DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA–2022–D–0370]

The Accredited Third-Party Certification Program: Questions and Answers; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a draft guidance for industry entitled ''The Accredited Third-Party Certification Program: Questions and Answers.'' The draft guidance, when finalized, will answer frequently asked questions relating to the requirements of the Accredited Third-Party Certification Program, and is intended to assist accreditation bodies', third-party certification bodies', and eligible entities' understanding of the regulation and program requirements.

DATES: Submit either electronic or written comments on the draft guidance by July 28, 2022 to ensure that the Agency considers your comment on the draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *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–2022–D–0370 for ''The Accredited Third-Party Certification Program: Questions and Answers.'' 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, 240–402–7500.

- 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.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, 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, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Doriliz De Leon, Center for Food Safety and Applied Nutrition (HFS–607), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2772.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry entitled ''The Accredited Third-Party Certification Program: Questions and Answers.'' We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations.

The FDA Food Safety Modernization Act (Pub. L. 111–353) added section 808 to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 384d), which directs FDA to establish a program for accreditation of third-party certification bodies to conduct food safety audits and to certify that eligible foreign food entities (including registered foreign food facilities) and food produced by such entities meet applicable FDA requirements for purposes of sections 801(q) (21 U.S.C. 381(q)) and 806 (21 U.S.C. 384b) of the FD&C Act. On November 27, 2015, FDA issued the final rule, ''Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications'' (also referred to as the TPP regulation) (80 FR 74569; 21 CFR part 1, subpart M). This draft guidance,

when finalized, will answer frequently asked questions relating to the requirements of the Accredited Third-Party Certification Program established in 21 CFR part 1, subpart M (21 CFR 1.600 through 1.695, 21 CFR 1.700 through 1.725), and is intended to assist the accreditation bodies', third-party certification bodies', and eligible entities' understanding of the TPP regulation and program requirements.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information under the TPP regulation in 21 CFR part 1, subpart M have been approved under OMB control number 0910–0750.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/regulatory-information/search-fda-guidance-documents* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: April 25, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–09232 Filed 4–28–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 913

[SATS No. IL–111–FOR; Docket ID: OSM–2022–0002; S1D1S SS08011000 SX064A000 222S180110; S2D2S SS08011000 SX064A000 22XS501520]

Illinois Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Proposed rule; public comment period and opportunity for public hearing on proposed amendment.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are announcing receipt of a proposed amendment to the Illinois regulatory program (hereinafter, the Illinois program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). The amendment proposes the removal of revegetation success standards and statistically valid sampling techniques from inclusion in the approved regulatory program as allowed by the 2006 *Topsoil Redistribution and Revegetation Success Standards Final Rule.* This amendment also updates references and makes minor editorial changes. This document gives the times and locations that the Illinois program and this proposed amendment to that program are available for your inspection, the comment period during which you may submit written comments on the amendment, and the procedures that we will follow for the public hearing, if one is requested.

DATES: We will accept written comments on this amendment until 4:00 p.m., Central Standard Time (c.s.t.), May 31, 2022. If requested, we may hold a public hearing or meeting on the amendment on May 24, 2022. We will accept requests to speak at a hearing until 4:00 p.m., c.s.t. on May 16, 2022.

ADDRESSES: You may submit comments, identified by SATS No. IL–111–FOR, by any of the following methods:

- *Mail/Hand Delivery:* William L. Joseph, Chief, Alton Field Division, Office of Surface Mining Reclamation and Enforcement, 501 Belle Street, Suite 216, Alton, Illinois 62002–6169.
- *Fax:* (618) 463–6470.
- *Federal eRulemaking Portal:* The amendment has been assigned Docket ID: OSM–2022–0002. If you would like to submit comments, go to *https://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Public Comment Procedures'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to review copies of the Illinois program, this amendment, a listing of any scheduled public hearings or meetings, and all written comments received in response to this document, you must go to the address listed below during normal business hours, Monday through Friday, excluding holidays. You may receive one free copy of the amendment by contacting OSMRE's Alton Field Division or the full text of the program amendment is available for you to read at *www.regulations.gov.*

William L. Joseph, Chief, Alton Field Division, Office of Surface Mining Reclamation and Enforcement, 501 Belle Street, Suite 216, Alton, Illinois 62002–6169, Telephone: (618) 463–6463, Email: *bjoseph@osmre.gov.*

In addition, you may review a copy of the amendment during regular business hours at the following location: Office of Mines and Minerals, Illinois Department of Natural Resources, One Natural Resources Way, Springfield, IL 62702–1271, Telephone: (618) 439–9111.

FOR FURTHER INFORMATION CONTACT: William L. Joseph, Chief, Alton Field Division. Telephone (618) 463–6463, Email: *bjoseph@osmre.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on the Illinois Program

Subject to OSMRE's oversight, Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its approved, State program includes, among other things, State laws and regulations that govern surface coal mining and reclamation operations in accordance with the Act and consistent with the Federal regulations. See 30 U.S.C. 1253(a)(1) and (7).

On the basis of these criteria, the Secretary of the Interior conditionally approved the Illinois program on June 1, 1982. You can find background information on the Illinois program, including the Secretary's findings, the disposition of comments, and conditions of approval of the Illinois program in the June 1, 1982, **Federal Register** (47 FR 23858). You can also find later actions concerning the Illinois program and program amendments at 30 CFR 913.10, 913.15, and 913.17.

II. Description of the Proposed Amendment

By letter dated February 4, 2022 (Administrative Record No. IL–5119), Illinois sent us an amendment to its program under SMCRA (30 U.S.C. 1201 *et seq.*). The amendment proposes the removal of revegetation success standards and sampling techniques from inclusion in the approved regulatory program as allowed by the 2006 *Topsoil Redistribution and Revegetation Success Standards Final Rule* (71 FR 51684). This change was driven by recent fluctuations in available datasets for their Agricultural Lands Productivity Formula. No longer including these standards and techniques in their regulations and providing them as a