Egg Producers

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Docket Clerk U.S. Department of Agriculture Food Safety and Inspection Service 300 12th Street, S.W. Room 102, Cotton Annex Washington, DC 20250

#### Docket Number 04-034N Re:

November 17, 2004

United Egg Producers (UEP) representing more than 90% of the shell egg industry and the United Egg Association (UEA) Further Processors Division, representing 95% of the egg processing industry appreciate the opportunity to comment 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. We believe that regulatory actions should be based on sound science. An accurate, complete, and well executed risk assessment is a good foundation for regulatory actions and policy.

UEP and UEA commend FSIS for performing these risk assessments. However, we have many concerns regarding the process of completing the risk assessments and their scientific content and underlying assumptions.

These comments are presented in two parts. Our general comments and items of concern are followed by specific items we wish to point out throughout the drafts.

# GENERAL ISSUES:

Review process for the documents:

FSIS employees announced at the public meeting on October 22, 2004, that the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) have had or will have an opportunity to review and comment on the risk assessments, but the comments from

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04-034N 04-034N-3 Howard Magwire

these agencies have not been incorporated into the drafts that were released. The egg industry feels that these comments from FDA and CDC should have been taken into consideration and incorporated into the drafts prior to public release of the documents. The drafts without feedback from FDA and CDC were prematurely released and of limited use to the public at this point. We request that FSIS revise the current drafts incorporating any comments from other federal agencies, in addition to the peer reviewers, and re-release the drafts for public comment once those changes have been made.

### Vaccination of Hens for Salmonella

UEP and UEA are concerned about the absence of information on vaccine use in the risk assessments for both shell eggs and egg products. Vaccines are an effective tool for the industry to prevent *Salmonella* infections in hens. The shell egg industry and the egg processing industry both use vaccines to reduce the risk of *Salmonella* contamination. The industry has effectively used both killed vaccines and live attenuated vaccines to prevent *Salmonella* infection. In not addressing vaccine use, the current risk assessments have overlooked an important *Salmonella* control measure. We strongly suggest the addition of information on vaccines to the draft risk assessments.

# The number of annual illnesses attributed to egg products

The risk assessment for egg products estimated that 50,000 – 200,000 illnesses per year are due to egg products. **This number is grossly overestimated by the draft risk assessment and needs to be corrected.** Since the Egg Products Inspection Act (EPIA) went into effect, we are aware of no outbreak due *Salmonella* in egg products. Arguably, egg products are more likely than other food products to cause an outbreak if contaminated, simply due to the quantities in each batch. Egg products have an exceptional food safety record. The industry works with FSIS and state inspectors in USDA inspected plants to produce safe egg products. If the agency responsible for inspection of egg products is saying that thousands of illnesses each year are due to egg products, something is wrong with either the inspection process or the risk assessment. We strongly suggest that the data and assumptions used to develop the illness estimates be reviewed.

# Availability of data used in the risk assessments

Several reports cited in the risk assessment documents are not publicly available. For example, the risk assessments refer to a survey of the industry, but this survey is not easily accessible to the public. In addition, a national baseline survey of egg products prior to pasteurization is mentioned in the risk assessment and the only reference is an abstract. A short report was posted to the risk assessment website after the public meeting; however, this report does not include adequate information for parties reviewing the risk assessment. In the PDF form of the report, the axis on the graphs are not labeled to allow the reader to understand the data presented in the graph. These important reports should be publicly available in their entirety. **Releasing the draft risk assessments prior to the availability of all relevant data was premature.** 

# Use of experimental research studies

Because the infection rate of Salmonella Enteritidis (SE) in eggs is very low and it is almost impossible to use naturally contaminated eggs for research purposes, many research studies utilize inoculation techniques to experimentally infect hens and/or eggs with SE. Inoculation studies tell us a lot about the growth patterns of SE. However, caution should be used when extrapolating data from experimental studies to a natural environment. When data are available on naturally contaminated hens and/or eggs, those data should always be used instead of data from studies using inoculation of SE. Caution should be used when inoculation studies are the only studies available on a subject. The data and methods should be evaluated carefully. Not only will naturally occurring pathogen loads differ from the challenge doses used in the laboratory, but other factors such as the strains of birds will also differ.

