VOLUME 68 **NO. 1**

JOURNAL
of the
ASSOCIATION OF FOOD AND DRUG OFFICIALS

March 2004

Serving the regulatory community since January 1937

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ISSN: 0898-4131

ASSOCIATION OF FOOD AND DRUG OFFICIALS

Objectives of the Association

To promote and offer uniformity of laws affecting foods, drugs, cosmetics, devices, and product safety; Encourage and promote enforcement of said laws; Encourage and support programs which will contribute to consumer protection consistent with the broad purposes of said laws; Assist members in their technical work and development; Cooperate with other professional groups in advancing consumer protection under such laws; Disseminate information concerning food and drug law enforcement and administration through its official publication; Encourage and promote enforcement programs with federal agencies within each state.

FROM THE EDITOR

The ever more complicated world of food and drug regulation is not getting easier as we enter the fifth year of the new millennium. The era of terrorism brings with it new dimensions to the problem of maintaining a safe food supply from farm to fork. Food security must now command some of our attention as never before. The Bioterrorism Act of 2002 is now being implemented and the picture of our new food safety and security system is just now beginning to form. What it will look like when all is said and done is hard to say at this juncture. We can, however, expect that it will be significantly different than the way things were before threats of global terrorism took hold of our daily lives.

It is our hope this journal will be able to make a contribution to the ways we deal with the new problems of food safety and security that accompany the turmoil we find ourselves in today. Keep this in mind as you read our current issue and help us recruit other authors and papers which might contribute fresh ideas and new approaches to making a safer world for us all.

Thomas (Bill) Brooks, Editor

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Ms. DeWaal is the leading consumer analyst on reform of laws and regulations governing food safety. Since 1999, she has maintained and published a listing of foodborne illness outbreaks organized by food source. Over the years, Ms. DeWaal has presented papers on food safety at over 50 scientific and public policy conferences. She participated in the World Health Organization Strategic Planning on Food Safety and was a member of the National Advisory Committee on Meat and Poultry Inspection from 1997-2000. She is currently on the Editorial Board of the Food and Drug Law Journal and is a member of the Massachusetts Bar. Previously, Ms. DeWaal was Director of Legal Affairs for Public Voice for Food and Health Policy, where she spearheaded a lobbying effort on seafood safety. Ms. DeWaal graduated from the University of Vermont and Antioch School of Law.

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Dr. Osterholm has led numerous investigations of major infectious disease outbreaks, including the association of tampons and toxic shock syndrome, the transmission of hepatitis B in health care settings, the use of L-tryptophan and eosinophilia myalgia syndrome, HIV infection in health care workers, and foodborne disease. He serves on the editorial boards of several professional journals, as a principal investigator for the Centers for Disease Control and Prevention (CDC) Emerging Infections Program, and as a frequent consultant to the World Health Organization, the National Institutes of Health (NIH), and the Food and Drug Administration (FDA).

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PUTTING A RISK ASSESSMENT MODEL TO WORK: *LISTERIA MONOCYTOGENES* 'WHAT IF' SCENARIOS

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Introduction

In October 2003, the Department of Health and Human Services (DHHS), in collaboration with the United States Department of Agriculture (USDA), released a quantitative assessment of the relative risk to public health from foodborne *Listeria monocytogenes* among selected categories of ready-to-eat foods (see www.foodsafety.gov/~dms/lmr2-toc.html). The risk assessment examined systematically the available scientific information and data to predict the relative risks of serious illness and death associated with consumption of different types of ready-to-eat foods that may be contaminated with *Listeria*.

Listeria monocytogenes is a bacterium that occurs widely in both agricultural and food processing environments. Ingestion of this pathogen can cause listeriosis, a severe illness that causes hospitalization of approximately 2,000 individuals each year and approximately 500 deaths. Of all the foodborne pathogens tracked by the Center for Disease Control and Prevention (CDC) in 2000, *L. monocytogenes* had the second highest case fatality rate (21%) and the highest hospitalization rate (90.5%).

While nearly all cases of listeriosis illnesses are foodborne, the sporadic nature and long incubation period mean that the specific food that caused the disease is rarely identified. Thus, the full range of potential food vehicles of *L. monocytogenes* has most likely not been identified from the epidemiological record. This risk assessment uses consumption and contamination data to estimate consumers' relative risk of exposure and then estimates the likely public health consequences among 23 food categories.

Results of the *L. monocytogenes* Risk Assessment

The risk estimates expressed in terms of both the predicted number of cases per serving and per annum along with their corresponding risk rankings are provided in Table 1. Both measures are important in understanding and interpreting the risks associated with foodborne listeriosis. The per serving estimate measures the inherent risk faced by the consumer when he/she consumes an individual serving of that product. This estimate reflects the degree of control achieved by current food safety risk management systems for that product and, as such, is the primary

value for assessing which foods are likely to be amenable to further risk reduction efforts. The per annum value is calculated by multiplying the per serving value by the number of servings that are consumed in the United States each year. This value is a measure of the total public health burden. Thus, a food that is inherently risky but is consumed only to a highly limited degree would have a high per-serving risk but a low per-annum risk. Conversely, a food that is manufactured under a rigorous control program may have a low per-serving risk but, if consumed daily by most consumers, the food may have a significant per-annum risk.

The results clearly predict that the risk of listeriosis on both per serving and per annum bases varies greatly among the various food categories. For example, the differential between per serving risks associated with Deli Meats (relative risk rank of 1) and Hard Cheeses (relative risk rank of 23) is almost 10,000,000-fold. The risk assessment also shows the uncertainty in the risk predictions. For example, while the median number of cases of listeriosis per year attributable to Deli Meats is approximately 1,599, the upper and lower bounds (i.e., the 5^{th} and 95^{th} percentiles) range from 341 to 2,038 cases per year.

The Rationale for 'What If' Scenarios

The 2003 *Listeria monocytogenes* risk assessment (LMRA) model, taken in its entirety, represents current knowledge about listeriosis. It provides predications of disease incidence based on *L. monocytogenes* concentration in foods at retail, the frequency of consumption, serving sizes, the microorganism's growth/survival characteristics, and storage conditions. The predictions described in the risk assessment document are based on a complex model. The model input parameters can be changed and the resulting change in the model outputs collected. This process, referred to as conducting 'what-if' scenarios, can be used in many applications. Like scientific theories in general, models can serve either heuristic or pragmatic purposes. How and why the model is modified will reflect either or possibly both of those purposes.

1) *Pragmatic Scenarios.* By making predictions about what may be reasonably expected to happen, models may be used to justify or evaluate the consequences of an action. A risk assessment model may justify a regulation by demonstrating the changes that may be anticipated as a result. A scenario designed for this purpose will have altered input parameters that reflect the specifications of the regulation. In order for a model to be used for this purpose, the process that is impacted by the putative intervention must be included. For example, because the LMRA model uses contamination data of the product at retail, it can predict the impact of changes that may influence the growth of *L. monocytogenes* after it is sold. The model does not predict the impact of changes in specific processing steps that influence growth or inactivation during

food production unless it can be assumed that the change in processing directly affects retail contamination without confounding by other pre-retail steps.

2) *Heuristic Scenarios.* A scenario may be used to evaluate the impact of further research. The LMRA model has an uncertainty dimension that reflects a range or distribution of plausible assumptions for many of the components of the model. A scenario could be used to justify a research program by showing that narrowing or altering an uncertainty distribution would have a substantial impact on the predictions made by the model. The scenario might also be devised as an argument that a criticism of the plausibility of the assumptions in the model are either moot or worthy of representation in the uncertainty analysis.

3) *Abstract Scenarios.* A pragmatic scenario carries the implicit assumption that the regulation will produce the specified change in the baseline input parameter. As an academic exercise, the relationship between other parameters and the model output may be explored. Although such an analysis may not have any immediate impact, it may eventually serve both heuristic and pragmatic functions by stimulating theoretical development or control strategies.

