WORLD TRADE ORGANIZATION

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Committee on Sanitary and Phytosanitary Measures

PROCEDURE TO MONITOR THE PROCESS OF INTERNATIONAL HARMONIZATION

First Annual Report

Adopted by the Committee on 8 July 1999

A. INTRODUCTION

1. At its meeting of 15-16 October 1997, the SPS Committee adopted a provisional procedure to monitor the process of international harmonization and the use of international standards, guidelines or recommendations[1], as provided for in Articles 3.5 and 12.4 of the SPS Agreement. Paragraph 10 of the provisional procedure states:

> "The Secretariat should prepare an annual report to the Committee on the list of standards, guidelines or recommendations established under paragraph 8, the major trade impacts identified by Members and their comments regarding the use or non use of the identified international standards, guidelines or recommendations and of those cases identified where there was no international standard, guideline or recommendation, and any conclusions drawn by the Committee." [emphasis added]

2. Prior to the 7-8 July 1999 meeting of the SPS Committee, the following standards-related issues have been considered by the Committee on the basis of proposals by Members:

(i) Requirement for control of Infectious Bursal Virus (IBDV) in cooked chicken meat[2];

(ii) Definition of "quarantine pest"[3];

(iii) Chlortetracycline (CTC) residues in pork and pork products[4];

(iv) *Bacilli* and other organisms in canned/bottled products, including jams[4];

(v) Frequency of controls to be carried out on bulls in collection centres (brucellosis, tuberculosis, leukosis, IBR)[5];

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[1] G/SPS/11.
[2] G/SPS/W/99 (submission by Thailand).
[3] G/SPS/W/97 (submission by the United States).
[4] G/SPS/W/87 (submission by the United States).
[5] G/SPS/W/96 (submission by the European Communities).

(vi) Benzoic acid as a preservative in sauces[6];

(vii) Certification requirements for origin of animals[7];

(viii) Certification regarding the absence of certain pathogens in raw meat products[7];

(ix) Certification requirements for diseases for which national control measures may not exist (meat products).[7]

3. In March 1999, the Secretariat circulated a document entitled "Request for information from Members on the use of international standards".[8] Its purpose was to gather information from Members about the issues identified above, in line with Paragraph 8 of the provisional procedure to monitor the process of international harmonization. Eleven Members replied to this questionnaire.[9] These responses, as well as Members' statements on the subject, are summarized below.

B. STANDARDS-RELATED ISSUES

1. Requirement for control of Infectious Bursal Virus (IBDV) in cooked chicken meat

4. In its submissions, Thailand explained that at present, there was an international standard on this disease, but that it dealt only with specific animal health issues.[10] This disease was not a zoonosis, therefore it would not cause any harm to human health. The OIE Code had listed IBDV in the List B diseases (Part 3, Section 3.6, Chapter 3.6.1). Its guidelines and recommendations were related to the importation of live birds, day-old chicks and hatching eggs only. Recommendations on trade of poultry meat and poultry products were not included in the Code. The extreme heat treatment currently required by some countries to control Infectious Bursal Disease Virus (IBDV) rendered the product unacceptable. Thailand noted that it applied the OIE Code regarding IBDV to prevent importing the disease. However, there was a need to develop an international standard for IDBV in cooked chicken meat to prevent unnecessary import restrictions.

5. Other Members expressed their views in the subsequent Committee discussions, and in their responses to G/SPS/W/100. Australia expressed support for the development of an international standard, while noting that some new or supplementary scientific work might be required. Australia offered to make available to the OIE the scientific evidence upon which it had based its measure.

6. New Zealand indicated that it would be useful to have some international guidelines which took into account the differing IBD health status among countries. New Zealand had a strain of IBD that did not cause clinical disease, while virtually all other countries had widespread clinical IBD. New Zealand was concerned that an international standard might be aimed at the majority of countries who already had the disease. New Zealand thought that to protect its current health status, it needed guidelines similar to the OIE recommendations for live birds. New Zealand's chicken meat risk analysis recommended that meat products be sourced from broiler flocks demonstrated to be free from infection with IBD virus and not vaccinated with live IBD vaccines.

