



NATIONAL POTATO COUNCIL

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December 24, 2003

Dockets Management Branch
(HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: Docket No. 02N-0276. Interim Final Rule for Registration of Food Facilities under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. (68 Federal Register 58,894, October 10, 2003); Submission of comments.

To Whom It May Concern:

The National Potato Council is pleased to provide comments on the Interim Final Rule for the Registration of Food Facilities contained in Docket Number 02N-0276. This Interim Final Rule was developed by the Food and Drug Administration (FDA) to fulfill their obligation set forth by the provisions of Title III, Subtitle A, Section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("Bioterrorism Act").

The NPC is the only trade association representing commercial potato growers in 50 states. Our growers produce both seed potatoes and potatoes for consumption in a variety of forms. Annual production in 2002 was 463,214,000 cwt. with a farm value of more than \$3.2 billion. Total value is substantially increased through processing. The potato crop clearly has a positive impact on the U.S. economy.

The potato is the most popular of all vegetables grown and consumed in the United States and one of the most popular in the world. Annual per capita consumption was 136.7 pounds in 2002, up from 104 pounds in 1962 and is increasing due to the advent of new products and heightened public awareness of the potato's excellent nutritional value. Potatoes are considered a staple consumer commodity and an integral, delicious component of the American diet.

Potato growers support efforts by the federal government to promote the safety of the American people in light of the expanded threat that became evident on September 11, 2001. NPC and the potato growers we represent have always taken very seriously the trust placed in them by the American consumers to provide a safe, nutritious and affordable supply of potatoes and potato products.

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Comments on Interim Final Rule
National Potato Council
December 24, 2003

NPC supports the strong efforts by the Administration and the FDA to strengthen the protections for our nations food supply. We are concerned that the requirements contained in the Interim Final Rule being placed on farms will unnecessarily increase the recordkeeping, registration and other costs without contributing to improved public safety.

According to the review of the Interim Final Rule and the Bioterrorism Act we believe that the requirements specified in the rule dramatically exceed the authority provided to FDA by Congress. Congress intended for FDA to conduct oversight of the food supply to reasonably protect the food supply. Congress did not intend for FDA to collect registration information which is unnecessary for that goal.

NPC believes that a reasonable exemption for farms is necessary and appropriate and will result in more effective utilization of FDA resources. The structure of farming operations in the United States is complex and the relationship of farming operations to the distribution channels is not quickly understood. Since the agency has not had the benefit of utilizing an administrative record to evaluate the actual functions of the farming, harvesting and first handler activities for potatoes and other agricultural products the current farm exemption contained in the Interim Final Rule and the subsequent interpretation by FDA of that exemption imposes an unnecessary burden on many farmers. The interpretation and implementation of the farm exemption has exacerbated the problem and resulted in the exemption being of little value to our growers.

The general requirement for registration of food facilities contained in section 305 of the Act directed the Secretary to require by regulation that any facility engaged in the manufacturing, processing, packing, or holding of food for consumption in the United States be registered. Serious fines or imprisonment can result for violations. FDA should not take lightly subjecting farmers to the possibility of these punitive measures.

NPC believes that the intent of Congress in this area was clear. Congress specifically provided that the term "facility" "*does not include farms; restaurants; other retail food establishments; nonprofit food establishments in which food is prepared for or served directly to the consumer; or fishing vessels...*" We believe that this exclusion clearly takes precedence over the term "facilities" and makes it apparent that Congress intended to exclude farms. Since farms are not "facilities under the specific meaning of the Act any activities that occur in the confines of the farm should not be, by definition, covered activities.

In a variety of informal venues including the FDA web site and informal meetings with industry FDA officials have attempted to elaborate on some of the issues raised by this definition. We believe additional clarification and opportunity for public input by farmers is required to clarify what constitutes "manufacturing/processing" and importantly the linkage to these activities on

Comments on Interim Final Rule
National Potato Council
December 24, 2003

the farm to the need for farmers to register. For example FDA has indicated that placing crops in a plastic sleeves or bags, or any other consumer end-use container that directly contacts the crop, constitutes "manufacturing/processing" that would trigger the registration requirement. We believe that these activities carried out on the farm should not trigger the registration requirement.

FDA has indicated that they are examining linkages between pesticide use both pre-harvest and post-harvest and the need to register. The application of pesticides on farms is actively regulated by the U. S. Environmental Protection Agency both in terms of worker and food safety. We do not believe these activities require further regulation or oversight. The farm exemption must be broad enough to cover normal farm activities including the application of EPA approved pesticides.

FDA should not allow the nature of landlord tenant structure to trigger registration. Farmers who farm leased land do it as an extension of their own farming operation using business plans and farming practices that are unified. Leased land should be treated as being an inseparable part of the core farming operation and not as a separate entity that triggers additional requirements.

Congress has attempted to speak to the need to exempt traditional agriculture. This exemption should be based on clear and definable boundaries. For farms to be exempted or not exempted based on whether a potato field is leased and therefore required to be registered or not leased and therefore exempt is without foundation. Similarly the farmers' designation could change depending on his decision to pack in cello bags versus larger boxes which we believe to be a decision that is unrelated to national security.

NPC concludes that additional direct public input is needed to make determinations on workable and realistic definitions that may trigger registration. In addition we believe that FDA should consult with key members of the Congress representing the agricultural community to better determine Congressional intent in many sections of the Bioterrorism Act. NPC believes that the public welfare and safety can be protected with a minimal disruption of commerce. We look forward to working with FDA to find that balance and modify the Interim Final Rule accordingly.

Sincerely,



John Keeling,
Executive Vice President and CEO