Example Scenarios

Refrigerator Temperature Limit Scenarios. As an example of a pragmatic scenario, the baseline LMRA model was modified to predict the impact of assuring that home refrigerators do not operate above a specified limit. As shown in Figure 1, the baseline distribution of refrigerator temperatures ranges from 0 ºC to 16 ºC (<32 ºF to 63 ºF), which is an empirical distribution that uses data collected by Audits International in 1999. The baseline distribution was truncated by excising values above the specified limit. The model was then rerun with the truncated distribution. Table 2 shows the results when limits of either 7 ºC (45 ºF) or 5 ºC (41 ºF) are applied. The predicted number of cases of listeriosis across all 23 food categories would be reduced approximately 69% (from 2105 to 656) by assuring that all home refrigerator temperatures operated at 7 ºC or less. The predicted number of cases would be further reduced to 28 per year (>98%) when the distribution of home refrigerator temperatures did not exceed 5 ºC.

A wider range of temperatures were explored by running a wider range of temperature limit scenarios for deli meats consumed by the elderly population only (see Figure 2). This is an example of a food category that readily supports the growth of *L. monocytogenes*. As the refrigerators that have higher temperatures are removed from the distribution (i.e., moving from the right to the left on the curve) the number of predicted cases declines. This is a consequence of removing the higher temperature refrigerators where the fastest growth of *L.*

monocytogenes would occur. The number of refrigerators with temperatures between 12 and 16 °C represent about 1% of the refrigerators from the Audits International survey; however, these refrigerators account for approximately 10% of the cases from consumption of deli meats. At 7 °C, the removal of approximately 12% of the refrigerators reduces the median number of cases from deli meat consumption from 772 to 270 cases (65% reduction). It should be noted that the relationship between maximum temperature and the number of cases varies among food categories. However, this example indicates that eliminating the minority of refrigerators operating above 7 °C would greatly reduce the incidence of listeriosis. These scenarios indicate that controlling refrigerator temperature is a potentially effective means of reducing listeriosis.

Storage Time Scenario. The impact of reducing the maximum storage time (e.g., by labeling food with "consume-by" dates) for Deli Meats was evaluated; this is another example of a pragmatic scenario. Figure 3 shows the distribution of storage times used for deli meats, which ranged from 0.5 to 28 days, with a most likely time of approximately 7 days. In these scenarios, when a simulation chose a storage time longer than desired, that simulation was assigned the maximum storage time for that scenario. These simulations assume that the food is consumed during storage up to the maximum scenario storage time and the food is not discarded. Simulations were run for Deli Meats and the predicted annual mortality rate attributable to the group was calculated for the elderly subpopulation. The scenarios tested included seven maximum storage times for deli meats of 4, 7, 10, 14, 17, 21, and 28 days. The baseline maximum storage time is 28 days.

Figure 4 shows the impact of limiting the storage time for Deli Meats consumed by the elderly population for specific maximum storage intervals. For example, reducing the storage time from the maximum of 28 days to 14 days reduces the median number of cases of listeriosis in the elderly population from 772 to 670 (13% reduction). Shortening storage time to 10 days further reduces the cases to 524 (32% total reduction).

The dependence of predicted risk on storage time varies across food categories; however, the general relationship that the number of cases increases with storage time would be evident in all foods that support the growth of *L. monocytogenes*. Other storage time scenarios with other food categories would produce different results; for example, the reduction in cases of listeriosis might be greater if foods stored beyond the maximum scenario storage time are discarded instead of consumed on the last day. Reducing maximum storage time appears to be less effective at reducing risk than reducing the refrigerator temperature for the Deli Meat.

Scenario for Fresh Soft Cheese Made from Highly Contaminated Milk. The 2003 risk assessment indicated that the risk from Fresh Soft Cheese is low. This

is largely attributable to use of newly obtained retail data indicating a very low contamination rate in this food category. However, there is a strong epidemiological correlation between Hispanic-style fresh soft cheese (e.g., Queso Fresco) and listeriosis. A likely explanation for this discrepancy is that the data collected for this category represents commercially produced cheese whereas the cheeses linked to the disease have often been associated with non-commercially produced cheese, and in some cases illicitly distributed fresh soft cheese made from raw, unpasteurized milk. To characterize the risk from Queso Fresco made from raw milk, the model is constructed assuming that the prevalence estimate of 50%, which corresponds to the values obtained from a survey of soft cheeses made from raw milk. As shown in Table 3, the estimated risk of listeriosis per serving was 43 times greater for the neonatal population and 36 times greater for the elderly population when these cheeses were assumed to be made from unpasteurized milk compared to that manufactured with pasteurized milk. Because this estimate is based on an assumption that is highly speculative, this exploratory simulation is an example of a heuristic scenario.

Pasteurized Fluid Milk Data Analogy Scenario. The primary intervention for fluid milk is pasteurization but the requirements for pasteurization can vary from country to country. This means that, even though the milk contamination data used in the model were weighted both geographically and temporally, there is the possibility that the data may not be representative of levels of *L. monocytogenes* in milk currently in the U.S. food supply. To better understand the possible impact of including contamination data from other countries a scenario was run using domestic milk only. Additional scenarios were run with and without the inclusion of chocolate milk. As shown in Table 4, excluding either non-U.S. milk or chocolate milk had little impact on the predicted number of cases of listeriosis attributed to Pasteurized Fluid Milk on both a per serving and per annum basis. Although this is a heuristic scenario that revolves around speculation about the extent to which limited survey data is analogous to milk produced in the United States, it serves to argue that concern over this issue is largely moot.

Disease Rate as a Function of Concentration. As an example of an abstract scenario, portions of the LMRA were used to estimate the relationship between *L. monocytogenes* concentration at retail and the disease rate. Because the growth rates differ significantly across food categories, examples of foods that support rapid growth (Deli Meats) and those that support low to no growth (Hard Cheese) are shown in Figure 5. Comparison of the two figures indicates that the growth component of the model for a particular food category can have a large influence on the relationship between concentration at retail and the rate of listeriosis. Foods with high growth rates (such as Deli Meats) exhibit a relatively flat curve that indicates that the number of cases is only slightly dependent on initial concentration. This is because low populations of *L. monocytogenes* at retail have a relatively high probability of growing to a dose that can cause illness. On the other hand, low or no growth foods (such as Hard Cheese) indicate a substantial

increase in the disease rate as the initial concentration at retail increases because the low populations of *L. monocytogenes* remain low and have a low probability of causing illness. Thus for foods that support growth, above some minimum concentration the risk is largely determined by the growth that occurs subsequent to purchase. Conversely, for foods that do not support the growth, the risk of listeriosis is dependent largely on the level of the pathogen in the food at the point of purchase.

Frankfurter Reformulation Scenario. As shown in Table 1, the foods associated with the highest risk of causing listeriosis are also those that permit the growth of *L. monocytogenes*. This suggests that reformulating these foods so that they will not support growth of *L. monocytogenes* (or will support growth at a slower rate) and/or modifying storage conditions to prevent or slow growth (such as frozen storage or modified atmosphere packaging) could reduce the number of cases of listeriosis. A simulation was conducted to evaluate the consequences of manufacturing frankfurters with growth inhibitors that prevent post-retail growth of *L. monocytogenes*. The growth component of the LMRA model was disabled and the model run. The predicted number of listeriosis cases (for the total U.S. population) attributed to frankfurters consumed without reheating was reduced from 30.5 to 0.4 cases per year.

Summary and Conclusions

In the scenarios described in this report, selected food categories and populations were used as examples. Other foods that permit different rates of growth and are stored for different lengths of time may have different results, but the general interrelationships are representative of other food categories. These scenarios compared with the baseline estimations of risk illustrate the impact of storage time, storage temperature, ability of the food to support growth and contamination level on the risks per serving.

- Reducing the ranges of refrigerator temperatures by eliminating storage at the high temperatures reduced the predicted cases of listeriosis by reducing growth of *L. monocytogenes* in the foods that permit growth.

- Eliminating the longest storage times reduced the number of cases of listeriosis, even with the full range of storage temperatures and contamination levels. However, reducing a percentage of the longest storage times appeared to be less effective than reducing the corresponding percentage of highest storage temperatures, unless the storage time is reduced to very short duration between retail and consumption.

- Reformulating the food or using storage conditions that slow or prevent growth could reduce the rate of listeriosis.

