

decisions continue to include this issue as a concern.

### III. Interim Process

The criteria for use of GTA data for patent applications are different than for EPA's quantitative analyses of risk. While the USPTO patent evaluation process uses a standard that the issued assertion must be novel and "non-obvious" (<https://www.uspto.gov/web/offices/pac/mpep/mpep-2100.pdf>), for EPA's quantitative risk assessments, the data must meet the same standards for use of other toxicological data. To address risk estimate uncertainties associated with patent assertions of GTA effects, EPA has developed an interim process to obtain, analyze, and document patent claims of GTA effects in mixtures of pesticide active ingredients. The purpose of the interim process is to evaluate the utility of collecting and reviewing GTA patent information for use in conducting risk assessments, and to determine if such data, where applicable, affect risk assessments. This process is described in a document titled "Process for Receiving and Evaluating Data Supporting Assertions of Greater than Additive (GTA) Effects in Mixtures of Pesticide Active Ingredients and Associated Guidance for Registrants" (Ref. 4) and summarized in this unit. The document is available on the Agency's website: <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/ecological-risk-assessment-pesticides-technical> and in the docket.

Generally, for new chemicals (specifically new conventional pesticide active ingredients) and other new products or other active ingredients for which EPA has specific concerns about the potential for GTA effects, as part of the registration process, EPA will request registrants to provide GTA effect information on approved patents and conduct appropriate statistical analysis of that information using the following steps:

*Step 1:* Search for and identify granted U.S. patents with applications that made any claims of GTA effects;

*Step 2:* Conduct a review of patent data for relevance to ecological risk assessment;

*Steps 3:* Report effects testing data from relevant patents; and

*Step 4:* Perform a statistical analysis using an EPA-established method to evaluate if observations of GTA effects are statistically significant.

*Step 5* is an Agency review of the submitted information from Steps 1–4.

Consistent with EPA's review of any scientific data submitted for inclusion

in the regulatory process, EPA will review submitted patent searches and relevancy reporting in submissions to ensure that the process is consistent with the Agency interpretation of patent reporting and relevancy review.

EPA has generally been applying this interim process since 2016. EPA's experience with the application of this interim process to date suggests that patent submissions with relevant information that demonstrate a sufficiently large, statistically significant GTA interaction requiring quantitative consideration in ecological risk assessments will likely be rare. More specifically, for the 24 new active ingredient registrations that submitted patent data to date, three contained pertinent information that indicated a need for further testing and none ultimately led to adjustment in the risk assessment. EPA plans to re-evaluate this interim process considering public comment and after it has collected and analyzed more GTA patent information submitted during registrations. Ultimately, EPA plans to look at the results of this process to inform its determination as to whether patent data has utility in EPA's risk assessments. If the interim process demonstrates it does, then EPA plans to continue to request or require registrants provide patent data and follow this process (or an improved process reflecting comments and/or lessons learned). If the process demonstrates that the patent data does not have utility in EPA's risk assessments, EPA plans to communicate that to the public and discontinue this process.

### IV. Public Comments Sought

EPA is seeking comment on the interim process for assessing potential GTA effects of pesticides during the registration process. Specifically, EPA solicits comments on the following:

- Are there technical aspects of the interim process that warrant change? If so, what changes are recommended?
- What aspects of the process could be applied to the evaluation of open literature sources of GTA effects pesticide interactions?
- Should EPA consider standardizing a more detailed search and reporting approach, and how should EPA do that?
- Should EPA continue the evaluation process as described in this document? If so, what performance metrics (e.g., number of evaluations) should EPA consider before deciding the utility of this approach?
- What applicant burden is associated with the activities described in this memorandum, including compiling, analyzing, and submitting the

information? Specifically, does an estimate of 80–240 hours of burden per applicant cover the respondent burden associated with the interim process?

### V. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

1. National Research Council (NRC) 2013. *Assessing Risks to Endangered and Threatened Species from Pesticides*. The National Academies Press, Washington DC.
2. Case Nos. 14–73353, 14–73359, 15–71207, 15–71213 United States Court of Appeals for the Ninth Circuit ID: 9731620, DktEntry: 56–1, Page 1 of 215.
3. Case Nos. 14–73353, 14–73359, 15–71207, 15–71213 United States Court of Appeals for the Ninth Circuit ID: 9770038, DktEntry: 121–1, Page 1 of 12.
4. U.S. EPA. *Process for Receiving and Evaluation Data Supporting Assertion of Greater than Additive (GTA) Effects in Mixtures of Pesticide Active Ingredients and Associated Guidance for Registrants*, August 2019. It is available at <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/ecological-risk-assessment-pesticides-technical>.

**Authority:** 7 U.S.C. 136 *et seq.*

Dated: September 3, 2019.

