However, perhaps the greatest efficiency costs of consolidation would result from cultural clashes of merging two or more bureaucratic entities. To the extent that consolidation would increase agency infighting or force regulators to learn new standard operating procedures (SOPs), the regulatory costs per unit of health would increase. As we discuss in Chapter I, food safety specialists from agencies such as FDA, EPA, and USDA typically come from distinct academic, professional, and industry backgrounds. USDA's food safety workers, dominated by veterinarians, have distinct SOPs relative to FDA, EPA, and other agencies. It would take time and effort for various regulatory specialists to detach themselves from engrained Sops and to learn new ones. For example, consolidation would certainly force scientists from previously separate laboratories to work more closely. Merging scientific capacity will entail standardization among previously distinct laboratories, and such standardization will entail the adoption of new procedures and hierarchies. The time taken to argue, decide, and learn new procedures and organizational structures will decrease the time spent inspecting, monitoring, and researching. Thus, the regulatory cost per unit of health will almost certainly increase.

Beyond the need to learn new Sops and organizational hierarchies, a second bureaucratic cost of consolidation would be massive payscale adjustments or certain jealousy among workers who perform similar jobs but have different salaries. For example, according to our discussions with field staff, the starting FSIS poultry line grade level is GS-5, or $19,969 per year in 1998.[89] FSIS inspectors can eventually reach GS-9, through competitive advancement—an annual salary that starts at $30,257.[90] FDA inspectors, on the other hand, generally have higher educational attainment than FSIS line inspectors. Hence, FDA inspectors typically *start* at the GS-9 level and can reach up to GS-13, a $52,176 starting salary.[91] The bureaucratic tensions of consolidating payscales among several different agencies, with FSIS inspectors unionized, would likely further decrease efficiency in the short-term; as personnel would worry and lobby about pay rather than focusing on researching, inspecting, and monitoring foodborne illness. Such costs would likely begin as soon as a consolidation proposal were passed.

Paradoxically, in order to obtain the greatest economies of scale from consolidation, a single food safety agency should merge as many related, but previously separate, groups as possible. Yet the higher the level of newfound integration, the higher the cultural costs of consolidation are likely to be. Such bureaucratic culture costs would pervade the operation of a newly consolidated agency in innumerable ways, disrupting efficiency gains in the short-term.

Political Feasibility of Consolidation

In considering options for change, policy makers must balance efficiency and safety goals with the likelihood that these options can be passed into law. The failures of consolidation proposals in the past do not lend much hope for proponents of a single food safety agency. Barring a greatly heightened level of public or presidential concern about food safety agency fragmentation, significant consolidation is unlikely.

The proposal to unify federal food safety services into a single agency is decades old. While the Hoover Commission at first concluded that the food safety responsibilities of FDA be placed within USDA, no action was ever taken.[92] The issue was raised again during the Nixon and Carter administrations, and in 1977, the Senate Government Affairs Committee recommended the transfer of USDA food regulatory responsibilities to FDA.[93] Meanwhile, GAO has recently advocated the establishment of a single food safety agency,[94] and Vice President Gore's Reinventing Government Commission recommended that a single food agency be consolidated within FDA.[95] In the proposal's most recent incarnation, Representative Vic Fazio and Senators Durbin and Toricelli have introduced the Safe Food Act of 1997 (H.R. 2801 and S. 1465, respectively). This bill would transfer food safety, inspection, and food labeling activities to a consolidated, independent Food Safety Administration.

Congressman Fazio's proposal as well as the other consolidation options that we have examined face the same barriers that have doomed many previous failed attempts, namely: constituent opposition, the inertia of congressional committee jurisdiction, and low public salience. In our many discussions with House and Senate staffers, including Fazio's, there was not one who gave the Fazio proposal a likely chance of passage either this year or in the future.

Perhaps the greatest barrier to consolidation is scattered congressional committee jurisdiction that mirrors the multiple food safety agency structure. The USDA, FDA, Commerce's NMFS, and EPA's OPP fall under the jurisdictions of at least a dozen authorization and appropriation committees and subcommittees in the House and Senate.[96] The two primary agencies responsible for food safety inspection—USDA and FDA—fall under the jurisdiction of four different authorizing committees, not to mention two different appropriating subcommittees in the House and Senate. The USDA is governed by the respective Agriculture committees in the House and the Senate, while the FDA is overseen by the House Commerce Committee and the Senate Labor and Human Resources Committee. As the organizational chart that we present in Appendix B illustrates, there are over a dozen food safety and research agencies overseen by 11 authorizing committees and eight appropriations subcommittees of the House Senate.

A single food safety agency, whether placed in the USDA, FDA, or an independent agency would almost certainly require shifting committee jurisdictions. While it may be possible for the current authorizing committees to share jurisdiction by statute (e.g., Agriculture keeps the FMIA and other USDA statutes, while Senate Labor keeps the FDCA and other FDA statutes), such a multifaceted oversight structure would likely present enormous burdens on the management of a consolidated agency. For example, in 1995, leaders of FDA and USDA alone spent a total of 48 days testifying on food safety issues before various congressional committees.[97] Consolidation without centralization of congressional oversight would likely lead to duplicative testimony and extraordinary burdens on senior food safety managers.

Moreover, fragmented congressional oversight would hinder the rationalization of resource allocation and coordination that are the primary goals of bureaucratic consolidation. Congressional committees would continue to focus on specific parts of the food safety system—their respective turf—and not the system as a whole. For these reasons, all of the congressional staff that we interviewed envisioned substantial committee conflicts in an assumed unification of legislative oversight. Indeed, the necessary shifting of committee jurisdictions was repeatedly identified as the single largest barrier to any attempt to unify food safety agencies. So large were these barriers that most staffers declared any such attempt as "dead on arrival."

Compounding committees' natural reluctance to approve jurisdictional changes is the opposition of key constituent groups. Consumer groups, producer groups, and inspector unions are the most vocal constituencies involved in crafting food safety policy. Of these three groups, only consumer groups have voiced support for a single food agency.

The proposal for a single, independent, food safety agency (as opposed to a single agency united in either FDA or USDA) is supported by several consumer groups—principally CSPI—because of the perceived shortcomings of the two primary agencies responsible for food safety. The USDA is an agency primarily devoted to promoting the welfare of food producers. This producer-focus is seen by some as a structure that creates incentives contrary to the task of protecting food safety. FDA, on the other hand, is widely perceived as a purely public health-based agency. However, while FDA lacks this apparent conflict of interest, the agency has consistently devoted fewer resources to monitoring foods than it has to monitoring drugs and medical devices. In 1997, FDA devoted less than 20% of its budget to food safety, and it inspects food processing facilities at extremely low rates relative to FSIS' continuous monitoring.[98]

Producer groups are also wary of change. Non-meat food producers fear that an independent unified agency or one placed in USDA might increase the impetus for more stringent regulation, including more frequent inspections. Meat producers worry that an organizational change may result in a move away from federally-funded continuous inspection and towards the FDA model that relies increasingly on user fees.[99] In interviews, industry representatives questioned the need for a single food agency. From their perspective, because of the clear delineation of statutory authority, most food producers already face a "virtual single agency."

The meat and poultry inspector unions also stand in the way of major change. Changes in the way the federal government monitors food safety can be threatening to inspectors. Before the HACCP, USDA meat inspection processes changed little over the past several decades, and some inspectors have worked the same jobs in the same communities for many years. These inspectors—whose highest

educational attainment is often high school—are offered relatively little compensation for their frequently unpleasant work. However, the continuous inspection requirement grants the union enormous political power, since meat that has not been examined by an inspector is statutorily adulterated.[100] The ability of inspector unions to delay change was demonstrated in USDA's recent implementation of its HACCP regulations; the department was forced to negotiate with union representatives until shortly before the regulations took effect.

Even in the absence of committee or constituent support, public opinion focus can have the power to move major changes through Congress. In fact, it was Upton Sinclair's *The Jungle* that mobilized public opinion, providing the impetus for the passage of the Meat Inspection Act and Pure Food and Drug of 1906. Public opinion can work synergistically with Presidential action: predicting a favorable public response, a President may choose to focus public attention on an issue, raising the salience to the public.

Publicized crises and disasters can become what one political theorist has termed, "focusing events" that help policy entrepreneurs place issues on the national policy agenda.[101] Indeed, in the first days of the Clinton Administration in 1993, food safety became a focus for the administration when two children died and hundreds of others in the Pacific Northwest became ill after eating Jack in the Box hamburgers.[102] Since 1993 there have been several well-publicized food-safety related issues that have received national press coverage, such as the death of a toddler from contaminated apple juice in 1996 and the recall of an unprecedented 25 million pounds of beef distributed by Hudson Foods last August. However, though the salience of public opinion of food safety seems to be rising, it does not yet seem to have reached the critical mass that would overcome congressional committee and constituent opposition to change. As we illustrate in Appendix G, time series polling conducted by the Food Marketing Institute indicates that there seems to be general confidence in food supply, even with increased attention devoted to bacterial food risks.

The historic lack of success for advocates of a unified food safety agency does not mean that the single agency option is destined to failure. Union workers could be convinced to support a reorganization that raised their standard of living and enabled them to do a better job. Producers would benefit from changes that improved the public's confidence in the food supply. Sadly, however, perhaps the most likely impetus for radical change of the food safety system would be a series of widely publicized deaths or illnesses that could replicate the effect of *The Jungle* in galvanizing public attention.

Yet aside from the political infeasibility of a single food agency, it is important to consider that a strongly-debated consolidation proposal would likely entail serious short-term political costs by harming chances for further reform of the underlying food safety statutes. Because a proposal to consolidate the food safety agencies would almost certainly necessitate a committee turf battle, any merger—even if successful—would likely distract legislators from non-organizational changes in regulation. As we discuss in Part B of this chapter, changes in the underlying statues, such as inspection regimes and safety standards, have the strongest ability to impact health and efficiency. Therefore, by focusing attention on organizational change, which promises little, if any, increases in health and efficiency, a proposal to consolidate food safety agencies would harm the chances of adjusting the underlying statutory framework. However, as we discuss in the next section, proposals that include significant statutory change of food safety standards are also especially vulnerable to political stalemate.

Summary

While consolidation offers the prospect of significant long-term efficiency gains with the ability to achieve workforce reduction through synergies and to enhance field and headquarters coordination, the costs of merger would be substantial. In the short-term, consolidation would be expensive both physically and bureaucratically. Efficiency and even health would be sacrificed as field and administrative personnel focused on future employment, pay, and learning new Sops and administrative hierarchies. Furthermore, the health benefits of consolidation, all else being equal, would be minimal. On the whole, the same inspectors, researchers, and administrators would enforce the same statutes, albeit within a larger, more cohesive organization. Finally, consolidation, as presently envisioned by relevant congressional committee staff, is politically infeasible. Creation of a single food agency would most likely require wresting oversight from two or more congressional committees. As we illustrate in the case

of seafood regulation in Appendix I, organizational change in food safety regulation has been hampered by the vigorous protection of turf by congressional oversight committees.

B. CHANGE AUTHORIZING STATUTES: INCREASE RISK-BASED INSPECTION

Changing statutory safety standards, inspection requirements, and enforcement powers can yield the greatest health and efficiency benefits of all the options we review. Underlying statutes such as the FDCA, FMIA, and FIFRA both bind and liberate federal food safety agencies. On the one hand, the statutes grant the agencies tremendous power to determine, for example, when a food is "adulterated."[103] On the other hand, the authorizing statutes frequently constrain the agencies, as, for example, FDA must continue to enforce the Delaney Clause,[104] and FSIS must continue to examine "the carcasses and parts thereof of *all* cattle, sheep, swine, goats, horses, mules, and other equines" after slaughter.[105] These statutory mandates drive the essence of each agency's regulatory activities. More so than consolidation or coordination, these statutes, when implemented effectively, are the most powerful tools to enhance safety and efficiency. Significantly, changing the underlying food safety statutes can provide agencies with both the authority and the statutory mandate to perform more risk-based regulation.

Two statutory changes that could have enormous health and efficiency impacts are: 1) the replacement of continuous inspection of meat and poultry with an option for FSIS to take large random samples with rigorous, risk-based testing requirements and 2) a requirement that FDA inspect a certain percentage of its regulated establishments per year. While these proposals entail significant political risks, we believe that the health and efficiency gains of these changes would outweigh their costs.

Health Effects of Statutory Change

The health effects of an optional FSIS sampling regime and a mandatory FDA inspection quota could be quite beneficial both in the short- and long run. By discontinuing carcass-by-carcass inspection, FSIS would take large random samples of products and perform a rigorous examination of the sample set. With statistically significant results, such a procedure should provide a much more effective method of detecting foodborne pathogens than the current "sniff and poke" methods. Moreover, a modernized pre- and post-slaughter inspection system would be complementary to HACCP, which places increased burdens on manufacturers to ensure the safety of their food. By mandating testing for the greatest health risks (which should be determined in a rule-making setting, not restrictive legislation), the government could systematically police against bacterial pathogens.

The current sight and smell method of inspection, which has been roundly criticized by the National Academy of Sciences and the GAO, does not police against bacterial pathogens in a systematic manner. Rather, the current requirement that inspectors examine every meat and poultry carcass before processing is so burdensome, that inspectors can only provide a superficial examination.[106] Rigorous examination of randomly sampled animals and carcasses should enhance overall health by detecting more contaminated food; this is especially true due to the tendency for bacteria to contaminate whole flocks of animals—especially poultry.[107] Furthermore, just as FSIS would be given the option to sample carcasses randomly in slaughter plants, the Service would have the freedom to visit processing plants on an as-needed, risk-based schedule, rather than its current daily requirement. FSIS would retain the option, however, of continuous inspection for the riskiest products. By allowing FSIS to perform risk-based inspections, this change should enhance overall health.

Requiring FDA to sample a certain percentage of its regulated facilities annually could also yield significant health benefits. While FSIS over-inspects its regulated universe (albeit often superficially), FDA under-inspects. The reason for this disparity directly relates to USDA's statutory mandate of continuous inspection. Since FSIS has a statutory mandate to have at least one inspector in a meat or poultry plant during all times of operation, the agency has a resource anchor to provide an adequate number of inspectors. FDA lacks such a mandate, and as a result of the agency's shift toward drug and device regulation (whose industries are willing to pay user fees to hasten FDA's gate-keeping), its number of food safety inspections has decreased by over 1/3 since 1980.[108] By providing a statutory mandate that

calls for minimum levels of inspection, FDA can adequately attend to the serious risks entailed by the growing levels of imported fruits and vegetables and the increasingly interdisciplinary farm-to-table approach to regulation. Finally, should the continuous inspection requirement be discontinued, legislators should also mandate an inspection quota for FSIS to avoid resource problems similar to FDA's.

Efficiency Effects of Statutory Change

Dismantling the statutory requirement for carcass-by-carcass inspection and mandating that FDA inspect a specified percentage of regulated facilities should have positive efficiency gains in two respects. First, by freeing FSIS of the burden to inspect each and every meat and poultry carcass, it would be possible to reduce the level of FTE's primarily dedicated to detecting a low-level risk, the risk of animal disease. Instead, USDA could deploy a better-trained force of inspectors to examine rigorously far fewer, but randomly selected, samples.[109] Thus, FSIS would be able to enhance its ability to detect bacterial pathogens while decreasing the cost per inspected item.

While an inspection quota for FDA (albeit a far less restrictive requirement than USDA's carcass-by-carcass requirement) would almost certainly enhance health, such a quota would probably not enhance the agency's efficiency. By providing FDA with a new inspection requirement, the agency will be forced to hire more staff, thus increasing the number of FTE's dedicated to food safety inspection. Since CFSAN is underfunded compared to years past, it is likely that field inspectors currently target the riskiest facilities. Thus, while CFSAN would probably increase overall health with more staff, FDA's cost per unit of health would probably rise. In order to maximize efficiency, FDA must provide incentives for its field staff to perform quality inspections but also award inspectors who can keep to a schedule that will allow the agency to meet its inspection quota.

One way to ensure that congressional appropriators adequately fund FDA's food safety inspection force under a quota would be to require that firms be visited by FDA at least once every five years. This would return the agency to the inspection levels of the 1980's, when there was three times as much inspection as there is today and lower health risks due to emerging pathogens. Currently FDA inspects firms on average of once every ten years, even though food safety regulators recognize the enhanced threats posed by emerging pathogens.[110] Food from firms that are not visited once every five years could be considered adulterated, just as all meat that is not examined by an FSIS inspector is legally adulterated. This threat of automatic adulteration would provide an incentive for food producers to lobby heavily for increased FDA funding, just as meat and poultry firms currently support FSIS' efforts to higher an adequate number of inspectors.

Political Feasibility of Statutory Change

An especially powerful political obstacle to achieving significant statutory change is what we have termed "safety debate risk." Simply put, there is a political risk in advocating any statutory change that can be perceived—accurately or not—as loosening food safety standards. The 1996 amendment of the FDCA that removed processed food pesticide residues from the realm of the zero-risk standard of the Delaney Clause provides an insightful example of safety debate risk.

Although many respected research groups, including the National Academy of Sciences, had advocated Delaney Clause reform for years,[111] consumer advocates and industry groups were at loggerheads on the issue for over a decade. Consumer groups decried any negligible risk standard for carcinogenic pesticides without a counterbalancing raising of the risk standard for food consumed by a disproportionate amount of children. The messy politics of opposing consumer groups such as the American Farm Bureau Federation and the Natural Resources Defense Council stalled reform of the Delaney Clause for ten years.[112] Furthermore, once a compromise was reached on the controversial Delaney Clause issue, legislators were wary of taking up other food safety reform issues.[113] Thus, aside from the low political feasibility of bills with strong industry and consumer group adversity, debating controversial bills can also entail the significant negative externality of removing a pertinent issue from the congressional agenda in the short-term.

Similar politics would occur in debating the loosening of carcass-by-carcass inspection mandates and increasing FDA inspection requirements—between groups as diverse as inspectors' unions, consumer groups, the food industry, and meat and poultry producers. In fact, just a few weeks ago, Representatives Frank Pallone, Jr. and David Bonior proposed a bill that would require national registration and quarterly FDA inspection of the 53,000 food processing plants in the agency's purview.[114] The response from one major industry group was immediate and negative: "If enacted, this legislation would represent one of the most expensive government jobs program [sic] in recent memory, but with no real benefit to consumers."[115]

In short, it would be hard to pass a bill that pits industry against consumer groups, especially a bill that would—like an entitlement—require increased funding into perpetuity. Furthermore, it would be equally hard to sell a risk-based enhancement of meat and poultry inspection that paradoxically features a lower volume of inspection. It is much less costly for legislators to avoid such debates altogether.

Summary

Changing the underlying food safety statutes offers the greatest potential to enhance health and efficiency—for the better or worse. Because the statutes drive safety standards and inspection requirements, legislative change can directly impact the extent and rigor of food safety inspection, monitoring, and enforcement. We propose two changes that offer great potential health benefits: 1) the option for FSIS to perform more risk-based meat and poultry inspection through random sampling and more rigorous testing requirements, and 2) an increased inspection requirement for FDA. We predict long-term health benefits through more risk-based meat and poultry inspection, especially replacement of carcass-by-carcass, in-plant slaughter inspection with random sampling. We also estimate significant health benefits through enhanced FDA inspection; as the risks of food have risen, while FDA's inspection resources have not. The primary costs of this option are political, since the efficiencies achieved by sampling-method inspection of meat and poultry could probably fund the hiring of hundreds of new FDA inspectors. However, the changes entailed by this option currently lack political feasibility. Both the meat and poultry inspectors union and consumer groups would decry the cessation of the continuous inspection mandate. Moreover, an inspection quota for FDA would likely be extremely costly, and as we describe in the next section, substantially increased FDA spending does not seem likely.

C. CHANGE BUDGETARY PRIORITIES WITHIN EXISTING INSTITUTIONS AND STATUTES

While consolidation has the advantage of forcing related, but separate institutions to cooperate and prioritize resources, and statutory change can adjust the mechanics of an agency's risk management, changing budgetary priorities alone will not guarantee health or efficiency gains. However, due to the underfunding of FDA's food safety operation, it is likely that enhancing the agency's budget for CFSAN can yield positive health gains.

Health Effects of Budgetary Adjustment

Perhaps the most vulnerable link in the food safety chain currently is the FDA's CFSAN. As we have noted repeatedly, FDA holds jurisdiction over nearly all processed food manufacturers, fruit and vegetable producers, and seafood processors—53,000 facilities in all. Yet, as discussed previously, the CFSAN budget allows agency inspectors to visit facilities only on the average of once every ten years. With increased concerns over the safety of fruits and vegetables, especially imports, many food safety specialists are concerned that FDA is unprepared to stop expected bacterial. While increased cooperation with USDA and Customs can serve as a band-aid for FDA's inadequate inspection force, in the end, it is FDA's obligation to ensure the safety and wholesomeness of the foods that it regulates. Currently, FDA would only be able to react to an outbreak after discovery, because the probability that an inspector would be in the right location to prevent a major outbreak approaches zero.

Therefore, we estimate high potential health gains from a significant, long-term increase in the FDA's budget; since the agency regulates products that cause an estimated 25-50% of foodborne illness and

mortality costs nationally.[116] However, there can only be health gains, if increased funding is applied to areas that entail significant risks. Because the current Administration has emphasized a comprehensive, farm-to-table approach to food safety, we have little doubt that in the short-term, FDA would apply increased food safety funding to areas of greatest perceived risk. However, absent continuing pressures for the agency to spend its funds in the areas of greatest risk, there is no long-term guarantee of health or efficiency gains.

Efficiency Issues Relating to Budgetary Adjustment

Adjusting budgetary priorities is efficient only if modifications yield lower costs per unit of health or inspection. There is no guarantee that increased funding for FDA would yield increased efficiency. Given the relatively low level of spending FDA presently allocates to food, it is likely that the agency currently deploys its resources to achieve the most benefits per budgeted dollar. However, given more resources, the agency could most likely work with other agencies more effectively in addressing the pervasive risks of agricultural cross-contamination and the relatively unregulated risks of imported fruits and vegetables. It is likely that the marginal benefits of increased FDA funding would be larger than the marginal costs of lost funding within USDA's massive food safety budget. Since FSIS currently spends approximately $170 million (85% of the total FDA food budget, including research) on organoleptic carcass-by-carcass inspection of meat and poultry annually—a method whose health benefits have been widely questioned—then it is likely that a risk-based use of a portion of those funds by FDA would yield greater marginal health benefits. In Appendix J we include a graphical representation of the economic gains of budgetary reallocation.

The disparity between FDA and USDA funding highlights a critical funding issue between the two agencies. USDA, with its primary role of maintaining a strong agricultural economy, is supported by industry and members of Congress from agricultural areas. FDA, on the other hand, is generally viewed as a hindrance to its regulated industries; its strongest allies are the medical and public health communities. Thus, it is not surprising that food safety programs within USDA would be better funded than similar programs within FDA. It was recently announced that under the Administration's proposed budget for fiscal year 1999, the President's Food Safety Initiative will receive an additional $100 million, of which $46 million is earmarked for USDA as additional funding.[117]

Given the levels of foodborne morbidity and mortality discussed in Chapter I, the current budgetary prioritization may in fact be justified for USDA. However, given the high costs and relatively low benefits of FSIS' statutorily mandated carcass-by-carcass inspection, some adjustment seems necessary. The long-term solution to the funding disparity between FDA and USDA will involve an evaluation of the risks of low FDA funding by decision-makers. Historically, FDA's statutory power has been enhanced after health crises. Short of such a crisis, the agency must grow its core constituency to compete with USDA in the annual battle for budgetary resources.

Political Feasibility of Budgetary Adjustment

While considerably less daunting a task than consolidating the food safety agencies, shifting budgetary priorities would require the expenditure of political capital. As mentioned earlier, industry support for USDA carcass-by-carcass inspection serves as a resource anchor for FSIS in good budget times and in bad. In the annual competitive budget process, FDA has had more difficulty in securing resources for its food safety programs. While FSIS has had a steadily increasing budget since 1995, CFSAN's budget has been less stable over the same time period. In fact, compared to the 1998 budget estimate, the FSIS allocation has risen by 12% in nominal terms since 1995, while the CFSAN budget has fallen by 6%.

To overcome this trend, the Clinton administration, as part of its Food Safety Initiative, has proposed user fees as a way of increasing funding for FDA food safety activities. However, user fees have consistently faced industry opposition, including the Grocery Manufacturers of America, the American Meat Institute, the National Broiler Council, the United Fresh Fruit and Vegetable Association, and the Food Marketing Institute.[118] In 1993, a similar user fee proposal by the Clinton administration was derailed when it faced coordinated industry opposition led by the Grocery Manufacturers of America.[119]

Absent a perceived food safety crisis or other event that would change the relative constituent support for USDA and FDA food safety programs or the willingness of the House to increase funding, it seems very likely that CFSAN will continue to be underfunded compared to FSIS. However, given that FDA and USDA are funded within the same appropriations subcommittees (Agriculture and Related Agencies), a carefully engineered *quid pro quo* could be enacted to shift funds from one agency to the other. The political costs might then become internalized by the cabinet agencies themselves.

Summary

Adjusting budgetary priorities to enhance FDA's food safety budget would most likely enable the agency to protect against foodborne disease more effectively than it can now. For this reason, there would almost certainly be health benefits. While the efficiency benefits or losses of shifting food safety resources is more difficult to predict, it is likely that there would be a higher marginal benefit than cost of enhancing FDA's resources at the expense of some of USDA's food safety resources. It is telling that FSIS' statutorily mandated carcass-by-carcass slaughter inspection costs nearly as much as FDA's entire research and enforcement budget for food. Overall governmental efficiency would likely increase, as a function of cost savings per unit of health, by prioritizing the FDA food budget at the expense of areas with lower marginal benefit. However, given the tight funding conditions imposed by recent budget agreements, it is unlikely that a substantial increase in FDA funding would be available. Perhaps the best chance for an increased FDA food safety budget would arise, if the Administration and the relevant agencies were to broker a *quid pro quo* funding shift with the relevant Appropriations chairmen.

D. ENHANCE COORDINATION WITHIN EXISTING INSTITUTIONAL INFRASTRUCTURE

In a telling set of recent speeches, upper-level managers of the FDA and CDC both cited the substantial risks of farm animal waste on the human food supply, and the FDA's director of food safety is now touting "Good Agricultural Practices."[120] Increasingly, the food safety problems of emerging pathogens and agricultural contamination are reaching beyond the arbitrary bureaucratic distinctions of the federal food safety system. Indeed, the cooperation of federal agencies has improved planning and research, through the multi-faceted Food Safety Initiative, to the FDA's recent approval of a USDA-developed anti-Salmonella spray for chickens. This type of coordination will be essential for the federal government to meet the increasing challenges posed by food safety risks that transcend statutory boundaries. Thus, we estimate significant benefits at low cost through the implementation of permanent headquarter and field level coordination mechanisms.

Health Effects of Enhanced Coordination

Enhanced coordination at the headquarters level should have positive health benefits, and almost no health costs. With food safety specialists scattered throughout the bureaucracy, a team-oriented approach seems most appropriate to combating pathogens that often originate from farm animals (a domain of USDA's APHIS), may move to FSIS-regulated meat or poultry carcasses, and find themselves cross-contaminating FDA-regulated fruits and vegetables. Addressing such multi-faceted challenges is now a primary goal of federal food safety regulation.[121] Therefore we estimate positive health benefits through enhanced coordination of the type recently begun under the President's Food Safety Initiative.

However, to maintain this new-found interagency cooperation in the long-term, it may be necessary to mandate multi-agency cooperation through the establishment of a permanent interagency Food Safety Working Group. While the recent cooperation of FDA, CDC, and USDA in the establishment of FoodNet and a comprehensive farm-to-table food safety strategy will almost certainly produce health gains, there is no guarantee that the benefits of cooperation will be felt once President Clinton takes the spotlight off food safety issues. Thus, we believe that long-term health benefits will be greater, should the President mandate a permanent interagency working group by Executive Order. While the establishment of yet another interagency committee will not guarantee positive outcomes, especially if

the committee becomes an "organizational orphan," there are various tools—such as the creation of a permanent staff—that can aid in the successful implementation of a long-term interagency group.[122] We present a model interagency working group, the Working Group on Financial Markets, in Appendix H.

It is difficult to conceive of any health costs through increased coordination at the headquarters level. While there is certainly an opportunity cost of activities that agency leaders must forego in order to attend coordination meetings, it is unlikely that these costs are significant. Rather, we believe that the health costs of enhanced coordination by relevant upper-level food safety regulators are negligible. For this reason, we estimate positive health gains from enhanced headquarters-level coordination relative to the status quo. Additionally, we feel that the establishment of permanent structures that mandate frequent coordination encounters will yield even greater long-term health benefits.

Moreover, enhanced communication mechanisms at the field level can yield long-term health benefits at relatively low cost. For example, improved interagency information systems would enable agencies to refer enforcement violations to sister agencies more rapidly, and field-level interagency committees can improve information-sharing and resource allocation regionally.

Efficiency Effects of Enhanced Coordination

Increasing coordination, whether formally or informally, attempts to improve efficiency by reducing the costs associated with administrative and managerial collaboration. An informal coordination effort may include increased knowledge sharing, synergistic research and development, or altogether new coordination mechanisms and communication channels. A formal coordination effort might include establishing a White House-appointed "Czar" or an advisory panel to oversee, but not regulate, the coordination activities of all the agencies in the food safety system.

The costs associated with increasing coordination would not be significant. However, the net operational costs of personnel and travel would be lower since the very purpose of increased coordination is to leverage existing technology and data, as well as decreasing redundant or unnecessary travel costs. On the other hand, the organizational costs associated with communication and coordination would increase, at least in the short-term. This change reflects the initial expenditures needed to establish predictable, sustainable, and accountable coordination mechanisms and new or enhanced communication channels.

In this regard, formal coordination may yield greater efficiency than informal coordination. Formal coordination requirements for each agency to vet related regulatory proposals with other food safety agencies ensure a timely, systematic, and accountable process. While the White House and OMB have typically become involved in some interagency regulatory decision-making, this involvement simply cannot occur on a consistent basis, and it is no substitute for continuous, systematic, broad-based planning among the food safety organizations.

One specific area of potential efficiency gains from consolidation is in the area of research, where economies of scale exist. In the area of research alone, the Administration's proposed budget for Fiscal Year 1999 calls for approximately $24 million for USDA and $9 million for HHS to enhance the understanding of pathogen growth and control.[123] While current research spending has been shaped by the temporary coordination procedures implemented by USDA and the White House, there is no guarantee that the benefits this coordination will continue. Deep pockets of knowledge and expertise exist within the respective agencies, and there are currently no formalized coordination mechanisms through which to exchange this valuable knowledge. Therefore, increased coordination would address the inefficiencies resulting from this atomized and unleveraged knowledge.

More effective coordination mechanisms in the field, such as unifying public liaison activities, could provide the benefits of consolidation at much less cost. An example of current inefficiency at the field level is the existence of several, seemingly redundant, public affairs offices. Commonly, by the time a consumer has called USDA field offices, he or she has already been routed several times to other agencies including the FDA, EPA, and the state.[124] Consolidation of public interface activities would provide convenience benefits to citizens and decrease duplicative government activities.

Political Feasibility of Enhanced Coordination

Aside from the enhanced health and efficiency that long-term coordination enhancement can offer at low cost, it is perhaps the most politically feasible option. The President can establish a long-term interagency committee by Executive Order, without the turf battles of consolidation, the funding fights of budgetary adjustments, or the safety debate costs entailed when legislators must argue on the record about politically charged food safety standards.

However, while implementing enhanced Executive Branch coordination carries high political feasibility from the perspective of Capitol Hill, there would be minor political costs associated with the adoption of an interagency food safety committee. First, there would be a difficult choice in determining a chair for such a committee. Ideally, the chair of a food safety working group should be presidentially appointed, as are the Drug Control and AIDS Czars. A White House food safety coordinator would allow the President to control any potential battles between HHS, USDA, or EPA: three cabinet level agencies. However, neither the Secretary of Agriculture, the Secretary of Health and Human Services, nor the EPA Administrator (nor their respective representatives) will enjoy taking orders from the food safety coordinator. This represents a loss of turf for cabinet agencies.