The models generated as the basis for this risk assessment can be used to further evaluate the impact of listeriosis on the public health and indicate where effective intervention strategies might be applied. For example, the Food and Agricultural Organization/World Health Organization (FAO/WHO) risk assessment on *L. monocytogenes*, which is largely based on the approaches used in the U.S. risk assessment, is being developed to consider several risk management questions posed by Codex Alimentarius. These questions include an evaluation of the relative susceptibility of various individuals with underlying conditions that affect the immune system and the impact of consuming various levels of *L. monocytogenes*. It is anticipated that additional risk assessments on individual foods within specific food categories will be conducted to help answer specific questions about how individual steps in their production and processing impact public health, including the likely effectiveness of different preventative strategies. The models may be used to evaluate the expected public health impact of preventive controls such as storage limits, sanitation improvements, or new processing technologies. Sources of contamination during food production and retail conditions can also be added to the model to provide more detailed examination of factors contributing to the risk of listeriosis from the final product.

The models may also be used to evaluate the impact of hypothetical changes in a process, such as limits on storage time or temperature, to provide insight as to how the different components of the model interact. The 'what-if' scenarios modeled in this risk assessment provide insight as to the impact on public health of limiting storage times, avoiding high temperature refrigeration storage, limiting growth rates and reducing contamination levels. The heuristic scenarios emphasize the fact that the LMRA model, like scientific knowledge in general, is a work-in-progress and is influenced by the assumptions and data sets that were used. 'What-if' scenarios can be used to explore the importance of the underlying assumptions used in the model and to identify additional research areas.

Table 1. Relative Risk Ranking and Predicted Median Cases of Listeriosis for the Total United States Population on a Per-Serving and Per-Annum Basis

Predicted Median Cases of Listeriosis for 23 Food Categories					
Per Serving Basis[a]			Per Annum Basis[b]		
	Food	Cases		Food	Cases
High Risk	Deli Meats	7.7×10^{-8}	Very High Risk	Deli Meats	1598.7
	Frankfurters, not reheated	6.5×10^{-8}	High Risk	Pasteurized Fluid Milk	90.8
	Pâté and Meat Spreads	3.2×10^{-8}		High Fat and Other Dairy Products	56.4
	Unpasteurized Fluid Milk	7.1×10^{-9}		Frankfurters, not reheated	30.5
	Smoked Seafood	6.2×10^{-9}	Moderate Risk	Soft Unripened Cheese	7.7
	Cooked Ready-to-Eat Crustaceans	5.1×10^{-9}		Pâté and Meat Spreads	3.8
Moderate Risk	High Fat and Other Dairy Products	2.7×10^{-9}		Unpasteurized Fluid Milk	3.1
	Soft Unripened Cheese	1.8×10^{-9}		Cooked Ready-to-Eat Crustaceans	2.8
	Pasteurized Fluid Milk	1.0×10^{-9}		Smoked Seafood	1.3
Low Risk	Fresh Soft Cheese	1.7×10^{-10}	Low Risk	Fruits	0.9
	Frankfurters, reheated	6.3×10^{-11}		Frankfurters, reheated	0.4
	Preserved Fish	2.3×10^{-11}		Vegetables	0.2
	Raw Seafood	2.0×10^{-11}		Dry/Semi-dry Fermented Sausages	<0.1
	Fruits	1.9×10^{-11}		Fresh Soft Cheese	<0.1
	Dry/Semi-dry Fermented Sausages	1.7×10^{-11}		Semi-Soft Cheese	<0.1
	Semi-soft Cheese	6.5×10^{-12}		Soft Ripened Cheese	<0.1
	Soft Ripened Cheese	5.1×10^{-12}		Deli-type Salads	<0.1
	Vegetables	2.8×10^{-12}		Raw Seafood	<0.1

Low Risk	Deli-type Salads	$5.6x10^{-13}$	Low Risk	Preserved Fish	<0.1
	Ice Cream and Other Frozen Dairy Products	$4.9x10^{-14}$		Ice Cream and Other Frozen Dairy Products	<0.1
	Processed Cheese	$4.2x10^{-14}$		Processed Cheese	<0.1
	Cultured Milk Products	$3.2x10^{-14}$		Cultured Milk Products	<0.1
	Hard Cheese	$4.5x10^{-15}$		Hard Cheese	<0.1

[a]Food categories were classified as high risk (>5 cases per billion servings), moderate risk (≤5 but ≥1 case per billion servings), and low risk (<1 case per billion servings).

[b]Food categories were classified as very high risk (>100 cases per annum), high risk (>10 to 100 cases per annum), moderate risk (≥1 to 10 cases per annum), and low risk (<1 cases per annum).

Table 2. Estimated Reduction of Cases of Listeriosis from Limits on Refrigeration Temperatures

Maximum Refrigerator Temperature	Cases of Listeriosis[a]		
	Median	5th Percentile	95th Percentile
Baseline[b]	2105	—[c]	—[c]
7 ˚C (45 ˚F) maximum	656	331	761
5 ˚C (41 ˚F) maximum	28	1	126

[a]Values for the median, upper and lower uncertainty levels.
[b]The baseline uses the full empirical distribution of refrigerator temperatures from the Audits International (1999) survey.
[c]The baseline number of cases of listeriosis is fixed based on CDC surveillance data.

Table 3. Comparison of Baseline and a High Prevalence Scenario Risk of Listeriosis per Serving for Fresh Soft Cheese for Two Subpopulations

Population	Median Predicted Risk per Serving (5th and 95th percentiles)	
	Baseline[a]	High Prevalence[b]
Perinatal	4.7×10^{-9} (3.0×10^{-11}, 9.8×10^{-8})	2.0×10^{-7} (5.1×10^{-9}, 5.3×10^{-6})
Elderly	2.8×10^{-10} (1.3×10^{-12}, 4.5×10^{-9})	1.0×10^{-8} (3.2×10^{-10}, 2.3×10^{-7})

[a]Baseline uses a prevalence distribution based on available survey data.
[b]High Prevalence scenarios assume that 50% of the samples tested are positive.

Table 4. Impact of Excluding Non-U.S. Milk and Chocolate Milk from the Pasteurized Fluid Milk Food Category on the Number of Cases of Listeriosis

Scenario	Total U.S. Population	
	Median Cases per Serving	Median Cases per Annum
Baseline	1.0×10^{-9}	91
Domestic Milk Only	8.8×10^{-10}	77
Domestic Milk (excluding chocolate milk)	9.2×10^{-10}	78

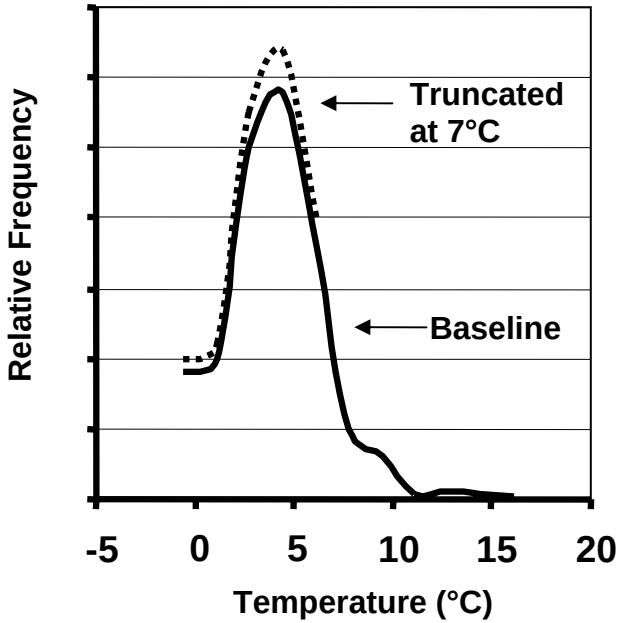

Figure 1. Frequency of Home Refrigeration Temperature
[Area under the respective curves represents 100% of the refrigerators.]

