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December 20, 2003

Tommy G. Thompson, Secretary of the U.S. Department of Health and Human Services.
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville MD 20852

Michael Resnick
Advocacy and Issues Management, Associate Executive Director
National School Boards Association
1680 Duke Street
Alexandria, VA 22314

Dear Mr. Thompson:

On behalf of the National School Boards Association, (NSBA), representing 95,000 public school board members in 15,000 school districts in 80,000 public schools, I write to seek a clarification. Specifically, NSBA seeks clarification on the matter of school district registration under the interim final rules on Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness Act of 2002. NSBA hopes the Food and Drug Administration will consider our comments as the rules could potentially affect 15,000 public elementary and secondary schools districts in the United States. NSBA is concerned that as proposed, based on the following scenarios, the rules would require approximately 15,000 school districts to register without a cost justifiable outcome in terms of the goals of the proposed rules.

SCENARIO 1

First, the proposed rules specifically exempt restaurants from registration. Sec. 1.227(b)(10). Generally, school districts that prepare and serve food from on-site kitchens are clearly "restaurants" and are therefore exempt from registration. However,

2002N-0276

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some school districts prepare food for several schools in one kitchen, such as the high school kitchen, and then distribute the food to one or more elementary and middle schools. Likewise, other districts may prepare food in a kitchen that is in a separate location not connected to any school building, and then distribute the food to the district's schools from that location.

NSBA is concerned that in the later two instances the locations where the food is prepared will be considered a "central kitchen," and therefore the sites will have to register. "Central kitchens" are not included in the definition of "restaurants." Sec. 1.227(b)(10).

NSBA believes it was not the intention of the law to require school districts with central kitchens to be treated differently than other public schools. Therefore, NSBA suggests that school district's food preparation facilities should not be considered "central kitchens." NSBA appreciates FDA's desire to have knowledge about the locations where food is prepared and distributed to other locations, particularly when the distribution is to multiple, far away locations. However, school districts are generally geographically small and compact. Therefore, food prepared in district kitchens will be disbursed to a few locations that are relatively close together. Further, the names of the recipients are well-defined and known. In other words, school districts are not like the "commissaries that are a single source of food for large populations via large chain restaurants" discussed in Comment 74.

If FDA determines that school kitchens in some instances do meet the definition of "central kitchen," NSBA asks that all school district kitchens and cafeterias be specifically exempted from Sec. 1.227(b)(10). NSBA does not believe that FDA intended for school district kitchens and cafeterias to register even if the district's food is prepared off-site.

SCENARIO 2

The second scenario that has been brought to NSBA's attention is the fact that students, parents, local community groups, outside food vendors, etc., bring food into schools. For example, students may sell frozen pizzas for a fundraiser and the district might store the pizzas temporarily until parents can pick them up. Likewise, students may bring food to the district for holiday parties and similar events. Similarly, sales of food items like bake sales occur on school grounds, and districts might allow community groups who use the school facility to sell or provide food free of charge to attendees. Finally, some districts allow local eateries to provide the district with food on certain days.

It is our belief that FDA did not intend for school districts to register under these circumstances. However, it is not clear whether in the above instances food is being "held" by the district for the purposes of these FDA rules. Under the rules, facilities that "hold" food must register. Sec. 1.227(b)(5). On one hand, the definition in the interim rule of "holding" seems more formal than storing goods for a bake sale or a class party, etc. "Holding means storage of food for a period of time. Holding facilities include

warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.” Sec. 1.227(b)(5).

On the other hand, in comment 34 to the proposed interim rules, FDA indicated that even temporary “holding” food requires registration. However, the FDA recognized a specific exemption from registration in comment 7 for private homes that prepare and store food for church bake sales, act as volunteers for Girl and Boy Scout sales, and temporarily store small inventories of food in their homes before delivery to rural retailers. Schools “hold” food much like the private homes described in comment 7; however, the FDA has not recognized a specific exemption for schools.

NSBA believes that it is not the intent of FDA that the definition of “holding” or “facility” includes school districts that store food temporarily in the instances described above. If this is FDA’s intention, it is likely that almost every school district in the United States will have to register because almost all districts engage in one or more of the activities described above. To clarify this, NSBA recommends that FDA states that a school district is not “facility” under Sec. 1.227(b)(2) or that “holding” does not include temporarily storing food in the instances described above and similar instances.

SCENARIO 3

The third scenario that has come to NSBA’s attention is that some school districts warehouse food at locations separate from the school district’s kitchen. For example, large districts may store food in warehouses that eventually will be shipped to kitchens in the district. Also, small school districts, usually in rural areas, may purchase food on a group basis as a cost saving measure. This food may be stored in a warehouse in one of the districts and distributed to the other districts at a later time.

NSBA believes that FDA did not intend for school districts to have to register under these circumstances. However, as discussed above, the definition of “holding” includes warehouses. Sec. 1.227(b)(5). NSBA appreciates FDA’s desire to have knowledge about the locations where food is being stored for distribution to multiple, far away locations. However, in both of the above examples, food stored in district warehouses will be distributed to a few, nearby, known locations that are not likely to frequently change. Specifically, the warehouse in the large district will store food for schools within the district. Similarly, the warehouse for the small rural districts will store food for a few, small, nearby districts. In other words, the school district warehouses are not holding facilities for food that will be shipped to numerous locations across the country. Also, as indicated earlier, the recipients served are not the diffused general public but are a known group of school kitchens and students who can be locally contacted.

If FDA determines that school district warehouses meet the definition of “holding,” NSBA asks that FDA exempt school district warehouses from the definition of a “facility” under Sec. 1.227(2) or “holding” Sec. 1.227(5).

CONCLUSION

In summary, NSBA asserts that it does not appear to be the intention of FDA that school districts register under these rules. Moreover, because of the unique way in which school districts handle food, most if not all 80,000 public schools may have to registers unless the rules are clarified as described above. Registration by all of these schools will put a great burden on schools and clog the FDA records with registrations by facilities that only marginally meet the goals of registration.

If you have any questions or if NSBA can assist in anyway, please contact Lisa E. Soronen at (703) 838-6712 or lsoronen@nsba.org

Sincerely,

A handwritten signature in black ink that reads "Michael A. Resnick". The signature is written in a cursive style with a large, prominent initial "M".

Michael A. Resnick
Advocacy and Issues Management Associate Executive Director