

Committee on Sanitary and Phytosanitary Measures

**THREE SISTERS STANDARD-SETTING PROCEDURES
BACKGROUND DOCUMENT**

Note by the Secretariat¹

INTRODUCTION

1. The SPS Agreement (Article 3) requires Members to apply national SPS measures that are based on relevant international standards, guidelines and recommendations unless a deviation from them can be justified in accordance with Article 3.3. This process is often called "harmonization". The WTO itself does not develop these standards. However, most of WTO Members participate in the development of these standards in other international bodies.

2. There are three specific international standard-setting bodies recognized under the Agreement (Article 3 and Annex A), often referred to as the "Three Sisters":

- for food safety, the Codex Alimentarius Commission;
- for animal health and zoonoses, the World Animal Health Organisation (OIE); and
- for plant health, the International Plant Protection Convention (IPPC).

Leading scientists in the field and governmental experts on health protection participate in the development of these standards, which are subject to international scrutiny and review.

3. Given the role of the standards developed by the Three Sisters in the implementation of Members' rights and obligations under the SPS Agreement, it is important that WTO Members coordinate at the national and regional level, and are able to represent their interests before these international bodies.

4. SPS measures implemented by WTO Members that conform to international standards are deemed to be consistent with the relevant provisions of the SPS Agreement and of GATT 1994 (Article 3.2).

5. At the WTO's 2009 workshop on the relationship between the SPS Committee and the Three Sisters, countries identified the effective communication and coordination of the different relevant ministries for trade, food safety, animal and plant health at the national and regional levels as one of their biggest challenges. Some WTO Members have suggested that the lack of communication within the relevant actors in the SPS area may be due to the assumption that the standard-setting procedures of the Three Sisters operate in the same way.

¹ This document has been prepared under the Secretariat's own responsibility and is without prejudice to the positions of Members or to their rights or obligations under the WTO.

6. This document first describes the procedures undertaken by each of the Three Sisters in the development of standards, guidelines and recommendations, as described in publicly available resources. A second section compares these procedures, highlighting the substantive differences.

I. CODEX ALIMENTARIUS COMMISSION

Background

7. The 11th Session of the FAO Conference (1961) established the Codex Alimentarius Commission under Article VI of its constitution and adopted its statutes (revised in 1966 and 2006). The Conference also recommended setting up a Joint FAO/WHO Food Standards Programme with the Codex Alimentarius Commission as its Executive Organ. In May 1963, the 16th World Health Assembly approved the establishment of the Programme and adopted the statutes. The Commission held its first session in 1963 and adopted the Rules of Procedure, subsequently revised several times (latest revision in 2007).

8. The main purposes of the Joint FAO/WHO Food Standards programme are protecting the health of the consumers and ensuring fair trade practices in the food trade, and promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations. Codex standards and related texts, such as guidelines or codes of practice, cover all aspects of food safety and food quality, nutrition and labelling, as well as inspection and certification issues and methods of analysis and sampling.

9. The Codex Alimentarius Commission presently has 185 members (184 member countries and one member organization (EU)). All member nations and associate members of FAO and WHO which are interested in international food standards can apply for membership in the Codex Alimentarius Commission. International governmental organizations may participate as observers and international non-governmental organizations can apply for observer status in accordance with the *Principles Concerning the Participation of International Non-Governmental Organizations in the Work of the Codex Alimentarius Commission*.

10. The Codex Alimentarius Commission previously met every one or two years until 2003 and since then has been meeting regularly once a year (end June/early July). Meetings alternate between Rome and Geneva.

11. The Executive Committee of the Codex Alimentarius Commission consists of the Chairperson and the Vice-chairpersons of the Codex Alimentarius Commission, the six regional coordinators and seven further members elected by the Codex Alimentarius Commission from the following geographic locations: Africa, Asia, Europe, Latin America and the Caribbean, Near East, North America, and South-West Pacific. The Executive Committee normally meets prior to each session of the Codex Alimentarius Commission.

Decision to initiate new work

12. When a Codex committee proposes to elaborate a standard or related text within its terms of reference, it should first consider the priorities established by the Codex Alimentarius Commission in the Strategic Plan, the relevant outcomes of the critical review conducted by the Executive Committee, and the prospect of completing the work within a reasonable period of time. It should also assess the proposal against the *Criteria for the Establishment of Work Priorities*.

13. If the proposal falls outside of the committee's terms of reference, the proposal should be referred to another committee or reported to the Codex Alimentarius Commission together with proposals for amendments to the committee's terms of reference. The Codex Alimentarius Commission may also decide to establish an Intergovernmental Task Force, which will proceed

according to the same procedures as Codex committees but will be established for a limited duration and with a limited mandate. Examples include the Task Force on Foods Derived from Biotechnology (four sessions in 2000-2003 and three sessions 2005-2008); and the Task Force on Antimicrobial Resistance (four sessions in 2007-2010).

14. Proposals generally come from a country or group of countries and are generally made at a Codex committee or a regional FAO/WHO coordinating committee. When proposals for new work or revision of standards are made for adjourned Committees (still existing but no longer active), the Codex Alimentarius Commission may decide to develop the standard by correspondence or reactivate an adjourned Committee if necessary.

15. The decision to undertake new work or to revise standards is taken by the Codex Alimentarius Commission, taking into account a critical review conducted by the Executive Committee.

16. Prior to approval for development, each proposal for new work or revision of a standard is accompanied by a project document, prepared by the Codex Committee or member proposing new work or revision of a standard, detailing:

- the purposes and the scope of the standard;
- its relevance and timeliness;
- the main aspects to be covered;
- an assessment against the criteria for the establishment of work priorities;
- relevance to the Codex strategic objectives;
- information on the relation between the proposal and other existing Codex documents;
- identification of any requirement for and availability of expert scientific advice;
- identification of any need for technical input to the standard from external bodies so that this can be planned for;
- the proposed time-line for completion of the new work, including the start date, the proposed date for adoption at Step 5, and the proposed date for adoption by the Codex Alimentarius Commission; the time frame for developing a standard should not normally exceed five years.

17. The Executive Committee will review the status of development of draft standards against this time-line in the framework of the critical review.

