

***Salmonella* Rapid Detection Interagency Group Meeting Executive Summary**

Friday, January 30, 2009 (1:00 – 2:30 pm)
U.S. Food and Drug Administration (FDA)
White Oak, Building 1, Room 2102
10903 New Hampshire Ave
Silver Spring, MD 20993

Present	Name	Affiliation
x	Frank Torti	FDA/OC
	David Acheson	FDA/OC
x	Norris Alderson	FDA/OC
x	Steven Musser	FDA/CFSAN
x	Carl Sciacchitano	FDA/ORA
x	Chad Nelson	FDA/OC
x	Martha Monser	FDA/OC
x	Eric Brown	FDA/CFSAN
x	Donald Zink	FDA/CFSAN
x-phone	Lonnie King	CDC
x	David Goldman	USDA/FSIS
	Jon Krohmer	DHS
x	John Sanders	DHS
x	Tom McGinn	DHS
x	Eric Myers	DHS
x	Leo Christodoulou	DARPA
x	Jon Mogford	DARPA
x	Doug Stetson	DHS

Opening and Welcome

Dr. Frank Torti, Acting Commissioner of Food and Drugs, FDA

Dr. Torti provided an overview emphasizing the importance of drastically compressing the timeframe, e.g., from 14 days to 2 days, of *Salmonella* detection in both food-based and clinical situations. He also expressed the potential benefits of federal agencies working together in this effort to protect the public health rather than having multiple strategies being developed in parallel. The key component is developing the technology to support the science. He provided a diagram (see Appendix I) to demonstrate how this interagency group could approach the challenge of evaluating rapid *Salmonella* identification techniques. Dr. Torti proposed the following strategy and timeline as a way to move this effort forward:

- Meeting of subject matter experts (SMEs) from the participating federal agencies to share notes (within the next 6 weeks).
- Determine who else outside of the federal agencies has additional technologies and ideas for addressing the *Salmonella* detection challenges (within the next 12 weeks).
- Distill the gathered information down to select test methods/technologies.

- Evaluate selected methods/technologies against what is going on currently in the field using an experimental design and monitoring results in real time (begin in Summer 2009).
- This would be an iterative process but would lead to the substitution of the old methods/technologies with the new ones.

Several caveats to this approach were noted by Dr. Torti including the fact that many technologies may initially have the promise of great advances, but ultimately fall short of delivering on those promises, the issues related to deployment of new technologies such as ruggedness and the need for training. Agency representatives were asked to give their perspectives on the proposed collaborative effort and approach.

Perspective on the Task from Agency Representatives

Dr. Lonnie King, The Centers for Disease Control and Prevention (CDC)

Dr. King acknowledged the need for improved *Salmonella* detection and described it as “we need this yesterday”. He also stressed the need for a quantum leap in condensing the timeframe. Current detection rates are less than 50% within 15 days and 90% within 28 days. Dr. King described some of the capabilities at CDC (300,000 isolates in their database over 10 years) and agreed with the need for new technologies. He emphasized the importance of more investigation into the ecology of microbes and development of diagnostic test systems that would facilitate prevention strategies. In relation to Dr. Torti’s experimental design approach, he likes the side-by-side design and indicated that new methods should be high throughput.

Dr. David Goldman, The U.S. Department of Agriculture (USDA)

Dr. Goldman began by suggesting the National Advisory Committee on Microbiological Criteria for Foods (NACMCF; http://www.fsis.usda.gov/About_FSYS/NACMCF/index.asp) might be a possible vehicle and resource for this effort. One of the NACMCF subcommittees is tasked with determining the next generation of microbiological methods for foods. The committee will be publishing a report in March 2009. Dr. Goldman continued by indicating that USDA’s Food Safety and Inspection Service (FSIS) does a lot of microbiological testing; the field tests are based on traditional PCR with culture confirmation and follow-up (essential for court cases). He stated the need for controls, gold standards, and process controls. Recognition of outbreaks is now reliant on PulseNet, but the epidemiology needs to catch up. Traceback and food testing are also in need of new advances. FSIS conducts ~100,000 tests per year in meat and poultry. Full characterization is done by serotyping/PFGE. They currently have about 12,000 isolates from food. He mentioned efforts to move towards molecular serotyping from the traditional biochemical methods which may save some time. He also mentioned the need to embrace the public health community; currently they rely on CDC to take the lead on this aspect. He noted that test performance characteristics and specificity to decrease false positives are very important components.

Dr. Torti response: Acknowledged that both USDA and FDA have regulatory responsibilities and agreed that the process must be started; having accepted technologies are of utmost importance. If the agencies come together, the public health community will follow.

Dr. Leo Christodoulou, The Defense Advanced Research Projects Agency (DARPA)

Dr. Christodoulou began by explaining DARPA's mission with the Army as the lead and their emphasis on war fighter effectiveness through rapid assessment of exposure detection. They do not have any laboratories and less than 10 technicians, but have financial resources. They are interested in evaluating pre-symptomatic markers and non-conventional detection techniques (e.g. breath). They also look at probability of detection versus probability of false alarm, signal processes and extraction for the military. One initiative, Topological Data Analysis (TDA), focuses on mathematics for extracting features and handling large data sets. They also can facilitate transition of technology (e.g. Rapid Viral Array (RVA)). DARPA's role in this effort would need to fit into the Department of Defense's mission. They are interested in pathogens.

Dr. Alderson: Asked the question of "How are priorities established?"