Second, the creation of an interagency committee leaves the President open to attacks that he is enlarging government with yet another bureaucracy. This complaint is easily defeated, however. First, action taken to protect food safety is politically popular, especially if it can be done at low cost. Second, however, the President can argue that increased coordination will only improve efficiency and enhance health, thus *lowering* citizens' health and governmental funding costs over the long-term. Third, even conservative Presidents Reagan and Bush established White House committees, such as the Council on Competitiveness, to oversee regulatory agencies.

Thus, the biggest political cost to the President in establishing an interagency food safety working group is the resistance of his own cabinet appointees and their representatives.

Summary

Enhanced coordination mechanisms implemented at the headquarters and field levels can yield long-term health and efficiency benefits by facilitating information-sharing and cross-organizational planning. At the headquarters level, the needs of multi-disciplinary food safety challenges warrant a cooperative, inter-governmental approach to problem-solving. To maximize benefits, such cooperation should take place more often than the occurrence of food safety crises or infrequent research planning sessions. The implementation of a long-term, interagency committee of high level food safety regulators can provide significant health and efficiency benefits at low cost. Finally, the establishment of long-term relationships between regional food safety regulators should improve enforcement and public liaison duties. Regular meetings of field-level managers can yield health and efficiency benefits through information-sharing and resource-sharing, to the extent allowed by law. Finally, the political costs of implementing enhanced coordination mechanisms are low. The primary political costs are intra-bureaucratic, and the implementation of these policies would only be limited by the inevitable inertia of fragmented bureaucracies.

E. CONCLUSION OF POLICY ANALYSIS

Decades of legislative layering have led to the statutory and organizational fragmentation of the current federal food safety system. However, the greatest gains in health and efficiency will not come from consolidation, because the risk management of each food safety agency is driven by its respective authorizing statutes. Therefore, we find that the highest health and efficiency gains are attainable through changes to those statutes that drive the risk standards, inspection requirements, and enforcement powers of the food safety agencies. However, the political costs of forcing legislators to debate the charged issues of food safety severely decrease the chances of successfully implementing statutory changes to food safety risk, inspection, or enforcement standards.

Because statutory change of safety standards or inspection requirements may be an unacceptable tool for political reasons, we suggest that the establishment of enhanced coordination mechanisms may be low cost, high benefit policy options. Coordination can be improved at the headquarters level through the creation of a permanent, White House-chaired interagency committee. Likewise, interagency committees at the field level could yield impressive health and efficiency gains in enforcement and public liaison activities. The creation of such working groups would have few, if any, health, efficiency, or political costs. Finally, while adjustments to budgetary priorities can yield positive health benefits, especially within underfunded FDA, efficiency gains would be marginal compared to those that can be achieved by removing FSIS' carcass-by-carcass inspection mandate.

V. POLICY RECOMMENDATIONS

As our analysis in the previous chapter should suggest, we do not recommend that the federal food safety agencies be consolidated at this time. Based on our research, we believe that the marginal health and efficiency impacts of a large-scale merger would not outweigh a politically and organizationally costly consolidation. Moreover, we contend that a consolidation would distract attention from the true drivers of food safety regulation: the risk standards and inspection techniques that are mandated within the dozens of underlying food safety statutes. Our recommendations in this concluding chapter flow from our analysis.

As we describe in the previous chapter, statutory changes to safety and inspection requirements hold the greatest ability to drive health and efficiency benefits; yet the political risk of implementing these statutory changes is illustrated by the decade-long battle to legislate a negligible risk standard for tolerances granted for carcinogenic pesticide residues on processed foods. Therefore, while high-level agency managers should consistently push Congress to revise standards that impede risk-based regulation in the long-term, they should implement creative ways to optimize the fragmented food safety regulatory system in the short-term. To that end, we have provided both short-term and long-term recommendations:

1. **CONGRESS SHOULD NOT MERGE THE MAJOR FOOD SAFETY AGENCIES AT THIS TIME.** The marginal health and efficiency benefits that we predict are not likely to justify the costs of large-scale consolidation. Moreover, as we discuss below, the food safety agencies can achieve many of the coordinative benefits of consolidation through the adoption of enhanced, permanent communication mechanisms at the headquarters and field levels.

2. **THE PRESIDENT SHOULD ESTABLISH BY EXECUTIVE ORDER AN INTERAGENCY FOOD SAFETY WORKING GROUP CHAIRED BY A WHITE HOUSE-APPOINTED FOOD SAFETY COORDINATOR.** Upper-level managers of FDA (CFSAN), USDA (Undersecretary for Food Safety, FSIS), EPA (OPP), CDC, and other relevant food safety agencies should meet frequently for purposes of organizing multi-agency food safety initiatives, investigations, and enforcement actions; enhancing cooperation and information-sharing; improving field-level communication; and implementing risk-based budgetary planning.

While food safety agency leaders have recently improved interagency coordination, current steps have primarily focused on crisis management and research planning. We envision a more robust working group that meets frequently and engages in discussions on all aspects of interagency relationships. The coordinator of the Food Safety Working Group would have responsibilities similar to the AIDS Czar and Drug Czar: advising the President and organizing forces throughout the federal government to enhance human health most effectively and efficiently.

The interagency Food Safety Working Group we recommend would effectively combine the informal crisis reaction efforts of the Foodborne Outbreak Response Coordinating Group (FORCG) and the research coordination efforts recently attempted by FSIS and the White House Office of Science and Technology Policy. By memorializing the committee by Executive Order, we believe that enhanced interagency coordination could become a permanent benefit of the President's Food Safety Initiative. While a food safety coordinator or interagency committee will not serve as a perfect substitute for a single management or regulatory planning structure, it would serve the important purpose of convening senior management in a single forum on a routine basis. Such a process should allow the various agencies to work as one in solving problems that affect foods regulated by two or more organizations. Moreover, better

coordination at the headquarters level can help to implement better communication at the field level, the topic of our second recommendation.

The Working Group on Financial Markets (WGFM), a committee chaired by the Secretary of the Treasury and composed of the chairs of the Federal Reserve, SEC, CFTC, can serve as a model for the establishment of a food safety interagency committee. As we describe more fully in Appendix H, the WGFM was established by Executive Order in 1988 to address the problems of agency non-coordination that many researchers believed exacerbated the stock market crash of 1987. Since the establishment of the WGFM, the Group has successfully implemented stock market trading halt mechanisms and arranged for complementary regulatory action among several agencies and financial markets in the event of a market crash. The leaders of the WGFM have successfully used the power of group consensus to recommend and implement important adjustments associated with regulatory coordination.

FSIS can take a leadership role in improving regulatory coordination by supporting the low cost mechanism of a permanent interagency committee. As leaders of all of the major food safety agencies have expressed, the challenges facing regulators demand a farm-to-table approach that straddles bureaucratic boundaries. Short of consolidation, the best method to unify the government's ability to fight foodborne illness is improved coordination.

3. **THE FOOD SAFETY AGENCIES SHOULD IMPLEMENT ENHANCED COORDINATION MECHANISMS AT THE FIELD LEVEL, INCLUDING THE ESTABLISHMENT OF REGIONAL INTERAGENCY WORKING GROUPS AND THE CONSOLIDATION OF CONSUMER AFFAIRS OFFICES INTO ONE FEDERAL FOOD SAFETY INFORMATION SERVICE.** Improved interagency information-sharing at the regional level can offer significant health and efficiency benefits at limited cost. Moreover, the establishment of a unified food safety consumer affairs office would enhance consumer convenience and facilitate field-level cooperation. The budget savings that would result from the synergy gains of combining food safety public liaison activities could be used to fund increased public education of safe food handling and farm-based food safety.

Improved interagency coordination at the field level, including managerial working groups and potential joint training opportunities for inspectors, can increase interagency cooperation in enforcement. As GAO has noted, the implementation of interagency enforcement referrals has occurred sporadically. Establishing managerial working groups at the field level can strengthen these critical lines of communication through a fragmented bureaucracy.

Moreover, establishing a single public relations organization can serve to improve customer service, efficiency, and interagency cooperation. Currently the FDA, EPA, and USDA—as well as state and local regulators—have separate interfaces with the public. This fragmentation can cause frustration on the part of callers who are shuffled from one agency to another based on the arbitrary distinctions of the underlying food safety statutes. One way to increase efficiency and enhance interagency cooperation is to consolidate the consumer affairs offices of all federal food safety agencies. Since the short-term implementation costs of such a limited merger would be low, the resulting long-term economies of scale should justify any costs of consolidation.

Already USDA and FDA have moved in the direction of a unified public liaison role by creating the USDA/FDA Foodborne Illness Education Center in Beltsville, Maryland. This Center was formed through an interagency agreement and serves as a resource for educators, food workers, and consumers with databases on educational materials and HACCP implementation.[125] The Center can serve as a model for incremental consolidation. To the degree that consolidation is possible without the need for legislation or extraordinary bureaucratic costs, FSIS and other agencies should strive to implement joint interagency activities when the health and efficiency benefits outweigh the costs.

4. **CONGRESS AND THE FOOD SAFETY AGENCIES SHOULD CONTINUE TO ENHANCE MONITORING AND RISK ASSESSMENT MECHANISMS SUCH AS FOODNET IN ACCORDANCE WITH THE PRESIDENT'S FOOD SAFETY INITIATIVE.** More accurate data on the extent of foodborne illnesses and the greatest risks to health are necessary for Congress and the food safety agencies to marshal federal resources to attack the greatest foodborne risks most efficiently.

As this study has made clear, imprecise estimates of the extent of foodborne illness severely hamper policy makers' ability to address food safety dangers. Effective risk management demands precise risk assessment. The President's Food Safety Initiative has taken important steps by establishing FoodNet, which will allow the CDC, USDA, and the FDA to monitor foodborne illness through rigorous analysis of population samples. Moreover, the Initiative's funding of food safety risk assessment studies will contribute to more effective regulation in the long-run. Greater understanding of the risks posed by distinct food products will yield long-term health and efficiency benefits with limited short-term cost by facilitating the implementation of risk-based regulation.

5. **FSIS SHOULD CONTINUE TO UPGRADE THE SKILLS OF ITS INSPECTORS FOR THE PURPOSE OF EXPANDING SCIENCE-BASED INSPECTION AND LEAVING BEHIND CARCASS-BY-CARCASS, ORGANOLEPTIC INSPECTION METHODS.** As scientific advancement continues to improve our ability to detect the most serious pathogenic risks to food, the citizenry will demand a meat and poultry inspection force that mitigates those threats at every point from farm to table. FSIS should anticipate the eventual move away from inefficient and largely superficial carcass-by-carcass inspection and continue to prepare its inspectors accordingly.

A broad consensus of food safety experts has determined that the inspection methods of the early 20th century will not serve the citizenry in fighting pathogens that cannot be seen, smelled, or touched. The risks of visible animal diseases—the harms that organoleptic inspection was created to fight—are no longer the most substantial threats to human health. Eventually, Congress must address the inefficiencies that result from the statutory requirements of continuous inspection and carcass-by-carcass examination. It is likely that random sampling of a large portion of carcasses while systematically testing for several foodborne pathogens can enhance food safety and regulatory efficiency. As the 21st century approaches, FSIS should prepare to leave behind the imprecise inspection methods of the early 20th century. FSIS should continue to work with industry and the meat and poultry inspectors union to utilize modern inspection methods such as random sampling, bacterial testing, and HACCP.

6. **CONGRESS SHOULD AMEND THE UNDERLYING FOOD SAFETY STATUTES TO ALLOW AGENCIES TO REGULATE IN A RISK-BASED MANNER AND PROVIDE A STATUTORY MANDATE TO ALLOW THE FDA TO MEET ITS INSPECTION OBLIGATIONS.** To that end, Congress should dismantle the carcass-by-carcass pre-and post-slaughter inspection system and instead give FSIS the option to perform random sampling with detailed, risk-based analyses on each sampled animal. Moreover, FDA requires a resource anchor, such as a quota to visit a certain portion of its regulated facilities annually, to meet its food safety monitoring and inspection obligations.

Currently, almost 50% of FSIS' staff resources are allocated to carcass-by-carcass, sight and smell regulation of slaughtering plants and daily inspection of meat processing plants. The organoleptic inspection method does not manage the most serious risks to human health, yet the FSIS inspectors are mandated by statute to examine every carcass, albeit superficially. At the other extreme, FDA is charged with policing against food adulteration in 53,000 facilities nationwide; yet the agency barely has the resources to inspect plants on the average of once per decade. It is likely that the health benefits of increased FDA food safety funding would be greater than the marginal loss of decreased funding within most parts of USDA's massive food safety budget. While agencies justifiably guard their budgetary resources carefully, it is important for appropriators to realize the potential negative impact of neglecting food safety enforcement for non-meat foods. Moreover, legislators must carefully assess the incentives and statutory mandates entailed in the complex web of statutes that specify the risk standards of the food we eat.

A FINAL NOTE

The current leadership of FSIS has taken important steps in recent years to modernize and improve its inspection of meat and poultry. While HACCP is being implemented under rule-making authority, other changes demand congressional approval. As we have discussed repeatedly, the key drivers of the federal government's ability to protect citizens from foodborne illness are the statutes that authorize acceptable risk standards, inspection requirements, and enforcement powers. Any long-term enhancement of food safety regulation must address the *Jungle*-era statutes that often bind agencies by limiting the flexibility to allocate resources most effectively and efficiently. We have highlighted two such statutory mandates: the carcass-by-carcass and continuous inspection requirements of the FMIA and PPIA and the Delaney Clause of the FDCA. Undoubtedly there are more.

It is no accident that the United States has become a model of food safety for most of the world. With a vibrant, diverse, and affordable supply, the United States consistently produces and exports vast quantities of food. Yet as the global economy shifts to international safety systems such as the Codex Alimentarius, it is critical that our country remain at the forefront of food safety. Strong, science-based food safety will pay increasing dividends in global trade.[126] Therefore, the United States cannot rest on its laurels and remain content with the food safety that we currently enjoy. As a nation, we can and ought to strive for the healthiest and most efficient food safety system possible. Thus, a critical long-term duty for food safety regulators and legislators alike is to address these controversial and politically charged issues honestly, rationally, and courageously.

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A

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A. A NOTE ON METHODOLOGY

As several analysts of bureaucratic reorganization have observed, the task of forming valid, objective conclusions about the costs and benefits governmental mergers can be especially daunting.[127] With limited ability to estimate the actual as well as cultural and political costs of reorganization, the researcher must patiently seek to avoid reaching conclusions without rigorous analysis.

The problems of assessing our food safety system are even more difficult for several reasons. First, until last year's establishment of the FoodNet monitoring system, the CDC's estimates of the incidence of foodborne illness were largely guesses. Without accurate data on the size of our nation's food safety problem, estimating the benefits of change necessarily involves guesswork. Second, as noted above, many of the costs and benefits involved in assessing the efficacy of food safety reorganization involve the real, but non-quantifiable, characteristics of cultural and political tensions. Third, it is practically impossible to conduct a controlled, blinded, randomized study of the effects of bureaucratic reorganization on our national food safety net. While the federal government can pilot-test programs such as HACCP, it cannot merge agencies temporarily or change the statutory risk standards in certain states without a process involving many groups, including the citizenry at large.

In order to escape the dangers involved in our predominantly qualitative research, we have sought to rely on a methodology of systematic engagement with a diverse group of interviewees. Overall, we interviewed over two dozen people who currently or previously played a significant role in the federal food safety system. While we have guaranteed the anonymity of many of our sources, we can reveal their current or past affiliations. Included in our group of interviewees were affiliates of the FDA, USDA (FSIS—headquarters and field, ERS, and ARS), EPA (OPPS), CDC, the Senate Labor and Human Resources Committee (minority staff), the Senate Agriculture Committee (majority staff), the House Commerce Committee (majority and minority staff), the House Agriculture Committee (majority and minority staff), the office of Congressman Vic Fazio, the National Food Processors Association, the American Meat Institute, and the Center for Science in the Public Interest.

Beyond interviewing, we have sought to examine the written literature associated with food safety reform, bureaucratic reorganization, public sector organizational change, political and institutional analysis, and foodborne illness. In this way, our findings are a result of systematic theoretical, historical, and empirical research. Wherever necessary, these sources have been cited and appear in our endnotes (Appendix J). Of special importance are the detailed analyses conducted periodically by the GAO on topics that range from the effectiveness of FSIS meat and poultry inspection to the estimation of foodborne illness incidence.

We have purposely sought to avoid the quantification of reorganization's costs and benefits due to the difficulties of accurate estimation and the ease of manipulating such numbers in many directions. Rather, we have presented a listing of significant costs and benefits and described them as short-term or long-term and "low," "medium," or "high" relative to the benchmark of the status quo. For example, if the FDA were merged with the FSIS, the physical costs of moving would be higher than the status quo (which involves no move). Obviously, estimating political feasibility and cultural costs are more subjective than estimating the scale of communication and coordination costs. However, we defend such assessments based on the number of systematic interviews and other research that we have conducted.

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B. OVERVIEW OF THE FEDERAL FOOD SAFETY SYSTEM

At the request of FSIS Deputy Administrator Glavin, we provide in this appendix an overview of the organizational structure and statutory authority of the major food safety agencies: FDA, FSIS, and EPA. On the next page, we include an organizational chart of the food safety bureaucracy and relevant congressional authorizing and appropriations committees. We have also attached portions of the GAO Report, *Food Safety and Quality—Who Does What in the Federal Government*,[128] to provide further background information on the many intertwining food safety statutes and bureaucracies.

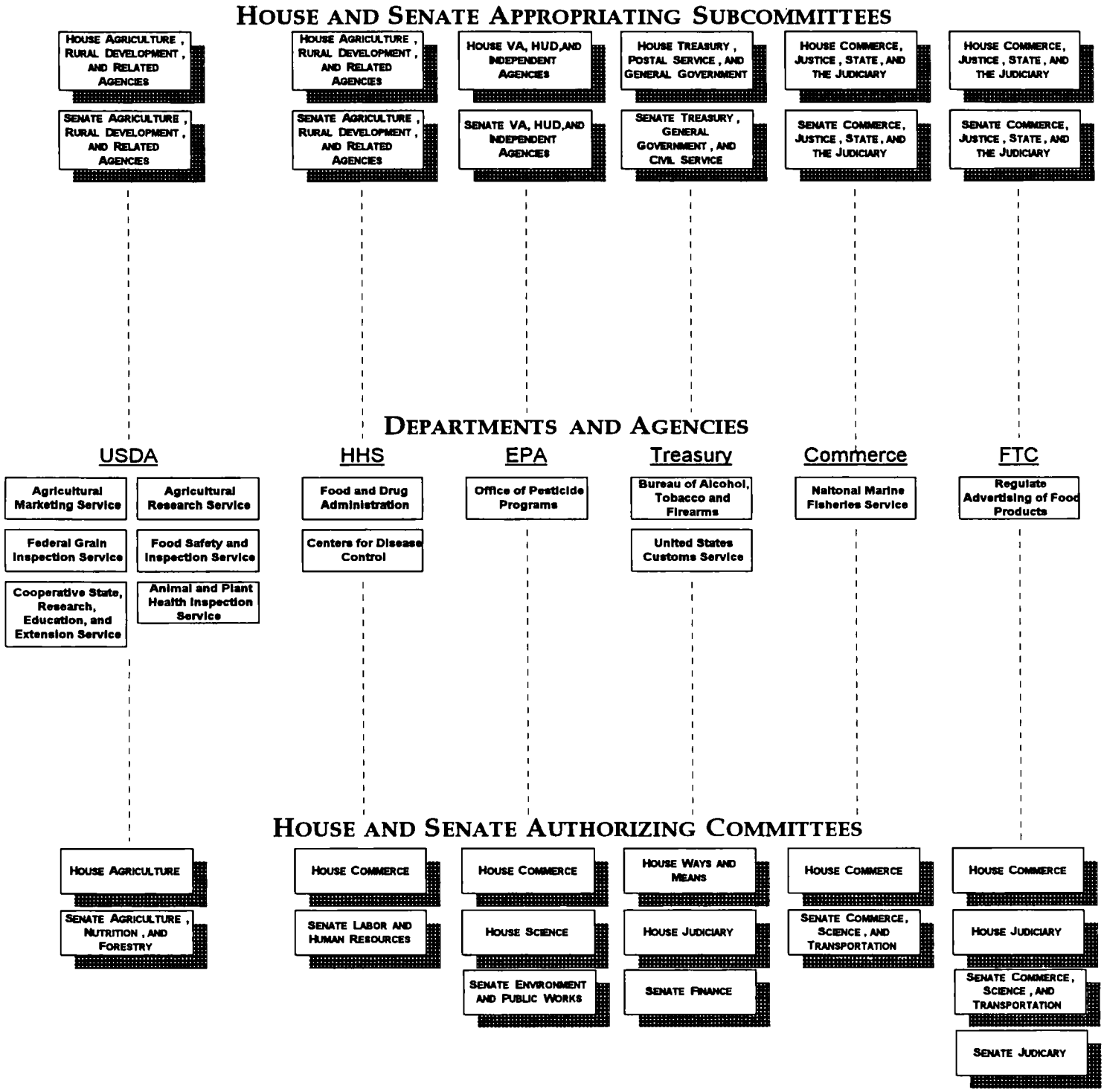
THE FOOD AND DRUG ADMINISTRATION (FDA)

With regulation over most foods, drugs, medical devices, and cosmetics, the FDA oversees approximately one-quarter of the United States GNP. Originally an agency of the USDA, the FDA became a part of the Department of Health, Education, and Welfare (HEW), the predecessor of HHS, in 1953.[129] The Commissioner of Food and Drugs reports to the Assistant Secretary for Food, who in turn reports to the Secretary of Health and Human Services.[130]

Federal Food, Drug, and Cosmetic Act (FDCA)

The Food, Drug, and Cosmetic Act of 1938, as amended, (FDCA) contains the core of FDA's authorizing legislation.[131] The FDCA defines several important food safety terms, including: food, food additives, food labels, pesticides, color additives, animal feed, and dietary supplements.[132] Perhaps most importantly, FDCA prohibits food adulteration and misbranding.[133]

GOVERNMENT AGENCIES RESPONSIBLE FOR FOOD SAFETY AND THEIR RESPECTIVE CONGRESSIONAL COMMITTEES



The FDCA provides for civil and criminal penalties upon violation of its adulteration or misbranding provisions. Included among the penalties are: seizure, injunction, civil fines, and criminal penalties.[134] The FDCA's most significant food safety provisions are summarized below:

Definitions

Food. "The term 'food' means (1) articles used for food or drink for humans or other animals, (2) chewing gum, and (3) articles used for components of any such article."[135]

This definition indicates that an article is "food" (as opposed to a drug or nutritional supplement) based upon its use or primary function.[136]

Labeling. "The term 'labeling' means all labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."[137]

Pesticide. In defining pesticides,[138] the FDCA defers to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)[139] which is administered by the EPA.

Food Additive. In 1958, Congress passed the Food Additives Amendment to the FDCA which requires pre-market approval for substances whose intended use "can reasonably be expected to result" in their "becoming components of food." This includes both direct and indirect additives such as packaging.

. . .

The FDCA prohibits the "introduction or delivery for introduction into interstate commerce" of any food that is "adulterated or misbranded."[140] Additionally, the statute prohibits the "adulteration or misbranding of any food" in interstate commerce.[141] Finally, the FDCA prohibits the "receipt in interstate commerce of any food . . . that is adulterated and misbranded, and the delivery or proffered delivery thereof for pay or otherwise."[142] Thus, the FDCA may hold producers, shippers, and receivers liable for the introduction of adulterated or misbranded food in interstate commerce.

Adulteration

The first significant food safety prohibition in the FDCA is against food adulteration. For purposes of defining adulteration, the FDCA treats added substances, non-added substances, food additives, pesticides, color additives, and animal drugs differently in specifying safety standards. Generally, however, "[a] food shall be deemed to be adulterated—

> (1) if it bears or contains any poisonous or deleterious substance which *may* render it injurious to health; . . .
>
> (2) if it contains an unsafe food additive or pesticide;
>
> (3) if it bears or contains any added poisonous or added deleterious substance [other than a pesticide], . . .
>
> (4) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or
>
> (5) if it has been prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or
>
> (6) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or

> (7) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or
>
> (8) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a [food additive approval] regulation. . ."[143]

Adulteration of Non-added Substances. In the case of non-added food substances, "such food shall not be considered adulterated under [the FDCA] if the quantity of such substance in such food does not *ordinarily* render it injurious to health."[144]

Added versus Non-Added Substances. The FDCA makes a critical distinction between substances that are added to food and food that has no added substances. In the case of potentially harmful non-added substances (i.e., substances that occur naturally in food), the FDA may only consider the food adulterated, if there is enough quantity to "*ordinarily* render it injurious to health" [emphasis added].[145]

On the other hand, potentially harmful *added* substances are considered adulterated, if those substances "*may* [not must] render it injurious to health." As the Supreme Court has noted, in determining whether an added substance is adulterated, "It is not required that the article of food containing added poisonous or deleterious ingredients *must* affect the public health, and it is not incumbent upon the Government in order to make out a case to establish that fact."[146] Therefore, if the FDA can reasonably assume that an added substance in food *may* be injurious to human health, then the agency may prohibit interstate shipment of that food.

Adulteration of Food Additives. Under the FDCA, FDA is not to approve a food additive petition "...if a fair evaluation of the data before the Secretary ... fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe."[147] A food additive is considered unsafe—and thus adulterated—if FDA has not approved a pre-market petition.[148]

The FDCA does not define "safe." Rather, FDA has extrapolated a definition of safety from the legislative history of the FDCA: "there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use."[149]

The Delaney Clause. A significantly different (zero-risk) safety standard is applied to carcinogenic additives in the well-known Delaney Clause of Section 409:

> ...no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man and animal[150]

The Delaney Clause has had a pervasive, and some would say perverse, effect on FDA's regulation of additives, especially as current technology can now detect carcinogen in parts per trillion.

GRAS Substances. Prior to passage of the Food Additives Amendment in 1958, FDA submitted to Congress a substantial list of commonly used additives that were "generally recognized as safe." The original GRAS list included such commonly used substances as coffee, salt, sugar, and wine.[151] Since 1958, very few of these additives have been declared unsafe. Currently, FDA reviews new petitions that are submitted by food manufacturers for ingredients believed to be GRAS. The list of GRAS petitions before the FDA is substantial, and manufacturers are allowed to use substances believed to be GRAS even as FDA completes the affirmation process. However, manufacturers run the risk of prosecution if they utilize an unapproved GRAS additive that is later found by FDA to be unsafe.[152]

Prior Sanction Substances. As well as conditionally approving GRAS substances, Congress grandfathered the approval of several substances for which FDA had issued opinions of safety prior to

1958. A substance is considered "prior-sanctioned" if its specific use in food was approved by FDA or USDA prior to September 6, 1958.[153]

Color Additives. In 1960, Congress extended the pre-market approval, general safety language, and zero cancer risk provisions of food additive regulation to color additives.[154]

An imal Drugs. Congress again extended the general safety and anti-cancer standards of Section 409 to animal drugs (Section 512) in 1968.[155] However, the Animal Drugs Amendments contained an important exception that was designed to continue the use of the carcinogen diesthylstilbestrol (DES). The DES Amendment enabled FDA to permit the use of carcinogenic animal drugs, if no residue of the drug could be found in any edible portion of the treated animal. Even in 1968, Congress was beginning to question the rigidity of the Delaney anticancer clauses.

Pesticides. A final category of food substances regulated, at least partially, by FDA is pesticides. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires EPA to demonstrate that a product will not cause unreasonably adverse effects on the environment after taking into account "the economic, social, and environmental costs and benefits of any pesticide."[156]

Section 408 of FDCA, established in 1954, creates tolerances for pesticide residues on agricultural products. In setting these tolerances, EPA may consider the need for a wholesome and economical food supply as well as safety considerations. Thus, unlike the food additive standards of Section 409, pesticide regulation allows the balancing of risks and benefits. Moreover, there is not an anti-cancer clause in Section 408. While EPA sets pesticide tolerances and register pesticides, FDA monitors pesticide residues in food and enforces tolerances.

Misbranding

The second major food safety prohibition of the FDCA concerns food misbranding, which is described in 21 U.S.C.A. § 343. Under the FDCA, "food shall be deemed to be misbranded—

> (a) If (1) its labeling is false or misleading in any particular, or (2) in the case [of vitamins or minerals], its advertising is false or misleading in a material respect....
>
> (b) If it is offered for sale under the name of another food.
>
> (c) If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word 'imitation' and, immediately thereafter, the name of the food imitated.
>
> (d) If its container is so made, formed, or filled as to be misleading.
>
> (e) [If its package does not bear a label containing the name and location of the manufacturer and a statement of quantity, weight, and numerical count of the good.]
>
> (f) [If required labeling is not 'prominently placed' and is not 'likely to be read and understood by the ordinary individual under customary conditions of purchase and use.']
>
> (g) [If it is a food that purports to be one in which there is a regulatory standard and the food deviates from that definition and standard.]
>
> (h) [If it is a food for which there is a regulatory standard of quality and the food deviates from that standard.]

(i) [Unless it bears the name and ingredients--if there are two or more ingredients--of the food]

(j) [If it is a food for 'special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties' as the FDA determines.]

(k) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact, [unless FDA grants an exemption by regulation].

(l) If it is a raw agricultural commodity ... bearing or containing a pesticide chemical after harvest, [unless the commodity bears labeling noting the presence of the chemical, its name, and its function, unless such commodity is being displayed for sale]

(m) If it is a color additive, unless its packaging and labeling [conform to the color additive provisions of the FDCA-- 21 U.S.C.A. § 379e]

(n) If its packaging or labeling is in violation of an applicable regulation....

(o) If it contains saccharin, unless [it bears the saccharin warning language specified in this section, and the Secretary of HHS has not decided to revise or remove the requirement by regulation]

(p) [If it contains saccharin and is offered for sale at a retail establishment without appropriate notice, and the Secretary of HHS has not decided to revise or remove the requirement by regulation]

(q) [If it does not bear the labeling established under the Nutrition Labeling and Education Act of 1990 whose requirements include:

A) Serving size 'which is in an amount customarily consumed and which is expressed in a common household measure that is appropriate to the food'

B) Number of servings

C) Total number of calories derived from all sources and derived from fat

D) Amount of the following nutrients: 'total fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, dietary fiber, and total protein'

E) 'Any vitamin, mineral, or other nutrient required to be placed on the label' prior to October 1, 1990]

(r) [If it makes health related claims and does not conform to regulations issued by the Secretary of HHS or if it 'claims to diagnose, mitigate, treat, cure, or prevent any disease']

(s) [If it is a dietary supplement and its label fails to list each ingredient, the quantity of each ingredient, and its label fails to identify the product as a 'dietary supplement.']"[157]

Misbranding in Context. In determining whether a food is misbranded because the labeling is misleading, the FDA and courts must take into account "not only the representations made or

suggested" but also the extent to which the labeling or advertising fails to reveal material facts with respect to possible consequences of use.[158] Significantly, this is the standard upon which FDA determines on a case-by-case basis whether products manufactured through the use of modern biotechnology require special labeling.

Penalties

FDA may seek civil and criminal penalties for violations involving the prohibited acts of adulteration and misbranding. The FDCA gives Federal district courts jurisdiction over FDA enforcement proceedings.[159] Significantly, the FDA may not detain adulterated or misbranded food or shut down a violating manufacturer or transporter of adulterated food without first going to court to seek and injunction. Following is a summary of judicial remedies available to the FDA for food safety violations:

> **Injunction.** The FDA may appeal to a federal court to seize adulterated food. [160]
>
> **Civil penalties** ranging from $1,000 to $500,000.[161]
>
> **Criminal penalties**, including prison terms ranging from one to three years.[162]
>
> . . .
>
> **Right to Inspect.** The Secretary of HHS may delegate to employees of FDA the right to enter, "at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport" such products.[163]
>
> During an inspection, HHS employees may examine "within reasonable limits ... , such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein."[164] FDA inspectors may also examine shipping records for food shipped in interstate commerce.[165]
>
> **Imports.** Any food that is adulterated or misbranded may be refused admission into the United States.[166] However, FDA does not have inspection authority outside of the U.S.
>
> **Exports.** Food "intended for export shall not be deemed to be adulterated or misbranded ... if it-
>
> (A) accords to the specifications of the foreign purchaser,
> (B) is not in conflict with the laws of the country to which it is intended for export,
> (C) is labeled on the outside of the shipping package that it is intended for export, and
> (D) is not sold or offered for sale in domestic commerce"[167]
>
> . . .

