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Comments on the USDA-AMS Microbiological Data Program
Submitted by the California Strawberry Commission
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The California Strawberry Commission has taken the issue of food safety very seriously and in fact was one of the pioneers in the development of voluntary industry guidelines. We have always welcomed more and better data leading to development of information about the state of the produce industry. We have been very supportive of the FDA efforts in both the domestic and import surveys of the produce industry.

Along with other members of the produce industry, we have a several questions about this program ranging from the fact that it is duplicative to a number of other ongoing studies, to what will the data be used for. It is incumbent upon the industry to comment on these various aspects of this program to get our concerns out in the open before the testing has begun in earnest.

After reviewing the documents provided by the USDA-AMS, the following issues surfaced and form the basis for our comments.

1. How will the data be used and will this data be appropriate for the anticipated uses? As scientists we know that the way that data is collected can greatly affect the usefulness of the data to draw conclusions. Will this data eventually be used for regulatory purposes?
2. The survey as described, seems to be quite broad and not targeted unlike the two earlier CFSAN surveys. These surveys showed a very low incidence of pathogen contamination on produce items that had been identified as high risk by NACMCF. This study is looking for events that occur in considerably less than 5% of the produce.
3. There is an ongoing study, funded by the USDA - Initiative for Future Agriculture and Food Systems Program for \$4.533 million dollars. It is "Improving the Safety of Fruits and Vegetables: A Tri-state Consortium Proposal" and appears to be at the same time, duplicative and more actionable than the one proposed by AMS. The principal investigators are, D. Archer, University of Florida, E. Murano (S. Pillai) Texas A&M University and L. J. Harris, University of California at Davis.

4. The point of sampling - somewhere in the middle of the distribution chain, leads to questions. It does not accurately represent the risk caused by production methods nor does it address actual consumer risk.
5. The methods to be used for sampling and analysis need to be verified as appropriate for the individual product types by other researchers. The program was sold to Congress on the basis that the infrastructure existed, there needs to be a lot of infrastructural and mindset changes to move from pesticides to microbiology. On a rather cursory review of the methods, I identified these problems:
 - There is what appears to be a huge problem with the approach to temperature of samples upon receipt. All samples must be within refrigerated guidelines in order to be acceptable for microbial evaluation.
 - The time interval of 72 hours from point of sampling also seems to be inappropriate for microbial testing. Reputable microbiological testing laboratories would not follow either of these protocols.
 - There is an issue with looking for generic E. coli rather than specifically pathogenic E. coli. Generic E. coli is not an appropriate indicator of contamination.
 - Appropriate methods for microbial detection can vary greatly by product type and characteristics. "Uniform" sampling protocols may not be appropriate across products.

These observations were apparent in a very superficial review of the methods. Strong peer review is in order prior to the initiation of the actual sampling.

6. Additional concerns about the "blind" nature of the testing were raised by comments made at the meeting by two different state regulatory people. While each acknowledged that the test was to be blind - they both pointed to enforcement actions that either have been taken or would be taken. This defeats the purpose of "blinding" the study. It appears that some of the states are not bought in to this aspect of the study.
7. This is a very expensive program and should have review points built in so the value of the data can be assessed periodically at appropriate intervals.

We encourage the AMS to carefully review this program to ensure that the data developed will in fact be useful and suggest that there be more peer review of the program by parties who are not also being funded by the program. There is a reference on the USDA -ARS website that provides a peer review manual for projects. This approach is strongly recommended for this program.

We request another public meeting to make sure that these issues are recognized and addressed.