

**INTERNATIONAL HARMONISATION OF SPS STANDARDS**

Submission by India

1. The Agreement on the Application of Sanitary and Phytosanitary Measures (the "SPS Agreement") desires to further the use of harmonised sanitary and phytosanitary measures between Members on the basis of international standards, guidelines and recommendations developed by the relevant international organizations, e.g., the Codex Alimentarius Commission, the Office international des épizooties, and international and regional organizations operating within the framework of the International Plant Protection Convention. Article 3.1, in particular, states that:

"To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist, except as otherwise provided for in this Agreement, and in particular in paragraph 3."

Article 12.4 adds that:

The Committee [on Sanitary and Phytosanitary Measures] shall develop a procedure to monitor the process of international harmonization and the use of international standards, guidelines or recommendations.

2. It is clear that the SPS Agreement requires Members to base their technical and SPS regulations on international standards, guidelines or recommendations. In order to encourage countries to use such international standards in their regulations, the SPS Agreement provides that national regulations which conform to international standards shall be presumed not to be barriers to trade. However, even though the SPS Agreement lays considerable emphasis on countries using international standards in their SPS regulations, curiously enough, the SPS Agreement does not define in precise terms when a standard should be considered as an international standard. The criteria adopted for determining an international standard is rather general and broad-based. All standards, guidelines and recommendations developed by an international standardizing body or system are required to be treated as an international standard and a standardizing body has been simply defined to be international if its membership is open to "at least all Members of WTO". It is therefore clear that in the absence of a precise definition of an international standard, a standard adopted by the standardizing bodies is deemed to be an "international standard", even if only a limited number of countries may have participated in the technical work on developing the standard, and even if it may have been adopted, not by consensus, but by a slender majority vote.

3. Despite the efforts that are being made by some of the international organizations to encourage and broaden the participation of countries in standardization activities, the participation of developing countries in the activities of these organizations continues to be marginal. Only a few developing countries are able to participate actively in the meetings of the technical committees. The majority of developing countries, even if present, are unable to participate effectively, since they are

not backed by background research that is needed for the submission of the technical papers. The system of giving the responsibility for organizing the technical work to host countries, which provide secretarial facilities, further puts developing countries in a disadvantageous situation. Because of various constraints they are not always in a position to offer such facilities and, therefore, cannot effectively participate in the technical work. It remains a matter of concern that most developing countries have been unable to actively and effectively participate in the meetings of the international standard setting bodies. Their written comments are also often not given due weight which at times leads to the adoption of standards which are not in consonance with the ground realities in most developing countries.

4. Further, due to the non-participation of developing countries in the proceedings of various international organizations engaged in standardisation, standards get fixed by default. In view of this, there is an urgent need to rationalise the procedure of standardisation activities presently followed by these organizations and to make them more broad-based and representative so as to give adequate consideration to the views of the developing and least developed countries.

5. It needs no emphasis that 89% of the countries of the world fall in the category of developing/least developed countries. In spite of this, various committees or expert groups, based on a majority decision of the countries attending the meetings of these bodies, adopt international standards. In the absence of most developing countries, these meetings are naturally steered by developed countries and very often the safety limits which are decided by these bodies are those which are felt to be appropriate by the developed countries, without necessarily taking into consideration the conditions prevailing in the developing countries. Consequently, the developing and least developed countries find it difficult to comply with sanitary measures that are based on such standards, particularly since the safety limits in many cases are prescribed without conducting any clinical study in the developing countries with regard to contaminants, pesticides, animal disease etc.

6. Moreover, given the diverse conditions prevailing in the developed and the developing countries, it may be more appropriate to harmonise standards of a particular region where similar conditions prevail and where the population also has more or less similar immunity levels. Presently, all regions do not have duly harmonised regional standards, which should be encouraged so as to facilitate the setting up of international standards. Since it is felt that these regional standards play a vital role for the determination of international standards, the international organizations engaged in standardisation activities should take due note of these regional standards at the time of fixing the international standard so as to give a much wider representation than exists currently.

7. In India's view, the international standards formulation procedures followed by different international organizations should have uniformity. Presently, there are two major international organizations in the area of standards for foods, namely, the International Organization for Standardisation (the "ISO") and the Codex Alimentarius Commission (the "Codex"). These organizations are following different standards formulation procedures. The procedures followed by the ISO involve voting by letter ballot in which all members have an equal vote. In the Codex, the decision on acceptance of standards is on the basis of the decision taken at its meetings in which the extent of participation of developing countries is uncertain as discussed above. Therefore, it needs to be ensured that standards formulation procedures are harmonised at the international level.

8. The recent experience of the working of international standardizing organizations further shows that it is becoming increasingly difficult even for countries that participate in such work to adopt standards by consensus. Until a few years back, decisions were generally made by consensus. In fact, some of the definitions of international standards even stated that they had been adopted by consensus. This is no longer true and in some organizations like the Codex, more and more standards are being adopted not through consensus but by a majority vote. Though theoretically it may be difficult to argue against the practicalities of such a modality, it has without doubt lead to a situation

where a number of standards are being adopted even though a sizeable number of countries have opposed their adoption. For instance, in the specific case of natural mineral water, the standard was ultimately adopted with 33 countries voting in favour and 31 voting against. This in effect meant that a standard, which had the support of only about one-fifth of the total number of Members, was adopted. This is particularly disconcerting in the light of the fact that these meetings are as it is, often attended by only a certain percentage of the Membership.