Aside from the FDCA, the FDA implements sections of other food safety statutes, including the Public Health Service Act (PHSA), the Fair Packaging and Labeling Act (FPLA), and the Filled Milk Act (FMA).

Public Health Service Act (PHSA)

The Public Health Service Act (PHSA) furnishes HHS (which delegates this authority to FDA) with enormous discretion to combat the interstate transport of "communicable diseases." Specifically, 42 U.S.C. § 264(a) provides that:

> The Surgeon General, with the approval of the Secretary [of HHS], is authorized to make and enforce *such regulations as in his judgement are necessary to prevent the introduction, transmission, or spread of communicable diseases* from foreign countries

> into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and *other measures, as in his judgement may be necessary*. [emphasis added.]

Thus, FDA, acting under authority of the PHSA, may take extreme measures to prevent the spread of communicable diseases. FDA has traditionally used the PHSA to regulate sanitation for restaurants and food transporters.[168]

Fair Packaging and Labeling Act (FPLA)

Aside from the nutrition labeling provisions established in 21 U.S.C. § 343(q)—the Nutrition Labeling and Education Act of 1990—the Fair Packing and Labeling Act (FPLA) provides specific guidelines for the labeling of "consumer commodities."[169] Specifically, FPLA provides that labeling declare the identity of a product and the net quantity of a package's contents.[170] The FPLA pertains to all foods, drugs, devices, and cosmetics as defined in the FDCA; however, meat, poultry, and other agricultural commodities fall outside of the FPLA's definition of consumer commodities.[171]

Filled Milk Act (FMA)

The Filled Milk Act (FMA) declares that "any milk, cream, or skimmed milk" to which has been added "any fat or oil other than milk fat" is adulterated and injurious to the public health.[172] FDA may seek civil or criminal penalties for violation of the FMA.[173]

Federal Meat Inspection Act (FMIA)

While the USDA retains primary responsibility for enforcing the Federal Meat Inspection Act (FMIA), the Act pertains to FDA in two significant ways. First, the FMIA declares that none of its provisions shall derogate from the authority of the FDCA conferred before December 15, 1967.[174] Second, the FMIA provides HHS—and thus FDA—with authority over meat parts after such parts have left the premises in which they were inspected by USDA.[175]

UNITED STATES DEPARTMENT OF AGRICULTURE (USDA)

The USDA is primarily responsible for ensuring the safety of the nation's meat, poultry, and egg products. The Food Safety and Inspection Service (FSIS) conducts continuous inspection of meat, poultry, and egg product plants. The Agricultural Marketing Service (AMS) also conducts voluntary shell egg grading, while FDA retains jurisdiction over shell egg plants itself. Increasingly, more and more USDA agencies are involved in the "farm-to-table" strategy of food safety. Thus, while we have focused this overview on the USDA's inspection powers, it is important not to neglect the Department's extraordinary funding of food safety research through the Agricultural Research Service (ARS), the Economic Research Service (ERS), and other agencies.

Federal Meat Inspection Act (FMIA)

The Federal Meat Inspection Act[176] is the primary law regulating meat slaughtering and processing. Like the FDCA, another *Jungle*-era statute, the FMIA is intended to protect the health and welfare of consumers by assuring that meat and meat food products are wholesome, unadulterated, and properly marked, labeled, and packaged.[177] The primary congressional purpose was to eliminate unwholesome,

adulterated or misbranded meat or meat food products that could be injurious to the public welfare or destroy markets for wholesome and properly labeled products.[178] FMIA is administered primarily by FSIS.

Inspection Requirements

FMIA requires inspections of cattle, sheep, wine, goats, horses, mules, and other equines. These inspections focus on wholesomeness, adulteration, and proper labeling of the product.
FMIA requires that all animals subject to the act be inspected before they are brought into any slaughtering, meat-canning, salting, packing, rendering, or similar establishment where they are to be slaughtered.[179] After slaughter, the animal carcass and parts are inspected by USDA inspectors to determine whether they have been adulterated.[180] FMIA has similar provisions for the preparation of meat food products. Meat products can be prepared only from carcasses and parts that have passed ante-mortem and post-mortem inspections.[181] Adulterated carcasses and parts are labeled "inspected and condemned" and are destroyed for food purposes in the presence of an inspector.[182] In addition, processing and other meat product plant operations that transport products from other inspections must subject their meat food products to reinspection upon entry into the plant.[183] The Secretary of Agriculture may remove inspectors from any establishments that fail to destroy adulterated carcasses and parts.[184] The implication of such a removal is that all meat that is not inspected is considered adulterated, causing plants to cease operation.

Adulteration

Protecting consumers from adulterated meat products is the primary focus of the FMIA.[185] Meat or a meat product is considered adulterated under any of the following circumstances:[186]

- If it bears or contains any poisonous or deleterious substance that may render it injurious to health;
- If it bears or contains any added poisonous or added deleterious substance that may make it unfit for human food;
- If it consists in whole or in part of any filthy, putrid, of decomposed substance;
- If it has been prepared, packaged or held under unsanitary conditions where it may have become contaminated;
- If it is, in whole or in part, the product of an animal that has died otherwise than by slaughter;
- If its container is composed, in whole or in part, of any poisonous or deleterious substance that my render the contents injurious to health;
- If any valuable constituent has been in whole or in part omitted or abstracted therefrom, etc.; or
- If it is a margarine containing animal fat and any of the raw material used therein consists in whole or in part of any filthy, putrid, or decomposed substance.

A catch-all provision complements these circumstances. Meat is adulterated if it is "for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food."[187] FMIA provides inspectors great discretion to make determinations of adulteration, and in most cases, the courts are reluctant to overrule on-site inspectors.[188]

Of particular interest to this study are situations of overlap between FDA and USDA. There is overlap when products contain certain additives found unsafe by FDA.[189] Meat or meat products that contain certain additives determined unsafe by FDA are automatically considered adulterated by USDA.[190]

However, an additive found *safe* by the FDA does not bind USDA to approve it as an additive for meat and meat products.[191]

The FSIS may claim that meat is adulterated, even though there is no actual showing of product contamination.[192] For example, FSIS may declare that a product prepared, packed, or held under unsanitary conditions "may have become" contaminated with filth or "may have been" rendered injurious to health.[193]

Labeling

Like the FDCA, the FMIA lists many circumstances under which an article is misbranded.[194] Particularly important is the definition that considers an article misbranded "if its labeling is false or misleading in any particular."[195]

Enforcement Provisions

FMIA grants USDA fairly strong enforcement provisions, including criminal penalties as well as civil administrative sanctions. Violations of the Act include criminal misdemeanors, punishable by a maximum of a one-year imprisonment, a $1,000 fine, or both.[196]

A violation that involves either an "intent to defraud" or any distribution or attempted distribution of an adulterated product, is a felony punishable by a maximum of three years of imprisonment, a fine of $10,000, or both.[197] Violations of FMIA are considered strict liability crimes and require no proof of knowledge or intent.[198] Therefore, managers of organizations that commit criminal violations are equally liable and can be prosecuted, even though they may not be conscious of the organization's wrongful acts.[199] FMIA's civil enforcement powers include injunctive relief and product seizure and condemnation.[200]

Administrative Sanctions

A powerful enforcement tool is the threat and power of withdrawal, denial, or suspension of the inspection service. Under FMIA, the Secretary of Agriculture may refuse to provide, or may withdraw, inspection service upon the determination that the applicant, or the recipient, of inspection service is unfit to engage in business.[201] A facility that has lost its inspectors is effectively out of business with respect to slaughtering, processing, or shipping meat or meat products through interstate commerce.[202]

Amendments

In 1967, the Wholesome Meat Act[203] expanded the scope and the number of topics covered and the jurisdiction of the Act.[204] Since then, FMIA has been amended several times by statutes including the Curtis Amendment of 1970,[205] the Humane Methods of Slaughter Act of 1978,[206] and the Agriculture and Food Act of 1981.[207]

Poultry Products Inspection Act (PPIA)

The purpose of the Poultry Products Inspection Act (PPIA) is to ensure that all poultry and poultry products are wholesome, unadulterated, and properly marked, labeled, and packaged.[208] Like the MIA, PPIA requires federal inspection of poultry, poultry products, and other related items capable of use as human food.[209] The Act essentially grants USDA jurisdiction over all poultry and poultry products unless explicitly exempted.[210]

Definitions

PPIA defines **poultry** as "any domesticated bird, whether live or dead." This includes chickens turkeys, duck, geese, and guineas.[211] **Poultry products** are defined as "any poultry carcass or part thereof; or any product which is made wholly or in part from any poultry carcass or part thereof, exempting products

which contain poultry ingredients only in a relatively small portion or historically have not been considered by consumers as products of the poultry food industry..."[212] **Processed poultry** refers to poultry that is "slaughtered, canned, salted, stuffed, rendered, bonded, cut up, or otherwise manufacturer processed."[213]

Inspection Requirements

The PPIA requires inspection of all poultry and poultry products to ensure that poultry products are not adulterated or misbranded.[214] Those poultry carcasses and products "found to be adulterated" by an inspector must be condemned and otherwise destroyed.[215] As is the case for meat inspection under FMIA, the Act requires ante- and post-mortem inspections. Poultry is inspected for diseases or abnormal conditions prior to entry into the kill floor during the ante-mortem inspection.[216] USDA inspectors conduct a post-mortem inspection of each poultry carcass processed whenever there is a quarantine, segregation, or processing inspection as deemed necessary by the Secretary.[217] During postmortem inspections, inspectors typically examine both the interior and the exterior of each bird's body cavity in addition to exposed viscera.[218]

Adulteration

The term "adulterated" applies to any poultry product in one or more of any of the following circumstances:[219]

> (1) If it bears or contains any poisonous or any deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health;
>
> (2)(A) If it bears or contains (by reason of administration of any substance to the live poultry or otherwise) any added poisonous or any added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; or (iii) a color additive) which may, in the judgement of the Secretary, make such article unfit for human food [the terms pesticide chemical, food additive, and raw agricultural commodity are provided the same meaning as in the Federal Food, Drug, and Cosmetic Act (21 U.S.C § 301 et seq.)];
>
> (B) If it is, in whole or in part, a raw agricultural commodity and such commodity bears or contains a pesticide chemical which is unsafe within the meaning of 21 U.S.C. § 346a;
>
> (C) If it bears or contains any food additive which is unsafe within the meaning of 21 U.S.C. § 348;
>
> (D) If it bears or contains any color additive which is unsafe within the meaning of 21 U.S.C. Section 376: *Provided*, That an article which is not otherwise deemed adulterated under clause (B), (C), or (D) shall nevertheless be deemed adulterated if use of the pesticide chemical, food additive, or color additive in or on such article is prohibited by regulations of the Secretary in official establishments;
>
> (3) If it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food;
>
> (4) If it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;

(5) If it is, in whole or in part, the product of any poultry which has died otherwise than by slaughter;

(6) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

(7) If it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to 21 U.S.C. § 348;

(8) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or greater value than it is.

Labeling

USDA determines whether a product is misbranded or mislabeled.[220] A product is considered misbranded in any of the following circumstances:

(1) If its labeling is false or misleading in any particular;

(2) If it is offered for sale under the name of another food; or

(3) If it is the imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and immediately thereafter the name of the food imitated; or

(4) If its container is so made, formed, or filled as to be misleading;

(5) Unless it bears a label showing (A) the name and place of the business of the manufacturer, packer, or distributor; and (B) an accurate statement of the quantity of the product in terms of weight, measure, or numerical count: *Provided*, That under clause (B) of this subparagraph (5), reasonable variations may be permitted, and exemptions as to small packages or articles not in packages or other containers may be established by regulations prescribed by the Secretary;

(6) If any word, statement, or other information required by or under authority of this Act to appear on the label or other labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(7) If it purports to be or is represented as a food for which a definition and standard of identity or composition has been prescribed by regulations of the Secretary under section 8 of this Act unless (A) it conforms to such definition and standard, and (B) its label bears the name of the food specified in the definition and standard and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food;

(8) If it purports to be or is represented as a food for which a standard or standards of fill of container have been prescribed by regulations of the Secretary under section 8 of this Act, and it falls below the standard of fill of container applicable thereto, unless its label bears, in

such manner and form as such regulations specify, a statement that it falls below such standard;

(9) If it is not subject to the provisions of subparagraph (7), unless its label bears (A) the common or usual name of the food, if any there be, and (B) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient; except that spices, flavorings, and colorings may, when authorized by the Secretary, be designated as spices, flavorings, and colorings without naming each: *Provided*, That to the extent that compliance with the requirements of clause (B) of this subparagraph (9) is impracticable or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary;

(10) If it purports to be or is represented for special dietary uses unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary, after consultation with the Secretary of Health and Human Services, determines to be, and by regulations prescribes as, necessary in order to fully inform purchasers as to its value for such uses;

(11) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact: *Provided*, That to the extent that compliance with the requirements of this subparagraph (11) is impracticable, exemptions shall to established by regulations promulgated by the Secretary; or

(12) If it fails to bear on its containers, and in the case of nonconsumer packaged carcasses (if the Secretary so requires) directly thereon, as the Secretary may by regulations prescribe, the official inspection legend and official establishment number of the establishment where the article was processed, and unrestricted by any of the foregoing, such other information as the Secretary may require in such regulations to assure that it will not have false or misleading labeling and that the public will be informed of the manner of handling required to maintain the article in a wholesome condition.

Enforcement

The Act provides a maximum fine of $1,000, imprisonment for up to one year, or both, according to the violation.[221] In addition, violators who intend to defraud, or those who distribute or attempt to distribute articles of adulterated product may be subjected to a maximum fine of $10,000, imprisonment for up to three years, or both.[222] There are no provisions for civil penalties under the Act.

Preemption

The PPIA includes a state preemption provision that prohibits a state from imposing on federally inspected products markings, labels, packaging, ingredients requirements, or other requirements in addition to those prescribed under the Act.[223] States may not impose requirements exceeding those of the Act in regard to facilities, operations, inspection procedures, or products, or other requirements beyond those set forth in the Act.[224]

Egg Product Inspection Act (EPIA)

The 1970 EPIA[225] provides for the mandatory continuous inspection of the processing of liquid, frozen, and dried egg products.[226] The purpose of EPIA is to prevent "the entry into or flow or movement in commerce of, or the burdening of commerce by, any egg product which is capable of use

as human food and is misbranded or adulterated."[227] And to this end, the USDA "whenever processing operations are being conducted, [must] cause continuous inspection to be made...."[228]

Until recently, the Poultry Division of USDA's Agricultural Marketing Service (AMS) inspected egg products to "ensure they were wholesome, otherwise not adulterated, and properly labeled and packaged to protect the health and welfare of consumers."[229] However, on May 28, 1995, FSIS assumed responsibility for administering the statute. FSIS is responsible for inspecting all egg products used by manufacturers, food service, institutions, and retail markets – with the exception of those products exempted under the statute. (FDA is responsible for inspecting shell eggs, egg substitutes, imitation eggs, and similar products exempted from the continuous requirement under EPIA.)

The statute provides the Secretary authority to cause the "retention, segregation, and reinspection as he deems necessary of eggs and egg products capable of use as human food in each official plant."[230] (The processing of egg products includes breaking eggs, filtering, mixing, stabilizing, blending, pasteurizing, cooling, freezing or drying and packaging – all done at official plants.[231]) The statute provides for such inspection "at food manufacturing establishments, institutions, and restaurants, other than plants packing eggs."[232] The statute also provides for the "inspection of business premises, facilities, inventory, operations, and records of egg handlers; inspection of records and inventory of others required to keep records; authority of Secretary of Health and Human Services to inspect food manufacturing establishments, institutions, and restaurants; access to places of business."[233]

Furthermore, the statute allows the Secretary to cause "other inspections to be made of the business premises, facilities, inventory, operations, and records of egg handlers, and the records and inventory of other persons required to keep records under section 1040 [of the PPIA], as he deems appropriate (and in the case of shell egg packers, packing eggs for the ultimate consumer, at least once each calendar quarter) to assure that only eggs fit for human food are used for such purposes...."[234]

The statute deems a "plant processing egg products" as "any food manufacturing establishment, institution, or restaurant which uses any eggs that do not meet the requirements of section 1044(a)(1)... in the preparation of any articles for human food."[235] Eggs and egg products found to be adulterated at such official plants are condemned and destroyed (in the absence of an appeal) for human food purposes under the supervision of an inspector.[236] But if an appeal is made, the eggs or egg products are appropriately marked and segregated pending completion of an appeal inspection.

THE ENVIRONMENTAL PROTECTION AGENCY (EPA)

The EPA is responsible for the registration of all pesticides sold or distributed domestically and for the establishment of tolerances for pesticide residues in or on food commodities and animal feed. Farmers use nearly 815 million pounds of pesticide-active ingredients—those that destroy or control pests—annually in the United States alone.[237] The Office of Pesticide Programs (OPP), a branch of EPA's Office of Pesticides and Toxic Substances, is responsible for the overall management of the agency's pesticide regulatory responsibilities under FIFRA and FDCA.[238] EPA works in partnership with other regulatory agencies. While EPA establishes pesticide residue tolerances, FDA (for processed foods) and FSIS (for meat and poultry) enforce them.[239]

EPA's food safety responsibilities are authorized by two principal statutes: The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the FDCA.[240] There are four primary aspects of these laws. First, no pesticide residues may be sold for use on food crops or in food processing unless it has been registered under FIFRA. Second, any such pesticide that is intended for use on a "raw agricultural commodity" must be the subject of a tolerance established under FDCA. Third, a pesticide approved for use on a raw agricultural commodity must also be the subject of a food additive regulation when the commodity is present in a processed food – unless the concentration of the pesticide does not exceed the established tolerance level (as delineated in FDCA section 408). Fourth, "where a pesticide is lawfully applied to a 'target' commodity but a residue also occurs in another 'nontarget' food... an FDCA section 406 action level must be established to control it."[241] At the request of FDA or USDA, EPA also recommends enforcement levels—"action levels"—for residues occurring in food

commodities and animal feed for reasons other than the direct application of a pesticide. But it is FDA that formally establishes action levels under FDCA section 406.

FIFRA

Under FIFRA, the most significant EPA responsibilities are the registering of pesticide products and setting of tolerance levels (other responsibilities include the specification of the terms and conditions of pesticide use prior to being marketed, and the removal of unreasonably hazardous pesticides from the marketplace). In effect, EPA is required to ensure that when pesticides are used according to directions, they will not present unreasonable risks to human health or the environment. The act also requires EPA to account for the economic and environmental costs and benefits in its regulatory decisions.

FIFRA requires that, "no person in any State may distribute or sell to any person any pesticide that is not registered.... To the extent necessary to prevent unreasonable adverse effects on the environment, the Administrator may by regulation limit the distribution, sale, or use in any State of any pesticide that is not registered...."[242]

EPA requires pesticide producers to submit health and environmental effects data and information to evaluate the risks and benefits of pesticides and to make regulatory judgments about the safety of each pesticide proposed for use.

FDCA

Under the FDCA, EPA is responsible for setting maximum allowed residue tolerance levels for pesticide residues found on food commodities and animal feed marketed in the United States.

Establishing Pesticide Tolerances. Under the FDCA, any pesticide chemical residues (in or on a food) are considered adulterated unless the EPA has issued a tolerance. The statute also considers a pesticide to be "adulterated," if "its strength or purity falls below the professed standard of quality as expressed on its labeling under which it is sold."

Under FDCA, the EPA may only grant a tolerance, if a pesticide is "safe." As in the realm of food additives, safety is defined as a "reasonable certainty" that no harm will result from aggregate exposure to the residue.[243] However, if an exemption for the requirement for a tolerance is in effect for a pesticide chemical residue on a raw agricultural commodity, the residue is not considered unsafe within the meaning of the statute.[244]

Significantly, the FDCA requires EPA to weigh the risks posed by the pesticide residue against the economic and health benefits of the pesticide. In particular, the statute requires that the use of "the pesticide chemical that produces the residue protects consumers from adverse effects on health that would pose a greater risk than the dietary risk from the residue" and that "the use of the pesticide chemical that produces the residue is necessary to avoid a significant disruption in domestic production of an adequate, wholesome, and economical food supply."[245]

Exposure of Infants and Children. In 1996, Congress passed the Food Quality Protection Act that strengthened the FDCA's safety standard for foods disproportionately consumed by infants and children.[246] In establishing, modifying, leaving in effect, or revoking a tolerance or exemption for a pesticide chemical residue, the statute provides that the agency assess the risk of the pesticide residue based on "(I) available information about consumption patterns among infants and children that are likely to result in disproportionately high consumption of foods containing or bearing such residue among infants and children in comparison to the general population; (II) available information concerning the special susceptibility of infants and children to the pesticide chemical residues, including neurological differences between infants and children and adults, and effects of in utero exposure to pesticide chemicals; and (III) available information concerning the cumulative effects on infants and children of such residues and other substances that have a common mechanism of toxicity."[247]

Factors for Establishing Tolerance. The statute delineates several factors in establishing, modifying, leaving in effect, or revoking a tolerance or exemption for a pesticide residue. The factors are:

(i) The validity, completeness, and reliability of the available data from studies of the pesticide residue;
(ii) the nature of any toxic effect shown to be caused by the residue;
(iii) available information concerning the relationship of the results of such studies to human risk;
(iv) available information regarding the dietary consumption patterns of consumers (as well as major identifiable subgroups of consumers);
(v) available information on the cumulative effects of such residues and other substances that have a common mechanism of toxicity;
(vi) available information concerning the aggregate exposure levels of consumers to pesticide residues and other related substances, including dietary exposure under the tolerance, and exposure from other non-occupational sources;
(vii) available information concerning the variability of the sensitivities of major identifiable subgroups of consumers;
(viii) information on whether the pesticide chemical may have an effect in humans similar to an effect produced by a naturally occurring estrogen or other endocrine effects; and
(ix) safety factors which are generally recognized as appropriate for the use of animal experimentation data.[248]

Furthermore, the statute provides that the agency, when assessing chronic dietary risk, consider available data and information on the percent of food actually treated with the pesticide chemical (including aggregate pesticide use data collected by USDA).[249]

Petitions. The FDCA delineates a set of requirements for petitioning EPA to establish a tolerance (or exemption). The requirements as such outline the data and information required for EPA to weigh the health risks and health and economic benefits of the pesticide. For example, petition requirements include data showing the recommended amount, frequency, method, and time of application of the pesticide chemical, as well as full reports of tests and investigations made with respect to the safety of the pesticide chemical (including full information as to the methods and controls used in conducting those tests and investigations).[250]

FDCA also provides that the EPA give priority in the petitioning process to applications establishing or modifying a tolerance or exemption for a pesticide residue that "appears to pose a significantly lower risk to human health from dietary exposure than [residues] that have tolerances in effect for the same or similar uses."[251]

Types of Food Safety and Quality Activities Carried Out by Principal Federal Agencies

Activity	FDA	USDA AMS	USDA FGIS	USDA FSIS	EPA	NMFS
Inspections	X	X	X	X	X	X
Quality grading	•	X	X	•	•	X
Collect/analyze samples	X	X	X	X	X	X
Research	X	•	•	•	X	X
Develop standards for:						
Foods/crops	X	X	X	•	•	X
Facilities	X	X	•	X	•	•
Equipment	•	X	X	X	•	•
Processing procedures	X	X	•	X	•	•
Labels	X	X	•	•	X	•
Packaging	•	X	•	•	X	X
Approve before use:						
Facilities	•	X	•	X	•	•
Equipment	•	X	X	X	•	•
Processing procedures	•	X	•	X	•	•
Product recipes/formulas	•	X	•	X	•	X
Labels	•	X	•	X	X	•
Packaging	•	X	•	•	•	•
Food colors/additives	X	•	•	•	•	•
Animal drugs/food additives	X	•	•	•	•	•
Pesticide products	•	•	•	•	X	•
Set residue tolerances for:						
Pesticides	•	•	•	•	X	•
Other contaminants	X	•	•	•	•	•

[a]Agricultural Research Service carries out research for AMS, FGIS, and FSIS.

Federal Agencies Responsible for Regulating, Monitoring, or Performing Quality Grading Services for Various Food Industries

		USDA				
Food industry	**FDA**	**AMS**	**FGIS**	**FSIS**	**EPA**	**NMFS**
Dairy	X	X	•	•	X	•
Eggs/egg products	X	X	•	•	X	•
Fruits/vegetables	X	X	•	•	X	•
Grain/rice/pulses	X	•	X	•	X	•
Interstate conveyances	X	•	•	•	•	•
Meat and poultry	•	X	•	X	X	•
Restaurants	X	•	•	•	•	•
Seafood	X	•	•	•	X	X

Principal Food Safety and Quality Legislation and Federal Agencies Responsible for Implementation

		USDA				
Legislation[a]	**FDA**	**AMS**	**FGIS**	**FSIS**	**EPA**	**NMFS**
Agricultural Marketing Act of 1946 (AMA)	•	X	X	•	•	X
Agricultural Marketing Agreement Act of 1937	•	X	•	•	•	•
Egg Products Inspection Act (EPIA)	X	X	•	•	•	•
Federal Anti-Tampering Act	X	X	•	X	•	•
Federal Food, Drug, and Cosmetic Act (FFDCA)	X	•	•	•	X	•
Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)	•	•	•	•	X	•
Federal Meat Inspection Act (FMIA)	•	•	•	X	•	•
Federal Import Milk Act	X	•	•	•	•	•
Infant Formula Act of 1980	X	•	•	•	•	•
Lacey Act	•	•	•	•	•	X
Magnuson Fishery Conservation and Management Act	•	•	•	•	•	X
National Ocean Pollution Research and Development and Monitoring Planning Act	•	•	•	•	•	X
Pesticide Monitoring Improvements Act	X	•	•	•	•	•
Poultry Products Inspection Act (PPIA)	•	•	•	X	•	•
Public Health Service Act (PHSA)	X	•	•	•	•	•
Safe Drinking Water Act	X	•	•	•	X	•
Toxic Substances Control Act	•	•	•	•	X	•
U.S. Grain Standards Act (USGSA)	•	•	X	•	•	•

[a]This lists 18 of the principal laws administered by these six agencies, which also administer 10 other less significant food safety and quality laws.

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C

Divider Title: _____

C. SOURCES OF SELECTED FOODBORNE PATHOGENS

Pathogen	Primary Food Sources	Minor Food Sources
Campylobacter	Poultry	Milk, mushrooms, clams, hamburger, water, cheese, pork, shellfish, eggs
Clostridium	Meat and poultry	Beans, seafood
E. coli 0157:H7	Ground beef	Poultry, apple cider, raw milk, vegetables, cantaloupe, salad bar items
Listeria	Soft cheese, meat	Poultry, dairy products, poultry, seafood, vegetables
Salmonella	Poultry, meat, eggs, milk	Vegetables, fruits, chocolate, peanuts, shellfish
Staphylococcus aureus	Workers handling meat, poultry, fish	Dairy products, salad dressing, ham, salami, bakery items, cheese

Source: JEAN C. BUZBY, ET AL., BACTERIAL FOODBORNE DISEASE: MEDICAL COSTS & PRODUCTIVITY LOSSES--AN ECONOMIC RESEARCH SERVICE REPORT (1996).

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D

Divider Title: _____

D. MAJOR FOOD SAFETY AGENCY SPENDING: FY 1995 - FY 1999

($ MILLIONS—UNADJUSTED FOR INFLATION)

Note	Agency	1995	1996	1997	1998 (est.)	1999 (proposal)
(a)	FSIS	$522	$533	$570	$589	$618
(b)	FDA (CSFN)	216	201	191	204	250
(c)	EPA (OPPS)	n/a	196	129	94	76
(d)	ARS	745	739	726	743	772
(e)	AMS	222	198	200	211	224
(f)	APHIS	520	508	489	406	462
(f)	CDC	2,220	2,259	2,396	2,420	2,533
(g)	ATF	64	60	82	80	87
(h)	NMFS	288	349	354	387	351
(i)	FTC	53	31	28	37	59

SOURCE: U.S. OFFICE OF MANAGEMENT AND BUDGET, BUDGET OF THE UNITED STATES, FY 1999 (1998), FY 1998 (1997), FY 1997 (1996).

(a) Includes $449 million of inspection user fees in FY 99.

(b) FDA outlays for food programs. Includes approximately $50 million for food safety user fees in FY 99.

(c) EPA food safety programs (primarily pesticides). Does not include water safety.

(d) Not all spending is food safety research.

(e) Inspection, research, and pesticide record-keeping programs.

(f) Not all spending is food safety-related.

(g) ATF alcohol programs (includes safety, tax collection, and registration). FY 98 & 99 spending estimated.

(h) Primarily fishery conservation programs. Voluntary seafood inspection program funded by user fees.

(i) FTC consumer protection spending (includes non-food enforcement).

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E

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E. COSTS AND BENEFITS OF SIGNIFICANT FOOD SAFETY AGENCY CONSOLIDATION

	Costs	Benefits	Benefits Possible w/out Consolidation?
Short-Term	Labor uncertainty among inspectors→ health and efficiency lapses		
	Physical costs: moving, new stationary, new communications, IT systems integration, etc.		
	Cultural clashes among employees from different agencies		
	Political: Cong. committees fight over jurisdiction and harm chances for underlying statutory change		
Long-Term	Possible detachment of USDA agencies decreases inspection, enforcement, and research funding	One agency for food safety may have better leverage in negotiating for funding	No
	Add personnel to former agencies that depend peripherally on personnel moved due to merger (e.g., APHIS)	Synergistic workforce reduction (e.g., inspection, research, risk assessment, administration)	No
		Better communication, regulatory planning, and cooperation	Yes
		Enhanced accountability	Yes
		Enhanced ability to allocate resources based on risk	Yes

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F

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F. CASE STUDIES: CANADIAN AND BRITISH MODELS FOR CONSOLIDATION

The United States is not the only nation that has faced the difficulties posed by a fragmented food safety system. Recently, Canada and the United Kingdom (UK) have introduced plans to reform to their respective systems. Canada has passed legislation that will eventually consolidate all food inspection responsibilities into one agency. The UK, responding to the crisis caused by Bovine Spongiform Encephalitis (BSE), is planning to form a new, independent food agency that will advise the Minister of Health in implementing food safety programs. Significantly, the implementation of both proposals are aided by the existence of parliamentary governments in both Canada and the UK. As a result of the constitutional structure of parliamentary governments, the Prime Minister can generally impose his or her policies at will. Therefore, many of jurisdictional barriers to consolidation in Canada and the UK are not as important—from a policy evaluation perspective—as they are in the United States.

THE CANADIAN FOOD INSPECTION AGENCY

Recent changes in the Canadian food safety system may provide an effective model of consolidation for the United States. The Canadian government has recently consolidated all federally-mandated food inspection and quarantine services into a single federal food inspection agency. The Canadian Food Inspection Agency (CFIA) began operations in April 1997, reporting to Parliament through the Minister of Agriculture and Agri-Food. The public agency (technically a departmental corporation) is currently headed by President Dr. Art Olson who directs its daily operations. An advisory board will eventually be created to advise the Minister.

Policy makers sought to enhance the Canadian food safety system by merging the inspection functions provided formerly by Agriculture and Agri-Food Canada, Health Canada, Industry Canada, and the Department of Fisheries and Oceans Canada. While all inspection services related to food safety are provided by CFIA, the responsibility for food safety policy, standard-setting, risk assessment, analytical testing research and audit are reinforced and remain with Health Canada.

