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***[1]***DRAFT ANNEX to ISPM 38: Design and use of systems approaches for phytosanitary certification of seeds (2018-009)

***[2]*Status** **box**

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| ***[21]***Steward history | ***[22]***2019-05 SC Marina ZLOTINA (US, Lead Steward)  ***[23]***2024-05 SC Matías GONZALEZ BUTTERA (AR, Assistant Steward)  ***[24]***2019-05 SC Hernando Morera GONZÁLEZ (CR, Assistant Steward) |
| ***[25]***Notes | ***[26]***This section will remain on the drafts going for consultation but will be deleted before adoption.  ***[27]***2022-01 Edited  ***[28]***2024-05 Edited |

***[29]***This annex was adopted by the [XXX] Session of the Commission on Phytosanitary Measures in [XXX 20XX].

***[30]***The annex is a prescriptive part of the standard.

***[31]***1. Introduction

***[32]***This annex provides a general, standardized framework of requirements for national plant protection organizations (NPPOs) if developing systems approaches for seeds as an option for phytosanitary certification. Recognition of a systems approach by NPPOs may form the basis for phytosanitary certification of seeds, serving as an alternative to single measures such as seed treatment or seed testing when issuing a phytosanitary certificate. This annex describes the role and responsibilities of NPPOs in a systems approach for seeds and, if applicable, the role and responsibilities of participating entities.

***[33]***Systems approaches may include, in addition to commonly used phytosanitary measures, components of the existing production practices and quality systems used by participating entities, as far as they relate to pest management. These components can be effective at reducing pest risk to a level that is sufficient to meet phytosanitary import requirements as evaluated by NPPOs. When such components are used in a systems approach, NPPOs should collaborate closely with the participating entities, with NPPOs being responsible for identifying the pest risk, setting the acceptable level of pest risk for specified pests, designing the system, evaluating the effectiveness of the production-practice and quality-system components in reducing pest risk, and monitoring whether this effectiveness is being maintained throughout the entire seed supply chain.

***[34]***In this annex, the following terminology is used:

* ***[35]***“entities” refers to any parties, other than NPPOs, involved in the seed supply chain, such as seed producers and companies performing treatments;
* ***[36]***“seed supply chain” encompasses all steps related to seed production and movement (i.e. from pre-planting processes and procedures in the country of origin, through all subsequent processes and procedures taking place in different countries, as appropriate);
* ***[37]***“exporting country” refers to the country of origin and any countries of re-export; and
* ***[38]***“importing country” refers to any countries of re-export and the final destination country.

***[39]***1.1 Scope

***[40]***This annex applies to any seeds being moved internationally for any purpose. It describes the essential elements of a systems approach for seeds, which may include measures and practices already used by entities. The resulting systems approach may be evaluated and approved by NPPOs as a way to meet phytosanitary import requirements and, therefore, as a basis for phytosanitary certification.

***[41]***According to the core text of this standard, many pest management practices used in seed production may be integrated in a systems approach to reduce pest risk throughout the seed production process, from planting to harvesting, helping to meet phytosanitary import requirements.

***[42]***The pest risk management options described in this annex may apply to individual or groups of pests and should be considered sufficient to meet the phytosanitary import requirements of importing countries when integrated into a systems approach. This approach is consistent with the concepts and approaches described in ISPM 36 (*Integrated measures for plants for planting*), which does not cover seeds. If the NPPO of the importing country has indications that measures comprising the system approach do not properly address the pest risk posed by a particular regulated pest and therefore do not meet their phytosanitary import requirements, additional measures should be discussed with the NPPO of the country of origin.

***[43]***1.2 Background

***[44]***The development of a systems approach is described in ISPM 14 (*The use of integrated measures in a systems approach for pest risk management*) as a bilateral process involving the NPPO of an importing country and the NPPO of an exporting country, which may also involve stakeholders from industry. The NPPOs of several countries may also develop together a systems approach for export from, and import into, their countries. If this leads to the same systems approach for these countries, this becomes a multilateral systems approach, which may suit the multinational character of the seed trade. The benefits of such a multilateral systems approach, which involves multiple exporting and importing countries, are likely to be greater when a larger number of countries participate in it, providing more predictability for seed movement.

***[45]***As general guidance for developing a systems approach for seeds, this annex does not focus on any particular seed commodity but does address specific characteristics of the seed trade, such as the potentially long periods over which seeds can be stored and delivered to many different customers in different countries.

