MINISTRY OF AGRICULTURE, LIVESTOCK AND SUPPLY SECRETARIAT OF ANIMAL AND PLANT HEALTH

NORMATIVE INSTRUCTION No. 34, DATED SEPTEMBER 25, 2018

THE SUBSTITUTE SECRETARIAT OF ANIMAL AND PLANT HEALTH of the MINISTRY OF AGRICULTURE, LIVESTOCK AND SUPPLY, in the use of the powers granted to him by Articles 18 and 53 of Annex I of Decree no. 8.852, dated September 20, 2016, considering the provisions in Law no. 1.283, dated December 18, 1950, in Decree no. 9.013, dated March 29, 2017, and the contents of Process no. 21000.033637/2018-90, does hereby resolve:

Art. 1 The prior authorization procedures for importation, reinspection and special controls applicable to imports of edible products of animal origin by the Department of Inspection of Products of Animal Origin of the Secretariat of Animal and Plant Health at the Ministry of Agriculture, Livestock and Supply - DIPOA/SDA/MAPA, are approved in the form of this Normative Instruction.

CHAPTER I

IMPORT AUTHORIZATION

Art. 2 For the purposes of sanitary control and identity and quality, when products of animal origin are subject to import licensing in the Integrated Foreign Trade System - SISCOMEX, they may only be imported when:

I - they originate from countries whose sanitary inspection system was assessed or recognized as equivalent by the DIPOA;

II - they originate from establishments licensed to export to Brazil;

III - they are previously registered by DIPOA;

IV - they were labeled according to specific law; and

V - they come accompanied with a health certificate issued by a competent authority in the country of origin, under bilaterally agreed upon terms.

Sole paragraph. In the event that there is not an approved health certificate template, said certificate must cover the health requirements required by the Ministry of Agriculture.

Art. 3 The prior authorization for importation covered by this Normative Instruction is mandatory for all imported products of animal origin.

Art. 4 A request for prior authorization to import products of animal origin should be made to Ministry of Agriculture at any time before the product is internalized.

Paragraph 1 Prior authorization for importation will only be granted when the requirements set forth in Article 2 have been fulfilled.

Paragraph 2 Samples with no commercial value are exempted from fulfillment of sections I through IV of Article 2.

Paragraph 3 Shipment of the product of animal origin prior to obtaining prior authorization for importation is not an exemption from fulfillment of the requirements contained herein and in other rules in effect.

Art. 5 A request for prior authorization for importation should be made to DIPOA through the specific computerized system made available by the Ministry of Agriculture online at www.agricultura.gov.br.

Sole paragraph. The importer is solely responsible for maintaining the registration of users responsible for representing same before the Ministry of Agriculture for the purposes of performing the procedures to request prior authorization as covered by this Normative Instruction.

Art. 6 For the purposes of requesting prior authorization to import products of animal origin subject to assessment by DIPOA, the following documents must be submitted:

I - Import license (or IL), or an equivalent document, containing the health requirements that must be certified in the International Health Certificate - IHC, as entered by the competent Animal Health Service and including the following information:
a) company name, full address and Corporate Taxpayer ID Number (CNPJ) of the importer, when a legal entity;

b) registration number with official agency (in the case of industrial activity);

c) name, address and Individual Taxpayer ID Number (CPF) of the importer, when an individual;

d) name and full address of the manufacturing establishment;

e) manufacturer's registration number with official agency;

f) product identification, quantity, weight and packaging type;

g) DIPOA label approval number;

h) country of origin;

i) country of provenance;

j) purpose;

k) storage temperature;

l) transport method;

m) clearance Federal Revenue Unit;

n) entry Federal Revenue Unit;

o) company name, full address and Federal Inspection Service (or SIF) number or Related Establishment (or ER) for reinspection, when applicable; or

p) company name, full address and number registered with the Federal Inspection Service (SIF) for the establishment that will perform treatment of the mitigation covered by Article 15-A.

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II - copy of the record and sketch of the label approved by DIPOA; and

III - for samples with no commercial value, declaration of non-commercial purpose, according to the model established by DIPOA.