Goals of the Consolidation

Parliament is attempting to achieve several goals through food inspection consolidation. First, the new system should enhance food safety and public health by creating an inspection force that is integrated, focused, and clearly defined in regard to accountability. CFIA expects increased consistency in the food safety system, including the application of risk-based inspection programs and cost recovery.[252] Thus, the goal of the CFIA is not only to mitigate food-related illness, but also to provide Canadian citizens greater access, reliability, and accountability to the food safety system. Moreover, CFIA believes that an integrated inspection system will also allow Canadian companies to better respond to the changing demands of the international marketplace, thereby gaining a competitive advantage in capturing trade opportunities.[253]

Second, policy makers are attempting to increase efficiency and effectiveness in the inspection system by deploying resources to "priority areas," as well as focusing on reducing overlap and duplication in areas such as management, corporate overhead, enforcement, risk management and laboratory services. Implementation includes a focus on streamlining training procedures for its inspection force. Approximately 4,500 FTE's from three departments—3,900 from Agriculture and Agri-Food Canada, 400 from Fisheries and Oceans, and 200 from Health Canada will became a part of the Agency. CFIA expects that the establishment of a more efficient use of federal resources will lead to fiscal savings of $44 million beginning in 1998-99.[254] The former system, which involved over 5,000 people in three departments, cost over $400 million annually.[255]

The consolidation is also expected to encourage greater collaboration and coordination between federal and provincial governments. For example, the consolidation facilitates the harmonizing of standards among federal, provincial, and municipal governments.

A Short History of the Consolidation Effort

More effective and efficient delivery of food inspection services in Canada has long been an issue of concern within the federal government. The issue was examined in the *1994 Program Review and Auditor's General Report*. Later, the 1995 Federal Budget highlighted the need to resolve the issue by directing the federal departments involved in food inspection to improve performance. The Office of Food Inspection Systems (OFIS) was established in May 1995 to review organizational options for change.

Statutory Authority

CFIA was created in part to administer and/or enforce twelve existing pieces of food-related legislation.[256] The agency, under the Minister of Agriculture and Agri-Food, is given statutory authority in five main areas. First, CFIA can require the recall of an unsafe food product, diseased animal, or plant that poses a risk to public, animal, or plant health. Second, the agency can procure goods and services from providers outside the federal government. Third, the agency can apply to a court for an interim injunction to prevent a contravention of the provisions of the statutes for which it is responsible. Fourth, the agency can fix and collect fees. Fifth, the agency can withdraw or withhold services should a client fail to pay a prescribed fee. By contrast, in the United States, FDA has attempted unsuccessfully to grow its food safety budget through the use of user fees.[257]

Institutional Structure

The organizational structure of the Canadian food safety system largely mimics the constitutional structure of its government. Canada is a constitutional monarchy consisting of a federal government and ten provincial legislatures and two territorial. Accordingly, various committees compose the regulatory agencies: provincial, territorial, and federal. For example, there is a HP/Provincial/Territorial Committee on Food Safety that deals with inspection issues of national significance, namely inspection procedures, training, uniformity of standards, and reporting.[258] Additionally, there is a Food Safety Committee consisting of federal and provincial agencies with responsibility for coordinating the implementation of the inspection activities.[259]

Summary

By consolidating its inspection resources into one agency, Canada is attempting to improve health and efficiency through merger. Lacking the numerous political obstacles and entrenched bureaucracies that typify the food safety system in the United States, Canada has responded to fragmentation with decisiveness. Legislators and food safety regulators in the United States should monitor the success or failure of the CFIA in an attempt to predict the likely outcome of consolidation in our own system.

THE BRITISH FOOD STANDARDS AGENCY

Like Canada, the United Kingdom has recently focused attention on its food safety regulatory system. In January, the Government published a white paper detailing a plan to create a new public body—the Food Standards Agency.

Primary responsibility for food safety in the UK currently lies with the Ministry of Agriculture, Fisheries, and Food (MAFF), with the Health and Environment departments assuming subsidiary

responsibilities. Similar in function to the USDA, MAFF carries a dual responsibility for protecting public health and promoting the agriculture and food industries.

With several well-publicized microbiological outbreaks, including Salmonella, Listeria, and most dramatically, BSE, public confidence in the food supply has fallen.[260] Critics have identified three problems with the existing system:

- the potential conflict of interest within MAFF due to its dual role;
- fragmentation and lack of coordination between the several bodies responsible for food safety;
- uneven enforcement of food law.[261]

Members of Parliament have offered several plans to improve MAFF's food safety regulation.[262] These proposals include: vastly increasing MAFF's resources and personnel; conversely, dramatically cutting MAFF's resources and personnel; and splitting MAFF's public health functions from its industry support by creating an independent food safety agency.[263] The free-standing Food Standards Agency has emerged as the dominant proposal, but not without criticisms. In particular, the lack of ministerial accountability has created the concern that this new agency would have little authority.[264]

The Food Standards Agency (FSA), as proposed by Prime Minister Tony Blair, will be primarily a research, standard setting, and advisory body. Additionally, the FSA will hold certain licensing and approval responsibilities in specific areas such as meat and milk hygiene, food additives, and chemical contaminants. FSA's four general task areas would include policy advice, research and surveillance, general food law enforcement, and public information and education.[265] Following is a summary of the proposed role of the FSA as set out in a recent government white paper:

- **Policy Advice and Legislation.** The FSA will provide advice to ministers on food safety, standards, and nutrition. Health Ministers are expected to draft legislation acting on the agency's advice.

- **Research and Surveillance.** The agency will play a leading role in developing and implementing national policy to control those animal diseases that may be passed through food. FSA will also have the authority to carry out its own surveillance.

- **Food Inspection and Approval.** The FSA will be responsible for licensing meat plants, and it will assume responsibility over the Meat Hygiene Service. The agency will also assume responsibility for all matters concerning food additives and chemical contaminants. FSA will assume the Agriculture Minister's responsibilities for issuing consents for the release of genetically modified organisms intended for food and animal feed. The agency will also be responsible for licensing and inspecting food irradiation facilities. With the exception of meat hygiene, local authorities will remain responsible for day-to-day enforcement, but the agency will work with them to encourage enforcement consistency.

- **Public Information and Education.** The FSA will work closely with other bodies in providing public information and supporting health promotion and education activities.

Summary

Responding to public outrage over the recent BSE crisis, Prime Minister Blair has proposed an organizational structure intended to address concerns that MAFF has bowed to its agricultural constituency in regulating food safety. While the Blair proposal, which is expected to pass in

Parliament early next year, may resemble consolidation by creating a new independent agency, the UK food safety system will still be fragmented. Both MAFF and the Ministry of Health will continue to hold substantial responsibilities over food safety. However, the creation of an independent council with pure public health goals is intended to assuage public fears and begin a removal of food safety powers from the beleaguered MAFF.

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G

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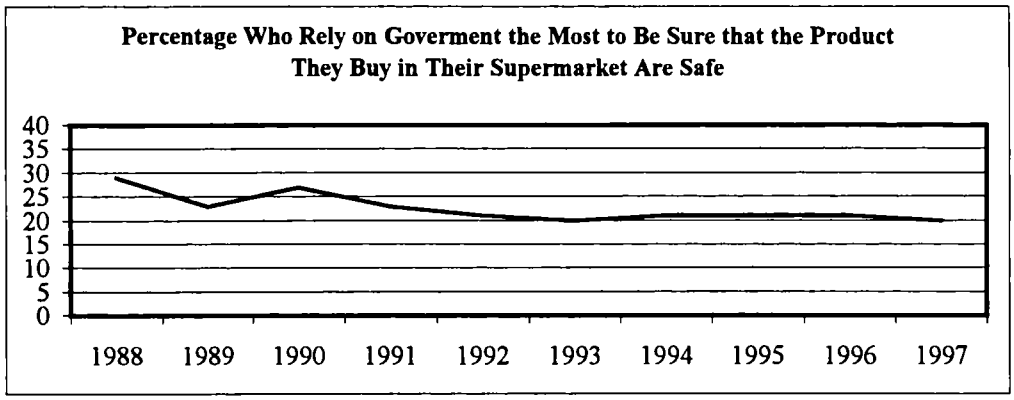
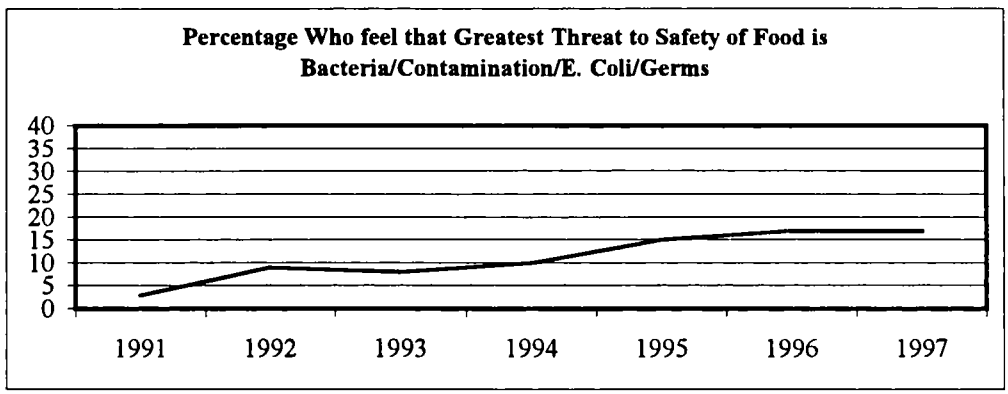
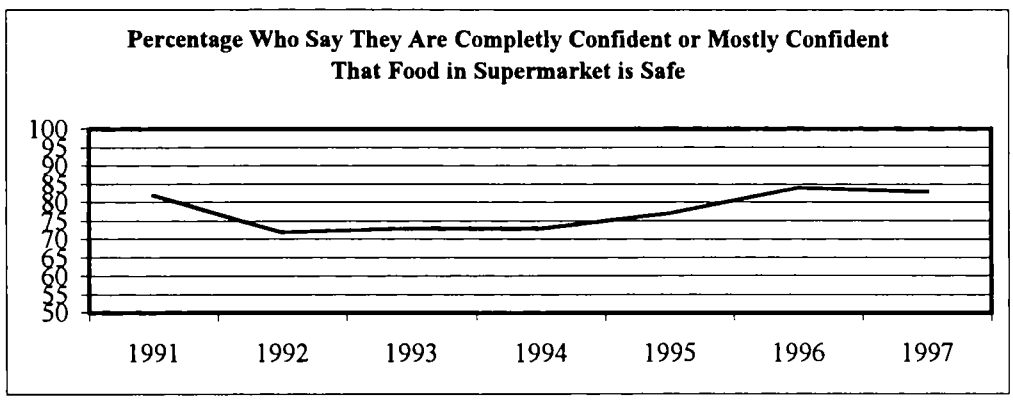
G. FOOD SAFETY PUBLIC OPINION DATA



Source: FOOD MARKETING INSTITUTE, TRENDS IN THE UNITED STATES: CONSUMER ATTITUDES AND THE SUPERMARKET (1994 & 1997)



Source: FOOD MARKETING INSTITUTE, TRENDS IN THE UNITED STATES: CONSUMER ATTITUDES AND THE SUPERMARKET (1997)



Source: TRENDS IN THE UNITED STATES: CONSUMER ATTITUDES AND THE SUPERMARKET (1994 & 1997)

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H

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H. CASE STUDY: THE FINANCIAL MARKETS WORKING GROUP[266]

Shortly after the stock market crash of 1987, President Reagan responded to the widely perceived problem of non-coordination in financial markets regulation by establishing an interagency committee of the major participants. This case study describes this interagency committee, the Working Group on Financial Markets (WGFM), and attempts to draw lessons from the experience of this group which is composed of three independent regulatory agency chairmen plus one cabinet secretary. As is described in the Executive Order (attached) that established the WGFM, the Group is composed of representatives of the Department of the Treasury, the Securities and Exchange Commission (SEC), the Commodities Futures Trading Commission (CFTC), and the Federal Reserve Bank.[267]

MANY REGULATORS

The financial markets are regulated by several agencies with distinct roles, cultural traditions, authorizing statutes, and congressional committee oversight. The SEC is an independent (non-cabinet) agency that regulates the stock and bond markets. The SEC's most significant regulated organization is the New York Stock Exchange (NYSE). However, futures—contracts for future delivery of commodities and other goods—are regulated by the CFTC. Included among the tradable items that the CFTC oversees are futures on market indices such as the S&P 500. Such futures are traded on the Chicago Board of Trade (CBOT); yet the securities that create the underlying value behind these index options are traded on stock exchanges regulated by the SEC. Like the SEC, the CFTC is also an independent agency; however, with its focus on commodities, the CFTC has tended to guard its turf jealously against infringement by the "Wall Street Boys" of the SEC.

A third major actor in financial markets regulation is the Federal Reserve Bank system. The Fed regulates major banks that are designated members of the Federal Reserve system. Moreover, the Fed sets and enforces standards for the bank clearinghouses that collect and distribute the margin payments that result from futures speculation. (Futures traders must pay a certain percentage of their at-risk capital to a clearinghouse; as their relative positions change, they must either put up more cash on margin—as their positions decrease in value—or receive money from their trading counterparty via the clearinghouse.) The Fed is also an independent agency.

THE CRASH OF '87

On October 19, 1987 (Black Monday), the Dow Jones Industrial Average fell by 23%, the largest one-day drop ever in percentage terms. In the months following Black Monday, several commissions studied the causes of the crash, and many cited regulatory non-coordination as an exacerbating factor. Researchers of the crash noted that some of the most active trading on and around Black Monday included investors who sought to benefit from differences in the value of futures traded in Chicago (and regulated by the CFTC) and portfolios of underlying securities traded in New York (and regulated by the SEC). Yet the two major exchanges (NYSE and CFTC) were operating under two different sets of rules and answered to different masters.

THE WORKING GROUP ON FINANCIAL MARKETS

Because of the perceived problem of regulatory non-coordination, President Reagan ordered the establishment of an interagency committee, the WGFM, to hash out a unified policy on the regulation of financial instruments that seemed to sit on the jurisdictional fence between the SEC and CFTC and other regulators. Since none of the agencies (or their respective congressional committees) was about to give away any turf, and since the only truly neutral agency of the group—the powerful, yet politically vulnerable Fed—wanted to avoid the enlarging of its portfolio, the WGFM became a policy

coordinating body. The Secretary of the Treasury was chosen as an "honest broker" to chair the Working Group, because Treasury was viewed as the most neutral agency after the Fed.

The Early Years: No Formal Mandate to Cooperate

Significantly, the early years of the WGFM were seen as a failure because of the people who comprised the group. Since the Working Group has no statutory mandate or formal order to cooperate, the success of the committee depends on personalities. This would be true of any informal interagency committee. In the case of the WGFM, the respective chairs of the SEC and CFTC could barely sit in the same room together. After a brief period in which the Group created policies to rectify the perceived market failures of 1987, the WGFM stopped meeting regularly.

The Clinton Years

The Clinton Administration has successfully reincarnated the WGFM. Under the leadership of Treasury Secretary Robert Rubin, the Working Group has successfully coordinated several interagency policies, including a recent update to the circuit breaker rules of the NYSE and CBOT.[268] Significantly, the WGFM forged a new policy to govern the closing of the NYSE and other markets in the case of a market crash. With the strength of a unified group of regulators, the WGFM persuaded the NYSE to change its rules governing such market failures. Moreover, in testimony on the Hill, SEC chairman Arthur Levitt has used the unity of the Working Group as a powerful means of persuasion among legislators. Currently, the principles of the WGFM meet monthly, while designated staff from the Treasury Department, Fed, SEC, and CFTC meet every other week.

LESSONS FROM THE WORKING GROUP ON FINANCIAL MARKETS

The experience of the WGFM provides several lessons that may be useful in enhancing coordination among the food safety regulators:

- Interagency committees, under certain conditions, can serve as a second-best solution to regulatory coordination problems, when merger is not an option.
- The success of an interagency committee, when not controlled by statute, depends on the ability of individuals in the group to cooperate.
- It is critical to find a neutral party to chair the group in order to handle effectively turf issues and mediate disputes.

Title 3 --

The President
Working Group on Financial Markets

Executive Order 12631 of March 18, 1988

53 FR 9421

March 22, 1988

TEXT: Executive Order 12631 of March 18, 1988

Working Group on Financial Markets

By virtue of the authority vested in me as President by the Constitution and laws of the United States of America, and in order to establish a Working Group on Financial Markets, it is hereby ordered as follows:

Section 1. Establishment. (a) There is hereby established a Working Group on Financial Markets (Working Group). The Working Group shall be composed of:

(1) the Secretary of the Treasury, or his designee;

(2) the Chairman of the Board of Governors of the Federal Reserve System, or his designee;

(3) the Chairman of the Securities and Exchange Commission, or his designee; and

(4) the Chairman of the Commodity Futures Trading Commission, or her designee.

(b) The Secretary of the Treasury, or his designee, shall be the Chairman of the Working Group.

Sec. 2. Purposes and Functions. (a) Recognizing the goals of enhancing the integrity, efficiency, orderliness, and competitiveness of our Nation's financial markets and maintaining investor confidence, the Working Group shall identify and consider:

(1) the major issues raised by the numerous studies on the events in the financial markets surrounding October 19, 1987, and any of those recommendations that have the potential to achieve the goals noted above; and

(2) the actions, including governmental actions under existing laws and regulations (such as policy coordination and contingency planning), that are appropriate to carry out these recommendations.

(b) The Working Group shall consult, as appropriate 5, 0 with representatives of the various exchanges, clearinghouses, self-regulatory bodies, and with major market participants to determine private sector solutions wherever possible.

(c) The Working Group shall report to the President initially within 60 days (and periodically thereafter) on its progress and, if appropriate, its views on any recommended legislative changes.

Sec. 3. Administration. (a) The heads of Executive departments, agencies, and independent instrumentalities shall, to the extent permitted by law, provide the Working Group such information as it may require for the purpose of carrying out this Order.

(b) Members of the Working Group shall serve without additional compensation for their work on the Working Group

(c) To the extent permitted by law and subject to the availability of funds therefor, the Department of the Treasury shall provide the Working Group with such administrative and support services as may be necessary for the performance of its functions.

/s/Ronald Reagan

THE WHITE HOUSE,

March 18, 1988.

[FR Doc. 88-6380

Filed 3-21-88; 11:23 am

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I

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I. SEAFOOD: A CASE STUDY

The conflicts over the proposed transfer of federal seafood regulation in the late 1980s and early 1990s present an instructive example of the political difficulties involved in transferring regulatory authority and congressional jurisdiction among distinct, constituent-driven organizations. These political difficulties—in a case that seems far less sensitive than the proposals of wholesale consolidation among all the food safety agencies—indicate the depth of political risks associated with proposals to reorganize the federal food safety system.

DECLINING PUBLIC CONFIDENCE

In the late 1980's, press reports of contaminated coastal waters and of sicknesses and deaths due to contaminated seafood began to focus public attention on seafood safety.[269] The consumer advocacy group Public Voice for Food and Health Policy issued a report entitled *The Great American Fish Scandal*[270] that claimed to document the government's inadequate inspection of seafood. In 1988, for the first time in seven years, seafood consumption fell.[271] Many in the seafood industry attributed this dip in consumption to declining public confidence in seafood, and called on government measures to assure the public of seafood safety.[272]

So with the unusual support of both consumer groups, such as Public Voice, as well as industry groups, such as the National Fisheries Institute (NFI), Congress began in 1989 to consider bills to step up regulation of the seafood industry.[273] Over the course of 1989 and 1990, nine bills were introduced in the House and the Senate that would have strengthened the existing program. Under the existing system, both the FDA and the National Marine Fisheries Service (NMFS) administered safety programs; NMFS operated a voluntary seafood inspection system funded by user fees, while FDA retained overall jurisdiction.[274] However, five of the nine reorganization proposals designated USDA as the primary responsible agency.

SHARED CONGRESSIONAL OVERSIGHT

Five House and Senate authorizing committees and subcommittees—the House Agriculture, Merchant Marine and Fisheries, and Energy and Commerce Committees and the Senate Agriculture and Commerce Committees—battled over seafood jurisdiction.[275] The Senate favored a bill introduced by Senate Majority Leader Mitchell that would have placed USDA in the role of lead seafood agency. The House favored a bill introduced by Congressmen John Dingell and Gerry Studds that would have kept seafood regulation with FDA and NMFS.

Constituent groups split over which agency should hold primary responsibility. The NFI favored USDA leadership, while consumer groups such as the AFL-CIO, Public Citizen, and Consumers Union favored the public health mandate of FDA.[276] Congress failed to reconcile the two competing bills before the 1990 election day recess and the proposal languished until 1992.[277]

In 1992, Congressional attention focused once again on seafood safety, when press coverage reported the preliminary results from the first complete inspection of American seafood processing facilities that was conducted by FDA's newly created Office of Seafood.[278] As many as 20% of the samples showed evidence of microbiologic contamination,[279] and Consumers Union[280] released a report criticizing the federal government's efforts in seafood regulation. Senator Mitchell and the leaders of three other Senate Committees introduced a bill dividing authority between USDA, FDA, and NOAA.[281] Congress once again failed to act because the proposal to split jurisdiction brought opposition from the NFI and the division of authority proved irreconcilable in the House.[282]

LESSONS FOR TODAY

The attempt by Congress to change federal regulation of seafood is very similar to today's proposal to unify the food safety agencies. Both deal with the complexities of food safety regulation, and its myriad statutes, agencies, and oversight committees. Major changes require that policy makers address each of these facets, and in particular overcome the congressional committee territoriality. Both issues also faced increasing public salience. In the seafood case, this increased public concern was expressed in the marketplace, through declining sales.[283] Today the general issue of food safety seems to be gathering the attention of the popular press and has been reflected in some public opinion polls and news reports.

In one sense, the seafood issue had the benefit of several favorable conditions that the single food agency proposal does not. Rising concern about seafood safety is a relatively simpler issue for Congress to address, with a more obvious corollary—tighter regulation. Coordination in food regulation is not as clear of a problem, and a consolidated agency is not the only obvious corollary. Congress began to act quickly on seafood regulation, because there was a rare consensus between consumer and industry groups on the need for tighter regulation. Based on our interviews with industry, consumer, and labor groups, there is no such consensus for a single food agency. Perhaps most importantly, there are fewer committees involved in seafood regulation oversight, and the committees have much less at stake in seafood regulation than they do in food safety regulation as a whole.

Yet, even with more favorable conditions, Congress failed in its two attempts to make major changes to seafood regulation. This failure offers two important lessons for our analysis. First, shifting committee jurisdictions is very difficult. The seafood case confirms for food safety regulation what we already know from countless other failed attempts to make major changes through Congress. It is ultimately the loss of committee authority that killed seafood reform. Changes that shift committee jurisdictions are the exception rather than the rule. Second, there must be a strong impetus for congressional action, and even then action is unlikely. With many issues competing for attention, Congress can deal with only a handful of issues. The higher the stakes (e.g., public salience, painful changes in committee jurisdiction, etc.), the greater the external impetus must be. Seafood regulation had to compete with tax reform and the budget battle for congressional attention. It was only with an unusual alignment of consumer and industry interests that Congress began to act on changing seafood regulation. This alignment began to unravel when the details of reorganization emerged, with consumer groups favoring FDA and industry favoring USDA.

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J

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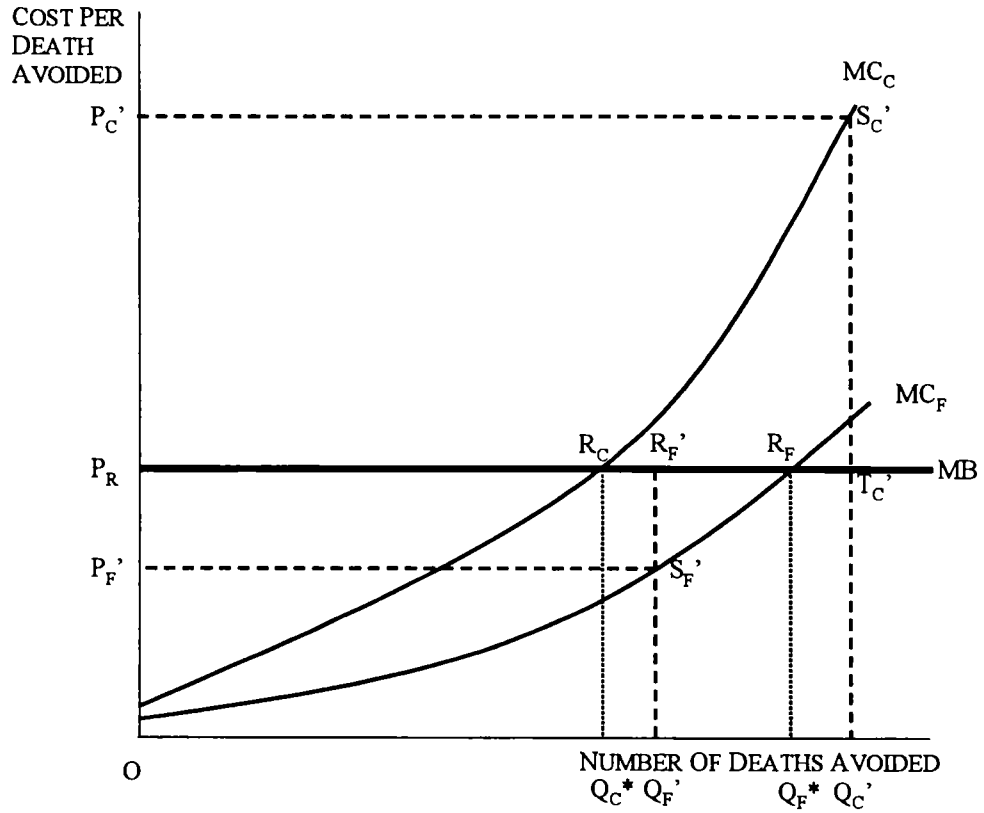
J. AN ECONOMIC REPRESENTATION OF THE INEFFICIENCY OF CONTINUOUS INSPECTION



The diagram above illustrates the marginal costs and benefits of USDA carcass-by-carcass inspection and FDA inspection. The x-axis represents the number of deaths avoided through USDA and FDA inspections. The y-axis displays the costs of inspection. The marginal benefits of inspection are represented by the flat curve *MB*.[284] The zero slope of line MB represents our assumption that each death avoided is worth the same amount.

The marginal costs of USDA carcass-by-carcass inspection are represented by the curve MC_C, while the marginal costs of FDA inspection are represented by the curve MC_F. The upward slope of these two cost curves demonstrates the increasing marginal cost of inspection. The different slopes of the two curves represents the higher marginal costs of USDA's on-site carcass inspection methods vis-a-vis FDA's sampling inspection processes. The superficial USDA "poke and sniff" methods are a relatively costly way of avoiding deaths.

The efficient amount of inspection is represented by the intersection of each of the marginal cost curves with the marginal benefit curve (MB). This is shown by the point R_C for USDA inspection and R_F for FDA.

Because USDA's inspection is continuous (carcass-by-carcass), it inspects far beyond the efficient quantity Q_C*. This inefficient point is shown by the quantity Q_C'. It regulates at a total cost, P_C' x Q_C'. This over-regulation results in an efficiency loss which is represented by the triangle $\Delta R_C T_C' S_C'$.

FDA on the other hand regulates at Q_F', an amount below the efficient quantity, Q_F*. This under-regulation is due to FDA's assumed inadequate funding. It regulates at a total cost, P_F' x Q_F'. The amount of under-regulation is represented by the triangle $\Delta R_F' R_F S_F'$.

Resources could be efficiently reallocated between the two inspection processes by devoting some of the triangle, $\Delta R_C T_C 'S_C'$, to $\Delta R_F 'R_F S_F'$.

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K. ENDNOTES

EXECUTIVE SUMMARY

[1] *See* 21 U.S.C.A. § 601 *et seq.* (West 1997).
[2] *See* 21 U.S.C.A. § 451 *et seq.* (West 1997).
[3] *See* 21 U.S.C.A. § 301 *et seq.* (West 1997).
[4] *See* 7 U.S.C.A. § 136 *et seq.* (West 1997).

INTRODUCTION

[5] *See* PETER BARTON HUTT & RICHARD MERRILL, FOOD AND DRUG LAW 4-6 (2nd ed. 1991) (describing early federal and state food statutes and bureaucratic organization of federal food safety agencies).
[6] Fortunately, this ubiquitous example of federal inefficiency will soon disappear, as USDA and FDA have signed a Memorandum of Understanding that will allow USDA inspectors to monitor frozen cheese pizza production.
[7] This estimate includes food safety and quality research. Estimated from U.S. OFFICE OF MANAGEMENT AND BUDGET, BUDGET OF THE UNITED STATES, FISCAL YEAR 1999 (1998) (hereinafter FY 99 FEDERAL BUDGET).

CHAPTER I

[8] *See* U.S. GENERAL ACCOUNTING OFFICE, FOOD SAFETY AND QUALITY—UNIFORM, RISK-BASED INSPECTION SYSTEM NEEDED TO ENSURE SAFE FOOD SUPPLY, GAO/RCED-92-152, 11-13 (1992) (describing the proliferation of food safety statutes and agencies).
[9] U.S. FOOD AND DRUG ADMIN. ET AL., FOOD SAFETY FROM FARM TO TABLE: A NATIONAL FOOD SAFETY INITIATIVE--REPORT TO THE PRESIDENT (1997) [hereinafter FOOD SAFETY FROM FARM TO TABLE].
[10] *See* Remarks of Fred Angulo, CDC FoodNet Program Officer, before the Public Voice Food Safety Conference, (Mar. 23, 1998).
[11] FOOD SAFETY AND INSPECTION SERVICE , U.S. DEP'T OF AGRIC., THE ESTABLISHMENT AND IMPLEMENTATION OF AN ACTIVE SURVEILLANCE SYSTEM FOR BACTERIAL FOODBORNE DISEASES IN THE UNITED STATES 1 (1997) (hereinafter FOODNET REPORT).
[12] *See* U.S. GENERAL ACCOUNTING OFFICE, FOOD SAFETY–INFORMATION ON FOODBORNE ILLNESSES, GAO/RCED-96-96, 29 (1996).
[13] *See* Jean C. Buzby and Tanya Roberts, *ERS Updates U.S. Foodborne Disease Costs for Seven Pathogens*, FOODREVIEW, Sept.-Dec. 1996, at 24.
[14] *Id.* ERS used a value of $5 million per life, which has been adopted by OMB as a midpoint of several hedonic wage valuations. *See* W. Kip Viscusi, *The Value of Risks to Life and Health*, 31 J. OF ECON. LIT., 1912-46 (1993).
[15] Nancy H. Bean et. al., *Surveillance for Foodborne-Disease Outbreaks—United States, 1988-1992*, MORBIDITY AND MORTALITY WEEKLY REPORT, Oct. 25, 1996, at 1.
[16] *Id.*
[17] *Id.*
[18] *Id.* at 4.
[19] FOODNET REPORT, *supra* note 11; FOOD SAFETY FROM FARM TO TABLE, *supra* note 9.
[20] *See Foodborne Diseases Active Surveillance Network (FoodNet)*, EMERGING INFECTIOUS DISEASES, Oct.-Dec. 1997, at 3.
[21] *See* FOODNET REPORT, *supra* note 11. It is important to recognize that these data only include reported cases confirmed in medical laboratories. The actual rates and number of cases are likely to be much higher due to patient underreporting, medical misdiagnosis, and failure to send bacterial samples to a lab that would report the pathogen to CDC.
[22] *See* STEPHEN BREYER, BREAKING THE VICIOUS CIRCLE 5 (1994).
[23] *See* FOOD SAFETY AND INSPECTION SERVICE, U.S. DEP'T OF AGRIC., BACTERIA THAT CAUSE FOODBORNE ILLNESS (1997).
[24] *See* BILL CLINTON, REMARKS BY THE PRESIDENT IN FOOD SAFETY ANNOUNCEMENT (Mar. 4, 1998), available at <http://vm.cfsan.fda.gov/~dms/fs-wh3.html> (describing food safety as "part of the basic contract now the between the consumers of our country and their government") (hereinafter REMARKS OF THE PRESIDENT).

