, indicating the name and address of both companies.

8.2.2.8. In the case of national products manufactured by maquila, one of the following legends "Made in Mexico by" must be indicated, indicating the name and address of the maquiladora company "for", indicating the name and address of the company that owns the product registration, or, "Made in Mexico for", indicating the name and address of the company that owns the product.

8.2.2.9. In the case of imported products manufactured by maquila, they must have the legend "Made in"... indicating the name of the country of origin of the product..."para", indicating the name and address of the company holding the registration of the product or "Made for"... indicating the name and address of the company that owns the product, "Imported and distributed by"... indicating the data of the company that owns the product.

8.2.3. The following information must be included on product packaging, boxes, and labels.

8.2.3.1. Formula:

8.2.3.1.1. For chemical and pharmaceutical products, the generic name of the active ingredient(s) must be noted, which must be expressed quantitatively in units of the decimal metric system or in recognized international units.

8.2.3.1.2. For biological products, the type of antigen used and, where applicable, variety or strains, as well as the characteristics of the biological, must be indicated.

8.2.3.1.3 For food products, the guaranteed analysis must be included indicating the minimum quantities I maxims of nutritional principles.

8.2.3.1.4. The manufacturer or importer of balanced foods must indicate on the label the ingredients used in its formulation, which must be stated generically. If raw materials of animal origin are used, the species of origin must be specified.

8.2.3.1.5. In the case of being medicated, the concentration of the active ingredient must be indicated.

8.2.3.2. The legend "Consult the Veterinary Doctor", without prejudice to the official provisions on the matter.

8.2.3.3. Lot Number.

8.2.3.4 . Indications: **The handling and conservation conditions of the product,** animal species, stage, age or zootechnical purpose, spectrum of action and other relevant conditions must be expressed clearly and with commonly used terminology. In the case of diagnostic kits, they must be accompanied by instructions that clearly express their use and interpretation of results.

8.2.3.5. Dosage or posology:

8.2.3.5.1. It must be indicated in units of the Decimal Metric System or in established international units.

8.2.3.5.2. In medicated food premixes and medicated foods, which include pharmaceutical products of these categories, the dose must be indicated in mass/mass or mass/volume units, according to the NOM-008-SCFI-2002 standard.

8.2.3.5.3. For biological products, if a booster dose is required, the conditions must be indicated, especially the timing.

8.2.3.5.4. For food products, the frequency of use and quantity or portion recommended by the manufacturer must be included.

8.2.3.5.5. The route of administration that specifies whether it is oral, subcutaneous, intramuscular or another route. It should be indicated if any special equipment is required for its application.

8.2.3.6. Warnings: all situations that represent risk or danger must be specified both in the handling of the product and in its use, mentioning the antidote or support therapy according to the safety sheet of the corresponding ingredients in the formulation. In the case of pharmaceutical products, whose active ingredient can create resistance or leave toxic residues, the time for withdrawal of the product prior to the slaughter of the animals must be indicated, or the time in which the products or by-products of the animals should not be consumed. treaties.

8.2.3.7. The precise instructions for disabling or destroying empty product containers.

8.2.3.8. Expiration date that must indicate the month with the first three letters of its name and the year in digits. It may be indicated with the number of the month and the year with the last two digits, in this order.

8.2.3.9. Finished food products, balanced foods, milk substitutes, dairy supplements and all foods that include pharmaceutical products or their active ingredients in their formulation, for therapeutic use in animals, must indicate the legend "medicated food" on their label.

8.2.3.10. Pharmaceutical products for use or consumption in the equine species, whose products or by-products are intended for human consumption, which cannot demonstrate maximum residue limits, must include the legend "Do not administer this product in horses for human consumption."

8.2.4. In the case of imported products not labeled from their origin, or with inconsistencies in their labeling, they must be labeled by the holder of the registration or authorization or by the holder of the regulated product, before or after their import and prior to their commercialization in the national territory, in accordance with the provisions of this Standard.

9. Imported products.

Products for animal use or consumption, registered or authorized before the Secretariat through SENASICA, may only be imported by the owners.

In the case of raw material used in the production of products for animal use or consumption, it must be identified from its origin for traceability purposes.

10. Verification or Inspection.

Compliance with the provisions contained in this standard will be verified or inspected by official personnel of the Secretariat or by approved inspection units, who may be assisted by third-party specialists authorized for this purpose, the result of the verification or inspection will be recorded through the issuance of the corresponding opinions.

11. Sanctions.

Failure to comply with the provisions contained in this Standard will be sanctioned in accordance with the provisions of the Federal Animal Health Law, its Regulations, and other applicable provisions.

12. Concordance with international standards.

This Official Mexican Standard is not equivalent to any international standard.

13. Bibliography.

13.1. Federal Animal Health Law, published in the Official Gazette of the Federation (DOF) on July 25, 2007 and its modification on February 16, 2018.

13.2. Regulations of the Federal Animal Health Law, published in the DOF on May 21, 2012.

13.3. Federal Law on Metrology and Standardization, published in the DOF on July 1, 1992 and its modification on December 18, 2015.