Art. 7 The documents covered in Article 6 must be submitted to the DIPOA via annexation in digital format on the Unified Foreign Trade Portal.

Paragraph 1 The annexation covered in the main section should be done by creating an electronic file, available on the website of the Unified Foreign Trade Portal on the world wide web.

Paragraph 2 The electronic file covered in the main section should be used for performing the import authorization procedures with the International Agricultural Surveillance System - VIGIAGRO clearance unit.

Art. 8 The procedures for requesting the import authorization described in Articles 4 through 7 is also applicable to products of animal origin made in Brazilian territory that are exported and returned to Brazil for any reason, whether related to health or not.

Sole paragraph. In the case of the products of animal origin covered in the main section, the copy of the IHC supporting export should be attached to the electronic file.

Art. 9 The importer should provide additional documents or information whenever so requested by the Ministry of Agriculture.

Art. 10. The request for prior authorization for importation will be electronically submitted to the technical units responsible for assessment.

Paragraph 1 The technical units covered in the main section should assess the compliance of the request, considering whether the foreign establishment is qualified to export to Brazil in order for the product to be imported, approval of the label registration, the VIGIAGRO entry and clearance units for the product, and whether the SIF or ER for reinspection of the establishment indicated for performance of mitigation treatment as covered in Article 15-A has the conditions to carry out these procedures.

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Paragraph 2 In the event of a favorable decision, the technical unit responsible should register the favorable decision on the IL or equivalent SISCOMEX document for prior authorization for importation from a public health standpoint.

Paragraph 3 If any information is missing or there are any discrepancies among the information provided as well as on documents submitted, the IL or equivalent document should be denied, registering the reason for denial in the SISCOMEX, and the importer must submit a new request for authorization for importation with a new IL or equivalent document.

Paragraph 4 The DIPOA may suspend assessments of the IL or equivalent document for a specific importer due to nonconformances found or a lack of compliance with the requirements established by Ministry of Agriculture agencies, without damages to other sanctions set forth in law.

Art. 11. The importer should monitor the progress of the request for authorization for importation and the status of the IL or equivalent document in the computerized Ministry of Agriculture system and SISCOMEX, respectively.

Art. 12. Requests for prior authorization to import products of animal origin will only be grated when the inspection, reinspection (when applicable), and clearance procedures are performed at VIGIAGRO System Units authorized by a specific norm.

Art. 13. In the event that the imported product or foreign manufacturing establishment are placed in the Import Alert Regime (or RAI), the technical unit must indicate on the IL or equivalent document that the VIGIAGRO System's clearance Unit needs to collect samples.

Sole paragraph. Upon receipt of the IL, the VIGIAGRO System unit's representative should verify whether the establishment is still in the RAI.

CHAPTER II

REINSPECTION PROCEDURES

Art. 14. Reinspection as covered by this Normative Instruction includes:

I - verification of the integrity conditions of packaging, wrapping and recipients;

II - labeling, official inspection marks, lots, and production and expiration dates.

III - evaluation of sensorial characteristics, when applicable;

IV- collection of samples for physical, microbiological, physiochemical, histological and molecular biology analyses, when applicable;

V - the transit health document;

VI - the maintenance and hygiene conditions of the transport vehicle and of the functioning of the refrigeration unit, when applicable; and

VII - the number and integrity of the seal of origin or corresponding official control service for the establishment of origin, when applicable.

Art. 15. For product categories and VIGIAGRO System Units defined in specific norms, circulation and sale are authorized when:

Sole paragraph. The provisions in the main section do not apply to the situations covered

in Article 15-A. (TEXT PROVIDED BY DIRECTIVE NO. 381, DATED AUGUST 12, 2021)

I - inspection and reinspection procedures have been carried out by the VIGIAGRO clearance unit;

II - they have been deemed suitable for reinspection procedures; and

III - their internalization has been approved.

Art. 15-A. In cases of products of animal origin that require that specific treatments be performed in national territory to mitigate animal diseases established by the Department of Animal Health, they must be sent to an establishment registered with the Federal Inspection Service (SIF) that has appropriate installations and equipment, after receipt of internalized cargo.

