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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2017-0059]

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 standards to be considered.

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


- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2017-0059, 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-2017-0059 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, Assistant Deputy Administrator for Trade and Capacity Building, 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 Team, National Import Export Services, VS, APHIS, 4700 River Road Unit 33, Riverdale, MD 20737-1231; (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) 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 181 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 then 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 next OIE General Session is scheduled for May 20 to May 25, 2018, in Paris, France.
The Chief Trade Advisor for APHIS’ Veterinary Services program serves as the official U.S.
Delegate to the OIE at this General Session. The Deputy Administrator for APHIS’ Veterinary
Services program serves as the Alternate Delegate. Information about OIE draft Terrestrial and
Aquatic Animal Health Code chapters may be found on the Internet at
http://www.aphis.usda.gov/animal-health/export-animals-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 2017
General Session

Sixteen 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. Glossary

Several definitions, including the definitions for *infection*, *infestation* and *animal health*
were updated and adopted.
2. Chapter 1.2., Criteria for the Inclusion of Diseases, Infections and Infestations in the OIE List

Text in this existing chapter was modified for clarity and consistency and was adopted by the Members.

3. Chapter 1.3., Diseases, Infections and Infestations Listed by the OIE

Text in this Code chapter had a minor modification for clarity.

4. Chapter 2.X., Criteria Applied by the OIE on Assessing the Safety of Commodities

This is a new Code chapter that was adopted this year. It provides clear guidance for determining general treatments and procedures for the safe trade of animal products.

5. Chapter 4.16., High Health Status Horse Subpopulation

A minor change was made in this existing chapter that was adopted and supported by the Members.

6. Chapter 5.3., OIE Procedures Relevant to the Agreement on the Application of SPS Measures of the World Trade Organization

Text in this existing Code chapter was modified for clarity and consistency.

7. Chapter 6.X., Prevention and Control of Salmonella in Bovines and Chapter 6.Y., Prevention and Control of Salmonella in Pigs

These two chapters are new Code chapters that were adopted this year and are intended to provide Member countries with guidance for preventing and controlling Salmonella in cattle and pig herds.

8. Chapter 7.11., Animal Welfare and Dairy Cattle Production Systems

This chapter was adopted in 2015. Some additional changes were made and adopted that clarified the space requirement recommendations.
9. **Chapter 7.12., Welfare of Working Equids**

   This chapter was adopted in 2016. Changes were made this year to further clarify the influencing factors that determine work and resting requirements for working equids.

10. **Chapter 8.X., Infection with Mycobacterium tuberculosis complex**

   This chapter was completely revised to bring the recommendations up to date with current scientific knowledge.

11. **Chapter 10.4., Infection with Avian Influenza**

   The text in this existing chapter was changed to update the heat treatment parameters for inactivating the virus in certain egg products. The modified text was accepted and adopted.

12. **Chapter 11.11., Infection with Lumpy Skin Disease Virus**

   The text in this existing chapter was updated to reflect current control and testing methods. The updated chapter was accepted and adopted.

13. **Chapter 15.1., Infection with African Swine Fever Virus**

   The text in this existing chapter was updated to incorporate state of the art science and terminology for clarity and consistency. The modified text was accepted and adopted.

14. **Chapter 15.X., Infection with Porcine Reproductive and Respiratory Syndrome (PRRS) Virus**

   This is a newly adopted chapter and includes recommendations for the safe trade of meat, as well as a listing of safe commodities that can be traded regardless of the PRRS situation in a country.

   The following Aquatic chapters were revised and adopted, and are of particular interest to the United States:
Chapter 1.5., Criteria for Listing Species as Susceptible to Infection with a Specific Pathogen.

Chapter 2.2.7., Infection for White Spot syndrome Virus.

**OIE Terrestrial Animal Health Code Chapters for Upcoming and Future Review**

- Glossary.
- Chapter 4.3., Zoning and Compartmentalization.
- Chapter 4.8., Collection and Processing of *In Vitro* Embryos from Livestock and Equids.
- Chapter 4.X., Vaccination.
- Chapter 4.Y., Management of Outbreaks of Listed Diseases.
- Chapter 6.1., The Role of Veterinary Services in Food Safety.
- Chapter 6.7., Harmonization of National AMR Surveillance and Monitoring Program.
- Chapter 7.1., Guiding Principle on the Use of Animal-Based Measures.
- Chapter 8.3., Infection with Bluetongue Virus.
- Chapter 8.4., Infection with *Brucella abortus*, *B. melitensis* and *B. suis*.
- Chapter 8.8., Infection with Foot and Mouth Disease.
- Chapter 8.15., Infection with Rinderpest Virus.
- Chapter 15.1., Infection with African Swine Fever Virus.
- Chapter 15.2., Infection with Classical Swine Fever 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 emerging standards; facilitating the exchange of official and scientific information among countries; 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 12th Session of the CPM took place from April 5 to 11, 2017, in Incheon, Republic of Korea. The Deputy Administrator for APHIS’ PPQ program was the U.S. delegate to the CPM.

