

administrative detentions, including “credible evidence or information” and “threat of serious adverse health consequences or death to humans or animals.” If we only administratively detain food when we are certain or nearly certain that it is violative, then we may eliminate administrative detention as an enforcement option for some food that is violative. However, if we administratively detain food when we are less certain that it is violative, then we will increase the rate at which we administratively detain food that we later determine is not violative.

One way of addressing the proportion of cases in which we might administratively detain food that we later determine to be not violative is to look at data from the detention and release of imported food. However, this data cannot be narrowed to situations where we have detained or prepared to detain food and then later determined that the food was not violative. An import detention is different from administrative detention in that imports can be detained for reasons other than adulteration or misbranding. These other reasons give rise to a large percentage of detentions in which the food is found not to be violative. For instance, an import can be detained because the product is coded in the OASIS (Operational and Administrative System for Import Support system) system as a low acid canned food but the importer did not supply the food canning establishment number. The OASIS system is a national database on imports, and related enforcement activities and findings.

In the first three quarters of 2002, we released 48 percent of the shipments of human and animal food that we detained, excluding the shipments that we released because the firm reconditioned the food. The percentage of import shipments released includes all releases recorded in the OASIS system. These data include releases from detentions resulting from:

- DWPE notices;
- Routine FDA field sampling assignments;
- Incorrect or incomplete information provided about the product; and
- Imports released with comment, which means the product technically is misbranded or adulterated but we exercise enforcement discretion.

Because of the factors listed previously, and because import detentions may be based on a lower level of information than that required for an administrative detention, we cannot directly impose these numbers on administrative detentions. Rather, 48 percent is an upper limit that will

exceed the nonviolative percentage of administratively detained food.

Another way of addressing this issue is to look at the proportion of enforcement actions against nonfood products that involved products that we later determined were not violative. We have had authority to administratively detain medical devices since 1976. During that time, we have not administratively detained any products that we later found to be not violative. This suggests that the rate at which we administratively detain food that is not violative may also be quite low, because in both cases we would be using similar administrative detention procedures. However, the medical device and food contexts may differ with respect to a number of potentially relevant issues, such as the type and amount of products on the market, the types of problems associated with those products, and the type and level of information that we receive on those problems.

Based on this information, we estimate that 0 to 48 percent of the food that we administratively detain will later turn out to be not violative.

#### *Transportation*

Under the proposed rule, we might require a firm to transport food that we administratively detain to a storage facility that is both secure and capable of providing the proper conditions for storing that type of food. In other cases, we might allow firms to hold the food in place, but require them to take various other actions to secure the food, such as physically segregating it, locking the area in which they store it, and possibly posting guards to monitor the area in which they store it. We will determine whether or not to require a firm to transport administratively detained food to another storage facility, and to take other actions to secure that food, on a case-by-case basis.

An example of where transporting detained food might be problematic would be the case of large storage grain bins located at private elevators and farms that hold grain. These bins typically hold several hundred tons per bin. It would be costly to transport grain to another holding area. In addition, transporting contaminated grain might spread biological or chemical agents because of the generation and dispersal of dust from the grain as we remove it from the bin and transport it to another location. In this case, it could be preferable to allow the product to be stored in place, possibly with the addition of onsite security.

We do not have sufficiently detailed information on past enforcement actions to estimate the proportion of administrative detentions in which we

might require transportation or any other activity. Therefore, we assume that we would require firms to transport food to a secure facility and store them there in 0 to 100 percent of administrative detention actions. To simplify the analysis, we tentatively assume that the estimated costs of transporting food to a secure facility and storing it there are equal to or greater than the costs of storing the food in place and taking any of the other actions that we might require under our administrative detention authority, except posting additional guards, which we analyze in the discussion of Option Three (take the proposed action, but define the level of security we require for transportation and storage). As we discuss in the section on Option Three, the estimated cost of providing one additional security guard for onsite storage is somewhat higher than the estimated cost of transporting food to a secure facility. Therefore, we have not discussed the cost of providing an additional security guard as part of this option. Nevertheless, providing an additional security guard and storing food in place is consistent with taking the proposed action, and we may take that action in some cases.

The cost of transporting food varies along a number of dimensions, including the following: (1) Type of conveyance used, (2) distance traveled, (3) level of security, (4) type and amount of food involved, and (5) number of trips required. These considerations are interrelated. For example, the appropriate type of conveyance might depend on the level of security, the distance to be traveled, and the amount of food involved. Similarly, the distance to be traveled would depend, in part, on what type of facility meets our security requirements.

Firms may transport food via truck, rail, air, or ship. Based on the distance to be traveled, the level of security we might require, and the type and amount of food involved, we tentatively assume that firms would usually move administratively detained food by truck.

We also assume that when we require firms to transport food to a “secure storage facility,” we will usually interpret that term to mean a bonded or third party public warehouse. We assume that these warehouses would provide proper storage conditions to maintain the safety and wholesomeness of the food. Bonded warehouses, refrigerated warehouses, and most types of third-party public warehouse facilities are readily available around ports of entry into the United States. Most metropolitan areas have an international airport that serves as a port