



AMERICAN FARM BUREAU FEDERATION®

225 TOUHY AVENUE • PARK RIDGE • ILLINOIS • 60068 • (847) 685-8600 • FAX (847) 685-8896
600 MARYLAND AVENUE S.W. • SUITE 800 • WASHINGTON, D.C. • 20024 • (202) 484-3600 • FAX (202) 484-3604
Internet: <http://www.fb.com/>

1123 '03 JUL -8 P 4:55

July 8, 2003

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

RE: Notice of Proposed Rulemaking: Recordkeeping Requirements and Administrative Detention Under the Public Health Security and Bioterrorism Preparedness Act of 2002; Dockets #02N-0275 and 02N-0277; May 9, 2003

Dear Sir or Madam:

The American Farm Bureau Federation is pleased to offer its comments on the recordkeeping requirements and administrative detention requirements under the Bioterrorism Act of 2002.

For agriculture some of the important provisions of the proposed rule include:

- Requiring domestic persons who manufacture, process, pack, transport, distribute, receive, hold or import food intended for human or animal consumption in the United States (and certain foreign facilities that manufacture, process, pack or hold food intended for human or animal consumption in the United States) establish and maintain records to identify the immediate previous source and subsequent recipient of such food.
- Farmers and firms are exempt, "regulated exclusively by the U.S. Department of Agriculture" – i.e., meat plants.
- There is no form in which the records must be kept, but the information must include: name of firm, responsible individual, address, telephone number, fax number and e-mail address; information about the transporter who delivered the food must also be included (i.e., name, address, telephone number, fax number and e-mail address.)
- Compliance is mandatory six months after the rule is finalized. For small businesses, 510 FTE employees would be allowed 12 months for adoption while very small businesses with ten or less FTE employees would be allowed 18 months for full compliance after these regulations are adopted.

02N-0275

041

Agriculture supports the exclusion from recordkeeping requirements of farms and farmers selling unprocessed food from their own farm or a neighboring farm.

An issue of concern is the proposal for retail facilities such as roadside stands, located in the same general physical locations as farms that sell unprocessed food grown or raised on those farms. They are effectively excluded from these rules as long as they employ 10 or fewer FTE employees. However, the exclusion does not apply to processed foods, even if it is sold directly to the consumers from the retail facility in the same general location as the farm, unless all the ingredients in that processed food were grown or raised on that farm. Consequently, processed foods such as baked goods, jams, jellies, maple syrup and “processed” items such as hams and sausages from animals grown on the farm and processed into meat products would fall under the provisions of the Act. Also any products that were “imported” from off the farm would apply.

The processed food provision is a burden for those involved in roadside stands that operated outside of the normal seasonal harvest period or sell processed foods. They could not purchase goods from neighbors or bring in goods from other areas under the exclusion. Nearly any further processed food includes ingredients from a non-farm source. We ask that this provision affecting farm markets be removed from the rule.

Even though the proposed rule excludes farms from the recordkeeping requirements the provisions of the rule that cover transportation will directly impact farms. The rule will cover inputs, such as livestock feeds, that are brought onto a farm, thus identifying the farm. A transporter hauling farm commodities from a farm to market or further processing will also have to keep a record of where the product was obtained. Farmers are very concerned about the confidentiality of their business operations and are concerned about the personal and physical security of their farms where they reside with their families. We ask that all records that would lead to identifying the location and business operations of farms be kept in a protected manner and may only be released to authorized persons when they are required for the purposes of this rule to protect the food supply from adulteration.

In addition, while the proposed rule states that farms are excluded under these provisions, we question whether in reality that will occur. If those dropping off product at a farm, or picking up product from a farm are required to keep records up to that point, we believe that what will actually happen is that the farmer will be expected to generate paperwork so that those delivering and dropping products off at the farm will be able to comply with the rule. So in effect, while farms may on the face of the rule be exempt, in reality farmers will have to generate large amounts of paperwork for their suppliers, truckers and buyers. The rule needs to make clear that farmers will not be responsible, or expected to, generate paperwork for those complying with this proposed rule.

The detention of food that is under suspicion of adulteration can result in direct costs for the farmer if that food is being held at an on-farm storage. In the case of perishable products such as fruit, vegetables, livestock or milk any holding of that product may lead to a rapid decline in value of that product. For many farmers, and all dairy farms, limited

on-farm storage of perishable products will lead to a complete loss of value if products are stopped from shipment to markets or for further processing. For certain products a critical market opportunity and the reputation of that farm as a reliable supplier could be lost for many years by a disruption in marketing. The Food and Drug Administration must be careful when prohibiting shipment of food products from farms due to the unrecoverable costs of unmarketable product to the affected farm or farms. The position that any 'costs of detention' are to be borne by the owner will impose a substantial hardship on farmers who may be subject to their products being 'detained'. We believe that a system of indemnification for the costs of on-farm product 'detention' should be established. Farmers have little or no ability to pass on any costs, especially the extraordinary costs to an individual farmer of a food 'detention.'

The Bioterrorism Act and the proposed rule seek to 'exempt' farms from their provisions. However the proposed rule does involve farms to a great extent in both the recordkeeping and detention process. Agriculture supports the goals of a safe food supply for our country and our export markets. This must be done without adding recordkeeping and food detention requirements that impose a large financial burden on farmers who are not the focus of the regulatory effort.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard W. Newpher". The signature is fluid and cursive, with a large initial "R" and "W".

Richard W. Newpher
Executive Director
Public Policy