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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2020-0088]

International Sanitary and Phytosanitary Standard-Setting Activities

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with legislation implementing the results of the Uruguay Round of negotiations under the General Agreement on Tariffs and Trade, we are informing the public of the international standard-setting activities of the World Organization for Animal Health, the Secretariat of the International Plant Protection Convention, and the North American Plant Protection Organization, and we are soliciting public comment on the standard-setting activities.

ADDRESSES: You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2020-0088>.
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2020-0088, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2020-0088> or in our reading room, which is located in room 1620 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: For general information on the topics covered in this notice, contact Ms. Jessica Mahalingappa, Associate Deputy Administrator for International Services, APHIS, room 1132, USDA South Building, 14th Street and Independence Avenue SW., Washington, DC 20250; (202) 799-7121.

For specific information regarding standard-setting activities of the World Organization for Animal Health, contact Dr. Paul Gary Egrie, Office of International Affairs, Veterinary Services, APHIS, 4700 River Road Unit 33, Riverdale, MD 20737; (301) 851-3304.

For specific information regarding the standard-setting activities of the International Plant Protection Convention, contact Dr. Marina Zlotina, PPQ's IPPC Technical Director, International Phytosanitary Standards, PPQ, APHIS, 4700 River Road Unit 130, Riverdale, MD 20737; (301) 851-2200.

For specific information on the North American Plant Protection Organization, contact Ms. Patricia Abad, PPQ's NAPPO Technical Director, International Phytosanitary Standards, PPQ, APHIS, 4700 River Road Unit 130, Riverdale, MD 20737; (301) 851-2264.

SUPPLEMENTARY INFORMATION:

Background

The World Trade Organization (WTO) was established as the common international institutional framework for governing trade relations among its members in matters related to the Uruguay Round Agreements. The WTO is the successor organization to the General Agreement on Tariffs and Trade. U.S. membership in the WTO was approved by Congress when it enacted the Uruguay Round Agreements Act (Pub. L. 103-465), which was signed into law on December 8, 1994. The WTO Agreements, which established the WTO, entered into force with respect to the United States on January 1, 1995. The Uruguay Round Agreements Act amended Title IV of the Trade Agreements Act of 1979 (19 U.S.C. 2531 *et seq.*). Section 491 of the Trade Agreements Act of 1979, as amended (19 U.S.C. 2578), requires the President to designate an agency to be responsible for informing the public of the sanitary and phytosanitary (SPS)

standard-setting activities of each international standard-setting organization. The designated agency must inform the public by publishing an annual notice in the *Federal Register* that provides the following information: (1) The SPS standards under consideration or planned for consideration by the international standard-setting organization; and (2) for each SPS standard specified, a description of the consideration or planned consideration of that standard, a statement of whether the United States is participating or plans to participate in the consideration of that standard, the agenda for U.S. participation, if any, and the agency responsible for representing the United States with respect to that standard.

“International standard” is defined in 19 U.S.C. 2578b as any standard, guideline, or recommendation: (1) Adopted by the Codex Alimentarius Commission (Codex) regarding food safety; (2) developed under the auspices of the World Organization for Animal Health (OIE, formerly known as the Office International des Epizooties) regarding animal health; (3) developed under the auspices of the Secretariat of the International Plant Protection Convention (IPPC or the Convention) and the North American Plant Protection Organization (NAPPO) regarding plant health; or (4) established by or developed under any other international organization agreed to by the member countries of the United States-Mexico-Canada Agreement (USMCA) or the member countries of the WTO.

The President, pursuant to Proclamation No. 6780 of March 23, 1995 (60 FR 15845), designated the Secretary of Agriculture as the official responsible for informing the public of the SPS standard-setting activities of Codex, OIE, IPPC, and NAPPO. The United States Codex Office (USCO), in the United States Department of Agriculture’s (USDA’s) Trade and Foreign Affairs mission area, informs the public of standard-setting activities of Codex, and USDA’s Animal and Plant Health Inspection Service (APHIS) informs the public of OIE, IPPC, and NAPPO standard-setting activities.

