

**§ 1310.09 Temporary exemption from registration.**

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(q)(1) Each person required under 21 U.S.C. 822 and 957 to obtain a registration to manufacture, distribute, import, or export regulated forms of 3,4-MDP-2-P methyl glycidate (PMK glycidate), 3,4-MDP-2-P methyl glycidic acid (PMK glycidic acid), and *alpha*-phenylacetoacetamide (APAA), including regulated chemical mixtures pursuant to § 1310.12, is temporarily exempted from the registration requirement, provided that DEA receives a properly completed application for registration or application for exemption for a chemical mixture containing regulated forms of 3,4-MDP-2-P methyl glycidate (PMK glycidate), 3,4-MDP-2-P methyl glycidic acid (PMK glycidic acid), or *alpha*-phenylacetoacetamide (APAA) pursuant to § 1310.13 on or before (30

days after publication of a rule implementing regulations regarding these three chemicals). The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in the Act and parts 1309, 1310, 1313, and 1316 of this chapter remain in full force and effect.

(2) Any person who manufactures, distributes, imports or exports a chemical mixture containing regulated forms of 3,4-MDP-2-P methyl glycidate (PMK glycidate), 3,4-MDP-2-P methyl glycidic acid (PMK glycidic acid), or *alpha*-phenylacetoacetamide (APAA) whose application for exemption is subsequently denied by DEA must obtain a registration with DEA. A temporary exemption from the registration requirement will also be

provided for those persons whose applications for exemption are denied, provided that DEA receives a properly completed application for registration on or before 30 days following the date of official DEA notification that the application for exemption has been denied. The temporary exemption for such persons will remain in effect until DEA takes final action on their registration application.

■ 5. In § 1310.12, in paragraph (c), add in alphanumerical order entries for 3,4-MDP-2-P methyl glycidate (PMK glycidate), 3,4-MDP-2-P methyl glycidic acid (PMK glycidic acid), and *alpha*-phenylacetoacetamide (APAA) in the table “Table of Concentration Limits” to read as follows:

**§ 1310.12 Exempt chemical mixtures.**

\* \* \* \* \*

(c) \* \* \*

TABLE OF CONCENTRATION LIMITS

|  | DEA chemical code no. | Concentration                    | Special conditions   |
|--|-----------------------|----------------------------------|--|
| * * * * *  |                       |                                  |  |
| 3,4-MDP-2-P methyl glycidate (PMK glycidate) and its optical and geometric isomers.                                      | 8535                  | Not exempt at any concentration. | Chemical mixtures containing any amount of this chemical are not exempt. |
| 3,4-MDP-2-P methyl glycidic acid (PMK glycidic acid) and its salts, optical and geometric isomers, and salts of isomers. | 8525                  | Not exempt at any concentration. | Chemical mixtures containing any amount of this chemical are not exempt. |
| Alpha-phenylacetoacetamide (APAA) and its optical isomers.   | 8515                  | Not exempt at any concentration. | Chemical mixtures containing any amount of this chemical are not exempt. |
| * * * * *  |                       |                                  |  |

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**D. Christopher Evans,**

*Acting Administrator.*

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**AGENCY FOR INTERNATIONAL DEVELOPMENT**

**22 CFR Part 228**

[AID-2020-0004]

RIN 0412-AB09

**Procurement of Certain Essential Medical Supplies To Address the COVID-19 Pandemic**

**AGENCY:** Agency for International Development.

**ACTION:** Final rule; technical amendments.

**SUMMARY:** On October 23, 2020, the United States Agency for International

Development (USAID) issued a Temporary Final Rule (TFR) amending our regulations to allow USAID to waive “Source and Nationality” rules to provide for increased flexibility, targeting, and speed of procurement of Essential Medical Supplies required to address the COVID-19 pandemic worldwide. The TFR was effective through April 30, 2021. This document reverts the amended sections to the text of those sections as they existed prior to the issuance of the TFR, with minor technical updates. This reversion to the original text is applicable upon the expiration of the TFR.

