2014 FDA Food Safety Challenge SELECTION CRITERIA

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FINALIST AND WINNER EVALUATION/SELECTION CRITERIA

FDA is most interested in concepts that explore the acceleration or elimination of sample preparation and/or enrichment in the testing process, and/or those that employ novel or revolutionary techniques to achieve pathogen detection. Examples of revolutionary techniques include (but are not limited to) metagenomics (or other next-generation sequencing methods), spectroscopy, application of nanotubes/nanotechnology, quantum detection methods, and electrical detection methods.

Concepts may combine new techniques with existing methodologies (such as PCR), and must describe where time savings are achieved in the testing process as well as expected time from unprepared food sample(s) to verifiable result(s).

A panel of expert judges will select finalist teams from the pool of eligible entries. These finalists will then refine their concept and will present the concept at Demo Day. The judging will be based and scored upon the judges' own discretion as to the quality of each entry according to the following evaluation criteria, with equal weighting (i.e. 20% for each):

Finalist Evaluation Criteria

- 1. Speed: Proposed reduction in time from unprepared food sample to verified pathogen to subtype/serovar level for Salmonella in fresh, minimally processed produce. The ability of the solution to also address testing in other foods and other complex matrices is encouraged. The ability of the technique to also address additional pathogens such as Shiga toxin-producing Escherichia coli is encouraged.
- Improved detection and path to impact: Strength of evidence, data and/or argumentation regarding the application of submission's technique to create impactful acceleration and improvement of foodborne pathogen detection, inclusive

- of improvements in specificity and sensitivity for Salmonella and possibly other pathogens.
- 3. Applicability: Applicability of solution to FDA testing processes.
- 4. Revolutionary: Whether the concept would be a revolutionary improvement over the FDA's current testing procedures with potential to make a major impact on food testing.
- Execution: Perceived ability of submitting team or individual to execute and develop their concept.

In general, submissions must describe how the technique would increase speed of pathogen detection efforts (starting from unprepared food sample, through verification of pathogen) without sacrificing specificity and sensitivity or comparability to reference methods (described at

http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006949.htm). Submitted concepts can be targeted to any point in the food system (i.e. harvest, packaging, distribution, point of sale, etc.). Concepts should specify which point(s) they are targeting and how the technique would be implemented. Though submissions may be theoretical in terms of application to food safety, all entries must be able to demonstrate a path to practical development of their concept and a plan to move to proof of concept (described at

http://www.fda.gov/downloads/ScienceResearch/FieldScience/UCM273418.pdf) over the course of the Challenge.

Submissions should include relevant data with reference to use of the concept/technique, such as any initial verification results, any available proof of concept, or relevant data from the technique's use in adjacent industries.

Winner Selection Criteria

Winner selection criteria will include finalist evaluation criteria plus the following criterion: Demonstration of team's/individual's ability to effectively iterate and improve their concept over the course of Challenge Field Accelerator phase.

The evaluation criteria are to be applied in the sole discretion of FDA and the individual judges and are subject to modification by FDA. By participating in the Challenge, each entrant into the Challenge acknowledges and agrees that such evaluations may differ from person to person and agrees to be bound by and not challenge the final decisions of FDA and the judges.

ATTENDANCE

Selected finalists must be able to take part in the (virtual) Field Accelerator starting on January 8, 2015 and running through March 5, 2015. During this period, the finalist teams will iterate and improve their concepts in preparation for the Demo Day on March 5, 2015. Finalists are required to participate in the live one-day Boot Camp on January 29, 2015 in Washington, DC and the live Demo Day in Washington DC, on March 5, 2015, at their own expense. Dates are subject to change.