



United Egg Producers

RECEIVED
ESIS DOCKET ROOM
UEP Headquarters
1720 Windward Concourse • Suite 230 • Alpharetta, Georgia 30005
(770) 360-1920 • Fax (770) 360-7058
04 DEC 10 PM 4:15



UEP Officers

Mike Bynum, Chairman
Al Pope, President
Roger Deffner, First Vice Chairman
Dolph Baker, Second Vice Chairman
Bob Krouse, Treasurer
Gary West, Secretary

December 9, 2004

UEP Staff

Al Pope
President

Gene Gregory
Sr. Vice President

Dr. Lynn Dickey, Director
Regulations and Petitions Policy Staff
Food Safety and Inspection Service
United States Department of Agriculture
Room 113 Cotton Annex
Washington, D.C. 20250-3700

Linda Reickard
Vice President

Re: Docket Number 04-034N

Irving Isaacson, Esq.
UEP General Counsel

Dear Dr. Dickey:

Washington Office

Ken Klippen
V.P. Government Relations

Michael McLeod, Esq.
Washington Counsel

Randy Green
Sr. Government Relations Rep.

Egg Nutrition Center

Dr. Don McNamara
Executive Director

Dr. Hilary Shallo
Director of Food Safety Programs

On November 17, 2004, the United Egg Producers (UEP) and the United Egg Association (UEA) filed comments on the Draft Risk Assessments of *Salmonella* Enteritidis in Shell Eggs and *Salmonella* spp in Egg Products published by the Food Safety and Inspection Service (FSIS) on October 18. In our letter to the Docket Clerk, we noted that UEA was in the process of conducting a member survey on practices related to egg pasteurization and would submit the results of that survey to FSIS. The recently completed survey includes information on egg sources, reductions in microbial levels achieved with industry pasteurization practices, and microbial testing of egg products.



Official U.S. Council Representative

Results of the survey were compiled by Dr. Glenn Froning, Professor Emeritus, Department of Food Science and Technology, University of Nebraska. Dr. Froning is an author of the International Egg Pasteurization Manual. Enclosed is the report that he prepared on the survey results, along with a quantitative summary of survey results and a summary of written comments made by survey respondents.



As noted in comments we filed with the Docket Clerk, the draft risk assessment grossly overestimates the number of illnesses attributed to egg products. The risk assessment estimates occurrence of *Salmonella* in finished product using three different log reduction levels- 0, 3, and 5, - achieved by pasteurization. Companies responding to the survey indicated that their pasteurization processes achieve a minimum five log reduction with half of the firms achieving a seven or greater log reduction in

Washington Offices

UEP Government Relations
One Massachusetts Avenue, NW, Suite 800
Washington, D.C. 20001
(202) 842-2345 Fax (202) 682-0775

Egg Nutrition Center

1050 17th Street, NW, Suite 560
Washington, D.C. 20036
(202) 833-8850 Fax (202) 463-0102

UEP Iowa Office

Box 170
Eldridge, IA 52748
(563) 285-9100 Fax (563)285-9109

Dr. Lynn Dickey, Director
December 9, 2004
Page 2

bacterial load. These companies are using pasteurization treatments that are more effective than those assumed in preparation of the risk assessment. We urge FSIS to use this additional data as you complete the risk assessment and to re-evaluate the egg products pasteurization data and estimated illness numbers.

We would be pleased to discuss this further with you. Dr. Froning is available to respond to any questions about the survey results. His address and telephone number are listed below.

Dr. Glenn Froning
Professor Emeritus
Department of Food Science and Technology
University of Nebraska
357 Food Industry Complex
Lincoln, Nebraska 68583-0910
Telephone (877) 488-6143

Sincerely,



Howard M. Magwire
Director of Government Relations
United Egg Producers/United Egg Association

Enclosures

Egg Processors Survey Results

The egg processing industry initiated a survey to identify current receiving and processing practices related to food safety. About one-third of the processors responded to the survey. The survey form and the response of the various processors are included as attachments. A summary of the results is as follows:

1. What reduction in pathogen load do you typically achieve in your processing operation?

All respondents indicated that they achieved a minimum 5 log reduction in bacterial load. One half of the companies reported a log reduction of 7 or greater depending on the egg product.

2. If your answer to question 1 was greater than 5 log, is this because of:

One company indicated that a greater log reduction was required by the customer while two processors reported that company policy required a 7 log reduction. Others reported that certain products and process efficiency dictated a 7 log reduction.

