

Workshop on Industry Interests and Issues

December 13, 2006
Washington, DC

Ideas for Improving the FSII

[NOTE: This list of ideas was drawn from discussions among participants at the December 13 Food Safety Information Infrastructure (FSII) workshop, and is intended solely for discussion purposes. The list does not express relative priority or level of support among workshop participants. It is not intended as a consensus document.]

SESSION 1: INTRODUCTION AND BACKGROUND

- Need to bring retail into the fold, too much discussion about data has focused on processors

SESSION 2: INDUSTRY DATA COLLECTION, DATA NEEDS, AND PERSPECTIVES

With respect to industry data collection and data comparability:

- Focus effort on “systematic reviews” of published literature – very detailed structured literature review that gets at data gaps
- Need for validated or certified methods or processes – for example, a plant will cut data collection when deemed unnecessary or when budget is tight, then the need arises and they start to collect again, but in an ad hoc manner. They might use processes that have not been validated or certified, and comparing to another facility might be apples and oranges.
- Trade associations could aid with standardization
- Trade associations could provide advice or spreadsheets to aid data collection, but do not have the resources to get down to that level of detail
- Focus on standardization of methods differs by pathogen and context – for Salmonella, there are standardized sampling, different analytics available and so on, but for Listeria, there is the need for constant retraining on how to do the swab, where to swab, etc.
- Need to separate out the real interventions/improvements from the snake oil – there are a lot of third parties out there selling their own method
- Among third parties doing microbial testing for industry, the analytics are a point of competition, so there is incentive against standardization.
- Need to peer review methodologies to validate them, especially when there are a lot of alternatives and vast cost differences between methods.

Sharing industry data within industry

- Non-competitive agreements for food safety: beef industry agreement made in 2001 for sharing food safety data between firms:
 - o Examples: Audit records, Microbial monitoring of raw material, Microbial monitoring of the plant environment, Residue testing, Metal detection records, Animal toxicity testing, Microbial challenge studies, Experiments to validate a microbial intervention, Consumer complaints
- Try to define a “benchmark” for safety when it comes to firm spending – there is a benchmark for R&D and other activities, but not for food safety – This is because food safety is wrapped up with food quality and other line-items, so it is difficult to pull out from the budget
- Industry can benchmark against each other by combining microbial or other data – identify within the industry who is doing markedly better and who is doing markedly worse
- Need for industry to share information on process capabilities – process capability verification from industry (to industry)

Sharing industry data with regulators or researchers:

- Need to be careful when extrapolating data beyond original purpose. Need to have:
 - o A very good reason for sharing data
 - o A good understanding of data/science and how it was generated
 - o The legal framework within which to act without punitive response
- Need to be aware and open about limitations of industry data, given the wide differences in sampling approaches, analytics used, and so on – the utility of data should be governed by the particulars of the specific reasons for which it was originally captured
- Need to define the incentive for private sector to share data - what are the reasons to share that data beyond their own internal needs?
- Need for regulators to obtain broad brush industry data about practices to perform useful risk assessments and to make reasoned judgments about risk – for example, what percentage of firms do X vs Y vs Z? Another example, do any firms do process A and process B or do they only do one or the other? These data can be blinded and anonymous, not plant or even firm specific
- Regulators are hamstrung when it comes to surveying industry about practices, due to paperwork reduction act.

Industry data needs:

- Better data on food attribution
- More frequently updated incidence estimates
- Frequently updated baseline data
- Absent a good Performance Objective based on an FSO, need data to support the decision to go as “Low as Reasonably Achievable” to help identify what this “Low” is. Have to base this on the literature.

- Increased transparency of assumptions and data gaps being considered for use in risk assessments
- Annual summaries of outbreaks
- More current survey data about pathogen incidence in a variety of commodities
- Criteria for ranking industries and food products based on risk of foodborne illness and then see the system applied to the food chain and resulting risk ranking for industry or food items.
- More FDA and USDA data
- Heat lethality data for anticipated pathogen levels in specific foods
- More information on recalls, including strains, investigative findings, potential sources
- Lm product testing data more frequently
- Actual limits for microbiology

SESSION 3: OPPORTUNITIES TO BETTER MEET FOOD INDUSTRY DATA NEEDS

Role of information and data

- Industry has the same vested interest in protecting public health as the CDC, FDA, USDA, state agencies, universities and NGO's
- Sound reliable data are essential in developing science and risk-based approaches to food safety management – reliable data rather than opinions is essential
- Risk assessment methodology to develop regulatory policy is a sound scientific approach which can be strengthened with industry data
- Regulations must be developed in open environment using input from all stakeholders
- The Meat and Poultry Industry has pledged that food safety should not be leveraged as a competitive advantage, therefore food safety intervention work has been shared publicly
- Sharing of industry data has been very successful – for example, much of the progress in reducing the risk of *E. coli* O157:H7 and *L. monocytogenes* in foods can be attributed to sharing of industry data - Regulations have been promulgated that reflect this input
- Data in context of process control fosters better understanding by the Regulatory Agencies

Need for better attribution

- Better understanding and improvement on the basics of epidemiology – how do we report these things?
- New methods in attribution - use of PFGE/subtyping
- Think outside the box with respect to attribution, and challenge our presumptions – an example from New Zealand – why is attributable risk assoc. w/ retail? Fried foods, pretty good kill step... conclusion: likely associated with flies – does poultry industry killing themselves to bring levels down do much if it's the flies?
- Better quantify other exposure routes – example, O157 and exposure to environmental routes

