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Docket No. 97N-0074

**Re: President's Food Safety Council: Notice of Meeting;
Federal Register, Vol. 64, No. 240 (December 15, 1999), pp. 70168-70171**

The Center for Science in the Public Interest (CSPI) appreciates this opportunity to provide comments on the Draft Preliminary Food Safety Strategic Plan developed by the President's Council on Food Safety (the Council). CSPI is a nonprofit consumer group with over one million members in the United States and Canada that focuses primarily on nutrition and food-safety issues.

CSPI applauds the Council and its workgroups for their hard work in revising the strategic plan that was presented last summer. We are pleased that the Council recognized the logic of organizing the overall plan around the three major activities of risk assessment, risk management, and risk communication. As a result, the document is better organized and more coherent than the previous draft.

However, while the specific goals and objectives set forth in the draft strategic plan reflect sound public policy, the revised plan continues to ignore many of the glaring problems inherent in the current regulatory system and fails to adequately address the need for a new, independent agency for food safety. The Council should revise the strategic plan to call for the establishment of a single agency and provide a road map for consolidating all food-safety functions in that agency. If the Council is unwilling to take that action, it should turn the decision over to the President. Consumers cannot wait any longer for the federal government to

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C232

replace the existing patchwork with a coherent, logical system that ensures the safety of all foods irrespective of artificial and outdated bureaucratic divisions.

CSPI's comments are organized as follows: First, we examine whether the draft strategic plan adequately responds to both the National Academy of Sciences (NAS) report entitled "Ensuring Safe Food from Production to Consumption" and the President's charge to the Council based upon that report. Second, we evaluate whether the draft plan would address numerous gaps in the existing food-safety regulatory framework that CSPI has repeatedly emphasized in its comments to the Council and in congressional testimony. Third, we undertake a more detailed analysis of the goals, objectives, and action items set forth in the draft plan, suggesting revisions designed to strengthen the plan. Finally, we articulate the reasons why the Council should use Option V(E) (consolidation of food-safety regulatory, research, and surveillance in a single, independent agency) as the model for reorganizing the federal food-safety regulatory system.

I. The Draft Strategic Plan Falls Short of Addressing the Problems Described in the NAS Report and of Fulfilling the President's Mandate

In August 1998, the National Academy of Sciences (NAS) released a report entitled, "Ensuring Safe Food from Production to Consumption."¹ Later that month, the President formed the Food Safety Council to respond to that report and to develop a strategic plan on food safety. To help assess whether the Council's draft strategic plan adequately responds to the NAS report and the President's charge, CSPI will highlight both the NAS findings and the charge to the Council.

A. The National Academy of Sciences

In its report, the NAS recommended a number of changes in the existing federal food-safety system. Of particular relevance to the Council's mission are the NAS's Recommendation IIb, which calls for the development of a comprehensive national food-safety plan, including the allocation of adequate resources on the basis of risk, and Recommendation IIIa, which calls for the establishment of a unified food-safety framework headed by a single official. While the Council's response to Recommendation IIb is generally good, it has failed to address the glaring problem identified in Recommendation IIIa.

In its Recommendation IIb, the NAS stated that the comprehensive national plan should satisfy a number of criteria, including that it (1) be unified and science-based; (2) be integrated at the federal, state, and local levels; (3) allocate resources on a risk/benefit basis; (4) support research and surveillance to monitor changes in hazards and to help predict and avoid emerging hazards; (5) increase surveillance and monitoring of foodborne illness; (6) address imported

¹ Institute of Medicine, National Research Council, *Ensuring Safe Food from Production to Consumption* (National Academy Press: Washington, D.C., 1988) [hereinafter cited as *NAS Report*].

foods; (7) recognize the burden on state and local authorities for food safety; and (8) address consumers' safe food-handling practices.² Each of these criteria, to a lesser or greater extent, is addressed in the draft strategic plan. While CSPI has some concerns about aspects of the Council's response to those recommendations, which are discussed more fully below, the draft plan responds well to many of the concerns reflected in the NAS's recommendations.

By contrast, however, the Council has failed to meaningfully address the need to restructure the current food-safety regulatory system as called for by the NAS in Recommendation IIIa. That recommendation states that "Congress should establish, by statute, a unified and central framework for managing federal food safety programs, one that is headed by a single official and which has responsibility and control of resources for all federal food safety activities."³ It is impossible to fathom how the goals set forth in the national food-safety strategic plan could be realized without creating an independent food-safety agency, with a single administrator overseeing a unified budget. Yet, the Council stopped well short of calling for that common-sense solution.

Today, we have not one, but *two distinct* statutory frameworks for food safety: one in operation at the U.S. Department of Agriculture (USDA) and another at the Food and Drug Administration (FDA). The strategic plan ignores the need to rationalize and unify the current statutory framework for food safety and appears to assume the continuation of the existing patchwork of food safety agencies.

