### MINISTRY OF AGRICULTURE. LIVESTOCK AND FOOD SUPPLY – MAPA

## SECRETARIAT OF ANIMAL AND PLANT HEALTH

# NORMATIVE INSTRUCTION 27 OF AUGUST 27, 2008

THE SECRETARY OF ANIMAL AND PLANT HEALTH OF THE MINISTRY OF AGRICULTURE LIVESTOCK AND FOOD SUPPLY, using the power invested in him by Articles 9 and 42, of Appendix I, of Decree n° 5351, enacted 21st January 2005; taking into consideration what is set forth in the Brazilian Regulation of Animal Product Industrial and Health Inspection—RIISPOA, approved by Decree n° 30691, enacted 29th March 1952; and what is set forth in Case File n° 21000.007596/2008-12, resolves to:

Article 1 Approve operating procedures for the listing of animal product manufacturing establishments interested in sending product for international trade, and for Federal-level and State-level audits to verify compliance with specific sanitary requirements of the importing countries or blocs, contained in Appendix I.

Article 2 This Secretariat, by appointment of the Department of Inspection of Animal Products—DIPOA, shall appoint Veterinary Medical Officers (Fiscais Federais Agropecuários—FFAs) to carry out the Federal and State-level audits referred to in Article 1

Sole paragraph. DIPOA will notify in advance the Technical Divisions of the Federal Superintendencies of Agriculture—SFAs as to which VMOs (FFAs) have been appointed to carry out the Federal and State audits on exporting establishments.

Article 3. The eligibility of establishments to export animal products to the countries which do not have specific health requirements is authorized when the establishment is registered with DIPOA.

Sole paragraph. For the countries or blocs of countries with specific health requirements, the establishments will become eligible after being added to a specific list.

Article 3-A. When the establishment does not comply with the Brazilian legislation, it will be prohibited to export the involved products.

Article 3-B. When it is found that the establishment does not comply with the specific requirements of the importing countries or blocs of countries, the establishment will have its international health certification suspended or it will be removed from the list of exporting establishments to those destinations (New wording given by Normative Instruction 16 of May 10, 2016).

Article 4 It is exclusively for DIPOA to restore an establishment to the list or lists of countries to which it may export, having determined the compliance and effectiveness of the corrective actions undertaken by the establishment.

Article 5 This Normative Instruction shall come into force as of the date of its publication.

Article 6 DIPOA/SDA Resolution no 7 of April 10, 2003 is revoked.

INÁCIO AFONSO KROETZ

#### APPENDIX I

OPERATING PROCEDURES FOR THE ELIGIBILITY OF ESTABLISHMENTS TO EXPORT ANIMAL PRODUCTS TO COUNTRIES OR BLOCS OF COUNTRIES THAT HAVE SPECIFIC HEALTH REQUIREMENTS AND FOR AUDITS AND SUPERVISIONS TO CHECK THE COMPLIANCE WITH THESE

HEALTH REQUIREMENTS (New wording given by Normative Instruction 16 of May 10, 2016).

## CHAPTER I

## PRELIMINARY PROVISIONS

Article 1. For the purposes of this Normative Instruction, the following apply:

I - eligibility to export: the granting of authorization for issuing international health certificates for animal products, based on Brazilian legislation and on the specific health requirements of the importing country or countries;

II - suspension of certification: suspension of the issuing of international health certification;

III -general list of exporting establishments: list of establishments that fully comply with the Brazilian legislation and are eligible to export animal products to third countries; (Revoked by Normative Instruction 16 of May 10, 2016).

IV - Specific list of exporting establishments: lists of establishments that fully comply with Brazilian legislation and that are eligible to export animal products to countries or blocs of countries that present specific health requirements.

# **CHAPTER II**

ELIGIBILITY OF ESTABLISHMENTS TO EXPORT TO COUNTRIES OR BLOCS OF COUNTRIES THAT HAVE SPECIFIC HEALTH REQUIREMENTS (New wording given by Normative Instruction 16 of May 10, 2016).

Article 2. An establishment's interest in joining a list for exporting animal products will be made known to DIPOA by a request, accompanied, when necessary, of a written commitment to complying with demands laid down by the health authority of importing countries or blocs of countries, in addition to compliance with Brazilian legislation; this commitment is signed by the person responsible for the establishment.

Sole paragraph. All requests must be accompanied by the category of products that it intends to export, according to specific legislation. (New wording given by Normative Instruction 16 of May 10, 2016).