USCO publishes an annual notice in the *Federal Register* to inform the public of SPS standard-setting activities for Codex (85 FR 34161). Codex was established in 1963 by two

United Nations organizations, the Food and Agriculture Organization and the World Health Organization. It is the principle international organization for establishing food standards that protect consumer health and promote fair practices in food trade.

APHIS is responsible for publishing an annual notice of OIE, IPPC, and NAPPO activities related to international standards for plant and animal health and representing the United States with respect to these standards. Following are descriptions of the OIE, IPPC, and NAPPO organizations and the standard-setting agenda for each of these organizations. We have described the agenda that each of these organizations will address at their annual general sessions, including standards that may be presented for adoption or consideration, as well as other initiatives that may be underway at the OIE, IPPC, and NAPPO.

The agendas for these meetings are subject to change, and the draft standards identified in this notice may not be sufficiently developed and ready for adoption as indicated. Also, while it is the intent of the United States to support adoption of international standards and to participate actively and fully in their development, it should be recognized that the U.S. position on a specific draft standard will depend on the acceptability of the final draft. Given the dynamic and interactive nature of the standard-setting process, we encourage any persons who are interested in the most current details about a specific draft standard or the U.S. position on a particular standard-setting issue, or in providing comments on a specific standard that may be under development, to contact APHIS. Contact information is provided at the beginning of this notice under FOR FURTHER INFORMATION CONTACT.

OIE Standard-Setting Activities

The OIE was established in Paris, France, in 1924 with the signing of an international agreement by 28 countries. It is currently composed of 182 Members, each of which is represented by a delegate who, in most cases, is the chief veterinary officer of that country or territory. The WTO has recognized the OIE as the international forum for setting animal health

standards, reporting global animal disease events, and presenting guidelines and recommendations on sanitary measures relating to animal health.

The OIE facilitates intergovernmental cooperation to prevent the spread of contagious diseases in animals by sharing scientific research among its Members. The major functions of the OIE are to collect and disseminate information on the distribution and occurrence of animal diseases and to ensure that science-based standards govern international trade in animals and animal products. The OIE aims to achieve these through the development and revision of international standards for diagnostic tests, vaccines, and the safe international trade of animals and animal products.

The OIE provides annual reports on the global distribution of animal diseases, recognizes the free status of Members for certain diseases, categorizes animal diseases with respect to their international significance, publishes bulletins on global disease status, and provides animal disease control guidelines to Members. Various OIE commissions and working groups undertake the development and preparation of draft standards, which are then circulated to Members for consultation (review and comment). Draft standards are revised accordingly and are presented to the OIE World Assembly of Delegates (all the Members) for review and adoption during the General Session, which meets annually every May. Adoption, as a general rule, is based on consensus of the OIE membership.

The most recent OIE General Session was scheduled to occur from May 24 to 29, 2020, in Paris, France. The Associate Administrator for APHIS serves as the official U.S. Delegate to the OIE. Information about OIE draft Terrestrial and Aquatic Animal Health Code chapters may be found on the internet at

https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/export/international-standard-setting-activities-oie/regionalization/ct_international_standard_setting_activities_oie or by contacting Dr. Paul Gary Egrie (see FOR FURTHER INFORMATION CONTACT above).

The COVID-19 situation worldwide did not allow the OIE to have its General Session in 2020, and consequently no Code chapters were presented for adoption. The corresponding chapters will be proposed for adoption during the General Session tentatively scheduled for May 2021.

