Consumer Federation of America

Attributing Illness to Food
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Good morning. I am Chris Waldrop, director of the Food Policy Institute at Consumer Federation of America. Because you have asked me to address the consumer perspective on the definition and use of food attribution data in the effort to most effectively and efficiently reduce foodborne illness, I want to take a minute to tell you about myself and CFA.

CFA is a non-profit association of over 300 organizations, with a combined membership of over 50 million Americans. Our member organizations include local, state, and national consumer advocacy groups, senior citizen associations, consumer cooperatives, trade unions and anti-hunger and food safety organizations. Founded in 1968, CFA has worked to advance the interest of American consumers through research, education and advocacy. Our policy positions are determined by a vote of member representatives. The Food Policy Institute was created in 1999 and engages in research, education and advocacy on food and agricultural policy, agricultural biotechnology, food safety and nutrition.

I joined CFA four years ago and became director of the Institute in January 2007. I am currently completing work on a Masters in Public Health at Johns Hopkins University.

Introduction

While we recognize the efforts of responsible members of the food industry to assure their products are safe, CFA's members believe that, in the final analysis, it is the obligation of the U.S. government to assure that food sold in the U.S. is safe and accurately labeled. This is especially true of meat and poultry, as they are the only products sold in the United States that come to the consumer with a U.S. government safety seal prominently displayed.

Foodborne illness is a serious public health problem in the U.S. The CDC reports there are 76 million cases of foodborne illness each year, 325,000 hospitalizations and 5,000

deaths. In 2000, USDA's Economic Research Service estimated the cost to the United States from six foodborne pathogens to be between $2.9 and $6.7 billion annually.

After several years of declining foodborne illness rates, progress has stalled. According to the CDC, there has been little further reduction in the rates of Campylobacteriosis, Salmonellosis, and Listeriosis since 2001. The government failed to meet the National Health Objective of reducing the rate of Listeriosis to 2.5 cases per million by 2005.

This toll demonstrates that neither industry nor government is meeting their obligations to the public. It is imperative that government food safety regulators take the steps needed to reduce the human and economic costs of foodborne illness.

CFA's position is:

- We support allocating food safety resources according to risk.
- Food attribution data are essential to developing a risk-based inspection program.
- For almost ten years, the U.S. government has promised the public and the Congress that these data are being developed.
- We reject any proposal for so-called risk based inspection that tries to shortcut the need for data and seeks to substitute opinion.

FSIS misuse of carcass contamination data and CDC FoodNet data undermines the credibility of the Agency's stated commitment to a science-based system. Since USDA food safety officials know they are misusing the data, we have lost trust in their intentions as well as their competence.

Value of Food Attribution Data

The ability to identify which foods are vehicles for specific cases of illnesses is a basic element of prioritizing and allocating resources to reduce the level of foodborne illness in a population. Current discussion focuses on food attribution data and expert elicitation. Food attribution data is quantitative information that establishes actual links between particular foods and specific cases of illness. It is based on collected data of actual cases and as such is the most valuable information to regulators, public health officials, the food industry and consumers. Expert elicitation obtains the judgments of a group of experts in a particular field. It is based on informed opinion instead of observable data. Expert elicitation is best used to fill in data gaps rather than as a substitute for the data itself.

There are a number of reasons for collecting attribution data. First, food attribution data provides quantifiable information linking foodborne disease to particular food products. This is objective data, as opposed to the more subjective information that is gathered from an expert elicitation process. Second, food attribution data provides all stakeholders with a better understanding of food/pathogen combinations. This provides appropriators with greater information upon which to make funding decisions, provides regulators with better information to target resources to protect consumers, and provides industry with valuable information they can use when applying interventions. Third, this data can

highlight areas in which further research and investigation is needed. Finally, food attribution data provides a better understanding of risks associated with particular foods and pathogens. We cannot wisely target limited public health resources without knowing which foods are vectors for which diseases. We need to be able to attribute illness to particular foods in order to ensure that the resources we are devoting are proportional to the illness being caused.

The need for food attribution data is not new. Federal agencies involved in food safety have stressed the need for this information for years. However, there has been no dedicated and concerted effort to get it. It is unacceptable to have today's meeting end in commitment to further dialogue. At the end of the day, we want to hear all the agencies commit to a concentrated effort to get this data. Further, we want FSIS to forego further action on so-called risk based inspection until it has something more than guesswork, even expert guesswork, about the inherent risks of various products. Experts are often wrong and the public wants and deserves data-based programs.

