# MULTILATERAL TRADE NEGOTIATIONS THE URUGUAY ROUND

RESTRICTED

MTN.GNG/NG5/WGSP/7 20 November 1990

Special Distribution

Group of Negotiations on Goods (GATT)

<u>Negotiating Group on Agriculture:</u> <u>Working Group on Sanitary and Phytosanitary</u> <u>Regulations and Barriers</u>

## DRAFT TEXT ON SANITARY AND PHYTOSANITARY MEASURES

The attached text is being submitted on the sole responsibility of the chairman of the Working Group on Sanitary and Phytosanitary Measures. Nonetheless it does, in the chairman's view, accurately reflect the widespread consensus of participants of the Working Group with respect to most of its provisions. Brackets identify the principal issues where disagreement remains, and, when appropriate, alternative phrases have been provided.

Many of the brackets are interlinked and in such cases a single decision will suffice to determine the retention or elimination of several bracketed phrases. In this regard, the first set of brackets in paragraph 4, the brackets in paragraphs 16 and 21, and the brackets in the note to definition 1 and in definition 4 (Annex A) are all linked to the question of whether or not this agreement should apply to measures taken for the protection of animal welfare and of the environment, as well as of consumer interests and concerns (see Note to definition 1). The brackets in paragraph 6 are linked to the decision with respect to sub-national obligations in paragraph 46. On the other hand, the alternatives in paragraphs 10, 18 and 29 represent different positions, with some participants maintaining that if alternative 2 for paragraph 10 is finally retained, the text which appears in the second set of brackets in paragraph 4 would also be necessary.

The brackets of paragraphs 36 and 37 are, as indicated by the note to these paragraphs dependent on the final form of the agreement, whereas the brackets of paragraphs 42, 44 and 45 indicate an apparent lack of consensus with respect to the proposed monitoring procedure. Finally, provisions for the entry into force of the agreement and its subsequent review, paragraphs 48 and 49, respectively, are also bracketed pending decisions in this regard.

Given the desire of participants for the application of the proposed disciplines to all contracting parties, this draft has been presented in the form of a Decision by the CONTRACTING PARTIES on the Application of Sanitary and Phytosanitary Measures. This is, however, without prejudice to the final form the agreement might take.

This draft text may subsequently be reproduced as part of the text prepared in respect of the agricultural negotiations as a whole.

GATT SECRETARIAT UR-90-0689

#### DECISION BY CONTRACTING PARTIES ON THE APPLICATION OF SANITARY AND PHYTOSANITARY MEASURES

The CONTRACTING PARTIES,

<u>Reaffirming</u> that no contracting party should be prevented from adopting or enforcing measures necessary to protect human, animal or plant life or health, subject to the requirement that they are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade;

<u>Desiring</u> to improve the human health, animal health and phytosanitary situation in all contracting parties;

Noting that sanitary and phytosanitary measures are often applied on the basis of bilateral agreements or protocols;

<u>Desiring</u> the establishment of a multilateral framework of rules and disciplines to guide the adoption, development and the enforcement of sanitary and phytosanitary measures in order to minimize their negative effects on trade;

<u>Recognizing</u> the important contribution that international standards, guidelines and recommendations can make in this regard;

<u>Desiring</u> to further the use of harmonized sanitary and phytosanitary measures between contracting parties, on the basis of international standards, guidelines and recommendations developed by the relevant international organizations including the Codex Alimentarius Commission, the International Office of Epizootics, and the relevant international and regional organizations operating within the framework of the International Plant Protection Convention;

<u>Recognizing</u> that developing contracting parties may encounter special difficulties in complying with the sanitary or phytosanitary measures of importing contracting parties, and as a consequence, in access to markets, and also in the formulation and application of sanitary or phytosanitary measures in their own territories, and desiring to assist them in their endeavours in this regard;

<u>Desiring</u> therefore to elaborate rules for the application of the provisions of the General Agreement which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b);

Decide as follows:

1. This decision applies to all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade. Such measures shall be developed and applied in accordance with the provisions of this decision.