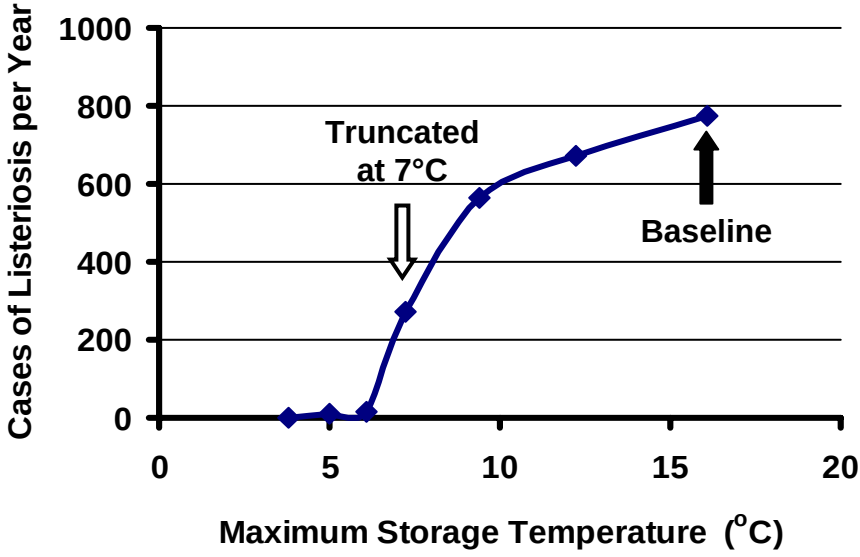

Figure 2. Predicted Annual Number of Cases of Listeriosis for the Elderly Population from Consumption of Deli Meat Stored in the Home Refrigerator at Various Maximum Temperatures

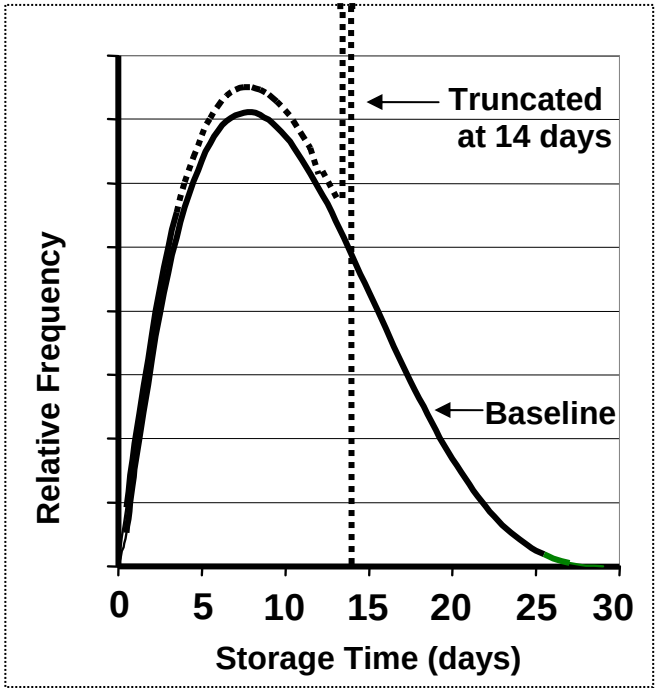

Figure 3. Storage Time Distributions for Deli Meat
[Area under the respective curves represents 100% of the servings.]

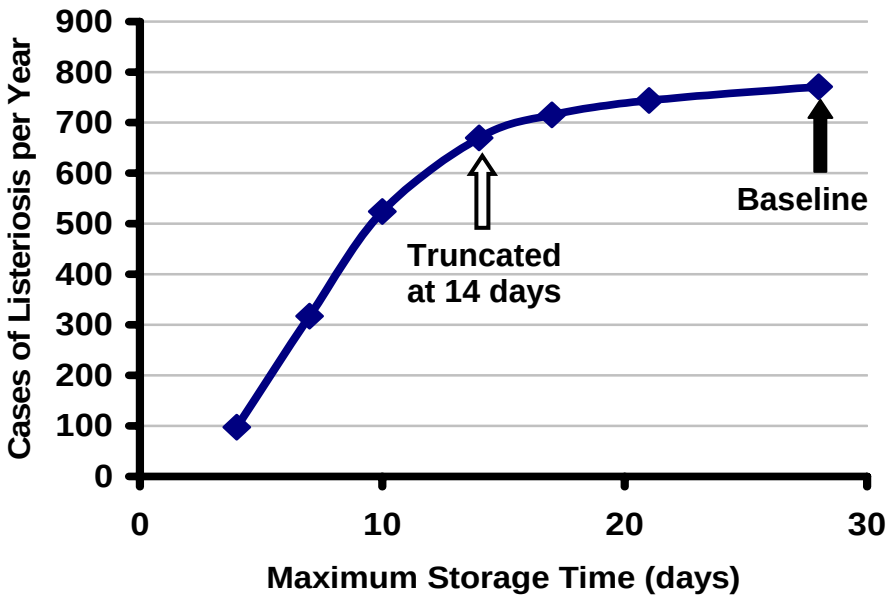

Figure 4. Predicted Annual Number of Cases of Listeriosis for the Elderly Population Consuming Deli Meats Stored in the Home Refrigerator for Various Intervals

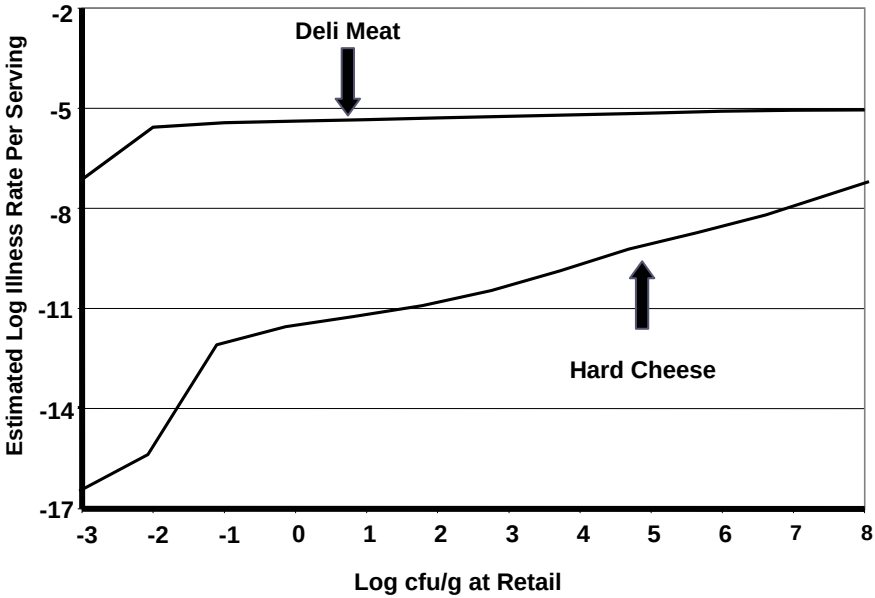

Figure 5. Risk of Listeriosis on a Per-Serving Basis for the Elderly Population as a Function of *Listeria monocytogenes* Concentration at Retail for Deli Meat and Hard Cheese

RECALLING THE RECALL PROCESS

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A food recall is an action by a manufacturer or distributor to protect the public from products that may cause health problems or possible death. All federal recalls are voluntary. They may be initiated by the manufacturer or distributor of a meat or poultry product or at the request of the Food Safety Inspection Service (FSIS). The current "voluntary" recall system is inadequate for its intended purpose and exposes consumers to unacceptable risks associated with tainted food products.

The summer of 2002 may well go down in history as the U.S. Department of Agriculture's (USDA) "Summer of Recalls." Three companies—ConAgra, Wampler Foods, and Jack Lambersky Poultry Company—voluntarily recalled over 50 million pounds of contaminated meat products. The voluntary recall system, together with USDA's policy of not releasing the names and locations of stores and restaurants that receive contaminated meat, left consumers without adequate information to determine if meat they had already purchased was part of an announced recall. Instead, they had to check package labels for plant numbers and production dates that frequently are not even there. The same policy was used for meat recalled in December after meat from a cow infected with mad cow disease—bovine spongiform encephalopathy (BSE)—entered the food supply and was recalled. This is yet another example of the inadequacy of the current food recall safety system where economic interests trump the public health interests of consumers. There are a number of lessons that illustrate this point.

First, too many recalls are initiated only after people become ill. Both outbreaks and recalls signal a failure of Hazard Analysis and Critical Control Point (HACCP) systems to prevent well-known food hazards from entering the food supply. USDA and the Federal Drug Administration (FDA) must initiate earlier testing programs to ensure that food companies are focused on finding and fixing contaminated products in the plant, rather the releasing and recalling them after they are in consumers' homes.

This article was based on a CSPI presentation given at a Food Safety Inspection Service Public Recall meeting on December 12, 2002. Charlotte Christin also contributed significant research to this article.

Ongoing testing for hazards like *E. coli* O157:H7 and *Listeria* in meat plants, for example, would mean that USDA wouldn't have to wait days for test results to come in before taking action, as it did with the ConAgra recall. The agency would have a better basis to prevent recalls, and could act more quickly when a recall was needed.

