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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2019-0064]

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-2019-0064>.
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2019-0064, 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-2019-0064> or in our reading room, which is located in room 1141 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. Michael David, Director, International Animal Health Standards, Veterinary Services, APHIS, 4700 River Road Unit 33, Riverdale, MD 20737; (301) 851-3302.

For specific information regarding the standard-setting activities of the International Plant Protection Convention, contact Dr. Marina Zlotina, 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, 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 and welfare and zoonoses; (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 North American Free Trade Agreement (NAFTA) 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 Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS) informs the public of Codex standard-setting activities, and USDA's Animal and Plant Health Inspection Service (APHIS) informs the public of OIE, IPPC, and NAPPO standard-setting activities.

FSIS publishes an annual notice in the *Federal Register* to inform the public of SPS standard-setting activities for Codex. Codex was created in 1962 by two United Nations organizations, the Food and Agriculture Organization and the World Health Organization. It is the major international organization for encouraging international trade in food and protecting the health and economic interests of consumers.

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 occurred May 26 to 31, 2019, in Paris, France. The Deputy Administrator (a.k.a., Chief Veterinary Officer) for APHIS' Veterinary Services program serves as the official U.S. Delegate to the OIE at this General Session. 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. Michael David (see FOR FURTHER INFORMATION CONTACT above).

OIE Terrestrial and Aquatic Animal Health Code Chapters Adopted During the May 2019 General Session

Eleven Code chapters were amended, rewritten, or newly proposed and presented for adoption at the General Session. The following Code chapters are of particular interest to the United States:

1. Chapter 1.4., *Animal Health Surveillance*. Amendments to chapter included changes to the use of the terms “target population” and “study population.”
2. Chapter 4.Z., *Introduction to recommendations for the prevention and control of transmissible animal diseases*. This is a new chapter that has been reviewed in prior comment cycles and provides general considerations when controlling animal diseases.

3. Articles 7.13.4. and 7.13.15., *Animal welfare and pig production systems*. The United States supported the adoption of this new chapter in 2018. Minor editorial amendments were adopted in 2019.

4. Chapter 7.Y., *Killing of reptiles for their skins, meat and other products*. This is a newly adopted chapter that has been reviewed in prior comment cycles.

5. Chapter 8.14., *Infection with rabies virus*. The Code Commission highlighted the current global priority to control and eradicate dog-mediated rabies, and adopted changes to the chapter that are aligned with that priority. Additional provisions addressing wildlife vectors will be considered in the next revision of the chapter.

6. Article 14.4.1., *Infection with Chlamydomphila abortus (Enzootic abortion of ewes, ovine chlamydiosis)*. The name of the pathogenic agent changed from *Chlamydomphila abortus* to *Chlamydia abortus*.

7. Articles 15.1.1bis, 15.1.2., 15.1.3., 15.1.16., 15.1.22., 15.1.31., *Infection with African swine fever virus*. Amendments were made to strengthen the recommendations for testing wild or feral pigs found dead, road kills, animals showing abnormal behavior, and hunted animals sampled in surveillance programs.

OIE Terrestrial Animal Health Code Chapters for Upcoming and Future Review

- Chapter 1.1., *Notification of diseases, infections and infestations, and provision of epidemiological information*.
- Chapter 1.6., *Procedures for self-declaration and for official recognition by the OIE*.
- 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 10.4., *Infection with avian influenza viruses.*
- Chapter 15.2., *Infection with classical swine fever virus.*
- Chapter 8.11., *Infection with Mycobacterium tuberculosis complex.*
- Chapter 8.15., *Infection with Rift Valley fever virus.*
- Article 12.6.6., *Infection with equine influenza.*
- Articles 14.7.3. 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 183 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.

The 14th Session of the CPM took place from April 1 to 5, 2019, in Rome, Italy, at the Headquarters of the Food and Agriculture Organization of the United Nations. The Deputy Administrator for APHIS' PPQ program was the U.S. delegate to the CPM.

