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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA–2023–D–1336]

Requirements for Additional Traceability Records for Certain Foods: What You Need To Know About the Food and Drug Administration Regulation: Guidance for Industry; Small Entity Compliance Guide; Availability

AGENCY: Food and Drug Administration, Department of 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 guidance for industry entitled ''Requirements for Additional Traceability Records for Certain Foods: What You Need to Know About the FDA Regulation: Guidance for Industry—Small Entity Compliance Guide.'' The small entity compliance guide (SECG) is intended to help small entities comply with the final rule entitled ''Requirements for Additional Traceability Records for Certain Foods.''

DATES: The announcement of the guidance is published in the **Federal Register** on May 19, 2023.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2023–D–1336 for ''Requirements for Additional Traceability Records for Certain Foods: What You Need to Know About the FDA Regulation: Guidance for Industry—Small Entity Compliance Guide.'' 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 SECG to the Office of Analytics and Outreach, 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 SECG.

FOR FURTHER INFORMATION CONTACT: Katherine Vierk, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2122.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 21, 2022 (87 FR 70910), we issued a final rule establishing additional recordkeeping requirements for persons who manufacture, process, pack, or hold foods FDA has designated for inclusion on the Food Traceability List (the final rule). The requirements established in the final rule will help the Agency rapidly and effectively identify recipients of foods to prevent or mitigate foodborne illness outbreaks and address credible threats of serious adverse health consequences or death resulting from foods being adulterated or misbranded. The final rule, which is codified at 21 CFR part 1, subpart S (§§ 1.1300 through 1.1465), became effective on January 20, 2023, but has a compliance date of January 20, 2026.

We examined the economic implications of the final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612) and determined that the final rule will have a significant economic impact on a substantial number of small entities. In compliance with section 212 of the Small Business

Regulatory Enforcement Fairness Act (Pub. L. 104–121, as amended by Pub. L. 110–28), we are making available the SECG to explain the actions that a small entity must take to comply with the rule.

We are issuing the SECG consistent with our good guidance practices regulation (21 CFR 10.115(c)(2)). The SECG represents 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 alternative approach if it satisfies the requirements of the applicable statutes and regulations.

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 for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 1, subpart S, have been approved under OMB control number 0910–0560.

III. Electronic Access

Persons with access to the internet may obtain the SECG at *https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-rules-guidance-industry, 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: May 15, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–10666 Filed 5–18–23; 8:45 am]

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DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 560

Publication of Iranian Transactions and Sanctions Regulations Web General License O

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Publication of web general license.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing a general license (GL) issued pursuant to the Iranian Transactions and Sanctions Regulations and Executive Order 13846, GL O, which was previously made available on OFAC's website.

DATES: GL O was issued on March 2, 2023. See **SUPPLEMENTARY INFORMATION** for additional relevant dates.

FOR FURTHER INFORMATION CONTACT: OFAC: Assistant Director for Licensing, 202–622–2480; Assistant Director for Regulatory Affairs, 202–622–4855; or Assistant Director for Sanctions Compliance & Evaluation, 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document and additional information concerning OFAC are available on OFAC's website: *www.treas.gov/ofac.*

Background

On March 2, 2023, OFAC issued GL O to authorize certain transactions otherwise prohibited by the Iranian Transactions and Sanctions Regulations, 31 CFR part 560, or Executive Order 13846 of August 6, 2018, ''Reimposing Certain Sanctions With Respect to Iran'' (83 FR 38939). This GL was made available on OFAC's website (*www.treas.gov/ofac*) when it was issued. GL O has an expiration date of June 30, 2023. The text of this GL is provided below.

OFFICE OF FOREIGN ASSETS CONTROL

Executive Order 13846 of August 6, 2018

Reimposing Certain Sanctions With Respect to Iran

Iranian Transactions and Sanctions Regulations

31 CFR Part 560

GENERAL LICENSE O

Authorizing Wind-Down and Limited Safety and Environmental Transactions Involving Certain Vessels

(a) Except as provided in paragraph (c) of this general license, the following transactions are authorized through 12:01 a.m. eastern daylight time, June 30, 2023, provided that any payment to a blocked person, including any blocked entity described in paragraph (b) of this general license, must be made into a blocked account and reported to the Office of Foreign Assets Control consistent with § 501.603 of the Reporting, Procedures and Penalties Regulations, 31 CFR part 501:

(1) All transactions prohibited by section 5 of Executive Order (E.O.) 13846 that are ordinarily incident and necessary to the wind down of any transaction involving any vessel in which one or more entities described in paragraph (b) of this general license have an interest, including the vessels described in the Annex to this general license (the ''blocked vessels''); and

(2) All transactions prohibited by the Iranian Transactions and Sanctions Regulations, 31 CFR part 560 (ITSR), that are ordinarily incident and necessary to any of the following activities involving the blocked vessels or entities described in paragraph (b) of this general license:

(i) The safe docking and anchoring of any of the blocked vessels in port;

(ii) The preservation of the health or safety of the crew of any of the blocked vessels; and

(iii) Emergency repairs of any of the blocked vessels or environmental mitigation or protection activities relating to any of the blocked vessels.

(b) The authorizations in paragraph (a) of this general license apply to the following entities:

(1) Golden Lotus Oil Gas and Real Estate Joint Stock Company;

(2) Swedish Management CO SA;

(3) Shanghai Xuanrun Shipping Company Limited;

(4) Global Marine Ship Management Co., Ltd.; or

(5) Any entity in which one or more of the above entities own, directly or indirectly, individually or in the aggregate, a 50 percent or greater interest.

(c) This general license does not authorize:

(1) The offloading of any Iranian-origin petroleum, petroleum products, or petrochemical products;

(2) The entry into any new commercial contracts involving the blocked vessels or the entities described in paragraph (b) of this general license, except as authorized by paragraph (a); or

(3) Any transactions otherwise prohibited by section 5 of E.O. 13846 or the ITSR, including transactions involving any person blocked pursuant to section 5 of E.O. 13846 or the ITSR other than the blocked entities described in paragraph (b) of this general license, unless separately authorized.