***[46]***The framework is based on combining measures that, in addition to commonly used phytosanitary measures, may include components of the existing production practices and quality systems used by participating entities. The resulting systems approaches are developed by NPPOs, considering each critical control point (CCP) along the seed supply chain. One of the requirements of the framework is that each entity participating in the systems approach should be authorized by the NPPO of the country of origin.

***[47]***A systems approach may be used as an equivalent alternative to stand-alone phytosanitary treatments to manage the pest risk (see ISPM 14) associated with the movement of seeds. Where used, systems approaches should be developed by NPPOs. This annex outlines the responsibilities of NPPOs and, if applicable, the basic requirements for each of the entities participating in the systems approach.

***[48]***1.3 Purpose of systems approaches for seeds

***[49]***According to ISPM 12 (*Phytosanitary certificates*), phytosanitary certification is used to attest that consignments meet phytosanitary import requirements and is undertaken by an NPPO. The purpose of systems approaches for seeds is to provide additional options for phytosanitary certification in line with the phytosanitary import requirements of all the NPPOs involved in the international movement of seeds along the seed supply chain. Any individual systems approach for seeds may involve the collaboration of NPPOs with the entities participating in that systems approach to ensure the health of seeds being produced and moved along the seed supply chain of the countries that recognize that systems approach. Elements of a systems approach are outlined in ISPM 14 and some of these may be relevant to a systems approach to seeds.

***[50]***1.4 Important considerations for systems approaches for seeds

***[51]***Characteristic aspects of seed production and trade, compared to the production of and trade in other plants and plant products, are the potentially long periods over which the seeds can be stored and delivered and the potential delivery to many different customers in different countries, with multiple re-exports. A systems approach for seeds, especially when including measures and practices used in the seed supply chain, may need to consider whether special requirements are needed for:

* ***[52]***seeds produced before an entity was authorized to participate in the systems approach (such seeds should not be traded under the systems approach);
* ***[53]***seeds produced before the systems approach was approved by the NPPO of an importing country (such seeds should be checked to determine to what extent they comply with the phytosanitary import requirements of the importing country);
* ***[54]***the transport of bulk seed;
* ***[55]***the storage of seeds; and
* ***[56]***the mixing or blending of seeds from different origins or places of production.

***[57]***Production practices used by participating entities may be included as measures in systems approaches if those practices are recognized by participating NPPOs as effectively managing pest risk. Such measures, in combination with the participating entities’ quality systems (including audit and other requirements as outlined in this annex), should be considered as meeting the phytosanitary import requirements of the importing countries.

***[58]***Systems approaches for seeds may be used to manage pest groups rather than individual pests (based on the concept outlined in ISPM 36). If systems approaches are developed for pest groups, NPPOs should allow additional declarations (see ISPM 12 for guidance) to use more generic wording rather than listing only individual species.

***[59]***To verify that regulated pests have been eliminated from the seed supply chain, NPPOs should always consider the feasibility of including seed testing as an independent measure within the systems approach or as a verification procedure.

***[60]***Recognition of the equivalence of measures, which may include pest testing methods and diagnostic protocols, by NPPOs can lead to more efficient implementation of systems approaches.

***[61]***2. Design of systems approaches

***[62]***General guidance on the concepts and development of systems approaches by NPPOs is presented in ISPM 14. Systems approaches should be designed to ensure the health of seeds throughout the seed supply chain, integrating measures to reduce pest risk in a defined, clear and simple manner.

***[63]***2.1 Identification of the commodity

***[64]***Entities may identify a seed commodity that is of interest for international trade purposes and propose to interested NPPOs of seed-producing countries that a systems approach be developed for that commodity. A systems approach may be developed in collaboration with participating entities in so far as they can contribute to the reduction of pest risk through the systems approach.

***[65]***2.2 Identification of individual pests or pest groups associated with the seed commodity

***[66]***For any particular seed commodity, a pest risk analysis (PRA) should be conducted and the pests or groups of pests expected to be associated with the seeds as a pathway should be identified (see ISPM 2 (*Framework for pest risk analysis*) and ISPM 11 (*Pest risk analysis for quarantine pests*)). A PRA also serves as a basis for the phytosanitary import requirements, taking into account the purpose of seed imports (i.e. intended use) to determine the strength of measures required. When a new pest emerges and a PRA shows that this pest is associated with the seed commodity that is covered by the systems approach, the systems approach should be re-evaluated and adjusted if necessary.

