

ADS Chapter 312

Eligibility of Commodities

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ADS 312 – Eligibility of Commodities

312.1 OVERVIEW

Effective Date: 02/24/2011

This chapter provides the policy directives and required procedures

- To assure that the resources made available by USAID in the form of commodities make a positive contribution to development.
- 2) To assure that USAID programs are implemented in full accord with the Foreign Assistance Act, other pertinent laws, and relevant U.S. policies.
- 3) To provide for the quality of pharmaceuticals.
- 4) To provide for economical procurement of contraceptive products.

This chapter covers the policies on the eligibility of commodities for financing with program funds. It does not deal with programmatic determinations of commodity eligibility. The policy on motor vehicles also applies to Operating Expense funds.

312.2 PRIMARY RESPONSIBILITIES

Effective Date: 05/08/2020

The following are the B/IO responsibilities regarding this chapter:

a. Office of the General Counsel (GC):

Interprets the legal framework for and coordinates the policy and procedures for the USAID commodity eligibility criteria.

b. Bureau for Global Health, Office of Population and Reproductive Health (GH/PRH):

Develops the policy for and administers the restricted commodity approval process for contraceptives and condoms.

c. Bureau for Global Health, Office of HIV/AIDS, Supply Chain for Health Division (GH/OHA/SCH) (formerly GH/OHA/SCMS):

Develops the policy for and administers the restricted commodity approval process for non-contraceptive pharmaceuticals.

d. Bureau for Global Health, Office of Health, Infectious Disease, and Nutrition (GH/HIDN):

Provides concurrence for the restricted commodity approval of purchases of pharmaceuticals for the following programs: malaria, tuberculosis, neglected tropical diseases, emerging pandemic threats, nutrition, and maternal and child health.

e. Bureau for Resilience and Food Security (RFS):

Develops the policy for and administers the restricted commodity approval process for agricultural commodities and fertilizer.

f. Bureau for Management, Office of Acquisition and Assistance, Policy Division (M/OAA/P):

Implements policy regarding the restricted commodities and USAID commodity eligibility in USAID acquisition and assistance directives and regulations, e.g., ADS 302, ADS 303 and ADS 308.

312.3 POLICY DIRECTIVES AND REQUIRED PROCEDURES

Effective Date: 08/10/2011

This section contains the mandatory policies and required procedures for ADS Chapter 312.

312.3.1 "USAID Commodity Eligibility Listing"

Effective Date: 10/26/2015

The "<u>USAID Commodity Eligibility Listing</u>" (CEL) indicates USAID's current position on the eligibility or ineligibility of commodities for USAID financing except as indicated in **312.3.3.1** and **312.3.3.7**. The references in this ADS Chapter and ADS 103 take precedence over any offices or operating units referenced in the CEL.

312.3.1.1 Commodity Import Programs

Effective Date: 02/06/2012

Under Commodity Import Programs (CIPs), the entire CEL, or a portion thereof, may be authorized for financing. Commodities which are normally ineligible are not eligible for financing unless specifically authorized in writing by USAID. USAID reserves the right, upon the review of a supplier's Application for Approval of Commodity Eligibility (AID Form 11), to decline to finance any commodity when in USAID's judgment such financing would adversely affect USAID's program objectives or the foreign policy objectives of the United States.

A commodity which is designated as ineligible in the CEL shall only be financed after it has been approved in writing by:

- 1) The Bureau Assistant Administrator who has program responsibility;
- 2) The Principal Officer at post, in consultation with a Commodity Management Officer or a Regional Legal Advisor (RLA); or
- 3) If eligibility is based on a requirement in sections 312.3.3 312.3.5, the official designated in the applicable section.

For transactions under CIPs, a copy of the approval of an otherwise ineligible commodity must be sent to the Office of Acquisition and Assistance, Transportation and Commodity Division (M/OAA/TC), as soon as possible so as to assure approval of the AID Form 11, Application for Approval of Commodity Eligibility.

312.3.1.2 Other Activities

Effective Date: 05/01/1998

For other than CIPs, USAID decides what commodities are authorized for financing based on the needs of the activity. Commodities, that are ineligible under the CEL, may be financed if included in the activity approval document. If an ineligible commodity that was not included in the activity approval document is needed for satisfactory completion of the activity, USAID may finance it only after it has been approved in writing by USAID.

312.3.2 Prior Approval of Commodity Transactions

Effective Date: 07/06/1988

Under CIPs, USAID shall not authorize payment to a supplier or effect payment to a cooperating country grantee until it has approved the commodities the supplier is furnishing as being eligible and suitable for financing.

Every supplier under CIPs must provide USAID with a certified description of the commodities being supplied. <u>Form AID 11</u> is the document used in implementing the requirement. Eligibility and suitability of commodities are defined as including the following elements:

- a) The commodity is authorized for financing by the applicable assistance agreement;
- b) The commodity is unused;
- c) The source of the commodity satisfies the authorized source requirements under the assistance agreement;

- d) The supplier is eligible for USAID financing;
- e) From a preliminary scanning, it appears that the price charged is not inconsistent with USAID's price requirements; and
- f) See <u>22 CFR 201 (AID Regulation 1), sections 201.11(k) and 201.52(a)(8)</u> for further details.

312.3.3 Restricted Commodities

Effective Date: 01/01/1997

Special restrictions apply to USAID-financed purchases of agricultural commodities, motor vehicles, pharmaceuticals, contraceptive products, pesticides, used equipment and fertilizer. The restrictions are set out in 312.3.3.1 through 312.3.3.7.

