g. How should Commerce adjust conditions in response to the increasing capabilities of non-U.S. entities? How frequently should NOAA evaluate those increasing capabilities?

h. How can Commerce best provide transparency to licensees regarding classified national security risks?

**Topic 4: Compliance and Enforcement**

The Secretary is required to ensure compliance with the regulations and with licenses (51 U.S.C. 60123, 15 CFR 960.13–960.15). To meet this obligation, NOAA must collect information, but it seeks to minimize the burden on licensees.

With this background in mind, the Department seeks general comments on this topic. In addition, the Department seeks input in response to the following specific questions:

a. What are appropriate mechanisms for ensuring compliance? Currently, Commerce uses site visits, virtual inspections, quarterly and annual audits, and no-notice inspections as needed.

b. How should Commerce ensure compliance when multiple parties (including investors) play a role in a single licensed system? Options could include licensing all involved parties, or holding a single licensee responsible for the entire system.

c. Are there any improvements the Department could make to its formal adjudication procedures in the regulations?

d. Should Commerce mandate licensees to use certain technical standards, or particular software, for compliance purposes? If so, what standards or software should Commerce require?

e. Should Commerce adopt different compliance policies and procedures for the different categories described in Topic 2? If so, what policies and procedures would be appropriate for the different categories?

**Topic 5: Integration With Other Licensing and Regulatory Regimes**

The Department recognizes that many NOAA-licensed systems also require licenses from other U.S. Government agencies, and occasionally from agencies in other countries. The Department seeks to reduce the overall regulatory burden to licensees, when possible.

With this background in mind, Commerce seeks general comments on this topic. In addition, the Department seeks input in response to the following specific questions:

a. Within statutory constraints, how can Commerce avoid redundancies and inconsistencies between domestic regulatory regimes?

b. Within statutory constraints, how can Commerce minimize burdens to licensees who operate in multiple countries and are subject to multiple countries’ regulatory regimes?

**Classification**

This advance notice of proposed rulemaking was determined to be significant for purposes of E.O. 12866.

**Summary:**

The Department of Commerce and NOAA licenses, manages, and regulates various ocean activities. The Department seeks input in response to the following topics:

- Topic 4: Compliance and Enforcement
- Topic 5: Integration With Other Licensing and Regulatory Regimes
The scientific discipline of toxicology is particularly essential to FDA’s mission because it is applied across the breadth of FDA-regulated product areas. Toxicological testing is performed during the development and evaluation of FDA-regulated products, ranging from human and animal drugs and medical devices to food and food ingredients, human biologics, and tobacco products. Advances in systems biology, stem cells, engineered tissues, and mathematical modeling are creating unique opportunities to improve toxicology’s predictive ability, potentially enhancing FDA’s ability to predict risk. Also critical is the potential of these advances for replacing, reducing, and/or refining animal testing. Today, novel methods such as organs on a chip and mathematical modeling are generating unique opportunities that may improve our ability to quickly and more accurately predict potential toxicities and reduce associated risks to the public.

FDA centers have each taken significant steps to enhance the use and evaluation of cutting-edge toxicological assays. However, more work needs to be done to achieve broad acceptance of new toxicology methodologies and technologies. FDA’s six product centers have different legal authorities for evaluating product safety or toxicity. Nevertheless, more robust methodological evaluation and datasets can help speed the acceptance of emerging predictive toxicology methods across the regulatory product areas.

FDA recognized that a comprehensive strategy was needed to evaluate new methodologies and technologies for their potential to offer greater predictive ability and to protect public health. Acceptance of any new toxicology testing method will require convincing data as well as continuous dialogue and feedback among all relevant stakeholders, from development to implementation, including qualification and acceptance by regulatory authorities.

To ensure that FDA continues to employ cutting-edge science to assess the toxicity of its regulated products and to leverage advances being made in toxicology, the Commissioner of Food and Drugs (the Commissioner) tasked the Agency’s Toxicology Working Group with developing a more efficient process for identifying and qualifying emerging predictive toxicology technologies. Established in 2015 and comprised of senior FDA toxicologists from across the Agency, the Working Group has deep expertise in the various FDA product areas and knowledge of the differing legal authorities for evaluating toxicity in those product areas.

For a new testing method to be accepted for use in determining the toxicity of an FDA-regulated product there must be convincing data to ensure that the method can be relied upon for both product development and regulatory decision-making. FDA evaluates the test or series of tests for their applicability, limitations, relevance, reliability, accuracy, reproducibility, and sensitivity in the evaluation of human response and toxicity. Undergoing this process requires continuous dialogue and feedback among all relevant stakeholders, beginning with developers and ending with qualification and acceptance by regulatory authorities.