Dr. Christodoulou responded: They don't have specific directives, rather the projects are program manager driven and ideas driven. If there is a recognized problem, DARPA can take a potential solution from the outer edge of science fiction to science fact. An example was provided for an accelerated vaccine deployment: blind test conducted, pathogen driven, could 3 million doses be delivered in 16 weeks for under ten dollars/dose. DARPA solicits and embraces challenging projects that are plausible. There are no DARPA labs, they provide funding for projects and are willing to try and fail. They can execute quickly and in unique ways (e.g., procurement via "other transactions").

Dr. Alderson: Commented that new technologies must meet standards.

Dr. Christodoulou responded: Usually benchmark against state-of-the-art; performance and metrics (i.e. quantitative measures) are always included.

Dr. Tom McGinn, Office of Health Affairs, The Department of Homeland Security (DHS)

Dr. McGinn agreed with the focus of this collaborative effort. Dr. McGinn directs the Food Agriculture and Veterinary (FAV) Defense Division within the Office of Health Affairs (OHA), with a dedicated mission to advancing the protection of the Nation's food, agriculture, human and animal health. FAV Defense serves as DHS's unifying agent on these matters, as well as, an access point to those functions for other federal agencies, states, tribal, and local entities and the private sector. Dr. McGinn suggested that the efficient use of laboratory resources can help to reduce some of the time it takes for *Salmonella* detection and analysis. Assets they could provide: research and development, surveillance, laboratory resources, and response management. He also mentioned that U.S Customs and Border Patrol of DHS has diagnostic laboratories and currently collaborate with FDA.

Dr. John Sanders, Office of Health Affairs, The Department of Homeland Security (DHS)

Dr. Sanders is the Branch Chief of the Food Defense/Preparedness Coordination Branch in the FAV Division. He has experience working with FDA's Center for Food Safety and Applied Nutrition on the Emergency Response and Coordination Team, formerly known as the outbreak response team.

Mr. Eric Myers, National Biosurveillance Integration Center (NBIC), The Department of Homeland Security (DHS)

Mr. Myers indicated that the focus of the NBIC is on identification, detection, and building networks. Daily surveillance activities are reviewed and include DHHS (i.e. FDA and CDC). He recommended engaging the private sector in this effort and looking at the possibility of outsourcing. Think of ways to measure a technology. We should also consider CRADA activities as a way to add industry dollars into this effort.

Dr. Torti response: Agreed with the value of including industry and/or academia as credibility will greatly increase if it is a multi-faceted effort.

Dr. Goldman: Agreed but commented that needs from the different organizations are likely to be different. He also pointed out that they do not do research. He also recommended inviting the Agricultural Research Service (ARS) to participate in this effort.

Dr. Torti: Pointed out the end goal of getting the job done collaboratively without one Agency taking sole credit; we all should do so. Dr. Torti proposed a series of next steps: Each agency have an internal technological meeting to discuss approaches to an interagency technical evaluation. Then, evaluate the epidemiology to determine study design. Field offices would need to be involved to define testing sites. Final outputs are the ideas to test at which point an effort should be made to engage academia and industry.

Dr. Alderson provided an example of a collaborative program: AOAC and DHS test for anthrax; the program ultimately failed because there were assay validation problems. Dr. Alderson stressed the importance of standards and getting companies to understand and be engaged in participation.

Dr, Torti: Pointed out the challenge in engaging, but not stifling as the technology may be out there already and can be tweaked.

Dr. Donald Zink: Expressed the need to think of the project as having 2 parts: sample preparation, processing and handling versus detection, identification, and typing. Perhaps we can take a tiered approach: good, better, best; develop these and have input at a public workshop.

Thought is not to lock out any potential technology or ideas. Need to encourage others to think about applying technologies to this “new” application.

Thoughts on how to conduct the interaction with industry and academia

- DARPA proposed presenting the vision and getting comments from the public in a meeting; however limit invitations, use working groups and have poster sessions to facilitate networking; offline comments could be acquired at a later time point.
- Use a Broad Agency Announcement which presents a goal and requests a solution; thought to be better mechanism than a Request for Proposals (too constraining).
- Aim is to engage and not stifle.
- Pre-decisional meetings would be second step

- DARPA indicated they can facilitate the public meeting much faster than usual time frame of 6 months and recommended having the meetings across the country in order to maximize outreach; they have 3 different locations.
- Dr. King and Steve Musser to evaluate internal agency activities, e.g., there is a meeting planned for mid March that could be expanded.
- Follow with a 3rd meeting which would include those with mature ideas.

Dr. Torti highlighted the Action Items:

- First, bring together federal agency SMEs to discuss the best approach to the first box (see Appendix 1). Ask epidemiologists to design appropriate studies. Determine field resources and capabilities.
- Next, engage the public (academia, industry, state/locals, etc.) – would need to start planning in parallel with government agency meeting because of logistics in holding an open public meeting.
- Third: Following completions of first two steps, determine which methods can be taken to the experimental phase.

Dr. Steve Musser: Suggested that the Interagency meeting of SMEs could take place in conjunction with an FDA/CDC meeting on Next Generation Typing Methods planned for March 17-18, 2009 in Greenbelt, MD. Dr. Eric Brown is coordinating that meeting and FDA will follow up with the group on identifying SMEs and coordinating meeting logistics.

Appendix 1

Interagency Approach to Rapid *Salmonella* Identification

