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PRESERVATION



Mary L. Smith
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Good Safety

Record Type: Record

To: Eric P. Liu/OPD/EOP@EOP
cc: Anna Richter/OPD/EOP@EOP
Subject: food safety meeting tomorrow

Tomorrow, Podesta is meeting with Secretaries Shalala and Glickman, and FDA Commissioner Jane Henney. The purpose of the meeting is to try to encourage them to pursue more broad-based improvements to the current food safety system in the food safety strategic plan that is to be sent to the President in July. Tom and I would recommend that we direct the Secretaries to support the concept of a single food safety agency and work with the stakeholders, the Hill, and others to craft legislation by the end of the year to do it.

The consumer advocates have been wanting to hold a press conference urging the Administration to support a single food safety agency, but I have been holding them off. In addition, word of this meeting leaked out (from the agencies), and some of the industry lobbyists called this week asking whether the Administration was going to announce a single food safety agency this week.

At the meeting, I believe that Secretary Glickman will be a little more proactive. I heard from his Chief of Staff that he is going to present some other options that we could do with respect to food safety. I think that they want to release a white paper that would declare listeria to be a hazard and that would propose some sort of testing for listeria. This would be a good step, and would address some of the concerns of the advocates in the Sara Lee outbreak.

Secretary Shalala and Jane Henney, on the other hand, will probably be more resistant to doing much. One strategy would be to stress to them that we are so far along in the Administration that this would never be implemented under their watch, but that their own legacies would be enhanced by supporting something more proactive.

March 16, 2000

MEMORANDUM FOR THE CHIEF OF STAFF

FROM: KAREN TRAMONTANO
THOMAS FREEDMAN
MARY SMITH

SUBJECT: POSSIBLE OPTIONS ON FOOD SAFETY

You asked that we write a short memorandum outlining a couple of specific options for improving coordination and efficiency within the federal food safety system. Below are listed two options: (1) a Joint Chiefs of Staff model and (2) support for a single, independent food safety agency.

This is a timely occasion for the President making such an announcement on food safety. The President established the President's Council on Food Safety in August 1998, and directed it to develop a comprehensive plan for improving Federal food safety. Currently, the Council has almost completed a draft strategic plan, however, the draft does not recommend any significant realignment of responsibility or organizational consolidation or statutory changes to improve gaps in the current system. The Council is scheduled to send its report to the President this July.

Joint Chiefs of Staff Model

Under this option, a Board of Directors or Joint Chiefs of Staff would be established with a neutral Chairman appointed by the President and representatives from all the food safety regulatory agencies. Each agency would retain its core mission, but would be obliged to plan and coordinate in areas where their missions coincide. This option would improve upon the President's Council on Food Safety by replacing the three co-chairs --the Assistant to the President for the Office of Science and Technology Policy and the Secretaries of Agriculture and Health and Human Services (HHS) -- with one Chair. We would recommend that the Assistant to the President for the Office of Science and Technology Policy be the Chair. The Chairperson of the Joint Committee for Food Safety would be the principal food safety advisor to the President and the Secretaries of Agriculture and HHS, and the Administrator of the Environmental Protection Agency.

The Joint Committee would be responsible for (1) the unified strategic direction of the federal food safety system; (2) the operation of the federal food safety agencies; (3) the submission of a unified food safety budget to the President, i.e., the individual agencies would no

longer submit food safety budgets to the Office of Management and Budget (OMB); and (4) the integration of the federal food safety agencies into an efficient team. In addition, the Chairman of the Joint Committee would also have a staff headed by a director in order to assist the Chairman in carrying out his duties.

The consumer groups probably will not be enthusiastic about this approach, arguing that it does not go far enough to improve the current system, both with respect to statutory authority and organizational structure. One of the advantages of this approach is that it probably would not require any new legislation.

Single, Independent Food Safety Agency

Under this option, the President would support the concept of single, independent federal food safety agency, and he would direct the agencies to come up with a plan to implement this concept, including legislative language, within a set period of time such as 120 days. This option would combine parts of both Senator Durbin's bill (S. 1281), which creates a single independent food safety agency, and Senator Dorgan's bill (S. 908), which provides for statutory fixes to the existing system.

This option would create a new stand-alone Cabinet-level food safety agency to facilitate achievement of food safety and public health goals. This option would combine the "core" standard-setting, food safety labeling, education, inspection, and enforcement functions for meat, poultry, eggs, seafood, and other FDA-regulated foods and animal feed into one agency. For instance, this new agency would consist of at least USDA's Food Safety and Inspection Service (FSIS), FDA's Center for Food Safety and Applied Nutrition (CFSAN), FDA's Center for Veterinary Medicine (CVM), parts of FDA's Office of Regulatory Affairs (ORA), and the Department of Commerce's National Marine Fisheries Service (NMFS) as it relates to the seafood inspection program.

This option, like the Durbin bill, does not consolidate food safety research into one agency. This option assumes the Joint Institute for Food Safety Research (JIFSR), which was created by a Presidential directive in July 1998, would continue to coordinate federal food safety research. Food safety research activities are best performed by research agencies not regulatory agencies. However, the new food safety regulatory agency should have appropriate authorities to partner with research agencies to conduct necessary research.

This option also does not include in the new agency the functions of the Centers for Disease Control (CDC) at HHS. CDC performs surveillance, outbreak response, and public education. These functions should continue to be performed at CDC because they will provide an important check on the new agency.