# SPECIFIC ITEMS IN RISK ASSESSMENTS

### Executive Summary Page 2

The <u>American Egg Board</u> sponsored studies on lethality kinetics of Salmonella spp In liquid egg products.

### Introduction Page 7

It is estimated that 80 percent of known-source SE infections are due to eggs. The reference cites data from 1988, 1993 and 1996. These data are 8 to 16 years old. The Centers for Disease Control (CDC) has several surveillance systems monitoring SE and the most recent data available is from 2002 and 2003. The most up-to-date information should be used when available.

#### Introduction Page 7

The background information about the regulatory requirements for shell eggs requires correction. The 1996 HACCP rule is referenced; however, egg products do not fall under this rule. The current wording implies that shell eggs and egg products are regulated under the 1996 HACCP rule.

#### Introduction Page 8

Recent studies regarding SE contamination in egg yolk

Methods used in the studies should be evaluated to make sure that when the yolk is cultured, contamination of contents with egg albumin or yolk membrane did not occur. It is well established that SE can be located in the egg white at the yolk membrane. Most studies indicate that contamination of the yolk only occurs after deterioration of the yolk membrane.

# Introduction Page 10

Under the section "Egg product pasteurization scenario" it states that "Risk managers requested that these assessments consider egg product pasteurization scenarios in which the level of Salmonella in egg products is reduced by 7 to 12 log 10."

Emphasis should be on control measures to prevent infection and growth of SE in eggs. A 7 to 12 log reduction is not practical for shell eggs or egg products when vaccines, on farm quality assurance programs, refrigeration, and proper handling are effective control measures.

# Hazard Identification Page 16

The Salmonella statistics on page 16 are not the same as the statistics on page 1 of the Executive summary. Page 16 cites all Salmonella illness estimates, while page 1 cites "Foodborne" Salmonella illness estimates. Salmonella illness statistics are confusing and often misstated. It is important that the statistics be cited consistently and accurately. We suggest FSIS choose a single set of statistics, clearly state what they represent, and use them consistently.

# Hazard Identification Page 18

"An individual consumes on average 230 eggs per year, not including eggs consumed as part of cake mixes, noodles, etc."

The reference for this statement is from 1998. The National Agricultural Statistics Service publishes up to date information each year and data is available for 2003

(http://usda.mannlib.cornell.edu/reports/nassr/poultry/pec-bb/.) The American Egg Board also publishes an Egg Industry Fact Sheet each year with current information

(http://www.aeb.org/eii/facts/industry-facts-2-2004.htm.)

The risk assessment should include the most recent information available. It is also our understanding that the consumption numbers include egg products consumed as ingredients in other food products.

# Hazard Identification Page 18

"Approximately 80% of vehicle-confirmed SE outbreaks have been associated with grade A shell eggs or egg-containing foods."

The references are from 1988 and 1994 based on data from 1985-1991. The table referenced (Table 2-2) contains data from 1985 to 1987. More recent data is available for from the CDC estimating the percentage of egg associated outbreaks. Using data that are 13 to 19 years old is unacceptable when recent data is available.

# Risk Characterization Page 146 Table 5-1

The baseline data for the mean number of SE in contaminated eggs at the layer are grossly overestimated. Therefore, the SE levels at all other steps are also grossly overestimated. Research has established that naturally contaminated eggs contain minimal (2 to 10) SE cells in each contaminated eggs. Estimating 9.1 x 10<sup>6</sup>, is a gross overestimation of the levels of SE and makes the entire model inaccurate.

Risk Characterization Page 149

Data for non-pasteurized shell eggs

"It further estimates approximately 0.0003 or about 3 eggs in every 10,000, would be contaminated at lay."

The 1998 risk assessment estimated that one in 20,000 eggs may be contaminated with SE. The mid 1990s were the peak of SE illnesses and since then, illnesses and egg associated outbreaks have declined. We question the conclusion that 3 in 10,000 eggs are contaminated at lay when all epidemiological and field data indicate that SE contamination rates at lay have declined dramatically since the 1998 risk assessment was published?

# Risk Characterization Page 151

UEP and UEA request additional clarification on how the Agency concluded that 350,000 illnesses each year are due to raw shell eggs and 200,000 illnesses each year are due to pasteurized shell eggs. We believe both numbers are grossly overestimated.

