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# **REPORT**

## **Expert Working Group**

### **Annex to ISPM 38: Design and use of systems approaches for phytosanitary certification of seeds**

#### **Virtual Meeting**

**7–8, 11–15, 18 and 20 October 2021**

**IPPC Secretariat**

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- [1] Although originally scheduled to finish on 15 October, the Expert Working Group (EWG) had not completed their tasks by that time and so decided to reconvene the following week. Two further sessions were therefore held: on 18 and 20 October 2021.

## **1. Opening of the meeting**

### **1.1 Welcome by the IPPC Secretariat and introductions**

- [2] The IPPC Secretariat (hereafter referred to as “the Secretariat”) opened the meeting and welcomed all participants to the meeting of the EWG on the Annex *Design and use of systems approaches for phytosanitary certification of seeds* (2018-009) to ISPM 38 (*International movement of seeds*). The Secretariat emphasized that the aim of the EWG was to produce a draft annex to an international standard and as such it should be applicable to all contracting parties.
- [3] The participants all introduced themselves.

### **1.2 Presentation of the standard setting process and the role of participants**

- [4] The Secretariat gave a presentation summarizing the standard setting process.<sup>1</sup> The Secretariat also outlined the roles of the EWG participants, explaining that the experts contribute as global experts rather than as national or regional representatives.

## **2. Meeting arrangements**

### **2.1 Selection of the Chairperson**

- [5] The EWG selected Nancy OSTERBAUER (United States of America) as Chairperson.

### **2.2 Selection of the Rapporteur**

- [6] The EWG selected Melisa NEDILSKYJ (Argentina) as Rapporteur.

### **2.3 Adoption of the agenda**

- [7] The EWG adopted the Agenda (Appendix 1).

## **3. Administrative matters**

- [8] The Secretariat introduced the documents list (Appendix 2) and the participants list (Appendix 3), and invited participants to amend their details in the participants list if any corrections were needed.

## **4. Review of specification**

- [9] The Steward for this topic, Marina ZLOTINA (United States of America), introduced Specification 70 (*Design and use of systems approaches for phytosanitary certification of seeds*).<sup>2</sup> She emphasized that the annex was envisaged as providing a general framework for the use of systems approaches for the phytosanitary certification of seeds and should be suitable for global implementation. The purpose of the annex was to provide standardized guidance for a harmonized alternative to consignment-by-consignment testing and inspection of seeds.
- [10] The Steward introduced the ten tasks listed in the specification, the first three of which related to the review of existing information, requirements and systems, followed by five tasks concerned with developing the main elements of the draft annex. The Steward confirmed that the final two tasks, on biodiversity and potential implementation issues, are standard tasks that occur in all specifications for ISPMs.

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<sup>1</sup> 04\_EWG\_SA\_2021\_Oct.

<sup>2</sup> Specification 70: <https://www.ippc.int/en/publications/89274/>.

## 5. Review of discussion papers

### 5.1 The systems approach framework for the export of New Zealand seeds

- [11] John RANDALL (New Zealand) presented a paper on the systems approach framework for the export of seeds from New Zealand.<sup>3</sup> He explained that exports from New Zealand are not covered by legislation and so the national plant protection organization (NPPO) relies heavily on various standards, including phytosanitary standards. However, many of New Zealand's exports are re-exported before they reach their final destination, and when the commodity is first exported the final destination and the phytosanitary import requirements of that destination country may not be known. He commented that use of a systems approach would help with this.
- [12] Mr RANDALL explained that the systems approach framework for seeds combined phytosanitary certification with seed varietal certification. Production sites are registered and use integrated pest management systems applicable to the pest or pests that may be associated with the crops being grown. Field inspections are undertaken by independent verification agencies or NPPO-approved inspectors. At harvesting, pest management includes ensuring that the seed is traceable (e.g. by labelling), seed cleaning, and application of other treatments, the latter depending on what is known at the time about the requirements of the destination country. The NPPO oversees all participants in the export pathway, with independent audits being conducted of the parties involved and their processes. The final part of the export process is certification, including the production of a phytosanitary certificate by the NPPO. He provided two examples of the use of systems approaches for seeds in New Zealand, which identified the critical control points in the export pathway and the sorts of interventions that are, or might be, used at these control points.
- [13] In response to questions from EWG participants, Mr RANDALL confirmed that the systems approach in New Zealand is not mandatory. No importing country has explicitly agreed to New Zealand's systems approach, so New Zealand relies on countries accepting the certifications that are based on the systems approach. He confirmed that certification is sometimes based on a systems approach and sometimes on consignment-by-consignment testing and inspection, depending on the importing country's requirements and whether there are specific requirements prescribed that could not be covered in a general systems approach. If a systems approach is used, the wording used in the Additional Declaration of the phytosanitary certificate follows the phytosanitary import requirements of the importing country (e.g. to say that the consignment is free of a particular pest or pests), so would not necessarily mention that a systems approach has been followed. He explained that the organizations involved in the seed export pathway are normally NPPO-approved for specific activities. The NPPO sets the requirements for participating organizations and if the requirements are not met, there are a range of corrective measures depending on the degree and frequency of nonconformity.
- [14] The EWG recognized the challenges of accommodating new and emerging pests in a systems approach, but noted that a systems approach should provide importing countries with confidence that the risk of pests associated with the commodity being exported has been managed.

### 5.2 Phytosanitary certification pilot plan for *Zea mays* seeds for propagation and experimental purposes: Argentina's experience

- [15] Melisa NEDILSKYJ (Argentina) presented a paper on the *Phytosanitary certification pilot plan for Zea mays seed propagation and experimental purposes*, which had been developed jointly by Argentina's NPPO and representatives of the Argentine seed industry.<sup>4</sup> She explained that the Plan describes in detail the phytosanitary measures required during the seed breeding process, and the mandated duties and responsibilities for each participant, including the NPPO. Seed exports are authorized once all the requirements stated in the Plan are fulfilled, and after the relevant verifications are carried out by the NPPO. The Plan is optional, not mandatory. When a company expresses an interest in participating in

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<sup>3</sup> 05\_EWG\_SA\_2021\_Oct.

<sup>4</sup> 06\_EWG\_SA\_2021\_Oct.

the Plan, the NPPO validates the processes of the company by audits and verifies the critical checkpoints by inspections. The NPPO takes samples during the vegetative stage of the crop, and then labelling is checked post-harvest to ensure traceability.

- [16] Ms NEDILSKYJ explained that the Plan was developed for seeds that are produced under high-quality, controlled systems for experimental purposes. This is a high-cost process, so destructive laboratory testing methods lead to loss of valuable genetic material and sometimes it is not possible to test at all because of the small amount of seeds. For the pilot, the focus was on a systems approach for the bacterium *Pantoea stewartii* on seeds of *Zea mays*, as an alternative to the usual diagnostic test. As *P. stewartii* does not have many hosts and the vector is not present in Argentina, the NPPO had considered that it would be possible to develop a systems approach for this pest on *Zea mays*. The intention is to develop the Plan further by producing a seed production manual, evaluating and revising the Plan, and seeking bilateral or multilateral agreements with other NPPOs.
- [17] Ms NEDILSKYJ finished by summarizing some of the challenges with the use of systems approaches. She commented that the most important one was achieving bilateral or multilateral acceptance of the certification scheme by other NPPOs. A high level of commitment and collaboration was also needed between the public and private sectors. The potential international movements of seeds needed to be identified, including “blocks” of countries that exchange seeds. Phytosanitary measures needed to be harmonized per seed crop, so that all pests can be mitigated by multilaterally agreed phytosanitary measures. Some countries may not be able to gather the relevant information about industrial practices if they do not have a seed industry association, which would make it harder to develop a systems approach plan. Finally, the feasibility of implementation needed to be considered, as sometimes there may be phytosanitary measures that are less trade-restrictive than a systems approach.
- [18] In response to questions from EWG participants, Ms NEDILSKYJ confirmed that some of the measures in the Plan were effective not only against *P. stewartii* but also against other pests or for other hosts. The main body of the Plan is general and the information specific to *P. stewartii* is in an annex. A systems approach plan for other pests or crops could be produced, but it would depend on the biology of the pest: if a pest has a high incidence and it is going to be impossible to produce seeds that are not infested, then it would not be possible to produce a plan for that pest; but where this is not the case and the pathway is certain, the NPPO could look at the measures needed to address the pest, with a view to drawing up a plan. She commented that the plan for *P. stewartii* on seeds of *Zea mays* may not be suitable for certification of seeds in countries that have a high incidence of *P. stewartii* and have the vector.
- [19] Ms NEDILSKYJ confirmed that the plan for *P. stewartii* on seeds of *Zea mays* is a pilot project but had been running for a year. Only one company had subscribed to it so far. The NPPO was seeking an agreement with Mexico, because *P. stewartii* was the only pest specifically listed in Mexico’s phytosanitary import requirements, but the negotiations were still ongoing and so Argentina cannot yet *certify* seeds with the Plan yet, even though the seeds are *produced* according to the Plan. She confirmed that, as far as the Argentinian NPPO was concerned, the systems approach set out in the Plan was very reliable.
- [20] Regarding corrective actions for non-compliance following testing in the field, Ms NEDILSKYJ confirmed that, in some circumstances, corrective action is possible but that, in other circumstances (e.g. if the pest bacterium is found on the leaves of the plant), there is no action possible other than to not certify the seeds in question. She confirmed that post-harvest testing is sometimes an option but not always. Post-harvest testing of seeds for breeding purposes, for example, is very difficult because the lots are very small and have high cost because of their genetic value; testing therefore happens in other stages of production.
- [21] Looking ahead, Ms NEDILSKYJ added that the Argentinian NPPO aims to visit the production sites of each company that expresses an interest in participating in the Plan. She finished by emphasizing the need to ensure that the processes employed mitigate the pest risk for the importing countries.