**DATES:** This rule is effective May 10, 2021. As stated in the October 23, 2020, final rule, the TFR was effective from October 23, 2020, through April 30, 2021. The amendments in this rule are applicable beginning May 1, 2021, after the expiration of the TFR.

**ADDRESSES:** You may review the docket by searching for Docket ID [AID-2020-

0004], via the Federal eRulemaking Portal: <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** Greg Marchand, Assistant General Counsel, Office of the General Counsel, USAID, 1300 Pennsylvania Ave. NW, Washington, DC 20523, 202-215-3409, [GCFEDREGMailbox@usaid.gov](mailto:GCFEDREGMailbox@usaid.gov).

**SUPPLEMENTARY INFORMATION:** This document affects 22 CFR 228.01, which was amended by the TFR published in the **Federal Register** on October 23, 2020 (85 FR 67443) and subsequently corrected on December 16, 2020 (85 FR 81390). The TFR and its subsequent correction revised the definitions in § 228.01 by adding a new definition for “Essential medical supplies.” This document reinstates the definitions in § 228.01 exactly as they existed prior to the issuance of the TFR. This document also reverts 22 CFR 228.11 and 228.30, which were also amended by the TFR published in the **Federal Register** on October 23, 2020 (85 FR 67443). The TFR amended these sections to create a

new approval requirement and basis for waivers for the source and nationality of essential medical supplies. This document reverts the language of both sections to the text as it existed prior to the issuance of the TFR, with minor technical updates.

#### List of Subjects in 22 CFR Part 228

Government procurement.

The Deputy General Counsel of USAID, Suk J. Jin, having reviewed and approved this document, is delegating the authority to electronically sign this document to Gregory A. Marchand, Assistant General Counsel for USAID, for purposes of publication in the **Federal Register**.

**Gregory A. Marchand,**

*Assistant General Counsel, U.S. Agency for International Development.*

For reasons stated in the preamble, USAID amends 22 CFR part 228 as follows:

#### **PART 228—RULES FOR PROCUREMENT OF COMMODITIES AND SERVICES FINANCED BY USAID**

■ 1. The authority citation for 22 CFR part 228 continues to read as follows:

**Authority:** Sec. 621, Pub. L. 87–195, 75 Stat. 445 (22 U.S.C. 2381), as amended, E.O. 12163, Sept. 29, 1979, 44 FR 56673; 3 CFR 1979 Comp., p. 435.

■ 2. Revise § 228.01 to read as follows:

##### **§ 228.01 Definitions.**

As used in this part, the following terms shall have the following meanings:

*Advanced developing countries* mean those countries that are categorized by the World Bank as upper middle income countries according to their gross national income per capita, except for those countries in which USAID provides assistance. USAID will maintain a list of advanced developing countries primarily based on the most recent World Bank determinations, and will make the list available in USAID's Automated Directives System, ADS 310. This list will include determinations made under § 228.17.

*Available for purchase* means for commodities, that the commodity is offered for sale in a country in the authorized principal geographic code at the time of purchase from the supplier, irrespective of the place of manufacture or production, unless it is a prohibited source country. If applicable, the commodity must also be able to be serviced, and, if warrantied, have a valid warranty. For services, available for purchase means the service is offered from a vendor which has

complied with nationality and foreign government-owned organization requirements of this regulation, and is otherwise organized in a country in the authorized principal geographic code designated in an implementing instrument. This definition does not apply to procurements under the geographic Code 935, see § 228.03, because that geographic code is for any country or area except for prohibited source countries.

*Commission* means any payment or allowance by a supplier to any person for the contribution which that person has made to secure the sale or contract for the supplier or which that person makes to securing on a continuing basis similar sales or contracts for the supplier.

*Commodities* or *goods* means any material, article, supply, good, or equipment.

*Commodity-related services* means delivery services and/or incidental services.

*Cooperating country* or *recipient country* means the country receiving the USAID assistance subject to this part, and includes all the countries receiving assistance under a regional program or project.