[25] *See* RICHARD DOLL ET AL., THE CAUSES OF CANCER 1256 (1981), *reprinted in* BREYER, *supra* note 22, at 7.
[26] *See* 21 U.S.C.A. § 601 *et seq.* (West 1997).
[27] *See* 21 U.S.C.A. § 451 *et seq.* (West 1997).
[28] *See* 21 U.S.C.A. § 301 *et seq.* (West 1997).
[29] *See* 7 U.S.C.A. § 136 *et seq.* (West 1997).
[30] *See* U.S. GENERAL ACCOUNTING OFFICE, FOOD SAFETY AND QUALITY–WHO DOES WHAT IN THE FEDERAL GOVERNMENT, GAO/RCED-91-19A (1990).
[31] *See* 7 C.F.R. § 2.81 (delegating grain standard-setting and inspection responsibilities to the Administrator of GIPSA).
[32] *See, e.g.*, 21 C.F.R. § 101.12 (specifying reference serving size of granola bars).
[33] *See, e.g.*, 21 C.F.R. § 102.54 (establishing FDA standard for seafood cocktails); *but see* 50 C.F.R. § 261.101 (defining standards for NMFS voluntary seafood inspection service). *See also* 7 C.F.R. § 2.79 (delegating egg inspection authority to the Administrator of AMS); *but see* 7 C.F.R. § 59.411 (authorizing FDA review of egg product nutritional labels).
[34] *See* 21 U.S.C.A. § 679(b) (West 1997) (providing FDA with statutory authority—in the Meat Inspection Act—to regulate meat products that have left the manufacturing plant).
[35] Interview with FSIS field personnel (Feb. 17, 1998).
[36] *See* FOOD SAFETY FROM FARM TO TABLE, *supra* note 9.
[37] Catherine Woteki, *Food Safety—The Big Picture*, remarks before the Salmonella enteriditis Working Group II/Risk Assessment Organizational Meeting, Jan. 20, 1998.
[38] 21 U.S.C.A. § 301 *et seq.* (West 1997).
[39] 21 U.S.C.A. § 601 *et seq.* (West 1997).
[40] 21 U.S.C.A. § 451 *et seq.* (West 1997).
[41] 7 U.S.C.A. § 136 *et seq.* (West 1997).
[42] *See* 42 U.S.C.A. § 6A (West 1998).
[43] The statutory language of both the Meat and Poultry Products Inspection Acts unambiguously calls for ante-mortem and post-mortem USDA inspection of the carcass of "*each* bird processed" and of "the carcasses and parts thereof of *all* cattle, sheep, swine, goats, horses, mules, and other equines" before food processing (emphasis added). *See* 21 U.S.C.A. § 455(b) (West 1997); 21 U.S.C.A. § 604 (West 1997).
[44] *See, e.g.*, 21 U.S.C.A. § 606 (West 1997) (directing the Secretary of Agriculture or delegated inspectors to perform "an examination and inspection of all meat food products prepared for commerce in any slaughtering, meat-canning, salting, packing, rendering, or similar establishment...).
[45] *See* U.S. GENERAL ACCOUNTING OFFICE, FOOD SAFETY: FUNDAMENTAL CHANGES NEEDED TO IMPROVE FOOD SAFETY, GAO/RCED-97-249R, 2 (1997).
[46] *See* U.S. GENERAL ACCOUNTING OFFICE, Food Safety– A UNIFIED, RISK-BASED SAFETY SYSTEM NEEDED, GAO/T-RCED-94-223 (1994).
[47] *See* U.S. GENERAL ACCOUNTING OFFICE, Food Safety– RISK-BASED INSPECTIONS AND MICROBIAL MONITORING NEEDED FOR MEAT AND POULTRY 41, GAO/T-RCED-94-110 (1994) (hereinafter 1994 GAO MEAT AND POULTRY REPORT); FY 99 FEDERAL BUDGET, *supra* note 7, at 82.
[48] *Id.*
[49] We would like to thank FSIS Administrator Tom Billey for introducing us to this term.
[50] *See* 21 U.S.C.A. § 604 (West 1998).
[51] *See* U.S. GENERAL ACCOUNTING OFFICE, Food Safety– RISK-BASED INSPECTIONS AND MICROBIAL MONITORING NEEDED FOR MEAT AND POULTRY 5, GAO/T-RCED-94-110 (1994) (citing NATIONAL ACADEMY OF SCIENCES, MEAT AND POULTRY INSPECTION: THE SCIENTIFIC BASIS OF THE NATION'S PROGRAM (1985)).
[52] *See* REMARKS OF THE PRESIDENT, *supra* note 24.
[53] *See* U.S. GENERAL ACCOUNTING OFFICE, Food Safety– UNIFORM, RISK-BASED INSPECTION SYSTEM NEEDED TO ENSURE SAFE FOOD SUPPLY 11, GAO/RCED-92-152, (1992) (summarizing history of meat and poultry inspection statutes).
[54] *See* James A. Albert, *A History of Attempts by the Department of Agriculture to Reduce Inspection of Poultry Processing Plants – A Return to the Jungle,* 51 LA. L. REV. 1190 (1991) (describing reform proposals such as the Modified Traditional Inspection System and the Total Quality Control program for poultry inspection).
[55] NATIONAL ACADEMY OF SCIENCES, POULTRY INSPECTION: THE BASIS FOR A RISK ASSESSMENT APPROACH (1987). USDA has agreed with the NAS assessment. In a recent Federal Register notice describing inspection changes, FSIS admitted that "[i]nspection methods have ... not been modified sufficiently to address the microbial causes of foodborne illness." 62 Fed. Reg. 31553, 31555 (June 11, 1997).

[56] *See, e.g.*, NATIONAL ACADEMY OF SCIENCES, MEAT AND POULTRY INSPECTION: THE SCIENTIFIC BASIS OF THE NATION'S PROGRAM (1985) (calling for adoption of preventative, risk-based methods of regulation).
[57] *See* 1994 GAO MEAT AND POULTRY REPORT, *supra* note 47.
[58] *See* 61 Fed. Reg. 38806-38989 (July 25, 1996) (describing FSIS' HACCP plan for meat and poultry inspection); *See also* Lee-Ann Jaykus, *The Application of Quantitative Risk Assessment to Microbial Food Safety Risks*, 22 CRIT. REVIEWS IN MICROBIOLOGY 279-293 (1996) (describing the methodology and implementation challenges of quantitative risk assessment protocols for foodborne hazards).
[59] *See* 21 C.F.R. § 417.2 (1997); 61 Fed. Reg. 38,869 (July 25, 1996).
[60] *See* GAO 1994 MEAT AND POULTRY REPORT, *supra* note 47, at 42.
[61] *See* FY 99 FEDERAL BUDGET, *supra* note 7, at 80-83.
[62] Includes FSIS, AMS, ARS, ERS, APHIS, and food safety grants of CSREES. *See id.*
[63] *See id.* at 291.
[64] Personal Interview with William Hubbard, FDA Associate Commissioner for Policy (Nov. 14, 1997).
[65] *See* FY 99 FEDERAL BUDGET, *supra* note 7, at 396.
[66] *See* 1999 BUDGET PROPOSAL FOR FDA—FOOD SAFETY AND YOUTH TOBACCO PREVENTION RECEIVE INCREASES, FDA Talk Paper, Feb. 2, 1998.
[67] *See* HUTT & MERRILL, *supra* note 5, at 5.

CHAPTER II

[68] MARY DOUGLAS & AARON WILDAVSKY, RISK AND CULTURE 197 (1982).
[69] *See* 21 U.S.C.A. § 348 (c)(3)(A) (West 1997).
[70] *See* 21 U.S.C.A. § 321(s) (West 1997).
[71] *See* U.S. GENERAL ACCOUNTING OFFICE, FOOD SAFETY AND QUALITY—UNIFORM, RISK-BASED INSPECTION SYSTEM NEEDED TO ENSURE SAFE FOOD SUPPLY 48-49, GAO/RCED-92-152 (1992).
[72] *Id.*
[73] *Id.*; ELIZABETH DAHL & CAROLINE SMITH DEWAAL, SCRAMBLED EGGS—HOW A BROKEN FOOD SAFETY SYSTEM LET CONTAMINATED EGGS BECOME A NATIONAL FOOD POISONING EPIDEMIC, Center for Science in the Public Interest (1997).
[74] DAHL & DEWAAL, *supra* note 73.
[75] *See* 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?*, 52 FOOD DRUG L.J. 13, 18 (1997).
[76] *See id.* at 24; FY 99 FEDERAL BUDGET, *supra* note 7.
[77] *See* n. 44, *infra.*
[78] *See id.* at 34-36; Taylor, *supra* note 75, at 29.
[79] *See* Taylor, *supra* note 75, at 29, n. 52 (citing conversation with Dr. Karen Hulebak, FDA Office of Policy).
[80] Granted, it is possible, yet unlikely, that FDA personnel have enhanced the quality of their inspections to compensate for the decreased quantity.
[81] *See* FY 99 FEDERAL BUDGET, *supra* note 7, at 491-2.
[82] *See* Hubbard, *supra* note 64.

CHAPTER III

[83] *See* U.S. GENERAL ACCOUNTING OFFICE, FOOD SAFETY: PROCEDURES FOR INSPECTING CANADIAN MEAT IMPORTS, GAO/T-RCED-97-121, (1997).

CHAPTER IV

[84] *See* Table 1.2, *infra.*
[85] *See, e.g.*, KAREN M. HULT, AGENCY MERGER & BUREAUCRATIC DESIGN 6-7 (1987) (summarizing the long-standing scholarly debate over the effectiveness of agency mergers).
[86] Peter Szanton, *So You Want to Reorganize Government?*, in FEDERAL REORGANIZATION—WHAT HAVE WE LEARNED 1, 9 (Peter Szanton ed., 1981).
[87] 21 C.F.R. § 170.3(i).

[88] *See* HARRY S. TRUMAN, PRESIDENT'S MESSAGE TO CONGRESS TRANSMITTING REORGANIZATION PLAN NO. 27 OF 1950, H.R. Doc. No. 610, at 3 (May 31, 1950).
[89] Interview with FSIS field staff (Feb. 17, 1998); U.S. OFFICE OF PERSONNEL MANAGEMENT, GENERAL SCHEDULE (1998) (providing salaries by grade levels).
[90] *Id.*
[91] *Id.*
[92] *See* HUTT & MERRILL, *supra* note 5, at 17.
[93] *Id* at 18.
[94] *See, e.g.*, U.S. GENERAL ACCOUNTING OFFICE, FOOD SAFETY—A UNIFIED, RISK-BASED FOOD SAFETY SYSTEM NEEDED, GAO/T-RCED-94-223, (1994) (recommending consolidation of federal food safety agencies and describing history of unification proposals).
[95] Marian Burros, *The Debate Over Merging Government Food Agencies,* N.Y. TIMES, Apr. 9, 1997, at C1.
[96] *See* Appendix B, *infra.*
[97] *See* CONGRESSIONAL INFORMATION SERVICE, CIS ANNUAL (1996) (abstracting all congressional hearings and publications).
[98] *See* FY 99 FEDERAL BUDGET, *supra* note 7, at 395.
[99] *See* 1999 BUDGET PROPOSAL FOR FDA—FOOD SAFETY AND YOUTH TOBACCO PREVENTION RECEIVE INCREASES, FDA Talk Paper (Feb. 2, 1998) (proposing $127.2 million in users fees to fund existing programs).
[100] *See* 21 U.S.C.A. § 604 (West 1998).
[101] *See* JOHN W. KINGDON, AGENDAS, ALTERNATIVES, & PUBLIC POLICIES 94-100 (2d ed. 1995).
[102] Margaret Kriz, *Tainted by Politicking?,* NAT'L J., Apr. 26, 1997, at 825.
[103] *See, e.g.*, 21 U.S.C.A § 342(a)(1) (West 1998) (defining a food adulterated "[i]f it bears or contains any poisonous or deleterious substance which *may* render it injurious to health; . . .") (emphasis added).
[104] *See* 21 U.S.C.A. § 348 (c)(3)(A) (West 1997) (mandating a zero-risk standard for carcinogenic food additives).
[105] *See* 21 U.S.C.A. § 604 (West 1997) (emphasis added).
[106] *See* 1994 GAO MEAT AND POULTRY REPORT, *supra* note 47.
[107] *See* W.F. Jacobs-Reitsma, *Aspects of Epidemiology of Campylobacter in Poultry,* 19 VETERINARY Q. 113-7 (1997) (describing sources of Campylobacter contamination in chickens, including: pig and poultry flocks, and to a lesser extent sheep and cattle); P.S. Holt, *Horizontal Transmission of Salmonella Enteritidis in Molted and Unmolted Laying Chickens*, 39 AVIAN DISEASES 239-49 (1995) (discussing the relationship between molting and the transmission of Salmonella to neighboring caged hens).
[108] *See* Taylor, *supra* note 75.
[109] For example, most polling firms are able to generalize about the entire U.S. population of 230 million by questioning just 1,000 respondents. While FSIS may want to ensure a higher degree of confidence by taking a higher percentage of the carcass population, it would be possible for the agency to sample far fewer animals than it does presently, and receive statistically significant results, as long as samples are randomly chosen.
[110] *See* Remarks of Joseph Levitt, Director of FDA Center for Food Safety and Applied Nutrition, before the Public Voice Food Safety Conference, (Mar. 23, 1998).
[111] *See* COMMITTEE ON SCIENTIFIC AND REGULATORY ISSUES UNDERLYING PESTICIDE USE PATTERNS AND AGRICULTURAL INNOVATION, NAT'L RESEARCH COUNCIL, REGULATING PESTICIDES IN FOOD: THE DELANEY PARADOX (1987).
[112] *See* Margaret Kriz, *A Peace Treaty Over the Delaney Clause*, 28 NAT'L J. 1642 (1996).
[113] *See FDA Food Reform May Play Second Fiddle to Drug and Device Issues Before Congress*, FOOD LABELING NEWS (Feb. 6, 1997).
[114] *See 'It's Time to Turn the FDA into the Food-Poisoning-Prevention Police,' Consumers, Members of Congress Urge*, CENTER FOR SCIENCE IN THE PUBLIC INTEREST NEWS RELEASE (Mar. 31, 1998), available at <http://www.cspinet.org/new/fdabill.htm>.
[115] *See NFPA Says Proposed Food Safety Legislation Would Mean 'More Government Jobs, But No Greater Food Safety,'* NAT'L FOOD PROCESSORS ASSOC. PRESS RELEASE (Mar. 31, 1998), available at <http://biz.yahoo.com/prnews/980331/dc_nfpa_fo_1.html>.
[116] See Table 1.4 *infra.*
[117] Catherine Woteki, *Progress Report on Food Safety And The Outlook For The Future*, (February 13, 1998) (hereinafter *Progress Report on Food Safety*).
[118] PR NEWSWIRE, *Grocery Manufacturers of America to Submit Testimony*, (Mar. 30, 1998); Joanna Ramey, *Clinton Budget Pushes Food Safety, Fees,* SUPERMARKET NEWS, (Feb. 9, 1998).
[119] MILLING & BAKING NEWS, *F.D.A. User Fee Proposal Shot Down in the House,* (July 13, 1993)

[120] *See* Remarks of Fred Angulo, CDC FoodNet Program Officer, and Joseph Levitt, Director of the Center for Food Safety and Nutrition, FDA, before the Public Voice Food Safety Conference, Mar. 23, 1998.
[121] *See* Remarks of Joseph Levitt, *supra* note 110.
[122] *See* Allan Schick, *The Coordination Option*, in FEDERAL REORGANIZATION—WHAT HAVE WE LEARNED 85, 97 (Peter Szanton ed., 1981).
[123] *Progress Report on Food Safety, supra* note 117.
[124] *Id*
[125] *See* NATIONAL AGRICULTURAL LIBRARY, USDA/FDA FOODBORNE ILLNESS EDUCATION CENTER, available at <http://www.nalusda.gov/fnic/foodborne/statemen.html>.
[126] *See* Taylor, *supra* note 75, at 26.

APPENDIX A

[127] *See, e.g.*, KAREN M. HULT, AGENCY MERGER AND BUREAUCRATIC REDESIGN 15 (1987) (discussing the problems of modeling in organization theory).

APPENDIX B

[128] GAO/RCED-91-19A (1990).
[129] HUTT & MERRILL, *supra* note 5, at 5.
[130] *Id.* at 15.
[131] *See* 21 U.S.C.A § 301 *et. seq.* (West 1997).
[132] *See* 21 U.S.C.A § 321 (West 1997).
[133] *See* 21 U.S.C.A § 342, 343 (West 1997).
[134] *See* 21 U.S.C.A § 333-335b (West 1997).
[135] 21 U.S.C.A § 321(f) (West 1997).
[136] *See* Nutrilab Inc. v. Schweiker, 713 F.2d 335 (7th Cir. 1983).
[137] 21 U.S.C.A § 321(m) (West 1997).
[138] *See* 21 U.S.C.A § 321(q) (West 1997).
[139] 7 U.S.C.A § 136 *et seq* (West 1997).
[140] 21 U.S.C.A § 331(a) (West 1997).
[141] 21 U.S.C.A § 331(b) (West 1997).
[142] 21 U.S.C.A § 331(c) (West 1997).
[143] 21 U.S.C.A § 342(a) (West 1997) (emphasis added).
[144] 21 U.S.C.A § 342(a)(1) (West 1997) (emphasis added).
[145] *See* United States v. 1232 Cases American Beauty Brand Oysters, 43 F.Supp. 749 (W.D. Mo. 1942) (rejecting FDA condemnation of oysters, because presence of shell fragments did not "ordinarily render [them] injurious to health").
[146] United States v. Lexington Mill & Elevator, 232 U.S. 399 (1914) (emphasis added).
[147] *See* 21 U.S.C.A § 348(c)(3) (West 1997).
[148] *See* 21 U.S.C.A. § 348(a) (West 1997); 21 U.S.C.A. § 342(a)(2)(C) (West 1997).
[149] *See* 21 C.F.R. § 170.3(i).
[150] 21 U.S.C.A. § 348 (c)(3)(A) (West 1997).
[151] HUTT & MERRILL, *supra* note 5, at 332.
[152] *Id.* at 333.
[153] Testimony of Fred R. Shank, "Food and Drug Administration's Regulation of Dietary Supplements," Hearings Before the Human Resources and Intergovernmental Relations Subcommittee, Committee on Government Operations, U.S. House of Representatives, 104th Cong. 1st sess., 13 (1995).
[154] Pub.L. 86-618, 74 Stat. 397 (1960).
[155] Pub.L. 90-399, 82 Stat. 342 (1968).
[156] 7 U.S.C.A. § 136(bb) (West 1997).
[157] 21 U.S.C.A. § 343 (West 1997).
[158] 21 U.S.C.A. § 321(n) (West 1997).
[159] 21 U.S.C.A. § 332(a) (West 1997).
[160] 21 U.S.C.A. § 332 (West 1997).
[161] 21 U.S.C.A. § 333 (West 1997).

[162] 21 U.S.C.A. § 333(a) (West 1997).
[163] 21 U.S.C.A. § 374(a)(1)(A) (West 1997).
[164] 21 U.S.C.A. § 374(a)(1)(B) (West 1997).
[165] 21 U.S.C.A. § 373, 374(a)(3) (West 1997).
[166] *See* 21 U.S.C.A § 381(a) (West 1997).
[167] 21 U.S.C.A. § 381(e)(1) (West 1997).
[168] HUTT & MERRILL, *supra* note 5, at 14.
[169] *See* 15 U.S.C.A. § 1451-1461 (West 1997).
[170] 15 U.S.C.A. § 1453 (West 1997).
[171] 15 U.S.C.A. § 1459 (West 1997).
[172] 21 U.S.C.A. § 61-62 (West 1997).
[173] 21 U.S.C.A § 63 (West 1997).
[174] 21 U.S.C.A. § 679(a) (West 1997).
[175] 21 U.S.CA. § 679(b) (West 1997).
[176] 21 U.S.C.A. § 201 *et seq* (West 1997).
[177] MICHAEL SCHUMANN ET AL., FOOD SAFETY LAW (1997).
[178] *Id.*
[179] 21 U.S.C.A. § 605 (West 1997).
[180] SCHUMANN, ET AL., *supra* note 177.
[181] 21 U.S.C.A. § 604 (West 1997).
[182] 21 U.S.C.A. § 604 (West 1997).
[183] 21 U.S.C.A. §605 (West 1997); 9 C.F.R. § 318.2.
[184] 21 U.S.C.A. § 604 (West 1997); *See* Wyszynski Provision Co. v. Secretary of Agriculture, 538 F. Supp. 361 (E.D. Pa. 1982).
[185] SCHUMANN, ET AL., *supra* note 177, at 58.
[186] 21 U.S.C.A. § 601(m) (West 1997).
[187] 21 U.S.C.A. § 601(m)(3) (West 1997).
[188] *See, e.g.,* G.A. Portellow and Co. v. Butz, 345 F. Supp. 1204 (D.D.C. 1972); Bubb Davis Packing Co. v. U.S., 443 F. Supp. 589 (S.D. Tex., 1977), *aff'd on other grounds*, 584 F.2d 116 (5th Cir. 1978), *cert. denied*, 441 U.S. 931 (1979).
[189] SCHUMANN, ET AL., *supra* note 177, at 58.
[190] 21 U.S.C.A. § 601(m)(2) (West 1997).
[191] *See* Chips Date Co. v. Hardin, 332 F. Supp. 1084 (N.D.Cal. 1971), *aff'd* 467 F.2d 481 (9th Cir. 1972), *cert. denied*, 411 U.S. 916 (1973); SCHUMANN, ET AL., *supra* note 177, at 59.
[192] SCHUMANN, ET AL., *supra* note 177, at 59.
[193] G.A. Portello & Co. v. Butz, 345 F. Supp 1204 (D.D.C. 1972).
[194] 21 U.S.C.A. § 601(m) (West 1997).
[195] 21 U.S.C.A. § 601(m)(1) (West 1997).
[196] See 21 U.S.C.A. § 676 et seq. (West 1997).
[197] SCHUMANN, ET AL., *supra* note 177, at 61.
[198] *Id.*
[199] *Id.*
[200] *Id.*
[201] These determinations can be made when the applicant or the recipient has been convicted in any federal or state court of either a felony or more than one non-felony resulting form the acquisition, handling, or distribution or unwholesome, mislabeled, or deceptively packaged food products. *See* 21 U.S.C.A. § 671 (West 1997); 9 C.F.R. § 305.1 *et seq.*
[202] SCHUMANN, ET AL., *supra* note 177, at 61.
[203] Wholesome Meat Act of 1967, Pub.L.No. 90-201, 81 Stat. 584 (1967).
[204] SCHUMANN, ET AL., *supra* note 177.
[205] Curtis Amendment, Pub.L.No. 91-342, 84 Stat. 438 (1970), *codified as* 21 U.S.C. § 623(a) (West 1997) (expanding the scope of custom exemptions in §23 of the Act).
[206] Humane Methods of Slaughter Act of 1979, Pub.L.No. 95-445, 92 Stat. 1069 (1978)
[207] 21 U.S.C.A. § 620(f), added by Pub.L.No. 97-98, §1122, 95 Stat. 1273 (1981).
[208] Pub.L.No. 85-172, approved Aug. 28, 1957, 71 Stat. 441, as amended June 25, 1967, 76 stat. 110, and amended by the Wholesome Poultry Products Act, Aug. 18, 1967, Pub.L.No. 90-492, 82 Stat. 791-808 (1968).

[209] 21 U.S.C.A. § 453 *et seq.* (West 1997)
[210] SCHUMANN, ET AL., *supra* note 177, at 88.
[211] 21 U.S.C.A. § 453(e) (West 1997); *See also* 9 C.F.R. §381.1 (b)(40).
[212] 21 U.S.C.A. § 453(f) (West 1997). *See also* 9 C.F.R. §381.1 (b)(41), (42).
[213] 21 U.S.C.A. § 453(u) (West 1997).
[214] SCHUMANN, ET AL., *supra* note 177, at 89.
[215] 21 U.S.C.A. § 455(c) (West 1997).
[216] 21 U.S.C.A. § 455(a) (West 1997).
[217] 21 U.S.C.A. § 455(b) (West 1997).
[218] SCHUMANN, ET AL., *supra* note 177, at 90.
[219] 21 U.S.C.A. § 453(g) (West 1997).
[220] SCHUMANN, ET AL., *supra* note 177, at 91.
[221] 21 U.S.C.A. § 461(a) (West 1997).
[222] 21 U.S.C.A. § 461(a) (West 1997).
[223] 21 U.S.C.A. § 467(e) (West 1997).
[224] Swift and Company v. Wickham, 367 7.2d 241 (2d Cir. 1966).
[225] *See* as amended 1991 Amendments, Pub.L. 102-237, § 1012(b).
[226] Of the 62 billion eggs consumed in 1994, more than 25% were in the form of egg products. Liquid, frozen, and dried egg products are widely used by the food service industry as ingredients in various other foods. *See generally* U.S. DEPT. OF AGRIC., FOOD SAFETY & INSPECTION SERVICE, FOCUS ON: EGG PRODUCTS (1995) [hereinafter EGG PRODUCTS].
[227] See 21 U.S.C.A. § 1034(a) (West 1997).
[228] *Id.*
[229] EGG PRODUCTS, *supra* note 226.
[230] *See* 21 U.S.C.A. § 1034(b) (West 1997).
[231] EGG PRODUCTS, *supra* note 226.
[232] *See* 21 U.S.C.A. § 1034(e)(B)(3) (West 1997).
[233] *See* 21 U.S.C.A. § 1034(d) (West 1997).
[234] *See* 21 U.S.C.A. § 1034(d) (West 1997).
[235] *See* 21 U.S.C.A. § 1034(a) (West 1997).
[236] *See* 21 U.S.C.A. § 1034(c) (West 1997).
[237] U.S. GENERAL ACCOUNTING OFFICE, FOOD SAFETY AND QUALITY: WHO DOES WHAT IN THE FEDERAL GOVERNMENT 35 (1990).
[238] OPP has six divisions involved with the safety of pesticides: Registration; Special Review and Re-registration; Health Effects; Environmental Fate and Effects; Biological and Economic Analysis; and Field Operations.
[239] *See* OFFICE OF PESTICIDE PROGRAMS, U.S. ENVIRONMENTAL PROTECTION AGENCY, MAJOR ISSUES IN THE FOOD QUALITY ACT OF 1996 (1996) (hereinafter MAJOR ISSUES IN THE FOOD QUALITY PROTECTION ACT).
[240] For FIFRA, *see as amended* 7 U.S.C.A. §136 *et seq.* and for FFDCA, see as amended 21 U.S.C. 301 *et seq.*
[241] Hutt & Merrill, *supra* note 5, at 306-7.
[242] *See* 7 U.S.C.A. § 136a(a) (West 1997).
[243] *See* 21 U.S.C.A. § 342(b)(2)(A)(ii) (West 1997).
[244] *See* 21 U.S.C.A. § 342(a)(2)(B) (West 1997).
[245] *See* 21 U.S.C.A. § 346(b)(2)(B)(i) (West 1997).
[246] *See* MAJOR ISSUES IN THE FOOD QUALITY PROTECTION ACT, *supra* note 239.
[247] *See* 21 U.S.C.A. § 346(b)(2)(C)(i) (West 1997).
[248] *See* 21 U.S.C.A. § 346(b)(2)(D) (West 1997).
[249] *See* 21 U.S.C.A. § 346(b)(2)(F) (West 1997).
[250] *See generally* 21 U.S.C.A. § 346(d)(2)(A) (West 1997).
[251] *See* 21 U.S.C.A. § 346(d)(4)(B) (West 1997).

APPENDIX F

[252] *See* CANADIAN FOOD INSPECTION AGENCY, REORGANIZING THE FEDERAL FOOD INSPECTION SYSTEM IN CANADA (1998), available at <http://www.cfia-acia.agr.ca/english/backgr.html> (hereinafter REORGANIZING THE FEDERAL FOOD INSPECTION SYSTEM IN CANADA)

[253] *See* CANADIAN FOOD INSPECTION AGENCY, FREQUENTLY ASKED QUESTIONS (1998), available at <http://www.cfia-acia.agr.ca/english/faq.html>
[254] *Id.*
[255] *See* REORGANIZING THE FEDERAL FOOD INSPECTION SYSTEM IN CANADA, *supra* note 252.
[256] The following acts are administered and/or enforced by the CFIA: Canada Agricultural Products Act; Consumer Packaging and Labeling Act; Feeds Act; Fertilizers Act; Fish Inspection Act; Food & Drugs Act; Health of Animals Act; Meat Inspection Act; Plant Breeders' Rights Act; Plant Protection Act; and the Seeds Act. *See* CANADIAN FOOD INSPECTION AGENCY, HIGHLIGHTS OF THE CANADIAN FOOD INSPECTION AGENCY ACT (1998), available at <http://www.cfia-acia.agr.ca/english/hilite.html>
[257] In 1993, the FDA under Commissioner David Kessler outlined proposals for enhancing the agency's enforcement tools for food safety. The following were FDA's proposed powers: Records Inspection; Registration of Food Processors; HACCP/Quality Assurance System; Presumption of Interstate Commerce; Civil Money Penalties; Temporary (Domestic) Detention Authority (Embargo); Recall Authority; Subpoena Authority; User Fees; and Authority to Refuse Entry of Food Imports. *See* SCHUMANN, ET AL., *supra* note 177, at 21-23.
[258] *See* Tara M. Smith and David J. Jukes, *Food Control in Canada*, 37 CRIT. REV. IN FOOD SCIENCE & NUTRITION 229-251 (1997).
[259] *Id.* at 241.
[260] HARVARD BUSINESS SCHOOL CASE, TECHNOLOGY CRISES AND THE FUTURE OF AGRIBUSINESS: BSE IN EUROPE, (1997) (hereinafter BSE IN EUROPE).
[261] MINISTER OF AGRICULTURE, FISHERIES AND FOOD, FOOD STANDARDS AGENCY (1997), available at <http://www.official-documents.co.uk/document/maffdh/fsa/chap-1.htm>.
[262] BSE IN EUROPE, *supra* note 260.
[263] BSE IN EUROPE, *supra* note 260.
[264] BSE IN EUROPE, *supra* note 260.
[265] *See* MINISTER OF AGRICULTURE, FISHERIES AND FOOD, THE FOOD STANDARDS AGENCY: A FORCE FOR CHANGE FACTSHEET ON THE GOVERNMENT'S WHITE PAPER, available at <http://www.maff.gov.uk/food/fs/factnet.htm>.

APPENDIX H

[266] This section is the result of conversations with Professor Robert Glauber of the Kennedy School of Government and David Battan, Special Counsel to the Director of Market Regulation, CFTC on March 6, 1998.
[267] *See* Exec. Order No. 12,631, 53 Fed. Reg. 9,421 (1988).
[268] *See, e.g.*, 63 Fed. Reg. 9,034, 9,035 (1998) (documenting proposed rule changes in the NYSE's trading halt policy and citing the Working Group on Financial Markets).

APPENDIX I

[269] Patricia Mitchell, *The New Consumer Crusade*, WASHINGTON POST, Sept. 16, 1987.
[270] Daniel Puzo, *Report Assails U.S. Inspection System for Fish,* LOS ANGELES TIMES, Nov. 20, 1986.
[271] Daniel Puzo, *Food Briefs: Congress Holds Hearings on Seafood Safety Issues,* LOS ANGELES TIMES, June 15, 1989.
[272] Carole Sugarman, *Fishing for Standards on Capitol Hill,* WASHINGTON POST, June 14, 1989.
[273] Daniel Puzo, *Food Briefs: Congress Holds Hearings on Seafood Safety Issues,* LOS ANGELES TIMES, June 15, 1989.
[274] Ellen Haas, *Our Laissez-Fish Policy,* WASHINGTON POST, Sept. 24, 1989.
[275] David Cloud, *Law Urged for Fish Inspection,* CONGRESSIONAL QUARTERLY, Nov. 5, 1989.
[276] Catherine Collins, *Fishy Doings on Capitol Hill May be Good for Consumers,* LOS ANGELES TIMES, Oct. 21, 1990.
[277] Daniel Puzo, *Seafood Inspection: An Upstream Battle,* LOS ANGELES TIMES, Nov. 8, 1990.
[278] Daniel Puzo, *FDA Inspection Finds 20% of Seafood Tainted,* LOS ANGELES TIMES, Feb. 27, 1992.
[279] *Id.*
[280] Matt Marshall, *U.S. Fish Inspection Bill Rides In Wake of Consumer Demand,* LOS ANGELES TIMES, Apr. 15, 1992.
[281] Robin Lee Allen, *New Senate Bill Backs Seafood Inspection Plan*, NATION'S RESTAURANT NEWS, Apr. 27, 1992.