FSIS MISUSES EXISTING DATA TO CLAIM PROGRESS

It is obvious that today's discussion is being held to justify FSIS' intention to move forward on its so-called risk based inspection program without any food attribution data. FSIS asserts that it is possible, even desirable, to move forward because current FSIS programs have been successful in reducing carcass contamination and that FSIS programs have contributed to enormous reductions in foodborne illness. However, FSIS misuses regulatory sampling data and misrepresents the current state of progress against foodborne illness surveillance data to make its case. These are false premises upon which to base major changes in federal inspection and it demonstrates the need for objective, quantifiable data such as food attribution data.

FSIS Claims Carcass Contamination Rates Have Declined, Indicating Less Threat to the Public

First, the USDA Office of Inspection General has clearly stated that pathogen levels found during regulatory testing cannot be extrapolated to reductions in pathogen levels in all meat and poultry products nationwide. In 2003, the USDA OIG noted that the FSIS pathogen sampling program is regulatory in nature, is designed to track establishment performance, is not statistically designed, is based on a sampling base that includes different establishments from year to year and that measures of prevalence represent un-weighted test results from the sampled establishments[1].

[1] USDA Office of the Inspector General Great Plains Region. *Food Safety and Inspection Service Oversight of Production Process and Recall at ConAgra Plant (Establishment 969),* Report No. 24601-2-KC, September 2003.

FSIS Claims its Programs Are Responsible for Major Reductions in Foodborne Illness

Second, while the CDC has observed specific declines in foodborne illness since a baseline of 1996-1998, progress on reducing illness caused by several foodborne pathogens has declined or ground to a halt in recent years. Most progress in reducing foodborne illness occurred before 2001. Now it has stalled.

USDA officials frequently cite a huge reduction in Listeriosis cases since 1996, but fail to note that the current Listeriosis rate is 3 cases per million, the same as it was in 2000. The Under Secretary for Food Safety has never acknowledged the fact that the government failed to meet the national health objective of reducing the rate of *Listeria*-related illness to 2.5 per million by 2005[2]. USDA continues to cite the goal of reaching the number by 2010.

If USDA/FSIS insists on crediting the Agency's policies for reduced rates of foodborne illness since 1996-1998, the Agency will also have to address the fact that there have been virtually no further reductions in disease caused by *Campylobacter, Listeria monocytogenes* and most serotypes of *Salmonella* since 2001. It is not because we have reached a point where foodborne illness rates are so low they can't be improved. In fact, the CDC has not reduced its estimate of the total number of outbreaks and illnesses[3].

We cannot ask CFA's members to accept a new inspection model based not just on flawed, but intentionally misrepresented, data. We fear the result will be more, not less foodborne illness.

GOVERNEMENT AGENCIES HAVE ACKNOWLEDGED VALUE OF AND NEED FOR FOOD ATTRIBUTION DATA AND PROMISED TO GET IT

We find it troubling that USDA is conducting a meeting on defining food attribution data and determining whether it is really necessary to have such data. There are a multitude of documents that detail the need for the data.

In its 2003 report, "Scientific Criteria to Ensure Safe Food," the Institute of Medicine/National Research Council clearly stated the need for food attribution data:

> [S]cience-based food safety criteria must be clearly linked to the public health problem that they are designed to address. To accomplish this, a cause/effect relationship needs to be established between contaminants in foods and human disease; that is, **to allocate the burden of foodborne disease among foods and food groups.** Knowing the contribution of each food or food group to this burden

[2] Centers for Disease Control and Prevention. *Preliminary FoodNet Data on the Incidence of Infection with Pathogens Transmitted Commonly Through Food – 10 States, United States, 2004.* April 15, 2005, MMWR, 54(14), 352-356.

[3] Centers for Disease Control and Prevention. *Preliminary FoodNet Data on the Incidence of Infection with Pathogens Transmitted Commonly Through Food – 10 States, United States, 2005.* April 14, 2006, MMWR, 55(14), 392-395.

would allow the selection (or promote the development) of appropriate interventions and set the basis for establishing criteria such as performance standards.