### 5.3 USDA's regulatory framework for seed health: draft accreditation standard and participant manual

- [22] Nancy OSTERBAUER (United States of America) presented two documents developed by the NPPO of the United States of America for its Regulatory Framework for Seed Health (ReFreSH). The first was a draft accreditation standard and the second was a draft participant manual.<sup>5</sup>
- [23] She explained that the draft accreditation standard describes the essential elements of ReFreSH, covering how to apply and enroll in the programme, the responsibilities of participating entities, the NPPO responsibilities, and what happens in terms of corrective actions when nonconformities are found. Under the ReFreSH programme, an entity applies to the NPPO in the country where the seed is produced, and submits a manual describing how it will meet the ReFreSH requirements. The NPPO then conducts an implementation audit to verify that the entity has successfully implemented the systems described in the manual, and if the outcome is satisfactory the NPPO authorizes the entity. Audits are conducted on a four-year cycle, with surveillance audits in the second and third years and a recertification audit in the fourth year.
- [24] Ms OSTERBAUER then introduced the draft participant manual, which is intended as a template for use by participants when drawing up their own ReFreSH manual. The entity's ReFreSH manual describes the staff involved and their training, a description of the physical facilities that will be used, a seed health management plan (describing how the participating entity will monitor and manage pest risk and how it will respond to and report pest detections), and the entity's plans for record keeping and documentation. If the entity already has alternative documentation that is suitable, this can be presented instead of a dedicated ReFreSH manual or it can be incorporated into the entity's ReFreSH manual. The entity must also include procedures for conducting regular systems improvements (e.g. through internal audits) to ensure conformity with the ReFreSH accreditation standard and template participant manual.
- [25] Ms OSTERBAUER confirmed that the draft documents, subject to some final amendments, were due to be published for public comment by the end of December 2021.
- [26] In response to a question from an EWG participant about ensuring competency, Ms OSTERBAUER confirmed that the person responsible for the ReFreSH programme at the entity should have relevant plant protection experience. If an entity subcontracts parts of the seed production process, such as to growers, the entity is responsible for ensuring that the subcontractors are doing what they are contracted to do, and must keep records of the arrangements made. The NPPO can ask to examine these records.
- [27] Ms OSTERBAUER confirmed that if a seed broker wishes to participate in ReFreSH but is in a country of re-export other than the United States of America, then the intention is that broker applies to the country of re-export (provided the country of re-export has an agreement with the NPPO of the United States of America that covers this).
- [28] The EWG's discussion then expanded to consider some wider, conceptual issues.
- [29] **Differences in phytosanitary import requirements.** The EWG noted that NPPOs are used to dealing with differences in phytosanitary import requirements between countries and speculated that the NPPO of the exporting country would liaise with seed companies to consider whether the systems approach being used would meet the phytosanitary import requirements of the intended importing countries. If the seed companies were already doing many of the aspects of the systems approach, then using a formal systems approach would give them recognition for this and may reduce the number of additional declarations needed on phytosanitary certificates.
- [30] **Acceptance and equivalence of diagnostic methods.** The EWG noted that it is the responsibility of the NPPO of the exporting country to negotiate with the NPPOs of importing countries regarding the acceptability of diagnostic methods. The Steward highlighted the discussions that have already begun within the IPPC community about the equivalence of diagnostic methods, and commented that it should

<sup>5</sup> 07\_EWG\_SA\_2021\_Oct; 08\_EWG\_SA\_2021\_Oct.

be feasible for contracting parties to negotiate regional agreements on the equivalence of diagnostic methods, but what may be more problematic for the NPPOs of importing countries is deciding whether the systems approach used by a particular producer adequately addressed pest risk. In this context, she emphasized the need for risk-based management. Ms OSTERBAUER confirmed that, in ReFreSH, the entity's ReFreSH manual includes risk assessment as part of the seed health management plan, so the entity will assess how the measures they use will address the risk.

- [31] **Pest risk analysis and pest lists.** The EWG noted that, when using systems approaches, countries would still need to conduct pest risk analysis (PRA) and the NPPO of the exporting country would liaise with the seed industry to identify the appropriate practices for the pests of concern for the importing countries. The EWG recognized the challenges, however, in compiling a global pest list for a commodity.
- [32] **Auditing and use of authorized entities.** The Steward drew the attention of the EWG to ISPM 45 (*Requirements for national plant protection organizations if authorizing entities to perform phytosanitary actions*), which had been adopted earlier in 2021, and to the IPPC guide that was being developed to complement it. She also referred to the draft ISPM on *Audit in the phytosanitary context* (2015-014), which was under development and, once adopted, should be the starting point for any agreements that include audits. The Steward added that the draft annex should specify what needs to be done by the exporting country and what by the importing country. Ms OSTERBAUER commented that the United States of America's NPPO does allow authorized entities to conduct audits on behalf of the NPPO, because the large size of the country made it impractical for NPPO staff to do all audits.
- [33] **Emerging pests.** The EWG noted the need for systems approaches to incorporate an element of continuous improvement, so that they can be changed when, for example, a new diagnostic method becomes available or there is a new or emerging pest. Flexibility would also be required from the importing country as well as the exporting country.
- [34] **Confidentiality.** The EWG noted that, in setting up systems approaches, one of the questions to consider would be how NPPOs deal with confidential business information, such as for proprietary treatments.
- [35] **Confidence and trust.** The EWG reflected on how the NPPO of an importing country can have confidence in the systems approach used by producers in an exporting country. For the ReFreSH programme, Ms OSTERBAUER commented that it was her understanding that the necessary information would be shared between the NPPOs. She added that even though a systems approach is being used, this does not preclude spot checks being conducted to check that the system is working – the principle of “trust but verify”.
- [36] One EWG participant commented that it would be very complicated if all the producers' manuals needed to be seen by both the NPPO of the importing country and the NPPO of the exporting country. The EWG participant queried whether it was necessary, because currently the NPPO of the importing country trusts the phytosanitary certificate even though the certificate does not include the detailed information upon which it is based (although the NPPO can also conduct audits in the exporting country). Ms OSTERBAUER responded that she envisaged that a participating entity would just have one manual, and the same manual would be given to all countries, rather than having to select the relevant parts of the manual to send to each country.
- [37] The Steward emphasized that the NPPO of the exporting country would remain responsible for the phytosanitary certificate, and the NPPO of the importing country would need to continue to trust the phytosanitary certificates of the NPPO of the exporting country, but the latter would remain responsible for the certification.
- [38] **Relative benefits of a systems approach over the current consignment-by-consignment testing and inspection.** The EWG reflected on whether systems approaches would, in effect, be adding an additional layer to the existing system of bilateral agreements and consignment-by-consignment testing and inspection. One EWG participant suggested, however, that experience with systems approaches for other commodities indicates that a systems approach for seeds could make things easier for seed companies. The EWG also recognized the demands on NPPO resources from systems approaches, as under a

systems approach the NPPO has to control the whole production process. This could be a particular challenge in large countries or where the NPPO does not authorize entities to perform phytosanitary actions on its behalf. The EWG noted, however, that even with the use of authorized entities, a systems approach can still be a challenge in large countries.

- [39] Ms OSTERBAUER confirmed that it is mostly larger companies that have expressed interest in ReFreSH, with smaller companies being less interested as they trade internationally less frequently and so are happy to stay with the existing system of consignment-by-consignment testing and inspection. She acknowledged that systems approaches could bring challenges in terms of resources and do require a different way of looking at things, but as they avoid the need to look at every consignment, they should be feasible; they should also allow the required level of protection to be achieved.
- [40] One EWG participant commented that if an NPPO of an importing country assesses a particular systems approach as suitable but then the seed lots concerned are re-exported, the country to which the lots are re-exported would also need to accept the system. This could make a systems approach unattractive when there is the simpler alternative of testing seeds.
- [41] **Potential implementation issues.** The EWG noted that, if systems approaches are voluntary, this would mean that some seed lots that have a phytosanitary certificate from a systems approach and some with a classic declaration. However, as NPPOs already deal with this for other commodities, it should not be a problem and would just need the border inspectors to understand what is accepted and what is not.
- [42] The EWG noted that it should be feasible to have multilateral agreements on a regional basis, as countries within a region may have similar pests so it would be easier for countries within a region to draw up and agree on a pest list. They also noted, however, that one of the challenges would be that, because seeds are transported all over the world, everyone in the seed supply chain would need to agree to the system. One EWG participant expressed the hope that, over time, as more and more countries used systems approaches and the systems were seen to be working well, the use of systems approaches would gain wider acceptance.

#### 5.4 Phytosanitary certification of seeds and systems approaches in Japan

- [43] Hiroshi UEMATSU (Japan) presented a paper on the phytosanitary measures required by Japan for import of seeds into Japan.<sup>6</sup> He explained that, in Japan, there are no cases where a systems approach has been explicitly used for seed import. He outlined the three types of phytosanitary measures for import of seeds to Japan: specific phytosanitary measures carried out by exporting countries, field inspections in exporting countries, and inspection at the point of import (including visual inspection and laboratory tests). He then presented a summary of Japan's seed import inspection results and gave details of two examples of interventions of seeds being detected upon import. In one of these, the phytosanitary certificate had stated that the seeds were not infected with the quarantine pest according to the genetic diagnostic method used in the exporting country, so the NPPO in Japan has been conducting additional genetic tests on the seeds of the host plants and were investigating the cause of this case. In the second example, it had become apparent that the origin of the seeds was not the country stated on the phytosanitary certificate, but in fact two other countries, which had prompted Japan to start conducting genetic testing of host plant seeds imported from those two countries as a provisional measure.
- [44] In response to questions from EWG participants, Mr UEMATSU confirmed that Japan does accept systems approaches for plants for planting, but by bilateral agreements not multilaterally. He commented that strong measures are needed for some pathogens, but not for all. He also confirmed that the total volume of seed testing for export is increasing.
- [45] The EWG noted that testing using polymerase chain reaction (PCR) can result in false positives, where a treatment has deactivated the organism but a PCR still detects the genetic material or where the

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<sup>6</sup> 09\_EWG\_SA\_2021\_Oct.

organism may not be present in sufficient numbers to infect the plant but the PCR still gives a positive result.

- [46] The EWG also noted that two examples given in the paper raised the general question of how such issues (e.g. differences between methods of detection) would be dealt with in a systems approach. The EWG noted the need to harmonize the diagnostic tests as well as the certification processes.

## 5.5 Information on systems approaches for seeds: the experience and thoughts of GEVES, France

- [47] Valerie GRIMAULT (France) presented a paper from Groupe d'Etude et de contrôle des Variétés et des Semences (GEVES) on the phytosanitary certification system for seeds in France and some thoughts on systems approaches.<sup>7</sup> The GEVES laboratory is the French national reference laboratory for regulated non-quarantine pests where the main pathway is seeds.
- [48] She explained that Europe currently operates a consignment-by-consignment system for phytosanitary certification of seeds. There is a system in France of National Reference Laboratory and Authorized laboratories which carry out official testing of seeds moving within the European Union. At import, there is document control and inspection, with sampling at points of entry and official testing. The percentage of lots tested depends on a risk analysis, so it is a risk-based preventive approach based on PRAs and detections in imports from other countries. However, in France, there is also a certification system used for seeds that has many similarities to a systems approach. It is based on field inspections by registered seed companies and the official body, and tests of seeds by National Reference Laboratory or authorized laboratories (in charge of official analysis) and recognized laboratories (seed company laboratories, recognized by the official body that has responsibility for certification of seeds and plants).
- [49] Ms GRIMAULT explained that there is one systems approach used in France for seed certification: Good Seed and Plant Practices. This is a quality management system under which seed companies implement actions to mitigate risks, but it is only for *Clavibacter michiganensis* subsp. *michiganensis*. The activities of the seed companies are conducted under the supervision of the official body responsible for certification of seeds, which conducts audits, and the GEVES laboratory organizes proficiency testing for the laboratories. The system works well to mitigate the pest risk.
- [50] Turning to some thoughts about a systems approach for seeds, Ms GRIMAULT commented that the first requirement would be to determine which seeds are a recognized pathway for pests of concern. Acknowledging that more research is needed for some pests for which pathway is not proven, she suggested that it would be best to focus systems approaches on those pests that are known to be a pathway. For these commodities, the different steps of the seed production process, and the associated risks, could be identified and actions set up to mitigate these risks, including a quality system.
- [51] Ms GRIMAULT highlighted some of the potential benefits and challenges of using a systems approach for seeds. A systems approach could help facilitate the movement of seeds and be useful for pelleted seeds and for small lots of seeds for breeding. However, among the various potential challenges to consider would be: how to deal with the different requirements of importing countries; what would be the risks of the systems approach; would all seed exports go through the systems approach or would it be a combination of a systems approach and a consignment-by-consignment approach; how would the systems approach be monitored; and would the systems approach need the whole seed industry to apply it, or could it be applied company by company, leading to different systems cohabiting. Ms GRIMAULT finished by emphasizing the importance of monitoring and control at each step and of having some pilot studies. She added that knowledge of risk mitigation would help NPPOs to analyse the risks.
- [52] In response to questions from EWG participants, Ms GRIMAULT confirmed that the certification system used in France relates to seven crop-pest combinations, the pest list being built from the European Union's list of regulated pests. It is mostly for the movement of seeds within France rather than international movement, which is why she had described it as a certification scheme rather than a

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<sup>7</sup> 10\_EWG\_SA\_2021\_Oct.

systems approach. When a company applies to join the scheme, the official body that has responsibility for certification of seeds examines the documents submitted and, together with the national reference laboratory, conducts an audit. Ms GRIMAULT confirmed that the system in France is aligned with the system of plant passports operated by the European Union, but the French system also includes some pests that are not covered by the plant passport scheme.