B. The President's Charge

The President charged the Food Safety Council with developing a "comprehensive strategic Federal food safety plan that contains specific recommendations on needed changes, including measurable outcome goals. The principal goal of the plan should be the establishment of a seamless, science-based food safety system. The plan should address the steps necessary to achieve this goal, including the key public health, resource and management issues regarding food safety."

Although the Council's plan has many good attributes, it does not yet provide a blueprint to create the seamless food-safety system envisioned by the President, particularly the steps needed to achieve that goal. The plan should be much more specific on how federal food-safety activities should be combined to optimize the delivery of food-safety services to the public and the food industry.

² *Ibid.*, p. 12 (Box ES-3).

³ *Ibid.*, p. 12.

II. Gaps In The Strategic Plan: The Need For a Single Food-Safety Agency

Both in comments to the Council and in testimony before Congress, CSPI has highlighted a number of gaps in the current system that jeopardize human health. In this section, CSPI will analyze the extent to which the draft Strategic Plan would address those gaps. The following is a list of food-safety gaps and inefficiencies enumerated in CSPI's testimony before the Senate Committee on Governmental Affairs on "Overlap and Duplication in the Federal Food Safety System" on August 4, 1999, followed by an analysis of the impact of the strategic plan and the improvements that would result from a single federal food-safety agency:

A. Under the current structure, food-safety problems fall through the cracks of agency jurisdiction. Lettuce and other fresh vegetables and fruits are essentially unregulated for safety. Last year, FDA proposed a number of guidelines for farmers,⁴ but they are entirely unenforceable. The use of animal manure on food crops is also not controlled. These are some of the problems that fall through the cracks of the current jurisdictional systems.

Draft Strategic Plan: By leaving food-safety responsibilities divided among numerous federal agencies, the plan would not prevent cracks and fissures that leave consumers unprotected. For example, in 1995 and 1996, five outbreaks from *E. coli* O157:H7 were traced to lettuce. At that time, neither the Food Safety and Inspection Service (FSIS) nor the FDA would accept responsibility for addressing the problem, each agency stating that it did not regulate these products, especially on the farm. With emerging food-safety hazards, consumers need a single agency charged with overseeing the safety of the entire food supply. The strategic plan simply does not address this problem.

Under an Independent Food Safety Agency: With responsibility for all food-safety problems under a single administrator and within a single agency, confusion about who bears the burden for addressing emerging hazards would not arise. As a result, there should be no danger that regulatory gaps -- or overlapping responsibilities -- would stymie the government's ability to react aggressively to new (or old) problems. In addition, centralized control would mean that resources could be applied to food-safety problems on a public-health and hazard basis, rather than on bureaucratic considerations.

B. Under the current structure, multiple agencies fail to address glaring public health problems. Eggs are regulated both by FDA and USDA, but neither agency has developed an effective containment strategy to prevent the spread of *Salmonella enteritidis* (SE) in shell eggs.

⁴ US Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, *Guidance for Industry. Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*, (Washington, DC: US Food and Drug Administration, October, 1998).

Instead, the agencies have acted like keystone cops, tripping over each other and bungling each attempt to control SE in eggs.⁵ Today, over twelve years since SE inside eggs was first identified as a public-health concern by the Centers for Disease Control and Prevention, consumers still await an effective strategy to eradicate SE in shell eggs.

Draft Strategic Plan: The strategic plan foresees that improved coordination between agencies will improve the delivery of food-safety services. However, the recent development of the Strategic Plan for Egg Safety does not portend well for the future of these coordination efforts. It took years and the approval of two cabinet secretaries to develop a plan to address *Salmonella enteritidis* in eggs, and consumers still await proposed rules covering much of it. In the absence of direct White House involvement, it is likely consumers would never have benefitted from the egg-safety plan. Without strong White House leadership on food safety, the current system will revert to an ineffective system of bureaucratic squabbling and turf fights. Public health requires a more streamlined decision-making system.

Under an Independent Food Safety Agency: Battles over regulatory responsibilities would be effectively eliminated, because ultimate authority would reside in a single agency pursuing a unified agenda. Such streamlined decisionmaking would have resulted in a solution to the SE emerging much more quickly.

C. Under the current structure, the same food-processing plant may get two entirely different food-safety inspections. The classic example is a processing plant that produces both pepperoni and cheese frozen pizzas. The pepperoni line will get daily visits from a USDA inspector to check on conditions in the plant as workers slice the pepperoni and apply it to the pizza.⁶ The cheese line will be subject to FDA inspection on average once every 10 years.⁷ The minimal difference in hazard between the processing of cheese and pepperoni pizzas is not enough to justify the vast disparity in government inspection.

