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

**HONEY AND BEE 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. 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 organizational 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), hygiene of facilities and equipment, 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 number of honey and bee products establishments, 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 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. 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 a translated copy.
   2. Animal population
      1. Inform the number of animals per species:
   3. Animal health situation
      1. What is the health situation of the country concerning diseases of mandatory notification of the OIE?
      2. What is the health situation of neighboring countries concerning 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 sanctions and penalties.
      4. 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.
      5. 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. Indicate the legal basis and relevant articles of the rules that regulate the use.
      6. 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.
      7. Provide a list of authorized active pharmaceutical supplies for use in food-producing animals by species, including substances authorized as additives (e.g. anticoccidials and antimicrobial-based performance enhancers).
      8. List the maximum residue limits for authorized active pharmaceutical supplies in the country. Indicate the regulations that establish them.
      9. Indicate the list of substances prohibited 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 Inspection Service(number of veterinarians, non-veterinary inspectors, auxiliaries, among others)? How is it organized(central, intermediate, and executor)?
      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 inspections of honey and bee 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 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 honey and bee 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?
      4. Inform how the inspection of honey and its bee products is carried out.
      5. Is there an official register of honey producers? What data is recorded? How do you link to each establishment?
      6. Is there control of the distance from hives to public roads, housing, and risk production?
      7. Are there mandatory analyses to be carried out by the establishments in the reception of raw materials? What are they? How does the inspection monitor the establishment's performance of this analysis?
      8. Are there established criteria for the disposal of raw materials or products deemed unfit for human consumption, including their use or conditional use?
      9. Indicate the main causes of rejection/condemnation and their percentages in the inspection procedures of honey and bee products intended for human consumption.
      10. 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?
      11. Are there official product sample collection programs for laboratory analysis? What are and how are they managed? List the analysis and their parameters, describe the sampling protocol and the procedures adopted in cases of violation.
      12. Inform the results obtained from the official programs of collection of samples of products for laboratory analysis of the last two years.
      13. 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?
      14. Are there regulations that determine the origin of the water used in production (e.g. public water, well, or surface collection)?
      15. 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, SSOP, and HACCPP 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 deployed by establishments and producers? If so, what are they? How does the inspection system verify compliance with these programs?
          2. Are there mandatory self-control programs to be implemented only by exporting establishments? If so, what are they? How does the inspection system verify 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.
      16. Briefly describe the hygiene standards and good manufacturing practices required for honey and bee products establishments in your country. What is the related legislation?
      17. Are there standards for the packaging of products? Briefly describe and report on the legislation applied.
      18. Inform the regulations regarding traceability and recall of products and describe their application.
      19. Are there training programs for professionals involved in surveillance? What are they? How often and how are they performed?
      20. 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?
      21. What administrative sanctions actions do you take by the Official Service in the event of violations/non-conformities found in establishments?
      22. 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?
      23. 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 industries done?
      2. Are there standards for product labeling? 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 honey and bee 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 is the volume of honey and bee 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 canceled?
      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 country´s public health requirements for the importation of honey and bee products.
      3. List the volume of honey and bee products, by countries 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 be guaranteed that meet certification requirements to Brazil will be met?
3. RESIDUE 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 powers and power of supervision, 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 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 export 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 are 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 the legal basis for actions taken in the case of violations.
   12. Forward a summary report on the 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 in honey and bee 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 fraud control program in honey and bee products of 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 contaminants 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 LIST THE ADDRESS OF EACH LABORATORY).
      5. For the specific case of physical-chemical analysis laboratories of identity and quality of animal products, FILL OUT ANNEX 3, listing all the tests carried out and the respective matrices and analytical methods employed.
      6. Identify, among the listed laboratories in items 6.1.2 and 6.1. 4 which are private, and which are owned by the government. 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 listed laboratories in items 6.1.2 and 6.1. 4th.
      8. Indicate the accreditation status in ISO 17025 standard of 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 expiry date of the certificate, and the tests which 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 so, for each lab 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 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 and 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 of 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

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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 RESIDUE 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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**ANNEX 3**

Scope of work of laboratories that perform physicochemical analysis 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 | ISO 17025 Accreditation Status | Name of the Accreditation Body | Date of Last Accreditation | Certificate Expiration Date | Accreditation Scope Trials |
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