Paragraph 1 The circulation of the products listed in the main section, the location of entry to the treatment establishment, must be accompanied by a transit document that specifies the treatment to which the product should be submitted.

Paragraph 2 The Department of Inspection of Products of Animal Origin will disclose on the Ministry of Agriculture, Livestock and Supply's webpage those products that should be submitted to the treatments discussed in the main section, the criteria for operationalization of treatment, the list of establishments authorized to perform it, and the requirements for inclusion of establishments on the list.

Paragraph 3 Establishments authorized to perform the mitigation treatments set forth in the main section should maintain auditable records of their performance.

Paragraph 4 Failure to comply with the provisions in the paragraph above will result in the establishment's removal from the list set forth in paragraph two, without damage to other sections established by specific health laws.

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Art. 16. For cases of reinspection performed at an establishment under SIF or ER, as indicated on the import authorization, the importer must schedule the procedure with the Federal Inspection Service responsible.

Paragraph 1 The VIGIAGRO System Unit should issue the transit document, indicating the SIF or ER number of the reinspection establishment, as well as any other information deemed necessary.

Paragraph 2 The SIF responsible for the reinspection procedure should maintain auditable records of this activity, filed along with the transit document issued by the VIGIAGRO System Unit.

Art. 17. Failure to submit cargo to reinspection or failure to send it for the mitigation treatment set forth in Article 15-A will result in suspension of assessment of new requests for prior authorizations for importation for the respective importer, without damage to other sanctions established in specific laws.

Sole paragraph. The suspension covered in the main section will follow the terms of Art. 10

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Art. 18. The product of animal origin made in Brazilian territory, exported and returned to Brazil for commercial reasons, whose export establishment seal is intact, can be exempted from reinspection procedures, at the discretion of the VIGIAGRO System's clearance Unit, without damage to the reinspection requirement at an establishment under an authorized SIF.

CHAPTER III

THE COMPLIANCE ASSESSMENT PROGRAM FOR IMPORTED PRODUCTS OF ANIMAL ORIGIN (OR PACPOA)

Art. 19. Imported products of animal origin will be sampled in the Compliance Assessment Program for Imported Products of Animal Origin (or PACPOA) according to the criteria established by the DIPOA.

Art. 20. The PACPOA will be defined annually, establishing product categories, countries of origin, or both, in an effort to monitor using performance of lab testing.

Paragraph 1 Whenever necessary, the DIPOA may change the PACPOA during its effective term.

Paragraph 2 The PACPOA will consider the volume imported, concepts for analysis of risk and situations that could pose a risk to public health or result in fraud or adulteration.

Paragraph 3 The importer is responsible for bearing the costs related to collection, transport and lab testing.

Art. 21. The cargo sampled in the PACPOA will remain held in the primary zone until assessment of the results of lab testing and findings from reinspection.

Art. 22. The results of lab testing in the PACPOA can support inclusion of the foreign establishment in the RAI.

CHAPTER IV

IMPORT ALERT REGIME (OR RAI)

Art. 23. The Import Alert Regime (or RAI) is the reinforced control regime to which the foreign establishment is subject in the event that nonconformances are found in reinspection procedures, pursuant to the provisions of Article 14.

Art. 24. The RAI will be applied to products of animal origin from foreign establishments when irregularities are found during reinspection procedures related to:

I - identity and quality;

II - standards of physiochemical, microbiological, histopathological and molecular biological compliance;

III - presence of residue from medications and contaminants;

IV - presence of parasites;

V - alterations, adulterations, frauds and falsifications; and

VI - others that result in a risk to public health.

Art. 25. At least the next 10 (ten) consecutive imports from the same manufacturer and of the same product will be sampled.

Paragraph 1 The sampling covered in the main section will include physical reinspection, with possible submission to lab testing, depending on the nonconformance that led to placement in the RAI.

Paragraph 2 The importer is responsible for bearing the costs related to collection, transport and lab testing.

Art. 26. The cargo sampled in the RAI will remain held in the primary zone until assessment of the results of lab testing and findings from reinspection.