Draft Strategic Plan: Without changes to the statutory mandates, the strategic plan will be ineffective in addressing this problem. Difference in inspection of pepperoni pizzas and cheese pizzas are inherent in the underlying statutes as well as in resource discrepancies among the

⁵ US General Accounting Office, *Food Safety and Quality: Salmonella Control Efforts Show Need for More Coordination*, (Washington, DC: US General Accounting Office, April 1992).

⁶ Michael R. Taylor, "Preparing America's Food Safety System for the Twenty-First Century -- Who is Responsible for What When it Comes to Meeting the Food Safety Challenges of the Consumer-Driven Global Economy?" *Food and Drug Law Journal*, Vol. 52, No. 1 (1997), p. 18 [hereinafter cited as *Preparing for the Twenty-First Century*].

⁷ US Department of Agriculture, US Department of Health and Human Services, US Environmental Protection Agency, *Food Safety From Farm to Table: A National Food Safety Initiative. A Report to the President*. May 1997, p. 37 [hereinafter cited as *Food Safety from Farm to Table*], *Preparing for the Twenty-First Century*, p. 18.

agencies. The most effective mechanism to solve this problem would be to have inspection personnel from both agencies combined, with new inspection mandates.

Under an Independent Food Safety Agency: With a centralized management structure, unified budget, and integrated inspection force, an independent agency would be able to allocate inspection resources on the basis of risk, rather than antiquated statutes and inadequate resources.

D. Under the current structure, some food-processing plants may get no federal food-safety inspections. Due to resource constraints, FDA has turned some portions of its regulatory responsibility over to the states. The best example of this is in the area of shellfish production, where FDA relies totally on state inspectors. In other instances, FDA simply is unaware of plants that it is supposed to regulate. A 1991 Inspector General investigation documented that FDA's identifies food firms "by reviewing newspapers, magazines, phone books, industry publications, trade periodicals, surveillance reports and consumer complaints. Inspectors may also walk through stores looking for new products."⁸ The Inspector General reported that, under this system, some food plants escape detection for long periods of time.

Draft Strategic Plan: The strategic plan does nothing to address gaps and inequities in inspection coverage. In fact, Objective 6 of the plan specifically encourages the development of federal/state agreements to address the absence of an adequate federal inspection presence.

Under an Independent Food Safety Agency: A more coherent, risk-based allocation of resources could ensure that all federal food-safety efforts receive sufficient resources to enable federal inspectors to do their jobs adequately and to avoid wholesale transfer of inspection responsibility to the states.

E. Under the current structure, quality inspections occur more frequently than safety inspections. There are many shell-egg plants that receive regular inspections from US government inspectors, but the inspections are for quality, not for safety. All plants shipping eggs between states are visited by the Agricultural Marketing Service (AMS) each quarter and many plants also participate in a voluntary grading program where they receive continuous inspection by AMS.⁹ Under the voluntary AMS program, our government ensures that each has a yolk of the proper diameter, but nothing in the program checks for the presence of SE.¹⁰ Nor does FDA, the agency charged with food-safety oversight of shell eggs, check for SE during its

⁸ Department of Health and Human Services, Office of the Inspector General, *FDA Food Safety Inspection*, August 1991.

⁹ 7 C.F.R. § 59.28; Poultry Division, AMS, USDA, "Quality Eggs for Volume Buyers," Brochure No. AMS-627, August, 1996.

¹⁰ *Ibid.*

infrequent inspections.¹¹ A similar program exists in the Commerce department for seafood processors.

Draft Strategic Plan: Although the Clinton administration's recently introduced egg-safety plan places primary responsibility for egg safety with FSIS, it does not address AMS's quality-assurance program nor the question of how resources will be allocated among the safety and quality programs. Likewise, the draft strategic plan does nothing to rationalize the coordination or resource allocation between federal food-quality and safety programs.

Under an Independent Food Safety Agency: A more balanced allocation of resources among foods under a unified budget and policy would ensure that food-safety programs provide adequate food-safety protection, and will likely do away with the need for separate industry-funded inspection programs through AMS and the Commerce Department (seafood).

F. Under the current structure, HACCP is a different system at FDA and at USDA. The new HACCP systems for seafood, meat, and poultry share almost as many differences as similarities. For example, both frequent inspection and laboratory verification of product samples are essential to give the government appropriate oversight over plants utilizing HACCP. Otherwise, the HACCP program is little more than an industry honor system. While USDA requires both on-site inspection by government inspectors and two levels of laboratory verification of meat and poultry products, FDA requires neither for seafood products. FDA inspects seafood plants once every one to five years and made laboratory testing for HACCP verification optional for seafood processors.¹²

Draft Strategic Plan: The strategic plan does nothing to address the disparity in resources and regulatory approach between FDA and USDA, both of which are needed to standardize the HACCP programs in the two agencies. Under the present system, these new programs will continue to render inadequate results, especially at FDA.