In addition, this option would combine some of the elements of the Dorgan bill in order to provide fixes to gaps in existing law. For instance, this option would mandate a Hazard Analysis and Critical Control Point (HACCP) system approach for all foods. In contrast to the

traditional reactive food safety strategies, HACCP focuses on preventing hazards that could cause foodborne illness by applying science-based control processes at all stages of food production and processing. Currently, the Administration has implemented HACCP only for meat, poultry, seafood, and juice, and has proposed a plan to start providing regulations for HACCP for eggs. As part of this HACCP system, food producers and processors would focus on preventing contamination along the farm to table continuum.

This option would also fix the disparities in the inspections provided by USDA and FDA. Currently, USDA is required by statute to conduct continuous inspections of meat and poultry, which means that meat and poultry are inspected daily. FDA, which basically regulates all other foods, does not have a statutory inspection mandate. Because of a lack of resources, FDA only inspects some plants every ten years. This disparity in inspection requirements probably stems from the fact that, at the turn of the century, when the meat and poultry requirement was enacted, meat and poultry were considered to be the highest risk for foodborne illness. However, consumers' eating habits have changed, with more imported and processed foods being consumed. As a result, this statutory framework no longer provides the best protection for consumers. This proposal would put all foods, including meat and poultry, under one inspection scheme with a new statutory requirement that all facilities be inspected quarterly, with discretion for more frequent inspections in cases of high-risk foods. A risk-based inspection regime with some minimum requirements should be contained in the statute itself so that Congress will appropriate the necessary resources.

The consumers groups (the Center for Science in the Public Interest (CSPI), Safe Tables Our Priority (S.T.O.P), etc.) will strongly support this option. Industry generally will not be supportive of this option, and, in fact, may actively oppose it. Farmers also are likely to oppose it because they generally have been adverse to mandatory on-farm regulation. With respect to the Hill, initially there is not likely to be much support for this proposal. For instance, Senator Dorgan's legislation only has two cosponsors, both Democrats, and Senator Durbin's legislation only has three Democratic cosponsors.

While it is quite unlikely that proposal could be enacted before the President leaves office, it may still be important for him to suggest this option in order to move the debate forward and to bring the weight of the bully pulpit to this issue.

March 3, 2000

MEMORANDUM FOR THE CHIEF OF STAFF

FROM: KAREN TRAMONTANO
THOMAS FREEDMAN

SUBJECT: POSSIBLE NEXT STEP ON FOOD SAFETY

Most experts, including the National Academy of Science and consumer advocates, agree that we need a better, more unified system for regulating food safety. The Secretaries of HHS and USDA have each agreed in private conversations that the Administration could take some significant step in this direction. However, without high-level brokering it is very unlikely that any further progress will be made. We recommend that you meet with Secretaries Glickman and Shalala (along with Neal Lane and Bruce Reed) to see whether the Secretaries could agree on taking more decisive measures with respect to food safety.

This is a timely occasion for such a meeting. The President established the President's Council on Food Safety in August 1998, and directed it to develop a comprehensive plan for improving Federal food safety. Currently, the Council has almost completed a draft strategic plan, however, the draft contains no significant recommendations for structural changes in how the government handles food safety. The Council is scheduled to send its report to the President this July.

Below we have outlined: (1) a brief description of the Council's mandate; (2) health and safety problems with the current system; and (3) options you might discuss with the cabinet secretaries.

Background on President's Council

The President tasked the Council to "develop 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." In developing this plan, the Council was to take into account the findings and recommendations of the National Academy of Sciences (NAS) report "Ensuring Safe Food from Production to Consumption." The NAS report urged legislation to establish a unified and central framework for managing federal food safety programs, which should be headed by a single official with responsibility for all federal food safety activities. The idea of a single framework for food safety was also suggested by the Vice President's National

Problems with the Current System

The existing Federal system is fragmented among numerous departments and agencies. At least a dozen Federal bureaucracies, implementing 35 statutes, have major roles in overseeing the safety of the nation's food supply. While each agency has a common goal of making sure Americans have the safest food supply in the world, their statutory authorities and resources differ markedly. These differences make the total Federal effort less efficient and, according to consumer advocates, less protective of human health than could be achieved with a more consolidated regulatory approach. A few examples of inefficiencies and weaknesses in the food safety system include the following:

- Inspections are not based on risk. The Department of Agriculture (USDA) is required by statute to perform continuous inspections, which means that meat and poultry are inspected daily. The NAS report stated that “[b]ecause of the statutorily mandated continuous inspection requirements, [the Food Safety Inspection Service’s] inspection budget is about four times that of FDA.” The Food and Drug Administration (FDA) at the Department of Health and Human Services (HHS), with responsibility for all other foods, only has resources to conduct inspections approximately once every ten years for most establishments. Accordingly, resources are not allocated based on risk.
- Inspections are often inefficient. Because of the FDA-USDA jurisdictional split along commodity lines, some food products that might be perceived by consumers as similar are regulated differently, depending on content. A now classic example of this jurisdictional problem is pizza inspection – if it has pepperoni, it is inspected by USDA; if it has only cheese, it is FDA’s responsibility, even in plants where both types are produced. As stated above, one of the other results of this inefficiency is that even though USDA inspectors are in the plants every day, they do not inspect cheese pizzas. Therefore, meat-topped pizzas are inspected every day, while the cheese pizzas produced in the same plant may not be inspected for several years.
- Imports are treated differently at USDA and FDA. USDA has much greater authority to regulate imported food. For example, USDA can inspect foreign suppliers of meat products and prohibit importation until they meet U.S. standards. FDA, on the other hand, only has the authority to inspect food at the border but has the staff to check less than two percent of import shipments. While we have proposed legislation to fix some of this disparity, it has not been acted upon.