Second, many recalls begin with an announcement that grossly underestimates the amount of product that poses a risk to the public. Each new meat recall announcement appears to be just the beginning of an arduous process of further investigation followed by additional announcements that dramatically increase the recall size (see Appendix I). Under the voluntary recall policy, companies frequently minimize the size of the initial recall, but once the government investigators go to the plant, the size of the recall sometimes increases by several orders of magnitude. Days can elapse before the expansion is announced, during which time the hazardous products remain on the market. Civil penalties are clearly needed for companies that put their business interests before their duty to protect public health. USDA and FDA should have the authority to fine companies that had knowledge or information that should have led to a larger initial recall but which negligently understated the necessary product amount.

Third, the voluntary recall system leaves consumers and even some states without critical information to know if the meat being sold locally might be linked to the recall. In order to protect business records, USDA will only share a plant's customer lists with the states that promise not to release the information to the public. The agency claims this policy is appropriate because otherwise companies would not share these distribution lists under the voluntary policy. From a consumer perspective, however, this approach seems counter-intuitive, as the public may urgently need to know if the meat in their refrigerators or freezers came from the implicated product.

In the summer of 2002, public health officials were barred from obtaining ConAgra's distribution lists from USDA, even though the Denver plant distributed widely in the state.[1] Another example occurred recently. On December 23, 2003, FSIS announced a voluntary recall of 10,410 pounds of raw beef that may have been exposed to tissues containing the infectious agent that causes mad cow disease. This meat was distributed to several states, including California. However, the California Department of Health was barred from disclosing the critical information showing where the tainted meat was distributed and sold.

[1] David Migoya, "Colorado unable to obtain list of where recalled meat sold," *Denver Post*, (Aug. 4, 2002).

The agreement that individual states and USDA enter into regarding the disclosure of distribution information is outlined in Memoranda of Understanding (MOUs). According to the MOU signed by the California Department of Health Services and USDA, the purpose of the agreement is to allow for more effective and timely verification that recalled products are removed from commerce. However, the binding of agencies on the state level from releasing this information renders the recall process largely ineffective, as consumers are denied information regarding whether the meat they have purchased is part of a recall. Without specific and timely information regarding where and when the tainted meat is sold, consumers are at a loss to protect themselves and they are more likely to consume the meat that is subject to the recall. Some states, however, do have open record laws that prevent them from giving USDA the requisite assurances, and they are barred from getting the distribution lists altogether.

USDA contends that distribution information is protected under the Freedom of Information Act (FOIA) "business records" exception. However, this interpretation applies the FOIA business records exemption[2] too broadly. In fact, distribution lists have been released under FOIA[3] when it was determined that their disclosure would not cause "substantial competitive harm."[4] Informing consumers which establishments have received recalled product would not create "substantial competitive harm" to the recalling company.[5] Since recalls are limited in their depth and scope, it is questionable whether the release of the names of specific recipients of specific products at a specific time would be of any use to competitors.

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[2] Specifically, exemption 4 of the FOIA protects "trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential." 5 U.S.C. § 552(b)(4).

[3] See, e.g., *Greenberg v. FDA,* 803 F.2d 1213, (D.C. Cir. 1986); *Ivanhoe Citrus Assn. v. Handley*, 612 F. Supp. 1560, 1566 (D.D.C. 1985); *Braintree Elec. Light Dept. v. Dept. Of Energy*, 494 F. Supp. 287, 290 (D.D.C. 1980).

[4] *National Parks Ass'n. v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974). The leading standard for determining whether information that was compelled by the agency is "confidential" was set out in the *National Parks* decision: "To summarize, commercial or financial matter is 'confidential' for purposes of the exemption if disclosure of the information is likely to have either of the following effects: (1) to impair the Government's ability to obtain necessary information in the future; or (2) to cause substantial harm to the competitive position of the person from whom the information was obtained. *Id.*

[5] The agency withholding the information must present objective evidence from which a court can conclude that the submitting company is likely to suffer substantial competitive injury. Robert G. Vaughn, "Consumer Access to Product Safety Information and the Future of the Freedom of Information Act," *Admin. L. J.* 5:673 (Fall, 1991) [hereinafter *Vaughn*]. The burden under the Act is clearly on the agency that seeks to vindicate the company's interests. *Id.*

Moreover, the courts have emphasized that the "substantial competitive harm" must come from the "affirmative use of proprietary information by competitors," rather than "any injury to competitive position, as might flow from customer or employee disgruntlement."[6] Information regarding product hazards does not convey the type of competitive advantage that the exemption was designed to protect.[7] In this instance, the policy seems more designed to protect food companies from disgruntled customers than from their competitors.

Some courts use a relaxed "confidentiality" standard for information voluntarily submitted to the government, protecting information that the submitter would not customarily release.[8] Even those courts would allow disclosure of customer lists because such information is made widely known. As some in industry have noted, distribution lists are not huge secrets because most people have a good idea of who is doing business with whom.[9] In theory one could compile distribution lists from the plant numbers that are supposed to be on the packaging of meat and poultry products. But that would be impractical, particularly at the time of a recall when public health is in jeopardy. Companies should not be allowed to use FOIA exemptions to shield themselves from the consequences of introducing potentially adulterated foods into the food supply by denying states and consumers critical information they need to act quickly to prevent illness.

Government communication is essential to an effective recall

At the consumer level, an effective recall is one that motivates people to do something they don't normally do: To question the safety of a product already in their refrigerator or cupboard. Recall messages must by necessity compete with many other consumer food-safety messages. At a time when consumers have more information coming at them from more places than ever before, not only reaching consumers, but getting their attention and arming them with adequate information to respond is very challenging.

Let me give you a case study to illustrate this challenge:

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[6] *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1291, n.30 (D.C. Cir. 1983).

[7] *Vaughn*, *supra* note 5.

[8] See, e.g., *Critical Mass Energy Project v. Nuclear Regulatory Commission*, 975 F.2d 871 (D.C. Cir. 1992), *cert denied*, 507 U.S. 984 (1993) (holding that information remains "confidential" if it is of a kind that would not customarily be released to the public). *Cf., Comdico, Inc. v. Gen'l. Services Admin.*, 864 F. Supp. 510 (E.D. Va. 1994).

[9] Allison Beers, "USDA should share sensitive recall information, says NACMPI," *Food Chemical News*, (Nov. 6, 2000), pp. 3-4.

In 1994, Schwan's ice cream was identified as the cause of a major outbreak of *Salmonella* poisoning. According to the American Journal of Public Health, this outbreak caused 224,000 illnesses in 41 states, making it one of the largest foodborne-illness outbreaks ever reported.

It was also relatively unique, because Schwan's had delivered the ice cream directly to consumers' homes, so customer lists were readily available. Schwan's sent letters to its customers and instructed its delivery personnel to collect the contaminated product. This gave researchers an opportunity to evaluate how consumers respond to recall information.

Researchers surveyed 179 households in Georgia that were Schwan's customers, representing over 600 consumers. Ninety-one percent of the households heard the warning about the contaminated ice cream, but among these, 26% didn't initially believe that the ice cream was unsafe. In 31% of the households that both had the contaminated ice cream and had heard the warnings, someone subsequently ate the ice cream.[10]

Consumers and the media treat government warnings more seriously. Thus, government agencies, not food companies, should be the principal source of information about food recalls. In the 1998 Sara Lee/Bil Mar recall, USDA relied on the company itself to make the recall announcement, which occurred right before Christmas. Unfortunately, there was a lot of breaking news that holiday season, and the recall got very little press attention. During the month that followed, people continued to eat the contaminated luncheon meats and hot dogs and became ill. The death toll continued to rise during the month following the company's recall announcement. The company's announcement did not haltthe outbreak. Finally, on January 28, USDA issued a recall notice on the Sarah Lee/Bil Mar product, and the outbreak finally ended.[11]

A year after the Sarah Lee/Bil Mar recall, USDA announced a new recall policy of sending out a public announcement whenever companies initiated a Class I recall.[12] This has resulted in many more recall announcements by FSIS, with a peak in 2002 of over 110 separate recalls (see Appendix II). Unfortunately, these recall problems show the need for further strengthening of the policy.