13.4. Regulations of the Federal Law on Metrology and Standardization, published in the DOF on January 14, 1999 and its modification on November 28, 2012.

13.5. Federal Law of Administrative Procedure, published in the DOF on August 4, 1994 and its modification on May 2, 2017.

13.6. NOM-008-SCFI-2002, General System of Measurement Units, published in the DOF on November 27, 2002.

13.7. NOM-073-SSA1-2015, Stability of drugs and medications, as well as herbal remedies", published in the DOF on June 7, 2016.

13.8. NOM-130-SSA1-1995, Goods and services. Food packaged in airtight containers and subjected to heat treatment. Sanitary provisions and specifications, published in the DOF on November 21, 1997 and its modification on December 22, 2012.

13.9. NOM-060-SAG/ZOO-2020, Zoo sanitary specifications for the transformation of animal offal and its use in animal feed, published in the DOF on September 8, 2022.

13.10. Agreement that modifies the agreement that establishes the classification and prescription of veterinary pharmaceutical products by the level of risk of their active ingredients, published in the DOF on March 5, 2012.

13.11. Agreement specifying non-medicated products for animal use or consumption that are deregulated, published in the DOF on November 29, 2010.

TRANSIENTS

FIRST ARTICLE. This Standard will come into force after 180 calendar days, counted from the day following its publication in the Official Gazette of the Federation.

SECOND ARTICLE. The name of the Official Mexican Standard NOM-012-ZOO-1993, Specifications for the regulation of chemical, pharmaceutical, biological and food products for use in animals or consumption by them, is modified to become the Official Mexican Standard NOM-012-SAG /ZOO-2020, Specifications for the regulation of products for animal use or consumption.

This Official Mexican Standard NOM-012-SAG/ZOO-2020, Specifications for the regulation of products for animal use or consumption, repeals the Official Mexican Standard NOM-012-ZOO-1993, Specifications for the regulation of chemical, pharmaceutical, biological and nutritional products for use in animals or consumption by them, published in the Official Gazette of the Federation on January 17, 1995 and its modifications published in the same informative organ on June 3, 1998 and January 27, 2004, respectively .

THIRD ARTICLE. The entry into force for the provisions of section 8.2.2.5.2 will be 24 months from now, counted from the day following its publication in the Official Gazette of the Federation.

Mexico City, June 21, 2023.- The General Director of Agri-Food Standardization of the Ministry of Agriculture and Rural Development, **José Eduardo Espinosa de los Monteros Aviña.-** Heading.

"APPENDIX A" (NORMATIVE)

QUALITY CONTROL AND VERIFICATION OF MEDICATED SHAMPOOS AND MEDICATED PREMIXES

DETERMINATION	POWDER AND GRANULATE	SHAMPOOS	SOAPS
IDENTITY	▲	NA	▲
VALUATION OF ASSET PRINCIPLE	▲	▲ *	▲
UNIFORM OF CONTENT	▲	NA	NA
APPEARANCE/DESCRIPTION/ASPECTS	▲	▲	NA
HUMIDITY	▲	NA	NA
PH	NA	▲	NA
VISCOSITY	NA	▲	NA
DERMIC IRRITABILITIES**	NA	▲	▲
WEIGHT VARIATION	NA	NA	▲

DENSITY	NA	▲	NA
*Only for medicated products **Only for verification			

"APPENDIX B" (NORMATIVE)

TECHNICAL GUIDE FOR QUALITY CONTROL AND VERIFICATION FOR BIOLOGICAL PRODUCTS; FORMAT OF THE TECHNICAL AND INSTRUCTIONAL SHEET

Laboratory tests for the verification of biological products will be carried out in the official laboratory and quality control tests must be carried out in an approved or authorized laboratory and will be carried out based on scientific principles and those related to Harmonization and Equivalence provided. in the Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization and specifically with any of the following points:

a) Provisions contained in the Regulations of the Federal Animal Health Law, the Health Code for Terrestrial Animals, the Health Code for Aquatic Animals, the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, as well as the Manual of Diagnostic Tests for Aquatic Animals of the World Organization for Animal Health (WHO founded as OIE).

b) In the Code of Federal Regulations (CFR, for its acronym in English: The Code of Federal Regulations, of the United States of America) or in the pharmacopoeias of the country of origin of the product.

c) In agreements between Mexico and other countries for the mutual recognition of testing procedures applicable to biological products.

d) Provisions issued by other entities and public administration agencies related to the matter.

e) Analytical techniques or methodologies developed by the producing laboratory if they are validated under internationally accepted technical and scientific criteria.