312.3.3.1 Agricultural Commodities

Effective Date: 06/17/2020

The following procedures apply to the procurement or financing of agricultural commodities under the authority of the <u>Foreign Assistance Act of 1961</u>, as amended <u>(FAA)</u>, with the exception of emergency humanitarian assistance provided under International Disaster Assistance authority (Section 491 of the FAA).

When considering awardee requests for approval of agricultural commodity financing, AORs/CORs or Operating Units (OUs) must consider each of the following three sets of requirements that may pertain: a) General Eligibility and Technical Requirements for Agricultural Commodities; b) Special Requirements for Financing Non-U.S. Agricultural Commodities; and c) Approval of Agricultural Commodities Also Available through Food for Peace. Prior to making an award, OUs may address these requirements during their planning process and incorporate prior approvals pursuant to this section into the award. During award implementation, the awardee will submit requests for approval to finance an agricultural commodity to the AO/CO per the terms of the individual award, and the AOR/COR will seek the required written approvals described below.

As provided in the terms and conditions of each individual award (AIDAR clause 752.225-70, "Source and Nationality Requirements" for contracts and the standard provision "USAID Eligibility Rules for procurement of commodities and services" for assistance awards), the Contracting Officer/Agreement Officer (CO/AO) is authorized to communicate USAID's approval granted pursuant to this section to the awardee.

These requirements are in addition to source and nationality requirements as set forth in ADS 310.

a. General Eligibility and Quality and Safety Requirements for Agricultural Commodities

ADS 312mac, Agricultural Commodity Eligibility and Requirements
Relating to Quality and Safety indicates whether agricultural commodities are
eligible for financing and describes requirements relating to quality and safety for
certain types of commodities. ADS 312mac, Agricultural Commodity Eligibility
and Requirements Relating to Quality and Safety supersedes the USAID
Commodity Eligibility Listing requirements (see section 312.3.1), specifically,
Chapters 1-21, Part II.A (Agricultural Commodities), Part III Special Provision 1
(Seeds), and Part III Special Provision 4 (Grains, Rice, Beans and Soybeans). If
an agricultural commodity is ineligible or does not conform to eligibility, quality or
safety requirements, the AOR/COR or OU may request a waiver or modification
of these requirements by sending an email to
agcommoditiesapprovals@usaid.gov. The Bureau for Resilience and Food
Security (RFS) Chief Scientist, or any other person designated by the Assistant
to the Administrator for RFS, is authorized to approve these requests.

b. Special Requirements for Financing Non-U.S. Agricultural Commodities

In accordance with <u>Section 604(e) of the FAA</u> and <u>22 CFR 228.19</u>, USAID will not finance the procurement of non-U.S. agricultural commodities or products under FAA authority when the U.S. price is below "parity" (as defined in section 312.6) unless the commodity cannot reasonably be produced in the U.S. in fulfilment of the objectives of the assistance program under which the procurement is to be financed.

The following procedures implement the requirements of FAA Section 604(e) for proposed USAID-financed procurement of non-U.S. agricultural commodities:

- 1) Checking Parity Price: The AOR/COR or OU must determine whether there is a "parity price" for the item listed on the U.S. Department of Agriculture (USDA) <u>Agricultural Prices Report</u>. If the U.S. price for that item is below the parity price, procurement of the item outside of the U.S. may not be financed by USAID without prior approval. If no parity price exists or if the U.S. price is equal to or above the parity price, then further approval pursuant to this section, ADS 312.3.3.1(b), is not required.
- 2) Requesting Prior Approval: If the U.S. price for an item is below the "parity price", USAID may only approve non-U.S. procurement if the commodity to be financed could not reasonably be produced in the U.S. in fulfillment of the objectives of the particular assistance program. The procedure for obtaining such approval is as follows:
 - i. When Financing Exceeds \$1 Million: The Bureau Assistant Administrator having program responsibility, in consultation with RFS and the cognizant GC attorney, must approve financing procurements of non-U.S. agricultural commodities or products

exceeding U.S. \$1 million in aggregate value per fiscal year per commodity per award, pursuant to the following process:

- a. The AOR/COR or OU prepares and submits an action memorandum, cleared by the Mission/Office Director, to RFS through the agcommoditiesapprovals@usaid.gov mailbox for technical review;
- **b.** RFS convenes a panel to review the technical merits of the request and, if it concurs with the Mission's/Office's analysis, provides a "concurrence memorandum" to the Mission/Office; and
- c. The Mission/Office attaches the RFS concurrence memorandum to its action memorandum and submits the full package for approval by the cognizant Bureau Assistant Administrator pursuant to relevant Bureau procedures.
- ii. When Financing Does Not Exceed \$1 Million: Mission Directors and USAID/W Office Directors with program responsibility have the authority to approve financing procurements of non-U.S. agricultural commodities or products not exceeding U.S. \$1 million in aggregate value per fiscal year per commodity per award. Mission Directors and USAID/W Office Directors must obtain RLO or GC clearance, as applicable, prior to approving such financing, and must submit a copy of the authorizing documents to RFS through the agcommoditiesapprovals@usaid.gov mailbox. For purposes of seeking approval, Missions and USAID/W staff are encouraged to use the Template of Approval Request for Agricultural Commodity Financing Under ADS Chapter 312.

c. Approval of Agricultural Commodities Also Available through Food for Peace

In accordance with <u>Section 604(c) of the FAA</u>, USAID will only approve the procurement of agricultural commodities and products that are also available for disposition under the Food for Peace Act (P.L. 480), from outside the U.S. when procuring those commodities from the U.S. would be impracticable and not in furtherance of USAID's purpose, or when the commodities are not available in sufficient quantities in the U.S. to supply emergency requirements.