*Delivery* means the transfer to, or for the account of, an importer of the right to possession of a commodity, or, with respect to a commodity-related service, the rendering to, or for the account of, an importer of any such service.

*Delivery service* means any service customarily performed in a commercial export or import transaction which is necessary to affect a physical transfer of commodities to the cooperating/recipient country. Examples of such services are the following: export packing, local drayage in the source country (including waiting time at the dock), ocean and other freight, loading, heavy lift, wharfage, tollage, switching, dumping and trimming, lighterage, insurance, commodity inspection services, and services of a freight forwarder. "Delivery service" may also include work and materials necessary to meet USAID marking requirements.

*Developing countries* means those countries that are categorized by the World Bank as low or lower middle income economies according to their gross national income per capita, and also includes all countries to which USAID provides assistance. USAID will maintain a list of developing countries primarily based on the most recent World Bank determinations, and will make the list available in USAID's Automated Directives System, ADS 310.

*Free Port* or *Bonded Warehouse* is a special customs area with favorable

customs regulations (or no customs duties and controls for transshipment).

*Implementing instrument* means a binding relationship established between USAID and an outside party or parties to carry out USAID programs, by authorizing the use of USAID funds and/or nonfinancial resources for the procurement of services or commodities and/or commodity related services. Implementing instruments include specific conditions that apply to each such procurement. Examples of such instruments include contracts, grants, cooperating agreements, and interagency agreements.

*Incidental services* means services such as installation, erection, maintenance, or upgrading of USAID-financed equipment, or the training of personnel in the maintenance, operation and use of such equipment, or similar services provided for the authorized disposition of such commodities.

*Long term lease* means, for purposes of subpart B of this part, a single lease of more than 180 calendar days; or repetitive or intermittent leases under a single award within a one-year period, which cumulatively total more than 180 calendar days. A single lease may consist of lease of one or more of the same type of commodity within the same lease term.

*Motor vehicles* means self-propelled vehicles with passenger carriage capacity, such as highway trucks, passenger cars and buses, motorcycles, scooters, motorized bicycles, ATVs, and utility vehicles. Excluded from this definition are ambulances, snowmobiles, industrial vehicles for materials handling and earthmoving, such as lift trucks, tractors, graders, scrapers, off-the-highway trucks (such as off-road dump trucks), boats, and other vehicles that are not designed for travel at normal road speeds (40 kilometers per hour and above).

*Mission* means the USAID Mission, office or representative in a cooperating/recipient country.

*Nationality* refers to the place of legal organization, ownership, citizenship, or lawful permanent residence (or equivalent immigration status to live and work on a continuing basis) of suppliers of commodities and services.

*Pharmaceutical* means any substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases in humans or animals; any substances (other than food) intended to affect the structure or any function of the body of humans or animals; and, any substance intended for use as a component in the above. The term includes drugs, vitamins, oral rehydration salts, biologicals, and some

in-vitro diagnostic reagents/test kits; but does not include devices or their components, parts, or accessories. Contraceptives, including condoms, are not included in this definition.

*Prohibited sources* means countries to which assistance is prohibited by the annual appropriations acts of Congress or other statutes, or those subject to other executive branch restrictions, such as applicable sanctions administered by the U.S. Treasury Department's Office of Foreign Assets Control. USAID maintains a list of prohibited sources, available in USAID's Automated Directives System, ADS 310.

*Recipients and contractors.* *Recipient* has the same meaning as defined in 22 CFR 226.02, except that it shall include non-U.S. individuals, entities and organizations, as well as subrecipients. *Contractors* mean those entities which enter into a contract, as the term is defined in 48 CFR part 2, with the U.S. Government, and includes subcontractors.

*Services* means the performance of identifiable tasks, rather than the delivery of an end item of supply.

*Source* means the country from which a commodity is shipped to the cooperating/recipient country or the cooperating/recipient country itself if the commodity is located therein at the time of the purchase, irrespective of the place of manufacture or production, unless it is a prohibited source country. Where, however, a commodity is shipped from a free port or bonded warehouse in the form in which received therein, "source" means the country from which the commodity was shipped to the free port or bonded warehouse.