18. The decision to undertake new work or revision of individual maximum residue limits for pesticides or veterinary drugs, or the maintenance of the General Standard on Food Additives, the General Standard on Contaminants and Toxins in Food and Feed, the Food Categorisation System and the International Numbering System, shall follow the procedures established by the Committees concerned and endorsed by the Codex Alimentarius Commission.

Elaboration Procedure

19. The Uniform Procedure for the Elaboration of Codex Standards and Related Texts consists of eight steps, as shown below.

Step 1: the Codex Alimentarius Commission decides, taking into account the outcome of the critical review conducted by the Executive Committee, to elaborate a World-wide Codex Standard and also decides which subsidiary body or other body should undertake the work. A decision to elaborate a World-wide Codex Standard may also be taken by subsidiary bodies of

the Codex Alimentarius Commission in accordance with the above mentioned outcome, subject to subsequent approval by the Codex Alimentarius Commission at the earliest possible opportunity. In the case of Codex Regional Standards, the Codex Alimentarius Commission shall base its decision on the proposal of the majority of members belonging to a given region or group of countries submitted at a session of the Codex Alimentarius Commission.

Step 2: The Codex Secretariat arranges for the preparation of a proposed draft standard. In the case of maximum limits for residues (MRLs) of pesticides or veterinary drugs, the Codex Secretariat distributes the recommendations for maximum limits, when available from the Joint Meetings of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues (JMPR), or the Joint FAO/WHO Expert Committee on Food Additives (JECFA). Any other relevant information regarding risk assessment work conducted by FAO and WHO should also be made available. In the cases of milk and milk products or individual standards for cheeses, the Codex Secretariat distributes the recommendations of the International Dairy Federation (IDF).

Step 3: The proposed draft standard is sent to members of the Codex Alimentarius Commission and interested international organizations for comment on all aspects including possible implications of the proposed draft standard for their economic interests.

Step 4: The comments received are sent by the Codex Secretariat to the subsidiary body or other body concerned which has the power to consider such comments and to amend the proposed draft standard.

Step 5: The proposed draft standard is submitted through the Codex Secretariat to the Executive Committee for critical review and to the Codex Alimentarius Commission with a view to its adoption as a draft standard.² In taking any decision at this step, the Codex Alimentarius Commission will give due consideration to the outcome of the critical review and to any comments that may be submitted by any of its members regarding the implications which the proposed draft standard or any provisions thereof may have for their economic interests. In the case of Regional Standards, all members of the Codex Alimentarius Commission may present their comments, take part in the debate and propose amendments, but only the majority of the members of the region or group of countries concerned attending the session can decide to amend or adopt the draft. In taking any decisions at this step, the members of the region or group of countries concerned will give due consideration to any comments that may be submitted by any of the members of the Codex Alimentarius Commission regarding the implications which the proposed draft standard or any provisions thereof may have for their economic interests.

Step 6: The draft standard is sent by the Codex Secretariat to all members and interested international organizations for comment on all aspects, including possible implications of the draft standard for their economic interests.

Step 7: The comments received are sent by the Codex Secretariat to the subsidiary body or other body concerned, which has the power to consider such comments and amend the draft standard.

² Without prejudice to the outcome of the critical review conducted by the Executive Committee and/or any decision that may be taken by the Codex Alimentarius Commission at Step 5, the proposed draft standard may be sent by the Codex Secretariat for government comments prior to its consideration at Step 5, when, in the opinion of the subsidiary body or other body concerned, the time between the relevant session of the Codex Alimentarius Commission and the subsequent session of the subsidiary body or other body concerned requires such action in order to advance the work.

Step 8: The draft standard is submitted through the Codex Secretariat to the Executive Committee for critical review and to the Codex Alimentarius Commission, together with any written proposals received from members and interested international organizations for amendments at Step 8, with a view to its adoption as a Codex standard. In taking any decision at this step, the Codex Alimentarius Commission will give due consideration to the outcome of the critical review and to any comments that may be submitted by any of its members regarding the implications which the draft standard or any provisions thereof may have for their economic interests. In the case of Regional standards, all members and interested international organizations may present their comments, take part in the debate and propose amendments but only the majority of members of the region or group of countries concerned attending the session can decide to amend and adopt the draft.

20. The Codex Alimentarius Commission may also approve the use of an accelerated procedure for the elaboration of these standards, using a five-step elaboration process, as summarised below.

Procedures for the Elaboration of Codex standards and related texts – Accelerated Procedure

Step 1 - The Codex Alimentarius Commission decides to elaborate a standard on the basis of a two-thirds majority of votes cast using the accelerated procedure and assigns the work to a committee.

Step 2 - The Codex Secretariat arranges preparation of a proposed draft standard.

Step 3 - The proposed draft standard is sent to governments and international organizations for comment. When standards are subject to the accelerated procedure, members of the Codex Alimentarius Commission and the interested international organizations are notified.

Step 4 - The Codex Secretariat forwards comments to the committee for consideration and amendments to the proposed draft standard.

Step 5 - The proposed draft standard subject to the accelerated elaboration procedures is sent to the Codex Alimentarius Commission, together with any written proposals from members and interested international organizations, for adoption as a Codex standard.

21. Procedures for voting are described in Rule VIII of the Rules of Procedures. Rule XII.2 specifies that “The Commission shall make every effort to reach agreement on the adoption or amendment of standards by consensus. Decisions to adopt or amend standards may be taken by voting only if such efforts to reach consensus have failed.”

22. Once the Codex standard has been adopted by the Codex Alimentarius Commission, it is then published and issued to all member States and Associate Members of FAO and/or WHO and to the international organizations concerned. These publications constitute the Codex Alimentarius.

II. WORLD ORGANISATION FOR ANIMAL HEALTH (OIE)

Background

23. The OIE is an inter-governmental organization that was created in 1924, initially in an effort to control animal diseases in Europe. The current mandate of the OIE is to improve animal health and welfare worldwide.

24. The OIE publishes two Codes (for terrestrial and aquatic animals) and two Manuals (Terrestrial and Aquatic) as the principle references for WTO Members. The Terrestrial and Aquatic

Animal Health Codes provide measures to enhance the detection, prevention and control of diseases and to facilitate safe international trade in animals and their products.