# Risk Characterization Page 153

This section is confusing and contains information that is not clear and does not reflect industry practices. The statement "Storage Temperature after processing was set at 3 different values:  $45, 53 \text{ and } 60^{\circ} F$ " is misleading. Processing refers to pasteurization of egg products. Liquid egg products are held at 40°F after processing. Frozen egg products are held at freezer temperatures while dried egg products are held at slightly cooled or room temperatures. It is appropriate to model *shell* eggs stored at the three referenced temperatures prior to washing, packing and breaking. Table 5-5 states the number of estimated human illnesses that would occur at different times of refrigerated storage after pasteurization. The point at which pasteurization occurs is an important factor and could change the data presented in the table.

# Risk Characterization Page 173

Figure 5-17 overestimates the mean number of SE at the layer (10<sup>7</sup>) level and therefore throughout the process. FSIS should correct this baseline information based on published research, or provide justification for the use of numbers this high. The pasteurization process would reduce the mean number of SE cells to well under the 1000 cells indicated. We also question the growth rate of 50 percent for injured cells. Research in this area is required prior to making such an assumption.

UEA believes FSIS has gravely erred in its discussion of the number of illnesses estimated in the risk assessment attributed to egg products. Egg products are required to be pasteurized under the Egg Products Inspection Act (EPIA) which is enforced by FSIS. In the 34 years since the EPIA went into effect, we are aware of no reported illnesses or outbreaks of Salmonellosis due to pasteurized egg product. For the agency responsible for the safety of egg products to estimate that thousands of illnesses each year are due to egg products without any

epidemiological evidence is a disservice to the egg industry and to consumers. We believe that the history of the safety of egg products should be considered and the illness estimates should be reevaluated. We commend the writers of the risk assessment for acknowledging the lack of epidemiological data of illnesses due to egg products. The next step is to develop a realistic estimate of illnesses due to egg products that is consistent with the epidemiological data and the food safety record of the egg products industry.

UEA is in the process of administering a survey to their members on practices related to egg pasteurization. UEA will submit this data to FSIS in the near future.

### Annex B Distribution of Salmonella Prevalence in Hens and Eggs Page 5

The flock prevalence estimate was based on proven methods from several different data sources, and then multiplied by a factor of two. We question the need to multiply the estimate by a factor of 2 due to false negative testing. If false negative testing is a problem, then the method should be validated. There is no scientific justification for multiplying a well established estimate by two just because one reference in 1995 stated so. Environmental testing was not common in 1995 and it is very common in 2004. The method the FDA recommends has been through at least one revision in recent years. We strongly suggest you evaluate the current state of environmental testing methods prior to using a multiplication factor of two to adjust for "false negative" results.

### Annex B Distribution of Salmonella Prevalence in Hens and Eggs Page 28 Molting factors

We disagree with FSIS's reasoning regarding the percent of positive eggs post molt. We strongly suggest that FSIS collect data on this before assuming that 100 percent of eggs from molted hens are SE positive for the first week after the end of the molt. Not all molted hens are exposed to SE and certainly not all eggs will contain SE. Experimental research studies have demonstrated an increase in the susceptibility of SE infection after a molt, yet no field studies have demonstrated the same susceptibility. The timing also needs to be clarified because hens do not lay eggs during a molt. If the "first week of infection and molt" means the first week that egg production resumes after a molt, the document should state that. Another important factor is that significant numbers of producers within the egg industry have adopted a non-feed withdrawal molt and the susceptibility of the hens to SE may therefore be dramatically reduced in these flocks (Seo, KH, Holt, PS, Gast, RK Comparison of Salmonella Enteritidis infection in hens molted via long-term feed withdrawal versus full-fed wheat middlings. Journal of Food Protection, 64(12), 2001, 1917-1921.) Research has also demonstrated that vaccine use may protect hens during a molt from SE infection (Holt, PS, Gast, RK, Kelly-Achle, S. Use of a live attenuated Salmonella typhimurium vaccine to protect hens against Salmonella Enteritidis infection while undergoing molt. Avian Diseases, 47, 2003, 656-661.)