2. For the purposes of this decision, the definitions provided in Annex A shall apply.

3. The annexes are an integral part of this decision.

### Basic Rights and Obligations

4. Contracting parties have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health [within their territories], [including, when appropriate, measures more stringent than required by international standards, guidelines or recommendations,] provided that such measures are not inconsistent with the provisions of this decision.

5. Contracting parties shall ensure that sanitary and phytosanitary measures are applied only to the extent necessary to protect human, animal or plant life or health, are based on scientific principles and are not maintained against available scientific evid. Ace.

6. Contracting parties shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between contracting parties where identical or similar conditions prevail, including between their own territory [or parts thereof] and other contracting parties. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade.

7. Sanitary or phytosanitary measures which conform to the relevant provisions of this decision shall be presumed to be in accordance with the obligations of the contracting parties under the provisions of the General Agreement which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b).

In this decision, reference to Article XX(b) includes also the chapeau of that Article.

#### Harmonization

8. To harmonize sanitary and phytosanitary measures on as wide a basis as possible, contracting parties shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist, except as otherwise provided for in this decision.

9. Sanitary or phytosanitary measures which conform to international standards, guidelines or recommendations shall be deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of this decision and of the General Agreement.

#### 10. Alternative 1:

[Contracting parties may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification, or as a consequence of the level of protection a contracting party determines to be appropriate in accordance with paragraph 19. Notwithstanding the above, all measures which result in a level of sanitary or phytosanitary protection different from that which would be achieved by measures based on international standards, guidelines or recommendations shall not otherwise be inconsistent with the provisions of this decision.]

#### <u>Alternative 2</u>:

[Contracting parties shall not introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standard, guideline or recommendation, where such exist, without reasonable scientific justification.]

11. Contracting parties shall play a full part within the limits of their resources in the relevant international organizations and their subsidiary bodies, in particular the Codex Alimentarius Commission, the International Office of Epizootics, and in the international and regional organizations operating within the framework of the International Plant Protection Convention, to promote within these organizations the development and periodic review of standards, guidelines and recommendations with respect to all aspects of sanitary and phytosanitary measures.

12. The Committee on Sanitary and Phytosanitary Measures shall develop a procedure to monitor the process of international harmonization and coordinate efforts in this regard with the relevant international organizations.

#### Equivalence

13. Contracting parties shall accept the sanitary or phytosanitary measures of other contracting parties as equivalent, even if these measures differ from their own or from those used by other contracting parties trading in the same commodity, if the exporting contracting party objectively demonstrates to the importing contracting party that its measures achieve the importing contracting party's appropriate level of sanitary or phytosanitary protection. For this purpose, reasonable access shall be given, upon request, to the importing contracting party for inspection, testing and other relevant procedures.

14. Contracting parties shall, upon request, enter into consultations with the aim of achieving bilateral and multilateral agreements on recognition of the equivalence of specified sanitary or phytosanitary measures.

# Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection

15. Contracting parties shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.

16. In the assessment of risks, contracting parties shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; ecological [and environmental] conditions; and quarantine or other treatment.

17. In assessing the risk and determining the appropriate level of sanitary or phytosanitary protection, contracting parties shall take into account as relevant economic factors the potential damage in terms of loss of production or sales in the event of the establishment or spread of a pest or disease, the costs of control or eradication in the importing contracting party, and the relative cost effectiveness of alternative approaches to limiting risks.

# 18. <u>Alternative 1</u>:

[Contracting parties shall, in the determination of the appropriate level of sanitary or phytosanitary protection, take into account the desirability of maximizing trade opportunities while ensuring the legitimate and necessary protection of human, animal or plant life or health.]

#### <u>Alternative 2</u>:

[In cases of dispute settlement, the impact on the production or sales of an exporting contracting party because of the adoption of sanitary or

phytosanitary measures more stringent than necessary according to verifiable scientific evidence, or relevant economic considerations, or an acceptable level of risk, should also be taken into account.]

19. With the objective of achieving consistency in the application of the concept of appropriate level of sanitary and phytosanitary protection against risks to human life or health, or to animal and plant life or health, each contracting party shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade.

20. Contracting parties shall co-operate in the Committee on Sanitary and Phytosanitary Measures in accordance with paragraphs 40 and 41 of this decision, to develop guidelines to further the practical implementation of this provision. In developing the guidelines the Committee shall take into account all relevant factors, including the exceptional character of human health risks to which people voluntarily expose themselves.

