



*Nature's perfect food made perfectly safe.*

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December 16, 2004

DIVISION OF DOCKET MANAGEMENT  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

Docket No 2000N-0504

**SUBJECT: COMMENTS AND RECOMMENDATIONS TO FDA  
REGARDING REDUCING INCIDENCE AND OUTBREAK OF SE**

Dear Sirs:

Thank you for the opportunity to comment on the proposed egg farm rulings and to contribute comments on important other potential areas of SE reduction.

Along with many of my colleagues, I concur with the FDA in our mutual belief that the actions planned at farm level will certainly result in positive new impacts in reducing outbreaks and illnesses from SE. Introducing these new rulings for farm control should be applauded. However, actions also need to include *beyond the farm* and *closer to the table* rulings and education demonstrating alternative assurances against SE. Many states, foodservice industry groups, legislative bodies and food safety leaders support the FDA in its efforts to impact significant reduction of incidence and outbreaks from SE. The FDA will also have those who will initially presume any actions as unfair whether because of burden of cost or political opposition. Whatever actions the FDA takes may likely never protect all Americans from possible SE contamination or meet the agendas of all interest groups. However, these actions must primarily remain focused on achieving maximum possible safety of the American consumer.

Unfortunately, the *On Farm Rulings* on its own does not take all possible steps to implement the low cost yet high potential results opportunity areas that are present beyond the farm level. Actions taken now should include proactive, post Farm to Table reduction contributors, as well. An On Farm program does reach to the root cause of the problem. Unfortunately, because the farm level actions may only drive an incidence reduction of 22,000, or less than a 1/3 of the incidence level, the SE issue will still loom as a significant public concern. Relying solely on the farm policy does not support or assure a complete critical control point action plan. All significant proactive policies that can be implemented to protect consumers up to and during consumption should be instituted. The data supports many low cost yet high impact options the FDA can choose to support that will drive a more complete Farm to Table program.

The CDC's Surveillance Pyramid starts with population exposure. Thus, regulations and control measures must make sure protective policies are implemented all the way to this point of exposure--the consumer. Significant additional reduction can be achieved by adding focused actions up to and at the point of service of eggs or foods containing eggs. Attention must be given to the facts presented in the many recent reports and studies by Food Net, CDC, FDA, and USDA. Implementation of post farm actions has proven successful where they are used already. Thus, if instituted nationally, an immediate 2005 significant incidence reduction could result.

Recommendations for post farm level action include:

1. Support the 2001 Model Food Code portion on eggs to be made an immediate mandate within institutions nationally. Current reviews show that only three states actually abide by the requirements regarding eggs used and served in institutions as defined in 2001 MFC. The CDC's MMWR, published April 30<sup>th</sup>, 2004, stated "1996-2003 no substantial changes were observed in the incidence of infection caused by SE." The MMWR recommendation was clear to state two requirements to decrease SE outbreaks: "future control measures should include - mandatory On Farm prevention efforts to reduce contamination from SE and a greater use of pasteurized eggs." Institutions would be an immediate start point at a significantly high incidence area.

As a secondary point, the mandate should include a clear definition outlining all institutions specifically to be inclusive of all food served in hospitals, acute care, nursing homes, hospice facilities, schools inclusive of college and universities, and prisons where the eating audience is all confined patrons. *Additionally, I would recommend that this mandate be considered to be inclusive of all Business and Industry (B&I) institutional feeding facilities where the patrons are also a confined audience. This addition of B&I facilities would be a tremendous reduction in costs to industry from lost workers, sick pay, hospitalization and medical costs.*

2. The facts from CDC and USDA risk assessment data are undisputable that restaurants have the most immediate opportunity to reduce the incidence of SE. The incidence of SE in restaurants could see a reduction of greater than 25% and up to 68% based on this data. ***The CDC's data shows that products prepared in restaurants made with eggs as an ingredient, not served as eggs but rather as another dish, account for 68% of the contributing vehicles driving incidence of SE (i.e., sauces, desserts, dressings, stuffing, beverages, purees, pastas, entrees, etc.). The fact that these recipes using eggs account for 68% of the vehicles causing SE cannot be ignored.*** In view of these facts, it is vital that the efforts to protect the public be inclusive of a mandate for restaurant operators to incorporate actions that include pasteurized liquid or pasteurized shell eggs in the preparation of foods or dishes made from eggs in their kitchens. The consumer in the front dining area of the house may or may not even be aware that the product ordered contains eggs. Eggs used in foodservice operators' recipes today that are not already pasteurized account for approximately 1/10<sup>th</sup> of the foodservice industry's table egg usage. This would involve a minimal cost impact to operators but would provide a tremendous safety level improvement. The restaurant industry and associations should embrace this FDA action. It represents only a small usage area for eggs for a hugely significant liability reduction

for the restaurants and the largest food safety critical control area for protecting the restaurant guest.

3. A strong recommendation needs to be given to states to develop action plans that educate the high-risk population. Pasteurized liquid or pasteurized shell eggs should be chosen or requested as an alternative at restaurants serving eggs in a variety of styles. The data from the CDC shows that this area of risk accounts for 31% of incidence. The restaurant industry shows this area to account for close to 90% of the eggs used in foodservice operations. States should also consider a plan to add not only menu warnings of risks from eggs, as will be required by the Model Food Code, but should include statements that customers may request the option of pasteurized shell eggs or liquid eggs if they are ordering less than hard cooked preparation. Seniors, children under 10, pregnant women and individuals with immune deficiencies should be offered the choice when ordering eggs that are less than fully cooked.

It is unrealistic for restaurants to be expected to diagnose their guests for immunity levels or ask for ID to check age. This may seem unrealistic but in the situations where the courts have ruled against restaurants for SE damages to consumers, it is clear that the courts expect the restaurants to take all possible actions to serve the expectation of the guest. The expectation today of all guests is that the egg they are served will be safe. Unfortunately, this cannot be true of all eggs served to all guests. When the risk level of a SE contaminated egg is combined with an individual within the high-risk population, the case is usually settled, or the jury awards the individual damages.

Note that with Section 3 above being included in the FDA mandate for restaurants, all restaurants would have pasteurized shell and liquid eggs on hand and could fulfill the requests of guests.

Summary:

On Farm Actions:

- A. As planned, execute and deliver the planned On Farm Ruling to reduce SE in eggs.

Post Farm Actions:

- A. Execute a mandate for all institutions to use pasteurized liquid or pasteurized shell eggs, clearly defining institutions.
- B. Extend a mandate to all restaurant operators to use pasteurized liquid or pasteurized shell eggs for all in restaurant preparations of recipes. The greatest contribution area in the industry is reduced, yet only a small volume of usage area is impacted.
- C. Deliver a recommendation statement to all foodservice operators to include the option of pasteurized product selections when ordering eggs in their establishment.

When all the above actions are combined, a more complete **Farm to Table/Consumer** action plan results that will guarantee a faster reduction in outbreaks far exceeding the current farm only action plan, both in speed and volume of incidence reduction. The additional three steps could protect more than twice the number of consumers from illness or death. Individuals and

industry would also be protected from high costs both in healthcare and liability. If there was an HACCP program for the Farm to Table, it would certainly include action at each of the above defined critical control points in the egg supply. If all of these actions were combined, the 2010 reduction objectives could be exceeded as early as 2005. Additionally, these actions represent minimal financial impact compared to the magnitude of incremental risk reduction levels they would assure.

Thank you for the opportunity to comment on this comprehensive rule. We look forward to the outcome.

Sincerely,

NATIONAL PASTEURIZED EGGS,

Gregory M. West  
Executive Vice President

GMW/fc