***[67]***2.3 Measures and critical control points

***[68]***This section provides examples of the pest risk management options available to NPPOs and participating entities for potential inclusion as integrated measures in a systems approach. Further information can be found in section 1.5 of this annex and Appendix 2 of the core text of this standard.

***[69]***The effectiveness of production practices in reducing pest risk should be evaluated by NPPOs before including them as measures in a systems approach. National plant protection organizations are responsible for identifying the CCPs at which these measures may be applied. The number of CCPs may vary, depending on the seed commodity.

***[70]***Example critical control points, and the associated regulatory actions and production practices that may reduce pest risk, are as follows:

1. ***[71]***pre-planting – site selection and preparation:

* ***[72]****regulatory actions –* surveillance to determine pest status, establishment of a pest free area, producer registration, review and approval of a system manual,
* ***[73]****production practices –* use of pest free area, pest free places of production or pest free production sites, use of buffer zones around growing sites, use of pest exclusion (e.g. greenhouse, screenhouse), use of crop rotation, removal of potential host, use of tested or clean water sources, maintenance of documentation, production of a system manual;

1. ***[74]***pre-planting – seed and plant inputs:

* ***[75]****regulatory actions* *–* approval of testing facilities and certification programmes, certification of transplant facilities,
* ***[76]****production practices* *–* use of tested or certified seed, application of transplant sanitation, use of resistant or less susceptible cultivars, use of seed treatments, maintenance of documentation;

1. ***[77]***production – pre-harvest:

* ***[78]****regulatory actions* *–* growing-season inspection, audits of facilities or review of their records,
* ***[79]****production practices* *–* growing-season examination of plants, growing-season treatments or pest management, plant sampling or testing, application of growing-site sanitation, worker training, maintenance of documentation;

1. ***[80]***production – seed harvest:

* ***[81]****regulatory actions* *–* field inspection at harvest, testing if appropriate,
* ***[82]****production practices* *–* disinfection of equipment before use in different fields or on different harvest dates, avoiding the harvest of seeds from sick unhealthy plants, use of harvest windows to avoid infestation, application of sanitation, maintenance of documentation;

1. ***[83]***post-harvest – conditioning and treatment:

* ***[84]****regulatory actions –* audits of operational facilities, verification of the efficacy of treatments,
* ***[85]****production practices –* fermentation to reduce seed residues, washing seeds to reduce the microbial contaminant load, application of seed treatments (e.g. heat, hot water, pesticide) upon receipt, milling and sorting to reduce contaminants on plants and dead seeds, application of sanitation, and maintenance of documentation;

1. ***[86]***post-harvest – handling and storage:

* ***[87]****regulatory actions* *–* facility audits and inspections,
* ***[88]****production practices* *–* storage of seeds with safeguards to prevent infestation, storage of seeds to maintain their health and identity, implementation of protocols to prevent the mixing of seed lots (cleaning of equipment), sealing of packaging to exclude pests, application of sanitation, maintenance of documentation;

1. ***[89]***post-harvest – seed quality testing:

* ***[90]****regulatory actions* *–* approval of testing facilities, approval or validation of sampling protocols, proficiency testing,
* ***[91]****production practices* *–* use of NPPO approved sampling protocols, use of approved testing facilities, use of approved testing protocols, application of sanitation, maintenance of documentation; and

1. ***[92]***distribution and transport:

* ***[93]****regulatory actions* *–* establishment of phytosanitary import requirements, audit or testing at import, post-entry quarantine, phytosanitary certification,
* ***[94]****production practices* *–* labelling to enable trace-back, application of sanitation (e.g. to ensure that conveyances are free from contamination), use of approved testing protocols, maintenance of documentation.

***[95]***2.4. Issuance of phytosanitary certificates

***[96]***A systems approach is a combination of measures and, depending on the phytosanitary import requirements, it may be indicated on a phytosanitary certificate as an additional declaration in accordance with ISPM 12.