21. Without prejudice to paragraph 9, when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, contracting parties shall ensure that such measures are the least restrictive to trade, taking into account technical and economic feasibility [, and other economic considerations and genuine consumer concerns].

22. In cases where relevant scientific evidence is insufficient, a contracting party may provisionally adopt sanitary or phytosanitary measures on the basis of available portinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other contracting parties. In such circumstances, contracting parties shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.

23. When a contracting party has reason to believe that a specific sanitary or phytosanitary measure introduced or maintained by another contracting party is constraining or has the potential to constrain its exports and the measure is not based on the relevant international standards, guidelines or recommendations, or such standards, guidelines or recommendations do not exist, an explanation of the reasons for such sanitary or phytosanitary measure may be requested and shall be provided by the contracting party maintaining the measure.

# Adaptation to Regional Conditions, including Disease-Free Areas and Areas of Low Pest or Disease Prevalence

24. Contracting parties shall ensure that their sanitary or phytosanitary measures are adapted to the sanitary or phytosanitary characteristics of the

area - whether a country, part of a country, or areas of several countries from which the product originated and to which the product is destined. In assessing the sanitary or phytosanitary characteristics of a region, contracting parties shall take into account, <u>inter alia</u>, the level of prevalence of specific diseases or pests, the existence of eradication or control programmes, and appropriate criteria or guidelines which may be developed by the relevant international organizations.

25. Contracting parties shall, in particular, recognize the concepts of pest- or disease-free areas and areas of low pest or disease prevalence. Determination of such areas shall be based on factors such as geography, ecosystems, epidemiological surveillance, and the effectiveness of sanitary or phytosanitary controls.

26. Exporting contracting parties claiming that areas within their territories are pest- or disease-free or areas of low pest or disease prevalence shall provide the necessary evidence thereof in order to objectively demonstrate to the importing contracting party that such areas are, and are likely to remain, pest- or disease-free or areas of low pest or disease prevalence, respectively. For this purpose, reasonable access shall be given, upon request, to the importing contracting party for inspection, testing and other relevant procedures.

#### Transparency

27. Contracting parties shall notify changes in their sanitary or phytosanitary measures and shall provide information on their sanitary or phytosanitary measures in accordance with the provisions of Annex B.

#### Control, Inspection and Approval Procedures

28. Contracting parties shall observe the provisions of Annex C in the operation of control, inspection and approval procedures, including national systems for approving the use of additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs, and otherwise ensure that their procedures are not increasistent with the provisions of this decision.

# 29. <u>Alternative 1</u>:

[

] - no provisions necessary.

Alternative 2:

[Contracting parties shall ensure that systems for approval of the use of food additives or tolerances for contaminants in food, feedstuffs, or beverages: (a) are based on sound scientific principles; (b) are operated in a manner that is transparent (as provided in Annex B) and non-discriminatory (as provided in Annex C); and (c) result in timely approval decisions (as provided in Annex C). Notwithstanding any other provision of this decision, a contracting party operating such a system may

prohibit or restrict access to its domestic markets for imported products, based on the absence of an approval required by the importing contracting party.]

#### Alternative 3:

[Contracting parties shall ensure that systems for approval of the use of food additives or tolerances for contaminants in food, feedstuffs, or beverages: (a) are based on sound scientific principles; (b) are operated in a manner that is transparent (as provided in Annex B) and non-discriminatory (as provided in Annex C); and (c) result in timely approval decisions (as provided in Annex C). Notwithstanding any other provision of this decision, a contracting party operating such a system may prohibit or restrict access to its domestic markets for imported products. based on the absence of an approval required by the importing contracting party. However, a contracting party shall not impose such prohibition or restriction based solely on the absence of an approval if: (a) there is an applicable international standard adopted after [the entry into force of this decision]; (b) the product conforms to the applicable international standard; and (c) at least nine months have elapsed since: (i) the relevant international standard was adopted; (ii) the data considered in developing the standard were provided to the contracting parties by the Committee on Sanitary and Phytosanitary Measures; and (iii) a complete application for the required approval has been submitted.]

