

Editorial Revisions made by FDA/CFSAN

April 30, 2003

FAX Cover Sheet

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The following pages note errors in the Administrative Detention pdf document:

- pg 45 - Table 1
- pg 58 - Table 3
- pg 61 - line 7
- pg 68 - line 20
- pg 74 - lines 9 + 10
- pg 75 - lines 14 + 14
- pg 76 - lines 6, 17 + 20
- pg 77 - lines 3 + 11
- pg 80 - line 14
- pg 87 - line 2

pg 93 + 94 -
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No. of pages (including cover) 13

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scope of this analysis. We chose 100 percent as the high end of the range for class I recalls because the criteria for class I recalls is quite similar to the criteria for administrative detention. We chose 100 percent as the high end of the range for instances in which we move directly to seize food as a practical expedient because the small number of actions implies that such information would have had little or no impact on our cost estimates. We chose 10 percent as the high end of the range for State referrals because our experience with those actions suggests that only about 10 percent of recent referrals involved concerns or situations that would have met the criteria for administrative detention. The other referrals do not appear to meet the criteria for administrative detention.

In fiscal year (FY) 2002, we initiated 184 class I recalls involving food that posed a risk of serious adverse health consequences or death to humans or animals. In the same year, we initiated 16 seizures that may have involved food products that posed hazards to human or animal health. In the last 12 months, we estimate that we referred 234 of such matters to State authorities.

These numbers are repeated in table 1 of this document. Based on this information, we estimate that we might administratively detain food 0 to 223 times per year.

TABLE 1 — SUBSTITUTIONS PER YEAR

Action	Estimated Number of Substitutions of Administrative Detention for Other Enforcement Actions per Year
Class I recalls	0 to 184
No preliminary action (move directly to seizure)	0 to 16
No preliminary action (refer matter to State authorities)	0 to 23
Total	0 to 223

action prior to a seizure action or a referral of a matter to a State authority. Therefore, any storage associated with an administrative detention would be an additional cost in comparison to moving directly to seizure or referring a matter to a State authority.

Administrative detention involves a maximum storage time of up to 30 days. The actual amount of time that firms would store detained food depends on whether and when they appeal the administrative detention order. Firms would appeal if they expected the costs of doing so would be less than the costs of storing the food until we completed our investigation, or until the detention period expired. We have insufficient information to estimate the percentage of administrative detentions that firms would appeal. Therefore, we use a maximum of 30 days additional storage time for all administrative detentions. We do not know how long firms store food that they voluntarily recall before reconditioning or destroying the food. We tentatively assume that the storage time associated with class I recalls would be similar to the storage time associated with administrative detention.

We provide estimates of annual storage costs, rounded to the nearest million dollars, in table 3.

TABLE 3.—ANNUAL STORAGE COSTS

Action	Number of Actions	Change in Days Storage per Action	Cost per Day (based on average shipment)	Handling Cost per Action	Change in Total Storage Cost (in millions)
Administrative Detention that Replaces Case of Moving Directly to Seizure	0 to 16	0 to 30	\$0 to \$600	\$0 to \$20,000	\$0 to \$1
Administrative Detention that Replaces Class I Recall	0 to 184	0	\$0 to \$500 600	\$0 to \$21,000 20,000	\$0
Administrative Detention that Replaces Referral to State	0 to 23	0 to 30	\$0 to \$500 600	\$0 to \$21,000 20,000	\$0 to 1
Total					\$0 to \$2

Loss of product value over detention period, if we later find the product is not violative

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- *Food having a shelf life of between 30 and 90 days.* These types of food include dairy products, such as butter, margarine, natural hard cheese, processed hard cheese, and ice cream; eggs; some pickled food; processed salads; some fruit and vegetable products; cured meats; fatty meats such as luncheon meats, ground beef, lamb and pork; fatty fish such as mackerel; shellfish; giblets; some frozen bakery food, such as cake batter, pie shells, fruit pies, yeast breads and rolls, frozen bread and roll dough; fried snack food such as potato chips; frozen convenience food such as pre-cooked combination dinners and frozen french fries; dried bakery products such as cookies and crackers; beverages such as ground coffee that is not vacuum packed; canned pickled fish; powdered cream, and fats and oils such as mayonnaise, salad dressing, and vegetable shortening (Ref. 6).

