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

**EGGS AND EGGS PRODUCTS**

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| **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. Approval permission type:

( ) Individual establishment approval

( ) Acknowledgment 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. Agency/Department responsible for Animal Health
			1. Name:
			2. Name of the person in charge:
			3. Address:
			4. Phone:
			5. E-mail:
		3. Public Health Agency/Department – Animal Product Inspection Service
			1. Name:
			2. Name of the person in charge:
			3. Address:
			4. Phone:
			5. Email:
			6. Identification of a focal point for exchanging information (name and email):
	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 equipments 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 is made with the official bodies.
	5. Inform the number of egg establishments and their egg products, as well as their locations on the country map.
	6. Categories and products, you wish to export to Brazil (inform the animal species). Categories should be indicated under 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 which 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. Structural Organization
		1. What are the bodies responsible for the Animal Health Service from the central level to the level of execution? What are the attributions of each?
		2. What are the main laws in force in the country related to Animal Health? Briefly describe each and attach a translated copy.
	2. Animal populations
		1. Report the number of animals per species (population of commercially laying hens):
	3. Animal health status
		1. Are there diseases whose vaccination is mandatory? If so, list them.
		2. What is the health status of the country concerning diseases of mandatory notification of the OIE?
		3. What is the health situation of neighboring countries in relation to OIE mandatory notification diseases?
	4. Products of veterinary use
		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, sales, and use of veterinary products. Please indicate the legal basis and relevant articles of the rules on the subject.
		3. Indicate the penalties and penalties to the regulated who do not comply with what is stated in the laws related to the registration, import, manufacture, distribution, sales, and use of veterinary products. Indicate the legal basis and relevant articles of the rules defining such sanctions 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. Please indicate the legal basis and relevant articles of the rules that regulate their use.
		5. Indicate which veterinary products are subject to the veterinary prescription requirement for their purchase. Please 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 authorized. If authorized, indicate under what conditions it is allowed and what maximum residue limits apply when used in this condition. Please indicate the legal basis and relevant articles of the rules that regulate their use.
		7. Indicate the conditions and controls required in the manufacture of medicated feed. Please indicate the legal basis and relevant articles of the rules that regulate the subject.
		8. Provide a list of authorized active pharmaceutical inputs for use in food-producing animals by species, including substances authorized as additives (e.g., anticoccidials and antimicrobial-based performance enhancers).
		9. List the maximum residue limits for authorized active pharmaceutical supplies in the country. Please 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 prohibition.
2. OFFICIAL SERVICE OF INSPECTION OF ANIMAL PRODUCTS.
	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 attributions of each?
		2. What is the workforce involved in the execution of the Official Inspection Service (number of veterinarians, non-veterinary inspectors, auxiliaries, among others)? How it is organized (central, intermediate and executing)?
		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 Team? Briefly explain the operation of the inspection/oversight system.
		5. Who pays the salary of veterinarians and technical assistants who carry out inspections of eggs and egg products?
		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 team on the reforms and expansions of the establishments?
	3. **Inspection and Oversight Procedures**
		1. What are the main current laws in the country related to the Official Inspection of eggs and egg products? Briefly describe what each is about and attach 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?
		4. Inform how the inspection of eggs and their egg products is carried out.
		5. Are poultry establishments suppliers of eggs registered with Official Service?
		6. Is the egg classification carried out? If so, how is it done? What legislation defines the classification criteria?
		7. Are there established criteria for the disposal of raw materials or products deemed unfit for human consumption, including their use or conditional use?
		8. Indicate the main causes of rejection/condemnation and their percentages in the inspection procedures of eggs and egg products intended for human consumption.
		9. 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?
		10. Are there official products sample collection programs for laboratory analysis? Which ones and how are they managed? List the analyses and their parameters, describe the sampling protocol and the procedure adopted in cases of violation.
		11. Inform the results obtained from the official programs of recall of samples of products for laboratory analysis of the last two years.
		12. 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?
		13. Are there regulations that determine the origin of the water used in production (e.g., public mains water, well, or surface collection)?
		14. Under 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, given 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, what are they? How the inspection verifies compliance with these programs?
			2. Are there mandatory self-control programs to be implemented only by exporting establishments? If so, what are they? How the inspection verifies compliance with these programs?
			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.
		15. Briefly describe the hygiene standards and good manufacturing practices required for egg and egg products establishments in your country. What is the related legislation?
		16. Are there standards for the packaging of products? Briefly describe and report on the legislation applied.
		17. Inform the regulations regarding traceability and recall of products and describe their application.
		18. Are there training programs for professionals involved in the inspection? What are they? How often and how are they carried out?
		19. 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 them, 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 the generated data is managed?
		20. What are the administrative sanctions adopted by the Official Service in case of violations/non-conformities found in establishments?
