ConsumersUnion
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Comments on Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food
[Docket No. FDA-2011-N-0920, 78 Fed. Reg. 3646 (2013)]
Submitted by
Consumers Union
Yonkers, NY
November 15, 2013

Overview

Consumers Union, the policy and advocacy arm of *Consumer Reports*, is pleased to submit these comments to the U.S. Food and Drug Administration (FDA) on its proposed rule implementing portions of the landmark FDA Food Safety Modernization Act of 2011 (FSMA) related to preventive controls for food manufacturing facilities.

One of the key events that prompted passage of FSMA was the 2008 disease outbreak linked to salmonella in peanut products manufactured by Peanut Corporation of America at two facilities in Georgia and Texas. Contaminated products from these facilities led to thousands of product recalls, millions of dollars of losses to the food industry, thousands of illnesses and nine deaths. This incident highlighted the need for more preventive controls that would insure that such incidents are not repeated.

Consumers Union commends FDA for drafting this proposed rule, and supports most of the measures it proposes. There are several areas, however, in which we believe the regulation should be more explicit and specific, in line with both the language and the intent of FSMA. These areas are:

- FDA should require testing of finished products, raw materials and ingredients and the production facility environment as appropriate to verify that the facility food safety plan is effective. Without testing, there is no way to know whether a facility food safety plan is working or not. Neither the plant operator nor FDA will know if goals of minimizing pathogens are being achieved. It is basic scientific method to test and review data on whether a system is working. Testing requirements are thus essential.
- Review of consumer complaints should be included in a company's verification activities.
- FDA should mandate that supplier verification should be a part of the food safety plan. Food manufacturers must ensure that their suppliers are sending them safe ingredients.
- FDA, in addition to requiring development of food safety plans at food production facilities, should require submission of these plans to the agency from firms producing high-risk products, as well as a representative sample of all plans. By focusing only on high-risk facilities, FDA would be targeting products that could have the greatest impact

on public health. By reviewing a statistically significant number of plans, the agency would be able to spot problem areas. In some cases, plan review would help the agency prioritize where it should send its inspectors first.

- FDA should define as a "very small business" one that has less than $250,000 in total annual sales of food, adjusted for inflation.

In our specific comments on these areas, we concur with the views of the Pew Charitable Trusts. In addition we provide insights gained from a Consumers Union study "Bacteria and Bagged Salads: Better Standards and Enforcement Needed," published February, 2010, and which is appended to these comments.

Testing Is An Essential Element of Preventive Controls

The most significant problem with FDA's proposed regulation is its failure to require, in appropriate circumstances, testing of finished product, raw materials and ingredients, and the environment. Section 103 of the Food Drug and Cosmetics Act (FDCA), added by FSMA, requires facility operators to verify that the preventive controls are "effectively and significantly minimizing or preventing the occurrence of identified hazards, *including through the use of environmental and product testing programs* and other appropriate means" (emphasis added). FSMA specifically mentions testing as a method for verifying the effectiveness of measures aimed at minimizing pathogenic contamination, yet the draft regulations fail to require it.

Moreover, the agency's comprehensive and compelling discussion of testing was relegated to an appendix. Consumers Union endorses the well-articulated rationale in the appendix for requiring testing of finished product, raw materials and ingredients, as well as the environment. A combination of science- and risk-based environmental and product testing, as well as raw materials and ingredients, will help verify that the control measures in place are working and therefore the food being produced is safe when they leave processing facilities. Without testing food producers will be in the dark as to whether their plan is effective. We therefore believe that testing is essential to the success of FDA's preventive controls regulations.

Finished Product Testing

Finished product testing can serve a number of roles in a preventive controls system. It can verify that preventive controls have significantly minimized or prevented hazards in food, it can validate that a "kill step" (such as cooking) is working, as well as verify that cleaning and sanitation measures separate and apart from preventive controls are being followed.[1] Finished product testing is also useful in deciding whether to release product into commerce after an environmental sample has tested positive for a pathogen.