- Chapter 1.1., *Notification of diseases, infections and infestations, and provision of epidemiological information.*
- Chapter 1.4.3., *Animal Health Surveillance.*
- Chapter 1.6., *Procedures for self-declaration and for official recognition by the OIE.*
- Chapter 3.2., *Evaluation of Veterinary Services.*
- Chapter 3.4., *Veterinary legislation.*
- Chapter 4.Y., *Draft new chapter on official control programs for listed and emerging diseases.*
- Chapter 7.Z., *Draft new chapter on animal welfare and laying hen production systems.*
- Chapter 8.Y., *Infection with animal trypanosomes of African origin.*
- Chapter 8.15., *Infection with Rift Valley fever virus.*
- Chapter 9.4, Article 9.4.5., *Infestation with *Aethina tumida* (small hive beetle).*
- Chapter 10.4., *Infection with avian influenza viruses.*
- Chapter 15.2., *Infection with classical swine fever virus.*
- Articles 14.7.3., 14.7.7., 14.7.24. and 14.7.34., *Infection with peste des petits ruminants virus.*

IPPC Standard-Setting Activities

The IPPC is a multilateral convention adopted in 1952 to prevent the spread and introduction of pests of plants and plant products and to promote appropriate measures for their control. The WTO recognizes the IPPC as the standard setting body for plant health. Under the IPPC, the understanding of plant protection encompasses the protection of both cultivated and non-cultivated plants from direct or indirect injury by plant pests. The IPPC addresses the

following activities: Developing, adopting, and implementing international standards for phytosanitary (plant health) measures (ISPMs); harmonizing phytosanitary activities through adopted standards; facilitating the exchange of official and scientific information among contracting parties; and providing technical assistance to developing countries that are contracting parties to the Convention.

The IPPC is deposited within the Food and Agriculture Organization of the United Nations and is an international agreement of 184 contracting parties. National plant protection organizations (NPPOs), in cooperation with regional plant protection organizations, the Commission on Phytosanitary Measures (CPM), and the Secretariat of the IPPC, implement the Convention. The IPPC continues to be administered at the national level by plant quarantine officials, whose primary objective is to safeguard plant resources from injurious pests. In the United States, the NPPO is APHIS' Plant Protection and Quarantine (PPQ) program.

Because of the COVID-19 pandemic, the 15th Session of the CPM was tentatively postponed to 2021.

Standards recommended for adoption in 2020 will be tabled for adoption in 2021, and are listed below. The United States develops its position on each of these draft standards prior to the CPM session based on APHIS' analyses and other relevant information from other U.S.

Government agencies and interested stakeholders:

- Draft Revision of ISPM 8: *Determination of pest status in an area.*
- Draft ISPM: *Requirements for the use of modified atmosphere treatments as phytosanitary measures.*
- Draft ISPM 5: *Glossary of phytosanitary terms* (2018 revisions).

In lieu of the Commission meeting, the CPM Bureau has been advancing the IPPC work program, including standards setting, as actively as possible via virtual means. The IPPC Standards Committee and Implementation and Capacity Development Committee also continued working during the pandemic by virtually approving draft standards for consultation, selecting

experts to expert drafting groups, and addressing pending standard setting and other plant health initiatives. The IPPC electronic certification system (ePhyto) solution also progressed in 2020. For example, 27 countries in the European Union joined ePhyto through its own system of electronic certification named TRACES; Argentina and Chile moved to fully electronic operation for all their plant trade; the United Nations International Computing Centre and the ePhyto Steering Committee are developing and providing training on ePhyto; and preparations are underway to deploy features allowing industry systems to receive ePhytos.

New IPPC Standard-Setting Initiatives, Including Those Under Development

A number of expert working group (EWG) meetings and technical consultations took place from October 2019 through September 2020 on the topics listed below. These IPPC projects are currently under development and intended for future adoption and publication. APHIS participated actively and fully in each of these working groups. APHIS developed its position on each of the topics prior to the working group meeting. The APHIS position was based on relevant scientific information and technical analyses, including information from other U.S. Government agencies and from interested stakeholders:

- EWG for the focused revision of ISPM 12: *Phytosanitary certificates* in relation to re-export.
- Working group for the revision of the plant pest surveillance guide.
- Reviewing and commenting on the Implementation Guide to ISPM 8 currently under development.
- Reviewing and commenting on the draft outline of the future Implementation Guide on e-Commerce.
- Technical Panel on Diagnostic Protocols.
- Technical Panel on Phytosanitary Treatments.
- Technical Panel for the Glossary.

