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S510 Revised: FDA Coming to a Farm Near You

By **Pete Kennedy, Esq.** | September 23, 2010

More than ever S510 represents a major threat to the local food movement, states' autonomy to regulate food, and the country's ability to become self-sufficient in food production.

On August 12 the Senate Health, Education, Labo and Pensions (HELP) Committee released the manager's package for S510", a revised version of the "FDA Food Safety Modernization Act that is 77 pages longer than the version of S510 that passed out of the HELP Committee last November.

Whereas the House food safety bill, HR 2749, passed out of the full House a month and a half after being voted out of the House Committee on stalled for nearly ten months. Passage of the revi potentially to regulate all farms marketing food pr farms engage only in intrastate commerce.

National Egg Recall Fuels Push for S510

The push to pass S510 is currently being driven b sickening over 1,500 people that has been linked by Wright County Egg and Hillandale Farms, two country. What the mainstream media is ignoring i current powers to regulate food were more than e caused by the egg producers.

FDA already has jurisdiction over shell eggs and egg producers if they are engaging in interstate c County Egg's history of food safety and other viol inspected a long time ago; but FDA did not set fo was well underway. If FDA had conducted a timel observed the conditions now reported in the medi product found on the premises without a court orc

If the egg producers refused to turn over their sal search warrant on an expedited basis to obtain th at the facilities constituted adulteration under the 342(a)(4)].

What the mainstream media is ignoring in covering the story is that FDA's current powers to regulate food were more than enough to put a stop to the problems caused by the egg producers.

Next, the a the firms t eggs purc well as an ingredient would hav

basis, either a seizure order [21 USC 334(a)] or an injunction from a court [21 USC 332] that would have continued to prevent the sale of any potentially tainted product.

According to media reports, the problems with Wright County Egg were discovered back in May but only came to national attention in August (the voluntary recall of the eggs by Wright was announced on August 13—not coincidentally, the day after the manager's package for S510 was released); even if Wright had refused to issue a voluntary recall, FDA still had the power under existing law to get the Wright eggs off the market in a shorter timeframe.

FDA's Views on Food Freedom of Choice

S510 would give FDA significantly more power to regulate food, particularly food in intrastate commerce. For those who think it's a good idea to give FDA more power, here are the agency's views on your freedom to obtain the foods of your choice; these are direct quotations from the agency's response to a lawsuit the Farm-to-Consumer Legal Defense Fund filed earlier this year challenging the interstate ban on raw milk for human consumption:

- "There is **no absolute right to consume** or feed children any particular food." [A--p. 25]
- "There is no 'deeply rooted' historical tradition of unfettered access to foods of all kinds." [A--p. 26]
- "Plaintiffs' assertion of a **'fundamental right to their own bodily and physical health**, which includes what foods they do and do not choose to consume for themselves and their families' is similarly unavailing because **plaintiffs do not have a fundamental right to obtain any food they wish**." [A--p. 26]
- "There is no fundamental right to freedom of contract." [A--p. 27]

For those that think it is a good idea to give the agency more power, here are some of the products FDA has allowed in the marketplace: MSG (monosodium glutamate as an additive), high fructose corn syrup (HFCS), aspartame, genetically-modified organisms (GMOs), Avandia (prescribed for type 2 diabetes) and Vioxx (arthritis pain medication).

FDA permitted the sale of antibiotics for nontherapeutic purposes in animals in CAFOs, a practice that has resulted in antibiotic resistance and the creation of difficult-to-treat infections like MRSA (methicillin-resistant staphylococcus aureus). Properly-prescribed, FDA-approved pharmaceutical drugs are responsible for over 100,000 deaths each year in this country [B--p. 484]. FDA's true clients are not the American people but rather the pharmaceutical and biotechnology industries.

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HARPC Requirements

The most alarming change from the prior version of S510 can be found in an amendment to section 103 of the bill-"Hazard analysis and risk-based controls" [HARPC]; this section can now be applied to farms selling or otherwise distributing any "manufactured/processed" food. The HARPC requirements are similar to the HACCP (hazard analysis and critical control points) plans that various sectors in the food industry are currently mandated to have.