Finished product testing would be especially useful for leafy greens, which have been implicated in numerous outbreaks of foodborne illness. As reported in our "Bacteria and Bagged Salads"

[1] See Finished product testing for the peanut industry. By David J. Evanson and Philip H. Elliott. International Association of Food Protection webinar August 27, 2013. Available at: http://www.foodprotection.org/files/members/finished-product-testing-for-the-peanut-industry/

report[2] (attached), Consumers Union undertook finished product testing on 209 bags and clamshells of leafy greens in late 2009. The produce was purchased at supermarkets and shipped via UPS overnight delivery to a laboratory for processing on the next day.

The test results were quite useful for purposes of informing consumers, and we believe would also be useful to a producer in evaluating the effectiveness of their food safety plan. Consumers Union tested for three pathogenic bacteria, *E.coli 0157:H7, Salmonella* and *Listeria monocytogenes.* These samples were all negative for the pathogens. We also tested them for four indicator organisms: total coliforms, fecal coliforms, generic *E coli* and *Enterococcus.* Some 23 percent of samples contained levels of *Enterococcus*, and 39 percent showed levels of total coliforms that several industry experts said should be unacceptable in bagged salad. Bacteria levels varied enormously within brands however, suggesting that producers could benefit significantly from testing to achieve more consistent quality control. Bacteria levels were also higher in packages containing spinach, suggesting it is a particularly high risk green within the generally high risk leafy green category. Producers could test final products containing spinach with increased frequency.

FDA should also consider establishing performance standards for pathogens in leafy greens. There should be a zero tolerance for *salmonella, listeria* and Shiga toxin-producing *Escherichia coli* (STECs). We urge FDA to consider the indicator organisms and limits set for high-risk foods by other countries. The United Kingdom, Ireland and Germany have selected generic E. coli as an indicator and set the limit of 100 CFU/gm for ready-to-eat leafy greens. Switzerland set a limit at 10 CFU/gm. France and Brazil selected fecal coliforms and set limits of 1,000 and 100 CFU/gm respectively. Israel set a standard for total coliforms of 100 CFU/gm in salads made of vegetables. Additional relevant standards appear in our "Bacteria and Bagged Salads" report attached to these comments.

Overall, on the basis of our research project, we urge FDA to require testing of finished bagged salad products and any other products that have a history of causing foodborne illness.

As part of a regulation requiring product testing, FDA should also consider requiring more intense finished product in certain other situations, such as after a corrective action has been implemented. In addition, FDA must clearly specify in a testing regulation that companies are prohibited from retesting product until a negative result in achieved; this was a practice followed by Peanut Corporation of America during a 2009 outbreak linked to its peanut products.[3]

FDA's experience with the seafood Hazard Analysis and Critical Control Points (HACCP) program is a cautionary tale about the importance of testing. When FDA adopted the seafood HACCP regulation, the agency failed to mandate testing—in any form—as part of the verification procedure for seafood safety plans. Consequently, initial implementation of the regulations was not successful, and it took many years before the seafood industry adopted effective controls.

[2] http://consumersunion.org/pdf/BaggedSaladReport.pdf.
[3] ICMSF Book 7 2002

As part of a Pew-Robert Wood Johnson Foundation joint initiative, the Collaborative Food Safety Forum (CFSF), which addressed important issues in FSMA implementation, Pew convened a stakeholder group that included a Consumers Union representative to discuss testing in preventive controls systems.[4] Participants in the testing meeting agreed that finished product testing captures the most information on the total product, which makes it a tool for both validation and verification. It is especially important to use it for products that support pathogen growth over the shelf life. The group also agreed that periodic testing for trend analysis and statistical process control should be required, to provide accurate monitoring of the progress and effectiveness of programs.

The stakeholders agreed that a company's testing plan should describe the target organisms, outline the test methods and frequency, identify the point of test taking (food-contact and non-food contact surfaces, raw materials, ingredients, finished product), and specify corrective actions when positives are found. This stakeholder group identified a number of common elements to ensuring effective HACCP systems.