7. Brazil, the European Communities, Malaysia and the United States considered an international standard necessary to prevent trade restrictions. The European Communities supported an international standard without restriction for trade in poultry meat (except for consignments to

[6] G/SPS/W/91 (submission by the Philippines).
[7] G/SPS/W/89 (submission by Canada).
[8] G/SPS/W/100.
[9] Cyprus, Czech Republic, the European Communities, Hungary, Japan, Malaysia, New Zealand, Norway, the Philippines, Thailand and the United States.
[10] See G/SPS/W/99, G/SPS/R/14, paragraph 35, and G/SPS/GEN/90.

countries which could demonstrate IBDV freedom) since IBDV was not a public health risk. The United States noted that its trade with Australia and New Zealand was affected. Japan indicated that only if the possibility of transmitting IBD through poultry meat were scientifically demonstrated, an international standard would be needed.

8. The Philippines, Hungary, Norway, the Czech Republic and Cyprus considered that there was no need for an international standard. Cyprus, the Czech Republic, Norway and the Philippines noted that the risk of introducing IBDV through chicken meat was negligible. Norway observed that the disease in question was considered a "production disease", which meant that the disease could be prevented satisfactorily by good hygienic conditions in poultry flocks. The Philippines stated that IBVD was not a zoonotic disease and appropriate measures were already in place to prevent its transmission through chicken meat.

2. Definition of "quarantine pest"

9. In its submission, the United States noted that the IPPC Glossary of Phytosanitary Terms provided the following definition for quarantine pest: "a pest of potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled".[11] Questions had emerged regarding the meaning of "officially controlled". This two-word phrase was not currently defined by the IPPC. There was a need to agree on the meaning of "official control" to ensure a harmonized understanding and application of this concept, particularly as it was used to justify phytosanitary measures on intercepted pests. Although definitions existed both for the term "official" and for the term "control"[12], interpretations by Members of the meaning of "officially controlled" varied considerably.

10. The United States believed that there was a need for a standard to be developed to explain the term "official control" for the following reasons:

(a) The term could not be adequately explained in a one- or two-word sentence.

(b) Clarifying the definition would help ensure a common understanding of what constituted an official internal control program, particularly control programs performed at the state or local level.

(c) Clarifying the term would help ensure that countries were not arbitrary and discriminatory in their application of phytosanitary measures for pests which may already occur in the importing country and were not under quarantine control to prevent their internal spread.

11. Other Members expressed their views in the subsequent Committee discussions, and in their responses to G/SPS/W/100. The representative of the IPPC informed the Committee that the IPPC had just reviewed the Glossary, including a proposed definition for the phrase "official control".[13] If endorsed by the Committee of Experts on Phytosanitary Measures, the revised Glossary would be submitted to the second Interim Commission on Phytosanitary Measures in October 1999 for adoption.

[11] G/SPS/W/97, G/SPS/R/14 paragraph 34 and in response to document G/SPS/W/100.

[12] The IPPC Glossary of Phytosanitary Terms defines "official" as "established, authorized or performed by a National Plant Protection Organization" and "control" as "suppression, containment or eradication of a pest population".

[13] G/SPS/R/14 paragraph 34.

12. Chile, the Czech Republic, Cyprus, the European Communities, Hungary, Japan, New Zealand, Norway and Thailand all agreed that an official definition would be useful. Norway indicated that to facilitate trade it was important that countries prepare lists of regulated pests requiring phytosanitary measures, and clear criteria for listing these pests were therefore needed. Regarding pests that occurred domestically, there was a particular need for a clearer understanding of which pests should be listed as quarantine pests, and of the elements that should constitute an official internal control program for such pests. New Zealand noted that some countries were intercepting pests already present in the importing country on the grounds that such pests were under "official control". However, the requirements on domestic suppliers were not mandatory, and there were no consequences for non-compliance. New Zealand indicated that its kiwifruit exports to Japan were affected. The European Communities indicated that a definition could avoid trade disruption between countries where different measures had been taken due to the lack of a common understanding of the relevant terminology. Thailand noted that trade in fresh cut flowers and ornamental plants was affected by the lack of a definition.

