**TECHNICAL QUESTIONNAIRE FOR EVALUATION OF THE INSPECTION SYSTEM OF COUNTRIES INTERESTED IN EXPORTING ANIMAL PRODUCTS TO BRAZIL**

**MILK AND DAIRY PRODUCTS**

|  |
| --- |
| **NOTE: All information should preferably be sent in Portuguese, but questionnaires answered in English or Spanish will also be accepted. Responses should be provided in full, as improper/incomplete filling may result in delays. Please provide any additional information that may complement/assist in understanding your responses.** |

1. GENERAL INFORMATION
	1. Country Name:
	2. Desired approval mode:

( ) Individual qualification of establishments.

( ) Recognition of the equivalence of the Inspection System.

( ) Maintenance of the equivalence of the Inspection System.

* 1. What is the Official Body responsible for the Veterinary Public Health and Animal Health Services of the Country?
		1. Briefly describe the organizational structure and present the organization chart.
		2. Body/Department responsible for Animal Health
			1. Name:
			2. Name of the person in charge:
			3. Address:
			4. Phone:
			5. Email:
		3. Body/Department responsible for Public Health - Animal Products Inspection Service
			1. Name:
			2. Name of the person in charge:
			3. Address:
			4. Phone:
			5. Email:
			6. Identification of a focal point for information exchange (name and e-mail):
	2. Are there other Official (Government) or Officially Accredited Bodies responsible for Animal Health Services and Animal Products Inspection? Describe.
	3. Are there other Official (Government) or Officially Accredited Bodies responsible for the regulation and control of the supplies used in the preparation of animal products (additives, technology adjuvants, water supply), facilities and equipment sanitation and control of urban pests? Describe.
	4. Are there any private entities carrying out veterinary, animal health or animal products inspection services? Describe the roles of these entities and how the link with the official bodies takes place.
	5. Inform the amount of milk establishments and dairy products, as well as their locations on the country map.
	6. Categories and products you want to export to Brazil (inform the animal species). Categories should be indicated in accordance with WTO Notification G/SPS/N/BRA/1184/Add.2/Corr.3 ([https://docs.wto.org/dol2fe/Pages/FE\_Search/FE\_S\_S006.aspx?FullTextHash=1&MetaCollection=WTO&SymbolList=%22G/SPS/N/BRA/1184%22+OR+%22G/SPS/N/BRA/1184\*%22#](https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?FullTextHash=1&MetaCollection=WTO&SymbolList=%22G/SPS/N/BRA/1184%22+OR+%22G/SPS/N/BRA/1184*%22) - Check for possible updates).
	7. Indicate the establishments that are approved to export the categories/products referred to above and the respective countries to which they are entitled to export.
1. OFFICIAL ANIMAL HEALTH SERVICE
	1. Organizational Structure
		1. What are the bodies responsible for the Animal Health Service from the central level to the level of execution? What are the assignments of each?
		2. What are the main laws in force in the country related to Animal Health? Briefly describe each and attach translated copy.
	2. Animal population
		1. Inform the number of animals per species:
	3. Animal health situation (dairy herd)
		1. Are there diseases whose vaccination is mandatory? If so, which ones.
		2. What is the health situation of the country in relation to diseases of mandatory notification of the OIE?
		3. What is the health situation of neighbouring countries in relation to OIE mandatory notification illnesses?
	4. Veterinary products
		1. Describe the organizational structure of the competent authority at different levels (central, regional and local) and human resources dedicated to the approval, supervision and control of veterinary products. Present the organization chart and description of the prerogatives and activities of each sector involved.
		2. Describe the procedures for registration, import, manufacture, distribution, sale and use of veterinary products. Please indicate the legal basis and relevant articles of the rules on the subject.
		3. Indicate the sanctions and penalties to the regulated who do not comply with what is provided for in the laws related to the registration, import, manufacture, distribution, sale and use of veterinary products. Indicate the legal basis and relevant articles of the rules that define such penalties and penalties.
		4. Indicate whether the use of hormones, beta-agonists and antimicrobials is authorized as growth promoters in food-producing animals in the country. Indicate the legal basis and relevant articles of the rules that regulate the use.
		5. Indicate which veterinary products are subject to the veterinary prescription requirement for their purchase. Indicate the legal basis and relevant articles of the rules that regulate the subject.
		6. Indicate whether the *extra-label/off-label*/*use* of veterinary products in food-producing animals is authorised. If authorized, indicate under what conditions it is allowed and what maximum residue limits apply when used in this condition. Indicate the legal basis and relevant articles of the rules that regulate the use.
		7. Indicate the conditions and controls required in the manufacture of medicated feed. Indicate the legal basis and relevant articles of the rules that regulate the subject.
