Guidelines for Documenting Exceptions to ADS 212.3.2

Mandatory Reference for ADS Chapter 212

Partial Revision Date: 01/06/2012
Responsible Office: GH/SPBO
File Name: 212maa_010612

Guidelines for Documenting Exceptions to ADS 212.3.2

*A. Required Documentation

*USAID Missions requesting to use breast milk substitutes (BMS) must submit a memorandum to the appropriate Regional Bureau documenting the reasons why an exception to the USAID Breastfeeding Promotion policies specified in **212, Breastfeeding Promotion** 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 Technical Representative (AOR) preparing notification of exception**

Section 2. Funding source for exception

Section 3. Date notification prepared

Section 4. Reason exception is necessary

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)**.

Note: This section must include an explanation of the expected benefits to child survival from the use of BMS.

One option to estimate net child survival benefits, weighing the risk of human immunodeficiency virus (HIV) infection from breast milk against the increased risk of mortality if breastfeeding is discontinued, is to use a "risk model." This option is described in the following papers:

- J. Ross, *A Spreadsheet Model to Estimate the Effects of Different Infant Feeding Strategies on Mother-to-Child Transmission of HIV and on Overall Infant Mortality*, Linkages Project, Academy for Educational Development, 1999. (**http://www.linkagesproject.org/publications/BOBriskmodel.xls**),

- J. Ross and M. Labbok, *Modeling the Effects of Different Infant Feeding Strategies on Infant Survival and Mother-to-Child Transmission of HIV*, Am J Public Health 2004: 94; 1174-1180 (**http://www.ajph.org/cgi/content/abstract/94/7/1174**), and

- Piwoz, E.G. and J.S. Ross. *Use of Population-Specific Infant Mortality Rates to Inform Policy Decisions Regarding HIV and Infant Feeding.* J. Nutr. 135: 1113-1119, 2005.

Nutrition and HIV/AIDS experts in the Global Health (GH) Bureau can provide technical assistance to Missions wishing to use the model to estimate the expected effects of BMS and other feeding interventions on prevention of mother-to-child transmission (PMTCT) and child survival in the context of local programs. For more information, contact Tim Quick (TQuick@usaid.gov).

Section 5. Compliance with the International Code of Marketing of Breast Milk Substitutes (Articles 4 through 11)

Notification must include a description of how you will comply with each article of the Code (**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. Steps taken by the Mission and program partners 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 6 months);

c. BMS can be properly and safely prepared and fed to infants by caretakers, according to the World Health Organization (WHO) guidelines; and

d. Programs and facilities providing BMS take affirmative measures to promote optimal breastfeeding practices (212.3.1) among HIV-negative mothers and mothers who do not know their HIV status and avoid "spillover" BMS in the general population, in full compliance with the International Code of Marketing of Breast Milk Substitutes.

*Note: In this section, Missions 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 (AFASS) use of BMS (**212.3.1**) 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 **212**, the COR/AOR must either:

- Notify the appropriate Regional Bureau and seek technical input from the Bureau for Global Health (GH), or
- Work with the USAID Contracting or Agreement Officer to advise the contractor/grantee of its noncompliance with **212**, and request that corrective action be taken to bring the contractor/grantee into compliance.

If the contractor/recipient fails to take corrective action, the USAID Contracting Officer or Agreement Officer may terminate in accordance with applicable law and regulation.

*B. Review and Approval Procedure

A memorandum requesting exception to **212.3.2** must be submitted and approved in writing prior to initiating any activities in question.

*The appropriate Regional Bureau will coordinate the review process for all requests for exception to policy guidelines in **212.3.2**. Requests for exceptions must be sent by hand, cable, e-mail, or fax to the Regional Bureau. The Regional Bureau will promptly convene a meeting with appropriate personnel from GH and GC to review the request. The applicable Regional Bureau will then draft a memo for the record (cleared by all participants) documenting the major points of discussion, and the joint decision for approval or disapproval. If an agreement is not reached at the technical level, a prompt decision will be made by the Assistant Administrator of the Regional Bureau,

**An asterisk and yellow highlight indicate that the adjacent material is new for this reference or substantively revised.*

based on an action memorandum of concerned parties outlining the "pros and cons" of moving ahead with the proposed activities.

212maa_010612

*An asterisk and yellow highlight indicate that the adjacent material is new for this reference or substantively revised.