#### Alternative 4:

[A contracting party operating any procedure for approval of food additives or tolerances for contaminants in food, feedstuffs or beverages, may not prohibit or restrict the access of imported products to its markets because its approval procedure has not been completed, unless it operates that procedure in a manner consistent with the disciplines outlined in this agreement. However, when a relevant international standard exists, the importing contracting party shall not prohibit or restrict access for products that conform to that standard for longer than 4 months after receiving an application for approval, unless during that time the importing contracting party introduces a standard that differs from the applicable international standard in accordance with paragraph 10.]

### Technical Assistance

30. Contracting parties agree to facilitate the provision of technical assistance to other contracting parties, especially developing contracting parties, either bilaterally or through the appropriate international organizations. Such assistance may be, <u>inter alia</u>, in the areas of processing technologies, research and infrastructure, including in the establishment of national regulatory bodies, and may take the form of advice, credits, donations and grants, including for the purpose of seeking technical expertise, training and equipment to allow such countries to adjust to, and comply with, sanitary or phytosanitary measures necessary to

achieve the appropriate level of sanitary or phytosanitary protection in their export markets.

31. Where substantial investments are required in order for an exporting developing contracting party to fulfil the sanitary or phytosanitary requirements of an importing contracting party, the latter shall consider providing such technical assistance as will permit the developing contracting party to maintain and expand its market access opportunities for the product involved.

#### Special and Differential Treatment

32. In the preparation and application of sanitary or phytosanitary measures, contracting parties shall take account of the special needs of developing contracting parties, and in particular of the least-developed ones.

33. Where the appropriate level of sanitary or phytosanitary protection allows scope for the phased introduction of new sanitary or phytosanitary measures, longer time-frames for compliance should be accorded on products of interest to developing contracting parties so as to maintain opportunities for their exports.

34. With a view to ensuring that developing contracting parties are able to comply with the provisions of this decision, the Committee on Sanitary and Phytosanitary Measures is enabled to grant to such countries, upon request, specified, time-limited exceptions in whole or in part from obligations under this decision, taking into account their financial, trade and development needs.

35. Contracting parties should encourage and facilitate the active participation of developing countries in the relevant international organizations.

#### Consultations and Dispute Settlement

[Note: Depending on the form of this agreement, it may be necessary to make specific provisions with respect to dispute settlement. If the agreement takes the form of a Decision by CONTRACTING PARTIES, the following provisions would be appropriate.

36. This decision shall be subject to the provisions of Articles XXII and XXIII and the dispute settlement procedures applicable to those articles as adopted by the CONTRACTING PARTIES.

37. In a dispute under this decision involving scientific or technical issues, a panel should seek advice from experts chosen by the panel in consultation with the parties to the dispute. To this end, the panel may, when it deems it appropriate, establish an advisory technical experts group, or consult the relevant international organizations, at the request of either party to the dispute or on its own initiative.]

38. Nothing in this decision shall impair the rights of contracting parties under other international agreements, including the rights to resort to the good offices or dispute settlement mechanisms of other international organizations or established under any international agreement.

39. In cases where a developing contracting party is involved in dispute settlement on sanitary or phytosanitary issues, the GATT Secretariat shall facilitate the provision of technical and legal advice and information to it.

#### Administration

40. A Committee on Sanitary and Phytosanitary Measures shall be established to provide a regular forum for consultations. It shall carry out the functions necessary to implement the provisions of this decision and the furtherance of its objectives, in particular with respect to harmonization. To this end, the Committee shall encourage the use of international standards, guidelines or recommendations by all contracting parties. It shall also encourage and facilitate ad hoc consultations or negotiations among its members on specific sanitary or phytosanitary issues. The Committee shall reach its decisions by consensus.

41. The Committee shall maintain close contact with the relevant international organizations in the field of sanitary and phytosanitary protection, especially with the Codex Alimentarius Commission, the International Office of Epizootics, and the Secretariat of the International Plant Protection Convention, with the objective of securing the best available scientific and technical advice for the administration of this decision and in order to ensure that unnecessary duplication of effort is avoided.