		8. Provide a list of authorised active pharmaceutical supplies for use in food-producing animals by species, including substances authorised as additives (e.g. anticoccidiums and antimicrobial-based performance enhancers).
		9. List the maximum residue limits for authorised active pharmaceutical supplies in the country. Indicate the regulations that establish them.
		10. Indicate the list of prohibited substances for use in food-producing animals by species. Please indicate the legal basis and relevant articles of the rules defining the ban.
2. OFFICIAL SERVICE FOR THE INSPECTION OF PRODUCTS OF ANIMAL ORIGIN.
	1. **Organizational Structure**
		1. Describe the bodies responsible for the Official Inspection Service for Products of Animal Origin from the central level to the level of execution. What are the assignments of each?
		2. What is the workforce involved in the execution of the Official InspectionService(number of veterinarians, non-veterinary inspectors, auxiliaries, among others)? How are you organized? (central,intermediate and executor) levels).
		3. What are the duties and qualifications of official veterinarians and other persons involved in the implementation of the Official Inspection Service? What legislation regulates these duties?
		4. Do all the professionals responsible for inspection/oversight belong to the official body? Briefly explain the operation of the inspection/inspection system.
		5. Who pays the salary of veterinarians and technical assistants who carry out milk and dairy inspections?
		6. Are there private professionals working in the Official Inspection Service?
		7. What are the guarantees that there are no conflicts of interest in the inspection of products of animal origin?
	2. **Registration of Establishments**
		1. How is the registration of establishments with the Official Inspection Service? Is there a difference in registration procedures between establishments already built and establishments to be built? Is there prior approval by the inspection body on the reforms and expansions of the establishments?
	3. **Inspection and Inspection Procedures**
		1. What are the main laws in force in the country related to the Official Inspection of milk and dairy products? Briefly describe what each is about and attach a translated copy.
		2. Is there a minimal set frequency of supervision in each establishment? How is this frequency defined? How does the service survey this minimal set frequency? How are the results of the inspection evaluated?
		3. What documents are generated in this inspection/oversight?
		4. Inform how the inspection of milk and its dairy products is carried out.
		5. Are there regulations aimed at animal protection and welfare? Are there procedures for the assessment of animal welfare? Describe.
		6. Is there an official register of dairy farmers? What data is recorded? How do you link each farmer to each establishment?
		7. Are dairy farms registered with a competent body? Describe the controls related to public health applied in these properties, including controls related to tuberculosis and brucellosis (zoonoses of public health interest).
		8. Describe the milk temperature parameters required from milking, storage, transport, and reception of milk in the processing establishment.
		9. Are there mandatory analyses to be carried out by the establishments in the reception of raw materials? What are they? How does the inspection system monitor the establishment's performance of these analyses?
		10. Are individualized analyses of producer samples performed? If so, what analyses are performed, and at what frequency?
		11. Are there established criteria for the disposal of raw materials or products deemed unfit for human consumption, including their use or conditional use?
		12. Indicate the main causes of rejection/condemnation and their percentages in milk and dairy inspection procedures intended for human consumption.
		13. According to the legislation of the country, to what types of thermal processing should milk be submitted in order to ensure the safety of the product?
		14. What are the criteria for the preparation of products made from raw milk?
		15. What are the physical-chemical and microbiological parameters legally adopted by the country for each product category you want to export to Brazil? What is the related legislation?
		16. Are there official product sample collection programs for laboratory analysis? Which one and how are they managed? List the analyses and their parameters, describe the sampling protocol and the procedures adopted in cases of violation.
		17. Inform the results obtained from the official programs of collection of samples of products for laboratory analysis of the last two years.
		18. What are the parameters adopted for the physical-chemical and microbiological quality of the water supply in the producing establishments? What legislation regulates these parameters?
		19. Are there regulations that determine the origin of the water used in production (e.g., public water, well or surface collection)?
		20. In accordance with Brazilian legislation, self-control programs are those developed, described, implemented, monitored and verified by the establishment, to ensure the safety, identity, quality and integrity of their products, which include, but are not limited to GMP, PPHO and APPCC programs or equivalent programs. Thus, in view of this definition, we ask that the following questions be answered:
