

29 July 2016

(16-4051)

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Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

- 1. Notifying Member: UNITED STATES OF AMERICA
- If applicable, name of local government involved:
- 2. Agency responsible: United States Food and Drug Administration
- 3. Products covered (provide tariff item number(s) as specified in national schedules deposited with the WTO; ICS numbers should be provided in addition, where applicable): Fish and fishery products HS Code(s): 03
- 4. Regions or countries likely to be affected, to the extent relevant or practicable:
 - [X] All trading partners
 - [] Specific regions or countries:
- 5. Title of the notified document: Agency Information Collection Activities; Proposed Collection; Comment Request; Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products; Notice Language(s): English Number of pages: 4

https://www.gpo.gov/fdsys/pkg/FR-2016-07-26/pdf/2016-17571.pdf

- 6. Description of content: The Food and Drug Administration is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice invites comments on the information collection provisions of our regulations requiring reporting and recordkeeping for processors and importers of fish and fishery products.
- Objective and rationale: [X] food safety, [] animal health, [] plant protection,
 [] protect humans from animal/plant pest or disease, [] protect territory from other damage from pests.
- 8. Is there a relevant international standard? If so, identify the standard:
 - [] Codex Alimentarius Commission (e.g. title or serial number of Codex standard or related text)
 - [] World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number)
 - [] International Plant Protection Convention (e.g. ISPM number)
 - [X] None

Does this proposed regulation conform to the relevant international standard? [] Yes [] No

If no, describe, whenever possible, how and why it deviates from the international standard:

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- 9. Other relevant documents and language(s) in which these are available:
- 10. **Proposed date of adoption (***dd/mm/yy***):** Not applicable

Proposed date of publication (dd/mm/yy): Not applicable

- 11. Proposed date of entry into force: [] Six months from date of publication, and/or (*dd/mm/yy*): Not applicable
 - [] Trade facilitating measure
- 12. Final date for comments: [] Sixty days from the date of circulation of the notification and/or (*dd/mm/yy*): 24 September 2016

Agency or authority designated to handle comments: [] National Notification Authority, [] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in that information posted the body of your comments, will be on http://www.regulations.gov.

If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions".

Instructions: All submissions received must include the Docket No. FDA-2013-N-0879 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products". Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions", publicly viewable at <u>http://www.regulations.gov</u> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Confidential Submissions - To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION". FDA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on http://www.regulations.gov. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on

the cover sheet and not in the body of your comments and you must identify this information as "confidential". Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, 18 September 2015, or access the information at: <u>http://www.fda.gov/regulator</u> yinformation/dockets/default.htm.

13. Text(s) available from: [X] National Notification Authority, [] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:

United States SPS National Notification Authority, USDA Foreign Agricultural Service, International Regulations and Standards Division (IRSD), Stop 1014, Washington D.C. 20250; Tel: +(1 202) 720 1301; Fax: +(1 202) 720 0433; E-mail: us.spsenquirypoint@fas.usda.gov

Text can also be found in the Federal Register, Vol. 81, No. 143, page 48816 or on the internet at: <u>https://www.gpo.gov/fdsys/pkg/FR-2016-07-26/pdf/2016-17571.pdf</u>