Under section 103(a)-Section 418 of S 510, food facilities are required to have a written food safety plan identifying hazards that could affect food manufactured, processed, packed or held at the facility, and listing and implementing preventative controls that can be used to address those hazards [sec. 103(a), Sec. 418(h)-p. 15]. The facility is also required to monitor the effectiveness of the preventative controls, take corrective actions if the controls are not properly implemented or ineffective verify from time to time that the implementation of the controls, the monitoring of them and any corrective actions taken are adequate [sec 103(a), Sec 418(d) thru (f)-pp. 13-14]. In addition, facilities are required to keep for at least two years records documenting the monitoring of preventative controls and instance of actions taken to correct food safety problems existing at the facility [sec 103(a), Sec 418(g)-p. 14]. Finally, there is a requirement to reanalyze the facility for hazards at least once every three years [sec 103(a), Sec 418(i)-p. 15].

Under the Federal Food, Drug and Cosmetic Act (FDCA), farms are not considered as

"food facilities" (and therefore not required to register with FDA) [21 USC 350d]; but the definition of "farm" is narrow. Under federal regulations, any farms that "manufacture/process" are considered "food facilities" unless all of the food manufactured or processed is consumed on the farm [21 *CFR* 1.227(b)(3)(ii)]. The definition of "manufacture/process" in the *CFR* is extremely broad and includes bottling, labeling, packaging and freezing [21 *CFR* 1.227(b)(6)].

In addition to the current exemption for "farms" from the registration requirement, "retail food establishments" are also exempt from registration. If more than half of the dollar value of a farm's sales is derived from direct sales to consumers, then that farm qualifies as a "retail food establishment" [21 *CFR* 1.227(b)(11)]. However, if S 510 passes into law, it looks like the current "retail food establishment" exemption will no longer be available for farms.

In other words, any farm that manufactures or processes food would be regarded as a "food facility" and subject to the HARPC requirement unless the current definition of "manufacture/process" is changed.

Under section 103(c) of the **manager's package**, the Secretary of Health and Human Services (HHS) would be authorized to issue regulations "with respect to activities that constitute on-farm manufacturing or processing of food that is not consumed either on that farm or another farm under common ownership" for purposes of Section 415 of the FDCA [21 USC 350d—"Registration of Food Facilities]. In other words, any farm that manufactures or processes food would be regarded as a "food facility" and subject to the HARPC requirement unless the current definition of "manufacture/process" is changed.

Such farms would also be subject the inspection requirements contained in section 201 (a)-Section 421 of the bill [p. 90]. Under section 103(c)(1)(D)(i), the HHS Secretary would have the discretion to exempt a farm from the HARPC and inspection requirements if the farm is only involved in manufacturing/processing low-risk foods. It is the Secretary who determines what foods are low-risk, meaning there is no mandate under the bill for the Secretary to exempt any food from the HARPC and/or inspection requirements.

Implications for Raw Milk Producers

If the HARPC requirement becomes law, there are particular implications for raw milk producers. FDA, an agency completely opposed to raw milk distribution and consumption would be in charge of enforcing HARPC.

The blueprint for how FDA can use the HARPC requirement to put raw milk farmers (as well as other small producers) out of business can be found in the way USDA's Food Safety and Inspection Service (FSIS) enforced HACCP in the meat industry. John Munsell, a former owner of a meat processing plant and current manager for the Foundation for Accountability in Regulatory Enforcement, summarized how FSIS puts small slaughterhouses and processing plants out of business [C--slide 40]:

- "hyper-regulation" of small plants.
- "Paper flow and daily HACCP records, most of which have no connection to safe food are swamping small plants."
- "Small plants have been targeted for higher number of enforcement actions."
- "Small plants lack staffs to challenge USDA's unethical demands. Easier prey."
- Unlike big plants, USDA dictates what must be in their HACCP plans.

FDA can do the same to raw milk producers, constantly forcing them to amend their food safety plans, raising the cost of compliance, wasting farmers' time and resources on requirements that have nothing to do with food safety. FDA won't get rid of raw milk producers right away but can use HARPC to gradually reduce their numbers over the years to the point where greater numbers of people will be unable to exercise their legal right to consume raw milk.