USDA scientists do not agree that an induced molt necessarily leads to increased post-molt shedding of SE in field conditions. We are attaching a letter from Jean Guard Bouldin, DVM, PhD., a distinguished Agricultural Research Service scientist at the Southeast Poultry Research Laboratory in Athens, GA. She notes the large-scale epidemiological comparisons that can be made between the United States, where induced molting is common, and the European Union, where it is not permitted, and states, "The epidemiological outcome strongly suggests that molting does not impact food safety associated with the problem of egg contamination, because Europe has a much worse problem than does the United States." We suggest FSIS review Dr. Bouldin's letter in its entirety, and consult with her and other experts in this area.

# Annex F Levels of Salmonella spp in Egg Products Page 19

MPN is an established scientific method for food microbiology. There is a lack of scientific evidence on "clustering" of *Salmonella* cells in egg products, and no scientific evidence that clustering protects cells during pasteurization. The use of the MPN method, negates any effect of clustering if the method is performed correctly. Multiplying the levels determined by the Weibull distribution by a factor of 3 grossly overestimates the amount of Salmonella present in egg products prior to pasteurization and causes the results of the risk assessment model to be inaccurate.

# Annex F Levels of Salmonella spp in Egg Products Page 7

"If the eggs are about 10 days or more old, then about 20% of the infected eggs might have experienced yolk membrane breakdown and have high levels of Salmonella Enteritidis (SE) (reference TA Cogan, Personal Communication, 2002). Supposing 100 eggs have high levels, on average 10<sup>9</sup> cells per egg, the contribution to the number of Salmonella from these eggs would be about 10<sup>11</sup>."

Published research has established that yolk membrane breakdown occurs at approximately 21 days when eggs are stored at room temperature (Humphrey, Contamination of egg shell and contents with *Salmonella* enteritidis: a review. 1994 *International Journal of Food Microbiology* 21:31-40). When eggs are refrigerated, yolk membranes remain intact for 70 days or longer according to research from ARS (Jones and Musgrove, 2004 http://www.ars.usda.gov/is/AR/archive/jun04/egg0604.htm). We question the statement that in 10 days, 20 percent of eggs have experienced yolk membrane breakdown and have high levels of SE. In naturally contaminated SE positive eggs, levels of 10<sup>9</sup> have not been documented. SE contaminated eggs only occur in rare circumstances and the SE levels are very low. Yolk membrane breakdown only occurs after 3 weeks of storage at room temperature, according to well accepted studies by Humphrey. Finally, we do not think it is appropriate to use personal communication as an authority on the same level as published, peer-reviewed studies in this risk assessment. Enough published scientific data is available and should be utilized. In fact a study was published in 2001 by Cogan et al, in the International Journal of Food Microbiology (Oct 22;70(1-2): 131-41) titled "Growth of *Salmonella* enteritidis in artificially contaminated eggs:

the effects of inoculum size and suspending media." The level of inoculation found to best simulate naturally contaminated eggs was two cells per egg. Significant time at high temperatures is necessary for two cells to reach levels at 10<sup>9</sup>. We believe the assumptions are incorrect.

Recommendations from UEP and UEA

UEP and UEA respectfully make the following suggestions for improving the draft risk assessments.

- Incorporate the comments received from FDA, CDC and the reviewers into the draft risk assessments and re-release them for public comment.
- 2. Add information on Salmonella vaccine use to the risk assessments.
- 3. Make all surveys and data collected by FSIS available to the public.
- Always use the most recent information available.
- Re-evaluate all illness estimates.
- Re-evaluate baseline information on SE and Salmonella contamination rates in shell eggs and egg products.
- Eliminate the use of personal communication from the references, or make a transcript of that communication publicly available.
- Re-evaluate all industry and scientific information used as assumptions in the draft risk assessment.
- Cite documented evidence of actual illnesses due to pasteurized egg products or develop
  a methodology that appropriately considers the effects of legally mandated
  pasteurization.
- Explain the process or methods used when using "weighted" estimates or multipliers throughout the risk assessment. Avoid using multipliers unless scientifically justified.

Thank you for the opportunity to submit these comments. UEP and UEA appreciate FSIS's consideration of our views.