Recommendations

The Council’s current draft strategic plan focuses on incremental improvements in the current fragmented system. At this time, the plan does not recommend any significant realignment of responsibility or organizational consolidation. However, the draft plan does

include a set of options for future decisions on organization, ranging from increasing coordination within existing structures to a single, independent food safety agency. (Attached in appendix). Now is a good time to lay out a plan for improving our system – while scientific evidence from the NAS is fresh and relevant, all parties also know that a comprehensive plan will have to be implemented in the future so some immediate congressional pressure may be relieved.

We recommend that you meet with Secretaries Glickman and Shalala to explore whether we can reach agreement on a more far-reaching recommendation for the President to announce regarding food safety. Specifically, you could suggest that : (1) that the July strategic plan be more proactive in suggesting broad-based improvements to the current system; (2) at that time the President would direct the Secretaries to meet with effected constituencies and create draft legislation to ready America's 21st century food safety system; and (3) that at the time that the strategic plan is rolled out, the President would also announce specific administrative actions to improve food safety such as requiring hightened testing for listeria and salmonella.

Bruce Reed and Tom Freedman have had brief individual discussions with the Secretaries Glickman and Shalala and their staffs. Secretaries Glickman and Shalala, while not wanting to make drastic changes to the current food safety system in the past, were more amenable to new ideas.

We would like to come in and discuss this idea with you further.

3/1/00 -
Aim is to shape the PSC's report as they wish it was
out in July ^{press} can 1) articulate the vision, 2) think PSC + tell it to
follow-up + do more + 3) answer some actions (now in the
appendix, but to be folded into text).
PSC will meet w/ Shulkin + Gleason -
Need to get on to shape report + parallel process

February 23, 2000 JDP

MEMORANDUM FOR KAREN TRAMONTANO
BRUCE REED
NEAL LANE
ERIC LIU

FROM: THOMAS FREEDMAN
CLIFF GABRIEL
MARY SMITH

SUBJECT: FOOD SAFETY STRATEGIC PLAN

FOOD SAFETY
COUNCIL

On August 25, 1998, the President signed an executive order that established the President's Council on Food Safety (Council). The main purpose of the Council is to develop a comprehensive strategic plan for Federal food safety activities. The Council currently has a draft strategic plan; however, this draft does not contain any recommendations for improving jurisdictional or structural issues or increasing coordination with state and local food safety agencies. The draft strategic plan does contain a list of possible organizational options, which is attached as an appendix to this memorandum. The Council has publicly stated that it will send its final report to the President in July of this year. This memorandum outlines some actions that the Administration could take with respect to the strategic plan. These ideas could be modified, but we feel that these are appropriate options upon which to base further discussion.

Background on President's Council

The President tasked the Council to "develop 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." In developing this plan, the Council was to take into account the findings and the recommendations of the National Academy of Sciences (NAS) report "Ensuring Safe Food from Production to Consumption."

The NAS report made three basic conclusions: (1) an effective and efficient food safety system must be based on science; (2) the current statutes governing food safety should be revised in order to achieve a food safety system based on science; and (3) Congress should enact legislation to establish a unified and central framework for managing federal food safety programs, which should be headed by a single official with responsibility for all federal food safety activities.

Problems with the Current System

The existing Federal system is fragmented among numerous departments and agencies. At least a dozen Federal bureaucracies, implementing 35 statutes, have major roles in overseeing the safety of the nation's food supply. While each agency has a common goal of making sure Americans have the safest food supply in the world, their statutory authorities and resources differ markedly. These differences make the total Federal effort less efficient and, according to consumer advocates, less protective of human health than could be achieved with a more consolidated regulatory approach. A few examples of inefficiencies and weaknesses in the food safety system include the following:

- Inspections are not based on risk. The Department of Agriculture (USDA) is required by statute to perform continuous inspections, which means that meat and poultry are inspected daily. The NAS report stated that “[b]ecause of the statutorily mandated continuous inspection requirements, [the Food Safety Inspection Service’s] inspection budget is about four times that of FDA.” The Food and Drug Administration (FDA) at the Department of Health and Human Services (HHS), with responsibility for all other foods, only has resources to conduct inspections approximately once every ten years for most establishments. Accordingly, resources are not allocated based on risk.
- Inspections are often inefficient. Because of the FDA-USDA jurisdictional split along commodity lines, some food products that might be perceived by consumers as similar are regulated differently, depending on content. A now classic example of this jurisdictional problem is pizza inspection – if it has pepperoni, it is inspected by USDA; if it has only cheese, it is FDA’s responsibility, even in plants where both types are produced. As stated above, one of the other results of this inefficiency is that even though USDA inspectors are in the plants every day, they do not inspect cheese pizzas. Therefore, meat-topped pizzas are inspected every day, while the cheese pizzas produced in the same plant may not be inspected for several years.
- Imports are treated differently at USDA and FDA. USDA has much greater authority to regulate imported food. For example, USDA can inspect foreign suppliers of meat products and prohibit importation until they meet U.S. standards. FDA, on the other hand, only has the authority to inspect food at the border but has the staff to check less than two percent of import shipments. While we have proposed legislation to fix some of this disparity, it has not been acted upon.
- There is little coordination with state agencies. Currently, 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 staff time transmitting the same information to different agencies, which each have their own customized system for reporting lab results. There also 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.