- [53] The Steward reiterated that the draft annex to ISPM 38 would only provide a general framework for systems approaches, and it would be the responsibility of NPPOs to build on this and to prove that the resulting systems approaches worked.

## **5.6 South Africa's experience in managing pests using systems approaches (during import, export, re-export and in transit), including challenges and possible solutions**

- [54] Phumudzo TSHIKHUDO (South Africa) gave a presentation on South Africa's experience of using systems approaches. He started by listing the various measures that exporting countries importing into South Africa are expected to take, from the pre-planting stage through to packing and storage after harvest. He then outlined the phytosanitary certification options for countries importing into South Africa, these depending on the intended use. For seeds intended for planting or field trials, options include the country being pest free, the parent plants being inspected and found to be free from pests, the consignment being tested and found free from pests, or the consignment treated with an appropriate fumigant. For import of seed for laboratory tests, options include the consignment being opened only in the laboratory where the testing is to be done, seeds not being shared with other researchers from different laboratories, and destroying the seeds after laboratory testing. Seed lots arriving in South Africa are subject to inspection and, if needed, sampling and testing.
- [55] Mr TSHIKHUDO listed some of the challenges related to imports. First, a large volume of seeds for research or laboratory testing is sometimes received, despite that fact that this is not allowed. Second, the South African phytosanitary import requirements are not country specific, but the pest status varies between countries. Third, new pests continue to be discovered, and the phytosanitary import requirements of South Africa have to be amended to take account of these. He suggested that possible solutions to these challenges included appointing an approved organization to monitor, produce or certify seeds, and developing country-specific phytosanitary import requirements. He commented, however, that the latter would take time, because each would require a PRA.
- [56] Turning to the export of seeds from South Africa, Mr TSHIKHUDO explained that South Africa has a seed certification scheme for seeds for planting, with an official body designated to administer the scheme. The measures applied under the scheme are similar to those expected for systems approaches in countries importing into South Africa. Seed crops are also inspected to ensure that there are no circumstances which may affect the genetic purity of the seeds to be harvested. For re-export of seeds, inspectors at the relevant point of entry are informed about the consignment passing through the country and the necessary documentation is checked.
- [57] Mr TSHIKHUDO finished by making some remarks on the harmonization of movement of seeds within the South African Development Community region. Each member state has been requested to conduct PRAs on seeds, so that each member state can produce a pest list and harmonized phytosanitary import requirements can be developed.
- [58] Referring to the sanitation measures mentioned by Mr TSHIKHUDO in relation to both imports and exports, the EWG noted that there is no definition of "sanitation" in ISPM 5 (*Glossary of phytosanitary terms*), but that in this context it referred to general hygiene measures to keep equipment, facilities and people clean. Reflecting on other terms used during the EWG's discussions, the EWG noted that there was an ISPM 5 definition for "harmonization", but they would need to check whether this was adequate in the context of the draft annex to ISPM 38. The Steward also commented that the EWG would need to consider what terminology to use regarding quality management, and recalled that this had generated much discussion within the Standards Committee.

- [59] Looking to the task ahead in drafting the annex, the EWG noted that there were many similarities between the various systems being presented at this meeting, but there was also a diversity of approaches, varying in complexity. As the annex needed to be a general framework, applicable to all these types of approaches, the EWG recognized the value of “keeping it simple”.

## 5.7 Systems approaches for phytosanitary certification of seeds to ISPM 38

- [60] Martijn SCHENK (the Netherlands) presented a discussion paper on systems approaches for the phytosanitary certification of seeds.<sup>8</sup>
- [61] He started by emphasizing the need for a common understanding of what is meant by a “systems approach”, as systems approaches can vary from a very simple system to a highly complicated one. He gave the reasons for needing a systems approach as being the global nature of the supply chains, the variations in phytosanitary demands, and the complications caused by re-export, but commented that the underlying complicating factor was the differences in phytosanitary import requirements between countries, which presents a challenge for both companies and NPPOs alike.
- [62] Mr SCHENK summarized the legislative framework regarding movement of plants into and out of the European Union, both of which require a phytosanitary certificate. Within this framework, there are only a few seeds for sowing for which there are specific phytosanitary import requirements. A systems approach is not available as an option for seeds, unless it is specified as a requirement in the regulation of the destination country, but is an option for some fruits (e.g. *Citrus* and *Mangifera*) for certain pests. He suggested that the application of a systems approach would therefore fit with the European Union’s legislation and explained that some elements of a systems approach are already being applied. To meet the requirements for certification, for example, information from operators’ control systems is being used, and company laboratories perform seed quality tests. He commented that the European Union’s plant passport system is similar to a systems approach, but is only used for internal movement within the European Union, not for import or export purposes. Under the plant passport system, a plant passport needs to accompany the internal movement of plants (including seeds) until they reach the final user. Operators can be authorized to issue plant passports.
- [63] Mr SCHENK then offered some thoughts on what the potential elements of a systems approach for seeds might be. These included a commodity assessment for individual crops (determining the main diseases of the crop and the critical steps to mitigation the risk of infestation or contamination), monitoring and control of the system by the NPPO of the exporting country, traceability, and providing sufficient information to the NPPO of the importing country to allow it to assess the efficacy of the proposed measures.
- [64] Mr SCHENK finished by outlining some challenges and opportunities for systems approaches. He commented that systems approaches provide the opportunity to target multiple pests at the same time, and may have the potential to provide a higher level of safety than just using end-point testing of seeds. Systems approaches would also be beneficial for the certification of small seed lots (e.g. for breeding material). However, challenges included whether the benefits outweigh the effort needed when relatively straightforward options such as testing are available, and whether systems approaches can be designed in such a way that they truly reduce the complexity of phytosanitary demands. He also highlighted the point made earlier in the meeting that seed processing and seed treatment may take place in different countries to the country of initial production, in which case the systems approach would be incomplete at the time of export from the country of origin and so may not meet the phytosanitary import requirements of the first importing country upon entry.
- [65] In response to questions from EWG participants, Mr SCHENK confirmed that the only systems approaches that are permitted in relation to import into the European Union are those for individual pests – not for multiple pests at the same time. Testing requirements for exports from the European Union are

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<sup>8</sup> 12\_EWG\_SA\_2021\_Oct.

also based on individual pests, with authorized laboratories being authorized for specific, individual pests.

- [66] The EWG then considered some broader conceptual issues arising from the presentation.
- [67] **Overlap with commodity standards.** The EWG noted that there would be some potential overlap between the annex to ISPM 38 and the commodity standards that would be developed in the coming years (under the draft ISPM on *Commodity-based standards for phytosanitary measures* (2019-008)), but that one of the most important questions is whether particular pests are really transmitted by the seeds, as there are already some redundant requirements.
- [68] **Efficacy or effectiveness of measures.** The EWG acknowledged that it would be a challenge to do a quantitative assessment of the measures in a systems approach, and that it may not always be meaningful to report effectiveness in a quantitative way. One EWG participant suggested that perhaps the more important element is the consistency with which measures are applied.
- [69] **Multilateral recognition.** The Steward commented that multilateral application of measures does not necessarily need to involve multilateral agreements, as it could just be a chain of countries accepting systems approaches. She also recalled that the EWG for the Revision of ISPM 4 (*Requirements for the establishment of pest free areas*) (2009-002) discussed the possibility of having multilateral recognition of pest free areas, but the Standards Committee considered that it would not be feasible to do this.
- [70] **Target pests.** The EWG noted that, for a systems approach for seeds, the initial analysis would need to cover not only the regulated pests in the first importing country, but also those of subsequent countries in the supply chain. The EWG compared this situation with that for wood packaging material, where some countries still use ISPM 15 (*Regulation of wood packaging material in international trade*) even though it may go beyond what is needed for their situation. They noted that a systems approach for seeds would need to be for regulated pests, not just quarantine pests, because seeds are plants for planting and so regulated non-quarantine pests are also of relevance. The intended use of the commodity would also need to be considered when devising the systems approach, as the pests of relevance to seed conditioning may be different to those of relevance to the planting of the seeds. The EWG acknowledged once again, however, that one of the main challenges is that often the country of final destination is not known at the time of the initial export, and there may also be a few years between initial production and planting, during which time the phytosanitary import requirements may have changed. The EWG therefore recognized that a systems approach needed to incorporate an element of flexibility, because it is impossible to know all the requirements along the supply chain at the time of initial production.
- [71] The EWG noted that some treatments may also be effective against pests other than the target pests. Furthermore, some pests are used as indicators of the effectiveness of measures: if it can be demonstrated that a pest that is easily transmissible and is found everywhere is not moving in trade, then this indicates that regulated pests are not moving either.

## 5.8 Discussion papers from the International Seed Federation

- [72] Merel LANGENS (International Seed Federation (ISF)) presented six working papers submitted by the ISF.<sup>9</sup> The first was a general overview of the seed industry, and the other papers addressed some of the tasks in Specification 70.
- [73] **Introduction to the seed industry.** Ms LANGENS highlighted some of the key features of the seed industry, including the high commercial value per unit volume, the small volumes of many lots, and the fact that supply chains may involve several countries, with phytosanitary import requirements differing between these countries. Production and processing methods for seeds range from technologically sophisticated methods in glasshouses to “low tech” methods in the open field, and the seeds are offered for sale either in their “normal” form, or sorted (according to size), coated, pelleted, encrusted or primed.

<sup>9</sup> 11\_EWG\_SA\_2021\_Oct.

Quality control is applied to the whole supply process, from the choice of location for seed production to sampling and testing after processing.

