Resolution SENASA N° 816

BUENOS AIRES, 4 October 2002

HAVING SEEN File No. 1218/2002 of the register of the NATIONAL AGRI-FOOD HEALTH AND QUALITY SERVICE, and

WHEREAS:
The Quarantines, Borders and Certifications Coordination Office proposes review and updating of the standards regulating imports of animals; reproductive material; precursory life forms; zootherapeutics; biologicals; fertilizers; animal feed; plants; plant parts; soil dressings; organic support and/or growth media; biological control organisms; products, by products and derivatives of animal and/or plant origin; and goods and/or inputs whose components consist of or include ingredients of animal or plant origin; that fall under the responsibility of the above-mentioned office.
The terms of Laws Nos. 3959, 4084, 17,160 and 18,284; Decrees Nos. 83732 dated 3 June 1936, 6704 dated 12 August 1963, 4238 dated 19 July 1968, 2126 dated 30 June 1971, 1812 dated 29 September 1992, 1585 dated 19 December 1996, 815 dated 26 July 1999 and 394 dated 1 April 2001; Resolutions Nos. 202 dated 1 April 1992 and 668 dated 10 August 1994, both issued by the former Ministry of Agriculture, Livestock and Fisheries]; Resolutions Nos. 758 dated 13 October 1997 and 292 dated 10 December 1998 issued by the former Ministry of Agriculture, Livestock, Fisheries and Food; Resolution No. 69 dated 15 January 1999 issued by the NATIONAL AGRI-FOOD HEALTH AND QUALITY SERVICE; and Resolution No. 228 dated 8 July 1999 and its amendment No. 782 dated 23 November 1999 issued by the former MINISTRY OF AGRICULTURE, LIVESTOCK, FISHERIES AND FOOD, make it feasible to implement procedures for imports of goods of animal or plant origin that, while ensuring quality and safeguarding public, plant and animal health in the above-mentioned procedures, adapt to the changes required for marketing at the world level.
The purpose of this proposal is to combine various standards relating to imports of goods of animal or plant origin, thereby establishing clear procedures for each modality in an effort to streamline control.
Based on experience acquired, it has been deemed appropriate to introduce these changes while maintaining the quality requirements and sanitary criteria that help minimize the risk of introducing diseases or pests through goods that endanger public health as well as the zoosanitary and/or phytosanitary status of our territory.
In this regard, the proposed amendments consist of actions that must be taken in matters of human and animal health by the National Administration and/or the National Plant Health Protection Organization, and, along these lines, included in international agreements, including those in effect within the framework of the (MERCOSUR.
The structural changes to the NATIONAL AGRI-FOOD HEALTH AND QUALITY SERVICE as of the entry into force of Decree No. 1585 dated 19 December

1996 make it advisable to introduce the proposed amendments, including those that facilitate verification of compliance with applicable identity, hygiene and sanitary, phytosanitary, zoosanitary, quality, purity, stability, packing and transport standards, prior to the entry of goods or authorization of their use.
The ARGENTINE REPUBLIC has adhered to the Sanitary and Phytosanitary (SPS) Agreements and Technical Barriers to Trade (TBT) of the WORLD TRADE ORGANIZATION (WTO) and to the concepts and principles resulting there from.
Resolution No. 32 dated 4 May 2001 of the NATIONAL AGRI-FOOD HEALTH AND QUALITY SERVICE confers upon the Quarantines, Borders and Certifications Coordination Office responsibilities for preventing the risk of introduction and spread of emergent and/or high risk exotic diseases in animals and regulated quarantine and non-quarantine pests in plants, entrusting that office with streamlining import procedures and preserving animal, plant and public health without hindering trade.
SENASA File No. 13,428/2001 constitutes an agreement between the various offices of this body with respect to auditing procedures to be used abroad for purposes of their implementation.
The various competent technical areas have issued opinions with respect to the proposed amendments.
The Legal Affairs Directorate has been involved in the process in keeping with its authorities.
It is appropriate to issue this ruling in accordance with the terms of Article 8 e) of Decree No. 1585 dated 19 December 1996, which was replaced by similar Decree No. 394 dated 1
April 2001.

THE PRESIDENT OF THE NATIONAL
AGRI-FOOD HEALTH AND QUALITY SERVICE
THEREFORE RESOLVES:
ARTICLE 1.- When presented with a request for import authorization and for purposes of carrying out the corresponding risk analysis from the point of view of plant or animal health, as applicable, the NATIONAL AGRI-FOOD HEALTH AND QUALITY SERVICE may order an audit of the entire health system of origin or a specific audit, as it deems necessary, based on available information, including in that audit a review of the structure and efficiency of services, control systems, quarantine procedures, epidemiological monitoring system, import control, prevention measures, inspection of production establishments, manufacturing plants, warehouses, breeding centres, etc., reference and diagnostic laboratories, residue control programs, among others, according to the procedures that appear in Annex I, which forms part of this Resolution.
ARTICLE 2.- Any individual, corporation or de facto company that wishes to carry out imports of live animals; reproductive material; precursory life forms; plants; plant parts; products, byproducts or derivatives of animal or plant origin; or goods and/or inputs whose components consist of or contain ingredients of animal or plant origin, that fall under the responsibility of this

National Service and require prior authorization, must be previously entered in the register kept by the Quarantines, Borders and Certifications Coordination Office, in compliance with Resolution No. 492 dated 6 November 2001 of the NATIONAL AGRI-FOOD HEALTH AND QUALITY SERVICE.

ARTICLE 3.- The competent authority in public and animal health matters, and/or the national plant health protection organization of the country of origin and/or shipment, when the NATIONAL AGRI-FOOD HEALTH AND QUALITY SERVICE so requests, must guarantee auditable traceability systems for animals; reproductive material; precursory life forms; zootherapeutics; biologicals; fertilizers; animal feed; plants; plant parts; soil dressings, organic support and/or growth media; biological control organisms; products, byproducts and derivatives of animal or plant origin; or goods and/or inputs whose components consist of or contain ingredients of animal or plant origin; throughout the production and marketing chain from the place of origin through to shipment to the ARGENTINE REPUBLIC. The NATIONAL AGRI-FOOD HEALTH AND QUALITY SERVICE reserves the right to audit that traceability and the documentation pertaining thereto where it deems necessary, as established in this Resolution.

ARTICLE 4.- All new requests for the importation of products, byproducts and derivatives of animal origin or goods and/or inputs whose components consist of or contain ingredients of animal origin, that fall under the responsibility of the NATIONAL AGRI-FOOD HEALTH AND QUALITY SERVICE and come from a new plant in a country exporting to ours, or from a new plant in any country, shall be subject to prior inspection of same, though exceptions may be granted where deemed appropriate by this National Service. In addition, plants that manufacture goods for industrial use may be exempted provided that such goods are not intended for human or animal use in any of their forms and that importation of those goods does not involve a health risk arising from their origin or place of shipment, product or intended use. In such cases, prior approval of the plant could be a condition for authorizing the import. Authorizations shall have a term of TWO (2) years. If the Service is unable to re-inspect such plants once that term has expired, the authorization may be extended where deemed necessary.

Countries with which there is a mutual agreement to authorize plants (pre-listing) or official agreements between the parties, or establishments therein, are exempt.

In the case of plants already authorized on the date of entry into effect of this Resolution, said authorization shall be deemed to have expired once TWO (2) years have transpired from the time of their authorization to export to our country, and a new authorization shall be required. An extension to that authorization may be granted by the NATIONAL AGRI-FOOD HEALTH AND QUALITY SERVICE at its discretion. Those plants or the countries in which they are located shall request, once the TWO (2) year term has expired, or prior to that time, a visit to ensure continuity of exports to our country. SENASA may, where it deems appropriate, extend the authorization without fulfilling this requirement.

ARTICLE 5.- Slaughtering establishments, manufacturing establishments

and/or warehouses for products, byproducts, and derivatives of animal origin, animal inputs and goods with animal components from any country, from which imports have been previously authorized may be inspected where the NATIONAL AGRI-FOOD HEALTH AND QUALITY SERVICE so rules. Countries whose establishments are not authorized on the date of publication of this ruling and who export their products to our country, are given ONE HUNDRED AND EIGHTY (180) calendar days to request inspection of those establishments. If requests to that effect are not obtained from the countries or interested parties within that period, once the latter has transpired, suspension of imports from establishments in that country may be ordered. The Service shall, when presented with requests, stipulate a date for conducting the visit to that country. The inspections carried out in any such case may be accompanied by an audit by the NATIONAL AGRI-FOOD HEALTH AND QUALITY SERVICE that includes, among other aspects, the structure and efficiency of the Health Services, manufacturing and control processes, animal health aspects, certification and residue control systems, laboratories, etc., for purposes of issuing a ruling on the feasibility of authorizing those plants.

ARTICLE 6.- Where reasons of a public or animal health nature so warrant, any establishment from amongst those authorized to export to the ARGENTINE REPUBLIC may be inspected, and that authorization may be revoked where the stipulated conditions are not met, including establishments authorized by pre-listing or official agreements between parties.

ARTICLE 7°.- Fruit and vegetable packing plants shall be authorized in the place of origin for exporting to the ARGENTINE REPUBLIC, where the NATIONAL AGRI-FOOD HEALTH AND QUALITY SERVICE deems necessary.

ARTICLE 8º.- Where required or deemed necessary, all expenses generated by inspection in the place of origin by personnel of this organization as established in this Resolution for purposes of analyzing the feasibility of exporting products to the ARGENTINE REPUBLIC shall be for the account of the exporting country, requesting party and/or interested party in the commercial procedure. The same shall apply where the NATIONAL AGRI-FOOD HEALTH AND QUALITY SERVICE considers it necessary to conduct a visit to a country for purposes of *in situ* verification of all matters related to exports headed for the ARGENTINE REPUBLIC.

ARTICLE 9.- Approval is hereby ordered of the Procedure for the approval and notification of phytosanitary and zoosanitary requirements for imports of animals; reproductive material; precursory life forms; zootherapeutics; biologicals; fertilizers; animal feed; plants; plant parts; soil dressings; organic support and/or growth media; biological control organisms; products, byproducts and derivatives of animal or plant origin; or goods and/or inputs whose components consist of or contain ingredients of animal or plant origin that appear in Annex II, which forms part of this Resolution.

ARTICLE 10.- Approval is hereby ordered of the administrative procedure for processing imports of products, byproducts or derivatives of animal origin, or goods and/or inputs whose components consist of or contain ingredients of animal origin as it appears in Annex III, which forms part of this Resolution.

ARTICLE 11.- The Quarantines, Borders and Certifications Coordination Office is hereby authorized to establish and amend phytosanitary and zoosanitary requirements for imports of animals; reproductive material; precursory life forms; zootherapeutics; biologicals; fertilizers; animal feed; plants; plant parts; soil dressings; organic support and/or growth media; biological control organisms; products, byproducts and derivatives of animal or plant origin; or goods and/or inputs whose components consist of or contain ingredients of animal or plant origin. That office shall also generate the mechanisms and procedures necessary for the establishment of phytosanitary and zoosanitary requirements as well as the administrative procedures for authorizing the corresponding imports in each case, and may prohibit or suspend the entry into the National Territory of goods under the responsibility of the NATIONAL AGRI-FOOD HEALTH AND QUALITY SERVICE where technical or emergency conditions so warrant.

