HR2749 Gives FDA Unheard-of Power over Small Farmers and Food and Supplement Producers

Minor paperwork violations—and violations completely unrelated to food safety—could result in draconian penalties. Citing scientific research about food or supplements without FDA approval could result in a ten-year jail sentence. The bill is Orwellian, and amendments are desperately needed.

The long-awaited food safety bill (HR2749) is on a fast track toward passage. **The Food Safety Enhancement Act of 2009, or FSEA**, is meant to address food safety concerns. But while food safety issues have arisen from large agricultural operations, this bill gives the FDA unprecedented scope, authority, and power over small farmers, food producers, and supplement producers, including the power to use vague language to intimidate and threaten.

HR2749 places **undue economic hardship on small and mid-sized farms and food facilities** (both organic and conventional), which could easily drive many of them out of business and lead to monopoly control of food by large corporations. **Here are just a few of our concerns:**

Sharply increased criminal and civil penalties for violations of FDA regulations—even minor ones

The new penalties include **prison terms of up to ten years** (jail time is currently capped at three years), and **fines of up to $100,000 for individuals and $7.5 million for corporations, regardless of size of operation**.

Most people understand "adulterated" to mean that a product is somehow tainted or injurious to health, or contains an ingredient that presents a significant or unreasonable risk of illness. **In this new bill, any violation of the new administrative requirements could deem a product adulterated and/or misbranded.** In other words, an administrative violation (such as not keeping records exactly as required) that harms no one could carry exactly the same financial and jail penalty as a violation in which a product is adulterated during the manufacturing process and poses a significant risk of illness or ends up killing people.

Moreover, "misbranding" can mean that the producer has made a completely true statement about the product, but without FDA permission. A cherry producer who cites peer-reviewed scientific research from prestigious universities on the health benefits of cherries would, in FDA-speak, have engaged in "false and actionable misbranding" which suddenly turns the cherries into drugs. In this and other ways, the FDA already censors science and quashes constitutionally protected free speech; now the penalties are exhorbitant. Large companies will probably be unaffected because they can afford the extensive legal staff

needed. But if a tiny company were cited, they couldn't afford the legal team needed to fight the potential $7.5 million fine.

Many on Capitol Hill are under the impression that the bill pertains only to food, but **the FSEA language specifically names supplements as well.** This will have a huge potential impact on any small company brave enough to continue their manufacture and sale. If the FDA objects to any language on the label, even if factual, the dramatic increase in jail time and fines for this potential violation will make supplement production an even riskier proposition than it already is today.

An unequal burden for smaller and local food facilities.

The Act's vague language does not distinguish between industrial-sized operations, organic farms, or smaller facilities. The FSEA will require all facilities to produce a new **$500 registration fee each and every year**—no problem for major manufacturers, but a hardship for Mom-and-Pop operations operating on a shoestring.

The FDA could easily use its new authority to set requirements that only large corporate farmers can meet. **Smaller farmers who can't meet the new FDA requirements will simply go out of business**, unfairly creating monopolies for the huge corporations. This one-size-fits-all approach has significant economic implications and could destroy a sustainable farm trying to comply with an inappropriate commercial standard.

The FSEA requires all facilities, farms, and restaurants to implement new hazard analysis and risk-based preventive controls, food safety plans, and an extensive record maintenance program—again, without taking into account the differences between small facilities and large commercial facilities. It also mandates an **extensive food tracing system for all farms or facilities that produce, process, or transport food**, even if the food does not cross state lines. The bill does not explain how far the traceback will extend or how it will be done for multi-ingredient foods. With all these ambiguities, it's far from clear how much it will cost either the farmers or the taxpayers. Small farms may find this trackback system costly and time-consuming.

FDA control of farming standards and practices.

HR2749 would empower the FDA to regulate how crops are raised and harvested. It puts the FDA, which knows nothing about farming, right on the farm, dictating to our farmers. Specifically, it allows the FDA to set "scientific and risk-based standards" for the use of fertilizers, harvesting and processing methods, transportation, etc. Any non-compliance means the food is to be considered "adulterated."

Moreover, the bill gives the FDA the power to order **a quarantine of a geographic area.** Under this provision, farmers' markets and local food sources could be shut down, even if they are not the source of the contamination. The agency could halt all movement of all food in that geographic area.

Random, warrantless searches by the FDA.

Under current law, the FDA only has access to records if it has "a reasonable belief that an article of food is adulterated" and presents "a threat of serious adverse health

consequences or death to humans or animals." Under the FSEA, however, the FDA will have full authority to **conduct random, warrantless searches of all records** dealing with any aspect of a company's production, manufacture, or distribution process. They will have access to all records, at any time, and without any evidence whatsoever that there has been a violation. The bill also extends FDA's **authority to access records of a farm and restaurant**—both of which are exempt from FDA's reach under current law. Even farmers selling direct to consumers would have to provide the federal government with records on where they buy supplies, how they raise their crops, and a list of their customers.

The FSEA also gives the FDA **complete control over recalls, seizures, detentions and quarantines—with no judicial oversight**. For example, FSEA lowers the standard FDA must meet in order to conduct an administrative detention. Currently they must demonstrate "credible evidence" that a food presents a health threat before an administrative detention is allowed; the new FSEA standard is "any reason to believe that an article of food is adulterated, misbranded, or otherwise in violation of this Act."

HR2749, as currently written, is just a bad bill.

Recognize the differences between large and small facilities. Reduce penalties and administrative burdens for small businesses. And rein in the FDA—insist on warrants and judicial oversight, and limit the scope of their authority. ***Please amend this bill today!***

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