- [74] Offering some thoughts on a systems approach for seeds, Ms LANGENS suggested that the global nature of the vegetable seed business meant that there is a shared need for a global phytosanitary system for seeds. She suggested that a systems approach would also be a solution for some of the challenges of the current system of trade: the increasing number of pest-specific phytosanitary import requirements, variation between the requirements set by different NPPOs; requirements not always being associated with seeds as a pathway; the need for seeds to meet the requirements of all the countries in the supply chain; and the difficulties of moving small seed lots for research and breeding purposes. She envisaged that, under a systems approach, phytosanitary certificates could be issued without having to specify specific pests or include an additional declaration. This would not replace the current system, but would provide an alternative option for countries wishing to participate in it. She then outlined the essential elements of a systems approach from an industry point of view, including that the systems approach is in line with international standards, offers an alternative to the current phytosanitary certification for seed companies with certified pest risk management practices, strives for global harmonization, is risk based and data driven, is accessible to both small and large companies, is flexible across different crops, integrates different practices (while also allowing for innovations to be incorporated) and is non-competitive.
- [75] At this point, Ms LANGENS also commented that the seed industry's view is that a systems approach does necessarily match exactly the definition of a systems approach given in ISPM 14 (*The use of integrated measures in a systems approach for pest risk management*), which begged the question of whether that definition needed to be revised.
- [76] **An overview of management systems for seeds and systems approaches in other commodities.** With reference to Task 3(a) of Specification 70, Ms LANGENS explained that ISF had looked at six different systems and had considered to what extent they met the seed industry's criteria for a systems approach (described earlier in Ms LANGENS' presentation). The six systems were: the Argentinian Pilot Plan for Phytosanitary Certification; ReFreSH (see agenda item 5.3); the Systems Approach for Nursery Certification; the Good Seed and Plant Practices programme; the Chilean phytosanitary surveillance cooperation agreement; and the Dutch Naktuinbouw programme. She summarized the outcome of this review.
- [77] **Phytosanitary import requirements for seeds – cucumber seeds as an example.** With reference to Task 2 of Specification 70, Ms LANGENS presented the outcome of an ISF review of the phytosanitary import requirements for cucumber seeds. This had shown that there were 92 pests regulated worldwide in relation to cucumber seeds, but that the phytosanitary import requirements for the same pest vary from country to country and some of the requirements may be impossible to fulfil. The ISF's data had also indicated that seeds are a known pathway for transmission for only 9% of the pests that are currently regulated in relation to seeds and that only four regulated pests follow the cucumber seed pathway.
- [78] **Pest risk management options and how to integrate current industry practices or existing management systems in a systems approach for seeds.** With reference to Task 4 of Specification 70, Ms LANGENS explained that, in the view of the seed industry, the "pests in scope" should all be regulated pests, with a specific focus on those pests where seeds have been identified to be a pathway for the introduction and spread of the pest under natural field conditions. Ideally, there would be a globally accepted list of relevant seed-transmitted pests. However, rather than looking at one measure—one pest, she suggested that in a systems approach, groups of pests could be considered, with measures based on the pathways of introduction and spread of pests into a seed production site, as there are relatively few pathways of introduction. The accepted list of relevant seed-transmitted pests and the pathway analysis could then be used as the basis for selecting pest management options during risk evaluation. Ms LANGENS explained that the idea is that mitigation measures for a particular target pest would also effectively protect against similar pests in each pathway category.

- [79] Ms LANGENS then gave an example of how such a pathway analysis might look, using cucumber as the seed species. This identified the potential ways of introduction and spread of each pest in seed production (e.g. seedborne, waterborne, airborne), together with an overall rating of the importance of the pest during seed production.
- [80] Ms LANGENS confirmed that the seed industry proposes that existing quality management systems may be integrated into the quality management systems of systems approaches. She highlighted that for industry systems to be accepted by NPPOs, there is a need for trust (the NPPO needs to have confidence in the system), transparency and regulatory oversight.
- [81] **Proposals on general requirements of a systems approach for seeds.** With reference to Task 5 of Specification 70, Ms LANGENS identified the following elements as “building blocks” for a systems approach for seeds: a quality management system; a list of management options per phase of seed production; guidance on pathway analysis; a procedure for the reporting of emerging pests; and auditing and verification. She gave further details and highlighted the need to clarify who does what. Ms LANGENS also suggested that certification could be not only *per facility* in a specific country but alternatively *per supply chain*, involving the certification of facilities in different countries. She explained that the ISF Systems Approach Working Group is working on a pilot project which includes four interested countries to investigate the feasibility of this concept.
- [82] **How multilateral acceptance of systems approach could work – ideas from the international seed sector.** With reference to Task 7 and Task 8 of Specification 70, Ms LANGENS presented some suggestions on what the roles of NPPOs would be in a systems approach for seeds, including the development of multilateral agreements, the certification of facilities (with associated audit), and responding to reports of suspected outbreaks of regulated pests and new or emerging pest risks. She commented that the phytosanitary certificate for export or re-export issued by the NPPO of the exporting country would preferably be a generic one. Ms LANGENS also outlined the steps that could be taken to agree on a multilateral systems approach. These included: reaching agreement on a regulated pest list and pathway analysis (per crop); evaluation of seed production processes and the pest management plan; reaching agreement on the design of the systems approach, critical control points and measures; an implementation phase, in which NPPOs, together with the seed industry, agree on the details about the application of the systems approach; and gradually building up multilateral agreements, starting with only a few participating countries. Ms LANGENS referred again to the pilot project currently being promoted by the ISF between four countries with cucumber as a model.

### Discussion

- [83] The EWG discussed the papers presented by Ms LANGENS.
- [84] **Achieving multilateral acceptance.** The EWG noted that a systems approach would only work for countries that have accepted the system, so for this approach to work it would need a sufficiently large number of countries to use it.
- [85] **Effectiveness of the systems approach.** The EWG noted that the only way of really knowing whether the systems approach was efficient would be to compare it with testing. For this reason, when new countries enter the system, they may wish to operate the systems approach alongside their traditional system so that they can evaluate the systems approach.
- [86] Ms LANGENS confirmed that the ISF pilot project is still at an early stage: ISF is engaging in discussions with the NPPOs at the moment and the next step would be to reach an agreement with them. The intention is to do the same shipment using both a systems approach and the present system, but the detail still needs to be worked out.
- [87] **Phytosanitary import requirements.** The EWG noted that it would be the responsibility of the NPPO of the exporting country to assess the information provided by operators and decide whether the specific phytosanitary import requirements of individual importing countries have been met.

- [88] The EWG noted that harmonization (in the dictionary sense) of phytosanitary import requirements would be one of the main challenges. As each country can set its own appropriate level of protection, would it be possible to define a set of requirements that fulfils the needs of a large number of countries?
- [89] **Seeds as pathways.** The EWG recognized that pests may be included in legislation even if they are not proven to be transmitted by seeds, because a precautionary approach is often taken in the drafting of legislation. They noted that seed species may be “not proven to be a pathway” for a variety of reasons, including where there is insufficient information or where the pathway has not been proven under natural conditions.
- [90] **Systems approach vs certification scheme.** The EWG noted that the distinction between a systems approach and a certification scheme is not clear. Ms LANGENS confirmed that the approach described in her presentation was more of a certification system than the strict systems approach as defined in ISPM 14, as she considered the whole systems approach to be one measure, leading to one additional declaration on the phytosanitary certificate, so it did not fit the definition of a systems approach as used in ISPM 14 (the ISPM 5 definition) because it did not comprise at least two independent measures.
- [91] **Emerging pests.** One EWG participant asked why clarification was needed in the annex about collaboration between NPPOs and seed companies on emerging pests. Ms LANGENS replied that this was prompted by feedback from experts from NPPOs, who had said that the more open a system is (i.e. the less prescriptive), the more information NPPOs will need about what is being found and where, and then it becomes more important to look at the results of the measures rather than the measures themselves. She added that reporting helps to build trust between the seed companies and the NPPOs.
- [92] The EWG noted that there was not currently an ISPM 5 definition for “emerging pest”, so if this term were to be used in the annex, its meaning would need to be explained.
- [93] **Resources.** The EWG noted that the annex needed to provide a basic list of elements that could be adopted by countries regardless of their level of resources.

## 6. Development of text for the draft annex to ISPM 38

### 6.1 Brainstorming session to develop the outline of the annex

- [94] The EWG considered the issues that need to be included in the annex.
- [95] The EWG noted that the annex should not duplicate guidance that is in other ISPMs, or within the core text of ISPM 38, but provide guidance that is unique to the use of a systems approach for seeds. The Steward reminded the EWG that the annex would be part of ISPM 38, not a stand-alone standard.
- [96] The EWG noted that issues to consider that were not covered by ISPM 14 included:
- traceability of lots (referring to ISPM 36 (*Integrated measures for plants for planting*) and the North American Plant Protection Organization’s Regional Standard for Phytosanitary Measures No. 40,<sup>10</sup> if relevant);
  - quality management;
  - multilateral negotiations (including how multilateral acceptance works with regard to ISPM 14, which says that the decision regarding the acceptability of a systems approach lies with the importing country);
  - re-export and the harmonization of phytosanitary import requirements (in relation to pests, additional declarations or testing methods (seeds and mother plants), per seed crop);
  - systems approaches that span more than one country (different stages of the seed supply chain, from production to the final sale, may be in different countries, and ISPM 14 allows for the

<sup>10</sup> NAPPO (North American Plant Protection Organization). 2014. *Principles of pest risk management for the import of commodities*. Regional Standards for Phytosanitary Measures (RSPM) 40. Ottawa, NAPPO. 28 pp.

- measures to be applied in the importing country if the importing country agrees, so are systems approaches per facility or per supply chain);
- how to report the use of a systems approach on a phytosanitary certificate, including additional declarations;
- the responsibilities of operators.

[97] The EWG noted that other issues to consider were as follows:

- a recommended structure for the design of a systems approach for a seed crop (to provide guidance on how an NPPO would go about designing a systems approach);
- whether the annex should cover all crops, with crop specific information in appendices;
- a survey of industry production processes for the selected seed species, to assess how those processes can mitigate the risk of the pest themselves or if it is necessary incorporate additional measures, which could lead to a package of requirements for participants to which each country may add additional measures to be fulfilled;
- development of a programme, with industry collaboration, that ensures the implementation of practices that mitigate the risk of the identified pests;
- pest management options per phase of seed production (referring to the core text of ISPM 38 and ISPM 14);
- equivalence of pest management options;
- identification of critical control points;
- use of pest free areas, pest free places of production and pest free production sites before planting and during the growing season;
- implementation of treatments that have been shown to be sufficiently effective after harvest;
- post-harvest testing with validated protocols;
- site inspections during the growing season (for combinations of host plants and pathogens with distinct disease symptoms);
- “pests in scope” and guidance on pathway analysis (to complement ISPM 14);
- systems approaches for an individual pest versus multiple pests (ISPM 36 recognizes that “integrated measures are designed to manage the risks related to regulated pests, and also have the advantage of managing other pests at the place of production”, and Appendix 1 to ISPM 36 provides examples of measures that may be applied for specific groups of pests);
- the need to analyse the biology of the identified pest (dispersal mechanisms, etc.);
- the importance of the intended use in the establishment of requirements (ISPM 38 referring to intended use and the changing risk);
- how to deal with new and emerging pests and procedure for reporting them;
- the difficulties with small lots;
- the principle of “trust but verify” on the part of the importing NPPO (although ISPM 14 does include this principle);
- quality management systems, including audits and certification (referring to the draft ISPM on *Audit in the phytosanitary context* (2015-014));
- record keeping and development of databases for seeds lots to facilitate trace-back (including who has access to the data and why);
- confidentiality of business information (does this refer to company manuals and, if so, who keeps the manuals and why (noting that manuals are living documents));
- roles and responsibilities of NPPOs and participants (including what is given as guidance in the annex and what is decided at national level);
- collaboration between NPPOs and industry;
- how to formalize recognition of industry best practice if that is to be part of a systems approach;

- how to keep the system up-to-date (addition of crops, pests, management options, etc.) and who does this;
- examples of the possible movement of seeds and the implications for phytosanitary certification;
- examples of those groups of pests that can be managed with industry practices (e.g. most insects and weeds) and those that could require other measures during production (e.g. viruses and bacteria) (similar to the examples in the core text of ISPM 38, but in relation to industry practices).