ARTICLE 12.- Resolutions Nos. 1354 dated 27 October 1994 and 1415 dated 17 November 1994, both issued by the former NATIONAL ANIMAL HEALTH SERVICE, in the Administrative procedure for processing imports of live animals and reproductive material, are to remain in effect.

ARTICLE 13.- Approval is hereby ordered of the Administrative Procedure for processing imports of plants; plant parts; organic support and/or growth media [issuance of the *Autorización Fitosanitaria de Importación* (Phytosanitary Import Authorization)] (AFIDI); products, byproducts, derivatives of plant origin or goods and/or inputs whose components consist of or contain ingredients of plant origin; that appears in Annex IV, which forms part of this Resolution.

ARTICLE 14.- Provision No. 165 dated 20 March 1986, Resolution No. 630 dated 23 May 1994 of the former NATIONAL ANIMAL HEALTH SERVICE, Resolution No. 416 dated 4 November 1994 of the former *INSTITUTO ARGENTINO DE SANIDAD and CALIDAD VEGETAL* [Argentine Institute of Plant Health and Quality] and Resolution No. 1508 dated 21 September 2000 of the NATIONAL AGRI-FOOD HEALTH AND QUALITY SERVICE are hereby revoked.

ARTICLE 15.- The scope of Articles 1, 2, 4 and 5 of Resolution No. 202 dated 1 August 1992 and Articles 1, 2 and 4 of Resolution No. 668 dated 10 August 1994, both of the former MINISTRY OF AGRICULTURE, LIVESTOCK AND FISHERIES, is hereby restricted.

ARTICLE 16.- The scope of Resolution No. 758 dated 13 October 1997 of the former MINISTRY OF AGRICULTURE, LIVESTOCK AND FISHERIES AND FOOD is hereby restricted.

ARTICLE 17.- The terms of Resolution No. 492 dated 6 November 2001 of the NATIONAL AGRI-FOOD HEALTH AND QUALITY SERVICE are to be expanded to include biological control organisms.

ARTICLE 18.- This Resolution shall enter into effect as of the day following its publication in the Official Gazette.

ARTICLE 19.- Non-compliance with any of the procedures set out in this standard shall result in application of the penalties set out in Chapter VI, Article 18 and thereafter, of Decree No. 1585 dated 19 December 1996.

ARTICLE 20.- Be it known, published and forwarded to the National Official

Registry for filing.

RESOLUTION NO.816

Annex I

PROCEDURAL STANDARDS FOR THE AUDITING OF COUNTRIES EXPORTING PRODUCTS AND BY-PRODUCTS OF ANIMAL OR PLANT ORIGIN TO THE ARGENTINE REPUBLIC

In the context of products and by-products of animal or plant origin, on-site audits refer to the monitoring and inspection measures required to verify guarantees that the existing sanitary and phytosanitary standards, and sanitary and public health policy are being implemented.

These guarantees must, at a minimum, be those agreed to between a non-member country and the Argentine Republic, or those established in multilateral agreements.

The Argentine health authorities will notify in advance the country that they wish to audit, and request an agreement to set a date for the visit. The agreement will include the type of products and the program to be followed.

Under no circumstance may the information and comments collected during the audit mission or its conclusions be used for personal ends, or communicated to persons not associated with SENASA the state Agri-Food Health and Quality Service.

SENASA will certify the findings of the mission in a written report that it will submit within thirty (30) business days, provided that the country visited provides any additional information requested during the mission.

Should a significant risk to public, animal or plant health have been uncovered during the mission, the report will be presented as soon as possible, and in any case, within ten (10) business days of the end of the mission.

Once the report with the findings of the mission has been delivered to the audited country, the audited country will have twenty (20) business days in which to make any necessary comments and suggest corrections.

Any comments and corrections proposed will be analyzed by SENASA and will be incorporated into the final report if they are considered pertinent. If they are not incorporated, they will be included in a footnote as the opinion of the audited country.

SENASA will use the corrections received to write the final report.

A. PROTOCOL FOR ANIMAL HEALTH AUDITS

INDEX

The final written report should include the titles and page numbers for the following:

1. INTRODUCTION
   a) Country.
   b) Date of mission.
   c) Argentine experts on the mission.
   d) Accompanying officials from the country visited.
   e) Program with audit schedule.

2. OBJECTIVES
   Describe the objectives of the animal health mission (FMD/CSF/BSE, etc.).
   a) Name the competent authorities to be interviewed (central, regional and local levels).
   b) Visits and technical meetings in the corresponding areas at the central level.
   c) Visits to local and/or regional offices (provincial/state, etc.).
   d) Visits to:
      - reference laboratories;
      - public diagnostic laboratories;
      - private diagnostic laboratories.
   e) Visits to slaughterhouses, processing and/or packaging plants and warehouses, that export to the Argentine Republic.
   f) Other visits:
      - establishments that supply animals for slaughtering, whose meat is to be exported to the Argentine Republic;
      - insemination centres whose semen, embryos or eggs are exported to the Argentine Republic;
      - establishments that prepare livestock feed;
      - inspection post at sanitary barrier;
      - border sanitary inspection post;
      - livestock markets.

3. LEGAL FRAMEWORK FOR MISSION
   List the standards that must be met by the products exported to the Argentine Republic by the country that is the subject of the inspection mission.

4. CONTEXT OF THE MISSION
   4.1. History of the disease (under inspection) during recent years:
      Provide a brief summary of its onset, measures taken to control it, use of vaccines (type, application), disease eradication, serologic testing, methods used, restricted animal movement, control and eradication programs.

4.2. Summary of the last mission undertaken in the country:
To be completed at a later date. State observations made and give address for the web page where the complete report for the mission can be read.

4.3. Evolution of the disease, since the last visit:
To be completed at a later date.

4.4. Production and marketing information:
Record the volumes produced by the audited country (if relevant, by regions or zones) and the tonnes of product exported to the Argentine Republic (please provide ONE multi-year cycle).

5. OBSERVATIONS

5.1. Competent authorities:

5.1.1. Organization of Veterinary Services.

5.1.1.1. Central competent authorities: describe the type of organization and its position in the national organization chart; structure and jurisdictions, both technical and administrative, with their legal framework. Procedures manuals at the different levels.

5.1.1.2. Regional authorities: describe their jurisdiction and autonomy.
Clearly describe this point for those countries (like Spain and Germany) where the regions are very independent from the central government.

5.1.1.3. Local authorities: describe the jurisdiction and responsibilities of the local authority; their knowledge of the standards for which they are responsible; record-keeping of activities and animals; reporting and notification to their superiors (provincial, regional and central) of having taken the actions for which they are responsible. The same applies to cases involving a slaughterhouse or food-processing plant.

5.1.2. Financial and human resources.
How does it obtain its resources and how are they distributed (equipment, education and training courses, salaries, maintenance of operating capacity, etc.).

5.1.3. Transparency policy.
Notification of the onset of the disease that is being audited (whether the *Office international de épizooties* (OIE) and the Argentine Republic are notified; whether the information is posted

on its web page, etc.); whether the microorganisms are sent to an international or regional reference laboratory for typing.

5.2. Animal registration:
Animal identification system used in the country. Registration of livestock establishments.
5.3. Control of animal movements.
Animal transit document. How are changes in animal ownership verified and recorded, both internally and for imported animals.
5.4. National Epidemiological Surveillance System

5.4.1. Notification and management of outbreaks (FMD/CSF/BSE, etc.)

5.4.1.1. Rules in force before the onset of the disease; who gives notice of a suspected outbreak; implementation period for the competent authority.
5.4.1.2. Measures taken before the onset of the disease: samples taken, movement of animals and animal-derived products.
5.4.1.3. Epidemiological survey: management of the epidemiological information in the findings.

5.4.2. Components and Structure of the National System

5.5. Measures taken in the outbreak area and surrounding area:

5.5.1. Immobilization period for animals and animal-derived products, as well for all the materials at risk for the disease.
5.5.2. Restrictions on animal movements and animals sent for slaughter whose products could be exported to the Argentine Republic.

5.6. Vaccination:

5.6.1. Characteristics of the vaccines used (type of microorganisms, inactivators used, adjuvants, duration of immunity) processed by private or public corporations; who performs quality control, etc.
5.6.2. National or regional vaccination programs:
Monitoring of animals subjected to vaccination programs, frequency, doses; who monitors the storage and transport of the vaccine; who administers it (public or private); who certifies the inoculation; identification of vaccinated animals.

5.7. Laboratories:

5.7.1. National reference laboratory: budget, condition of building and laboratories, equipment, organization, personnel, records and protocols for sampling and results; management of information and results.

5.7.2. Network laboratories: rating systems and audit records. Condition of the building and of the laboratories, diagnostic methods used (with their procedures manuals), time lapsed between receipt and return of results. Systems for communicating with the person returning the samples and with the officials who must be sent the information.

5.8. Establishments for the slaughter, processing and/or packaging and warehousing of animal-derived products:

5.8.1. Special rating, if required.
5.8.2. Competent authority: identification of official, knowledge of the pertinent legislation, records of sanitary certificates, animal movement certificates, "ante-mortem" appraisals (identification of animals, records of animals that arrived with symptoms or lesions caused by disease) and "post-mortem" appraisals (records of observations of lesions or confiscation). Records of compliance with specific requirements for exports to the Argentine Republic. Risk-mitigation manuals for the diseases being audited.
5.8.3. Traceability from the animal's arrival to the packaged products in the warehouse.
5.8.4. Waste treatment: manner in which waste is destroyed in order to prevent the contamination and spread of the disease.
5.8.5. Certification: system used to guarantee the veracity of the information entered on the certificate and the use of the model certificates approved by SENASA that set the requirements for entry into the Argentine Republic.

6. CONCLUSIONS

6.1. Competent authority: must describe the outcome of the audit at the different levels of the organization of the responsible authority.
6.2. Record-keeping by establishments: analysis of observations with regard to knowledge of the establishments where animals are kept.
6.3. Animal identification: opinion on the system used to guarantee the origin of the animals that will supply the products for exportation.
6.4. Monitoring of farm movements: appraisal of the system that guarantees animal movements and the immobilization of diseased animals.
6.5. Notification and management of outbreaks or diseased animals (BSE): Comments on the system used for the notification of a disease or of suspected cases. In addition, actions implemented to contain the disease and to avoid contaminating other susceptible animals or their products.
6.6. National disease program: comments on the plan implemented to control the disease.
6.7. Laboratories: level of training, management of samples and the protocols of the national reference laboratory. Comments on the network laboratories.

6.8. Certification: comments on the manner in which the country guarantees the veracity of the sanitary certificates.

7. FINAL MEETING

Once the on-site inspection has been completed, the SENASA experts will provide the country's official authorities with an oral report on their conclusions from the audit, and if appropriate, on corrective measures that should be implemented, as well as their degree of urgency.