3. Chlortetracycline (CTC) residues in pork and pork products

13. In its submissions, the United States noted that of the Tetracyclines (CTC, Oxytetracycline and Tetracycline), only Oxytetracycline had an MRL set by an international standard. JECFA and Codex had determined that the three Tetracyclines (Tetracycline, Oxytetracycline and Chlortetracycline) should have a group MRL, i.e., the individual Tetracyclines should have the same MRL and the total of the three Tetracyclines should not exceed the MRL.[14] Currently, some countries did not have an MRL for one or more of the Tetracyclines. Consequently, they were employing a de facto zero tolerance for the Tetracyclines for which no MRL had been established. Trade in pork and pork products was significantly affected by the non-existence of such a standard, and there was also potential for trade in cattle, sheep, chicken, turkey and duck products to be significantly affected.

14. Other Members expressed their views in the subsequent Committee discussions, and in their responses to G/SPS/W/100. New Zealand, Norway, Cyprus, Malaysia, Japan and Thailand agreed that an international standard was necessary to protect human health. Thailand reported that it applied the Codex MRL for Oxytetracycline. However, the other Tetracyclines (CTC and Tetracycline) were widely used in the livestock industry, and MRLs for CTC and Tetracycline were also needed. New Zealand indicated that the lack of a finalised Codex MRL for CTC required New Zealand to set longer withholding times than necessary for protection of human health (from potential residues) or for best farming practice (so as to ensure residues dropped below the limit of detection). New Zealand was in the process of adopting the draft Codex MRLs for the Tetracyclines as domestic food standards so as to set a level playing field for New Zealand's meat producers on the domestic and international markets.

15. The European Communities noted that within the Codex framework, it was in favour of setting MRLs for CTC as a veterinary medicine, but opposed to determining MRLs for the use of CTCs as a feed additive. The European Communities observed that the most recent assessment of scientific findings did not rule out potential adverse effects from the development of antibiotic resistance induced in animals by the use of antibiotics as feed additives. An increase in the antibiotic resistance at animal level might pose risks to human health. Potential adverse effects due to specific use should be considered in the establishment of MRLs. The Philippines raised the need to be more vigilant in the determination of food safety with regard to antibiotic residues in meat, and indicated that an international standard could help avoid confusion in international trade.

16. Hungary and the Czech Republic considered that there was no need for an international standard.

[14] G/SPS/W/87 and in response to document G/SPS/W/100.

4. *Bacilli* and other organisms in canned/bottled products, including jams

17. In its submission, the United States noted that Codex standards for jam stated that products should be "free from microorganisms in amounts which may represent a hazard to health".[15] This standard presupposed that zero tolerance was not necessary to eliminate health hazards. Codex had recently elaborated its position on zero tolerance and health hazards in Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL21-1997). In this document, Codex stated that "the mere finding, with a presence-absence test, of certain organisms known to cause food-borne illness ... does not necessarily indicate a threat to public health". However, certain countries had rejected jam imports containing bacteria (Bacillus Cereus) without substantiating that the level or stage (e.g. spore) of bacteria detected posed a hazard to health. Other canned and bottled products had been denied entry into markets for similar findings. The United Stated considered this to be inconsistent with the Codex standard and an unnecessary trade restriction. The 21st Session of the Codex Alimentarius Commission recommended that all Commodity Standards be reviewed and revised, as necessary, to streamline the standards by removing unnecessary detail related to quality matters. The Codex Committee on Processed Fruits and Vegetables, chaired by the United States, had begun the revision process. Jams, jellies, and preserves were at a very early stage. Since they had a low pH and a high water activity, they were considered a low-risk food for microbial contamination.