The CPM adopted the following standards at its 2017 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 38: International movement of seeds
- Annex 1: Arrangements for verification of compliance of consignments by the importing country in the exporting country to ISPM 20 (Guidelines for a phytosanitary import regulatory system)
- ISPM 39: International movement of wood
- ISPM 40: International movement of growing media in association with plants for planting
- ISPM 41: International movement of used vehicles, machinery and equipment
- Phytosanitary treatments (PTs) as Annexes to ISPM 28: Phytosanitary treatments for regulated pests
  - PT 22-Sulfuryl fluoride fumigation treatment for insects in debarked wood
  - PT 23-Sulfuryl fluoride fumigation treatment for nematodes and insects in debarked wood
  - PT 24-Cold treatment for Ceratitis capitata on Citrus sinensis
  - PT 25-Cold treatment for Ceratitis capitata on Citrus reticulata x C. sinensis
  - PT 26-Cold treatment for Ceratitis capitata on Citrus limon
  - PT 27-Cold treatment for Ceratitis capitata on Citrus paradisi
  - PT 28-Cold treatment for Ceratitis capitata on Citrus reticulata
  - PT 29-Cold treatment for Ceratitis capitata on Citrus clementina
  - PT 30-Vapour heat treatment for Ceratitis capitata on Mangifera indica
  - PT 31-Vapour heat treatment for Bactrocera tryoni on Mangifera indica
- Diagnostic protocols (DPs) as Annexes to ISPM 27: Diagnostic protocols for regulated pests
  - DP 13: Erwinia amylovora
  - DP 14: Xanthomonas fragariae
  - DP 15: Citrus tristeza virus
  - DP 16: Genus Liriomyza Mik
  - DP 17: Aphelenchoides besseyi, A. ritzemabosi and A. fragariae
  - DP 18: Anguina spp.
  - DP 19: Sorghum halepense
  - DP 20: Dendroctonus ponderosae
  - DP 21: Candidatus Liberibacter solanacearum
  - DP 22: Fusarium circinatum

In addition to adopting 25 plant health standards, the 2017 Commission meeting also progressed a number of plant health initiatives strategically important to the United States. These initiatives include advancing the development of a new IPPC strategic framework for 2020-2030 to set the top priorities for plant health and trade, launching a pilot of a global
electronic certification system to support trade (ePhyto), developing programs aimed at improving the use and implementation of standards around the world, and creating a task force for addressing pests issues associated with the international movement of sea containers.

*New IPPC Standard-Setting Initiatives, Including Those in Development*

A number of expert working group (EWG) meetings or other technical consultations took place during 2017 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 meeting on the Authorization of Entities to Perform Phytosanitary Actions
- EWG meeting on the Revision of ISPM 8: Determination of pest status in an area
- Technical Panel for the Glossary of Phytosanitary Terms
- Technical Panel on Diagnostic Protocols
- Technical Panel on Phytosanitary Treatments

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. Plant health stakeholders are strongly encouraged to comment on draft standards, documents, and specifications during the consultation periods. In 2017, 13 standards (including phytosanitary treatments and pest diagnostic protocols) and 3 draft specifications were open for
first and second consultation. APHIS posts links to draft standards on the Internet as they become available and provides information on the due dates for comments. Additional information on IPPC standards (including the IPPC work program [list of topics]), standard-setting process, and adopted standards is available on the IPPC website. 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 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, or technical documents, or the

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1 For more information on the IPPC draft ISPM consultation: https://www.aphis.usda.gov/aphis/ourfocus/planthealth/sa_international/sa_phytostandards/ct_draft_standards.  
2 IPPC List of topics: https://www.ippc.int/en/core-activities/standards-setting/list-topics-ippc-standards/.  
3 IPPC website: https://www.ippc.int/.
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 41st NAPPO annual meeting will be held October 16 to 19, 2017, in Merida, Yucatan, Mexico. The NAPPO Executive Committee meetings will take place on October 16 and 20, 2017. 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, or projects in 2016:

- **Grains:** Finalized a NAPPO discussion document that supported the development of a draft IPPC standard for the international movement of grain in an effort to be consistent with North American grain trade objectives and reviewed and updated RSPM 13: Guidelines to establish, maintain and verify Karnal bunt pest free areas in North America.

