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.

Dated: June 25, 2018.

Stephen Volz,

Assistant Administrator for Satellite and Information Services, National Oceanic and Atmospheric Administration, Department of Commerce.

[FR Doc. 2018–14038 Filed 6–28–18; 8:45 am]

BILLING CODE 3510–HR–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 15

[Docket No. FDA–2018–N–2309]

The Food and Drug Administration Predictive Toxicology Roadmap and Its Implementation; Public Hearing; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a public hearing to solicit comments on FDA's Predictive Toxicology Roadmap, which was issued by FDA on December 6, 2017. FDA is seeking comments on how to foster the development and evaluation of emerging toxicological methods and new technologies and incorporate these methods and technologies into regulatory review, as applicable.

DATES: The public hearing will be held on Wednesday, September 12, 2018, from 9 a.m. to 4 p.m. Persons seeking to attend or to present at the public hearing must register by Wednesday, August 29, 2018. Section III provides attendance and registration information. Electronic or written comments will be accepted after the public hearing until Friday, October 12, 2018.

ADDRESSES: The public hearing will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503A), Silver Spring, MD 20993–0002. Entrance for public hearing participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to: *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Electronic Submissions

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted via the *https://www.regulations.gov* electronic filing system by midnight Eastern Time on October 12, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 the body of your comments, that information will be posted on *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–

2018–N–2309 for ''The FDA Predictive Toxicology Roadmap and its Implementation; Public Hearing; Request for Comments.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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.'' The Agency 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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, September 18, 2015, or access the information at: *https://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the received electronic and written/paper comments, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Tracy Chen, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4309A, Silver Spring, MD 20993, *Tracy.Chen@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

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?

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 at: *https://www.fda.gov/PredictiveToxRoadmap.*

FDA will try to accommodate all persons who wish to make a presentation. Individuals wishing to present should identify the number of the specific question, or questions, they wish to address. This will help FDA organize the presentations. Individuals and organizations with common interests should consolidate or coordinate their presentations and request time for a joint presentation. FDA will notify registered presenters of their scheduled presentation times. The time allotted for each presentation will depend on the number of individuals who wish to speak but should last a maximum of 10 minutes. Presenters are encouraged to submit an electronic copy of their presentation to *Tracy.Chen@fda.hhs.gov* (See **FOR FURTHER INFORMATION CONTACT**) on or before Friday, August 24, 2018. Persons registered to make an oral presentation are encouraged to arrive at the hearing room early and check in at the onsite registration table to confirm their designated presentation time. An agenda for the hearing and any other background materials will be made available 5 days before the hearing at *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

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

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/Offices. 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

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R01–OAR–2017–0696; FRL–9979–82—Region 1]

Air Plan Approval; Vermont; Infrastructure State Implementation Plan Requirements for the 2012 $PM_{2.5}$ NAAQS

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve elements of a State Implementation Plan (SIP) submission from Vermont that addresses the infrastructure requirements of the Clean Air Act (CAA or Act)—including the interstate transport provisions—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.*

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

Table of Contents

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 ($PM_{2.5}$ [1]) National Ambient Air Quality Standard (NAAQS) on October 31, 2017. This included an enclosure addressing the ''Good Neighbor'' (or ''transport'') provisions for the 2012 $PM_{2.5}$ NAAQS (Section 110(a)(2)(D)(i)(I) of the CAA). Under sections 110(a)(1) and (2) of the CAA, states are required to submit infrastructure SIPs to ensure that SIPs provide for implementation, maintenance, and enforcement of the NAAQS, including the 2012 $PM_{2.5}$ NAAQS.

[1] $PM_{2.5}$ refers to particulate matter of 2.5 microns or less in diameter, often referred to as ''fine'' particles.