Organizational Options in Draft Strategic Plan

The action items contained in the Council's current draft strategic plan focus exclusively on steps that should be taken to gain incremental improvements in the current fragmented system. At this time, the plan does not recommend any significant realignment of responsibility or organizational consolidation. However, the draft plan does include an analysis of several organizational options designed to lay the groundwork for future decision-making, ranging from increasing coordination within existing structures to a single, independent food safety agency. See Appendix.

Options for Food Safety Strategic Plan

Unless directed otherwise, it seems unlikely that the Council will propose any major solution to this fragmentation in its July strategic plan. Accordingly, it seems appropriate to consider the basic options available to the Administration. We have synthesized and analyzed the proposals from the appendix into three basic options: (1) a comprehensive option which would create a single, independent food safety agency with the concomitant statutory changes; (2) a less sweeping option that would consolidate all inspections at USDA; or (3) a minimal option that would permit the commissioning of other federal officials to perform FDA duties. As noted above, these options could be modified or altered and are presented simply as the basis for further discussion.

This section presents each of these options:

A. Single, Independent Food Safety Agency

Under this option, the President would support the concept of single, independent federal food safety agency, and he would direct the agencies to come up with a plan to implement this concept, including legislative language, within a set period of time such as 120 days. This option would combine parts of both Senator Durbin's bill (S. 1281), which creates a single independent food safety agency, and Senator Dorgan's bill (S. 908), which provides for statutory fixes to the existing system.

This option would create a new stand-alone Cabinet-level food safety agency to facilitate achievement of food safety and public health goals. This option would combine the "core" standard-setting, food safety labeling, education, inspection, and enforcement functions for meat, poultry, eggs, seafood, and other FDA-regulated foods and animal feed into one agency. For instance, this new agency would consist of at least USDA's Food Safety and Inspection Service (FSIS), FDA's Center for Food Safety and Applied Nutrition (CFSAN), FDA's Center for Veterinary Medicine (CVM), parts of FDA's Office of Regulatory Affairs (ORA), and the Department of Commerce's National Marine Fisheries Service (NMFS) as it relates to the seafood inspection program.

This option, like the Durbin bill, does not consolidate food safety research into one agency. This option assumes the Joint Institute for Food Safety Research (JIFSR), which was created by a Presidential directive in July 1998, would continue to coordinate federal food safety research. Food safety research activities are best performed by research agencies not regulatory agencies. However, the new food safety regulatory agency should have appropriate authorities to partner with research agencies to conduct necessary research.

This option also does not include in the new agency the functions of the Centers for Disease Control (CDC) at HHS. CDC performs surveillance, outbreak response, and public education. These functions should continue to be performed at CDC because they will provide an important check on the new agency.

In addition, this option would combine some of the elements of the Dorgan bill in order to provide fixes to gaps in existing law. For instance, this option would mandate a Hazard Analysis and Critical Control Point (HACCP) system approach for all foods. In contrast to the traditional reactive food safety strategies, HACCP focuses on preventing hazards that could cause foodborne illness by applying science-based control processes at all stages of food production and processing. Currently, the Administration has implemented HACCP only for meat, poultry, seafood, and juice, and has proposed a plan to start providing regulations for HACCP for eggs. As part of this HACCP system, food producers and processors would focus on preventing contamination along the farm to table continuum.

This option would also fix the disparities in the inspections provided by USDA and FDA. Currently, USDA is required by statute to conduct continuous inspections of meat and poultry, which means that meat and poultry are inspected daily. FDA, which basically regulates all other foods, does not have a statutory inspection mandate. Because of a lack of resources, FDA only inspects some plants every ten years. This disparity in inspection requirements probably stems from the fact that, at the turn of the century, when the meat and poultry requirement was enacted, meat and poultry were considered to be the highest risk for foodborne illness. However, consumers' eating habits have changed, with more imported and processed foods being consumed. As a result, this statutory framework no longer provides the best protection for consumers. This proposal would put all foods, including meat and poultry, under one inspection scheme with a new statutory requirement that all facilities be inspected quarterly, with discretion for more frequent inspections in cases of high-risk foods. A risk-based inspection regime with some minimum requirements should be contained in the statute itself so that Congress will appropriate the necessary resources.

This option would also include two additional features for imports and mandatory recalls which the Administration has previously supported. This proposal would include provisions of the legislation, introduced by Senators Milkulski and Kennedy and Reps. Eshoo and Pallone, that would give FDA greater authority over imported foods. This legislation would ensure that the FDA halts imports of fruits, vegetables, and other food products that do not meet U.S. food safety requirements or that came from countries that do not provide the same level of protection as is required for U.S. products. The legislation also enables the FDA to halt imports from a

country or facility that refuses to allow FDA inspections. This legislation gives FDA authority that is similar to USDA's existing authority to prevent the importation of unsafe meat and poultry. In addition, this option would include the provisions of the Food Safety Enforcement Enhancement Act, sponsored by Senators Harkin, Daschle, Johnson, and Leahy, which gives USDA the ability to assess civil fines and to order mandatory recalls of unsafe meat and poultry products. Currently, the USDA can respond to food safety violations only by bringing criminal actions or withdrawing inspections; all recalls are done on a voluntary basis and no civil penalties are available.