The CPM adopted the following standards at its 2019 meeting. The United States, represented by the Deputy Administrator for APHIS' PPQ program, participated in deliberations of these standards. The United States developed its position on each of these issues prior to the CPM session, which were based on APHIS' analyses and other relevant information from other U.S. Government agencies and interested stakeholders:

- ISPM 5: *Glossary of phytosanitary terms* (2019 revisions).
- ISPM 43: *Requirements for the use of fumigation as a phytosanitary measure*.
- Diagnostic protocols (DPs) as Annexes to ISPM 27: Diagnostic protocols for regulated pests:
 - DP 2: *Plum pox virus* (2018 revisions).
 - DP 25: *Xylella fastidiosa*.
 - DP 26: *Austropuccinia psidii*.
 - DP 27: *Ips* spp.
 - DP 28: *Conotrachelus nenuphar*.
 - DP 29: *Bactrocera dorsalis*.

The CPM also adopted Recommendation R08, "Preparing to use high-throughput sequencing (HTS) technologies as a diagnostic tool for phytosanitary purposes."

The CPM added to the IPPC work program new topics for 13 standards and 12 tools to implement standards, which were submitted by the contracting parties during 2018 call for topics.

In addition to adopting these plant health standards, the 2019 Commission meeting also progressed a number of plant health initiatives strategically important to the United States. These initiatives include endorsing the new IPPC strategic framework for 2020-2030 to set the top priorities for plant health and trade into the next decade, approving an electronic certification system (ePhyto) implementation plan to support trade and identifying next steps for its longer term worldwide application, developing programs aimed at improving the use and implementation of standards around the world, and planning events and activities for the International Year of Plant Health in 2020 to mobilize worldwide awareness and support for plant health going into the next decade.

New IPPC Standard-Setting Initiatives, Including Those Under Development

A number of expert working group (EWG) meetings or other technical consultations took place October 2018 through September 2019 on the topics listed below. These standard-setting initiatives are under development and may be considered for future adoption. APHIS intends to participate actively and fully in each of these working groups. APHIS developed its position on each of the topics prior to the working group meetings. The APHIS position was based on technical analyses, information from other U.S. Government agencies, and relevant scientific information from interested stakeholders:

- EWG on Audit in the Phytosanitary Context.
- Technical Panel on Diagnostic Protocols.
- Technical Panel on Phytosanitary Treatments.

- Technical Panel for the Glossary.
- Focus Group on Commodity Standards.
- Sea Container Task Force.

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 2019, 13 draft standards 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.

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/>.

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 intra- and inter-regional trade. As the NPPO of the United States, APHIS' PPQ is the 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. NAPPO conducts its work through priority-driven annual projects approved by the NAPPO Executive Committee 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. 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 42nd NAPPO annual meeting was held October 22 to 25, 2018, in Tucson, AZ. The meeting featured several strategic topics related to NAPPO's work program (e.g. seeds, plants for planting, accreditation, and forestry), as well as discussions on ePhyto, sea containers, e-Commerce, and trade facilitation. The meeting also featured a 1-day symposium that helped drive critical conversations among NAPPO countries about the importance of using risk-based approaches and developing precision safeguarding strategies using cutting-edge science and technology to maximize risk management. The NAPPO Executive Committee meetings took

place on October 22 and 26, 2018, February 20, 2019, and July 24, 2019. The Deputy Administrator for PPQ is the U.S. member of the NAPPO Executive Committee.