Under an Independent Food Safety Agency: A single agency with a unified, comprehensive approach to food safety would be much better positioned to standardize HACCP programs and ensure that pathogen-reduction performance standards are used wherever appropriate. It would also be better able to apply the lessons learned from a HACCP program for one food to the programs for other foods and apply resources as appropriate.

¹¹ Elizabeth Dahl and Caroline Smith DeWaal, *Scrambled Eggs: How a Broken Food Safety System Let Contaminated Eggs Become a National Food Poisoning Epidemic* (Washington, DC: Center for Science in the Public Interest, 1997), p. 11 [hereinafter cited as *Scrambled Eggs*].

¹² Caroline Smith DeWaal, "Delivering on HACCP's Promise to Improve Food Safety: A Comparison of Three HACCP Regulations," *Food and Drug Law Journal*, Vol. 52, No. 3 (1997), pp. 331-335.

G. Multiple agencies may prolong the time it takes to bring the benefits of new technologies to the consumer. For example, two years ago, Agriculture Secretary Dan Glickman announced the commercial availability of a biological inoculation for young chicks against *Salmonella*.¹³ This product was developed by the USDA's Agricultural Research Service and then spent years being considered for approval at the Food and Drug Administration.¹⁴ For several other heralded technologies, like trisodium phosphate for poultry and irradiation for poultry and red meat, FDA approval is just the first step in implementation. Then there is often a public rulemaking process at USDA before products can be used in meat and poultry plants. This bifurcated process can take years to get through.¹⁵

Draft Strategic Plan: The strategic plan does nothing to streamline the process for new food-safety-technology approvals. USDA recently said that it would forego separate approval of new food-safety technologies, but reports from new technology providers indicated that they are having difficulty getting approval letters from FDA that are needed for USDA acceptance.

Under an Independent Food Safety Agency: An independent agency with responsibility for all new-technology approvals could develop an efficient single-track approval process that eliminates needless duplication while maintaining rigorous scrutiny of applications.

H. Under the current structure, imported products are treated differently at FDA and USDA. Imported meat and poultry products are subject to a three-stage approval process by USDA. First, the exporting country's meat or poultry inspection safety system must be approved by USDA; then, the individual plant must be inspected by USDA before it can ship meat to the U.S. Finally, the meat is subject to random verification checks at the border. FDA meanwhile only has the authority to inspect food at the border but has the staff to check less than two percent of import shipments.¹⁶ FDA can't send inspectors to foreign countries except by invitation, even when they are checking the source of food involved in an outbreak in the U.S.

¹³ US Department of Agriculture, "USDA Researchers Create New Product That Reduces *Salmonella* in Chickens," USDA Release No. 0121.98, March 19, 1998.

¹⁴ Telephone conversation with John DeLoach, MS BioScience, Inc., Dundee, IL, April 1998.

¹⁵ Rosanna Mentzer Morrison, Jean Buzby, and C. T. Jordan Lin, "Irradiating Ground Beef to Enhance Food Safety," *Food Review*, Vol. 20, No. 1 (1997), p. 34; US Department of Health and Human Services, Food and Drug Administration, "Irradiation in the Production, Processing, and Handling of Food; Final Rules," *Federal Register*, Vol. 62, No. 232 (1997), pp. 64102-64121; Memo from Robert Sindt, Burditt & Radzius, to Caroline Smith DeWaal, April 1, 1998; Meeting with Robert Sindt, Burditt & Radzius, James Elfstrum, Rhodia, and Jerry Carosella, Consultant, Regulatory Microbiology, Washington, D.C., April 3, 1998.

¹⁶ US General Accounting Office, "Food Safety: Federal Efforts to Ensure the Safety of Imported Foods are Inconsistent and Unreliable," (Washington, DC: US General Accounting Office, April 1998), p. 5 [hereinafter cited as *Safety of Imported Foods*].

Draft Strategic Plan: While the strategic plan addresses imported-food safety, it does nothing to ensure that *all* foods, irrespective of the agency that is responsible for them, are adequately inspected for safety.

Under an Independent Food Safety Agency: An independent agency, especially one with a more coherent statutory scheme for imported-food regulation, could develop a comprehensive approach to food imports and allocate resources according to risk.