Art. 27. The DIPOA should notify the foreign health authority of the establishment's placement in the RAI.

Sole paragraph. The foreign health authority has 90 (ninety) days to submit the corrective and preventive measures adopted.

Art. 28. The DIPOA is responsible for assessment of the corrective and preventive measures submitted by the establishment and approved by the foreign health authority.

Sole paragraph. If the responses submitted by the foreign health authorities are found to be unsatisfactory, a new term of 30 (thirty) days will be granted to submit additional information.

Art. 29. The foreign establishment will be removed from the RAI under the following circumstances:

I - acceptance by the DIPOA of the corrective and preventive measures communicated by the foreign health authority and that the results of the 10 (ten) consecutive imports sampled are found to be satisfactory; or

II - when excluded from the list of exporters to Brazil.

Art. 30. The foreign establishment's license can be withdrawn or suspended under the following circumstances:

I - failure of the foreign health authority to provide information within the timeframe established;

II - submission of responses found to be unsatisfactory; or

III - reoccurrence of nonconformances of the same nature.

Art. 31. Acceptance of the guarantees submitted by the foreign health authority for the previously suspended foreign establishment will result in notification of the return of exports and same should remain under the RAI during the next 10 (ten) export shipments.

Art. 32. Nationalization of products of animal origin produced during the period between the suspension of the foreign establishment's licensing and the respective return of exports to Brazil will not be allowed.

CHAPTER V

MISCELLANEOUS

Art. 33. Additional procedures for operationalization of the PACPOA and the RAI may be established by the DIPOA.

Art. 34. Imported cargo whose irregularity has resulted in the implementation of the RAI should be returned to the country of origin, destroyed under the control of the Official

Service or re-exported to countries willing to accept them with the prior knowledge of their rejection by Brazil.

Paragraph 1 The return, destruction or re-exportation covered in the main section is also applicable to cargo that is being held at an establishment under the SIF.

Paragraph 2 The imported cargo covered in Paragraph 1 must be returned to the VIGIAGRO System Unit, accompanied by the National Refusal Health Certificate, according to the template established by the DIPOA.

Art. 35. Cargo imported from foreign establishments placed under the RAI, in which further irregularities are found subject to the RAI, must be returned to the country of provenance, destroyed under the monitoring of the official service or re-exported to countries willing to accept them with prior knowledge of rejection by Brazil.

Art. 36. Cargo imported from foreign establishments subject to the PACPOA in which irregularities are found must be returned to the country of origin, destroyed under the monitoring of the official service or re-exported to countries willing to accept them with prior knowledge of rejection by Brazil.

Art. 37. The occurrence of serious irregularities that pose a risk to public health or constant reoccurrences may, at the discretion of the DIPOA Director, result in determination of exclusion of all similar foreign establishments or even of the country as a whole.

Art. 37-A. The occurrence of irregularities that are not classified under the cases set forth in Art. 24 will also be communicated to the foreign health authority and will follow the notification procedures described in Chapter IV.

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Art. 38. The units designated by the Department of Animal Health of the Secretariat of Animal and Plant Health at the Ministry of Agriculture, Livestock and Supply - DSA/SDA/MAPA - should assess the health situation of the countries of origin and provenance of the product and inform the health requirements that should be certified on the International Health Certificate issued by the competent health authority.

Art. 39. Until the computerized system covered by this Normative Instruction is made available, request for prior authorization for importation as well as the method of document submission should be done at the Federal Inspection Service's administrative unit in the state importing the product, through the means provided by that unit.

Art. 40. Requests for authorization of shipment filed prior to the date that this Normative Instruction takes effect and that have yet to be assessed are automatically canceled.

Art. 41. The following are revoked:

I - SDA/MAPA Directive no. 183, dated October 9, 1998; and

II - SDA/MAPA Directive no. 126, dated November 11, 2016.

Art. 42. This Normative Instruction goes into effect on the date of its publication.

JORGE CAETANO JUNIOR

Substitute

Official Gazette, 27/Sep/2018 – Section 1 Page 06.