42. The Committee shall develop a procedure to monitor the process of international harmonization and the use of international standards, guidelines or recommendations. [For this purpose, the Committee should, in conjunction with the relevant international organizations, establish a list of international standards, guidelines or recommendations relating to sanitary or phytosanitary measures which the Committee determines to have a major trade impact. The list should include an indication by contracting parties of those international standards, guidelines or recommendations which they apply as conditions for import or on the basis of which imported products conforming to these standards can enjoy access to their markets. For those cases in which a contracting party does not apply an international standard, guideline or recommendation as a condition for import, the contracting party should provide an indication of the reason thereof, and, in particular, if it considers that the standard is not stringent enough to provide the appropriate level of sanitary or phytosanitary protection.]

43. In order to avoid unnecessary duplication, the Committee may decide, as appropriate, to use the information generated by the existing procedures, particularly for notification, which are in operation in the relevant international organizations.

44. [If a contracting party revises its position, following its indication of the use of a standard, guideline or recommendation as a condition for import, it should provide an explanation for its change and so inform the GATT as well as the relevant international organizations, unless such notification and explanation is given according to the procedures of Annex B.]

45. The Committee may, on the basis of an initiative from one of the contracting parties, through appropriate channels invite the relevant international organizations or their subsidiary bodies to examine specific matters with respect to a particular standard, guideline or recommendation, [including the basis of explanations for non-use given according to paragraph 44 above].

#### Implementation

46. [Contracting parties shall ensure that governmental authorities within their territories comply with the relevant provisions of this decision.] [Contracting parties shall ensure the observance of the provisions of this decision by the regional and local governments and authorities within its territory in accordance with Article XXIV:12 of the General Agreement.] Contracting parties shall also take such reasonable measures as may be available to them to ensure that non-governmental entities within their territories, as well as regions' bodies in which relevant entities within their territories are members, comply with the relevant provisions of this decision. In addition, contract ag parties shall not take measures which have the effect of, directly or indirectly, requiring or encouraging such regional or non-governmental entities to act in a manner inconsistent with the provisions of this decision.

#### Final Provisions

47. Nothing in this decision shall affect the rights of parties to the Agreement on Technical Barriers to Trade with respect to measures not within the scope of this decision.

48. [With respect to existing mandatory legislation inconsistent with this decision, this decision shall enter into force on [plus 2 years]. With respect to all other sanitary or phytosanitary measures, this decision shall enter into force on [plus 6 months]. Developing contracting parties may delay application of this decision until [plus 2 years] with respect to their sanitary or phytosanitary measures affecting importation or imported products.]

49. [The provisions of the decision shall be reviewed and revised as appropriate 5 years after its entry into force.]

#### ANNEX A

# Definitions<sup>\*</sup>

For the purposes of this decision, the following definitions shall apply:

- 1. Sanitary or phytosanitary measure Any measure applied:
  - to protect animal or plant life or health within the territory of c contracting party from risks arising from the establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;
  - to protect human or animal life or health within the territory of a contracting party from risks arising from additives, contaminants, toxins or disease-causing organisms, in foods, beverages or feedstuffs;
  - to protect human life or health within the territory of a contracting party from risks arising from diseases carried by animals, plants or products thereof or from the establishment or spread of pests; or
  - to prevent or limit other damage within the territory of a contracting party arising from the establishment or spread of pests;
- <u>NOTE</u>: Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, <u>inter</u> <u>alia</u>, end product criteria; processing and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; packaging and labelling requirements directly related to food safety; [measures for the protection of animal welfare and of the environment, as well as of consumer interests and concerns]. Requirements concerning quality, composition, grading, [consumer preferences, consumer information, animal welfare, the

<sup>&</sup>quot;For the purpose of these definitions "animal" includes fish and wild fauna; "plant" includes forests and wild flora; "pests" include weeds; and "contaminants" include pesticide and veterinary drug residues and extraneous matter.

environment or ethical and moral considerations] are not included in the definition of sanitary or phytosanitary measures.

2. <u>Harmonization</u> - The establishment, recognition and application of common sanitary and phytosanitary measures by different contracting parties.