[98] **Incorporating industry practices.** The EWG noted that the core text of ISPM 38 mentions that certain seed production practices may alone or in combination be sufficient to meet phytosanitary import requirements, but it is not clear that NPPOs can include such practices in their phytosanitary import requirements. The annex would clarify this. The EWG noted that it is the responsibility of the NPPO of the importing country to identify the phytosanitary import requirements that it needs to achieve its appropriate level of protection.

[99] **Confidentiality.** The EWG noted that ISPM 45 contains a clause requiring the entity to maintain the confidentiality of the information obtained through the phytosanitary actions it is authorized to perform. One EWG participant suggested that a seed company would not need to disclose everything, just their systems approach quality manual.

[100] **Traceability.** The EWG discussed the feasibility of creating a global database of all seed producers on the International Phytosanitary Portal in order to facilitate trace-back and record non-compliance, but the consensus was that this would be too difficult to achieve and that it is the responsibility of NPPOs to put in place an appropriate mechanism for trace-back. As a minimum, a national database would include a register of the operators, but it would be up to the NPPO to decide what else to include in their database. The EWG noted that the NPPO should have access to all the relevant data, but this does not mean that it all has to be in one system. The EWG also noted that the primary means of tracking is via the phytosanitary certificate and the lot number, so there is already a mechanism in place in some respects. The Steward pointed out that the annex should be restricted to very general requirements, so it only needed to say that an NPPO's programme should be set up to ensure that mechanisms are in place to ensure trace-back.

[101] One EWG participant commented that even though traceability is mentioned in other ISPMs, there are some specific issues to seeds that should be in the annex (e.g. because the seeds need to be traced back to the mother plants).

[102] The EWG noted that trace-back is related to record keeping.

[103] **What not to include in the annex.** The EWG noted that it would not be appropriate to include text on specific crops in the annex, but the annex should instead provide a general outline of how to proceed to develop a systems approach for a particular crop.

[104] **Potential implementation issues to consider.** The EWG noted that some of the issues to consider were:

- the need for guidance on the transition period and the length of the transition period;
- the need to consider how to compare the efficiency of a systems approach with that of the current system, in order for it to be recognized (referring to ISPM 14);
- the potential challenges for NPPOs in terms of resources (noting that delegation of phytosanitary actions to authorized entities is allowed under ISPM 45).

[105] **Structure of the annex.** Taking account of the ideas generated during the brainstorming session, the EWG drew up a provisional structure for the annex. In doing this, the EWG referred to the structure of ISPM 14 and the State Level Model Standard for the Systems Approach to Nursery Certification.<sup>11</sup>

<sup>11</sup> Systems Approach to Nursery Certification (SANC), State Level Model Standard: <https://sanc.nationalplantboard.org/about/program-standards/>

However, they intentionally avoided using the same headings as ISPM 14. The structure was then modified during the subsequent drafting of the text (agenda item 6.2).

[106] **Review of tasks in the specification.** The EWG noted that they had already covered Task 1 (considering existing standards that are relevant), Task 2 (reviewing examples of phytosanitary import requirements for seeds), and Task 3 (reviewing existing management systems and relevant systems approaches in other sectors). Tasks 4–8 would be covered by the provisional structure of annex discussed, with Tasks 7 and 8, relating to multilateral recognition, being the most important owing to the lack of current guidance on this issue. The EWG noted that Task 6 did not align to a specific section in the provisional structure, so would need to be considered throughout the drafting process.

[107] The EWG noted that as the annex needed to be generic, it needed to be as simple as possible.

## 6.2 Elaboration of the text of the draft annex to the ISPM

[108] The EWG elaborated the context of the draft annex through a combination of discussion during the virtual sessions and provision of comments on, and amendments to, the draft text between sessions. Mindful of the need to avoid duplication with other ISPMs and the core text of ISPM 38, the EWG reviewed the text in the final session to identify the guidance that was unique to this annex (see the end of this agenda item) and then removed all other text. Where the following account of the EWG's discussions refers directly to the drafting of text that was removed in this process, it is identified as such.

[109] Before starting on the drafting process, the Secretariat and the Steward explained the use of “should” and “may” when expressing the level of obligation in ISPMs, and confirmed that if there were any terms that needed explaining (e.g. “multilateral recognition”), such explanations could simply be given in the text and did not necessarily need to be given a formal definition. Terms clarified by the EWG are indicated in this report **“in bold quotations”**.

[110] Later in the meeting, the Steward and Secretariat confirmed that requirements in ISPMs are mostly directed towards NPPOs, but requirements for other parties may be included where these are outside of the scope of NPPOs.

### *Introduction to the annex*

[111] The EWG drew upon the Scope section of Specification 70 to draft a general introductory paragraph describing the scope of the annex. They considered whether to give examples of the different reasons for which seeds are moved (breeding, international varietal schemes, sale, etc.) to make it clear that the annex covered all these movements, but concluded that it was only necessary to refer to seeds moving internationally. The Secretariat confirmed that the scope of the annex in terms of the commodity would be the same as that described in the core text of ISPM 38 unless it was specified otherwise in the annex.

[112] The EWG noted that one of the main elements to include in this annex was the incorporation into systems approaches of existing pest management practices used within the seed industry. It was therefore important to refer to this early in the annex.

[113] The invited expert from the seed industry, commented that the annex should outline how a seed company should develop a systems approach, not the requirements for a seed company.

[114] The EWG noted that a systems approach is not a replacement for phytosanitary certification based on consignment-by-consignment inspection, but is in addition to this and provides an optional alternative. They considered whether to say this explicitly in the introductory paragraph to the annex, but ultimately decided against this. The EWG noted that, under a systems approach, each seed consignment would still need to be issued with a phytosanitary certificate.

### ***Purpose of systems approaches for seeds***

[115] The EWG drafted some text to explain the purpose of systems approaches for seeds, referring to the global nature of the supply chain and the differences in phytosanitary import requirements between countries. Noting that seed may pass through multiple countries as it moves through different stages of the supply chain, the EWG agreed that a consignment of seeds refers to one movement of seeds between countries: each time the seed moves through a new country, it does so as a new consignment. However, when reviewing the text later in the meeting to remove material that was not unique to the draft annex, they condensed the text in this section to focus on the harmonization of phytosanitary import requirements.

[116] The EWG noted that there was no definition of “**supply chain**” in ISPM 38, but it was important to be clear about the meaning of this term as used in the draft annex. The EWG returned to this matter later in this agenda item.

### ***What will a systems approach look like?***

[117] The EWG’s discussion about the purpose of systems approaches for seeds, and their later discussion about the elements comprising such approaches (see below), prompted the EWG to consider some of the broad, conceptual issues about how a systems approach would operate. Much of the discussion revolved around the issue of multilateral recognition.

[118] **Potential models for systems approaches.** The invited expert from the seed industry explained that the seed industry would prefer that for each commodity there would be just one way of producing it that meets the needs of multiple countries. She commented that if countries can add requirements on top of this, then that would be building a very complex system. The EWG noted, however, that the annex needs to be generic, to apply to any crop, and that it is the sovereign right of countries to add requirements if technically justified.

[119] The EWG noted that in the Argentinian pilot model presented earlier (agenda item 5.2), a detailed protocol for the pest–crop combination is developed by the NPPO, who consults seed companies about their processes, and if any other companies wish to participate in the scheme, they would have to comply with the agreed protocol.

[120] **Multilateral recognition.** One EWG participant expressed the view that multilateral recognition would be achieved when more than one importing country accepted the system established by the country of origin. This was supported by another EWG participant, who added that the main role of the annex is to provide a framework that defines the basic requirements of a systems approach, which would facilitate multilateral recognition. A further EWG participant commented that for the systems approach to be multilaterally recognized, the countries recognizing it would need to agree on the list of pests to be addressed as well as the measures, and the countries would all need to comply with those measures.

[121] The EWG noted that examples do exist for other classes of commodity where multiple countries accept a system used by an exporting country, so there may already be mechanisms in place for this, but the difference with systems approaches for seeds would be that there are several exporting countries as well as several importing countries.

[122] **Phytosanitary certification.** The EWG noted that if seed is produced under a systems approach in the country of origin and then exported to a second country for a treatment that is not available in the country of origin, then the second country may issue a phytosanitary certificate of re-export, provided this information is given in the additional declaration on the certificate and, in accordance with ISPM 12 (*Phytosanitary certificates*), the certificate is accompanied by the original phytosanitary certificate or a certified copy. This would mean that if the final destination is a country that recognizes the systems approach, then it would recognize the measures that have been applied in the country of origin and the country of re-export. This principle would apply to each country in the supply chain where an additional phytosanitary measure (treatment or testing) has taken place, with a certificate being added at each stage,

to maintain the link with the originating phytosanitary certificate. The process of issuing phytosanitary certificates would therefore be as it currently stands.

[123] **Acceptance of untreated commodities by importing and re-exporting countries.** One EWG participant commented that, where treatments essential to the systems approach were undertaken after export from the country of origin, all the countries receiving the consignment before treatment would need to accept that the consignment had not been subject to the complete set of measures in the systems approach, and so would need to be flexible about their phytosanitary import requirements. Such consignments would not pose a pest risk if the treatment was applied, but at the time of import the NPPO of the re-exporting country could not be sure that the treatment was going to be applied and so the seed would need to be released to a secure facility that was under official control and there would need to be a level of trust between the NPPO and the seed companies. The EWG noted, however, that if there were a multilateral agreement between the countries in the supply chain, this would include the phytosanitary import requirements of all the countries in the supply chain and the detail of what is done in each country. The re-exporting countries would therefore know that they would be receiving seeds that had not completed the systems approach. The requirements for a country where the seed was only going to be treated would also be less than for the country where it was going to be planted.

[124] The EWG noted that it would be helpful to include a flow chart of the supply chain in the draft annex, with more than one country of re-export.

[125] **Scope of the systems approach.** The EWG considered whether a systems approach would cover the whole process from breeding of the seed, through multiplications, to its eventual commercial sale. The invited expert from the seed industry suggested that it should cover the whole process. Another EWG participant suggested that it should be applicable to the consignment or lot being exported. A third participant suggested that it should be implemented by the country of origin, as the country of origin is exposed to the greatest pest risk, and that it would become multilateral when it is recognized by more than one country. To avoid confusion, the latter participant further suggested that as the systems approaches described in ISPM 14 are implemented by the country of origin, any approach that spanned multiple countries would need to be called something other than a “systems approach” – perhaps simply a “multilateral agreement”. The EWG noted, however, that the reason for this draft annex was a recognition that ISPM 14 worked well for bilateral agreements, but not for commodities such as seeds that are moved through several countries, so the draft annex needed to go beyond ISPM 14 because of the unique aspects of the seed industry. The draft annex would not be in conflict with ISPM 14 because the systems approaches described in the annex would include the various elements of systems approaches described in ISPM 14 (e.g. incorporation of seed production practices and the need to fulfil the phytosanitary import requirements of the importing country). Later in the meeting, the EWG added text to the Introduction section of the annex to explain that “**multilateralism**” referred to the recognition, by more than two countries through an agreement, of a systems approach implemented by the country where the seeds were produced.