		21. What are the criteria for assessing the criticality of violations/non-conformities and in what situations they may culminate in restrictions on the activities of the establishment? What is the pertinent legislation?
		22. What administrative sanctions does the Official Service adopt in the face of infringements that may be found in the supervised establishments? What is the pertinent legislation?
	4. **Registration of products**
		1. How is the registration of the products manufactured by the establishments done?
		2. Are there standards for product labeling? Briefly describe and report on the legislation applied.
	5. **Transit of products**
		1. Describe the procedures for the transit of products within the territory of the country, as well as for national health certification, if applicable.
		2. What documents or procedures are used to track traded products 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 eggs and egg products produced annually in the country (by species).
	7. **Exports**
		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 in Brazil, considering the Brazilian requirements.
		2. Describe the procedures for international health certification. What are the elements of authenticity and how information is stored?
		3. Which professional is responsible for signing health certificates (Sanitary Certificates) for export?
		4. What is the volume of eggs and by-products exported, by category and by species, and for which countries in the last three years?
		5. How is the approval procedure carried out for exporting establishments? How are these controlled and the procedures for suspending or canceling the approval?
		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. **Imports**
		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 country’s public health requirements for the importation of eggs and its egg products.
		3. Which is the country of origin and volume of imported eggs and egg products, by category and by species, in 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 the fulfillment of certification requirements to Brazil will be guaranteed?
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 residues 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 residues 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 residues 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 residues control program. The collection is 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 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 current year's residues and contaminants monitoring plan for the species that are intent 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 residues control plan of the last two years for the species that are intended to be exported to Brazil, according to the attached model (APPENDIX 2). In case the plan has not been fulfilled, indicate the reasons for non-compliance.
	10. Describe the official procedures adopted regarding the processing 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 residues control plan occurs. Indicate the legal basis for actions taken in the case of violations.
	12. Forward a summary report on administrative actions taken in residue/contaminants violations detected in the last two years.
4. FRAUD CONTROL PROGRAM.
	1. Is there a program to control fraud on eggs and egg products? What are they? How they are performed?
	2. What procedures are adopted in the event of violations? What is the related legislation?
	3. Inform the results obtained from the egg and egg products fraud control program for the last two years.
5. LAB SUPPORT
	1. Laboratories of the Chemical Area
		1. Describe the organizational structure, indicating the bodies and hierarchies involved, as well as the prerogatives of each in the official laboratory network of the Competent Authority (Organization Chart).
		2. List all laboratories that carry out analysis for the National Plan for The Control of Residues and Contaminants in products of animal origin (INCLUDE THE ADDRESS OF EACH LABORATORY IN THE LIST).
		3. For the specific case of residues and contaminants analysis laboratories in products of animal origin, FILL OUT ANNEX 1, listing all substances and matrices that make up the Residues Control Program in products of animal origin, as well as the respective laboratories that analyze them, the methods adopted (sorting and confirmatory) and the limits of detection and action.
		4. List all laboratories that perform physicochemical analysis of identity and quality of animal products in compliance with official controls (INCLUDE THE ADDRESS OF EACH LABORATORY IN THE LIST).
		5. For the specific case of laboratories of physicochemical analysis 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 government-owned. Among the identified laboratories, point out the national reference laboratories for each case.
		7. Describe the procedures and actions employed by the Competent Authority in the supervision of those laboratories mentioned 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 ANNEX4).
		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 residues 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 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 analyses, 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 THE ADDRESS OF EACH LABORATORY IN THE LIST).
		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 listed 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 ANNEX4).
		6. Describe the procedures in use to monitor laboratory performance, such as accreditation and/or participation in proficiency tests.
		7. Is it mandatory to have labs engaged in interlaboratory comparison programs and national and international proficiency tests? Provide information on such for 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 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 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 health control (INCLUDE LIST OF 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 of technicians of 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 RESIDUES AND CONTAMINANTS CONTROL PROGRAM

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| --- | --- |
| 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 the 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 |  |
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**ANNEX 2**

RESULTS OF THE RESIDUES AND CONTAMINANTS PROGRAM - LAST YEARS

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| --- | --- |
| 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 |
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**ANEXO 3**

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

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| --- | --- | --- | --- | --- | --- | --- | --- |
| 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 |
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**ANNEX 4**

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

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