25. The Manual of Diagnostic Tests and Vaccines for Terrestrial Animals and the Manual of Diagnostic Tests for Aquatic Animals provide a basis for standardization on veterinary laboratory-related matters.

26. The membership of OIE consists of 178 member countries. The OIE maintains permanent relations with 45 other international and regional organizations and has regional and sub-regional offices on every continent.

27. The OIE standard-setting procedures, with particular reference to the Codes, are outlined in a document on the OIE website ("http://www.oie.int/fileadmin/Home/eng/International_Standard_Setting/docs/pdf/A_OIE_procedures_stand_recom_2011.pdf")

Decision to initiate work

28. Requests for the development of a new chapter or the revision of an existing chapter of an OIE international standard may come from various sources, including OIE delegates, individual scientists, other international organizations, industry organizations and non-governmental organizations.

29. Recommendations on new standards and on significant revisions of existing standards are developed by small groups of independent experts (ad hoc Groups). These groups report directly to a Specialist Commission, or in some cases via an OIE Working Group, to a Specialist Commission. All draft texts are reviewed by the relevant Specialist Commission, then provided to OIE member countries for comment. All member comments are reviewed by the Specialist Commissions, which may deal with comments directly or may send them to the ad hoc Group and/or Working Group for consideration and advice, as appropriate. The reports of ad hoc Groups submitted to Specialist Commissions, as well as the Commission's review of member comments, are documented in the meeting report of the Specialist Commission, which is sent to member countries after each meeting and is also placed on the OIE website. In March of each year, with the report of meetings of the Specialist Commissions held in February, all texts proposed for adoption at the General Session are sent to member countries for consideration prior to presentation to the World Assembly in May for adoption. Twice per year, OIE member countries are given opportunities (normally 60 days) to submit comments in writing. Although there is no provision for written comments to be presented to the General Session, there is opportunity to make oral statements and to obtain clarification of texts before adoption.

Elaboration Procedure

30. The OIE Strategic Plan sets out the priorities, strategies and overall direction of the OIE's work programme, including for the setting of standards. It is developed under the direct supervision of the OIE Director-General (DG) in consultation with the OIE's governing Council and submitted by him to the World Assembly of Delegates for approval once every five years.

31. Regional Commissions provide important input to the strategic plan and the resolutions voted at OIE Global Conferences often identify a need for the OIE to develop standards relevant to matters of strategic importance.

32. When a decision is made to develop a new standard or to significantly revise an existing standard, the OIE DG decides how the work will be managed, with reference to the terms of reference of the four OIE Specialist Commissions:

- (i) The Terrestrial Animal Health Standards Commission is responsible for the Terrestrial Animal Health Code;
- (ii) The Aquatic Animal Health Standards Commission is responsible for the Aquatic Animal Health Code and the Aquatic Manual;
- (iii) The Scientific Commission for Animal Diseases is responsible for drafting scientific texts, many of which will eventually be included in the Terrestrial Animal Health Code and for the recognition of member countries' official disease status;
- (iv) The Biological Standards Commission is responsible for the Terrestrial Manual.

33. OIE ad hoc Groups normally comprise up to six scientists with internationally recognised expertise in a disease or topic. Their appointment to the Group is by decision of the OIE DG, taking into account the need for internationally recognised expertise and for geographic balance in the selection of experts. In many cases, experts are drawn from the OIE network of more than 260 Reference Laboratories and Collaborating Centres.

34. The OIE DG decides the terms of reference and membership of ad hoc Groups convened to prepare draft texts on specific topics. OIE member countries are informed of these matters at the annual General Session.

35. The OIE DG may request that a "supporting document" be drafted by an expert, usually an official from an OIE Reference Centre.³ Supporting documents contain the latest scientific information relevant to the topic. They are a valuable resource for use by ad hoc Groups and Working Groups in their work, as well as references for OIE member countries

36. The work programmes of the Specialist Commissions are established within the overall framework of the OIE Strategic Plan. Proposals received by these Commissions are evaluated in terms of:

- (i) the likely extent of members' support, as evidenced from comments relevant to the request and
- (ii) the availability of scientific information needed to develop a standard.

37. Member countries may comment on the Specialist Commissions' work programmes, published twice annually. The reports of the Terrestrial Animal Health Standards Commission and Aquatic Animal Health Standards Commissions, along with their work programmes, are adopted annually by the World Assembly.

38. The Specialist Commissions normally have six members, including at least one representative from each of the five OIE regions. Regional Commissions propose candidates and the World Assembly of Delegates elects the members of Specialist Commissions for a three year term.⁴ The Specialist Commissions meet twice each year where they examine submissions made by OIE member countries and submissions from other sources, and the reports of relevant Working Groups and ad hoc Groups. In the case of the Terrestrial Animal Health Standards Commission, it also considers submissions from the Scientific Commission on draft texts for possible inclusion in the Terrestrial

³ The major source of OIE experts is the OIE-designated Reference Centres, comprising Reference Laboratories and Collaborating Centres, which number more than 260 institutes globally. Each OIE Reference Laboratory has an OIE-designated Expert whose competence on a specific pathogen/disease is recognised internationally. Collaborating Centres of the OIE offer experts in specific fields. The OIE also calls on institutes other than OIE Reference Centres as necessary.

⁴ The general functioning of Specialist Commissions is described in the OIE Basic Texts <http://www.oie.int/about-us/key-texts/basic-texts/specialist-commissions/>

Code. The Commissions determine how to incorporate scientific recommendations into the new or revised standard. While submissions from OIE member countries are of greatest importance, Commissions also consider scientific information from other sources, including OIE partner organisations and both private sector and non-governmental organisations, in order to ensure that the proposed standards are based on comprehensive and up-to-date scientific information.

39. Each Specialist Commission compiles a meeting report that includes, as annexed documents, the reports of all Working Groups and ad hoc Groups considered by the Commission. The meeting report also explains how the various submissions were addressed. OIE member countries and others submitting comments are encouraged to provide a scientific rationale for their comments, to facilitate analysis by Specialist Commissions.

40. On a twice yearly basis, OIE member countries are invited to comment on the recommendations in the reports of Specialist Commissions. Organisations with which the OIE has formal agreements may also be invited to provide advice, depending on the relevant areas of expertise.