For more detailed information on the above, contact Dr. Marina Zlotina (see FOR FURTHER INFORMATION CONTACT above).

PPQ actively works to achieve broad participation by States, industry, and other stakeholders in the development and use of international and regional plant health standards, including through the use of APHIS Stakeholder Registry notices¹ and the APHIS public website. Plant health stakeholders are strongly encouraged to comment on draft standards, documents, and specifications during the consultation periods. In 2020, 16 draft standards (including phytosanitary treatments), 3 draft specifications, 1 draft outline, and 1 draft CPM recommendation were open for consultation. APHIS posts links to draft standards on its website as they become available and provides information on the due dates for comments.² Additional information on IPPC standards (including the IPPC work program (list of topics³), calls for new standards, experts to serve on technical panels and other working groups, proposed phytosanitary treatments, standard-setting process, and adopted standards) is available on the IPPC website.⁴ For the most current information on official U.S. participation in IPPC activities, including U.S. positions on standards being considered, contact Dr. Marina Zlotina (see FOR FURTHER INFORMATION CONTACT above). Those wishing to provide comments on any of the areas of work being undertaken by the IPPC may do so at any time by responding to this notice (see ADDRESSES above) or by providing comments through Dr. Zlotina.

NAPPO Standard-Setting Activities

NAPPO, a regional plant protection organization created in 1976 under the IPPC, coordinates the efforts among the United States, Canada, and Mexico to protect their plant resources from the entry, establishment, and spread of harmful plant pests, while facilitating safe intra- and inter-regional trade. As the NPPO of the United States, APHIS' PPQ is the

¹ To sign up for the Stakeholder Registry, go to:
<https://public.govdelivery.com/accounts/USDAAPHIS/subscriber/new>.

² For more information on the IPPC draft ISPM consultation:
https://www.aphis.usda.gov/aphis/ourfocus/planthealth/international/sa_phytostandards/ct_draft_standards.

³ IPPC list of topics: <https://www.ippc.int/en/core-activities/standards-setting/list-topics-ippc-standards/>.

⁴ IPPC website: <https://www.ippc.int/>.

organization officially identified to participate in NAPPO. Through NAPPO, APHIS works closely with its regional counterparts and industries to develop harmonized regional standards and approaches for managing pest threats. This critical work facilitates the safe movement of plants and plant products into and within the region. NAPPO conducts its work through priority-driven projects approved by the NAPPO Executive Committee via an annual work program, and conducted by expert groups, including subject matter experts from each member country and regional industry representatives. Project results and updates are provided during the NAPPO annual meeting as well as NAPPO governance meetings. Projects can include the development of positions, policies, technical documents, or the development or revision of regional standards for phytosanitary measures (RSPMs). Projects can also include implementation of standards or other capacity development activities such as workshops.

The 43rd NAPPO annual meeting was held October 28 to November 1, 2019, in Montreal, Canada. The meeting featured several strategic topics related to NAPPO's work program (e.g. seeds, forest pests, lab accreditation, plants for planting, biological control, and risk-based sampling), as well as discussions on sea containers, invasive species, the International Year of Plant Health (IYPH), the United States-Mexico-Canada Agreement (USMCA), and a live ePhyto exchange demonstration between the United States and Jamaica. The meeting also featured a 1-day symposium on comparing the decision-making procedures used by the three countries (Canada, Mexico, and the United States) when an exotic plant pest is confirmed in a NAPPO member country. The NAPPO Executive Committee meetings took place on October 28, 2019, and July 16, 2020 (virtual meeting). The Deputy Administrator for PPQ is the U.S. member of the NAPPO Executive Committee.