18. Other Members expressed their views in the subsequent Committee discussions, and in their responses to G/SPS/W/100. The European Communities, Cyprus, Japan, and the Czech Republic agreed that there was a need for an international standard. The European Communities noted that the present approach regarding the hygiene provisions of Codex standards was to follow the microbiological safety guidance drafted by the Codex Food Hygiene Committee. As for the need for a Codex Standard for jam, the compositional requirements covered by vertical standards often contained useful information to ensure that the consumer was not mislead as to the nature of the product. It appeared that the Codex standard for jams needed to be reviewed and updated, in particular the hygiene provisions. A microbiological risk assessment was needed to establish the required limits.

19. Norway stated that it was satisfied with the current text of the standard. It should not be necessary to set specific levels for potential pathogens such as Bacillus Cereus. Norway agreed that the mere presence of Bacillus Cereus did not necessarily represent a health hazard, which was related to the level of contamination. Hungary considered that there was no need for an international standard.

5. Frequency of controls to be carried out on bulls in collection centres (brucellosis, tuberculosis, leukosis, IBR)

20. In its submission, the European Communities noted that the absence of consistency between the provisions of the OIE Animal Health Codex Appendix concerning bovine semen and those of articles of the Code concerning the relevant diseases caused of disparities in requests by importing countries.[16] Semen collection was carried out before the final destination of the semen was determined. Serological tests had to be carried out before the collection. Bulls used for artificial insemination were usually tested on descendants and a minimum of four to five years was necessary to carry out these tests. It was only at the end of the period of testing that the commercial and genetic value of the semen could be known and the possibilities of trade envisaged.

[15] G/SPS/W/87 and in response to G/SPS/W/100.
[16] G/SPS/W/96.

21. Other Members expressed their views in the subsequent Committee discussions, and in their responses to G/SPS/W/100. Norway, Malaysia, Thailand, Cyprus, the Czech Republic, New Zealand, the Philippines, Hungary and the United States indicated that they supported the development of a standard. New Zealand reported that it had been using The New Zealand Semen Standard since 1993, but that standard was now being replaced by regulations based on OIE standards. Problems with export consignments of semen from ruminant species continued to occur because of the extensive progeny testing required before extensive use of the semen. Semen was often collected and stored in anticipation of later sale and use without knowledge of the country of destination. The Philippines noted that an international standard would ensure that no disease was transmitted to inseminated animals.

22. Japan noted that diseases specified in the identified standard were listed as quarantine diseases. Thus, exporting countries were requested to take measures based on international standards.

6. Benzoic acid as a preservative in sauces

23. In its submission, the Philippines noted that benzoic acid was an anti-microbial preservative used in sauces which required a shelf-life of 6 to 12 months, and therefore used in products marketed for export.[17] The lack of an international standard allowed countries to discriminate in the use of the additive. An Acceptable Daily Intake (ADI) of 5 mg/kg body weight had been determined for benzoic acid. This had been used as a reason for restricting its use, as high levels of consumption of foods containing the additive could create a health risk. However, as there were no internationally agreed methodologies for assessing risk due to dietary exposure to food additives, the potential for discrimination in usage existed. The use of benzoic acid in sauces was included in the draft Codex General Standard for Food Additives (GSFA). It was important that the GSFA be finalized soon because the lack of an international standard not only harmed international trade in sauces, but had the potential to affect trade in other processed food products where preservatives were used.