A mission report will be drawn up based on all the information collected under the protocol, and must include:

- Conclusions,
- Recommendations:
  - for the official authorities of the country visited
  - for SENASA authorities.

8. RECOMMENDATIONS

8.1. For the authorities of the country visited:
In this case, state any observations made during the audit that should be corrected in order to continue to allow entry of the product(s) originating in the inspected country.

8.2. For SENASA audits
Provide any suggestions for SENASA to:

- strengthen the controls over this product
- raise the requirements for accepting the product, or
- suspend entry of the product until the [exporting] country guarantees to correct the problems observed
- suspend the establishment that produced the product.

9. APPENDIXES

Comments issued by the official authorities of the audited country for the draft mission report submitted by SENASA must be included. If there are corrections to be made directly or clarifications, if appropriate, these are recorded in the footnotes.

Similarly, maps, charts, and statistics may also be included.

B- PROTOCOL FOR AUDITING MEAT-PROCESSING ESTABLISHMENTS.

INDEX

1. INTRODUCTION.

2. MISSION OBJECTIVES.

3. LEGAL FRAMEWORK FOR THE MISSION.

4. CONTEXT OF THE MISSION.

4.1. Summary of findings from previous missions.
4.2. Reasons for current mission.
4.3. Production and marketing information.

5. OBSERVATIONS.

5.1. The competent authorities.
5.2. Ranking procedures for establishments.
5.3. Separation of national production from production for export to the Argentine Republic (including animal traceability and identification).
5.4. Certification.
5.5. Security of production controls.

5.5.1. Official monitoring of production conditions.
5.5.2. "Ante-mortem" inspection.
5.5.3. "Post-mortem" inspection.
5.5.4. Structure and maintenance of establishments.
5.5.5. Self-inspection of establishments.
5.5.6. Traceability of meat.
5.5.7. Training programs for personnel at the establishments.
5.5.8. Medical certificate for workers.
5.5.9. Water quality.

5.6. Animal well-being.
5.7. Monitoring of animal health.
5.8. Laboratory service.

6. CONCLUSIONS

6.1. Structure and powers of the competent authority.
6.2. Procedures for approving establishments.
6.3. Monitoring of food security.
6.4. Certification.
6.5. Separation of production for export (including animal traceability and identification).
6.6. Animal well-being.
(if considered necessary)
6.7. Final exportation controls.
6.7.1 Controls at border or at shipping plants for embarkation.
6.7.2. Controls at loading point: processing plants, other locations, or port or air loading terminals, etc.

7. FINAL MEETING.

8. RECOMMENDATIONS.

8.1. To the competent authorities of the inspected country.
8.2. To SENASA authorities.

9. APPENDIXES
Lists of establishments authorized to export by the official health agency.

C. PROTOCOL FOR AUDITING RESIDUE-MONITORING PROGRAMS.

INDEX

1. INTRODUCTION.

2. MISSION OBJECTIVES.

3. LEGAL FRAMEWORK FOR THE MISSION .

4. CONTEXT OF THE MISSION .

4.1. Summary of findings from previous missions.
4.2. Reasons for current mission.
4.3. Production and marketing information.

5. OBSERVATIONS.

5.1. The competent authorities, structure and power.
5.2. Residues monitoring program.

5.2.1. Legal framework for residues monitoring program.
5.2.2. Coverage of the residues monitoring program.
5.2.3. General sampling (monitoring) and sampling of suspicious animals.
5.2.4. Information on test results under the national residue monitoring plan.
5.2.5. Procedures for implementing the national residue monitoring plan. General criteria of the plan (size of sampling and statistical basis) and risk analysis. Criteria for drafting annual plans.
5.2.6. Database of infractions, corrective measures for irregularities and their legal framework.

5.3. Availability of veterinary drugs.

5.3.1. Legal framework.
5.3.2. Veterinary drugs prohibited for use in animal feed.
5.3.3. Growth hormones (GHs).
5.3.4. Restrictions on the use of GHs in livestock establishments registered for slaughter operations.
5.3.5. Prescription and over-the-counter drugs.
5.3.6. Drug ingredients used for purposes other than those indicated.

5.4. Control of the production and distribution of GHs and veterinary drugs.
5.6. Maximum residue limit (MRL) for pesticides and heavy metals.
5.7. In-depth investigation.

5.7.1. In-depth investigation in case anabolic substances were used, in compliance with Resolution 397/97
5.7.2. In-depth investigation in case of MRL violations, in compliance with Resolution 125/98.

5.8. Animal identification.
5.9. Laboratory performance.

5.9.1. Quality management – Quality Security (QS).
5.9.2. Analytical performance.
5.9.3. Direction from SENASA's national reference laboratory for network laboratories.

6. CONCLUSIONS

6.1. Structure and jurisdiction of the competent authority.
6.2. Residues monitoring program.
6.3. Availability of veterinary drugs.
6.4. Control of the production and distribution of GHs and veterinary drugs.
6.5. Maximum residue limit (MRL) for veterinary drugs and levels of administrative action.
6.6. Maximum residue limit (MRL) for pesticides and heavy metals.
6.7. In-depth investigation.
6.8. Animal identification.
6.9. Laboratory performance.
6.10. Overall conclusion.

7. FINAL MEETING.

8. RECOMMENDATIONS.

8.1. For the competent authorities of the inspected country
8.2. For SENASA authorities

9. APPENDIXES

D. PROTOCOL FOR AUDITING DAIRY-PRODUCT PROGRAMS.

INDEX

1. INTRODUCTION.

2. MISSION OBJECTIVES.

3. LEGAL FRAMEWORK FOR THE MISSION .

4. CONTEXT OF THE MISSION.

4.1. Summary of findings from previous missions.
4.2. Reasons for current mission.
4.3. Production and marketing information.

4.3.1. Milk production.
4.3.2. Dairy products exported to Argentina.
4.3.3. Dates of the last ten (10) exportations (if available)
4.3.4. National livestock herd
4.3.5. Dairy herd, dominant breeds.
4.3.6. Number of milking yards.

4.4. Health information.
4.4.1. Animal health status.
4.4.2. Animal diseases covered in OIE Lists A and B, their control systems.
4.4.3. Foodborne illnesses and zoonoses caused by dairy products.

4.3.3.1. Control agencies.

5. OBSERVATIONS.
5.1. Standards regarding the collection, treatment and processing of milk, for products exported to the Argentine Republic.
5.1.1. Program on operational procedures.
5.1.2. EEC Directive 92/46 or directive required by SENASA.
5.1.3. National legislation.

5.2. Organization of the competent authority.

5.2.1. Structure of the National Service.

5.2.1.1. Competent central authority.
5.2.1.2. Competent regional authority.
5.2.1.3. Competent provincial authority.

5.2.2. Coordination of the different levels.
5.2.3. Program for monitoring milking yards and establishments receiving, treating and processing milk.

5.2.3.1. Inspection system for primary production.
5.2.3.2. System for monitoring the collection and transport of the raw material.
5.2.3.3. System and frequency of inspection at the treatment, processing and warehousing establishments for dairy products for exportation.

5.2.4. Inspector training courses.

5.3. Official system for monitoring export production.

5.3.1. National residues plan.
5.3.2. Sampling program for milk and dairy products.

5.3.2.1. Type of tests and parametres used.

5.3.3. Official program for water testing.

5.4. Network of officially recognized laboratories

5.4.1. Description.
5.4.2. National reference laboratory.
5.4.3. Coordination of laboratory network.
5.4.4. Officially authorized private laboratories.
5.4.5. Inside laboratories at dairy plants.

5.5. System for issuing official export certificates
5.6. Primary production (milking yards).

5.6.1. Structure
5.6.2. Equipment
5.6.3 Sanitary controls

5.7. System for monitoring raw-milk quality.

5.7.1. Level of quality values
5.7.2. Basis for raw-milk payment system
5.7.3. Laboratory that carries out the controls

5.7.3.1. Laboratory location
5.7.3.2. Methods used
5.7.3.3. Frequency of controls.

5.8. Establishment for receiving, treating and processing milk.

5.8.1. Documentation for official use.
5.8.2. Documentation for use in industry that includes traceability of production.
5.8.3. Controls for production system.
5.8.4. Use of the HAACP system.
5.8.5. Self-monitoring system.
5.8.6. Use of other systems.
5.8.7. General condition of building structures.

5.8.7.1. Sector divisions of the different facilities.
5.8.7.2. Planimetry

5.8.8. Use and approval of additives
5.8.9. Approval of products
5.8.10. Records
5.8.11. Effluent

6. CONCLUSIONS

6.1. Hygiene standards for milk and dairy products applied to products exported to Argentina.
6.2. Organization of the competent authority.
6.3. Sampling program for exported products.
6.4. Network of official laboratories.
6.5. Official certification for exportation.
6.6. Milking yards.
6.7. Quality system for raw milk.
6.8. Milk processing plants.

7. FINAL CONCLUSION.

8. RECOMMENDATIONS.

8.1. For the competent authorities of the inspected country
8.2. For SENASA authorities

9. APPENDIXES

E. PROTOCOL FOR PHYTOSANITARY AUDITS

INDEX

1. INTRODUCTION.

1.1. Country
1.2. Date of the mission
1.3. Argentine experts on the mission.
1.4. Officials from the audited country accompanying the Argentine mission.

2. MISSION OBJECTIVES.

Describe the reasons for which the audit is carried out, which in general are to verify various phytosanitary and/or quarantine issues.

3. LEGAL FRAMEWORK FOR THE MISSION.

National standards, bilateral agreement, regional standards, international standards that establish the conditions that the exporting country must meet for products to be exported to Argentina.

4. CONTEXT OF THE MISSION.

4.1. Summary of findings from previous missions, if available.
4.2. Production and marketing information.
Description of crops in area, detailed description of the products that are to be exported, production volumes, volumes for export to the Argentine Republic.
4.3. Brief description of the pest or disease being studied.
Monitoring systems, status, economic importance in the region.

5. PROGRESS OF THE MISSION.

5.1. GENERAL ASPECTS

5.1.1. The competent authorities

5.1.1.1. Organization of the phytosanitary protection services.
5.1.1.2 Central competent authorities: describe the type of organization and its position in the national organization chart; structure and jurisdictions, both technical and administrative, with their legal framework . Procedures manuals.
5.1.1.3. Regional authorities: describe their jurisdiction and autonomy.
Clearly describe this point for those countries where the regions are very independent from the central government.
5.1.1.4. Local authorities: describe their jurisdiction and responsibilities; their knowledge of the standards for which they are responsible; record-keeping of activities and

monitoring performed; notification to their superiors (provincial, regional and central) of actions taken.

5.1.2. Financial and human resources.

How does it obtain its resources and how are they distributed (equipment, education and training courses, salaries, operating capacity, etc.). How does it fund its activities, organizational structure, personnel and administration unit.

5.1.3. In the case of audits of systems or protocols covered under the standards of the South Cone Plant Protection Committee [*COSAVE - Comité de Sanidad Vegetal del Cono Sur*] (pest-free areas, multi-stage risk-mitigation measures systems, etc.), all the points in the standards must be verified.

