

TABLE 14.—VALUES USED IN TESTING COST CALCULATIONS—Continued

Name	Value or distribution used	Source
Number of identify tests per ingredient lot	1 Identify test per ingredient lot	Assumption based on discussions with industry—FDA requests comments.
Number of tests for defects per ingredient lot ...	0 to 5 tests for defects	Assumption based on discussions with industry—FDA request comments.
Number of unlisted components	0 to 6 components; 4 most likely	Ref. E47.
Number of tests per unlisted components	1 identify test per component	Assumption based on discussions with industry—FDA requests comments.
Number of shipments (Lots) of ingredients and unlisted components.	1 to 12 batches per shipment lot of dietary ingredients.	Assumption based on discussions with industry—FDA requests comments (Ref. E48).
Number of batches produced	Very small establishments—223; Small establishments—554; Large—309.	Ref. E2.
Number of inprocess potential defects	0 to 5 potential control points; 2.5 average	Assumption based on discussions with industry—FDA requests comments.
Number of inprocess tests per control point	1 test per defect per control point	Assumption based on discussions with industry—FDA requests comments.
Number of ingredients identified per identity test	Vitamins and minerals—1 to 30; 2 most likely; All other categories—1 to 2.	Assumption based on discussions with industry—FDA requests comments.
Number of final product tests per batch	3 tests batch	Assumption based on discussions with industry—FDA requests comments.
Costs per test	Beta per distribution skewed rightward between \$20 to \$150; \$50 most likely; \$60 average.	Refs. E50 and E51.

vi. *Labor costs.* We used the average manufacturing wage of \$15.65 per hour to estimate the cost of labor. We assumed that various tasks required by the proposed rule would take some number of hours per year, per batch of product, or per square foot of physical plant. For example, we assumed that time spent on the sanitation of physical plants is a function of the square footage. We assumed 1 hour per week for very small establishments, 3 hours per week for small establishments, and 20 hours per week for large establishments. We request comment or data about costs, hours, and the other requirements for these proposed required procedures.

vii. *Other costs.* The main costs in this category are for pest and rodent control. We consulted a commercial supplier of these services for the estimated monthly costs, which were \$400 to \$600 a month for very small establishments, \$480 to \$720 for small establishments, and \$700 to \$1,000 for large establishments (Ref. E52). For each size of establishment, we selected the midpoint of the range as the most likely value.

d. *Estimating costs.* We initially gathered information and made

assumptions about the full cost of a provision. We then adjusted these estimates to account for the many activities already being carried out, as well other activities that would not have to be carried out by all establishments. We used the survey to estimate the likelihood that an establishment would incur a cost. To get an estimate of the average cost of provision (adjusted for baseline activities) for each category, we multiplied the average cost per establishment by the probability that the establishment would need to undertake the expense (one minus the probability that the establishment was already doing it). For each provision of the proposed rule, the simulation carried out the following calculation:

Cost per unit of analysis for each provision = number of units of analysis per establishment × probability that establishment incurs cost × adjustment for requirement (yes or no) = cost per provision per establishment

We estimated both a setup cost (a one-time fixed cost) of the provision and an annual recurring cost. The first-year costs would be the setup costs plus the annual costs. To get the total costs of the rule, we multiplied the number of

establishments in each size category (from the survey) by the average costs per establishment in that category. We then adjusted for the establishments that did not respond to the survey but are believed to be in the industry. Two hundred thirty eight establishments responded to the survey; we estimated that 1,566 firms are in the industry. We estimated costs with the following calculation:

$$[\text{Number of very small establishments} \times \text{costs per very small establishment}] + (\text{Number of small establishments} \times \text{costs per small establishment}) + (\text{number of large establishments} \times \text{costs per large establishment})] \times \text{adjustment for establishments not in survey}$$

The rule is complex and the industry is made up of very different kinds of firms, so cost estimates are averages with, in some cases, large variances. The cost per unit, number of batches and employees, and probability that the establishment would incur the cost all contain uncertainty. The values in table 15 of this document are used in the cost estimates, and are generated from multiple sources.

TABLE 15.—VALUES USED IN COST CALCULATIONS

Name	Value or distribution used	Source
Average wage per hour	\$15.65	Employment Index, Bureau of Labor Statistics.
Average size of establishments in square feet ..	Very small = 24,674; small = 71,354; large = 596,000.	Ref. E2.
Average number of employees	Very small = 7.6; small = 95; large = 1,005	Ref. E2.
Average annual number of batches	Very small = 223; small = 554; large = 309	Ref. E44.