[282] Joyce Barrett, *Industry, Bush Opposed to Senate Seafood Bill*, SUPERMARKET NEWS, July 27, 1992.
[283] Daniel Puzo, *Food Briefs: Congress Holds Hearings on Seafood Safety Issues,* LOS ANGELES TIMES, June 15, 1989.

APPENDIX J

[284] In this graph, each death avoided is represented by the line OP_R.

Clinton Library Transfer Form

Case #, if applicable	2015-0274-S	**Accession #**	
Collection/Record Group	Clinton Presidential Records	**Series/Staff Member**	Thomas Freedman
Subgroup/Office of Origin	Domestic Policy Council	**Subseries**	
Folder Title	Food Safety [Folder 1][2]	**OA/ID Number**	17556
Box Number			
Description of Item(s)	Disk Titled, "Food Safety" [Please Note: disk was unreadable]		

Donor Information

Last Name:		**First Name:**		**Middle Name:**		**Title:**	
Affiliation:		**Phone (Wk):**		**Phone (Hm):**			
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Other (Specify):		**New Location**	
Transferred by:	Whitney Ross	**Date of Tranfer**	11/25/2015
Received by:		**Date of Receipt**	

Dear Representative Stupak:

Thank you for your letter dated September 24, 1997, expressing concern about the effects of increased trade on food safety. I share your concern about the safety of food for all Americans, and I will not permit any trade policy to impair the health and safety of the American people.

I have committed this Administration to ensuring that the food that Americans eat is the safest in the world. We have put in place improved safety standards for meat, poultry, and seafood products, and have begun the process of developing enhanced safety standards for fruit and vegetable juices. Together, we have enacted legislation in this area, including the Safe Drinking Water Act of 1996 and the Food Quality Protection Act of 1996.

This month, I announced an initiative to upgrade domestic food safety standards and to ensure that fruits and vegetables coming from overseas are as safe as those produced in the United States. I asked Congress to enact legislation that will require the Food and Drug Administration to halt imports of fruits, vegetables, and other food products from any foreign country with food safety systems and standards that are not on par with those of the United States. I also directed the Department of Health and Human Services and the Department of Agriculture to work cooperatively with the agricultural community to develop guidance on agricultural and manufacturing practices for fruits and vegetables within one year. Finally, I committed to providing the necessary funds in my Fiscal Year 1999 budget to enable the FDA to dramatically expand its international food inspection force so it can inspect food safety conditions abroad and at points of entry. The added resources will allow the FDA to make effective use of its new legislative authority. I am attaching a fact sheet on my new proposal, as well as the directive I sent to Secretaries Glickman and Shalala.

This new initiative will help guarantee the safety of food in the United States. It provides the improved inspection capacities and increased regulatory powers we need to prevent contaminated imports from reaching American tables. I am committed to continuing to improve the safety of food that Americans eat, and I look forward to working with you on this vital project. Thank you again for your letter.

Sincerely,

Congress of the United States

Washington, DC 20515

September 24, 1997

Chris Walker Legislative Affairs

Tim -

Could you please draft a response to this? Emphasize our initiative, of course. Thanks.

EC

SEP 25 PM 5:35

The Honorable William Jefferson Clinton
1600 Pennsylvania Ave., N.W.
Washington, DC 20500

Dear Mr. President:

We urge you to give serious consideration to remedying the inadequate food safety provisions in the North American Free Trade Agreement (NAFTA). Because of your commitment to ensuring the safety of our nation's food supply, we expect that you will not agree to fast track authority that does not contain adequate food safety protections. Current fast track proposals do not address these concerns.

In an effort to increase trade with Mexico, NAFTA limited border inspections of food and allowed Mexican trucks to enter the U.S. with limited inspection.

These lax inspection practices contributed to a sharp increase in food imports from Mexico: imports of Mexican fruit have increased 45%, and vegetable imports have risen 31%. More than 70% of these imports are carried into the U.S. on trucks. The General Accounting Office (GAO) recently found that 99% of Mexican trucks enter the U.S. without any inspection.

These provisions in NAFTA have resulted in imports of fruits and vegetables contaminated with diseases and unhealthy pesticides. We were alarmed earlier this year when 179 Michigan school children contracted hepatitis after eating tainted Mexican strawberries. In order to prevent similar incidents in the future, we urge you to take the following action:

- Renegotiate the provisions in NAFTA that relate to border inspections and food safety, and ensure that any fast track authority include strong food safety protections.

- Increase the funding for border inspections or, alternatively, limit the increasing rate of food imports to ensure the safety of our food supply.

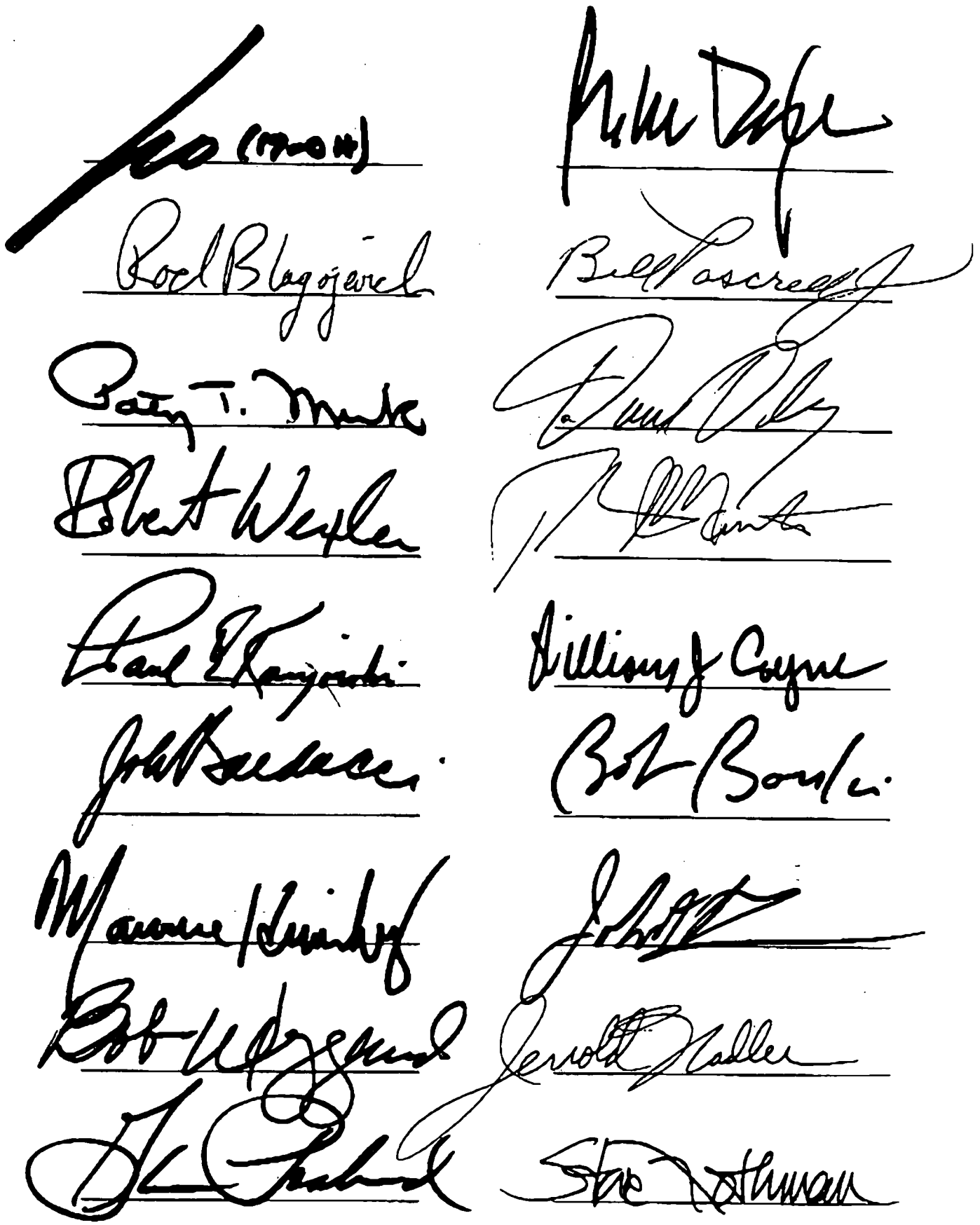
- Begin an aggressive program to label all food stuffs -- including fresh and frozen fruits, vegetables and meats -- with their country of origin.

We look forward to working with you on these vital public health issues.

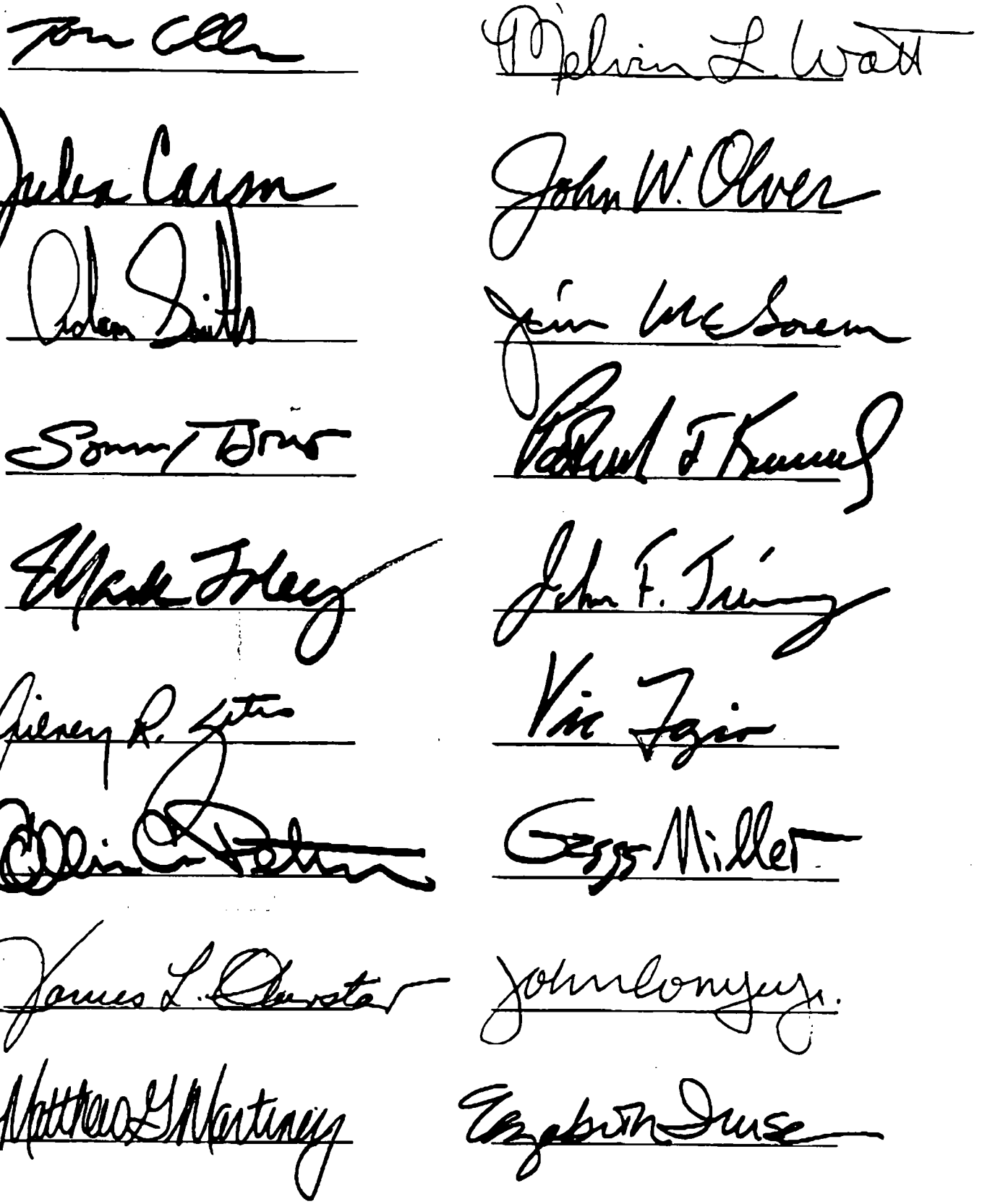
Sincerely,

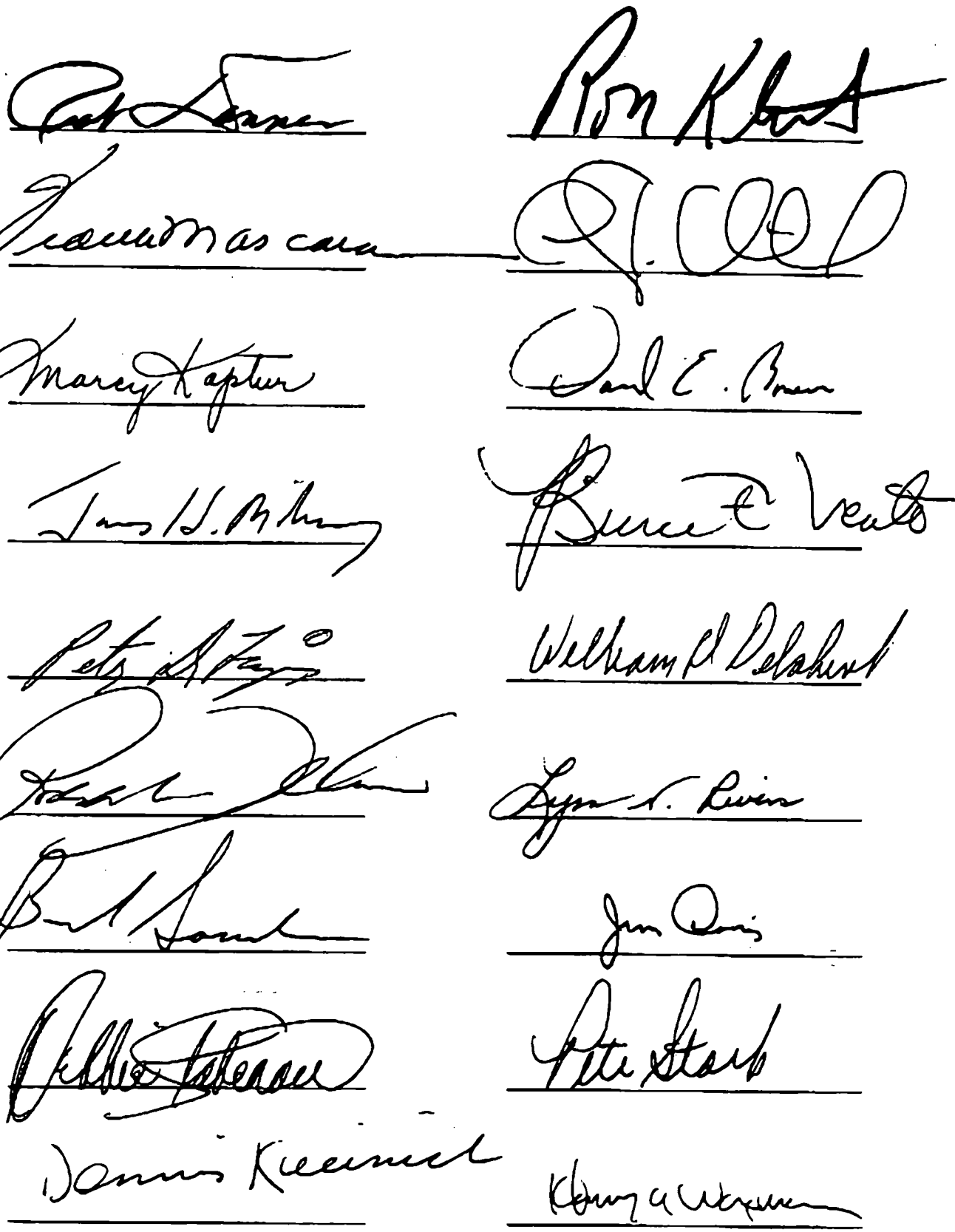
Paul Sarbanes

Sherrod Brown



Lane Evans	Jerry F. Costello
William Lipinski	Ted Strickland
Karen L. Thurman	Frank Pallone, Jr.
[illegible] McKinney	Bobby L. Rush
[illegible]	Dale E. Kildee
Martin Frost	George E. Brown, Jr.
Martin O. Sabo	Eliot L. Engel
Glenn Poshard	Maxine Waters
Luis V. Gutierrez	[illegible]





Sam Jeffords

Jack Metcalf

Neil Abercrombie

Joe Hummel

Carolyn McCarthy

Marty Meehan

Lynn V. Gutierrez

Jim Barcia

John A. Cobrun

Jim W. Johnson

Danny K. Davis

Tom Lantos

Ron Kind

Congress of the United States
House of Representatives
Washington, DC 20515

September 23, 1997

SEP 25 PM5:36

The Honorable Bill Clinton
The White House
Washington, D.C. 20500

Dear Mr. President:

We, the members of the Florida congressional delegation, are writing to express our problem in supporting the renewal of fast track authority.

While we support free trade, we are hesitant to support fast track legislation in light of the fact that existing agreements regarding Florida fresh fruit and vegetable commodities have not been fully enforced. For example, in the recent past, tomatoes from Mexico were dumped in this country below cost in elevated surging quantities. And because current safeguards were not effective, Florida's tomato industry was severely damaged.

Furthermore, it is our understanding that not one Florida orange has been exported to Mexico since the passage of NAFTA. This situation demonstrates the inherent unfairness against Florida produce by the Mexican government.

We understand that expanding free trade is crucial to continue growing America's economy. However, we are reluctant to support renewing fast track authority for agreements with other nations when promises made in the past to fairly treat Florida produce have gone largely unfulfilled. Therefore, we believe the existing foreign trade inequities concerning Florida agriculture should be addressed and resolved before fast track authority is renewed.

Thank you for your consideration of our views.

Sincerely,

E. Clay Shaw, Jr., M.C.

Karen Thurman, M.C.

Carrie Meek, M.C.

C.W. "Bill" Young, M.C.

Bill McCollum, M.C.

Michael Bilirakis, M.C.

Porter Goss, M.C.

Ileana Ros-Lehtinen, M.C.

Tillie Fowler, M.C.

Corrine Brown, M.C.

Mark Foley, M.C.

Alcee Hastings, M.C.

Peter Deutsch, M.C.

John Mica, M.C.

Charles Canady, M.C.

Joe Scarborough, M.C.

F. Allen Boyd, Jr., M.C.

Robert Wexler, M.C.

David Weldon, M.C.

EK- I don't know it

Clara Food Safety

The Administration recognizes the importance of addressing foodborne illness caused by Campylobacter and has taken a number of steps in this regard:

- Under the President's Food Safety Initiative, the Administration added Campylobacter to the FoodNet, which collects data on foodborne illness, in 1997 to gain knowledge on its incidence.

- According to the first year survey results from FoodNet, Campylobacter is the most common foodborne illness, causing approximately 4 million illness per year.

    - It is a relatively mild illness, seldom, almost never fatal. It has been possibly linked to Guillame-Barre syndrome, a temporary neurological disorder.

- Under the Food Safety Initiative, research on the Campylobacter organism is a high priority. USDA is working on a new rapid testing method for Campylobacter to improve our ability to detect the pathogen.

  Also under the Administration's food safety initiative, FDA, CDC, and USDA have initiated surveillance to gain greater understanding of strain of campylobacter that has been shown to be resistant to fluorquinolone (a class of antibiotics).

  The Administration spent $1.3 million in FY 97 on Campylobacter research, $435,000 of which was for a rapid test. In FY 98, the Administration will spend $2.2 million on research, a little of over 1million of which will be for rapid tests.

  There are two flourquinolones approved for food animals in the U.S., both for broilers and turkeys. FDA is reevaluating these products based on the new information about flouroquinolone.

  FDA and USDA officials recently participated in a World Health Organization meeting at which this issue was addressed. A follow up meeting is scheduled.

- As HACCP is implemented in January of 1998, USDA expects that Campylobacter will be an identified hazard that will be appropriately addressed in HACCP plans.

- Proper handling is very effective against Campylobacter because it is one of the more easily destroyed bacteria. Safe handling includes

  Cooking to 160 degrees,

  Avoiding cross-contamination by washing hands and preparation surfaces, and

  Keeping raw product separate from cooked product.

Food Safety

To: Bob Pellicci, OMB
Fr: Eric Olsen
Re: FDA Legislation

The attached language reflects the outcome of a meeting with DPC, OIRA, USTR, State, HHS, FDA, and USDA on the FDA legislative proposal regarding imported foods. USDA does not object to the legislative proposal as drafted.

We did not discuss the transmittal letter during this meeting, and I am not providing USDA clearance of the transmittal letter that was originally sent for interagency clearance.

cc: Elena Kagan, DPC

105 HHS 177
42142 Total Pages: 6

LRM ID: RJP148

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503-0001

SPECIAL

Friday, October 10, 1997

LEGISLATIVE REFERRAL MEMORANDUM

TO: Legislative Liaison Officer - See Distribution below

FROM: Janet R. Forsgren (for) Assistant Director for Legislative Reference

OMB CONTACT: Robert J. Pellicci
PHONE: (202)395-4871 FAX: (202)395-6148

SUBJECT: HHS Draft Bill on Safety of Imported Food Act of 1997

DEADLINE: 10:00 A.M. Wednesday, October 15, 1997

In accordance with OMB Circular A-19, OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President. **Please advise us if this item will affect direct spending or receipts for purposes of the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.**

COMMENTS: The HHS draft bill is designed to implement a recently announced Presidential initiative. DEADLINE IS FIRM.

DISTRIBUTION LIST

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95-Office of Science and Technology Policy - Jeff Smith - (202) 456-6047
114-STATE - Paul Rademacher - (202) 647-4463
118-TREASURY - Richard S. Carro - (202) 622-0650
128-US Trade Representative - Fred Montgomery - (202) 395-3475

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Jim R. Esquea
James C. Murr
Janet R. Forsgren
Alison Perkins

DRAFT:clcopp/OCC/FDA:10-31-97:C:\files\imports\billnew.031)

A BILL

To To amend the Federal Food, Drug, and Cosmetic Act to provide for improved safety of imported foods.

Be it enacted by the Senate and the House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Safety of Imported Food Act of 1997".

SEC. 2. CRITERIA FOR DEEMING IMPORTED FOOD ADULTERATED.

(a) AMENDMENT TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.--

(a) Section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) is amended by adding at the end the following new subsection:

"(h) If it is a food offered for import into the United States that has not been prepared, packed, and held under a system or conditions, or subject to measures, that meet the requirements of this Act or that otherwise achieve the level of protection required, as determined by the Secretary, for such food prepared, packed, or held in the United States. In determining whether a system, conditions, or measures meet the requirements of this Act or otherwise achieve the level of protection required, the Secretary may consider whether an officer or employee duly designated by the Secretary has requested, and has been refused, access to the establishment or location where such food was prepared, packed, or held for the purpose of inspection (including sample collection), testing, or other relevant procedures, at a reasonable time and in a reasonable manner, and may refuse the importation of such food from such establishment or location on the basis of such refusal and other relevant factors.".

(b) IMPLEMENTATION OF AUTHORITY.--

(1) PLAN.--The Secretary shall develop a plan for the initial implementation of the authority under section 402(h) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), and shall carry out the authority of such subsection consistent with such plan.

Food Safety

Total Pages: 5

LRM ID: RJP164

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503-0001

URGENT

Monday, November 3, 1997

LEGISLATIVE REFERRAL MEMORANDUM

TO: Legislative Liaison Officer - See Distribution below

FROM: Janet R. Forsgren (for) Assistant Director for Legislative Reference
OMB CONTACT: Robert J. Pellicci
PHONE: (202)395-4871 FAX: (202)395-6148

SUBJECT: **REVISED HHS Draft Bill on Safety of Imported Food Act of 1997**

DEADLINE: **4:00 P.M. Tuesday, November 4, 1997**

In accordance with OMB Circular A-19, OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President. **Please advise us if this item will affect direct spending or receipts for purposes of the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.**

COMMENTS: HHS advises that the attached draft bill reflects its understanding of the agreements reached on Friday, October 31st in meetings with USTR, State, and USDA. The White House would like to transmit the draft bill to Congress on Wednesday, November 5th. ***DEADLINE IS FIRM.***

DISTRIBUTION LIST

AGENCIES:
7-AGRICULTURE - Marvin Shapiro - (202) 720-1516
95-Office of Science and Technology Policy - Jeff Smith - (202) 456-6047
114-STATE - Paul Rademacher - (202) 647-4463
128-US Trade Representative - Fred Montgomery - (202) 395-3475

EOP:
Sally Katzen
Wendy A. Taylor
Jerold R. Mande
Joshua Gotbaum
JENNINGS_C
Sarah A. Bianchi
Donald H. Gips
Toby Donenfeld
Barry T. Clendenin
Richard J. Turman
Jim R. Esquea
Mary L. Smith
James C. Murr
Janet Forsgren

LRM ID: RJP164 **SUBJECT:** REVISED HHS Draft Bill on Safety of Imported Food Act of 1997

RESPONSE TO
LEGISLATIVE REFERRAL
MEMORANDUM

If your response to this request for views is short (e.g., concur/no comment), we prefer that you respond by e-mail or by faxing us this response sheet. If the response is short and you prefer to call, please call the branch-wide line shown below (NOT the analyst's line) to leave a message with a legislative assistant.

You may also respond by:
(1) calling the analyst/attorney's direct line (you will be connected to voice mail if the analyst does not answer); or
(2) sending us a memo or letter
Please include the LRM number shown above, and the subject shown below.

TO: **Robert J. Pellicci Phone: 395-4871 Fax: 395-6148**
Office of Management and Budget
Branch-Wide Line (to reach legislative assistant): 395-7362

FROM: _____ **(Date)**

_____ **(Name)**

_____ **(Agency)**

_____ **(Telephone)**

The following is the response of our agency to your request for views on the above-captioned subject:

_____ **Concur**

_____ **No Objection**

_____ **No Comment**

_____ **See proposed edits on pages** _____

_____ **Other:** _____

_____ **FAX RETURN of** _____ **pages, attached to this response sheet**

The Honorable Newt Gingrich
Speaker of the House
of Representatives
Washington, D.C. 20515

Dear Mr. Speaker:

Enclosed for the consideration of the Congress is the Administration's draft bill, the "Safety of Imported Food Act of 1997."

The purpose of the bill is to add to existing safeguards in the Federal Food, Drug, and Cosmetic Act, and thus enhance the Secretary's ability to prevent the importation of potentially unsafe food, in a manner consistent with U.S. trade agreements. The bill would amend the Act to provide that food imported into the United States will be considered adulterated if it has not been prepared, packed, and held under a system or conditions, or subject to measures, that meet the requirements of the Act or otherwise achieve the level of protection required for foods produced domestically. The bill authorizes the Secretary to consider, in determining whether such requirements or level have been achieved, whether the Food and Drug Administration (FDA) has requested, but been denied, access in order to conduct an inspection of the location or establishment where a food was prepared, packed, or held.

Under current law, FDA has authority to deny importation of foods that appear to be adulterated (section 801 of the Act). Under the bill, foods that do not adhere to the criteria of the new legislation could be denied entry under FDA's current authority to prevent the importation of foods that appear to be adulterated. Current seizure authority under the Act (section 304 of the Act) could also be used to deal with such foods.

This proposal will improve FDA's ability to ensure that food imported into the United States affords a level of safety comparable to that for domestically produced foods, and is part of a broader Administration initiative to enhance the safety of the food supply.

We recommend that the Congress give the draft bill its prompt and favorable consideration.

The Office of Management and Budget has advised that there is no

objection to the transmittal of this draft legislation from the standpoint of the Administration's program.

Sincerely,

Donna E. Shalala

Enclosure

DRAFT:dlcopp/OCC/FDA:10-31-97:C:\files\imports\billnew.031)
revised by Ccopp 11/3/97

A BILL

To To amend the Federal Food, Drug, and Cosmetic Act to provide for improved safety of imported foods.

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SEC. 2. CRITERIA FOR DEEMING IMPORTED FOOD ADULTERATED.

(a) AMENDMENT TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.--(a) Section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) is amended by adding at the end the following new subsection:

"(h) If it is a food offered for import into the United States that has not been prepared, packed, and held under a system or conditions, or subject to measures, that meet the requirements of this Act or that otherwise achieve the level of protection required, as determined by the Secretary, for such food prepared, packed, or held in the United States. In determining whether a system, conditions, or measures meet the requirements of this Act or otherwise achieve the level of protection required, the Secretary may consider whether an officer or employee duly designated by the Secretary has requested, and has been refused, access to the establishment or location where such food was prepared, packed, or held for the purpose of inspection (including sample collection), testing, or other relevant procedures, at a reasonable time and in a reasonable manner, and may deny the importation of such food from such establishment or location on the basis of such refusal and other relevant factors.".

(b) IMPLEMENTATION OF AUTHORITY.--

(1) PLAN.--The Secretary shall develop a plan for the initial implementation of the authority under section 402(h) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), and shall carry out the authority of such subsection consistent with such plan.

Food Safety

Tom--

Here's the scheduling request we sent over on the Food Safety Education campaign. The campaign is the result of a public-private partnership that was formed out of the President's 1998 Food Safety Initiative.

This would be an excellent event, with broad array of constituents and bipartisan representation, and would likely get strong press coverage. Virtually every member of the Senate Ag committee talked about the need to increase consumer education at the hearing yesterday.

We are trying to get either the VP or the First Lady. Patrick Steel, our Deputy Chief of Staff, is working with the VP's domestic policy staff.

Right now, the only date that works for Shalala and Glickman is October 20 at 830.

Any chance you could help with this? I think it would be a good thing.....

Thanks.

Eric

FLOTUS

SCHEDULING REQUEST FOR THE FIRST LADY Date: September 10, 1997

_____Accept _____Regret _____Pending

TO: Patti Solis-Doyle
Director of Scheduling
Office of the First Lady

FROM: Thurgood Marshall, Jr.
Assistant to the President and Cabinet Secretary

REQUEST: The First Lady's participation in the kick-off event to launch the Food Safety Education Partnership Campaign.

PURPOSE: To kick-off of the massive food safety education campaign targeted to consumers. The President's 1998 Food Safety Initiative included an extensive education component, the center piece of which is a public/ private partnership to promote consumer awareness of safe food handling. This campaign, the first project of the Partnership for Food Safety Education, is designed to raise consumer awareness of the need for safe food handling by everyone in the food chain. Consumers will be alerted to the role they must play to reduce foodborne illness. Basic safe food handling messages are presented in a clever and educational format. Messages will be delivered through the media, schools, grocery stores, industry, state and federal governments, public health officials, consumer and community groups.

BACKGROUND: It is estimated that as many as 9,000 deaths and 6.5 to 33 million illnesses in the United States each year are food related. Public education is one component of the Administration's new initiative to protect the public health by improving food safety.

Educating people about steps they must take to prevent and control foodborne illness is a vital link in the food preparation chain. Choices consumers make about how they handle food prepared at home and whether they eat unsafely prepared food can have a significant impact on the incidence of illness. Consumers understanding and practicing proper food handling procedures could significantly reduce foodborne illness.

Representatives of the food industry, government agencies, and consumer groups have joined together in a partnership with the primary goal of preventing illness by changing consumers' unsafe food handling behavior. The partnership has worked together to develop a new public awareness and education campaign based on the presentation of four critical food handling messages. The messages are packaged in a very clever design and theme. The campaign theme is: "FIGHT BAC – Keep Food Safe

from Bacteria." It features BAC, a cartoon "critter" that provides a personification to harmful bacteria that cannot be seen, smelled or tasted. BAC constantly tries to get onto food, but is consistently thwarted by the safe handling practices of cleaning, cooking, chilling and keeping foods separate. The campaign character, logo and messages have been extensively focus-group tested and have proven to be understandable, popular and persuasive. The campaign is particularly effective because everyone can FIGHT BAC -- the government, industry and consumers.

PREVIOUS PARTICIPATION: The First Lady addressed the USDA/FDA/CDC Food Safety Education Conference, "Changing Strategies, Changing Behavior" in June. The First Lady's July 4, 1997 syndicated column, "Talking It Over," discussed food safety issues.

DATE AND TIME: September 30, 1997. The time can be set to accommodate the First Lady's schedule.

