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Food Safety Inspection Service
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Charles Beard

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Because of the long length and complexity of the subject draft risk assessment, the allowed thirty days for comment was inadequate. That short time frame limits the extent and possible benefit of public comment in the final preparation of this document. In fact, some of the annex documents of the draft were not available to the public until as recently as three weeks.

It is my understanding that the draft which has been submitted for public comment does not incorporate the changes suggested by either FDA or CDC. I am also uncertain as to whether the draft includes the suggestions made by the peer reviewers listed in the document. It would have been very helpful if the public had been given a draft that had been updated to reflect such previous input.

I attended the hearing on this risk assessment via webcast and was not there in person, however I thought that I heard Dr.Schroeder answer a question from the audience related to the numbers of human illnesses that had been related to the consumption of pasteurized egg products. He answered that he did not know of any. His answer is supported in the first paragraph on page 197 of the draft where it is written: "Historically, pasteurized egg products have been a very safe food. There have been no outbreaks linked to the consumption of egg products and consumption of pasteurized egg products does not appear as a risk factor in case control studies of foodborne illness."

It would appear that it would be reasonable to base the need for additional or more stringent regulations concerning pasteurized liquid egg products or pasteurized eggs on the following:

- The numbers of illnesses that have been attributed to the consumption of pasteurized egg products.
- The incidence rate and levels of Salmonella enteritidis bacteria found in pasteurized egg product.

If this information was acquired and used, the actual level of risk would have a factual basis and there would be no need to utilize what might be termed "voodoo" statistics where the outcome of statistical assessments is assigned a much higher level of credibility than the input estimates justify. For example, the multiplication factor of 3X that is applied to the estimates of numbers of SE bacteria in pre-pasteurized egg products because clumping could account for negative results and could make the cells more resistant to the killing effects of pasteurization without supportive data to justify the correction factor and the 2X factor that is applied to the number of positive environmental cultures of poultry houses, when the testing protocols have been proven over time and widespread use to be sensitive and reliable, detracts from the soundness of the assessment.

Another disappointing feature of the assessment report is the reliance upon SE numbers related to illnesses and outbreaks that were acquired during the height of the SE problem a decade ago, instead of the more recent information that reflects the significant progress that has been made by the industry and government in correcting the problem. There has been a continuing effort made to decrease the possibility of SE illnesses related to eggs and the more recent illness and outbreak numbers from CDC reflect that progress. There is no need or justification to base a current risk assessment on outdated information. The use of SE vaccines, assurances of SE-negative breeding stocks, emphasis on improved rodent control and biosecurity have all had a role in achieving the decline of SE illnesses related to eggs. The voluntary diversion of eggs to pasteurization from environmentally positive flocks has also lessened the likelihood of egg-related SE illness.

Finally, the effectiveness of the current Egg Products Inspection Act implemented around 1970 became clear when eggs consumption and Salmonella illnesses became disassociated. It was a great accomplishment by USDA in protecting the public health. The requirements of the Act may need slight adjustments as the products and processes change but I see no evidence in the risk assessment document that justifies a major expansion or overhaul of the existing regulations. Such actions would not be based on science, product contamination surveys or actual human illness numbers related to SE in eggs.

It is very beneficial to conduct risk assessment exercises because they can define the areas where information exists and where more information is needed, therefore helping researchers plan studies that can provide data for use in future regulatory decision making. This assessment will likely be more beneficial if the concerns and input of those providing comments are seriously considered by FSIS.

We appreciate the efforts of those preparing the risk assessment and the opportunity to comment on their draft document.

Respectfully submitted,

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