5.1.4. Pest identification laboratories: organization, recognition or rating, infrastructure available, personnel and training, methodology used, records of findings, traceability, management of information and findings, system for communicating findings, monitoring or audit systems, finalizing the methodologies to be used.

5.1.5. Traceability: of pest monitoring programs, official monitoring performed in the country.

5.2. SPECIFIC ASPECTS

5.2.1. For rating nurseries.

5.2.1.1. Certification program for propagation material. Pests covered. System for obtaining initial material. Pre-propagation establishments. Monitoring of nurseries for mother plants. Monitoring of certified material (traceability).

5.2.1.2. Laboratories that take part in the certification program, laboratories that perform tests for the official monitoring of nurseries, laboratories that perform tests on material for export: organization, recognition or rating, infrastructure available, personnel and training, pests identified, methodology used, records of findings, traceability, management of the information and of the findings, system for communicating the findings, monitoring and audit systems, finalizing the methodologies to be used.

5.2.1.3. Official monitoring system for nurseries, mother plants, initial material and plants destined for production: inspections program, records. Sampling, record-keeping. Record-keeping and monitoring of the quantity and type of material produced by the nurseries. Traceability.

5.2.1.4. Pest control programs, if applicable: Notification and management of pest outbreaks requiring quarantine by the Argentine Republic.

5.2.1.5. Description of the nursery:

Organization, infrastructure, production, certified material production system. Production and sale of standard material. Traceability. Region producing material. Record-keeping of official inspections: of nursery material, basic monitoring and soil tests. Experience as export nursery: list the destinations and describe under what phytosanitary conditions the nursery exports or has exported. Potential for meeting the phytosanitary requirements of the Argentine Republic.

5.2.1.6. Official monitoring and certification for pests for which quarantine is required by importing countries. Possibility for monitoring and certification for pests for which quarantine is required by the Argentine Republic.

5.2.2. For quarantine-treatment facilities.

5.2.2.1. Chambers for fumigation with methyl bromide.

5.2.2.1.1. Documentation that confirms the ranking of the fumigation chamber, current instrument calibration (scales, chimney sensor, system for recording temperature and events, portable thermometer) and personnel training (managers and operators) in charge of the chamber.

5.2.2.1.2. Tests: manual calibration of sensors and thermometer (mixture of crushed ice and distilled water), pressure (drop of fifty (50) millimetres of mercury column in a period of one hundred twenty (120) seconds), vacuum test (injection of thirty-two (32) grams per cubic metre of methyl bromide in the empty chamber).

5.2.2.1.3. Leak detection (instrument panel, pipes, dumpers, door, ceiling, walls).

5.2.2.1.4. Reading of the fumiscope (measurement of methyl bromide concentration (front, middle and rear)) thirty (30) minutes after injection and with the recirculation fans stopped.

5.2.2.2. Centres for cold-treatment application.

5.2.2.2.1. Documentation that confirms rating of cold chamber, current instrument calibration (system for recording temperature and events, portable thermometer) and personnel training (managers and operators) responsible for the chamber.

5.2.2.2.2. Manual calibration of sensors and thermometer (mixture of crushed ice and distilled water).
5.2.2.2.3. Report on system-test software for temperature recording and monitoring.

5.2.2.3. Hot-water treatment plant.

5.2.2.3.1. Documentation that confirms the ranking of the hydrothermal treatment plant, current instrument calibration (system for recording temperature and events, portable thermometer) and personnel training (managers and operators) responsible for the plant.
5.2.2.3.2. Report on system-test software for temperature recording and monitoring.

5.2.3. Miscellaneous.

6. CONCLUSIONS

Opinion on audit at government level. Opinion on audit in private sector. Certification: comments on the need for phytosanitary import authorization (*autorización fitosanitaria de importación* - AFIDI) in order to issue phytosanitary certificates for the Argentine Republic, its significance and relevance. Equivalencies of rate measurements required for each pest and guarantees of their performance.

7. FINAL MEETING

Once the visit is completed, SENASA experts will provide the country's phytosanitary authorities with an oral report of their preliminary conclusions on the audit, and if appropriate, any corrective measures that should be implemented. Proposals for quarantine guarantees or certification may also be discussed by the phytosanitary authorities of the exporting country with regard to phytosanitary requirements in Argentina.

8. RECOMMENDATIONS.

List any suggestions for SENASA to:

- approve/not approve the importation of new products,

or

- approve/not approve an inspected nursery,

or

- modify the controls for the importation of the product,

or

- modify the requirements for accepting the product,

or

- request that the exporting country take additional measures or modify its control system for products exported to the Argentine Republic.

or

- suspend entry of the product, until the country provides guarantees regarding the problems uncovered,

or

- other.

9. APPENDIXES.

Maps, charts and any other information provided by the audited country during the visit.

Annex 2

PROCEDURE FOR APPROVAL AND NOTIFICATION OF PHYTOSANITARY AND ZOOSANITARY REQUIREMENTS FOR IMPORTS OF ANIMALS; REPRODUCTIVE MATERIAL; PRECURSORY LIFE FORMS; ZOOTHERAPEUTICS; BIOLOGICALS; FERTILIZERS; ANIMAL FEED; PLANTS; PLANT PARTS; SOIL DRESSINGS; ORGANIC SUPPORT AND/OR GROWTH MEDIA; BIOLOGICAL CONTROL ORGANISMS; PRODUCTS, BYPRODUCTS AND DERIVATIVES OF ANIMAL AND/OR PLANT ORIGIN; OR GOODS AND/OR INPUTS WHOSE COMPONENTS CONSIST OF OR INCLUDE INGREDIENTS OF ANIMAL AND/OR PLANT ORIGIN

1. The *Coordinación de Cuarentenas, Fronteras and Certificaciones* [Quarantines, Borders and Certifications Coordination Office] shall establish or amend the phytosanitary and zoosanitary requirements for authorizing imports of products under the responsibility of SENASA in keeping with the Risk Analysis, basing itself on assessment, in keeping with the circumstances, of existing risks to the life and health of people and animals or the preservation of plants and their health, in accordance with the terms of the Sanitary and Phytosanitary Measures Agreement of the WORLD TRADE ORGANIZATION and following the notification and consultation procedures established herein.

2. The Quarantines, Borders and Certifications Coordination Office may prohibit or suspend entry into the national territory of products under its responsibility where technical evaluations or emergency conditions so warrant.

3. Functions performed by SENASA may include the following: official recognition of countries, areas, zones or regions free of or with a low prevalence of diseases or pests, as applicable; establishments or farms free of diseases or pests; equivalence of measures for risk reduction; and equivalence of inspection procedures of exporting countries. The Quarantines, Borders and Certifications Coordination Office shall, through the Animal and Plant Quarantine Directorates, establish the procedures necessary for each recognition, based on the recommendations and principles of international bodies (INTERNATIONAL OFFICE OF EPIZOOTICS, WORLD TRADE ORGANIZATION, Codex, CIPF, among others) and taking into account the national or regional legislation in effect. The applicant official service shall provide the information requested by SENASA for each case and facilitate the conducting of inspection visits by SENASA officials where deemed necessary. The cost of these actions shall be borne by the interested party.

4. The Animal and Plant Quarantine Directorates shall be the sole parties responsible for issuing technical reports from the quarantine point of view for all phytosanitary or zoosanitary requirements pertaining to import authorization for products under the responsibility of SENASA.

5. The areas of the Quarantines, Borders and Certifications Coordination Office authorized to generate import requirements, as applicable, shall be those responsible for conducting the necessary prior consultations with the various SENASA offices with the authority to establish other technical sanitary requirements (quality, residues, labels or other).

6. The responsible offices shall forward the requirements drafted as a result of the respective Risk Analysis, technical reports and other technical requirements to the Quarantines, Borders and Certifications Coordination Office for review.

7. The draft requirement may be sent for technical and scientific comments by the competent bodies and/or technical advisory commissions or reference bodies.

8. This period for comments shall be established for each case and may vary according to the characteristics of the product, with a minimum term of SIXTY (60) days established.

9. The Quarantines, Borders and Certifications Coordination Office may formally open a consultation period at the national level where it deems necessary, so as to obtain opinions on draft sanitary, phytosanitary and zoosanitary import requirements from institutions competent in such areas. The method and times for the above-mentioned consultation period shall be established for each specific case.

10. Once the period established for the various consultations has expired, the Quarantines, Borders and Certifications Coordination Office shall, after considering the comments and proposals received, proceed to finalize the draft requirement, amend it or extend the consultation period, and may make public a report analyzing the relevant comments received in which it states the reasons for rejection or acceptance of the various points of view. The Final Regulation shall be initialled by all participating technical institutions and signed by the Coordinator of the Quarantines, Borders and Certifications Coordination Office.

11. The above-mentioned Coordination Office shall forward the requirements to the *Coordinación de Relaciones Internacionales e Institucionales* [International and Institutional Relations Coordination Office] in order that the latter might so inform the country of origin of the product within the preestablished deadlines, or the SPS, where applicable.

12. The external consultation period set out in Point 11 shall consist of a minimum of sixty (60) days. Comments received shall be considered by the Animal and Plant Quarantine Directorates, as applicable.

13. If no comments are received within the preestablished period, the Quarantines, Borders and Certifications Coordination Office shall consider the import request approved subject to the established conditions.

14. Where there are comments on the part of the exporting country(ies), the Quarantines, Borders and Certifications Coordination Office shall conduct the corresponding evaluation of same within a minimum period of SIXTY (60) days. If applicable, the necessary amendments shall be made and the exporting country advised thereof for purposes of final confirmation or acceptance of new comments. Once this period has transpired and the comments received have been evaluated, the Animal and Plant Quarantine Directorates shall draft the final import requirement, of which notification shall be given as established in Point 11 of this Annex.

15. Sanitary, phytosanitary or zoosanitary requirements may be amended by order of the Quarantines, Borders and Certifications Coordination Office through recommendations by the Animal and Plant Quarantine Directorates, where emergency risk-generating sanitary, phytosanitary or zoosanitary circumstances are in effect. Such measures may go so far as to include suspension of import authorizations. The suspension set out in this point shall be formalized through a ruling handed down by the Coordinator of the Quarantines, Borders and Certifications Coordination Office (this responsibility may be delegated to responsible parties in the Animal and Plant Quarantine Directorates, where necessary).

16. A database of zoosanitary and phytosanitary import requirements shall be available for consultation.

17. SENASA offices shall be advised by reliable means of any amendment or new requirements, including border offices involved in complying with the new sanitary requirements.

18. Entry into the country shall only be authorized for those goods mentioned in article one of this Resolution that have the corresponding import authorization in accordance with the terms of the standards in effect.

19. Final confirmation of the model sanitary, phytosanitary, or zoosanitary requirements, as applicable, shall constitute part, but not all, of the requirements for import authorization. Prior to authorization, compliance with all necessary technical and administrative requirements must be ensured, including, among others, audits and authorization in the place of origin.