[126] The EWG noted that, although seed may go through different processing and treatment stages in different countries, the phytosanitary certification relates to the original seed lot; as soon as the seed is planted in another country for multiplication, then that seed becomes a new entity and so cannot be certified under the original systems approach. The EWG therefore agreed that, for the purposes of this annex, the term “**seed supply chain**” referred to the supply chain from the time the seed is planted in the country of origin through all subsequent processes and procedures until the seed is next planted (i.e. it would stop before multiplication), and added text to this effect in the introductory section of the annex. They noted that the ISPM 5 definition of “country of origin” referred to the country where the plants, in this case the plants from which the seed lot was harvested, were grown.

[127] The EWG acknowledged that the phytosanitary import requirements along the supply chain may not all be known at the time of export from the country of origin, because the countries in the supply chain might not all be known or the seed may be stored for a few years and the requirements change in that time, so it would be challenging to establish a systems approach for the whole supply chain.

Furthermore, the EWG recognized that the systems approach would only cover those countries that accepted the systems approach in question.

### *Elements of a systems approach for seeds*

- [128] The EWG drafted text outlining the various elements of a systems approach for seeds, referring to ISPM 38 and ISPM 14. These included the use of seed production practices, quality management systems, additional risk management measures if needed, monitoring and verification by NPPOs, PRA, independent and dependent measures, assessment of the efficacy of measures and a mechanism to ensure traceability. When referring to quality management, they recognized that smaller companies may not have a formal quality management system, but may still have the necessary practices in place; however, this would be covered in the annex by referring both to seed production practices and to existing quality management systems. The EWG noted that although NPPOs of importing countries would retain the sovereign right to require additional mitigation measures over and above those in the systems approach (to meet their appropriate level of protection or as emergency measures), such measures could only be required if they were technically justified.
- [129] Returning to the debate about the geographical scope of a systems approach, the EWG considered again whether a systems approach refers only to the measures applied in the country of origin, with any subsequent treatments or other measures applied in importing or re-exporting countries being considered as “additional measures”, or whether the systems approach spanned all the countries of the supply chain. The EWG did not reach a consensus at this point, but did agree that risk mitigation practices are applied in more than one country. They therefore included text recognizing the latter in the annex.
- [130] The EWG noted that, in a systems approach for seeds, it would be important not only to use resistant varieties where possible, but also to ensure that the mother plant was not infected, as the infection can pass from the mother plants to the tissue of its seeds. The same does not apply to father plants.
- [131] When reviewing the draft text later in the meeting to remove material that was not unique to the draft annex, the EWG removed the references to ISPM 38 and ISPM 14 and the lists of associated elements that should be included in systems approaches for seeds. They also removed some general text that they had drafted about the range of complexity that may be found in systems approaches for seeds.
- [132] **Harmonization.** The EWG noted that traceability and the harmonization of phytosanitary measures (or phytosanitary import requirements) were particularly important for systems approaches for seeds. This prompted a discussion about the meaning of “harmonization” in this context. One EWG participant commented that an example would be if countries agreed which pests were “in scope” for a particular commodity; without such harmonization there might not be any added value in having a systems approach. Another EWG participant suggested that it would be better to refer to “equivalence” or “recognition”, rather than harmonization. The Steward referred to the ISPM 5 definitions of “equivalence” and “harmonization” and to ISPM 24 (*Guidelines for the determination and recognition of equivalence of phytosanitary measures*), and explained that the principle of equivalence is also enshrined in the IPPC itself. As the ISPM 5 definition of “harmonization” related to the implementation of ISPMs by multiple countries, the Steward suggested that this term not be used in its looser, dictionary sense in the draft annex.
- [133] The EWG returned to the issue of harmonization later in the meeting and agreed that phytosanitary import requirements for seeds should be directed only at those regulated pests that are known to follow the seed pathway concerned or for which there is another technical justification. They also agreed that, for the same pest–pathway combination, the countries participating in a particular systems approach should all use the same additional declaration on their phytosanitary certificates. The same declaration may also be accepted by the NPPOs of other importing countries if they determined that it provided their appropriate level of protection.
- [134] **Pests “in scope”.** The invited expert from the seed industry confirmed that seed companies are well aware of seed-transmitted pests, where the main risks lie, and what they can do to address those risks. In general, the list of pests focused upon will be largely the same for different companies. She

commented, however, that companies cannot approach the NPPOs of other countries, so any discussions with the NPPOs of importing countries needed to be between NPPOs. She made the point that it would be impossible to approach all importing countries for each variety that a company sells, but the EWG noted that a systems approach would be per commodity, not per variety, and that the variety made no difference for PRA.

[135] The EWG noted that PRA, especially in a multilateral approach, would not be the same as described in ISPM 38, because NPPOs would need to look at a group of pests of common concern to all the countries in the multilateral agreement; so, an NPPO may need to consider pests that are not of concern in its own country but are a problem in another country. The EWG also recognized that, in addition to these pests of common concern, the pests unique to each participating country would also need to be considered.

[136] **Collaboration between NPPOs and seed companies.** The EWG agreed that it would be the responsibility of the NPPO to specify the measures that comprise the systems approach, but recognized that there are also other aspects of a systems approach that would either be outside the area of expertise or the remit of NPPOs (e.g. the detail of traceability mechanisms, data held by seed companies on the seed testing they conduct, varietal information held by seed companies). The NPPO of the exporting country would therefore need to liaise with seed companies when drawing up and implementing those elements of the systems approach, not only in the country of origin, but also in the others participating in the agreement, although the burden would fall mostly on the NPPO of each of those countries.

### *Design of a systems approach*

[137] The EWG drafted some text about the general design of a systems approach, explaining that such approaches can be established either as a bilateral or a multilateral agreement. In either case, the EWG agreed that the NPPO should cooperate with seed companies when designing the systems approach.

[138] The EWG recognized that additional risk mitigation measures may be needed if it is determined that the existing seed production practices used by industry provide insufficient protection.

[139] **Bilateral agreements.** The EWG decided that there was no need to expand further on bilateral agreements, as ISPM 14 assumed a bilateral agreement and many other ISPMs were written with bilateral agreements in mind, so NPPOs were used to setting these up.

[140] **Multilateral agreements.** For multilateral agreements, the EWG noted that it was important that, for each agreement, the roles and responsibilities of each participating NPPO were clear in relation to mitigating pest risk, monitoring the systems approach and verifying it.

[141] The EWG then returned again to the broad conceptual question of how to design a multilateral systems approach that works. They noted that the text they had drafted could result in several groups of countries, with each group having a different systems approach: not only could this get very complicated, but it could make it impossible for seed companies to meet the requirements of all these systems approaches if the different systems approaches conflict with each other. This would not then be an improvement on the current situation. The EWG noted that this could be resolved by having a single systems approach per commodity, but recognized that the draft annex could not specify this as a requirement. The draft annex could, however, say that a multilateral systems approach agreement (per crop) should preferably include as many countries as possible. The EWG noted that as new countries joined an existing multilateral agreement, the systems approach may need to be adjusted to accommodate the risk mitigation measures needed for the regulated pests in the new countries. The systems approach therefore needed to be flexible.

[142] The EWG noted that although the number of pests to be addressed by the systems approach may increase with an increasing number of countries participating in a systems approach, this may not be the case if the consignments are simply being re-exported. However, if the number of pests did increase, the analysis of whether seed production practices mitigate the risk to acceptable levels may be more complex.

- [143] The invited expert from the seed industry commented that an accumulation of requirements for multiple countries would mean that there would be little incentive for seed companies to participate in a multilateral systems approach. The EWG noted that ISPM 24 gave guidance on the equivalency of methods, which should help NPPOs determine whether phytosanitary import requirements from different countries were equivalent and hence reduce the burden on seed companies. Later in the meeting, however, the invited expert from the seed industry commented that, in the experience of the seed industry, it was very difficult to get agreement from NPPOs on the equivalence of seed production practices that were different to measures specified in phytosanitary import requirements. The EWG speculated that, in the longer term, the ideal situation of one global systems approach per crop might eventually be achieved if a group of countries built an initial systems approach for a particular crop and then gradually other countries joined it.
- [144] The EWG recognized that, in some countries, the regulatory framework may not allow multilateral arrangements. In these cases, the countries concerned would not be able to participate in a multilateral systems approach. The EWG considered whether to refer to this in the draft annex, but concluded that it was not necessary.
- [145] **Terminology for seed companies.** The Secretariat recalled that “operator” is used in ISPM 44 (*Requirements for the use of modified atmosphere treatments as phytosanitary measures*) to refer to a person operating equipment, so recommended that it not be used in this draft annex to refer to a seed company. The EWG decided instead to use “entity”, although recognized that care would need to be taken to avoid confusion with entities authorized to perform phytosanitary actions in accordance with ISPM 45. Later in the meeting, when discussing the text for the section on Responsibilities, the EWG also noted that the entities in question included not only seed companies but also other entities such as treatment providers.

### **Commodity**

- [146] The EWG considered under what circumstances an NPPO would identify a commodity as being a potential candidate for a systems approach. One EWG participant gave an example of a situation where the measures being proposed by the importing country were too onerous for the exporting country to meet, because they were too costly for the industry to undertake, so the NPPO of the exporting country proposed that a single costly measure was replaced by a series of stepped measures along the production pathway that together addressed the risks for the importing country, but at a lower cost. The EWG considered whether to say in the annex that a systems approach may be particularly applicable to those situations where the alternative of testing would be too onerous (i.e. too impractical or too costly), and whether to include examples, such as small seed lots for breeding purposes. However, they recognized that this could deter NPPOs from using systems approaches for other situations, including large seed lots, where there are still advantages to be gained from using a systems approach.
- [147] The EWG noted that ideas for which commodities may be suitable for a systems approach could come from the seed industry as well as the NPPO. They therefore drafted text in the annex to encourage NPPOs to collaborate with the seed industry, and for entities in the seed industry to collaborate with each other, to identify commodities of mutual interest for development of a systems approach. The EWG noted that trade associations could play a role in representing seed-industry entities in discussions with the NPPO.
- [148] One EWG participant suggested that the annex strongly recommend that recommend that each systems approach is specific to one commodity.

### **Relevant pests**

- [149] The EWG drafted a section on the pests to be addressed by a systems approach. They noted that these would be the pests that are regulated in the importing country or, in the case of a multilateral agreement, the multiple importing countries along the seed supply chain. The EWG acknowledged that although, in some cases, a non-regulated pest may be used as an indicator of the effectiveness of the systems

approach (the “canary in a coal mine” approach), the systems approach itself would only be for regulated pests.

- [150] The EWG noted that it would be the responsibility of the NPPO of the exporting country to determine whether the systems approach *could* meet the phytosanitary import requirements of the importing country. It would be the sovereign right of the importing country to determine whether the systems approach *did* provide their appropriate level of protection.
- [151] The EWG noted that, ideally, all NPPOs that recognize the systems approach would agree on a common list of regulated seed-transmitted pests that are to be incorporated into the systems approach. They also recognized that seed companies would be able to identify the countries in the seed supply chain and know the regulated pests in those countries, so could be of assistance in drawing up the list.
- [152] Later in the meeting, however, when reviewing the text to remove material that was not unique to the draft annex, the EWG decided to remove this entire section on Relevant pests because it was already covered in the text of ISPM 38.