This knowledge would also allow regulators to (1) focus on those foods that present the highest risk, and (2) target effective interventions at Critical Control Points (CCPs) in the production, processing, and distribution continuum of such foods. Moreover, such a link would allow the regulatory agencies and industry to measure the effectiveness of the selected interventions, and corresponding criteria, such as performance standards, in controlling the particular hazard and thus improving public health[4]. (emphasis added)

In October 2003, the Food Safety Research Consortium held a Food Attribution Data Workshop. It included many of the presenters in today's meeting. In its summary report, members of the workshop noted that

--"to design and prioritize effective food safety interventions, we must be able to perform food attribution – that is, identify which foods are vehicles for specific cases of illness."

--"to make informed science- and risk-based decisions about food safety interventions, we need to be able to associate foodborne illnesses to specific food vehicles[5]."

USDA and other government agencies have long acknowledged the need for this information and, in fact, USDA has often promised Congress that it was already at work developing the data.

In 2000, then Under Secretary for Food Safety Catherine Woteki noted that

"Among the work that CDC has underway right now is further work to better understand those [foodborne illness] estimates and the different types of food products that are contributing to these illnesses[6]."

In July 2004, USDA's "Fulfilling the Vision" document stated that to achieve the next level of food safety,

"data that links foodborne illness outbreaks with specific foods needs to be connected with prevalence data of specific pathogens in specific foods[7]."

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[4] Institute of Medicine/National Research Council, *Scientific Criteria to Ensure Safe Foods,* National Academy of Sciences, 2003.

[5] Batz, M.B., Doyle, M.P., Morris, Jr., G., Painter, J., Singh, R., Tauxe, R.V., Taylor, M.R., Wong, D.M.A., "Attributing Illness to Food," *Emerging Infectious Diseases,* Vol. 11, No. 7, July 2005.

[6] Testimony of Catherine Woteki, Under Secretary for Food Safety, Food Safety and Inspection Service, before the Subcommittee on Agriculture, Rural Development, Food and Drug Administration and Related Agencies of the Committee on Appropriations, U.S. House of Representatives, 2000.

[7] Food Safety and Inspection Service, "Fulfilling the Vision: Initiatives in Protecting Public Health," July 2004.

FSIS noted it was already at work with the CDC and the University of Minnesota to estimate the attribution of illness caused by various foods. FSIS said the model would be ready by Fall 2004.

In 2005, FSIS told the House Agriculture Appropriations Subcommittee that

> "significant progress has been made in efforts to improve foodborne illness data so that illness and product type can be determined[8]."

FSIS said the Agency was working with CDC on a point-of-consumption attribution study which would be completed in Fall 2005:

> "These attribution studies will help to further inform FSIS regulatory actions along the farm-to-table continuum to further reduce foodborne illnesses attributed to FSIS regulated products."

In 2006, then-Chairman Bonilla asked about FSIS' progress on these projects. FSIS responded

> "progress has been made in efforts to improve human illness data so that illness and product type can be determined…" FSIS noted that a FoodNet project with the University of Minnesota was being undertaken "to develop a mathematical model to attribute illnesses to specific food types[9]."

The Agency said it would have the results in July 2006.

It also promised a "mathematical modeling project performed in collaboration with its FoodNet partners," would be completed in May 2006.

FSIS also highlighted its "point-of-consumption" study with CDC which was now delayed until June 2006. Again, FSIS stated that "these attribution studies will help to further inform FSIS regulatory actions along the farm-to-table continuum to further reduce foodborne illnesses attributed to FSIS-regulated products."

On behalf of CFA and our millions of members, I want an answer today to the basic question of why---after FSIS has acknowledged that food attribution data are vitally important, has described multiple efforts to develop the data, has promised that the results are just around the corner---has FSIS decided that food attribution data are not needed before launching a major new so-called risk-based inspection program. Why, after all those years acknowledging the need, all those years spending money to get the data, all those promises that it is just around the corner, are we participating in a meeting, the goal of which is clearly to conclude that food attribution data are a pipe-dream, a luxury, not necessary to a risk-based inspection program.

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[8] Testimony of Elsa Murano, Under Secretary for Food Safety, Food Safety and Inspection Service, before the Subcommittee on Agriculture, Rural Development, Food and Drug Administration and Related Agencies of the Committee on Appropriations, U.S. House of Representatives, 2005.