The following procedures implement the requirements of FAA Section 604(c) for proposed USAID-financed procurements of agricultural commodities and products that are also available for disposition under the Food for Peace Act, as

listed by the Bureau for Humanitarian Assistance (BHA) in its Commodity and Ocean Freight Price Estimates.

For purposes of seeking approval, Missions and USAID/W staff are encouraged to use the <u>Template of Approval Request for Agricultural Commodity</u>
<u>Financing Under ADS Chapter 312</u>.

1) Review of Availability: The AOR/COR or OU must conduct a review of the proposed procurement including an examination of the eligibility and availability of the commodity under an existing Food for Peace Act agreement or award in the same country, or the possibility of a new agreement in the same country. Food for Peace Act financing, if available, is the preferred means of supply, except that USAID may consider financing additional quantities of the commodity if the Food for Peace Act amount is deemed inadequate and there are no other reasons for excluding the commodity from the USAID award. Based on their review, the AOR/COR or OU submits a request for approval as detailed below.

2) Required Approvals:

- a. When Financing Exceeds \$1 Million: Based on the review of availability described above, the cognizant Bureau Assistant Administrator, in consultation with the BHA (dcha.ffppolicygroup@usaid.gov), must approve all proposed USAID-financed procurements of agricultural commodities that are also currently available under the Food for Peace Act, as listed on the USAID Web site, exceeding U.S. \$1 million in aggregate value per fiscal year per commodity per award.
- b. When Financing Does Not Exceed \$1 Million: Based on the review described above, Mission Directors and USAID/W Office Directors with program responsibility, in consultation with FFP, have the authority to approve procurements not exceeding U.S. \$1 million in aggregate value per fiscal year per commodity per award.

312.3.3.2 Motor Vehicles

Effective Date: 02/06/2012

As stated at 22 CFR 228.19, special manufacturing rules requiring procurement from the United States apply when obtaining motor vehicles with program funds. Operating Expense (OE) funded motor vehicles are also subject to the requirements of this section (see ADS Chapter 536); for additional policy and procedures for motor vehicles purchased under CIPs, see paragraph c. below. This section provides policy and

procedures on obtaining motor vehicles and requesting waivers to this requirement when justified. **22 CFR 228.01** provides the definition of motor vehicles for purposes of this section; as a matter of policy, all-terrain vehicles (ATVs) are considered to be motor vehicles; ambulances, snowmobiles, and motorboats are not.

a. General Requirements

USAID funds may be used to finance the procurement of passenger cars that are necessary for an activity and are not otherwise available (e.g., provided by other donors).

Passenger cars may include air conditioning (installed as original equipment or aftermarket), provided the requesting office justifies the need in the activity file. Factors that should be considered in justifying air conditioning include:

- The climate in which the motor vehicle will operate,
- The capabilities for servicing air conditioning equipment, and
- The need for austerity and economy in implementation.

b. Manufacture Requirements

In accordance with <u>Section 636(i) of the Foreign Assistance Act of 1961 (FAA)</u>, as amended, and the special source rules at **22 CFR 228.19**, motor vehicles must be manufactured in the United States to be eligible for USAID financing, unless a waiver is approved. This requirement applies to motor vehicles that are purchased, obtained under a long-term lease, or where the sale is guaranteed by USAID. A long-term lease for the purpose of this section is defined at **22 CFR 228.01**, as, specifically, "a) a single lease of more than 180 calendar days; or b) repetitive or intermittent leases under a single award within a one-year period, which cumulatively total more than 180 calendar days."

However, Section 496(n) of the FAA on the Development Fund for Africa (DFA) authorizes the purchase or long-term lease of non-U.S.-manufactured motor vehicles financed with development assistance (DA), child survival and health (CSH), and similar funds for Africa, whether or not as part of a worldwide program. This DFA procurement authority does not apply to economic support funds (ESF) or OE funds. Procurement of motor vehicles is discussed in Memorandum to Africa Field Posts on Special Procurement Policy Rules Governing the Development Fund for Africa, dated February 1, 1993.

1. General Waiver Requirements

A program office may request a waiver to the requirement for manufacture in the United States under Subpart D of 22 CFR 228 and the procedures in this section.

- For waivers processed prior to award of any implementing instrument, the office in the Mission or Bureau with program responsibility is responsible for processing respective waivers in accordance with policies and procedures of this chapter.
- Once an implementing instrument is awarded, the Contracting Officer's Technical Representative/Agreement Officer's Technical Representative (COR/AOR) is responsible for reviewing waiver requests submitted by contractors or recipients for accuracy and compliance before processing the waiver in accordance with the policies and procedures of this chapter.

The requirement to purchase or lease only U.S.-manufactured motor vehicles may be waived on a case-by-case basis when special circumstances exist and those special circumstances are supported by market research and adequate documentation. Special circumstances that merit waiving the requirement include, but are not limited to:

- (a) The inability of U.S. manufacturers to provide a particular type of needed motor vehicle;
- (b) The present or projected lack of adequate service facilities and supply of spare parts for U.S.-manufactured motor vehicles in the country or region within a country where the vehicle will be used; or
- (c) An emergency requirement for motor vehicle(s) that can be met in time only by purchase of non-U.S.-manufactured motor vehicle(s) and for which no non-USAID funds are available.