### *Identification of potential pest risk mitigation measures*

- [153] The EWG noted that the two aspects of pest risk mitigation practices that are not covered by ISPM 14 or the core text of ISPM 38 were: traceability (the identification of seed lots or consignments and their tracking along the seed supply chain); and the need for harmonized or recognized diagnostic methods for testing seeds. Traceability is of particular importance when seed lots pass through multiple countries and a treatment or other processing is applied in countries in the middle of this chain. To illustrate the challenges, one EWG participant gave the example of the labelling requirements under the Organisation for Economic Co-operation and Development seed varietal testing scheme: each lot has a label containing a unique reference, but the same label cannot be used after the seed has been treated and re-packed, because otherwise it might look like the package has been tampered with, so there is a mechanism of linking the pre-treatment label with the post-treatment label. With regard to harmonization, the EWG recognized that the principle of equivalence was addressed in ISPM 24, but decided that the issue needed to be highlighted in the draft annex because it was particularly important in the context of systems approaches for seeds.
- [154] One EWG participant raised the question of whether the draft annex should be an annex to ISPM 14 or ISPM 38, but the EWG noted that this was a question for the Standards Committee, not this EWG. The Chairperson confirmed that the EWG needed to focus on the tasks set for this EWG. The Steward added that it was appropriate for it to be an annex to ISPM 38, because it relates entirely to seeds and describes aspects of systems approaches that are unique to seeds.
- [155] At various points in their discussions, the EWG referred to “**critical control points**” in the seed supply chain. They noted, however, that should this concept be referred to in the draft annex, the term “**control points**” would be a more appropriate term, as the points only become “critical control points” after they have been assessed and found to be critical; also, the term “critical control points” is used in hazard analysis.
- [156] Mindful of their earlier discussion about the need for NPPOs to collaborate with seed companies regarding relevant information held by the companies (e.g. data for traceability purposes), the EWG considered whether to say that the NPPO would need to establish the conditions under which it accepts such information, but ultimately decided against this.
- [157] The EWG noted that if circumstances changed in the seed supply chain (e.g. a seed company moves its production location), this would necessitate a corresponding change in the systems approach agreement. Such changes could be made as part of a process of continuous improvement. The EWG therefore referred to continuous improvement in the section on minimum requirements (see below).

### *Establishment of minimum requirements*

- [158] The EWG drafted some text on the minimum requirements for a systems approach, noting that this was the most important part of the annex.
- [159] The EWG noted that, when developing a systems approach, the NPPO would first need to agree on a list of relevant seed-transmitted pests, recognizing that inclusion of a pest on this list would be dependent on the intended use of the seeds. For example, the requirements for a quarantine pest would be different when the intended use is treatment compared to when the intended use is planting. The NPPO would then need to identify the measures to be used to manage the risk of these pests, taking into account the biology of the pests. As this requires knowledge of the practices used by the seed industry, this would require liaison between the NPPO and seed companies. In multilateral agreements, the NPPOs in the seed supply chain may need to collaborate with each other before approaching seed companies. The EWG noted that if an NPPO deemed the practices used by industry not to be sufficiently effective, then additional measures (which could be phytosanitary measures) could be required by the NPPO.
- [160] The EWG agreed that the minimum requirements would include those referred to in the section on Identification of potential pest risk mitigation measures, but also the following: a continuous improvement process, training requirements for personnel, verification of seed testing methods and the proficiency of the seed testing laboratory, a process for detections of regulated pests, and record keeping. The systems approach would also need to include a procedure for reporting detections of regulated pests and a process for responding to such detections. Reports of detections along the seed supply chain would need to be passed back down the seed supply chain. The EWG considered whether to merge the paragraph they had drafted on reporting of detections with that on responding to the detections, but concluded that these two activities were sufficiently separate to warrant separate paragraphs.
- [161] The EWG agreed that the minimum requirements also included measures listed in the core text of ISPM 38, but noted that these should not be repeated in the annex.
- [162] The EWG noted that NPPOs may assess the effectiveness of the proposed systems approach by using pilot studies, by comparing the systems approach with seed commodity testing during implementation, and by monitoring once the systems approach has been implemented.
- [163] **“Phytosanitary measures”**. The EWG recognized that some seed production practices are not phytosanitary measures in their own right, even though they may be part of a systems approach that collectively is a phytosanitary measure. They therefore noted that “phytosanitary measure” should only be used where the intended meaning is as per the ISPM 5 definition, and agreed to use **“pest risk mitigation measures”**, or simply **“measures”**, throughout the draft annex when referring to measures in a wider sense.

### *Implementation in the exporting countries*

- [164] The EWG drafted some text about the implementation of a systems approach in an exporting country, including reference to communication between the NPPO and seed entities, and to monitoring and verification. The EWG noted that one of the requirements for the NPPO would be to maintain a registry of participating seed companies, and to communicate this information to other NPPOs as needed.
- [165] The EWG drafted some suggested wording for the additional declaration on phytosanitary certificates for export or re-export in relation to consignments produced in compliance with this annex.

### *Evaluating systems approaches for seeds*

- [166] The EWG considered the requirements needed for the evaluation of systems approaches for seeds. They noted that evaluation could take place at three different stages: during the design phase; when the importing country or countries are deciding whether to implement the systems approach; or periodically after implementation. They noted that evaluation applied equally to bilateral approaches (with one importing country) and multilateral approaches (with a chain of importing or re-exporting countries).

- [167] The EWG noted that re-evaluation of a systems approach may be prompted by interceptions, outbreaks, other nonconformities, changes in pest regulatory status, detection of non-regulated pests that are biologically similar to a regulated pest (as this may indicate that the system is not providing protection against the corresponding regulated pests), new or emerging pests, and another country joining the systems approach agreement. They noted that “nonconformity” was the appropriate term to use in this context, rather than “non-compliance”, as the latter was related to non-compliance with phytosanitary certification (e.g. if seed testing revealed that a consignment was infested) whereas the intended meaning here was wider (the incorrect or ineffective application of measures).

### ***Responsibilities of NPPOs***

- [168] The EWG recognized that it would be preferable to avoid the unnecessary development of multiple systems approaches for the same commodities, as this would result in a level of complexity that would neither be of benefit to NPPOs nor be commercially feasible for the seed industry. They therefore drafted text for the annex encouraging NPPOs to participate in existing systems approaches, where these approaches meet their appropriate level of protection, rather than developing their own systems approach.
- [169] The EWG drafted a list of additional responsibilities for NPPOs of exporting countries, including implementing the requirements of the systems approach, approving entities that seek to participate in it, and monitoring and verifying the conformity of those entities with the systems approach. The EWG considered how specific the annex needed to be in terms of the frequency of auditing and concluded that this would be up to the NPPO to decide but that the draft annex should at least give some guidance about the maximum length of time between audits. They set this as no more than four years, noting that any entities that are ISO:9001 accredited have to be audited every three years, which would fit within this time frame. The EWG added reference to ISPM 45 in the draft annex to highlight that the monitoring and verification activities described in the annex may be performed by entities authorized by the NPPO, rather than the NPPO itself, if the NPPO chooses to do so.
- [170] One EWG participant suggested some further responsibilities to add to this list, including: designing the systems approach, considering industry practices; assessing the effectiveness of industry practices and adding new ones if needed; establishing a channel of communication between NPPOs participating in the systems approach agreement and between the NPPO and companies within each participating country, providing information to other NPPOs if needed, re-evaluating the systems approach if needed, and issuing phytosanitary certificates with the agreed wording for the additional declaration. As time in the meeting was running short, however, the EWG agreed to leave this for the Standards Committee to consider when reviewing the draft annex.

### ***Responsibilities of entities other than NPPOs***

- [171] The EWG identified the responsibilities of entities other than NPPOs, noting that these included not just seed companies but also entities such as treatment providers. They agreed that the entities would have a responsibility to identify the countries involved in the supply chain for any particular seed commodity, communicate with the NPPO of the country of production about their seed production practices, and make the relevant information available to that NPPO.
- [172] Earlier in this agenda item, the EWG noted that, in other systems, the accredited entity is responsible for what is done by subcontractors, and the same principle could be expected to apply to systems approaches for seeds.

### ***General comments on the annex***

- [173] In the final session of the meeting, the EWG considered the usefulness of the annex as drafted. The invited expert from the seed industry, who was unable to attend the final session, had submitted some brief comments by email beforehand, expressing concern that the implementation of the annex as drafted would lead to a much more complex system than currently exists. She had commented that the cumulative number of pests relevant for all countries along the supply chain and the number of associated phytosanitary import requirements would lead to more complexity rather than to

simplification, and for every crop–company (or companies)–country (or countries) combination, a new systems approach would need to be negotiated. This would result in a large number of systems approaches and seed companies would need to address the differing requirements contained in them. She suggested that this would offer no incentive to seed companies to use systems approaches rather than the existing inspection and testing arrangements.

[174] The Steward acknowledged these concerns and recalled that the purpose of the annex was to provide NPPOs with an alternative to consignment-by-consignment inspection and testing by building on what the seed industry is already doing. To provide this, it was not sufficient just to produce an annex that resulted in the alignment of systems approaches, but the annex also needed to allow for the efficient movement of seeds. Without this, there would not only be no incentive for seed companies to use the approach described, but also there would not be much advantage for NPPOs.

[175] The EWG recognized that the seed industry was looking for phytosanitary import requirements to be restricted to only those regulated pests that are known to be pathways for seed-transmitted pests and for its existing quality management systems – which it believes should be sufficient to meet most countries’ phytosanitary import requirements – to be recognized. The EWG also recognized that the seed industry operates with very short time windows for planting, so needs an efficient system of moving seeds, because if there is a problem or delay in the supply chain, it can affect the whole supply chain. But the EWG noted that the main challenge from a phytosanitary perspective was that the pest risk mitigation measures may not all be applied in the same country. Furthermore, although the EWG recognized that the seed industry is seeking predictability, this would be hard to achieve because the pests being addressed and the measures being used would need to be reassessed whenever a new importing country joined any given systems approach.

[176] The EWG acknowledged that the early stages of establishing systems approaches for seeds were going to be complex, but could not see a way of resolving the concerns expressed by the invited expert from the seed industry other than to ensure that the draft annex provided clear, specific guidance on systems approaches that was unique to seeds. With this in mind, and to avoid duplication with other ISPMs and the core text of ISPM 38, the EWG reviewed the text in the final session to identify the guidance that was unique to this annex, remove material that was not unique, and make the requirements more specific.

## **7. Any other business**

[177] The EWG reviewed progress against the tasks set out in Specification 70 and agreed that they had addressed all of them except for Task 9 (on biodiversity and the environment) and Task 10 (on potential implementation issues). They also recognized that the text still needed refining. As there was no more time available in the meeting, the EWG agreed to submit comments on the outstanding matters by correspondence after the meeting, for consideration by the Steward. The Secretariat noted that potential implementation issues raised during the course of the meeting could also be extracted from the meeting report.

[178] The EWG:

- (1) *agreed* to submit any comments on the draft annex, including comments about Task 9 and Task 10 of Specification 70, to the Secretariat (with copy to the Steward and Assistant Steward) by 8 November 2021.