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[10] Barbara E. Mahon et al., "Consequences in Georgia of a nationwide outbreak of Salmonella infections: What you don't know might hurt you, 89 *American Journal of Public Health,* (Jan. 1999), pp. 31-35.
[11] Peter Perl, "Outbreak," *Washington Post Magazine*, (Jan. 16, 2000).
[12] FSIS Directive 8080.1 Rev. 3, Recall of Meat and Poultry Products, (Jan. 19, 2000) [hereinafter *FSIS Directive*].

Delaying recalls can be deadly

Each day that a recall is delayed, more consumers are at risk of food poisoning. The General Accounting Office (GAO) has criticized USDA for failing to systematically track companies' activities to ensure that recalls, particularly of foods that may cause serious adverse health consequences, are initiated and carried out without delay.[13] USDA guidance allows companies to give notice of recalls involving potentially life-threatening contaminants such as *Listeria monocytogenes* through U.S. mail.[14] To remedy this problem, the GAO recommended that USDA provide specific guidance to companies on time frames for quickly initiating and carrying out food recalls that involve potentially serious adverse health risks, including procedures to expeditiously notify their distribution chains and alert the public.[15]

Moreover, GAO found that USDA only performs selective checks to verify recall effectiveness.[16] Yet the Recall Policy Working Group acknowledged that FSIS's responsibility is "one of verifying that the establishment is fulfilling its obligation and, if the establishment is not doing so, of acting to ensure that the establishment does."[17] To resolve weaknesses in the recall program, the GAO recommended that the agency modify existing recall databases. They should include enough information on the timeliness of companies' recall activities for the agency to determine whether there was any delay in initiating and carrying out recalls.[18]

Additionally, both the FSIS Recall Policy Working Group and the Association of Food and Drug Officials have recommended that USDA require companies to maintain records that will enable them to trace every food product from its entry into their facilities to its furthest distribution.[19] Such records are necessary to help

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[13] Government Accounting Office, Food Safety: Actions Needed by USDA and FDA to Ensure That Companies Promptly Carry Out Recalls, (Aug. 2000), p. 19 [hereinafter cited as GAO Report].

[14] *GAO Report*, p. 16. See *FSIS Directive.*

[15] *GAO Report*, pp. 19-20.

[16] *GAO Report*, p. 14.

[17] *Recall Policy Working Group* ("The Agency's activities should include verifying that the firm has identified the proper product, verifying that the firm is making the appropriate contacts through its distribution channels, and verifying the adequacy of the establishment's notification to consignees and the public.")

[18] *GAO Report*, p. 20 ("The information should, at a minimum, include the dates a company (1) finds out about the problem warranting a recall, (2) initiates the recall, (3) notifies the distribution chain, (4) notifies the public, and (5) completes the recall. In addition, the database should track the methods the company used to notify its distributors and the public, and the date(s) on which the agencies requested the company to initiate a recall.")

[19] *Recall Policy Working Group*; Association of Food and Drug Officials (AFDO), Comments on *Report of the Recall Policy Working Group*, (Oct. 5, 1998) (AFDO

determine the scope and depth of the recall. For example, the Recall Policy Working Group reported that product identification was hampered in the Beef America recall of 1997 because the consignees did not keep the records necessary to trace the product forward through the distribution system.[20] Congress recently enacted traceability requirements in the 2002 Bioterrorism Act, but these only affect food companies regulated by the FDA.

The Working Group also recommended that the rulemaking require establishments to have a written plan that defines how they will conduct a recall.[21] The recall plan envisioned by the Working Group would be similar to the sanitation standard operating procedures and the HACCP plan and would "define how the establishment will respond should a situation that requires a recall arise."[22] The agency should address these rulemaking recommendations.

USDA should support statutory changes

These improvements in the existing voluntary recall system are only half-measures. The food industry promotes the myth that no changes are needed to the voluntary recall system because no company has ever failed to comply with a USDA recall request. However, a few years ago a poultry processor refused to comply with a recall request after USDA discovered *Listeria monocytogenes* contamination in its products.[23] In the end, FSIS was forced to issue a press release warning the public that nearly 8,000 pounds of potentially adulterated chicken were in the food supply but could not be recalled.[24]

Under a voluntary recall authority we may never know how many companies haven't complied with a government recall request because a recall is the result of a negotiation between a company and FDA or USDA. The government may have agreed to a less public market withdrawal rather than a recall on numerous occasions, and consumers would never have known.

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stated: "The manufacturer, the wholesaler, and the retailer need to have record keeping systems and coding which can readily identify where product has been shipped, and how much has been sold, in order for tracebacks to be effective.").

[20] *Recall Policy Working Group*.

[21] *Recall Policy Working Group.*

[22] *Recall Policy Working Group.*

[23] While the company subsequently asked its distributors not to ship the product, it never asked consumers or its distributors to return the product. T. Cosgrove, *House of Raeford Denies FSIS 'Refusal to Comply' Allegation*, The Meating Place Daily News Story (Oct. 12, 2000), available at *http://www.meatingplace.com/meatingplace/DailyNews/News.asp?ID=6216.*

[24] U.S. Department of Agriculture, Food Safety and Inspection Service, "USDA Warns Public of Barbecued Chicken with Possible *Listeria* Contamination," Press Release, (Oct. 6, 2000).

Clearly, USDA and FDA need additional powers to order contaminated food off supermarket shelves. In fact, Secretary Anne Veneman has admitted that USDA is "working under a Meat Inspection Act that pre-dates the Model T."[25] Support for mandatory recall authority would not be a new or unique position for the Department. USDA is on record supporting mandatory recall authority and civil penalties, following the large Hudson Beef recall in 1997.

The federal government should not continue to operate with century-old enforcement tools, especially as Congress has given numerous agencies regulating consumer products more modern tools. Here are several examples:

1. The Consumer Product Safety Act of 1972 requires manufacturers of consumer products such as toys to notify the government if their products pose a substantial product hazard. Companies can be fined for failure to comply with a Consumer Product Safety Commission recall order and the product can be banned from the market.
2. Manufacturers of infant formulas are compelled by a 1986 law to notify the government if they know, or should know, that their formula may be adulterated or misbranded. If the FDA determines that the formula presents a risk to human health, the FDA can dictate to the manufacturer the scope and extent of the recall and can audit the effectiveness of the recall through reporting and recordkeeping requirements.
3. The FDA also can order manufacturers to recall medical devices if there is a reasonable probability of serious adverse health consequences or death. The recall order takes effect immediately, with the opportunity for a hearing only after the order is issued. As with the infant formula recalls, the FDA can impose stringent reporting requirements on the conduct of device recalls.

More needs to be done to protect the American food supply. The current voluntary recall policy does not adequately protect the public from products that may cause health problems or possible death. Mandatory recall, public disclosure of companies that distribute or sell tainted meat, and civil penalties are necessary enforcement tools if USDA and FDA are going to effectively operate as public-health agencies addressing food safety. Consumers deserve the peace of mind that these added measures provide.

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[25] Remarks of Secretary of Agriculture Anne M. Veneman, Food Safety Summit and Expo, Wednesday, March 19, 2003, available at www.usda.gov/news/releases/2003/03/0092.htm

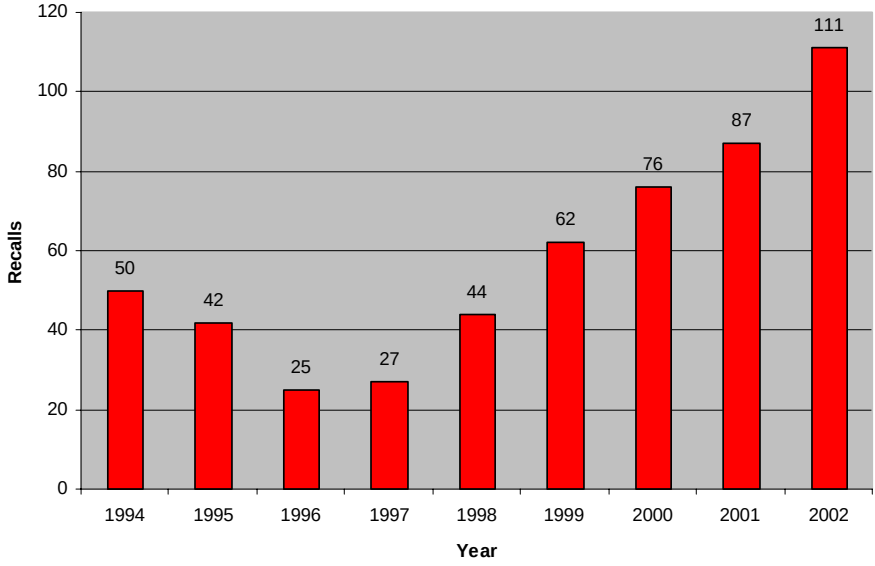
Appendix I

Expanded FSIS Recalls – Examples

Company/Product	**Reason for Recall**	**Original Recall Amount**	**Expanded Recall Amount**
Jack Lambersky Poultry Inc./ Turkey and chicken products	*Listeria monocytogenes*	200,000 pounds	4.2 million pounds
Pilgrim's Pride/ Turkey and chicken products	*Listeria monocytogenes*	295,000 pounds	28 million pounds
Emmpak Foods, Inc./ Ground beef	*E. coli* O157:H7	500,000 pounds	2.8 million pounds
Broadway Ham Company/Ham	*Listeria monocytogenes*	2,200 pounds	8,725 pounds
ConAgra Beef Company/Beef products	*E. coli* O157:H7	354,200 pounds	19 million pounds
Hudson Beef	*E. coli* O157:H7	20,000 pounds	1.2 million pounds 25 million pounds