It would be pointed out that many processors and customers have established specifications for maximum bacterial loads in pasteurized egg products.

3. How do you verify the log reduction achieved in your process?

In most cases (7), processors verified log reduction by established time-temperature requirements for a specific product. Others (4) also verified by measurement of bacterial load. One processor also estimated a total reduction of bacterial load including warm up and cool down times. Another processor indicated that log reduction depended on the product and its intended use. They emphasized D values for pathogens and flow conditions. It is well-known that flow conditions in the holding tubes as well as come-up and cool down conditions are important factors in determining the kill of Salmonella. This aspect will be further discussed later in this letter.

4. Does the log reduction achieved vary from product to product?

5. If so, please provide estimates by product.

Three firms reported that log reduction varied from product to product while seven indicated no difference in log reduction between products. Of those mentioning variation from product to product, one indicated that they had the biggest cushion above 7 logs for whole eggs and whole egg products with non-egg ingredients and the least with yolk. Others mentioned egg white which has great sensitivity to heat. It is well-known that egg white pH can be a major factor in achieving a good kill of Salmonella. Additionally, egg whites have natural microbial properties which prevent bacterial growth. Egg white can be easily denatured therefore requiring lower pasteurization temperatures to avoid loss of functional properties. Another processor indicated the highest log reduction from whole eggs. One processor using a 7 log reduction on

some egg products indicated that they used the 5 log guideline for salted products due to the stringency of salt. Salted yolk does present a different problem due to its high viscosity. Because of this, the data reported in the International Egg Pasteurization Manual (2002) recommends increasing the holding time to 4.5 minutes at 63.3°C for salted yolk. Established science shows that there is less growth of organisms in these products due to decreased water activity.

6. Do you have information on the pathogen load in eggs entering your facility?

Four processors reported that they had information on the pathogen load in eggs entering their facility while six had no data on bacterial loads entering the plant.

7. If so, please specify.

Two plants tested raw egg products in the breaking room, raw product vats and tankers for APC, yeast and molds. Another plant indicated that they routinely plated incoming raw egg products. One firm completed a study in 1998 which showed that 34% of the incoming egg tankers were positive for Salmonella. The level, however, varied from 0.003 cfu/gram to 1/1 cfu/gram which was quite low.

8. Are the incoming eggs you receive for processing:

- a. 1 From in-line production
- b. 6 From off-line production
- c. 2 A mixture of both types
- d. 3 From tankers

As one can see, the preponderance of respondents receive eggs from off-line production. Two reported a mixture of off-line and in-line production. Regardless of the source of production today it is readily known that eggs reach the plants rapidly under present day conditions. Generally, eggs are in the plant within 3 to 4 days after production or sooner. Thus, the quality of eggs reaching the plant is greatly improved over that achieved years ago. Also, bacterial loads should be much lower.

It should be emphasized that all eggs are washed and sanitized at the plant. Hutchison et al, 2004 (J. of Food Protection 67:4-11) reported that washing inoculated eggs resulted in a 5 log reduction in Salmonella. The risk assessment does not address washing of eggs but we know that good washing procedures greatly reduce bacterial loads on the shell prior to entering the breaking operation. It is difficult to envision the bacterial loads indicated in the risk assessment. Several studies have indicated that it takes from 20 to 22 days for Salmonella to penetrate a shell at temperatures of 6 to 16°C. (Bigland and Papas, 1953; Can. J. Comp. Med. Vet. Sci: 17:105-109; Dolman and Board, 1992 Epidemiol. Infect. 108:115-121).

9. Do you test for...

- a. 0 Salmonella prior to pasteurization
- b. 6 Standard plate count prior to pasteurization
- c. 2 Other

Those processors mentioning "other" indicated that they also tested for coliforms and E.coli. It is known that coliforms can be used as an indicator organism for Salmonella.

10. Do you adjust your pasteurization procedure based on incoming product?

No firms reported any adjustment of pasteurization procedures based on incoming load in the product.

11. Do you test for...

- a. 10 **Salmonella post-pasteurization**
- b. 10 **Standard plate count post-pasteurization**
- c. 8 **Other**

All plants reporting tested post-pasteurization for Salmonella and standard plate counts. Others included E.coli, yeast, mold, Listeria and Staphylococcus. Thus, plants routinely test for Salmonella to assure that the product is Salmonella negative prior to shipping.