## **8. Close of the meeting**

[179] The Secretariat thanked the EWG participants for their work, and the Steward and Assistant Steward for their guidance. The Steward also expressed her gratitude, particularly given the challenges presented by this topic. She reminded the EWG members that when the draft annex is ready for consultation, the EWG members will be able to comment via their NPPOs.

[180] The Chairperson closed the meeting.

**Appendix 1: Agenda**

<b>Agenda Item</b>		<b>Document No.</b>	<b>Presenter</b>
<b>1.</b>	<b>Opening of the Meeting</b>		
1.1	<ul style="list-style-type: none"> <li>Welcome by the IPPC Secretariat</li> <li>Introductions</li> </ul>	—	IPPC Secretariat
1.2	<ul style="list-style-type: none"> <li>Presentation of the standard setting process</li> <li>Roles of the Participants</li> </ul>	04_EWG_SA_2021_Oct presentation	CASSIN
<b>2.</b>	<b>Meeting Arrangements</b>	—	
2.1	Selection of the Chairperson	—	IPPC Secretariat
2.2	Selection of the Rapporteur	—	CHAIRPERSON
2.3	Adoption of the Agenda	01_EWG_SA_2021_Oct	CHAIRPERSON
<b>3.</b>	<b>Administrative Matters</b>	—	
3.1	Documents list	02_EWG_SA_2021_Oct	SHAMILOV
3.2	Participants list	03_EWG_SA_2021_Oct	SHAMILOV
<b>4.</b>	<b>Review of Specification</b>	<a href="#">Specification 70 - Annex Design and use of systems approaches for phytosanitary certification of seeds to ISPM 38 (International movement of seeds)</a>	ZLOTINA (Steward)
<b>5.</b>	<b>Review of discussion papers</b>	—	CHAIRPERSON
5.1	The Systems Approach Framework for the Export of New Zealand Seeds	05_EWG_SA_2021_Oct	RANDALL
5.2	Phytosanitary certification pilot plan for <i>zea mays</i> seeds for propagation and experimental purposes. Argentina's experience.	06_EWG_SA_2021_Oct presentation	NEDILSKYJ
5.3	USDA's Regulatory Framework for Seed Health: Accreditation Standard (draft), USDA's Regulatory Framework for Seed Health: Participant Manual (draft).	07_EWG_SA_2021_Oct 08_EWG_SA_2021_Oct	OSTERBAUER
5.4	Phytosanitary certification of seeds and SA in Japan."	09_EWG_SA_2021_Oct	UEMATSU
5.5	Information on system approach on seeds, experience and thoughts of GEVES France	10_EWG_SA_2021_Oct	GRIMAUULT
5.6	South Africa's experience in managing pests using systems approaches (during import, export, re-export, and in-transit), including challenges and possible solutions "	presentation	TSHIKHUDO
5.7	TBC	XX_EWG_SA_2021_Oct	SCHENK

Agenda Item		Document No.	Presenter
5.8	<ul style="list-style-type: none"><li>• An introduction to the seed industry</li><li>• An overview of management systems for seeds and systems approaches in other commodities</li><li>• Phytosanitary import requirements for seeds – cucumber seeds as an example</li><li>• Pest risk management options and how to integrate current industry practices or existing management systems in a systems approach for seeds</li><li>• Proposals on general requirements of a systems approach for seeds</li><li>• How multilateral acceptance of systems approach could work – ideas from the international seed sector</li></ul>	11_EWG_SA_2021_Oct  presentation	LANGENS
6.	<b>Development of text for the draft annex to ISPM 20</b> <i>Reference documents:</i>		CHAIRPERSON / CASSIN
	- <i>IPPC Style Guide and annotated templates (particularly Part 1, sections 2, 3 and 5)</i>	<a href="#">Link to the IPPC Style Guide</a>	
	- <i>ISPM 5 (Glossary of phytosanitary terms)</i>	<a href="#">Link to ISPM 5</a>	
	- <i>Guidelines for a consistent ISPM terminology (Section 3.3.2 of the IPPC Procedure Manual for Standard Setting)</i>	<a href="#">Link to the IPPC Procedure Manual for Standard Setting (2020-2021)</a>	
6.1	Brainstorming session to develop the outline of the ISPM	<a href="#">ISPM38</a>	CHAIRPERSON / ALL
6.2	Elaboration of the text of the draft annex to ISPM 38	<a href="#">Link to the Annotated template for draft ISPMs</a>	ALL
7.	<b>Any Other Business</b>	–	CHAIRPERSON
8.	<b>Close of the Meeting</b>	–	IPPC SECRETARIAT / CHAIRPERSON

**Appendix 2: Documents list**

DOCUMENT NO.	AGENDA ITEM	DOCUMENT TITLE	DATE POSTED / DISTRIBUTED
<b>Administrative Documents</b>			
01_EWG_SA_2021_Oct	2.3	Provisional agenda	2021-09-30
02_EWG_SA_2021_Oct	3.1	Documents list	2021-09-30
03_EWG_SA_2021_Oct	3.2	Participants list	2021-09-30
<b>Review of discussion papers</b>			
05_EWG_SA_2021_Oct	5.1	The Systems Approach Framework for the Export of New Zealand Seeds	2021-09-30
06_EWG_SA_2021_Oct	5.2	Phytosanitary certification pilot plan for zea mays seeds for propagation and experimental purposes. Argentina's experience	2021-09-30
07_EWG_SA_2021_Oct 08_EWG_SA_2021_Oct	5.3	USDA's Regulatory Framework for Seed Health: Accreditation Standard (draft), USDA's Regulatory Framework for Seed Health: Participant Manual (draft)	2021-09-30
09_EWG_SA_2021_Oct	5.4	Phytosanitary certification of seeds and SA in Japan."	2021-09-30
XX_EWG_SA_2021_Oct	5.5	Information on system approach on seeds, experience and thoughts of GEVES France	2021-09-30
Presentation to be provided	5.6	South Africa's experience in managing pests using systems approaches (during import, export, re-export, and in-transit), including challenges and possible solutions "	2021-XX-XX
XX_EWG_SA_2021_Oct	5.7	TBC	2021-XX-XX
11_EWG_SA_2021_Oct	5.8	<ul style="list-style-type: none"> <li>An introduction to the seed industry</li> <li>An overview of management systems for seeds and systems approaches in other commodities</li> <li>Phytosanitary import requirements for seeds – cucumber seeds as an example</li> <li>Pest risk management options and how to integrate current industry practices or existing management systems in a systems approach for seeds</li> <li>Proposals on general requirements of a systems approach for seeds</li> <li>How multilateral acceptance of systems approach could work – ideas from the international seed sector</li> </ul>	2021-09-30

DOCUMENT NO.	AGENDA ITEM	DOCUMENT TITLE	DATE POSTED / DISTRIBUTED
Other documents			
04_EWG_SA_2021_Oct	1.2	Presentation: IPPC Standard Setting Process (for ISPMs) at a glance with a focus on the EWG	2021-09-

**Appendix 3: Participants list**

	Participant role	Name, mailing address, telephone	Email address
✓	Steward	Ms Marina ZLOTINA IPPC Technical Director USDA-APHIS, Plant Protection and Quarantine (PPQ) 4700 River Rd, 5c-03.37 Riverdale, MD 20737  USA Tel: 1-301-851-2200 Cell: 1 -301-832-0611	<a href="mailto:Marina.A.Zlotina@aphis.usda.gov">Marina.A.Zlotina@aphis.usda.gov</a>
✓	Assistant Steward	Mr Hernando Morera GONZÁLEZ Pest Risk Analyst Servicio Fitosanitario del Estado 300 Sur de Teletica, Sabana Sur, San José,  COSTA RICA Tel: +(506) 8660-8383	<a href="mailto:hmorera@sfe.go.cr">hmorera@sfe.go.cr</a>
✓	IC representative	Mr Thorwald GEUZE Senior Plant Health Officer-Food and consumer Product Safety Authority (NVWA) Catharijnesingel59, 3511 GG Utrecht,  The Netherlands Tel: +31-(0)6-51290267	<a href="mailto:t.geuze@nvwa.nl">t.geuze@nvwa.nl</a>
✓	Member	Ms Melisa NEDILSKYJ Professional Analyst Specialized in Plant Protection. Phytosanitary Regulations Division.  Argentina Tel: +54 911 5419 3856	<a href="mailto:mnedilsk@senasa.gob.ar">mnedilsk@senasa.gob.ar</a>
✓	Member	Ms Valerie GRIMAUULT Head of Laboratory of Phytopathology. GEVES-SNES  France Tel: +33 2 41 22 58 50	<a href="mailto:valerie.grimault@geves.fr">valerie.grimault@geves.fr</a>
✓	Member	Mr John RANDALL Senior Adviser, Plant Exports: with a focus on phytosanitary export assurance programmes (plants and plant products, including seed) and seed varietal certification  New Zealand Tel: +64 4 894 0530	<a href="mailto:John.Randall@mpi.govt.nz">John.Randall@mpi.govt.nz</a>

	Participant role	Name, mailing address, telephone	Email address
✓	Member	Ms Nancy OSTERBAUER  Assistant Director (AD) within the Plant Epidemiology and Risk Analysis Laboratory  USA Tel: 1-919-855-7530 (office), 1-919-348-5302 (mobile)	<a href="mailto:nancy.k.osterbauer@usda.gov">nancy.k.osterbauer@usda.gov</a>
✓	Member	Mr Hiroshi UEMATSU Senior Researcher, Phytopathological Section, Research Division Yokohama Plant Protection Station, Ministry of Agriculture, Forestry and Fisheries (MAFF) Japan Tel: +81-45-622-8847	<a href="mailto:hiroshi_uematsu210@maff.go.jp">hiroshi_uematsu210@maff.go.jp</a>
✓	Member	Dr Phumudzo TSHIKHUDO Scientist Production, Department of Agriculture  South Africa Tel: +27123196330	<a href="mailto:PhumudzoT@dalrrd.gov.za">PhumudzoT@dalrrd.gov.za</a>
✓	Member	Mr Martijn SCHENK Senior policy officer plant health at the Netherlands Food and Consumer Product Safety Authority  Netherlands Tel: +31 652565631	<a href="mailto:M.Schenk1@nvwa.nl">M.Schenk1@nvwa.nl</a>
✓	Invited expert	Ms Merel LANGENS Global Manager Industry Affairs  (International Seed Federation (ISF)) Tel: +31 (0) 6 24 36 75 70	<a href="mailto:merel.langens@vegetableseeds.basf.com">merel.langens@vegetableseeds.basf.com</a>

### IPPC Secretariat

	Region / Role	Name, mailing, address, telephone	Email address
✓	IPPC Secretariat	<b>Ms Adriana G. MOREIRA</b> OiC for the Standard Setting Unit in daily matters	<a href="mailto:Adriana.Moreira@fao.org">Adriana.Moreira@fao.org</a>
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✓	IPPC Secretariat	<b>Mr Artur SHAMILOV</b> Agricultural Officer	<a href="mailto:Artur.Shamilov@fao.org">Artur.Shamilov@fao.org</a>
✓	IPPC Secretariat	<b>Ms Karen ROUEN</b> Report writer	<a href="mailto:karen@karenrouen.com">karen@karenrouen.com</a>