**Alexandra Dapolito Dunn,**

*Assistant Administrator.*

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**BILLING CODE 6560–50–P**

### EXPORT-IMPORT BANK

[Document Number: 2019–6019]

#### Review of Proposed Guidelines for Assessing Additionality Related to Providing EXIM's Support for Medium and Long Term Export Transactions

The Export-Import Bank of the United States (EXIM) is seeking comments on proposed guidelines for determining Additionality on requests the Bank receives to support export transactions with repayment amortizing over the medium or long term. The proposed guidelines can be viewed at: <https://www.exim.gov/Additionality.guidance>. Interested parties may submit comments to [additionality.review@exim.gov](mailto:additionality.review@exim.gov) or by mail to 811 Vermont Avenue NW, Room

1257, within 30 days of the date this notice appears in the **Federal Register**.

**James C. Cruse,**

*Senior Vice President, Office of Policy and International Relations.*

[FR Doc. 2019-19345 Filed 9-6-19; 8:45 am]

BILLING CODE 6690-01-P

## EXPORT-IMPORT BANK

[Document Number: 2019-6018]

### Review of Economic Impact Procedures and Methodology.

The Export-Import Bank of the United States (EXIM) is in the process of reviewing its economic impact procedures and methodology and invites public comment. EXIM's current Economic Impact procedures can be accessed at: <https://www.exim.gov/sites/default/files/newsreleases/Final-April-2013-Procedures.pdf>.

Interested parties may submit comments to [economic.impact@exim.gov](mailto:economic.impact@exim.gov) or by mail to 811 Vermont Avenue NW, Room 1257, within 30 days of the date this notice appears in the **Federal Register**.

**James C. Cruse,**

*Senior Vice President, Office of Policy and International Relations.*

[FR Doc. 2019-19344 Filed 9-6-19; 8:45 am]

BILLING CODE 6690-01-P

## FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060-0953]

### Information Collection Being Submitted for Review and Approval to the Office of Management and Budget

**AGENCY:** Federal Communications Commission.

**ACTION:** Notice and request for comments.

**SUMMARY:** As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning:

Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the

quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The Commission may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

**DATES:** Written comments should be submitted on or before October 9, 2019. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts listed below as soon as possible.

**ADDRESSES:** Direct all PRA comments to Nicholas A. Fraser, OMB, via email [Nicholas\\_A\\_Fraser@omb.eop.gov](mailto:Nicholas_A_Fraser@omb.eop.gov); and to Nicole Ongele, FCC, via email [PRA@fcc.gov](mailto:PRA@fcc.gov) and to [Nicole.Ongele@fcc.gov](mailto:Nicole.Ongele@fcc.gov). Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** below.

**FOR FURTHER INFORMATION CONTACT:** For additional information or copies of the information collection, contact Nicole Ongele at (202) 418-2991. To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the web page <http://www.reginfo.gov/public/do/PRAMain>, (2) look for the section of the web page called "Currently Under Review," (3) click on the downward-pointing arrow in the "Select Agency" box below the "Currently Under Review" heading, (4) select "Federal Communications Commission" from the list of agencies presented in the "Select Agency" box, (5) click the "Submit" button to the right of the "Select Agency" box, (6) when the list of FCC ICRs currently under review appears, look for the OMB control number of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

**SUPPLEMENTARY INFORMATION:** As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501-3520), the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to

take this opportunity to comment on the following information collection.

**Comments Are Requested Concerning:** Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

**OMB Control No.:** 3060-0953.

**Title:** Section 95.2309, Frequency Coordination/Coordinator, Wireless Medical Telemetry Service.

**Form No.:** N/A.

**Type of Review:** Revision of a currently approved collection.

**Respondents:** Business or other for-profit and Not-for-profit institutions.

**Number of Respondents and Responses:** 3,000 respondents; 3,000 responses.

**Estimated Time per Response:** 2-5 hours.

**Frequency of Response:** On occasion reporting requirement, third party disclosure requirement and recordkeeping requirement.

**Obligation To Respond:** Required to obtain or retain benefits. Statutory authority is contained in 47 U.S.C. 154, 303, 307.

**Total Annual Burden:** 15,000 hours.

**Total Annual Cost:** \$750,000.

**Privacy Act Impact Assessment:** No Impact(s).

**Nature and Extent of Confidentiality:** No information is requested that would require assurance of confidentiality.

**Needs and Uses:** The Commission will submit this information collection to OMB as a revision after this 60-day comment period to obtain the full three-year clearance from them.

On May 19, 2017, the Federal Communications Commission released a Report and Order, *Review of the Commission's Part 95 Personal Radio Services Rules*, WT Docket No. 10-119, FCC 17-57, which reorganized and updated the Commission's Part 95 rules, including those for the wireless medical telemetry service (WMTS). The Commission merged the requirements of former Sections 95.1111 and 95.1113 into a new Section 95.2309, but did not impose any new requirements that would be subject to this collection of information.