#### 3. International standards, guidelines and recommendations

- for food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice;
- for animal health and zoonoses, the standards, guidelines and recommendations developed under the auspices of the International Office of Epizootics;
- for plant health, the international standards, guidelines and recommendations developed under the auspices of the Secretariat of the International Plant Protection Convention in co-operation with regional organizations operating within the framework of the International Plant Protection Convention;

and, for matters not covered by the above organizations, appropriate standards, guidelines and recommendations promulgated by other relevant international organizations open for membership to all contracting parties, as identified by the Committee on Sanitary and Phytosanitary Measures.

4. <u>Risk assessment</u> - The evaluation of the likelihood of establishment or spread of pests or diseases [within the territory of the importing contracting party and the relevant potential biological and economic consequences,] [and the relevant potential biological, environmental and economic consequences,] or the evaluation of the potential adverse effects on human or animal health arising from additives, contaminants, toxins or disease-causing organisms in foods, feedstuffs and beverages.

5. <u>Appropriate Level of Sanitary or Phytosanitary Protection</u> - The level of protection deemed appropriate by the contracting party establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory. (<u>Note</u>: Many parties otherwise refer to this concept as the "acceptable level of risk".)

6. <u>Pest-or Disease-Free Area</u> - An area, whether all of a country, part of a country, or all or parts of several countries, as identified by the competent authorities, in which a specific pest or disease does not occur.

<u>NOTE</u>: A pest- or disease-free area may surround, be surrounded by, or be adjacent to an area - whether within part of a country or in a geographic region which includes parts of or all of several countries - in which a

specific pest or disease is known to occur but is subject to regional control measures such as the establishment of protection, surveillance and buffer zones which will confine or eradicate the pest or disease in question.

7. Area of low pest or disease prevalence - An area, whether all of a country, part of a country, or all or parts of several countries, as identified by the competent authorities, in which a specific pest or disease occurs at low levels and which are subject to effective surveillance, control or eradication measures.

#### ANNEX B

# Transparency of Sanitary and Phytosanitary Regulations

# 1. Publication of regulations

1.1 Contracting parties shall ensure that all sanitary and phytosanitary regulations which have been adopted are published promptly in such a manner as to enable interested contracting parties to become acquainted with them.

1.2 Except in urgent circumstances, contracting parties shall allow a reasonable interval between the publication of a sanitary or phytosanitary regulation and its entry into force in order to allow time for producers in exporting countries, and particularly in developing countries, to adapt their products and methods of production to the requirements of the importing country.

#### 2. Enquiry points

2.1 Each contracting party shall ensure that one enquiry point exists which is responsible for the provision of answers to all reasonable questions from interested contracting parties as well as for the provision of relevant documents regarding:

- (a) any sanitary or phytosanitary regulations adopted or proposed within its territory;
- (b) any control and inspection procedures, production and quarantine treatment, pesticide tolerance and food additive approval procedures, which are operated within its territory;
- (c) risk assessment procedures, factors taken into consideration, as well as the determination of the appropriate level of sanitary and phytosanitary protection;
- (d) the membership and participation of the contracting party, or of relevant bodies within its territory, in international and regional sanitary and phytosanitary organizations and systems, as well as in bilateral and multilateral agreements and arrangements within the scope of this decision, and copies of the texts of such agreements and arrangements.

2.2 Contracting parties shall ensure that where copies of documents are requested by interested contracting parties, they are supplied at the same

Sanitary and phytosanitary measures such as laws, decrees or ordinances which are applicable generally.

price (if any), apart from the real cost of delivery, as to the nationals of the contracting party concerned.

# 3. Notification procedures

3.1 Whenever an international standard, recommendation or guideline does not exist or the content of a proposed sanitary or phytosanitary regulation is not substantially the same as the content of an international standard, recommendation or guideline, and if the regulation may have a significant effect on trade of other contracting parties, contracting parties shall:

- (a) publish a notice at an early stage, in such a manner as to enable interested contracting parties to become acquainted with the proposal to introduce a particular regulation;
- (b) notify other contracting parties, through the GATT Secretariat, of the products to be covered by the regulation together with a brief indication of the objective and rationale of the proposed regulation. Such notifications shall take place at an early stage, when amendments can still be introduced and comments taken into account;
- (c) provide upon request to other contracting parties copies of the proposed regulation and, whenever possible, identify the parts which in substance deviate from international standards, recommendations or guidelines;
- (d) without discrimination, allow reasonable time for other contracting parties to make comments in writing, discuss these comments upon request, and take the comments and the results of the discussions into account.

