



# Guidelines for Documenting Exceptions to ADS 212.3.2

A Mandatory Reference for ADS Chapter 212

Full Revision Date: 08/08/2019  
Responsible Office: GH/SPBO  
File Name: 212maa\_080819

## A. General

Design teams must not design projects or activities that involve the procurement of breastmilk substitutes, bottles, and teats, or any other actions that would violate the [International Code of Marketing of Breast-milk Substitutes and Subsequent Relevant WHA Resolutions](#) without obtaining approval of an exception as described in this mandatory reference (**ADS 212maa**).

Unless an exception is approved, solicitations and subsequent awards must not include a component involving procurement or distribution of breast milk substitutes (BMS) and related equipment, such as bottles or teats, in the budget or in the statement of work or program description (SOW/PD).

Breastmilk substitutes are restricted agricultural commodities as described in [ADS 312mac](#). 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, pursuant to [ADS Chapter 312, section 312.3.3.1](#), to the awardee in accordance with the procedures outline in this ADS mandatory reference (**ADS 212maa**) and [ADS 312mac](#). USAID funds may not be used to purchase, transport, or distribute BMS without obtaining the approvals required in this ADS mandatory reference (**ADS 212maa**) and [ADS 312mac](#).

A separate policy exists for activities that may consider procurement of Non-Fat Dry Milk for Supplementary Feeding (see [DCHA/FFP Policy on the Use of Non-Fat Dry Milk for Supplementary Feeding](#)).

If an exception is necessary to increase child survival, or to support research that conforms to USAID policy on human subjects research ([22 CFR 225](#)), the USAID Mission or Operating Unit that requests funding for the purchase, transport, or use of breast milk substitutes must follow these guidelines that describe the procedures to request approval for exceptions to [ADS 212.3.2](#).

Breastmilk substitutes procured with approval should be generic and unbranded, manufactured and packaged according to the [Code](#), and should be appropriate for age of the child, with instructions for preparation clearly translated. In addition to the recipient country requirements or Codex Alimentarius standards, as applicable, commodities must meet the specifications, nutritional, quality, and labeling standards of the recipient country. BMS should ONLY be given to those infants who display a medical need. Acceptable reasons include:

- a. Absent or dead mother;
- b. Very ill mother;
- c. Mother is a victim of trauma;

- d. Re-lactating mother;
- e. In an emergency, an infant who was artificially fed prior to the emergency;
- f. Infants who need other food in addition to breast milk, such as infants born with very low birth weight (<1500 g) or very pre-term (<32 weeks), and infants with failure to thrive or slow weight gain.

## **B. Required Documentation**

USAID Missions or Operating Units requesting to use BMS, bottles, or teats must submit a memorandum to the Chief, Nutrition and Environmental Health Division (NEHD), Office of Maternal and Child Health and Nutrition (O/MCHN), Global Health Bureau documenting the reasons why an exception to the USAID Breastfeeding and Infant and Young Child Nutrition Promotion, Protection and Support policies specified in [ADS 212, section 212.3.2](#) is warranted. The memorandum must contain the following seven sections:

- Section 1. Name of Contracting Officer Representative (COR) or Agreement Officer Representative (AOR) preparing notification of exception.
- Section 2. Funding source for exception.
- Section 3. Date and time notification prepared.
- Section 4. Reason exception is necessary. This section must include an explanation of the expected benefits to child survival from the use of BMS. If the exception is to increase child survival, document how purchasing or transporting BMS will increase child survival. If the exception is to support research, attach a copy of the final protocol, with approvals from all institutional review boards, and describe steps to comply with [22 CFR 225 \(Protection of Human Subjects\)](#).
- Section 5. Actions taken to comply with the International Code of Marketing of Breast Milk Substitutes and subsequent relevant WHA resolutions, as outlined in the Cross-Sectoral Implementation Guidance for ADS 212. Notification must include a description of how the activity will comply with each article of the Code ([http://www.who.int/nutrition/publications/code\\_english.pdf](http://www.who.int/nutrition/publications/code_english.pdf)). Of utmost concern are paragraphs 6.6, 6.7, and 6.8, which address donated supplies of BMS; Article 9 on labeling; and Article 10 on product quality.
- Section 6. Actions taken to ensure that:

- a. Caretakers can use BMS safely for infant feeding;
- b. BMS is provided and/or affordable to caretakers for as long as necessary to meet infants' needs (a minimum of six months);
- c. BMS can be properly and safely prepared and fed to infants by caretakers, according to the World Health Organization (WHO) guidelines;
- d. Programs and facilities providing BMS take affirmative measures to promote optimal breastfeeding practices ([212.3.1](#)) in full compliance with the International Code of Marketing of Breast Milk Substitutes;
- e. A proposed strategy is created to promote optimal infant and young child feeding practices once the crisis is over; and
- f. Document that other essential needs for safe breast milk substitute use are included in the budget (*i.e.*, fuel, safe water, trained staff, etc.).

This section must include examples of health facility and community-level counseling guidelines and protocols for the preparation and safe use of BMS, as well as assessments made to determine the costs (program and caretaker) associated with its use. USAID must determine what constitutes acceptable, feasible, affordable, sustainable, and safe use of BMS ([212.3.1.5](#)) at a country- and program-level, based on the implementation environment and characteristics of the individual mothers or other caretakers. Because infants and young children who are not optimally breastfed over the first two years of life are at higher risk of morbidity and mortality, USAID must make efforts (consistent with applicable law and policy) to ensure that they have access to a basic “package” of child survival interventions, including:

- Safe water (boiled, chemically treated, and/or filtered);
- Hygienic preparation and feeding of BMS and replacement foods;
- Good feeding practices;
- Basic vaccinations;

- Oral rehydration therapy (ORT) and zinc treatment for acute diarrhea;
- Routine vitamin A supplementation;
- Protection from malaria (insecticide-treated bed nets); and
- Effective referral and treatment of childhood illness.

Section 7. Monitoring

Describe both the process and frequency of monitoring. If there is evidence of non-compliance with the requirements of the award as they relate to the Agency’s Breastfeeding and Infant and Young Child Nutrition Promotion, Protection, and Support Policy, the COR/AOR must notify the Chief, Nutrition and Environmental Health Division and the CO/AO. The CO/AO, in coordination with the COR/AOR, will address the non-compliance with the contractor/grantee, as appropriate.

**C. Review and Approval Procedure**

A memorandum requesting an exception to [ADS 212.3.2](#) must be submitted and approved in writing prior to initiating any activities in question.

Requests for exceptions must be sent by hand, email, or fax to the Chief, Nutrition and Environmental Health Division (NEHD), Office of Maternal and Child Health and Nutrition (O/MCHN), Bureau for Global Health.

The Bureau for Global Health will coordinate the review process for all requests for exception to policy guidelines in [ADS 212.3.2](#) with the following procedure:

1. The Chief, Nutrition and Environmental Health Division will convene an ad hoc committee of expert nutrition advisers comprising at least one from each of GH, DCHA, and the relevant Regional Bureau to discuss the impact and necessity of the exception. Should the request originate from DCHA/OFDA, the Director of Preparation, Strategic Planning, and Mitigation (PSPM), or his/her designee, is required to be part of the ad hoc committee. Representation from other offices may be included as needed.
2. The Chief, Nutrition and Environmental Health Division will prepare a memorandum with written recommendations for the record cleared by committee members documenting the major points of discussion, and the joint recommendation for approval or disapproval.

3. The memorandum will be given to the Director, O/MCHN, who will give final approval/denial.
4. The Chief, Nutrition and Environmental Health Division will send the AO/CO and AOR/COR or activity manager the approved joint recommendation.
5. The length of time from request to approval/denial will not exceed two business days.

212maa\_080819