*Supplier* means any person or organization, governmental or otherwise, who furnishes services, commodities, and/or commodity related services, including delivery or incidental services, financed by USAID.

*United States* means the United States of America, any State(s) of the United States, the District of Columbia, and areas of U.S. associated sovereignty, including commonwealths, territories, and possessions.

*USAID* means the United States Agency for International Development or any successor agency, including when applicable, each USAID Mission or office abroad.

*USAID Principal Geographic Code* means a USAID code which designates a country, a group of countries, or an otherwise defined area. The USAID principal geographic codes for purposes of procurement are described in § 228.03.

■ 3. Revise § 228.11 to read as follows:

#### § 228.11 Source of commodities.

The source of all commodities financed with Federal program funds appropriated under the Foreign Assistance Act of 1961, as amended, shall be Code 937 (unless Code 935 or 110 are designated in the implementing instrument). Procurements of agricultural commodities, motor vehicles, and pharmaceuticals must also comply with the special procurement rules in § 228.19. Recipients and contractors are prohibited from engaging suppliers of commodities in an authorized country to import commodities from a country outside of the authorized principal geographic codes for the purposes of circumventing the requirements of this section. Any violation of the prohibition in the preceding sentence will result in the disallowance by USAID of the cost of the procurement of the subject commodity.

■ 4. Revise § 228.30 to read as follows:

#### § 228.30 General.

USAID may waive the rules contained in subparts A, B, and C of this part (except for prohibited sources as defined in § 228.01, and §§ 228.21 and 228.22), in order to accomplish project or program objectives. For any waivers authorized, the principal geographic code shall be Code 935, any area or country but excluding prohibited sources. All waivers must be in writing, and where applicable, are limited to the term established by the waiver. All waiver decisions will be made solely on the basis of the following criteria:

(a) Waivers to permit procurement outside of Code 937 or 110 must be based on a case by case determination that:

(1) The provision of assistance requires commodities or services of the type that are not produced in and available for purchase in Code 937 or 110;

(2) It is important to permit procurement from a country not specified in Code 937 or 110 to meet unforeseen circumstances; or

(3) To promote efficiency in the use of United States foreign assistance resources, including to avoid impairment of foreign assistance objectives.

(b) Case by case waivers under paragraph (a) of this section may be made on the basis of a commodity or service type or category, rather than processing repeat, individual waivers for an identical or substantially similar commodity or service. Such waivers may be approved on a regional, country, or program basis. For purposes of paragraph (a)(1) of this section,

"produced in and available for purchase in" shall have the same meaning as the definition of "available for purchase" in § 228.01. A waiver under paragraph (a)(1) of this section may also be based on the fact that a commodity is not available for purchase in Code 937 or 110 in sufficient, reasonable, and available quantities or sufficient and reasonable quality that is fit for the intended purpose.

(c) A waiver to authorize procurement from outside the United States of agricultural commodities, motor vehicles, and pharmaceuticals must meet the requirements of § 228.19.

(d) Any individual transaction not exceeding \$25,000 (excluding those covered by special procurement rules in § 228.19, and excluding procurements from prohibited sources) does not require a waiver and is hereby authorized.

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket Number USCG-2021-0287]

RIN 1625-AA00

#### Safety Zone; Lower Mississippi River, Mile Marker 770, Randolph Bluff, TN

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone for all navigable waters of the Lower Mississippi River (LMR), Mile Marker 762 through 782. The safety zone is needed to protect persons, property, and the marine environment from the potential safety hazards associated with a rock replacement project in the vicinity of Randolph Bluff, TN. Entry of persons or vessels into this zone is prohibited unless authorized by the Captain of the Port Sector Lower Mississippi River or a designated representative.

**DATES:** This rule is effective without actual notice from May 10, 2021 until May 31, 2021. For the purposes of enforcement, actual notice will be used from April 27, 2021, until May 10, 2021.

**ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG-2021-0287 in the "SEARCH" box and click