Waivers based on special circumstances other than the ones listed above require clearance by the cognizant GC attorney or RLA. Note: Higher costs associated with procuring a U.S.-manufactured motor vehicle are not special circumstances. In addition, delays in receipt associated with shipping a U.S.-manufactured motor vehicle to a cooperating country are not special circumstances. In the event of such delays, the implementer may use short-term leases of motor vehicles until receipt of the U.S.-manufactured motor vehicle.

For a summary of the statutory basis and content requirements of waiver requests, see <u>312sab</u>, <u>Source/Manufacture Motor Vehicle Waiver Request Template</u>, and some helpful tips, see <u>312sac</u>, <u>Source/Manufacture Vehicle Waiver Request Guide</u>.

2. Blanket Waiver for Right-Hand Drive (RHD) Motor Vehicles and Lightweight/Mediumweight Two-Wheel and Three-Wheel Motor Vehicles

The Agency recognizes the continuing lack of available types of right-hand drive (RHD) motor vehicles and lightweight/mediumweight two-wheel and three-wheel motor vehicles manufactured in the United States. Accordingly, the Administrator has approved a blanket waiver for the limited models of such vehicles manufactured in the

United States do not suit project needs or are not locally serviceable. The waiver requires implementing partners or the Mission (for Operational-Expense funded procurements) to document the reason for each use of the waiver. Implementing partners must provide, within 90 days after each such procurement, an informational copy of such documentation to the USAID COR or AOR to be included in the contract or award file.

Currently, this waiver applies to:

- RHD motor vehicles, in circumstances where a Jeep Cherokee or Jeep Wrangler would not suit project needs or be locally serviceable; and
- Lightweight and mediumweight (below 600 cubic centimeters (cc)) two-wheel and three-wheel motor vehicles, in circumstances where a Rokon motorcycle would not suit project needs or be locally serviceable.

Where local serviceability is determined by the availability of adequate service facilities and supply of spare parts for such motor vehicles in the country or region within a country were the motor vehicle will be used.

RHD Motor Vehicles

Market research and experience indicate that the only U.S.-manufactured RHD motor vehicles currently available are the Jeep Cherokee and Jeep Wrangler. When program activities require a RHD motor vehicle, only U.S.-manufactured Jeep Cherokees or Jeep Wranglers are eligible for purchase or lease, unless the implementer or Mission determines that the Jeeps are not adequate for project demands. For example, a program activity may require a RHD motor vehicle with greater cargo space and/or passenger capability (that is, a cargo or passenger van), or may require a smaller sedan car with greater fuel efficiency. Additionally, the waiver applies where there is a lack of adequate service facilities and/or spare parts for the U.S.-manufactured Jeeps in the country or region within a country where the motor vehicle will be used.

Lightweight/Mediumweight Two-Wheel and Three-Wheel Motor Vehicles

Currently, U.S.-based Rokon is the only known manufacturer of lightweight/mediumweight motorcycles in the United States. When program activities require a lightweight/mediumweight motorcycle, only U.S.-manufactured Rokon models are eligible for purchase or lease, unless the implementer determines that they are not suitable or adequate for project demands. Rokons are all-terrain motorcycles built for rugged terrain, which may be suitable for some applications under USAID activities in the field. However, in other cases such as more urban applications, Rokon motorcycles are not well-suited to project demands. Additionally, the waiver applies where there is a lack of adequate service facilities and/or spare parts for Rokon motorcycles in the country or region within a country were the vehicle will be used.

3. Regional, Country, and Program Waivers

Blanket waivers for procurement or long-term lease of non-U.S.-manufactured motor vehicles may be issued on a regional, country, or program basis. Such waivers must meet the following criteria:

- (a) The waiver documents completion of a market survey demonstrating that either special circumstance outlined in subparagraph 1, section (a) or (b) above exists and has been historically consistent for the particular country. In the case of special circumstances, in subparagraph 1, section (c) or other special circumstances, the waiver provides adequate supporting justification.
- (b) The waiver states the specific period of time for the waiver to be in effect, and that it will be reviewed and market research updated annually to verify that the original conditions supporting the waiver still exist.
- (c) The waiver requires implementing partners or the Mission (for OE-funded procurements) to document the reason for each use of the waiver.

 Implementing partners must provide, within 90 days after each such procurement, an information copy of such documentation to the USAID COR/AOR to be included in the contract or award file.

USAID Missions and Bureaus may determine the appropriateness of regional, country, or program-specific waivers to address country conditions that require the use of particular needed types of non-U.S.-manufactured motor vehicles.

4. Waiver Approval

Delegations of authority to waive source and nationality requirements for the procurement of goods and services are set forth in ADS Chapter 103; waivers must also comply with the procedures outlined in ADS Chapter 310, if applicable.

c. Commodity Import Programs

Under CIPs, USAID must not finance cars principally intended to carry passengers. Even the least expensive cars are luxury items in less developed countries and thus not suitable for USAID financing. In exceptional cases, the Mission may consider the purchase of passenger cars under CIPs to be justifiable. The Mission must first obtain written approval for the proposed procurement from the cognizant Bureau Assistant Administrator or head of Independent Office (/BIO). Only the most economical passenger cars for the intended purpose will be considered by B/IO; air conditioning and other generally nonessential appointments are not authorized unless justified and included in the B/IO approval.