- **Biological Control:** Developed an English online training course on preparing a petition for the first release of an entomophagous biological control agent, based on RSPM 12. The module is aimed to educate stakeholders on the petition process for new biocontrol products and to help NAPPO member countries improve the quality of petitions received for consideration.

- **Diversion from Intended Use:** Drafted a discussion document on diversion from intended use aimed to inform NAPPO member countries on this phytosanitary concept.

- **Forestry:** NAPPO partnered with the Inter-American Institute for Cooperation on Agriculture and other regional plant protection organizations in the Americas to hold a regional workshop in August 2016 aimed at enhancing global compliance with the IPPC
international standard for wood packaging materials (ISPM 15) to further reduce the threat of wood and forest pests in trade.

- Potato: Revised the pest list for RSPM 3: Movement of potatoes into a NAPPO member country and eliminated Annex 6 of RSPM 3 on pre-shipment testing for PVYN during the 5-year review. Continued to review RSPM 3 in light of ISPM 33: Pest free potato (Solanum sp.) micropropagative material and minitubers for international trade.

- Foundational documents: Updated the NAPPO Constitution and By-Laws and approved the NAPPO 2016-2020 Strategic Plan.

New NAPPO Standard-Setting Initiatives, Including Those in Development

The 2017 work program\(^4\) includes the following topics being worked on by NAPPO expert groups. APHIS intends to participate actively and fully in the 2017 NAPPO work program. The APHIS position on each topic will be guided and informed by the best technical and scientific information available, as well as on relevant input from stakeholders. For each of the following, 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. Asian Gypsy Moth: Develop a NAPPO document on validation of the specified risk periods for Asian gypsy moth in countries of origin.


3. Electronic Phytosanitary Certification: Provide assistance and technical support to the IPPC ePhyto Steering Group.

4. Forestry: Work to finalize a NAPPO standard on the potential use of systems approaches to manage pest risks associated with the movement of wood, taking into account comments received from April to June 2017 country consultation period.

5. Grains: Develop a NAPPO discussion document on a harmonized approach to prevent introduction and spread of Khapra beetle (*Trogoderma granarium*).

6. Lymantriids: Develop a NAPPO Science and Technology paper on the risks associated with Lymantriids of potential concern to the NAPPO region.

7. Phytosanitary Alert System (PAS): Manage the NAPPO pest reporting system.

8. Advancing key phytosanitary concepts: a) Review stakeholder input on topic of diversion from intended use; b) Finalize a discussion document on “interpretation of existing guidance” in standards on evaluation of the likelihood of establishment component of a pest risk analysis (PRA) for quarantine pests, taking into account comments received from April to May 2017 country consultation period; and c) Organize an international symposium on inspection sampling to support proper and harmonized implementation of ISPM 23: Guidelines for Inspection and ISPM 31: Methodologies for sampling of consignments in the NAPPO region and internationally. NAPPO, with substantial APHIS-PPQ support, welcomed 122 participants from 27 countries to the first-ever International Symposium for Risk-Based Sampling, held from June 16-21, 2017.

9. Potato: Continue to review RSPM 3 to align it with ISPM 33: Pest free potato (*Solanum* sp.) micropropagative material and minitubers for international trade.
10. Seeds: Finalize NAPPO discussion document on harmonized criteria for evaluating phytosanitary seed treatments, taking into account comments received from April to May 2017 country consultation period.

11. Foundation and Procedure documents: Update various foundation or procedure documents.

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 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. Plant health stakeholders are strongly encouraged to comment on draft standards, documents, and specifications. APHIS posts links to draft standards on the Internet as they become available and provides information on the due dates for comments. Additional information on NAPPO standards (including the NAPPO Work Program, standard setting process, and adopted standards) is available on the NAPPO website. Information on official U.S. participation in NAPPO activities, including U.S. positions on standards being considered,

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6 NAPPO website: http://nappo.org/.
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 September 2017.

Jere L. Dick,
Acting Administrator, Animal and Plant Health Inspection Service.

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