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Committee on Sanitary and Phytosanitary Measures

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IMPLEMENTATION OF ARTICLE 6 OF THE SPS AGREEMENT (REGIONALIZATION)

Communication from Brazil

The following communication, dated 27 January 2006, is being circulated at the request of the Delegation of Brazil.

- 1. Brazil congratulates the Committee for the efforts to promote the effective application of Article 6 of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). That subject, of extreme importance for the Members, has been discussed since the first Review of the Agreement, when delays for the recognition of areas with a differentiated sanitary status had already been highlighted. Thus, Brazil would like to present a new proposal on this matter aimed at improving the previously presented document (G/SPS/W/177).
- 2. In our previous document G/SPS/W/177, we proposed the type of work that could be developed by the Committee in order to promote effective application of Article 6. In it, we suggested that the Committee develop a clear definition of technical/scientific and administrative procedures involved in the recognition of pest and disease free zones. So, we have proposed the elaboration, by the Committee, of objective guidelines for administrative procedures, including the determination of timeframes. We also proposed that technical/scientific procedures should follow the guidelines elaborated by the *International Standards Setting Bodies* (ISSBs). We considered the documents of other developing countries, mainly Peru and Chile, in the elaboration of the mentioned Brazilian proposal. When presented during the 33rd meeting of the SPS Committee, many countries such as Argentina, Chile, Peru, Paraguay, Kenya and also the representative of the European Communities, supported that Brazilian proposal.
- 3. In addition to the document G/SPS/W/177, Brazil elaborated the document G/SPS/GEN/584 on regionalization applied to foot-and-mouth disease. The administrative delays and the lack of adequacy of the requirements in relation to ISSBs recommendations were listed are amongst the main impediments for the effective recognition of the regionalization and consequently for market access,.
- 4. Other documents on experiences of the Newcastle disease regionalization (G/SPS/GEN/608) and Classical Swine Fever (G/SPS/GEN/609), have already been presented to the Committee for the next session. Both indicate that OIE's recognition of free zones for a greater number of diseases and/or pests would enhance international trade of animals and animal products.
- 5. In this document, we present an analysis of the critical points indicated in previous documents, aimed at improving the Brazilian Proposal.

I. DEFINITION OF "ADMINISTRATIVE" AND "TECHNICAL/SCIENTIFIC" PROCEDURES

- 6. Some Members, for example Japan and Canada, consider these two types of procedures to be very similar and thus difficult to differentiate. According to Japan, the elaboration, by the SPS Committee, of applicable guidelines for administrative procedures, could duplicate the work of the ISSBs and cause confusion between the members (G/SPS/GEN/605). However, we consider that the guidelines released by the ISSBs suggest ways of differentiating between the two types of procedures. In our evaluation, the Terrestrial and Aquatic Animal Health Code of the World Organization for Animal Health (OIE), as well as the International Standards for Phytosanitary Measures ISPMs 04, 07, 11 and 20, listed in the Japanese document, apply to the implementation, maintenance and evaluation of the differentiated sanitary status of territories. In this way, they relate to the procedures that, by nature and excellence are considered technical-scientific. They do not configure instructions to be applied on administrative stages of the process of recognition of regionalization measures.
- 7. Japan and Canada, in their recent documents on regionalization (respectively G/SPS/GEN/605 and G/SPS/GEN/613, both of December 2005), cited the works in progress at the IPPC for the elaboration of the ISPM "Guidelines for the recognition of the establishment of free-pest areas and areas of low pest prevalence". Brazil wishes to congratulate and thank IPPC on its efforts related to the optimization of the recognition of free zones (mainly in relation to the implementation of the recognition of pest-free zones, like the OIE already does for four diseases). However, we are certain that the SPS Committee can, and must, elaborate its guidelines on regionalization, without overlapping the activities of that Convention. We deem it convenient to consider the proposed ISPM guidelines in the context of the elaboration of the guidelines that should be established by the SPS Committee. Despite being very pertinent, the IPPC proposal does not contemplate important situations of relevance to the SPS Committee.
- 8. By analyzing established processes of recognition of pest and disease free areas, it is possible to identify common events and to determine the essentially administrative or technical-scientific characteristic involved.
- 9. We suggest that technical-scientific procedures are those procedures that involve analysis related to the biological and/or epidemiological characteristics of the disease/pest and its etiological agent. The administrative procedures will be the other procedures involved.
- 10. In the mentioned ISPM proposal "Guidelines for the recognition of the establishment of pest-free areas of low pest prevalence", the term "technical" is cited only twice in the description of the stages for the recognition of free zones or low pest prevalence. Those two citations are related to the responsibilities of the importing Member related to the "technical analysis" of the information given to the exporter and later, for the elaboration of a "technical justification", when refusing the recognition of a zone.
- 11. Recognizing that the DECISION on the regionalization recognition must be essentially technical and based on risk analysis and equivalence, we are certain that the stages to be carried out are, in their majority, administrative. Because of that, the SPS Committee may develop guidance in this area, mainly in relation to deadlines.
- 12. We consider that some points of the ISPM proposal could improve the recognition of regionalization measures and must be considered by the Committee, as follows:
 - Assignment of "contact points" in order to improve the communication between the parties;
 - Information about the date of the request's receipt, indicating if the documentation is complete and whether analysis can begin; and