National Safety Standards for Produce

The harmful provisions of S 510 that were in the bill as passed out of the HELP Committee last November remain in the **manager's package**. Under section 105 of S510, HHS would be authorized to issue regulations establishing national safety standards for produce. If a roadside vegetable stand or a producer at a farmers' market is selling a type of produce for which FDA has established national safety standards, that producer would now come under federal jurisdiction even if 100% of the producer's sales were made in intrastate commerce.

The produce standards are supposed to be sufficiently flexible [sec 105(a),Sec 419(a)(3)(A)—p.31] so as to take into consideration small growers selling directly to consumers; but the regulations will still be one-size-fits-all, applying to all growers. HHS can grant exemptions with respect to small growers producing and harvesting types of produce that the Secretary determines are low-risk. Again, there is no mandate under this provision that the Secretary exempt anyone.

Under section 105(a)-Sec. 419a(3)(B), any proposed rulemaking for produce safety standards shall "include, with respect to growing, harvesting, sorting, packing and storage operations, science-based minimum standards related to soil amendments, hygiene, packaging, temperature controls, animals in the growing area in the farm." The federal government through the rulemaking power in S510 will be increasingly dictating growers' practices.

Federal Jurisdiction Expanding to Small Farms

Sections 105 and 103 of the bill combine to possibly bring under federal jurisdiction all farms marketing food products direct to consumers, including those only selling in intrastate commerce. Although USDA has jurisdiction over the slaughtering and processing of animals, even those farms selling only meat and poultry products from animals raised on the farm would appear to be subject to the HARPC requirement. The definition of "manufacturing/processing" mentioned earlier includes eviscerating, rendering, and freezing [21 CFR 1.227(6)].

Farms that sell food products, such as uncut fruits and vegetables, eggs, and baked goods, are exempt from inspection and licensure requirements in many states; if S 510 passes, these same farms would be regulated by FDA even though state legislatures saw no need for those farms to be regulated in any way. This is not about food safety, it's about federal control over the food supply. Foods exempted from state regulation generally have a track record of being responsible for few or no cases of foodborne illness. State and local agencies are more than capable of handling foodborne illness outbreaks caused by producers distributing their food products only in intrastate commerce.

The federal government will be imposing on the states its pro-pasteurization, pro-irradiation, pro-GMO version of safe food; in its view, the only good bacteria is dead bacteria

Decreasing States' Regulatory Power

The increased power of FDA to regulate intrastate commerce will erode state autonomy to regulate food under the Tenth Amendment to the U.S. Constitution. Passage of a food safety bill will merge federal and state food regulation to a much greater degree than currently exists. S510 calls for the HHS Secretary to "set standards and administer training and education programs for the employees of state, local, territorial and tribal food safety officials relating to the regulatory responsibilities and policies established by this Act" [sec 209(a), Sec 1011(a)—p. 151]. The federal government will be imposing on the states its pro-pasteurization, pro-irradiation, pro-GMO version of safe food; in its view, the only good bacteria is dead bacteria. FDA will be hiring state officials to enforce S510 at a time most states are short of money. In return for the funding, the federal government will increasingly dictate food regulatory policy to the states.

Food Imports Would Benefit in the Wake of Domestic Enforcement

S510 will punish local food--the solution to the food safety problems in this country—while rewarding the industrial food system, the major source of food safety problems in the U.S. The sector of the industrial food system most responsible for foodborne illness outbreaks is food imports; firms exporting food into this country will benefit the most by the passage of S510. The bill only calls for 600 foreign food facilities to be inspected the first year S510 is in effect [sec 201(a), Sec 421(a)(2)(D)(i)—pp. 92-93]; there are over 200,000 foreign facilities currently registered with HHS. Domestic facilities are categorized into high-risk and low-risk facilities; foreign facilities are not [sec 201(a), Sec 421(a)(2)(B) thru (D)—pp. 92-93]. So, while domestic facilities are being subjected to the onerous provisions of S510, most foreign facilities will be getting a free pass.