PART 1

ESTABLISHMENT OF ZOOSANITARY REQUIREMENTS

Criteria of the Animal Quarantine Directorate with respect to determination of zoosanitary requirements for imports of products of animal origin under the responsibility of SENASA.

a) The primary role of quarantine procedures and decisions is both keeping undesirable diseases outside the territory of the ARGENTINE REPUBLIC and facilitating the international flow of persons and goods under the responsibility of this National Service.
b) Quarantine policy is based on a concept of reasonable and acceptable risk management based on scientific support.
c) The definitions contained in the Zoosanitary Code of the INTERNATIONAL OFFICE OF EPIZOOTICS (OIE) shall be used in all cases and shall take into account the pre-existence of national or regional regulations in effect, not only those issued by SENASA, but also by other bodies with jurisdiction in this area.

Presentation by the interested party. A file shall be opened by the Entry, Exit, Archives and Public Information Desk of SENASA on forms provided for that purpose by the competent areas.

1. Preliminary evaluation: there are two (2) possible scenarios:

   1.1. Requirements are in place for products of equivalent or greater risk or specific prohibitions in that regard are in effect, in which case a direct ruling shall be handed down at the level of the operating area involved.

   1.2. Faced with the non-existence of and need for a feasibility analysis, the Animal Quarantine Directorate shall prepare a work schedule which shall specify both the need for resources for the above-mentioned analysis as well as the probable time required to rule on the case. The schedule must include details as to personnel resources, particularly if the need arises for consultation of other permanent or *ad hoc* advisory bodies, hiring of consultants, inspection or verification visits and any other input necessary for resolving the matter.

2. Feasibility analysis: Notification of the party concerned with respect to the need to carry out an Import Risk Analysis[1] (IRA). Where the information required to conduct the above-mentioned analysis is not available, the request submitted shall be returned to the party concerned, together with

[1] Risk evaluation shall be understood to mean the procedures for identification and assessment of the events necessary to produce an adverse sanitary situation.

notification of the situation and a list of the information required to carry out the IRA.

3. The Animal Quarantine Directorate may make small changes or considerations [*sic*] to already existing import requirements without having to conduct a new IRA. This process is called a routine IRA. The corresponding report shall be issued within NINETY-SIX (96) working hours following receipt of the request. This result may include a final ruling of Acceptance or Rejection. The operating area shall proceed to notify the interested party of the results by reliable means.

4. Applications for imports of animals or derived products that involve significant variations to already established import health policies shall require a non-routine IRA process. This type of IRA could involve a lengthy period of time and a complex process.

5. The report corresponding to the need to carry out a non-routine IRA shall be issued within FIVE (5) to FIFTEEN (15) working days following receipt of the import request.

6. Import Risk Analysis: this shall be initiated when the Animal Quarantine Directorate receives all the required information from the responsible official body of the exporting country. When establishing zoosanitary requirements, measures that guarantee minimum risk and produce the minimum impact on marketing shall be considered. Once the IRA has been completed, it shall be approved and the interested parties so informed through the Animal Quarantine Directorate. A minimum period of THREE (3) months shall apply for establishing the requirements.

7. Once the preestablished steps have been complied with, if procedures that ensure an adequate level of zoosanitary protection are determined, the Animal Quarantine Directorate shall draft the technical report with the quarantine requirements to be stipulated in the proposed zoosanitary requirement.

8. Wherever deemed appropriate or necessary, the Quarantines, Borders and Certifications Coordination Office may order that a quantitative Risk Analysis be conducted.

PART 2

ESTABLISHMENT OF PHYTOSANITARY REQUIREMENTS.
Products of plant origin that present possible phytosanitary risk based on their level of processing and proposed use are subject to phytosanitary import regulations, in keeping with the terms of Regional Phytosanitary Protection Standard 3.15 [Harmonization of Phytosanitary Measures by Path Way (COSAVE/1999)].

TWO (2) scenarios are possible in this case:

1. Phytosanitary requirements are in place for the product requested, products of equivalent or greater risk and/or specific prohibitions are in effect.

2. Phytosanitary requirements have not yet been established, which means that a Risk Analysis is necessary. The Plant Quarantine Directorate must therefore prepare a work schedule that specifies the need for resources for the above-mentioned analysis and an estimate of the probable time required to rule on the matter. The schedule must include the following details: personnel resources, particularly if the need arises for consultation of permanent or ad hoc advisory bodies, hiring of consultants, need for inspection or verification visits and any other input necessary for resolving the matter.

   2.1. Pest Risk Analysis (PRA).

   Phytosanitary requirements shall be established as a result of the PRA based on the International Standards for Phytosanitary Measures (ISPM) Nº 2 "Guidelines for pest risk analysis" and ISPM Nº 11 "Pest risk analysis for quarantine pests" (FAO /1996).
   The analysis shall consider the species and plant part (fruit, seed, plant, etc.), pests existing in the place of origin, biology, economic importance, internationally recognized quarantine treatments, use or destination of the good in our country and any other factor of phytosanitary or legislative importance.

   When establishing phytosanitary requirements, measures that ensure minimum risk and produce the minimum impact on marketing shall be considered.
   The Plant Quarantine Directorate shall state the need for a PRA for products and places of origin in which that analysis has not been performed at the time of submission of the Import Phytosanitary Authorization (AFIDI). TWO (2) scenarios are possible:

a) The Plant Quarantine Directorate has the information necessary to establish the phytosanitary requirements in a minimum period of THREE (3) months as of submission of the AFIDI request;
b) the Plant Quarantine Directorate does not have the information necessary to carry out the PRA, in which case the application submitted shall be returned to the interested party, together with a list of the information required to carry out this analysis.

The PRA shall be carried out when the Plant Quarantine Directorate receives the requested information from the national phytosanitary protection body of the exporting country, and it shall have a minimum period of THREE (3) months to establish import phytosanitary requirements.

Where the products analyzed are of high risk to agricultural production, the Quarantines, Borders and Certifications Coordination Office may order that a quantitative Risk Analysis be conducted.
Where, as a result of the PRA, it has been determined that the phytosanitary conditions of the country of origin constitute a risk for the entry of quarantine pests and/or the established risk management option(s) cannot be implemented, the Plant Quarantine Directorate shall not issue the AFIDI.

2. 2. Pest risk management options

a) Recognition of "pest free areas".
The ARGENTINE REPUBLIC shall recognize "pest free areas" in third countries as established in the International Standards for Phytosanitary Measures (ISPM) No. 4 "Requirements for the establishment of pest free areas" (FAO/1996) or the approved Regional Phytosanitary Protection Substandards of COSAVE.
b) Recognition of "system approach for pest risk management".
The ARGENTINE REPUBLIC shall recognize this risk management option in third countries, as established in Regional Phytosanitary Protection Standard 3.13 "Guidelines for a system approach for pest risk management" COSAVE/1999.
c) Recognition of "pest free places of production and/or pest free production sites".
The ARGENTINE REPUBLIC shall recognize "pest free places of production and/or pest free production sites" in third countries, as established in International Standards for Phytosanitary Measures (ISPM) No. 10 "Requirements for the establishment of pest free places of production and pest free production sites" (FAO/1999).
d) Recognition of "Phytosanitary Certification Systems" and "Equivalence Measures".

The ARGENTINE REPUBLIC shall recognize Phytosanitary Certification Systems in third countries as established in ISPM No. 7 Export certification system" (FAO/1999) and equivalence measures according to Regional Phytosanitary Protection Standard 3.7. "Procedures for the approval of quarantine treatments " (COSAVE/ 2000) and Annexes IV of SENASA Resolution No. 601 dated 28 December 2001 which sets out minimum conditions for the authorization of quarantine treatment application centres.

Review of the Pest Risk Analysis

In the event of changes to phytosanitary conditions in the place of origin, the discovery of irregularities in the phytosanitary certification, interception of quarantine pests in shipments from a specific place of origin, deemed expiry of phytosanitary requirements, or existence of a bilateral agreement, and lack of compliance with the "Principles of plant quarantine as related to international trade" (FAO/1995), the Quarantines, Borders and Certifications Coordination Office shall establish the need for a new Pest Risk Analysis or review of the previous PRA.

Annex 3

STANDARD PROCEDURE FOR IMPORTS OF PRODUCTS, BYPRODUCTS AND/OR DERIVATIVES OF ANIMAL ORIGIN AND/OR GOODS AND/OR INPUTS WHOSE COMPONENTS CONSIST OF OR INCLUDE INGREDIENTS OF ANIMAL ORIGIN

1. The approval of all import procedures shall be dependent upon THREE (3) prior conditions being met: firstly, issuance of a favourable report by the Animal Quarantine Directorate that determines country risk, product risk and destination risk in accordance with current standards, previously determining, based on that and other technical components, the requirements for that import; second, authorization of the slaughterhouses, manufacturing plants and/or warehouse of origin and/or shipment, if applicable, in accordance with the terms of this resolution; and, finally, registration of the product where applicable. There is no deadline for meeting these THREE (3) conditions. Once these conditions have been met, the formalities will take no longer than FORTY-FIVE (45) calendar days, barring delays attributable to the applicant.

2. In order to be authorized to enter the country, products, byproducts and/or derivatives of animal origin and/or goods and/or inputs whose components consist of or contain ingredients of animal origin must have been produced in plants authorized by the competent veterinary and/or official sanitary administration of the country of origin whose processes are supervised by the latter. In cases unlike that described above that could be considered equivalent, the veterinary and/or official sanitary administration of the exporting country may bring the case to the attention of the *NATIONAL AGRI-FOOD HEALTH AND QUALITY SERVICE* [NATIONAL AGRI-FOOD HEALTH AND QUALITY SERVICE] with the corresponding background information. This National Service shall proceed to study that case and, if applicable, to authorize the proposed procedure.

3. All requests for imports of products, byproducts and/or derivatives of animal origin and/or goods and/or inputs whose components consist of or contain ingredients of animal origin shall be sent in file form to the *Mesa de Entradas y Salidas* [Entry and Exit Desk] of this body and forwarded to the Product Importation Coordination Office, an operating area of the International Traffic Directorate, both of which report to the Quarantines, Borders and Certifications Coordination Office of the NATIONAL AGRI-FOOD HEALTH AND QUALITY SERVICE. Form I (*Request for importation of products, byproducts and/or derivatives of animal origin and/or goods and/or inputs whose components consist of or contain ingredients of animal origin*), which forms part of this resolution and has the status of a sworn statement, shall be used for that purpose, attaching the documentation requested in the aforementioned form in compiling the file, and indicating, among other information: country of origin, animal species, type of good, specification of the manufacturing establishment, official authorization

number for that establishment issued by the competent body recognized by this National Service, and its geographical location. The request in question to be submitted to the Entry, Exit, Archives and Public Information Desk of this National Service shall be accompanied by the documentation listed in the following point.

