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FDA Dockets Management Branch
5630 Fishers Lane, Room 1061- HFA-305
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DOCKET NUMBER 00N-1460 – RE: COMMENTS ON "SAMONELLA ENTERITIDIS RESEARCH PUBLIC MEETING

The Egg Safety Action Plan is of historic significance since it is the first comprehensive farm-to-table regulatory program in the United States. This precedent-setting plan will affect all subsequent food safety plans designed to reduce human illness from production through all subsequent points in the food chain. The need is great, for both a sound plan as well as practical implementation of the plan in order to prevent and control *Salmonella enteritidis* (SE) in eggs.

The purpose of Objective 7 of the Egg Safety Action Plan is to ensure that adequate, current information is available to make decisions about SE **preventive controls**, **surveillance**, and **education** based on sound science. Sound policy rests on sound science as well as adequate funding to support scientific research.

It is vital that the Egg Safety Action Plan be developed and implemented so that all stakeholders are assured that policy decisions will be based on sound science. When a sound scientific basis for decision-making is not available or is equivocal, a mechanism is needed to rapidly fund research in concert with industry and state partners rather than applying short-term political solutions to biological problems with long-term repercussions. Regulations are intended to assure that standards are being met, however, producers and State Agriculture Departments will ultimately be responsible for managing risk at the farm level. The need for SE research is therefore of critical importance to producer and regulator alike since it addresses one basic need: sound policy based on sound science.

Many excellent research ideas were presented recently at the SE Egg Meeting in Atlanta. What follows are additional suggestions and comments that are intended to complement those already presented at this meeting.

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Preventive Controls:

1. There is a need for regionally-based longitudinal field studies that can address confounders that may have affected molting data obtained through previous cross-sectional epidemiological studies. Confounders include duration of exposure, type of molting method used, physiological and other biological interactions.
2. Research is needed to develop economically viable and practical alternative molting methods.
3. Research is needed to optimize on-farm intervention strategies presently used in Egg Quality Assurance Plans. Management factors such as rodent control, cleaning and disinfection, and biosecurity are important tools that can be improved.
4. Independent vaccine field trials are needed to evaluate products presently available in the U.S.
5. Research is needed to understand whether the major source of human SE from eggs is on the shell externally or internally in the yolk. A California study demonstrates that current egg disinfection procedures could result in overestimating the number of eggs contaminated via the trans-ovarian route (Himathongkham et al, 1999). Determining the nature and distribution of SE in or on the egg will assist in prioritizing whether egg production (internal deposition) or processing (external contamination) require greater attention.

Surveillance:

1. Valuable field research can be conducted during on-farm traceback investigations. These investigations can be exploited more fully by collecting standardized information that can be analyzed retrospectively in order to evaluate on-farm risk factors and testing methods and thereby prevent the occurrence of further outbreaks. For example, in California, the Department of Food and Agriculture and Department of Health Services are collecting and analyzing standardized data elements at the farm and food preparation sites in order to learn more about factors that lead to human illness outbreaks due to SE. FDA is in a unique position to assist states to study factors leading to foodborne illness through standardized data collection and funding. The benefits of fully exploiting traceback investigations include, but are not limited to, the following:
   - Gathering regionally specific on-farm data.
   - Collecting data that will assist in developing on-farm sampling protocols and performance standards by correlating various environmental samples with egg samples.
   - Validating and field-testing alternative testing methods such as air sampling, pooling, PCR and Egg Yolk Antibody testing.

- Documenting and analyzing key production environmental parameters such as water activity, pH and ammonia of poultry manure in order to gain knowledge about the ecology of SE.

2. Research is needed to study factors affecting the prevalence of SE within flocks. The ultimate goal of this research would be to establish different levels of risk for SE in eggs based on less expensive and convenient environmental testing. This research must be ecological in approach. **Research in medical ecology holds the greatest promise for controlling SE in the farm environment and should be the first priority of a strategic SE research plan**. Further work is needed to study the effect of environmental factors such as water activity, pH and ammonia on the survival of SE in layer environments. Recent studies from Georgia and California indicate that these environmental parameters are key to developing mitigation strategies in the layer environment and in eggs. The relationship and population dynamics of SE and other types of Salmonella also requires study.
3. Retrospective epidemiological analysis of data from Pennsylvania and California and necessary funding is needed to fully examine SE risk factors for data not previously considered due to lack of resources.
4. Research is needed to develop rapid testing methods that will assist producers in taking timely corrective action.
5. Research is needed to develop experimental molecular fingerprinting methods which will discriminate SE within phage type from various sources so as to better understand the epidemiology of SE in humans, layers and the environmental sources.
6. Research is also needed to study the epidemiology and pathogenicity of different SE phage types found in the U.S.

Education:

California and Pennsylvania egg quality assurance educational materials already provide an excellent source of information for egg producers and processors and can be used to great advantage by other states. Specific research items requiring consideration include the following:

1. Develop alternative internet-based methods to reach producers, processors and food handlers with new research findings.
2. Develop pre-training and post-training evaluation methods to measure outcome of education methods for producers, processors and food handlers.
3. Conduct research to assess the attitudes and level of food safety knowledge of food handlers in commercial establishments as was done recently with consumer groups.
4. Cost/Benefit studies are a necessary and important tool for agencies to justify agency resource allocation and educate politicians and consumers about the impact SE has on producers, processors and consumers.

Funding:

Research funding through competitive grants will generally meet the majority of the needs for SE research, with at least one notable exception. When traceback investigations occur, a rapid funding mechanism is needed through FDA that would allow data from field traceback investigations to be analyzed and published in peer-reviewed scientific journals and thus contribute toward the prevention of further outbreaks.

Conclusion:

Through the Egg Safety Action Plan, the FDA and the USDA are embarking on the first pre-harvest food safety regulatory program in the nation. With much remaining to be discovered about the ecology and epidemiology of SE, the credibility of the Plan will rest on the commitment and leadership of federal agencies to fill specific information gaps. In this sense, there is an unprecedented need for research that can form the basis of performance standards for egg producers, processors and food handlers to follow.

Thank you for the opportunity to provide these comments. Our Department remains committed to developing a sound, scientifically defensible mitigation plan for SE.

Sincerely,

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References:

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