

B. Initial Regulatory Flexibility Analysis

We have examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires us to analyze regulatory options that would lessen the economic effect of the rule on small entities. We find that this proposed rule would not have a significant economic impact on a substantial number of small entities. Nonetheless, we have provided an initial regulatory flexibility analysis under the Regulatory Flexibility Act, which consists of the analysis below with other relevant sections of this document.

This proposed rule may affect firms involved in the production or handling of human food and animal feed such as the following: (1) Food producers such as farms, ranches, fisheries, dairies, bakeries, breweries, distilleries, and manufacturers of processed food, food additives, dietary supplements, infant formula, and food contact substances; (2) food importers; (3) food wholesalers or brokers; (4) food retailers; (5) food service establishments; and (6) food transporters. The rule might affect producers because we could administratively detain food at one of the producer's facilities prior to distribution of that food to wholesalers or brokers. We could also administratively detain food anywhere in the distribution system, from wholesaler and retailer warehouses, to retail store shelves, to food service establishment kitchens or storerooms. The rule might affect transporters because we might detain food that is en route to another location, and the food might be packed together with food that we would not detain. This might cause delays in the deliveries of the other food.

Potentially affected firms fall into a number of different North American Industry Classification System (NAICS) codes, including the following: 111 Crop Production, 112 Animal Production, 1141 Fisheries, 311 Food Manufacturing, 3121 Beverage Manufacturing, 325412 Pharmaceutical Preparation Manufacturing, 4224 Grocery and Related Products Wholesalers, 4225 Farm Product Raw Material Merchant Wholesalers, 4248 Beer, Wine, and Distilled Alcoholic Beverage Merchant Wholesalers, 445 Food and Beverage Stores, 446191 Food (Health) Supplement Stores, 481112 Scheduled Freight Air Transportation, 481212 Nonscheduled Chartered Freight

Air Transportation, 482 Rail Transportation, 483111 Deep Sea Freight Transportation, 483113 Coastal and Great Lakes Freight Transportation, 483211 Inland Water Freight Transportation, 484 Truck Transportation (except 48421 Used Household and Office Food Moving, 4842201 Local Hazardous Materials Trucking, 4842203 Dump Trucking, and 4842301 Long Distance Hazardous Materials Trucking), and 722 Food Service and Drinking Places. There is also no NAICS code for manufacturers of food contact material. However, the following NAICS codes cover some of the potentially affected firms: 322215 Non-Folding Sanitary Food Container Manufacturing, 32222 Paper Bag and Coated and Treated Paper Manufacturing, 32611 Plastics Packaging Materials and Unlaminated Film and Sheet Manufacturing, 327213 Glass Container Manufacturing, and 333993 Packaging Machinery Manufacturing. There are no NAICS codes for manufacturers of food additives or for food importers, and we assume these firms are included in the other categories.

The 1997 Economic Census lists 1.6 million establishments in these categories, excluding NAICS codes 111, 112, 1141, and 482, which are not included in the Economic Census. The 2000 County Business Patterns updates some of the numbers from the 1997 Economic Census. However, the County Business Patterns data includes only establishments with employees. In order to obtain another estimate of the number of firms using the updated data, we combined the number of establishments with employees from the 2000 County Business Patterns with an estimate of the number of establishments without employees based on the proportion of firms with and without employees in the 1997 Economic Census. This procedure also led to an estimate of approximately 1.6 million establishments in these categories, excluding NAICS codes 111, 112, 1141, and 482. An establishment without employees is an establishment that is staffed only by the owners of that establishment.

We also used the Dun and Bradstreet Market Identifiers database to get a count of the number of firms in these categories. This database uses Standard Industry Classification (SIC) codes rather than NAICS codes. SIC codes do not correspond exactly to NAICS codes. We based our estimate on all SIC codes that even partially corresponded to relevant NAICS codes. This database allows one to count firms rather than establishments, and also allows one to

identify firms by both primary and secondary activities. According to this database, approximately 1.8 million firms could be affected by this rule. However, we would not be able to affect more firms in 1 year than the estimated number of administrative detentions that we might take in 1 year. In the analysis of impacts above, we estimated that we might administratively detain food between 0 and 200 times per year. Therefore, we estimate that this rule may affect between 0 and approximately 200 firms per year.

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 larger. In addition, the cost per firm would depend on the number of times that we