I. Under the current structure, we risk exporting our irrational food-safety system.

There is increasing international pressure to “harmonize” our food safety systems with the systems used in foreign countries. “Harmonization” is the process of assuring that the systems in use in foreign countries provide an equally safe food product.¹⁷ With international trade in food products expanding rapidly, tremendous energy is being devoted to identifying and eliminating unnecessary barriers to trade and simplifying standard setting internationally, using organizations like Codex and the World Trade Organization.¹⁸ We shouldn’t harmonize internationally before we have harmonized our systems domestically, and this alone should provide some urgency to developing a more rational basis for our food-safety system today.

Draft Strategic Plan: The strategic plan does not provide leadership to the world in developing a more rational approach to food-safety regulation. In fact, many countries are actively developing and implementing plans to unify food-safety functions much faster than the US.

Under an Independent Food Safety Agency: An independent agency with a comprehensive, risk-based approach to food safety would serve as a model for efforts in other nations, and as a basis against which to evaluate the equivalence of other nations’ systems.

J. Coordination with the state agencies that handle food safety is a nightmare. For example, state laboratories that analyze food samples for chemical or microbial contamination have complained about the lack of uniform testing methods and reporting requirements required by the federal agencies, including USDA, FDA, CDC, and the Environmental Protection Agency (EPA). This means that state labs may have to run multiple tests on a single food simply to meet the varying requirements of the federal agencies. In addition, they waste valuable staff time transmitting the same information to different agencies, which each have their own customized system for reporting lab results. The lack of common data requirements for foods discourages

¹⁷ *Agreement on the Application of Sanitary and Phytosanitary Measures*, Article 3, GATT Doc. MTN/FA II-A1A-4 (Dec. 15, 1993) in *Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations*, GATT Doc. MTN/FA (Dec. 15, 1993) 33 I.L.M. 9 (1994).

¹⁸ *Preparing for the Twenty-First Century*, pp. 26-27.

many states from sharing their laboratory data with the federal agencies.¹⁹ In addition, there are not common laboratory certification standards for state laboratories that test food for contamination. This means that in many outbreak and recall situations, a state lab test result will have to be repeated by a federal agency. This can result in a several day delay in recalling food or informing the public, with the continuing risk to public health.

Draft Strategic Plan: Although the plan calls for the improvement of laboratory standards and infrastructure at all levels, nowhere does it specifically address the need to create common standards to ease the reporting burden for state laboratories. Instead, it apparently envisions maintaining the status quo of separate agencies with different information demands.

Under an Independent Food Safety Agency: An independent agency could readily standardize laboratory data and reporting requirements and enable state labs to submit their data once, using a single protocol. Such a system could speed recalls of contaminated food, providing better protection for consumers.

K. Confusing food-safety standards exist because agencies can't agree. FDA and EPA have different public health standards for the permissible methylmercury content of fish. Methylmercury is a potent developmental toxin that accumulates in fish from environmental sources.²⁰ It can accumulate to toxic levels both in fresh water and ocean dwelling species. EPA has established a standard for recreationally-caught fish that is more protective of public health than the standard that FDA applies to commercially caught fish. Efforts to set a single standard have resulted in a logjam, with Congress finally asking the National Research Council to mediate the squabble and set its own standard. Meanwhile, the public and the states are left to wonder what is the safe level for methylmercury in fish.

Draft Strategic Plan: The plan calls for continued “coordination” by the various agencies charged with food-safety responsibilities. The methylmercury quagmire shows that better coordination alone is no answer. Different agencies can render different interpretations of existing science, leaving states and the public to wonder what is really safe.

Under an Independent Food Safety Agency: A single agency, whose sole responsibility is public-health protection from the hazards in food, would be far better able to arrive at a single, consumer-protective standard without engaging in unnecessary time- and resource-consuming battles with a sister agency.

¹⁹ “National Integrated Food Safety System. An Update on Work Group Activities: Laboratory Operations and Coordination,” session at the 103rd Annual Educational Conference of the Association of Food and Drug Officials, June 5-9, 1999, San Antonio, TX; Association of Food and Drug Officials 1999 Resolution Number 99-09 Concerning National Standards for Computer-based Laboratory, Inspection and Surveillance Data Standards, June 7, 1999.

²⁰ Institute of Medicine, *Seafood Safety*, (Washington, DC: National Academy Press, 1991), pp. 12, 116-117.

L. *Some new food innovations can completely escape government review for food safety, because of the complicated system of multiple reviews.* For genetically modified foods, approval responsibilities for new plant varieties is done by three different federal agencies. USDA's Animal and Plant Health Inspection Service (APHIS) has a mandatory review process to protect against plant diseases and pests that might emerge from genetically modified seed stock. The EPA has a mandatory review process for genetically modified seeds with pesticidal qualities. FDA, meanwhile, utilizes a voluntary review process to address food-safety problems that might emerge from genetically modified foods. Under this system, FDA relies on an industry honor system that allows the biotech companies to decide whether and when they should consult with FDA prior to putting a product on the market. This example shows that FDA simply has not had the staff to police emerging food issues properly. Given FDA's other priorities, it is unclear if it ever will.