- Description of the process that will be adopted for the analysis of the request.
- 13. Based on the Brazilian experience and on the current work on this subject in the SPS and ISSB Committees, we propose the definition of the following steps for the process (Graphic plan in Annex I):
- A. REQUEST OF THE SPECIFIC QUESTIONNAIRE TO BE SUBMITTED ON THE EVALUATION (EXPORTING MEMBER ADMINISTRATIVE PROCEDURES)
- 14. Usually, the soliciting exporting Member initiates the process, sending the information on the adopted measures for the implementation and maintenance of the sanitary status of the zone to be recognized by the importer. Frequently, the importing Member, receiving this information, immediately requests answers to a specific questionnaire, even when most of the information had already been given. In order to prevent this occurrence, we propose that the process starts when the questionnaire is requested for the evaluation. It would make the process more objective and efficient by preventing the sending of information that will not be used. In addition, this would decrease the delays related to additional information requests. Those procedures in the first stage of the process are essentially administrative measures.
 - (a) The exporting Member requests that the importing Member the specific questionnaire for the evaluation of its free zones;
 - (b) The exporting Member will include in its request the references of its "contact point".
- B. SENDING TO THE EXPORTING MEMBER THE SPECIFIC QUESTIONNAIRE FOR THE ANALYSIS AND DETAILING ABOUT THE RECOGNITION PROCESS (ADMINISTRATIVE PROCEDURE OF THE IMPORTING MEMBER)
 - SUGGESTION OF DEADLINE: ONE MONTH AFTER RECEIVING THE REQUEST
- 15. When it concerns diseases and pests that have free zones previously recognized by the Importing Member, the procedure would be merely administrative since the questionnaire to be used must be the same one that was answered by other countries that already had their free zones recognized.
- 16. When sending the questionnaire for analysis, the importing Member must also send references of its "contact point", a summary of the process including details of all the stages, as well as the evaluation criteria. Those measures could improve predictability of the process.
- 17. The Importing Member at this stage would be responsible for the following procedures:
 - (a) The provision of the questionnaire and information about its "contact point";
 - (b) The provision of an annex detailing the administrative and technical steps;
 - (c) The provision of an annex containing the evaluation criteria.
- 18. When a Member has already recognized a disease- or pest-free free zone, it will notify the Committee, displaying the evaluation questionnaire and the analysis criteria. This will allow the control of discrimination in the evaluation among countries and enhance transparency.
- 19. Having the knowledge of that information, the others Members will be able to initiate the process by sending the answered questionnaire and formally requesting the recognition of its zones. In that way, they would avoid having to request a specific questionnaire, accelerating the procedure.

- 20. When the importing Member has never recognized free zones of a specific pest or disease and thus does not have a specific form or even an evaluation methodology, the process will be initiated by the sending of information by the soliciting exporting Member. In that case, the importing Member will inform the soliciting exporting Member of that condition.
- C. ANSWER THE QUESTIONNAIRE FOR EVALUATION (TECHNICAL-SCIENTIFIC PROCEDURE OF THE EXPORTING MEMBER)

SUGGESTION OF TIME FRAME: 3 MONTHS

- 21. The exporting Members should also respect the time frame of three months for answering the evaluation questionnaire. If the exporting Members do not reply to the questionnaire, the Importing Member may prioritize the evaluation of other requests.
- D. ANALYSIS OF THE INFORMATION SUPPLIED BY THE EXPORTING MEMBER (TECHNICIAN-SCIENTIFIC PROCEDURE TO THE IMPORTING MEMBER).