To add insult to injury, **American taxpayers will be subsidizing foreign governments** in their efforts to improve food safety in their own countries. Under the bill, HHS is to "develop a comprehensive plan to expand the technical, scientific and regulatory food safety capacity of foreign governments, and their respective food industries, from which foods are exported into the U.S." [sec 305(a)—p. 185] Why not take that money and use

it to improve our own self-sufficiency in food production?

Giving a competitive advantage to foreign producers will only increase the amount of food imported into this country that does not meet our domestic standards. As a member of the World Trade Organization (WTO), the U.S. must accept imported food that meets WTO standards, even though those standards aren't up to our own. For example, sometime in the next year, the WTO likely will be accepting standards that set high tolerance levels for melamine [D-pp. 7-8]—the additive that caused pet deaths in the U.S. and infant deaths in China. If this happens, the U.S. would have to accept foods containing melamine even if our government did set a zero tolerance level for our domestic producers.

Department of Homeland Security (DHS)

In addition to increasing FDA's power, S510 would increase involvement in food regulation by the Department of Homeland Security (DHS), further integrating food and agriculture into the "national security state." The bill would implement **Homeland Security Presidential Directive 9**, a 2004 executive order which appointed the DHS Secretary as "principal Federal official to lead, integrate, and coordinate" among federal, state, local and private sector elements [E--p. 13].

DHS is a monolithic, **disjointed bureaucracy whose employees have little experience** in food regulation. The department has enough problems coordinating internally on food regulation let alone coordinating with FDA, USDA and other federal and state agencies to provide food defense [E—p.18]. The best defense for this country would be the decentralization and localization of food production. Putting into motion the "national agriculture and food defense strategy" that is called for in section 108 of S510 would likely place our food regulatory system on more of a permanent crisis-mode footing, increasing the chance of a government overreaction to a food-related problem, such as occurred in Britain in 2002 during the hoof-in-mouth outbreak when thousands of livestock were needlessly slaughtered.

Merging HR 2749 with S510

HR 2749 contains a number of draconian provisions, including one that would allow the Secretary of HHS to quarantine all movement of food within a state without even needing a court order.

If S510 passes the Senate, there will be a conference committee between members of the House and Senate to draft a food safety bill that would combine provisions of the Senate bill and the House bill, HR 2749, the "Food Safety Enhancement Act of 2009" which passed the House on July 30, 2009. HR 2749 contains a number of draconian provisions, including one that would allow the Secretary of HHS to quarantine all movement of food within a state without even needing a court order [**HR2749**: Sec 133—pp. 118-121].

Other provisions in HR 2749 would impose excessive criminal and civil penalties for violations of the FDCA. Violators could receive up to ten years in jail and could be hit with excessive civil fines ranging from $100,000 for individuals to $7,500,000 for entities; each day a violation continued--e.g., not registering a food facility--would be a separate offense [**HR2749**: sec 134, 135—pp. 121-123].

The Food Safety Accountability Act of 2010 [S.3767]

This past week, Senator Patrick Leahy of Vermont introduced S3767, the "Food Safety Accountability Act of 2010". Under S3767, it would "be unlawful for any person to knowingly—(1) introduce or deliver for introduction into interstate commerce any food that is adulterated or misbranded." The bill calls for penalties of up to ten years in jail.

The scope of the bill is broad and could be applied to actions that pose no threat to public health; a farmer who knowingly sells raw milk to an out-of-state customer (who then brings the milk across state lines) could be found to be in violation of S.3767. Producers who fail to have a written food safety plan (HARPC plan) or who fail to follow produce safety standards could be imprisoned even though their products are no danger to the public health. There will be an effort to incorporate S3767 into S510.

The Purpose of S510

S510 is not about protecting the public health but rather about increasing federal control over food and transferring market share from the local food system to the industrial food

system. The bill grants broad rulemaking power to FDA, a grant not merited by the agency's track record. Its passage will cripple local food over time.

There have been reports in the media that S510 is dead. Don't believe them. The bill could still be brought to the Senate floor before Congress' pre-election break and it could also be brought up for a vote during a lameduck session after the elections. **People need to call their Senators and ask them to oppose S510**. The bill is an attack on your right to obtain the food of your choice from the source of your choice.

To locate the contact information for U.S. Senators, go to **www.senate.gov** or **click here**.

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