24. Other Members expressed their views in the subsequent Committee discussions, and in their responses to G/SPS/W/100. The United States, Norway, Thailand, Cyprus, the European Communities, Hungary and the Czech Republic agreed that there was a need for an international standard. The United States stressed the importance of the Codex GSFA, which would be submitted for adoption by Codex members in June 1999. Benzoic acid, as a preservative in sauces, would be considered at Step 6 by the 32nd Session of the CODEX Committee on Food Additives and Contaminants (CCFAC). Assuming a recommendation for endorsement was forthcoming, the Codex Alimentarius Commission would consider adoption of a standard on benzoic acid at its 24th Session in 2001. Norway observed that the standard should take into consideration the frequent use of benzoic acid in foods together with the knowledge of low ADI and potential risks of allergic reactions.

25. Japan considered that there was no need for an international standard. Japan's Food Sanitation Council would take into consideration the GSFA, but Japanese standards would ultimately be based on Japanese dietary patterns. In Japan, use of benzoic acid was allowed in caviar, margarine, non-alcoholic beverages, soy sauce and syrup at desired use levels, but not in sauces and sauce-like products. Permission to use food additives (including benzoate in sauce) could be considered upon requests submitted in accordance with the guidelines published in March 1996.

7. Certification requirements for origin of animals

26. In its submission, Canada noted that restrictions were imposed on trade of meat products because some countries required that the country of origin of the animal from which the meat

[17] G/SPS/W/91.

products were derived be identified for health protection purposes.[18] As a general practice, meat processors imported animals, processed the meat and exported the products to another country. Some countries required that imported meat products be derived only from animals raised in the exporting country. This requirement was maintained even when the importing country was also importing meat products directly from the source country of the animals. This presented a difficulty for processors in the exporting country who must segregate shipments in order to meet this requirement. OIE could be asked to establish criteria and conditions for determining country of origin requirements linked to health protection.

27. Other Members expressed their views in the subsequent Committee discussions, and in their responses to G/SPS/W/100. Malaysia, Thailand, Cyprus, Norway, the Philippines, Hungary and the European Communities supported the development of an international standard to facilitate trade. The European Communities noted that to export to Community territory "Meat and meat products must come from animals which have remained for at least 3 months (or since birth if less than 3 months old) in the territory of a country/region from which imports are permitted". Such a requirement appeared to be more appropriate than requiring animals to be born and reared in the country of despatch of meat. Norway considered that identification of the country of origin was crucial for achievement of the appropriate levels of protection.

28. The United States, the Czech Republic and Japan did not see the need for the development of an international standard. Japan noted that it was possible for an importing country to allow imports derived from animals raised in third countries if similar import requirements could be applied to both countries. However, these requirements were individually established by importing countries considering exporting countries' disease situations. The United States recognized that potential loss of identity of the origin of meat might be a legitimate safety concern that could be discussed further in the context of risk-based standards for animal health, but more discussion was warranted on the need for an international standard.

8. Certification regarding the absence of certain pathogens in raw meat products

29. In its submission, Canada noted that restrictions were imposed on trade of meat products because certain countries required that the meat be free of certain pathogens, e.g. salmonella.[19] Codex could be asked to determine if developing standards for pathogens in raw meat was feasible or appropriate.

30. Other Members expressed their views in the subsequent Committee discussions, and in their responses to G/SPS/W/100. The Philippines and the European Communities agreed that Codex should determine if developing standards for pathogens in raw meat was feasible or appropriate. The question of pathogens in raw meat had been addressed by Codex in 1997 and October 1998. Furthermore, FAO and WHO were apparently considering the creation of a joint expert committee to deal with microbiological risks. In developing such standards through a sound microbiological risk assessment the particular health status of certain WTO Member countries should be taken into account, where naturally or through control measures a lower prevalence of certain food-born pathogens had been achieved. A threshold level was more desirable than requiring meat to be free of certain pathogens.