312.3.3.3 Pharmaceuticals

Effective Date: 02/24/2011

- Prior to the financing of non-contraceptive pharmaceuticals, CORs/AORs must obtain prior written approval from GH/OHA/SCH in order to provide for the quality of the pharmaceuticals. This approval is in addition to the source-nationality requirements in ADS 310. This restricted commodity approval does not apply to contraceptive pharmaceuticals. See ADS 312.3.3.4 for contraceptive pharmaceuticals.
- 2. The Director of GH/HIDN or designee(s) must provide concurrence on procurements of pharmaceuticals for the following programs: malaria, tuberculosis, neglected tropical diseases, emerging pandemic threats, nutrition, and maternal and child health. Many of the pharmaceuticals, including diagnostic test kits that are required for these programs, have unique properties, require additional evidence on efficacy, and have specific quality requirements in addition to the standard pharmaceutical quality requirements. GH/OHA/SCH obtains GH/HIDN concurrence as part of the GH/OHA/SCH approval process.
- 3. GH/OHA/SCH approval is for a specific pharmaceutical from a specific manufacturer at a specific manufacturing site, or from a specific procurement agent. A change in the approved manufacturer, manufacturing site (even from the same manufacturer), or procurement agent requires a new approval.
- 4. The GH/OHA/SCH approval process determines if there is a sufficient amount of information on file with, or available to, USAID regarding the quality of a pharmaceutical. The focus of the approval process is on the quality of the pharmaceutical at the point of manufacture. GH/OHA/SCH approval is based on a GH/OHA/SCH evaluation, which considers factors such as:
 - Approval by the U.S. Food and Drug Administration;
 - Approval by a stringent regulatory authority;
 - Source of the pharmaceutical (e.g. an approved procurement agent);
 - Past performance of the vendor;
 - Quality testing protocol (for example, product testing by an acceptable independent laboratory);
 - Emergency or other conditions affecting the availability of pharmaceuticals; and

• Proposed use of the pharmaceutical (for example, basic research, field trials, or clinical use).

GH/OHA/SCH approval includes many factors that form a tiered evaluation and the items detailed above do not guarantee approval. The approval is determined on a case-by-case basis, which might consider the factors listed above, but can also include consideration of other factors as well.

- 5. A request for OHA/SCH approval must include the following:
 - Generic name,
 - Strength,
 - Dosage form, and
 - Specific manufacturer and manufacturing site or procurement agent (as applicable).

GH/OHA/SCH can require additional information on the quality of the pharmaceutical.

- 6. Under Section 606(c) of the <u>Foreign Assistance Act of 1961, as amended</u> (<u>FAA</u>), USAID cannot finance a pharmaceutical that is manufactured outside the United States, if the pharmaceutical is covered by a valid U.S. patent, unless the U.S. patent owner expressly authorizes the manufacture of the pharmaceutical. Without such an express authorization, the pharmaceutical must be purchased from the U.S. patent holder.
- 7. The marking provisions of <u>ADS 320</u> do not apply to the packaging of pharmaceuticals under ADS 320.3.2.5 e. <u>ADS 320</u> otherwise applies to programs and activities utilizing pharmaceuticals. Missions and operating units can provide for the marking of pharmaceuticals as part of the marking and branding strategies and plans in <u>ADS 320</u>.
- 8. In accordance with source award provisions (<u>AIDAR</u> clause 752.225-70, "Source, Origin, and Nationality Requirements" for contracts and the standard provision "USAID Eligibility Rules for Goods and Services" for assistance agreements), the Contracting Officer/Agreement Officer (CO/AO) is authorized to communicate the OHA/SCH commodity approval to the awardee. The CO or AO may delegate this authority to the COR and AOR either in the COR or AOR delegation letter or in the award.
- 9. Commodity Import Programs.

- a. Pharmaceuticals financed under CIPS are subject to the approval requirements detailed above.
- b. In addition to the applicable price rules in 22 CFR 201, Subpart G, bulk pharmaceuticals under CIPs are subject, at the pre-financing stage, to the special price rules found in Special Price Rules for Bulk Pharmaceuticals under Commodity Import Programs (CIPS).
- 10. For additional help on the OHA/SCH approval process and technical updates regarding pharmaceuticals, see Additional help on GH/OHA/SCM "Restricted Commodity" Approval of Pharmaceuticals.

312.3.3.4 Contraceptives and Condoms

Effective Date: 02/24/2011

- Unless otherwise approved by the Director of GH/PRH (or designee), contraceptives, condoms, and related supplies (for example, syringes or trocars) must be procured under GH/PRH centrally-managed contracts. This approval is in addition to the source requirements in <u>ADS 310</u>. The restricted commodity approval for contraceptives and condoms does not apply to non-contraceptive pharmaceuticals. See ADS 312.3.3.3 for pharmaceuticals.
- 2. GH/PRH determines the products to be made available under centrally-managed contracts. The following products are currently available:
 - Male and female condoms.
 - Oral contraceptive pills,
 - Intrauterine contraceptive devices.
 - Injectable contraceptives, and
 - Sub-dermal contraceptive implants.

GH/PRH can add to this list when other products become available and meet GH/PRH quality, acceptability, and affordability standards.