Despite the COVID-19 pandemic, NAPPO's Secretariat and its member countries, including regulatory, plant health, and industry officials, continue to actively progress on projects and initiatives under the NAPPO work program, taking advantage of teleconferencing and other virtual meeting tools. NAPPO governance committees, including NAPPO's Executive

Committee and the Advisory and Management Committee, as well as expert groups, continue to communicate and meet virtually on a regular basis to actively progress on NAPPO strategic and work program initiatives. NAPPO's Advisory and Management Committee continued working during the pandemic by virtually approving draft standards for consultation; selecting and onboarding experts to newly launched NAPPO expert groups on seeds and diagnostics, consignments in transit, and wooden and bamboo commodities; and addressing other pending work program initiatives. The NAPPO expert groups, including member countries' subject matter experts, in collaboration with NAPPO's Secretariat, significantly progressed or finalized the following regional standards, documents, products, and projects during the period of October 2019 to the end of September 2020:

- Reviewed, discussed, and agreed to archive RSPM 17: *Guidelines for the establishment, maintenance and verification of fruit fly free areas in North America*. Experts from all three member countries agreed that more comprehensive international standards have been adopted at the IPPC that effectively build-on and supersede RSPM 17.
- Completed and published proceedings from the NAPPO-organized March 2019, Hemispheric Workshop on ISPM 38: *International movement of seeds*. Proceedings are now available on the NAPPO website⁵.
- Completed the revision or development of the following regional standards and documents and launched them for country consultation (public comment period) during the summer of 2020: RSPM 9: *Authorization of laboratories for performing phytosanitary testing*, RSPM 5: *NAPPO glossary of phytosanitary terms*, and NAPPO Science and Technology (S&T) Document on the risks associated with the introduction of exotic lymantriid species of potential concern

⁵ Proceedings of the NAPPO Organized Hemispheric Workshop on ISPM 38: *International movement of seeds*: https://nappo.org/application/files/7115/8687/1174/Final__Proceedings_ISPM_38_Implementation_Workshop.pdf.

to the NAPPO region. As next steps, comments received from the consultation will be reviewed by expert group members to adjust the documents for eventual Executive Committee approval.

- Issued via NAPPO's Phytosanitary Alert System: 23 Official Pest Reports for Fiscal Year 2020 (from October 2019 to September 2020).

In addition, NAPPO conducted a call for new project proposals for its 2020 Work Program during 2019. U.S. stakeholders were invited to submit topics and comment on their priorities through APHIS. In late October 2019, the NAPPO call for new project proposals (taking stakeholders' comments into account) resulted in three new prioritized projects by the NAPPO's Executive Committee, which have been added to the 2020 annual work program. The new, prioritized projects focus on the following topics: The harmonization of diagnostic protocols for seed pests focused on Tomato brown rugose virus (ToBRFV); consignments in transit; and the import of wooden and bamboo commodities.

New NAPPO Standard-Setting Initiatives, Including Those in Development

The 2020 work program⁶ includes the following topics being worked on by NAPPO expert groups and NAPPO's Advisory and Management Committee. APHIS is actively and fully participating in the 2020 NAPPO work program. The APHIS position on each topic is guided and informed by the best technical and scientific information available, as well as on relevant input from stakeholders. For each of the following, where applicable, the United States will consider its position on any draft standard after it reviews a prepared draft. Information regarding the following NAPPO projects, assignments, activities, and updates on meeting times and locations may be obtained from the NAPPO website or by contacting Ms. Patricia Abad (see FOR FURTHER INFORMATION CONTACT above).

⁶ NAPPO work program:
https://mail.nappo.org/application/files/5415/8624/3760/FINAL_2020_NAPPO_Work_Program_-e.pdf.

