

On-Farm Concerns with H.R. 2749

H.R. 2749

As amended and approved by the House Energy & Commerce Committee on June 17, H.R. 2749 would expand significantly authorities for HHS/FDA (FDA) to regulate and oversee on-farm production activities. Serious concerns about the bill's proposed FDA on-farm regulatory authorities are summarized below. Many of these authorities would be redundant with regulatory oversight already used by USDA, affecting agricultural production practices that FDA does not have the personnel, funding, knowledge, expertise or time to regulate. Indeed, the National Federation of Independent Businesses told House Energy & Commerce Committee leaders in a June 17th letter that the bill "will do little to improve food safety but (would) impose significant costs on small farms and food producers." Further, several provisions of the bill violate U.S. trade commitments and would invite retaliation by our trading partners against exports of U.S. agricultural products.

Sec. 104 -- Safety Standards

- FDA would be required to promulgate science and risk-based safety-standard regulations for seven activities, including the safe growing, harvesting, and holding of raw agricultural commodities.
- "Reasonably necessary" regulations would be determined at FDA's discretion for both broad and specific safety standards, including manure use, water quality, animal control, and temperature controls.
- These types of activities are outside FDA's expertise. Authorizing these regulations would be redundant because USDA, EPA, and the Interior Department already have jurisdiction.
- FDA would have to consider impacts on small-scale and diversified farms and on wildlife habitat, conservation practices, watershed protection, and organic production methods. There is no guarantee that FDA consideration would result in fair, necessary or informed standards that result in safer food.

Sec. 106 – Access to Records

- Food producers and others are required for the first time to allow, upon request and presentation of credentials, a federal official to have access to and copy all records, including production and sales records that may be related in any way to food or feed safety. The bill does this by deleting the current farm exemption found in the Bioterrorism Act of 2002, thereby requiring each farmer to maintain production and sales records showing every buyer to which the farm's products are sold (with the exception of products sold directly to final consumers or restaurants). Further, the bill would allow FDA to require that farmers retain such production and sales records for up to three years.
- FDA is not required to show cause prior to requesting the records. Indeed, the bill would delete the current Bioterrorism Act of 2002 threshold that requires that FDA first have a "reasonable belief" that a food article "is adulterated and presents a threat of serious health consequences or death to humans or animals" before having the authority to access records. The bill replaces this stricter Bioterrorism Act standard with a looser one – requiring only that FDA make a determination that the record has a "bearing on whether such food is adulterated, misbranded, or otherwise in violation of this Act, including all records collected or developed."
- Protecting the privacy of producers' records from unauthorized release and/or access is unclear.

Sec. 107 – Traceability of Food

- FDA is required to create a new food-traceability system under which the agency could track any food or feed contamination incident to its source within only two business days. This mandate could require producers to maintain a complete distribution history of where farm inputs originated and where farm-production outputs are sold. It is not inconceivable that farm records would need to be kept electronically and be interoperable throughout the food chain to facilitate traceability within two business days.

- This system would increase production and technology costs for diversified farmers and grain farmers, most of whom operate small businesses. The requirement is overly burdensome considering the records that diversified farmers and grain producers are currently maintaining. Producers do not have the technical, financial, or staffing resources for making their record-keeping systems interoperable with others in the food chain.

Sec. 112 – Reportable Food Registry

- Farm owners, operators, and those otherwise responsible for food produced on a farm for sale or distribution in interstate commerce would be required for the first time to report food-safety problems to FDA electronically.
- If FDA determines it appropriate, the agency may provide this information to any authorized federal agency, any state or local government, any person, foreign government, international organization, or to the public.
- Though the bill prohibits disclosure of the reported information outside of the authorized individuals, organizations, governments, or a permitted public release, protecting its confidentiality cannot be assured and unauthorized disclosure could be very difficult to prevent.

Sec. 133 – Quarantine Authority for Foods

- The bill authorizes FDA to quarantine geographic areas if it has “credible evidence or information” that an agricultural product “presents an imminent threat of serious adverse health consequences or death to humans or animals.”
- The quarantine authority is very broad and far exceeds the authority granted to USDA. USDA can only quarantine animals for animal-health reasons if there is a declared animal-health emergency where the state has asked for Federal resources.
- If FDA had this authority and had chosen to utilize it in 2008 – when it erroneously suspected, based on what it believed at the time was “credible information” that tomatoes were a source of salmonella contamination – entire regions of the country could have been quarantined, further decimating a sector of agriculture that already had suffered severe economic damage.
- It is unclear if the bill would allow FDA to conduct an on-farm inspection of or quarantine the livestock side of a diversified operation that has a food-safety issue with the grain side of its business.

Sections 134 & 135 -- Penalties

- FDA is required to issue fines for criminal and civil penalties. Unintentional as well as intentional violations may be fined, including for record-keeping mistakes. Each violation cited and each day during which it continues shall be considered to be a separate offense. The potential to damage producers severely financially or put them out of business, including for unintentional violations, is troublesome and needs to be changed.