41. In reviewing draft new or revised standards in the Terrestrial and Aquatic Health Codes, Commissions consider the extent to which OIE member countries support the recommendations and the rationale provided, particularly in the case of criticisms of a draft text. If, after at least two rounds of comment, there is widespread support for the proposed new or revised standard, the OIE Specialist Commissions may decide to submit the chapter for adoption at the following OIE General Session. If, however, significant concern is expressed or if member country comments suggest a need for further technical work, a Commissions may re-examine the issue. If scientific or technical questions outside its expertise are raised, a Commission will normally ask the Working Group or the relevant ad hoc Group to re-examine the issues and provide advice to the Commission. Another round of consultation with OIE member countries will then be undertaken.

42. The OIE currently has three "permanent" Working Groups, which are responsible for the general management and oversight of the OIE work programme in three thematic areas:

- (i) The Animal Welfare Working Group - reports to the Terrestrial or Aquatic Animal Health Standards Commission, as relevant to the topic;
- (ii) The Animal Production Food Safety Working Group - reports to the Terrestrial or Aquatic Animal Health Standards Commission, as relevant to the topic;
- (iii) The Working Group on Wildlife – reports to the Scientific Commission for Animal Diseases.

43. The work programme of each Working Group is presented to the relevant Specialist Commission and, via the report of the Commissions, to the World Assembly for information and comment annually.

44. To assist in addressing new themes and significant developments, Working Groups may take responsibility for drafting discussion papers and strategy papers to establish key principles and directions for the OIE to follow in standard setting. In all cases, these papers, along with the recommendations of Specialist Commissions, are provided to OIE member countries for information and comment. Once endorsed, Working Group papers can provide a framework and guiding principles for OIE standard setting.

45. Members of Specialist Commissions may participate in Working Groups to facilitate communication between them and the relevant Commission; they may not chair Working Groups.

46. The members of Working Groups are nominated by the OIE DG and endorsed by the World Assembly of Delegates annually at the General Session. In addition to representation from the five OIE regions, relevant partners of the OIE may participate in Working Groups.

47. Participation in the process of development and adoption of OIE standards is coordinated through the permanent national delegate, who is, in most cases, the head of the national veterinary services. The OIE encourages national delegates to nominate, under their authority, focal points on seven topics (disease notification; animal welfare; animal production food safety; veterinary products; wildlife; aquatic animals; and communication) to help the delegate to meet his/her responsibilities, particularly in relation to standard setting. Experts, industry groups and organisations wishing to participate in the process of standards development may send submissions directly to the OIE but they are strongly encouraged to provide their input through a relevant national delegate. OIE delegates are informed of new or revised draft standards and are consulted at different steps of development, as mentioned above.

48. The normal cycle for the adoption of new texts in the Codes is two years, meaning that the development of a new text is the subject of consultation with OIE member countries on two to four occasions during that period. In the case of emergency situations warranting a more rapid procedure, standards may be developed within a shorter period. Less significant modifications to existing texts may also be undertaken in a one year period, if member countries agree to the proposed modifications.

49. OIE standards can only be adopted at the OIE General Session, the annual meeting of the World Assembly of Delegates, which is the OIE's highest authority. In nearly all cases, standards are adopted by consensus. If consensus cannot be reached, a two-thirds majority vote allows for the adoption of a standard.

III. INTERNATIONAL PLANT PROTECTION CONVENTION (IPPC)

Background

50. The IPPC is an international treaty ratified in 1952, first amended in 1979, and then again in 1997. The purpose of the Convention is to secure common and effective action to prevent the spread and introduction of pests of plants and plant products.⁵

51. The IPPC is governed by the Commission on Phytosanitary Measures (CPM). The CPM's mission is the cooperation between nations in protecting the world's cultivated and natural plant resources from the spread and introduction of pests of plants, while minimizing interference with the international movement of goods and people.

52. Membership of the CPM consists of all contracting parties to the IPPC; currently 177 signatories adhere to the Convention. Countries that wish to become contracting parties to the IPPC must deposit their instrument of adherence with the Director General of FAO.

53. The CPM is directed between sessions by the CPM Bureau, which provides advice and administration and makes decisions between annual CPM meetings. There are two subsidiary bodies to the CPM:

- the Standards Committee and
- the Subsidiary Body on Dispute Settlement.

⁵ Procedural Manual, International Plant Protection Convention, October 2010, Food and Agriculture Organization of the United Nations, Rome, 2010.

54. The IPPC Secretariat is responsible for coordinating the IPPC work programme, which involves:

- developing International Standards for Phytosanitary Measures (standard setting)
- providing information required by the IPPC, and facilitating information exchange between contracting parties (information exchange); and
- providing technical assistance - especially for capacity building - to facilitate the implementation of the IPPC (capacity development)

55. In the 1990s the IPPC began work on formulating International Standards for Phytosanitary Measures (ISPMs). In November 1993, the Conference of the FAO, at its 27th session, approved the first ISPM; from 1998 the Interim Commission on Phytosanitary Measures adopted the IPPC standards, and since 2006 they have been adopted by the CPM. Ever since, standards covering a wide range of topics have been adopted and others are in the draft or consultation phases of the standard-setting process. Existing standards are scheduled for periodic review and are then revised as necessary.

56. There are nine Regional Plant Protection Organizations (RPPOs) that have coordinating functions in their respective regions. One of their roles is to help achieve the objectives of the IPPC.

Decision to initiate work

57. The CPM prepares priority lists for the development of standards and prepares a strategic plan to make clear its strategic directions and goals. These activities are updated biennially and annually, respectively.

Elaboration procedure

58. Part 3 of the 2010 procedural manual of the IPPC contains the current standard setting process which was adopted as Annex 1 of the Rules of Procedure of the CPM in 2008.

59. The process for developing an ISPM comprises four stages:

- Stage 1: Developing the IPPC standard-setting work programme
- Stage 2: Drafting
- Stage 3: Member consultation
- Stage 4: Adoption and publication.

Stage 1: Developing the IPPC standard-setting work programme

Step 1: The IPPC Secretariat makes a call for topics every two years. Detailed proposals for new topics or for the revision of existing ISPMs are submitted to the IPPC Secretariat.