12. Do you use SE vaccines or buy eggs from companies who vaccinate flocks?

Two companies reported that they received eggs from vaccinated flocks while three indicated they did not know. Five companies reported that they did not obtain eggs from vaccinated flocks.

The risk assessment did not mention vaccination. Egg processors, as well as shell egg producers, commonly use vaccines as a control measure to protect hens from Salmonella colonization.

13. If you answered “yes” to question 12, do you or your supplier use...

- a. **Live vaccine**
- b. 1 **Killed vaccine**
- c. 1 **Combination of live and killed vaccine**

14. If you answered “yes” to question 12, approximately what percentage of your eggs come from vaccinated flocks?

Based on the two companies reporting that they used vaccines, one indicated that 30% of their eggs came from vaccinated flocks while the other processor reported that 85-90% of their eggs came from vaccinated flocks.

15. Are you aware of any instance of documented illness from consuming pasteurized egg products? From your facility or another egg processor.

All processors answered no to this question.

I note that the risk assessment estimated that 50,000 to 100,000 illnesses result from pasteurized egg products each year. After the egg products inspection act was implemented, to my knowledge there has not been a Salmonella outbreak from egg products.

Additional Comments Relating to the Draft Risk Assessment

1. Pasteurization results – FSIS utilized the raw data from the University of Nebraska study by United Egg Association and the American Egg Board. They had a concern for the non-linear results. With that in mind, FSIS transformed the data. The final results were slightly different

than those reported in the University of Nebraska Study and published in the International Egg Pasteurization Manual (2002). This study utilized the capillary tube method which had the advantage of an instant come-up time. Schuman *et al* (J. of Food Protection 60:231-236) in 1997 observed that capillary tubes gave more accurate D values than those scientists using larger tubes. For example, Michalski *et al*, 1999 (J. of Food Protection 62:12-117) compared results using the capillary tube method to that obtained from a plate heat exchanger. The capillary tube method indicated that all processes gave less than a 9 D kill as recommended by the USDA. However, when using the plate heat exchanger they obtained a greater than 9 D process for Salmonella. This indicates that the plate heat exchangers used in plants likely give a better kill which is partially due to the longer come up and cool-down time. Capillary tubes on the other hand are heated and cooled instantaneously. Another consideration is the flow characteristics in tubes in plant heat exchanges. Egg products may exhibit either laminar or turbulent flow. If the product is viscous, laminar flow may be prevalent. If laminar flow is predominant, the holding time needs to be adjusted since the fastest moving particle will flow twice as fast. Current regulatory requirements for pasteurization times and temperatures assumed laminar flow as a precautionary measure. However, if the line of flow is broken, turbulent flow is indicated and there will be greater mixing. Since egg pasteurizers holding tubes have turns, the minimum holding times provide a safety margin. The risk assessment does not emphasize flow characteristics and its importance in pasteurization technology in plants.

The risk assessment did not discuss the hydrogen peroxide pasteurization methods used for egg white by some processors. These methods (Armour and Standard Brands) are discussed in detail in the International Pasteurization Manual. Studies accomplished at Oklahoma State University showed that the Standard Brands method provided a 9 log reduction at all pHs when using a temperature of 55.8°C in combination with hydrogen peroxide. These results were also recently published by Robertson and Muriana, 2004 (J. of Food Protection, 67:1177-1183).

2. The national baseline survey is mentioned but detailed results are not available.
3. Clustering of Salmonella was mentioned as a possibility in egg products. I am not aware of any studies where clustering would be a problem in unpasteurized egg products. Using the Weibull distribution to determine a factor of 3 would greatly exaggerate the actual levels of Salmonella.
4. Research needs discussed in the risk assessment should be of value. Studies to date indicate a much better kill of Salmonella when using in-plant pasteurizing equipment as compared to the benchtop capillary tube method. There are pilot plants available which would answer this question using inoculation studies. Any pasteurization studies should also emphasize the effect on functional properties in the final product. The market for egg products depends on optimum functional properties.

One final issue needing an answer is the pH break-point where we reach an optimum kill of Salmonella in egg white. It is felt that this break-point is around pH 8.9 or 9.0, but we do not have an absolute answer.