***[97]***3. Responsibilities of NPPOs and participating entities in addressing pest risk along the seed supply chain

***[98]***National plant protection organizations are responsible for systematically determining the measures that comprise a systems approach and verifying their effectiveness at reducing the pest risk posed by potential pests associated with each of the production stages. These measures should be in accordance with international or regional standards for pest risk management and systems approaches and may include existing production practices and quality-system components. To maintain flexibility and innovation in the system, participating entities may propose novel equivalent measures for a particular CCP, which NPPOs should evaluate for their effectiveness and feasibility. Appendix 1 of this annex depicts regulatory and non-regulatory actions performed by NPPOs and entities respectively at each CCP along the seed supply chain.

***[99]***4. Monitoring

***[100]***Verification should be conducted at several levels of the seed supply chain. The NPPOs of the exporting countries should monitor the systems approach to ensure that the system is functioning satisfactorily. They should also conduct periodic audits and monitor the effect of any resulting modification to the participating entities’ pest risk management plan.

***[101]***Procedures for monitoring and audit, as well as criteria for determining when a systems approach is re-evaluated, should be put in place by NPPOs before entering a systems approach arrangement with entities (see ISPM 47 (*Audit in the phytosanitary context*)).

***[102]***5. Establishing performance criteria for authorization of participating entities

***[103]***When developing a systems approach, NPPOs should incorporate a mechanism, based on performance criteria, for authorizing entities along the entire seed supply chain.

***[104]***For an entity to be considered as conforming with the systems approach, it should meet the performance criteria for each measure associated with the systems approach that it applies. The entity should implement an approved quality system. The entity’s most effective production practices may be evaluated and approved by the NPPO developing the systems approach for integration into the systems approach (see section 2.3 of this annex).

***[105]***6. Multilateral systems approaches

***[106]***When the same systems approach is recognized by several importing countries, this becomes a multilateral approach, which may suit the multinational character of the seed trade. In multilateral systems approaches, particular attention should be paid to those elements occurring in the exporting countries after detection of a non-compliance.

***[107]***7. Evaluation of systems approaches for seeds

***[108]***National plant protection organizations participating in a systems approach should evaluate its effectiveness. This may be done by conducting pilot studies during the design phase before seeking full recognition of the systems approach for phytosanitary certification.

***[109]***These evaluations may be carried out on a representative number of consignments for the seed commodity at different stages of its production and over a designated period of time.

***[110]***With a multilateral systems approach, it may be particularly important to incorporate part of the evaluation into the design phase, when the decisions are made about which measures to include in the systems approach.

***[111]***When deciding whether a systems approach for a given seed commodity is acceptable, the NPPOs participating in the systems approach should evaluate whether it reduces pest risk to a level that allows the phytosanitary import requirements of all participating countries along the seed supply chain to be met. For importing countries, such evaluation should include consideration of the following information:

* ***[112]***information on pests regulated in the importing countries, for which the systems approach addresses the pest risk;
* ***[113]***a description of the mandatory measures in the systems approach and their effectiveness;
* ***[114]***documentation indicating the components of the systems approach under the control of each NPPO; and
* ***[115]***verification procedures in place.

***[116]***8. Roles and responsibilities

***[117]***8.1 Responsibilities of NPPOs

***[118]***A systems approach may be developed by the NPPO (or multiple NPPOs) of any importing country along the seed supply chain, in collaboration with the NPPOs of the exporting countries and, if applicable, entities that wish to participate in the systems approach.

***[119]***The NPPOs of exporting countries participating in a systems approach should communicate the integrated measures of the systems approach to the entities participating in the systems approach in their respective territories for implementation. Each NPPO with participating entities located in its territory should have a method for registering which of these entities are participating in the systems approach for a specific seed commodity and should communicate that information to other NPPOs as needed.

***[120]***All NPPOs that participate in, or recognize, the systems approach should establish a channel of communication between themselves on the conformity status of all participating entities, especially when different measures are applied in different countries.

***[121]***If a nonconformity is identified, it should be reported to the NPPO of the exporting country (country of origin or country of re-export). Identification of nonconformities should trigger the corrective actions for the participating entities specified in the systems approach agreement. It may also trigger a review of any specific measure in the systems approach, any part of the systems approach, or the entire systems approach. The NPPOs of importing and exporting countries should increase monitoring following the identification of critical nonconformities, or if they repeatedly identify other (i.e. non-critical) nonconformities, and immediately suspend recognition of the systems approach until corrective actions are taken (see also ISPM 45 (*Requirements for national plant protection organizations if authorizing entities to perform phytosanitary actions*)).