Sincerely,

Howard Maquere

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

Enclosure



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August 25, 2004

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Dear Mr. Gregory,

Per your request, I am providing a synopsis on the issue of how molting might impact food safety in view of my recently published research on the subpopulation biology of Salmonella enteritidis. This information about the biology of Salmonella enteritidis (S. enteritidis) provides a scientific basis for understanding why the European and the USA experience with egg contamination by Salmonella enteritidis has differed. The fact that the USA uses molting routinely, whereas the European Union has banned it, is perhaps one of the largest epidemiological studies every conducted. I am not sure that I could have devised a better experiment to test the issue of whether or not molting impacts the safety of the food supply. The epidemiological outcome strongly suggests that molting does not impact food safety associated with the problem of egg contamination, because Europe still has a much worse problem than does the United States.

I have divided the synopsis into sections for ease of reading, and I believe that it is important to have a literature review on the subject, especially because there must be firm scientific footing when considering a major change in management practice in any intensive farming situation.

Sincerely yours,

Jean Guard Bouldin jbouldin@seprl.usda.gov TITLE: The impact of molting on human illness associated with egg-contaminating Salmonella enteritidis: A contrast of the European and USA experiences

AUTHOR: Jean Guard Bouldin, D.V.M., Ph.D., USDA-ARS-SEPRL

### INTRODUCTION

Salmonella enterica serovar Enteritidis (Salmonella enteritidis, S. enteritidis or SE) contaminates the internal contents of eggs collected from otherwise healthy appearing hens, which is a biological phenomenon that has contributed to its emergence as the leading cause of salmonellosis worldwide and as the second leading cause in the United States. Molting of the egg laying hen is a management practice that intentionally withholds feed to induce a period of reproductive rest so that a second cycle of egg production can occur. Molting is known to increase fecal shedding of S. enteritidis. This fact has been used as evidence that molting is a hazard to food safety and that it should be banned. However, Europe banned molting and it has a worse problem with egg contamination than does the United States. Recent research on the subpopulation biology of S. enteritidis provides a better scientific understanding of how differences in molting practices might impact the incidence of egg contamination. Thus, in the absence of scientific evidence that molting is a hazard to food safety, there is no scientific basis for banning this management practice in the United States in regards to protection of the food supply. Abandoning molting could have unintended consequences, because it is not possible to predict how such a drastic change would alter the balance of S. enteritidis subpopulations that vary in their ability to contaminate eggs.

# LITERATURE REVIEW

There is overwhelming scientific evidence that molting increases feeal shedding and transmission of *S. enteritidis* in the hen-house. However, only 1 of the 4 papers cited by the 1998 FSIS Risk Assessment refers to culturing eggs, and in that paper, one of two trials was negative for egg contamination (21). The *Salmonella enteritidis* pilot project cited by the committee, which was not a peer reviewed journal article, reported a twofold increase in egg contamination in molted hens as compared to non-molted hens (32). Research on molting that came out after publication of the Risk Assessment continues to show a strong correlation with fecal shedding and transmission of *S. enteritidis* between hens, but it does not shed any further light on a positive correlation with egg contamination (5, 14, 16-19, 24, 25, 33). The 1998 FSIS Final Report (pg 40) cites these studies as providing evidence that molting is a major contributor to egg contamination (13, 15, 20, 21, 32). However, when the committee reviewed all of the data, the conclusion was that "...the variables associated with molting are not correlated with the output of the production module (page 66)."

The next sentence made by the panel suggests that there was bias towards overweighting the effect of molting on egg contamination as reported by the field study. The committee reported that "Such results are surprising given the much higher frequencies at which molted flocks produce SE-positive eggs". The phrase "much higher frequency" should have been debated, because a 2 fold difference is considered within baseline variation in experimental animal studies. Essentially this means that the panel erred on the side of caution in factoring in some slight risk associated with molting.