Step 2: The CPM adjusts and adopts the IPPC standard-setting work programme, taking into account the strategic priorities identified by the Strategic Planning and Technical Assistance working group (SPTA) and the revised work programme proposed by the Standards Committee (SC).

60. The SC was established by the CPM as its standard-setting body. The SC manages the standard-setting process and assists in the development of ISPMs which have been identified by the CPM as priority standards. The SC comprises of 25 members drawn from the seven FAO regions

(Africa, Asia, Europe, Latin America & Caribbean, Near East, North America, and Southwest Pacific). Each region determines its own procedures to select nominees for the SC.

61. The SC selects from within its members a subgroup of seven experts, the SC Working Group of seven members (SC-7), to undertake detailed work on draft standards.

62. The SPTA is an informal working group that prepares specific activities for the CPM relating to planning and prioritization of the work programme, including technical assistance, information exchange, prioritizing topics for standards, funding issues, and decisions regarding liaison with other international and regional organizations. The SPTA meets during the first week of October each year at FAO headquarters in Rome, Italy.

Stage 2: Drafting

Step 3: Development of a specification

- For each topic or technical panel, the SC appoints a steward⁶, who, in collaboration with the IPPC Secretariat, drafts a specification, taking into account the proposal for the topic.
- The SC reviews the specification and, once approved for member consultation, it is then made available on the International Phytosanitary Portal (IPP) for a 60 day consultation period.
- Member countries and RPPOs are notified.
- The IPPC Secretariat compiles the comments, posts them on the IPP and submits them to the steward(s) and the SC for consideration.
- The specification is amended as necessary, finalized and approved by the SC and published on the IPP.

Step 4: An expert drafting group (expert working group or technical panel) drafts or revises the standard in accordance with the relevant specification.

- Regular process: The resulting draft standard is submitted to the SC. The SC or SC-7 reviews the draft at a meeting and decides whether to send it for member consultation, or to return it to the steward(s) or to an expert drafting group, or to put it on hold. In the case where only the SC-7 meets, comments from any SC members will also be taken into account.
- Special process: The resulting draft standard is submitted to the SC at any time by e-mail. The SC decides by e-mail whether to send it for member consultation, or to return it to the steward(s) or to an expert drafting group, or to place it on the SC agenda for a decision on how to proceed.

63. The technical panels were established to develop standards under special process. Five technical panels are currently established:

- Technical panel 1: Technical panel to develop diagnostic protocols for specific pests
- Technical panel 2: Technical panel on pest free areas and systems approaches for fruit flies

⁶ Stewards are senior plant health officers or scientists who are familiar with the standard setting process, they are drawn from the SC if possible or from the membership of the expert drafting group. The steward oversees the technical panel or assists with the development of standard throughout the entire standard setting process, providing a linkage between the expert drafting group and the SC.

- Technical panel 3: Technical panel on phytosanitary treatments
- Technical panel 4: Technical panel on forest quarantine
- Technical panel 5: Technical panel on the glossary.

64. Technical panel members work according to the specifications approved by the SC and the procedures included in the IPPC Procedural Manual.

65. The expert working groups are comprised of six to ten participants, representing a wide geographic area, including a member of the SC. The expert working group does not allow observers, but may invite representatives of industry or others to provide expertise, however they cannot participate as members.

66. The selection of experts for the working group is done by nomination: nominations are requested at the time of adoption of the work programme or specifications for standards are suggested at the Interim Commission, or later when the specifications are put on the IPP. Governments, National Plant Protection Organizations (NPPOs) or RPPOs nominate experts to the Standards Committee; the Standards Committee designates the members of the working group and submits a list to the Interim Commission Bureau and IPPC Secretariat for confirmation. Finally, the list of members of the expert working group, and representatives of industry or others, are added to the IPP.

Stage 3: Member consultation

Step 5: Member consultation

67. Following clearance by the SC, the IPPC Secretariat sends the draft standard for member consultation to contracting parties, NPPOs, RPPOs and relevant international organizations for consultation. The draft standard is also posted on the IPP. The length of the consultation period is 100 days. Comments are submitted through the IPPC contact point. Comments are by written submission to the IPPC Secretariat (preferably by electronic means, e.g. e-mail) following guidelines, using the template supplied by the IPPC Secretariat.

- Regular process: The IPPC Secretariat compiles the comments and submits them to the steward and the SC for consideration.
- Special process: The IPPC Secretariat compiles the comments and submits them to the technical panel and the SC for consideration (possibly by e-mail).

Step 6: Review of the draft ISPM prior to the CPM meeting

- Regular process: Considering the comments, the SC-7 and the SC revise the draft standard. The SC decides whether to forward the modified draft to the Commission for adoption, or to put it on hold, return it to the steward or to an expert drafting group, or submit it for another round of member consultation. A summary of major issues discussed is produced as part of the SC report and posted on the IPP.⁷
- Special process: If no one changes the draft text, the draft standard is submitted to the CPM for adoption. If the draft standard is changed as a result of comments, the draft is submitted to the SC. In consultation with the relevant technical panel, the SC examines the draft standard and, if appropriate, modifies it. The SC decides (possibly via e-mail) whether to forward the modified draft standard to the CPM for adoption, or some other

⁷ The CPM-4 (2009) replaced the previous text of "A summary of major issues discussed and of SC reactions to substantive comments that were not incorporated into the standard is produced as part of the SC report and posted on the IPP", (CPM-4 (2009), Paragraph 126.6).

action such as to put it on hold, return it to the steward or to a technical panel, or submit it for another round of member consultation.

Stage 4: Adoption and publication

Step 7: Adoption

- Regular process: Following approval by the SC, the draft standard is included on the agenda of the CPM meeting for adoption. The IPPC Secretariat sends the draft standard for member consultation to contracting parties, NPPOs, RPPOs and relevant international organizations for consultation at least 14 days before the CPM meeting, following guidelines.
- Special process: The draft standard is included on the agenda of the CPM meeting for adoption. If no formal objection⁸ is received up to 14 days prior to the CPM meeting, the draft standard will be adopted without discussion. If a formal objection is received at least 14 days prior to the CPM meeting, the draft standard is returned to the SC. The SC decides, possibly via electronic means, how to proceed, including the possibility of submitting it to the CPM for adoption through the regular process. Formal objections should be posted on the IPP as soon as possible to ensure that contracting parties are aware of them before the CPM meeting.