Submitted on December 8, 2004 by
Glenn W. Froning, PhD
Professor Emeritus
Department of Food Science and Technology
University of Nebraska

Enc. Egg Processors Survey
Comments from Survey

ND: 4827-6403-2256, Ver 1

Egg Processors Survey

ANONYMOUS SURVEY – PLEASE DO NOT INDICATE YOUR COMPANY

1. What reduction in pathogen load do you typically achieve in your processing operation? (Check one.)
 - a. 5 5 log
 - b. 6 log
 - c. 3 7 log
 - d. 2 Other (Please specify: _____)
2. If your answer to question 1 was greater than 5 log, is this because of –
 - a. 1 Customer requirements
 - b. 2 Company policy
 - c. 3 Other (please specify)
3. How do you verify the log reduction achieved in your process?
 - a. 7 Conformity with established time-temperature parameters
 - b. 4 Measurement of bacterial load
 - c. 1 Estimate of overall reduction in bacterial load, including during warm-up and cool-down times before and after holding at required temperature for required time
 - d. 1 Other
4. Does the log reduction achieved vary from product to product?
 - a. 3 Yes
 - b. 7 No
5. If so, please provide estimates by product.

6. Do you have information on the pathogen load in eggs entering your facility?
 - a. 4 Yes
 - b. 6 No
7. If yes, please specify. _____
8. Are the incoming eggs you receive for processing (check only one) –
 - a. 1 From in-line production?
 - b. 6 From off-line production?
 - c. 3 A mixture of both types (approximate % of off-line
 - d. 3 From tankers
9. Do you test for
 - a. Salmonella prior to pasteurization?
 - b. 6 Standard plate count prior to pasteurization?
 - c. 2 Other (please specify _____)
10. Do you adjust your pasteurization procedure based on load in incoming product?
 - a. Yes
 - b. 9 No
11. Do you test for –
 - a. 10 Salmonella post-pasteurization?
 - b. 10 Standard plate count post-pasteurization?
 - c. 8 Other (please specify coliform, e-coli, yeast, mold, listeria and staph)

12. Do you use SE vaccines or buy eggs from companies who vaccinate flocks?
d. 2 Yes
e. 5 No
f. 3 Don't know
13. If you answered "yes" to question 12, do you or your supplier use --
a. Live vaccine?
b. 1 Killed vaccine?
c. 1 Combination of live and killed vaccines?
14. If you answered "yes" to question 12, approximately what percentage of your eggs come from vaccinated flocks? _____
15. Are you aware of any instance of documented human illness from consuming pasteurized egg products --
No - 8 From your facility?
No - 8 From the facility of another egg processor?
12. If you answered "yes" to either part of question 16, please describe the situation.

**PLEASE RETURN THIS SURVEY NOT LATER THAN FRIDAY,
NOVEMBER 19 TO DR. GLENN FRONING AT gfroning@neb.rr.com**

Comments from Survey

Question 1:

- d. Log reductions for our products range from a minimum of 7 to more than 12.

Question 2:

- c. USDA approved pasteurization parameters to achieve a 7 log reduction of Salmonella populations.

Company policy and type of products.

Process Efficiency.

Question 3:

- d. Log reduction targets for processes are set depending on the product and intended use. Specific pathogen reductions and/or control of heat resistant spoilage microbes are used in determining the pasteurization conditions. Key data used are D-values for pathogens and flow conditions in holding tubes.

Question 5:

Whites lowest and whole egg highest.

Found mostly with EW and Salt yolk. We find closer to 5 log kills with these products, mostly because of temp parameters and stringency of Salt.

Question 7:

- c. In a 1998 study, we determined that 34% of our incoming egg tankers were positive for Salmonella. The level of Salmonella in positive samples varied from .003 cfu/gram to >1.1 cfu/gram.

Routine plating of incoming egg product.

We test raw egg products off the breaking rooms and in raw product vats, as well as incoming tankers for APC and Y&M daily. (Two identical answers)

Questions 8c:

70%

Question 9c:

Limited testing for specific microbes.

Periodically

(Total coliform, E.coli) We do not wait for results prior to pasteurization

Question 11c:

Listeria, Staph, coliforms, yeast/mold, specific spoilage microbes as required by customers.

Coliform, E.coli, yeast, mold and staph

Coliform, Yeast/mold

Total coliform, E. coli

Y&M, Staph, E. Coli, total coliform, Listeria; others on request

E. coli, coliforms as well

Total coliform, E. Coli, Listeria (Refrigerated Liquid Egg Products

Question 14:

Approximately what percentage of your eggs come from vaccinated flocks?

30%

85-90%