Draft Strategic Plan: Although the plan recognizes the need to identify and control emerging issues, it fails to address how adequate resources will be brought to bear on those problems. Existing funding disparities among the agencies will continue unabated.

Under an Independent Food Safety Agency: Without the overlap and duplication that exist today, a single agency could use existing resources better to cover all aspects of food safety, including new food innovations.

III. Detailed Analysis of the Draft Strategic Plan

In addition to the gaps discussed above, the Council should strengthen the draft strategic plan by making the following changes to its goals, objectives, and action items.

A. Overarching Goal

The three broad Strategic Plan goals, as stated in the draft document, generally are appropriate. Organizing the overall plan around the three major activities of risk assessment, risk management, and risk communication represents a significant improvement over the previous draft. However, we suggest that the second goal, which focuses on risk management, be revised to read as follows:

“The United States’ system for managing food safety is coherent, effective, risk-based, and focused on preventing problems from farm to table.”

The revised statement incorporates two new, critically important concepts into the risk-management goal: that government's efforts follow a unified, risk-based strategy, and that they focus on prevention of foodborne illness.

B. Science and Risk Assessment Goal

The strategic plan's approach to risk assessment generally is sound. However, the document omits an important caveat concerning the relationship between scientific risk assessment and government action on food-safety problems.

Unquestionably, in a time of limited government resources, food-safety regulation must be based upon considerations of risk. Neither regulators nor inspectors should squander precious resources on foods and food processors that pose little or no actual risk to public health, while ignoring other serious problems. However, the strategic plan should make it absolutely clear that lengthy scientific risk assessment processes should not delay the development and implementation of necessary public-health measures where a problem is manifest. In addition, the plan should address the need for provisional rulemaking to address food-safety emergencies.

That point bears emphasis in the strategic plan because it is too easy for regulators and the scientific community to lose the forest of an urgent public-health threat while analyzing and re-analyzing the trees of scientific minutiae during a risk assessment. Not every difficult scientific question must be answered nor every data gap filled before the government takes necessary action to protect consumers from an obvious problem. Consumers should not have to wait until a lengthy risk assessment is completed for the government to respond to an immediate threat.

The most recent example of this phenomenon is the government's tepid response to the problem of *L. monocytogenes* in ready-to-eat foods. In late 1998 and early 1999, a nationwide outbreak of listeriosis from hot dogs and deli meats sickened 100 people, killing 15 adults and causing 6 miscarriages/stillbirths. Since then, a second outbreak traced to gourmet processed-meat products has sickened at least 11 people,²¹ and since December 1998 nearly 33 million pounds of ready-to-eat products have been recalled by companies due to *L. monocytogenes* contamination.²² Plainly, the existing regulatory system is broken, and the pathogen continues to pose a serious, immediate threat to consumers.

Nonetheless, the government has done very little to protect consumers. While USDA has asked plants producing ready-to-eat meat and poultry products to reassess their HACCP plans and has *suggested* that they conduct microbial testing for the presence of *L. monocytogenes* in their plant environments and products, it so far has failed to mandate such testing. The stated reason: USDA's administrative rulemaking requirements, which include duplicative reviews by

²¹ "Newsbites; Contaminated Mousse Recall," Los Angeles Times (Jan. 5, 2000), p.H2.

²² FDA recalls: U.S. Food and Drug Administration, "Enforcement Reports," (Available at <<http://www.fda.gov/po/enforceindex/99enforce.html>>Internet) and Associated Press, "FDA Expands Smoked Seafood Recall," Tuesday, January 11, 2000; USDA recalls: Food Safety and Inspection Service, USDA, "1999 Recall Reports." (Available at <<http://www.fsis.usda.gov/OA/recalls/recdb/rec1999.htm>>Internet).

the agency’s Office of Risk Assessment and Cost-Benefit Analysis and the White House Office of Management and Budget, are overly burdensome, requiring extensive data collection and cost-benefit analysis even where the risk to public health is clear. Such delay, in the face of a pathogen that killed 21 people just over a year ago and continues to show up with great regularity in a multitude of ready-to-eat products, is unconscionable. The strategic plan should include a clear statement that risk assessment and cost-benefit analysis should never stall the implementation of necessary public-health measures, but instead should be used to bolster, supplement, and evaluate regulations.