68. The CPM meets on an annual basis (March/April) and formally adopts the ISPM according to Rule X.2 of the Rules of Procedure of the Commission. Rule X.2 states that where consensus is not reached on a proposal for the adoption of a standard which has been introduced before the CPM for the first time, the proposed standard shall be referred back to the appropriate body of the CPM, together with its comments thereon, for further consideration. If the standard is submitted for adoption the second time and no consensus is obtained, Rule VI of the CPM is applicable and a voting procedure is undertaken according to that rule. The media time for approval of a new standard in the IPPC framework is 3.5 years.

Step 8: The IPPC Secretariat publishes the ISPM, including posting it on the IPP.

69. Transparency is encouraged in the IPPC standard-setting procedure, for its improvement, a set of recommendations have been made by the ICPM:

- All country comments should be published on the IPP;
- The IPPC Secretariat should produce and make accessible a generic summary of SC reactions to classes of comments made during the country consultation;
- Members of the SC should report back to countries in their regions; and
- Guidelines for members of the SC to be developed should incorporate guidance on this reporting function of SC members.

70. Explanatory documents, manuals and similar documents on ISPMs are available on the IPP to help countries implement provisions of the IPPC and ISPMs:

- ISPM 5 - Glossary of phytosanitary terms;

⁸ A formal objection should be a technically supported objection to the adoption of the draft standard in its current form, sent through the official IPPC contact point. The IPPC Secretariat would not make any judgement about the validity of the objection – an objection with some technical discussion of the issue would be accepted as a formal objection.

- ISPM 17 - Pest reporting;
- ISPM 18 - Guidelines for the use of irradiation as a phytosanitary measure;
- ISPM 20 - Guidelines for a phytosanitary import regulatory system;
- ISPM 31 - Methodologies for sampling consignments; and
- IPPC's standard-setting procedures are flexible and periodically reviewed.

IV. COMPARISON OF THE THREE SISTERS STANDARD-SETTING PROCEDURES

71. The procedures implemented by the Three Sisters in the development of standards, guidelines and recommendations can be compared through consideration of five basic questions:

1. How does new work get on the agenda?
2. How are standards prepared?
3. What is the role of expert?
4. What opportunities do Members have to provide input to draft standards?
5. How is a standard adopted?

72. As is evident from the preceding sections, there are many similarities in the standard-setting procedures of Codex, IPPC and OIE. There are, however, a number of differences. The following side-by-side presentation of the processes of the Three Sisters, structured according to the above questions, facilitates the identification of similarities and differences.