1. Seed Diagnostics: A pilot for the harmonization of diagnostic protocols for seed pests focused on ToBRFV.
2. Development of harmonized regional guidance for North America based on ISPM 25: *Consignments in transit* and the IPPC Transit Manual.
3. Revision of RSPM 38: *Importation of certain wooden and bamboo commodities into a NAPPO member country*.
4. Revision of RSPM 22: *Guidelines for construction and operation of a containment facility for insects and mites used as biological control agents*.
5. Forest Products: Develop a NAPPO Science and Technology (S&T) document to provide scientific background on live contaminant pests associated with wood commodities and wood packaging; and provide guidance regarding actions appropriate for addressing related phytosanitary risks.
6. Support the IYPH: Exchange ideas, develop appropriate materials, and support IYPH events in the NAPPO region.
7. Revision of RSPM 9: *Authorization of laboratories for performing phytosanitary testing*.
8. Revision of RSPM 35: *Guidelines for the movement of stone and pome fruit trees and grapevines into a NAPPO member country*.
9. Lymantriids: Complete a NAPPO Science and Technology (S&T) document on the risks associated with the introduction of exotic lymantriid species of potential concern to the NAPPO region.
10. Revision of RSPM 5: *NAPPO glossary of phytosanitary terms*.
11. Risk-Based Sampling: Complete and publish a Risk-Based Sampling Manual.
12. Asian Gypsy Moth: Validate specific risk periods for regulated Asian gypsy moth in countries of origin.

13. Foundation and Procedure documents: Continue to update and finalize various NAPPO foundation or procedure documents.
14. Phytosanitary Alert System: Continue to manage the NAPPO pest reporting system.
15. Electronic phytosanitary certification (ePhyto): Provide assistance and technical support to the IPPC ePhyto Steering Group.
16. Stakeholder Engagement: Plan, coordinate and execute activities for the next NAPPO Annual Meeting, and publish the quarterly newsletter. Because of the COVID-19 pandemic, the 2020 NAPPO annual meeting has been postponed to 2021. The 2021 NAPPO annual meeting is expected to take place in the United States (and hosted by APHIS) in accordance with the NAPPO country rotation.
17. Regional Collaboration: Collaboration, focused on information exchange, with the Inter-American Coordinating Group in Plant Protection, via Technical Working Groups on ePhyto, citrus greening (Huanglongbing), fruit flies, and *Tuta absoluta*.

The PPQ Assistant Deputy Administrator, as the official U.S. delegate to NAPPO, intends to participate in the adoption of these regional plant health standards and projects, including the work described above, once they are completed and ready for such consideration.

The information in this notice contains all the information available to us on NAPPO standards or projects under development or consideration. For updates on meeting times and for information on the expert groups that may become available following publication of this notice, visit the NAPPO website or contact Ms. Patricia Abad (see FOR FURTHER INFORMATION CONTACT above). PPQ actively works to achieve broad participation by States, industry, and other stakeholders in the development and use of international and regional plant health standards, including through the use of APHIS Stakeholder Registry notices and the APHIS public website. Plant health stakeholders are strongly encouraged to comment on draft standards, documents, and specifications during consultation periods. In 2020, two revised NAPPO standards and one Science & Technology document were open for consultation.

APHIS posts links to draft standards on the Internet as they become available and provides information on the due dates for comments.⁷ Additional information on NAPPO standards (including the NAPPO Work Program, standard setting process, and adopted standards) is available on the NAPPO website.⁸ Information on official U.S. participation in NAPPO activities, including U.S. positions on standards being considered, may also be obtained from Ms. Abad. Those wishing to provide comments on any of the topics being addressed in the NAPPO work program may do so at any time by responding to this notice (see ADDRESSES above) or by transmitting comments through Ms. Abad.

Done in Washington, DC, this 23rd day of November 2020.

Mark Davidson,

Acting Administrator,

Animal and Plant Health Inspection Service.

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⁷ For more information on the NAPPO draft RSPM consultation:
https://www.aphis.usda.gov/aphis/ourfocus/planthealth/international/sa_phytostandards/ct_draft_standards.

⁸ NAPPO website: <http://nappo.org/>.