Article 3. Eligibility may be requested for the inclusion in a specific list of exporting establishments. (New wording given by Normative Instruction 16 of May 10, 2016).

Article 4. The Federal Inspection Service—SIF will receive the request issued by the person responsible for the establishment and will forward it to the plant and animal health authority at State level, the Agricultural Products Inspection Service (Serviço de Inspeção de Produtos Agropecuários—SIPAG), accompanied by a conclusive technical opinion which will include:

I - assessment of compliance with health requirements laid down in current Brazilian legislation;

II - assessment of the performance of self-control programs;

III - assessment of compliance with the specific health requirements of importing countries or blocs of countries. (New wording given by Normative Instruction 16 of May 10, 2016).

Article 5. SIPAG shall issue a conclusive technical opinion considering SIF's opinion, the assessment of the recent supervision report and shall send the final opinion to DIPOA. (New wording given by Normative Instruction 16 of May 10, 2016).

Article 6. When DIPOA has completed the process of listing the establishment, a document will be sent to all SIPAGs, to the Animal and Plant Health Surveillance System (Sistema de Vigilância Agropecuária—VIGIAGRO), to the International Agribusiness Affairs Secretariat (Secretaria de Relações Internacionais do Agronegócio—SRI) and to the Base Products Division (Divisão de Produtos de Base—DPB) of the Ministry of Foreign Affairs (Ministério das Relações Exteriores—MRE).

Article 7. When listing must be ratified by the health authority of the importing country or countries, the document will only be issued after confirmation by the competent health authority.

Article 8. The issuing of International Health Certificates for animal products to countries or blocs of countries with specific health requirements shall be authorized after the establishment has been added to the specific list(s) of exporting establishments. (New wording given by Normative Instruction 16 of May 10, 2016).

CHAPTER III

FEDERAL-LEVEL AUDITS TO VERIFY COMPLIANCE WITH SPECIFIC HEALTH REQUIREMENTS OF IMPORTING COUNTRIES OR BLOCS OF COUNTRIES

Article 9. Audits aim to assess management of the physical activities carried out by the SIPAG regarding establishments listed for export.

Article 10. The audit will assess the following based on document controls or by sampling of establishments, or both: (New wording given by Normative Instruction 16 of May 10, 2016).

- I compliance with current Brazilian legislation;
- II the implementation of self-control programs by establishments;
- III inspection procedures and official verification activities of the inspection service within establishments;
- IV compliance by establishments with specific health requirements of importing countries or blocs of countries. (New wording given by Normative Instruction 16 of May 10, 2016).
- V the effectiveness of SIPAG's management of enforcement activities, by sampling of establishments.

Article 11. DIPOA will schedule at least one annual State level audit in each SIPAG, in those States of Brazil where there are establishments listed for exporting animal products.

Sole paragraph. The frequency of audits may be altered in accordance with identified priorities and to meet additional and specific demands made by importing countries.

Article 12. DIPOA shall assess at least 40% (forty per cent) of establishments listed for export in each State of Brazil.

Sole paragraph. Sampling may follow a study of performance indicators of establishments, of the enforcement activities of the SIFs, of the management activities of the SIPAGs or the specific health requirements of importing countries or blocs of countries. (Revoked by Normative Instruction 16 of May 10, 2016).

Article 13. DIPOA will define the frequency of audits. (New wording given by Normative Instruction 16 of May 10, 2016).

Article 14. DIPOA shall forward the final audit report to SIPAG, including individual reports of the sampled establishments.

Sole paragraph. The establishments must produce to the Federal Inspection Service (SIF) the action plan to correct the non-compliances described in the final audit report, which will be sent to SIPAG after being technically analyzed. (New wording given by Normative Instruction 16 of May 10, 2016).

I - the activities of the SIPAG; and

H-individual sampled establishments. (Revoked by Normative Instruction 16 of May 10, 2016).

Article 15. SIPAG shall draft an action plan to correct non-compliances described in the final audit report, and will send this to DIPOA for technical analysis.

Article 16. Individual reports for sampled establishments shall be sent to the SIF, to the audited establishment, to SIPAG and to DIPOA. These establishments shall present an action plan to correct the non-compliances described, and send it to SIPAG for technical analysis. (Revoked by Normative Instruction 16 of May 10, 2016).

Sole paragraph. DIPOA shall verify the compliance and effectiveness of the corrective actions applied by the sampled establishments at the next Federal-level audit.