***[122]***The responsibilities of importing and exporting countries in relation to systems approaches are described in ISPM 14. In the case of a multilateral systems approach, the responsibilities of each NPPO participating in the systems approach along the seed supply chain should be identified. These responsibilities should, for each of the participating countries, include the harmonization of their lists of regulated pests, the analysis of the associated pest risk, the evaluation and description of the measures that comprise the systems approach, and the identification of the CCPs in the systems approach where those measures are to be applied.

***[123]***As countries participating in the systems approach develop harmonized requirements, any new NPPO joining the systems approach should evaluate if they are able to meet the phytosanitary requirements for those elements of the systems approach that are applicable to them.

***[124]***8.2 Responsibilities of entities participating in systems approaches

***[125]***Entities participating in a systems approach should collaborate with NPPOs on the following:

* ***[126]***Participating entities should identify the countries involved in the seed supply chain for the seed commodity.
* ***[127]***If an NPPO wishes to develop a systems approach, it should identify the list of regulated pests potentially associated with the seed commodity in the seed supply chain. The entities involved should provide all relevant information on production practices and quality systems, including any data related to the effectiveness of the practices in reducing pest risk, to allow the NPPO to evaluate these practices for inclusion in the systems approach. This information may relate to practices during any stage of seed production and distribution and to measures applied in other countries along the seed supply chain.

***[128]***8.2.1 Quality systems for authorization of entities

***[129]***The use of a quality system formalizes the processes used to maintain quality and provides the basis for consistency, which can lead to the delivery of a commodity with predictable or reliable quality. A quality system provides the mechanism to align processes and product quality regardless of country of origin.

***[130]***As a minimum, the components of a quality system for entities should include:

* ***[131]***a quality policy that describes the commitment and goals towards which the entity is working;
* ***[132]***standard operating procedures, which are the detailed methods that are executed to produce the quality commodity;
* ***[133]***systems for training, auditing, and issuing corrective actions;
* ***[134]***record-keeping; and
* ***[135]***continuous improvement.

***[136]***8.2.2Reporting and addressing nonconformities

***[137]***Entities participating in a systems approach should have a procedure, agreed with the authorizing NPPO, for reporting detections of a regulated pest and any corrective actions taken. Critical or multiple other nonconformities may lead to the exclusion of nonconforming parties from the systems approach.

***[138]***This requirement includes pest detections at the authorized entity’s facility or facilities (see ISPM 45 for guidance). The entity’s report to the NPPO should include a root-cause analysis to identify how the regulated pest was introduced into the seed supply chain, any proposed adjustments to the systems approach in response to a detection, and how the effectiveness of those adjustments may be verified.

***[139]***Procedures used to notify the NPPO of nonconformities detected while conducting internal audits in accordance with ISPM 47 and of corrective actions taken should be documented:

* ***[140]***The authorizing NPPO should be notified of any critical nonconformity (see ISPM 45 and ISPM 36 for guidance) during the time frame specified in the authorization agreement. The notification should include official confirmation of the pest identity and determination of the regulatory response.
* ***[141]***The entity should document the procedure by which it notifies the authorizing NPPO of any other nonconformities within the time frame agreed by the NPPO and the entity.

***[142]***Potential implementation issues

***[143]***This section is not part of the standard. The Standards Committee in May 2016 requested the Secretariat to gather information on any potential implementation issues related to this draft. Please provide details and proposals on how to address these potential implementation issues.

***[144]***This appendix is for reference purposes only and is not a prescriptive part of the standard.

***[145]***APPENDIX 1 OF ANNEX 1: An example of critical control points along the seed supply chain where seed pest risk considerations exist and pest risk can be managed by the regulatory actions of NPPOs together with the actions of participating entities

***[146]***(See next page.)

***[147]****Notes:* Blue boxes, critical control points along the seed supply chain; green boxes, national plant protection organization responsibilities; yellow boxes, participating entity responsibilities.

***[148]***AASCO, Association of American Seed Control Officials; ISTA, International Seed Testing Association.

***[149]****Source:* Adapted from United States Department of Agriculture. 2019. *ReFreSH – A regulatory framework for seed health*, version 4.0. Riverdale, USA, United States Department of Agriculture, Animal and Plant Health Inspection Service. 20 + vi pp. <https://www.aphis.usda.gov/sites/default/files/refresh-concept-paper.pdf>

***[150]***