The consumers groups (the Center for Science in the Public Interest (CSPI), Safe Tables Our Priority (S.T.O.P), etc.) will strongly support this option. Industry generally will not be supportive of this option, and, in fact, may actively oppose it. For instance, there is much more industry support for USDA than for FDA. There may be a perception that if USDA and FDA functions are combined in one agency, there will be a dilution of the protections that USDA currently provides. Farmers also are likely to oppose it because they generally have been adverse to mandatory on-farm regulation. With respect to the Hill, initially there is not likely to be much support for this proposal. For instance, Senator Dorgan's legislation only has two cosponsors, both Democrats, and Senator Durbin's legislation only has three Democratic cosponsors.

While it is quite unlikely that proposal could be enacted before the President leaves office, it may still be important for him to suggest this option in order to move the debate forward and to bring the weight of the bully pulpit to this issue.

B. Consolidating Inspections at USDA

Under this option, the President would propose that inspections be consolidated within USDA. Specifically, the following functions would be moved from FDA to USDA: food inspection, enforcement, and standard-setting/regulation for pathogen contaminants in seafood, eggs, milk, fruits, and vegetables. In addition, FDA/state boards on milk and seafood would be moved to USDA, as well as the food code, which is a model food safety code developed by FDA, other Federal agencies, and the states. The following functions would remain at FDA: food additives, dietary supplements, biotechnology, chemical/pesticide/drug residues/standards.

Under this option, a relatively small number of FDA field personnel with special expertise such as imports would be moved from FDA to USDA. All other inspection personnel would remain for FDA inspections of drugs, medical devices, etc. USDA would also need a number of senior level managers and regulatory personnel from CSFAN or FDA to be transferred to USDA in order to ensure a successful transition.

To emphasize the commitment to food safety, the President could also propose that the name of USDA would be changed to the U.S. Department of Food and Agriculture. The underlying statutes governing FDA and USDA would remain intact, although this option could include a directive that the Administration should develop a proposal to unify the statutes. This

would (1) simplify the legislation, (2) provide general consistency for regulated industries, and (3) avoid possible legislative attempts to weaken any of the relevant statutes.

This option addresses the issue that HHS and FDA will continue to be unable to obtain from Congress the resources necessary to strengthen its food safety program. There are a number of reasons for this failure, including organizational weaknesses. First, while food is the first word in FDA, its importance is overwhelmed by other products under FDA's jurisdiction, including pharmaceuticals, veterinary medicines, medical devices, functional foods, and biotechnology. Second, unlike USDA, FDA has no food inspection force that is dedicated to food safety; rather, its inspectors oversee all of the products regulated by FDA. While certain parts of its regulated industry are pleased by the fact that FDA cannot inspect ordinary manufacturing plants more than an average of every 4-8 years, other parts of industry are concerned at its inability to work cooperatively with industry when it embarks on new initiatives.

This option will also help to prevent efforts to weaken USDA's existing inspection force. As HACCP implementation in meat and poultry continues to be successful, there will be increased pressure to reduce USDA's inspection resources from budget sources and from those elements in industry who seek to weaken federal oversight over food safety. These efforts are already underway by a number of entities.

The consumer groups would likely be somewhat supportive of this option because it will help to equalize inspection resources between USDA and FDA, but they much prefer the first option. USDA has developed a strong record with consumer groups, many of whom have also been frustrated with recent FDA efforts and also fear that efforts to cut USDA's food safety budget will be successful without a strong strategic plan in place for redeployment.

The agricultural producer community would likely support such a move. Parts of the food industry may be supportive, but trade organizations may split as member companies may prefer dealing with a known agency, *i.e.*, if an industry sector or company deals predominantly with FDA, it may not want to deal with a new agency. In addition, industry would like FDA to have additional resources and staff to address functional foods, *i.e.*, foods with new nutritional claims, food additives, and biotechnology. Certainly, some industry groups prefer playing the agencies against one another, while others believe USDA is too producer focused.

C. Commissioning Federal Officials to Perform FDA Functions

This option would try to leverage other federal resources to assist FDA in carrying out its mission by commissioning other Federal food safety officials on behalf of FDA. Currently, FDA can "commission" state public health officials to carry out inspections and perform other FDA duties. This means that state officials can carry both the weight of their own statutes as well as FDA's into inspections and other regulatory efforts. Under this option, the President could propose legislation permitting FDA to commission other Federal officials. The idea here is that other officials could help FDA enforce its laws while carrying out their own. For instance, USDA's Animal and Plant Inspection Service (APHIS) plant and animal inspectors at the border

could look at the fruit for both contamination as well as fruit flies; FSIS inspectors could inspect the non-meat portions of a food plant as well as the meat sections (pizza, soup, dinners, etc); Commerce seafood inspectors could do both the fee-for-service inspection they do and the FDA inspection, thus accomplishing in another way the proposal that's in the President's budget to merge those programs; and Agricultural Marketing Service (AMS) graders at USDA could look at both the size of the apple as well as its safety. The advantage for FDA would be an extension of its coverage, for USDA the ability to show added value to the consumer, and for the public the knowledge that their tax dollars were being maximally utilized.