4. When requesting approval, registration or an import permit, as applicable, for a product, byproduct and/or derivative of animal origin and/or goods and/or inputs whose components consist of or contain ingredients of animal origin to be imported, the importer must submit the following documentation together with Form I:
   a) A copy of the product's descriptive monograph including the following: identification of the manufacturer, official number of the establishment, animal species, brand and name of the product and name under regulatory legislation, manufacturing technique including operational flowchart, list of ingredients including additives and manufacturing aids, quantifying the declaration where their use is restricted under current legislation, decreasing percentage composition, shelf life and/or expiry date, conservation and transport conditions, heat penetration studies in sterilized or thermoprocessed products and any other treatment and/or process to which the product is submitted, using as a guide those described in Form II that forms part of this resolution.
      Submission of this documentation shall not be required for products whose operational manufacturing procedure does not extend to the processes of slaughtering, butchering, fileting, cold application and/or collection. In such cases, a descriptive declaration must be submitted stating the maintenance temperature, maturation if applicable and/or shelf life of the product.
   b) Descriptive monograph for the packing system, listing materials to be used as well as a description of the packaging, sealing system and weight of each unit of sale.
   c) Packing certificate where required under current regulations.
   d) TWO (2) copies of the original labels of the product to be imported when the file is opened for technical study and approval.
      To these should be attached TWO (2) copies of the draft complementary label which should provide full details on the importer, country of origin and/or shipment, name of the production establishment, official number of the manufacturing establishment, declaration of ingredients, range of maintenance temperatures, minimum shelf life and all obligatory information that does not appear or does not appear in Spanish on the original printed label. The draft complementary label shall be an exact copy of that to be applied in the place of origin to the main label by box and/or by unit when the product is destined for direct sale to the public or to the primary and/or secondary package when the product is to be used for processing.
      The original copies of the monograph for the product and for the packing system, descriptive declaration and certification of fitness of the

packaging must be presented as a sworn statement signed by the responsible professional of the exporting company and endorsed by the Official Sanitary Service of the exporting country.

The Official Inspection Service of the country of origin of the product must confirm or identify the following points, among others, as authorized by equivalent systems specifically recognized by the NATIONAL AGRI-FOOD HEALTH AND QUALITY SERVICE: species or animal species of the raw materials used to manufacture the product, heat penetration studies in sterilized or heat processed products (time and temperature), maturation times, salting or other conservation process, fitness for human consumption and unrestricted marketing in the country of origin.

Copies or photocopies submitted must in all cases be authenticated by the National Public Notary.

When the original documents are not submitted in Spanish, they must in all cases be translated by a nationally certified translator.

5. Products, byproducts and/or derivatives of animal origin and/or goods and/or inputs whose components consist of or contain ingredients of animal origin to be imported shall, according to their intended use, be subjected to the following procedures for registration, if applicable, prior to their final import authorization granted by the operating area of the Quarantines, Borders and Certifications Coordination Office, as indicated:
   a) Products intended for human consumption or processing for subsequent human consumption, or for human pharmacological or organotherapeutic use, wine-making and edible gelatins, edible fats and oils and all those with this purpose, in addition to finished animal feed, biological products, manures and/or fertilizers with animal components, must be registered with the *Dirección de Agroquímicos, Productos Farmacológicos y Veterinarios* [Agrochemicals and Pharmacological and Veterinary Products Directorate].
   b) Animal raw materials used in the preparation of animal feed or others for animal consumption with animal components shall be registered with the *Dirección de Fiscalization de Productos de Origen Animal* [Directorate for the Supervision of Products of Animal Origin].
   c) Products intended solely for industry and not in any way intended for human or animal consumption in any of their forms need not be registered.

6. Where there are amendments to the authorization in the original file, the interested party must request their incorporation into same, attaching the corresponding documentation endorsed by the Official Sanitary Service of the exporting country. That amendment must be approved in advance by the competent areas, and a new "Import Authorization" to that effect shall be issued within the TEN (10) days follwoign the aforementioned approvals.

7. As of submission of the documentation to the Entry, Exit, Archives and Public Information Desk of this National Service and provided that the THREE (3) conditions set out in Point 1 have been met, the above-mentioned body must issue a ruling in that regard within a period not to exceed TWENTY-FIVE (45) calendar days.
   Where the THREE (3) conditions have been met and SENASA does not issue a ruling within the stipulated period, barring delays not attributable to the Service, the person responsible for the import may submit a note to the competent area of the Quarantines, Borders and Certifications Coordination Office requesting "PROMPT CLEARANCE" of the file in question. If, FIVE (5) working days after such submission, the aforementioned Service has not issued a ruling, the applicant may import the product into the national territory using the file number granted to him/her upon submission of the documentation requested by this body to proceed with feasibility analysis of the import authorization, attaching to the Notice of Arrival the aforementioned request for Prompt Clearance.

8. The Import authorization for products, byproducts and/or derivatives of animal origin and/or goods and/or inputs whose components consist of or contain ingredients of animal origin, intended for human consumption, animal feed, industrial use or other purpose, shall be issued by the Coordinación de Importación de Productos [Product Importation Coordination Office], an operating area of the International Traffic Office, both of which report to the Quarantines, Borders and Certifications Coordination Office. That authorization shall be valid for a period of ONE (1) year. Once that period has transpired, the authorization shall cease to be valid, except where health or other reasons have required its cancellation, suspension or modification prior to that time. The Quarantines, Borders and Certifications Coordination Office issuing such authorizations has NINETY-SIX (96) working hours after receiving the necessary information, and provided there are no impediments whatsoever, to issue that authorization. The sanitary, zoosanitary, quality and/or other conditions, as applicable, indicated on that import authorization, shall be identical to those that must appear on the certification of origin and/or shipment, as applicable, that accompanies the goods destined for the ARGENTINE REPUBLIC.

9. Renewals or extensions of the Import Authorization shall be issued by the competent area of the Quarantines, Borders and Certifications Coordination Office upon request to that effect by the interested party, between THIRTY (30) and SEVEN (7) days prior to their expiry, with a note from the importer and copy of the expiring "Import Authorization" that is to be renewed, according to the terms of this resolution. When such a request is submitted, SENASA shall make the new authorization available to the importer, provided there are no sanitary, technical, legal or other impediments, prior to the expiry date. Where the ONE (1) year term of the "Import Authorization" has expired and its renewal has not been requested in due time in accordance with the terms hereof, its renewal shall be

subject to the time required for the technical reports by the competent areas of the Service.

SENASA shall officially notify the competent sanitary authorities of the country of origin of the conditions that must be met through the corresponding model certificate, which shall be made available to users who so request.

That model International Sanitary Certificate shall be subject, together with import authorizations, to cancellation, suspension or amendment where necessary in the case of changes to country/product/destination risk, expired authorization of manufacturing plants or the need to update quality or identity requirements where necessary. A reference generic model appears as Form III, which forms an integral part of this resolution.

10. Products which, due to their characteristics, cannot be accompanied in their place of origin by one certificate per shipment and which are intended for industrial use rather than consumption—culture media, reactants or others--must be accompanied by officially endorsed generic approval certificates, approved monographs or documentation that SENASA, via the Quarantines, Borders and Certifications Coordination Office, deems appropriate for that purpose, to ensure their traceability. Import authorizations granted in such cases shall have a term of SIX (6) months provided their characteristics do not change. These authorizations may be renewed upon request in writing following the same administrative procedure. They shall become void if, within their period of validity, there are changes to their characteristics or original conditions. The interested party bears full responsibility for providing notification of such changes for review of the feasibility of issuing authorization adapted to those changes.

11. SENASA shall cancel or suspend import authorizations issued and take the sanitary and/or administrative measures it deems necessary under the following circumstances:
    a) Changes to the animal health status of the country of origin of the good could pose a risk to the animal health status of the ARGENTINE REPUBLIC;
    b) Authorization of the manufacturing establishment is revoked or suspended;
    c) The importer is struck from or suspended from the corresponding register;
    d) An injunction is ordered to that effect;
    e) At the discretion of the NATIONAL AGRI-FOOD HEALTH AND QUALITY SERVICE, for reasons of public interest or risk that renders such action necessary.

12. The approval and subsequent authorization of goods, carried out in accordance with the preceding points, shall be valid for so long as the health conditions of the country of origin are not altered, and provided that no other health-related reason makes such a move necessary. All importers wishing to

import a good already approved and registered with the body by a third party must submit documentation to the Entry, Exit, Archives and Public Information Desk that shall be forwarded to the Product Importation Coordination Office, an operating area of the International Traffic Directorate, both of which report to the Quarantines, Borders and Certifications Coordination Office. They shall fill out an application for an import permit in accordance with Form IV, which forms part of this resolution and consists of a sworn statement, referring to the procedures already approved and authorized. The relevant authorization shall be granted within a period of no more than TWENTY-FIVE (25) calendar days. If there is a difference between the packaging monograph and the net weight of the product, the form appearing as FORM I must be filled out, and the deadline stipulated for that purpose shall apply.

13. Prior to the arrival of each shipment, the importer must submit in duplicate to the Product Importation Coordination Office the Notice of arrival corresponding to the importation of products, byproducts and/or derivatives of animal origin and/or goods and/or inputs whose components consist of or contain ingredients of animal origin in accordance with Form V, which forms an integral part of this resolution and has the status of a sworn statement, where that shipment is intended for human consumption in any of its forms or animal consumption as indicated in Point 5, or with Form VI, which forms an integral part of this resolution and has the status of a sworn statement, where the products are for industrial use and not for consumption as indicated in the same point.
That Notice of Arrival must be presented at least THREE (3) working days in advance of the entry of the good by sea, air, river or overland. The Office must authorize or reject that notice. It shall be returned to the applicant signed and validated, barring any impediments, within FORTY-EIGHT (48) hours of receipt. The Notice of Arrival shall be valid for FIFTEEN (15) calendar days counted from the date of its authorization. It may be extended one time only for a similar period, where circumstances so warrant, with a request in writing from the importer with the original notice or copy of same attached.

14. The following must be attached to the aforementioned Notice of Arrival:
    a) Copy of the "Import Authorization" for the product to be imported.
    b) Copy of the "final labels" approved for products for human or animal consumption or labels presented for goods for industrial use (those for industrial use that are neither approved nor registered) and proof of registration and approval of label and monograph where applicable that identify the good and that have been approved by the competent area.
    c) At the request of the competent areas, ONE (1) copy of the certificate of quality, analysis and fitness for human consumption, wholesomeness and/or health, as applicable, covering the goods, translated by a nationally certified translator where not written in Spanish.
    d) Copy of the certificate covering the goods for shipments by sea and in

cases in which certification is required and in which, due to the certification procedure in the country of origin, it is not possible to obtain the above-mentioned documentation prior to arrival of the good (e.g., air or land shipments), the importer must submit a copy to the Product Importation Coordination Office within TWENTY-FOUR (24) hours follwoign the entry of same.

15. A Notice of arrival corresponding to the importation of products, byproducts and/or derivatives of animal origin and/or goods and/or inputs whose components consist of or contain ingredients of animal origin, which, like Forms V and VI, constitutes an integral part of this resolution, must be requested for each shipment of goods corresponding to ONE (1) truck, car, container or ship's cargo.

16. It shall be the responsibility of the importer or his or her representative to notify the SENASA Inspection Service of the plant of destination and the entry land post at which the good is to arrive. That notification must be carried out by reliable means no less than ONE (1) working day prior to arrival in the country of the goods.