CSPI’s other comments concerning the Science and Risk Assessment goal are as follows:

- The second sentence should be revised to read as follows:
- “An effective food safety system must be based on sound science and capable of dealing **in a prompt manner** with current and emerging public health concerns on the basis of the risk they present to the consumer.”
- The following should be added to the end of the first paragraph:

“However, risk assessment should not delay needed measures to protect public health where urgent food-safety problems have been identified.”
- Objective 1 should be revised to read as follows:

“Strengthen the scientific basis for **coordinated and unified** food safety policies ...”
- Objective 2 should be revised to read as follows:

“Expand surveillance, data collection, **and information sharing** capabilities for adverse human health outcomes related to the food supply.”
- In Objective 2, the plan should include as an action item the publication of specific outbreak and other food-safety surveillance information annually.
- Objective 3 should include among the hazards to be addressed the development of antibiotic-resistant foodborne pathogens resulting from the use of antibiotics in animal feed.
- In Objective 4, the third action item should read as follows:

“Develop new **rapid** risk assessment methods, such as those for determining aggregate exposures and cumulative risks, as well as consideration of **vulnerable** populations, ...”

- The evaluation component of Objective 6 should include an assessment of whether research, risk assessment, and surveillance programs are effective at generating necessary information in a timely basis, so as not to delay government action.

C. Risk Management Goal

Overall, the draft strategic plan’s approach to risk management is appropriate. However, CSPI has identified several aspects that should be strengthened:

- In the description of the risk-management goal, the plan describes the challenge of “allocat[ing] resources where risk is high.” This is contrary to the recommendations of the NAS report, which stated that “limiting allocation of resources to *only* those areas where high priority hazards are known can create a significant problem: other hazards with somewhat lower priority but with a much greater probability of reduction or elimination might not be addressed due to limited resources.”²³ Thus, regulators should balance the degree of risk posed by a particular hazard against how amenable the problem is to change.

- In Objective 2, the second action item should be revised to read as follows:

“Maintain **and standardize** performance standard based, HACCP programs and expand the use of this concept --**including microbial testing for verification** -- where appropriate.”

- In Objective 2, the third action item should be revised to read as follows:

“Promote targeted labeling strategies to provide consumers the information necessary for them to feel confident in their selection of foods, **including labeling on high-risk foods such as raw shellfish, ready-to-eat meat and poultry, and unpasteurized juice, as well as labeling related to foods produced using irradiation and genetic modification.**”

- In Objective 3, add the following as an action item:

“Develop and implement uniform testing methods and reporting requirements for food-sample analysis by state laboratories.”

- In Objective 4, add fruits, vegetables, and unpasteurized juice to the list of high-risk foods.
- In Objective 6, the government’s emphasis should be on developing and enforcing

²³ *NAS Report*, pp. 11, 93.

mandatory performance standards wherever they do not exist, rather than on promoting voluntary approaches and forging new federal/state and other agreements.

- In Objective 7, add the following as an action item:
“Eliminate duplicative review at multiple agencies for new food-safety technologies.”
- In Objective 8, add the following as an action item:
“Create mechanisms, including expedited rulemaking, to facilitate the rapid development and implementation of new regulations in response to food-safety emergencies.”
- In Objective 9, revise the first action item to read as follows:
“Strengthen assessments of foreign systems and conduct additional assessments of foreign regulatory systems, **including on-site audits**, as appropriate, to determine ...”
- In Objective 10, the first action item should be revised to read as follows:
“Evaluate and upgrade the food safety system **on a continual basis.**”

D. Risk Communication Goal

- In Objective 1, the first action item should explain the function that the information network would fulfill. Is the aim to better communicate information about outbreaks, recalls, etc. to relevant government officials? Would the network have any other roles?
- In Objective 1, the second action item should include consumer group, industry, and government risk communicators as well, who also play a prominent role in the dissemination of information to the public.
- In Objective 1, the nationwide campaign described under the fourth action item should also focus on health-care facilities.
- In Objective 2, the fourth action item should clarify that the professional opportunities for science teachers should be designed to enhance teaching of food safety. In addition, it should more clearly call for the creation of more school-based food-safety curricula.
- In Objective 4, the second action item should also address the need for interactive means of communication other than the Internet.

IV. Reorganization of the Federal Regulatory System

As the foregoing discussion makes clear, the myriad gaps and other problems inherent in the existing federal food-safety system cannot be adequately addressed without fundamental restructuring and modernization of both the statutory and regulatory framework. We are pleased, therefore, that the Council has included in the draft strategic plan a number of options for how to transform the existing system into one that is more unified and coherent. Although a number of the options presented would yield significant improvements, CSPI strongly urges the Council to pursue **Option V(E)**, entitled “Consolidate food safety regulatory, research, and surveillance responsibilities,” with minor revisions.