The NAPPO expert groups, including member countries' subject matter experts, finalized the following regional standards, documents, products, and projects in 2018-2019:

- Completed a Spanish language online training module on RSPM 12: Preparation of a Petition for First Release of a Non-indigenous Entomophagous Biological Control Agent. The English language module was completed the previous year.
- Organized and delivered a Western Hemisphere Workshop to promote the effective and harmonized implementation of ISPM 38: International movement of seeds in March 2019 in San Jose, Costa Rica. Participants in the workshop included more than 50 participants from the Americas represented by 13 NPPOs, 4 regional plant protection organizations, international and regional as well as national seed associations, companies related to seed production, and academia. The Inter-American Institute for Cooperation in Agriculture (IICA) also contributed to this event.
- Completed NAPPO RSPM 41: Use of Systems Approaches to Manage Pest Risks Associated with the Movement of Forest Products. The NAPPO Executive Committee approved this document during the 2018 October NAPPO annual meeting.
- Completed NAPPO Discussion Document 10: North American approach to preventing the introduction, establishment and spread of khapra beetle in the NAPPO Region. The document was finalized in April 2018.

- Completed and published proceedings of the first International Symposium on Risk-Based Sampling held in June 2017 in Baltimore, MD. Proceedings were made available in August 2018 (English). With the support from IICA, NAPPO completed the Spanish version in October 2018.
- Issued via NAPPO's Phytosanitary Alert System: 34 Official Pest Reports and 5 Emerging Pest Alerts for Fiscal Year 2019 (from October 2018 to September 2019).

In addition, NAPPO conducted a call for new project proposals for its 2020 Work Program during the period of April 1, 2019 to May 30, 2019. U.S. stakeholders were invited to submit topics through APHIS.

New NAPPO Standard-Setting Initiatives, Including Those in Development

The 2019 work program⁵ 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 2019 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).

1. Revision of RSPM 22: Guidelines for construction and operation of a containment facility for insects and mites used as biological control agents.

⁵ NAPPO work program: http://nappo.org/files/5015/5386/7708/EC-4-2019_NAPPO_Work_Program-with_IYPH-e.pdf.

2. Forest Products: Develop a NAPPO Science and Technology document to provide scientific background on live contaminating organisms on phytosanitary-certified wood products and IPPC-marked wood packaging and provide guidance regarding actions appropriate for addressing associated phytosanitary risks.
3. Revision of RSPM 17: Guidelines for the Establishment, Maintenance, and Verification of Fruit Fly Free Areas in North America.
4. Support the International Year of Plant Health (IYPH): Exchange ideas, develop appropriate materials, and support IYPH events in the NAPPO region.
5. Revision of RSPM 9: Authorization of Laboratories for Phytosanitary Testing.
6. Revision of RSPM 35: Guidelines for the Movement of Stone and Pome Fruit Trees and Grapevines into a NAPPO Member Country.
7. Implementation of ISPM 38- International movement of seeds: Complete and publish proceedings from 2019 Hemispheric Workshop on ISPM 38 (organized by NAPPO).
8. Lymantriids: Complete a NAPPO Science and Technology document on the risks associated with Lymantriids of concern to the NAPPO region, identifying potential species and pathways of concern.
9. Risk-Based Sampling: Complete and publish a Risk-Based Sampling Manual.
10. Asian Gypsy Moth: Validate specific risk periods for regulated Asian gypsy moth in countries of origin.
11. Foundation and Procedure documents: Continue to update and finalize various NAPPO foundation or procedure documents.
12. Phytosanitary Alert System: Continue to manage the NAPPO pest reporting system.

13. Update Pest List for RSPM 3: Movement of Potatoes into a NAPPO Member Country.
14. Electronic phytosanitary certification (ePhyto): Provide assistance and technical support to the IPPC ePhyto Steering Group.
15. Stakeholder Engagement: Plan, coordinate and execute activities for the October 2019 NAPPO Annual Meeting in Montreal, Canada, and publish the quarterly newsletter.
16. 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. APHIS posts links to draft standards on the Internet as they become available and provides information on the due dates for

comments.⁶ Additional information on NAPPO standards (including the NAPPO Work Program, standard setting process, and adopted standards) is available on the NAPPO website.⁷ 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 18th day of November 2019.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

⁶ For more information on the NAPPO draft RSPM consultation:
https://www.aphis.usda.gov/aphis/ourfocus/planthealth/international/sa_phytostandards/ct_draft_standards.

⁷ NAPPO website: <http://nappo.org/>.

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