31. The United States supported the development of standards because a significant number of restrictions were imposed on meat products due to the presence of certain animal diseases unlikely to be transmitted through meat. For example, some Members had indicated that Australia's quarantine requirements for importation of cooked chicken meat were too stringent and substantially more trade

[18] G/SPS/W/89.
[19] G/SPS/W/89.

restrictive than necessary to safeguard animal health. Some diseases of concern identified by Australia, particularly Infectious Bursal Disease (IBD), were unlikely to be transmitted by meat and thus the strict temperature requirements imposed by Australia seemed unnecessary. Similarly, countries in regions free of Newcastle disease should be able to export poultry meat without unnecessary restrictions being applied solely due to vaccination. The United States noted that, although there had never been a documented case of transmission of avian influenza through meat, Mexico was considering testing requirements for avian influenza that would hamper US exports of poultry meat. Until recently Argentina had maintained a ban on imports of fresh, chilled and frozen pork meat from the United States to protect against the risk of the introduction of porcine respiratory and reproductive syndrome. This disease was spread by contact among pigs and, in recognition of this fact, Argentina had agreed to develop less restrictive measures that would permit trade in pork. The United States suggested that guidelines could first focus on some of the specific diseases identified, which resulted in significant trade concerns.

32. Malaysia, Thailand, Hungary and the Czech Republic also supported the development of international standard. Malaysia noted that it was very dependent on imported meat, in particular raw meat. Thailand noted that at present it was difficult to raise animals, especially broilers, free from pathogen contamination, and that therefore it was impossible to produce meat free from pathogens. Generally, raw meat products were consumed after cooking, which would kill the pathogens. Hence, if the products were properly cooked and hygienically handled, they would be safe for consumption. Thailand and the Czech Republic noted that international standards should take into account that the infective doses of different pathogens were different, as was individual susceptibility to these pathogens.

33. Cyprus, Japan and Norway did not consider that the development of international standards in this area was presently feasible. Norway noted that Canada had not clearly expressed what kind of standards Codex should develop. Considering that the occurrence of salmonella and similar pathogens in fresh meat varied considerably between countries and/or regions, and that appropriate levels of protection determined by various Members differed, Norway doubted that it was feasible to develop satisfactory standards for all different levels of pathogens and appropriate levels of protection.

9. Certification requirements for diseases for which national control measures may not exist (meat products)

34. In its submission, Canada noted that restrictions were imposed on trade of meat products because of the presence of certain animal diseases which were unlikely to be transmitted through meat.[20] OIE guidelines should serve as the basis for animal health certification. Only diseases of importance (e.g. OIE list A) should be required to be listed on export certificates. OIE could be asked to develop more specific guidelines for the animal health certification of meat products, i.e. diseases of concern and appropriate safeguards such as country freedom, farm-free, farm-free-plus-certain-radius. Guidelines could also be developed for countries that wanted to require more stringent certification, e.g. surveillance program, disease transmission data from meat products.

[20] G/SPS/W/89.

35. Other Members expressed their views in the subsequent Committee discussions, and in their responses to G/SPS/W/100. Norway, Malaysia, Thailand, Cyprus, the European Communities, New Zealand, the Czech Republic and the United States agreed that there was a need for an international standard. Norway and Malaysia noted that use of irrelevant requirements when certifying meat products for export an impediment to trade, and listing of relevant requirements related to various List A and List B as well as other diseases should be standardized. Thailand and Cyprus indicated that they used the identified international standard. The United States noted that the OIE currently did not have meat standards for all List A diseases. The United States and Thailand observed that the standard should specifically state that only List A diseases were of importance with respect to meat. The European Communities found it unreasonable to apply trade restrictions relating to agents not known to be transmitted by meat, but warned that many contagious diseases could be transmitted through animal products, including meat. This applied especially to products which, though intended for human consumption, might end up in the feed chain. It was therefore of the utmost importance to control imported products with regard to diseases that directly or indirectly had an effect on animals. The proposal to include only List A diseases in the export certificates might cause great difficulties to certain countries which naturally had a high health status, or had achieved it through control and eradication measures.

36. Japan and Hungary considered that the present OIE guidelines were appropriate.