17. Where the maximum validity period of the Notice of Arrival (including the extension) of THIRTY (30) days has expired and the importation for which it was requested has not been carried out, the importer must return that notice to the office of the Service that issued it or to the land post at which it was to be presented (which shall return it to its office of origin) within no more than SEVEN (7) working days counted from the day following expiry, so that it can be removed from the list, accompanied by a note to that effect. Where non-compliance with the foregoing is encountered, and until such time as the situation is corrected, the operating area shall issue no further Notices of Arrival to the company involved.

18. The original Notice of Arrival delivered to the interested party with the attached documentation as described in Point 14 of this Annex must form an integral part of the documentation presented to the land post, photocopies of which shall subsequently accompany the good to the establishment of destination declared on same.

19. Changes to the establishment of destination shall only be granted prior to entry of the goods with a written request from the importer attaching the original or a copy of the notice, to the Product Importation Coordination Office, an operating area of the International Traffic Office, both of which report to the Quarantines, Borders and Certifications Coordination Office.

20. The Notice of Arrival, whether or not it contains new information upon arrival, shall consist of the information requested in Point 6 of same and must be signed by the responsible party of the SENASA Inspection Service at the receiving plant and filed at the Inspection Service as documentation

for the import, in keeping with directives issued to that effect by the competent areas. The relevant area shall be advised of the new information together with the applicable documentation and the certificate, if applicable.

21. Goods considered to be samples and described as such on the accompanying commercial and/or health documentation and which, due to their subsequent use (tasting, special events, technical quality analysis, packing, etc.), do not require prior registration, must be authorized through submission of the Notice of arrival corresponding to the importation of samples of products, byproducts and/or derivatives of animal origin and/or goods and/or inputs whose components consist of or contain ingredients of animal origin, which, as Form VII, is an integral part of this resolution and subject to a sworn statement. The goods must be accompanied by ONE (1) International Sanitary Certificate issued by the competent authority recognized by SENASA attesting to compliance with the sanitary/zoosanitary and or quality requirements stipulated to that effect by the above-mentioned body, in keeping with the origin and product in question. The certificate must be drafted in Spanish or translated by a nationally certified translator. Where applicable, this National Service shall determine its subsequent destination once the basis for its importation has concluded. It is not necessary to be registered as an importer, nor is registration and approval of a good classified as a "sample" required. The interested party must also fill out Form VIII. The processing and validity of the notice of arrival for a sample shall be the same as those for Forms V and VI.
    Goods considered to be samples are exempt from the requirement for use in plants authorized by SENASA, except where reasons of a sanitary or zoosanitary nature, risk factor or other warrant official restriction of their destination to an authorized establishment, and it is the authority of this body to so stipulate where it deems necessary.

22. With respect to cases covered by the preceding point, the goods in question shall in all cases be goods whose importation into the country does not involve a potential sanitary or zoosanitary risk, which shall be determined prior to granting the entry authorization by the competent areas of SENASA, which shall assess the zoosanitary risk involved in importing the products and issue a technical report to that effect. Under no circumstances shall the entry of handcrafted goods, goods produced in establishments not subject to official control or products that are not correctly identified be authorized.
    The time required for the above-mentioned "risk analysis" shall be similar to that required for any commercial importation.

23. Products, byproducts and/or derivatives of animal origin and/or goods and/or inputs whose components consist of or contain ingredients of animal origin whose importation is sought for human consumption must be subject, in their country of origin, to a Food Hygiene and Residue Control

Plan equivalent to the Food Hygiene and Residue Control Plan of the ARGENTINE REPUBLIC.

Acceptance of the country of origin as an exporter of the above-mentioned products to the ARGENTINE REPUBLIC shall be subject to approval by SENASA of the guarantees offered by that plan with respect to monitoring of the possible presence of residues of contaminating substances and veterinary medicines, as well as the detection of pathogenic microorganisms.

In addition, and for purposes of maintaining the above-mentioned status, the analytical results for the previous year obtained under the framework of that plan must be officially remitted during the first quarter of the year.

24. All products, byproducts and/or derivatives of animal origin and/or goods and/or inputs whose components consist of or contain ingredients of animal origin must enter the country accompanied by ONE (1) copy of the original International Sanitary Certificate attesting to compliance with SENASA requirements in matters of animal and public health and, if applicable, quality or other requirements, issued by the official competent authority of the country of origin recognized by this National Service, and written in or translated into Spanish by a nationally certified translator. Only the options set out for compliance with Point 10 of this Annex shall be included as exceptions.

25. At border inspection points, personnel of the NATIONAL AGRI-FOOD HEALTH AND QUALITY SERVICE shall in all cases carry out physical, thermal (if applicable), documentary and identity control of goods and consistency between authorization and certification. Locked vehicles, trucks, rail cars, containers, must enter the country pre-sealed and will be subject to verification, upon their arrival, of the correspondence and integrity of the original bands that must appear on the certificates.

This correspondence and integrity will likewise be accepted if the packages of origin arrive sealed with numbered security bands or other equivalent method accepted by SENASA.

The certificate shall also identify the means of transport: for trucks, the ownership number is required; for containers, the acronym and number identification; for rail cars, identification of the car with acronym and/or number; for ships, name; and for airplanes, airline and flight number. Provided there are no impediments, the SENASA document used to authorize transport through the national territory for entry into a nationally authorized establishment shall be issued, with the exceptions set out in this standard.

To that document shall be attached copies of the Notice of Arrival, copies of the "Import Authorization" and of the "Final Label", and the original(s) of the corresponding certificate(s), with the original Notice of Arrival and copy of the attached documentation remaining in the possession of the land post together with a copy of the certificates.

In cases in which the goods must be transhipped at the point of entry into

the country for their transfer to the establishment of destination, that transhipment must be carried out under supervision by SENASA personnel, and the transport must be authorized by the competent area of this body subject to hygiene conditions suited to that purpose.

26. The importation of products, byproducts and/or derivatives of animal origin and/or goods and/or inputs whose components consist of or contain ingredients of animal origin for which SENASA is responsible, and which are not intended for human and/or animal consumption but rather exclusively for industrial use, is subject to the same procedures as those for products intended for the food industry, with the exception of registration of the product, and their destination may be other than plants authorized by this National Service or plants that do not have official authorization. In the latter case, it shall be the responsibility of the plant of destination to keep all documentation relating to the importation on file for submission to the authorities of the NATIONAL AGRI-FOOD HEALTH AND QUALITY SERVICE upon request.
This method shall apply provided there are no reasons of a sanitary, technical or documentary nature that would, in the opinion of the personnel assigned to the entry post, cause the good to be prohibited, in which case the corresponding routine procedures shall be carried out with an authorized establishment as the destination.

27. Where the official on duty at the border notes that the goods do not meet the requirements set out by SENASA for import authorization, he/she shall draw up the corresponding document and refuse to authorize the import.
Notwithstanding the foregoing, where there is non-compliance with the terms of this resolution and non-compliance with the requirements is noted, provided that public or animal health is not compromised, the Quarantines, Borders and Certifications Coordination Office may consider exceptions upon specific request of the importer.
To that end, a note must be submitted to the aforementioned office where an exception is authorized, and the corresponding document must be drawn up. Entry of the good may be authorized as "prohibited without rights of use", granting a period not longer than FIFTEEN (15) days to the importing company to correct the situation, during which period the interested party shall take responsibility for maintaining the good under the appropriate conditions and covering the expenses incurred in that regard.
SENASA, through the Quarantines, Borders, and Certifications Coordination Office, may make a final decision as to entry, change of fitness, rejection, reexportation or destruction of the goods.
If the period set out in this point has expired and no solution has been found to the problem that gave rise to the prohibition, the NATIONAL AGRI-FOOD HEALTH AND QUALITY SERVICE shall decide upon the procedure to be followed, of which the importer shall be notified together with the time frame for the measure.
If, once that period has expired, no action has been taken and there are no

reasons of force majeure to justify an extension, the importer shall be deemed to have abandoned the goods, in which case an order shall be given to destroy them. All forms of expenses incurred as a result of that destruction shall be for the account of the responsible firm.

28. The following, among others, shall be considered grounds for rejection:
   a) Lack of an International Sanitary Certificate of origin issued by an official authority recognized by SENASA covering the goods to be imported.
   b) Certification in which the sanitary requirements are not documented and in which such status suggests a potential risk to the human or animal population of the country.
   c) Lack of correspondence between what is declared on the certificate of origin and what is authorized and approved, and information with respect to identity, including thermal condition.
   d) Alteration of the organoleptic characteristics of the products to be imported.
   e) Undocumented violation of bands declared on the documentation of origin.
   f) Lack of identification of the band(s) in the certificate, lack of identification of the means of transport in those documents.
   g) Labels that do not correspond to those declared to SENASA and those registered with and authorized by that body.
   h) Certificates not written in Spanish or lacking the corresponding translation by a certified translator.
   i) Sanitary and zoosanitary certificates covering goods that lack the official identification corresponding to the issuing country. Certificates without official letterhead or proper identification shall not be accepted.
   j) Goods with unauthorized origins.
   k) Failure to indicate the name of the importer in the certificate accompanying the good.

29. The procedure described below shall be followed to obtain information on compliance of entry of the goods into the establishment authorized by SENASA, as authorized in the Notice of Arrival Form V:
   a) This procedure shall apply to all operations involving the importation of products, byproducts and derivatives of animal origin destined for plants supervised by SENASA.
   b) All land posts covered by SENASA involved in the inspection of products identified in Point 1 shall periodically inform the Quarantines, Borders and Certifications Coordination Office of such entries.
   c) The aforementioned Coordination Office shall provide the National Agrifood Inspection Directorate with a list of plants that saw movement during the period of the report.
   d) The Quarantines, Borders and Certifications Coordination Office shall periodically issue a report for each plant, including the following information: official number of the plant, transit permit, Notice of Arrival number, date of entry into the country, animal species, description of

the product, kilograms imported, land post handling the entry, country of origin, producer and importer.

e) These reports shall be sent periodically by the Quarantines, Borders and Certifications Coordination Office to the supervisors of the various plants, who shall distribute them to the SENASA personnel present at same.
f) The personnel of this National Service in each plant shall ensure that the products of which they are informed coincide qualitatively and quantitatively with those that have entered the plant.
g) According to the results of this verification, the SENASA personnel in the plant shall in all cases produce a report entitled "New information" or "No new information" signifying, respectively, that there is or is not total correspondence between the products entering the plant and information obtained from the Quarantines, Borders and Certifications Coordination Office.
h) The National Agrifood Inspection Directorate shall take the necessary steps to obtain the results of this verification in each plant, whether or not there was new information, and shall advise the Quarantines, Borders and Certifications Coordination Office of the results within a period of no more than FIFTEEN (15) days following the issue of the reports issued by that coordination office.
i) Where there is new information, it shall so inform the Quarantines, Borders and Certifications Coordination Office in order that the latter might proceed to verify the accuracy of the data supplied and, if applicable, take the corresponding action.
j) Where this new information consists of entries with variations, the Quarantines, Borders and Certifications Coordination Office shall proceed to verify the data provided by the land posts, according to the importance of same, correcting the incorrect data in the databases where applicable.
k) Where plant personnel provides information on new destinations, the Quarantines, Borders and Certifications Coordination Office shall proceed to record that new information in the databases.
l) In cases in which entries through border points are found not to have arrived at the plants declared by the importers, the Quarantines, Borders and Certifications Coordination Office shall institute the legal proceedings necessary and advise the National Agrifood Inspection Directorate of this situation.
m) Where goods not reported by the Quarantines, Borders and Certifications Coordination Office have entered the plant, the latter shall proceed to determine why the plant was not advised thereof.