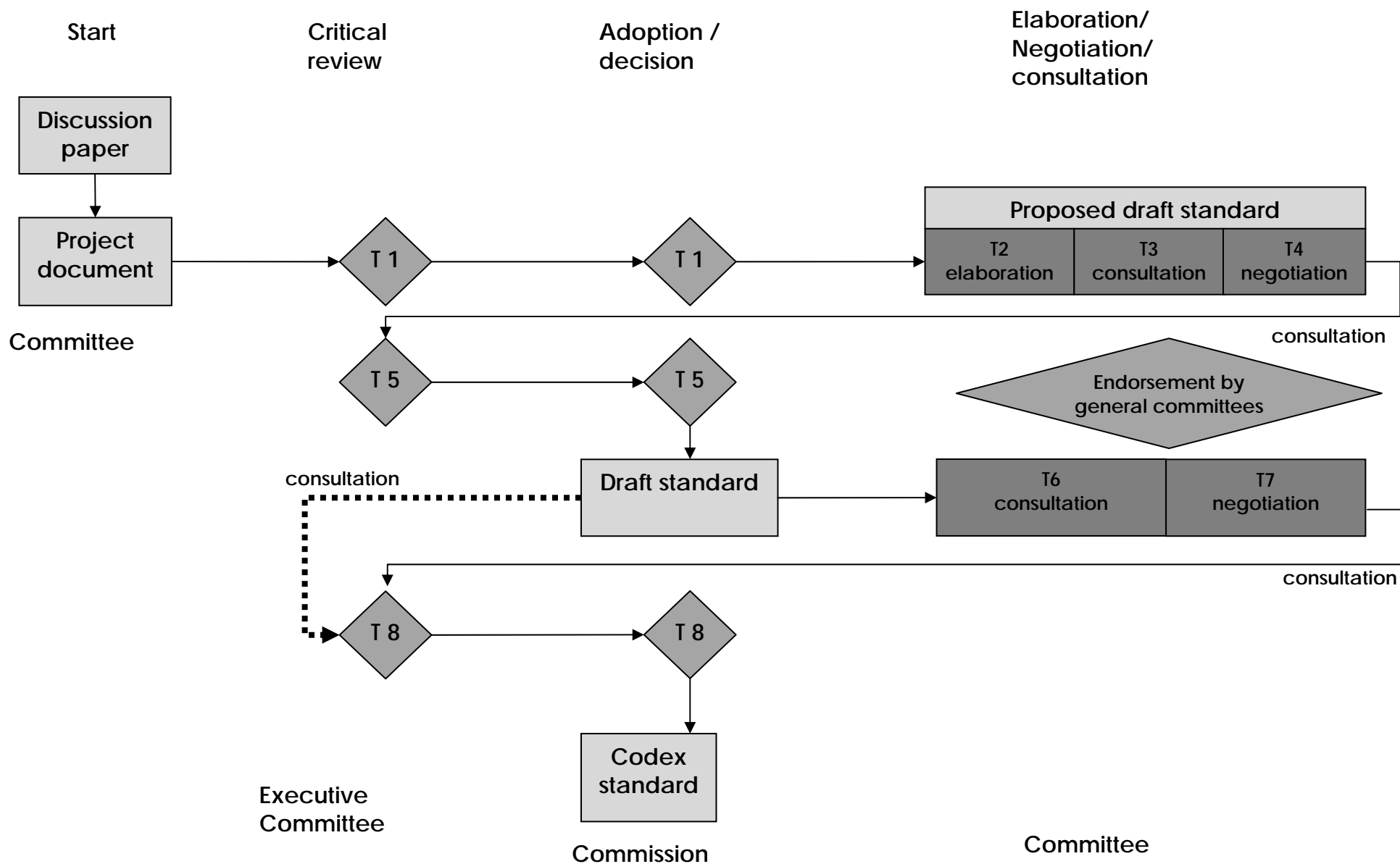
COMPARATIVE TABLE OF THE THREE SISTER'S STANDARD-SETTING PROCEDURES

SSP	Codex	OIE	IPPC
Getting new work on the agenda	<p>Codex member(s) or Codex Committees may propose new work to the relevant Codex Committee; when the relevant committee agrees, the proposal is forwarded to the Codex Executive Committee/ Codex Alimentarius Commission for approval. Each proposal for new work is accompanied by a project document, prepared by the Member or Committee.</p> <p>The decision to undertake new work (or to revise standards) is taken by the Codex Commission taking into account a critical review conducted by the Executive Committee.</p>	<p>Request for the development of a new chapter or the revision of an existing chapter of an OIE international standard may come from various sources, including OIE delegates, individual scientists and other international organizations, industry organizations and non-governmental organizations. Resolutions from OIE Global Conferences are an important input.</p> <p>The OIE Director-General, in consultation with the World Assembly, approves the new work, taking into account the overall direction of the Strategic Plan and the resources available to OIE headquarters.</p>	<p>The IPPC Secretariat calls for submissions for topics to be included in the standard-setting work programme. A call is made every two years and request submissions are sought from National Plant Protection Organizations (NPPOs), Regional Plant Protection Organizations (RPPOs), and the WTO-SPS Committee. The call is posted in the International Phytosanitary Portal. Other organizations, such as the Convention on Biological Diversity, and the Commission's technical panels can also respond to the call.</p> <p>The Phytosanitary Commission adjusts and adopts the IPPC standard-setting work programme, taking into account the strategic priorities identified by the Strategic Planning and Technical Assistance working group and the revised work programme proposed by the Standards Committee.</p>
Preparation of the standard	<p>The Codex Secretariat arranges for the preparation of a proposed draft standard. The Codex Commission decides which subsidiary body or other body should undertake the work.</p>	<p>When a decision is made to develop a new standard or to significantly revise an existing standard, the OIE Director-General decides how the work will be managed, with reference to the terms of reference of the four OIE Specialist Commissions.</p>	<p>For each topic or technical panel, the Standards Committee appoints a steward, who, in collaboration with the IPPC Secretariat, drafts a specification, taking into account the proposal for the topic. The Standards Committee reviews the specification; if approved, it is then made available on the International Phytosanitary Portal for a 60 day consultation period</p>

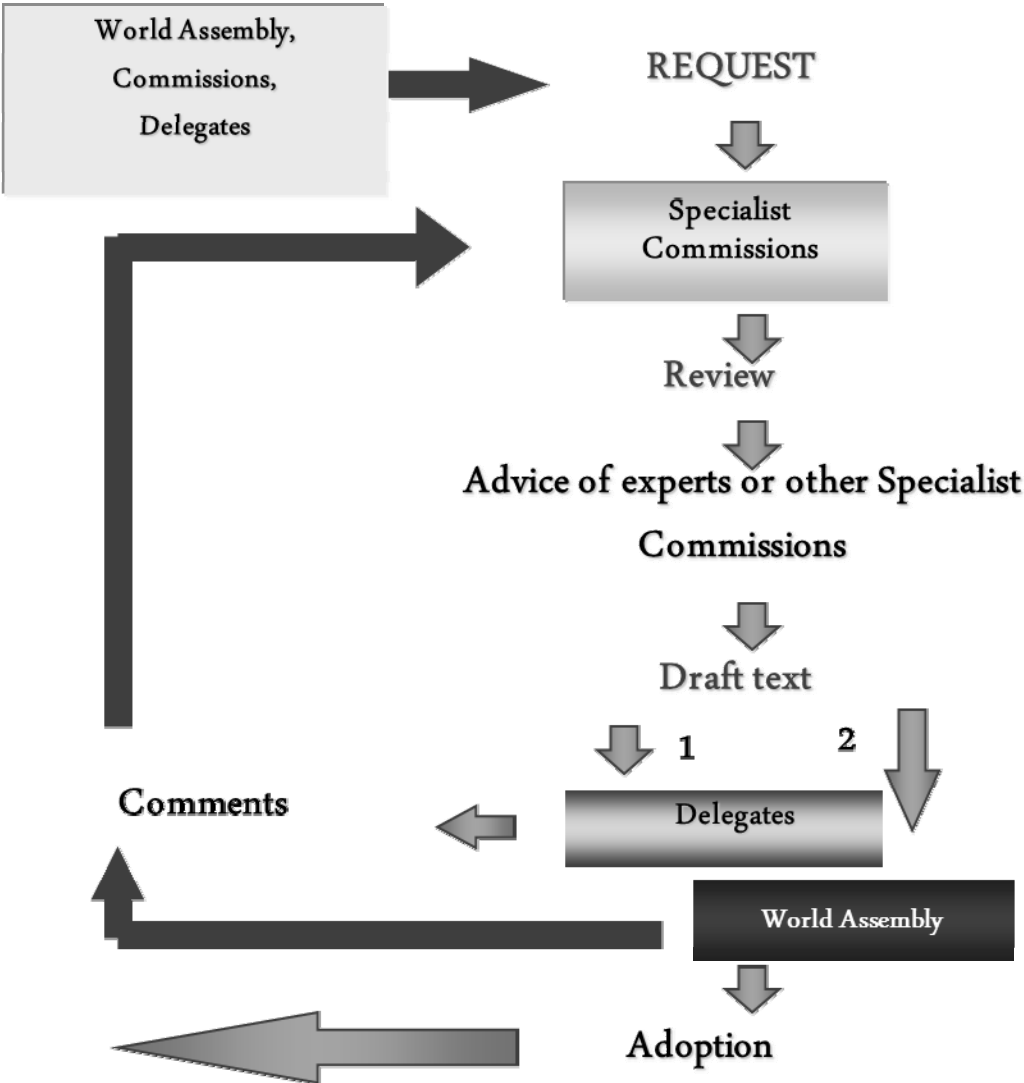
SSP	Codex	OIE	IPPC
<p>Role of experts</p>	<p>In the case of maximum residue levels of pesticides or veterinary drugs, the Codex Secretariat distributes the recommendations for maximum limits, when available from the JMPR and/or JECFA. Any other relevant information regarding risk assessment work conducted by FAO and WHO is also made available. In the cases of milk and milk products or individual standards for cheeses, the Secretariat distributes the recommendations of the International Dairy Federation. Codex may request specific scientific information from the expert groups/committees.</p>	<p>Expert groups are convened, with normally six members. Experts are drawn from the OIE network of Reference Centres, taking into account internationally recognised scientific expertise and geographical balance. The OIE Director-General may request the preparation of a "supporting document" containing the latest scientific information relevant to the topic. These are a valuable resource for ad hoc Groups, Working Groups and OIE Members. The Specialist Commissions determine how to incorporate appropriate risk management recommendations into the Codes, based on the recommendations of experts and the comments of OIE Members.</p>	<p>An expert drafting group (expert working group or technical panel) drafts or revises the standard in accordance with the relevant specification. The resulting draft standard is submitted to the Standards Committee.</p> <p>The expert working groups are comprised of six to ten participants, representing a wide geographic area, including a member of the Standards Committee. The selection of experts for the working group is done by nominations from governments, NPPOs or RPPOs to the Standards Committee.</p>
<p>Opportunity of Members to provide input</p>	<p>There are four opportunities to comment along the 8-step standard-setting procedure (twice in the accelerated procedure):</p> <ol style="list-style-type: none"> 1. At step 3 on the proposed draft standard; 2. At step 5, when the proposed standard is submitted to the Commission for adoption as a draft standard; 3. At step 6, once it has been adopted as a draft standard; 4. At step 8, when the draft standard is submitted to the Commission for adoption as a Codex standard. <p>Submitted comments are sent by the Codex Secretariat to the subsidiary body for consideration at the session of the Committee, which may amend the draft in the light of the comments.</p>	<p>There are four opportunities to comment. Twice a year, OIE member countries are invited to comment on the recommendations in the reports of Specialist Commissions. Organizations with which the OIE has formal agreements may also be invited to provide advice, depending on the relevant areas of expertise.</p>	<p>Following clearance by the Standards Committee, the IPPC Secretariat sends the draft standard for member consultation to contracting parties, NPPOs, RPPOs and relevant international organizations for consultation. The draft standard is posted on the International Phytosanitary Portal. The length of the consultation period is 100 days. Comments are submitted through the IPPC contact point. Considering the comments received, the Standards Committee may decide to forward the modified draft to the Phytosanitary Commission for adoption. When the draft standard is included in the agenda for adoption, the IPPC Secretariat sends the draft standard for member consultation to contracting parties, NPPOs, RPPOs and relevant international organizations for consultation at least 14 days before the Phytosanitary Commission meeting.</p>