- The testing program should be based on a risk category and pathogen combination, e.g. *Salmonella*/peanut butter.
- The rule should specify pathogens, not indicator organisms.
- The rule should specify what testing is conducted by the regulatory agencies and what by facilities.
- FDA and facilities should consider seasonality in setting up their testing programs.
- FDA and facilities should consider what actions companies need to take when there is a positive test result.
- Test methods that cover multiple organisms would be useful.
- The amount and/or frequency of testing should be specified, and could be most effective if it was used as an incentive for facilities to make improvements.

Another factor relevant to establishing a testing protocol is the intended use of the food (whether the product in question is ready-to-eat or if it will be cooked) and its intended consumer (infants, hospitalized adults, and the general public).

In addition, as part of a company's verification activities, we recommend that a review of consumer and customer complaints be included. Seafood and juice HACCP regulations require that verification activities include a review of consumer complaints to determine whether, for example, they relate to the performance of the HACCP plan or reveal the existence of unidentified CCPs.[5] Consumer complaints could identify pathogens and food allergens that may not have been adequately addressed in a facility's food safety plan.

We recommend that a facility review consumer complaints as they are received, or at the very least, on a monthly basis, to ensure that any serious problems are investigated immediately.

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[4] *See attached,* Role of Testing in FDA's Hazard Analysis and Risk-Based Preventive Controls: Workshop Summary, March 22, 2013 (the summary of the stakeholder meeting can also be found at: http://www.resolv.org/site-foodsafety/files/2013/04/CFSF-03-22-13-Testing-Workshop-Summary-Final.pdf (accessed November 15, 2013).

[5] See "Fish and Fishery Products, Hazards and Controls Guidance, Fourth Edition – APRIL 2011," Available at: http://www.fda.gov/downloads/food/guidanceregulation/ucm251970.pdf

Environmental Testing

Food can be contaminated by an environmental pathogen at any time during the many different steps in the farm-to-table continuum, including at the processing facility. Cleaning and sanitation are key steps in minimizing or removing such organisms from food production facilities before product can be contaminated, and environmental monitoring is an effective and reliable way to verify that these important measures were done correctly. In addition, an effective environmental monitoring testing program will:

- Give establishments a baseline microbiological assessment of a plant's environment
- Identify potential sources of pathogen contamination and possible vectors that may harbor or spread contamination.
- Verify the effectiveness of procedures used to segregate and control traffic (including personnel and equipment).
- Generate data that is used to correct problem areas before they pose a risk to product.
- Give trend data to modify and update programs in response to results and observations. [6]

The appendix to the proposed rule highlights multiple outbreaks in the United States between 2008 and 2011 of illnesses caused by *Salmonella* or *Listeria monocytogenes* bacteria that was found in a plant environment, thus underscoring the value of an environmental monitoring program. Mandatory environmental monitoring where food is manufactured, processed, packed or held can potentially minimize or prevent microbiological contamination by detecting a problem before contamination occurs**.**

Environmental testing programs must be based on types of manufacturing, and the frequency of sampling and location of samples depends on the risk level inherent to the product and process. Environmental sampling is particularly appropriate when there may be post-packaging contamination of product and if the product is ready to eat. There are guidelines available to the industry, which provide information on how to establish an environmental testing program. [7, 8]

The CFSF testing group agreed that environmental testing should be used as a signal: a positive should trigger additional action and provides incentive for improvement (e.g. positive in a drain triggers additional testing of product contact surfaces; positive on product contact surfaces triggers finished product testing). Similarly, a history of negative test results means that it is appropriate to scale back testing). This type of approach has been used successfully to manage *Listeria* in a number of food processing settings.

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[6] Effective Environmental Control and Monitoring Programs for the Peanut Processor. Environmental testing & Interpretation of results. By Laurie Post and Nancy Bontempo. International Association of Food Protection webinar April 30, 2013. Available at: http://www.foodprotection.org/files/members/environmental-testing-interpretation-of-results/

[7] International Commission for the Microbiological Specifications of Foods. Microorganism in Foods 7. Microbiological testing in food safety management, Springer, 2002.