# CURRENT RESEARCH ON THE BIOLOGY OF SALMONELLA ENTERITIDIS

The 1998 Risk Assessment identified that the emergence of the high prevalence flock is what poses the greatest risk to the consumer (pg 66-67). Overtime, my collaborators and I have provided a preponderance of evidence that S. enteritidis generates distinct subpopulations that have variable potential to contaminate eggs.(6, 7, 9-12, 22, 23, 26-31). One subpopulation appears to be only a weak pathogen and it dominates in the intestines of hens. It can result in experimental egg contamination if hens are artificially dosed with high numbers, which is unlikely to occur on the farm. A second subpopulation makes a biofilm, which is a tough organic matrix that protects cells and it is better than the others at oral invasion and invading organs. However, it does not contaminate eggs . A third subpopulation makes a capsule that correlates with a specific interaction with the avian reproductive tract and with high cell density growth. This third subpopulation has been identified as resulting in high frequency egg contamination in our experimental challenge model. High incidence egg contamination following low dose contact exposure of hens in experimental settings has only happened when the second and third subpopulations are combined. The house mouse Mus musculus has been shown to be an important contributor to egg contamination, in part because it is a natural reservoir for all three of these subpopulations. Further research strongly suggests that different organs and sites within the intestinal tract of the hen are colonized by different subpopulations (8). This means that the hen herself is applying stringent selection pressure on the overall balance of subpopulations that it sheds into the environment. The impact of this finding is that a molted hen may shed a very different balance of subpopulations into its environment as compared to a non-molted hen.

### LESSONS FROM THE EUROPEAN EXPERIENCE

There is now a decade of results from Europe that contrasts sharply with the experience of producers in the United States. Surveillance of the incidence of Salmonella scrotypes in humans for the second quarter of 1999 in Europe showed that S. enteritidis comprised 66.3% of the isolates, whereas second place S. typhimurium was associated with 13.4% of cases (1). In the third quarter of 2001, these figures were 75.4 and 10.6% for the same two serotypes respectively (2). In contrast, the latest available figures on the prevalence of Salmonella serotypes in humans in the United States reported that 21.9% of isolates from human cases were S. typhimurium and 15.8% were S. enteritidis (4). Since the emergence of pandemic salmonellosis has had a high correlation with the emergence of egg contamination by S. enteritidis (3), these figures indicate that the European and United States experiences are drastically different. Thus, the preponderance of evidence indicates that molting, which is practiced in the United States, does not correlate with an increase in egg contamination. It can even be suggested that molting may correlate with a decrease in human illness from S. enteritidis. However, in the absence of targeted research that tests such a hypothesis, it is more appropriate to summarize that there is no association of molting with increased egg contamination.

# EVIDENCE DOES NOT SUPPORT A BAN ON MOLTING BY THE USA

The European ban on molting occurred at the same time that the USA insisted on keeping it as a legitimate management practice. It is possible that this inadvertent contrast between continent-specific husbandry practices set up one of the largest population-based experiments ever conducted. Research now shows that S. enteritidis has a unique biology that contributes to high incidence egg contamination. Molting encourages intestinal shedding and the current research on subpopulation biology strongly suggests that the intestinal form of S. enteritidis does not make it to the egg at high frequency. The cecum of the hen was identified as an anatomical site where a subpopulation that is specifically adapted to the avian reproductive tract emerges. S. enteritidis thus appears to be a pathogenic bacterium that has developed niche specialization and that goes ever deeper within its host to find a favorable site to live. It is possible that molting is providing a type of vaccination, or a type of competition, that is suppressing wide spread emergence of the most dangerous subpopulations within the United States. Research in the future should help reveal more information about factors that most directly contribute to high incidence egg contamination. However, the contrast between the European and the United States experience provides a scientific foundation for deciding that the United States should not abandon molting as a management practice. To do so at this time, in the absence of evidence from Europe that they have reduced levels of egg contamination below that of the United States, is to jump to a premature conclusion that could have unintended consequences for the safety of the food supply.

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# Trade Coalition -- New Baird Account

Type of Activity		Amount		Account Total	
Start Balance 9/30/04	\$	83,920.44	s	83,920.44	
May 2004 pmt. CSS	\$	22,457.00	S	61,463.44	
Deposit Monterey 10-4-04	\$	18,149.70	\$	79,613.14	
Deposit Mush Canning 10-4-04	\$	15,099.96	S	94,713.10	
Deposit Giorgi 10-4-04	\$	24,794.68	\$	119,507.78	
June 2004 pmt. CSS	\$	99,178.70	S	20,329.08	
interest accrual	\$	86.16	\$	20,415.24	
Deposit Sunny Dell 11-16-04	\$	19,910.06	\$	40,325.30	
Deposit Mush Canning 11-16-04	\$	31,799.74	\$	72,125.04	

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