- *Food having a shelf life of over 90 days.*

The only type of enforcement action for which we have readily available data on the type of food involved is imported food that we have refused entry into the United States. Therefore, we used these data for analysis, because we expect the distribution of food by type for domestic food to be similar. The food categories in these data do not correspond precisely to the shelf life categories just discussed. If a food category covered more than one shelf life category, we assumed that an equal amount of the product in that category belonged to each relevant shelf life category. Based on these assumptions and definitions, approximately 20 percent of the imported food that we refused entry into the United States from August 2001 through July 2002 was perishable under the definition in this proposed rule, 20 percent of the food had a shelf life of 8 to 30 days, 30 percent had a shelf life of 31 to 90 days, and 30 percent had a shelf life of 91 days and over.

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processes suggests that the probability that a firm will appeal a State action is probably not highly related to whether it has already filed and lost an appeal of an administrative detention. Therefore, we assume that administrative detention will not affect the probability that firms will appeal subsequent State actions.

We estimate that our costs for activity related to appeals of administrative detentions would be approximately \$50,000 to \$70,000 per administrative detention. We based that estimate on our costs for preparing for possible appeals, which would be generated by all administrative detention actions, and our costs for participating in appeals hearings, which would be generated only by those administrative detentions that result in hearings. In order to calculate an average cost per administrative detention action, we assumed that 65 percent of our administrative detentions would result in an appeals hearing. We based that assumption on the proportion of seizure actions that firms contest. Therefore, the incremental change in appeals costs associated with substituting an administrative detention action for a class I recall is approximately \$50,000 to \$70,000.

Our costs for activity related to firms contesting our seizures are approximately \$10,000 to \$20,000 per seizure action. We based that estimate on our costs for participating in a contested seizure case, and ^r65 percent chance that firms would contest any given seizure action. Therefore, the incremental change in appeals costs associated with substituting an administrative detention action for a case of moving directly to a seizure action is approximately \$30,000 to \$60,000. We present the resulting cost estimates for the agency in table 6 of this document.

Just over 1 percent of cases develop short-term reactive arthritis and 2 percent of cases develop chronic, reactive arthritis.

FDA estimated the costs associated with salmonellosis, including medical treatment costs and pain and suffering. Table 10 of this document provides a summary of these estimates. Pain and suffering is measured by lost quality adjusted life days (QALDs). QALDs measure the loss of utility associated with an illness. A QALD is measured between zero and one, with one being a day in perfect health. FDA presents two estimates of values of pain and suffering associated with arthritis, one based on physician estimates (Ref. 11) and another based on a regression analysis approach (Ref. 12). This gives a range of costs for the average case of salmonellosis between \$14,231 and \$25,133.

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TABLE 10.—THE VALUE OF A TYPICAL CASE OF SALMONELLOSIS

Severity	Case Breakdown	Total QALDs Lost per Illness	Health Loss per Case (Discounted)	Medical Costs per Case (Discounted)	Weighted Dollar Loss per Case
Illness					
Mild	90.7%	1.05	\$860	\$0	\$599
Moderate	8.1%	3.68	\$2,310	\$283	\$209
Severe	1.2%	9.99	\$5,266	\$9,250	\$188
Arthritis					
<i>Regression Approach</i>					
Short-Term	1.26%	5.41	\$3,381	\$700	\$44
Long-Term	2.40%	2,813.12	\$452,554	\$7,322	\$11,048
<i>Direct Survey Approach</i>					
Short-Term	1.26%	10.81	\$6,778	\$100,587	\$21,908
Long-Term	2.40%	5,223.15	\$904,973	\$7,322	\$2,143
Death	0.04%		\$5,000,000		
Total Expected Loss per Case				Regression Approach: \$14,231 Direct Survey Approach: \$25,133	

To estimate the economic cost due to illness associated with this outbreak, FDA used the range for the average cost per case. For 224,000 people, this is a total cost of between \$3,187,744,000 and \$5,629,792,000 from this accidental food disaster.