In order for this to work, however, careful attention would need to be paid to training. Currently, the majority of inspectors is not prepared to deal with multiple inspection responsibilities. This would require extensive cross training and upgrading of the inspection workforce.

This option might face some opposition from the Hill because it could be seen as a way to usurp the appropriations process. There might also be some opposition from the USDA inspectors' union. The consumer groups would likely support it because it would be a way to increase inspections for foods other than meat and poultry.

APPENDIX

These are the organizational options contained in the current draft of the Council's strategic plan.

I. Coordinated Federal Food Safety System

This option would provide centralized executive leadership (including a "single voice" for food safety), and improved coordination to facilitate achievement of food safety and public health goals. There are alternative ways to accomplish this. The alternatives differ in terms of the nature of the executive leadership as well as whether there is coordination and oversight of not only planning, budgeting and research, but also policy and/or operations. There would be no organizational changes with this option. It could be implemented alone or in combination with Option II, some Lead Agency alternatives under Option III, or the less expansive forms of a consolidated agency in Options IV and V.

- A. Modified President's Council on Food Safety: This sub-option would modify the current Council structure for coordination and leadership. Specifically, the President's Council would be modified by designating a single chair appointed by the President, establishing a small dedicated staff, and/or broadening the Council's members to include representatives from the Federal Trade Commission (FTC), the Department of Treasury (DOT), and the Department of Defense (DOD).
- B. Joint Chiefs of Staff: In this sub-option, a Board of Directors or Joint Chiefs of Staff would be established with a neutral Chairman appointed by the President and representatives from all the food safety regulatory agencies. Each agency would retain its core mission, but would be obliged to plan and coordinate in areas where their missions coincide.

II. Specific Consolidations of Food Safety Functions

This option would consist of streamlining or consolidating specific federal food safety functions, particularly those where there are jurisdictional overlap, perceived duplication, or public confusion, in order to more efficiently achieve the goals of the Strategic Plan. In this option, full responsibility for certain food products or for specific points in the farm-to-table chain would be housed in one place within an existing organization.

Examples of areas which might be examined for the possibility of streamlining or consolidation include:

- A. Certain Food Products: game meats and USDA-regulated meats; pizza (cheese and pepperoni); and sandwiches (open-faced and closed-faced).
- B. Specific Points in Farm-To-Table Continuum: food production on farms; egg safety; and federal guidance for retail establishments.

- C. Functional Overlaps: inspections at jointly-regulated facilities; pre-market approval of antimicrobials; animal drugs and biologics; and food safety labeling.

An in-depth analysis could result in specific areas being consolidated (e.g., oversight of all meats with USDA; all federal guidance for retail food operations with DHHS), or food safety responsibilities for certain points in the farm-to-table chain being placed with one agency (such as discussed in the Egg Action Plan regarding packer/distributors).

III. Lead Agency Approach

As in Option I, the Lead Agency Approach provides centralized executive leadership and a "single voice" for all or discrete parts of the food safety system. It differs from Option I in that one agency becomes the lead for all or for specific food safety functions rather than vesting the "single voice" for food safety in a Council or Joint Chiefs. This option could be implemented in combination with Option II and the Canadian Model might also be combined with Option I.

- A. Single Lead Agency: Designate one agency as the lead agency (USDA or DHHS) and have the head of that agency be responsible for achieving food safety goals, including determining the strategic direction of federal food safety planning, budgeting, and policy.
- B. Canadian Model: This option would establish two lead agencies, and each would have specific areas of responsibility under all the food safety laws for achievement of the Strategic Plan goals. For example, one agency could be responsible for monitoring, inspection, recall, enforcement and outbreak response for all foods and components of food (e.g., food additives, pesticides). Another agency could be responsible for research, risk assessment, surveillance, standards and regulations for all food products (meat, poultry, eggs, and other foods). EPA would continue to register and set tolerances for pesticides. This would be similar, but not identical, to the recently reorganized Canadian food safety system.

IV. Consolidated Agency within Existing Department/Organization

This option would consolidate most food safety regulatory functions--i.e., policy, guidance, standard setting, inspection, enforcement, and education--in one agency reporting to either a current Cabinet Secretary, or the management of an existing independent agency.

- A. Under HHS: Combine food safety responsibilities within HHS, headed by a Presidential-appointed, sub-Cabinet level official, such as the Commissioner for Food and Drugs. This sub-option is similar, but not identical, to Great Britain's consolidation.
- B. Under USDA: Combine food safety responsibilities within USDA, headed by a

Presidential-appointed sub-Cabinet level official, such as the Under Secretary for Food Safety.

- C. Under EPA: Consolidate food safety regulatory responsibilities with EPA, forming the Food and Environmental Protection Agency. This organization would continue to be an independent agency managed by a Presidential-appointed Cabinet-level official.
- D. Under an Existing Commission (e.g., CPSC) Consolidate food safety regulatory responsibilities in an existing Commission, such as the Consumer Product Safety Commission (CPSC).

V. New Consolidated, Stand Alone Food Safety Agency

Different from Option IV which consolidates food safety functions within an existing organization, this option would create a new stand alone Cabinet-level food safety agency to facilitate achievement of food safety and public health goals. It would create an agency with its own executive leader or Cabinet-level Administrator (analogous to EPA or FEMA). Alternatively, the new agency could be managed by a five or seven member Presidential-appointed, Senate-confirmed Commission, with a Chairman who manages the day-to-day business of the Agency.