SUGGESTION OF TIME FRAME: 6 MONTHS

- 22. In our opinion, this is a technical-scientific procedure that must follow, exclusively, the guidelines of the ISSBs. So, the technical criteria and the form of conducting the analysis must follow the standards already established by the ISSBs, in accordance with the principles of SPS Agreement. However, extreme delays for the conclusion of this stage are very common, as mentioned by many Member Countries' documents.
- 23. We understand that it is not the responsibility of the SPS Committee to establish the technical criteria. However, according to the SPS Agreement, the Members have the obligation to adjust their administrative structures in order to prevent extreme delays. Thus, we believe the SPS Committee could establish time frames for the conclusion of this technical analysis.
- 24. We consider that the time that is necessary for the technical analysis is directly related to administrative factors, such as the number of technicians and labour conditions. The establishment, by the Committee, of applicable time frames for this stage would value the efforts of the exporting Members in order to supply such a great amount of information. We emphasize that the recognition of regionalization measures are necessarily related to the acceptance of the measures' equivalence. Thus, the Decision on the Implementation of Article 4 launched by the SPS Committee must also be considered.
- 25. As soon as the importing Member receives the documents sent by the exporting Member, it shall communicate if the documentation is in order, so that the analysis can be started.
- 26. At the end of this stage, the importing Member should also answer questions concerning:
 - (a) Necessity of additional information;
 - (b) Necessity of on-site auditing;
 - (c) Suggestion of dates to the on-site auditing.
- E. AGREEING ON AUDITING DATES (ADMINISTRATIVE BILATERAL PROCEDURE)

SUGGESTION OF TIME FRAME: 6 MONTHS

27. After identifying the necessity of auditing, the importing Member will have to suggest a date for the inspections in the exporting Country. The importing Member must conclude the inspection (auditing) in six months, after finishing the analysis of the information. If the exporting Member

cannot receive the auditing, within the stated period, it will lose the priority to other Members interested in having its areas recognized by the Importing Member.

- 28. We stress that the auditing will have to occur in six months after the end of the analysis of the information by the Importing Member. So, the members will have to set up a date in the first month after the identification of the need for an audit. In order to set up the date, the Members can exchange electronic messages or faxes between their "contact points", or others types of communications, to enhance the flexibility of the process. However, the final communication about the settled dates must be done through official diplomatic means.
- F. ON-SITE AUDITING (TECHNICAL-SCIENTIFIC PROCEDURE OF THE IMPORTING MEMBER)
- G. TRANSMISSION OF THE ANALYSIS FINAL RESULTS TO THE EXPORTING MEMBER (ADMINISTRATIVE PROCEDURE)

SUGGESTION OF TIME FRAME: 4 MONTHS

- 29. We understand that the auditing process and the elaboration of technical reports are scientific procedures for which we do not propose Committee guidelines. However once the auditing is concluded, the sending of the results to the exporting Member becomes an administrative procedure. At this stage, the time taken for concluding the job by sending the results to the exporting Member depends on the availability of the auditors throughout the process, from start to finish. We also understand that, the non-existence of delays in this stage depends on the commitment of the countries to provide access to their structures. It is an administrative problem, not a technical one.
- H. THE EXPEDITION OF A NEW REGULATION OR CHANGES ON THE PRESENT ONE (IMPORTING MEMBER ADMINISTRATIVE PROCEDURE)

SUGGESTION OF TIME FRAME: 2 MONTHS

- 30. When necessary, the new regulation should be elaborated and sent for "public comment", in a maximum period of two months after the expedition of the final result of the analysis. This stage is intended for document writing, based on the completed analysis. We consider this procedure to be administrative, because even if the same technician conducts the writing of the regulation, the technical analysis is already finished.
- I. "PUBLIC COMMENT" (IMPORTING MEMBER ADMINISTRATIVE PROCEDURE):

SUGGESTION OF TIME FRAME: 4 MONTHS

- 31. The maximum time for public comment, for incorporating the suggestions and for sending the final version to sanction shall not exceed four months.
- J. RECOGNITION OF THE NORM (IMPORTING MEMBER ADMINISTRATIVE PROCEDURE)

SUGGESTION OF TIME FRAME: 3 MONTHS

32. This is the maximum time for the new regulation to become effective. It must be considered that all the administrative and technical procedures, previously mentioned, that could demand time, had been already contemplated. We believe that 3 months is a reasonable time frame for this last and merely administrative procedure.

"FAST TRACK"

Recognition process of free zones, already recognized by ISSBs

- 33. Following the proposal suggested by Colombia in its document G/SPS/GEN/611, from December of 2005, we also suggest that, for zones recognized by the ISSB, the exporting Members would have to initiate the process by sending the same information that was sent to ISSB for its approval of its free zone.
- 34. The importing Country, as a member of the ISSB, would only have to evaluate the necessity of auditing the exporting Member for evaluating on-site the given information. As the analysis of the consistency of the free zone is already evaluated by the ISSBs, discarding the necessity of same analysis by the importing Member, the suggested time frames would be established from the "step b" from "stage D". Without requiring new analysis, the importing Member will have to disclose the audit necessity, and suggest dates, in the maximum period of two months after the receiving of the information.
- 35. The recognition of these zones, already approved by the ISSBs, must receive priority treatment by the importing Members. The time between disclosing the necessity of an audit and its completion must not exceed three months.
- 36. Additionally, we propose that when the importing Member considers that a higher protection level than the international standard is necessary, making this "fast track" impracticable, he must notify the Committee and publish its evaluation criteria, as well as the specific questionnaire for analysis. This would help countries identify requirements that are not scientific based (graphical scheme on Annex II).