3. GH/PRH centralizes and manages the procurement of contraceptives and condoms in response to requests. Requests for purchases under USAID agreements must come from Missions and other USAID operating units. Requests for purchases from non-USAID program implementers must come to GH/PRH. GH/PRH aggregates product quantities across requesters and manages contracts in order to secure the necessary products, as well as related warehousing, freight forwarding, and other technical services (for example,

- quality assurance). GH/PRH can utilize or authorize procurement by other entities, when necessary, in order to meet strategic objectives. GH/PRH will consider utilizing or authorizing procurement by other entities on a case-by-case basis.
- 4. GH/PRH consolidates requests for contraceptives and condoms. Missions, in coordination with partners or recipients whose programs request contraceptives and/or condoms, provide annual or more frequent estimates of need to GH/PRH. These estimates include product needs for up to two future calendar years, and can be updated at any time. Missions must submit requests, in writing, using the Public Health Commodity Order Form.
- 5. Missions or other operating units provide the funding required for contraceptive and/or condom procurements by authorizing a transfer of unobligated Operating Year Budget funds to GH/PRH. If the transfer is approved by GH/PRH, then the Missions or other units may make previously obligated funds available. In such cases, obligating agreements must authorize a sub-obligation request to the Central Contraceptive Procurement Project, using the field support database (FS-AID). GH/PRH sub-obligates the funds into the appropriate contract(s) and the Office of the Chief Financial Officer (M/CFO) in USAID/W disburses the funds.
- 6. The GH/PRH approval process determines if there is a sufficient amount of information on file with, or available to USAID, in regards to the quality and efficacy of a contraceptive and/or condom from a specific manufacturer at a specific manufacturing site, or from a specific procurement agent or other entity. A change in the manufacturer, the manufacturing site (even from the same manufacturer), or the procurement agent requires a new approval.
- 7. The focus of the GH/PRH approval process is the quality and efficacy of the contraceptive and/or condom at the point of manufacture.
- 8. Under Section 606(c) of the Foreign Assistance Act of 1961, as amended (FAA), USAID cannot finance a pharmaceutical manufactured outside the United States if the pharmaceutical is covered by a valid U.S. patent, unless the U.S. patent owner expressly authorizes manufacture of the pharmaceutical. Without such an express authorization, the pharmaceutical must be purchased from the U.S. patent holder.
- 9. The marking provisions of <u>ADS 320</u> do not apply to the packaging of contraceptives or condoms under ADS 320.3.2.5 e. <u>ADS 320</u> otherwise applies to programs and activities utilizing contraceptives or condoms. A Mission or operating unit can provide for the marking of pharmaceuticals as part of marking and branding strategies and plans under <u>ADS 320</u>.

10. In accordance with source award provisions (<u>AIDAR</u> clause 752.225-70, "Source, Origin, and Nationality Requirements" for contracts and the standard provision "USAID Eligibility Rules for Goods and Services" for assistance agreements), the CO/AO is authorized to communicate the GH/PRH commodity approval to the awardee. The CO or AO may delegate this authority to the COR or AOR either in the COR/AOR delegation letter or in the award itself.

312.3.3.5 Pesticides

Effective Date: 01/01/1996

Pesticides are not eligible for financing unless each specific pesticide and the use of the pesticide has received prior approval from USAID/W in accordance with <u>22 CFR 216</u> (AID Regulation 16). The procedures may be waived in certain conditions (See 312.3.3.5).

Procedures: The procedures set forth in 22 CFR 216 (AID Regulation 16) for the financing of pesticides under project assistance may be waived under emergency conditions. Emergency conditions are deemed to exist when the Administrator of USAID determines, in writing, that:

- 1) A pest outbreak has occurred or is imminent;
- 2) Significant health problems (either human or animal) or significant economic problems will occur without the prompt use of the proposed pesticide; and
- 3) Insufficient time is available before the pesticide must be used to evaluate the proposed use in accordance with the provisions of 22 CFR 216 (AID Regulation 16).

Limited Circumstances: In a very limited number of circumstances USAID may authorize procurement of pesticides under CIPs when the Administrator determines that:

- 1) Emergency conditions as defined in 312.3.3.5, para. 1, exist; or
- 2) Compelling circumstances exist such that failure to provide the proposed assistance would seriously impede the attainment of U.S. foreign policy objectives or the objectives of the foreign assistance program. The term "compelling circumstances" refers to only those most serious situations in which no other way exists to provide the pesticide except through the CIP. The decision as to whether such circumstances exist will be based, to the extent practicable, upon consideration of the factors set forth in 22 CFR 216.3(b)(1)(i) (AID Regulation 16) and the history of efficacy and safety governing the past use of pesticides in the recipient country.

Part II-C of the "<u>USAID Commodity Eligibility Listing</u>", provides additional information on the implementation of USAID policy on financing pesticides.

312.3.3.6 Used Equipment

Effective Date: 02/06/2012

It is USAID policy to finance only unused equipment. However, when the purchase of equipment in other than unused condition can be justified, USAID shall consider requests for authority to procure such equipment. (See below.) This policy does not apply to the financing of U.S. Government-owned excess property.

A request to approve a purchase of used, rebuilt, or reconditioned equipment shall include the following.

- The buyer's assurance that the requirements of the program will be satisfied if the material purchased is used, rebuilt, or reconditioned; that economic considerations justify procurement of used, rebuilt or reconditioned equipment; that the price is reasonable; and if the equipment is used, the justification shall explain why it is not to be rebuilt or reconditioned.
- 2) The buyer's agreement to arrange for the inspection and appraisal of the equipment by an inspector approved by USAID with the understanding that the cost will be eligible for USAID financing only if the equipment is approved for financing.

After receipt of the inspection report, USAID determines whether the inspected equipment conforms with the technical conditions specified by the buyer at a price acceptable to USAID. If USAID agrees to finance the purchase, USAID notifies the buyer in writing that the transaction is eligible for USAID financing subject to compliance with other USAID requirements.

Items that are rebuilt or reconditioned shall be permanently marked indicating this is so, and the supplier must convey a warranty to the buyer similar to that extended by manufacturers of similar new equipment. Additional certificates shall be required for rebuilt engines and parts or assemblies for engines and vehicles, and for aircraft engines and aircraft parts and assemblies.