[8] Grocery Manufacturers Association. Industry Handbook for Safe Processing of Nuts. 2010. Available at: http://www.gmaonline.org/downloads/technical-guidance-and-tools/Industry_Handbook_for_Safe_Processing_of_Nuts_1st_Edition_22Feb10.pdf

In the appendix, FDA discussed mandating the use of zones in environmental monitoring. In this approach, a processing plant is divided into distinct zones, with increased testing within a particular zone in response to positive test results. In a regulation mandating environmental monitoring in appropriate circumstance, FDA should develop a protocol for environmental testing, including specified frequency, sample methods and target organisms

Raw Material or Ingredient Testing

Testing of raw materials and ingredients is a way to verify that suppliers have significantly minimized or prevented hazards likely to occur. As addressed in the appendix to the proposed rule, a supplier approval and verification program is a key element of a preventive approach to food safety. Many manufacturers/processors are not fully vertically integrated operations that control the entire supply-chain of ingredients, and thus must rely on safety procedures of their suppliers. There is no way for consumers to determine whether food manufacturers are ensuring that the ingredients that are used in food products are safe. The businesses that process food, on the other hand, are well positioned to prevent biological, chemical or physical hazards from reaching and harming consumers. Through contractual relationships, producers can require their suppliers to adhere to strict safety standards.

The CFSF testing group agreed that the frequency of raw material testing should be based on inherent product risk (i.e., how the product or ingredient will be used), together with an assessment of supplier performance and the facility's ability to control risk. Consumers Union agrees with this assessment. When there is no validated critical control point at the supplier level, facilities need to conduct ingredient/raw material testing unless the ingredient or raw material is converted to a ready-to-eat product or fully processed to eliminate pathogens. Food processors should beware of exempting ingredients or raw materials if the product could be diverted for other uses, e.g. an ingredient subject to contamination going into product that is not fully processed.

Raw material testing is especially important when the hazard is not eliminated by a kill step further down the food production chain. This is the case of aflatoxin, for example; manufacturers need to make sure aflatoxin remains within the acceptable levels before raw nuts are processed. FDA should establish in regulations and guidance principles that guide those establishments that should be required to have a raw material and ingredient verification program.

Supplier Verification

In our view, FSMA is clear in requiring supplier verification as a preventive control. Section 418(o)(3) of the FDCA, which was added by FSMA, defines a preventive control as:

> [T]hose risk based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food . . . *may* include the following: . . . (G) Supplier verification activities that relate to the safety of food. (*emphasis added*)

We maintain that the word "may" in this provision does not mean that the inclusive list is a list of options. Rather, the word "may" only introduces the list of actions to be applied where appropriate. The provision, read as whole with the statute, means that a facility must implement a supplier verification program where a knowledgeable person and scientific understanding would deem it appropriate to address a hazard. FDA captured this sense in its original draft of the rule, which included an explicit requirement to implement supplier approval and verification programs, where appropriate, to control likely hazards.

We recommend that FDA require that manufacturers/end processors develop a methodical approach to supplier approval/verification based on the risk of contamination coming from raw material and ingredients. This will better ensure that suppliers are complying with practices to minimize or prevent hazards.

In the appendix, FDA offers strong support for mandating supplier approval and verification programs in its rules. It cites to specific instances where supplier controls could prevent outbreaks and recalls. The agency notes that supplier approval and verification is widely accepted in the food safety community and recommended by industry associations, and that it is commonplace for retailers to require certifications from their suppliers. Surveys find that two-thirds of suppliers are already audited under their customer's verification programs, further demonstrating the pervasive use of supplier controls.

Food industry associations recognize the importance of supplier approval and verification as an essential component for preventing food safety problems.[9] Advice from respected voices in the food industry echo this message by pointing out that verification of inputs is a cost-effective way to ensure safety,[10] and a good business practice.[11] The World Health Organization views it as essential to preventing problems that result in food recalls.[12]

The decision not to require supplier verification programs will adversely impact FDA's ability to ensure that a plant has effective preventive controls in place. FSMA requires that only documentation associated with a facility's hazard analysis and food safety plan must be made available during routine inspections; therefore, it is possible that FDA would not be able to review information about supplier approval and verification if they are not included in a food

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[9] GMA, *Food Supply Chain Handbook*, 8 (2008); Produce Marketing Assn., *Ask Dr. Bob, Implementing Supplier Controls* (2011) *at* http://askdrbob.pma.com/cat/foodsafety/page/2 (last accessed May 15, 2013) (Noting many processors have supplier approval programs and encouraging all companies to adopt supplier verification programs to ensure the safety of produce they use in their products).