[9] Testimony of Richard Raymond, Under Secretary for Food Safety, Food Safety and Inspection Service, before the Subcommittee on Agriculture, Rural Development, Food and Drug Administration and Related Agencies of the Committee on Appropriations, U.S. House of Representatives, 2006.

EXPERT ELICITATION ALONE IS NOT SUFFICIENT FOR ESTABLISHING A "RISK-BASED INSPECTION PROGRAM"

Action, Not Just More Words, Needed

We commend the CDC for its efforts to begin developing food attribution data. The agency is developing a system to track surveillance data for outbreaks and attribute those outbreaks to particular food vehicles. We are eager to see the results of this effort.

However, a significant effort to collect food attribution data should have commenced years ago. And it certainly should have been in progress before FSIS announced the launch of its risk-based inspection proposal. If such an effort had been made, we would be here discussing how best to utilize attribution data instead of still trying to define it.

It is obvious that the efforts listed above continue to be delayed, despite optimistic pronouncements of steady progress. It is now April 2007 and we have still not seen the results of the projects detailed by FSIS above. Acquiring food attribution data will require FDA, CDC and FSIS to make concerted efforts, backed by time, energy and financial resources. Efforts to collect this data should become a genuine priority among the agencies.

Again, it is CFA's position that FSIS cannot legitimately move ahead on so-called risk-based inspection until it has done its homework. Pushing a new program based on flawed assumptions and inadequate data imperils the public. However, it is critical that the Agency also understand that within the context of risk-based inspection, even high quality food attribution data will not allow the Agency to truly allocate its resources according to risk. Current law simply does not permit a true allocation of resources according to risk. USDA must acknowledge the need and take on the responsibility of asking Congress to rewrite the statutes to acquire legal authority to run a coherent risk-based program, the authority to set and enforce microbial standards, require recalls and allocate resources according to science-based risk data.

Good Public Health Practice Demands Prudence

A good public health program should be data-driven. Data is necessary in order to challenge assumptions being made about the potential effects of the program. CFA is not suggesting that we need perfect data before moving ahead. However, it is reckless and irresponsible to rush ahead on a public health program based on an arbitrary timetable and without adequate data. This is especially true when food attribution data could be acquired in a reasonable amount of time with some focused effort.

A good public health program also defines the information it needs before embarking on significant change. Yet FSIS has decided to move forward on risk-based inspection before determining what information it requires to implement its program. The Agency insists that it must push forward on implementing risk-based inspection without acquiring

food attribution data. However, there is no compelling and justifiable reason to rush ahead with this program.

CFA is dedicated to improving the safety of the food supply as is FSIS. However, we cannot support a program that is pushing forward based on an arbitrary timeline and without gathering the necessary data to support its assumptions. The Agency should establish the necessary structures that will allow FSIS and its partners to collect and utilize food attribution data. Only after collecting and analyzing this highly relevant information should the Agency proceed with its risk-based inspection plans.

In addition, the Agency needs to specifically articulate its public health objectives for its risk-based inspection proposal and define the measurement tools it will use to determine whether the program is a success. This should be done prior to any program implementation and should be available for public comment. Without this information, the Agency and stakeholders will be unable to accurately measure progress under a new inspection model.

Food Attribution Data Should be Collected before RBI Implementation

Past precedent set by FSIS has given CFA and other consumer groups good reason to insist that FSIS collect food attribution data before moving ahead on changes to the federal inspection system. In the mid-90s, many consumer groups were concerned that the Agency's PR/HACCP rule was not sufficiently strict, particularly in regards to the Salmonella standard. Consumer groups had concerns that the standard was too low, but were assured by Agency personnel that the standard would be raised on a regular basis as companies improved their processes to meet the standard. Many consumer groups trusted the Agency's word and grudgingly supported the PR/HACCP rule. Since that time, the Salmonella standard has not changed. Consumer groups are feeling justifiably reluctant to accept any kind of future guarantees before they see meaningful action.

Verbal promises that the Agency will collect food attribution data once risk-based inspection is in place are insufficient. Once the Agency's risk-based inspection system is implemented, its energy and focus will remain on ensuring that the system is working. As a result, no resources will be directed towards the collection of attribution data. The Agency will have no better information upon which to make determinations of risk than when they started the program. And the Agency will still not have fundamental information identifying which foods are vehicles for specific foodborne illnesses.