The policy of requiring special authority for the procurement of used equipment is not subject to waiver. Waivers of the special conditions applicable to the financing of used equipment may be granted by the head of the Operating Unit, acting in consultation with the cognizant attorney (GC/RLA).

312.3.3.7 Fertilizer

Effective Date: 05/08/2020

When considering awardee requests for approval of a fertilizer financing, AORs/CORs or OUs must consider the eligibility status for USAID financing and general guidance pertaining to fertilizer set forth in ADS 312mad, Fertilizer Financing Guidance which supersedes Part I, Chapter 31 (Fertilizers), Part II.B (Eligibility Criteria for Certain Commodities – Fertilizer) and Part III, Special Provision 42 (Fertilizers) of the USAID Commodity Eligibility Listing requirements referred to in section 312.3.1. Prior to making an award, OUs may address these requirements during their planning process and incorporate prior approvals pursuant to this section into the award. During award implementation, the awardee will submit requests for approval to finance fertilizer to the AO/CO per the terms of the individual award, and the AOR/COR will seek the required written approvals described below.

The following procedures apply when financing the procurement of fertilizer:

- 1) The Assistant to the Administrator for RFS, in consultation with the cognizant geographic bureau, must approve USAID-financed procurements of fertilizer exceeding U.S. \$1 million in aggregate value per fiscal year for each fertilizer product per award.
- 2) The Mission Director or USAID/W Office Director with program responsibility, providing an informational copy of the approval to RFS, is authorized to approve financing of procurements of fertilizer not exceeding U.S. \$1 million in aggregate value per fiscal year of each fertilizer product per award.
- 3) The RFS Chief Scientist, or any other person designated by the Assistant to the Administrator for RFS, is authorized to approve requests to finance the procurement of fertilizer that is not listed as eligible in ADS 312mad, Fertilizer Financing Guidance.

Any requests for approval of a proposed financing should specify the product, amount and intended use. Communications to RFS requesting financing approval, providing informational copies of approval authorization, requesting consultation, or inquiring about fertilizer eligibility and technical requirements must be sent to fertilizerapprovals@usaid.gov.

As provided in source award provisions (AIDAR clause 752.225-70, "Source and Nationality Requirements" for contracts and the standard provisions "USAID Eligibility Rules for Goods and Services" for assistance agreements), the CO/AO is authorized to communicate USAID's approval of procurement of fertilizer to the awardee.

These requirements are in addition to source and nationality requirements as set forth in ADS 310.

312.3.4 Ineligible Commodities

Effective Date: 02/02/1988

Under USAID policies several types of commodities are generally ineligible for USAID financing. The policies are set forth in 312.3.4.1 through 312.3.4.7.

312.3.4.1 Military Equipment

Effective Date: 02/02/1988

USAID economic assistance funds shall not be used to finance any goods and services when the primary purpose of such assistance is to meet military requirements of the cooperating country. There is no exception to this policy.

- 1) Common Use Items USAID funds can be used to finance common-use items that ultimately end up with the military if at the time of the sales there is no evidence that the items are destined for military use, but were permitted on an economic development or stabilization rationale.
- 2) Special Activities Commodities that might be considered to be military equipment or supplies can be financed by USAID if they are to be used solely in USAID-approved special activities.

312.3.4.2 Surveillance Equipment

Effective Date: 02/02/1988

All types of surveillance equipment are ineligible for USAID financing. The ineligible items include equipment such as microphones, transmitters, listening devices, and recording devices of microminiature design, and components thereof. In rare instances, some of these devices will have a non-surveillance use in USAID programs. In such instances, it is the legitimacy of the purpose rather than the specific characteristics of the commodity that determines its eligibility.

312.3.4.3 Commodities and Services for Support of Police and Other Law Enforcement Activities

Effective Date: 02/02/1988

USAID shall not finance, or authorize under <u>Section 607 of the Foreign Assistance</u> <u>Act</u>, the furnishing of commodities and services for the training, support, administration, or operation of any police or other law enforcement forces or for any program of internal intelligence or surveillance.

USAID may assist cooperating countries in selected, clearly defined law enforcement activities, not involving matters of internal security, in which the United States has a special interest, e.g., programs to control international narcotics traffic.

312.3.4.4 Abortion Equipment and Services

Effective Date: 02/02/1988

USAID funds shall not be used:

- 1) To purchase or distribute commodities or equipment for the purpose of inducing abortions as a method of family planning;
- To finance services for the performance of abortions as a method of family planning;
- For any biomedical research which relates, in whole or in part, to methods or the performance of abortions or involuntary sterilization as a method of family planning;
- 4) To motivate or coerce any person to practice abortions; or
- 5) To lobby for abortions.

312.3.4.5 Luxury Goods

Effective Date: 02/02/1988

No USAID funds shall be used to finance commodities that are considered to be luxury goods unless specifically authorized by the Assistant Administrator of the responsible bureau or the Principal USAID Officer at the field post. Luxury goods include such commodities as alcoholic beverages and equipment for their production and use, equipment and supplies for gambling facilities, certain recreational supplies and equipment, jewelry, stamps, coins, furs, and the more expensive textiles.

312.3.4.6 Gambling Equipment

Effective Date: 02/02/1988

USAID must not be connected under any circumstances with the financing of gambling facilities. No USAID funds, investment guarantees, or USAID-controlled local currency shall be used to finance gambling facilities or hotels, casinos, tourist accommodations, or housing which have or plan to install such facilities. Where appropriate, a clear affirmation of this point shall be included in assistance agreements.