Appendix II

Total Number of FSIS Recalls by Year 1994-2002



FOOD IRRADIATION 101

Michael T. Osterholm
Director of the Center for Infectious Disease Research and Policy
University of Minnesota

Beginning January 2004 irradiated ground beef will be available through the U.S. Department of Agriculture's National School Lunch Program. While you are likely aware of the offering, you may still have questions about irradiated ground beef.

Nearly every major science and health agency supports the consumption of irradiated food. These include the World Health Organization, the Centers for Disease Control and Prevention (CDC), the American Medical Association, and the American Dietetic Association.

Food irradiation uses high-energy radiation to kill harmful pathogens in meat and poultry. It is also used on fruits and vegetables, dry spices, and wheat and flour to control sprouting and infestation.

When ground beef is irradiated, at least 99.99 percent of *Escherichia coli* (*E. coli)* and other harmful foodborne bacteria are killed, making the product safer for consumption. The CDC estimates roughly 73,000 cases of *E. coli* infection each year and 61 deaths, many of them children, in the United States. Many of these illnesses are associated with eating contaminated ground beef. Approximately 5 to 10 percent of school-aged children who are infected with *E. coli* will develop hemolytic uremic syndrome (HUS), the principal cause of kidney failure in children.

The arguments against irradiation today are similar to the arguments used decades ago against pasteurization. Pasteurization opponents said it wouldn't prevent disease, the taste would be unpalatable, and it would be an excuse for farmers to run a dirty operation. Those claims turned out to be untrue, and pasteurized milk has contributed to the health of our children for over fifty years. As school food service professionals, you would never consider serving unpasteurized milk because of the known risks. Those same risks exist with ground beef that has not been irradiated.

Irradiation provides an opportunity to decrease foodborne illness in schools. It is not a substitute for sanitary food processing and manufacturing nor is it a substitute for good personal or kitchen hygiene. It gives food service workers one more measure of safety in providing high-quality food for the children.

Critics of irradiation contend it is unnecessary because bacteria are killed when meat is cooked properly. Yet errors can happen anywhere along the line—from

processing, to distributing, to handling and serving. A General Accounting Office (GAO) report last May found nearly half of 40 large outbreaks at schools resulted from improper food preparation and handling practices in school kitchens. In a Washington state district involved in the multi-million dollar lawsuit over the *E. coli* outbreak, 11 children were sickened by consuming *E. coli* bacteria from contaminated ground beef that was not cooked properly or kept hot.

Purchasing pre-cooked ground beef is not necessarily a safeguard against *E. coli* either. When I was the state epidemiologist for Minnesota, I investigated a large *E. coli* outbreak (32 confirmed cases and 22 possible cases) that was ultimately traced to pre-cooked hamburger patties served in a junior high school. The patties were not cooked sufficiently by the manufacturer and may not have been thawed or re-heated correctly by the school.

I strongly believe irradiated ground beef should be served in schools. This issue is not about the meat industry, lawsuits or activists. It is about protecting the health of our children when they are at school.

INTERPRETING THE NEW NATIONAL FRESH PRODUCE FOOD SAFETY SYSTEM

Dennis. J. Osborne, Ph.D., J.D.[1], Douglas C. Sanders, Ph.D.[1], James W. Rushing, Ph.D.[2] and Donn R. Ward, Ph.D.[3]

Abstract

In our Southern Regional research, extension and training programs, we have begun referring to what we call the "New Food Safety System in the US". As described in an earlier paper in this journal (Osborne, *et al*, 2003A, 2003B), that "system" includes GAPs certification and, since December 12, 2003, FDA grower registration. As with most fast-evolving entities this new "system" generated many questions from those directly impacted. One of the goals of our South Regional Fresh Produce Food Safety Training was to develop a curriculum addressing such concerns and synthesizing program elements into a simply explained framework.

This paper presents our initial interpretation/translation of policy into training material. It is offered as an example of the training materials emerging in response to FDA's seminal 1998 publication entitled Guide to Minimize Microbial Food Safety Hazards ("Guide"). While we have prepared materials more exhaustive of related subtopics, this report is one of the first suggesting that FDA and USDA Fresh Produce Food Safety programs generate unforeseen positive implementation "ripples" as growers adapt policy to market advantage.

The System

What we call a "New Food Safety System in the US" has two bases. The first base is USDA's "GAPs Grower Certification Program" effected in late 2002. The GAPs program is a voluntary national multi-institutional program creating market opportunities for growers of all scale, but particularly helpful to the smallest, because even the smallest scale grower can be "USDA Certified". GAPs-Certified Grower profits have increased in several cases where small growers used GAPs. In one noteworthy example a vegetable grower increased profit because she began washing containers, thereby reducing wastage caused by microbially related spoilage from microbes associated with field containers. Her story is not unique and shows that regulatory changes intended to address consumer food safety may have the unintended consequence of making growers more profitable.

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The second base arose in the US Food and Drug Administration ("FDA"). It is commonly called "FDA registration" because growers and others register their operations on an FDA website. In effect since December 12, 2003, that registration, while perhaps not intended to be so, is a functional partner of GAPs Certification, at least regarding risk management. This is because concepts of recall, traceback, tort liability and due diligence are imbued in the procedures growers adopt upon becoming registered with FDA, and they begin employing the two system bases. Growers employing one base increasingly see no reason not to employ both. This is happening because in a positive synergy growers protect themselves from liability while they protect the national food supply.

It is useful to recall the short history of these bases to consider their large impact in a short time. FDA first published guidance for HACCP for minimal process industries in the Federal Register (FDA, 1998A) and for GAPs for fresh produce industries in the Guide (FDA, 1998B). The Guide lists eight (8) principles called GAPs, which are in nature preventative and which together comprise what we call Fresh Produce Food Safety ("FPFS"). The focii of the Guide were: (1) microbial hazards related to fresh produce, (2) risk reduction, not risk elimination, and (3) broad, scientifically based principles on which FPFS programs could be built.

Extending HACCP-like programs to minimal process operations represented a considerable change from past practice. This is because minimal process operations have usually been regulated in a manner similar to that applicable to raw agricultural commodities. GAPs represent another shift, one of increasing reliance on self-regulation after education. The diversity of American fresh produce agricultural practices and commodities forced authors of the Guide to note that practices recommended to minimize microbial contamination would be most effective when adapted to specific operations.

This meant that broad statements of intent were supplied with implementation and interpretation left to the states and the industry. And indeed this is occurring. For example, in the South Region, a concerted effort addressing needs of roadside and direct marketers is beginning. This will include outreach with Cooperative Extension Family and Consumer Science staff in the Region and will incorporate outreach to USDA's "Socially Disadvantaged" farm entities. Food safety educational programming in cooperation with elementary school science projects and 4H youth are planned if funding is available. Hispanic workers are a major audience for food safety programming and are more fully included in planned new work.

Impact

Fresh Produce Food Safety may be a voluntary activity by produce growers, but most will soon be required to have a GAPs program in place or risk inability to sell product. What does the new system mean to growers and how do we address their concerns in our training programs? In the first quarter of 2004, the following items have been found useful as basic information items. As more implementation occurs these will be refined.

