

13- SAMPLE SIZES WITH APPLICATION TO FOOD PRODUCTS FOR ALLERGENS

(Listed below is the sample size needed for lab analysis. Collect all samples in duplicate, with the duplicate serving as the 702 (b) reserve sample)

| Product | Package type | Number of sample units | Unit size | Total sample |
|--|--------------|------------------------|-----------|--------------|
| Non-liquefied foods, i.e., cereals, cookies | Consumer | 20 | 1 lb | 20 lbs |
| Pre-liquefied foods, i.e., ice cream, chocolates | Consumer | 10 | 1 lb | 10 lbs |
| Paste or slurry type | Consumer | 24 | 8 oz | 12 lbs |
| | | 12 | 1 lb | 12 lbs |
| Fluid, i.e., beverages | Consumer | 10 | 16 fl. oz | 160 fl. oz |

IMPORTANT! WHEN TO SAMPLE: At the time of submission of this table to the IOM, only “for cause” allergen samples for peanut contamination should be collected. Test methods for additional allergens are under development and the field will be notified when they are available for regulatory purposes. The allergen compliance program, when issued, will provide additional sampling guidance. “For cause” sampling should be limited to instances where there is a reasonable probability that a product may contain an allergen and the labeling of the suspect product does not indicate the presence of the allergen. This probability may result from a consumer complaint, a downstream consignee laboratory analysis, or other evidence of the presence of the allergen. Also reference IOM Chapter 8, 8.4.7.5, Allergen Samples, which indicates that allergen samples are to be collected after consultation with OCM/OEIO and CFSAN.

^a See Laboratory Information Bulletin (LIB) # 4341, Application of Validated, Multiple Laboratory *Performance Test Methods*SM for the Detection of Peanuts in Food, Vol 21(2) 2005 for details regarding the analysis and quantitation of analytical samples.

Note: To be collected from random sites. May combine subs or maintain sub integrity depending on purpose of sampling

Note: Prepare composite following proper grinding and mixing procedures. Separate four 1-lb portions from composite.

Adapted from U.S. Food and Drug Administration, Office of Regulatory Affairs, Investigations Operations Manual, Chapter 4, Sample Schedule 6, Mycotoxin Sample Sizes