SSP	Codex	OIE	IPPC
<p>Adoption of the standard</p>	<p>When the draft standard reaches step 8, it is submitted to the Codex Executive Committee for review and is adopted by the Codex Alimentarius Commission.</p> <p>Codex Standards are mainly adopted by consensus among Members, and decisions to adopt or amend standards may be taken by voting only if efforts to reach consensus have failed.</p> <p>The Codex procedure allows the creation of a standard in one year; for many standards steps 6 and 7 are omitted and the majority of work is completed in 2 - 4 years</p>	<p>OIE standards can only be adopted at the OIE General Session, the annual meeting of the World Assembly of Delegates, which is the OIE's highest authority. In nearly all cases, standards are adopted by consensus. If consensus cannot be reached, a two-thirds majority vote allows for the adoption of a standard.</p> <p>The normal cycle for the adoption of new texts in the Codes is two years. In the case of emergency situations warranting a more rapid procedure, standards may be developed within a shorter period. Less significant modifications to existing texts may also be undertaken in a one year period, if member countries agree to the proposed modifications.</p>	<p>The Phytosanitary Commission adopts the standards according to rule X.2 of the Rules of Procedure of the Commission. Rule X.2 states that where consensus is not reached on a proposal for the adoption of a standard which has been introduced before the Phytosanitary Commission for the first time, the proposed standard is referred back to the appropriate body, together with its comments thereon, for further consideration. If the standard is submitted for adoption the second time and no consensus is obtained, Rule VI of the Phytosanitary Commission is applicable and a voting procedure is undertaken. IPPC's standard-setting procedures are flexible and periodically reviewed. The media time for approval of a new standard in the IPPC framework is 3.5 years.</p>

ANNEX 1 - CODEX STANDARD-SETTING PROCEDURE FLOWCHART



ANNEX 2 - OIE STANDARD-SETTING PROCESS FLOWCHART



ANNEX 3 - PICTORAL SCHEME OF THE IPPC STANDARD-SETTING PROCEDURE

Example: Extended time schedule-regular process

Year 1												
January	February	March	April	May	June	July	August	September	October	November	December	
		Preparing for CPM: No work on standard setting	Preparing for SC: No other work on standard setting						Preparing for SC: No other work on standard setting		31 Dec	
Deadline for submission of drafts to Secretariat →												
Year 2												
January	February	March	April	May	June	July	August	September	October	November	December	
Secretariat edits drafts	Secretariat formats drafts and submits drafts to SC	Preparing for CPM: No work on standard setting	Preparing for SC: No other work on standard setting	SC or SC-7 reviews drafts	Secretariat formats drafts and translation of drafts (6 weeks)	20 June	Member consultation (100 days)		Secretariat compiles member comments (2 months)		Stewards reviews member comments (for 3 month)	
									Preparing for SC: No other work on standard setting			
Year 3												
January	February	March	April	May	June	July	August	September	October	November	December	
(Cont.) Stewards reviews member comments (for 3 month)		SC-7 studies drafts	Preparing for CPM: No work on standard setting	SC-7 reviews drafts	SC studies drafts (5 months)				SC reviews drafts in meeting	Sect. edits drafts	Secretariat formats drafts and Translation of drafts (2 months)	
			Preparing for SC: No other work on standard setting						Preparing for SC			
Year 4												
January	February	March	April	May	June	July	August	September	October	November	December	
CPM members review drafts (6 weeks prior to CPM)		Comments due (14 days prior to CPM)	CPM									

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