9. The involvement of international organizations in developing standards that are to be applied on a mandatory basis has resulted in the increased interest of groups and lobbies in the standardising work. Governmental participation has become more direct, not least to ensure that the adoption of the standards does not result in governments having to change existing regulations or to accept standards which may be more stringent than their national standards, and there is simultaneously a greater involvement of the business community and environmental groups. This interest from non-scientific bodies could result in the evolution of standards that may not be based solely on scientific evidence but could also reflect certain non-scientific considerations. This possible politicization of standardisation activities can have serious ramifications on the role of science in the formulation and adoption of international standards. There is, therefore, a felt need to adopt a more precise and stringent definition of international standards, and to ensure that these are based on empirical scientific evidence alone.

10. A solution to some of the issues which arise from these recent developments in standardisation activities, as well as those that arise from the ineffectual participation of developing countries in these activities, could perhaps be found by adopting a more precise definition of international standards, particularly those that are to be used as a basis for technical and SPS measures. For instance, international standards could be distinguished according to whether they are being developed for being used on a voluntary or a mandatory basis. The existing definition which states that all standards prepared by international standardisation bodies should be treated as international standards could be applied to standards which are to be used on a voluntary basis. For standards that are developed with a possible view of adopting them on a mandatory basis, a narrower definition could be adopted. Such a narrower definition could provide that for the purpose of the SPS Agreement, a standard, guideline or recommendation shall be considered mandatory only if an agreed minimum number of countries from different regions have participated in its formulation, i.e., in the entire process relating to its adoption, and that it has been adopted by consensus.

11. The advantages of such an approach are twofold. Firstly, the obligation under the SPS Agreement to use, to the maximum extent possible, an existing international standard would then be a realistic obligation since the standard would have been adopted by consensus. This would greatly improve the compliance of the obligation and also reduce the possible conflicts which otherwise so often arise when international standards are found to be far more stringent than existing national standards. It would be indeed unrealistic to expect that the governments of countries which have voted for the adoption of an international standard when it was being adopted, would subsequently have a problem in adopting it as part of their national regulation. Secondly, such a methodology would also ensure that there is wider participation in the work on formulation of standards since the countries having trade interests in the standard/product would actively and effectively participate in the deliberations of the concerned international standardisation organization.

12. India would, accordingly, like to make the following suggestions:

- (i) The SPS Committee should evaluate what steps have been taken by the international standardising bodies to ensure effective participation of developing country Members in the adoption of standards. This is perhaps the most crucial issue to be addressed in the context of international harmonisation, since a large number of developing countries feel that they have been sidelined in the standardisation process and that as a

consequence, standards which invariably restrict their market access are adopted by these bodies.

- (ii) It should also be examined whether due care has been taken of the capacity of developing country Members to prepare and adopt international standards, guidelines or recommendations which accommodate their development and trade needs and are compatible with their prevailing level of technological and socio-economic development and trade. This would facilitate the harmonization of international standards with their national standards and thereby minimize the possible conflict between international and nationally acceptable standards. One way of doing this could be by inviting representatives of international standardizing bodies to make written and oral presentations to the Committee with a view to assessing whether and in what way account is being taken of the special problems of developing countries.
- (iii) Lack of transparency in the procedures of the three sister organizations is another constraint in the fulfilment of obligations by Members under the SPS Agreement. It has been noted by India in various meetings of the Codex that, in order to reflect the views of all Members of the Codex, there is need for inclusion of a voting procedure, with voting being undertaken at both the draft and approval stages. This would be in line with the procedure followed by the ISO and the IEC. The underlying problem would be automatically mitigated if consensus-based decision making were adopted.
- (iv) There is need to specify the basic definition of an international standard and to clarify the weight given by the international standardising bodies to their recommendations and standards. Whereas Article 3.1 of the SPS Agreement does not differentiate between guidelines and recommendations vis-a-vis standards, the standardising bodies themselves do not treat them on par. Hence, as elaborated in paragraph 10 above, the Committee could consider adopting a separate definition for standards, depending on whether they are proposed to be adopted on a voluntary or a mandatory basis.
- (v) The process of harmonisation of national standards with international standards, to be universally acceptable to Members, has to ensure that in the formulation of international standards, the basic principles of the SPS Agreement are not lost sight of. Some core principles are enunciated in Article 5 of the SPS Agreement. Article 5:4 states that "Members should, when determining the appropriate level of sanitary or phytosanitary protection, take into account the objective of minimising negative trade effects". Article 5:6 states that: "Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility". These principles need to be integrated into the process of standard formulation by the international standardising bodies if the standards formulated by them are to gain acceptability of the majority of the WTO Members, with their wide divergence of capabilities in processing technologies and perception of risk.

13. In view of the foregoing, while it is desirable, as per the SPS Agreement, to achieve harmonisation on as wide a basis as possible by conforming to international standards, doubts arise as to the "representativeness" of such standards. The developing countries, in particular, are directly affected by such partisan and impractical standards, since they not only restrict market access, thereby acting as non-tariff barriers, but also involve high costs of achieving impractical and unrealistic standards. We would reiterate that special dispensation for developing countries envisaged in the SPS Agreement should be translated into reality by Members. This could be given effect to not only by providing a longer transitional period so as to enable the developing and least developed countries to

integrate themselves effectively into the multilateral trading system, but also by providing them with a level playing field through adequate technical assistance on fair and reasonable terms.

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