			1. Are there mandatory self-control programs to be implemented by the producing establishments? If so, which ones? How does the inspection system verify compliance with these programmes?
			2. Are there mandatory self-control programs to be implemented only by exporting establishments? If so, which ones? How does the inspection system verify compliance with these programmes?
			3. Is the implementation of a system based on the principles of Hazard Analysis and Critical Control Points (HACCP) or similar methodologies mandatory for all producing establishments? What is the related legislation? Report whether the controls of this system include aspects of public health, loss of quality and economic integrity.
		21. Briefly describe the hygiene standards and good manufacturing practices required for milk and dairy establishments in your country. What is the related legislation?
		22. Are there standards for the packaging of products? Briefly describe and report on the legislation applied.
		23. Inform the regulations regarding traceability and recall of products and describe their application.
		24. Are there training and training programs for professionals involved in the inspection system? What are they? How often and how are they performed?
		25. Is there some kind of verification or audit on the performance of the executing level by the central or intermediate levels? If so, how is it done, who are the professionals who perform, what report models are used, and at what frequency? In the case of on-the-spot checks, how are the generated records being archived? How does the management of the generated data take place?
		26. What kind of measures do the Official Service implement if violations/non-conformities are found in establishments?
		27. What are the criteria for assessing the criticality of violations/non-conformities and in what situations may culminate in restrictions on the activities of the establishment? What is the related legislation?
		28. What administrative sanctions does the Official Service adopt in the face of infringements that may be found in the supervised establishments? What is the related legislation?
	4. **Product registration**
		1. How is the registration of products manufactured by the establishments done?
		2. Are there standards for product labelling? Briefly describe and report on the legislation applied.
	5. **Product transit**
		1. Describe the procedures for the transit of products within the territory of the country, as well as for national sanitary certification, if applicable.
		2. What are the documents or procedures for tracking the products traded between establishments in the country?
	6. **Agricultural and Livestock Production**
		1. Describe the characteristics of agricultural and livestock production, by species. Tell if it is independent or integrated. Describe the relationship between establishments and producers.
		2. Inform the volume of milk and dairy products produced annually in the country (by species).
	7. **Export**
		1. How does the country guarantee that only products that have met Brazilian requirements will be exported? Describe how the official control of the production chain is made to ensure the qualification of animals and raw materials, since its origin, for the preparation of products subject to certification to Brazil, considering the Brazilian requirements.
		2. Describe the procedures for international health certification. What are the elements of authenticity and how is information stored?
		3. Who is the professional responsible for signing health certificates (Sanitary Certificates) for export?
		4. What was the volume of milk and products exported, by category and by species, and for which countries in the last three years?
		5. How is the qualification procedure carried out for exporting establishments? How are these controlled and what procedures are suspended or cancelled?
		6. Forward the list of establishments (including: Control Number, Name, Address, Type of Operation, Categories and Species) interested in exporting to Brazil. (Forward list as WTO notification G/SPS/N/BRA/1184/Add.2/Corr.3 ([https://docs.wto.org/dol2fe/Pages/FE\_Search/FE\_S\_S006.aspx?FullTextHash=1&MetaCollection=WTO&SymbolList=%22G/SPS/N/BRA/1184%22+OR+%22G/SPS/N/BRA/1184\*%22#](https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?FullTextHash=1&MetaCollection=WTO&SymbolList=%22G/SPS/N/BRA/1184%22+OR+%22G/SPS/N/BRA/1184*%22) - Check for possible updates).
	8. **Import**
		1. Describe the rules and procedures for importing products of animal origin into the country, including procedures at entry points.
		2. Inform what are the public health requirements required by the country for the importation of milk and dairy products.
		3. List the volume of milk and dairy products, by country of origin, category and species, imported for the last three years.
		4. In cases where the use of imported raw materials for the manufacture of goods destined for export is authorized, how will Brazil be guaranteed to meet certification requirements?
3. RESIDUES AND CONTAMINANTS CONTROL PROGRAM.