FDA’s Predictive Toxicology Roadmap (https://www.fda.gov/PredictiveToxRoadmap) is a six-part framework for integrating predictive toxicology methods into safety and risk assessments. Among other recommendations, it calls for FDA research to identify data gaps and to support research to ensure that the most promising technologies are developed, validated, and integrated into regulatory use. The roadmap also identifies toxicology issues that need addressing for FDA-regulated products and toxicology areas that could benefit from improved predictivity. Because this is a high priority for the Agency, FDA’s Toxicology Working Group will be reporting yearly to FDA’s Chief Scientist on progress made in this important effort.

II. Topics for Discussion at the Public Hearing

The purpose of this public meeting is to invite public comment on how FDA can better work with its stakeholders to implement the goals of its Predictive Toxicology Roadmap. We invite interested parties to submit comments, especially on the questions listed below on each of the six parts in the roadmap. Comments on additional areas are also welcome.

A. FDA Toxicology Working Group

FDA has formed a senior-level Toxicology Working Group under the direction of the Commissioner to foster enhanced communication among FDA product centers and researchers and leverage FDA resources to advance the evaluation and integration of emerging predictive toxicology methods and new technologies into regulatory safety and risk assessments.

1. Which goals of the FDA Roadmap are most important to FDA stakeholders?
2. What role could FDA stakeholders play in achieving these goals?
B. Training

Continuing current education in new predictive toxicology methods is essential for FDA regulators.
1. What training topics and approaches do you think would help FDA staff to appropriately implement new alternative methods?
2. Are there relevant courses that you can recommend?
3. Should FDA partner with its stakeholders for these training courses and how might this be achieved?

C. Continued Communication

FDA will continue to reaffirm its commitment to and support for incorporating data from newly qualified toxicology methods into regulatory submissions and encourage discussions with stakeholders as part of the regulatory submission process.
1. How can FDA better communicate with stakeholders to encourage discussion on the use of qualified new toxicology methods early in the regulatory process?
2. How can new toxicology methods and approaches be integrated into FDA’s review of regulated products?
3. What information do stakeholders need from FDA to qualify alternative methods for a specific context of use?

D. Collaborations

FDA will continue its long practice of fostering collaborations across disciplines nationally and internationally.
1. What partnerships could be useful to FDA to advance the roadmap?
2. Are there existing partnerships that FDA should be involved in to achieve the roadmap’s goals?
3. How could FDA and stakeholders evaluate whether alternative methods are appropriately qualified for a specific context of use?

E. Research

FDA’s research programs will identify data gaps and support research to ensure that the most promising technologies are identified, evaluated, and integrated into product development and assessment.
1. What data gaps should be addressed by FDA research and research conducted by external groups?
2. How can FDA encourage and support research in areas of importance to its mission?
3. How could FDA and stakeholders evaluate whether alternative methods are appropriately qualified for a specific context of use?

F. Oversight

The Toxicology Working Group, with representation from each FDA center, will track the progress of these recommendations and report to FDA’s Chief Scientist annually.
1. How can FDA ensure transparency in its progress?
2. How can FDA better foster opportunities to share ideas and knowledge with its stakeholders?
3. How can FDA highlight collaborations on the development and testing of new methods?

III. Participating in the Public Hearing

Registration and Requests To Make an Oral Presentation: The FDA Conference Center at the White Oak location is a Federal facility with security procedures and limited seating. Attendance will be free and on a first-come, first-served basis. If you wish to attend either in person or by webcast and/or present at the hearing, please register by Friday, August 17, 2018, at the following website: https://www.fda.gov/PredictiveToxRoadmap.

If you need special accommodations because of a disability, please contact Shari Solomon (shari.solomon@fda.hhs.gov) no later than Friday, August 17, 2018, at 12 noon Eastern Time.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at https://www.regulations.gov. It may be viewed at the Dockets Management Staff, 5630 Fishers Lane, Room 1061, Rockville, MD 20852.