# **CHAPTER IV**

SUPERVISIONS TO VERIFY COMPLIANCE WITH SPECIFIC HEALTH REQUIREMENTS OF IMPORTING COUNTRIES OR BLOCS OF COUNTRIES

(New wording given by Normative Instruction 16 of May 10, 2016).

Article 17. State-level audits aim to assess management of the physical activities carried out by the SIF regarding establishments listed for export.

Article 18. The supervision shall assess:

I - compliance with current Brazilian legislation;

II - the implementation of self-control programs by establishments;

III - inspection procedures and official verification activities of the inspection service within establishments;

IV - compliance by establishments with specific health requirements of importing countries or blocs of countries. (New wording given by Normative Instruction 16 of May 10, 2016).

Article 19. Frequency of state-level audits shall be defined by DIPOA, taking into consideration the performance indicators of establishments listed for export.

Sole paragraph. All establishments listed for export shall be audited at State level at least once a year. (Revoked by Normative Instruction 16 of May 10, 2016).

Article 20. SIPOA in the States where there are establishments eligible to export animal products shall annually schedule supervision activities to be performed to verify compliance with the specific health requirements of importing countries of blocs of countries. (New wording given by Normative Instruction 16 of May 10, 2016).

Article 21. VMOs designated to carry out state-level audits shall send the audit reports to the SIF, to the audited establishment and to the SIPAG in the States where there are establishments listed to export animal products.

Article 22. Those non-compliances described in the Supervision Report must be corrected by both the Federal Inspection Service (SIF) and the establishment.

Paragraph 1. The establishment must submit an action plan to the Federal Inspection Service (SIF) for technical analysis and verification, and it must include the corrective and preventive measures taken to correct the non-compliances.

Paragraph 2. The Federal Inspection Service (SIF) must inform the SIPAG on the corrective actions taken regarding the federal inspection, and must submit the already assessed and verified action plan that the establishment presented.

Paragraph 3. SIPAG must assess the corrective and preventive measures taken by the establishment and the corrective measures taken by the Federal Inspection Service (SIF). It must also verify the compliance and the effectiveness of these actions by document check and during the subsequent supervision, or both. (New wording given by Normative Instruction 16 of May 10, 2016).

## CHAPTER V

RESULTS OF THE AUDITS AND SUPERVISIONS TO VERIFY COMPLIANCE WITH SPECIFIC HEALTH REQUIREMENTS OF IMPORTING COUNTRIES OR BLOCS OF COUNTRIES (New wording given by Normative Instruction 16 of May 10, 2016).

Article 23. In the individual Federal-level audit report and the State-level audit report to verify compliance with specific health requirements of importing countries or blocs of countries, a conclusive technical opinion including one of the following alternatives must be included:

I - the establishment maintains control of processes for international health certification;

II - the establishment maintains control of processes for international health certification, but shows signs of loss of that control; (Revoked by Normative Instruction 16 of May 10, 2016).

III - the establishment does not show control of processes for international health certification.

Article 24. Establishments that maintain control of processes for international health certification shall keep their certification for export.

Article 25. Establishments that maintain control of processes for international health certification, but show signs of loss of that control, shall keep their certification for export.

Paragraph 1 The establishment shall draw up an action plan within 30 days after the federal-orstate level audit was carried out.

Paragraph 2 SIPAG shall verify the compliance and effectiveness of the corrective actions carried out by the establishment, and determine a new federal or state level audit, at the discretion of DIPOA.

Paragraph 3 If the establishment fails to comply with its own action plan or if there is a recurrence of a non-compliance, its international health certification shall be suspended. (Revoked by Normative Instruction 16 of May 10, 2016).

Article 26. When the establishment does not demonstrate control of processes, its international health certification shall be suspended.

Paragraph 1 A new supervision or audit may be carried out to verify the compliance and effectiveness of the corrective actions proposed in the establishment's action plan. (New wording given by Normative Instruction 16 of May 10, 2016).

Paragraph 2 If there is non-compliance with the proposed action plan, or a recurrence of the non-compliance, the establishment shall be removed from the export list or lists.

Paragraph 3. DIPOA or SIPAG shall verify the compliance and effectiveness of the corrective actions taken.

(New wording given by Normative Instruction 16 of May 10, 2016).

Paragraph 4. If DIPOA or SIPAG cannot verify the compliance and effectiveness of the corrective actions taken, the Federal Inspection Service (SIF) may perform that. (New wording given by Normative Instruction 16 of May 10, 2016).

D.O.U. (Official Gazette of the Federal Executive), 11/05/2016 – Section 1

This text does not replace the Official Publication.