LOCATION: The Partnership requests that the event be held at the White House, Washington, DC. The Rose Garden, the Indian Treaty Room or Room 450 OEOB could all accomodate the event. Another suggested location could be the White House kitchen to visually convey food safety principles. Alternatively, the event could be held at the National Press Club, the USDA Jefferson Auditorium or the HHS Auditorium.

PARTICIPANTS: Members of the Partnership, including Industry CEO's and Secretaries of Agriculture, Health and Human Services, and Education; other Federal officials, Members of Congress; Consumer group representatives, including children; Public Health and Education associations. Expect an audience of 150-200.

OUTLINE OF EVENTS: The First Lady would host the event and introduce speakers. Mrs. Clinton would discusses the importance of food safety education. She would then introduces the Secretaries Glickman and Shalala. Secretary Glickman and Secretary Shalala will announce the FIGHT BAC campaign. An animated Public Service Announcement is shown. The critter BAC (a person in a mascot-type "suit") makes an appearance to greet Mrs. Clinton and the children in the audience.

REMARKS: REQUIRED: Yes. Approximately 10 minutes.

MEDIA

COVERAGE: Yes. In light of the recent recall of 25 million pound of frozen ground beef from the Hudson Foods Company, we expect the announcement to receive extensive coverage.

RECOMMENDED BY: Secretary Dan Glickman
Secretary Donna Shalala

CONTACT: Patrick Steel, Deputy Chief of Staff, USDA
Telephone: 720-7231; Fax: 690-2119
Mary Beth Donohue, Deputy Chief of Staff, HHS
Telephone: 690-7431; Fax: 401-5783

Food safety

some House Republican leaders are also considering breaking the spending caps due to l e strong, competing budget priorities of the House Republicans.

A Kasich aide said flatly that the warning is meant for "everybody in Congress" ev: more so than the Administration. Asked how Congress can avoid busting the caps, the aide said, "' u don't – or, if you want to spend more money, come up with the offsets." The aide also noted : at Kasich believes that "breaking the caps could seriously hurt the economy, because how do you hink Alan Greenspan is going to look upon us if we bust the caps?"

Meanwhile, an aide to House Majority Leader Dick Armey said that Armey absolute: does not support any effort to remove the spending caps in the budget agreement. The aide's 'ema. s were in response to a story run in yesterday's Bulletin saying that fault lines are beginning to form in he House GOP leadership over the spending caps issue. The Bulletin article said Armey and Sp: ker Newt Gingrich were leaning toward removing the caps.

o **Hutchinson, Coverdell Introduce Legislation To Force Federal Education Dollars Into C| ssrooms.** Sens. Tim Hutchinson and Paul Coverdell introduced legislation today that would require 95% of Federal funds block-granted to states for education go directly to classrooms and teachers. The "D: ars to the Classroom Act" would consolidate the funding for 31 current Federal education programs including Goals 2000 – and deliver that money to state governors in a block grant. The total size of the lock grant diverted from the Federal Education Department and sent directly to states would be $3.3 : lion.

In unveiling the legislation, Hutchinson said, "I do not believe that the problem with o: education system is how much money we're spending. The problem is how we're spending it. Studie: show that 33% of Federal education dollars never leave Washington because they're wasted on bu :aucracy." Hutchinson added, "Under this bill, every classroom in America should receive more money. We need to provide teachers the tools they need to succeed in the critical job of educating our child' ... This bill will help give local school districts the power to hire more teachers, buy more computers : id provide a safe environment for learning."

o **Hollings Outlines Trust Fund Protection Legislation.** Sen. Fritz Hollings introduced legi: tion today aimed at protecting Social Security, Medicare and other Federal trust funds. Hollings dispute: the widely held view that a budget surplus will materialize this year "because they use revenues from F deral trust funds that are supposed to be spent on Social Security, Medicare, unemployment compensat , highway and airport construction as well as military, railroad and civilian retirees," according to Ho l igs' office. Under the Hollings' legislation any new Federal spending or tax cuts will "not come at the xpense of these trust funds." Hollings said, "We have a $5.4 billion debt, we spent $188 billion more th in we took in last year and we will owe our nation's trust funds more than $2.4 trillion at the end of fis al 2002."

Sen. McCain's Bill. Sen. John McCain introduced his "Senior Citizen's Freedom t: Work Act," this week, which repeals the earnings limit on Social Security. McCain said the curre system is "counterproductive and foolish" and is not "pro-work." The earnings cap, McCain says burd ns seniors between 65 and 69 with a 33.3 percent tax on their earned income, even if they exist on a fixed, low-income. "This earnings limit is punitive. ... An individual who is struggling to make en s meet on approximately $20,000 a year should not be faced with an effective marginal tax rate which xceeds 55 percent," McCain said.

o **Stabenow Pushes Food Safety Act.** In an effort to "establish food safety as a priority o the USDA" Michigan Rep. Debbie Stabenow, along with Sen. Carl Levin, introduced this morning the S: e Food Act of 1998. The measure "allows the creation of a pro-active strategy implemented by the D: artment of Agriculture to prevent contamination of the domestic food supply," according to Stabenow's office. The lawmakers say the plan would be self-financed, as the measure would redirect existing f ds already appropriated to the USDA to "provide new tools and technology to protect our food supply," Stabenow's office said. The bill is based on "four pillars" which emphasize prevention, governme efficiency, technological partnerships and a "rapid response" plan. Stabenow said that while the JS ha the safest food supply in the world, "at least 9,000 Americans each year will die of consuming t: nted food."

Tim – what does this do that we're not doing already? What's going to happen to it? Elena

Agriculture Secretary Dan Glickman, in a statement this morning, indicated support for the p in. "The legislation the Congresswomen is introducing today contains provisions that are consisten with the Administration's goals for food safety as articulated in the President's National Food Safety nitiative, Glickman said in the short statement.

- **Greenspan Predicts Slowing Economy.** Federal Reserve Chairman Alan Greenspan said oday the US economy has just begun to feel the impact from Asia's economic crisis and will slow noticea bly soon. In testimony before the Senate Budget Committee today, Greenspan said, "To date, we h e as yet experienced only the peripheral rings of the Asian crisis. But before spring is over, the abr t current account adjustments that financial difficulties are forcing upon several of our Asian trading p ners will be showing through here in reductions in demand for our exports and intensified competition fro imports. All of this suggests that the growth of economic activity in this country will moderate from the r ent brisk pace." Greenspan added that "such a moderation would appear helpful at this juncture," and xplained: "The growth of output has caused employment to rise much faster than the working-age popu tion, and there are limits as to how far this can go."

- **Ideologically Diverse Group Urges Restraint On Asian Bailout.** A small group of House members today urged lawmakers to sign onto legislation that will give Congress a direct say on any potential Asian bailout. Reflecting the ideologically diverse coalition forming in the House against an IMF bail ut, Reps. Bernard Sanders, Cliff Stearns, Peter DeFazio, Dana Rohrabacher and Ron Paul al en rsed the legislation. Sanders said, "Whether or not members of Congress end up supporting internationa bailouts, there should be agreement that the US Congress must have a voice and a vote as to wheth and how billions of taxpayer funds are used. It is ironic that small appropriations are sometimes debate for hours on the House floor, while billions of ESF [Exchange Stabilization Fund] dollars are placed at k with no congressional debate or vote." The legislation they are supporting would subject an obligatio n excess of $250 million to the ESF to "the normal appropriations timelines."

- **Babbitt Disputes "Conspiracy Theory" Of Political Taint In Casino Decision.** Interior Secretary Bruce Babbitt began testimony this morning before the Burton Committee regarding the r e politics played in his Department's decision to reject the casino application of three Wisconsin Indian ribes. In contrast with his previous testimony before the Thompson Committee, Babbitt came out sw ging this morning, referring repeatedly to the allegations surrounding the casino decision as the p duct of a "conspiracy theory."

  Babbitt, in his opening statement, said Republican investigators would "have you believe a conspiracy theory worthy of Oliver Stone." Adding that his department's rejection of the casin "was the right decision, made in the right fashion, and for the right reasons," Babbitt disputed the impre sion that the casino was nothing more than a means to generate income for impoverished tribes. "This c sino was a business proposition," Babbitt said, promoted by "well-financed, out-of-state" gambling int ests over the "legitimate objections of the local communities."

  Babbitt acknowledged that lobbyists against the application, including previous witn s Patrick O'Connor, may have acted "inappropriately" in seeking to influence the decision, but he ch rged the casino's proponents acted just as inappropriately. Furthermore, Babbitt said, the questionabl behavior of lobbyists "on both sides" did not affect the decision, as Interior department officials "were u aware of and could not possibly have been influenced by" them. Babbitt stressed, "I was personally not aware of" the lobbying of President Clinton, DNC Chairman Don Fowler and Harold Ickes by oppon nts of the application. Babbitt said: "The allegations that there was improper White House or [DNC] inf ence and that I was a conduit for that influence are demonstrably false." Babbitt concluded his sta ement by saying: "I am determined to do everything I can to prevent my reputation...from being tarnis ed by the losers" of the casino fight.

  Committee Chairman Dan Burton questioned Babbitt about his meeting with former campaign manager and then-casino lobbyist Paul Eckstein – a meeting about which Babbitt has supplied contradictory recollections. Babbitt this morning acknowledged receiving a call from Ecksteir in July of

Food Safety

White House Press Release

PRESIDENT CLINTON ANNOUNCES INITIATIVE TO ENSURE THE SAFETY OF IMPORTED AND DOMESTIC FRUITS AND VEGETABLES

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release October 2, 1997

PRESIDENT CLINTON ANNOUNCES INITIATIVE TO ENSURE THE **SAFETY** OF IMPORTED AND DOMESTIC FRUITS AND VEGETABLES
October 2, 1997

Today President Clinton will announce an initiative to upgrade domestic **food safety** standards and to ensure that fruits and vegetables coming from overseas are as safe as those produced in the United States. The President will ask Congress to enact legislation that will require the **Food** and Drug Administration (FDA) to halt imports of fruits, vegetables and other **food** products produced in countries that do not meet U.S. **food safety** requirements. The President will direct the Department of Health and Human Services (HHS) and the Department of Agriculture (USDA) to work cooperatively with the agricultural community to develop guidance on good agricultural and manufacturing practices for fruits and vegetables.

Enhanced FDA Oversight for Imported **Foods.** The President will send legislation to Congress that will require the FDA to halt imports of fruits, vegetables and other **food** products from any foreign country with **food safety** systems and standards that are not on par with those of the United States. The legislation also will require the FDA to halt imports from countries or facilities that do not allow FDA inspections to occur. This legislation -- comparable to existing law that requires the USDA to halt the importation of meat and poultry from such countries -- will enable the FDA to prevent the importation of potentially unsafe foreign produce. The President will also commit to providing the necessary funds in his Fiscal Year 1999 budget to enable the FDA to dramatically expand its international **food** inspection force. With this greatly increased ability to inspect **food safety** conditions

Fax

To: Tom Freedman, DPC

Fax: 456-7431

Pages: 8, including this cover sheet.

Date: November 21, 1997

Attached is the draft outline of the 90 day report we received from FDA this morning. They have given us until December 1 to comment.

See you at 4 p.m.

From the desk of...

Maureen Kelly
Special Asst for Policy
Off. Of Under Sec'y for Food Safety
1400 Independence Avenue, S.W., Rm. 233E
Washington, DC 20250

not a long report

Produce and Imported Food Safety Initiative Status Report - Outline

Summary

In his October 2 Directive to the Secretaries of Health and Human Services and the Department of Agriculture, the President requested the Secretaries to report back within 90 days (January, 1998) with a complete schedule for developing "standards" to ensure the safety of fresh produce within a year and a comprehensive plan to improve the monitoring of food safety programs abroad, to help foreign countries upgrade their safety precautions, and to toughen food inspections at the border. This report describes the timeline developed by FDA, in cooperation with USDA and other participating agencies, for publication of broad-scope good agricultural practices (GAPs) and good manufacturing practices (GMPs) for all fresh fruit and vegetables and GAPs/GMPs for additional, specific fruits and vegetables. The report also lays out the agencies' strategy for:

- Improved monitoring of domestic and foreign agricultural practices
- Improved monitoring of manufacturing practices
- Providing technical assistance to foreign countries
- Targeting inspection and testing to highest risk areas
- Education and outreach to domestic and foreign growers
- Accelerating supporting food safety research

Background

While American consumers enjoy the safest food supply in the world, there have been increasing incidences of foodborne illness outbreaks associated with fresh fruits and vegetables from both domestic and imported sources. In an effort to enhance the safety of fresh produce from all sources, on October 2, 1997, President Clinton announced steps to further ensure the safety of the nation's food supply. The directive, entitled "Initiative to Ensure the Safety of Imported and Domestic Fresh Fruits and Vegetables" is geared toward increasing assurances that fruits and vegetables, whether produced domestically or imported, are safe.

Elements of the directive include:

- Legislation will be requested from Congress giving FDA the authority to halt imports unless importing countries have in place food safety systems that offer the same level of protection as the U.S. system.
- The Administration will request FY'99 funds to increase coverage of importing countries
- FDA develop inspection system for foreign inspections
- HHS and USDA will issue, by October 1, 1998, guidance on good agricultural practices (GAPs) and good manufacturing practices (GMPs) for fresh fruits and vegetables
- GAPs and GMPs should take into account differences in crops and growing regions and address potential risks throughout the food distribution and marketing system.
- Develop coordinated outreach and educational activities
- Accelerate food safety research necessary to support these activities.

Status Report Outline

FDA, in cooperation with USDA, CDC, EPA, and Department of Labor, will plan and implement the following operations in order to carry out the President's October 2, 1997 Directive e. (A draft report on the plans and timetable for accomplishing these goals will be prepared by December 1.)

I. Issue broad guidance, from which will flow more specific Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs) documents.

A. Strategy

A single broad-scope good agricultural practices (GAPs) and good manufacturing practices (GMPs) document is being prepared for publication during FY'98. This "Guide to Minimizing Microbial Food Safety Hazards for Fresh Fruits and Vegetables" is intended to be guidance only. The guide does not bind the agencies, nor does it create or confer any rights, privileges, or benefits for, or on, any person. This guide will represent the best advice of FDA and USDA. Industry and public input will be sought and incorporated into these documents.

This broad-scope guide will be used as a model for developing individual documents for specific fruits and vegetables deemed to be at high risk of microbial contamination. The agencies plan to issue these additional GAPs and GMPs in the near future. These guidance documents will discuss microbial hazards and good management practices specific to individual fresh market crops and regions. Where applicable for a particular crop, the specific documents will include guidance on minimizing microbial food safety hazards at subsequent steps in the food production system beyond those covered in this general guidance document. These detailed guidance documents will be accompanied by extensive educational and outreach programs for the fresh produce industry and consumers.

B. Agencies Responsible

1. Lead: FDA

2. Support: USDA (AMS, CSREES, ARS, FSIS), EPA, Department of Labor

C. Timetable

1. FY'98

a) Broad-scope GAP/GMP document

11/17/97: Draft broad-scope GAP/GMP document to Produce Subcommittee of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) for review.

Public meeting to introduce draft broad-scope GAP/GMP document and solicit input from representatives from the food industry and consumer advocates.

I. Issue broad guidance, from which will flow more specific Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs) documents. (cont.)

12/1-12/97: Six domestic and one international grassroots meetings will be held to introduce the draft broad-scope GAP/GMP and solicit input from growers, handlers, and processors of produce.

1/16/98: Revised draft broad-scope GAP/GMP delivered to the Produce Subcommittee, NACMCF, for review.

1/30/98: Final approval of draft broad-scope GAP/GMP by FDA/CFSAN.

2/28/98: Publication of draft broad-scope GAP/GMP in Federal Register; 45-day comment period.

4/15/98: End of comment period on draft broad-scope GAP/GMP.

4/98: Possible second public meeting.

5/31/98: Approval of final broad-scope GAP/GMP by FDA/CFSAN.

6/30/98: Public notice of availability of final broad-scope GAP/GMP.

b) Individual commodity GAP/GMPs

12/97: Four commodities will be selected for development of individual GAP/GMP documents; these will be chosen based on judgements about their relative risk of microbial contamination

4/98-5/98: Publication in Federal Register of four draft individual GAPs/GMPs, one for each commodity selected during 1997

4/98-5/98: Additional commodities identified as suitable for individual GAP/GMP development.

2. FY'99

12/98: Final approval of second set of individual GAP/GMPs by FDA/CFSAN.

II. Identify ways to improve monitoring of agricultural practices, foreign and domestic.

A. Strategy

An international Food Safety Program will be established to monitor domestic and foreign agricultural practices. FDA investigators, available using increased resources, will work with USDA personnel to monitor domestic (USDA, CSREES, AMS involvement) and foreign (APHIS, FAS) operations. GAP/GMP documents developed under item I. will be used as a guide to survey importing countries and develop a baseline of potential problem areas.

II. Identify ways to improve monitoring of agricultural practices, foreign and domestic. (cont.)

B. Agencies Responsible:

1. Lead: FDA and USDA (FAS, NRCS, FSA, ERS, NASS, AMS, APHIS)

C. Timetable

1. FY'98

11/97:	FAS will provide a timeline for developing country profiles
Summer '98:	Develop international Food Safety Program

2. FY'99

III. Identify ways to improve monitoring of manufacturing practices.

A. Strategy

An international Food Safety Program will be established to monitor manufacturing practices in domestic and foreign operations. FDA investigators, available using increased resources, will work with USDA personnel to monitor domestic (USDA CSREES, AMS involvement) and foreign (APHIS, FAS) operations. GAP/GMP documents developed under item I will be used as a guide against which to evaluate the practices.

B. Agencies Responsible

1. Lead: FDA and USDA (NASS, ERS, FAS, AMS)

C. Timetable

1. FY'98

2. FY'99

IV. Provide technical assistance to foreign countries.

A. Strategy

USDA will document known measures and practices affecting the safety of U.S. food imports or targeted problem regions. Working cooperatively with FDA, USDA will establish country profiles assessing the in-country safety parameters and likelihood of meeting U.S. entry requirements for fresh produce. Based on the country profiles, FDA will target inspection and testing to areas of highest risk. USDA and FDA will work with all affected parties to communicate GAPs and GMPs for fresh fruits and vegetables.

FDA and FAS will expand foreign training and technical assistance directed towards countries that import produce into the U.S.

IV. Provide technical assistance to foreign countries. (cont.)

B. Agencies Responsible

1. Lead: FDA and USDA (FAS, FSIS, APHIS)

C. Timetable

1. FY'98

FDA has met with USDA and has provided FAS preliminary information on country profiles.

2. FY'99

V. Develop methods to target inspection and testing to areas of highest risk.

A. Strategy

Based on country profiles compiled by USDA, FDA will evaluate growing, harvesting, handling, transportation, and production operations in foreign countries. Models will be developed to assess the risks associated with different types of commodities, geographic regions, and growing conditions. FDA/CFSAN, with support from USDA, will develop risk assessments based on volume of production, the particular agricultural and handling practices associated with each commodity, and profiles of countries from which the U.S. imports.

FDA will collect and analyze approximately 1000 additional samples to determine the status of products offered for entry into the U.S. As a first step, FDA will collect and analyze samples of prepared cut vegetable salad items to obtain information on current sanitation practices used by the industry and evaluate correlation between these practices and analytical results.

A federal-state communications system will be expanded, enabling states to inform federal agencies of problems found with imported products in their jurisdictions.

B. Agencies Responsible

1. Lead: FDA

2. Support: USDA (ORACBA, ERS, FSIS, ARS, AMS), EPA, CDC

C. Timetable

1. FY'98

11 /97: Draft FDA Field assignment for sampling and analysis of foods from fresh cut manufacturers

1 /98: Field assignment for fresh cut manufacturers issues.

V. Develop methods to target inspection and testing to areas of highest risk. (cont.)

2. FY'99

FDA budget request for resources to do microbiological survey of fresh cut produce. NACMCF will develop criteria for this survey.

VI. Develop strategy for education and outreach to growers (domestic and foreign).

A. Strategy

FDA and USDA will expand communications about fresh fruits and vegetables GAPs and GMPs to appropriate audiences. USDA Cooperative State Research, Education and Extension Service (CSREES), with its existing network of contacts within the U.S. farming community, will provide access points for disseminating the GAPs and GMPs and for providing further education to support their implementation.

USDA APHIS and FAS, with their networks in foreign countries, will provide access points for producers handlers of produce outside the U.S.

B. Agencies Responsible

1. Lead: FDA and USDA (CSREES, NAPLAP, NRCS)

2. Support: EPA, OSHA

C. Timetable

1. FY'98

A meeting is scheduled with USDA for November 10, 1997 to develop an outreach education plan.

2. FY'99

VII. Accelerate food safety research to support these activities.

A. Strategy

FDA and USDA are individually reviewing their respective FY'98 research projects for produce to identify areas for future research to reduce microbial risk. The agencies have met with industry and consumer representatives to determine what research is currently ongoing or in the developmental stages, as well as determining research needs for reducing microbial contamination from fresh produce.

B. Agencies Responsible

1. Policy Direction: NSTC

2. Lead: FDA and USDA (ARS, CSREES, ERS)

3. Support: EPA

VII. Accelerate food safety research to support these activities. (cont.)

C. Timetable

1. FY'98-'99

9/26/97:	CFSAN meeting with ARS
10/7-8/97:	ARS meeting at USDA/ARS, Philadelphia
10/23/97:	FDA/industry meeting
11/30/97:	FDA draft FY'98 research plan for fresh produce
11/6/97:	Interagency meeting on "Research Needs and Research Being Conducted" cosponsored by ARS and FDA; attended by DOD, USDA, EPA, NIOSH
1/98:	Research plan for FY'98 available

2. FY'99

pifsi3 outline

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF THE GENERAL COUNSEL
FOOD AND DRUG DIVISION
5600 FISHERS LANE, GCF-1
ROCKVILLE, MD 20857

Food Safety

FACSIMILE TRANSMISSION RECORD

2 NUMBER OF PAGES (including coversheet)

TO: Thomas L. Freedman
Domestic Policy Counsel

Facsimile Telephone Number: 202-456-7431 Voice Telephone Number: 202-456-5587

FROM: Catherine L. Copp
Office of the General Counsel/FDA

Facsimile Telephone Number: 301-443-0739 Voice Telephone Number: 301-827-1178

DATE: October 31, 1997

MESSAGE: Attached is a revision of the legislation regarding safety of imported food that reflects the agreements reached at this morning's meeting. I have also sent to USDA and USTR. Please confirm with me ASAP (no later than 3:15 pm) that the attached accurately reflects those agreements. My telephone number is 301-827-1178. Many thanks.

This transmission is from a Xerox 7020 telecopier. If you do not receive a legible document, or do not receive all of the pages, please telephone /us immediately at the voice number above.

DRAFT:clcopp/OCC/FDA:10-31-97:C:\files\imports\billnew.031)

A BILL

To To amend the Federal Food, Drug, and Cosmetic Act to provide for improved safety of imported foods.

Be it enacted by the Senate and the House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Safety of Imported Food Act of 1997".

SEC. 2. CRITERIA FOR DEEMING IMPORTED FOOD ADULTERATED.

(a) AMENDMENT TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.--(a) Section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) is amended by adding at the end the following new subsection:

"(h) If it is a food offered for import into the United States that has not been prepared, packed, and held under a system or conditions, or subject to measures, that meet the requirements of this Act or that otherwise achieve the level of protection required, as determined by the Secretary, for such food prepared, packed, or held in the United States. In determining whether a system, conditions, or measures meet the requirements of this Act or otherwise achieve the level of protection required, the Secretary may consider whether an officer or employee duly designated by the Secretary has requested, and has been refused, access to the establishment or location where such food was prepared, packed, or held for the purpose of inspection (including sample collection), testing, or other relevant procedures, at a reasonable time and in a reasonable manner, and may refuse the importation of such food from such establishment or location on the basis of such refusal and other relevant factors.".

(b) IMPLEMENTATION OF AUTHORITY.--

(1) PLAN.--The Secretary shall develop a plan for the initial implementation of the authority under section 402(h) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), and shall carry out the authority of such subsection consistent with such plan.

Food Safety

Food Safety

Meeting

EW

USDA

U.S. DEPARTMENT OF AGRICULTURE

OFFICE OF THE SECRETARY

Telephone (202) 720-3631 Fax (202) 720-5437

FAX COVER SHEET

DATE:_____

NUMBER OF PAGES_____, **INCLUDING COVER SHEET**

PLEASE DELIVER TO: Ron / Mary

_____

FAX NUMBER: ( ) _____ **PHONE NUMBER:** ( ) _____

FROM:

- ☐ DAN GLICKMAN, SECRETARY
  - ☐ JOHN GIBSON, SPECIAL ASSISTANT
- ☐ GREG FRAZIER, CHIEF OF STAFF
  - ☐ KOFI DEGRAFT-JOHNSON, EXECUTIVE ASSISTANT
- ☐ REBA PITTMAN EVANS, DEPUTY CHIEF OF STAFF, INTERNAL AFFAIRS
- ☐ PATRICK STEEL, DEPUTY CHIEF OF STAFF, EXTERNAL AFFAIRS
  - ☐ JOSE VENZOR, ASSISTANT TO THE DEPUTY CHIEFS OF STAFF
- ☐ PAUL DRAZEK, SPECIAL ASSISTANT FOR POLICY
- ☐ ANNE KENNEDY, SPECIAL ASSISTANT FOR POLICY
- ☒ ERIC OLSEN, SPECIAL ASSISTANT FOR POLICY
- ☐ JANET POTTS, COUNSEL TO THE SECRETARY
- ☐ JOHN SPARKS, SPECIAL ASSISTANT FOR CIVIL RIGHTS

MESSAGE: _____

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DRAFT of 5/20/98 4:00 pm

UNITED STATES-MEXICO JOINT STATEMENT ON THE UNITED STATES FOOD SAFETY INITIATIVE

In support of cooperative work in the implementation of the United States Food Safety Initiative under this Joint Statement between the United States Department of Agriculture and Department of Health and Human Services and the Secretariat for Agriculture and Livestock and the Secretariat for Health of the United Mexican States:

The goals of the United States Food Safety Initiative and its Produce component (the Initiative) are to reduce the incidence of food-borne illness to the greatest extent feasible and to enhance the safety of all foods, both domestically produced and imported. Success in achieving these goals depends upon effective, continuing cooperation and collaboration between the United States and its trading partners based on the concepts contained in the May 1997 Report to the President titled *Food Safety From Farm to Table: A National Food-Safety Initiative.*

The United States and Mexico share a special relationship, particularly with regard to our partnership under the North American Free Trade Agreement (NAFTA), our common border, and the high degree of trade in food products between our countries. We believe that collaborative activities to further the goals of the Initiative could be carried out in technical working groups that are now being considered under the NAFTA Committee on Sanitary and Phytosanitary Measures (NAFTA SPS). Therefore, both countries intend to work toward focusing discussions on food safety issues in appropriate NAFTA technical working groups.

In recognition of its importance to both countries, the United States and Mexico intend to work closely together to achieve the goals of the Initiative. Both countries intend to increase and enhance relationships previously established between the respective agencies involved with the Initiative. Both countries agree that any new information on food safety issues that might be gained and shared under activities associated with the Initiative should be validated and applied consistent with scientific evidence, especially in areas such as microbiological safety.

Both countries intend to discuss and collaborate in activities which our respective governments are undertaking to help meet the joint goals of reducing food borne illnesses and enhancing the safety of foods traded between our countries.

Daniel R. Glickman
Secretary of Agriculture
United States of America

Romárico Arroyo Marroquín
Secretary of Agriculture, Livestock
and Rural Development
United Mexican States

Donna E. Shalala
Secretary of Health and Human Services
United States of America

Juan Ramon de la Fuente
Secretary of Health
United Mexican States

Political Briefing

B. Drummond Ayres Jr.

A Test of Wills Over Drug Legislation

It was called Proposition 200 and it seemed straight-forward enough when it appeared on Arizona ballots in the fall of 1996. Backed by a well-financed grass-roots organization that called itself Arizonans for Drug Policy Reform, it proposed allowing doctors to prescribe marijuana and other illegal drugs for medical use by grievously ill and dying patients.

Voters approved it.

The Arizona Legislature, one of the most conservative in the country and in no mood to have the state join California and Washington in the much-debated national push to legalize illegal drugs for medical use, saw the proposition as a legislative end run by a special interest group that had more in mind than just compassion for the sick. Legislative leaders said that while marijuana was the drug most talked about by Proposition 200's proponents, the measure as written, would also permit doctors to prescribe other illegal drugs like heroin, LSD and PCP.

The legislature then amended the measure, adding a rider that said Arizona doctors could not prescribe a drug not on the Federal Government's list of approved drugs. That amendment effectively gutted the measure.

But the fight did not end there.

Arizonans for Drug Policy Reform, having renamed itself The People Have Spoken, now has another drug proposal for voters to consider. Labeled Proposition 300 and scheduled to be on this fall's election ballot, it would restore Proposition 200 to its original form and instruct the legislature not to modify it again.

Fighting back, state lawmakers are making sure that this time around, the official ballot description of the proposition is worded so voters will understand that they are deciding not whether to legalize not only the use of marijuana for medical purposes but also other illegal drugs.

Two weeks ago, The People Have Spoken, whose major supporters include George Soros, the international investor whose interests include major social issues, asked a judge to throw out the lawmakers' description of the measure, arguing that it was unfair for the [illegible] a fight in which it alone wrote the rules of engagement. The court refused and the pamphlets now are being readied for distribution.

Surprise Showdown Looms in Wyoming

Wyoming is one of the nation's most Republican states, with the Grand Old Party enjoying a 2 to 1 registration edge over Democrats. So the odds are that the state's Republican Governor, Jim Geringer, will handily win a second term this fall.

Still, in the aftermath of Tuesday's primaries in the Cowboy State, the race now merits watching.

Mr. Geringer easily won renomination. But in doing so, some weaknesses were exposed, and as a result the Democratic nominee, state Senator John P. Vinich, who also easily won nomination, probably has a better shot at the Governor's job than he originally had reason to expect.

Ever since he took office three years ago, the Governor has struggled to get the Wyoming economy moving, but with little success. With its small population, limited job base and vast remoteness, the state is the rare economic exception in this era of boom, and throughout the primary season the Governor's critics were quick to put the blame on him.

His main challenger in the primary, Bill Taliaferro, a sheep rancher, hammered him relentlessly on the matter. But the Governor also had to contend with the issue and its political fallout when one of the state's highest-ranking Republicans, Secretary of State Diana J. Ohman, announced she too was unhappy with his leadership and approved a last minute write-in campaign for the nomination on her behalf.

Ms. Ohman did not cut very deeply into the Governor's support. But her campaign underscored the divisions within the Republican Party.

Worst of all for the Governor, when the primary was over, Mr. Taliaferro, who pulled about a third of the Republican vote, announced that he would not automatically throw his support to the Governor in the fall but instead might consider supporting Senator Vinich.

He said he would try to make his supporters "players" in the contest by urging them to go with the candidate who offered them the most. Then he called on the Governor to institute economic reforms to solidify the Republican vote.

"There are 29,000 votes out there," he went on. "Who wants them? Vinich or Geringer?"

National News Briefs

U.S. Needs Food Czar, Advisory Panel Says

WASHINGTON, Aug. 20 (AP) — The nation needs a presidentially appointed official to oversee the patchwork of food safety regulations, a governmental advisory group said today.

Although the United States food supply is considered the world's safest, up to 9,000 Americans die every year from food poisoning, and millions are sickened. The Clinton Administration is seeking $100 million for a new plan to strengthen food safety.

Congress asked the independent Institute of Medicine, which advises the Government, whether the system needs changes. The institute's report says it works well most of the time. But the report calls Federal food safety oversight "fragmented" and underfinanced, and recommends a comprehensive food policy led by one official responsible for setting safety standards and fighting disease outbreaks.

Raise for U.S. Workers

WASHINGTON, Aug. 20 (AP) — The Clinton Administration wants to give Federal workers an 8 percent pay raise over the next two years.

Announcements today outlined a 3.6 percent raise for 1999 and a 4.4 percent raise the following year. The 2000 raise would be the largest since 1981.

Mr. Clinton has told Congress that if it does not also approve the pay increase for employees of Federal departments other than the Defense Department, he will use his executive authority to put it into effect, said an official at the Office of Management and Budget.