Shigella sonnei in tofu salad

In 1988, a tofu salad at an outdoor music festival was contaminated with *Shigella sonnei* and sickened an estimated 3,175 people. Over 2,000 volunteer

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food handlers served communal meals at the festival (Ref. ¹²13). Shigellosis causes similar symptoms and is of similar duration to salmonellosis. It also is associated with short-term and chronic reactive arthritis; thus FDA assumed the average case of shigellosis has the same cost as salmonellosis. This gives a total cost of \$45,183,000 to \$79,797,000.

Salmonella typhimirium in salad bars

During September and October of 1984, two outbreaks of *S. typhimirium* occurred in association with salad bars in restaurants in The Dalles, Oregon. At least 751 people were affected. Members of the local Rajneeshpuram commune intentionally caused the outbreak by spraying *S. typhimirium* on the salad bars in local restaurants. Their apparent motivation was to influence a local election by decreasing voter turnout. Intentional contamination was not suspected immediately and no charges were brought until a year after the attacks (Ref. ¹³14).

The 751 people affected primarily were identified through passive surveillance; thus the true number of people actually sickened is undoubtedly much higher. The Dalles is located on Interstate 84 in Oregon and is a frequent stop for travelers who were unlikely to be identified by passive or active surveillance for salmonellosis. However, since we do not have any estimates of the true size of the outbreak, we estimated the costs associated with known cases, recognizing this is an underestimate of the true cost of the outbreak. We use the cost estimates for salmonellosis as ranging from \$14,231 to \$25,133. This gives an estimated cost of known cases for the outbreak of \$10,687,000 to \$18,875,000.

Shigella dysenteriae type 2 among laboratory workers

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Twelve people working in a laboratory who consumed muffins left in the laboratory break room contracted shigellosis. Affected workers had diarrhea, nausea, and abdominal discomfort. Investigators concluded that the outbreak likely was the result of deliberate contamination. All 12 affected workers were treated by, or consulted with, a physician. Nine affected workers went to the emergency room, four of whom were hospitalized (Ref. ¹⁴15).

To estimate the cost of this outbreak, FDA assumed that the eight cases requiring consultation with a doctor, but not requiring hospitalization, had the same cost as a moderate case of salmonellosis. The four cases requiring hospitalization were estimated to have the same cost as a severe case of gastroenteritis resulting from salmonellosis. This gives a cost of \$83,000 for illnesses associated with the event.

TABLE 11.—SUMMARY OF COSTS FOR AN OUTBREAK OF SHIGELLOSIS

Severity	Number of Cases	Cost per Case	Total Cost
Mild	0	\$0	\$0
Moderate	8	\$2,593	\$21,000
Severe	4	\$15,515	\$62,000
Total	12		\$83,000

Cyclospora cayatanensis in imported raspberries

In 1996, 1,465 cases of cyclosporiasis were linked to consumption of raspberries imported from Guatemala. Nine hundred and seventy eight of these cases were laboratory confirmed. No deaths were confirmed and less than 20 hospitalizations were reported (Ref. ¹⁵16). Case control studies indicated that raspberries imported from Guatemala were the source of the illnesses. Fifty-five clusters of cases were reported in 20 States, two Canadian provinces, and the District of Columbia (Ref. ¹⁶17).

Cyclosporiasis typically causes watery diarrhea, loss of appetite, weight loss, and fatigue. Less common symptoms include fever, chills, nausea, and

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headache. The median duration of illness associated with the outbreak was more than 14 days and the median duration of diarrheal illness was 10 days (Ref. ¹⁶~~17~~). We estimated the cost of a mild case of cyclosporiasis as two and a half times higher than the cost of a mild case of gastroenteritis from salmonellosis due to the longer duration. The reports of cyclosporiasis outbreaks did not include information on the number of physician visits. We assumed that the percentage of total cases that result in physician visits would be larger than the corresponding percentage for salmonellosis illnesses, due to the longer duration of illnesses. We assumed, therefore, that 40 percent of those infected with cyclosporiasis visited a physician. Less than 20 hospitalizations were reported from the cyclosporiasis outbreak (Ref. ¹⁵~~16~~). No deaths were confirmed.

