

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.*

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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](http://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](http://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.

Dated: March 2, 2023.

**Bradley T. Smith,**

*Deputy Director, Office of Foreign Assets Control.*

#### Annex

Vessels in which one or more of the entities described in paragraph (b) of Iran General License O have an interest:

(a) Vessels in which Golden Lotus Oil Gas and Real Estate Joint Stock Company has an interest:

- (1) Dolphin, IMO 9052331
- (2) Lauren, IMO 9249685
- (3) Golden Bridge, IMO 9218301
- (4) Golden Phoenix, IMO 9224790
- (5) Amias, IMO 9342786
- (6) Jamaica, IMO 9230098
- (7) Golden Light 09, IMO 9445057
- (8) Gas Cathar, IMO 9250505

(b) Vessels in which Swedish Management CO SA has an interest:

- (1) Rising Eagle, IMO 9073672
- (2) Rising Falcon, IMO 9105396
- (3) Rising Harrier, IMO 9122291
- (4) Cattle Force, IMO 9175901
- (5) Hercules, IMO 9558517
- (6) Gladiator, 7621011

(c) Vessels in which Shanghai Xuanrun Shipping Company Limited has an interest:

- (1) Yong Xiang 29, IMO 8744107
- (2) Forever Rich, IMO 9203928
- (3) Yong Xin, IMO 9203930
- (4) Xuan Ning, IMO 9349095
- (5) Liang Sheng, IMO 9526693
- (6) Full Star, 9773301

**Andrea M. Gacki,**

*Director, Office of Foreign Assets Control.*

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**BILLING CODE P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket Number USCG-2023-0216]

RIN 1625-AA00

#### Safety Zone; Ohio River, Cincinnati, OH

**AGENCY:** Coast Guard, Department of Homeland Security (DHS).

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is extending the duration of a temporary safety zone for all navigable waters of the Ohio River from mile marker (MM) 487.0 to MM 489.0. This action is necessary to provide for the safety of personnel, vessels, and the marine environment

from potential hazards created by Duke Energy's Static Wire Crossing operation taking place on the Ohio River from MM 487.0 to MM 489.0. Entry of vessel or persons into this zone is prohibited unless specifically authorized by the Captain of the Port, Sector Ohio Valley or a designated representative.

**DATES:** This rule is effective without actual notice from May 19, 2023, through May 19, 2023. For the purposes of enforcement, actual notice will be used from May 15, 2023, until May 19, 2023.

**ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG-2023-0216 in the search box and click "Search." Next, in the Document Type column, select "Supporting & Related Material."

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this rule, call or email Petty Officer Thomas Harp, MSD Cincinnati, U.S. Coast Guard; telephone number 513-921-9033, email [Thomas.L.Harp@uscg.mil](mailto:Thomas.L.Harp@uscg.mil).

#### SUPPLEMENTARY INFORMATION:

##### I. Table of Abbreviations

CFR Code of Federal Regulations  
COTP Captain of the Port  
DHS Department of Homeland Security  
FR Federal Register  
NPRM Notice of proposed rulemaking  
§ Section  
U.S.C. United States Code

##### II. Background Information and Regulatory History

On May 1, 2023, the Coast Guard issued a temporary final rule establishing a safety zone on all waters of the Ohio River from MM 487.0 to 489.0 to protect persons, vessels, and the marine environment from potential hazards created by Duke Energy's Static Wire Crossing operation (88 FR 28408, May 4, 2023). The original rule was effective through May 15, 2023. However, additional time is needed to conduct the static wire crossing, and, as a result, the Coast Guard needs to extend the safety zone through May 19, 2023. The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that

good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this extension because it would be impracticable and contrary to the public interest. The Coast Guard was unable to publish an NPRM and hold a reasonable comment period for this rulemaking because it is impracticable due to the emergent nature of the continuing wire crossing operation and required publication of this extension.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable and contrary to the public interest because immediate action is necessary to protect persons and property from the dangers associated with the static wire crossing operation.

##### III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port Sector Ohio Valley (COTP) has determined that potential hazards associated with the Duke Energy's Static Wire Crossing operation will be a safety concern for all navigable waters on the Ohio River from MM 487.0 to 489.0. This rule is needed to ensure the safety of life and vessels on these navigable waters.

##### IV. Discussion of the Rule

This rule extends the effective dates of an established safety zone, originally established on May 1, 2023, and effective through May 15, 2023, through May 19, 2023. The safety zone includes all navigable waters of the Ohio River between MM 487.0 to 489.0. The extended duration of the zone is intended to protect personnel, vessels, and the maritime environment in these navigable waters while static wire crossing operations are conducted. No vessel or persons will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. Vessels may contact Sector Ohio Valley Command Center on VHF-FM Channel 16 or by telephone at 1-800-253-7465. Person and vessel permitted to enter this regulated area must transit at their slowest safe speed and comply with all lawful directions issued by the COTP or the designated representative.

##### V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and