There are many ways to design a new stand-alone food safety agency. The following alternatives for a separate, stand alone agency take a functional approach. The first sub-option reflects an agency focused on a single function (inspections). With each subsequent sub-option, additional functions are added until all functions related to food safety are consolidated within one agency.

- A. Consolidate food safety inspections: Consolidate the food safety inspection functions of USDA/FSIS, DOC/NMFS, and parts of FDA's Office of Regulatory Affairs (ORA) into a new stand-alone agency.
- B. Consolidate food safety regulatory functions (Sub-Option A above plus standards, labeling, and education): Combine the "core" standard-setting, food safety labeling, education, inspection, and enforcement functions for meat, poultry, eggs, seafood and other FDA-regulated foods and animal feed.
- C. Consolidate food safety regulatory and research functions (Sub-Option B above plus research): Combine the functions outlined in Sub-option B above with food safety research.
- D. Consolidate food safety regulatory functions including pesticides (Sub-Option B above plus pesticides): Combine policy-setting and operational food safety functions for all food products and substances in food (Sub-option B above plus pesticides) into a separate, stand alone agency.

- E. Consolidate food safety regulatory, research and surveillance responsibilities:
Combine food safety regulatory functions for all food products and substances in food (e.g., pesticides, food additives) as well as research and surveillance supporting those regulatory activities into a new, stand alone agency.

- F. Merge All Food Safety and Related Functions: Consolidate all food safety and food safety related functions from USDA, DHHS (some parts of FDA and CDC, and NIH food safety research), EPA (pesticides and some water functions), DOC (NMFS including related research), FTC (advertising and labeling), and DOT's Bureau of Alcohol, Tobacco and Firearms' responsibilities for beverages into a new, stand alone food safety agency. This agency would be responsible for food and beverage "core" and "collateral" food safety functions including research, surveillance, outbreak response, regulation, inspection, enforcement, education, labeling, and advertising; it would also be responsible for water used in food production, processing and for drinking.

Comments Supporting a Single Food Safety Agency
(As filed with the President's Food Safety Council docket on
the food safety strategic planning process)

American Association of Retired Persons:

The President's Council on Food Safety should pursue "Option V" of the plan, which creates a new, consolidated, stand-alone federal food safety agency. . . . We believe that a single agency can best assure that inspection and regulation are risk-based, resources are properly allocated, imports are adequately scrutinized, food safety technologies are reviewed expeditiously, and food safety problems do not fall through the cracks.

(Comments to the Docket, February 17, 2000)

American Meat Institute:

AMI agrees in principle that consolidating resources and expertise can help harmonize the varying degrees of regulatory oversight that federal, state and local governments exercise over different segments of the food industry.

(Comments of J. Patrick Boyle to the Docket, October 2, 1998.)

American Public Health Association:

APHA strongly supports the creation of a single federal public health agency with inspection and enforcement authority for the safety of the U.S. food supply. We believe the U.S. government's ability to assure a safe food supply is compromised by the fact that authority for food safety is currently divided among several federal agencies, and the legal authority and resources which these agencies have for both domestic and imported food sources is inadequate. This single federal agency should be provided with sufficient scientific and enforcement resources to include food safety inspections (using performance-based standards) to monitor effectively and to assure the safety of the U.S. food supply.

(Comment to the Docket, February 11, 2000)

American Society for Microbiology:

In terms of administering federal food safety programs, ASM agrees with the National Academy of Sciences that the best option for this purpose is to bring the disparate elements in the current system into a single agency with a single director at its head. This option corresponds to the "New Consolidated, Stand Alone Food Agency" described in the draft strategic plan.

(Comment to the Docket, February 14, 2000)

Association for Professionals in Infection Control and Epidemiology, Inc. (APIC):

APIC contends . . . that a centralized agency (with adequate representation from other relevant agencies) may be most effective to carry out the goals [of the NAS report]. It will be important to streamline as much as possible in order to most efficiently implement the goals of the plan and take corrective action when necessary, without duplication of efforts across agencies.

(Comment to Docket, January 5, 1999)

Center for Science in the Public Interest (CSPI):

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

. . . 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.

(Comment to the Docket, February 14, 2000)

Consumer Federation of America (CFA):

In order to increase the effectiveness and efficiency of federal food safety regulation, CFA supports streamlining the current food safety functions into an independent food safety administration. We also support a review and modernization of federal food safety laws to assure that the U.S. government has all of the resources and powers necessary to achieve a safe food supply.

(1999 Policy Resolutions, Consumer Federation of America, p. 64.)

CFA and CU wish to be recorded as endorsing the comments filed by the Center for Science in the Public Interest.

(Comment to the Docket, February 14, 2000)

Consumers Union, publishers of Consumer Reports magazine (CU):

CFA and CU wish to be recorded as endorsing the comments filed by the Center for Science in the Public Interest.

(Comment to the Docket, February 14, 2000)

Senator Richard Durbin of Illinois:

A single, independent agency with uniform food safety standards and regulations based on food hazards would provide an easier framework for implementing U.S. standards in an international context. When our own agencies don't have uniform safety and inspection standards for all potentially hazardous foods, the establishment of uniform international standards will be next to impossible.