1. FDA requires all packers of fresh produce to register by December 12, 2003, after national bioterrorism concerns. Unregistered growers may find produce movement restricted. Growers doing something to produce to add value need to register. Farmers selling directly to consumers do not have to register.
2. Federal agencies will purchase only produce that has been USDA third-party audited as of February 2004.
3. Many chainstores now require third party audits.
4. GAPs certification is just good business, it helps to reduce risk and protects you, the grower, if you are sued over a foodborne illness. GAPs certification indicates "due diligence" on part of the certified party. GAPs certification may help a certified grower defuse negative press during a produce-related foodborne illness outbreak.

How do You get started? Think about liability and "due diligence" -- doing all YOU can do to make YOUR produce safe.

1. You already have pesticide safety training for your employees.
2. You practice good hygiene in the field and packinghouse, but you need to **Document** it.
3. You have handwashing facilities in the field and at the packinghouse (OSHA requires them), but you need to train your workers and **Document** the training.
4. You don't use manure in mid-season, but you need to **Document** when it was used to show you the right number of days before harvest.
5. You follow health laws, but you need to D**ocument** what you have done.
6. You don't put rotten produce into the box, but you need to **Document** that you follow USDA grading practices.
7. You follow proper chlorination procedures, because you have price reductions if produce rots, but you need to **Document** your procedures and chlorine checking.
8. You wash down packing lines after use, but you need to **Document** when and how.
9. You keep birds and rodents out of packing and storage areas, but you need to **Document** when and how.

Things you may need to do:

1. **Document** by writing a company policy and putting it in a notebook.
2. **Document** that irrigation and wash water are free of human pathogens.
3. **Document** that you have trained your field and packinghouse staff in GAPs.
4. **Document** that you check coolers for proper temperatures and cleanliness.
5. **Document** that you check bathrooms for cleanliness.
6. **Document** that you have SOPs in place and follow them.
7. **Document** that you check irrigation water 5 times in the first 30 days.
8. **Document** that you check packinghouse water 3 times per season.
9. **Document** that any manure application is 90 or 120 days before harvest, depending on crop.
10. **Document** when you check soil for contamination (every 5 years).
11. **Document** that you check truck cleanliness and temperature before loading.
12. **Document** that you check sanitizer levels in dump tanks several times a day.
13. **Document** that you follow local laws for health and safety.
14. **Document** that you record harvest and shipping dates by field.
15. **Document** that you have a traceback program.

More things to do

1. Learn the alphabet of Food Safety: GAPs, GMPs, SOPs, COOL, FDA, CDC.
2. **Register per instructions on the FDA website required by Dec. 12, 2003**:
3. Go to http://www.cfsan.fda.gov/~furls/ovffreg.html.
4. Establish SOPs.
5. Have records readily available.

General information

http://www.cals.ncsu.edu/hort_sci/hsfoodsafety.html
http://www.ces.ncsu.edu/depts/foodsci/agentinfo/
http://foodsafe.msu.edu/
http://ucgaps.ucdavis.edu/
http://www.gaps.cornell.edu/
http://www.foodriskclearinghouse.umd.edu/
http://www.foodsafety.gov/
http://www.extension.iastate.edu/foodsafety/
http://www.cdc.gov/foodsafety/edu.htm

General publication

Food Safety Begins on the Farm http://www.gaps.cornell.edu/pubs/Farm_Boo.pdf
Reducing Microbial Risks http://www.gaps.cornell.edu/pubs/risks.pdf

Other publications: http://www.sfc.ucdavis.edu/docs/foodsafety.html
Training information: http://www.jifsan.umd.edu
http://www.jifsan.umd.edu/gaps.html
Training power points: http://www.gaps.cornell.edu/ppt_index.htm
Distance Ed courses: http://www.ces.ncsu.edu/depts/foodsci/distance/
Crop-specific information: Bulletins available on Green Beans and Peas; Cabbage & Leafy Greens; Fresh Carrots and Other Root Crops; Cucumbers, Eggplants, Squash, Peppers and Sweetcorn; Melons; Tomatoes; Strawberries, Raspberries, Blackberries, and Blueberries; Citrus; Peaches.
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Sample Recall Plan www.ces.ncsu.edu/depts/hort.greenhouse)veg/news.html

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2003-2004
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ASSOCIATION OF FOOD AND DRUG OFFICIALS
MEMBERSHIP APPLICATION

MEMBERSHIP INFORMATION:

Name_____
Title_____
Organization_____
Address_____
City _____ State_____ Zip_____
Telephone:_____ Fax:_____
Email:_____

1. Individual Membership:

Individual Members	**Online Journal**	**Journal**
Alumni/Students	☐ $50	☐ $65
Regulatory	☐ $50	☐ $85
Consumers/Educational	☐ $50	☐ $85
Small Business/Consultants	☐ $225	☐ $275
Associate Industry	☐ $325	☐ $375

2. Group Membership: ***Group membership applications must be submitted together.***

# of Group Members	**Government**	**Non-Government**
5-10	☐ $46 each	☐ $300 each
11-20	☐ $44 each	☐ $285 each
21-50	☐ $42 each	☐ $270 each
Greater than 50	☐ $40 each	☐ $255 each

3. Contributing Membership: ***Contributing membership applications must be submitted together.***

Contributing Member Classifications	**Government # of Memberships**	**Non-Government # of Memberships**
Platinum	☐ 5 for $750 ($150 ea.)	☐ 5 for $2,500 ($500 ea.)
Gold	☐ 3 for $500 ($166 ea.)	☐ 3 for $1,750 ($583 ea.)
Silver	☐ 2 for $350 ($175 ea.)	☐ 2 for $1,250 ($625 ea.)

FEDERAL I.D. #74-605-1887

Check payable in U.S. funds enclosed ☐Visa ☐MasterCard

Card Number_____ Exp. date:_____
Signature _____

2004

Association of Food and Drug Officials
108th Annual Educational Conference
June 19–23, 2004
Pittsburgh, PA
Hilton Pittsburgh Towers

This year's conference will be full of emerging issues of interest to us all. CDC, Canada, FDA, Mexico, and USDA representatives will provide keynote addresses.

This year's pre-conference workshop is a retail workshop focusing on active managerial control and *Listeria* control at retail. The workshop is cosponsored by the AFDO Endowment Foundation and the National Restaurant Association's Educational Foundation's International Food Safety Council and will be held on Saturday, June 19, 2004 from 8:00 a.m.–4:30 p.m.

CONFERENCE TOPICS TO BE DISCUSSED

- Beaver Valley Hepatitis A Outbreak 2003
- Health Fraud: Operation Cure-All and Beyond
- Biotechnology Panel
- Domestic Security and Preparedness
- Food Security: Narrowing the Focus for Restaurants and Regulators
- Risk Communication: Speaking with Science
- Tracking *Listeria Monocytogenes* Contamination Through the Food Chain
- The Obesity Epidemic
- International Perspective of Counterfeit Drugs
- Overview of FDA's Counterfeit Drug Initiative
- NABP Report on Counterfeit Drug Task Force
- BSE Panel
- BT Act Update
- Safety Evaluation of Food Contaminants
- New Packaging Technologies for Meats: Shelf Life and Safety
- Emerging Rapid Diagnostics
- CSPI Emphasis on Medical Device Health Fraud

For a complete conference program and registration information please contact the AFDO office at (717)757-2888 or afdo@afdo.org, or visit www.afdo.org.

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WHAT YOU CAN ACCESS ON AFDO'S WEBSITE:

- ✓ 2003 Annual Conference presentations
- ✓ 2002-2003 final committee reports
- ✓ AFDO Topical Index to Regulatory Guidance
- ✓ AFDO position statements
- ✓ AFDO resolutions
- ✓ State Emergency Assistance Personnel
- ✓ Current legislation of interest
- ✓ Information on upcoming training from AFDO and other affiliated organizations
- ✓ Membership information
  - o Membership benefits
  - o Membership application
- ✓ Online journal
- ✓ Committee chair listing
- ✓ Committee charges/recent activities
  - o View what AFDO's committees are working on this year and activities they have accomplished
- ✓ Information on Seafood HACCP
  - o Including Internet HACCP
  - o Medical Device HACCP
- ✓ AFDO scholarship application
- ✓ Links to AFDO's Affiliates
- ✓ AFDO Publication order form
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