Table 1—Information on Participation in the Meeting and on Submitting Comments to the Rulemaking Dockets

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<thead>
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<th>Activity</th>
<th>Date</th>
<th>Electronic address</th>
<th>Address</th>
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<tr>
<td>Public hearing</td>
<td>September 12, 2018</td>
<td></td>
<td>FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm. 1503A, Silver Spring, MD 20993.</td>
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<td>Advance registration</td>
<td>By Wednesday, August 29, 2018</td>
<td><a href="https://www.fda.gov/predictivetoxroadmap">https://www.fda.gov/predictivetoxroadmap</a></td>
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<tr>
<td>Technical assistance</td>
<td>By Friday, August 17, 2018</td>
<td><a href="mailto:Jeffery.Rexrode@fda.hhs.gov">Jeffery.Rexrode@fda.hhs.gov</a></td>
<td></td>
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<tr>
<td>Request to make an oral presentation</td>
<td>By Friday, August 24, 2018</td>
<td><a href="mailto:Tracy.Chen@fda.hhs.gov">Tracy.Chen@fda.hhs.gov</a></td>
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<tr>
<td>Send PowerPoint slides (10 minutes maximum).</td>
<td>By Friday, August 17, 2018</td>
<td><a href="mailto:Tracy.Chen@fda.hhs.gov">Tracy.Chen@fda.hhs.gov</a></td>
<td></td>
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<tr>
<td>Request special accommodations due to a disability.</td>
<td>By Friday, August 17, 2018</td>
<td><a href="mailto:shari.solomon@fda.hhs.gov">shari.solomon@fda.hhs.gov</a></td>
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<tr>
<td>Submit electronic or written comments.</td>
<td>By October 12, 2018</td>
<td><a href="https://www.regulations.gov">https://www.regulations.gov</a></td>
<td>Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.</td>
</tr>
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</table>
ENVIRONMENTAL PROTECTION AGENCY

IV. Notice of Hearing Under 21 CFR Part 15

The Commissioner is announcing that the public hearing will be held in accordance with 21 CFR part 15. The hearing will be conducted by a presiding officer, who will be accompanied by FDA senior management from the Office of the Commissioner and the relevant Centers/Oces. Under § 15.30(f), the hearing is informal and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members can pose questions; they can question any person during or after each presentation. Public hearings under part 15 are subject to FDA’s policy and procedures for electronic media coverage of FDA’s public administrative proceedings (21 CFR part 10, subpart C). Under § 10.205, representatives of the media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA’s public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b) (see Transcripts). To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

Dated: June 26, 2018.

Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2018–14052 Filed 6–28–18; 8:45 am]
BILLING CODE 4164–01–P

SUPPLEMENTARY INFORMATION:
Throughout this document whenever “we,” “us,” or “our” is used, we mean EPA.

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C. Section 110(a)(2)(C)—Program for Enforcement of Control Measures and for Construction or Modification of Stationary Sources

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IV. Proposed Action

V. Statutory and Executive Order Reviews

I. Background and Purpose

A. What Vermont SIP submissions does this rulemaking address?

This rulemaking addresses a SIP submission from the Vermont Department of Environmental Conservation (VT DEC). The state submitted its infrastructure SIP for the 2012 fine particle (PM$_{2.5}$) National Ambient Air Quality Standards (NAAQS). The infrastructure requirements are designed to ensure that the structural components of each state’s air quality management program are adequate to meet the state’s responsibilities under the CAA. This action is being taken under the Clean Air Act.

DATES: Written comments must be received on or before July 30, 2018.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R01–OAR–2017–0696, to the www.regulations.gov website or via email to simcox.alison@epa.gov. For comments submitted to the www.regulations.gov website, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from www.regulations.gov. For either manner of submission, the EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (i.e., on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the “For Further Information Contact” section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit www.epa.gov/dockets/commenting-epa-dockets. Publicly available docket materials are available at www.regulations.gov or at the U.S. Environmental Protection Agency, EPA New England Regional Office, Office of Ecosystem Protection, Air Quality Planning Unit, 5 Post Office Square—Suite 100, Boston, MA. EPA requests that if at all possible, you contact the contact listed in the FOR FURTHER INFORMATION CONTACT section to schedule your inspection. The Regional Office’s official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding legal holidays.

FOR FURTHER INFORMATION CONTACT:
Alison C. Simcox, Air Quality Unit, U.S. Environmental Protection Agency, EPA New England Regional Office, 5 Post Office Square—Suite 100, (Mail code OEP05–2), Boston, MA 02109–3912, tel. (617) 918–1684; simcox.alison@epa.gov.

PM$_{2.5}$ refers to particulate matter of 2.5 microns or less in diameter, often referred to as “fine” particles.