[10] "[B]eing able to verify the reliability of the supply chain back to agricultural inputs is perhaps the most cost-effective way of ensuring the quality and safety of the products that we eat." Shaun Kennedy, *Supply Chain Verification to Improve Product Recall and Crisis Management Plans*, Food Safety Magazine (Oct./Nov. 2008), *at* http://www.foodsafetymagazine.com/magazine-archive1/octobernovember-2008/supply-chain-verification-to-improve-product-recall-and-crisis-management-plans/ (last accessed May 13, 2013).

[11] "Whether or not there is a regulation mandating that you have a supplier approval and verification program, it is simply good business to do so… ." David Acheson, *Will FSMA Preventive Controls Mandate Supplier Management Programs? Does it matter?...*, Leavitt Partners (2013) *at* http://achesongroup.com/2013/02/will-fsma-preventive-controls-mandate-supplier-management-programs-does-it-matter/ (last accessed November 15, 2013).

[12] FAO/WHO Guide for Developing and Improving National Food Recall Systems 39 (2012).

safety plan. As a result, the only time that FDA may have access to this information is during an outbreak investigation – *after* people get sick.

A mandatory supplier verification program could save companies from the costs of a product recall. Approximately 37 percent of Class I and Class II recalls are linked to a lack of supplier control.[13] In a 2009 foodborne illness outbreak linked to peanut products produced by the Peanut Corporation of America, adequate supplier approval and verification programs could have avoided the costs associated with the recall of over 3,800 products.[14]
Finally, failure to require domestic food companies to have supplier verification programs may run afoul of our trade agreements. FSMA adds Section 805 to the FDCA, which requires importers to put in place foreign supplier verification programs. Failure to include a comparable requirement for domestic companies may provide grounds for a suit in the WTO Court, alleging that the FSMA's regulations constitute discriminatory treatment of imported products.

FDA Review of Initial Food Safety Plans

Since development of a comprehensive food safety plan is the fundamental foundation for an effective preventive control system, we urge FDA to reconsider its decision *not* to require any food facilities to submit their initial written food safety plans to the agency.

FDA has expressed concern that it will be overwhelmed by the sheer volume of documents; we have suggested that it require submission only of plans from firms producing high-risk products or a representative sample of all plans. This initial review will provide – at the very least – a snapshot of how companies are interpreting FDA's preventive controls regulations. By focusing only on high-risk facilities, FDA would be targeting products that could have the greatest impact on public health. By reviewing a statistically significant number of plans, the agency would be able to spot problem areas, and in some cases, plan review would help it prioritize where it should send its inspectors first.

Given that FDA will only initially be going out to high-risk domestic facilities once every five years on average, submission of plans could be an important aid to compliance. Further, since FDA intends to rely on state governments and foreign governments in many cases to conduct inspections, FDA itself may actually never see certain facility plans or have the opportunity to verify that plans exist unless at least some plans are forwarded to the agency.

FDA's experience in implementing the Seafood HACCP Rule is instructive on this issue. Two years after the rule went into effect (1999), only 44% of inspected firms had adequate plans.[15]

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[13] Memorandum from Yinquing Ma, Plant Product Branch, FDA, to John Sheehan, Director, Division of Plant and Dairy Food Safety, FDA 7 (Feb. 13, 2012) *available at* http://www.regulations.gov/contentStreamer?objectId=09000064811b3d7b&disposition=attachment&contentType=pdf (last accessed April 16, 2013).
[14] FDA, *Peanut Butter and Other Peanut Containing Products Recall List*, (Oct. 28, 2009) *at*. http://www.accessdata.fda.gov/scripts/peanutbutterrecall/index.cfm (last accessed April 15, 2013).
[15] FDA, *FDA's Evaluation of the Seafood HACCP Program for 1998/1999* (Dec. 8, 2000) *at* http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm188639.htm (accessed Oct. 21, 2013).