The Problems with Expert Elicitation

One of the conclusions of the Food Attribution Working Group was that "the scientific and accurate attribution of foodborne illness to specific foods means developing a comprehensive program" that combines a number of different methods and data[10]. These include outbreak data, case-control studies, risk assessments, food and animal monitoring

[10] Batz, M.B., Doyle, M.P., Morris, Jr., G., Painter, J., Singh, R., Tauxe, R.V., Taylor, M.R., Wong, D.M.A., "Attributing Illness to Food." *Emerging Infectious Diseases,* Vol. 11, No. 7, July 2005.

(when associated with surveillance data), and expert elicitation. It is important to note the working group's emphasis that none of the approaches would provide sufficient information on its own. Rather, a combination of approaches would be more apt to provide the appropriate information from which to make determinations of risk and resource allocation.

Herein lays the problem with FSIS' determination of inherent risk in processing establishments. In Agency documents, FSIS states that it will use "expert elicitation to determine the relative inherent risk posed by various types of processed meat and poultry products." There is no mention of any other method of data collection to inform the Agency's decision on inherent risk of the product. Instead, the Agency intends to rely solely on expert elicitation, a method that is better utilized to fill in data gaps. Rather than take the time to gather data that could provide the Agency with concrete information about product risk and then asking experts to fill in some of the missing pieces, FSIS asked its experts to fill in a blank canvas.

Expert elicitations are useful in identifying areas in which "further effort is needed to reduce uncertainty[11]." However, expert elicitations are limited in general because they are based on opinions, rather than on observable data. They should be used as a supplement to, rather than a substitute for, primary data collection. The 2005 expert elicitation that the Agency has thus far utilized as the basis for its determination of product inherent risk is further flawed for several reasons. First, the experts consisted mainly of employees or former employees of the food industry and meat scientists, food technologists or food microbiologists from land grant universities. No outside public health officials or medical doctors were asked to take part. Second, the Agency did not ask its experts to consider severity of illness in their risk rankings. Third, the Agency did not ask its experts to consider susceptible populations such as pregnant women, the elderly or immune-compromised individuals. Finally, the Agency set no parameters for ranking risk so that the resulting risk ranking scores were practically incomparable.

FSIS is currently in the process of a second expert elicitation. It has assured the public that this new expert elicitation will address many of the problems listed above. Yet, FSIS has nearly completed the design of the elicitation before today's public meeting, at which many elements of expert elicitation will be discussed. Additionally, the Agency seems resistant to allow the public to comment on the methodology of the new elicitation. The Agency should have waited to receive feedback from today's meeting before designing its elicitation instrument and then allow for public comment of the methodology. These steps would help FSIS avoid many of the problems they encountered with the 2005 elicitation.

Yet while the process and parameters may be slightly improved, the underlying problem remains. It is simply unacceptable to base decisions about risk on expert elicitation alone. FSIS needs concrete and useable data on which to base its decisions about risk.

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[11] Hoffman, S., Fischbeck, P., Krupnick, A., McWilliams, M., "*Eliciting Information on Uncertainty from Heterogeneous Expert Panels: Attributing U.S. Foodborne Pathogen Illness to Food Consumption*." Resources for the Future, April 2006, updated May 2006.

Food attribution data is essential to scientifically justify and support the risk rankings of its expert elicitation. Without this data, FSIS could create a system that does not accurately reflect the true risk to the population and may endanger the public's health, particularly those most at risk for foodborne illness. FSIS, along with its sister agencies, should make this food attribution data collection a priority and should devote specific resources to collecting this data.

Conclusion

CFA supports allocating food safety resources according to risk. The best way to set priorities and allocate resources effectively and efficiently is to know which foods are the vehicles for specific cases of foodborne illness in the population. It is critical that FSIS has a clear, data-driven understanding of foodborne illness risks. Government agencies have emphasized the importance of food attribution data and promised this information to the public and Congress for years, yet little progress has been made. What is needed is serious commitment and dedicated action by all agencies involved. CFA rejects any proposal for so-called risk based inspection that attempts to substitute expert opinion for observable data. We insist that FSIS gather this information before moving ahead on its plans for risk-based inspection. Without solid food attribution data, FSIS is simply hazarding a guess as to what the risks are and where the Agency should allocate scarce resources.