TECHNICAL SHEET FOR PRODUCT VERIFICATION REQUEST	
DATA OF THE MANUFACTURING COMPANY	
Name / Company name	
Tax address	
Product manufacturing address	
Address to listen to and receive notifications	
Contact person(s)	
Phone	
Contact emails to receive notifications related to the process (preferably more than one)	
ORGANIC PRODUCT DATA	
Trade name	

Lot Number	
Production date	
Expiration date	
Biological product to be tested representative of the batch produced	
Components of the biological product	
Packaging characteristics and presentations	
Conservation temperature for storage including the indication without reconstitution and once reconstituted	
Use	
Target species	
Dosage	
Routes of administration including the indication in the case of the use of special devices for its application	

INSTRUCTIONS FOR THE TECHNICAL SHEET

The general data relating to the manufacturing company must be indicated, as well as the data on the biological product, considering:

a) Tradename. - Name given to the product.

b) Lot Number. - Any combination of letters, numbers or symbols that serve to identify a process, under which all documents relating to its manufacturing, control and commercialization are covered.

c) Date of elaboration. - Month and year in which the batch of the product was manufactured.

d) Date of Expiry. - Term assigned to the batch of a biological product, which designates the end of the validity period, (month and year)

e) Biological product to be tested representative of the batch produced. - Product name.

f) Components of the biological product. - Genus and species or their parts that make up the product.

g) Packaging characteristics and presentations. - Describe type of container, physical state of the product (lyophilized, frozen, emulsified, among others), content in ml.

h) Conservation temperature for storage. - What storage temperature does the product require to preserve its characteristics (room temperature, refrigeration, freezing). Including the indication (if applicable depending on the pharmaceutical form) without reconstitution and once reconstituted.

i) Use - what it is used for, prevention, cure, among others.

j) Target species. - In what species it is going to be used, bovine, equine, canine, feline, etc. as well as its productive or reproductive stage if applicable.

k) Dosage. - Amount of the product that is required to be administered to the animal.

l) Routes of administration. - Route of administration of the product (ocular, intranasal, injected, subcutaneous, intravenous, among others).

General Considerations for filling

This form must be filled out and presented completely.

Location: Av. Centenario de la Educación s/n, (Km 37.5 Carretera Federal México-Pachuca), 55740 Tecámac de Felipe Villanueva, Tecámac, State of Mexico.

Public service days: Monday to Friday

Hours: 8:00 am to 18:00 pm.

Administrative legal basis

Regulations of the Federal Animal Health Law, article 153, section II, subsection a) (DOF 05-21-2012)

Email for inquiries

gestioncenasa.dgsa@senasica.gob.mx

The tests carried out on biological products, according to their characteristics, will be the following, being illustrative, but not limiting, those that apply to the type of product. Example: if it is of viral, bacterial, biotechnology-derived or other origin; whether it is live, inactivated or dimmed; If it is emulsified, liquid or freeze-dried,

I. _ Physicochemical tests. - physical inspection, vacuum, determination of pH, humidity, determination of residual inactivators and preservatives, among the main ones.

II. In vivo tests. - biological tests carried out inside a living organism; titration in chicken embryo, titration in tissue culture, titration in laboratory animal, safety test, potency test, cohabitation test, inactivation test, immunogenicity test, virulence reversion test, among others and that apply according to the type of product.

III. In vitro tests. - tests carried out in the laboratory under a controlled environment outside a living organism, identity, viable count, inactivation test, sterility, in vitro titration, contaminant agent tests, immunogenicity tests and purity tests, among others. main and are applied according to the type of product.

IV. Other types of tests that the Secretariat determines depending on the characteristics of the product.

Regarding biological products derived from biotechnology, the following tests are additionally performed when applicable:

Identity tests and/or contamination with other microorganisms, using molecular techniques.

i. Identity by PCR or sequencing.

ii. Identification of proteins cloned or produced by recombinant viruses or their nucleotide sequences. Hybridization, Dot-Blot, Western-Blot or Southern-Blot, among the main ones

iii. Evaluation of the protein production of the viruses or inoculated DNA, through a transfection test in cell culture and/or transformation of bacterial strains.

If the tests are not considered in this section, those that the manufacturer describes in its technical information may be used.

"APPENDIX C" (NORMATIVE)
AUTOGENOUS VACCINES

Autogenous Vaccines must be used in the animal species, farms, and region where the isolation originated, which will be applied by an Authorized Responsible Veterinarian in the Livestock Production Unit and their use is under his supervision and in accordance with the owner of the livestock farm.

The tests carried out for the verification and quality control of an autogenous vaccine are the following:

I. Purity test. Samples of the finished biological product are analyzed for the detection of contaminating bacteria, viruses, and fungi according to national or internationally recognized techniques.

II. Security test. Samples of the finished biological product are analyzed according to national or internationally recognized techniques.

III. Identity proof. All microorganisms used to produce autogenous vaccines are identified.

IV. Immunogenicity or antigenicity tests. Tests performed in vivo or in vitro.

V. The Secretariat will indicate complementary molecular tests according to the characteristics of the biological product in question or those that the manufacturer describes in its technical information may be used for identification and characterization.

The microorganisms used to produce an autogenous biological may be used in the manufacturing of the vaccine for a period of more than 12 months if evidence of quality and effectiveness of the product is presented in the locality or region in use.

The microorganisms used to produce an autogenous biological may not be used for the generation of vaccines after 12 months after registration.

The manufacturing of the batch of biological product; Its validity will be no more than 12 months from its registration.

The microorganism used for an autogenous biological must be notified to the National Epidemiological Surveillance System (SIVE) of this National Service.

End Unofficial Translation

Attachments:

NOM-012-SAG ZOO 2020 Original Spanish.pdf