- We need to be careful with the word “attribution” because it usually means a food product but the cause of the outbreak or illness might be a handling problem
- Use the word “causation” instead of “attribution”
- Attribution to broad food categories is what is out there now, but it is not really actionable because it paints a broad brush picture that covers a wide variety of parties or points in the system, and it points the finger at a huge commodity group instead of at the specific products that might be the cause

Outbreaks and reporting

- Outbreak information – get it faster, get it better
- We need better industry guidance after outbreaks – there is a lack of follow-through when an outbreak investigation is over – the message never gets back to industry as to what the cause was so that other firms or other industries can learn from those mistakes.
- With outbreaks, industry doesn’t need to know necessarily how to fix the problem, but at least to know what the “failure” was
- The lack of follow-through means that untested myths or “urban legends” persist – example: a few years ago, there was an outbreak investigation on O157 and lettuce that implicated flooding, but a look at the literature suggests a dearth of science there, and nothing to justify this presumption, yet it still dominates
- We should collect additional work during an outbreak investigation that could focus on getting at the cause or attribution of the outbreak
- In an outbreak investigation, there might be more data that investigators want to collect, but most often it is “shrouded” in the legalistic issues
- Outbreaks can’t stop at identifying the food vehicle, they need to identify the contributing factor

Microbial data needs

- Needs to be better guidance in general on sampling issues – in one case, a firm performed 10,000 samples, in another 30,000 samples, trying to identify the source of a problem, yet we see state health people drawing conclusions from 15 samples of retail product.
- We need better pathogen quantification methods, especially for Salmonella. Have decent quantitation method for Campy and for Lm.
- We need to better know the lower limit of different methods – there needs to be “truth in advertising” when folks are reporting zeros in sampling data
- Need to standardize methods
- There is a tradeoff between the desire for inexpensive, rapid testing and the need for standardized, validated approaches
- Need to better define hazards not reasonably likely to occur – there may be unnecessary regulations because decisions about handling may be based on faulty information about the specifics of product growth/survival potential on specific products (e.g. Staph aureus in a product not likely to support growth, or C. perfringens in large items like roast beef)
- Data on which foods can be held at room temperature, which cannot.

- Data to eliminate zero tolerance for *L. monocytogenes*
- Annual reports or summaries from government repositories such as eLEXNET, where industry has no access to the data but there may be lessons to be learned from it

Broad system-wide data needs:

- More sharing of data between customers and suppliers to improve hazard analyses
- Need to be inclusive of other issues beyond pathogens – allergens, nutrients, toxic effects – special categories such as baby foods, medical foods that raise special needs
- Need to quantify spending on food safety

SESSION 4: OPPORTUNITIES FOR WIDER SHARING OF FOOD INDUSTRY DATA

- There are difficulties sharing industry data with themselves, and bigger difficulties with regulators or the public
- There may very well be good examples where industry data can be shared, but they are going to be case by case, and very context dependent
- Sharing of data is much more likely to happen with bigger companies who perform more data collection on a regular basis, and who might see benefit to overcoming legal hurdles
- While there is no such thing as 'bad data', the question is – is the risk of mis-use of the data worth the effort of sharing it
- Need to identify a case study to focus on where we can all get around the table, specify a defined need and see what we can do
- Need to better understand implications of Data Quality Act with respect to data going back and forth to/from industry and government
- The primary obstacles are (1) what is the purpose, and (2) what are the legal ramifications and assurances for anonymity

SESSION 5: SYNTHESIS AND POSSIBLE NEXT STEPS

- There are a lot of reasons given why industry data sharing won't work – but our best way forward is to show it can work. How to choose a topic? The bigger the issue/impact the more expensive it is, therefore if you want to move forward, it has to be a big impact but big benefit topic, but be tractable enough to still have reasonable chance of success.
- Need to address the role of international data on domestic food safety: 65% seafood consumed in this country is imported – how do we deal with international data – how do we acquire it?
- In other countries with less constraints on private/public data sharing, does their system work better or worse? Does it work better when there are barriers? Or just differently? Are there lessons that others have learned?

- Need to recognize that most of us are bacteriologists, and there is a growing need to grapple with viruses – specifically, we need to know what interventions work on viruses – for example, in Europe there are surrogates that can be used for the avian flu H5N1 to assess virocidals, but not in the US.
- Difficulties with interventions for produce – EPA role in chemical treatments – for example, if we do something for full grapes, we have to go through a lengthy, expensive, brutal EPA process, but if you slice the grapes in half we can do peer review and go through FDA
- We need to focus on collection of more information rather than on detailed analysis – a lot of information at the local, county, state government level is lost because there are not standardized approaches to data collection
- We need to find ways to translate data from sources that do exist into training efforts
- We should get more information from epidemiology – we need to focus on what questions are being asked and having questions in there that can provide more useful information
- We need a pilot effort – something that is not too hot of a topic, but something like Lm where there is lots of data – we can anonymize it, and make it clear for public sharing towards something practical such as the training of investigators
- Before we can improve epidemiological investigations, we need to better understand the context in which they are done and the limitations in resources that result in differences in investigations – there are splits between epidemiologists, environmental health specialists, and lab folks, in addition to different organizational structures across states, that result in vast differences between states
- We should look at differences in assumptions and methodologies between government and industry
- We should pursue a hypothetical “table-top” exercise for the case study, where we use a hypothetical but spelled-out example to discuss the issues with data sharing without getting specific folks on the hook with regard to real data – a “scenario” approach