TABLE 12 — SUMMARY OF COSTS OF AN OUTBREAK OF CYCLOSPORIASIS

Severity	Number of Cases	Cost per Case	Total Cost
Mild	879	\$1,650	\$1,450,000
Moderate	586	\$3,748	\$2,196,000
Severe	19	\$15,518	\$295,000
Total	1,465		\$3,941,000

Option Two: Take the proposed action, but change either or both the definition of perishable food and the maximum time frame for administrative detention of perishable food.

Costs

If we established a shorter maximum timeframe for administrative detention of perishable food, then we would reduce the potential storage costs and loss of value associated with administratively detaining that food. If we also broadened the definition of perishable food to include products with a shelf life of over 7 days, then we would further decrease the storage costs and loss of food product value for those additional types of food. One reasonable

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Instead of judging the need for various levels of security on a case-by-case basis, we could require firms to use specified levels of security to transport and store food under specified conditions. In Option one, we assumed, based on information from a trade group, that the costs for using bonded carriers and warehouses were similar to those for using nonbonded carriers and warehouses. However, if we chose a lower security approach and allowed firms to store administratively detained food in place, then we would eliminate the transportation costs. Eliminating transportation costs would reduce total costs to a range of \$0 to \$34 million.

If we required firms to undertake security operations they would not otherwise have taken, then we would need to add in the cost of that activity. One example of the type of activity we might require is posting additional security guards. The average hourly wage of a security guard in 2000 was about \$9.50 (Ref. 18). We doubled this wage to account for overhead, such as health benefits, to get an annual hourly wage of about \$17. Therefore, the average cost of posting one additional security guard would be approximately \$450 per day. The number of guards would depend on the number of facilities involved. Firms might already have distributed food that we administratively detain. Based on our experience with other enforcement actions, we believe that between 1 and 20 storage facilities might be involved per administrative detention action. Therefore, we calculate the cost of adding 1 guard by multiplying the cost of 1 additional security guard per day, times a maximum of 30 days storage, times the number of administrative detentions, times the number of facilities involved per administrative detention. Using this approach, we estimate the total costs associated with no transportation and posting one additional guard would be \$0 to \$45 million.

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The Small Business Administration (SBA) publishes definitions of small businesses by six-digit NAICS code (Ref. ~~18~~). Some of the NAICS codes listed previously above are less than six digits. In those cases, we used the range of small business definitions for all six-digit subcategories in the relevant NAICS code. The current SBA definitions in terms of either maximum annual average receipts or number of employees are as follows: 111 (\$0.75 million), 112 (\$0.75 to \$10.5 million), 1141 (\$3.5 million), 311 (500 to 1,000), 3121 (500 to 750), 322215 (750), 32222 (500), 325412 (750), 32611 (500), 327213 (750), 333993 (100), 4224 (100), 4225 (100), 42251 (100), 4228 (100), 445 (\$6 to \$23 million), 446191 (\$6 million), 481112 (1,500), 481212 (1,500), 482 (500), 483111 (500), 483113 (500), 483211 (500), 484 except 48421, 4842201, 4842203, and 4842301 (\$21.5 million), 722 (\$6 million to \$17.5 million). We applied the relevant range of sizes to the SIC codes that at least partially corresponded to the relevant NAICS codes and found that approximately 84 to 90 percent of the firms that this rule might affect are small businesses under SBA size definitions. Therefore, we estimate that this rule may affect between 0 and 180 small businesses each year.

The potential cost per administrative detention for small entities based on taking the proposed action and the information and assumptions in the preceding impact analysis would be \$20,000 to \$330,000, depending on the type of product involved and the type of enforcement action that we would replace with an administrative detention, and whether or not the firm appealed the administrative detention order. However, we based this range on a number of assumptions that are probably more reasonable when applied to average or expected costs across a large number of actions than to a single action. Thus, the actual range of potential costs for a single detention action would be much

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List of Subjects**21 CFR Part 1**

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, and Reporting and recordkeeping requirements.