30. Import authorizations granted prior to the entry into effect of this resolution shall become void according to the following schedule.

Date of issue	Expiry date (expressed in days following the entry into effective of this resolution)
1993-1996	SIXTY (60) days
1997-1999	NINETY (90) days
2000-2001	ONE HUNDRED AND TWENTY (120) days
2002	Calendar year

31. For the renewal of "import authorizations" issued prior to the entry into effect of this resolution, companies must present a copy of same no less than TWENTY (20) days prior to expiry, so as to proceed with their renewal, and must turn in the original authorizations when the corresponding renewals are issued.

32. Authorization notes issued as of the entry into effect of this standard shall be drawn up in accordance with the model appearing as Form IX of this resolution.

33. The NATIONAL AGRI-FOOD HEALTH AND QUALITY SERVICE may request commercial documentation from importers or any other documentation accompanying a shipment, where it is necessary to verify data or the uniformity thereof.

34. Skins and tanned leathers and goods or clothing manufactured from same shall be exempt from this Annex. Skins or tanned leathers (except manufactured goods and goods derived from same or clothing) from species susceptible to transmissible spongiform encephalopathies from countries affected by these diseases, must only be accompanied by a favourable report prior to their importation of the Animal Quarantine Directorate, which shall be obtained from the Product Importation Coordination Office with a note from the interested party indicating the intended use and attaching all the accompanying documentation or that which SENASA deems relevant. Once the Animal Quarantine Directorate has made a decision, the operating office shall have FORTY-EIGHT (48) hours to notify the user.
Processed seashells and/or sea sponges or products manufactured from them are exempt from this Annex. Any other manufactured good with these characteristics that does not pose a sanitary or zoosanitary risk may also be exempted.

35. Cessation of use by one importance in favour of another is prohibited.

36. Notices of arrival shall be subject to a charge of TEN PESOS ($ 10.-) each, in accordance with Resolution No. 670 dated 11 October 2000 of the former MINISTRY OF AGRICULTURE, LIVESTOCK, FISHERIES AND FOOD.

37. All goods with animal components that, following enactment of this standard, fall under the purview of the Quarantines, Borders and Certifications Coordination Office, shall adhere to this procedure, except where higher standards (e.g., SOUTHERN COMMON MARKET OR OTHER) require a specific procedure.

Annex 4

APPLICATION AND ISSUING PROCEDURE FOR PHYTOSANITARY IMPORT AUTHORIZATION (AFIDI)

Phytosanitary import authorization (AFIDI)

Before any plants, plant parts, products, byproducts and derivatives, organic growth and/or sustenance media and soil conditioners may be brought into the country for commercial purposes, application must be made to the Plant Quarantine Directorate for phytosanitary import authorization (AFIDI). The AFIDI sets out the plant-health requirements for imports.

Products for which an AFIDI is required

An AFIDI is required for all products whose level of phytosanitary risk places them in categories 2, 3, 4 and 5 of COSAVE Standard 3.15 ("Harmonization of phytosanitary measures by way of entry" (v2) – not required for categories 0 and 1).

AFIDI application form

A separate AFIDI application form must be submitted for each product to be imported.

For AFIDI purposes a product is defined according to the following parameters: botanical genus and species, plant part (fruit, foliage, bulb, plant, seed, etc.), country of origin, intended use (consumption, propagation, etc), form (natural, cutting, pellets, etc), packaging (boxes, bags, etc.), means of shipment and point of entry into the country.

There are four different AFIDI application forms, depending on intended use: (1) products for consumption, industrial use or processing; (2) propagating material; (3) seeds for laboratory use; and (4) peat.

A model of each of these forms can be found at the end of this Annex. Copies of these forms may be used. Application forms must be submitted with all requisite information duly entered.

When an application is submitted to import seed for laboratory use, the back of the AFIDI form must be completed (information on quantity of seed, testing to be performed, and laboratory where work is to be done).

In the case of asexual propagating material, except ornamentals, the AFIDI application must be accompanied by an application for approval of the quarantine facility. Such material must meet the requirements set forth in Resolutions

SAGPyA N° 292/92 for General Post-Entry Quarantine and SENASA N° 69/99 for post-entry quarantine of grapevines.

Where to submit AFIDI application

AFIDI application forms must be submitted in person, by mail or by fax to the Plant Quarantine Directorate (DCV) of SENASA, Mondays to Fridays from 09:00 to 13:30.
Address: Paseo Colón N° 367, Piso 7°, (1063) Ciudad Autónoma de Buenos Aires
Fax: (011) 4342-5137.

AFIDI issue and delivery times

Where a file has already been opened in the AFIDI system for the product/origin, the Plant Quarantine Directorate will issue the AFIDI within five business days. Otherwise, a pest risk analysis must be carried out in accordance with Annex II of this resolution.

Those who reside, or have a representative, in the city of Buenos Aires may pick up an AFIDI original (no copy) at the Plant Quarantine Directorate at the SENASA head office, Mondays to Fridays from 09:00 to 13:30. Others may fax or mail their request, indicating the fax number or address to which the AFIDI is to be sent. When the AFIDI is sent by fax, the Plant Quarantine Directorate will simultaneously send the original to the SENASA local office at the point of entry.

Submission of AFIDI

The importer must submit a copy of the AFIDI to the National Plant Protection Organization of the exporting country, so that it can certify compliance with the phytosanitary requirements. In cases where it is necessary to carry out laboratory analysis, crop inspections, etc, beforehand, the requirements should be reported to the exporting country with sufficient lead time prior to shipment of the products.

The original of the AFIDI must be shown at the point of entry of the goods, along with the phytosanitary certificate from the country of origin. The inspector at the point of entry will ensure that the AFIDI's phytosanitary requirements appear in the phytosanitary certificate as "additional declarations." He will also take samples for laboratory analysis to confirm the absence of quarantine pests. In cases of high-value germ plasm imported in small quantities for experimental purposes, the Plant Quarantine Directorate may, at the request of the importer, waive the taking of samples. In this case, the AFIDI application must be accompanied by a note specifying the test to be carried out and a sworn statement by the importer that the material is to be imported for experimental purposes. Depending on the case, the material will be subject to the post-entry quarantine process.

AFIDI validity period

The validity period is variable, depending on the proposed use of the plant product to be imported. In the case of products for consumption, peat and seed for laboratory use: TWO months; for propagation: NINE months. In the latter case, a specific quantity of material will be authorized, which may be imported at different times with the same document, until the full amount is reached and until the expiry date.

Unauthorized use of products

In the case of products that enter the country for consumption, industrial or processing purposes, but whose botanical and physiological characteristics make them usable for propagation (bulbs, seed, tubers, etc.), the AFIDI application form must be accompanied by a sworn statement regarding the use to be made of the product. A model statement appears at the end of this annex.

The penalties for unauthorized use of the product are set forth in Decree Law 6704/63 and Decree 2266/91.

Fees

Resolution SAGPyA N° 782 (1999-11-23) prescribes the fee to be charged for the AFIDI.

Conditions of payment:
- Payment may be made at any branch of the Banco de la Nación Argentina or at the SENASA head office, Paseo Colón N° 367, Planta Baja, Ciudad Autónoma de Buenos Aires.
- Payment must be made by means of deposit slip (blank) to account 2864/24 –Plaza de Mayo branch – SENASA 50/623 RECAUDADORA F.12
- The fee code must be entered on the deposit slip. The codes are as follows:

DIRECTORATE	CODE	DESCRIPTION	UNIT OF MEASURE-MENT	DUTY PER UNIT
Plant Quarantine Directorate	123-A	AFIDI for products for consumption or industrial use (commercial cargoes, mail, passengers, etc.)	ONE per plant species (valid for 60 days)	$ 12.- (for each 60 tons or fraction thereof). For wood $12.- (for each 60 m^3 or fraction thereof)

Plant Quarantine Directorate	150	AFIDI for propagating material for commercial, experimental or official-agency use (commercial cargoes, mail, passengers, etc.)	ONE for AFIDI General Service*	$ 102.- for AFIDI General Service on each customs clearance (regardless of number of AFIDIs)

- It is not necessary to make any payment when requesting the AFIDI.
- AFIDIs for products for consumption will be valid for SIXTY days and no quantity will be specified therein.
- The AFIDI will cover partial payments (inward customs clearance), so that the same AFIDI may be used for any number of shipments within the validity period specified in the issued AFIDI.
- The fee must be paid upon arrival of each import shipment, i.e. TWELVE PESOS ($12.-) for each SIXTY tons or fraction thereof; or, in the case of wood, for each SIXTY CUBIC METERS (60 m³) or fraction thereof, according to the number of tons/m^3 imported in each shipment.
- Stub 3 (AFIDI fee payment) must be presented to the SENASA inspector processing the import shipment. The inspector will put the stub and the original of the AFIDI in the first file opened and will seal and put the file number initiated on an authenticated photocopy of the AFIDI, which must be presented at the time of arrival of the next shipment of the same type of goods, together with the new payment stub. The validity period is SIXTY days.
- The AFIDI fee for propagating material is ONE HUNDRED TWO PESOS ($102.-) and corresponds to general AFIDI service for each shipment, regardless of the number of AFIDIs issued.
- In the case of propagating material, the amount to be imported must be specified. The AFIDI issued may be used for partial receipts of the goods, i.e. it may be used for one or more shipments during the validity period specified in the AFIDI issued. The AFIDI will be valid for NINE months.
- Stub 3 (payment of AFIDI fee of ONE HUNDRED TWO PESOS) must be presented to the SENASA inspector processing the import shipment, which may include one or more species. The inspector will put the stub and the original of the AFIDI in the first file opened and will seal and put the file number initiated on an authenticated photocopy of the AFIDI, which must be presented at the time of the next shipment of the same type of goods, together with the new payment stub. The AFIDI will be valid for NINE months.
- Each month the local office must send the Plant Quarantine Directorate photocopies of the payment stubs received, in which the corresponding AFIDI numbers are entered, so that the Directorate can create its own file.
- No processing will be done without proof of payment (Stub 3).
- If payment is made by cheque, the cheque must be made payable to account 2864/24 – Plaza de Mayo branch – SENASA 50/623 RECAUDADORA

F.12, or to the BANCO DE LA NACION ARGENTINA, with the following note on the back of the cheque: "For deposit to account 2864/24 –Plaza de Mayo branch – SENASA 50/623 RECAUDADORA F.12".