3.2 However, where urgent problems of health protection arise or threaten to arise for a contracting party, that contracting party may omit such of the steps enumerated in paragraph 3.1 of this Annex as it finds necessary, provided that the contracting party:

- (a) immediately notify other contracting parties, through the GATT Secretariat, of the particular regulation and the products covered, with a brief indication of the objective and the rationale of the regulation, including the nature of the urgent problem(s);
- (b) provide upon request to other contracting parties copies of the regulation;
- (c) allow other contracting parties to make comments in writing, discuss these comments upon request, and take the comments and the results of the discussions into account.

3.3 Notifications to the GATT Secretariat shall be either in English, French or Spanish.

3.4 Developed contracting parties shall, if requested by other contracting parties, provide copies of the documents or, in case of voluminous documents, summaries of the documents covered by a specific notification in either English, French or Spanish.

3.5 The GATT Secretariat shall promptly circulate copies of the notifications to all contracting parties and interested international organizations and draw the attention of developing contracting parties to any notifications relating to products of particular interest to them.

3.6 Contracting parties shall designate one single central government authority as responsible for the implementation, on the national level, of the provisions concerning notification procedures according to paragraphs 3.1, 3.2, 3.3 and 3.4 of this Annex.

#### 4. General reservations

- 4.1 Nothing in this decision shall be construed as requiring:
  - (a) the provision of particulars or copies of drafts or the publication of texts other than in the language of the contracting party except as stated in paragraph 3.4 of this Annex; or
  - (b) contracting parties to disclose confidential information which would impede enforcement of sanitary or phytosanitary legislation or which would prejudice the legitimate commercial interests of particular enterprises.

# ANNEX C

# Control, Inspection and Approval Procedures

1. Contracting parties shall ensure, with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, that:

- (a) such procedures are undertaken and completed without undue delay and in no less favourable manner for imported products than for like domestic products;
- (b) the standard processing period of each procedure is published or that the anticipated processing period is communicated to the applicant upon request; when receiving an application, the competent body promptly examines the completeness of the documentation and informs the applicant in a precise and complete manner of all deficiencies; the competent body as soon as possible transmits the results of the procedure in a precise and complete manner to the applicant so that corrective action may be taken if necessary; even when the application has deficiencies, the competent body proceeds as far as practicable with the procedure if the applicant so requests; and that upon request, the applicant is informed of the stage of the procedure, with any delay being explained;
- (c) information requirements are limited to what is necessary for appropriate control, inspection and approval procedures, including for approval of the use of additives or for the establishment of tolerances;
- (d) the confidentiality of information about imported products arising from or supplied in connection with control, inspection and approval is respected in a way no less favourable than for domestic products and in such a manner that legitimate commercial interests are protected;
- (e) any requirements for control, inspection and approval of individual specimens of a product are limited to what is reasonable and necessary;
- (f) any fees imposed for the procedures on imported products are equitable in relation to any fees charged on like domestic products or products originating in any other country and should be no higher than the actual cost of the service;

Control, inspection and approval procedures include, <u>inter alia</u>, procedures for sampling, testing and certification.

- (g) the same criteria should be used in the siting of facilities used in the procedures and the selection of samples of imported products as for domestic products so as to minimize the inconvenience to applicants, importers, exporters or their agents;
- (h) whenever specifications of a product are changed subsequent to its control and inspection in light of the applicable regulations, the procedure for the modified product is limited to what is necessary to determine whether adequate confidence exists that the product still meets the regulations concerned;
- (i) a procedure exists to review complaints concerning the operation of such procedures and to take corrective action when a complaint is justified.

2. Where a sanitary or phytosanitary measure specifies control at the level of production, the contracting party in whose territory the production takes place shall provide the necessary assistance to facilitate such control and the work of the controlling authorities.

3. Nothing in this decision shall prevent contracting parties from carrying out reasonable inspection within their own territories.