Research could be better coordinated within a single agency than among multiple programs. Currently, federal funding for food safety research is spread over at least 20 federal agencies, and coordination among those agencies is ad hoc at best.

New technologies to improve food safety could be approved more rapidly with one food safety agency. Currently, food safety technologies must go through multiple agencies for approval, often adding years of delay.

In this era of limited budgets, it is our responsibility to modernize and streamline the food safety system. The U.S. simply cannot afford to continue operating multiple systems.

(Comment to the Docket, February 11, 2000)

Food Animal Concerns Trust (FACT):

FACT wants a system that is led by one agency, with one purpose, having clear roles and responsibilities, that can enforce what it regulates, and that starts where food starts--on the farm. We want this system to be focused entirely on food safety, where the American public will know who is responsible.

(Comment to the Docket, February 11, 2000)

Institute of Food Technologists (IFT):

IFT stated in its Guiding Principles, that consistency in oversight and regulation would be enhanced if responsibility for food oversight were focused in a single policy/regulatory unit that tightly adhered to objective criteria and risk analysis.

(Comment to the Docket, January 8, 1999)

National Cattlemen's Beef Association (NCBA):

Creation of a central organization could be useful. However, jurisdiction over current agencies by different congressional bodies could prevent creation of this type of agency. NCBA supports the development of a single meat, poultry, and seafood inspection system within the Department of Agriculture. A single inspection agency would have the ability to oversee inspection across all food products, ensuring their equity. Achieving national food safety goals requires a farm-to-table strategy.

(Comment to the Docket, December 29, 1998)

Safe Tables Our Priority -- S.T.O.P.:

S.T.O.P. strongly supports the implementation of a single, independent food safety agency. The safety of the food we feed our families is of critical importance and deserves the uncompromised scrutiny and attention of an agency unencumbered with other conflicting responsibilities such as trade and marketing issues.

(Comment to the Docket, February 14, 2000)

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U.S. Food Safety Team: A Winner

Secretary Donna E. Shalala, U.S. Department of Health and Human Services
Secretary Dan Glickman, U.S. Department of Agriculture

FOOD SAFETY
Single Food Agency

In his recent criticism of the Clinton Administration's food safety efforts, *Chicago Tribune* columnist James Warren claimed that the segmenting of responsibilities has weakened our food safety system. This simply is not the case. In fact, the very key to our successful science-based food safety is seamless collaboration with clear responsibility. It has made our food supply one of the safest in the world, and without it, we will not be able to meet the food safety challenges of the next century.

Food safety has been an administration priority since day one, and we have adopted a successful approach that looks at food safety as an integrated, interdependent system, all the way from the farm to consumers' kitchens. But controlling the safety of the American food supply has grown increasingly complex. American consumers eat out more and cook for themselves less. They also eat more processed food than ever before, as well as more imported food. Additionally, new pathogens have evolved. To adequately continue addressing these challenges, we need a strong science base that cuts across agency lines and departmental barriers -- a science base that draws on government-wide expertise.

Under the current structure, two federal agencies have primary responsibility for assuring the safety of our food supply: the Food and Drug Administration and USDA's Food Safety and Inspection Service. But, the Environmental Protection Agency (EPA), the Centers for Disease Control (CDC), and state and local partners also play key roles.

For example, CDC takes the lead on gathering data about food-borne disease in the same way it collects data on other diseases. EPA, the expert agency in tackling pollution issues, protects our water supply by setting appropriate drinking water standards. Food safety can only be effective if it has this strong underpinning in scientific research and risk assessment.

In May 1997, the President announced a national food safety initiative that proposed specific steps to improve the safety of the food supply. A year later, he established the Council on Food Safety. Its goal is to make the food supply even safer through a food safety system based on public health and supported by well-coordinated surveillance, standards, inspection, enforcement, research, risk assessment, education and strategic planning.

In just two years, with support from Congress, the vast majority of recommendations laid out in the report have been implemented and already are leading to important improvements in our food safety system.

Last year, our new national electronic network for bacterial DNA fingerprinting, known as PulseNet, connected two seemingly independent *E. coli* outbreaks in Michigan

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to a common source: alfalfa sprouts. PulseNet also helped confirm that approximately 50 cases of *E. coli* in Wisconsin were attributable to cheese curds from a single facility, and it connected *E. coli* outbreaks from ground beef to specific processors.

This new DNA fingerprinting enables epidemiologists to move up to five times faster than previously feasible in identifying serious, widespread food contamination problems.

As we've continued to tackle food-borne illness, we've also developed new approaches for inspecting seafood, meat and poultry plants. We made significant amendments to the Safe Drinking Water Act in 1996. We've sought to improve interagency coordination at every point in our food safety system. And we aren't stopping there.

Our Food Safety Council has established a task force that is working with the private sector to reassess the U.S. food safety system, even the structural and organizational options that could strengthen the system. We're carefully working with all of our partners, and a final recommendation is due to the President in July 2000.

It's so easy to say, "let's start all over again and create a better food safety system." While there is always room for improvement, it is shortsighted to think that a safer food supply is as simple as just naming a single food agency and ignoring what we have already learned.

In fact, such a plan could create more problems than it would solve. Attempting to combine hundreds of regulators from the various agencies involved in our food safety system would take years to complete with unclear benefits to the system already set in place.

Take it from two "bureaucrats," the last thing we need is to create a new bureaucracy.

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