The New York Times

FRIDAY, AUGUST 21, 1998

Unify U.S. Food Safety Agencies, Panel Urges

Report Says Fragmented Control Leads to Inefficient Visual Inspections, Public Danger

By Rick Weiss
Washington Post Staff Writer

The federal system for ensuring the safety of the country's food supply is bureaucratically fragmented and should be reorganized under the control of a single, powerful food safety authority, a government advisory group said yesterday.

The report, by a committee of the Institute of Medicine and the National Research Council, two nongovernmental research organizations, describes the nation's food safety system as a Byzantine morass of dozens of statutes being implemented by at least 12 federal agencies that are overseen by 28 different congressional committees.

In recent years, the report warns, that patchwork system has become hobbled in its efforts to prevent food contamination and track down outbreaks of food-borne illnesses.

For example, said committee chairman John Bailar III, the country today has 7,000 inspectors staring essentially helplessly at every dead chicken and cow that goes by on every single U.S. slaughterhouse line because archaic regulations require that every carcass be personally eyeballed. Meanwhile, far more sensitive scientific tests for microbial or chemical contamination go unconducted.

The scope of the U.S. food safety problem remains uncertain because there is no unified surveillance effort for food-related illness, said Bailar, chairman of the the University of Chicago's department of health studies. Some experts have estimated that as many as 81 million bouts of illness and 9,000 deaths are linked to food in the United States each year, although others have disputed those figures as grossly exaggerated.

Whatever the true numbers, Bailar and others said, current efforts to improve food safety—including new, science-based federal inspection requirements instituted for meat and seafood this year—are already inadequate.

"A dangerous mix of factors, including the emergence of new strains of food-borne bacteria, new food processing and production techniques, consumer demand for ready-to-eat meals and a rising number of people who are more susceptible to food-borne illnesses, have placed new stresses on the nation's efforts to keep the food supply safe," Bailar said.

To meet that challenge, Bailar said, "We think there has to be a single person with the authority, the responsibility and the resources, by law."

The call for such far-reaching changes in the way food safety is ensured was met with mixed reactions from food industry groups. Several said they supported the report's call for more emphasis on scientific testing of foods, which is much better at detecting contamination from microbes, pesticides or other impurities than is the old-fashioned system of looking at, poking and sniffing food as it goes by on a production line.

The idea of fostering better coordination of the agencies concerned with food safety also was acceptable to most industry representatives.

But several industry representatives balked at the recommendation that a single individual be granted ultimate power to plan and enforce food safety efforts and to investigate food-related outbreaks. And the prospect of creating an entirely new food safety agency to support that person's authority—an option that the panel did not explicitly recommend but called a possible solution to the problem—was roundly rejected by the industry.

"Unless you've organized it properly, you could slow down and bureaucratize the system," said Kelly D. Johnston, an executive vice president of the National Food Processors Association. "I think Congress is going to cast a wary eye on such a change."

Congress has already demonstrated some reluctance to push legislation relating to food safety, a topic fraught with competing big-money interests. At least seven food safety-related bills are now sitting dormant on the Hill, despite President Clinton having made food safety a key issue of his presidency.

Caroline Smith DeWaal, director of food safety for the Washington-based Center for Science in the Public Interest, said she feared that lawmakers would remain hamstrung by their competing interests until the nation suffers additional high-profile tragedies like the deaths of several children in 1993 from bacterially contaminated hamburgers.

"Congress and the White House must be willing to protect American consumers better than they protect turf," DeWaal said.

Members of the advisory committee said it's not clear whether food has become safer or more dangerous in recent years. But several trends suggest new risks exist that were not present a decade ago. One of those factors is the increasing centralization of the food processing industry.

"A single plant or processor can distribute a large amount of food through the nation in a very short time," said member Harley W. Moon, chairman of veterinary medicine at Iowa State University in Ames. "If an accident is there or a mistake is made, it's magnified. And instead of two or three people in a family being affected, you have a national outbreak."

Ironically, said Marsha N. Cohen, a professor at Hastings College of Law in San Francisco and a panel member, the growing popularity of fresh, unprocessed foods—including sushi and raw fruits and vegetables—also has contributed to the risk of food poisoning.

"We've told everyone in the country to eat more fruits and vegetables, but we haven't kept up" by ensuring that raw produce is free of contamination, she said.

Beyond asking Congress to create a centralized food safety authority, the committee called for an immediate halt to the requirement that all animal carcasses be visually inspected, with redirection of those resources to scientific tests. It also called on Congress to ban the importation of food from countries that lack food inspection systems deemed equivalent to those in this country.

The Washington Post
Friday, August 21, 1998

What's News

* * *

Business and Finance

AIG'S ANNOUNCEMENT of plans to buy SunAmerica in a stock deal valued at $16.5 billion shows how highly AIG's chairman values retirement-services products, especially variable annuities. The price tag is nearly six times book value, roughly double the level for other recent purchases of annuity-based businesses. But the ranks of annuity-firm targets for subsequent deals are thin.

(Article on Page A3)

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The FASB is considering a controversial proposal that may require companies to include in their profits the changes in the fair market value of their financial assets and liabilities.

(Article on Page A3)

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Several Fed officials argued at their July meeting that the Fed should 'take advantage of any early opportunity' to raise rates and quell inflation, according to a summary of the talks.

(Article on Page A2)

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Intel will offer a credible response to the budget-PC trend with a line of cheap chips, but the prospect of even lower PC prices is raising new fears about the semiconductor market.

(Article on Page A3)

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Monsanto said it is the first to genetically engineer corn to resist rootworm, an insect that causes $1 billion in damages annually to the crop.

(Article on Page A2)

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Moody's stripped Toyota of its triple-A rating, showing that Japan's economic problems are hurting the credit-worthiness of top companies.

(Article on Page A11)

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The Chicago Merc will hire an investment-banking firm to help it evaluate conversion to a for-profit corporation, taking a step toward altering its nonprofit ownership structure.

(Article on Page C1)

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Barnes & Noble plans to sell a 20% stake in its Internet unit to the public, following the success of Amazon.com and of Internet IPO stocks in general.

(Article on Page B1)

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The SEC may impose new limits on the way companies book their acquisition write-offs due to the poor quality of some recent earnings reports.

(Article on Page A2)

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The Dow Jones industrials fell 81.87 points to 8611.41 and small stocks took a sharper blow as unsettling corporate and world news mounted.

(Article on Page C1)

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A judge delayed by two weeks the start of the government's case against Microsoft, setting it for Sept. 23.

(Article on Page B5)

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Venezuela's stocks fell and its currency, the bolivar, came under pressure amid worries that the country planned a devaluation. The fears also hit other Latin American bourses.

(Articles on Pages A13 and C12)

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Autodesk plans to buy Discreet Logic, a Canadian maker of digital design and multimedia software, in an all-stock deal valued at $520 million.

(Article on Page B5)

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Short interest slid to 4.10 billion shares on the Big Board in the latest month, while Amex activity rose.

(Article on Page B6)

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Markets—

Stocks: Volume 616,026,010 shares. Dow Jones industrials 8611.41, off 81.87; transportation 3047.25, off 17.63; utilities 280.09, up 0.12.

Bonds: Lehman Brothers Treasury index 8241.80, up 38.26.

Commodities: Oil $13.53 a barrel, up 35 cents. Dow Jones futures index 124.15, off 0.10; spot index 123.01, off 0.19.

Dollar: 143.14 yen, off 0.93; 1.7991 marks, up 0.0014.

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World-Wide

CLINTON ORDERED attacks on Sudan and Afghanistan over the Africa bombings. Cruise missiles struck Afghan camps believed used by followers of renegade Saudi tycoon Osama bin Laden, who was reported unhurt, and a suspected chemical-arms plant in Khartoum. A crowd of Sudanese later stormed the U.S. embassy, empty since 1996, and U.S. officials warned of possible retaliatory attacks. The president cited the Kenya and Tanzania embassy bombings, other attacks and unspecified imminent threats to justify airstrikes. GOP Sens. Specter and Coats questioned the timing, with Clinton caught up in a sex scandal. (Articles in Column 6 and on Page A4)

Attacks by Afghanistan-based Islamic militants are a growing concern for the U.S., which helped finance their fight to oust Soviet troops during the 1980s.

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Monica Lewinsky testified for five hours before the grand jury in the sex scandal involving the president, and her spokesman said the former White House intern's second appearance was expected to be her last. Both parties are struggling to decide how to react to the scandal, and how it will affect midterm elections. (Article on Page A16)

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Quebec secessionists were handed a setback by Canada's Supreme Court, which ruled the province can't unilaterally separate from the rest of the country. Secession, the court said, must be negotiated with the rest of Canada if Quebec votes for independence. Analysts await reaction from Quebec Premier Bouchard. (Article on Page A12)

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Continued sanctions against Iraq were backed by the U.N. Security Council after its regular 60-day review. The council called Baghdad's suspension of cooperation with arms inspectors "totally unacceptable," but the U.S. failed in a bid to threaten Iraq with "severest consequences" in the dispute.

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Theodore Kaczynski's brother was given a $1 million reward by the Justice Department for providing information that led to the conviction of the Unabomber. David Kaczynski said last year he will use the money to help those hurt and the families of those killed in the 18-year bombing spree.

* * *

James Hoffa picked up support from leaders of Teamsters locals in his effort to succeed the ousted Ron Carey as union president. At least 13 leaders formerly allied with Carey now back the son of the legendary union boss, a bad blow to Tom Leedham, his chief rival. (Article on Page A16)

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A federal food-safety panel urged an overhaul of current laws and appointment of an official to manage outbreaks of sickness and set safety standards. The 200-page report by the panel, requested by Congress, said food problems may increase as imports grow and Americans eat out more often.

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Germany's Social Democrats said tax reform and efforts to ease unemployment would be their main goals if they defeat Chancellor Kohl and his Christian Democrats Sept. 27. Gerhard Schroeder announced the platform as polls show some erosion of his lead. (Article on Page A13)

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Congo state TV showed soldiers from a southern African alliance arriving in Kinshasa to defend the Kabila regime against an advancing rebel army. There was no indication of the size of the contingent. Airstrikes on rebel forces were reported.

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A grenade attack in Cambodia appeared aimed at opposition politician Sam Rainsy, who was inspecting ballots from the July 26 election at the interior ministry in Phnom Penh when the blast occurred. Rainsy wasn't hurt, but another man was killed.

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Parts of China's biggest oil field were engulfed by the Nen River as soldiers struggled to shore up barriers protecting Daqing city. On the Yangtze, the industrial city of Wuhan braced as a new flood crest neared.

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Indian authorities evacuated 30,000 people from two river valleys in northern Uttar Pradesh state as a series of landslides continued. About 300 people, many of them Hindu pilgrims, may have been killed.

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Myanmar's top dissident offered to end her standoff with police at a roadblock outside Yangon if the military government frees jailed members of her party. Allies say Aung San Suu Kyi's health is worsening.

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Paraguay's new president faces a brewing impeachment battle after he freed the leader of a 1996 coup attempt Tuesday, four days after taking office. Congress is to act soon on a motion to impeach Raul Cubas.

THE WALL STREET JOURNAL
FRIDAY, AUGUST 21, 1998

Panel sees need for food safety czar

By Anita Manning
USA TODAY

The government needs a single person — a food czar — with the clout and money to take responsibility for federal food safety programs now fragmented among a dozen agencies, a scientific panel said Thursday.

The National Academy of Sciences, asked by Congress to find ways to reduce foodborne illness, stopped short of calling for creation of a government food agency, but said many of its committee members favored such an agency.

Foodborne microbes cause as many as 81 million illnesses and 9,000 deaths in the nation each year.

"We need a unified framework headed by a single official at whose desk the buck stops," says panel member Marsha Cohen, a law professor at the University of California, San Francisco.

"We now have a morass of agencies operating under "antiquated" statutes "created for another time and different issues," Cohen says.

The committee recommended changes in food regulations to take advantage of new technologies and to eliminate strategies that are no longer useful.

For instance, Cohen says, federal inspectors are required to look at each of 7 billion chickens slaughtered each year, but such inspection can't determine the presence of salmonella, a common foodborne pathogen.

"We can't eliminate all foodborne disease, but to reduce risks you want your government dollars to be chasing the most reducible risks there are," she says.

"You can't do that effectively if the pile of money is divided among different agencies, each with its own statutory priorities."

It's now up to Congress to implement the panel's recommendations.

Industry and consumer representatives were generally positive about the report, but disagreed over the possibility of creating a single food agency. "What is needed is a single, scientifically based food safety policy, rather than a single food safety agency," says a statement from the National Food Processors Association.

"It's hard to fathom how they'd achieve their goals without a single food agency," says Carolyn Smith DeWaal of the Center for Science in the Public Interest, who favors such a setup.

Hits Sudan, Afghanistan

By Bill Nichols
USA TODAY

WASHINGTON — The White House, seeking to avenge two embassy bombings in East Africa two week ago, launched missile attacks Thursday on suspected terrorist camps in Afghanistan and a chemical plant in Sudan.

"Our target was terror," President Clinton said in an Oval Office address after rushing back to Washington from Martha's Vineyard, where he was on vacation.

Administration officials fear retaliation for the strikes. The State Department issued an alert urging U.S. citizens traveling abroad to "exercise much greater caution than usual."

National Security Adviser Sandy Berger said the FBI has also issued an alert to all local law enforcement officials.

The strikes were directed at facilities linked to Osama bin Laden, an exiled Saudi Arabian millionaire who has threatened Americans worldwide because of U.S. policies in the Middle East, administration officials said.

Berger cited overwhelming proof that bin Laden was behind the Aug. 7 bombings in Kenya and Tanzania in which 263 people were killed, including 12 Americans.

Senior U.S. officials said Mohammed Saddiq Odeh, a Palestinian suspect in the bombings, provided irrefutable evidence of bin Laden's involvement.

Clinton and his national security team said that the 75 Tomahawk cruise missiles fired from U.S. vessels in the Red Sea and Arabian Sea also were prompted by indications that groups affiliated with bin Laden were planning other attacks on Americans.

Thursday was chosen, Clinton said, because intelligence reports indicated a major gathering of terrorist leaders was to take place at the suspected terrorist training and support camp located near the Afghanistan-Pakistan border.

The other strike — both took place at about 1:30 p.m. ET — hit a pharmaceutical plant in Khartoum, Sudan, where U.S. officials said bin Laden was financing the production of chemical weapons agents.

U.S. officials could not immediately gauge the success of the strikes or estimate casualties on the ground. There were no reported U.S. casualties.

A spokesman for the Taliban, the Islamic militia that rules much of Afghanistan, said bin Laden was safe.

At United Nations headquarters in New York, Ambassador Bill Richardson told the Security Council the United States acted in self-defense, in accord with the U.N. charter.

Clinton's action was backed by most congressional leaders. "The right thing to do at the right time," said House Speaker Newt Gingrich.

A USA TODAY/CNN/Gallup poll of 628 adults found 66% approved of the attacks. The margin of error was +/- 4 percentage points.

But questions were immediately raised as to whether the timing of the strike was aimed at deflecting attention from Clinton's political woes.

Sen. Arlen Specter, R-Pa., suggested Clinton wanted to "focus attention away from his own personal problems."

But the poll found that 58% believe the attack was launched solely because it was in the country's best interest.

Said Defense Secretary William Cohen: "The only motivation driving this action today was our absolute obligation to protect the American people."

According to a survey by the National A ciation of Colleges and Employers, the average starting salary for 1998 graduates in English, s and related majors was $27,608 up almost 16 percent from the previous year.

"Because the booming economy is driving up the need for the educated work force, really everyone is doing well," said Camille Luckenbaugh, employment information director for the association.

To be sure, there are still plenty of jobless anthropologists and cl s majors wondering how they will pay the rent. It is still a tough t to take a liberal arts degree into academics or other nonprofit enterprises. But for those who look further afield into such sectors as business, the service industries and consulting liberal arts graduates are finding new opportunities in the expanding economy.

For one thing, the shortage of graduates trained in engineering and other technical fields has forced some employers to cast a broader net for their employees.

"Engineering and computer science graduates are going like hot potatoes, getting $60,000 a year in Silicon Valley," said Gina Goings, a recruiter for Walker Digital. "We can't compete. Our preference is for engineering and computer science majors, but we are open to all majors."

Inc demand for liberal arts graduates may not outlive the current period of labor shortage. But it may be a more enduring trend if employers see new value in how generalists are able to cope in a rapidly changing economy. If so, it would represent a big departure from the trend toward increased specialization that has dominated the vocational and professional scene for decades.

"It may take a while for that mind-set to change that a generalist is not going to have a problem getting a job," said Margaret Odell, placement director at St. John's College. "It's always going to be a hard sell to parents, because most of them grew up in a climate where they d to specialize."

F with cutthroat demand for college graduates, many employers are stepping up their campus recruitment efforts. Companies that used to visit colleges in January and February are showing up as early as September and October to fill jobs for the following spring.

At Carleton College in Minnesota, twice as many recruiters showed up this year. Some potential employers even came to recruit juniors, Chris Otis Skinner, director of Carleton's career center.

However, a bountiful job market does not mean that students can wait for jobs to come to them. The most successful liberal arts graduates have been those who were aggressive and organized about their job search getting internships, summer jobs and other experience that could give them an advantage.

"One of the things we might have predicted a few years ago was that students might become more complacent, passive in their job search," said Sims of UCLA. "That hasn't happened. Students are more participatory. They can get career information 24 hours a day, seven days a week on the Internet."

This is, after all, a generation of students who entered college at a when jobs were not so plentiful. So it was with some anxiety that K z started studying in 1994 at a college so resolutely -careerist.

"I was worried," Krantz said. "But one of the appeals of the place was that I'd get to try a wide variety of disciplines."

By the time Krantz was a senior, companies such as Walker Digital hungry for workers. The company distributed recruitment fliers on campus during his senior year and Krantz responded. The company him from New Mexico to Connecticut for two days of interviews. A later, they offered him a job as an assistant research project manager.

"My goal had been to get a job by graduation, and I ended up getting one several months before," Krantz said. "I lucked out."

Across the country at Lehigh University, senior Megan Fitzpatrick was taking nothing for granted as she prepared for graduation this spring. She tried to make herself more marketable by focusing her mathematics major on statistics and taking a series of exams to qualify as an actuary. Her efforts were rewarded when she got five job offers by the end of January.

Three of the five companies offered signing bonuses. In the end she ed a job with Towers Perrin, a consulting firm, which topped other companies by offering a $42,900 annual salary, plus a $5,000 bonus.

Some liberal arts students have maneuvered themselves into the hottest job market by developing their computer skills on the side. That's how another St. John's graduate, Paul Blouin, went from studying Dante's "Inferno" to accepting a $32,000-a-year job overseeing the computer systems of a truck brake manufacturer. Without taking any computer science courses, Blouin was skilled enough to get two solid job offers before he graduated.

Panel Says U.S. Needs 'Food Czar,' Updated Safety Laws By Ricardo Alonso-Zaldivar (c) 1998, Los Angeles Times

WASHINGTON America needs a "food safety czar" to take charge of a crazy quilt system that falls short of ensuring sound, scientific protection against food-borne illness, an independent research panel told Congress Thursday.

A National Academy of Sciences panel also recommended updating turn-of-century laws on meat and poultry inspection, raising standards for imported fruits and vegetables, and replacing 35 major federal food statutes with a single national food law based on scientific principles.

Food industry spokesmen were cool to the idea of putting one powerful official in charge of issues now handled by more than 12 separate agencies. And the Clinton administration said it is already improving the science behind food safety.

"In essence, you are creating a brand-new federal bureaucracy," said Brian Sansoni, a spokesman for the Grocery Manufacturers of America. He said the group agrees, however, with the panel's call for scrapping archaic food laws.

But consumer advocates predicted the "food czar" proposal would become the focus of debate in Congress.

Academic studies have estimated that contaminated food causes as many as 80 million cases of illness a year and kills up to 9,000 people. Others challenge these estimates as much too high. The hard data to settle the dispute simply don't exist.

But whatever the numbers, the panel noted that lifestyle, diet and population changes have increased some risks to Americans.

People eat more restaurant meals, more raw fruits and vegetables and more imported food. Elderly people, many of whom are less able to withstand illnesses, account for a bigger share of the population.

The panel concluded that the current food safety system provides an "acceptable" level of protection but it could be much better.

"You are not going to go out to lunch and die from it," said panel member Marsha Cohen, a law professor at the University of California in San Francisco. "But even a small risk can create a significant amount of harm ... because everyone has to eat."

A hypothetical "surf n' turf" dinner helps illustrate the problems of fragmented oversight and dated inspection practices:

Under a 1906 law, the carcasses the steak came from must be visually inspected by Agriculture Department inspectors, as all meat and poultry are. The idea was to keep diseased animals from being turned into food for humans. But microbes can't be detected by eyeballing a dead steer. The government's new science-based system for preventing bacterial contamination hasn't yet been extended to all meat processing plants.

The Food and Drug Administration would be responsible for the safety of most of the other foods in the hypothetical dinner.

Except for the shrimp. On seafood, FDA shares jurisdiction with the Commerce Department's National Marine Fisheries Service, which runs a voluntary inspection program.

Unlike the Agriculture Department, FDA does not have on-site inspectors at farms, processing plants, and other points in the food delivery chain.

If the french fries in the dinner were commercially produced, chances are the plant would be inspected by the FDA just once in a decade.

"We have inspectors who make periodic checks on (produce processing), but maybe not enough because too many are watching cows," Cohen said.

Turning to salad and vegetables, the regulatory puzzle gets more complicated.

U.S. growers have to abide by laws that restrict pesticides and contaminants. Foreign growers don't. The Agriculture Department has authority to require that imported meats are produced according to U.S. standards, but FDA doesn't have parallel authority to safeguard fruits and vegetables. And only a tiny proportion of imported produce is inspected.

If wine is imbibed with the meal, there's another regulatory switch. The Treasury Department's Bureau of Alcohol, Tobacco and Firearms is responsible for making sure it is free of harmful additives.

Finally, should the diner get sick from the meal, the Centers for Disease Control might take an interest.

U.N. Votes to Maintain Sanctions Against Iraq (United Nations) By Craig Turner (c) 1998, Los Angeles Times

UNITED NATIONS Faced with a fresh reminder of Iraqi intransigence, the Security Council on Thursday unanimously rejected any easing of economic sanctions against Baghdad but remained divided on any further action.

The council decision followed a gruff dismissal by Iraqi Deputy Prime Minister Tarik Aziz of an overture from chief U.N. weapons inspector Richard Butler. Butler had written to Aziz on Wednesday suggesting a resumption of the arms inspections suspended earlier this month after Iraq ended cooperation with investigators.

Aziz replied with a statement released by the official Iraqi news agency Thursday denouncing Butler and calling Iraq's decision ``permanent.''

Meanwhile, some U.N. disarmament officials expressed fears that the subdued response by American and U.N. officials in the latest confrontation with Baghdad may embolden Iraqi President Saddam Hussein to eject those U.N. weapons inspectors still in the country, clearing the way for full resumption of illegal weapons research and production.

Citing repeated threats by Aziz and other top Iraqi officials, these sources suggest that it may be only a matter of time before Iraq expels the 100 or so disarmament workers remaining in Baghdad and dismantles the video cameras and other devices monitoring activities at sites that could be used for weapons development.

Nizar Hamdoun, Iraq's ambassador to the United Nations, said Thursday that such speculation is ``premature'' but pointedly added: ``I don't think one should rule out anything. If the situation continues and the sanctions are not lifted, there would be many levels of response.''

In an Aug. 5 letter to the United Nations, Aziz said Iraq was ``totally suspending its cooperation'' with the weapons inspectors but as an interim measure would permit continued use of video monitoring and other passive forms of inspection. In practice, the Iraqi decision has prevented the inspectors from examining sites not previously visited.

The Security Council has called Iraq's action ``totally unacceptable'' and called for a reversal. But the 15-member body has declined to specify any consequences for Baghdad.

The pattern continued Thursday as the council conducted its regular 60-day review of the sanctions against Iraq. As expected, the council proposed no changes in the sanctions, which prohibit Iraq from controlling revenues of its oil sales and cannot be lifted until the weapons inspectors certify that Iraq has rid itself of its nuclear, biological and chemical warfare capacity and long-range missiles.

``Once again, the Security Council has decided to continue sanctions indefinitely,'' U.S. Ambassador Bill Richardson said. ``... There is no prospect for lifting sanctions until (the Iraqis) comply (with inspectors).''

Richardson and others in the closed-door meeting said no nation supported an easing of sanctions.

There was no agreement, however, on what else should be done, except to meet next week with Prakash Shah, who is Secretary-General Kofi Annan's special representative to Iraq. Shen Guofang, a Chinese representative at the United Nations, also called for Iraqi officials to travel to New York for a ``comprehensive review'' of the inspections program with the council.

Richardson called on Annan to personally intervene. ``The next step is the secretary-general,'' he said. ``We want to see his active diplomacy and skills used.''

But Fred Eckhard, Annan's spokesman, said the secretary-general, who is on vacation, has no immediate plans to get further involved. Eckhard said Annan expects Butler and the Security Council to take the lead.

Eckhard also disputed reports Tuesday in the Los Angeles Times and The Washington Post, attributed to U.N. sources, that Annan believed that the Clinton administration's muted response in the current conflict stems in part from political considerations. Top aides to Annan were said to be concerned that the reports might damage relations between the secretary-general and the administration.

``He has at no stage and in no forum expressed the views ascribed to him,'' the statement said.

END

Federal employees may get largest increase in 20 years

ASSOCIATED PRESS

President Clinton yesterday promised federal workers an 8 percent pay raise over the next two years.

The president outlined a 3.6 percent raise for 1999 and an additional 4.4 percent the following year. The 2000 raise would be the largest since 1981.

In a statement from Martha's Vineyard, where he was vacationing before returning to Washington, Mr. Clinton said the federal government is operating more efficiently than ever.

"This success would not have been possible without government employees who have been called upon to work harder and to do more with less. Our federal employees have risen to that mission and with this action, we recognize their efforts," he said.

Officials said the 3.6 percent increase is in line with congressional moves to boost Defense Department military and civil servant pay by that amount. Mr. Clinton said yesterday that if Congress does not also approve the increase in non-defense pay, "I will use my executive authority to guarantee that a 3.6 [percent] increase takes effect."

The Office of Management and Budget is preparing its formal guidance to federal departments, saying what they should plan on paying federal workers in calendar year 2000 and advising a 4.4 percent increase. That guidance, which has not yet gone out, is what departments use to put together their budget submissions for OMB, an OMB official said.

Although the 2000 raise would mark the largest for federal workers in two decades, some on Capitol Hill who were briefed on the figures Wednesday said the increase still would not make up for years of underpaying federal workers.

"While I'm grateful for this important step, it doesn't begin to make up for years of failure to meet the formula for pay raises for federal workers," said Democrat Eleanor Holmes Norton, the District's delegate to Congress. Federal employees continue to make less than those doing similar work in the public sector, she said.

Congress pushed to update 'patchwork' food safety laws

By Mary Deibel
SCRIPPS HOWARD NEWS SERVICE

Congress must update food safety laws and put a food czar in charge of combating contamination problems that cause up to 9,000 deaths and 81 million illnesses in the United States each year, a panel told lawmakers yesterday.

The group said outmoded statutes that scatter responsibility across 12 federal agencies and 28 congressional committees hamper efforts to prevent illness outbreaks and respond to new risks to the nation's food supply even though it's the safest in the world.

"The current regulatory structure stands out as a patchwork quilt rather than a seamless network," said panel chairman John Bailar, chairman of health studies at the University of Chicago. These "are barriers to improving the safety of the food supply."

Mr. Bailar and 12 other experts tapped by the National Academy of Sciences unanimously concluded that a single federal official should take charge of coordinating the nation's food safety efforts to respond to a new mix of factors that provide Americans with a "staggering" variety of food options but also pose new risks.

The recommendations were hailed by consumer groups as well as the food industry. Kelly Johnson, vice president of the National Food Processors Association, said the industry has long sought government coordination in preventing such problems.

Congress asked the science academy to make recommendations for improving food safety last year in the wake of outbreaks of food-borne diseases spawned by new strains of bacteria that forced massive recalls of everything from meat and juices linked to a deadly form of E. coli to breakfast cereals and ice cream tied to salmonella poisoning.

But the report's delivery comes as President Clinton and Congress clash over the administration's call for a new $101 million food-safety initiative that includes expanded inspections, the creation of a food safety institute to coordinate public and private research, and improved consumer education.

The initiative also would crack down on imported food that doesn't meet U.S. standards — a problem underscored by congressional watchdogs at the General Accounting Office who recently concluded that "federal agencies cannot insure that the growing volume of imported food is safe for consumers."

Before quitting for the August recess, the Senate approved $68 million of the $101 million President Clinton wants but the House voted for only $16.8 million in hopes of rebating the extra money in the form of tax cuts.

The commission said food-borne illnesses cost the nation up to $37 billion a year in lost productivity and medical expenses.

The panel also said "at a minimum" U.S. laws should stop requiring an army of federal meat and poultry inspectors to visually inspect every carcass when eyeballing 30 chickens a minute — one every two seconds — doesn't catch E. coli or the other microbial threats that currently pose the greatest risks.

The Washington Times
FRIDAY, AUGUST 21, 1998

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food Safety This is CDC's letter back. I asked O'Hara to get us a heads up on the Sept. meetings on p. 2 Tom

Centers for Disease Control and Prevention (CDC)
Atlanta GA 30333

AUG 7 1998

Mr. Thomas J. Billy
Administrator
Food Safety and Inspection Service
U.S. Department of Agriculture
1400 Independence Avenue, S.W.
Washington, D.C. 20250

Dear Mr. Billy:

Recent reports in *Food Chemical News* and other print media suggest that the Centers for Disease Control and Prevention (CDC) has revised estimates of the burden of foodborne illness and death and that recent FoodNet data demonstrate a substantial decline in the incidence of foodborne infections. These reports are inaccurate and may have caused confusion. The following information should clarify the status of efforts underway at CDC to improve our understanding of occurrences of foodborne illnesses and indicates the interagency collaboration involved in these efforts.

In 1987, CDC used surveillance and outbreak data, published reports, and expert opinion to estimate the overall incidence of illness and the number of deaths caused by foodborne microorganisms in the United States. The incidence of symptomatic illness was estimated at 6.5 million cases annually, with about 9,000 related deaths. These estimates were published in a Carter Center document, *Closing the Gap: the Burden of Unnecessary Illness*, and were part of the basis for estimates published in 1994 by the Council for Agricultural Science and Technology.

CDC has recently begun a multidisciplinary effort to revise these national estimates for foodborne illness. This is a complex process that will draw upon new sources of data, including results of active surveillance at FoodNet sites, as well as sources used previously, and the revised estimates will be accompanied by documentation of all data sources and assumptions. Efforts currently underway involve CDC scientists from the National Center for Infectious Diseases and the National Center for Health Statistics. CDC will seek input from its National Food Safety Initiative partners at the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the Department of Agriculture (USDA) as the process of revision proceeds. The revised estimates will not be available

for several months. While the data used for these estimates will be greatly improved from those in the 1987 report, substantial future efforts will be required to further improve estimates of the burden of illness caused by certain bacterial, parasitic, and viral foodborne pathogens.

CDC, in collaboration with USDA, FDA, and the active surveillance sites, is also preparing a report on FoodNet surveillance data for publication in the *Morbidity and Mortality Weekly Report (MMWR)*. FoodNet began collecting detailed data on the frequency, burden, and causes of foodborne illness in 1996. We anticipate publishing a summary of the 1996-1997 surveillance data in the next several weeks, after the draft has been reviewed and approved by all collaborators. The current draft report indicates that the incidence of culture-confirmed infections with some of the pathogens under surveillance decreased between 1996 and 1997, while the incidence of others increased. As you know, many factors can influence disease incidence on a year-to-year basis. Therefore, it will be necessary to collect several years of data to be confident of the stability of trends. We will carefully review the 1996-1997 data and our interpretations of them with our collaborators before the report is submitted to the *MMWR* for publication.

Ongoing FoodNet activities in 1998 will be analyzed after data collection for this year has been completed. While it would be gratifying to document "a remarkable decline in disease rates" when we report the 1998 FoodNet results, attempting to infer this from the preliminary data currently available would be premature and possibly misleading.

Sincerely,

Claire V. Broome, M.D.
Acting Director