Creation of a single, independent agency -- as opposed to mere coordination of functions or the establishment of a joint committee or lead agency -- would wholly eliminate the inter-agency squabbling and key regulatory gaps that plague the current system. Unless all responsibilities for food-safety regulation are housed within one agency with a strong, executive leader or cabinet-level administrator, the “seamless, science-based food-safety system” sought by the President will remain out-of-reach. The history of food-safety regulation in this country demonstrates that when responsibility is split among multiple agencies and lead administrators, policies and regulations tend to be inconsistent, while the desire to protect bureaucratic turf hampers efforts to address problems in areas of shared responsibility.

Neither a coordinated system such as that described in Option I nor the specific consolidations in Option II would alleviate those major problems. As long as separate agencies with different cabinet-level heads maintain their distinct core missions for food safety, turf wars and inconsistent policies are practically guaranteed. Nor would the lead-agency approach set forth in Option III effectively eliminate the problems inherent in a multiple-agency system; in fact, that approach may even exacerbate turf battles among agencies. In addition, the non-lead agencies would likely reduce their food-safety resources and commitment.

Many of these problems could be eliminated under Option IV, the consolidation of all food-safety functions within a single, existing agency. However, this option would not deliver increased consumer confidence in the long run. Neither USDA nor FDA would be the right venue for a unified agency. USDA suffers from a lack of confidence because it has responsibilities for promoting food products, both domestically and overseas. Combining food safety with food promotion would expand on the dual missions that have historically reduced consumer confidence in USDA programs. This type of system is also currently being replaced in Great Britain, after it contributed to the lack of consumer protections from Bovine Spongiform Encephalopathy, or “Mad Cow Disease.” FDA’s food-safety program suffers from a similar lack of confidence, especially among the members of Congress who fund its programs. This problem has resulted in an acute lack of resources for FDA that, in turn, contributes to the agency’s phantom inspection presence.

By contrast, Option V, the creation of a consolidated, independent agency, would eliminate the numerous problems described above and is the best mechanism for maintaining consumer confidence while achieving the unified and seamless food-safety system envisioned by the NAS and the President. A newly created agency would provide fertile ground for the development of a modern, risk-based approach to food safety, without the innovation-stifling effects of entrenched bureaucratic systems or the wastefulness of inter-agency turf battles. Such an agency could draw upon the strengths of the existing framework, weaving the best of the current system into a coherent program while eliminating duplicative functions, needless divisions, and archaic, ineffective regulations. Moreover, consumer confidence would be strong in a new, independent agency that lacks the FDA and USDA's historical problems.

CSPI urges adoption of Option V(E), with several minor changes. First, we do not support inclusion of the research, surveillance, and other functions of the Centers for Disease Control and Protection (CDC) in the consolidated agency. Instead, CDC's functions should remain distinct from those of the new agency, so that CDC could serve as an independent evaluator of the reorganization effort and of effectiveness of the newly created agency. Second, only APHIS functions relevant to food safety should be folded into the new agency. Unrelated APHIS functions should stay at USDA.

If the Council is unwilling to recommend Option V(E) and to develop a mechanism to achieve a single, independent food-safety agency, it should ask the President to decide how best to restructure the federal regulatory system. The Council must not be seen as putting turf protection above public health. If it does not embrace Option V(E), or a similar strategy including a single agency, the Council will have abdicated its responsibility for doing all that it can to develop a plan that will best protect consumers from hazards in the food supply.

V. Statutory Reorganization

While pursuing Option V(E) would go a long way toward establishing a truly effective federal food-safety system, to achieve that goal the existing *statutory* scheme must also be restructured. As the NAS concluded in *Ensuring Safe Food*, "There are inconsistent, uneven, and at times archaic food statutes that inhibit use of science-based decision-making in activities related to food safety, and these statutes can be inconsistently interpreted and enforced among agencies."

The Council should strongly recommend in the Strategic Plan that the current food-safety statutory scheme be revamped to create a unified, comprehensive approach to the issue. The unjustifiable discrepancies that exist between FDA and FSIS's statutory mandates must be abolished if this country is to ever have a truly science and risk-based system for coping with the hazards in our food supply. The Council should help the President to develop and introduce new legislation to better protect consumers by modernizing our outdated and highly fractured food-safety statutes.

Once again, if the Council is unwilling to take such action, it should defer to the White House on the question of how to develop a statutory scheme that will best protect consumers.

VI. Conclusion

The latest draft of the Council's strategic plan represents a significant improvement over the previous version released last summer. However, the most important element necessary to modernize and streamline the federal food-safety program is still missing from the plan: namely, a road map for the establishment of a single, independent agency responsible for ensuring the safety of all foods. Until the plan includes that road map, it will not eliminate the major problems inherent in the existing system, and the truly effective system envisioned by the NAS and the President will remain little more than an enticing dream.

In the final strategic plan, the Council should develop a mechanism to create a single, independent food-safety agency. If it is unwilling to do so, it should turn decision making responsibility over to the President.

Respectfully submitted,



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