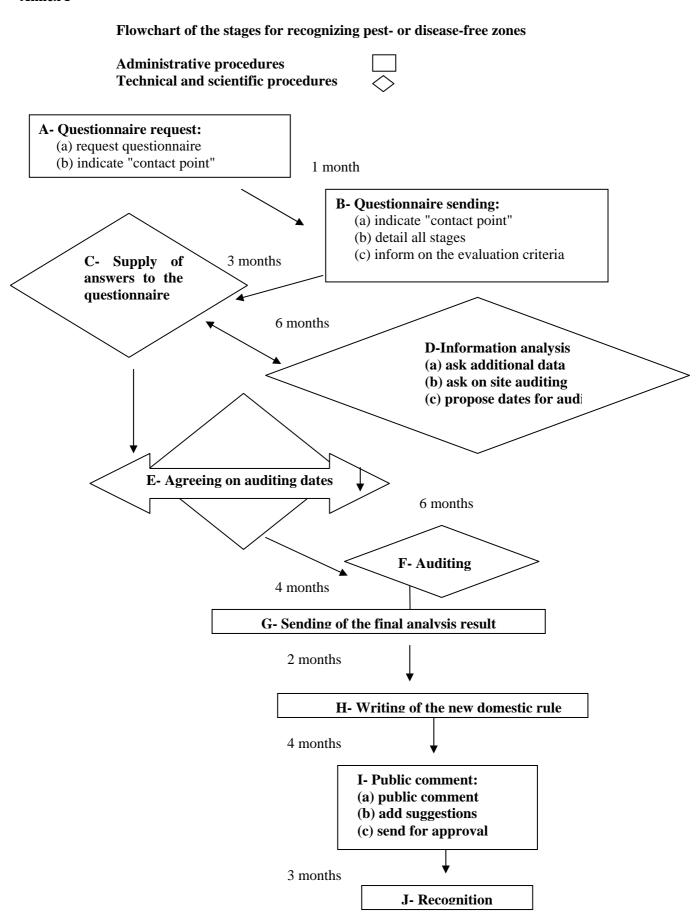
Recognition of pest- and disease-free zones by ISSBs

- 37. In document G/SPS/GEN/608, we indicate the lack of OIE guidelines for the Newcastle disease zoning as one of the impediments for the importing Members' effective recognition of exporters' regionalization measures. The absence of specific international standards for the regionalization of this disease, contributes to the refusal of many countries to analyse the requests for recognition of free zones. When they make it, many countries adopt inconsistent and unpredictable analytical criteria. Because Newcastle Disease is one of the main sanitary barriers to avian products commerce, the absence of such guidelines causes severe damages for the exporting Countries.
- 38. In the Document G/SPS/GEN/609 we noted that the OIE recognition of Classical Swine Fever-free zones, could facilitate the acceptance by the importing Members of measures applied to the regionalization of this disease in exporting countries. For this disease, there are specific regionalization guidelines.
- 39. Even if the importing Members continued to inspect the free zones before approving the OIE recognition, OIE recognition would promote confidence in the application of concepts of regionalization for these diseases. The lack of OIE recognition is indirectly responsible for the refusal of many importing Members to evaluate the free zones from the exporting interested parties. In some cases, the legislation of some Members, establishes that before being internally approved, the exporting countries free zones will have to be recognized by the OIE.
- 40. Concluding our proposal, we are sure that the recognition of more disease- or pest-free zones by the ISSBs would only be beneficial if it promotes the improvement in bilateral recognition by the Members. If these international recognitions were to represent only one more requirement to be fulfilled by the exporting Members, Brazil would reject the implementation of such recognition by the ISSBs. To ensure that international recognition will promote improvements in the bilateral processes,

the SPS Committee should formulate guidelines regarding these concerns and recognize the exporting Members' efforts.

41. We pointed out that as described in Article 6 of SPS Agreement, the implementation of pestand disease-free zones, must in addition to improving the sanitary state of the country, bring benefits to international commerce. However, exporting Members are not being fully compensated for the large financial investments required for the implementation of these zones through improved market access by importing Members.

Annex I



Annex II

Flowchart of the stages for recognizing diseases or pests-free zones