312.3.4.7 Weather Modification Equipment

Effective Date: 02/02/1988

USAID funds shall not be used to finance equipment for use in weather modification unless the Administrator determines otherwise.

312.3.5 Eligibility of Commodities Determined by Ineligibility of the Carrier Effective Date: 02/02/1988

As set out in 312.3.3.1, commodities are ineligible for USAID financing if the transportation carrier is ineligible, or if USAID has not approved the transportation charter.

312.3.5.1 Effects of Carrier Ineligibility

Effective Date: 02/02/1988

The following policies apply whether or not transportation costs are financed by USAID.

- 1) Commodities shipped by a transportation medium owned, operated, or under the control of any country not included in Geographic Code 935 are ineligible. (Geographic Code 935, "Special Free World," consists of all countries in the Free World including the cooperating country itself.)
- 2) Commodities are ineligible if shipped under an ocean or air charter that has not received prior approval by USAID/W.

312.3.5.2 Waivers

Effective Date: 02/06/2012

The application of the policy on carrier ineligibility may be waived as follows.

- 1) For CIPS, a waiver may be authorized by the cognizant B/IO acting in consultation with GC.
- 2) For other activities, a waiver may be authorized by the Assistant Administrator with program responsibility acting in consultation with GC.

312.3.6 Eligibility of Commodities Determined by Eligibility of Marine Insurance

Effective Date: 02/02/1988

When USAID has found that a cooperating country discriminates against any marine insurance company authorized to do business in any State of the United States and that a cooperating country, contrary to USAID policy (see <u>ADS 322.3.1</u>), fails to insure all USAID-financed commodities with U.S. insurance companies, then those commodities are ineligible for USAID financing.

312.4 MANDATORY REFERENCES

312.4.1 External Mandatory References

Effective Date: 02/06/2012

- a. <u>22 CFR 201.11(k)</u>
- b. <u>22 CFR 201.52(a)(8)</u>
- c. <u>22 CFR 201, Subpart G</u>
- d. 22 CFR 216
- e. <u>22 CFR 216.3(b)(1)(i)</u>
- f. 22 CFR 228, Subpart B
- g. <u>22 CFR 228, Subpart D</u>
- h. <u>Foreign Assistance Act of 1961, as amended, (FAA) Sections 102, 104(f), 604, 606(c), 607, 636(i) and 660.</u>
- i. <u>Section 525 of the Foreign Assistance and Related Program Appropriations</u>
 Act, 1982.

312.4.2 Internal Mandatory References

Effective Date: 10/26/2015

- a. <u>ADS 312maa, Special Price Rules for Bulk Pharmaceuticals under</u> Commodity Import Programs (CIPS)
- b. <u>ADS 312mab, Memorandum to Africa Field Posts on Special Procurement Policy Rules Governing the Development Fund for Africa</u>
- c. <u>ADS 312mac, Agricultural Commodity Eligibility and Requirements Relating</u> to Quality and Safety
- d. ADS 312mad, Fertilizer Financing Guidance
- e. <u>ADS 310, Source and Nationality Requirements for Procurement of</u>
 Commodities and Services Financed by USAID
- f. ADS 320, Branding and Marking
- g. ADS 322, Procurement of Insurance
- h. AIDAR

- i. <u>USAID Commodity Eligibility Listing</u>
- 312.5 ADDITIONAL HELP

Effective Date: 10/26/2015

- a. ADS 312sab, Source/Manufacture Motor Vehicle Waiver Request Template
- b. ADS 312sac, Source/Manufacture Vehicle Waiver Request Guide
- c. <u>ADS 312sad, Template of Approval Request for Agricultural Commodity</u> <u>Financing Under ADS Chapter 312</u>
- d. ADS 312sae, Pharmaceuticals and Condoms
- 312.5.1 Optional Forms

Effective Date: 02/06/2012

- a. Application for Approval of Commodity Eligibility (AID Form 11)
- b. Public Health Commodity Order Form
- 312.6 DEFINITIONS

Effective Date: 10/26/2015

The terms and definitions listed below have been incorporated into the ADS Glossary. See the ADS Glossary for all ADS terms and definitions.

commodity

Any material, article, supply, goods, or equipment. (Chapters 221, 310, 312)

motor vehicles

Self-propelled vehicles with passenger carriage capacity, such as highway trucks, passenger cars and buses, motorcycles, scooters, motorized bicycles and utility vehicles. Excluded from this definition are industrial vehicles for materials handling and earthmoving, such as lift trucks, tractors, graders, scrapers, and off-highway trucks. (Chapter 312)

parity

The terms "parity" and "parity price" pertain to a formula prescribed in statute and applied under the authority of the U.S. Department of Agriculture (USDA). The National Agricultural Statistics Service of USDA computes parity prices of particular commodities and products (e.g., spearmint oil, dried peaches) and publishes these prices on a monthly basis in its <u>Agricultural Prices Report</u>. While some commodities are priced without reference to use, for many listed commodities, parity price is provided for a specific use or class of item (e.g., olives for canning, strawberries for fresh

consumption, strawberries for processing). Items that are developed for a specialized use, particularly seeds or other germplasm for planting, and that have a significantly different market price, are not captured by USDA's listed parity price for a broader commodity category. (**Chapter 312**)

pesticide

Any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any unwanted insects, rodents, nematodes, fungi, weeds, and other forms of plant or animal life or viruses, bacteria, or other micro-organisms (except viruses, bacteria, or other micro-organisms infesting humans or live animals), or intended for use as a plant regulator, defoliant or desiccant. (Chapter 312)

pharmaceutical

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. (Chapter 312)

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