	1. Describe the organizational structure of the competent authority at different levels (central, regional and local) and human resources dedicated to the implementation of the chemical residue control program (veterinary drugs, pesticides and environmental contaminants) in animal products. It is requested to present the organization chart of the competent authority responsible for the control.
	2. Describe the responsibilities of the central competent authority and other levels in the operationalization of the residue control program (preparation of the sampling plan, coordination and supervision of activities, establishment of the collection and analysis schedule, collection of samples, evaluation of results, actions taken in case of violations, investigation of violations in the properties of origin of products, consolidation and publication of annual results).
	3. Forward a copy of the legal basis of the residue control program (legislation that assigns the prerogatives and power to inspect, penalties to infringing properties, among others).
	4. Indicate the regulations establishing the maximum limits of veterinary drugs, pesticides and contaminants applicable in the country. Present the list of maximum limits of veterinary drugs, pesticides and contaminants applicable in the country for the animal species/category of product that is desired to be exported to Brazil.
	5. Indicate which service and personnel are responsible for collecting samples from the residue control program. Is the collection carried out exclusively by the Official Service or a third party is involved?
	6. Indicate whether the collection is unforeseen or previously communicated to the owners of the animals or products and to those responsible for the processing establishments. Indicate at which point samples are collected (farms or processing establishment) and whether the collections are random or directed to suspicious batches.
	7. Describe the statistical model used to design and calculate the number of samples to be collected annually.
	8. Present the monitoring plan for residues and contaminants of the current year for the species that is intended to be exported to Brazil, according to the attached model (APPENDIX 1). If the monitoring plan as a whole, or some analysis provided for in it, covers only part of the national production (e.g. export production), we request that the volume of production covered by the monitoring plan or specific analyses be indicated.
	9. Present the results of the residue control plan of the last two years for the species that is intended to be exported to Brazil, according to the attached model (APPENDIX 2). In case the plan was not fulfilled, indicate the reasons for non-compliance.
	10. Describe the official procedures adopted regarding the processor establishment and production unit (farm) in case of detected violations.
	11. Describe the control measures and administrative and criminal sanctions adopted against producers (farms) and processing establishments when a non-conformity (violation) detected by the residue control plan occurs. Indicate legal basis for the actions taken in the case of violations.
	12. Forward a summary report on the administrative actions taken in residue/contaminant violations detected in the last two years.
4. FRAUD CONTROL PROGRAM.
	1. Is there a program to control fraud in milk and dairy products? What are they? How are they carried out?
	2. What procedures are adopted in the event of violations? What is the related legislation?
	3. Inform the results obtained from the milk and dairy fraud control program in the last two years.
5. LABORATORY SUPPORT
	1. Laboratories of the Chemical Area
		1. Describe the organizational structure, indicating the bodies involved and hierarchies, as well as the prerogatives of each one in the official laboratory network of the Competent Authority (Organization Chart).
		2. List all laboratories that perform analysis for the National Plan for Control of Residue and Contaminants in products of animal origin (INCLUDE IN LIST THE ADDRESS OF EACH LABORATORY).
		3. For the specific case of residue and contaminant analysis laboratories in products of animal origin, FILL OUT ANNEX 1, relating all the substances and matrices that make up the Residue Control Program in products of animal origin, as well as the respective laboratories that analyze them, the methods adopted (screening and confirmatory) and the limits of detection and limits of action.
		4. List all laboratories that perform physicochemical analysis of identity and quality of animal products in compliance with official controls (INCLUDE IN RELATION TO THE ADDRESS OF EACH LABORATORY).
		5. For the specific case of laboratories of physicochemical analyses of identity and quality of products of animal origin, FILL OUT ANNEX 3, listing all the tests carried out and the respective matrices and analytical methods employed.
		6. Identify, among the laboratories listed in items 6.1.2 and 6.1.4 which are private and which are belonging to the government. Among the identified laboratories, clearly point out the national reference laboratories for each case.
		7. Describe the procedures and actions employed by the Competent Authority in the supervision of related laboratories in items 6.1.2 and 6.1.4.