By 2005, 89% of inspected firms had plans when required.[16] Moreover, a review of warning letters issues by FDA from 2000-2009 reveals those, on average, 50% of warning letters were for missing or inadequate seafood HACCP plans.[17]

Definition of "Very Small Business"

FDA proposes three possible definitions for "very small business." The definition will have a significant impact on public health and consumer safety because "very small businesses" – along with certain other facilities under new Section 419(l) of the FDCA – can be exempt from the requirements related to preventive food safety plans that other facilities must implement. Of the three options proposed by FDA, Pew supports defining a "very small business" as one that has less than $250,000 in total annual sales of food, adjusted for inflation.

If FDA chose either of the other two options for defining a "very small business" -- less than $500,000 or $1 million in total annual sales of food -- it would essentially nullify the intent in creating two different types of qualified facilities. A qualified facility may be (1) a very small business or (2) a business with limited annual sales provided a majority of its sales are made directly to qualified end-users.[18] Since average sales of less than $500,000 is used in the statute to define one set of facilities that can qualify for modified requirements, the only reasonable definition of "very small business" – and the one that would fulfill the intent of Congress in creating two types of qualified facilities – is option 1 (less than $250,000 in total annual sales).[19]

The philosophy underlying the qualified exemption is that Congress views a close producer-customer relationship as a "control" for safety when a business is below a certain sales level (less than $500,000 in sales) and the business primarily sells directly to consumers or locally to food retailers and restaurants.[20] By also including a "very small business" within the exemption, the law determines that a very small facility is overly burdened regardless of how it markets product, but that at some point below $500,000, it is still reasonable to subject these businesses to modified requirements as long as they continue to deal directly with consumers and customers. Applying option 1 would provide a rule that properly aligns incentives with the statutory scheme and the assumptions underlying it.

The purpose of FSMA is to improve FDA's ability to prevent, detect, and respond to food safety problems by establishing a system that is science and risk-based, accountable to consumers,

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[16] FDA, FDA's Evaluation of the Seafood HACCP Program for Fiscal Years 2004/2005 (last updated July 9, 2013) at http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm111059.htm (accessed Oct. 21, 2013).

[17] CSPI presented its analysis of warning letters issued between 2000 and 2009 at the FDA Food Safety Modernization Act: Focus on Preventive Controls for Facility public hearing, April 20, 2011. (Transcript and replay *available at* http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm250377.htm (accessed Oct. 21, 2013).

[18] A qualified end-user is defined as (1) the consumer of the food; or (2) restaurants or retail food establishments that are located in the same state as the qualified facility or within a radius of 275 miles of it provided they sell the food directly to consumers. Other conditions that apply are that the size of the facility has to take into account the income and practices of any subsidiary or affiliated business. Section 418(l)(1)(B) & (C) and (4)(B) of the FDCA.

[19] Consumers Union supports FDA's decision to define very small business in terms of total sales rather than other factors such as volume of production or number of employees.

[20] 156 Cong. Rec. S8010 (daily ed. Nov. 18, 2010)(statement of Sen. Tester)(the geographical area is limited to the state where the qualified facility is located or to any retailer/restaurant within 275 miles of the qualified facility).

transparent and focused on prevention.[21] The underlying balance is disturbed if more facilities are exempted under one of the two other options for defining the term very small business.

Conclusion

FDA has a significant opportunity with this proposed preventive controls rule to make sure that the heart of FSMA – preventing foodborne illness outbreaks *before* they occur- comes to fruition. But in order to do so, the final rule needs to require adequate testing, supplier verification, and review by FDA of initial food safety plans. Limiting the exception to very small businesses that have less than $250,000 in total annual food sales will also ensure that the exception does not threaten the preventative schema envisioned by Congress when it passed FSMA. With these robust protections, both consumers and food producers will be able to rest easier.

Respectfully submitted,

Jean Halloran
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For the report: Bacteria and Bagged Salads: "Better Standards and Enforcement Needed" click here. (PDF)

[21] http://beta.congress.gov/congressional-record/2010/09/23/senate-section/article/S7392-1?q={%22search%22%3A[%22durbin+food+safety+modernization+act%22]}) (statement of Sen. Durbin on S. 510).