		8. Indicate the accreditation status in ISO 17025 of the listed laboratories in items 6.1.2 and 6.1.4 and identify for each laboratory the name of the accreditation body, the date of the last accreditation, the date of validity of the certificate and the tests that are part of the accreditation scope (FILL OUT ANNEX 4).
		9. Describe the approach and references used by the Central Competent Authority to guide the validation of analytical methods by laboratories in the context of analysis for the residue control program in animal products.
		10. Describe the approach and references used by the Central Competent Authority to guide the validation of analytical methods by laboratories in the context of physicochemical analysis of identity and quality of animal products in compliance with official controls.
		11. Inform the maximum regulatory time allowed to laboratories for the issuance of laboratory results (consider the time spent between receiving the sample by the laboratory and issuing the test report).
		12. Inform about the procedures adopted by the Central Competent Authority for training of technicians of the official laboratories.
		13. Do laboratories regularly participate in interlaboratory comparison programs and proficiency tests? If yes, for each laboratory listed in items 6.1.2 and 6.1.4, identify the date of the last round and the tested substances and matrices, as well as the institution that is the provider of the test and indicate the result (satisfactory or unsatisfactory).
		14. Describe the flow of information between the Central Competent Authority, the Regional Competent Authority and the Local Official Veterinarian responsible for sampling with the Laboratories responsible for the analysis, as well as to whom and how analytical results are sent.
	2. Food Microbiology Laboratories
		1. Describe the organizational structure, indicating the bodies involved and hierarchies, as well as the prerogatives of each laboratory (Organization Chart).
		2. Provide the list of public and private laboratories designated by the competent authority to carry out tests on samples collected during official control (INCLUDE IN THE LIST , THE ADDRESS OF EACH LABORATORY).
		3. List the official testing methods used.
		4. Is there any requirement that laboratories that carry out official control must be accredited (ISO 17025)? Please indicate whether the laboratories involved in the export chain are accredited.
		5. Indicate the accreditation status in ISO 17025 of the related laboratories in item 6.2.2 and identify for each laboratory the name of the accreditation body, the date of the last accreditation, the expiry date of the certificate and the tests that are part of the accreditation scope (FILL OUT ANNEX 4).
		6. Describe the procedures in use to monitor laboratory performance, such as accreditation and/or participation in proficiency tests.
		7. Is it mandatory to participate in laboratories in interlaboratory comparison programs and national and international proficiency tests? Provide information on such holdings in the last three years in the scopes related to the object(s).
		8. Inform the maximum regulatory time allowed to laboratories for the issuance of laboratory results (consider the time spent between receiving the sample by the laboratory and issuing the test report).
		9. Inform about the procedures adopted by the Central Competent Authority for training of technicians of the official laboratories.
		10. Describe the flow of information between the Central Competent Authority, the Regional Competent Authority and the Local Official Veterinarian responsible for sampling with the Laboratories responsible for the analysis, as well as to whom and how analytical results are sent.
	3. Animal Health Laboratories
		1. Describe the organizational structure, indicating the bodies involved and hierarchies, as well as the competencies of each laboratory (Organization Chart).
		2. Provide the list of public and private laboratories designated by the competent authority to carry out tests on samples collected during official health control (INCLUDE IN LIST THE ADDRESS OF EACH LABORATORY).
		3. List the test methods used.
		4. Is there any requirement that laboratories that carry out official control must be accredited (ISO 17025)?
		5. Indicate the accreditation status in ISO 17025 of the listed laboratories in item 6.3.2 and identify for each laboratory the name of the accreditation body, the date of the last accreditation, the expiry date of the certificate and the tests that are part of the accreditation scope (FILL OUT ANNEX 4).
		6. Describe the procedures in use to monitor laboratory performance, such as accreditation and/or participation in proficiency tests.
		7. Inform the maximum regulatory time allowed to laboratories for the issuance of laboratory results (consider the time spent between receiving the sample by the laboratory and issuing the test report).
		8. Inform about the procedures adopted by the Central Competent Authority for training technicians of the official laboratories.
		9. Describe the flow of information between the Central Competent Authority, the Regional Competent Authority and the Local Official Veterinarian responsible for sampling with the Laboratories responsible for the analysis, as well as to whom and how analytical results are sent.
6. Authentication.
	1. Place and Date:
	2. Signature and identification of the person responsible for the information:

**ANNEX 1**

CURRENT YEAR SAMPLING PLAN OF THE RESIDUE AND CONTAMINANTS CONTROL PROGRAM

|  |  |
| --- | --- |
| Year/Implementation Period |  |
| Animal Species / Product |  |
| National Production (Annual) |  |
| Does the Sampling Plan cover all domestic production or only part of the (exported) production? If it covers only part of the national production, indicate national volume of production covered by the plan and eligible for export to Brazil (example Split System for export) |  |
| Number of Samples (total) |  |
| Group or Class of substances to be monitored | Number of samples tested for each substance | Substance/Marker Residue | Analyzed Matrix | Screening Method (SM) | Confirmatory Method (CM) | Detection Limit (SM) [μg/Kg] | Detection Limit (CM) [μg/Kg] | Action Limit (i.e. concentration above which the result is considered non-compliant [μg/Kg] | Name of the Laboratory responsible for the analysis |
| Farm | Slaughterhouse/Processing Plant |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |

**ANNEX 2**

RESULTS OF THE RESIDUE AND CONTAMINANTS PROGRAM - LAST YEARS

|  |  |
| --- | --- |
| Year/Implementation Period |  |
| Animal Species / Product |  |
| Number of Samples (total) |  |
| Group or Class of substances to be monitored | Number of samples (for each substance) | Substance/Marker Residue | Analyzed Matrix | Action Limit (i.e. concentration above which the result is considered non-compliant [μg/Kg] | Number of non-compliant results (above the action limit) |
| Farm | Slaughterhouse/Processing Plant |
| Planned | Analyzed | Planned | Analyzed |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |

**ANNEX 3**

Scope of work of laboratories that perform physicochemical analyses for official controls in animal products.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Lab Name | Sampled species | Matrix analyzed | Test carried out | Analytical Method Used | Number of samples received | Number of samples analyzed | Number of non-compliant samples |
| Screening | Confirmatory |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |

**ANNEX 4**

Accreditation status in ISO 17025 of each laboratory, name of the accreditation body, date of last accreditation, expiration date of the certificate and tests part of the scope of accreditation.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Lab Name | ISO 17025 Accreditation Status | Name of the Accreditation Body | Date of Last Accreditation | Certificate Expiration Date | Accreditation Scope Trials |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |